# MAKING HANDS: A HISTORY OF SCIENTIFIC RESEARCH AND TECHNOLOGICAL INNOVATION IN THE DEVELOPMENT OF MYOELECTRIC UPPER LIMB PROSTHESES, 1945 TO 2010

by

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# ABSTRACT

The dissertation examines the history of scientific research and technological innovation in the development of myoelectric, upper-limb prostheses from 1945 to 2010. A general history of the field is presented, as well as individual case studies on the development of commercially significant technologies and products. The field history and cases are examined against major concepts of research and development (R&D) and technological innovation during the second half of the twentieth century. The major forces behind changes in the field have been technological innovation in other industries, especially transistors, microprocessors and batteries, government funding programs, and the engineers/entrepreneurs who, alone or in collaboration with others, directed the development projects. The engineers/entrepreneurs were in turn influenced by changing conceptions and practices of R&D, innovation, and entrepreneurship.

The field history shows how conceptions and practice of R&D and product development changed over the period. Funding and R&D programs were designed in light of the linear model of innovation in the 1940s and 1950s. In the 1960s more pragmatic design engineering programs were originated at universities and hospitals, leading to the development of myoelectric upper limb devices by the 1970s. Government funding programs changed in the mid-1970s, with a reduction in support for design engineering, and increased support for research. This led to new approaches within the field, including development of pattern recognition systems and targeted muscle reinnervation. The 1990s saw the rise of innovation oriented projects, with an increasing emphasis on development activties,

international collaboration, project governance and strategic management, the use of complex legally binding agreements, intellectual property management, and commercialization.

# DEDICATION

To my parents, Wilfred and Jacqueline Foord.

# ACKNOWLEDGMENTS

The idea for this dissertation arose in conversation at the UNB Grad House with Dr. Edmund Biden, UNB's dean of graduate studies. He suggested the idea of writing a history of UNB's institute of biomedical engineering (IBME), and more broadly of the field of upper limb myoelectric R&D, as the pioneers from the 1960s were not getting any younger. I thank Dr. Biden for his suggestion and the time he made available to talk about the topic and history of the IBME

I am the student of four UNB professors who oversaw the design, research and writing of this dissertation. I thank each of Drs. Turner, Kyberd, McLaughlin, and Kealey for their patience and guidance, and detailed comments and questions on each of the drafts of the dissertation.

Dr. R. Steven Turner is a historian of science, and was my mentor in both science and technology studies and historiography. Reading and discussion with Dr. Turner in both areas informed my approach to the dissertation. It was during these conversations that the idea shaped up to expand the dissertation to other micro-histories. I am grateful for Dr. Turner's detailed comments on the first and second drafts of the dissertation, and his suggestion to add a chapter on the history of the field.

Dr. Peter Kyberd is the UNB chair in rehabilitation cybernetics and professor of electrical engineering. He is also a leading authority on control of prosthetic limbs. He kindly tutored me on the field, helped me gain a rudimentary understanding of the technologies described in this dissertation, suggested micro-histories to research, and made introductions to most of the interview subjects outside of UNB.

Dr. John Mclaughlin is an engineer, professor emeritus and president emeritus of UNB. Our conversations about R&D, innovation and entrepreneurship predate my graduate studies, and laid a foundation for both my studies and interest in this dissertation topic. This dissertation benefitted from my readings in Dr. McLaughlin's determinant of development course, and our on-going conversations on the history of science, technology, engineering and business.

Dr. Greg Kealey is a former vice president, research of UNB and professor of history. As my dissertation supervisor he was intimately involved in the development of each chapter of this document, prior to finalization of a first draft and delivery to my other dissertation committee members. The process included monthly meetings in Dr. Kealey's office and I am appreciative of his patience and advice as I 'made sense' of each chapter. I am also thankful for the reading course he led on the history of higher education. It helped frame the discussion in the dissertation on university involvement in the development of myoelectric upper limb devices.

I am also greatly indebted to my interest subjects who generously gave of their time and . They are: G. Bush, H. Deitel, D. Gow, S. Hubbard, Dr. B. Hudgins, Dr. K. Engelhart, E. Iverson, Dr. S. Jacobsen, Dr. R. Jerrard, Dr. P. Parker, G. McLearly, M. Mifsud, Dr. M. Milner, Dr. H. Sears, R.N. Scott, I. Timmen. I appreciate the time made available by Dr. Paul Forman for his review of select chapters of the dissertation and our discussion about the application of his ideas about modernity and postmodernity in this dissertation. His thoughtful comments were gratefully received.

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Last, I acknowledge the generous and kind services of archival staff at the University of Edinburgh Archives in Edinburgh, the National Academy of Sciences Archives in Washington, D.C., and Library and Archives Canada in Ottawa. I especially thank Ms. Laura Gould at the University of Edinburgh Archives, Ms. Janice Goldblum at the National Academy of Sciences Archives and Ms. Vicky Dalrymple and Ms. Suzanne Lemaire at Library and Archives Canada.

# TABLE OF CONTENTS

CURRICULUM VITAE

# LIST OF FIGURES AND ILLUSTRATIONS

# LIST OF SYMBOLS, NOMENCLATURE, AND ABBREVIATIONS

AC means alternating current.
ANT means actor network theory.
AOPC means American Orthotics and Prosthetics Center.
CAD/CAM means computer aided design/computer aided manufacturing.
Canadian N.R.C. means the Canadian National Research Council.
CEO means chief executive officer.
CIBC means the Canadian Imperial Bank of Commerce.
CPRD means Committee on Prosthetics Research and Development.
$CO_2$ means carbon dioxide.
DARPA means US Defense Advanced Research Projects Agency.
EMAS means electronic modular arm system.
EMG means electromyography.
IBM means International Business Machines.
IBME means the Institute of Biomedical Engineering, UNB.
IP means intellectual property.
LTI means Liberating Technologies Inc.
Mode 2 means the Mode theory of knowledge production.
NAS means US National Academy of Sciences.
NASA means the US National Aeronautics and Space Administration.
NIDRR means the US National Institute on Disability and Rehabilitation Research.
NHS means UK National Health Service.
NRC means National Cash Register Corp.
NSERC means the Natural Sciences and Engineering Research Council of Canada.
MEC means UNB Myoelectric Controls Symposium.
MIT means the Massachusetts Institute of Technology.
MRC means Medical Research Council of Canada.
OBU means Orthopaedic BioEngineering Unit.
OCCC means Ontario Crippled Children's Centre.
ORTC means Ontario Rehabilitation Technology Consortium.
OECD means Organization for Economic Cooperation and Development.
PPU means powered prosthetics unit.
PRTU means Prosthetic Research and Training Unit.
R&D means research and development.
RD&D means research, development and demonstration.
RED means OCCC/Bloorview Centre Rehabilitation Engineering Department.
RES means Rehabilitation Engineering Services.
RIC means the Rehabilitation Institute of Chicago.
RIM means Rehabilitation Institute of Montreal.
SBIR means Small Business Innovation Research.
SCOT means social construction of technology.
SHIL means Scottish Health Innovations Ltd.
SMART means Southeast Mobility and Rehabilitation Technology.

TARGPR means Technical Assistance and Research Group for Physical Rehabilitation.
Triple Helix means the triple helix model of university–industry–government relations.
TMR means targeted muscle reinnervation.
UNB means the University of New Brunswick.
UCLA means the University of California at Los Angeles.
U of T means the University of Toronto.
UK means United Kingdom.
US means United States of America.
US NRC means the US National Research Council.
VASI means Variety Ability System Inc.
VA NYU means Veterans Administration Hospital, New York University.

# LIST OF INTERVIEWS

Ed Biden, author interview, May 5, 2010.
G. Bush, author interview, May 14, 2010.
H. Deitel, author interview, November 11, 2010
D. Gow, author interview, November 10, 2010.
S. Hubbard, author interview, April 22, 2010.
B. Hudgins, author interview, May 5, 2010.
K. Engelhart, author interview, May 5, 2010.
E. Iverson, author telephone interview, June 21, 2010.
S. Jacobsen, author telephone interview, June 28, 2010.
R. Jerrard, author interview, April 29, 2010.
P. Parker, author interview, April 23, 2010.
G. McLearly, author interview, November 10, 2010.
M. Mifsud, author telephone interview, June 25, 2010.
M. Milner, author interview, April 22, 2010.
M. Milner, author telephone interview, June 25, 2010.
H. Sears, author telephone interview, June 21, 2010.
R.N. Scott, author interview, May 5, 2010.
R.N. Scott, author interview, May 12, 2010.
I. Timmen, author telephone interview, June 30, 2010.

# 1. INTRODUCTION

## Purpose of Study

This project has two purposes. The first is to publish a history of scientific research and technological innovation of myoelectric upper limb prostheses during the period from 1945 to 2010, with a focus on work that has resulted in commercial products.

A primary question for the history is what were the major forces that acted on the field and shaped the myoelectric hands, arms, wrists and other devices that were designed in the second half of the twentieth century? In brief, the list is technological innovation in other fields, especially microprocessors and batteries, government funding programs, and changing approaches to research and development within electrical and biomedical engineering. These forces do not operate together in a clockwork fashion where God sets everything in motion and the laws of science govern every subsequent movement. Rather, each played a part. Although technology from other fields was literally and figuratively instrumental, the devices and systems that were developed were hardly inevitable, with government dollars and engineers in the role of mere servants to technological determinism. Governments were motivated by the desire to respond positively to veterans and the thalidomide tragedy (plus, litigation was in the mind of governments from the start), and to make productive citizens. Governments used contemporary conceptions of research to formulate funding programs to make good on these motivations, initially inspired by the linear model of innovation during the period from World War II to the mid-1970s, followed by a period of reduced R&D funding from the mid-1970s to 2000s, and then, in the 2000s, the emergence of innovation and commercialization funding programs. Engineers and other biomedical professionals were not merely acted upon by technology and funding programs. They exploited them to do research, but also, in many cases, to work beyond their institutional mandates to do engineering design, prototype development, commercial product design and testing with users in clinics, and, in some cases, product manufacturing and fitting of amputees. In doing so they helped legitimate university and hospital activities that went well beyond university missions of teaching and research and hospital missions of clinical care, research and education.

The second purpose is to examine the history against theories on scientific research and technological innovation, in particular the linear model of innovation; two technology-oriented theories of research and development ("R&D"), mode 2 knowledge production and triple helix of university–industry–government relations (triple helix); and fourth, concepts of science and technology, modernity and postmodernity. The first three theories are well known to students of R&D and innovation public policy, and have been used to provide a basis for public policy and programs. To the extent that government programs have been closely modeled on a theory, this second purpose overlaps with the first. For instance, in the case of the US National Academy of Sciences Committee on Prosthetics Research and Development, there is a good argument that its programs were initially drawn from the linear model of innovation. Were the programs successful in generating products? Did R&D and innovation follow the prescribed linear path? If not, is there another model that better describes what occurred? In addressing these theories I hope to contribute to the discussion of the applicability of these models in R&D and innovation case studies.

The field of upper limb powered prostheses is particularly relevant to this second purpose because of the involvement of universities, hospitals, companies and governments in collaborative R&D, technology transfer and product development for over a half century, predating the growth of technology transfer and commercialization in other research fields in the 1980s. Indeed, some university research institutes were designing, manufacturing and fitting myoelectric upper limb prostheses to patients as early as the 1960s, going well beyond present-day conventional boundaries of academic involvement in commercialization (manufacturing and selling products derived from research, excepting books and articles, is still a bridge too far for most universities). Given this experience, what models are useful in understanding this field, and how might they be modified to better fit with field and case studies?

The theories and models are anticipated to be useful in explaining both how the field of myoelectric upper limb R&D has changed, and in identifying the forces of change. I also anticipate that the history of the field and case studies will also offer a modest contribution to the far ranging, disjointed and tendentious discussion that has been ongoing since the 1990s about scientific research and how technological innovation has been changing since the 1980s, the depth and scope of the change, and the underlying causes of the change (or lack of change, for some). The discussion is far ranging and disjointed in part because of the breadth of backgrounds of the participants. It includes historians of science and technology; sociologists of knowledge and higher education; science and technology studies scholars; philosophers of science; micro and micro-economists; public policy researchers; professors of business; academic, corporate and government scientists and research engineers; professional engineers; corporate executives and politicians. It covers topics as diverse as how to encourage more high-technology entrepreneurship in regional economies, to the changing practices in university scientific research, to firm-level innovation case studies, to whether there is an ongoing transition from modernity to postmodernity. The change described in many of the models involves an increasing emphasis of scientific and engineering R&D away from questions of fundamental discovery to the task of practical application, whether making myoelectric hands or innumerable other goods and services. The consensus view among many scholars, whether advocates or critics of the change, is that it has been accelerating since the 1980s, is profound, and is occurring within many fields of R&D.

The discussion is not just a scholarly examination of whether and how science is changing, and of historical causation, but also a practical debate among students of public policy, corporate officers and directors, and politicians about the role of the state in science, technology, and innovation. There is no simple consensus within governments about the change, but with increased funding by governments in industrialized countries of application-oriented R&D since the 1980s, there is an ever-growing sense of urgency in how to maximize the benefits to the state from investments in scientific research and technological innovation.

The urgency is driven by a view that, despite massive increases in government funding for government and academic industry oriented research, technology transfer, and commercialization, little progress has been made in the commercialization of knowledge.

This study of the history of scientific research and technology innovation in the field of myoelectric upper limb devices addresses questions of how conceptions and practices of R&D have changed from 1945 to the present, the forces behind this change, and how some of the best known commercial products in the field of upper limb myoelectric devices were developed and commercialized. I side with the majority view on the profound nature of the changes in conceptions and practices of R&D and commercialization, especially within universities. But there is not an exact fit with any of the theories or models. For instance, there is also a trend beginning in the 1970s and continuing to the present on an increased focus on research and away from the design, building and manufacturing of devices. The major forces that acted on the field and in the cases were government funding programs, technological innovation in other fields, and changing approaches to R&D, innovation and entrepreneurship. These changing approaches in turn influenced the engineers and engineer-entrepreneurs at the centre of my micro-histories who, whether alone or in collaboration with others, directed the engineering-design projects to make the world's modern upper limb myoelectric products.

## Summary of Chapters

Chapter 2 provides definitions of science, R&D, engineering design, innovation, and entrepreneurship, and describes the four major concepts that are used to analyze the field history and case studies. The definitions offer a brief sketch of the changing usage of these words and phrases during the second half of the twentieth century, and in turn inform the definitions of the four major concepts: the linear model of innovation; mode 2 knowledge production; triple helix; and Paul Forman's theory of postmodernity.

Chapter 3 summarizes historical accounts of upper limb myoelectric prosthetic research, development, and innovation. These historical accounts are, with the exception of David Serlin, written not by historians, but by engineers, occupational therapists, company executives and others who work or have worked in the field of myoelectric upper limb prosthetics. They provide an impression of how practitioners conceived of their field, how it changed, and the forces underlying the change.

Chapter 4 offers a field essay of upper limb myoelectric prosthetic research, development and innovation. It offers a macro or world history of the field, before getting to the micro-history details of the cases in Chapter 6. It includes a description of how governments applied ideas of R&D. Although the theory of the linear model may have died a thousand deaths at the hands of scholars, I show how in the realm of public policy and state research funding programs the linear model remained a guiding precept. For upper limb prostheses R&D, the model legitimated the development of funding programs in the United States to support researchers to develop devices to help get veterans back to work, and in Canada and Europe to bring researchers into hospitals to design devices for children whose mothers had taken the drug thalidomide. The chapter also shows that since the 1990s funding programs based on the linear model have increasingly shared government budgets with new innovation and commercialization programs, offering engineers and researchers a means to undertake fundamental research as well as a more direct means to legitimize extra-research activities, such as design, prototype development, and product development.

Most of Chapter 4 focuses on the history of the R&D field from 1945 to 2010. The history begins in Germany in the 1940s with the first proof-of-concept myoelectric upper limb prosthesis. This is followed by the development of the electric hands and arms in the late 1950s and 1960s at universities, hospitals, government agencies, and companies in Austria, Canada, Germany, Italy, the United Kingdom, the United States, and the USSR. Here we see government research funding programs inspired by the linear model of innovation being used by engineering professors to design devices. By the mid-1970s, the long-awaited commercial myoelectric upper limb systems were first launched, which coincided with the withdrawal of government support for myoelectric prostheses R&D. In the 1980s and 1990s university research groups turned to national research programs, private support, and other funds to do applied research on control strategies, and devices for higher level amputees (e.g. above elbow amputees with limited muscle control sites). In the 2000s, with support from the new innovation funding programs, engineers were again designing prosthetic devices for the marketplace, such as the i-Limb with its five powered digits, pattern recognition systems, and techniques for targeted muscle reinnervation (TMR), making good on the research of the 1980s and 1990s to develop electronic prostheses for above elbow amputees.

Chapter 5 outlines the methodology and method used in the study. I use a qualitative methodology informed by social history methods. My central research questions are how did commercial upper limb myoelectric systems arise, how did the practice of R&D and innovation represented in the cases correspond to concepts of R&D and innovation, and what were the forces of change in the way R&D and innovation were practiced during the period of the study?

Chapter 6, the longest of the chapters, presents case studies of the following major commercial advancements in the field:

1. electronic arms, wrists, and elbows from Otto Bock;
2. myoelectric control systems from the University of New Brunswick's (UNB) Institute for Biomedical Engineering (IBME);
3. electronic arms, wrists and elbows from the Ontario Crippled Children's Centre (OCCC), its successor organizations, and Variety Ability System Inc (VASI);
4. the Boston Arm from Massachusetts Institute of Technology (MIT) and Liberty Mutual;
5. the Utah Arm from the University of Utah and Motion Control Inc.; and

6. the i-Limb at the Bioengineering Centre in Edinburgh (formally at The Princess Margaret Rose Orthopaedic Hospital) and TouchBionics.

These case studies show research engineers, prosthetists, occupational therapists, product managers and others at work in laboratories, hospitals and clinics from the 1960s to the present. Common to many of the cases is a move from laboratory to clinic or hospital. The focus of the activities was in designing, fitting and testing products, communication among interdisciplinary teams and with patients, and long cycles of product improvement. It is people who come to the fore in the fine-grained cases, with leaders who are not so much merchant scientists, with one foot in the market and the other in laboratory, but design engineers, who straddle the worlds of the clinic and engineering.

In addition to the micro-histories, Chapter 6 also includes a discussion of each case in light of the key terms, concepts and models presented in Chapter 2.

These cases were chosen as they were commonly cited as primary examples of myoelectic upper limb technological innovation during the interviews I conducted in 2008 and 2009 with researchers and company representatives in the industry. I sought cases that had resulted in systems that moved beyond the clinic and quasi-product status into commercial systems and products that introduced new technology to amputees. Not all cases that met these criteria have been included in this study. I would have liked to include a case on Northwestern University and the Rehabilitation Institute of Chicago, but this was not possible given the budget for the project. A case study on the RSL Steeper bebionic hand would also have enriched this dissertation, but unfortunately the bebionic hand had not been announced or launched at the time I was conducting my initial interviews for this study.

In Chapter 7, I draw conclusions on the applicability of the concepts to the theories.

## Background: Electromyography

Electromyography is the study of muscle function by investigation of electric signals. It has its origins in the reawakening of science during the Renaissance.[1] According to Basmajian and De Luca, authors of the masterly *Muscles Alive: Their Functions Revealed by Electromyography*, although Leonardo da Vinci was a student of muscles and their functions, it was not until the year of the great fire of London in 1666 that the Italian physician and naturalist Franceso Redi first documented muscle-generated electricity, based on the suspicion that the shock of the electric ray fish was muscular in origin.[2] But it was not until 1791 that the first observation was made of the relationship between electricity and muscle contraction, by another Italian Luigi Galvani, a physician and anatomy professor at the University of Bologna. The discovery was the result of experiments to depolarize a frog's leg muscles, and is "generally acknowledged as representing the birth of neurophysiology, thereby making Galvani the father of this field . . ."[3] The concept of galvinism, that animal electric fluid provided the stimulus for contraction of muscles, also made its way to the European public as a result of sensational experiments, and provided the scientific supposition for Mary Shelley's *Frankenstein*.[4]

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[1] Allen J. Thurston,"Pare and Prosthetics: The Early History of Artificial Limbs," *ANZ Journal of Surgery* 77, (2007): 1114.

[2] John V. Basmajian and Carlo J. De Luca, *Muscles Alive: Their Functions Revealed by Electromyography*, 5d ed. (Philadelphia: Williams & Wilkins, 1985), 1.

[3] Ibid.

[4] The first line of the preface reads: "The event on which this fiction is founded has been supposed, by Dr. Darwin, and some of the physiological writers of Germany, as not of impossible occurrence." Mary Wollstonecraft Shelley, *Frankenstein or The Modern Prometheus* (London: Thomas Davison, Whitefriars, 1823), v.

It was nearly forty years later that another Italian proved that electrical currents did originate in muscles. Carlo Matteucci, a medical doctor from the University of Bologna, made the discovery while head of the laboratory of a hospital in the nearby city of Ravenna. This was followed by the work of the German Du Bois-Reymond. Educated at and subsequently the chair of physiology at the University of Berlin, Du Bois-Reymond was the first to show that the nerve impulse was an electrical wave of negativity transmitted along the nerve.[5]

Advancements in the study of myoelctric signals from human muscles were challenged during the second half of the nineteenth century by the limitations of instruments to measure electrical currents. The instrument in use since its invention in 1820, the galvanometer, consisted of a magnetic compass needle connected to a moving coil. The needle moved in response to an electric current flowing through its coil in the magnetic field. By contemporary standards, it provided for only rudimentary measurements of electrical activity.

The employment of metal surface electrodes in the first decade of the twentieth century made the measurement of muscle signals by the galvanometer more accessible. The application of the cathode ray tube (invented in 1897) in 1920 made possible the amplification of muscle signals detected by the galvanometer. The galvanometer was replaced in 1922 when Herbert Gasser and Joseph Erlanger used a cathode ray oscilloscope to "show" the signals from the muscles. The two received the Nobel Prize in Physiology or Medicine in 1944 for their use of the

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[5] http://www.nobelprize.org/nobel_prizes/medicine/laureates/1944/press.html (June 5, 2012). The research was conducted from the 1840s to 1880s.

instrument in the discovery of the highly differentiated functions of single nerve fibres.

The next major advancement of instrumentation was the introduction of vacuum tube amplifiers in the late 1920s. This simplified the task of detecting the electromyographic signals, allowing the new art of electromyography to find practical usages in the clinical environment. According to Basmajian and De Luca, "As the quality and availability of electronics apparatus improved anatomists, kinesiologists, and orthopedic surgeons began to make increasing use of electromyography."[6] This, in turn, set the stage for the first application by Ronald Reiter at the University of Munich in the 1940s of electrodes, vacuum tube-based controllers and electronic hardware in the production of a proof-of-concept upper limb myoelectric arm.

## What is an upper limb myoelectric prosthesis?

The upper limb, also called the upper extremity, in human anatomy extends from the deltoid region, or chest, to the tip of the fingers and thumb. The elements of the musculoskeletal systems in humans are the shoulder (including both a girdle and joint), the arm, forearm, wrist, and hand. The word "myoelectric" combines the Greek word "myo," meaning muscle, with "electric." It is, in brief, electricity from muscles. R. N. Scott[7], one of the pioneers in the development of upper limb myoelectric controls, provides this concise one sentence definition of an analog upper limb myoelectric prosthesis: "The concept of a myoelectric prosthesis is

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[6] Basmajian and De Luca, *Muscles Alive*, 6 and 7.

[7] R. N. Scott was the founding director of UNB's Institute of Biomedical Engineering.

simple. The electrical activity naturally generated by contracting a muscle in a residual limb is amplified, processed and used to control the flow of electricity from a battery to a motor, which operates an artificial limb."[8]

Figure 1 illustrates the five elements of a myoelectrically controlled prosthetic hand: muscle, electrode, battery, controller, and electric hand.

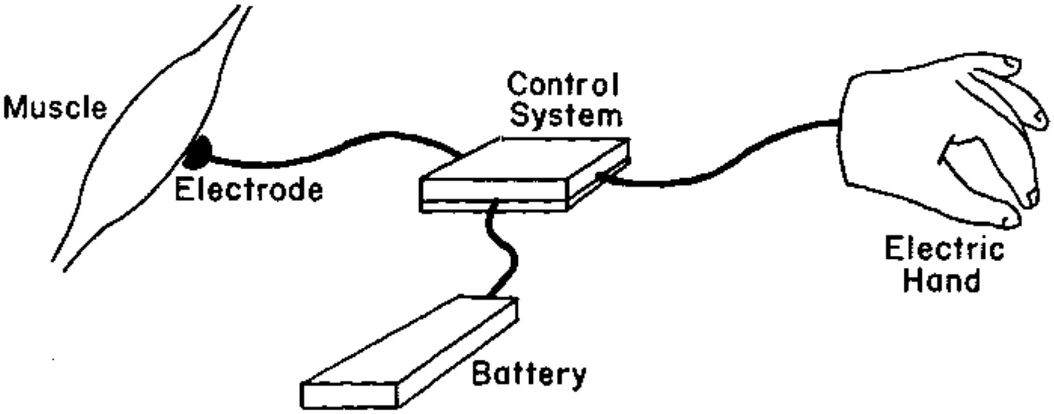

**Figure 1: Components of a Myoelectric Prosthesis (Image source: R.N. Scott)**

Most systems use electrodes placed on the skin, not implanted in the body. The electrodes convert the ionic activity generated by the muscle into an electrical signal that is amplified for use in control of a prosthesis.[9] As the electrodes are not focused on a single muscle fibre or motor unit, they act as a coarse measure of the upper limb muscles. The control system can, however, distinguish between low, medium, and high muscle contraction levels.

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[8] L. McLean and R. N. Scott, "The Early History of Myoelectric Control of Prosthetic Limbs (1945-1970)" in *Powered upper limb prostheses: control, implementation and clinical application*, ed. Ashok Muzumdar (Berlin: Springer Verlag, 2004), 1.

[9] Dennis Lovely, "Signals and Signal Processing for Myoelectric Control" in *Powered upper limb prostheses: control, implementation and clinical application*, ed. Ashok Muzumdar (Berlin: Springer Verlag, 2004), 35-53.

**Figure 2: Surface Electrodes: Image Courtesy of Liberating Technologies**

The batteries, currently lithium ion, are usually specially adapted to ensure safety and produce power that balances weight and electricity for the control system and terminal device or devices.

The control system often includes an amplifier to boost the signal from the muscle and a microprocessor to read the signal and decide on what signal to communicate to the terminal device or devices. Microprocessors are computers on a single, or a few, integrated circuits. Unlike personal computers that use general-purpose microprocessors capable of running a number of programs, these are like the microprocessors in automobiles and cellular phones, designed for specific input-output operations as part of a larger system. In this system, the inputs are electrical currents from electrodes and outputs. The outputs are electrical currents to an electric hand, hook, elbow, or wrist.

## What is a myoelectric signal?

A myoelectric signal is a small electrical signal generated by a muscle during contraction. The signal is measured by microvolts (one millionth of a volt), and can be measured using electromyography (EMG) techniques like the electrocardiograms or ECG signals produced by the heart muscle. Figure 2 is an illustration of a myoelectric signal. If you have an electrode on your bicep and contract the muscle, this is the kind of signal that would be read by the controller and allow you to open or close an electric hand.

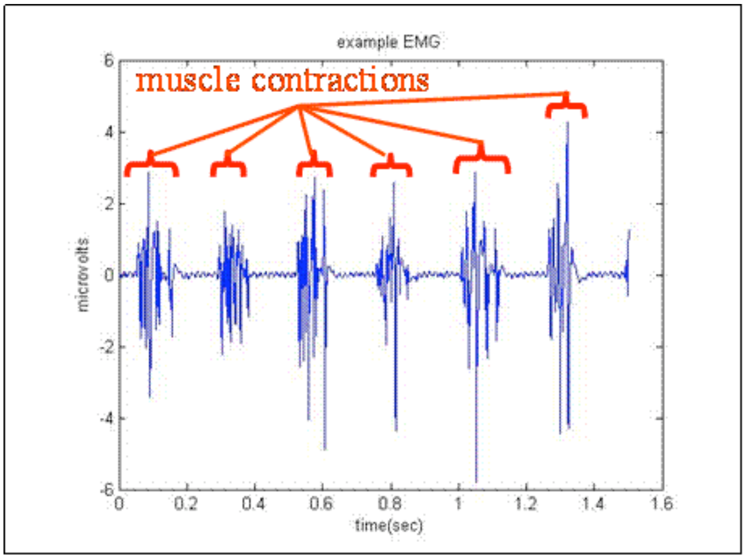

**Figure 3: Myoelectric Signal (Image source: Temple University)**

## How do skeletal muscles generate electric signals?

Skeletal muscles are made up of fibres that are arranged in bundles called fascicles.[10] Each fascicle contains spaghetti-like muscle fibres, and each muscle fibre contains hundreds or thousands of rod-like myofibrils. These myofibrils are the contracting agents in muscles, and generator of the electrical signals. The following figure illustrates the elements of this muscle system.

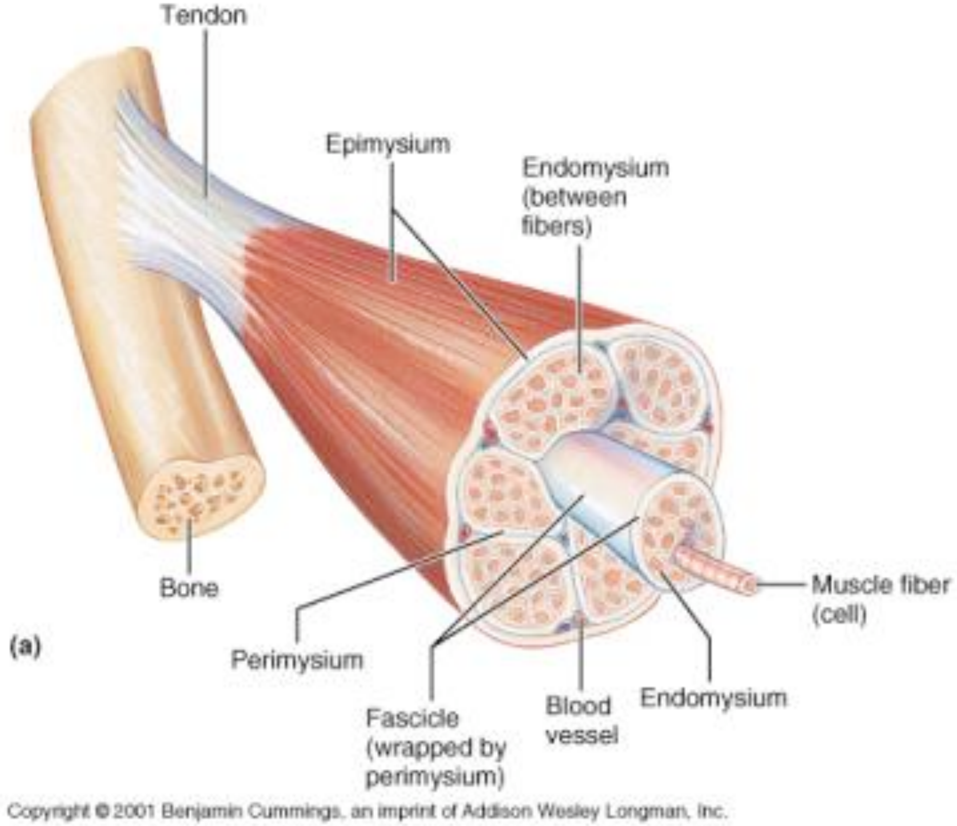

**Figure 4: Image courtesy Benjamin Cummings**

Muscle fibres or cells are sheathed by a polarized membrane. The inside of the membrane is negative (because of its higher concentration of potassium) with

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[10] Denis Lovely, "The Origins and Nature of the Myoelectric Signal" in *Powered upper limb prostheses: control, implementation and clinical application*, ed. Ashok Muzumdar (Berlin: Springer Verlag, 2004), 17-33.

respect to the outside (containing a higher concentration of sodium). A contraction occurs when an impulse from a motor nerve travels through the spinal cord to a group of muscle fibres called a motor unit. This process is illustrated on the following page. The motor impulse generates a biochemical reaction that causes the sodium channels in the cell membrane to open up and sodium ions to move into the cell, resulting in a depolarization of the fibre and shortening of the myofibril and the muscle. It is the cycle of resting potential, depolarization and repolarization that generates the electrical activity that is detected by external electrodes.[11]

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[11] Ibid.

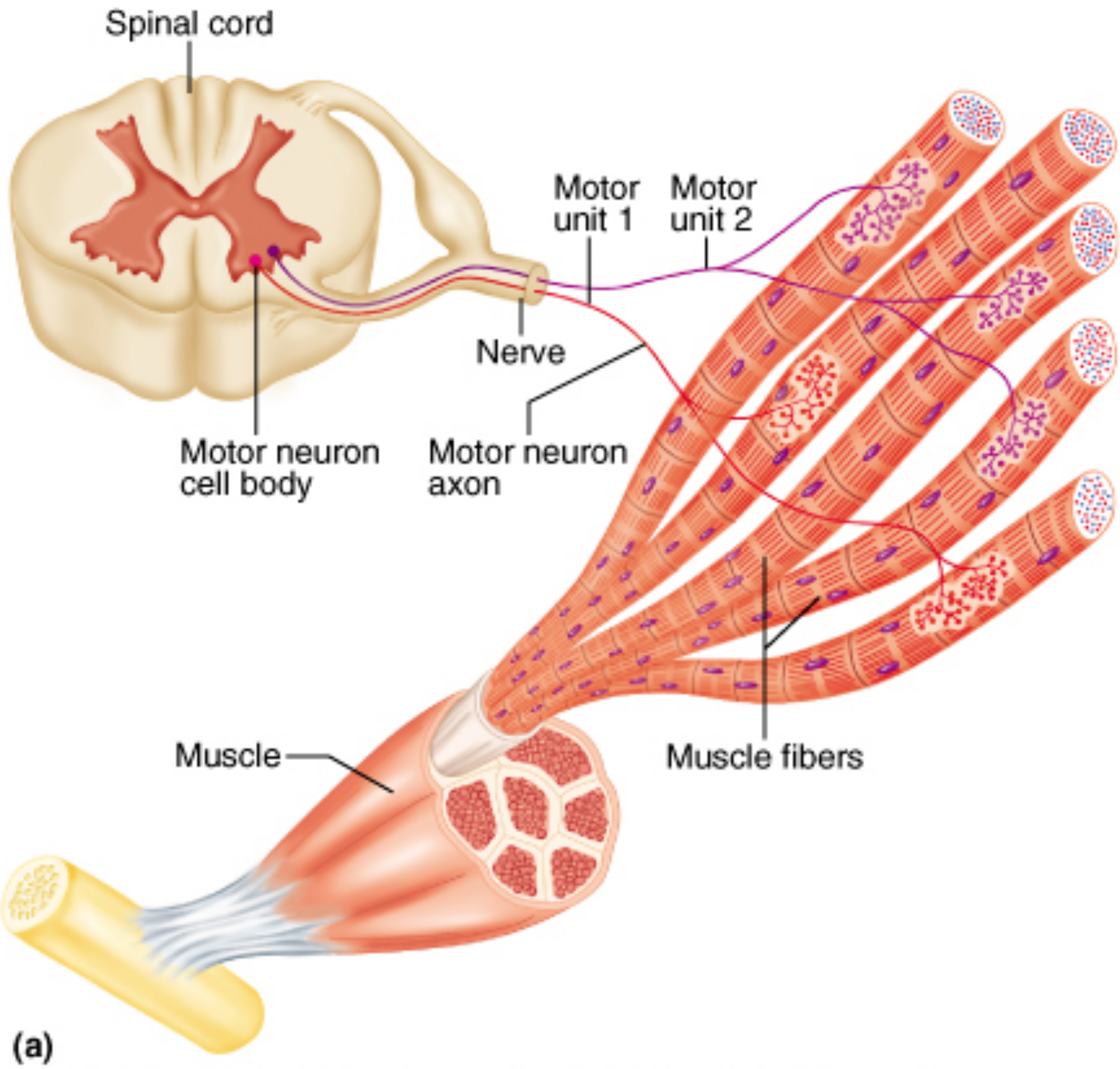

**Figure 5: Image courtesy Benjamin Cummings**

## What are the markets for upper limb myoelectric prostheses?

The markets for upper limb myoelectric prostheses are small, limited by the upper limb amputee population. In the United States there are about 6,000 upper extremity amputees a year. The US Veterans Administration has 40,000 amputees currently receiving services in its health care system.[12] The majority of upper limb amputations occur as a result of trauma involving young people,[13] but this is decreasing compared to disease-related limb loss.[14] In the United Kingdom, most traumatic amputations occur as a result of industrial accidents.[15] Major upper limb amputations (excluding thumb and fingers) make up about 15% of all acquired major limb amputations in the US.[16] In other countries the figures were 3% in Denmark, 17% in the UK, and 5%-6% in Australia.[17] Prosthetic legs have a much bigger market in terms of numbers of fittings.

A number of factors influence the kinds of upper limb prostheses that gain acceptance by amputees. These include the amputation level (at the shoulder or the wrist, for instance), stump muscle capacity (the number of muscle sites influences the kind of myoelectric control system that may be used), needs (functional, recreational and vocational), availability of health care resources, and insurance coverage.[18] Cultural factors are also important. According to one study, 72% of upper limb prosthesis users in the United States preferred hooks as a terminal

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[12] Grant McGimpsey and Terry C. Bradford, *Limb Prosthetics Services and Devices Critical Unmet Need: Market Analysis White Paper* (Worcester, Mass.: Worcester Polytechnic Institution, Bioengineering Institute Center for Neuroprosthetics, 2011).

[13] A. Esquenazi, "Amputation rehabilitation and prosthetic restoration. From surgery to community reintegration," *Disability Rehabilitation* Jul 22-Aug 5; 26, no. 14-15, (2004): 831-6.

[15] Paul Chappell, "Arm amputation statistics for England 1958-88: an exploratory statistical analysis," *International Journal of Rehabilitation Research* no. 15, (1992): 57-62.

[16] Ibid.

[17] G.H. Kejlaa, "The social and economic outcome after upper limb amputation," *Prosthetic and Orthotic International* Apr; 16, no. 1 (1992): 25-31.

[18] S. Godfrey, "Workers with prostheses," *Journal of Hand Therapy*. 3 April-June (1990): 101-10.

device; whereas in three European countries this percentage was lower, varying between 12%-30%.[19]

More body powered upper limb prostheses are fitted to amputees than powered ones.[20] Advantages of body powered prostheses are that, in general, they are lighter, more durable during heavy work, less susceptible to damage by environmental exposures (mechanical, electrical, chemical), cause amputees fewer skin problems, have less heat build-up in the socket, suffer fewer technical failures, have a quicker response time, offer more choice of interchangeable terminal devices, are easier to learn to use, may be fitted by a greater number of clinics and experts, and require no battery charging or glove changing.[21] Body powered prostheses also have lower up front and maintenance costs. Nevertheless, surveys of amputees have found that myoelectric hands are preferred for light manual tasks, office work, activities of daily living and social occasions, whereas body powered, cable-assisted prostheses are preferred for heavier jobs and farm work.[22]

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[19] M. LeBlanc, "Use of prosthetic prehensors," Prosthet Orthot Int. Dec; 12, no . 3 (1988): 152-4.

[20] S.G. Millstein, H. Heger and G.A Hunter, "Prosthetic use in adult upper limb amputees: a comparison of the body powered and electrically powered prostheses," *Prosthetics and Orthotics International*, 10, (1986): 27-34.

[21] Craig Martin, *Upper Limb Prostheses: A Review of the Literature With a Focus on Myoelectric Hands* (Victoria, BC: WorkSafeBC Evidence-Based Practice Group, 2011), 3.

[22] Ibid, 49-50.

## Who manufacturers myoelectric prostheses?

There are six major manufacturers of upper limb myoelectric control components, four in Europe and two in the United States. Otto Bock of Germany (its upper limb myoelectric group is located in Vienna) has designed myoelectric components and hands since the 1960s and has the largest market share of any of the companies. Touch Bionics of Edinburgh is the youngest of the six and has grown with the launch, in the mid-1990s, of its i-Limb product, the first myoelectrically controlled hand with five individually powered and controlled digits. RSL Steeper of Leeds, UK, is, like Otto Bock, a long-standing manufacturer of prosthetic limbs. The company recently launched the bebionic hand, which is the second entrant into the market pioneered by the i-Limb. Centri of Sollentuna, Sweden is the fourth manufacturer of myoelectrical controlled prosthesis for upper extremity. Systemteknik of Sweden used to manufacturer a myoelectric hand, but is no longer in the market.

In North America a number of myoelectric component manufacturers have come and gone. Fidelity Electronics, Leaf Electronics, Veterans Administration-New York University, Variety Abilities Systems Inc. and UNB all used to manufacture upper limb myoelectric products and components, but are no longer in the business. UNB's technology was transferred to Liberty Mutual and VASI. VASI was bought by Otto Bock in 2005. The two companies from this list that continue to manufacture and sell systems are Liberating Technologies Inc. of Hopkinson, Massachusetts, a spin-off company from Liberty Mutual Insurance. The other company is (like Centri) owned by Fillauer LLC, based in Chattanooga, Tennessee.

Motion Control of Salt Lake City, Utah began development of its Utah Arm in the early 1970s and launched the system in the early 1980s.

**How much do myoelectric arms cost?**

Upper limb amputees can buy a nonfunctional cosmetic hand for about $3,000 to $5,000 that "just fills a sleeve.” A conventional body powered prosthesis can cost around $5,500. For $10,000, a functional "split hook" device can be purchased for a below elbow amputee. The cost of a myoelectric hand ranges from about $7,500 to approximately $30,000 for an i-Limb.[23] A neuroprosthetic arm may cost as much as $100,000. Prices are significant for these devices because they are not mass produced, made of custom materials, designed to use a variety of components, and sized and adapted for the needs of each amputee.

And these are just the capital costs. According to a study on behalf of the US Department of Veterans Affairs, the average five-year projected cost for an upper limb prosthesis in the Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) group was higher than for the Vietnam group: $117,440 USD vs. $31,129 USD. [24]

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[23] Martin, *Upper Limb Prostheses*, 3.

[24] D. K. Blough, S. Hubbard, L.V. McFarland, D.G. Smith, J.M. Gambel, and G.E. Reiber, “Prosthetic cost projections for service members with major limb loss from Vietnam and OIF/OEF,” Journal of Rehabilitation Research and Development 47 no 4 (2010): 387-402.

## What happens if I want to be fitted with a myoelectric arm?

Upper limb loss can occur anywhere, but it occurs most frequently at work. Following the trauma, the amputee often goes directly to a local hospital where he or she (more often, it's a man) is put under the care of a surgeon, who works with teams of other doctors, occupational therapists, prosthetists and others. The aim of surgery includes construction of a stump conducive for the fitting of a prosthesis.

The occupational therapist typically works at the hospital or clinic, and is in charge of the process to identify the amputee's needs. They present options to the amputee for a prosthesis that will meet those needs. They liaise with the insurance company or third-party payers for the coverage of the costs of the prosthesis and maintenance services. They develop a program of training for the amputee on the use of the myoelectric prosthesis. The occupational therapist may work at the hospital or at a separate clinic.

Likewise, the prosthetist will typically work at a hospital or clinic. He or she is responsible for design, fitting, and maintenance of the prosthesis. Each device must be customized for the amputee. The hardware and software components may all come from one company or from a number of companies. The prosthetist will work with other professionals and technicians to craft a device that provides an appropriate fit for the stump, and replicates the natural shape, colour and appearance of the missing limb.

In the case of the US Department of Veterans Affairs, its prosthetics and sensory aids service operates regional prosthetic/orthotic amputee clinics and laboratories for custom fabrication and fitting of prostheses, and also has local contracts with prosthetic and orthotic facilities. Its process begins with an evaluation of the amputee at the clinic. Decisions as to whether or not a myoelectric prosthesis should be prescribed are made by an interdisciplinary team assembled to assess a number of criteria:

- Does the patient have the cognitive ability to use a sophisticated device and the ability to don and duff the prosthesis correctly?
- Will the patient be able to care for the prosthesis (such as keeping electrodes clean, not immersing the prosthesis in water, charging the battery)?
- Is the residual limb free of scars at the proposed electrode sites?
- Will the patient be able to tolerate the myoelectric prosthesis as the fit is more intimate and the prosthesis is likely to be heavier than a conventional prosthesis?
- Is the patient motivated to use the myoelectric prosthesis?
- Does the patient live in a remote area where they may not be able to have the myoelectric prosthesis appropriately serviced?
- Has the patient worn a prosthesis prior to evaluation, conventional or myoelectric? Does the patient work, and if so, where?
- Is the work environment unsuitable for a myoelectric prosthesis?[25]

Other funding organizations use similar criteria to make decisions on whether to prescribe a myoelectric prosthesis. With five-year costs of these decisions in excess of $100,000, it is likely these rigorous assessment processes will continue to be a part of getting fitted for a myoelectric prosthesis.

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[25] Martin, *Upper Limb Prostheses*, 44.

**Who pays?**

The principal reimbursement sources for prosthetic services and devices are insurance companies, individuals, hospitals, vocational rehabilitation programs, workers' compensation programs, and government programs. In the United States, government programs such as Medicare (for persons aged 65 or older or disabled) and Medicaid (for persons in financial need) provide reimbursement for prostheses and services. As well, the Department of Defense, and the Department of Veterans Affairs, provide health insurance programs for active duty military, and for veterans. In the United States, Medicare, Medicaid, and the Department of Veterans Affairs collectively account for approximately 40% to 50% of such reimbursements.[26]

Yearly third-party health insurance caps on prosthetic services range from $500 to $3,000, and lifetime restrictions range from $10,000 to one prosthetic device during a person's lifetime (from birth to death). The trends in coverage have been to higher deductibles (20% to 50% of the device price), lower coverage amounts, and greater focus on cost-effective equipment that meets the criteria of medical necessity.

In Canada, health care is a provincial responsibility and programs for reimbursement of prostheses vary by province. Generally, most provincial health care insurance plans and most workplace compensation programs provide some coverage for prostheses. For instance, the British Columbia PharmaCare Plan covers designated permanent prosthetic devices, and replacement every three

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[26] Blough, "Prosthetic cost projections," 387-402.

years. The provincial health care plan in Manitoba offers reimbursement when provided by a practitioner certified by the Canadian Board for Certification of Prosthetists and Orthotists, with replacements every two years. The Manitoba plan will also reimburse the cost of another regular prosthesis for back up. Ontario covers up to 75% of the cost of conventional upper and lower limb prostheses and powered upper limb prostheses (electric and myoelectric arm prostheses), excepting devices that can be provided by the Workplace Safety and Insurance Board. If repair, adjustment, or replacement is needed as a result of general wear and tear, these are also covered. There is also a special section about payment for the provision, repair and/or replacement of a swim-leg, a special waterproof prosthesis.

# 2. LITERATURE REVIEW I: SCIENCE, RESEARCH AND DEVELOPMENT, ENGINEERING DESIGN, INNOVATION, ENTREPRENEURSHIP

This is the first of two literature review chapters. This chapter provides definitions of key words and phrases, and a description and analysis of the four key concepts that are used to analyze the cases. The definitions of science, R&D, engineering design, innovation, and entrepreneurship are provided to inform the discussion of the four concepts, each of which integrate, to varying degrees, these five terms. The definitions offer a brief sketch of the changing usage of these words and phrases, showing how they grow closer together in their meanings during the second half of the twentieth century, so that by the final decades of the century the concepts of knowledge production in mode 2, triple helix, and Forman's theory of postmodernity can at least be understood as coherent concepts, if not something that actually happens in practice. Chapter 3 summarizes historical accounts of upper limb myoelectric prosthetic R&D and innovation.

## Science

The New Shorter Oxford English Dictionary provides four definitions of "science,"[27] two of which pertain to the natural sciences: (i) "A branch of study that deals either with a connected body of demonstrated truths or with observed facts systematically classified and more or less comprehended by general laws, and which includes reliable methods for the discovery of new truth in its own domain;"

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[27] Lesley Brown, Ed. *The New Shorter Oxford English Dictionary* (Oxford: Claredon Press, 1993), 2717.

and (ii) " . . . the intellectual and practical activity encompassing those branches of study that apply objective scientific method to the phenomena of the physical universe (the natural sciences), and the knowledge so gained." Although most scientists and research engineers may nod in agreement with the definitions, few historians of science or students of science studies would nowadays include "truth" or "objective" in their definitions. In the following paragraphs I provide a brief outline of how the divergence in the definition of "science" occurred, referencing the scholarship of four influential students of science since World War II.

### *Mertonian Norms: CUDOS*

The first is an American sociologist, Robert Merton, who in an article published in 1942 articulated four norms of modern science: communism, universalism, disinterestedness, and organized skepticism, referred to by the acronym CUDOS.[28] These norms articulate an approach to scientific research that has much in common with the OED definition. Communism means: "The substantive findings of science are a product of social collaboration and are assigned to the community."[29]

The principal of universalism is that "Truth-claims, whatever their source, are to be subjected to preestablished impersonal criteria: consonant with observation and with previously confirmed knowledge. The acceptance or rejection of claims entering the lists of science is not to depend on the personal or social

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[28] Robert K. Merton, "The Normative Structure of Science." in *The Sociology of Science: Theoretical and Empirical Investigations*, ed. Robert K. Merton, (Chicago: University of Chicago Press, 1973). Originally published as "A Note on Science and Democracy," *Journal of Legal and Political Sociology*, Vol. 1, Nos.1-2, (1942), 115-126.

[29] Ibid.

attributes of their protagonist."[30] Disinterestedness, for Merton, meant: "There should be no interference between personal, political, religious, economical, . . . interests with the acceptance of scientific work."[31] Last, organized skepticism required " . . . temporary suspension of judgment, and the detached scrutiny of beliefs in terms of empirical and logical criteria . . ."[32]

According to science and technology policy scholar Peter Phillips, Merton and fellow philosophers of science, Michael Polanyi and Karl Popper, together "define the critical elements of the 'scientific method' used by most of the positivist physical and social sciences . . ."[33] These consisted of a deductive approach focused on problems or questions that could be tested or empirically examined, use of theory-driven hypothesis to explain phenomenon, prediction, and use of tests or empirical examination to falsify or support a hypothesis. The historian of science, Paul Forman (one of the major theorists considered in this dissertation, discussed below), referred to Merton's CUDOS as " . . . a set of norms that mirrored the left-leaning, liberal-democratic, social-intellectual values that the Allies opposed to the Axis. So long as modernity continued–but only so long–CUDOS retained . . . wide acceptance not merely in the sociology of science but in the scholarly world generally."[34]

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[30] Ibid.

[31] Ibid.

[32] Ibid.

[33] Peter W.B. Phillips*, Governing Transformative Technological Innovation: Who's in Charge?* (Edward Elgar: Cheltenham, UK/Northampton, MA, 2007), 150.

[34] Paul Forman, "On the Historical Forms of Knowledge Production and Curation: Modernity Entailed Disciplinarity, Postmodernity Entails Antidisciplinarity," *OSIRIS* 27, (2012): 71.

### *Thomas Kuhn's "Normal Science"*

What changed? According to Forman the "cultural storm . . . began with Thomas Kuhn's *The Structure of Scientific Revolutions*.[35] In it, Kuhn presented an alternative explanation to the dominant view of scientific progress as a result of incremental accumulation of knowledge and separation of ignorance, on the one hand, and facts on the other. Instead, Kuhn argued, "paradigms" provided the conceptual frameworks for "normal science," which involved puzzle-solving games to address anomalies. In the book, "paradigm change" occurred as a result of a build-up of anomalies (e.g. in the Ptolemaic system) and the emergence of revolutionary science (e.g. Copernican Revolution) resulting in the creation of a new paradigm, reorientation of the rules of the game and initiation of a new round of puzzle solving. The book not only provided new words and phrases for the fields of history, philosophy and sociology of science, but also it opened up these fields of science studies beyond the study of Mertonian norms to the study of scientific communities, and the substance of theory choice with the physical sciences. As revolutionary as this book may have been, according to Forman and many others, it " . . . was only a halfway house."[36]

### *Empirical Programme of Relativism*

Halfway houses offer people a stepping off point in the process of reintegration with society. *The Structure of Scientific Revolutions* provided science

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[35] T.S. Kuhn, *The Structure of Scientific Revolutions* (Chicago: University of Chicago Press, 1962).

[36] Forman, *Antidisciplinarity*, 94 and 95.

studies scholars of the 1980s with a doorway to apply the social construction movement to the study of science. One of the major papers to announce the arrival of the field was authored in 1984 by the Scottish sociologist Trevor Pinch and Dutch social scientist, Wiebe E. Bijker. Titled "The Social Construction of Facts and Artefacts: Or How the Sociology of Science and the Sociology of Technology Might Benefit Each Other," they argued that " . . . the study of science and the study of technology should . . . benefit from each other . . ." and that " . . . the social constructivist view prevalent within the sociology of science, and which is also emerging within the sociology of technology, provides a useful starting point."[37] The starting point, then, was the empirical programme of relativism (EPOR), which defined science as a social process explained by a process of achieving consensus. It operated in three stages. In the first, there is "interpretative flexibility" of scientific findings, meaning these findings are open to more than one interpretation. In the second, a scientific consensus will usually emerge as a result of "social mechanisms," which limit interpretative flexibility. In the third, "closure mechanisms" operate on the wider social-cultural milieu, communicating the ending of the controversy.[38] What the article suggested is that science studies bequest this approach to technology studies, and that technology studies would give back insights " . . . to relate the content of a technological artefact to the wider sociopolitical milieu . . . ." Pinch and Wiebe suggested that for science studies " . . . describing technological artefacts by focussing upon the meanings given to them by

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[37] Trevor J. Pinch and Wiebe E. Bijker, "The Social Construction of Facts and Artefacts: Or How the Sociology of Science and the Sociology of Technology Might Benefit Each Other," *Social Studies of Science*, Vol. 14, No. 3 (1984): 400.

[38] Ibid.

relevant social groups seems to suggest a way forward."[39] Science studies would not just investigate scientific communities (whether in puzzle solving or revolutionary science phases) and theory choice, but now would be broadened to include all of the relevant social groups that had previously been understood to operate outside of science.

The next step in the definition of science, discussed in each of the mode 2, triple helix, and postmodernity theories, but especially mode 2, is the expansion of science to include not just non-scientists, but also environments beyond the traditional realms of science, such as laboratories, classrooms, conference halls, journals and libraries. mode 2 theory calls it the "context of application," and it includes everywhere, from hospitals to factory floors.

## Research and Development

For an introductory definition of R&D a good place to start is the *Frascati Manual*[40] published by the Organization for Economic Cooperation and Development's (OECD). It documents the internationally recognized methodology for collecting and using R&D statistics. It is also, as will be discussed later, an artifact of the statistician's reception of the linear model of innovation in the 1960s. The *Frascati Manual* defines R&D in three categories:

- ***Basic research*** is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of

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[39] Ibid, 428.

[40] Organization for Economic Cooperation and Development, *Frascati Manual 2002: Proposed Standard Practice for Surveys on Research and Experimental Development, The Measurement of Scientific and Technological Activities*, 6d ed., (Paris: OECD Publishing, 2002), 30.

> phenomena and observable facts, without any particular application or use in view.
>
> - ***Applied research*** is also original investigation undertaken in order to acquire new knowledge. It is, however, directed primarily towards a specific practical aim or objective.
>
> - ***Experimental development*** is systematic work, drawing on existing knowledge gained from research and/or practical experience, which is directed to producing new materials, products or devices, to installing new processes, systems and services, or to improving substantially those already produced or installed.

These concepts appear to have been well understood in the field of myoelectric upper limb R&D. The following statements were made in a 1976 US National Academy of Sciences publication entitled *Science and Technology in the Service of the Physically Handicapped,* showing how basic research differs from applied research.[41]

> The business of science is the search for new knowledge. A useful partition of research is into basic or fundamental research versus applied or goal-oriented research. Both are vital in the advance against handicapping conditions. Basic research tends to follow disciplinary lines, leading the investigator wherever the theory or data take him. Although nonspecific to handicapping conditions, basic neurophysiological research into the central nervous system, for example, leads to sensory input and motor control information central to cybernetic limb prostheses and sensory orthoses.[42]

But the authors of the publication also acknowledge the ambiguity that exists between the concepts of basic and applied research. Later in the same section the authors write of applied research.

> The boundary between basic and applied research, however, is almost always somewhat blurred. In contrast to the search for new knowledge,

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[41] Committee on National Needs for the Rehabilitation of the Physically Handicapped, Division of Medical Sciences, Assembly of Life Sciences, National Research Council and National Academy of Sciences, *Science and Technology in the Service of the Physically Handicapped,* (National Academy of Sciences: Washington, 1976).

[42] Ibid, 26.

> applied medical research identifies a specific need in a target population and designs a device or therapy to satisfy that need. But, for example, research in prosthetics does not necessarily begin that way. Instead it may begin in relation to theoretical aspects of cybernetics, just as much biomedical research relates to fundamental knowledge in biochemistry. For example, research on multiple-degree-of-freedom, power-driven, upper- and lower-limb prostheses with force and position feedback using electromyographical signals on the man machine interface should be classified as basic research, at least for the present.[43]

There may be something more happening in this quote than a mere acknowledgement of porous boundaries of the concepts. If there is the appearance of multiple hands at work on the document, one articulating the well-known linear model with its separate and distinct four steps in the first quotation,[44] and another arguing for the special definition of basic research in the myoelectric limb field, it may be because two of the eleven authors were Stephen Jacobsen from the University of Utah and his former professor, Robert Mann from MIT, lead designers of, respectively, the Utah Arm and the Boston Arm. It would not be surprising if they were responsible for the argument that applied research, or experimental development in other medical device fields, should instead be understood as fundamental research in the myoelectric limb field. This is not a small point. The implication is that examination of theoretical concepts of cybernetics and the man-machine interface requires the design, procurement, construction and testing of devices. In this way, the field appears not unlike other areas of research involving collaboration among experimentalists and theoreticians. But much depends on the intentions, as these are fundamental elements of the three definitions. Is the work

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[43] Ibid, 27.

[44] The steps in the publication are basic research, applied research, device development and evaluation, and then device availability to users. Knowledge dissemination is left out of this version.

being solely done to design a device, or to generate knowledge with no eye to application, or instead with a specific practical objective? Or is there a combination of motivations? For design-oriented engineers, it may have also provided a way to conceptualize their work as basic research, but nevertheless move right down the linear path of innovation past "applied science" and into "experimental development."

## Engineering Design

There is overlap in the definitions of R&D, engineering design, and technological innovation. To clarify some of the boundaries, engineering design may be part of basic research, applied research, and experimental development. One of its most obvious roles is in the design of scientific instruments such as microscopes or the Large Hadron Collider. Engineering design may also have nothing to do with these activities, for instance, when used in the construction of a municipal bridge. The same may be said of technological innovation, although it is distinguished from engineering design in having a broader definition. What is new may be the result of neither engineering nor design, such as the invention of a vaccine.

According to Eugene Ferguson, a historian of engineering design, one of the earliest and best definitions of engineering design, and one that remains accurate, comes from the 1828 charter of the (British) Institution of Civil Engineers: "the art of directing the great sources of power in nature for the use and convenience of man."[45] The use of the word "art" in the definition reminds us that engineering was as long ago as the Renaissance understood as an art before it was re-conceptualized as an applied science. Ferguson distinguishes between two separate but closely related processes that make up engineering design: (i) the conversion of visions in the mind to drawings and specifications; and (ii) preparation of finished drawings and specifications that will allow a third party to "make or build the machine, structure of system. . . ."[46] The first is shared with art, the second is unique to engineering.

The influence on engineering design from science is much more recent, strengthening in the first half of the nineteenth century. According to Ferguson: "The formal knowledge that engineering designers use is not science, although a substantial part of it is derived from science. It includes as well knowledge based on experimental evidence and on empirical observations of materials and systems."[47] But unlike norms of positivist science, it is not a method-driven process, at least according to Ferguson: "Design is not, as some textbooks would have us believe, a formal sequential process that can be summarized in a block diagram. . . ."[48] For some engineering text-book writers it can be reduced to a well defined linear process, e.g. need -> analysis of problem -> statement of problem -> conceptual design -> selected schemes -> embodiment of schemes -> detailing -> working drawings, etc. This is not to be confused with the broader and more

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[45] Eugene Ferguson, *Engineering and the Mind's Eye* (Cambridge: MIT Press, 1991), 1. Ferguson referenced the quote from an article by another historian of technology: Edwin Layton, Jr., "American Ideologies of Science and Engineering," *Technology and Culture* 17 no. 4 (October): 696.

[46] Ferguson, *Mind's Eye*, 3.

[47] Ibid, 9.

[48] Ibid, 37.

abstract linear model of innovation, which begins with science and ends with diffusion.

The origins of design-engineering education, along with engineering, date to Renaissance Italy in the fifteenth century. But, engineering schools were an innovation of the French. They were established shortly after the creation of artillery schools in the early eighteenth century (the French led in artillery and siegecraft, the Italians in fortress design and construction), and followed a similar curriculum, emphasizing algebra, geometry, trigonometry, and engineering mechanics.[49] The first engineering school was for military engineers and was established in 1749. The second was for civil engineers, and opened in Paris in 1775. According to Ferguson, "Engineering education in the United States followed closely the precedents set in les grandes écoles, particularly adopting the central core of mathematical studies."[50]

The adoption of the schools in the United States in the nineteenth century led to conflict with the older generation of engineers trained through apprenticeship. The craft or traditional engineering, called "shop culture" in some histories of technology, saw engineering as a commercial occupation.[51] The newer "school culture," defended by the first students of engineering colleges in the 1860s and 1870s, emphasized training in mathematics and sciences. The shopmen's attack on the school culture in the 1880s and 1890s resulted in a compromise curriculum at Cornell University that combined both cultures. This model, the

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[49] Ibid, 73.

[50] Ibid, 74.

[51] Jonathan Harwood, "Engineering education between science and practice: rethinking the historiography," *History and Technology*, 22, no. 1, (2006): 55.

"sandwich" degree-structure, came to dominate American higher education for engineers, combining both science and mathematics courses with design instruction and projects.[52] This is relevant for the study as some of the prominent engineers in the cases occupied design engineer faculty positions that derived from this longstanding compromise between the shop and school cultures.

Also relevant to this study is the rise of the "applied science" model in United States' higher education research. Its origins were later, beginning after 1900, and took hold at only a few institutions at first (e.g. MIT, Purdue University, Univerity of Illinois.) The big change occurred after 1945, and was influenced by Vannevar Bush's popularization of the applied science model and new government funding programs (the older "externalist" view), the influx of European engineering academics, and engineers seeking to "up" their status within universities or amongst other more science-oriented engineering departments (the newer "internalist" approach). Whatever the cause, with the new applied science research funding, design engineers found another client to pay for their practice, whether or not it was the R&D of the Franscati manual.

## Innovation

According to Jan Fagenberg in the introductory chapter of the *Oxford Handbook of Innovation*, innovation is the first attempt to carry out an invention in practice; it primarily happens within firms, usually involving a continuous process

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[52] Ibid.

between invention and innovation.[53] It may involve a "stage-gate" type process, which consists of go/no-go decision points for (usually) increasingly expensive and lengthy stages in development of a new product or service, from initial screening of the business concept to laboratory tests, pilot demonstrations, and so on.[54] The more generally accepted definition is from Joseph Schumpeter, who includes the following five kinds of innovation: new products, new methods of production, new sources of supply, the exploitation of new markets (or customers), and new ways to organize business (including new business processes).[55]

Technological innovation may be part of all five kinds of innovation. For the upper limb prosthetics field, new products include myoelectris prostheses. New methods of production include university and hospital involvement, not just in R&D, but also product development and, in some cases, production. The development in the 1970s of university-based production and marketing businesses, spin-off companies, and non-profit entities to make and sell prosthetic devices and technologies would all, even in the case of unsuccessful business experiments, count as new ways to organize business. For this dissertation I use the broader definition of innovation from Schumpeter.

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[53] Jan Fagenberg, "Innovation: A Guide to the Literature," in *Oxford Handbook of Innovation*, ed. Jan Fagerberg, David C. Mowery and Richard R. Nelson (New York: Oxford University Press, 2006), 1-27.

[54] Robert G. Cooper, "Managing Technology Development Projects," *IEEE Engineering Management Review*, 35, no. 1 (2007): 70.

[55] Joseph Schumpeter, *The Theory of Economic Development: An Inquiry into Profits, Capital, Credit, Interest, and the Business Cycle* (New Brunswick, New Jersey: Transaction Publishers, 2004), 57-95.

### *Technology Push and Pull*

Technology push and technology pull, or supply and demand, are terms that get used in discussions about R&D, entrepreneurship and technological innovation. Technology push presumes that advances in scientific understanding determine the rate and direction of innovation. It may unfold in a simple linear model, or in a less deterministic and sequential manner with multiple non-scientific influences, but still with the push from science. Technology pull presumes that demand drives the rate and direction of innovation. Demand factors include customers, market conditions, and changing prices, causing firms to work on certain problems.

A pair of US studies from the 1960s framed a famous debate about technology push and pull. In Project "HINDSIGHT," the United Sates Department of Defense studied the role that research played in the development of weapons systems between the end of World War II and about 1962. The conclusion in its 1967 paper was that "Nearly 95 percent of all Events were motivated by a recognized defense need. Only 0.3 percent came from undirected science."[56] "Events" were defined to include science and applied sciences R&D on new materials and technologies, such as alloys and radio technologies. It also found that even after a period of twenty years "fragments" of undirected science were still infrequently utilized.[57] In response, the National Science Foundation sponsored the project "TRACES" (Technology in Retrospect and Critical Events in Science) at the Illinois Institute of Technology to assess the role of research in the overall process,

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[56] C.W. Sherwin and R.S. Isenson, "Project HINDSIGHT," *Science* 156 (1967): 1577.

[57] Ibid.

which eventually leads to technological innovation.[58] The project traced the key events that led to five major technological innovations: magnetic ferrites, the video tape recorder, oral contraceptives, the electron microscope, and matrix isolation. It took a longer view than the HINDSIGHT study, focusing on a thirty year period, and found that of the significant R&D events behind these innovations, approximately 70 percent were non-mission research, 20 percent mission-oriented research and about 10 percent were development or application.

If polarization was emblematic of these academic debates in the late 1960s, with explanations of technical progress as mutually exclusive, more recent scholarship has instead explained the push and pull concepts in relation to radical or disruptive and incremental innovation. Disruptive innovation, which may or may not involve technology, helps create a new market and disrupts an existing market, whereas incremental innovation does not. Contemporary scholarship has suggested that incremental innovation is more likely to respond to demand-pull than technology-push, and that non-incremental innovation is more responsive to technology-push.[59] Benoît Godin and Joseph Lane, in an article published in a series on the idea of innovation, suggests that the idea of "demand" eventually got integrated into multidimensional innovations models that supplanted the then dominant linear model.[60]

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[58] *Technology in retrospect and critical events in science (Project TRACES), Report, Illinois Institute of Technology (IIT) – National Science Foundation*. (Chicago, Illinois: Illinois Institute of Technology, 1968).

[59] G. Dosi, "Sources, procedures, and microeconomic effects of innovation." *Journal of Economic Literature* 26, no. 3 (1998): 1120–1171.

[60] Benoît Godin and Joseph P. Lane, "Pushes and Pulls": The Hi(story) of the Demand Pull Model of Innovation," www.csiic.ca (February 2, 2013).

### *User Innovation*

In an article on user innovation in the *Handbook of Science and Technology Studies* titled "User-Technology Relationship: Some Recent Developments," Nelly Oudshoorn and Trevor Pinch (author of the previously noted 1984 article on social construction and science studies) wrote that: "Within innovation studies it has long been assumed that production innovations are mainly developed by product manufacturers. The piece of conventional wisdom has been turned on its head. While leading scholars like Nathan Rosenberg and Bengt-Ake Lundvall have shown growing recognition of the importance of users, it is the detailed research carried out by Eric von Hippel and his students that has been particularly influential."[61] In the model developed by von Hippel, the user: (i) perceives the need for the innovative industrial good; (ii) conceives of a solution; (iii) builds a prototype device; (iv) proves the value of the prototype by using it. Based on this, the manufacturer's contribution, according to the model, is typically product engineering to improve the prototype, and manufacturing, marketing, and selling the product. Since von Hippel's studies of user innovation in the development of scientific instruments,[62] and then semi-conductor and electronic subassembly manufacturing equipment,[63] there has followed numerous studies on a range of products that have found user innovation at work, including one on medical

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[61] Nelly Oudshoorn and Trevor Pinch, "User-Technology Relationship: Some Recent Developments," in *Handbook of Science and Technology Studies, 3d ed.*, (Cambridge: Massachusetts Institute of Technology, 2008), 542.

[62] E. von Hippel, "The Dominant Role of Users in the Scientific Instrument Innovation Process," *Research Policy* 5, (1976): 3.

[63] E. von Hippel, "The Dominant Role of the User in Semi-conductor and Electronic Subassembly Process Innovation," *IEEE Transactions on Engineering Management* EM24 no. 2, (1977).

equipment, which found that 34 medical products were subject to multiple and continuous interactions between the user and manufacturer.[64] Since then, Oudshoorn and Pinch write: "Over the last two decades the maxim that "users matter" has become evident in a number of different areas of technology studies. The old view of users as passive consumers of technology has largely been replaced and along with it the linear model of technological innovation and diffusion."[65]

One of those areas is the social construction of technology (SCOT), referred to in the above noted Pinch and Bijker article. The concept that users are one of the relevant social groups that shape technology was illustrated in a study of the design of what was known at the turn of the twentieth century as the "safety bicycle," and is now known just as the bicycle. The case shows how groups of older men and women influenced the movement of the dominant bicycle design away from the high-wheeled, penny farthing-type design, favoured by riders wanting speed, to a "safer" design: the now dominant bicycle design with its two wheels of equal diameter. Pinch's co-author on the bicycle article, W.E. Bijker, introduced the term "technological frame" in a subsequent paper to describe the connection between designers and users.[66] Pinch wrote of it: "This term is rather akin to Kuhn's notion of paradigm. Users, designers, and intermediaries can be said to share a technological frame associated with a particular technology, for example, electric lighting. The frame provides heuristics as to how users should interact with the technology such that the technology and user become part of a common "form of

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[64] Brian Shaw, "The Role of the Interaction between the User and the Manufacturer in Medical Equipment Innovation," *R&D Management*, 14, no. 4 (1991): 1985.

[65] Oudshoorn and Pinch, "User-Technology Relationship: Some Recent Developments," 543.

[66] W.E. Bijker, *On Bikes, Bicycles and Bakerlite* (Cambridge, MIT Press, 1995).

life."[67] SCOT, like other approaches that Oudshoorn and Pinch describe in their article (including from feminist studies, philosophy, semiotics, and cultural and media studies), differ from von Hippel's approach in focusing on users as consumers of technologies, and not on users as producers. Interestingly, Pinch and Oudshoorn find this to be a shortcoming within technology studies and call for a repair of this imbalance.[68] I have tried to be mindful of these differing approaches in designing the research project, and, in the concluding discussion in Chapter 7. I, am helped by the fact that myoelectric upper limb products are made by one kind of user (like those in von Hippel's model), and amputee users (like the consumers in the SCOT model). And so I draw on both the "user innovation" and SCOT literature.

### *Open Innovation*

Another ascendant innovation concept is "open innovation." Like "user innovation" it has a primary developer of the concept, Henry Chesbrough, a professor at the University of California, Berkeley. His widely cited book on the topic is: *Open Innovation: The new imperative for creating and profiting from technolog*y.[69] Reflecting the change that resulted in the 1980s when large firms began to divest themselves of R&D departments and refocus their remaining R&D working on technology scouting and in-licensing, the underlying concept with open innovation is that firms can and should use external ideas as well as internal ideas

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[67] Oudshoorn and Pinch, "User-Technology Relationship: Some Recent Developments," 544.

[68] Oudshoorn and Pinch, "User-Technology Relationship: Some Recent Developments", 556.

[69] Henry Chesbrough, *Open Innovation: The new imperative for creating and profiting from technology* (Boston: Harvard Business School Press, 2003).

to create shareholder value. The assumption is that they can rent or buy knowledge and technology for less than they can develop it in-house.

## Entrepreneurship

A major theorist of both innovation and entrepreneurship is Joseph Schumpeter. He was a student of Karl Marx, born about a month before Marx died in the late winter of 1883. Schumpeter was raised in Vienna where he studied law and economics. After unsuccessful forays in banking and politics as a minister of finance, he moved to the University of Bonn in 1925. He remained there until he left Europe for Harvard University in 1932, where he taught and researched until his death in 1950.

Marx theorized the new economic system and social class: capitalism and the bourgeoisie; Schumpeter drilled down to the revolutionizing figure and economic activity: entrepreneurs and innovation. Like Marx, Schumpeter believed that capitalism was both evolutionary and revolutionary, a historically unique development that had transformed the economic and social conditions of society.[70] They also shared the view that capitalism contained the seeds of its own destruction, although, for Schumpeter, it was not through socialist revolution. Rather, the growth of big businesses and institutionalization of R&D that would eventually reduce innovation to routine and suffocate the entrepreneurial spirit.

For Marx, the growth of science was not, by itself, a sufficient condition for the growth of productivity, but rather the ability of science to act on machinery.

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[70] John E. Elliott, "Schumpeter and Marx on Capitalist Transformation," *The Quarterly Journal of Economics*. 98, no. 2 (1983): 333-336.

Capitalism was created by the urge to rationalize economic activity, and entrepreneurs were the agents who combined science with economics.

For Schumpeter, the entrepreneur was the person who carried out new combinations of productive forces, distinguished from the capitalist who funds these activities, and the manager who plans and oversees them. According to Schumpeter, entrepreneurs form no social class, and entrepreneurship is not inherited, as is shown by the history of manufacturing families. Entrepreneurial leadership, in his writing, had little glamour and was in essence task focused. The task was breaking up old traditions and creating new ones. The entrepreneur was driven by the dream and will to found a private kingdom, the will to conquer, and the joy of creating.

Scholars refer to Schumpeter Mark I, and Schumpeter Mark II. Mark I refers to earlier works, before the move to Harvard, in which he explored the role of entrepreneur in innovation. In Mark II, Schumpeter focused on the role that corporations play in innovation, in particular large R&D firms that arose around the turn of the nineteenth century. The common assumption from the 1950s to the early 1970s was that the large corporation was the locus of technology advancement, and entrepreneurship studies waned during this period.

Interest in entrepreneurship began to be rekindled in the 1980s. One factor was that stagflation and high unemployment caused a renewed interest in supply side economics. Another was that with the rise of information technology start-ups in the 1970s, growth of venture capital and biotechnology start-ups in the 1980s, and realization of the potential linkages between Mark I and Mark II. If Mark I is the thesis and Mark II is the antithesis, the synthesis was an entrepreneurial start-up company led by an entrepreneur, but staffed by professional managers and R&D personnel. It offered a potential pathway from Mark I to Mark II, either by going public or by being acquired by a large, public company.[71]

With the rekindling of interest in the subject came an upsurge in the 1980s in the creation of journals focused on entrepreneurship, including the *Journal of Business Venturing*, *Small Business Economics*, *Entrepreneurship Theory and Practice*, and *Entrepreneurship and Regional Development*.[72] Existing journals that published articles on entrepreneurship saw an increase in the number of articles on the topic. The list of titles of these journals emphasized the interdisciplinary nature of the field: *American Economic Review*, *American Sociological Review*, *Administrative Science Quarterly*, *Journal of Financial Economics*, and the *Strategic Management Journal*.[73] By the late 1980s there was a call for a more unified approach to the study of entrepreneurship, with more theory driven research.[74]

In the 1990s and 2000s research moved away from the traditional focus on the traits of entrepreneurs and on to a number of new topics. Many disciplines contributed to the field, including business history, macro-economic growth theory, industrial economics, evolutionary economics, history of economic growth, and

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[71] Richard Florida and Martin Kenney, "Venture-Capital Financed Innovation and Technological Change in the USA," *Research Policy* 17, (1998): 119-137.

[72] Zoltan J. Acs and David B. Audretsch, "Introduction to the Handbook of Entrepreneurship Research," *Handbook of Entrepreneurship Research: An Interdisciplinary Survey and Introduction*, eds. Zoltan J. Acs and David B. Audretsch, (New York: Springer, 2010), 4.

[73] Ibid, 5.

[74] Murray Low and Ian MacMillan, "Entrepreneurship: Past Research and Future Challenges," *Journal of Management*, 14, no. 2 (1988): 129-161.

management studies.[75] These new topics included a focus on the existence, discovery and exploitation of opportunities.[76] There was also a move to explore entrepreneurship in existing corporations.[77] Economists like William Baumol developed the concept that what was important was not the entrepreneur by him or herself (they exist in all societies), but the payoffs society offers entrepreneurs between productive activities such as innovation, as opposed to unproductive ones like rent seeking or organized crime.[78] This was part of a broader move to understanding the connection between entrepreneurship and economic development, and why some regions seemed to benefit more than others from entrepreneurial activities.[79] All of these topics bear on the dissertation, but of greatest interest has been the movement of entrepreneurship and innovation into the university. It is here where we see the closest connection to the field of study and in particular the concepts of mode 2 and triple helix knowledge production. Instead of the Mark I entrepreneur, we have the merchant scientist and in the place of Mark II is open innovation and externally sponsored R&D.

## Introduction to the Four Models Examined in this Dissertation

The social science historian Lawrence Stone writes there is ". . . nothing wrong with poking about in a social science to try to find some formula, some

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[75] Ibid.

[76] Scott Shane and S. Venkataraman, "The Promise of Entrepreneurship as a Field of Research," *The Academy of Management Review*, 25, No. 1 (2000): 217-226.

[77] Howard H. Stevenson and J. Carlos Jarillo, "A Paradigm of Entrepreneurship: Entrepreneurial Management," *Strategic Management Journal*, 11 (1990): 17-27.

[78] William Baumol, "Entrepreneurship: Productive, Unproductive and Destructive," *The Journal of Political Economy*, 98, no. 5, Part 1 (1990): 893-921.

[79] Sander Wennekers and Roy Thurik, "Linking Entrepreneurship and Economic Growth," *Small Business Economics,* 13 (1999): 27–55.

hypothesis, some model, some method which has immediate relevance to one's own work. . . ."[80] The fields of science and technology studies, and innovation studies, are of interest because they both provide three of the conceptual frameworks for understanding what may be found in the case studies. The other comes from a historian of science and student of Thomas Kuhn, Paul Forman. I plan to test these three social-science concepts and one theory of historical change against the cases to assess their applicability and expand my investigation of the cases. The four theories examined are the linear model of innovation, mode 2 knowledge production[81] [82] triple helix of university-industry-government relations[83] [84] [85] [86] , and Paul Forman's concept of science in modernity and postmodernity (called 'postmodernity' hereafter.)

Why these theories and concepts? There are many other concepts that could be used to examine this study of myoelectric upper limb prosthetics. The list includes: post-normal science,[87] [88] finalisation science,[89] [90] strategic

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[80] Lawrence Stone, *The Past and the Present* (Boston: Routledge and & Kegan Paul Co., 1981), 20.

[81] M. Gibbons, C. Limoges, H. Nowotny, S. Schwartzman, P. Scott, and M. Trow, *The New Production of Knowledge: The Dynamics of Science and Research in Contemporary Societies* (London: Sage, 1994).

[82] H. Nowotny, P. Scott, M. Gibbons, *Re-Thinking Science: Knowledge and the Public in an Age of Uncertainty* (Cambridge: Polity Press, 2001).

[83] H. Etzkowitz, "Research groups as 'quasi-firms': the invention of the entrepreneurial university," *Research Policy* 32, (2003): 109–121.

[84] H. Etzkowitz and L. Leydesdorff, "The endless transition: A "triple helix" of university–industry–government relations," *Minerva* 36, (1998): 203–208.

[85] H. Etzkowitz and L. Leydesdorff, "The dynamics of innovation: from National Systems and "mode 2" to a triple helix of university–industry–government relations," *Research Policy* 29, no. 2, (2000): 109–123.

[86] H. Etzkowitz, A. Webster, C. Gebhardt, B. Terra, "The future of the university and the university of the future: evolution of ivory tower to entrepreneurial paradigm," *Research Policy* 29, no. 2, (2000): 313–330.

[87] J.R. Ravetz, "Usable knowledge, usable ignorance: incomplete science with policy implications," In W.C. Clark and R. C. Munn, ed. *Sustainable development of the biosphere* (New York: Cambridge University Press, 1986), 415-432. .

research/strategic science,[91] innovation systems,[92] Pasteur's quadrant,[93] academic capitalism,[94] or post-academic science.[95] Perhaps the two most studied, and best suited to fine-grained, case-study analysis, are the social construction of technologies (SCOT) concept,[96] and the actor network theory (ANT).[97] However, there have followed from the pioneering works of Trevor Pinch and Wiebe Bijker (SCOT), Bruno Latour and Steve Woolgar (ANT), numerous cases uncovering the sociological factors in scientific and technology knowledge construction, and I saw little new criticism or concepts that I could contribute to either theory.

I have included the linear model in this review as it was the dominant concept of R&D for most of the twentieth century, and is still highly influential outside of academia.[98] Mode 2 has been included because, with the fall of the linear model of innovation among scholars in the 1970s and 1980s, it has emerged as the

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[88] John Turnpenny, Mavis Jones and Irene Lorenzoni, "Where Now for Post-Normal Science?: A Critical Review of its Development, Definitions, and Uses," *Science Technology Human Values* 36, no. 3 (2011): 287-306.

[89] S. Funtowicz and J. Ravetz. "Science for the post-normal age," *Futures* 25,(1993): 735–755.

[90] P. Weingart, P., "From "Finalization" to "mode 2": Old wine in new bottles?" Social *Science Information* 36, no. 4, (1997): 591–613.

[91] G. Böhme, W. Van den Daele, R. Hohlfeld, W. Krohn, W. Schfer, *Finalization in Science: The Social Orientation of Scientific Progress*. (Dordrecht: Reidel, 1983).

[92] C. Edquist, C., *Systems of Innovation: Technologies, Institutions and Organisations* (New York: Pinter Publishers, 1997).

[93] D. Stokes, *Pasteur's Quadrant: Basic Science and Technological Innovation* (Brookings Institution Press, 1997).

[94] S. Slaughter and L. Leslie, *Academic Capitalism: Politics, Policies, and the Entrepreneurial University* (Baltimore: The John Hopkins University Press, 1997).

[95] J. Ziman, J., *Real Science: What it is, and What it Means* (Cambridge: Cambridge University Press, 2000).

[96] Pinch and Bijker. "The Social Construction"

[97] B. Latour, and Steve Woolgar, *Laboratory Life: The Construction of Scientific Facts* (Princeton, New Jersey: Princeton University Press, 1979).

[98] B. Godin, "The Most Cherished Indicator: Gross Domestic Expenditures on R&D (GERD)." www.csiic.ca/PDF/Godin_22.pdf (June 5, 2010).

"normal science" of the R&D and innovation studies research field.[99] Triple helix is included because it is a major theory among innovation scholars and public-policy professionals. It is a variant of the concept of the national system of innovation and it is highly influential among public-policy professionals.

## The Linear Model of Innovation

The linear model of innovation holds that innovation starts with basic research, is followed by applied research and development, and ends with production and diffusion. Benoît Godin tells us that the linear model of innovation was one of the first conceptual frameworks developed for understanding the relation of science and technology to the economy.[100] He divides the development of the model into three periods. In the first, from 1900 to 1945, research was divided into "basic research" and "applied research." The famous popularization of this formulation is from Vanevar Bush's *Science: The Endless Frontier*:

> Basic research leads to new knowledge. It provides scientific capital. It creates the fund from which the practical applications of knowledge must be drawn. New products and new processes do not appear full-grown. They are founded on new principles and new conceptions, which in turn are painstakingly developed by research in the purest realms of science.[101]

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[99] Laurens K. Hessels and Harro van Lente, "Re-thinking new knowledge production: A literature review and a research agenda," *Research Policy* 37 (2008): 740–760.

[100] B. Godin, "The Linear Model of Innovation: The Historical Construction of an Analytical Framework" www.csiic.ca/PDF/Godin_30.pdf (June 5, 2010).

[101] V. Bush, *Science The Endless Frontier: A Report to the President by Vannevar Bush, Director of the Office of Scientific Research and Development, July 1945* (Washington: United States Government Printing Office, 1945), 13–14. According to cultural historian Paul Forman, "what almost all readers took away from the report was what they brought to it, the unqualified affirmation of 'the linear model' of technological innovation." See Paul Forman, "The Primacy of Science in Modernity, of Technology in Postmodernity, and of Ideology in the History of Technology," *History and Technology*, 23, no. 1/2, March/June (2007): 33.

In the second period, from *1934-circa 1960, "*development" was added. In the third, occurring in the 1950s, economists in business schools added "production" and "diffusion" of knowledge to the model.

The model has been highly influential throughout most of the twentieth century, influencing scholarly and policy fields, as well as the practice of research, development and innovation. Godin argues that its longevity was due, in part, to the interests it served of scientists, engineers, and industrialists for defining, demarking, and controlling their profession by excluding amateurs; for financial support of scientists; for raising the status of the engineering discipline, and for attracting scientists to industry and vice versa. Also, its use in the OECD's *Frascati Manual*[102] has meant a kind of enshrinement among statisticians and policy professionals of the linear model in the aforementioned categories of basic research, applied research, and experimental development.

The concept, however, has fallen out of favour among scholars. Nathan Rosenberg observed in 1994, that "Everyone knows that the linear model of innovation is dead."[103] Paul Forman wrote in 2007, that "To campaign today against the linear model is to throw oneself against a door that has been wide open for two decades."[104]

Why has this occurred? How could something so elegant, revered for its importance to material progress, and so widely accepted be so wrong? One explanation is that the scholarship on R&D and innovation that has examined the

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[102] OECD, *Frascati Manual*, 30.

[103] Nathan Rosenberg, *Exploring the Black Box: Technology, Economics and History* (New York: Cambridge University Press, 1994), 139.

[104] Forman, "Primacy," 2.

linear model against case studies has found few instances of the model in practice.[105] Research only rarely begets new technologies. More commonly, the major outcome is information. In addition to providing information for publications and presentations, the information may also be used in preparation of a conceptual design, and in undertaking the basic engineering for a new product. But, it is often just one input into the conceptual design. Another reason for its demise may be that it did not fit with intellectual movements in the 1970s, in particular the social construction of technology (SCOT) movement that came to have a strong impact on the newly emerging field of science and technology studies. A third reason, argued by the authors of the mode 2 concept, is that R&D changed in the second half of the twentieth century to a more network-oriented form of "knowledge production."[106]

Nevertheless, the linear model lives. It continues to inform public policy, statistical analysis, university research funding programs, and industry-technology roadmaps, even if the linearity sometimes gets hidden because the authors now know the linear model is no longer in fashion, or because their experience has taught them that R&D and innovation is not so straightforward. As proof of existence, it continues to grow and adapt to new contexts. The acronym RDD&D has recently been used in government policy documents in the US, UK, Canada, and elsewhere, referring to research, development, deployment, and demonstration.

Why does the linear model continue to guide research and innovation policy and programs despite being continually declared dead by scholars? One answer is

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[105] S. J. Kline, "Innovation is not a Linear Process," *Research Management*, July-August, (1985): 36-45

[106] Gibbons, *The New Production of Knowledge*.

that its ambiguity as a concept has prevented any one group from being able to deliver a knock-out punch. Indeed, the component concepts of the linear model, research, applied research, and development, are notoriously difficult to define, making the master concept all the more slippery. Another answer is that, as Godin suggests, the linear model has enrolled the interest of too many groups, including universities, governments, industry, and statisticians, to be abandoned. Moreover, the new theories, like mode 2 discussed below, do not offer the “big tent” (that arose with the expansion of research funding programs in the United States and other developed states after 1945) to steal away the interests of these parties, especially universities and government labs whose cultures and ways of doing research do not easily fit into mode 2 and requirements for knowledge production outside of the laboratory. And although the mode 2 concept also combines science, engineering and business, it does not offer each discipline and profession an independent place in the model, but instead integrates them into a single mode of knowledge production – likely a tough sell to scientists and engineering researchers. The challenge, then, for models of innovation like mode 2 is to enroll the interest of separate disciplines, professions and sectors into a new multi-disciplinary model, or risk greatly reduced funding because of the inability to connect the dots between the various innovation systems players. In other words, they risk retreating to the smaller and older foundation of the Enlightenment narrative to legitimize and support fundamental research, on the one hand, and the merchant scientists in the marketplace, on the other.

## Mode 2

The concept of mode 2 was first presented in the 1994 book *The new production of knowledge: the dynamics of science and research in contemporary societies*, co-authored by Michael Gibbons, Camille Limoges, Helga Nowotny, Simon Schwartzman, Peter Scott and Martin Trow.[107]

The authors, all leaders in the field of science and technology policy, provide an interesting portrait of the diversity of backgrounds in the field. All held positions as professors at universities at one time or another, most finding positions right after their doctoral programs, with the exception of Scott who first had a career in journalism. Only one does not have a degree in the humanities or social sciences (Gibbons has undergraduate degrees in mathematics and physics, and graduate degrees in astronomy and theoretical physics). Two have engineering undergraduate degrees (Gibbons, electrical, and Trow, mechanical). Two have graduate degrees in sociology (Nowotny, Swartzman), three in public administration/policy (Trow, Scott, Swartzman), and one in the history of science (Limoges). Once in professorial positions, most have stayed in academia, with the exception of Limoges who became a senior civil servant with the Quebec provincial government. Two have moved on to research council administration (Nowotny, Scott) and two have become senior academic administrators (Scott and Gibbons: Gibbons, notably, was director of the Science Policy Research Unit (SPRU) at the University of Sussex from 1992-1996.)

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[107] Gibbons, *The New Production of Knowledge*.

There is not just a diversity of academic disciplines among the authors, but also a common interest in public and academic administration. As administrators or students of administration they would all be familiar with the latest government policies and new granting-council programs that support the kind of activities that the mode 2 authors describe in their model. They might have even had a hand in the development of regional mode 2 type funding programs. They would also have seen first hand the rise of innovation, network and intellectual property management programs in the 1980s and 1990s, the creation of research careers by faculty members who exploited these programs, the intricacies of the inter-institutional agreements, and perhaps a few commercialization success stories.

It is not surprising then that the authors of the mode 2 concept draw a sharp distinction between the old paradigm of "scientific discovery" (mode 1) and the new one of "knowledge production" (mode 2). The old approach consists of experimental science, internally driven by autonomous, university and discipline-based researchers. In contrast, the new knowledge is produced through socially distributed, application-oriented, trans-disciplinary projects, subject to multiple accountabilities. The key concepts of mode 2 include:

- "contextualization", involving the generation of problems and methodologies, dissemination of results and definition of users all within a context of application, vs. mode 1 science where basic research is done in the laboratory and technology is demonstrated somewhere else, further segmented by "weak contextualization," (such as national R&D programs)

  "middle range," (vaguely referred to as "trading zones and transaction spaces") and "strong contextualization";
- "trans-disciplinarity," meaning the use of non-discipline-based theories, methods, experience and tacit knowledge to solve problems;
- the diversity of sites of knowledge production, which the authors of *Mode 2 Revisited* refer to as a "communicative free-for-all"; Michael Gibbons uses "agora," the public space in which both science meets the public and the public speaks back to science (i.e. the domain in which contextualization occurs);
- "reflexivity" or "speaking back to science," referring to the dialogical process between research actors and subjects; and
- "novel forms of quality control," meaning multiple definitions of quality of research results, not just by disciplinary peers.

Michael Gibbons in a solo article added a few additional concepts to highlight the erosion of traditional boundaries between university and industrial science, basic and applied research, and research for truth, and research for provisional understandings.[108] The concepts are:

- socially robust knowledge, which has followed from "reliable knowledge" (and before that, "truth"); it is superior, he writes, because it has been subject to more intensive testing in more contexts, and because of its malleability and connective capacity;

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[108] Michael Gibbons, "Science's New Social Contract with Society," *Nature* 402 (1999): C81-C84.

- co-evolution, meaning the open interaction between science and society, responding to uncertainty and complexity, leading to more of the same; and
- the construction of narratives of expertise, which means a new social vision of scientists as working outside of their laboratory and engaged in the public and private realms.

The mode 2 concept was further explored in the 2001 book authored by Helga Nowotny, Peter Scott and Michael Gibbons titled *Re-thinking science: knowledge in an age of uncertainty*.[109] As the title suggests, the book focuses on the social and historical context for the "new R&D." The central argument is that changes in society now make two-way communications between science and society more likely and more common, and this is transforming science not only in its research practices and the institutions that support it, but also deep in its epistemological core. The underlying concept is that the line that formerly demarcated society from science (like that between public and private, government and industry and so on) is now regularly transgressed. This gives rise to the closer interaction of science and society and the resulting emergence of a new kind of "context-sensitive science."

Both the originators and critics of the mode 2 concept are in general agreement that there are two ideas of science, whether instrumental and non-instrumental, mode 1 and mode 2, pre-World War II innovation and the triple helix,

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[109] Nowotny, *Re-Thinking Science*.

[110] or science in modernity and postmodernity. They differ, however, in characterizing that change. Michael Gibbons calls mode 2 knowledge superior to that of mode 1 science.[111] Likewise, Henry Etzkowitz and Loet Leydesdorff (authors of the mode 2 associated concept "triple helix," presented below, see universities playing an enhanced role in innovation in knowledge-based societies, where science is the basis of much future regional economic and social development. The sympathies of the critics appear to lie with unreformed science. Terry Shinn, for instance, writes that "contextualization" commits mode 2 to "de-differentiate" between science and society.[112] In other words, "Society decides on what knowledge is to be. Knowledge producers accept and follow. Knowledge is socially relevant learning, and is generated in fluid relations between the state, markets and industry."[113]

But despite the agreement on the fundamental distinction, the critics find many issues. Arguably the strongest criticism concerns the empirical validity of the theory.[114] Is it a policy prescription, not an empirical description? According to Godin,[115] the mode 2 talk is more a political ideology than a descriptive theory. Similarly, Shinn[116] complains: "Instead of theory or data, the New Production of Knowledge - both book and concept - seems tinged with political commitment."

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[110] However, Terry Shinn appears not to accept the distinction, or rather that the separation has been exaggerated by both critics and boosters.

[111] Nowotny, *Re-Thinking Science*, 16.

[112] Terry Shinn, "The Triple Helix and New Production of Knowledge: Prepackaged Thinking on Science and Technology," *Social Studies of Science* 32 (2002): 607.

[113] Ibid.

[114] Hessels and van Lente, "Re-thinking new knowledge production," 741.

[115] Benoit Godin, "Writing performative history: the new new Atlantis?" *Social Studies of Science* 28 (1998): 465–483.

[116] Shinn, *Prepackaged*, 604.

David Mowery and Bhaven Sampat, in a review article on universities in national innovation systems, state that the authors offer little research on the changes in government and industry, they overstate the university role in innovation, their theory has yet to yield major empirical or research advances, and it lacks criteria to assess the strength of linkages, nor indicators to guide the collection of data.[117] Mowery and Sampat also say it offers limited guidance for policy or evaluation and plays down the tensions inherent in this new science.[118]

Several critics argue that mode 2 is not new, and was the original format of science before its academic institutionalization in the 19th century. Steve Fuller, in his book *The Governance of Science* argues that the two modes were institutionalized only within a generation of each other, mode 1 by the 1870s and mode 2 by 1900.

There are differing views on how deep are the inroads of mode 2 into contemporary science. On the one hand, there is evidence from citation analysis that the sources of knowledge production have become more trans-disciplinary and diverse, suggesting an increase in mode 2 science.[119] There has also been an increase in the steering of research priorities, which Nowotny et al. include among the trends,[120] or changes in practice that have given rise to new discourses of science and research. The case against wide adoption of mode 2 is acknowledged

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[117] David Mowery and Bhaven Sampat, "Universities in National Innovation Systems," in *The Oxford Handbook of Innovation*. ed. Jan Fagerberg, David Mowery, and Richard Nelson. (New York: Oxford University Press, 2005), 209-239.

[118] Ibid.

[119] Ibid.

[120] Nowotny, *Re-thinking Science*, 180-81.

by Nowotny et al. (i.e. the theory describes ". . . social and political epiphenomena; the core of science remained inviolate.")[121]

Another weakness is that the theory is general to science and university-government-industry partnerships. Scientific methodologies, methods, and practices differ among academic disciplines, as they do in industrial R&D departments. R&D spending, organization, and divisions of labour also differ by research sector. Pulp and paper research and pharmaceutical research, for instance, both benefit from university laboratory work, but the former has low R&D spending, few business development resources to make connections with outside groups and rarely uses university intellectual property, whereas the latter is a relatively large R&D spender, employs thousands of business development professionals and is highly engaged in collaboration with biotechnology firms and universities.

Mode 2 theory has also not adequately addressed the tension between the interest of timely and full disclosure of research results and the interest of protecting intellectual property. Nowotny et al. state the quality of science is largely determined by its exposure to refutation and counterargument, and this process becomes much more difficult if the circulation of research findings are restricted. These restrictions can occur in subtle ways. For instance, the incentive of a future research contract can be a more effective restriction than a publication delay clause. Recent research has shown that scientists seeking to patent their work do, in fact, withhold presentation of their data at scientific meetings, and there is a

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[121] Ibid, 189.

more widespread change in the behavior of university scientists, who exhibit increased secrecy even when not seeking patents.[122] This is a topic that requires more discussion by mode 2 theorists.

Part of the problem may be the confusion among mode 2 theorists, critics, as well as university inventors, about how intellectual property protection occurs, and misunderstanding of the commercial value of much university inventive subject matter. On the concept of commercial confidentiality, Nowotny et al. write: "If 'intellectual property' is valuable, it cannot be given away 'freely' by open publication in peer-reviewed journals, or at scientific conferences open to all."[123] This confuses the distinction between disclosure of information in a patent application or patent and the right to exclude others from making, using or selling the invention. The information contained in patents and patent applications can be disclosed freely by open publication in these journals and at these conferences. Patenting also means that the information is further described and disclosed in the patent application and published on the Internet. The patent systems, after all, are among the world's largest technical and scientific publishers. John Ziman claims that instrumental science "often produces "intellectual property" whose value can only be preserved by being kept secret."[124] Scientific research may produce published reports and articles (protected by copyright law), and some scientific programs, such as the human genome project discussed in the Ziman article, may produce an abundance of patentable inventions, but this offers a poor guide to

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[122] Jeremy M. Grushcow, "Measuring Secrecy: A Cost of the Patent System Revealed," *The Journal of Legal Studies* 33, no. 1 (January 2004): 59-84.

[123] Ibid, 183.

[124] John Ziman, "Non-Instrumental Roles of Science," *Science & Engineering Ethics* 9.1 (2003): 21.

what is happening across the board at universities. A better generalization is that only in exceptional circumstances does a university research project result in a patent, and rarer still does it result in work that is both patented and commercialized.[125]

Is the mode 2 concept too flawed to shed light in my history and cases? Despite these criticisms, the concept accords closely with that of many of its critics about how knowledge creation is changing. This suggests that mode 2 is at least addressing a phenomenon and that is broadly recognized. More interesting, however, is that the observation made in the above discussion of the definition of "science" that mode 2 connects the separate fields of science and technology studies, innovation studies, and entrepreneurship studies, and expands science studies beyond laboratories and into what the mode 2 authors call 'contexts of application.' From Merton's analysis in the 1940s of the structures and functions of science, to Kuhn's 1960s focus on scientific communities and the content of normal science and theory creation, and then Pinch and Weibe's expansion of that community in the 1980s to non-scientists, mode 2's new ground (literally and academically) comes in leaving the laboratory for the hospital, shop floor, etc. And it is this feature of mode 2 that makes it particularly relevant for the field of upper limb prosthetics R&D, which has likewise not confined itself to laboratories and offices, and has, since at least the 1960s, been equally at home in rehabilitation clinics and engineering machine shops.

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[125] Note, for instance, that the Association of University Technology Managers (AUTM) reported in Canada in 2010 the total sponsored university funding was $40 billion, there were 1,000 patent applications filed, and $60 million in licensing revenue. In 2010 NSERC and CHIF reported sponsoring a total of over 10,000 research projects.

## Triple Helix

The sociologists Henry Etzkowitz and Loet Leydesdorff in "The Dynamics of Innovation: from National Systems and "Mode 2" to a Triple Helix of University – Industry – Government Relations" tell us that a key concept of triple helix is that universities in knowledge based societies play an enhanced role in innovation. Like the creation of the category of the "research university," which established another dimension for scholarly discussion of universities in modernity as well as a practical goal for university administrators and government policy professionals, the triple helix authors inform both scholarship and practice by defining a new university, the entrepreneurial university, and a new relationship between universities and the knowledge society. Key concepts in the triple helix theory include:

- the "endless transition" in which basic research is linked to utilization through a series of intermediate processes, and where Marx's vision of modernity as a process where "all that is sold melts into air" transitions into a state of constant flux within and between the three helices;
- the "second academic revolution,"which involves a move to an entrepreneurial university, underway since the end of World War II, but has been more visible since the end of the Cold War;
- the "entrepreneurial university," which has attracted significant scholarship but little specificity in its meaning, characterized by

mode 2 knowledge production, development of the third university mission of "service," and consequent "third steam" revenue sources (i.e. other than public grants for operating budgets and tuition); and

- "profit," the driving force of the interactions between the parties, although broadly read to include not just the profit of the balance sheet but also opportunities for new knowledge.

The triple helix authors do not use the phrase "socially robust knowledge," nor make bold claims about moving from reliable to another kind of knowledge. They do, however, use the concept of profit to describe the driving force of partnerships between the three-helix partners. Profit may clearly impinge on the motives for disinterested research, and prompt and full disclosure of research results. But "profit" is defined broadly and includes things like new research results, and so leaves open the opportunity for scientific inquiry to be driven by the profit of the balance sheet, but also the "profit" of peer reviewed publications.

The triple helix concept is meant to provide the social context for the mode 2 concept. Etzkowitz & Leydesdorff state: "The Triple Helix overlay provides a model at the level of social structure for the explanation of mode 2 as an historically emerging structure for the production of scientific knowledge, and its relation to Mode 1."[126]

Many of the criticisms made of the mode 2 concept can also be applied to triple helix: its concepts are fuzzy, it does not offer an empirical program and is not

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[126] Etzkowitz and Leydesdorff, "The dynamics of innovation," 118.

empirically specific, it is general to all areas of science, and it seems more like policy prescriptions than a description of contemporary science.

As with mode 2, there is a consensus among authors and critics that something fundamental is changing in R&D. Peter Weingart states: "the transfer time from basic research to technologies has been reduced to such an extent that the institutional distinction between the context of basic (academic) research and the (non-academic) context of application has become obsolete in organizational terms".[127] However, Weingart states that these are changes to a fairly small sector of the scientific enterprise, that is, biotechnology and information technology while the triple helix authors find it applies to all sciences and all the types of universities. According to others, it is even narrower, with biomedical research in one study to have been found to be the only academic discipline that affects innovation significantly and directly.[128] But whatever the view of which disciplines contributes most to technological innovation, it is the case that university research projects only occasionally contribute relevant inventions, and university research results play little if any role in triggering new industrial R&D projects (with customers and manufacturing among the highest sources of new innovations). According to industrial R&D managers, no basic sciences were deemed to be relevant to their innovative activities, with the exception of chemistry.[129] However, this must be balanced against the point that for research related to engineering or applied

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[127] Weingart, "From "Finalization" to "mode 2"," 607.

[128] Mowery and Sampat, "Universities in National Innovation Systems," 221.

[129] Ibid, 222.

sciences, virtually all fields of university research have been rated by industrial R&D managers as important or highly important for their innovative activities.

The triple helix concept that generates the most discussion is the entrepreneurial university. It is one of those phrases that can mean something either very terrible or very great, with little middle ground.[130] It can be linked to the older idea from Clark Kerr of the multiversity. Kerr's multiversity offered faculty members "several patterns of life to choose from"[131] based on an expanded list of missions, not just teaching and research. The entrepreneurial university shares with Kerr's multiversity the "massive impact of federal programs beginning with World War II,"[132] although for both the critics and boosters it is the mission of commercialization that is the entrepreneurial university's most notable feature. The two concepts of the university also share the assumption that the university is deeply shaped by its times. The argument is that the lines of causation are relatively short and that within a generation the university can be profoundly influenced by its society.

A weakness of the entrepreneurial university concept, whether of the boosters or critics, is that it underemphasizes the influence of the medieval mission of teaching and the enlightenment mission of research. These missions, plus university administrative service, continue to dominate the working life of most full-time faculty members. Also, university entrepreneurial activities are largely neither profitable nor capable of reimbursement of university incurred costs, and

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[130] For instance, Sheila Slaughter may be placed in the first camp, and Forbes Magazine in the second. See: http://www.forbes.com/sites/scottshane/2011/09/04/entrepreneurial-universities/. (June 5, 2012).

[131] Clark Kerr, *The Uses of the University*, (Cambridge: Harvard University Press, 1962): 33.

[132] Ibid, 34.

this widely known fact within universities tends to dampen senior administrative enthusiasm for the concept. In this sense, the concept of an entrepreneurial university is like that of an entrepreneurial government. In the case of their research enterprises, both are highly reliant on federal government tax dollars and generate little revenue from resulting inventions. According to the Association of University Technology Managers, in 2010 US universities received $59.1 billion in total sponsored research expenditures, of which $39.1 billion came from federal sponsors and $4.3 billion from industry. Total licensing income, mostly from inventions arising from sponsored research, was $2.4 billion, less than five percent of total sponsored research expenditures.[133] The US federal government had approximately $33 billion in research expenditures and $150 million in total licensing income associated with federal technology transfer activities in 2009.[134]

## The Reversal of the Primacy of Science and Technology

Paul Forman is an historian of science and a curator emeritus of the Division of Medicine and Science at the Smithsonian National Museum of American History. His primary research focus has been the history of physics, in which he has helped pioneer the application of cultural history to scientific developments.

The idea that the relationship between science and technology has been reversed is the focus of a 152-page article in *History and Technology* by Forman titled “The Primacy of Science in Modernity, of Technology in Postmodernity, and of

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[133] The AUTM Licensing Activity Survey for Fiscal Year 2010 is located at this address: 2010http://www.autm.net/FY_2010_Licensing_Survey/7008.htm (June 5, 2010).

[134] The Federal Laboratory Consortium for Technology Transfer report to the President, Congress, and appropriate agencies for Fiscal Year 2010 is located at this address: http://www.federallabs.org/store/annual-report-2010/ (June 5, 2010).

Ideology in the History of Technology."[135] The thesis of the article is that there has been an abrupt reversal of culturally ascribed primacy in the science–technology relationship. The longstanding primacy of science relative to technology was reversed circa 1980, indicating a boundary crossed from modernity to postmodernity. Modernity, according to Forman, "is when 'science' could, and often did, denote technology. . . . postmodernity is when science is subsumed under technology."[136] Forman sees the prime mover of this change to be culture:

> In modernity, the cultural rank of science was elevated by that epoch's most basic cultural presuppositions–not merely the presupposition of the superiority of theory to practice, but more importantly the elevation of the public over the private and the disinterested over the interested, and, more importantly still, the belief that the means sanctify the ends, that adherence to proper means is the best guarantee of a 'truly good' outcome. Today, on the contrary, technology is the beneficiary, and science the maleficiary, of our pragmatic-utilitarian subordination of means to ends, and of the concomitants of that predominant cultural presupposition, notably, disbelief in disinterestedness and condescension toward conceptual structures.

"The dissing of disinterestedness, . . ."according to Forman, ". . . formed a prominent and characteristic feature of the revolts of the 1960s."[137] Skepticism to science in scholarly disciplines began later, in the 1970s, with the Edinburgh school of the sociology of scientific knowledge. The crack in the door began with modernist suspicion and then moved to postmodernist dismissal of disinterestedness.

One of the outcomes of the cultural revolt of the 1960s, according to Forman, was the demand for relevance in science: "Yet although the undermining

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[135] Forman, "Primacy."
[136] Ibid, 1.
[137] Ibid.

of the cultural standing of for-its-own-sake science was begun by the demand for 'relevance' that came forward so broadly and insistently in the 1960s, . . . the fundamentally modernist epistemological presupposition of the primacy of science to and for technology continued to govern ideational constructs and their rhetorical expression into the late 1970s."[138] To see evidence of this change in the 1960s, Forman suggested we look at the "little science" academic laboratories, which he described in opposition to "big science" laboratories, such as high-energy, particle physics accelerator laboratories. Forman wrote: "If we want to see postmodernism working radically and admittedly upon the scientific role and knowledge production, we should look, rather, into the 'little science' academic laboratories that in high modernity were lauded as the sites of true science. With an irony that none could have anticipated 40 years ago, it is today just those 'little science' academic laboratories that have reoriented themselves most completely toward technologically defined ends . . ."[139]

In an article published last year titled "On the Historical Forms of Knowledge Production and Curation: Modernity Entailed Disciplinarity, Postmodernity Entails Antidisciplinarity," Forman continued and extended his project "to map the change in state of mind constituting the transition to postmodernity."[140] The central argument is that, between the early 1960s and the early 1970s, there was a fall in the cultural valuation of professions and of disciplines. "Disciplinarity" is defined not in terms of Mertonian norms, but four

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[138] Ibid, 5.

[139] Ibid, 11.

[140] Forman, "Disciplinary," 56.

culturally presupposed values: proceduralism, disinterestedness, autonomy, and solidarity, which he wrote, “were characteristic for modernity and indispensable to the conception and sustentation of disciplinarity.”[141] With the fall, these take-for-granted values changed, according to Forman, allowing him to make the argument that postmodernity is antithetical to disciplinarity.

As to the values, “proceduralism” in the natural science is the “scientific method.”[142] “Disinterestedness” is similar to Merton’s norm of the same name, which Forman defines as “the capacity to think and to act, and the practice of thinking and acting, in disregard of one’s personal interest–[and] was the most highly respected quality of mind and character in modernity.[143] With its loss, Forman argued, the scientist was demoted from “the high cultural rank he enjoyed in modernity, elevating into his place the intensely self- interested entrepreneur.”[144] ‘Autonomy’ “ . . . is that conception of personhood that Burckhardt, and many following him, identified as distinctive of the Renaissance, and consequently of modernity; namely, individualism.”[145] Last, “socialism” is different than Merton’s “communism,” which Merton restricted to the findings of science. “Socialism,” for Forman, “ . . . was the cultural consensus of those last decades of modernity. Viewing the world emerging from World War II, both Friedrich Hayek in Britain and Joseph Schumpeter in the United States saw it just

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[141] Ibid.
[142] Ibid, 72 and 73.
[143] Ibid, 76.
[144] Ibid.
[145] Ibid, 80.

that way, and both deplored what they saw."[146] Forman's value of "socialism" is broader than Merton's norm of "communism."

The reason Forman's concept has been included for analysis of the case studies and field history is not because it explains how the devices were designed and built, but rather how it explains the change in cultural assumptions in science and engineering during the period of study. It is not that the change described by Forman is fundamentally different than that described in the mode 2 and triple helix concepts. For instance, the mode 2 concepts of "trans-disciplinarity," (use of non-discipline-based theories, methods, experience and tacit knowledge to solve problems) and "novel forms of quality control" (definitions of quality of research results from non-disciplinary peers); and the triple helix concepts of "profit" and "entrepreneurial universities" are in keeping with Forman's change in values. But rather that Forman provides a broader analysis of how the change occurred, the forces behind it, and the implications of the change.

For Forman, postmodernity's " . . . predominant political expression is the world-wide rise of the "neoliberal" conception of the relation between the individual and society."[147] He compares postmodernity with Philip Mirowski's writings on neoliberalism and science. Mirowski is a prominent scholar in the field and co-author of the article "The Commercialization of Science and the Response of STS" in *The Handbook of Science and Technology Studies*[148] and author of the book

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[146] Ibid, 85.

[147] Forman, "Primacy," 160.

[148] Mirowski, Philip and Sent, Esther-Mirjam, "The Commercialization of Science and the Response of STS," in *The Handbook of Science and Technology Studies*, 3ed., ed. Edward J. Hackett et al. (Cambridge: MIT Press, 2008), 635- 689.

*ScienceMart: Privatizing American Science.*[149] Forman and Mirowski share the view that "We are living through a profound transformation of American science base."[150] Both focus on the transition period of the 1980s and the rightward nature of the change, with an increasing focus on science as an end to technology and economic competitiveness, and less about science as an end to itself or as an agent to the progress and expansion of an enlightenment culture.

There is a commonality in their response to the argument that this move from truth to use is nothing new: that science in earlier periods has had a practical dimension and has never been pure and insulated from the interests of sponsors. The common response is that this is true, but there is something different that is happening now in science that distinguishes it from previous periods of aristocratic, industrial and government-military influence. Mirowski writes: "The indisputable fact that scientists and their institutions have always and everywhere been compelled to "sing the prince's tune when taking the prince's coin" in one form or another does nowhere imply that the modern trend toward the escalated and enhanced commercialization of science has not altered the makeup of the supposedly invariant "scientific community," not to mention the nature of the "outputs" of the research process.[151]

But there is a difference in primary causes. Mirowski argues that science in the United States has changed over the course of three primary periods. The first period from 1890 to WWII was the era of the "captains of erudition," when

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[149] Philip Mirowski, *ScienceMart: Privatizing American Science* (Cambridge: Harvard University Press, 2011).

[150] Ibid, 19.

[151] Ibid, 89-90.

research was strongly influenced by the industrial R&D laboratories such as those housed by DuPont, General Electric, and Bell. The second occurred from World War II to 1980 and was characterized by military funding and priorities. The last, from 1980 onwards, he calls the globalized privatization regime. On its root causes, he writes: " . . . the knowledge economy, the spread of the Internet, the strengthening of IP, corporate outsourcing of R&D, and the withdrawal of state provision of education. . . . were all inspired by a particular vision of the economy and the polity, one that we will associate with the set of propositions concerning society called neoliberalism. . . . The key neoliberal doctrines that abide at the heart of each of the trends identified in the previous section are the reification of the ideal economy as a 'marketplace of ideas' and the conviction that the state as an actor can never measure up to the ability of the abstract marketplace in both conveying existing ideas and in summoning forth further innovation in ideas."[152] Mirowski dates the origins of this political and cultural doctrine to the 1930s, identifying Friedrich Hayek as the "pivotal protangonist" and "godfather of the rise of the neoliberal movement in social thought."[153] The influence began to be felt first in the United States, " . . . the first to pioneer the neoliberal reorganization of science in the last half of the twentieth century."[154]

Forman's view is that Mirowski overrates "the role of formal thought and thinkers in the making of this global 'thought collective'. To put the point bluntly:

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[152] Ibid, 25.
[153] Ibid, 27.
[154] Ibid, 286.

ideas do not make history; history makes ideas."[155] The causal links for Forman are not long and deep, but shallow and broad. Influence does not extend back to the first decade of the twentieth century in Vienna, but rather a broadly based change that occurs seemingly over the course of a few years, with roots that only go back to the 1960s.

The strength of the Forman argument is the case it makes for the primacy of science to technology, and the change in disciplinary values. As to the criticisms, he is less convincing in his argument for a sudden and drastic shift circa 1980 in cultural presuppositions, sown by the cultural revolt of the 1960s. However, Forman's focus is on documenting the change, not so much the forces behind that change. Second, it may be that scholars changed their minds about the primacy of science and technology, but Forman does not present evidence to make a strong case for broad cultural change. The linear model may be dead in academia, but as mentioned earlier, it continues to be applied in government and business. Last, there are ambiguities. What does Forman mean when he says there was a change in, "belief that the means sanctify the ends, that adherence to proper means is the best guarantee of a "truly good' outcome"?[156] What "means" are subordinated to what "ends?" What is a "truly good" outcome? Is the methodology of scientific research subordinated to the ends of technology development? I presume so, but it's not clear.

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[155] Forman, "Primacy."

[156] Ibid.

## How Might These Concepts and Models Apply to the History of Myoelectric Upper Limb Prostheses?

The concepts and models were used in formulating the questions I have asked in this dissertation and the questionnaires prepared for the interview subjects. For the linear model, the broad question is whether it provides an approximation of how research was connected to development, production, and diffusion. It may seem like a plate of spaghetti at the time, but if you stand back far enough in time, does it appear linear? Or does it appear linear within the case studies, even if the steps take decades and traverse continents? This is the first question I ask of the cases.

For the mode 2 theory, was there a move from mode 1 to mode 2 over the period under study? To answer this question, I had to define the "context of application." Is it where prostheses were manufactured? Or is it university laboratories where research was being undertaken as part of a national R&D program (which the mode 2 authors call "weak contextualization")? The "strong" context of application for upper limb myoelectric prosthetics R&D is where the prosthetic occupational therapists fit patients (i.e. hospitals and clinics). This is what I interpret as the "context of application," and not the weak definitions. The pertinent question for the field are has there been a move from university laboratory-based research to generation of problems and methodologies, dissemination of results in hospitals and clinics, as well as user homes and workplaces? Has R&D changed from being the sole domain of electrical engineers to involving prosthetists, occupational therapists, users, company managers, and others involving their own theories, methods, experience, and tacit knowledge to solve problems? Do amputees talk back to engineers? Have definitions of quality emerged that are judged not just by research disciplinary peers, but by prosthetists, patients and others? Do researchers see laboratory tests as most important, or patient feedback?

For the triple helix model, is basic research linked to utilization through a series of intermediate processes involving government, university, and industry collaboration? Is this biomedical R&D field part of a "second academic revolution,"which involves a move to an entrepreneurial university? Are the universities that host these biomedical and bioengineering programs "entrepreneurial universities?" Can the biomedical research at these universities be characterized as "knowledge production?" Did the development of these programs expand the university mission of "service?" What were significant "third steam" revenue sources? For biomedical researchers were there new incentives in academic life during the fifty-five year period of this study? Or were the motivations of faculty in the 1950s and 1960s similar to those of today?

Last, the question Forman raises for this study is whether there is a similar change of value and views expressed among funding bodies, researchers, companies, and others in the field of upper limb myoelectric prosthetics? Was there a belief, even if not made explicit, from the 1940s to the 1970s that science was the senior partner in the project to provide veterans and others with powered upper limbs? Were the laboratories used to design the Boston Arm at MIT, the Technical Assistance and Research Group for Physical Rehabilitation at UNB, and the Center for Design Engineering at the University of Utah examples of these “little laboratories?” Was there a widespread change in the views by the 1980s that the disinterested practice of science was now a servant to technology? Was science now viewed as the mere service provider of research results and data for engineers and others involved in product development and improvement? Or was it viewed as a relationship among equals, with each contributing to the purpose of the other. These questions find answers in the discussions of the cases.

# 3. LITERATURE REVIEW II: HISTORICAL ACCOUNTS OF UPPER LIMB MYOELECTRIC PROSTHESIS RESEARCH AND DEVELOPMENT

The scholarly literature on upper limb myoelectric prosthesis is extensive. A search using Google scholar returned 3,350 articles with the words myoelectric and upper-limb in the title.[157] This literature review does not describe the entire technical literature, but only seven articles that summarize advances in the field from 1945 to the present.[158] With one exception, all of these works are articles written by engineers and/or researchers working or retired from the field. The literature forms a historiography of the field. It provides not just concepts about how to understand the field over the period of study, but also an insight into the mentality of the engineers and researchers.

The North American oracle of the field is Dudley Childress, a former director of the Prosthetics Research Program at Northwestern University. He has written a number of essays describing advances in the field from his unique perspective as a participant from the mid-1940s to the 2000s. In an essay on the application of science to prosthetics and orthotics, he divides the years from 1945 to 2002 into three periods.[159]

The first, called "Scientific Developments," occurred from 1945 to 1965. Childress said it ". . . was an unparalleled period for advances in prosthetics and

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[157] The search was undertaken on August 23, 2011.

[158] The following chapter surveys the history of the research and development of myoelectric prostheses, and this considers the broader literature.

[159] Dudley Childress, "Editorial," *Journal of Prosthetics and Orthotics*, 14, no. 3, (2002): 97.

orthotics, technically and scientifically."[160] It was initially driven by US federal government funding programs to address the needs of World War II veterans. The period included fundamental studies at UCLA of the hand and arm that led to substantially improved prosthetic fitting methods and components for the upper arm. Childress claims that the "rapid progress of this period was due to several things, (1) the relatively primitive nature of prosthetics and orthotics previous to that time, (2) the "can do" approach that was typical of investigators during the post-war period, (3) the commitment of funds to R&D by governmental agencies, and (4) the effective coordination of research efforts and evaluation projects brought about by the Committee on Prosthetics Research and Development ("CPRD") of the National Academy of Sciences/National Research Council ("NAS/NRC")…."[161] He underlined the importance of the NAS/US NRC connection: "The NRC venue was key to the success of the Committee because the NRC imprimatur provided the Committee and its successors with national prominence, recognition, and credibility for the next 30 years. "[162]

Childress calls the second period, "Advancements," occurring from 1965 to 1992: ". . . by 1965, or thereabouts, many of the fundamental principles currently used in prosthetics had been established. Advancements since then seem to have emphasized technical developments, with less concentration on principles than during the previous 20-year period."[163] Technical progress, according to Childress,

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[160] Ibid.

[161] Ibid.

[162] Dudley S. Childress, "Development of rehabilitation engineering over the years: As I see it," *Journal of Rehabilitation Research and Development* 39, no. 6 November/December (2002): Supplement, 6.

[163] Ibid.

occurred through the introduction of new materials, such as thermoplastics and composites, new socket designs, commercial availability of electric powered arm components and myoelectric controls, and computer-aided-design and computer-aided-manufacturing ("CAD/CAM").

The third period, occurring from 1992 to 2002, consisted of both a "relatively high state of development" and residual "nagging questions" about the field. The apparent source of the frustration was the lack of science in orthotics and prosthetics, informing why prosthetics and orthotics should be made or applied in certain ways, and supporting "logical and verifiable reasons for using one kind of technical component rather than another."[164]

Childress concluded in his paper:

> Science appears at this time to be immature in the fields of prosthetics and orthotics. It has been applied to the fields mainly through engineering approaches. If prosthetics and orthotics are like other fields that were at one time primarily empirical in nature, it is likely that a scientific component will evolve in these fields to augment their empirical aspects.[165]

The three-stage history both fits and does not fit with the linear model. It fits with the view of Childress that fundamental research leads to applied science. The applied science at universities, hospitals, and institutes such as the Rehabilitation Institute of Chicago ("RIC"), eventually in this account resulted in the development of products and services. But contrary to the model, a mature science, one that produced a broad theory of orthotics and prosthetics, did not arise from the fundamental studies that informed design-engineering projects of the 1960s.

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[164] Ibid.
[165] Ibid.

Childress saw prosthetics like astronomy before Nicolaus Copernicus' concept of a sun-centred system and without Johannes Kepler's accurate description of planetary motion using Copernicus' theory. There was only, in Childress's view of his field, Tycho Brahe's data generated from his use of new astronomical instrumentation (bought from a grant from King Frederick of Denmark) and his experience in making precise measurements. Just as Brahe's experimental data contributed to Kepler's mathematical descriptions of planetary motion, so too Childress saw the possibility for prosthetics engineering to give back to science. So the field advanced in a linear model, from scientific development to advances of clinical products, with an, as yet, unrealized feedback mechanism that leads to the development of science specific to the field.

I share with Childress a view of the post-World War II period in the United States as being characterized by strong government support, and an abiding corporate and academic interest in the field. And while I agree that the advancements to commercial products came in a following period, it paints the period with too broad a brush, failing to capture the research that continued before, during and after products initially came to market. I also concur with Childress's observation about the lack of science in the field, or perhaps the many sciences that find application in the field.

Another surveyor of the field with research experience from the 1960s to the 1990s is Douglas Hobson. He referred to the period from 1945 to 1960 as "The

Prosthetics and Orthotics Heyday."[166] Like Childress, his view was that the field was driven by returning veterans with amputations who "created the political and social will to do something to compensate veterans for their tremendous personal sacrifice."[167] He characterized the field, somewhat nostalgically, as rising with the will created first by World War II, the polio epidemic in the early 1950s, the thalidomide tragedy[168] in the 1960s, and finally the Vietnam War.[169] This led to the creation of R&D funding programs delivered by the US Department of Health, Education and Welfare and the Veterans Administration. The key figures in his narrative are the engineers, technical personnel, and clinical colleagues who, significantly, work together in rehabilitation settings.

According to Hobson:

> In the mid-40s, there was clearly a coalescence of national need and emotions regarding the returning WWII veterans that translated into a political will and funded programs within leading federal agencies in both Canada and the US. In the US, the agencies and their program administrators worked in a true spirit of cooperation. They boldly reached out nationally and internationally for the best clinical and technical minds and brought them together into interdisciplinary settings with very focused agendas. The majority of the engineering and other technical personnel worked side by side with their clinical colleagues in rehabilitation settings. The results of their collective efforts were widely disseminated in form of detailed technical reports, information bulletins, journal articles and sponsored training programs. Funding was provided to stimulate the availability of preproduction prototypes for use in structured multi-site clinical trials.[170]

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[166] Douglas Hobson, "Reflections on rehabilitation engineering history: Are there lessons to be learned," *Journal of Rehabilitation Research and Development*. 39, no. 6, November/December (2002): Supplement, 17-22.

[167] Ibid.

[168] Thalidomide is a sedative that was prescribed in the 1960s to pregnant women for nausea. It caused severe congenital limb deficiencies in children. Governments in Canada and Western Europe, where the problem was most acute, established research centers to develop prostheses for these children.

[169] As a result of this conflict, there was again a dramatic increase in the number of US servicemen returning home with amputations and spinal cord injuries.

[170] Ibid, 17.

The fall in Hobson's history came in 1976, when the US Academy of Sciences disbanded the Committee on Prosthetics and Research and Development. According to Hobson, this resulted in decreased levels of interagency and international collaboration in rehabilitation technology. Efforts were made to find another home for the CPRD, but this never materialized as its two main funding partners, the US Department of Health, Education and Welfare and the Veterans Administration were now focused on the development and support of rehabilitation engineering centres. Ironically, it was at the time when these US funding bodies shifted from grant-funding of individual researchers to institutional funding of centres. In Canada, the federal government ended funding for the four research centres at the universities of British Columbia, Winnipeg, Toronto and New Brunswick in the mid-1970s. The effect, however, was similar in that funding for university-based R&D was cut in both Canada and the United States. The difference is that in the US, the Veterans Administration Office of Research and Development developed internal centres on rehabilitation in New York and Tampa. In Canada, responsibility for prosthetics R&D was transferred to the National Research Council.

I concur with Hobson's point about the importance of World War II in the US and the thalidomide crisis in Canada in moving governments to fund R&D in the field. I also agree that device development in rehabilitation clinics meant a more interdisciplinary approach. This is an important development for the field. But Hobson's history is a partisan one, shaped by his participation in the battles over the fate of the CPRD and CPOE in the 1970s, and so they enjoy a prominence that might otherwise have focused more on what was done in the laboratory and clinic, and instead of the meeting rooms of the National Academy of Sciences.

Another insider account was written by Robert Gailey, director, Miami Veterans Affairs Healthcare Systems Functional Outcomes Research and Evaluation Center, in Miami, and a professor at the University of Miami School of Medicine.[171] He took a broader view than Hobson and argued that the field did not rise and fall, but changed in a cyclical fashion. Like Childress and Hobson, it was World War II that drove the creation of government programs and funding for prosthetic research and development, not the thalidomide tragedy, given the US focus of the article. In Gailey's narrative, prosthetic research funding dried up from the late 1970s through the 1990s, as the primary cause for loss of limb changed from trauma to diabetes and dysvascular disease, and the funding priority shifted to prevention of amputation. There is also a move during and after the Iraq wars from prosthetic product development and service under government sponsored programs to delivery of these products and services by private prosthetic companies to veterans under government-funded contracts.[172] The wars in Iraq, according to Gailey, began the cycle anew.

This is "history as progress," where the cycles and technology move ever upwards. "The fact is with every war thousands lose limbs, Government funding spawns new developments never expected, and ultimately each generation of prosthetic devices and training further enhances the quality of life for the returning

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[171] Robert Gailey, "As history repeats itself, unexpected developments move us forward," *Journal of Rehabilitation Research and Development*, 44, no. 4, (2007): xii.

[172] Ibid.

warrior and the civilian population." The new frontier of prosthetics, according to Gailey, is neuroprosthetics, where electrodes are surgically implanted within muscle tissue that allow nerve impulses to control the upper limb prosthesis. He also mentions the surgical procedure known as "osseointegration," first developed in Sweden, where there is direct skeletal attachment of a lower limb prosthesis, eliminating the need for a socket.

University of New Brunswick researchers, Phillip Parker, Kevin Englehart, and Bernie Hudgins argued in a paper on 50 years of myoelectric control technology that progress has been incremental in the field, due in part to the alternating focus of R&D between control methodology and device hardware.[173] They focused their history on the myoelectric signal processing challenge, and its move from single muscle control of a single prosthesis function to muscle group activity control of multifunction prostheses. The core challenge was (and still is) in extracting information from the myoelectric signal. This is an internal history of the field, focused on the development of myoelectric controls, and not focused on non-technological forces that shape the discipline.

There are three periods in their narrative. In the first period, pre-1960s, myoelectric communication channels used two-state amplitude modulation (meaning control was limited to two states, e.g. open hand and close hand), and were limited clinically by the electronics technology of the period. "With the development of semiconductor device technology and the associated decrease in

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[173] P. Parker, K. Engelhart, and B. Hudgins, "Myoelectric signal processing for control of powered limb prostheses," *Journal of Electromyography and Kinesiology* 16 (2006): 541.

device size and power requirements, clinical application saw promise and research and development increased dramatically."[174]

During the second period, in the 1960s and 1970s, significant progress was made in the development of myoelectric signal amplitude and rate modulation for multistate controllers. This means control of more than two prosthetic functions with one muscle (e.g. open hand, close hand, etc). The first two-state channels were taken up commercially by such companies as Otto Bock, Hugh Steeper, Motion Control Inc., Liberty Mutual, Variety Ability Systems, and Fidelity Electronics. They were the most commonly available commercial systems, and had good performance, but were limited in that each function required a muscle control source, the availability of which decreased as the amputation level increased. Prosthetist Bill Sauder wrote of the two-state systems that they were, ". . . specifically designed for the traumatic below-elbow amputee and require two different muscles for the control of the electrically powered hands. The prosthetist can easily identify these muscles, and the average amputee learns quickly to produce clean and strong EMG signals from them."[175]

But the two-state system was not useful for people with short congenital below elbow stumps. With no bicep or triceps muscles, prosthetists had trouble finding a good second forearm muscle for the two-state system. To address this limitation, three-state control systems were developed. In three-state systems a chosen muscle was trained to produce a strong EMG signal to do one function (e.g.

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[174] Ibid.

[175] Bill Sauder, "Application of a Three-State Myoelectric Control System," *Journal of the Association of Children's Prosthetic Orthotic Clinics*, 16, no. 1 (1977): 9-12

open the hand), and a moderate signal to do another function, close the hand. In other words, one muscle controlled two functions. In North America, UNB pioneered the three-state system, first designing and manufacturing systems in 1961 for use in experimental fittings at the Ontario Crippled Children's Centre. In Europe Professor Hannes Schmidl at INAIL in Italy developed and used a similar circuitry in a three state controller.[176] These three-state systems were taken up commercially by such companies as Otto Bock, Hugh Steeper, Hosmer, and Fidelity Electronics.

The third period, from 1975 to the mid-2000s, was characterized by large improvements in performance for multifunction control through the application of new approaches including optimal detection/estimation, pattern recognition, and electrode arrays. It was during this period that the microprocessor was first introduced into myoelectric prostheses.

This Parker et al. narrative most resembles the Childress history, with systems initially developed at universities and institutes, and subsequently taken up by companies and introduced as new products. There followed a relatively long period of system improvement as a result of both R&D and product development at universities, hospitals, institutes and companies. Some improvements, like pattern recognition, are still at a stage of introduction to commercial systems. There is little to disagree with in this article. Two quibbles are that it does not give enough emphasis to the ongoing research during the third period, nor to the rise in innovation projects during the end of this period. However, as the paper was

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[176] Ibid.

published in 2006 and likely written in 2005, it would probably have been difficult to see clearly the rise of the innovation approach.

Christopher Lake and John Miguelez in an article in *Technology and Disability* presented a similar three–stage history of microprocessor based control systems for power limb prostheses from the early 1960s to the early 2000s.[177] Like the Parker narrative, the first generation of electronics consisted of digital systems using an on and off control system to move electronic terminal devices (electric hands and hooks), wrist rotators, and elbows. These had a single speed and limited sophistication of input devices.

The second generation consisted of proportional control (meaning the output signal to a terminal device, e.g. electronic hand is proportional to an input from the muscle) and "large-scale threshold manipulation, gain or muscle amplification as well as adjustment of muscle contraction rate in an attempt to minimize effort in first generation co-contraction type switching."[178] This meant less muscle power was needed and more control could be exercised over the hand, wrist or elbow. More people could use prostheses and make better use of them. The challenges with these second-generation control systems were that each system had its own electronics package. They had to be installed into the prosthesis, creating additional expense and fabrication time.

The third generation of prosthetic electronics used programmable microprocessors. They allowed for modification of control options without

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[177] Christopher Lake and John M. Miguelez, "Evolution of microprocessor based control systems in upper extremity prosthetics," *Technology and Disability*, 15 no. 2 (2003): 63-71.

[178] Ibid, 63.

purchasing or changing components, and provided relatively simple controls for changing thresholds and sensitivity of the prosthesis as the user's strength and ability evolves.[179]

A. Bennet Wilson, a former technical director and director of the US National Academy of Science's Committee on Prosthetics Research and Development (CPRD), in his essay, "History of Amputation Surgery and Prosthetics" in the *Atlas of Limb Prosthetics: Surgical, Prosthetic, and Rehabilitation Principles* shares with Gailey, and many others, the thesis that major wars are the stimulus for development of improved prostheses.[180] He argues that considerable progress occurred after World War II because of US Government-sponsored research programs. The results of the research were "responsible not only for delineating the basic principles of fitting and alignment, but also for initiating a preparatory education program that has had a very strong influence on improving the practice of prosthetics throughout most of the world."[181] In Great Britain and Germany there was also increased funding for prosthetics research after World War II. In the early 1970s, research in Germany moved from universities to the private manufacturers, according to Wilson, and these manufacturers, in particular Otto Bock, had a significant influence on prosthetics practice throughout much of the world given its role as the dominant hardware manufacturer in the industry,

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[179] Ibid, 64.

[180] A. Bennet Wilson, "History of Amputation Surgery and Prosthetics," *Atlas of Limb Prosthetics: Surgical, Prosthetic, and Rehabilitation Principles,* ed. John H. Bowker and John W. Michael (Saint Louis: Mosby-Year Book, 1992). http://www.oandplibrary.org/alp/chap01-01.asp (July 31, 2009).

[181] Ibid.

comparable to IBM in computer hardware.[182] Support for research in prosthetics in Canada, according to Wilson, was sporadic, but some of the results have been important, in particular the work of R. N. Scott at UNB and Bill Sauter at the Hugh MacMillan Medical Centre (formerly Ontario Crippled Children's Centre).[183]

Like the other narratives, the field moves from government research programs and funding for universities, hospitals and institutes to the development and improvement of products by companies and collaboration with these other organizations. Specific to Canada and the United States, the government funding programs in support of upper limb myoelectric prosthesis were ended in the mid-1970s. As was Hobson, Wilson was a participant in the battles over the CPRD and CPOE in the 1970s, and so his narrative reflects his experience as an officer of the CPRD. The fall of the organization was a hard blow for Wilson, and as part of the change he resigned his position at the CPRD. Wilson wrote that no new programs were developed for company commercialization of products, although university spin-off companies such as Motion Control from the University of Utah successfully obtained grants from the Small Business Innovation Research (SBIR) Program to support work on myoelectric upper limb projects.

David Serlin, an American historian and researcher in the field of disability studies, provides an alternative historical account in his essays: “Engineering Masculinity: Veterans and Prosthetics after World War Two”[184] and “The Other

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[182] Wilson does not address whether that shift was accompanied by a decline in state funding of university research, or just a shift in where the state-funded research was performed.

[183] Ibid.

[184] David Serlin, “Engineering Masculinity: Veterans and Prosthetics after World War Two,” in Katherine Ott, David Serlin, and Stephen Mihm *Artificial Parts, Practical Lives: Modern Histories of Prosthetics* (New York: New York University Press, 2002).

Arms Race".[185] He divides his history into before and after World War II. The central argument is that " . . . the physical design and construction of prostheses help[ed] to distinguish the rehabilitation of veterans after World War Two from earlier periods of adjustment for veterans. Prosthetics research and development in the 1940s was catalyzed, to a great extent, by the mystique of scientific progress. The advent of new materials science and new bioenegineering principles during the war and the applications of these materials and principles to new prosthetic devices helped to transform prosthetics into its own biomedical subdiscipline."[186] To bring plastics and engineering into patriotic service for veterans, the US National Academy of Sciences, and the National Research Council, "funded and supported advanced prosthetics research, especially at university and military laboratories."[187] The first US program into power driven artificial limbs (it was not yet clear whether power would come from hydraulic, pneumatic or electric sources) was announced in late August 1945, two weeks after the war in Japan ended. In Serlin's narrative, science, engineering, technology, military-industry production techniques, and government funding programs of the 1940s to 1960s were pressed into the service of a larger strategy and cultural preoccupation. He wrote that: "The association between amputees and state-of-the-art prosthetics research may have been an intentional strategy to link disabled veterans with the positive, future aura surrounding military-industrial science."[188] Why the need for the aura? It was the ". . . postwar preoccupation with masculinity and productivity. .

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[185] David Serlin, "The Other Arms Race," in *Replaceable You: Engineering the Body in Postwar America*. (Chicago: The University of Chicago Press, 2004).

[186] Ibid, 47.

[187] Ibid, 54.

[188] Ibid, 55.

. .” and “. . . among other things, the fiercely heterosexual culture of postwar psychology, especially in its orthodox zeal to preserve the masculine status of disabled veterans.”[189] Cultural ideals emerge as the primary force in the project making the damaged male body productive. What Serlin characterizes as “. . . perhaps the greatest conceptual challenge to modern industrial capitalism. . . .”[190] was met by the development of prostheses such as the cable driven hand designed by Henry Dreyfuss for the US Veterans Administration. In contrast, Serlin writes, the Boston Arm was atypical, in that it took a long time to move from initial design to commercial product “. . . and then its exorbitant cost was anathema to most patients and many insurance companies.”[191]

This focus on using science and engineering to get disabled service men into productive work and a normal family life was not only an American preoccupation. Writing about Canada’s Department of Veterans Affairs in the 1940s, Walter Woods (an employee of Veterans Affairs) wrote that “. . . Prosthetic Services are designed . . . to provide scientific physical rehabilitation of the disabled veteran which is so essential to his establishment in a useful occupation.”[192] A few pages later on the topic successful cases of rehabilitation where the veteran was “…able to compete in the labour market on a par with the non-disabled workman….” he wrote:

> One of the tidiest Veterans’ Land Act holdings in a certain area belongs to a veteran with a triple amputation. The loss of both legs and a right hand does not prevent him from earning a good living. He is in charge of the stationary store of a large plant. He likes his work, is a most popular plant employee,

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[189] Ibid, 56.

[190] Ibid.

[191] Ibid, 50.

[192] Walter Woods, *Rehabilitation (a Combined Operation): Being a History of the Development and Carrying Out of a Plan for the Re-establishement of a Million Young Veterans of World War II* (Ottawa: Queen's Press, 1953), 348.

> has a wife and two small children of whom he is justly proud, and last but not least, he plays on the War Amputations Softball team; occasionally rides horses and drives his own car.[193]

Serlin's history seeks to fill in the gaps in the linear model. Instead of arrows pointing from scientific research to applied research, there is post-war American culture and the ideal of the masculine, productive, able-bodied man. Science provides its mystique of progress and materials. Clinical research determines the power source, electric, not hydraulic or pneumatic. But in Serlin's history it is the engineers and prosthetists that operate in the foreground, practicing their engineering design and construction of devices. They are the primary agents of the post-war American cultural ideal.

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[193] Ibid, 364.

# 4. HISTORY OF UPPER LIMB MYOELECTRIC PROSTHESES

My field history of upper limb myoelectric incorporates many elements from the narratives in the previous chapter. Childress's phrase "Scientific Developments" is particularly apt for the period from 1945 to 1965, emphasizing both the fundamental and practical work of this period, such as selecting electric as opposed to pneumatic power sources, and the use of muscles in the arm for exercising control over the electronic prosthesis. Childress, Hobson, Gailey, Serlin, and others emphasize the divide of pre- and post-war periods, not the continuity, and that the divide was cleaved by US federal government funding programs, although, unlike Serlin, they do not look for cultural forces behind government action. I side with Childress and the majority view on this matter of World War II being a major force in the field. I also agree with Childress that a science specific to the field has yet to develop. Aptly then, the key figures in Hobson's narrative were engineers, technical personnel, and clinical colleagues.

I differ with Childress' characterization of the second period, "Advancements," occurring from 1965 to 1992. There are two issues. It misrepresents the development activities of groups behind Liberty Mutual, Motion Control, VASI, and Otto Bock hardware and various control systems to say they were applying new technologies in light of scientific research of the 1940s to 1960s. The second objection is that it does not adequately address the development of an engineering research culture following the wind-up of clinical and development oriented programs in the US and Canada. There is a divide that occurred during the period between the work that resulted in the aforementioned hardware and software, and then the improvement of these products from the mid-1970s to the present, and another line of work that investigated what systems may be developed for above elbow amputees that have only one muscle site and want multifunctional control (i.e. that can, ideally, simultaneously control a shoulder, elbow, wrist, fingers and thumb). Parker and colleagues at UNB addressed this second area of research in their narrative.

The fall in Hobson's history occurred in 1976, when the United States Academy of Sciences disbanded the Committee on Prosthetics and Research and Development (CPRD). According to Hobson, a CPRD supporter, this was the primary cause of decreased levels of interagency and international collaboration in rehabilitation technology. Gailey suggests that the reason for disbanding the CPRD was because the primary cause for loss of limb had changed from trauma to diabetes and dysvascular disease, and the funding priority shifted to prevention of amputation. There was also a change during and after the Iraq wars from prosthetic product development and service under government-sponsored programs to delivery of these products and services by private prosthetic companies to veterans under government-funded contracts.[194]

I admired the way Serlin filled the gaps in the linear model with a discussion about cultural preoccupations instead of the typical "single-symbol" approach to understanding the workings of the linear model. I also found convincing Serlin's emphasis on the cultural preoccupation with masculinity and productivity, and

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[194] Ibid.

getting disabled servicemen into productive work and normal family lives. In my terms, he is arguing that cultural forces set in motion the application of the linear model. Where I disagree with Serlin is with what happened once the linear model was set in motion. I emphasize the discontinuity between the research and development, or the science and engineering, whereas Serlin appears to see the science and engineering fitting into a linear model.

My history of the field begins in 1945, with the first proof-of-concept device, arising about fifteen years after the introduction of the vacuum tube amplifier. I divide the history into four periods from 1945 to 2010. During 1945 to 1960, the first system was developed in Germany to use myoelectric signals from a muscle to control of a mechanical hand. In the United States, and to a lesser extent in Austria, Canada, England, Italy, and the USSR, governments funded research on powered artificial limbs. In the US the focus was on "fundamental" research, undertaken to lay a scientific foundation for advancement of the field. The second period, from 1960 to 1976, was marked by the thalidomide tragedy, new government sponsored programs to develop technologies for children with limb deficiencies, and the application of the transistor to prosthetic devices. According to Parker and colleagues at UNB, ". . . the emergence of this research was markedly dispersed, apparently disjointed and quite unaware of Reiter's pioneering work. Investigations had begun in the USSR, England, Sweden, Japan, the US and Canada."[195] The third period, from the mid 1970s to 2000, saw the introduction and

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[195] K. Englehart et al, "Multifunction control of prostheses using the myoelectric signal," in *Intelligent Systems and Technologies in Rehabilitation Engineering*. ed. Horia-Nicolai L. Teodorescu and Lakhmi C. Jain (Boca Raton: CRC Press LLC, 2001).

improvement of long-awaited commercial myoelectric upper limb systems. It also saw the development and maturation of research programs that were not focused so much on improvement of these devices, as developing new concepts for multifunction device control for high-level amputees. The fourth period began in 2000, and is characterized by new innovation funding programs that emphasize large, inter-institutional groups involving product development as well as commercialization.

## Scientific Developments and Proof of Concept, 1945-1960

Although the needs of World War I veterans drove growth in the design of prosthetics, it was not until World War II that governments became active in supporting research. In the case of Canada, it was in 1916 that the Department of Veterans Affairs was charged with the responsibility to manufacture, fit, and service all prosthetic appliances for veterans. The department's research mission was added in 1944.[196] In the United States it was in 1917 that the Surgeon General of the Army called to Washington the limb makers of the country to discuss the problem of supplying artificial limbs to veterans of World War I. But only in 1945 did the US National Academy of Sciences–National Research Council organize a sponsored cooperative research and development program to address issues in the field.[197]

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[196] The Department of Veterans Affairs's prosthetic limb factory was located at Sunnybrook Hospital in Toronto, which distributed materials and components to 11 service centers across the country.

[197] President Abraham Lincoln signed the charter of the Academy of Sciences when it was set up during the Civil War. That charter required that the academy act as adviser to the government in scientific matters, although it is not a government agency. The National Research

The motivation for the new research mission came, in part, from the International Conference on Amputations and Artificial Limbs, held in Ottawa, and at the Christie St. Hospital, Toronto, in February 1944. It was organized by the Canadian National Research Council and was attended by representatives from the United States, Great Britain, Australia, and the USSR. According to a history of Canadian rehabilitation during the period by National Research Council employee Walter Woods: "[The meeting]. . . laid the foundations for scientific study of the subject. Arising from this meeting the Advisory Committee on Artificial Limbs, National Research Council, US, the Standing Advisory Committee on Artificial Limbs, British Ministry of Pensions, and the Associate Committee on Artificial Limbs, National Research Council, Canada, were formed to direct the study of fundamental data, improvements of materials and development of prostheses."[198]

In this period, the concept of using myoelectric signals in stump muscles for control of a mechanical hand was first reduced to a proof-of-concept device. Although a bench-top electric prosthetic hand had been demonstrated in Berlin in 1919,[199] the use of myoelectric control would have to wait for the end of the next World War. The device was developed by Ronald Reiter during his graduate studies in physics at the University of Munich from 1944 to 1948. The system he designed and built was a literal bench-top tool due to its dependence upon A.C. electricity

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Council was established by the academy in 1916 at the request of President Wilson, to enable scientists generally to associate their effort with that of the limited membership of the academy.

[198] Woods, *Rehabilitation*, 348.

[199] G. Schlesinger, R.R. DuBois, R. Radike, S. Volk "Der mechanische Aufbau der künstlichen Glieder" I.: Der Eratzrarm. In: *Ersatzglieder und Arbeitshilfen für Kriegsbeschädigte und Unfallverletzte* ed. M. Borchardt, K. Hartmann, H. Leymann, R. Radike, G. Schlesinger. Berlin, Germany: Julius Springer-Verlag. (1919).

and the size of the vacuum tube amplifier, similar in size to an attaché case.[200] Although the device used three-state controller and proportional control as devices do today, it never proceeded to clinical investigation.[201] Reiter stated that in 1948, ". . . the political and economic conditions in Germany were not conducive to further work on the project."[202] Although published, the work would only be rediscovered after the initial development of similar myoelectric systems in the 1960s.

In the US, the federal government responded to World War II veterans through the sponsorship of R&D, education and training programs and conferences. The US National Academy of Sciences discovered that little modern scientific effort had gone into the development of artificial limbs, and in 1945 initiated a "crash" research program funded by the Veterans Administration Office of Scientific Research and Development. The state-of-the-art devices in 1945 were shoulder powered, artificial limbs for adult arm amputees, using cables to open and close the wooden, mechanical hand. For children, it was cable controlled hooks, as artificial hands had not been developed in small sizes.[203] One of the major outcomes from the sponsored programs of the Office of Scientific Research and Development came from a project at International Business Machines Corp. (IBM). IBM investigated the concept of an electric arm, and then developed a device with financial support

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[200] D.S. Childress and M.V. Podlusky, "Myoelectric control – Letter to the editor," *Medical & Biological Engineering* 7 no. 3 (1969): 345.

[201] Ibid.

[202] Louise Boldon, *A History of Myoelectric Control* (Fredericton, University of New Brunswick, 1983).

[203] US Department of Health, Education and Welfare, Office of Vocational Rehabilitation, *Progress in Prosthetics* (Washington: US Government Printing Office, 1962), 2.

from both IBM and the US Veterans Administration.[204] From that project came the realization that arm amputees could not control the electric arm without conscious thought, and that for most amputees the level of effort to control a prosthesis exceeded the benefits received. The suggestion was that future research should focus on electric arm control.

The program of the Office of Scientific Research and Development lasted for two years. In 1947, the National Academy of Sciences, on advice from its advisory committee on artificial limbs, set up a new program to fund research at universities and industrial laboratories. This program lasted 30 years, from 1947 to 1977, with a major change in 1955 when the National Academy of Sciences created the Prosthetics Research Board (PRB) to run this program. In 1959, the PRB created two committees, the committee on prosthetics research and development (CPRD) and the committee on prosthetics education and information (later called the committee on prosthetics and orthotics education), all of which continued until 1977 when the board and committees were dissolved by the National Academy of Sciences. The CPRD emerged as the major national coordinator of upper limb R&D funding during this period.

The broad mission of these programs was not just to replace wood with plastic, leather straps with suction cup sockets, and muscle with batteries and motors, but to understand the human body. The 1962 publication *Progress in Prosthetics* described how modern science would hopefully work on technology from the mid-1940s onwards: “The first decade of this research was of the patient,

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[204] Samuel W. Alderson, The Electric Arm,” In Chapter 13 Klopsteg and Wilson Ed. *Human Limbs and Their Substitutes* (New York: McGraw-Hill, 1954).

painstaking basic type which usually precedes dramatic discoveries in science. Now, breakthroughs are in sight which could bring prosthetics fully into step with this new age of electronics."[205] According to the authors, the process would unfold this way: "Developmental devices and techniques progress through four phases– basic research, model development and evaluation, clinical and field studies, and production by the limb industry."[206] The results in 1962 did not feature electronic artificial arms, but the authors did point to other areas of the linear model in practice: "Functional principles which have been disclosed by research on artificial arms and legs, in a series of experiments, have proven highly valuable in developing a new science of bracing the flaccid muscles of polio and stroke victims and also in surgically improving the bony structure and nerve and muscle function of these handicapped persons."[207]

One of the earliest US government funded projects to produce an electrically powered artificial arm occurred at New York University in the early 1950s. The research findings were that a myoelectric signal from muscle contractions varied in accordance with the size and location of the electrode as well as the type of contraction.[208] Evident of the early days of technology transfer and the challenges of making commercial products, the researchers wrote in their paper that "These research findings were passed on to the Prosthetic Research Division of the

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[205] Ibid, 2.

[206] Ibid, 21.

[207] Ibid, 2 and 3.

[208] W. Berger and C.R. Huppert, "The use of electrical and mechanical muscular forces for the control of an electrical prosthesis," *Amer. J. Occupational Therapy*, 6, no. 3, (May-June, 1952): 110-114.

International Business Machines Corporation for practical application."[209] The passing of research findings, however, did not end in the commercialization of a device.

Research in the late 1950s at the University of California at Los Angeles investigated whether electroencephalographic (EEG), electroneurographic (ENG), or myoelectric signals were the most promising for prosthetic device control. The authors favoured myoelectric control and outlined a number of concepts that would eventually be used in device designs.[210]

Applied research was not only undertaken by universities and government laboratories, but also by large firms. In addition to IBM, the defense contractor Litton Systems investigated the concept that a given amount of muscular activity produced a proportional amount of electrical activity.

The other major performer of research that arose in this period was the Prosthetic Research Center at the Rehabilitation Institute of Chicago (RIC). Incorporated in 1951, it became one of the largest research programs on upper limb electric arms in the United Sates. Unlike other internationally recognized research centres that would be created over the next twenty years, RIC was neither a unit of a hospital nor an academic institution, but from the beginning an independent body with its own board of directors and facilities.[211] Originally housed in a renovated warehouse, it would, in 1974, move into a new twenty-

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[209] Ibid, 9.

[210] G. Weltman, H. Groth and J. Lyman, *An Analysis of Bioelectrical Prosthesis Control. Report No. 59-49*, (Los Angeles: Department of Engineering, University of California,1959).

[211] Subsequent centres were created at Guy's Hospital Medical School in London, the Princess Margaret Rose Hospital in Edinburgh, and Sunnybrook Hospital and Bloorview Children's Hospital in Toronto, and academic institutions such as UNB and the University of Utah.

storey, state-of-the-art specialty hospital on the campus of the McGaw Medical Center in Chicago, overlooking Lake Michigan.

In the United Kingdom, the first research program into myoelectric control was begun in 1955.[212] It was initiated at Guy's Hospital Medical School in London. The initiators were Drs. C.K. Battye, Alfred Nightingale, and James Whillis. Battye and Nightingale were both members of the hospital's physics department. Nightingale would eventually become chief physicist at St. Thomas's Hospital in London, and the first editor in chief of Medical & Biological Engineering & Computing. Whillis was a medical doctor, although he never intended to practice given a longstanding interest in human anatomy. In 1935, he was appointed a reader in anatomy at Guy's Hospital Medical School.

The three constructed an apparatus to perform a simple open and close action based on myoeletric signals from the arm of a test subject. The aim was to have the device open and close when the subject made a light grasp with the fingers. The focus was on proving the concept of myoelectric control, not on designing a workable device, and so the apparatus was bulky. The wooden box containing the electrical power supply, amplifier, and discriminator (what would subsequently be called a controller) was about three feet wide by two feet tall. Although the researchers experienced difficulties with the design of the apparatus because of electrical interference from electrical machines nearby, they deemed the preliminary work promising enough to suggest that a useful and dependable

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[212] C.K. Battye, A. Nightingale, and J. Whillis, "The Use of Myoelectric Currents in the Operation of Prostheses," *J. Bone Joint Surg.*, 37-B, (Aug. 1955): 506.

prosthesis could subsequently be developed.[213]

It was about seven years later, in 1962, when the first British myoelectrical prosthesis was designed and built by Alistair Bottomley. Bottomley was then a member of the scientific staff of the medical research council at West Hendon Hospital, London. The design of the device stemmed from the work Nightingale had done when he was with the physics department of St. Thomas's Hospital, where Bottomley studied physiology. Englehart and colleagues at UNB wrote of the work: "The most significant design features of the device were its elimination of crosstalk, or signal interference with the two control sites and its proportional control."[214] Bottomley's prosthesis was subsequently handed off to the British Atomic Energy Research Department for "miniaturization and practical development."[215] Like plans for reduction to practice of research by IBM, it did not result in a commercial product.

As was the case in the UK, in Canada research on artificial hands and prostheses began in a hospital: in 1949 at the Sunnybrook Hospital in Toronto, the laboratory facility of Canada's Department of Veterans Affairs. However, research on myoelectric upper limb prostheses at Sunnybrook would have to wait for over a decade. In the 1950s, the focus was on making existing body powered and mechanical hand prostheses more useful through the use of new plastics and materials, novel suction socket fittings, and cosmetic gloves.

The major development in Canada during the period was the establishment

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[213] Ibid, 510.

[214] A.H. Bottomley, A.B. Kinnier-Wilson, and A. Nightingale, "Muscle substitutes and myoelectric control," *Journal of the British Institute of Radio Engineers* 26, no. 6 (December, 1963): 429-448.

[215] Ibid.

of prosthetic research and technical units (PRTUs) in 1963 as a result of the prescription sale of thalidomide from April 1, 1961 to March 2, 1962.[216] In 1962, the Department of National Health and Welfare convened an expert committee on the rehabilitation of congenital anomalies associated with thalidomide.[217] The committee reported and made recommendations. The department took action, providing $200,000 annually (starting in 1963) for three research and training units at the Rehabilitation Institute of Montreal, the OCCC, and the Rehabilitation Hospital in Winnipeg.[218]

As with space rocketry, the most sensational developments of the period occurred in the Soviet Union. The concept of using electrical signals from muscles to control a prosthesis was first formulated in 1957 by a joint group at the Machine Research Institute and the Central Research Institute.[219] At the 1958 World's Fair in Brussels, the USSR's pavilion of new technological breakthroughs showcased the myoelectric forearm prosthesis powered by a miniature D.C. motor and battery pack worn on the amputee's belt. The design was to have significant influence in the United Kingdom and Canada, where rights were licensed for manufacturing. Worldwide, it raised expectations about what could be done for amputees and provided fuel for scholarly and popular science articles on the future of the man-

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[216] By September 1964 the Department had identified 82 children affected by thalidomide, with most in Ontario and Quebec.

[217] Among the ten clinical experts on the committee were Dr. John Hall from the Ontario Crippled Children's Center and Dr. Gustav Gingras from the Rehabilitation Institute of Montreal. *The Report of the Expert Committee of the Habilitation of Congenital Anomalies Associated with Thalidomide*, dated December 1962, was obtained under an access to information request.

[218] The grant was continued until March 31, 1975, three years after the termination date of March 31, 1972.

[219] B. Popov, "The Bio-Electrically Controlled Prosthesis," *J. Bone & Joint Surg.*, 47B (1965): 3.

machine interface and the field of cybernetics.

## Biomedical Engineering Research and Design, 1965-1977

During the second period, from 1965 to 1976, R&D on myoelectric prostheses continued in the United States, Great Britain, Canada, and the Soviet Union, and new programs were initiated in Austria, Italy, Sweden, Japan, West Germany, and the Netherlands. These programs included research on electrodes, feedback, fittings, pattern recognition, and signal processing, as well as development of numerous myoelectric prostheses and control systems, spurred by the newly introduced transistor. It was near the end of this period that the first products began to emerge from research and/or engineering design activities begun in the early 1960s.

R&D during the period can be divided into two streams: one oriented to the design of control systems and hardware for below elbow amputees, and full arms systems that could generate signals from two or more muscles; and a second, more research-oriented, program that focused on above elbow systems that used only one muscle site. The former consisted of device design, build and test projects, and resulted in products by the end of the mid-1970s. The majority of upper arm amputees were potential users of these products. This was the shorter-term, lower-risk, and bigger-market stream.

The latter focus was, according to Englehart and colleagues at UNB, "based on the conviction that the most urgent need for externally powered prostheses was in high-level amputation. The efforts put forth to meet the intrinsic technical challenge of this complex control problem have produced anatomical and physiological models and have drawn upon statistical signal processing methods to maximally extract information from the myoelectric signal."[220] The rationale for signal or pattern recognition methods was that the most common functions of the elbow or hand occur from the work of groups of muscles, only some of which directly control the movement. For instance, when the elbow brings the forearm from beside the leg to the chest (as when lifting a dumbbell), there is also movement of muscles in the scapula or shoulder blade. Those back muscles do not control the movement, but rather fix and stabilize the arm so other muscles can exercise direct control. This means that the myoelectric signals are not simply a single pulse of electricity from a bicep or tricep muscle, but a complex pattern of signals. The development of pattern recognition systems was one major outcome from this biomedical research, although it still had yet to find commercial application in the 2000s.

Of the product stream, although Kobrinsky had first-mover advantage in developing the world's first transistor-based myoelectric hand and his group continued to improve upon it in the 1960s, it was the West German firm Otto Bock that emerged as the dominant manufacturer of prosthetic hands, arms, and components. Otto Bock benefited from collaboration with the Italian workers compensation R&D firm, INAIL, outside of Bologna, Italy, which had developed a myoelectric control system that served as a model for a version designed by Otto Bock. Otto Bock, along with Vienna based hearing aid manufacturer, Viennatone,

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[220] Englehart, "Multifunction."

were offering powered prostheses commercially in North America by 1967, although it would be another decade before these became commercial products.[221]

In North America during this period, the design of what would become major products occurred at MIT, the University of Utah, UNB, and the Ontario Centre for Crippled Children. At MIT, electrical engineering Robert Mann began design on what would become the Boston Arm. After substantial re-design by staff at Liberty Mutual (one of the major project sponsors) it would become the first myoelectrically controlled elbow in the early 1970s. At the University of Utah's Center for Engineering Design, a student of Robert Mann, Steven Jacobsen, began work on the Utah Arm in the early 1970s. In Canada, UNB's IBME began development of its three-stage control system for powered limbs, which was to become the first North American control system in 1965. And in the late 1960s, at the OCCC in Toronto, staff began work on the design of electronic elbows and hands for use by children.

The line between experimental design and commercial product was fuzzy. Work to produce products from these four initiatives was described by faculty and staff as biomedical engineering design, something between research on the one hand and commercial products on the other. It was experimental in that the newly designed or redesigned products were subject to testing in the laboratory and with patients in clinics, and in some cases publication of results and new design work. But the lack of uptake by amputees and ever-changing designs, not to mention a

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[221] The Veterans Administration Prosthetics Center (VAPC) improved this design with a controller developed at Northwestern University and contracted Fidelity Electronics (of Chicago, Illinois) to produce a hand which was marketed for a while.

likely lack of profitability on these designs, made the products something less than commercial products.

The Russian Hand not only helped spur development of myoelectric products in Europe, but also systems in Canada and the United Kingdom. In 1964, personnel from the Rehabilitation Institute of Montreal travelled to the Central Institute for Prosthetics and Prosthetic Development in Moscow and licensed the Canadian manufacturing rights to the Russian myoelectric arm. As with technology transfer in the previous period, expectations were greater than realities, although there were resulting clinical products from the Russian Hand licensing deal.[222] Upon initial investigation of the ten prototype arms the Montreal group took back with them from the Soviet Union,[223] they found that the arm was too heavy, the shape of the fingers "precluded fine prehension, the pressure between the thumb and finger was not graded, the skin-electrode contact was not sufficiently stable, and there was crosstalk or interference between the two sites leading to signal inhibition."[224] There were, however, advantages. "The lack of a harness was a plus, cosmesis was improved, the glove afforded a better grip, and no muscular effort was required to operate the prosthesis."[225] After replacement of the amplifier and battery components with North American hardware, redesign of the battery charger, integration of all hardware components, except the battery, into the arm,

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[222] Commercial products were to wait for the next period, starting in the mid-1970s.

[223] E. Sherman, G. Gingras, A.L. Lippay, "New trends in externally powered upper extremity prostheses," *World Medical Journal* 15, no. 5 (September-October, 1968): 121-125.

[224] G. Gingras, et al., "Bioelectric upper extremity prosthesis developed in Soviet Union: Preliminary report," Archives of Physical Medicine and Rehabilitation (1996): 232-237.

[225] Ibid.

and design of an adjustable wrist unit, the Montreal group clinically evaluated the devices and deemed them "basically practical and cosmetically acceptable."[226]

The Rehabilitation Institute of Chicago (RIC) grew not through in-licensing and use of the Russian Hand technology (indeed there is no record of any licensing transactions in the US), but rather through a combination of internal developments and external collaborations. It would expand to cover locations in southern Illinois and north central Indiana, and develop a collaboration with Northwestern University and its Feinberg School of Medicine. A residency program was created in 1967, and in 1968 the Institute became one of six research and training centres in rehabilitation medicine funded by the Rehabilitation Services Administration of the US Department of Health, Education and Welfare. Its watershed year occurred in 1974 when it opened a new twenty-storey building at Chicago's McGaw Medical Center, completing its transformation into a state-of-the-art specialty hospital.

The period was also characterized by sharing, critical evaluation and improvement of myoelectric control systems among leading centres. Examples of this included: an OCCC clinical evaluation of the UNB control system; collaboration between Viennatone and Otto Bock, and Otto Bock and INAIL in development of myoelectric controllers and hand hardware; development and improvement at Northwestern University in late 1960s of a three-mode controller based on a UNB design; and UNB evaluation of the Rehabilitation Institute of Montreal's improved Russian Hand. These examples of collaboration were different than the large budget, multi-institutional product development oriented projects that would

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[226] Ibid.

characterize the DARPA Revolutionizing Prosthetics Program launched 2006. The age of complex inter-institutional agreement, intellectual property protection and commercialization was only just beginning at a few major research institutions, and so these collaborations took the form of scholarly exchanges with little in the way of management or agreements.

Sharing and critical evaluation of new research also occurred in journals, both research and practitioner or industry oriented. One of the oldest research journals to publish articles in the field is the Institute of Electrical and Electronics Engineers (*IEEE) Transactions on Biomedical Engineering*. First published in 1953, it is one of the leading research journals in the field of biomedical engineering. Another scholarly journal is *IEEE Transactions on Systems, Man, and Cybernetics*. First published in 1960 under the name *IRE Transactions on Human Factors in Electronics*, it was changed in 1963 to *IEEE Transactions on Human Factors in Electronics*, after the merger of the Institute of Radio Engineers (IRE) and the American Institute of Electrical Engineers to create the new IEEE. With the rise in cybernetic theory, two spin-off journals were created in the 1960s. *IEEE Transactions on Systems Science and Cybernetics* was published from 1965 to 1970, and *IEEE Transactions on Man-Machine Systems* from 1968 to 1970. In 1971, the journals were combined under the name *IEEE Transactions on Systems, Man and Cybernetics* and focused on signal processing and analysis, and published monthly in three parts, with one dedicated to systems and humans, another to cybernetics, and a third to applications. The newest scholarly publication in the field is the *IEEE Transactions on Neural Systems and Rehabilitation Engineering*, which was first published in 1992. It is self consciously interdisciplinary covering the three fields of neuroscience, biomedical engineering, and physical medicine and rehabilitation. Its aim is to publish articles for researchers and clinicians to understand how neuroscience and biomedical engineering are changing physical medicine and rehabilitation. The goal is to be well out front of development, addressing topics such as artificial muscle research. At the other end of the spectrum is the International Society for Prosthetics and Orthotics' *Journal of Prosthetics and Orthotics International*, introduced in 1977, and the American Academy of Orthotists and Prosthetists' *Journal of Prosthetics and Orthotics*, first published in 1988. Its articles are aimed at health care professionals, not researchers.

A major international event on powered limb R&D between 1963 and late 1980s was the "Conference on External Control of Human Extremities," also known as the "Dubrovnik Conferences." It was first held in the former Yugoslavia in 1963 and then held every third year from 1966 to 1984. One of the early conferences on myoelectric control in the United States was the Conference on the Control of External Power in Upper Extremity Rehabilitation. It was held in Warrenton, Virginia in 1965 and was sponsored by the CPRD.

In the US, it was in 1976 that the CPRD was dissolved by the National Academy of Sciences. Since its inception in 1959, the CPRD had coordinated funds from the federal agencies to direct the national research efforts in prosthetics. It held meetings on R&D progress and needs, evaluated products and techniques, published documents, reviewed research proposals, and promoted education. According to Childress, the "CPRD was action orientated. On the other hand the

NRC was primarily an advisory group, and this difference in organizational function led to conflict between NRC and CPRD. In the mid 1970s, this conflict of operating styles resulted in CPRD losing its position within the NRC, which had been its "Alma Mater" for more than 30 years."[227] He continued: "After the demise of CPRD, around 1976, the agencies involved continued with their programs in rehabilitation engineering but without the same coordination or sense of mutual cooperation that had been previously evident."[228]

The demise of the CRPD was at least three years in planning. Ironically, CRPD insiders, including Clinton Compere and Colin McLaurin, called for the wind-up of the body in a 1973 review and report of the CPRD.[229] They called for reorganization of the CPRD and CPOE and upgrading from committee status to a unified "Board on Rehabilitation Engineering for the Musculoskeletal and Sensory Systems." The vision was a body that would not only oversee steps between fundamental studies and device development, but also have broad responsibilities in evaluation, education and service realms.[230]

The ad hoc committee was not acted upon. What was happening in the background was that the CPRD and CPOE had recently been transferred to the National Academy of Sciences' (NAS) newly created Assembly of Life Sciences. Previously it had been a part of the NAS Division of Engineering and Industrial Research. In early 1974 the Assembly of Life Sciences funded a project to review

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[227] Childress, "As I see it," 7.

[228] Ibid.

[229] *Report of Ad Hoc Committee to Review Activities of the Committee on Prosthetics Review and Development and the Committee on Prosthetic/Orthotic Education*, Division of Medical Sciences, National Academy of Sciences (Washington, D.C.: National Research Council, March 1973).

[230] Ibid, 2.

NAS activities in the field of prosthetics, orthotics, and sensory aid research, development and education. The project was led by a visiting committee on the CPRD/CPOE (the visiting committee), chaired by Dr. Melvin Glimcher, the Harriet M. Peabody professor of orthopaedic surgery at Harvard Medical School, and orthopadic surgeon-in-chief at the Children's Hospital Medical Center in Boston. The visiting committee members included three other professors of medicine and a professor of engineering and applied physics from Harvard University, as well as two NRC staff members. The visiting committee first met on June 28, 1974 in Washington, D.C., and the 222-page transcript of their meeting[231] provides a fascinating glimpse into its operation and its members. Glimcher, appropriately as chair, emerged as the strongest personality in the record. At the meeting of the visiting committee on September 3-5, 1974, the last of four meetings, it was agreed that Glimcher would prepare an initial draft of the committee's final report.[232]

The report's main conclusions were that the "CPRD/CPOE can no longer continue to respond to the needs of the Federal agencies and the handicapped in a manner commensurate with the high standards of the NAS." Core problems identified by the visiting committee included that the CPRD and CPOE committees had not met in the past three years, had devolved responsibilities and authority to staff, prepared reports that were not first rate, and directed peer reviews of grants and contracts for the Veterans Administration that were ". . . woefully inadequate in

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[231] *Transcript of Proceedings*, National Research Council, Meeting of the Visiting Committee for Committee on Prosthetics Research and Development and the Committee on Prosthetic-Orthotic Research, June 28, 1974, Washington, D.C. (Falls Church, Virginia: Bowers Reporting Company, 1974).

[232] Memorandum from T. Vogl to T.F. Rogers dated September 26, 1974, regarding "Meeting between Dr. Melvin J. Glimcher and T.F. Rogers in Boston, Massachusetts, on September 19, 1974."

terms of overall evaluation for scientific merit . . . "[233] The recommendation was that the NAS-NRC " . . . should undertake promptly a fundamental reorganization of its professional and administrative structure, and its organization, in the area concerned with the rehabilitation of the handicapped in order to be able to discharge its important responsibilities to the nation in a manner consistent with the highest professional standards."[234] According to the visiting committee ". . . the area of the handicapped includes, but now transcends, the fields of prosthetics and orthotics."[235] The committee also charged that, with respect to the CPRD's responsibility to keep abreast of relevant research advances, the CPRD had failed to ". . . broaden the accumulation of knowledge in this particular field, and to hasten its useful application to the handicapped population."[236] Among its strongest criticism of the CPRD was that "Instead of viewing their charge as one which involves a broad scope of basic and applied biomedical research, in addition to innovative development and sound engineering, so as to encourage truly signal advances, their attention remains fixed essentially as it has been in the past: an inordinate emphasis upon the relatively short-term development of immediately useful apparatus."[237]

The report was restricted in its distribution, and was limited to 50 copies.[238] Nevertheless, word leaked out about the visiting committee's conclusions and

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[233] Visiting Committee, *Transcript*, 1-2.
[234] Ibid, 4.
[235] Ibid, 5.
[236] Ibid, 23.
[237] Ibid.
[238] In a document dated November 13, 1974 from Dr. Thomas Kennedy, Jr. to Dr. Thomas Vogl, Kennedy wrote: "I spoke with Dr. Glimcher on November 12, 1974 and among other subjects we discussed the distribution of the Final Report. His feeling was that its distribution should be

recommendations. Criticism of the report and the study came from CRPD staff,[239] Douglas Hobson, then technical director of the University of Tennessee's Crippled Children's Hospital School,[240] R. N. Scott of UNB,[241] and many others. Dr. Colin McLaurin, chair of the CPRD, and A. Bennet Wilson, Jr. executive director of the CPRD, resigned their positions, as did a number of CRPD staff. It was all to no avail. Even a letter from the director of the Veterans Administration Research Center for Prosthetics, a major funder of CRPD/CPOE activities, to the president of the National Academy of Engineering, did not result in preventing the anticipated termination of the two committees. The letter suggested that the CPRD/CPOE would be better located in an assembly or commission of the NAS other than life sciences, as past history had shown successful operation of the CPRD/CPOE in the former division of Engineering and Industrial Research. At the January 17-18, 1977 meeting of the executive committee of the Assembly of Life Sciences, the development of a new, more broadly focused rehabilitation committee was approved, sealing the fate of the CPRD/CPOE.

Underlying the plan for wind-up of the two committees was a report published by the NAS titled *Science and Technology in the Service of the Physically Handicapped.*[242] It was authored by a committee of the NAS's Division of Medical Sciences, Assembly of Life Sciences, and chaired by Walter Rosenblith, provost of

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restricted as much as possible and to that end he believes that it is not necessary to give copies to the CPRD Committee or its Chairman since their terms have expired anyhow. He also feels that is not necessary to give copies to all CPRD staff."

[239] Memorandum from CRPD staff dated February 20, 1975 to Dr. Phillip Handler, President of the NAS.

[240] Letter from Douglas Hobson to Philip Handler dated August 21, 1975.

[241] Letter from R. N. Scott to Philip Handler dated March 17, 1975.

[242] National Academy of Sciences, *Science and Technology*.

MIT. The report called for a new board to be created within the Assembly of Life Sciences with an expanded mission to include blindness and low vision, hearing and speech, and manipulation and locomotion.

The last word goes to Douglas Hobson, taken from an article he wrote, at least partially, in response to the Rosenblith report.

> Traditionally, engineers in the field of rehabilitation have been involved largely on the periphery undertaking research and development projects in areas such as prosthetics and orthotics, but rarely becoming involved directly with patients. That is, very few engineers have become truly integrated into the clinical setting as functioning members of clinic teams. . . . A more realistic approach has placed engineers, physicians, and related professionals together in a clinical setting to work directly on patient problems. This approach has been termed Rehabilitation Engineering, and distinct from their biomedical or bioengineering research oriented "half-brothers", the new breed of engineers in this subspecialty are becoming known as rehabilitation engineers.[243]

Hobson was clearly on the side of the CPRD/CPOE. Rehabilitation engineers were applied scientists, not fundamental researchers.

> Relative to prosthetics and orthotics, it is visualized that the rehabilitation engineer will function in the capacity of technical consultant, particularly related to patient problems that require the application of more sophisticated technology. For example, the engineer may be of valuable assistance to the orthotist or prosthetist on the problems that require the application of materials such as newer plastics and light weight/high strength alloys, advanced electronics, or unique mechanical designs. In the realm of research, it is the author's opinion that the rehabilitation engineer as described above should not be considered a basic researcher, since his primary interest and charge is the direct application of current technology to patient problems. However, his clinical exposure gives him the unique opportunity to identify and define many complex clinical problems, which can then be transmitted to research scientists for solution. In this capacity the rehabilitation engineer acts as a resource person who is primarily involved in the early definition stage of a research project, and then again in taking the results of research and converting them into practical clinical applications. Therefore, relative to basic research it is important that the

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[243] D. A. Hobson, "Rehabilitation engineering—a developing specialty," *Prosthetics and Orthotics International*, 1 (1977): 56-60.

> rehabilitation engineer maintains an open communication between other professionals within the clinical setting, the patient, and his research colleagues in order to affect the best solution to complex clinical problems.[244]

It was far from the last word on the topic, but clearly Hobson was on the losing side of the debate. The CPRD and CPOE were finally disestablished in January 24, 1977.[245] It was the end of an era in the field of upper limb myoelectric prosthesis R&D.

In Canada, the process to terminate support in 1975 for the PRTU's was more straightforward. The plan had been to terminate funding in 1972, although it was extended for a few years. Behind the scenes there were discussions of the fate of the federal government's prosthetic services unit. Originally created in 1916 by the Department of Veterans Affairs, it was subsequently handed over to the Department of National Health and Welfare. In 1977 the decision was made to reorganize it.[246] Prosthetist training and other responsibilities were transferred from the department's centre at the Sunnybrook Hospital in Toronto to provincially run hospitals in 1978. The production, engineering, testing, and training unit was handed over to the National Research Council.

## Commercial Products and Improvements, 1977 to 2000

The third period, from mid 1970s to 2000, saw the introduction and improvement of long-awaited commercial myoelectric upper limb systems. It is not

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[244] Ibid, 56.

[245] Memorandum from Dr. S.D. Cornell, Executive Director of the Assembly of Life Sciences, National Research Council to Councilman Morgan, M.D., dated January 27, 1977.

[246] The Department of Health and Welfare assumed authority of Prosthetics Services in 1965.

that practice of scientific research and development of new technologies ended in the mid-1970s. It continued and expanded during and after this period, even with the demise of the CPRD, but what was new was the introduction of products, many of which had their roots in R&D funding programs during the first and second periods. These new products finally moved over the fuzzy line separating pre-commercial systems tested in clinical trials to "products." With the launch of products, a certain stream of research results could now be conceived as improvements, which became increasingly important with the winding-up of prosthetics research funding programs, and the consequent need for new ways to legitimate prosthetics research.

Englehart et al. wrote that "it was approximately 1977 that powered upper-limb prostheses might be said to have become clinically significant in North America."[247] Otto Bock had by this time emerged as the preeminent supplier of hand and wrist systems. Products were also available around this time from Variety Ability Systems Inc. of Toronto (the commercialization vehicle of OCCC and user of the myoelectric control system from UNB), Liberty Mutual, and Motion Control of Salt Lake City (commercializer of the Utah Arm).

Outside of the framework of "products and improvements," research continued at universities on multi-function control systems for above elbow amputees with only one functional muscle site. Three of the major research streams to the problem were to investigate and develop (i) endpoint control

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[247] Parker, *Myoelectric signal processing.*

systems; (ii) sensory feedback systems; and (iii) myoelectric statistical pattern recognition systems.[248]

Endpoint control systems promise amputees the benefit of less conscious effort to manipulate the limb and more natural movement. Research on these systems occurred at UCLA, Berkley, MIT, Case Western Reserve University, Rensselaer Polytechnic Institute, and the University of Southamptom.[249] With funding from the Veteran's Administration, research at UCLA focused on developing clinical systems for amputees that provided pre-programmed movements such as opening of a hand or hook when the arm reached out to grasp an object. An even more prescriptive device, called the Feeder Arm, was developed at Case Western Reserve University. It allowed users to select complex programmed functions such as the movement of a level hand for feeding oneself.

Sensory feedback research was undertaken at the University of Edinburgh, RIC and University of Ottawa. R&D at the University of Edinburgh resulted in a pneumatically powered prosthesis that controlled the artificial arm by movement of the collarbone. It also permitted sensory feedback to the collarbone and shoulder, providing users with position awareness of the arm.

Myoelectric statistical pattern recognition was undertaken at Temple University and the Moss Rehabilitation Hospital in Philadelphia, Chalmers University Hospital in Göteborg, Sweden, and UCLA. At UNB's IBME, systems were

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[248] Ibid.

[249] I.D. Swain, *Adaptive control of an arm prosthesis*, PhD Thesis (Southhampton: Electrical Engineering Department, University of Southampton, 1982). See also I.D. Swain and J.M. Nightingale, "An Adaptive Control System for a Complete Hand/Arm Prosthesis," *Journal of Biomedical Engineering*, 2 (1980): 163-166.

developed for pattern recognition-based control using the transient myoelectric signals.

For upper limb prosthesis myoelectrics, pattern recognition offered the possibility to recognize the patterns in myoelectric signals from specific movements such as "open hand" and "close hand." Each time the hand is closed the microprocessor analyzes the new data against all previous signal information, recognizes that this particular signal is similar to ones for closing the hand, and then selects a pre-programmed movement: close hand. UNB's IBME emerged as a leader in pattern recognition and in the turn from exploring ways to make the most of information from surface electrodes to making sense of information directly from the nerves. Although IBME's first pattern control system was developed under a sponsored contract for Hugh Steeper Ltd.,[250] it was doctoral research that generated broad recognition of UNB's leadership position. As part of his doctoral research in the late 1980s and early 1990s, Bernie Hudgins discovered a "motor plan" in the myoelectric signals accompanying the onset of arm or hand movement.[251, 252] The question he asked was why do these structured patterns occur? His thesis was that "motor plans" were the outcome of learning simple, ballistic contractions, which, once a movement had been learned, became stable for a given task. It is like artillery pre-planned or "predicted fire" plans in at least two

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[250] Hugh Steeper was a UK-based developer of prosthesis. The system developed under the contract was never used in a commercial product.

[251] B.S. Hudgins, P. Parker, and R.N. Scott: "A new strategy for multifunction myoelectric control," *IEEE Transactions on Biomedical Engineering*, 40, no. 1 (1993): 82-94.

[252] B.S. Hudgins, "A Novel Approach to Multifunction Myoelectric Control of Prostheses," Ph.D. Thesis, Department of Electrical Engineering, University of New Brunswick (Fredericton, University of New Brunswick: 1991).

respects. First, the individual guns in artillery units are trained to fire according to specific and detailed sequences. Like human movement, there may be improvisation in the field of battle, but the effectiveness of predicted firing by artillery is often in the ability of individual guns to execute highly coordinated plans worked out well in advance. Second, although artillery firing plans may be discerned by the sound of the guns, this provides only a very gross understanding of the intended movement of shells. It is no substitute for knowing gun position, elevation of the target, wind speed and direction, barometric pressure, gun barrel wear. and even propellant batch and temperature. Likewise, surface myoelectric signals provide only second order neuromuscular information, the by-product of complex temporal and spatial muscular signals, which are a subset of that delivered to the muscles by the motor neurons.

Although a control system based on Hudgins' work was designed at UNB and was used to identify four types of muscle contraction signals, it took over twenty years before it emerged into clinical use. It initially found trial in sequential control devices, in which electronic limb actions occur one at a time, and then the more challenging simultaneous, coordinated control, in which limb functions occurred all in the same time sequence, replicating normal human movement. The sequential control research program moved into the domain of robotics research. Sub-systems for pre-programmed control had to be developed because the information generated from surface electrodes was not detailed enough to provide the plan for simultaneous movement. But there remained challenges for robotics application in finding a balance between, on the one hand, being too prescriptive of movements, like the Case Western Reserve Feeder Arm, or, on the other hand, to address all of the potential situations and user complexities would make development projects prohibitively expensive.

It is not robotics research that has opened up as the next major field for electronic arms, but the concept of connecting artificial limbs to the nerves that controlled the missing limb. The view of Hudgins and his colleagues was that they had extracted all of the information they could from surface signals, and that to achieve significant advances in multi-function control, researchers would have to learn how to access and extract information from those nerves.

## Innovation and Revolutionizing Prosthetics , 2000-2010

In the last period, from 2000 to 2010, products launched during the 1970s continued to be sold, and the work to improve these products continued at industry and university laboratories. What was new were the US led wars in Iraq and Iran, and the Defense Advanced Research Projects Agency (DARPA) prosthetics R&D budgets, which led to funding programs to provide a new generation of devices for soldiers who had lost limbs. Limb loss for the veterans of these wars in Iraq and Iran was a bigger matter than in previous wars because of the body armour that protected the head and torso, but not the arms and legs, and improved medical treatment, which meant more battlefield survivors. The new programs were now described not as R&D, but innovation programs. What was new is not just the use of “innovation” in US, UK, and Canadian government funding program titles, but the size of budgets, degree of collaboration among private and public contributions (often from more than one country), requirement for project management and tightly controlling agreements, and expansion of these programs to specifically address commercialization and intellectual property protection. From US and Canadian innovation programs came clinical application of technologies and techniques for targeted muscle reinnervation (TMR), the connection of prosthetics hand and arms directly to nerves and muscles. In Edinburgh a high profile, new prosthetic hand with five powered fingers, designed by David Gow in the 1990s, was launched by Touch Bionics, opening up the market for others to introduce similar products. Although concepts underlying TMR had been around for decades before their clinical application, and the i-Limb was invented in the 1990s, their emergence in the 2000s benefited from new innovation funding programs.

In the case of TMR, Todd Kuiken from the RIC first developed the procedure for upper-limb amputees in 2002. It has been implemented in more than fifty amputee patients worldwide to date. In 2007, Otto Bock first demonstrated a TMR upper limb prototype. It allowed the user to move seven joints of the arm prosthesis in real time by imagining moving a phantom arm. It meant users did not have to learn counter-intuitive actions like flexing a bicep muscle to open a hand, but rather could move the electric arm like a natural arm. The version designed for everyday use, introduced in 2010, offered control of three joints. In the US the DARPA Revolutionizing Prosthetics Program, launched in 2006, was one of the major funding sources for TMR. Like the National Academy of Science's assessment of the field in the 1940s, DARPA in the 2000s found the state of upper limb prosthetic technology lagging. DARPA, however, responded differently. Funding focused on development of two modular prototype prosthetic arm systems, one by DEKA Integrated Solutions Corporation of Manchester, New Hampshire (which in 2012 was seeking approval to make the arm system commercially available) and the other by Johns Hopkins University Applied Physics Lab in collaboration with the RIC. DARPA awarded $18.1 million to DEKA beginning in 2007, and $30.4 million to Johns Hopkins University beginning in 2009. The overall goal of the program was development of a neurally controlled arm and hand prosthesis that performed and looked like a natural limb, and would be ready for clinical trials within four years.

Another major product commercialized during the period was the i-Limb, created by the engineer, David Gow, at the then Princess Margaret Rose Hospital in Edinburgh. The development of the i-Limb was supported by a modest SMART award of sixty thousand pounds (approximately USD$97,000) granted by Scottish Enterprise, which was matched by a fifteen-thousand-dollar award from the National Health Service. The funding was used to develop a prototype of the i-Limb. Angel funding organization Archangel Informal Investments and a local regional development body, the Scottish Co-investment Fund, invested to start up a company to commercialize the i-Limb, initially called Touch EMAS, now named Touch Bionics. The funding was used, in part, to reimburse the costs for a two-year secondment of David Gow into the company as its first president.

As to the forces behind the field during the second half of the twentieth century, the following table lists the major funding programs, products, conferences and journals described in this chapter.

**1940s 1950s 1960s 1970s 1980s 1990s 2000s**

- Ronald Reiter develops three-state controller & proof-of concept hand, 1944-48.
- Int'l Conf on Amputations & Artificial Limbs, Ottawa, 1944.
- US NAS discovery of 'little modern scientific effort' into development of artificial limbs, 1945
- US VA Crash R&D program begun, 1945.
- RIC incorporated, 1951.
- IEEE *Transactions on Biomedical Engineering* first published in 1953.
- First British myoelectric controller, Guy's Hospital Medical School, 1955.
- First Soviet myoelectric prosthesis, Kobrinsky Group, 1957.
- Thalidomide first sold in Germany, 1957.
- UCLA study selection of myoelectric signals as the most promising for prosthetic device control, late 1950s.
- US NAS forms CPRD & CPOE, 1959.
- Predecessor of *IEEE Transactions on Systems, Man, and Cybernetics*, first published in 1960.
- UK NHS funds a new powered prosthetic unit (PPU) at the Princess Margaret Rose, Edinburgh, 1963.
- First UK myoelectrical prosthesis designed by Alistair Bottomley, 1962.
- Canadian Department of Health PRTUs established in 1963.
- First Dubrovnik Conference, 1963, then every three years to late 1980s.
- Boston Elbow project begins, 1964.
- INAIL myoelectric upper limb controlled prosthesis developed in 1965.
- UNB develops first North American control system, 1965.
- First fitting on children's hands at the OCCC, 1965.
- Viennatone hand becomes first commercially available myoelectric device, 1967.
- Otto Bock designs Z6 myoelectric controllers, 1967.
- Dr. Rolf Sörbye's fitting of children with the systemteknik hand in 1971.
- Boston Arm commercially introduced, early 1970s.
- UNB's MEC first held, 1972.
- US NAS CPRD & CPOE dissolved in 1977.
- Cdn PRTUs dissolved in 1977.
- Utah Arm first offered for sale, 1981.
- Todd Kuiken conceives of TMR, 1985.
- i-Limb-conceived.
- Electrohand 2000 for children introduced in late 1980s.
- Multifuncton control, 1991.
- IEEE *Transactions on Neural Systems and Rehabilitation Engineering*, 1992.
- i-Limb commercially introduced.
- DARPA Revolutionizing Prosthetics Program, launched in 2006.
- Otto Bock introduces commercial versions of TMR and Michelangelo Hand, 2010.

**Major Funding Programs, Products, Conferences and Journals**

Government funding programs, hospitals, and universities come to the fore in this chapter. This distinguishes this field history from the case studies, in which the engineers and other clinical team members stand out. Government funding programs are especially instrumental in the US during the first period. In the second, from 1960 to 1976, governments funded the development of the sensational Russian Hand, as well as work on the Boston Arm, Utah Arm, various electronic hands in the UK, the UNB controls, and the VASI hands. The third period, from mid 1970s to 2000, is defined in some ways by the withdrawal of funding and requirement for those engineers who remain in the field to seek more research-oriented funding. Likewise, the fourth period is characterized by changing funding structures and requirements, supporting the rise of big engineering projects and a new focus on commercialization of products.

# 5. METHODOLOGY AND METHOD

## 5.1 Methodology

My central research questions are: how did commercial upper limb myoelectric systems arise; how does the practice of R&D, innovation and commercialization represented in the field history and cases correspond to concepts discussed in Chapter 2; and what were the forces of change in the way R&D and innovation were practiced during the period of the study?

The case studies are social science micro-history. I am following Lawrence Stone's prescriptions for social sciences history. His suggestions are to: (1) make hitherto unspoken and unconscious assumptions and presuppositions explicit and precise; (2) define key terms; (3) refine research strategies and define problems and issues to isolate the particular and unique from the general and make systematic comparisons over time and space; and (4) test social-science hypothesis against the evidence of the past.[253] The only one I have not adopted to use is quantitative research methodologies.

The (1) unspoken presupposition is that advancement in the area of upper limb myoelectric devices since World War II occurred as a result of R&D and its exploitation through a process that, more or less, followed the linear model of innovation, but changed sometime late in the century as mode 2 knowledge production became the "normal science" of innovation studies. The (2) key terms I define are science, R&D, design engineering, innovation, and entrepreneurship. The

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[253] Stone, *Past and Present*, 15-17.

(3) research strategy used is a field history and series of case studies, guided by the questions posed in the previous chapter. In taking this approach I was not only seeking to isolate the particular and unique from the general so as to make systematic comparisons, but also to avoid the problem that Pinch and Bijker point out in taking too narrow an approach to, as they call it, "stabilization of technological artefacts."

> An alternative location for micro-studies of science - the ethnographic study of the scientific laboratory - has recently been advocated. Such a location has proved to be particularly useful for showing the interpretative flexibility of scientific knowledge. However, the laboratory location is a rather poor place in which to study the formation of scientific consensus. This is because the processes of consensus formation are not usually to be found in a single laboratory. Unless one is prepared to use other data than purely ethnographic sources, it is difficult to study processes of consensus formation in individual laboratories. The problem is even worse in the case of the study of the stabilization of technological artefacts. This is because there is an even larger number of social groups to study, and one is likely to obtain even less relevant data from the individual laboratory. It is important that an ethnographic study - say of an R & D lab - be carried out, but such a study will, it seems, be more useful for showing the interpretative flexibility of technological artefacts than for the study of closure mechanisms.

Although I am not using a SCOT methodology, not doing a Latour-inspired laboratory study (the focus of Pinch and Bijker's criticism above), in (4) testing the social-science hypothesis against the evidence of the past, I have sought as broad a basis as possible, combining both micro-case histories and a meso-field history.

Will the dissertation show how each case study is unique and different from the others, and how incomparable one innovation is from another, or will it show the case studies as fitting into a larger pattern, or one of the models? The philosopher and historian R.G. Collingwood suggests that historians document the "inside" of the event, seeking the thought behind the action from not just the lead inventors, but also from their business partners, collaborators, testing laboratories, and others in the innovation chain.[254] I have tried to immerse myself in the motivations and details so as to challenge my ability to generalize. Collingwood's view is that "A positive science of the mind will, no doubt, be able to establish uniformities and recurrences, but it can have no guarantee that the laws it establishes will hold good beyond the historical period from which its facts are drawn."[255]

In testing the social-science hypotheses I am considering some very different assumptions about causation. The linear model has new technology based products caused by science and research. The mode 2 theory portrays change driven by researchers, motivated by academic curiosity within discipline-based fields of study. mode 2 knowledge production is motivated by profit, broadly defined (i.e. not just balance sheet profit, but also, for instance, the purchase of laboratory equipment from research contracts and matching government grant funding). The motivations of users are also important in the mode 2 concept. The triple helix theory brings institutional forces into the causation model, specifically industry and government. For Forman's concept of postmodernity, the change in primacy from science to technology and the move to "anti-disciplinarity" is driven by cultural forces. Likewise for David Serlin, it is cultural forces that are at work below the government funding programs from the 1940s and 1960s. For the neoliberal scholar Phillip Mirowski, it is the concept of the marketplace of ideas that is at root in the change of how we understand science and technology. In

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[254] R.G. Collingwood, *The Idea of History* (Cambridge: Oxford University Press, 1996).
[255] Ibid, 223-224.

considering the role of R&D concepts and the influence of researchers, there are longer chains of causation.

## 5.2 Method

I have used historical and case study methods. Both methods were used in the writing of the field essay and the case studies. The historical field essay was written after the case studies, so I had the benefit of those narratives as skeletal structures. I also had the benefit other essays on the field and access to archival records held by Library and Archives Canada in Ottawa and the National Academy of Sciences in Washington, D.C.

For the case studies, as a first step I selected cases based on the literature reviews and interviews with researchers and company representatives about advances in the field. I prepared a questionnaire for use with interview subjects in light of the research project goals and knowledge of the cases from the existing literature. I consulted UNB IBME faculty and staff on both my choice of case studies and the questionnaire for use with interview subjects. Next, I wrote outlines of the cases. The aim in writing the outlines was to present to the interview subjects a simple account of the case and have the interview subjects validate or correct the narratives and fill in the details of the case. This material was then used to prepare an ethics application to UNB's research ethics board. The list of interview questions included in the application is attached in Appendix A and, also included in the application, the form for making observations about the work places of the interview subjects is included in Appendix B.

The procedures for interviews with subjects consisted of obtaining contact information and referrals for primary and secondary interview subjects. I was fortunate in having UNB IBME researchers to provide referrals. The primary interview subjects were actors who played a key role in R&D and design of major technologies and products. The interviews were held by telephone with subjects in Chicago; Durham, New Hampshire; Holliston, Massachusetts; London, Salt Lake City, and Gothenberg, Sweden. Face-to-face interviews were held with subjects in Fredericton, Edinburgh, Southampton, Toronto, and Vienna. They were all semi-structured interviews. Consistent with interview methods used in other case studies of R&D and innovation,[256] I solicited email responses from interview subjects on key questions, and, where appropriate, included excerpts from the responses in this manuscript. After conducting the initial interviews with key participants, there were numerous follow-up interviews.

The data collection procedures for places and prosthetic devices consisted of taking digital photos and recording memorandum at the laboratories in Edinburgh, Fredericton, Toronto, and Vienna. The procedures for investigating existing written documents consisted of identifying relevant works and obtaining and/or making requests for copies. These included: Library and Archives Canada documents; National Academy of Sciences archival records; IBME archival records; statements of work for R&D, testing, and product development projects; specifications of products; project reports; conference proceedings; patents; results of patent searches; R&D contracts; licensing agreements; business plans; market

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[256] Paul Rabinow. *Making PCR: A Story of Biotechnology* (Chicago: University of Chicago Press, 1996).

research studies; and promotion materials. Needless to say, not all requests resulted in the delivery of documents, and I have had to rely on interviews and published literature.

# 6. CASE HISTORIES

## 6.1 Otto Bock

Otto Bock, a privately held company headquartered in Duderstadt, Germany, is the world's largest manufacturer and distributor of orthotic and prosthetic components. It has thirty six branches and more than 4,300 employees worldwide. Sales of its orthotic, prosthetic, and rehabilitation products and services totalled € 529 million ($688 million USD) in 2010. Research and development spending was about € 30 million (approximately USD$39 million USD),[257] or about 5.7% of gross revenue. Its Vienna R&D centre is located about a forty-minute walk from St. Stephen's Cathedral in the centre of Vienna. It has over 400 employees, approximately a third of whom are focused on microprocessor-controlled upper and lower limb prostheses.

Otto Bock is also the dominant designer and manufacturer of electronic hands in the marketplace. According to Dr. Richard Weir, a senior research scientist from the Rehabilitation Institute of Chicago and author of a review article on the design of prosthetic hands and arms, "the de facto standard for externally powered hand-like prosthesis is the single DOF [degree of freedom] Otto Bock Sensor Hand"[258] and the company has had "tremendous influence . . . upon the field of prosthetics."[259]

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[257] Currency conversion made using XE Currency Converter website on May 6, 2012. Website: http://www.xe.com/ucc/ (May 6, 2012).

[258] Weir, Richard, and Jonathon Sensinger, "The Design of Artificial Arms and Hands for Prosthetic Applications," ed Myer Kutz, *Biomedical Engineering and Design Handbook* (New York: McGraw Hill Professional, 2009), 15.

[259] Ibid.

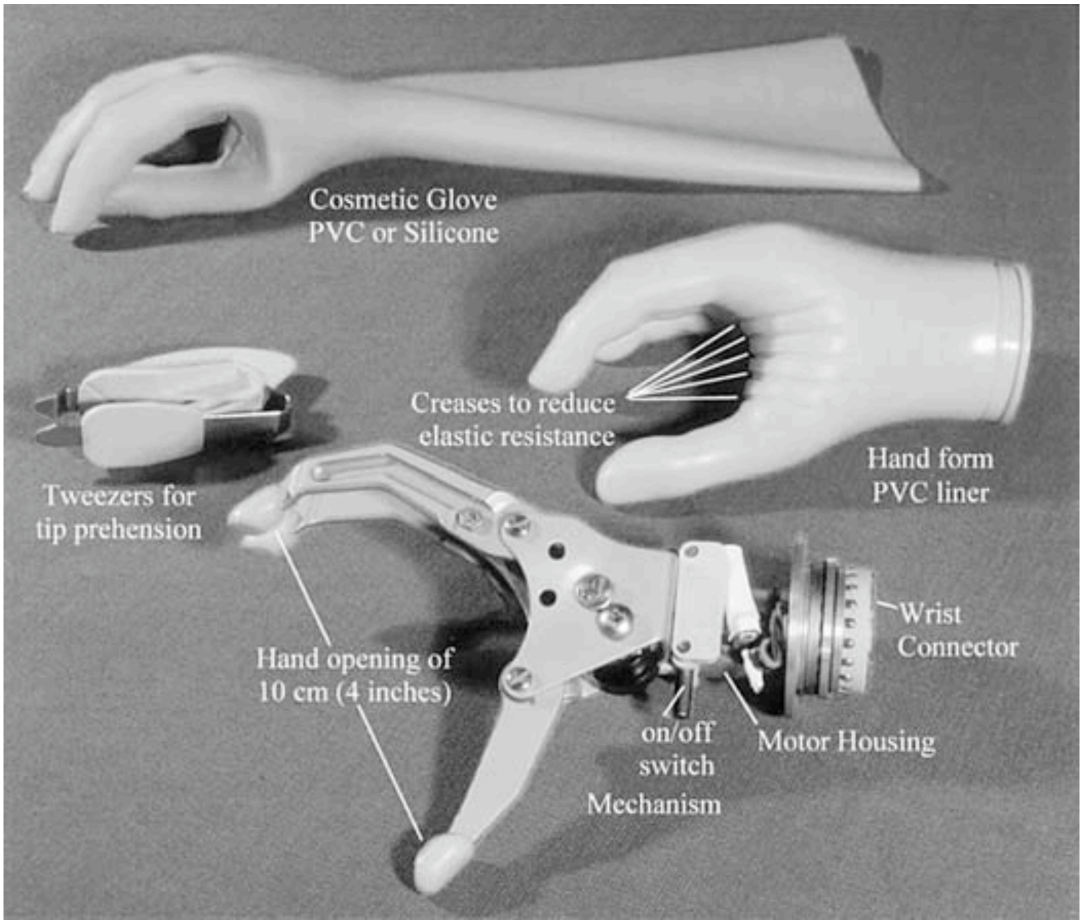

**Figure 6: Otto Bock Single Degree of Freedom System Electric Hand (Image source: Otto Bock)**

The company was founded in 1919 by the prosthetist Otto Bock with the goal of supplying war veterans with prostheses and orthopaedic products. To address the greatly increased demand for products, and the limited output using traditional artisan methods, Otto Bock applied the American system of manufacturing for prosthetic and orthopaedic production. As with Eli Whitney's pioneering use of the method in gun manufacturing, this meant a system for manufacturing interchangeable parts and mechanization of the production process. The company manufactured prosthetic components in series production and delivered these directly to the orthopaedic mechanics for crafting the final product for the amputee. The pioneering principle was, "mass production combined with the highest quality."[260] Otto Bock saw this as the cornerstone for the emerging orthopaedic industry.[261]

In addition to the adoption of new manufacturing methods, and consistent with the company's philosophy, "to always be on the look out for new ideas and technologies," Otto Bock experimented with the use of new materials in its products.[262] It conducted tests on aluminum in the 1930s and incorporated the material into its products to offer lighter weight components. Likewise, plastic and aluminum materials were incorporated in its components in the 1950s.

The second generation of company ownership and leadership rested with Dr. Max Näder, the son-in-law of company founder Otto Bock. Born in 1915, Näder was a doctor of engineering (Mechaniker Meister), who joined the company in 1935. He trained as an orthopaedic technician and sales representative. In 1943 Näder received permission from Otto Bock to marry his daughter, Maria Bock. When his father-in-law, Otto Bock, passed away in 1953 at the age of 64, Näder assumed control of the firm. He was 38 years old, and would direct the company until he was 75, in 1990, when his son, Professor Hans Georg Näder, was given the reins.

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[260] Ibid.

[261] Website: http://www.ottobock.com/cps/rde/xchg/ob_com_en/hs.xsl/696.html (June 5, 2010).

[262] Ibid.

**Figure 7: Otto Bock and Max Näder (Image source: Otto Bock)**

During Näder's tenure the company grew through the adoption of new business methods and materials, the opening of new fabrication facilities, creation of branch operations, internal innovation, and the acquisition of technology development companies. The first US central fabrication operation was opened in Minneapolis in 1962, followed by another in Winnipeg, Canada in 1981, and one each in Ohio and Florida in 2002. Major technology initiatives included development of the MyoBock prosthetic arm system in the 1960s, the Greifer in 1979 (a myoelectric gripper hand designed for work), and a new myoelectric elbow in 2006 (which, in addition to a fine design, could lift over 12 lbs. (about 5 kilograms) and swing naturally during walking, like the Utah Arm).

**Figure 8: Otto Bock Griefer was designed for working applications that requires strong grasping force and speed or that might injure or discolour the cosmetic hand (Image source: Otto Bock)**

Otto Bock's expansion through acquisitions has increased over time. It acquired the firm Engineered Therapeutic Systems in 1980, a producer of foam plastic articles designed for wheelchair use. A Salt Lake City manufacturer of seating and positioning equipment, Zero Gravity Medical, was acquired in 1995. There were four acquisitions between 2001 and 2005. The firm, Springlite, bought in 2001, provided Otto Bock with added R&D resources and wheelchair, rehabilitation and medical product manufacturing capabilities in Salt Lake City. Purchase of TEC Interface Systems, based in Waite Park, Minnesota, gave Otto Bock new custom and prefabricated liners for its products, as well R&D and manufacturing capabilities. It had two acquisitions in 2005. OrthoRehab provided Otto Bock with a nationwide network of patient care services in the United States.

Its major myoelectric acquisition was Variety Abilities Systems Inc. (VASI) of Toronto, which brought both enhanced R&D capabilities and new prosthetic and orthotic products for children.

The transition from Otto Bock the start-up company to the world's leading manufacturer or upper and low limb prosthetic devices resembled the transition from Schumpeter's Mark I to Mark II. Mark I is reflect in Otto Bock's leadership of the company, and the application of the American system of manufacturing to prosthetic and orthopaedic production. The Mark II period began with Näder's leadership. Although the company has remained a private firm, like almost all large public companies it grew through acquisitions and opening of branch offices and plants to become a multinational operation. But contrary the trend among many large multinational firms, Otto Bock did not divest itself of internal R&D resources and repurpose those remaining R&D personnel as technology scouts. It instead retained a large upper limb R&D group in Vienna, and continued its long-standing approach to adopting technologies and innovations developed outside the firm. This combination of Schumpeter Mark II and open-innovation strategies has served Otto Bock well, allowing it to avoid incurring the heavy expenses of fundamental research and pioneering of new concepts, while keeping it open to new ideas and able to exploit them with its large development group.

Näder delivered an informative presentation on the development of myoelectric prostheses at the 1995 MyoElectric Controls/Powered Prosthetics Symposium held at UNB. He divided the fifty-year history, from 1945 to 1995, into experimental and commercial stages, with myoelectric prosthesis emerging as the general standard in the 1960s. Since then, Näder said, the fundamental ideas have not changed.[263]

"In order to create an acceptable aid for the amputee, always keep abreast of the newest technological developments." This is the advice that Näder delivered in his 1995 presentation, and the ethic that Otto Bock followed in developing its myoelectric systems, whether through acquisitions or internal R&D. He balanced the advice with a recommendation to young engineers in attendance that the reason why many previous prosthetic hand development projects did not bring any results, and wasted a lot of time and energy, was because of missing reading lists, meaning a failure to do literature surveys before designing project research and, presumably, developing solutions to problems users did not want, or that companies like Otto Bock did not want, or repeating the work of earlier studies.[264]

What was particularly important in the development of myoelectric prostheses, according to Näder, were pneumatic powered prostheses and the proof-of-concept myoelectric systems developed in Germany immediately following World War I and II. The pneumatic systems allowed researchers to study the problems of power supply and storage, as well as the lack of control signals.

The bench-top electrical prosthetic hand developed in 1919 by Schlesinger of Berlin established the concept of an electric hand. Reports of electrically powered hands by Friesecke and Höpfner in 1945, Laltmer and Danklefsen in 1949, and the Vaduz in 1949, further legitimated the concept even if, according to Näder,

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[263] M. Näder, "Development of Myoelectric Upper Limb Prostheses: A Glance at the Past and a Glimpse of the Future" *Proceedings of the 1995 MyoElectric Controls/Powered Prosthetics Symposium*, (Fredericton, New Brunswick, Canada: University of New Brunswick, 1995).

[264] Ibid, 6.

the systems of the late 1940s were characterized by a lack of an appropriate control system. But the sensational development in the 1940s was the report by Roland Reiter, then a student at the University of Munich, of his experiments with myoelectrically controlled arms. Näder called it the "birth of myoelectrics."[265]

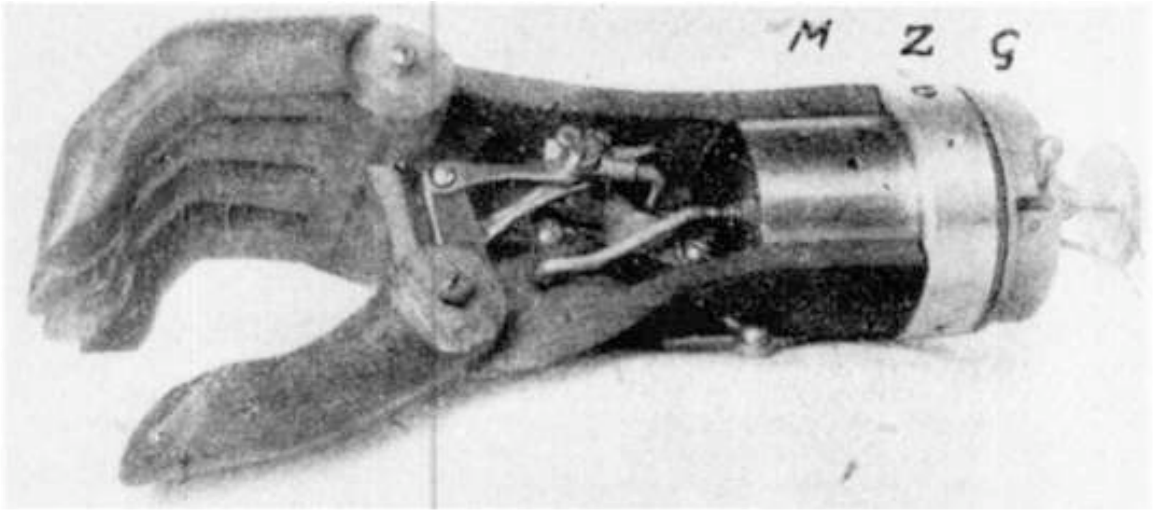

**Figure 9: Electric powered hand used by Reiter in development of first myoelectric prosthesis (Circa 1945). It consists of a Hüfner Hand in which a control magnet has been built. (Image source: Grenzgebiete der Medizin (Frontiers of Medicine) 1948.)**

The next major step for Näder was the presentation, in 1960, by Soviet researcher Kosbrinsky of a forearm prosthesis that used not the vacuum tubes of Reiter's system, but transistors, and thus had a much smaller control system, putting "myoelectrics, for the first time, into the realm of reality."[266] Adaptation and improvement in 1965 by Dr. Gustav Gingras[267] in Montréal resulted in what Näder called exaggerated media reports and raised public expectations.

This was important for Otto Bock because of the R&D project initiated by Mr. Hannes Schmidl of the Federal Vocational School for Orthopaedic Technoloy in

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[265] Ibid, 3.

[266] Ibid.

[267] Dr. Gustav Gingras was a physician and founder of the Montreal Institute of Rehabilitation in 1949.

Frankfurt, and a team from the Italian Workers' Compensation Authority (Istituto Nazionale Infortuni sul Lavoro or INAIL) of Budrio (near Bologna), Italy. Näder said this resulted in “the first really efficient myoelectrically controlled prosthesis.”[268]

**Figure 10: Prof. Hannes Schmidl (second from left) and colleagues (Image source: INAIL)**

But it was not without flaws. The hands were Hüfner hands modified by Otto Bock, and the wooden hand's interior space was too small and fragile for the electronics. Näder said the hollow hand was too fragile and could not take the strain, leading Otto Bock to begin development in 1965 of new prosthetic hands for myoelectric applications. It consisted of the hand mechanism, the inner hand of soft plastic and the cosmetic glove, but not the myoelectric controls, which were made by INAIL. The new prosthetic hands that Otto Bock developed for INAIL were

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[268] Ibid.

called, according to Näder, Type S Hand and had a direct current motor connected to a self-locking spindle drive mechanism.

According to a 1973 publication by Schmidl (then working for INAIL) it was in 1964 that the research department of the INAIL Prosthesis Centre began the development of a myoelectrically controlled prosthesis for upper limb amputees. Schmidl wrote:

> During that year prostheses were applied, experimentally, to one unilateral amputee and to one bilateral amputee in order to investigate the practicality of the controls and acceptability by the patients. After evaluating the initial research, we set up a small scale production run of fifty sets of parts to determine the problems associated with the application of myoelectric prostheses, and, above all, for the purpose of eliminating any weak points that might come to light during their use. This first phase of practical application lasted over a year. In 1965, when it was certain that the myoelectric prosthesis we had developed provided a definite advantage to the upper-limb amputee, we began mass production of this device. At first, our myoelectric prostheses could be applied only to below-elbow amputees. If at this initial stage, we had not foreseen the possibility of applying this principle to higher level upper-limb stumps, our program would have been terminated. In our opinion, the true value of myoelectrically controlled prostheses is found in the replacement of two, three, or four articulations. For this reason, concurrently with mass production of the below-elbow myoelectric prosthesis, the research team began a program to develop a multichannel myoelectric control system that would make it possible and feasible to utilize more than six myoelectric signals in a high level upper-limb amputee. Research in this difficult task extended over a period of three years and was conducted with financial support from the European Coal and Steel Community. The research was completed in 1970, and large scale application of the multichannel, myoelectrically controlled prosthesis was undertaken. This made possible the production of prostheses with myoelectric control over eight movements.[269]

Importantly, then, it was in 1965 when INAIL felt its electronic hand and controller were ready for mass production. Schmidl also mentioned that, as of

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[269] Hannes Schmidl, "The INAIL-CECA Prostheses," *Orthotics and Prosthetics*, 27 no. 1, (1973): 6.

1973, INAIL was using an electric hand mass produced to INAIL's specifications by Otto Bock, known as the 8E8 Model Z6 hand.[270]

Coincidentally, at the same time another Austrian, a Dr. Zemann, was working on a myoelectric control system as a result of publicity surrounding the Soviet myoelectric hand.[271] Zemann contacted Otto Bock for a suitable electric hand. Näder said that Otto Bock developed a new hand for Zemann, this one called the Otto Bock Systemhand Z1. As with the prosthetic hand for INAIL, it used the newest non-ferrous motor. According to Näder, this hand was subsequently built by the Viennatone Company, an Austrian manufacturer of hearing aids, who also continued developing myoelectric control for Dr. Zemann. Otto Bock continued with its development of the Type Z hands. In the 1995 presentation, Näder said the present Otto Bock System Electric Hands were based on the Type Z6.[272]

On the topic of the Viennatone Hand's paternity, Dudley Childress said that it came about as a result of contributions by both Otto Bock and Viennatone, and then, shortly thereafter, Otto Bock developed their own myoelectric system and a new hand mechanism. Childress also wrote that the Viennatone and Otto Bock hand mechanisms (as opposed to the myoelectric signal control systems) were both designed by Otto Bock and that their basic appearance and design principles had remained essentially unchanged to the date of his 1995 article.[273] In a

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[270] Ibid.

[271] Näder, "Development of Myoelectric Upper Limb Prostheses," 4.

[272] Ibid.

[273] D. Childress, "Myoelectric Control: Brief History, Signal Origins, and Signal Processing," presented at the International Society of Prosthetics & Orthotics World Congress, Melbourne, Australia in April 1995, and published in *Capabilities: Communicating the Science of Prosthetics and Orthotics,* (Chicago: Northwestern University Prosthetics Research Laboratory & Rehabilitation Engineering Research Program, 1995), 4, no. 2, 6-7.

subsequent 1995 article he wrote: “Suffice it to say that during the latter part of the 1960s, the Viennatone Hand, the first readily available commercial system, came to the market. The now dominant Otto Bock myoelectric hand system came on the scene soon thereafter.”[274] According to Englehart, it was around 1967 that it became possible to purchase a powered prosthesis commercially in North America, namely the Viennatone hand manufactured by Otto Bock and Viennatone.[275]

Soon after launch of the Type Z1 Hand, crucial disadvantages became apparent to Otto Bock: movement was too slow; gripping action too fast; grip force too limited; and there was no way to manually open the hand in case of an emergency situation; and it was full of technical bugs. Näder said that as a result, “The decision to develop a new model was soon made and in 1967 work on this model began. The design created was to result in the most widespread electric hand, the Z6.”[276]

The advantage Otto Bock had in commercializing myoelectric hands was in its ability not just to design the prosthetic hardware, or to produce the myoelectric control system, but also to provide services: after-sales service through interchangeable modules; education of technicians by seminars and workshops; and creation of an international after-sales service. But it also meant a changing business model. Otto Bock was no longer just a producer of individual components, but a supplier of complete prosthetic systems, and thus, a guarantor of the function and quality of an entire range of devices. This meant that, as with other system

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[274] Ibid.
[275] Englehart, “Multifunction control.”
[276] Näder, “Development of Myoelectric Upper Limb Prostheses.”

designers and builders, Otto Bock had to adjust to increasingly complex product design projects, as well as equally demanding internal and external (regulatory driven) testing projects and trials.

As with other myoelectric control systems and electronic hands, development of improvements was an ongoing activity. In 1973, a six-volt battery was introduced, removing the requirement for an external battery, making the hand compatible with the battery for the elbow prosthesis, and making irrelevant the great source of trouble that external battery cables posed for users. In 1975, an electric wrist rotator was introduced by Otto Bock.

The development of myoelectric hands for children followed a similar path in that pioneering work was done first elsewhere. Näder mentioned Dr. Rolf Sörbye's fitting of children with the systemteknik hand in 1971 and fitting on children's hands at the Ontario Crippled Children Centre in 1965. In 1985, Otto Bock developed a children's hand prosthesis. It offered new compact electrodes that became the standard for adult prostheses, and established a new industry standard given Otto Bock's role in supplying components to other firms. These hands were improved upon by Otto Bock's Children's Hand 2000, with reduced weight and optimized gripping and handling capabilities.

In summing up his comments on the development of myoelectric controls, Näder said "The history of myoelectrics points to the designers eagerly awaiting the invention of the transistor. Only the transistor allowed the realisation of their ideas."[277] The multi-channel system with proportional control and pulse width

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[277] Ibid, 6.

modulation began with Schmidl, according to Näder, in response to the patients needs and to the unique capabilities of the INAIL. It was followed by advancements in proportional control from Childress and others in 1970, and then application of pattern recognition, and subsequently implementation of a multiple-sensor concept by Nightingale and Todd.

For Näder, these advancements stand in contrast to the many control system R&D projects during the period that "did nothing but fill up valuable laboratory space" and "most never got beyond the stage of a laboratory sample."[278] The one exceptional university project he cited was the introduction of integrated circuits and development of the Utah Arm at the University of Utah. He called it a revolutionary component concept, and said it was way ahead of its time and ". . . the only product where the complexities of a university research project were successfully transferred into everyday prosthetics." [279] This view of universities has, however, changed somewhat in the 1990s and 2000s. Over the past twenty years Otto Bock has worked with a number of universities, including Johns Hopkins University, Northwestern University, and Vienna Medical University.

In a paper on the evolution of Otto Bock myoelectric control, Otto Bock employee Terry Sanderson has a similar narrative arc. It begins with Reiter's pioneering work in the 1940s using a vacuum tube amplifier to operate an electronic hand.[280] It is followed by the Russian Hand in 1960 and its first use of

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[278] Ibid, 7.

[279] Ibid.

[280] T. Sanderson, "The Evolution of Otto Bock Myoelectric Systems for the Pediatric Patient." *ACPOC News* 30, no. 4, (1996):1, 3-5, 7-8.

transistors, and then, in the 1960s, development of myoelectric systems by a number of groups around the world.

Sanderson then moved to the earliest myoelectric componentry offered by Otto Bock in the late 1960s. It was a twelve-volt system that used a large, external battery designed to be worn on the patient's waist or in a chest pouch. As might be imagined, wire breakage and electrical interference were common problems. The hand was made of aluminum, making it light in weight, but, combined with the relatively flat design of the fingers and thumb, it meant the digits were easily bent or broken.

By the early 1970s, battery technology had developed to the point where Otto Bock could design a six-volt myoelectric system. This meant the battery could be built into the forearm of the prosthesis. At the same time Otto Bock designed a prosthesis in a smaller glove size, 6 ¾.

The next major development occurred in the late 1980s with the introduction of the Electrohand 2000. It was the outcome of many years of research and development of a hand that would fit children from ages three to six, following pioneering work at the Ontario Crippled Children’s Centre and elsewhere. Otto Bock’s size 5 ½ Electrohand 2000 was developed specifically for children between the ages of three and six. The Electrohand 2000 featured a new finger/thumb design that allowed the fingers and thumb to rotate around the same axis, therefore simulating a more natural grasping motion. The battery was reduced from a six-volt battery to a 4.8-volt battery, allowing it to continue to be embedded in the smaller prosthesis forearm.

Subsequent advancements in materials, engineering and manufacturing techniques resulted in further reduction in the size of the Electrohand 2000 making it available for children as young as 1 ½ years. Otto Bock changed its manufacturing process to incorporate a unique grade of aluminum for the finger and thumb segments, involving heating, moulding, and then machining and milling the aluminum components to the hand's design specifications. The electronics within the circuit were changed to use a microprocessor, resulting in reduced power consumption and wear of the gears. Battery charging was also modified to use pulse charging and addition of a LED light to indicate when charging was completed, improving the cycling of the battery and extending battery life.

The current version of the Otto Bock System Electric Hand is illustrated on the following page. It is the most commonly used electric hand in North America. The three-finger mechanical hand is operated by an electric motor, and is covered by an inner glove, which, in turn, is covered by an outer cosmetic glove. To those who have not seen or used one, it is more than a pincer and less than a human hand. The index and middle fingers can move, as can the thumb. In addition to forming a pincer-like grasp, it is also capable of hook grasp, spherical grasp (as if holding a ball), and so on. It is different than the i-Limb, which has five individually powered and controlled digits.

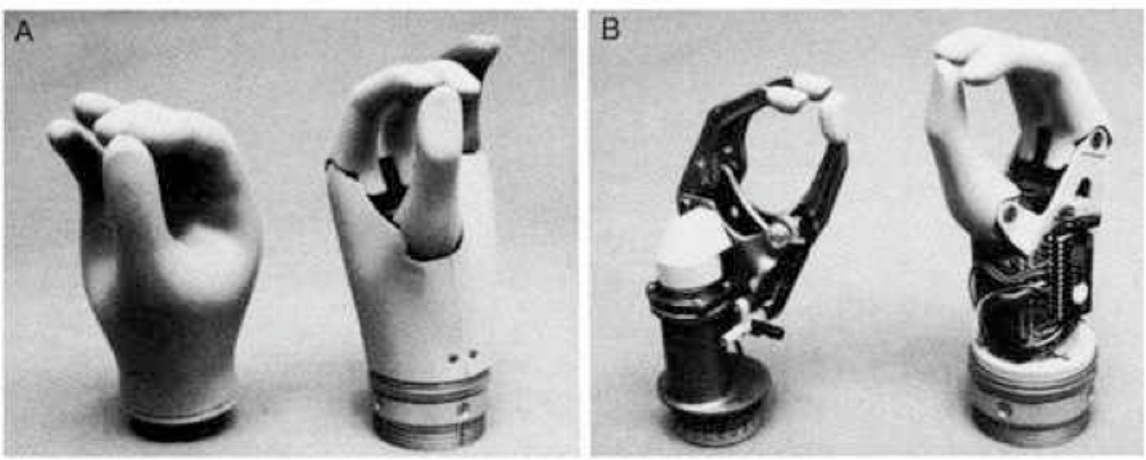

**Figure 11: Otto Bock System Electric Hand (left in both of Images A and B) and Steeper Electric Hand (right). (Image source: Digital Resource Foundation for the Orthotics and Prosthetics Community, Virtual Library Project)**

Otto Bock's most recently announced myoelectric and hand hardware system is the Dynamic Arm and Michelangelo Hand, illustrated below.

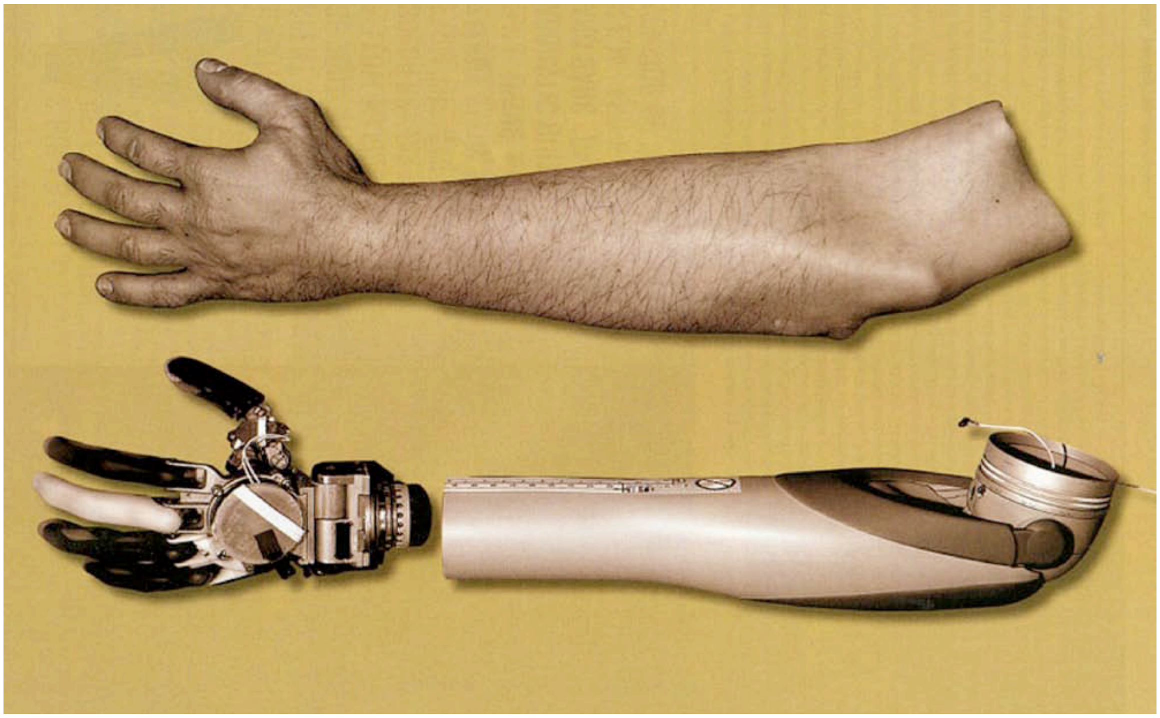

**Figure 12: Otto Bock Dynamic Arm and Michelangelo Hand with prosthesis covering (above) and without (below) (Image source: Otto Bock)**

Otto Bock calls its Michelangelo Hand the heart of its new prosthetic system. It shares with the i-Limb from Touch Bionics and the bebionic hand from RSL Steeper, the feature of having five digits that can be myoelectrically controlled. But it differs from both the Touch Bionics and RSL Steeper hand in not having separate drives for each finger without the two finger joints that curl when the fist is closed. The Michelangelo Hand instead has a single motor that drives fingers together, but which are a flexibly coupled unit. Otto Bock announced a controlled market launch of the Michelangelo Hand at the end of 2010, noting that "Detailed monitoring, especially at the start, is important even for a technically mature system in order to ensure first-class fittings and to create a transparent process for everyone involved."[281]

The most recent R&D interest for Otto Bock is prosthesis control by targeted muscle reinnervation (TMR).[282] [283] Otto Bock refers to it as a method of mind-control of the prothesis.[284] Others have pointed to the fundamental novelty of this approach. "In terms of the importance to the field of prosthetics, it's enormous," says Bernard Hudgins, director of the Institute of Biomedical Engineering at UNB.[285] The advance was in reducing to practice an idea Dr. Todd Kuiken had in 1985 when reading an article for his doctoral research. The idea was to rewire the

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[281] "We offer the technology which the market demands" *Dialog: The Magazine of Otto Bock*, May 2010.

[282] T. Kuiken, D. Childress, W. Rymer, "The hyper-reinnervation of rat skeletal muscle," *Brain Research* no. 1 (1995): 113-23.

[283] T. Kuiken et. al "Targeted reinnervation for enhanced prosthetic arm function in a woman with a proximal amputation: a case study," *The Lancet* Feb 3-9, 369, no. 9559, (2007): 371–380.

[284] Website: http://www.ottobock.com/cps/rde/xchg/ob_com_en/hs.xsl/32082.html (June 5, 2010).

[285] Ibid.

nerves used to control an upper limb into an unused muscle, such as a chest muscle. For an amputee seeking to move a missing elbow the result is a twitch of a chest muscle, which is picked up by electrodes and used to bend the prosthetic elbow.[286] The resulting dexterity of the pectoral muscle is remarkable by itself. But it is an advance with limits. It requires good quality nerves and muscles, which are often damaged in amputees. It also requires additional surgery.

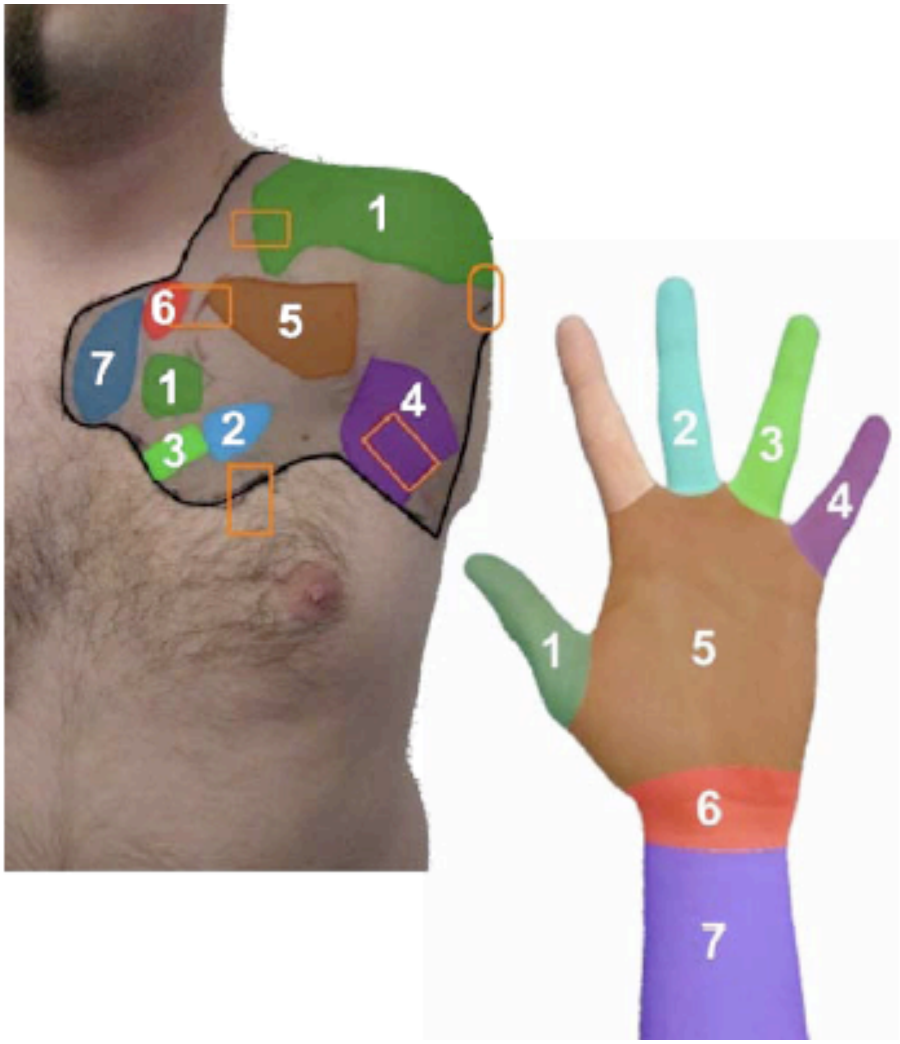

**Figure 13: Otto Bock Representation of TMR (Image source: Otto Bock)**

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[286] J. A. Hoffer and G. E. Loeb, "Implantable electrical and mechanical interfaces with nerve and muscle," *Annals of Biomedical Engineering* Volume 8, Numbers 4-6 (1980): 351-360.

The first Otto Bock TMR upper limb prototype was demonstrated in Vienna in 2007. It allowed the user to move seven joints of the arm prosthesis in real time by imagining moving a phantom arm. The version designed for everyday use, offering control of three joints, was introduced in 2010.

As with development of its myoeletric system in the 1960s, development of TMR has involved collaboration and reducing to practice concepts invented elsewhere. Otto Bock worked with Todd Kuiken and specialists from Vienna's General Hospital to perform TMR on patients to be fitted with an Otto Bock upper limb prosthesis. Otto Bock also undertook a project with researchers from the Division of Plastic and Reconstructive Surgery of the Medical University of Vienna.

**Figure 14: Christian Kandlbauer (Image source: Otto Bock)**

An important early collaborator was Christian Kandlbauer. He lost both arms in a high-voltage accident in 2006. He used the Otto Bock myoelectric DynamicArm for the right side and on the left what Otto Bock calls “the world's first prosthetic arm controlled by the power of the mind," an implementation of the TMR concept from Kuiken.[287] Tests with Otto Bocks' myoelectric prosthesis were carried out in collaboration with Kandlbauer, who was the first person outside the United States to wear a TMR controlled prosthesis.[288] According to Otto Bock, "The collaboration with him greatly advanced this pioneering technology in the laboratory and created good conditions for enabling future users to make use of the sensing function of this prosthesis."[289] Kandlbauer said of TMR control of the Otto Bock prosthesis, "I control my left prosthetic arm with my memories of my previous arm, and when I try to 'move' it, it moves my prosthetic arm. Over time, it's as if it's become a part of my body."

Tragically, Otto Bock lost its collaborator in October of 2010 when Kandlbauer died as a result of injuries he suffered when the car he was driving veered off the road and crashed into a tree.[290]

With the introduction of TMR, Otto Bock and its fellow manufacturers now face the challenge of developing technology that maximizes TMR surgery's prosthetic potential. This means prosthetic arms and hands that are capable of much greater control-input from the user, but also are able to transmit information from the prosthesis back to the user.

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[287] Otto Bock press release, http://www.newswire.ca/fr/story/582151/from-the-laboratory-to-the-reality-of-daily-life (August 23, 2011).

[288] http://www.guardian.co.uk/world/2010/oct/22/christian-kandlbauer-arm-dies-crash (August 23, 2011).

[289] Ibid

[290] Otto Bock press release, http://www.newswire.ca/fr/story/582151/from-the-laboratory-to-the-reality-of-daily-life (August 23, 2011). Andreas Waltensdorfer, a senior physician at the hospital where Kandlbauer had been in intensive care and the local police said that it was impossible to tell whether the accident was caused by problems with Kandlbauer's prosthetic arms.

This is the next step in Otto Bock's R&D roadmap, to develop commercial products that use not just efferent nerve fibres for motor control (e.g. signals from brain to limb via implanted chest muscles), but also afferent fibres to transmit sensory perceptions in the opposite direction. Dr. Hubert Egger, head of Otto Bock's mind-controlled arm project, described Otto Bock's development activities:

> Microscopic sensors which record the temperature, the grip strength and the surface properties of an object being touched are integrated into the fingertip of the prosthetic hand. The measured data is "translated" into suitable signals using a microchip and transmitted to actuators on the skin. These actuators generate lifelike stimuli for the sensory nerve endings, leading to restored perception in the brain: Prosthesis wearers can feel things as they did with the index finger of their natural hand prior to amputation.[291]

The sensing prosthesis, unlike the control system, remains at a prototype stage and continues to be researched and developed in the laboratory. Although the laboratory results have been promising, for instance Kandlbauer reported being able to feel his prosthetic finger just like he did before the accident, there remains much to be done. In a 2010 news release, Dr. Hans Dietl, CEO of Otto Bock HealthCare Products in Vienna, said Otto Bock "expects to bring the sensory arm prosthesis to market in approximately four years."[292]

## Otto Bock Case Analysis

Next to the Boston Elbow case study (to be subsequently presented), Otto Bock's development of its myoelectric control system and hand hardware in the

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[291] Otto Bock press release: www.ottobock.com/pm_Natuerliches_Gefuehl_en.pdf (August 23, 2011).

[292] http://www.newswire.ca/fr/story/582151/from-the-laboratory-to-the-reality-of-daily-life (August 23, 2011).

1960s is the best candidate for a linear narrative of innovation. This may be, in part, because of the relatively long time-frame of the case, as narratives can look more linear the further back you stand from them. The mode 2 concept is not a likely model as it pertains to a change in academic laboratory-based research to a generation of problems and methodologies, and dissemination of results in a context of application. The triple helix concept is applicable given the Otto Bock work with researchers at INAIL in the 1960s, the University of Vienna, and Todd Kuiken from the Rehabilitation of Chicago in the past few years on the application of TMR. However, the focus of its activities and the bulk of its R&D funding for upper limb prosthetics goes to its facilities in Vienna, where its upper limb R&D laboratories are located, along with production and sales. Last, it is difficult to answer the questions about postmodernity as the case does not focus on a scientific organization.

To the applicability of the linear model to the initial development of a myoeletric hand in the 1960s, the case did start with research. There was the bench-top electrical prosthetic hand developed in 1919 by Schlesinger of Berlin that established the concept of an electric hand. There followed the pneumatic systems that allowed researchers to study the problems of power supply and storage, as well as the lack of control signals. The big breakthrough in the 1940s was the report by Roland Reiter of his experiments with myoelectrically controlled arms. But it was not only research that precipitated Otto Bock's interest in a myoelectric hand. There was also the development of a transistor-based myoelectric prosthesis by the Soviet researcher, Kosbrinssky. This put myoelectrics into the realm of reality, according to Näder, and also raised public expectations.

The R&D that immediately preceded the development of the Otto Bock myoelectric hand system was the work directed by Schmidl of the INAIL, and Zemann for Viennatone. The former R&D resulted in the first really efficient myoelectrically controlled prosthesis, but was flawed because the wooden hand's interior space was too small and fragile. This led Otto Bock to begin development in 1965 of new prosthetic hands for myoelectric control. The work by Zemann was initiated as a result of publicity surrounding the Soviet myoelectric hand, and appears to have provided Otto Bock with another customer/collaborator to develop a new prosthetic hand device.

It was through these partnerships or open-innovation projects that Otto Bock was able to learn about these external R&D projects, and to apply the new knowledge in its own product-design process for both the myoelectric system and a new hand mechanism. It was also with external input that Otto Bock was able to improve upon its initial designs. This included the multi-channel system with proportional control and pulse width modulation from Schmidl, advancements in proportional control from Childress and others in the 1970s, and a multiple-sensor concept by Nightingale and Todd in the 1970s, not the mid-1980s as mentioned by Näder.

There is a similar argument to be made with the research and development of TMR. It builds on research by Todd Kuiken. To apply, test and demonstrate the work, Otto Bock engaged surgeons at the Vienna General Hospital to perform TMR on patients to be fitted with Otto Bock upper limb prosthesis. This in turn made possible the short-lived collaboration with Christian Kandlbauer. As with the myoelectric system development in the 1960s, the development process is not without challenges and is not a short-term process. There is the challenge of developing hardware that is capable of much greater control input from the user, and is also able to transmit information from the prosthesis back to the user.

How did R&D, innovation, and commercialization change in this case? There is an argument that it does not fundamentally change. Otto Bock appears as a sort of Schumpeter Mark II corporation for the field of upper limb prostheses. It grows through internal R&D, acquisitions and being second (or subsequent) mouse to the cheese in many areas of technological innovation, whether it's the American system of manufacturing or TMR. It applies its considerable R&D resources to product design and testing. It does not have to invest significant amounts of available capital in early stage R&D and technological innovation because its competitiveness derives primarily through the smallness of the market and Otto Bock's size and service network. In other words, Otto Bock can afford to let others experiment in how early stage R&D is conducted because there has always been an opportunity for Otto Bock to implement the results of this work, although it will be interesting to see how Otto Bock fares in the new regime of patenting and technology licensing.

## 6.2 The Boston Arm

The Boston Arm, illustrated below, was the world's first myoelectric controlled prostheses for upper arm (or above elbow) amputees. It was created by MIT electrical and mechanical engineering faculty and students in the 1960s, and then developed into a commercial product by Liberty Mutual staff in the early 1970s. In 2000, Liberty Mutual spun out Liberating Technologies Inc., which launched the Boston Digital Arm in 2001.

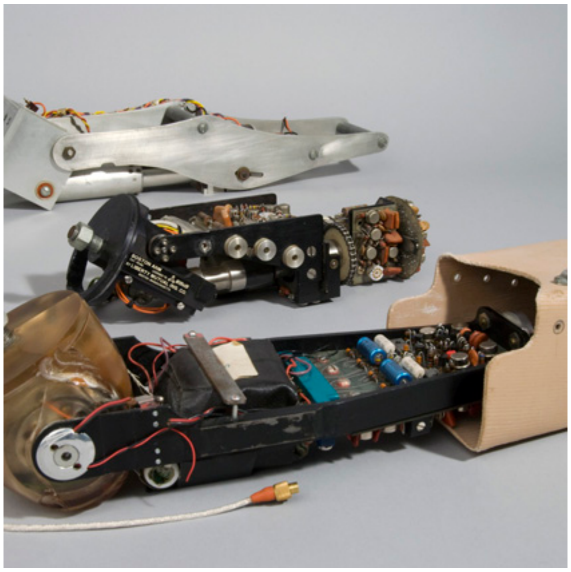

**Figure 15: Boston Arm (Elbow) Prototypes, Robert Mann, 1966–1973 (Image source: MIT)**

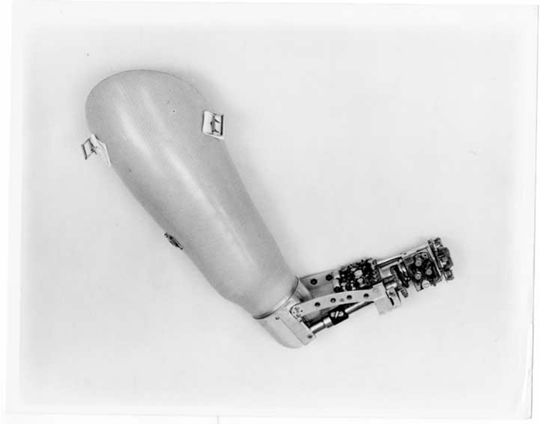

**Figure 16: Boston Arm (Image source: MIT)**

When first introduced it provided an alternative to body powered or externally powered switch-controlled elbows. Instead of using Bowden cables (known more generally as bicycle brake cables) to control an elbow or hand by movement of the shoulder or the pushing of buttons, the Boston Arm used a computer to interpret EMG signals from bicep and tricep muscles and sent orders to a motor to flex or extend the elbow, or open or close the hand. The elbow moved at speeds proportional to the intensity of the muscle contraction, imitating the flex and extension of a natural elbow joint. The batteries and electronics were housed in the forearm. It weighed about 2.5 pounds and could lift up to five pounds and hold objects over fifty pounds in a locked position.

The early research and development of the Boston Arm has been described in articles by MIT,[293] MIT Professor Robert Mann,[294] and a case study published in November 1984 as part of the US Congress Office of Technology Assessment's review of the influence of federal policies on the medical devices industry, a 1963 *Saturday Review* article, and a 2005 book *Dark Hero of the Information Age: In Search of Norbert Wiener, The Father of Cybernetics*.[295] I have reviewed each of these accounts.

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[293] MIT *Robert W. Mann—The "Boston Arm"* Website: http://mit150.mit.edu/multimedia/robert-w-mann%E2%80%94-boston-arm (June 5, 2012).

[294] R. Mann, "Engineering design education and rehabilitation engineering" *Journal of Rehabilitation Research and Development*, 39 no. 6, November/December (2002): Supplement, 23-38.

[295] S.J. Tanenbaum, *The Boston Elbow* (Health Technology Case Study 29), OTAHCS-29, (Washington, DC: US Congress, Office of Technology Assessment, 1984).

**Figure 17: MIT Electrical Engineering Building (Image source: MIT)**

The primary forces behind the development of the Boston Arm in all of these articles are captured in a 2005 article on advances in upper limb prosthetics: "Many of the biggest prosthetics developers are international corporations that buy the rights to projects nursed over many years by individual researchers at large universities like the Massachusetts Institute of Technology."[296] It is high agency or great-men history.

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[296] "The Bionic Man" *The Boston Globe*, July 31, 2005.

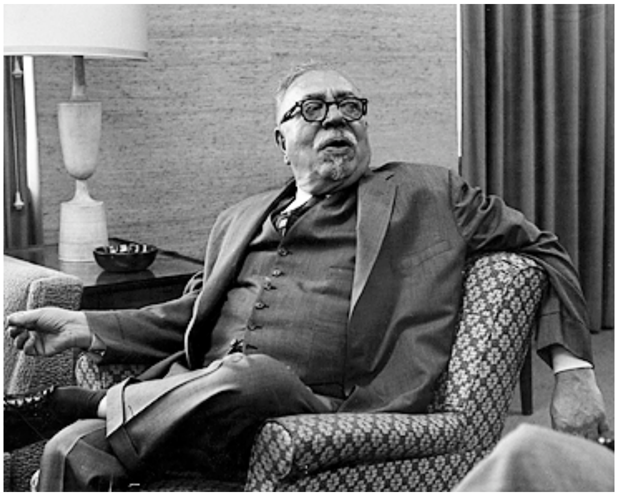

**Figure 18: Norbert Wiener (Image source: MIT)**

**Figure 19: Robert Mann (Image source: MIT)**

## MIT Narrative

The MIT website narrative begins with MIT mathematician and creator of the field of cybernetics, Norbert Wiener. Wiener was a child prodigy. He was born in 1894 in Columbia, Missouri. His education initially consisted of a few years of home schooling by his father, a professor of Slavic languages at Harvard University. He graduated from high school at age eleven and received a B.A. in mathematics from Tufts College at age fifteen. In 1913, at age 18, he received his Ph.D. in philosophy from Harvard University. Between graduation and appointment of his position at MIT, at age 23, in 1919 (he would remain in MIT positions until his death in 1964), he spent a postdoctoral year in Cambridge, studying mathematical logic with Bertrand Russell, and then another in Germany immediately before the war broke out. This was followed by teaching jobs at Harvard University and the University of Maine, a writing assignment for the Encyclopedia Americana, some journalism, and then service with the US Army during World War I as a "computer" and a private.

His wide recognition outside the field of mathematics came from his 1948 book *Cybernetics: the science of control and communication in the animal and the machine*.[297] According to the authors of *Dark Hero of the Information Age: In Search of Norbert Wiener, The Father of Cybernetics*, the origins of Cybernetics were in research Wiener performed during World War II on "predicting the future positions of fast-flying airplanes."[298] Underlying cybernetics was the observation that the information processing used to determine the position of enemy fighter planes over US aircraft was the same as that which ". . . lay at the root of all intelligent behavior . . . [such as] . . . light- and heat-seeking movements by plants and primitive creatures; homeostatic processes such as the body's internal mechanisms for regulating appetite and temperature; and virtually every form of higher-order animal behavior. All those purposeful actions were governed by

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[297] Norbert Wiener, *Cybernetics: the science of control and communication in the animal and the machine* (Cambridge: MIT Press, 1948).

[298] Flo Conway and Jim Siegelman, *Dark Hero of the Information Age: In Search of Norbert Wiener, The Father of Cybernetics* (New York: Basic Books, 2005).

circular communication processes and guided to their goals by error-correcting negative feedback."[299] Not everyone was clear what cybernetics meant. Michael Marcus in a review of *Dark Knight* wrote that not only was it not clear to him what cybernetics really is, but whether it is even a science.[300]

In *Cybernetics,* Wiener addressed what cybernetics meant for both engineering design and prostheses. In addressing the problem of optimum prediction, Wiener wrote:

> In general, engineering design has been held to be an art rather than a science. By reducing a problem of this sort to a minimization principle, we had established the subject on a far more scientific basis. It occurred to us that this was not an isolated case, but there was a whole region of engineering work in which similar design problems could be solved by methods of the calculus of variations…In doing this, we have made of communication engineering design a statistical science, a branch of statistical mechanics.[301]

This was consistent with the applied science model of engineering that had been in development at MIT since at least the 1930s.

On the application of cybernetic theory to prostheses, the promise was not just to control a prosthesis, but also to receive sensory feedback information to further enhance control and prosthesis movement:

> There are two other fields where I ultimately hope to accomplish something practical with the aid of cybernetic ideas, but in which this hope must wait on further developments. One is the matter of prostheses for lost or paralyzed limbs. . . .The loss of a segment of limb implies not only the loss of the purely passive support of the missing segment or its value as mechanical extension of the stump, and the loss cutaneous and kinesthetic sensations originating in it, The first two losses are what the artificial-limb maker now tries to replace. The third has so far been beyond his scope. . . . What we

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[299] Ibid.

[300] Ibid.

[301] Norbert Wiener, *Cybernetics, or Control and Communication in the Animal and the Machine* (Cambridge: The M.I.T. Press, 1961), 9 and 10.

> have said about the leg should apply with even more force to the arm, where the figure of the manikin familiar to all readers of books of neurology shows that the sensory loss in an amputation of the thumb alone is considerably greater than the sensory loss even in a hip-joint amputation.[302]

In 1962 Wiener broke his hip and while recovering at the Massachusetts General Hospital he met Dr. Melvin Glimcher, a resident surgeon, professor of orthopaedic surgery at Harvard Medical School, and an associate of Liberty Mutual. Wiener shared his speculations that servomechanisms[303] could be used to link the brain to an artificial limb. Melvin Glimcher was intrigued and recruited MIT mechanical engineering professor and former rocket scientist, Robert Mann, "to provide advice on the design of a small, lightweight power system similar to the ones he had developed for the *Sparrow* missile."[304] In the narrative, Mann developed a close collaboration with Melvin Glimcher and in 1968 they demonstrated the Boston Elbow,[305] "the first artificial limb that used electrical signals from the brain to control its movement."[306]

It took engineers at Liberty Mutual Insurance Company many more years of development to create a viable prosthesis."[307] The result in the MIT narrative was an artificial arm that could operate in much the same way as the arm of a normal

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[302] Ibid, 24-25.

[303] A servomechanism is an automatic mechanism that obtains feedback information to control performance. Cruise control is a servomechanism, using information from, in one implementation, driveshaft rotation to adjust the flow of fuel to the engine. The governor in James Watt's steam engine is another earlier example of a servomechanism.

[304] MIT *Robert W. Mann—The "Boston Arm"* Website: http://mit150.mit.edu/multimedia/robert-w-mann%E2%80%94-boston-arm (June 5, 2012).

[305] This MIT webpage adds an additional developer, Uncas A. Whitaker, professor of Biomedical Engineering, MIT: http://webmuseum.mit.edu/browser.php?m=subjects&kv=97&i=157552

[306] Ibid. This was not TMR, but use of surface electrodes to pick up electrical signals from a muscle contraction and then control a movement of the electronic device (e.g. an elbow or hand).

[307] MIT *Robert W. Mann—The "Boston Arm"* Website: http://mit150.mit.edu/multimedia/robert-w-mann%E2%80%94-boston-arm (June 5, 2012).

person does. It also mentioned that the research on the control systems for artificial arms by University of Utah Professor Stephen Jacobsen, Robert Mann's doctoral student, would become the basis for the development of the Utah Arm.[308] According to a *Boston Globe* article, another MIT faculty member was also involved in the early days of the project. Amar Bose, an electrical engineer who went on to found and run the speaker company, Bose Corporation, helped Wiener with the very first drawings of the Boston Arm. However, he later quit in disgust for what he called "the most politically intrigued project that I have ever witnessed at MIT."[309]

## Saturday Review Narrative

The political intrigue grew, in part, from a December 1963 article in *Saturday Review*. It is also high agency journalism. Wiener was mentioned as the "father of the science of cybernetics," recognized for a lecture he gave at Harvard Medical School in the 1940s on the topic of feedback theory. But the prime mover was Glimcher. The story of the realization of Wiener's concepts in the Boston Arm began with Glimcher as a Harvard medical student, attending Wiener's 1940s lecture.[310] The author of the article, John Lear wrote: "From the scientific point of view, it was student Glimcher–now associate professor of orthopaedic surgery at Harvard and director of the orthopaedic research laboratories at Massachusetts

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[308] Ibid.

[309] Ibid. See also: http://scopeweb.mit.edu/?p=1066

[310] *Saturday Review*, December 7, 1963, 87.

General Hospital–who deserves the applause for putting the Wiener theory to work. . . .”[311]

**Figure 20: Melvin Glimcher, Image Courtesy of Harvard University, used in the *Saturday Review* article**

Louis Pasteur, in a lecture delivered in 1854, said: “In the fields of observation chance favors only the prepared mind.” In the article, Glimcher’s education and development uniquely prepared him to see how Wiener’s concepts could be applied in an electronic arm. John Lear wrote:

> Glimcher was ready because, before he took up medicine, he had studied general science and mechanical engineering and had won bachelor's degrees in those subjects at Purdue. After reading all the literature he could dig up on cybernetics, Glimcher went to M.I.T. for a doctorate in biophysics. At Harvard he wrote a thesis on the biomechanics of gait. He further applied math and physics to human anatomy at the University of California, and did surgery one day a week on workmen's compensation cases in the

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[311] Ibid.

> rehabilitation clinic of the Liberty Mutual Insurance Company at Massachusetts General Hospital.[312]

With this education and experience, as well as his 1961 visit to the Moscow Institute to view a demonstration of the Russian Hand:

> He conceived a more sophisticated device that would pick up electrical signals transmitted over the nerves and then amplify those messages to tell an artificial hand what to do. This would require no mental or physical effort by the amputee, since the signals originate in the brain. The only problem was to catch such an order–"Close, fingers!" for example–en route through the nerves and pass it outside the body intact. While struggling with this concept, Dr. Glimcher came upon Professor Wiener in a hospital bed. The M.I.T. feedback genius had fallen down a stairwell and broken his hip. Since Wiener is a voluble man, and was bored by the necessity of lying flat on his back, it was inevitable that he should talk about cybernetics. Soon he was suggesting names of people at M.I.T. who might help on Dr. Glimcher's project. One of these men was Dr. Amar Bose, professor of electrical engineering, who persuaded a graduate student of his, Ralph Alter, to do a Ph.D. thesis on the possibilities of cvbernetic limbs. Working with amputee volunteers under local anesthetic in the Massachusetts General rehabilitation clinic of Liberty Mutual, the research team thus assembled around Dr. Glimcher (it also includes Dr. Joseph S. Rarr and Dr. Thomas Delorme and has Professor Wiener as a consultant) succeeded in tapping severed nerves into electrical circuits and recording what came out on the wire when a patient silently urged his brain to close a missing hand.

In response to the "Under Poetic License" article, a letter was published in the January 25, 1964 issue of Saturday Review from a vice president of MIT, the dean of Harvard Medical School, the medical director of Liberty Mutual, and Wiener, Glimcher, and Bose. Although appreciation was expressed for the interest in the work, three issues were raised: (i) the program was still at an early stage and publication in the magazine should not have preceded completion of the work and publication in a recognized scientific journal, especially if it may lead to false hopes

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[312] Ibid. This is also consistent with the biographical statement at this link, although without mention of the degrees at Purdue, accessed on November 12, 2012: http://www.childrenshospital.org/cfapps/research/data_admin/Site176/mainpageS176P0.html.

by amputees; (ii) that the Russian prosthesis Glimcher saw demonstrated was not "crude," but rather ". . . the product of serious research by Russian scientists; and (iii) that Glimcher had not "bluffed his way into a Moscow clinic to see it in action."[313] The authors wrote: "The word "bluff" has certain sinister implications and conveys the impression that he gained admittance to the Institute by misleading or deceiving the Russian authorities. Such was not the case. The visit to the Institute was at the suggestion of Russian scientists and Dr. Glimcher was cordially received."[314]

## Dark Hero of the Information Age Narrative

That Wiener and Bose were signatories to the letter, and that an alternative account of the development of the Boston Arm was not presented to the "Under Poetic License" article, is surprising given the narrative of the Boston Arm in the 2005 biography of Norbert Wiener: *Dark Hero of the Information Age: in search of Norbert Wiener, the father of cybernetics.*[315] It begins a decade earlier, in the early 1950s, with a speech by Wiener at the Harvard Medical School on the use of nerves to control electronic devices. As in previous narratives, it is at the Massachusetts General Hospital where "Harvard doctors" approach Wiener about their idea for an electronic arm project. But in this telling, Wiener and Bose are the main characters. Bose, who had worked with Wiener on several previous projects, was ". . . yanked

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[313] *Saturday Review*, January 26, 1964.
[314] Ibid.
[315] Conway, *Dark Hero*.

into the "Boston Arm" project. . . ." by Wiener.[316] According to the author: "Wiener laid out a detailed design for the first cybernetic arm. . . .Wiener's vision powered the project. Bose oversaw the venture and guided their team of doctors, electrical engineers, and biomedical technicians through the formative stages. Research facilities were provided by Mass General, MIT, and Harvard Medical School, with additional funding from the Boston based Liberty Mutual Insurance Company. . . ."[317]

> After two years of research and development, when the team was readying the first test of the device, a young doctor from Harvard who had come late to the project took Bose aside: "He said, 'Wiener's leaking this stuff. You've got to tell him we don't want any leaks. They would be bad for the project.'" Bose did what the doctor asked. "I went to Wiener and he was like a child. He was so apologetic. He said 'I can't think of anybody I talked to, but maybe I have, and I'm so sorry.' It turned out, he never had, but this doctor wanted him to suppress everything until he could make the release himself."

When the December 1964 *Saturday Review* article was published, Bose said: "I took the magazine to Wiener. He read the whole thing and then just put it aside. Didn't say a word. Not a word. No criticism. Nothing."[318] When an article was published in the New York Times on the presentation of the electric arm at an international orthopaedic seminar in 1965,[319] Bose recalled:

> "When it came out in The New York Times the whole thing was credited to this doctor and it was a hoax. He hadn't contributed to the project at all. He was there and then the last day, when we had a man with electrodes on and the thing was working, he appeared with the press and got his picture taken."[320]

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[316] Ibid, 323.

[317] Ibid.

[318] Ibid, 324.

[319] "New Process Will Help Amputee To Control Limb With Thought," *The New York Times*, Aug 16, 1965, 29.

[320] Ibid.

Consistent with the view of Wiener as author of the detailed design and Bose as the director of the project in the formative stages, Siegelman wrote: "Wiener's design of the Boston Arm was a coup for cybernetics, and a vivid demonstration of the power of science to foster man-machine interactions with tangible benefits for people's daily lives." In this telling it was an example of the linear model.

Bose's doctor of science student was Ralph Alter. Alter began work on the project in February 1962, and wrote in his doctoral dissertation that the project was instigated by Glimcher's visit to the Soviet Union in 1961 to witness a demonstration of the Russian Hand, followed by the conversation between Wiener and Glimcher at Mass General, and the recommendation from Wiener that Bose be contacted about the project.[321] Alter wrote that upon hearing the idea he expressed interest in a doctoral program on the topics, and subsequently under Bose's guidance performed his doctor of science thesis research on the electronic arm concept. Alter also mentioned that Glimcher and his collegue Dr. Thomas L. DeLorme ". . . provided a wealth of medical experience and assistance, without which many of the experiments described in this report would never have been undertaken."[322]

According to Alter, his project emphasized a fundamental approach to the problem of prosthesis control. That meant an initial year of "study in physiology, prosthetics, and related fields."[323] This was followed by two simultaneous

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[321] Ralph Alter, *Bioelectric Control of Prostheses*. (Cambridge: MIT, December 1, 1966).
[322] Ibid.
[323] Ibid, page 1.

investigations: the use of nerve signals in prosthesis control; and second, the use of a computer for a muscle-EMG controlled prosthesis. The use of nerve signals was the preferred approach, but Alter acknowledged that the practical and short-term approach would involve use of EMG signals from a muscle. The design goal for the EMG system was to make control of the prosthesis like that in a human arm. To achieve this natural arm movement, he chose a very flexible signal processor, a computer, as part of the experimental prosthesis. The small and compact system would have to wait for Mann and his student, Rothchild.

## US Congress Office of Technology Assessment Narrative

The case study for the US Congress Office of Technology Assessment (OTA) was written by Sandra J. Tanenbaum, who that same year had received her doctorate in political science from MIT. It was case study number twenty nine in the OTA's Health Technology Case Study Series, commissioned to inform public policy on the development and management of medical technology and issues of costs and quality. The chair of the advisory panel for the case studies was the renowned economist Richard Nelson, then at the Institute for Social and Policy Studies, Yale University and currently the George Blumenthal Professor of International and Public Affairs, Business and Law, at Columbia University. Eric von Hippel, professor of technological innovation in the MIT Sloan School of Management and aforementioned leader in the study of user-inspired innovation, was one of the advisory panel members.

Like the MIT account, it is a high agency history, although technological innovation in battery design and government also plays a role. The primary forces behind the development of the Boston Elbow were the MIT professors. Wiener gets credit as “godfather” for creating the concept of cybernetics and its application to prostheses in the late 1940s. Glimcher is identified as head of the amputee clinic at the Liberty Mutual Insurance Company (Liberty Mutual), a major seller of workers’ compensation policies. Glimcher raised with Wiener the problems that he saw for above elbow amputees in his work for Liberty Mutual. The major problem was that the single-cable design commonly found in above elbow prostheses did not allow for simultaneous control of both the elbow and hand, which meant unnatural body movements that were unattractive and inefficient. Glimcher, who had visited the Soviet Union and observed the myoelectric Russian Hand, suggested to Wiener the possibility of a project to surpass Soviet technology with a myoelectric elbow. For Glimcher, myoelectric control was more necessary for above elbow amputees. Below elbow amputees could function well with conventional devices.

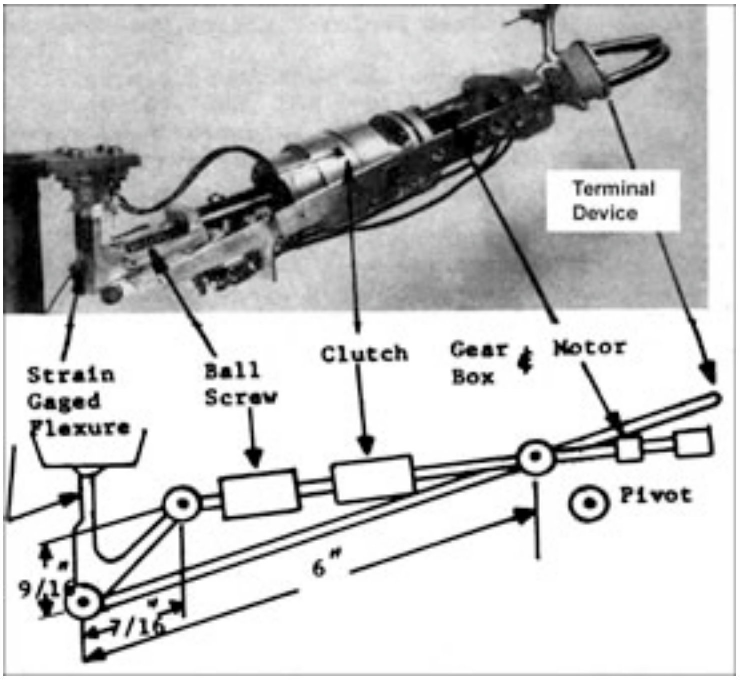

**Figure 21: The original Boston Arm, a master's thesis product (image source: MIT)**

Tanenbaum wrote: "Wiener encouraged Glimcher's interest in the elbow and put him in touch with two Massachusetts Institute of Technology professors, Amar Bose, an electrical engineer, and Robert Mann, a mechanical engineer."[324] This initially resulted in two graduate theses on the possibility of a myoelectric elbow prosthesis, both supported in part by Liberty Mutual. In 1966, Liberty Mutual hired two of Mann's former students to develop a prosthesis based on the MIT research.

In 1968, a first version of the Boston Arm was designed and built at the Institute. Tanenbaum wrote that the eighteen Boston Arms manufactured were rejected by every amputee fitted with the device, and deemed unsatisfactory by the

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[324] MIT *Robert W. Mann—The "Boston Arm"* Website: http://mit150.mit.edu/multimedia/robert-w-mann%E2%80%94-boston-arm (June 5, 2012)., 8.

National Academy of Sciences. "The most serious problem was that the first Boston Elbow ran on a battery so large it had to be mounted on the wearer's belt."[325]

**Figure 22: Liberating Technologies Inc. (LTI) Facility in Hopkinson, Mass. (Image source: LTI)**

The work to design and produce a commercial product was done by two unnamed Liberty Mutual employees. The battery issue was overcome by the work of a MIT mechanical engineering graduate student. He used smaller batteries and incorporated them into the prosthetic forearm. The student, Bob Jerrard, was subsequently hired by Liberty Mutual and built twenty-five Boston Arm prototypes during his one-year of employment with the firm, before beginning a tour of duty in Vietnam. In 1973, T. Wally Williams III was hired as Liberty Mutual's production engineer, and by 1974 had designed and produced twenty-five working commercial prostheses.[326] These achieved acceptance by amputees as well as third party evaluators and insurance companies. By 1976, another 100 Boston Arms had been designed and produced, with a slimmer forearm and more reliable electronics.

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[325] Ibid.

[326] He continued in employment with Liberty Mutual until the prostheses business was spun off to Liberating Technologies in 2001, and has continued in employment with this firm to the date of writing of this dissertation.

The study also found that public policy played a substantial role in distributing the Boston Elbow.[327] The role of government, law (such as the Rehabilitation Act of 1973) and public policy worked directly on the development of the Boston Elbow as a result of the purchasing power of workers' compensation insurance, Medicare and Medicaid. These government programs reimbursed the purchase of both prosthetic products designed to get people back to work, as well as rehabilitation programs for fitting and training of amputees.

Among the most interesting observations of the study was that the objectives of prosthetic technology are not obvious. For the Boston Arm, would not the obvious objective be to replicate the function of the human arm? And would not the design of a myoelectric elbow be much simpler than that for an electric hand, with merely one degree of freedom? What Tanenbaum found was that the Boston Arm embodied only a subset of the original functions of the human arm. Choosing among them was a complex process, involving disputed judgments as priorities arose in the fitting of prototype devices.[328] [329] One of the participants she interviewed for the study said: "It would be difficult to overstate the divergences of viewpoints expressed by the prosthetics experts interviewed for this study. What was a critical feature for one was a red herring for another, and, although some disagreements rested on data, others concerned ideas about what an artificial arm

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[327] Ibid, 33.

[328] Ibid, 9 and 10.

[329] Students of Science and Technology Studies know that there are many embodiments of the bicycle, but it may come as a surprise that this applies to the embodiments of the human arm.

should be expected to do."[330] For instance, was it more critical that the arm move like a human arm, or be easy to use?

The force behind the basic design goals was Mann and his co-creators. Mann's basic design included a force-sensing element that measured the power of the myoelectric signal and provided proportional power to the elbow motor. According to Tanenbaum the overriding concern of the creators was to achieve what Mann calls "innateness;" the goal was to imitate control of the natural arm, using the same muscles that control a natural elbow (i.e. the amputee's residual biceps and triceps muscles).[331] This also meant achieving control of the speed of the elbow movements and independent operation of the elbow hand or hook. Mann contrasted this with "access," or how easy it is to understand, maintain and use. In Tanenbaum's judgment, the Boston Elbow's innateness came at the expense of its accessibility given its technical complexity, training requirements, and need for specialized personnel to maintain the devices.[332] In other words, natural limb movement trumped ease of use.

## Robert Mann Narrative

The education, experience, and interests of Robert Mann are important not only because of his role in the development of the Boston Arm and his influence on the graduate education of Stephen Jacobsen, but also because of his ideas about engineering design and basic and applied research. As mentioned, Mann was one of

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[330] Ibid, 10.
[331] Ibid.
[332] Ibid, 10.

the co-authors of the 1976 US National Academy of Science publication *Science and Technology in the Service of the Physically Handicapped.*[333] It distinguished between basic research, as that performed along disciplinary lines and lead by investigator curiosity in theory or data, and applied research, which identified a specific need in a target population and focused on design of a device to satisfy that need. Research in prosthetics was, for the co-authors, an exceptional case in that basic research could consist of both curiosity in theoretical aspects of cybernetics, and the design of power-driven prostheses to test those theories. But Mann's deeper affiliation was with the engineering design process. This quote from an article he wrote in 2002 provided an indication of the depth of that identity, and what this meant in the field of rehabilitation engineering.

> My academic career of more than 50 years has been committed to involving undergraduate and graduate students in the engineering design process. A variety of experiences–childhood model making, vocational high school education, draftsman jobs, and military assignments during World War II–have convinced me that one learns to design by being required to design. At MIT, first as a research engineer and then as faculty, I mounted an unending search for appropriate topics to develop into engineering design goals as well as thesis topics for my students. As part of that search I became involved in rehabilitation engineering (RE) in the late 1950s and early 1960s through a combination of prior unrelated R&D work and the influence of two individuals. A chance meeting with John Kenneth Dupress led to blindness-related projects, and an accident befalling Norbert Wiener led indirectly to my limb prostheses research. For my students as well as for me, RE proved a winner! Students were challenged technically while working on projects that had real human significance–that indeed would ultimately improve the quality of life for thousands of people. The prospect of making such contributions attracted the best students to my research projects.[334]

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[333] Committee on National Needs for the Rehabilitation of the Physically Handicapped, *Science and Technology in the Service of the Physically Handicapped*.

[334] Mann, "Engineering design education and rehabilitation engineering."

Mann was a design engineer. His focus in both undergraduate and graduate students was on the engineering design process, and, according to Mann, the best teachers were challenging design projects. In addition to being a student of design engineering, he was also student of MIT in the 1950s. His undergraduate, masters and doctoral degrees were all from MIT in, respectively, 1950, 1951 and 1957, the year Sputnik was launched. After his doctorate he joined an MIT laboratory designing Sparrow and Hawk missiles, involving students in the evaluation of compact and lightweight energy systems for the missiles. The work turned out to be a fountainhead of projects. Mann wrote that " . . . students engaged with me on the Missile Internal Power Systems project produced twenty-six bachelor's, twenty-seven master's, two engineer's, and three doctor's theses, plus my own doctoral thesis, submitted in 1957." It also resulted in one thesis project that applied the concepts from the missile project to limb prostheses.[335] In 1963, he became a professor of mechanical engineering at MIT.[336] This design focus manifested itself in Mann positions as director of the MIT Dynamic Analysis and Control Laboratory and head of the machine design division of the Mechanical Engineering Department, which he combined and renamed the Engineering Design Division. In 1974 he helped found The Eric P. and Evelyn E. Newman Laboratory for Biomechanics and Human Rehabilitation, and served as its director. Even in his election to the National Academy of Sciences in 1982, Mann was surprised at such

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[335] I. Paul and R.W. Mann, "Evaluation of energy and power requirements for externally powered upper-extremity prosthetic and orthopaedic devices," *ASME* 62-WA-121 (1962).

[336] "Robert W. Mann, 81, Designer of Devices for Handicapped," *New York Times*, Jun 24, 2006, B6.

an honour being given to a design engineer.[337] He was also pleased with the titles of the articles written in honour of his retirement: “A Designer's Designer” and “A Life in Design.” His comments on an exhibition at the MIT Museum, “Mind and Hand: The Making of MIT Scientists and Engineers,” underscores the influence of his approach to engineering design. Mann said the exhibition:

> characterizes the Newman Laboratory as a paradigm of the MIT style of integrating education and research. The display cases include folding canes and ETAs [electronic travel aid] for the blind, prototype Boston Arms, the original Magic Light Pen, and the Hip Simulator with instrumented endoprostheses. The Laboratory bibliography cites 241 bachelor, 168 masters, and 56 doctoral theses conducted within Newman. Among these are the doctoral theses of three current MIT Mechanical Engineering faculty as well as those of seven others who now serve as faculty at other universities and who continue their effectiveness in rehabilitation-related research. In addition to those students directly involved in the Lab over the decades, our visibility enhanced the entire university community’s sensitivity to disabling conditions.

According to Mann’s account of the project, he had almost no knowledge of Wiener when in the spring of 1964 he was approached by representatives of Liberty-Mutual to develop an artificial elbow.[338] Mann said that although “Wiener’s speculations on cybernetic control of prostheses indirectly precipitated what became the Boston Arm,” he and Wiener never discussed the project due to Wiener’s death in April 1964. Mann said he instead drew on his early engineering career designing missiles, in particular his experience as a “ . . . designer and an expert on how to store and supply energy in small, light-weight packages–a clear requirement for any future wearable . . . prosthesis.”[339]

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[337] Mann was also elected to the Institute of Medicine of the National Academy of Sciences in 1971 and the National Academy of Engineering in 1973.

[338] Mann, “*Engineering design education and rehabilitation engineering*.”

[339] Ibid.

Mann also mentioned that Liberty Mutual ran a clinic in Boston, which fitted prostheses to amputees, and orthopaedic surgeons from the Massachusetts General Hospital served on the clinic staff. But what they did not have was a "design engineering faculty member already involved in rehabilitation." Mann had become aware of the limb-prostheses field through his American Orthotic and Prosthetic Organization (AOPA) and CPRD assignments.

The first graduate involved in the Boston Arm project was Ronald D. Rothchild who completed his master's thesis on the Boston Arm in May 1965. According to Mann it did not result in just a study and thesis: "Rothchild designed, built, and tested an artificial elbow controlled by electromyographic (EMG) signals from electrodes over the biceps-triceps musculature of the amputee's upper-arm residual limb."[340] Tests with above elbow amputees demonstrated natural control of the artificial elbow. Based on the results of the demonstration project, Liberty Mutual took the project in-house in 1967 and hired Mann as a consultant and two of his former students to produce a practical, wearable design. They worked at the company's facility and developed what he called the second generation Boston Arm in 1968. Following demonstrations at Massachusetts General Hospital, in London in the Fall of 1968 and in Yerevan, USSR, Mann said his student Robert Jerrard produced a third-generation design as part of his master's program in 1970, that added a powered wrist rotator and an electromechanical hand. Jerrard then joined Liberty Mutual upon graduation and incorporated his thesis work into the next

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[340] R.D. Rothchild and R.W. Mann, "An EMG controlled, force sensing, proportional rate, elbow prosthesis," *Proc Symp Biomed Eng, Vol. 1*, (Milwaukee: Marquette Univ., 1966), 106–9.

generation of the Boston Arm, which was then converted into a manufacturable version by Williams.

In a 1994 article written by Mann that addressed the development of the Boston Arm, he wrote of the "wearable version:"

> The practical realization of a wearable version of the "Boston Arm" and its subsequent manufacture and routine fitting came about as the result of the insurance company's interest in providing their Workmen's Compensation Insurance clients with an improved prosthesis through their funding the development of a practical, reliable device. I recruited two of my former students from industry, Cord Ohlenbusch and David Russell, and together, under my supervision as consultant at the Liberty Mutual Research Center to implement his design; this limb was redesigned for serial manufacture in the late 1960's by production engineer, T. Wally Williams 3rd, also at the Liberty Mutual Research Center. . . . "[341]

Mann also expressed surprise that the two US patents that issued from the inventive work by Olhenbesch and Russell, and subsequently Jerrard and Olhenbesch, did not acknowledge the prior work at MIT and Mann's article published at the October 1968 conference.[342] Both were assigned to Liberty Mutual. US Patent No. 3,557,387, filed November 12, 1968, protected the invention "Externally Powered Joint Prosthesis." The claimed invention was not the broad concept of the myoelectric controlled prostheses, as this had already been disclosed by others in Germany, England, Russia, and elsewhere, but the design that had been worked out for the elbow joint. The patent did include references to

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[341] R.W. Mann, 1994. "Sensory and Motor Prostheses in the Aftermath of Wiener," in *Proceedings of the Norbert Wiener Centenary Congress, 1994: Michigan State University, November 27-December 3, 1994* , Ed. Vidyadhar Mandrekar, Pesi Rustom Masani.

[342] R.W. Mann. "Efferent and Afferent Control of an Electromyographic, Proportional Rate, Force Sensing, Artificial Elbow with Cutaneous Display of Joint Angle ." *Symposium on the Basic Problems of Prehension, Movement, and Control of Artificial Limbs, Proceedings of the Institute of Mechanical Engineers, Vol. 183, Pt. 3J*. London: Institute of Mechanical Engineers, 1968-69, 86-92.

earlier patents, but did not, as stated by Mann, include reference to Rothchild's work. US Patent No. 3,883,900, entitled "Bioelectrically controlled prosthetic member," was filed in 1973. Mann said the re-designed elbow was based on Jerrard's MIT thesis work, but this was not referenced in the patent.

## Liberty Mutual and Liberating Technologies

The narrative would be incomplete without further mention of Liberty Mutual and the re-design and long history of improvement of the Boston Arm at Liberty Mutual and Liberating Technologies.

Liberty Mutual was more than a major seller of workers' compensation policies. It had a rehabilitation clinic in Boston, an R&D group at a nearby institute in Hopkinton, Massachusetts, and experience with university collaborations and product development.

Liberty Mutual's accident prevention department, formed in 1912, was initially focused on providing insurance policyholders with safety advice. It expanded to address the obligations of policy holders to assist injured workers return to work. Opening of a medical rehabilitation clinic in Boston in 1943 was a major part of this expansion. It was at this facility where Glimcher worked. In 1954 Liberty Mutual opened the Research Institute for Safety, which expanded its capacity to do R&D. It was here where the pre-commercial design and testing of the Boston Arm occurred, and which would become home to Liberating Technologies when spun-off from Liberty Mutual in 2001. The Institute initially focused on investigation of industrial accidents from machinery use and material handling and industrial hygiene, such as control of dust, vapors and noise. The latter was a form of scientific management,[343] which used controlled studies to produce tables of maximum weights that workers could lift and carry, and guidelines for policyholders to follow in decreasing claims for work-related injuries and disabilities. By the early 1950s Liberty Mutual had extended from scientific management into new product development projects. This included development of collapsible steering columns, arm and headrests, air bags, and seatbelts with researchers at Cornell University. The upshot is that although Liberty Mutual did not have a design engineer like Mann or Bose on staff, they had the cash, facilities, experience in both research and product development, as well as access to patients to support the project in the early days, and were also not merely acted upon by MIT.

Jerrard completed his master's degree in mechanical engineering under Mann at MIT from 1969-70 and then worked for Liberty Mutual from 1970-73. He then undertook (and completed) doctoral studies at the University of Utah from 1973-77 under Mann's former doctoral student (and creator of the Utah Arm), Stephen Jacobsen. Following his doctoral studies he took a position at the University of New Hampshire.

Jerrard gave much of the credit to Mann, although he also said that if Mann had not done it, someone else would have designed a similar system.[344] Asked about the external influences on Mann's work on the project, Jerrard said that

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[343] Scientific management was created Frederick Winslow Taylor in the 1880s to improve economic efficiency within manufacturing industries. Although as a distinct practice it peaked in influence during the 1910s, its broad concepts remain in practice in industrial engineering and management.

[344] R. Jerrard, author interview, April 29, 2010.

efforts to collaborate on a myoelectric arm with the Rehabilitation Institute of Chicago were fruitless. He was not aware of work in Canada or Europe on myoelectrics. Proximity to hospitals was a minor factor to the success of the project: Jerrard recalled only one trip to the Liberty Mutual Rehabilitation Centre in Boston. However, he said that user tests were a critical part of the development process, in particular the testing with a World War II veteran Hal Paradis, who lost his arm during the Battle of the Bulge.

Jerrard's masters thesis was a mechanical redesign of the proof-of-concept elbow initially designed by Rothchild in his masters program. The version designed by Rothchild had a ball screw motor, weighed six or seven pounds, and had a battery pack of equal weight. Jerrard redesigned it to use a harmonic drive developed by United Shoe Machinery Corporation in Haverhill, Massachusetts, north of Boston.[345] It allowed Jerrard to move the motor, brake, tachometer and gear reduction system away from the elbow, making room in the forearm for the battery and electronics. That was his major contribution. Jerrard said that other academics at MIT looked down on the design-based master's degree in favour of a research-based program, but Mann appreciated the design program because of his prior experience with complex design projects. According to Jerrard, Mann could hold his own in theory, but liked to develop hardware.

Jerrard said it was a smooth transition to move from MIT to Liberty Mutual, in part because Liberty Mutual was more like a university with its research facilities and budgets for design engineering projects that did not have to make

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[345] Ibid. It was also used in the wheels of the Apollo Lunar Rover.

money.[346] Fittings and testings were done at a facility in Hopkinton, Massachusetts. Jerrard, who was responsible for the second design while a student at MIT, handed-over responsibility for design to Williams when he joined Liberty Mutual in 1973. Jerrard then left to get married and begin his doctoral studies at the University of Utah. Jerrard said Williams had much more experience than he did and did a great job with the next redesign of the system.

**Figure 23: Liberty Mutual Press Photo (Image source: Liberty Mutual Insurance)**

Williams was the sole director of design activities from 1973 until 1984 when Liberty Mutual hired Bill Hanson. Hanson came to Liberty Mutual with mechanical engineering and MBA degrees and initially served as director of

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[346] Ibid.

acoustics research and then assumed the position of managing director of Liberty Mutual's Liberty Technology, responsible for design, manufacture and distribution of rehabilitation equipment. From 1984 onwards Williams and Hanson collaborated in design decisions.

Development of the Boston Arm continued at Liberty Mutual for the next seventeen years until the company decided to sell off some of its research subsidiaries in 2001. Hanson then created the privately held Liberating Technologies, making Williams its product development director.

Liberating Technologies' focus has been as a supplier of upper limb prosthetic devices for adults and children, including products from other prosthetic manufacturers: RSL Steeper of England, Otto Bock's Canadian subsidiary and Touch Bionics of Scotland. Although it has not continued Liberty Mutual's line of research work, it has continued its engineering design activities, including making a prosthetic controller for below elbow amputees, and a locking shoulder joint for shoulder disarticulation patients. It also did a major re-design of the Boston Arm to create the Boston Digital Arm in 2002. The arm's microprocessor controls the elbow plus four other prosthetic devices, such as hands, grippers, wrist rotators, and shoulder lock actuators. Bill Hanson said, "We were doing some of this 10 years ago, but the controllers were less sophisticated. Back then, we might have offered three control strategies and they had to fit all patients. For some, it was not the optimal system."[347]

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[347] "The Bionic Man" *The Boston Globe*, July 31, 2005.

Hanson took advantage of new processors, such as the high-speed digital signal processors developed by Texas Instruments Co. for consumer electronics. "Now we have about 32 control strategies for patients," he said.[348] Patients can control their arms by pushing switches, tensing muscles, or with sensors over muscles. "We can customize the arm to each patient, and if the clinician has done the job right, the patient will learn faster and be more proficient with it."[349]

Since its design in 2000, the controller has been overtaken by the introduction of upper limb designs and products that call for more than five motors. According to Hanson, since 2004 devices like wrists and grippers have included motors.[350] As well, the new multi-finger prosthetic hand products like the i-Limb are using more than five motors in their moving fingers and thumb. This has moved Liberating Technologies to redo the controller to include more inputs and outputs.

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[348] Ibid.

[349] Ibid.

[350] Ibid.

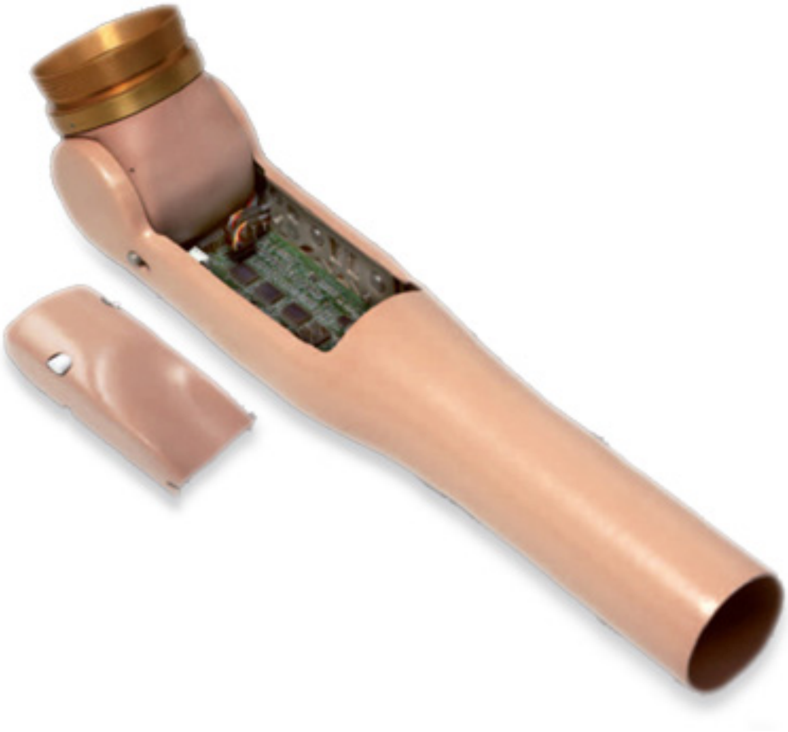

**Figure 24: Boston Digital Arm (Image source: LTI)**

Like many in the industry, Hanson acknowledged the role that battery technology, in particular lithium ion batteries, have played in upper limb prosthetic products. "They have twice the capacity and half the weight of nickel-cadmium batteries," Hanson noted. "They charge faster, don't lose capacity, seem to last as long, and don't have environmental problems."[351] They have allowed designers to add motors where they would have been impractical before.

As a small company with less than ten employees and annual revenue under $5 million, Liberating Technologies has sought out collaborations with universities and rehabilitation institutes to leverage their people and laboratories to develop new technologies. It has been involved since 2007 as a collaborator in a research

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[351] Ibid.

and development project with UNB's Institute of Biomedical Engineering to develop a new prosthetic hand. Total project costs are $4.3 million, with $2.9 million from ACOA, a Canadian regional economic development agency.

Liberating Technologies has also worked with Todd Kuiken of the Rehabilitation Institute of Chicago. Kuiken has led in the development of TMR. As mentioned in the field essay and Otto Bock case study, the procedure involves moving the nerves to a severed arm or hand into the chest muscles. When the person thinks to grasp a cup, the nerves controlling that movement cause the chest muscles to contract. The myoelectric electrodes sense the contractions and send the information to the microcontroller, which activates the arm or hand. The following image shows the use of a prototype version of the Boston Digital Arm used in an application with Kuiken's TMR patient Jesse Sullivan, as well as a second Boston Digital Arm (right arm), an electronic shoulder from the Scottish supplier Touch Bionics, and a hand from a Chinese manufacturer.

**Figure 25: Jesse Sullivan manipulates an experimental version of the Boston arm (Image source: Boston Globe)**

"I think what Dr. Kuiken is trying to do is push the envelope," said Bill Hanson. "It was a lot to ask. [The Boston arm] was never designed to do all that, because nobody had ever done it before."[352] TMR points to a very different engineering basic design and set of assumptions than those which guided the work of both Mann and his students in the 1960s, and Hanson and William in 2000. In

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[352] Ibid.

the 1960s, myoelectric arms read one signal at a time, and wearers had to switch controls from the elbow, to the wrist, to the hand. With the Boston Digital Arm, advances in software meant Liberating Technologies could now offer new hardware designs capable of simultaneous and more natural movement. It seems to reflect Parker, Hudgins and Englehart's concept of alternating software and hardware innovation in the field of upper limb prosthetics.[353] With TMR the amount of information increases because users are no longer faced with the challenge of control through use of muscle contractions different than those used in controlling the amputated limb. Using the nerves that controlled the amputated arm to also control the prosthetic arm means more signals, more information, and more simultaneous movement of elbows, wrist, hands, fingers, and thumbs. This also demands both new software to process the information and new hardware designs.

For Liberating Technologies collaboration with the Rehabilitation Institute of Chicago, Kuiken asked Williams and Hanson to "soup up a Boston arm that would let Sullivan bend his elbow, swivel his arm in and out and raise it over his head, rotate his wrist, and grasp."[354] Williams and Hanson developed an experimental version of the Boston Arm to cope with Kuiken's novel requirements.

## Boston Arm Case Analysis

The most obvious case to fit with the linear model of innovation is the Boston Arm. It begins at MIT, a fountainhead of the applied science model of

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[353] Parker, "Myoelectric signal processing," 541.

[354] Ibid.

engineering and one-time academic home of the best known proponent of the linear model, Vannevar Bush.[355, 356] It features Wiener's pioneering concepts on cybernetics in the 1940s, the Bose supervised doctoral fundamental project undertaken by Rothchild in the early 1960s, and Robert Mann's design projects in the mid-1960s on the practical application of myoelectrics in prototype prosthetic arms. Based on this work, in the 1960s and 1970s Liberty Mutual developed and produced the world's first myoelectrically controlled elbow. Production of the Boston Arm, with improvements, has continued up to the present. The concepts underlying the Boston Arm have subsequently diffused within the industry and influenced other prosthetic arms developed by Motion Control, VASI, and Otto Bock.

However, a closer look at the case suggests that the process was not so straightforward. The projects to develop prototype myoelectric arms at MIT arose not because Wiener was handing off fundamental research to Mann for an applied science project, but because Wiener was approached by Glimcher to develop an artificial elbow. Glimcher played a pivotal role in the case because of his background and viewing of the Russian Hand in 1961, and he had a foot in industry, medicine and academia, and was thus able to connect patients' demands with emerging technology.  The upshot is that as a result of Glimcher's request that a myoelectric arm be developed, the story turns from being a simple supply side case of technology transfer, to one involving both supply and demand or industry pull of

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[355] From 1932 to 1938 he was vice-president and dean of engineering at MIT.

[356] Vannevar Bush and Wiener worked together in the 1920s on the Bush differential and analyzer.

technology from the university. It also highlights how much depends on key individuals, and the importance of agency in this case.

As well, there appears to be only an indirect connection between Wiener's cybernetics and Mann's development activities. While it is clear that Wiener encouraged Glimcher's interest in the elbow and put him in touch with Bose and Mann, Mann said he had almost no knowledge of Wiener and they never discussed the project. And although the idea for cybernetic control of prostheses came from Wiener, Mann instead drew on his experience designing missiles to develop the myoelectric arm.

On the supply side, there was also the influence of pre-existing technology from Germany and Russia. According to Mann, the Russian myoelectric prosthesis produced in the 1960s was a version of the prosthetic hand developed by Dr. Reinhold Reiter in Germany in the 1940s. What followed at MIT was the design, build, and testing of a new artificial elbow controlled by EMG signals from electrodes over the bicep and tricep muscles. It employed the basic concepts used in the Russian and German prosthetic designs, employing muscle signals to control an electric device, although there were differences. It was an elbow that was controlled, not a hand. The Boston Arm offered proportional control, meaning the strength of signal from bicep or triceps muscle controlled the voltage to the motor and the speed of movement of the elbow. It also offered a way for the user to sense the weight of objects and the speed of movement of the arm.

Thus, the Boston Arm case does not fit squarely with the linear theory, as it was not a simple step-wise process from Wiener's concept to fundamental study to the reduction of practice of principles in new products and processes. It is not that the move from MIT to Liberty Mutual's laboratory in Hopkinton, Massachusetts was not successful. It is, even with the departure of Bose from the project and disagreements about the paternity of the Boston Arm, a model of technology transfer: four prestigious institutions involved, company sponsorship of a student design project, a transition point coming after university fundamental study and proof-of-concept tests, the involvement of the principal faculty member in the follow-up on development activities at the company's premises, the movement of graduate students into employment with the company, and development of a commercial product by the company. The major issue is that the model oversimplifies the product development process as a reduction to practice of new principles and conceptions, deemphasizing the inventiveness, collaboration with users, and improvements that occurred at Liberty Mutual. The first version of the Boston Elbow was rejected by every amputee fitted with the device, and deemed unsatisfactory by the National Academy of Sciences. It was only after Liberty Mutual employees, Jerrard (Mann's former student) and T. Wally Williams, found solutions to the problem of the external batteries and reliability of the electronics that it was able to achieve acceptance by amputees as well as third-party evaluators and insurance companies. It was only in 1976 that the first batch of 100 Boston Elbows were produced, with the slimmer forearm and more reliable electronics.

Is there a fit between the mode 2 concept and the Boston Arm case? There is a focus on design of useful of systems at MIT, and subsequent involvement of Mann and his students in on-going development activities at the Liberty Mutual clinic. There is talk back from users to designers at Liberty Mutual. But it is not a perfect fit. There is not "strong contextualization" in the research at MIT. The identification of problems with the device designed at MIT occurred as a result of testing and improvement at Liberty Mutual's facility outside of Boston. Instead of changing R&D at MIT, there was the design-engineering retained in the Cornell University "sandwich" compromise that kept design in engineering school curriculums. The 1960s projects that led to the initial development of a prototype device took the form instead of an externally sponsored research project and then technology transfer.

With respect to the triple helix concept, basic research is not linked to utilization through a series of intermediate processes involving government, university, and industry collaboration. The missing body is government. Government, law, and public policy did play a role in providing the framework to purchase of the Boston Elbow through workers' compensation insurance, Medicare and Medicaid programs. But it is a minor player, and not at the level of what triple helix theory contemplates, with its innovation funding programs, incubation facilities, and so on.

Other aspects of the triple helix theory are reflected in the case. The primary author of the triple helix concept grounds the second academic revolution at entrepreneurial universities like MIT.[357] Esktowitz wrote of this transition that:

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[357] H. Etzkowitz, "Research groups as 'quasi-firms': the invention of the entrepreneurial university," *Research Policy* 32 (2003): 109–121.

> Among the most significant changes was the attempt to integrate, in objective and by organizational tie, academic science research groups with industrial companies. Perhaps even more significant in the long run is the development of a new industrial sector based on academic research. Over the past century, at MIT, and then at other universities, academics and industrialists established a series of relationships involving consulting, research contracts, research centers and the formation of firms.[358]

The Boston Elbow fits well with all three sentences, although in the second sentence the word “sector” may be too broad, and “technology” might be better.

Does this case shed any light on a reversal in primacy in science and technology? If a March 1969 *Popular Science* article is any indication of the cultural presumption of the late 1960s, it is science, not technology, that gets the praise. In the article Authur Freese wrote of myoelectrics: “This is the bright hope of a brand-new science that seeks to unite man and the machine into one.”[359]

To Forman’s thesis of a reversal in the relationship of science and technology, was the Newman Laboratory one of the “little science laboratories?” It appears to be a good candidate. The bulk of the activity in the narrative is engineering design at MIT, Liberty Mutual, and Liberating Technologies, motivated by “demands of relevancy,” in this case in the service of amputees. Just as the National Academy of Sciences imprimatur lent prestige to the CPRD, so too cybernetics and the linear model of innovation appears to have helped legitimize the engineering design work that occurred over more than a dozen years to make the Boston Arm a commercial production.

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[358] Ibid, 115.
[359] Ibid, 131.

Last, what were the forces behind the development of the Boston Elbow? The long causal chains must include the work in Germany in the 1940s and Russia in the 1960s. There are also technological changes in battery technology and motors that underlie improvements in the Boston Elbow. Wiener, Bose , Alter, Mann, and Rothchild, Olhenbesch, Russell, Jerrard, and Williams all made important contributions to the project. Glimcher (who may be remembered as chair of the national academy of sciences visiting committee) is a key actor in connecting the interest of Liberty Mutual to reduce claims among amputees with the Russian developments and the capabilities at MIT, however unlikely it would be that the successful development of the Boston Arm would have contributed to Liberty Mutual's bottom line. There is also an argument for a cultural influence. Jerrard supported Eskowitz's argument that there was something different at MIT in the 1960s. According to Jerrard, industry consulting, research contracts, and spin-off companies were to varying degrees part of the MIT culture in the late 1960s and early 1970s, a claim that would seem extraordinary at most other higher education institutions in the United States at that time.

## 6.3 UNB'S IBME myoelectric controls

The University of New Brunswick's (UNB) Institute for Biomedical Engineering (IBME) owes its existence to a request for assistance in 1961 from Dr. Lynn Bashfield, the medical director of Fredericton's Forest Hill Rehabilitation Centre, now called the Stan Cassidy Centre for Rehabilitation. Dr. Bashfield, aware of work at UCLA on new prosthetic devices, asked the UNB dean of science if he knew of anyone who might be interested in the technological challenge presented by two quadriplegic patients. One of the UNB faculty members who attended the meeting convened by the dean of science was a young assistant professor of electrical engineering named R. N. Scott.

**Figure 26: R. N. Scott (Image source: UNB)**

Scott began his bachelor of science degree at UNB in 1950, graduating with twelve other electrical engineers in 1955. According to Scott, education in electrical engineering at the time was mostly practical, with very little theory in the curriculum. There were no electives outside of the eight courses per term. The curriculum did not include anything on solid-state electronics, nothing on computer/digital systems, and control systems theory was very much in its infancy.

The education of undergraduate electrical engineering students was still largely grounded in the craft tradition of engineering, not the applied science practice model emanating from US institutions like MIT and being transferred north via Canadian universities like the University of Toronto. For example, at the start of his studies, Scott was instructed to bring a good pair of pliers and an electrician's knife to his courses. One of the jokes among engineering faculty and students at UNB in the 1950s was: "An MIT student was asked how to reverse the rotation of a 3 AC induction phase motor. The student said you invert the matrix."[360] Those schooled in the craft tradition know that you need only change either of the two of the wires to the motor. You could, the joke goes, either change wires or change the model.

Scott joined the electrical engineering department in 1959. At that time no one in UNB's electrical engineering department had a doctorate degree. There were two faculty members with masters degrees, but, according to Scott, these were almost honorary, based on teaching experience and one paper. The faculty focus was on teaching, not research. However, the dean of UNB engineering, Jim Dineen, a recipient of a master of science degree in electrical engineering, saw the way the future was going and encouraged Scott to do research, even though it would not be

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[360] See also: J. C. Liebman, "Designing the Design Engineer," *Journal of Professional Issues in Engineering*. 115, no. 3 (1989).

easy with the lack of mentors and meagre equipment and budgets in the electrical engineering department.[361]

The result of the meeting to discuss the request from the Forest Hill Rehabilitation Centre was the provision of “low-tech” assistance to the quadriplegic patients to improve control of their wheel chairs and formation of a new group, called “The Technical Assistance and Research Group for Physical Rehabilitation (TARGPR).”

The “low-tech” assistance arose from discussions with Lynn Bashfield and the patients. The idea that emerged was to address a communication and control problem between the person and the wheel chair. Scott contacted the researchers at UCLA. UCLA was building a powered splint that was controlled by a tongue-operated switch. Users were able to feed themselves with the tongue-controlled arm. This was the seed of the idea–that muscles could be used to control a device – that would influence Scott and the Institute throughout its history. For the two patients at the Forest Hill Rehabilitation Centre, Scott built a tongue-operated controller for their electric wheel-chairs. It was, he claims, the most useful thing he did at UNB.

Scott decided to focus on myoelectric controls as it seemed the most promising technology. Of the technical program that developed he said: “We initially defined the objectives in terms of the clinical education, and not in terms of academically respectable research. We did not try not to do good science. We were not at this very long before we needed research to support the application we were

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[361] Electrical engineering was the first UNB department to move in that direction, mechanical engineering the last.

working on."[362] It was far from curiosity driven research, even for engineers, so much so that when the groups received initial funding from Canada's department of health, the first thing was not to hire graduate students, but professional technical staff. It was only afterwards that Scott realized that he could develop research topics that could be undertaken by graduate students.

The first graduate student to fill this role was Phil Parker, originally an electrical engineering graduate student of Scott's in the early 1960s, and subsequently a faculty member for twenty-nine years in UNB's department of electrical engineering. Both were interested in research to assist in developing a system to meet clinical requirements. It made for a good fit. Scott directed the Institute. He and Don Dorcas designed the control system. Parker developed the algorithms to control the switching levels among limb functions.[363] Parker was its research leader, with a focus on understanding the human neuromuscular system and control of prosthetics limbs.[364] Instead of importing systems from elsewhere to produce makeshift solutions, such as hardware from UCLA to make a tongue-controlled wheelchair, UNB now had the people to develop concepts and conceptual designs and implement them into engineered systems.

It was the changing of an era at UNB. Parker obtained his doctoral degree from UNB under the tutelage of Scott, the director of graduate studies in the department and recipient of a mere bachelor of science degree. In 1965, the

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[362] R.N. Scott, author interview, May 5, 2010.

[363] By 1975, the advances were published, permitting prosthetists to optimize the switching levels in a three-state system.

[364] Among his career achievements, Parker was invited to give the Basmajian Lecture at the International Society of Electromyography and Kinesiology—an honour afforded to those truly outstanding in this field.

informal, unincorporated and unaffiliated technical assistance and research group for physical rehabilitation (TARGPR, which, uncharacteristically of the age, emphasized technical assistance ahead of research), was constituted a UNB research institute by the senate and board of governors to undertake interdisciplinary research involving more than one faculty.[365] Named the Bioengineering Institute,[366] it was operationally and financially responsible to the senior UNB administration. The Bioengineering Institute was given a three-fold mandate that mirrored that of the university: teaching, research, and community service. The applied science model of engineering had come to UNB, as it had at many Canadian and US engineering schools in the 1960s.[367]

There were influences other than the applied science model of engineering research. The Institute was also influenced by the CPRD and the approach it fostered to research and development. Scott attended the conferences the CPRD hosted in 1961, 1963 and 1965, and learned about its model of research, development, testing and evaluation of new prosthetic devices.[368] Although the presentation of formal conference papers was often an excuse to obtain funding to attend the conference, according to Scott it offered excellent informal opportunities

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[365] In managing the group R. N. Scott was spending most of his time at UNB, supervising a staff of about a dozen involved in development, some clinical practice and research. Neither his wife, Joan, nor the dean of engineering, Dr. Jim Dineen, objected. However, Dr. Dineen suggested this arrangement was not fair to the department of electrical engineering. Sensing a lightening and openness of the mood of the UNB president, Colin B. Mckay, at one of their regularly scheduled meetings, the dean pulled from the bottom of his file a proposal for a new bioengineering institute. With no business plan or models presented, no supervisory group or structure, the president said "yes that sounds good," and at the next senate meeting in 1965 the Bioengineering Institute was approved.

[366] Subsequently it was re-named the Institute of Biomedical Engineering,

[367] In some engineering departments at UNB, such as surveying and chemical engineering, it was there at the outset in 1960.

[368] R.N. Scott, author interview, May 5, 2010.

to learn about advances in the field.[369] It was through the CPRD that Scott learned from Dudley Childress that effective myoelectric controls must provide for feedback to the person.[370]

Another major external influence on the development of myoelectric controls at UNB was the thalidomide tragedy. The use of the new drug thalidomide resulted in severe congenital abnormalities among infants in Europe and Canada. One of the Government of Canada's responses to the tragedy was to fund through the department of health "prosthetics research and training units" (PRTUs) in Montréal, Toronto and Winnipeg.

According to Scott:

> At the same time, it sought existing research in Canada that might be relevant, and invited TARGPR to re-focus its efforts toward the Thalidomide problem, offering very significant levels of funding. The Group agreed to investigate means of enhancing communications and control for persons with congenital limb deficiencies, with emphasis on myoelectric control. (It was noted that any advances there would also be helpful to arm amputees.) A condition of the related funding was that TARGPR would collaborate with the three PRTUs. This was important, as the group in Fredericton otherwise had no direct access to any medical research centre or, indeed, to any significant caseload from the Thalidomide victims or limb amputees. Through the newly mandated collaboration, access was provided to all Canadian Thalidomide victims, to medical centres in major Canadian cities, and as well to international prosthetics research and development activities through the Committee on Prosthetics Research and Development of the US National Research Council. It would be impossible to overemphasize the importance of this collaboration to the development of the work in Fredericton. As was the case with the PRTUs, all of the research was directed toward practical clinical application in the short term. Indeed, the

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[369] In contrast, patents, according to R. N. Scott, were not a useful source of information as commercially viable activity was very narrow and so few in the field saw the need to patent. The journals announced advances a year or two after they were disclosed at conferences or through informal channels, and so were also not useful at the cutting edge. If teams did not know about an advance before it was published in a journal, they were much too late.

[370] R.N. Scott, author interview, May 5, 2010.

> complaint was made from time to time that the work was too practical to constitute academically respectable research.[371]

According to the Institute's next director, Ed Biden, it was a once in a life-time opportunity: a brand new field with substantial long-term funding.[372] Indeed, it was a novel step to include an electrical engineering group from New Brunswick in the work at the three other research and training units in Montreal, Toronto and Winnipeg. As the authors of the 1963 *The Report of the Expert Committee of the Habilitation of Congenital Anomalies Associated with Thalidomide* wrote: ". . . limb abnormalities . . . can usually be met by existing paediatric facilities, particularly within university centres."[373] These were teaching hospitals associated with university medical schools, and it was here where the expert committee wanted the training courses to be located because of the already, ". . . very close relationships between the prosthetist, the physiatrist, and the orthopaedic surgeon."[374] But the expert committee also foresaw that: "The use of external power in artificial limbs is in its infancy, and will undoubtedly be required in the long-germ (sic) management of severely involved phocomelic children."[375] But the expert committee's recommendations only called for the development of three ". . . training and research centres. . . ." at Winnipeg, Montreal and Toronto, with no mention of

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[371] R.N. Scott, author interview, May 12, 2010.

[372] Ed Biden, author interview, May 5, 2010.

[373] Department of National Health and Welfare, *The Report of the Expert Committee of the Habilitation of Congenital Anomalies Associated with Thalidomide*, 1963, 1.

[374] Ibid, 3.

[375] Ibid.

electrical engineers among the list of critical professionals to be associated with these units.[376]

UNB's Bioengineering Institute was subsequently added to the list of the three other centres. R. N. Scott wrote on UNB's addition: "As to our inclusion, we were probably the only group in Canada actually conducting research relevant to new concepts in prosthetics. The work was oriented to control of powered orthoses for high-level quadriplegics, and the Feds were either funding it or being asked to fund it - not sure which - when the thalidomide "crisis" arose and the federal minister of health announced that her government was going to "solve" this crisis by creating a collaborative network of what we're now calling centres of excellence. . . . Toronto, Montreal and Winnipeg had interdisciplinary clinic teams in place, but no research funding (or mandate)."[377]

However, there was in the last appendix to the expert committee report another report prepared by the Department of Veterans Affairs prosthetic service centre.[378] It focused on the prescription and fitting of prosthetic appliances. It reviewed the state of the art, including experimental developments in external power. It mentioned that external power projects were new and development would be needed to design upper limb prostheses, and the requirement for research to be, ". . . performed by specialized people in research establishments. . . . and that a method of coordination be established . . . "[379] for the research units.

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[376] Ibid, 5.

[377] Ibid.

[378] R.E. Gilpin, Department of Veterans Affairs, Canada Prosthetic Services Centre, *The Prosthetic Treatment of Children with Congenital Deformities of the Extremeties, Report No. 28,* Government of Canada, October 1962.

[379] Ibid, 34.

The annual award to UNB from Canada's Department of National Health and Welfare was $50,000 per year (beginning in 1963), enough to hire, technical professional staff. UNB was unique in this staffing approach. U of T, UNB's closest PRTU collaborator, had research staff, not practicing engineers and technicians. The research staff approach was consistent with the funding, which was to be used for research and training of prosthetists. In progress reports, Scott sought to have the word "research" in every paragraph, to make clear the distinction between research, on the one hand, and patient care, on the other, which was a provincial responsibility. According to Scott, "That is a lot easier to define on paper than in the hospital."[380]

The four centres were required to meet twice a year to exchange information and work together. This was particularly important for UNB, as it was the only centre not in a university medical school, and so this connection to the other PRTU's provided direct access to patients and hospitals in the context of application. The U of T connection was particularly important. Others were less useful. According to Scott, the program could not "legislate collaboration" and, as may be expected, some PTRU meetings were less about collaboration than forums for presentation of success stories, with little discussion of the many issues that were yet to be addressed in developing useful devices for clinical practice.[381] The experience of failure, a great source of learning, was not spoken of at these meetings.

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[380] R.N. Scott, author interview, May 12, 2010.
[381] Ibid.

In the end, the Department of National Health and Welfare funding was not able to meet its goal of providing useful devices for victims of the thalidomide tragedy. This was not for lack of trying or development of useful devices for upper limb amputees. But most of the children effected by thalidomide had small upper limbs with normal sensation. The limbs typically permitted them to feed themselves, in many cases with fingers that were functional. Covering this up with an artificial limb was often not helpful.

Another external influence was the publicity and concept of the Russian Hand. The influence was twofold. It generated a lot of media attention, like the Sputnik satellite launched in 1957, more so than local works in progress. This raised both questions and expectations at Canadian and US universities. According to Scott, it was also "a good example of the idea being right but the technology not being there as the Russian Hand had a slight closing force, one size only (adult male), enormous power requirements, and quality issues with batteries (sometimes exploding when recharging)."[382] The Canadian licensee of the technology, the Rehabilitation Institute of Montreal (RIM), made electronics that were better in 1964, but were still not good enough for clinical practice.[383] Scott said that the publication of the concept of a myoelectric hand at Expo 1958 in Brussels opened up the imagination of engineers at UNB and elsewhere to the potential of basic design concept.[384]

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[382] Ibid.

[383] David Sherman, "A Russian Bio-Electric Controlled Prosthesis: Report of a Research Team from the Rehabilitation of Montreal," *Canadian Association Journal of Medical Practice* vol 91, (1964): 1268-1270.

[384] The UNB group did not see the Russian Hand directly, but did see and evaluate improved versions made by the Rehabilitation Institute of Montreal.

As it turned out, one of UNB's major contributions to the advancement of myoelectric hand technology was in signal processing. A challenge with signal processing was in trying to get an overall prosthetic package that was the right size and shape to match normal limbs, and to avoid bumps and bulges in accommodating the electronics. The importance of this concept came from collaborations with U of T. Throughout the early and mid-1960s UNB was committed to the idea of prosthetics as primarily functional devices, the equivalent of "pliers on wires".[385] John Hall, head of pediatric orthopaedics at the University of Toronto, introduced the UNB group in 1968 to a fifteen-year-old girl missing a limb below the elbow. She was highly functional with her prosthesis. She had been wearing a conventional prosthesis held on with a harness strap. But in her words she wanted Hall "to take that damn thing away from me." It didn't look good or fit. The message from Hall and the patient was that they wanted something comfortable, good looking, and last, but not least, functional. The UNB group had been focused on making an electric pair of pliers work better. That was a turning point for Scott. UNB's focus would have to change to listening to the patient, and fitting the technology to the requirements of a comfortable and attractive prosthesis.[386]

This allowed the Bioengineering Institute and the OCCC to get ahead of the pack in the development of myoelectric controls for integration in a natural looking and comfortable prosthetic device. In other words, the electronics and myoelectric

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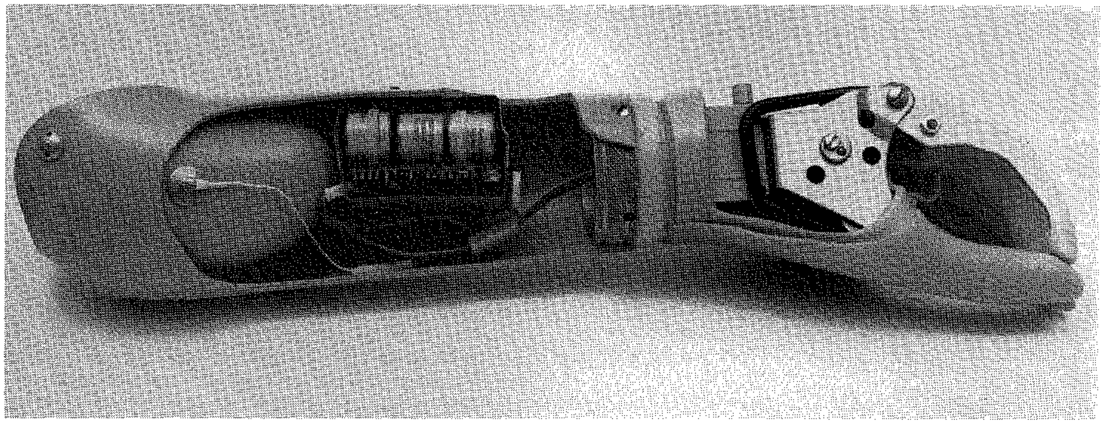
[385] Ibid.

[386] Patients were primarily children given the focus of the department of health funding. Unlike research at MIT and US rehabilitation research centers, the focus at UNB during the 1960s and 1970s was not on veterans.

controls would be built into the arm, not worn outside the prosthesis. A second novel feature of the UNB myoelectric controls is that it was not a highly intelligent device requiring minimal input from the user. The UNB group found that this design faced a psychological issue for patients. They did not get the same sense of satisfaction from a device that was highly automated (i.e. a device that responded to the command "feed me" by moving the arm and hand in a pre-programmed pattern to lift a spoon to a mouth). Scott recalled that quadriplegic patients at the local rehabilitation centre wanted a wheelchair they could drive, and did not want to be driven or pushed. For Scott it was about the feeling of being in control.[387]



*Below-elbow prosthesis with UNB 3-state control and Otto bock hand, cut away to illustrate components.*

**Figure 27: UNB myoelectric controller and Otto Bock Hand (Image source: UNB)**

A second major UNB contribution to the field, and to the industry, has been the MEC (myoelectric controls) Symposiums. First held in 1972, the focus of the symposiums has been on providing a forum for the presentation of papers on novel aspects of powered, upper limb prosthetics. In keeping with the common practice of conference organizers, MEC organizers have made the symposium a

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[387] R.N. Scott. author interview, May 5, 2010.

multidisciplinary event, including researchers, developers, prosthetists, prosthetic technicians, occupational and physical therapists, social workers, psychologists, physicians, surgeons, and manufacturers. Attendance figures rose in the 1970s, fell in the 1980s and 1990s, and then rose again in the 2000s with changes in funding for the field. Conventionally, all of the major manufacturers appear at the symposiums. Initially an annual event, it is now held every third year.

The year 1975 marked a major turning point for the UNB Institute: funding from the Department of Health and Welfare came to an end. At the time the Institute was running a budget of about $500,000 per year, and it was all "soft money," external funding to UNB. The largest sum was from the Department of Health and Welfare, provided under annual contribution agreements, announced a few days after the beginning of the new federal government fiscal year, April 1. Having been in regular contact with the department and with no indications that their funding would be cut, on April 10, 1975 the Institute was informed that there would be no contribution agreement for fiscal year 1975-76. Scott speculated that the program was terminated for political reasons.[388]

To help the Department of National Health and Welfare frame a decision on what to do in the area of prosthetic services, the federal government commissioned a report in 1973 from the chairman of the University of Ottawa's school of medicine sub-department of rehabilitation. Entitled *Prosthetic Services Study,*[389] it concluded there were three solitudes: (i) the prosthetic services of the federal government,

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[388] R.N. Scott, author interview, May 12, 2010.

[389] Bernard Talbot, *Prosthetic Services Study, No 228*, unpublished report for the Government of Canada.

(ii) the commercial sector, and (iii) universities and hospitals. It found that ". . . in most instances, Prosthetic Services seem to be weak in the areas of prescribing, manufacturing, fitting and servicing upper extremity amputees; the Commercial Sector is often found to be weak in servicing and maintaining, etc . . . "[390] It concluded: "If consolidation of resources seems logical in some regions, a "national" approach seems desirable to Research and, furthermore, to meet the needs of those patients few in numbers who present complex problems,"[391]

The study did not sit well with Dr. J.D. Coping, a medical doctor with the Department of Health and Welfare. His internal memorandum found the study ". . . biased from the beginning. . . ."[392] He also authored a 1973 report on behalf of the government's prosthetics services division entitled *Prosthetics Services Management Review and Other Related Material*. It called for a large role for the federal government's prosthetic services group, and raised questions about the university and clinical research groups. According to the review, there were problems with the supply side of the linear model: "The volume of devices emerging from the several research units in Canada was grossly exaggerated at the time the [PETT] Unit was set up, and after a year or two of operation, found itself in a position of having no new devices worthy of putting into production. They then undertook a programme of finding other researchers, testing commercially

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[390] Ibid, 17.
[391] Ibid, 19.
[392] Memorandum from Dr. J.D. Coping to M14, dated January 11, 1974.

available products, doing some research work on their own and involving themselves in some special fitting cases in the Toronto area."[393]

The emphasis was on continued operation of the federal government's prosthetics services division:

> Prosthetic Services operates a Production Engineering, Testing and Training Unit, consisting of two (2) registered professional engineers, a prosthetist-orthotist, and a design and technical section. The function of the unit is to conduct research, development and evaluation of prosthetic and orthotic devices and techniques . . . and to manufacture or purchase, test and evaluate appliances and component designs which originate in any of the research establishments in Canada, and in the event that the design is found suitable and useful, do the production engineering studies; order pilot production runs, and do follow-up studies until the device is ready for purchase through the distribution system." [394]

The PETT unit was the missing link in the linear model: "The PETT Unit is set up to bridge a gap between the researchers in the prosthetic and orthotic field, - who determine the need for the special devices and components, design them to suit the need, build and test prototypes, - and suppliers . . . Their function ends when the product is in such a condition that commercial production can be arranged by *any* manufacturer.[395] The major conclusion was: ". . . in the opinion of the management there is, and will continue to be, a large role for a federal agency, both in the service and in the supply fields. . . . In the Service element it is felt that the prime function should continue to be the treatment of patients. However, of almost equal importance is the continued development of appliance delivery systems, involving organizational and functional experimentation on a scale for which no single private or institutionally-based facility could muster sufficient

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[393] Ibid, 13 and 14.
[394] Ibid, 9.
[395] Ibid, 13.

human or financial resources."[396] By 1977, it was resolved that the PETT would be the major federal R&D laboratory and it was handed over to the National Research Council.

To fill the gap created by the loss of federal government funding, UNB's vice president, finance and administration, Jim O'Sullivan, provided the institute with "bridge funding, said not to nickel and dime yourselves, don't lay off people, and talk to the head of the development office, Susan Montague, about other funding sources."[397] It took about four months to secure new funding from a national bank, CIBC. The funding was in the millions of dollars,[398] had no strings attached, but with the obligation that UNB prepare press releases with the bank's public relations people.[399]

With changes in funding came changes in focus. Funding from the Department of Health and Welfare was for clinically targeted R&D. This meant prototyping of new controls with third-party hardware and clinical fittings. The CIBC money was for Institute directed research, to be used in developing new controls for prosthetic hands. Funding from the bank, although short-lived, provided a catalyst for the Institute's activities to become more research oriented, and permitted co-funding applications to national granting councils, such as the Medical Research Council and the Natural Sciences and Engineering Research

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[396] Ibid, 15.

[397] Ibid.

[398] The funding continued into the 1980s, and was expanded to cover items such as start up of an injection molding operation run by Mr. Murray Olive.

[399] Ibid. Another important foundation for financial stability came in the form of a contract with the provincial department of health. Beginning in 1972, the IBME has delivered a clinical engineering program for New Brunswick hospitals, which has evolved to focus on consultation and inspection services for health care facility new construction and renovation activities. The program continues to the present.

Council.[400] There were also collaborative R&D projects with Liberating Technologies Inc. and RSL Steeper in the United Kingdom. It was part of a broader move to a research culture.

Scott's role changed as well. Although the myoelectric control system development was still not theoretically oriented, he began writing research grant applications. This required him to frame technical issues in terms of theories from the academic literature, but according to Scott he was not sure he believed any of them.[401] Scott wanted answers to questions that arose in developing new systems and products. If researchers could answer the questions, then so be it. But ultimately he wanted answers, and didn't care where they came from."[402]

**Figure 28: R. N. Scott Hall on the UNB Campus (Image source: UNB)**

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[400] "I should recognize . . . I cannot recall ever in the time ever since the early 1960s until I retired in 1985 I cannot ever recall going to the administration and having been turned down. There was an incredible level of support from the administration." R.N. Scott, author interview, May 5, 2010.

[401] Ibid.

[402] Ibid.

In 1981 the Institute developed a regional limb fitting clinic and service, a myoelectric controls manufacturing group and a distribution group, all led by a long-time Institute technician, Bob Caldwell. Originally housed in an off-campus suburban neighbourhood, only the limb fitting service has continued into the present as an Institute operation, now housed on the main floor of the IBME's R.N. Scott Building. The manufacturing and distribution business, also conceived as an IBME activity, was relatively short lived.

The concept behind the manufacturing and distribution business was that it would make and sell products developed by Institute researchers as well as distribute products in Canada for firms such as Liberating Technologies Inc. in the US and RSL Steeper in the UK, with profits distributed back to the Institute to further the research agenda. Mark ups on UNB-based products were modest. For example, in 1980 a myoelectric trainer that had a cost of production of $3,300 was sold for $3,500.[403] It was a novel and unconventional approach. The convention was (and still is) for universities not to sell biomedical products, but rather to license technology to firms that can afford the cost of commercial or clinical product development and accept the liabilities that go along with product sales and service. However, with the exception of a handful of mostly US institutions such as MIT and the University of Wisconsin, these were still early days for university technology transfer and new product development. The Bayh-Dole Act had been passed, but the creation and staffing of technology transfer was just getting started.

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[403] Ibid.

According to Biden, the Institute's second director, who would take over from Scott in 1990, the fitting service and manufacturing and distributions groups (which were all treated as one functional unit) were losing money.[404] It was not just the small mark up on products, but low sales numbers. In the biggest sales year, twenty-two systems were sold. The decision to wind-up the manufacturing business occurred at an advisory board meeting in 1989, chaired by the then vice president of research, Frank Wilson. Initially the board decided to sell the fitting service, manufacturing and distribution businesses, but was subsequently persuaded by the Institute's Ashok Mazumber to keep the fitting service on the basis that the Institute's reputation relied as much on the fitting centre as it did on research. In 1989, the rights to the locally manufactured products were sold to Liberating Technologies Inc. for one dollar. This meant that some Institute technology found application in Liberating Technologies Inc. products, whereas others, such as the UNB wrist controls, were shelved. With the wind-up of his operation, Caldwell left the Institute and bought the distribution side of the business and became the Canadian distributor for Liberating Technologies Inc. and RSL Steeper. The Institute brought back the fitting service to its campus location.

Biden was also a UNB engineering graduate, although in mechanical engineering, not electrical, and with a doctoral degree from the University of Oxford. Unlike Scott, who saw the linear model as a reasonable approximation of what he did at the institute (although with applied science as the starting point),

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[404] E. Biden, author interview, May 5, 2010.

Biden saw the "spaghetti on the plate" analogy as closer to the truth.[405] Whereas Scott had focused his and the Institute's resources on myoelectric upper limb prosthetics, Biden reached out to a variety of groups on campus and off campus; he led strategic planning exercises and broadened the Institute's activities to include more mechanical related projects and motion capture-based research on gait analysis, and subsequently upper extremity analysis. Whereas the reputation of IBME was based on Scott's reputation, with the change in leadership it fell to a number of researchers, including Parker, Biden, and two of Parker's student, Bernie Hudgins (now the third director of the Institute) and Kevin Englehart (the associate director of the Institute). But there was also continuity, both in the staff, and in Scott's model of having technology development activities and limb fitting work performed by professional staff, with student efforts informing and feeding into this work. Biden also built on relationships with LTI and RSL Steeper to develop collaborative R&D projects, although this turned out to be a struggle for many of the typical reasons, such as differing expectations about time frames and deliverables.

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[405] Ibid.

**Figure 29: UNB IBME Faculty and Staff in 2012: Greg Bush is sitting second from left. Kevin Englehart is sitting on the far right. Bernie Hudgins is standing fourth from left. Phil Parker is standing fourth from right. (Image source: UNB)**

The current director, Hudgins, who took over from Biden in 2000, also received his undergraduate and doctoral engineering degree from UNB. His earliest publications were co-authored with Scott, and Parker, his dissertation supervisor. He began work as a research engineer at the Institute in 1980 after his undergraduate degree. His master's work addressed the basic problem of understanding a signal from a muscle contraction. The doctoral program advanced on the master's thesis, seeking to understand myoelectric signals and examining how they arose, as well as control systems. It was funded in part with a grant from NSERC under its collaborative research and development program and support from both Steeper and LTI.

During Hudgin's tenure researchers looked at expanding the control systems from three states to five states (i.e. to control a channel: rest, hand on, hand off, elbow on, and hand off). This, it turned out, confused people and so three-state feedback was developed during the 1980s. The path turned out to be another dead end, as researchers learned that trying to control more than two functions (open and close) using one channel and one signal was impractical.

But another research path that opened up in the late 1980s and early 1990s was directed toward the application of pattern recognition for control of myoelectric prostheses. According to Hudgins "We had gone through twenty years of a lull in the field" since the introduction of myoelectric systems by UNB and others in the 1960s."[406] Indeed, the control systems for single function electronic hands (e.g. that can only open and close) for below elbow amputees have remained unchanged since the late 1960s to the present.

Pattern recognition techniques are not unique to the myoelectric field, and are broadly applied in a number of fields. Pattern recognition technology, for instance, is applied in email programs to sort spam and non-spam email messages based on specific indicators (e.g. "estate executor" combined with "wire transfer" results in movement of an email message to the spam box). At the time there was much interest in the potential of neural network black boxes that could sort data that was difficult to understand into compartments. For the myoelectrics, the challenge was sorting the muscular signal for different uses (e.g., opening a hand and closing the hand). The aim was for the computer program to determine what was unique about it so it could be used for control. With each new contraction of a muscle, the pattern recognition program analyzed the new data against the old data, and then selected a predefined movement (e.g. open hand). UNB initially developed pattern control systems for Steeper, although they were not used in

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[406] B. Hudgins, author interview, May 5, 2010.

commercial products. As with the myoelectrics systems, it took more than two decades to apply the concept in clinical products. According to Hudgins, the biggest problem UNB encountered with pattern recognition was the training, although this is now changing with plans for Otto Bock, LTI, and UNB to include these systems in their myoelectric products.[407] For Hudgins this has meant persevering towards a long-term research goal of increasing the number of devices under control of the myoelectric signal, and thus finding ways to extract and exploit more information from the signal. This has meant continuously applying improvements in signal processing techniques to enhance the pattern recognition system.

One of the leaders in the application of digital signal processing to myoelectrics is Hudgins's colleague, Englehart. Like Hudgins, all of his electrical engineering degrees are from UNB. He is currently both a professor of electrical and computer engineering as well as associate director of the IBME.

According to Englehart, advances in the field have been bedeviled by challenges in developing systems and getting them to work with users. As a result, the manufacturers have had to be very conservative in the adoption of new technologies. But, nevertheless, there has been progress. A language has been developed, which physicians, surgeons and engineers use to work together. Second, there has been a move from "a very use oriented field, focused on how to make prosthesis work in the 1960s, to interest in the 1970s in the concept of a "man-machine interface,"[408] and then in the late 1970s a focus on commercialization of

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[407] K. Engelhart, author interview, April 23, 2010.

[408] Ibid. Engelhart mentioned the Debrovnik Conferences as one of the important symposiums for the research that came out of that era.

devices and use-oriented application of EMG signal processing."[409] And then, according to Englehart, advances in myoelectric controls sort of died for fifteen years with no fundamental change. What brought the field out of this lacuna was Hudgins's dissertation in 1991, which created an interest in the application of pattern recognition to EMG control, and was followed by hundreds of papers written thereafter.[410] For Englehart, it was here that he saw a role and potential for science. The relevant questions were how to make it work and how to measure it to improve the user experience.

Englehart combined this influence from Hudgins's work with experience he gained while working for Bell Northern on embedded systems–specific purpose computers embedded in another device. His doctoral dissertation presented a language for using pattern recognition in the field, and a series of papers he published in the 1990s demonstrated that it could be done with modest computer systems with low power requirements. The objective of his subsequent research has been ". . . to deliver clinically robust, dexterous control to myoelectric prostheses."[411] This means taking pattern recognition methods from controlled laboratory settings to clinical application in user's homes and at work. It also requires not just a new signal processing paradigm, but also developing new training programs for prosthetists, occupational therapists and users. The concepts have found their way into prototype upper limb devices built for Steeper, RIC, Johns Hopkins, and UNB (supported by a regional innovation funding program,

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[409] K. Engelhart, author interview, April 23, 2010.

[410] The paper based on the dissertation has been cited 436 times, according to Google Scholar on October 2, 2011. See: B. Hudgins, P. Parker, R.N. Scott, "A new strategy for multifunction myoelectric control" *IEEE Transactions on Biomedical Engineering*. 40, Issue 1, (1993), 82-94.

[411] http://www.unb.ca/research/institutes/biomedical/research/projects.html

described below). According to Englehart, "I did not see where the work was going, and was lucky to have met the right people to take the work from scientific bench-top curiosity to work and be relevant to the field."[412]

For Englehart, this experience of developing new systems in collaboration with other groups, often in international partnerships, has been part of a larger trend: "Teams that worked in isolation now work together. There is still a Europe vs. North America, although even that is now breaking down."[413] Englehart's international collaborations included work on neural interfaces and devices for the "Smart Hand" project led by Dr. Maria Chiara Carrozza, director of the Piaggio Research Centre at Pisa University. UNB has also been a subcontractor to two major DARPA funded projects under its revolutionizing prosthetics program: an $18.1-million program awarded in 2007 to DEKA Research and Development Corp. of Manchester, New Hampshire; and a $30.4-million program awarded in 2009 to the Applied Physics Laboratory (APL) of Johns Hopkins University. Both focused on the application of TMR and use of UNB's pattern recognition control system. The inroad for UNB was its long standing expertise in pattern recognition, and the partnership that Kevin Englehart had developed with Todd Kuiken at the Rehabilitation Institute of Chicago.[414] Englehart called it a big change from the "isolated

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[412] K. Engelhart, author interview, April 23, 2010.

[413] Ibid.

[414] Ibid. Their partnership has been focused on advancement on targeted muscle reinervation or TMR, which Dr. Engelhart calls the only thing that seemingly came from nowhere. It had been originally been performed by surgeons on rats to try and give some volume to a limb or sensory perception.

engineering for ten years," that predated their first meeting in 2002 and Dr. Englehart's move into physiatry, or rehabilitation medicine.[415]

A major source of R&D funding for the IBME in the 2000s has been a regional federal government funding body, the Atlantic Canada Opportunities Agency (ACOA), in particular its innovation funding program (AIF). UNB has been the recipient of three AIF awards in response to proposals submitted on behalf of the IBME. The first, for $1.9 million and awarded in 2003, was for the development of a wireless e-health device for the rehabilitation field. The second, in 2007, was for a $2.9 million sponsorship for a five-year project to develop a prosthetic hand. The estimated cost of the project was approximately $4.3 million. The third project, announced in 2010, was to develop a portable bio-tone toolkit for performance assessment of muscle impairment. This award was for $1.9 million over four years, with total estimated costs of $2.5 million.

The UNB Hand Project was structured to develop a commercially viable prosthetic hand, complete with user testing results from six North American rehabilitation clinics. As ACOA is a regional economic development body, emphasis was placed on commercialization. The funding announcement mentioned not just user groups, such as military amputees returning from Afghanistan and Iraq, but also the overall market size, approximately 60,000 in the United States and Canada, projected market growth of an additional 2,300 hand amputations annually, and the UNB Hand's value proposition: compact and lifelike, like the i-Limb from Touch Bionics and the bebionic hand from RSLSteeper, but different in offering sensory

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[415] Ibid.

feedback (addressing a long-term cybernetic goal) and a lower price. The stated price goal for the UNB Hand was $20,000, compared to approximately $100,000 for the i-Limb. The regional economic development mandate was also a factor in the recruitment of local partners to the project. The UNB nanotechnology chair was included to create the prosthetic gloves and a thin-film research group from the nearby Université de Moncton to supply the sensors to be built into the multilayer glove.

Dr. Englehart captured the tension in research that is oriented to both fundamental knowledge and customers, that, in Donald Stokes's model, fits into Pasteur's quadrant.[416] "This institute has a very strong culture in myoelectrics and does it very well. We have a clinic that grounds the research and provides a daily reminder of where the research needs to go, but that does not mean it guides the research. We do EMG and do very little outside of the prosthetics field (which is a minor part of the EMG). We have a well defined niche."[417] According to Englehart, the Institute has changed from Scott's focus on keeping the technology simple and trying to implement what works, to an emphasis on clinical over commercial activities during Biden's tenure. Hudgins and Englehart, under the mentorship of Dr. Parker, began their careers by publishing important work and establishing reputations in the academic realm, and then moved into applied work and international collaborations when the new innovation funding was there to support it.

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[416] Footnote 93.

[417] K. Engelhart, author interview, April 23, 2010.

## UNB Case Analysis

Opinions were mixed among interview subjects about the applicability of the linear model of innovation.[418] Scott said it was linear, but with feedback loops, so that sometimes it was one step ahead and two steps back. The starting point for his view of the model was applied research.[419] Bush had a similar view.[420] For Parker, basic and applied research moved back and forth over issues, and only after the proof-of-concept stage could the process appear to be linear. Biden was also critical of the linear model. He also observed that from the 1980s until quite recently the transition from university research on myoelectric controls to commercial systems has been frustrated by the fact that the controllers were more sophisticated than hardware.[421] Peter Kyberd, the Canada research chair in rehabilitation cybernetics at UNB, said that in the 1980s, in Europe, there was a change in all medical R&D from a paternalistic top-down approach to a more consumer-led approach, with North America following somewhat later. This would have meant more technology pull, and less linearity, if applied within the field of prosthetics. Englehart disagreed with what he called the waterfall model. He said that: "Until we can develop some kind of platform that will allow for the ideas of

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[418] Descriptions of the linear model, mode 2 and triple helix were provided to each of the UNB interviewees. The linear model was generally familiar to the researchers. The specific mode 2 and triple helix concepts were new to all, although appeared to be readily understandable.

[419] R.N. Scott, author interview, May 5, 2010.

[420] G. Bush, author interview, May 14, 2010.

[421] E. Biden, author interview, May 5, 2010. Biden said there are now some devices more sophisticated than the controllers, as a result of more mechanicals or mech-electronics getting into the field. A contemporary example of the control system getting ahead of the hardware arose in the Boston Arm case, presented below. Myoelectrical information from amputees with reinnervated muscles and pattern recognition control systems allow for natural movement of the arm, but generated more information that could be used by hardware that was designed for simpler two-state controllers and sequential movement. The commercialization issue is similar to trying to sell Word 2008 for computers designed in the 1990s.

neuroscience to be tested effectively I don't think we are going to see a compartmentalized process like the linear model."[422] He also agreed with Scott that the process was characterized with multiple feedback paths. Hudgins commented not on the linearity of research, but on the view held by funding agencies, saying it had been a linear process, but now basic research is being cut out of the model.

It can be said that there are two UNB cases: one design-engineering case that lacks the fundamental research base, and a second focused on pattern recognition research that has only begun to move into clinical application. The origins of the technical assistance and research group for physical rehabilitation (TARGPR) did not embody the linear model. Rather, it reflected the craft approach to engineering design (beginning with need, not research), not the ascendant applied science model. As the name suggests, technical assistance came first, and was subservient to ends of physical rehabilitation. This was the case with the "low-tech" assistance to quadriplegic patients to improve control of their wheel chairs. Objectives were defined in the clinic, not in the laboratory. Research was a means to the end of technical assistance, and was acquired only when it was discovered that issues could not be solved with existing knowledge.

But in the 1960s Scott knew that the research model was coming to UNB. At the CPRD conferences he attended in 1961, 1963 and 1965, he learned about its model of research, development, testing and evaluation of new prosthetic devices.

Ironically, the transition from the department of health one-year grants to CIBC funding was behind both an increased focus on research and expansion into

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[422] K. Engelhart, author interview, April 23, 2010.

production. Scott characterized the department of health money as "focused on clinically targeted research, and the CIBC money was about development."[423] He said, "It drove research more to the academic side so we could do better with the Medical Research Council and the Natural Sciences and Engineering Research Council."[424] But it was also used to make a new myoelectric hand. According to Scott: "Before the CIBC project it was prototyping and clinical fittings. During and after it moved to production." Eventually, he said that UNB moved away from manufacturing because commercial fabricators like Liberating Technologies Inc. and centres of influence, like the Rehabilitation Institute of Chicago, began incorporating some of their ideas into their products and systems.

It was the research culture within electrical engineering at UNB that grew as the craft tradition withered at UNB. With the growth in research funding programs in the 1980s, 1990s and 2000s, promising students were trained to do research. New faculty members were hired with appointments in the IBME. In embracing the research culture UNB was able to move to the forefront of myoelectric control research. Whether there followed practical application of new knowledge, new products and processes, and production and diffusion, depends on your timeline. With the VASI products, basic research was not the major influence, and the design process was more user-focused trial and error than a straight step-wise process. There is a better argument for linearity with pattern recognition, although it has not yet moved squarely into the production and diffusion phases.

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[423] R.N. Scott, author interview, May 5, 2010.

[424] Ibid.

On the move from mode 1 to mode 2, Scott said it is changing in the other direction, and that "the graduate work that is now central, came fairly late on in the history of this place."[425] Biden agreed that the IBME has become more research oriented.[426] Likewise, Greg Bush said "At UNB the research culture has been constantly growing."[427]

Parker saw it differently than Scott and Biden. Parker said research on signal processing is now more focused on outcome measurement and asking how well can patients use these signals. This, he said, is evidence of a move to a more patient focused research culture.[428] Hudgins' view was consistent with Parker's. He said that researchers are now aware of those other alternate definitions of what a good research result is, and recruit interdisciplinary teams into their R&D projects at UNB.[429]

Hudgins also said the R&D culture had changed from the days when Scott led the IBME and engaged directly with prosthetists, patients, and others and used Parker's research work when he needed information to develop a system. As the funding for myoelectric research dwindled from the mid-1970s to the late 1980s, the research focus was limited to fundamental issues. With the rise of new innovation oriented funding programs, asking that products be developed and commercialized, UNB has been able to tap into larger pots of money. In the case of the UNB Hand Project, he said that where they once were "research engineers" they

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[425] R.N. Scott, author interview, May 5, 2010.

[426] E. Biden, author interview, May 5, 2010.

[427] G. Bush, author interview, May 14, 2010

[428] P. Parker, author interview, April 23, 2010.

[429] The drive to outcome measurement is not unique to the field, and appears to have made inroads to the field from a variety of sources, i.e. insurance companies, researchers, prosthetist professional organizations, and companies.

are now really “development engineers,” and this has changed from the practices three decades ago. It is the difference between hypothesis driven research that uses design engineering towards that end, and design-based experimental development oriented to product development.

As to the triple helix concept, basic research did not appear to be strongly linked to utilization through a series of intermediate processes involving government, university and industry collaboration. In the UNB case there has been long term involvement of government and universities. What was missing was strong industry collaboration, at least with respect to R&D. Although the NSERC collaborative research and development program provided funding for collaboration between UNB and the firms RSL Steeper and Liberty Mutual, the linkages during Scott’s leadership and to the present had less to do with industry than with patients, hospital staff, and other researchers. This differentiates the Canadian experience from that at MIT and the University of Utah. Where there was strong industry involvement was in the UNB hosted Myoelectric Control Symposium and associated training programs. This was, and remains, an important forum for researchers and industry.

With respect to the reversal in primacy in science and technology and the move beyond disciplinarity, there are two reversals. The first occurred with the arrival of the applied science model at UNB’s electrical engineering department in the 1960s. One of the results is that the technology oriented TARGPR changed into an interdisciplinary research institute. With the hiring of Parker, and then his students, Hudgins and Englehart, the IBME became staffed by faculty members with doctorates and a research focus on not just myoelectric control, but also on the understanding of myoelectric signals. Then with DARPA and AIF funding programs came a new focus on "development and commercialization of technology-based products, processes or services."[430] The first change, then, occurred with the arrival of the applied science model in the 1960s and the rise of a research culture within IBME in the 1970s. The second occurred in the 2000s, with the rise in innovation funding programs, which oriented the Institute back to design engineering projects.

As to the forces behind UNB's work in myoelectric controls, the list must include the federal government funding programs in Canada and the United States, and the collaboration with colleagues in hospitals and clinics that have been funded under these programs. Patients feature in parts of the case. Technological advancement in other fields are clearly a factor. So too are the motivations of UNB faculty and staff. Parker said of his motivation: "What drove me was both curiosity. How do we take a myoelectric signal and get information from it? This is a challenging question. You get into the same kind of issues with other signals. I was also driven to solve problems in developing control systems."[431] It was curiosity with an eye to application of myoelectric control of prostheses. Scott, alternatively, was more clinically focused, with design engineering oriented more to meeting users needs that hypotheses

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[430] Website: http://www.acoa-apeca.gc.ca/eng/ImLookingFor/ProgramInformation/AtlanticInnovationFund/Pages/AIFProgramOverview.aspx (June 5, 2010).

[431] P. Parker, author interview, April 23, 2010.

The UNB research prosthetist, Greg Bush, connected technological innovation to patient influence. “Lighter more efficient batteries and materials allowed us to design and fit hands for younger children. We learned that kids who get their first prosthesis at 12-15 months use it more spontaneously. They wanted “broken arms” fixed more quickly because they were highly dependent on it. This led to more refined controls systems.”[432] This has the characteristics of mode 2 innovation, where innovation is driven by close proximity to the clinic and users.

Englehart added another influence: globalization. The IBME seems to have always had to be collaborative in its approach, whether with colleagues in clinics in Fredericton, Toronto, Chicago or elsewhere. But whereas in the 1960s and 1970s there was sharing of ideas and control concepts at international conferences, both in North America and Europe, development projects by teams connected by air travel were rare. Scott was the exception in his relationship with colleagues at the OCCC. With the rise of the personal computer and collaborative tools such as email in the 1990s, these collaborations became easier to undertake. Also, the perseverance of UNB personnel in the area of myoelectric control, combined with the smallness of the R&D field, uniquely positioned UNB to contribute to development projects in the United States and Europe. Last, the existence of common legal and institutional frameworks for collaboration provided a means for parties to “get on the same page.” Funding bodies could expect institutions to negotiate and administer inter-institutional agreements, explain to faculty and graduate students the meaning of these agreements, and complete forms for

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[432] G. Bush, author interview, May 14, 2010.

documenting ownership, disclosure, and protection of intellectual property. It is here that one can see the forces that shape the move to mode 2 knowledge production. And, although the triple helix model of relationships does not show up, we nevertheless see a move to a more formal and managed relationship than what existed in the 1960s.

## 6.4 Ontario Crippled Children's Centre

The history of the Ontario Crippled Children's Centre's (OCCC's) contributions to myoelectrically controlled hands, wrists, and elbows is complicated by its changing name. *The Ontario Crippled Children's Centre*, established in 1957, was renamed in 1985 as the *Hugh MacMillan Medical Centre*, after its first administrator. In 1990 it became the *Hugh MacMillan Rehabilitation Centre*, clarifying its focus. The Centre was subsequently amalgamated with the Bloorview Children's Hospital, and this resulted in the *Bloorview MacMillan Centre*. In line with the trend to informal names for children's hospitals, it later became known as *Bloorview Kids Rehab*. The most recent change occurred in 2010 following a donation from the Holland family of Toronto. It is now called *Holland Bloorview Kids Rehabilitation Hospital.* For the sake of simplicity, the OCCC successor and renamed organizations are collectively referred to as the Centre.

**Figure 30: Holland Bloorview Kids Rehabilitation Hospital (Image source: Holland Bloorview)**

From the early 1960s to the early 1990s the Centre's rehabilitation group were pioneers in the development of myoelectrically controlled hands, wrists, and elbows for children. These new prostheses, illustrated below, were created by an interdisciplinary team of researchers, occupational therapists, electrical engineers, mechanical engineers, and product managers from the Centre, UNB, and a local technology transfer company, Variety Ability Systems Inc. (VASI). The early years, from the 1960s to the mid-1970s, saw the creation of the technologies and institutional structures that would underlay the development of VASI's commercial products. The coming together of the interdisciplinary team and development of these legacy products occurred during the middle period, from the late 1970s to the early 1990s. By the late 1990s the novel development activities had begun to wind down, although VASI's production business continued throughout the decade until 2005, when it was acquired by Otto Bock.

**Figure 31: VASI Electric Hands for Children Aged 0 to 11 years (Image source: Liberating Technologies Inc.)**

**Figure 32: VASI Electric Wrist Rotator (Image source: VASI)**

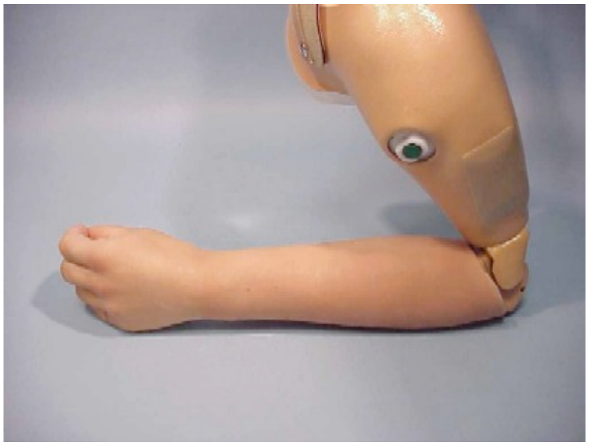

**Figure 33: VASI Electric Elbow for Children (Image source: VASI)**

The first leader of the OCCC's Prosthetic Research and Training Unit (PRTU) was Colin A. McLaurin. He is credited by Dudley Childress as being one of the founding fathers of the field of rehabilitation engineering, and is "perhaps the most prolific, practical, and broad-based designer/innovator the field has ever known."[433]

Born in 1922, McLaurin was educated in aeronautical engineering and served with the Royal Canadian Air Force in World War II. His work building artificial hands and prostheses began in 1949, when he was 27 and working at the

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[433] D. Childress, "A Tribute to Colin A . McLaurin, 1922-1997, Build, Don't Talk," *Journal of Rehabilitation Research and Development* 35 no . 1 (1998): vii.

Sunnybrook Hospital in Toronto, a facility of Canada's Department of Veterans Affairs. It was the year when a research section was added to the central limb factory at Sunnybook Hospital. According to a history of the period written by Walter Wood, "This allowed the researcher to meet amputees, occupational therapists and others working in the field. The focus of the work was not myoelectric upper limb prostheses, but rather in relation to upper limbs, the new use of plastics and other new materials, introduction of suction socket fitting, and a new mechanical hand with cosmetic glove." James Foort, who would subsequently lead the Winnipeg PRTU, described the laboratory facilities they had in 1951 as a "broom closet made available when the janitors moved to better quarters."[434] Notable achievements from work at Sunnybrook Hospital during this period included development of a hip prosthesis, the introduction of plastic laminate reinforcement of wooden prostheses, and the design of a prosthetic foot.

McLaurin left the Sunnybrook Hospital and Canada in 1957 for what would become a six-year sojourn at Northwestern University's Chicago campus. It was a move that would become characteristic of his career, following the research money to create new rehabilitation R&D programs. The position was the founding director of the Prosthetic Research Center at the Rehabilitation Institute of Chicago. Funding came from the US Veterans Administration. Among his major achievements was the development of the "Michigan Feeder Arm," an electrically powered limb for children born without arms.[435] It was one of the first electric-powered arms in the

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[434] Ibid.

[435] Ibid. It was developed in collaboration with a Michigan medical doctor, Dr. George Aitken,

US that was used in daily activities, and a precursor of other powered limbs that were to be developed around the world during the next two decades. Not insignificantly, it was also in this position that McLaurin developed relationships with the leaders of the US Artificial Limb Program, which was to become the influential committee on prosthetics research and development ("CPRD") of the US National Research Council.[436]

In 1963 McLaurin moved again to follow the money. He returned to Toronto to direct the OCCC's PRTU. This was one of three units (the other two in Winnipeg and Montreal) funded by a collective $200,000 National Health Grant from the Department of National Health and Welfare (although UNB would also become a recipient of the $50,000 annual grant in 1963).

By 1964 the Toronto PRTU personnel consisted of McLaurin, William Sauter and Karre Lind. Sauter was the chief prosthetist. Lind was the machinist and electronics technician, and was responsible for developing and producing prototype models. The Toronto PRTU had 1,600 square feet of floor space, new equipment, a prosthetists training program, an amputee out-patient clinic, research projects, and materials application activities.[437] Included in the 600 child amputees registered with the institution's clinic were twenty-one children born to mothers who had taken the drug thalidomide while pregnant.[438]

The first prosthesis developed by the group was a hook. The rationale for starting with a hook was that it was essential in all arms and represented the most

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[436] Ibid.

[437] Ontario Crippled Children's Centre. *Annual Report, October 15, 1964*. (Toronto: Ontario Crippled Children's Centre, 1964), 2.

[438] W. Sauter, "The use of electric elbows in the rehabilitation of children with upper limb deficiencies," *Prosthetics and Orthotics International*, 15 (1991): 993.

challenging design problems for electrical operation.[439] The group decided to focus on electric prostheses because of advantages over compressed gas in storage of energy, although they were concerned about the size, weight, and noise of the electric motors. After several commercially available motors were obtained and bench tested, all of which had issues with wearing and noisiness, a motor from Globe Motor Company of New Jersey, an aircraft and missile manufacturer, was chosen. One of the reasons for selecting the firm was that it provided motors without charge for trial purposes.[440]

In addition to the influence from electronic motor developers and manufacturers, there was technical guidance from the CPRD in the United States, and conceptual influence from the existence and design of the Russian Arm. The CPRD's recommendation that the hook and other electric devices use a twelve-volt power supply was followed by McLaurin.[441] The influence from the Russian Hand occurred indirectly. Unaware of Ronald Reiter's work in Germany, the Russian Hand suggested that a clinically useful myoelectric arm could be designed and manufactured. For the Toronto PRTU in the 1960s, the primary point of comparison was with the Russian Arm, and, in particular, its weight, which was deemed too heavy, and motor torque (or force) that was found to be too weak. Initial success for the Toronto group was to build and test a hook that weighed less and had twice the torque of the Russian Arm.[442]

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[439] Ontario Crippled Children's Centre. *Annual Report, October 15, 1964*, 5.

[440] Ibid, 5.

[441] Ibid, 6. The Toronto group used ten nickel cadmium button cell type batteries to achieve twelve volt supply.

[442] Ibid, 6.

McLaurin knew from the beginning that a critical element of any electric hand was the myoelectric control system. As a result, they monitored developments at other research centres on control systems, including electromyography or EMG systems under development in Russia, by Bottomley in the UK, Scott at UNB, and at UCLA and Philco. McLaurin's assessment in the mid-1960s was that although there were many claims that EMG could be used for proportional control, no practical examples had been demonstrated. Nevertheless, they were keen to see the technology develop and planned to make every effort to adapt these controls to their hands, hooks, elbows and wrists.[443]

The development model described in the Toronto PRTU's 1964 annual report appeared to be the conventional engineering model of design-build-test, and repeat.[444] Hooks, wrist, elbows and shoulder units were designed and built, tested in the laboratory, and then the hardware was applied to amputees.

By 1965 McLaurin had found a myoelectric system that showed enough promise for use in their program. It was the UNB myoelectric control system, and on this basis Scott from UNB was brought into the Toronto PRTU project as its electronics consultant.[445]

By 1967 twelve child sized electric elbows had been developed by the Toronto PRTU and fitted to a variety of patients. They were found to be "particularly acceptable," with the most common complaints being noise, wire

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[443] Ibid, 13. A UNB reviewer of document, likely R. N. Scott, placed an exclamation point next to this statement in the Toronto report.

[444] Ibid, 14.

[445] Ontario Crippled Children's Centre. *Annual Report, 1965*. (Toronto: Ontario Crippled Children's Centre, 1965).

breaking, and occasional clutch slipping.[446] The problem of masking gear noise was identified as one of the major improvements to be undertaken in 1968.[447] Five different types of controls were used on these elbows, one of them being the three-state UNB myoelectric control. By late 1967 the OCCC had, on the basis of these fittings and testing, developed plans for production engineering, manufacturing, distribution and servicing: "Now that a variety of prototype prosthetic components have been developed and shown to be feasible and desirable at this and other centres throughout Canada, the problem of making them more readily available to other amputees becomes apparent."[448]

The year 1967 also saw the Toronto PRTU acquire a new room to house three student prosthetists and a second temporary room for the myoelectric research programme.[449] In addition, the three student prosthetists, and two new staff members were formally added to the project: Mr. James Grice as draftsman, and Scott from UNB. The project also grew to include the operation of the amputee clinic, manufacturing and distribution of an electrically powered coordinated elbow and shoulder, motion powered by one gear motor.[450]

Although not mentioned in the 1967 annual report, an occupational therapist, Sheila Hubbard, was hired that year to work at the PRTU. First employed at the University of Toronto in 1967 to perform physiotherapy and occupational therapy at the U of T's Institute for Biomedical Engineering and the PRTU, she

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[446] Ontario Crippled Children's Centre. *Annual Report, 1967*. (Toronto: Ontario Crippled Children's Centre, 1967), 2.

[447] Ibid, 2.

[448] Ibid, 12.

[449] Ibid.

[450] Ibid, 1.

would eventually move into positions of manager of clinical technology and adjunct clinician investigator, running research projects under the supervision of academic staff. Her career path reflected the direction of the Toronto PRTU's move to a patient-centred R&D and management culture.

**Figure 34: Sheila Hubbard and myoelectric limb user in 2002 (Image source: OCCC)**

By 1968 the Toronto PRTU had created a clinical advisory body and recruited two medical doctors to serve on it, John E. Hall, chief of the OCCC's amputee clinic and R. Mutrie, the OCCC's medical director. Five years into the program, it was also the year when the Toronto PRTU began to report concerns about the electronic prostheses.[451] The good news was that they had "designed and constructed a fairly large number of electric hooks, wrists, elbows and coordinated

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[451] Ontario Crippled Children's Centre. *Annual Report, 1968*. (Toronto: Ontario Crippled Children's Centre, 1968), 3.

arms and fitted them to a variety of children."[452] Testing of these experimental prototypes built up experience in electrical devices. The bad news was that, with a few exceptions, external power had little impact except in research and experimental programs. The three or four available myoelectric control systems were expensive, mechanically complex, and little used. The other power source option, $CO_2$ cylinders, was ruled out because of the complexity in recharging or replacing bottles of $CO_2$, even though they had found acceptance in Montreal and Edinburgh upper limb prosthetic development programs.

The Toronto PRTU saw two other advantages of electricity. Batteries could store much more energy per pound than $CO_2$ bottles, and second, technological advances were foreseen for batteries, but not $CO_2$. In 1968, fast charging battery systems were newly introduced to the market, replacing the established overnight charging systems. According to the Toronto PRTU's 1968 report, battery technology was "progressing continuously" and eventually silver zinc or other cells would be available producing four times the energy per pound.[453]

For McLaurin and his group, if the power issue could be solved in a matter of time with the forecast design of lightweight, quiet, and reliable components at a reasonable cost,[454] then the critical technical challenge for effective powered devices was a much more sophisticated control system. The goal was to achieve electric controls that rivaled the $CO_2$ powered system Dr. Simpson of Edinburgh had developed. Simpson had achieved far greater acceptance of $CO_2$ powered arms

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[452] Ibid.

[453] Ontario Crippled Children's Centre. *Annual Report, 1969*. (Toronto: Ontario Crippled Children's Centre, 1969), 1-2.

[454] Ibid, 2.

in his Edinburgh rehabilitation clinic than other groups had achieved with electric systems. He achieved this through the use of position servo (position/speed) feedback and continuous coupling between the body and the device. What this meant was that any motion of the shoulder automatically caused a corresponding motion in the prosthesis, so it was easier to use for the patient. In other words, the user applied *appropriate* feedback to control it (instead of flexing bicep or tricep muscles); the $CO_2$ cannisters powered the movement of the prosthesis.[455]

UNB's Scott developed four models for control of the OCCC hook and other terminal devices. Fittings and testing were initially done at a clinical evaluation program in Los Angeles in 1970 under the auspices of the CRPD. The findings showed that although some difficulty was experienced in adjusting the resistance to match impedance of the globe motors (matching the voltage and current), the UNB control system was reliable and worthwhile enough to be included in the production designs.[456]

Production began in 1970 at a 3,600-square-foot facility in Toronto. It was organized by the Variety Club of Toronto, a chapter of an international charitable organization headquartered in Pittsburgh. Established in 1948, the Toronto chapter operated a vocational training school for boys with physical handicaps. This new production facility was intended to be something quite different. According to the 1970 Toronto Rehabilitation Centre report:

> The factory will be independent of the Prosthetic Research Program, but the Ontario Society of Crippled Children will be responsible for the

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[455] Ontario Crippled Children's Centre. *Annual Report, 1970*. (Toronto: Ontario Crippled Children's Centre, 1970), 2.

[456] Ibid, 8.

> Administration, and the Project Director of the Prosthetic Research Program will be responsible for the products produced at the Centre. Designs will not necessarily be those developed at the Ontario Crippled Children's Centre. It is believed that this manufacturing facility will fulfill a needed function in making available components that are much needed but cannot otherwise be obtained.[457]

The system that emerged was one in which the OCCC's PRTU researched, developed, designed and tested prosthetics devices,[458] the Variety Club of Toronto manufactured prosthetic devices, and the OCCC's prosthetic service delivery program performed the fittings. None of these relationships were exclusive. The OCCC licensed its devices to Liberty Mutual in the United States. The Variety Club manufactured the North Electric hand developed by Northern Electric Corporation (subsequently, Nortel).[459] The OCCC fit devices made by Otto Bock. The names of the OCCC would change over the years,[460] but the system endured.

With the move to production of clinical systems in 1970, the OCCC increased its list of clinical advisors to twelve persons. Myoelectric upper limb fittings were now being done partly at the OCCC and partly at UNB. The first two fittings were undertaken with the Otto Bock hand and the OCCC elbow, both controlled by a UNB myoelectric system. By 1971, the OCCC's William Sauter fitted the first child sized electric hand (the Northern Electric hand) to an eight-year-old, establishing the OCCC as one of the leaders in the movement to show that children of preschool age

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[457] Ibid, 6.

[458] W. Sauter, "The use of electric elbows," 93.

[459] The 1972-73 OCCC Rehabilitation Engineering report stated: "The child size electric elbow, developed at this centre and the Northern Electric hand are two items that are now manufactured and distributed through Variety Village Electro Limb Centre independent of this research program." Ontario Crippled Children's Centre. *Annual Report, 1973*. (Toronto: Ontario Crippled Children's Centre, 1973), 7.

[460] The PRTU of the OCCC would become the "Powered Upper Extremity Prosthetic Research and Development Programme of The Hugh MacMillan Medical Centre." The Variety Club incorporated a subsidiary corporation called the "Variety Ability Systems Incorporated" or VASI which would subsequently be acquired by Otto Bock.

could successfully operate myoelectric controls and electric hands.[461] In 1973, the OCCC established its Rehabilitation Engineering Department (RED), internalizing the goals of the federally sponsored PRTU program.

And then in the mid-1970s two major changes occurred at the OCCC. The first was the cancellation of the PRTU annual grant from the federal department of health in 1975. The second, in 1976, was the departure of McLaurin to a newly founded rehabilitation engineering centre at the University of Virginia that focused on wheelchair design and development.

The departure of McLaurin was a great loss for the Toronto group. During the thirteen years he directed the PRTU and RED he was involved not just in the development of new electronic hands, elbows and arms, but also in the development of VASI, which Childress called "one of the early, and one of the few really successful, ventures to transfer technology from the development laboratory to enterprise." He brought international recognition to the OCCC as a founding member of the International Society for Prosthetics and Orthotics in Copenhagen in 1972. He also brought prestige to the OCCC in influencing the development of rehabilitation engineering centres in the US. In 1969, he was appointed chairman of the US committee on prosthetics research and development of the National Academy of Science/National Research Council, serving in that role until 1975. Childress says of McLaurin's time as chair:

> It was during this period that CPRD recommended the development of Rehabilitation Engineering Centers (now supported by NIDRR). Colin played an important role in this process because he had already developed such a

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[461] In 1976, Systemteknik of Stockholm made available a hand appropriately sized for preschool aged children.

> center in Toronto and knew how effective such centers can be. Throughout his career, he emphasized the need for engineers in rehabilitation to immerse themselves in clinical activities that would enable them to define and solve problems of significance to persons with disabilities. In this regard, he influenced NIDRR's priority that their Rehabilitation Engineering Research Centers be located within rehabilitation environments.[462]

**Figure 35: Mickey Milner (Image source: U of T)**

Replacing McLaurin was Morris (Mickey) Milner. Born and educated in Johannesburg, South Africa, Milner received B.Sc. (Eng) and Ph.D. degrees, respectively in 1957 and 1968 for his work in the department of electrical engineering of the University of the Witwatersrand. His doctoral dissertation was titled "Models of nerve excitation and propagation with special reference to multi-fibre peripheral nerve." His next ten years were spent travelling from place to place, working at various bioengineering centres. From 1968 to 1978 he held appointments at the Canadian National Research Council, the University of Cape Town, and Groote Schuur Hospital (serving as first director of bioengineering and

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[462] D. Childress, "A Tribute to Colin A . McLaurin.

medical physics), Emory University, and Georgia Institute of Technology, and McMaster University in Hamilton. In 1978, he settled down to life in Toronto as the second director of the OCCC's RED, with academic appointments at the University of Toronto.

Shortly after the arrival of Milner came two other important members of the rehabilitation engineering department (RED). Mechanical engineer Issan El Timmen was hired in 1979 to design prosthetic products. He came to OCCC with an undergraduate degree in mechanical engineering from the University of Sheffield in the UK and seven years experience in product development at NCR Corporation (originally National Cash Register Company). He anticipated from his experience at NCR Corporation that trial and error would be a significant part of the process, and indeed it was.[463] Timmen's role was design engineering. As he saw it, on one side were colleagues at the RED who wrote grant applications and did research, and one of the other was the VASI production facility. His first major project was development, from 1979 to 1981, of an electric hand for children aged two to six years. Following successful testing of a design, it was passed to VASI for production at their machine shop in Scarborough, Ontario. Timmen would eventually work for twenty-six years for the Centre and VASI.

The other important new hire was Martin Mifsud. Like Hubbard and Issan El Timmen, he worked a majority of his career on the Centre's myoelectric systems. Mifsud was hired in 1981, four years after obtaining a diploma in electrical

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[463] I. Timmen, author telephone interview, June 30, 2010. Timmen said that development and testing of a product design had to typically occur three of four times before something useful was produced.

engineering technology from Ryerson Polytechnical Institute. He was initially responsible for electronic design, development, and production. That role lasted eleven years, including one year of overlap with his position as general manager at VASI. The VASI position began in 1991. At VASI he was responsible for all aspects of the company, including production, quality control, distribution, customer service, international sales and marketing.

According to Milner, the work to develop powered upper extremity prosthetic products was interdisciplinary and highly collaborative. This focus of the interdisciplinary activities was what he called the "Meccano Set" approach: developing prostheses that met the needs of growing patients and kept the costs down for the paying parties.[464]

Although the interdisciplinary approach was practiced well before Milner arrived at the OCCC, its practice intensified during his tenure. Milner's appreciation of this approach had roots in a personal tragedy. His first child was born with cerebral palsy. She was several months old when Milner and his wife discovered she wasn't passing regular milestones. This opened his eyes to the issues surrounding problems in medicine.[465] In interacting with various medical professionals he came to see that interdisciplinary approaches had much to offer the field.[466]

Another influence on Milner's interdisciplinary approach came from his doctoral studies. "I had tea with my supervisor twice a day. He was an excellent

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[464] M. Milner, author interview, June 25, 2010.

[465] Emily Sangster, "Morris Milner on Technology" *Features* 132, 2, (2004).

[466] M. Milner, "On the Odyssey: A Personal Journey," *Assistive Technology*. 13:59-65, (2001): 59.

communicator, and I learned from him the role that personal communication can play in research to bridge the gaps between people."[467] The focus on communication became a theme in his career. He was, for instance, a founding director of the Ontario Rehabilitation Technology Consortium (ORTC), an organization that linked Ontario rehabilitation facilities, academic centres, consumers, and manufacturers to develop and commercialize assistive technologies.

Interdisciplinary activities were structured and managed through collaborative projects, involving RED, VASI, and, initially, UNB personnel. Projects had weekly meetings involving therapists, prosthetists, VASI representatives, and researchers and, according to Milner, "Everything was discussed and there was a spirit of camaraderie. I thought it was the most potent model. The industrial model did not have everyone was under one roof. The only people who had to motor to these meetings were the VASI folks."[468] Milner chaired the meetings from 1978 to 1983. In 1983, when he became director of the research for the OCCC and associate director of the Institute of Biomedical Engineering at the University of Toronto, Milner was succeeded in his role as chair of the meeting by Steve Naumann.[469] According to Milner, "Continuity had built up by this point. Everyone was on the same page."[470]

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[467] M. Milner, author interview, June 25, 2010.

[468] Ibid.

[469] Naumann is currently the director of the Rehabilitation Engineering Department. He is adjunct assistant professor in the U of T Department of Rehabilitation Science, and associate professor in the Institute of Biomaterials and Biomedical Engineering.

[470] Ibid.

Toronto occupational therapist Hubbard concurred.[471] She said the bi-weekly meetings included researchers, clinicians, occupational therapists, prosthetists, engineers, and VASI representatives. Included in the group was Scott from UNB, who Hubbard said was a mentor, intimately involved in designing systems and almost like a clinical colleague.[472] The group discussed progress on everything they were working on. It was a forum for discussing what clinical ideas might be taken into research. Most important for Hubbard was the testing of the products involving the RED and then, if successful, VASI. An example of the group's utility was in identifying a simple change in an electronic wrist to make it bendable, which eventually made it into a product. According to Hubbard, Martin Mifsud, the product manager at VASI (and the former head of electronics at the PRTU before he went to VASI), was a catalyst in this innovative design work. He challenged people at the meetings, asking questions such as the anticipated caseload for devices and potential sales, which did not always stand out in the considerations of clinicians.[473]

By 1981 the RED had, in collaboration with VASI, produced commercial versions of the three-state myoelectric control units that were originally designed by the Bio-Engineering Institute at UNB.[474] The service groups in 1981 fitted sixteen three year-old children with myoelectric protheses. Most were built with the Swedish Systemteknik hand and the Otto Bock myoelectric control systems.

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[471] S. Hubbard, author interview, April 22, 2010.

[472] Ibid.

[473] Ibid. Although, interestingly, VASI was administered from the Centre, even though it had its own board.

[474] Ontario Crippled Children's Centre, *Annual Report, 1981* (Toronto: Ontario Crippled Children's Centre, 1981), 10.

The interdisciplinary R&D projects were guided by a user-focused ethic. The author of the 1987 RED annual report wrote: “Close proximity of the clinical service to the design process promotes ongoing interactions between engineering and clinical staff and communication with children and their families. This aids in understanding users' needs and expectations while examining the developmental feasibility in terms of a practical outcomes.”[475] It was thus not surprising that Hubbard, an occupational therapist by education, had by the mid-1980s moved into a role of coordinating R&D projects on the use of myoelectric prostheses aided by microcomputers, with supervision from professional research staff, including Naumann and Milner.[476]

However, this collaborative and interdisciplinary approach did not last. Milner said the pressure to publish research results increased as the discipline of engineering became more research intensive, and as the availability of research funding increased. “These people wanted to establish their careers,” Milner said.[477] This meant the researchers focused more on research projects that would generate publications and not necessarily clinical outcomes. Also, the patient mix changed at the Centre. Autism spectrum, for instance, rose in importance for the Centre and the number of children requiring myoelectric limbs began to decline.

Hubbard agreed. She said this collaborative and interdisciplinary approach lasted for about fifteen years from the late 1970s to the early 1990s. Among the reasons for the change, she cited the formation of a new research institute, creating

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[475] Hugh MacMillan Medical Centre, *Annual Report, 1987* (Toronto: Hugh MacMillan Medical Centre, 1987).

[476] Ibid, 58.

[477] M. Milner, author interview, June 25, 2010.

both physical and intangible distances between the clinics and research, the loss of regular attendance by the VASI personnel, and the change in the Centre's myoelectric provider. Hubbard said: "UNB in the early days was both a clinical collaborator and control system supplier. The UNB system was replaced by Otto Bock. Otto Bock was a supplier to the hospital." Otto Bock did not, however, replace UNB as a product development collaborator.[478]

Timmen also concurred with Milner and Hubbard's view about the decline of this interdisciplinary approach at the Centre, although Timmen attributed the change more to the loss of its leader. "It changed after Mickey Milner left. He was a people person and knew how to bring people together. He believed in teamwork and sharing. He was more consensus than directive."

The outcome of all this collaborative and interdisciplinary interaction was the extension of myoelectric devices to infants. One of the important outcomes was the development of a miniature circuit to permit one-muscle, voluntary opening control of infant electric hands. The key was in making it simple enough for an infant to use. Hubbard credits the work of Thomas Haslam, a prosthetist at the Saint Anthony Center in Houston, for designing what became the only practical circuit for infants. The version used by the Toronto group was developed by UNB and then designed by Haslam. In Hubbard's words it "revolutionized" their approach, allowing for fittings and trainings to ten months of age, instead of three

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[478] S. Hubbard, author interview, April 22, 2010.

years, and increasing the odds that myoelectric devices would be permanently used.[479]

According to Mifsud, the primary forces behind the OCCC's and VASI's development of children's myoelectric prosthetics were government funding and technological innovation in other fields, specifically transistor technology and plastic/synthetic materials. "Technology implemented in the rehabilitation field evolved from other fields and has been manipulated and molded into a useful rehabilitation solutions."[480] The outcome of this "little r & capital D" work, as Mifsud called it, and the fittings at OCCC of new prosthetic products to young children, was that commercial companies (which, unlike VASI, were not controlled by clinical organizations) were drawn into developing their own prosthetic products for children. In other words, OCCC and VASI pioneered a commercial market.

Although during the 1990s and early 2000s VASI continued to develop, improve, and sell upper limb prosthetic products, it was no longer building novel products to prove that myoelectric upper limb prosthetics could be used by infants and children, nor did it have the same kind of contributions from the Bloorview Centre. As a result the fortunes of VASI began to change. Development of myoelectric prostheses were now no longer a top priority for the Bloorview Centre. Autism and head injuries were demanding more of the Centre's time and resources, and creating new research funding opportunities. Milner proposed the idea of selling VASI. In 2005 the Centre found its buyer, Otto Bock. Mifsud, who had been

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[479] Ibid.

[480] M. Mifsud, author telephone interview, June 25, 2010.

leading VASI, moved to a sales and product manager position for Otto Bock's Canadian subsidiary, lasting two-and-a-half years before he left to run his own consulting company.

Looking back, Mifsud said that during his time at the OCCC and VASI he saw the R&D culture change ". . . from being altruistically driven to having a more pragmatic goal of delivering functional solutions that resulted in commercial profitability."[481] Driving that change, according to Mifsud, were the funding sponsors. "R&D culture was once a group of pioneers searching for possibilities. For example, we once did not believe children could operate or manage sophisticated devices like myoelectric prostheses."[482] R&D culture also changed "from delivering a technological solution–that appears to work –to necessitating the proof that the technological solution is in fact resulting in the best solution."[483]

Mifsud also stated there was a change in attitude to intellectual property. "The ideology in the younger rehab engineering world twenty years ago was that information paid for by tax payers should be shared with other researchers to advance the field. Perhaps less public funding, and the attitude R&D should be paid for by business, has fostered an atmosphere of confidentiality and protectionism."[484]

Milner concurred about the turn to commercialization in the field. "People are now focusing on intellectual property so they can know what is being bought and sold. We never paid attention to that stuff. We were doing good things for kids,

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[481] Ibid.
[482] Ibid.
[483] Ibid.
[484] Ibid.

and may have given away a lot of IP for nothing. People are now more cagey. For VASI we operated on know-how, and IP did not really make sense."[485]

Both Mifsud and Timmen saw the design work at OCCC and VASI to be linear. According to Timmen, the engineering design process did not change.[486] From the team meetings came the identification of user needs and the development of designs to address those needs. The next step was for development of prostheses at the machine shop, followed by testing and user trials. The need for corrections or modifications was identified in the trials and team meetings, and then the process would be repeated. Timmen estimated that a workable design might be developed within eighteen months, presuming no breakdowns. The next step was to release the design for production. Product developers worked closely with production to do the molding of the prostheses and product tweaks as VASI contracted for parts and prepared its assembly process and marketing plans. It was, according to Timmen, a typical product development cycle.[487]

Hubbard instead characterized the process as not linear, but as "command and control" or "trial and error" in approach.[488] At the heart of it was the generation of ideas at the bi-weekly team meetings and then iteration of designs as prototypes were built and tested. Milner, an experimentalist, agreed with Hubbard. Trial and error, not modeling based on theory, informed the group's design activities. "It was very pragmatic," said Milner. But Milner said this approach is

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[485] Ibid.

[486] I. Timmen, author telephone interview, June 30, 2010.

[487] As part of that cycle, Timmen had the opportunity to take apart an Otto Bock design for an adult myoelectric hand. He said: "The Otto Bock hand scared me. They did a great job and I learned from them." Author interview, June 30, 2010.

[488] S. Hubbard, author interview, April 22, 2010.

changing: “When I went for a grant, I had to say what people wanted to hear. Now it is getting richer in terms of theory. Now it is more of a blend of experimentalism and theory.” Likewise, Milner said: “The first director of the University of Toronto’s Institute for Biomedical Engineering was a very nuts and bolts guy. As time went by this approach died out in biomedical engineering at the University of Toronto. I saw this happening in the Institute.”[489]

Milner and Hubbard also agreed there was not been a move to user-oriented research during their time in the field. Rather, their field has become more research intensive, in part as a result of decreased clinical funding, such as the 1963-1975 grants from the ministry of national health and welfare, and increased R&D funding from research and innovation granting bodies. According to Hubbard, the research has become more “ivory tower.”[490] At the Centre this has been driven by the physical separation between researchers and clinicians. For Milner, the location of the Centre was an important factor. “If we had not been embedded with the Centre and mixing with clients we would not had done we did. It was critical to be in the context of application.”[491] Summing up his experience at the Centre, Milner said: “They need engineering units in hospitals.”[492]

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[489] M. Milner, author interview, June 25, 2010.
[490] S. Hubbard, author interview, April 22, 2010.
[491] M. Milner, author interview, June 25, 2010.
[492] Ibid.

## Toronto Case Analysis

Both Mifsud and Timmen saw the design work at OCCC and VASI to be textbook engineering that began with the identification of user needs, followed by design, machining of devices, testing and user trials. It was repeated as directed by the interdisciplinary committee overseeing the products, and once the final design was approved, it was released for production. Like Scott and Bush's view of the R&D process at UNB, it was linear (design engineering, not the linear model of innovation) with feedback.

How is this different from Hubbard and Milner's view that the process is not linear, but characterized by "command and control" and "trial and error?" It seems not very different. Milner and Hubbard saw it as not linear because trial and error, not modeling based on theory, informed the group's identification of user needs and designs. Both groups saw at the heart of the design process the generation of ideas at the bi-weekly team meetings and then iteration of designs as prototypes were built and tested. The difference between the two views of the process is that Hubbard and Milner saw that the first two steps of the linear model, basic research and applied research, were missing.

With respect to the mode 2 concept, there appears instead to be a reversal of the mode 1-mode 2 narrative, with a kind of mode 2 development from the 1960s to 1980s, and then a greater emphasis on research in the 1990s and 2000s. In the 1960s there was a move from university laboratory-based research to generation of problems and methodologies, and dissemination of results in hospitals and clinics. The work was trans-disciplinarity in the use of trial and error, instead of discipline-based theories and methods being used to solve problems. As well, R&D changed in the earlier period from being the sole domain of electrical engineers to involving occupational therapists, users, company managers, and others involving their own theories, methods, experience, and tacit knowledge to solve problems. There was “speaking back to science” from amputees at the clinic to the occupational therapists and then to the researchers in the biweekly meetings. The “novel forms of quality control” occurred, in part, through the meetings with representatives from product manufacturers, designers, and occupational therapists. But as Milner and Hubbard explained, there was a subsequent move to a more research-oriented culture, and this has been accompanied by less interdisciplinary collaboration.

The triple helix concept also does not fit well with the case study. In short, industry collaboration is missing, with the exception of the work at Northern Electric. In Canada, there was not, as was the case in the United States, funding and internal development of upper limb prosthetic devices at large companies in the 1950s and 1960s, such as IBM, Litton Systems, and Liberty Mutual Insurance. Nor were there the spin-off companies that arose from the University of Utah in the early 1970s (Motion Control) and Liberty Mutual in the early 2000s (Liberating Technologies Inc.) There was instead collaboration between the Centre, the University of Toronto, and UNB, as well as a longstanding and successful partnership with the Variety Club of Toronto in the creation and operation of VASI. But it is a stretch to call this industry collaboration. Likewise, and as was the case at

UNB, it appears the revenue generated from the production and dissemination of designs did not make a material difference to the intellectual property owners.

On the reversal in primacy in science and technology, it was not science that emerged as the primary source on the Centre's device concepts, but the interdisciplinary design meetings and the trial and error process. Likewise, there appears to have been a change in attitude within rehabilitation engineering about the nature of research results, from science as the creator of purely public goods to research engineering as the developer of designs for commercial production.

How did culture influence practices at the Centre from the 1960s to the present? As with UNB, the influence came through the implementation of ideas in public policies and funding programs, initially the ministry of national health and welfare grants for clinical and research activities, then through the Medical Research Council and NSERC funding programs, and then later through innovation funding investments. There were commonalities on the goals of the programs, but also significant differences. The ministry of national health and welfare funding brought researchers into the clinic and hospital, face-to-face with patients. The research council funding required knowledge of the current scholarly literature and a grounding of the project's hypothesis in that work. Although the actors come to the fore in the fine-grained case history, it's the location of interdisciplinary work at the Centre that seems most central to the development of the novel VASI arms and hands for children. The collaborative, user-oriented approach to development was of course critical, but it seems that only in this setting could there occur a half century of development and improvement in what became the VASI hands and arms. Other actors could have been part of the development group, but it would be hard to imagine similar work and products coming from a laboratory at the University of Toronto or at the National Research Council campus in Ottawa.

## 6.5 The Utah Arm

The Utah Arm is the progeny of the Boston Arm according to a United States government case study on the Boston Arm.[493] The link between the two was Stephen Jacobsen, who studied with Dr. Robert Mann at MIT.

**Figure 36: Stephen Jacobsen (Image source: University of Utah)**

Stephen Jacobsen was born in Salt Lake City, Utah on July 15, 1940. After graduating from high school in 1959 he entered the University of Utah's College of Engineering. According to Jacobsen "I wasn't that serious; I fooled around a lot, and I got into trouble every now and then."[494] He reportedly set off a widespread explosion in one of the engineering buildings, and rigged vending machines so they would respond only to him. He was asked by the university administration to leave, but was saved by the dean of the engineering college, who invited him to return if he could maintain at least a "B" average. Jacobsen returned, obtained the

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[493] S.J. Tanenbaum, *The Boston Elbow*.

[494] "Robots of the Future" *The Salt Lake Tribune* January 9, 2010.

appropriate grades, and received an undergraduate bachelor of science degree at the age of 27 in 1967. He stayed at the University of Utah to obtain a masters degree (again in science) in 1970, and then moved to study at MIT, receiving his doctoral degree in 1973, at the age of 33.

According to Jacobsen, the outline of every possible prosthetic hand had been disclosed years before he began his doctoral program, in a 1919 German publication.[495] Like Leonardo da Vinci's drawings of flying machines, it lacked modern power sources, electric controls, and computers.

This was fine with Jacobsen. His interest was in getting things out in the field, and if prior work helped, then all the better. He was involved in two prosthetic projects at MIT. He participated in a project to directly attach prosthetic devices to the skeleton, similar to dental implants. He implanted ceramic material in rabbits and performed tests. Although the implants were strong and effective, the consensus scholarly view at the time was that is was not a feasible procedure, and on this basis Jacobsen abandoned the line of research. The procedure, called osseointegration, was subsequently adopted for use in dental implants and implemented in Sweden for use in upper limb prosthetics.

Jacobsen's doctoral dissertation focused on myoelectric control of a multifunctional artificial arm, using pattern recognition for a mid-humeral (between elbow and shoulder) amputee. It was part of the larger "Boston Arm" project. In his academic program he studied quantitative anatomy, dissected cadavers, and examined the number of degrees of freedom that act in concert to

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[495] G. Schlesinger, R.R. DuBois, R. Radike, S. Volk "Der mechanische Aufbau der künstlichen Glieder."

control a hand. Amputees were fitted with EMG monitors, tests were undertaken and data recorded from the shoulder to understand how it could be used to control a terminal device. Predictions were made of how the shoulder could be used to control a prosthesis. Following this, he wrote differential equations to control the hand. According to Jacobsen, the system was too complex for practical use.[496]

Mann's comments about Jacobsen and the project were interesting both for the insight into Jacobsen's applied focus and the connection between the Boston Arm and the Utah Arm.

> At the University of Utah, Stephen C. Jacobsen had been engaged in the artificial heart program of Dr. Wilhelm Kolff. Jacobsen came to MIT to continue that study through a PhD in fluid mechanics, but our faculty in that field were not interested in such an applied project. He became interested in the problem of how to control multi-joint prosthesis in the BA [Boston Arm] natural manner for cases where the muscles for controlling the more distal joints were completely gone. He hypothesized that the musculature about the shoulder must anticipate the intent, and be prepared for the reaction forces arising from the actions of the more distal musculature; thus listening to and interpreting the EMGs from the shoulder girdle should provide the desired control information. His thesis proved his theory and he returned to Utah to demonstrate control of a multi-joint prosthesis. But having had first-hand exposure to the Boston Arm, by then with decade-old technology, he and his Engineering Design Center at Utah produced the Utah Arm, with Jacobsen founding a company to produce it.[497]

Nearing completion of his doctorate Jacobsen returned to the University of Utah in 1973 to direct the College of Engineering's Center for Engineering Design. It was an extraordinary offer for a doctoral candidate, although it proved to be a very shrewd hire for the university. As indicated by its name, the Center was given an exceptionally broad mandate, covering the entire linear model of innovation, from

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[496] S. Jacobsen, author telephone interview, June 28, 2010.

[497] R. Mann, "Engineering design education and rehabilitation engineering," 31.

R&D to engineering design and through to commercialization, and not limited to any one area of engineering, nor any one field of science.

Jacobsen's curriculum vitae suggests he vigorously exercised his broad mandate. Projects included development of photovoltaics, batteries, catheters, stents, drug delivery systems, artificial kidneys, artificial hearts, electrical and body powered arms and wrists, microsensors, virtual reality interfaces, and a wide variety of robots. He developed robots for NASA, Ford, the Carnegie Science Museum, and the movie, Jurassic Park. His appointments within the University of Utah also evidenced his broad range of capabilities, including appointments in the departments of bioengineering in 1983, surgery in 1989, computer science in 1992, and mechanical engineering in 1996.

A year after Jacobsen was hired at the University of Utah he incorporated Motion Control, Inc. Its original mission in 1974 was to commercialize the medical technology developed at the Center for Engineering Design. But plans changed and it became the commercial vehicle for the development and manufacturing of one of the Center's many projects, the Utah Arm. The Utah Arm, conceived by Jacobson in 1974, was developed for the next four years into working prototypes, then first plugged into the computer in 1978, and finally launched as a commercial product in 1981. Jacobsen said "I gave Motion Control to Harold."[498]

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[498] S. Jacobsen, author telephone interview, June 28, 2010. Sarcos Incorporated, established in 1983, took the place of Motion Control as the primary commercial collaborator of the Center for Engineering Design.

**Figure 37: Harold Sears (Image source: Monash University)**

Harold Sears was an undergraduate student in mechanical engineering at the University of Utah when Jacobsen was pursuing his master's studies. Sears obtained his undergraduate degree in 1969. In 1970, he earned a masters of science in engineering-science (with a focus on aeronautics and astronautics) from Stanford University. Between 1970 and 1975 he worked for the Peace Corps as a high school mathematics and english teacher. He returned to the University of Utah in 1975 and took a position as a research assistant at Jacobsen's Center for

Engineering Design. From 1975 to 1981 he did R&D on myoelectric controls, terminal devices and the Utah Artificial Arm, undertaking his Ph.D. studies for most of the period. He completed the Ph.D. program in bioengineering and obtained his doctorate in 1983. In 1981 Sears was hired to work for Motion Control. It was his first commercial position, and the beginning of a transition from the culture of academia to commerce, mostly gained by experience at Motion Control, but also supplemented by a technology management program taken from the University of North Carolina's graduate school of business in the late 1980s.

Ironically, it's the Motion Control president, Sears, who said that the entrepreneur is Jacobsen, the long-time university professor. But it was Jacobsen who created Motion Control in 1974. Sears' initial work for the company was during the final two years of his doctoral program, transferring the Utah Arm know-how and technology, and performing fittings for the first few paying customers. Sears said: "I just happened to be finishing my degree at the time and Motion Control lost its product manager. I suspect he was scared to death of this new technology with high technical risk and not a very long track record."[499] He had good reason. In the early days Sears and colleagues in Motion Control were challenged in translating successful laboratory systems into commercial products. Sears also had his concerns, but they were overcome by his confidence in Jacobsen. Sears said: "I had eight years of graduate school, but we had this fearless guy, Stephen Jacobsen, with almost total mastery of technology, as far as we knew. He

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[499] H. Sears, author telephone interview, June 21, 2010.

understood mechanical design and actuator design, plastics, etc."[500] It also helped, Sears stated, that Jacobsen had previously worked on the Boston Arm at MIT. According to the Tanenbaum's *The Boston Elbow*:

> The Boston Elbow and the Utah Arm are derived from the same idea; as a result, both are myoelectric and proportional. They do, however, diverge at several points, and these differences seem to indicate a divergence of objectives as well. First, the Utah Arm is a more attractive prosthesis than the Boston Elbow. The former has a slimmer forearm and is less noisy, and because it has completely free swing, the Utah Arm is also more natural looking. The Boston Elbow, in contrast, has a boxy forearm and only 30 degrees of free swing. It weighs more than the Utah Arm but will lift more weight. The makers of the Boston Elbow favor a capacity for simultaneous movement of the elbow and terminal device– this having been Glimcher's concern in initiating the Boston Elbow project. When the Utah Arm is worn with a powered terminal device, the 2 degrees of freedom have a single control site and therefore can be operated only sequentially. The Arm thereby loses what, at least according to Glimcher, is an important aspect of functioning. Technically, the Utah Arm and the Boston Elbow both can be wired for simultaneous movement of the elbow and the terminal device or for single-site control. Liberty Mutual has chosen to implement the first and Motion Control, maker of the Utah Arm, the second option.[501], [502]

But still, there were challenges with the battery power, longevity and recharging times. Existing connector technologies (connecting the various components of the hand-arm system) were unreliable, and better quality connectors were not available for the Utah Arm. In the end Motion Control designed and built their own connectors.[503] There were also issues in developing

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[500] Ibid.

[501] S.J. Tanenbaum, *The Boston Elbow,* 16.

[502] The difference in the two movement options may be part of the reason why no intellectual property issues arose between the intellectual property owners of the two systems. The University of Utah acquired a patent for its "Electrically driven artificial arm" invention, United States Patent No. 4521924, filed in 1983.

[503] H. Sears, author interview, June 21, 2010. Otto Bock made a great contribution in connectors, according to Sears, and sometimes Motion Control would use Otto Bock connectors, but they did not always fit. Instead Motion Control developed their own, which Sears says was an evolutionary process and a big headache.

new techniques for fitting patients with very different needs, especially transhumeral amputees, who Sears said were the most difficult to fit.[504]

Sears' responsibility included figuring out how to train prosthetists to fit patients. This meant a step-up in training for prosthetists and for the trainer. With only one other electric elbow on the market and a small number of overall sales, there was little experience among prosthetists with these devices. Sears also had no experience doing professional training.[505]

Sears learned to train by trial and error while travelling and doing on-site training and follow up visits. It turned out the training visits had an unanticipated benefit. It allowed Sears to recruit patients and prosthetists to participate in product development. Sears said: "The most helpful people were the local prosthetists. One prosthetics office printed out a list of patients names, and identified twenty who would be suitable candidates for field trials. Of the twenty, ten were involved in field travels. That was essential."[506]

The other critical person behind the Utah Arm was Edwin Iverson. Iverson, also a native of Utah, obtained his master's degree in mechanical engineering from Brigham Young University. He went to work for Jacobsen at Sarcos[507] as its general manager from 1983 to 1992, and then joined Motion Control as its vice president

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[504] Ibid.

[505] Prosthetists are important influencers in device sales. Amputees do not typically buy direct from product manufacturers, but select and have fitted the prosthesis by a prosthetist at the clinic. However, Otto Bock and Touch Bionics also run service businesses, with in-house prosthetists to sell and service in-house products.

[506] Ibid.

[507] Incorporated in 1983 by Jacobsen, Sarcos is an engineering and robotics firm based in the University of Utah Research Park in Salt Lake City. In 2000, DARPA awarded to Sarcos a grant to develop a design for a powered exoskeleton suitable for military applications, followed by a second grant in 2006 to produce prototypes based on the design.

for research and development in 1992. In this role Iverson saw himself as both an implementer of ideas from marketing, manufacturing, or others, as well as a visionary who saw potential needs before they were identified by prosthetists and users.[508]

Iverson's current procedure for R&D operations is a version of what he calls the "guess, try and guess-again approach."[509] It is a version of text book engineering, beginning with a statement of need in the market, then determining and selecting alternatives, followed by developing, testing and refining prototypes. Likewise, he routinized intellectual property management activities, including monthly patent searches and filing defensive patent applications.[510]

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[508] E. Iverson, author telephone interview, June 21, 2010.
[509] Ibid.
[510] Ibid.

**Figure 38: The Utah Arm (Image source: Motion Control)**

The project to develop the Utah Arm was conceived as engineering design and product development, not research. Nevertheless, the group surveyed both the academic research and existing technology to produce externally powered artificial arms. Included in the survey were works on the IBM arm, the Russian EMG controlled hand, the Viennatone hand, the Boston elbow initially developed at MIT, the Veterans Administration elbow, the Boston elbow developed at Liberty Mutual, the Otto Bock hand, the Fidelity hand designed by the Veterans Administration and Northwestern University, the Italian arm, the New York University elbow, the Variety Village elbow, more recent work in Japan, and the Otto Bock pincer. However, the Motion Control group found these prior works had not achieved overwhelming levels of success, largely because while most performed well in the laboratory, the developers had not been commercially oriented and so the devices were not designed to withstand the rigours of continual daily use.[511] The mechanical systems of the past, they wrote in their 1982 article, were poorly received by amputees, and more recent developments were plagued by problems.[512]

The review of artificial arm control systems included identification of promising methods under development around the world, including systems implemented in the Boston Arm by engineers at MIT and Liberty Mutual, as well as by Scott and colleagues at UNB, and David Simpson and colleagues in Edinburgh. The design team wrote:

> Although these methods are intellectually provocative, and will undoubtedly make contributions in the future, they are not yet refined, and typically involve complex decision processes for their implementation. Furthermore, "simple" problems, such as convenience, reliability, repeatability, number of recording channels required, time delays, and controller dynamics, minimize the chance of their early application. A practical prosthesis designed for near-term implementation must, therefore, use more limited control methodologies, and also address with considerable importance the hardware problems which have plagued previous developments.[513]

The University of Utah group wanted this to be a different project: practical and commercially successful. They considered economic and industrial factors at the outset of the project. Questions of system compatibility with existing prosthetics and fitting procedures were examined. Designers asked how to increase amputee acceptance of the device. Post-development activities were mapped

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[511] S. Jacobsen, D. Knutti, R. Johnson, and H. Sears, “Development of the Utah Arm” IEEE Transactions on Biomedical Engineering, BME-29, no. 4 (1982): 250.

[512] Ibid, 256.

[513] Ibid, 254.

during the basic design phase, such as the cost and performance of fittings, maintenance, repairs, government regulatory affairs, and of terms with entities that fund and purchase prosthesis for clients.

The broad concept was to develop a *practical* system (which the authors italicized in their 1982 paper) in the short term.[514] They acknowledged that the system would have to be a mix of compromises. It was engineering work, in the application of recent technologies. It was also a multidisciplinary project, which required "simultaneous and coordinated work in a number of normally unrelated areas, such as physiology, biomechanics, prosthetics, biological signal acquisition, information processing, control system design, materials, mechanisms, structural design, electronics, rehabilitation, psychology, etc, etc."[515]

The university design team was self-conscious about being different from other university projects and familiar with market considerations. The authors wrote in their 1982 paper on the project:

> As with other developments which begin within research environments, the eventual successful promulgation of a device or system, to benefit a general user group, depends on industrial participation. Specifically, the industrial sector possesses a number of capabilities (listed below), which are not normally interesting to, or present within, research groups. These include 1) long term project continuity; 2) production and maintenance capabilities; 3) investment capital available over extended periods; 4) attention to certain details; 5) information dissemination to user populations; and 6) the establishment and training of distributors of the product.[516]

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[514] Ibid, 250.

[515] Ibid, 250.

[516] Ibid, 251.

While they acknowledged they existed in a research environment, they thought of themselves as an engineering design and production group oriented to market considerations.

The design group conceived of the project in three phases: (i) development; (ii) field trials; and (iii) third party evaluation. Phase (i) involved continuous design, development, and evaluation over a period of six years. Ten artificial arms were developed, beginning with a purely laboratory prosthesis and building to a self-contained system. Testing was done primarily in the laboratory, with some limited experience in the field. Evaluation protocols and amputee questionnaires were designed for use in later phases.

Phase (ii) involved extensive field trials of the prosthesis. The goal was to more clearly understand the needs of the amputee, using a myoelectric prosthesis in activities of daily living. Twenty-two engineers, prosthetists, physicians, and amputees were involved in order to understand the mix of capabilities required to achieve an acceptable artificial arm. Seven prostheses were taken home by amputees and field trialed. Electromechanical problems were identified and suitable modifications made for their correction.

Phase (iii) compared the Motion Control prosthesis to competitive systems and available standards. The evaluation was conducted by external organizations selected for minimal bias and the broad qualifications required for such an assignment.[517]

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[517] Ibid, 267.

The original version of the Utah Arm weighed three pounds, compared to six to eight pounds of a natural arm, and was powered by a twelve-volt rechargeable battery pack with (a now quite modest) 450 milliamp-hour capacity. The arm included a number of novel features. It looked like a human arm, made possible by the location of control circuits in the upper arm. It was able to mimic the ability of the natural arm to fall freely when the wearer relaxed their muscles. It allowed users to lower their forearms with minimal effort.

Since its initial commercial launch in 1981, the Utah Arm has been the subject of continuous design and improvement. The Utah Arm 2, released in 1997, was made more rugged and dependable as a result of improvements in electronics, battery power, and motor technologies. A major change came with the introduction of microprocessor control, giving more flexibility in control. As with the first version, advances in electronics, batteries, and motors came from other industries and were adapted for use in upper limb prosthetics. Likewise, the second generation of its microprocessor to control its hand and wrist devices, released in 1999, also borrowed from technological innovation outside the prosthetics field.

In 2002 Motion Control expanded its product offering to include the hand and hook devices (illustrated below), developed in collaboration with the Artificial Intelligence Laboratory at MIT.

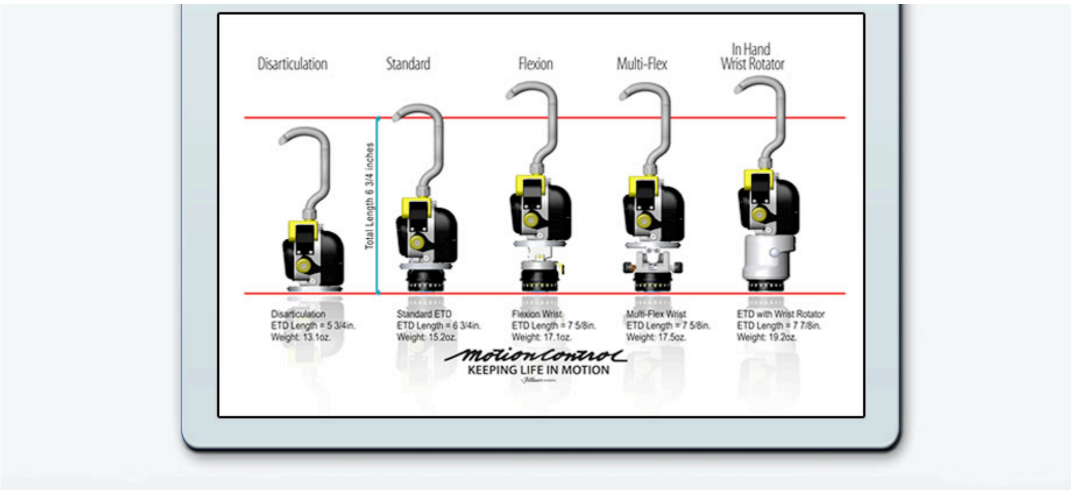

**Figure 39: Motion Control Hooks or Electronic Terminal Devices. Image courtesy of Motion Control.**

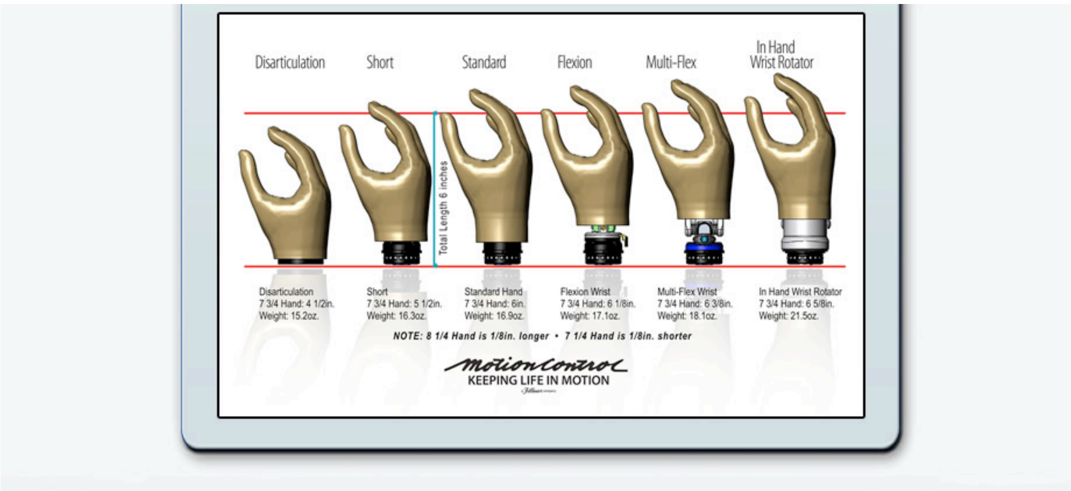

**Figure 40: Motion Control Electronic Hands. Image courtesy of Motion Control.**

Funding came from the National Institutes of Health.[518] The devices were designed for work activities, and filled a gap Motion Control saw in the market for water and dirt resistant devices. Power was supplied by lightweight lithium ion batteries. Iverson said it was designed with the goal of saving space in the envelope of the hand for a wrist. “We were the first to give the wrist space for flexion, and Otto Bock has followed suit. They have made a similar wrist in their transcarpal

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[518] NICHD grant #R44HD36119-03

hand (lighter duty hand) and Michelangelo Hand."[519] The idea for the wrist came not from the market, but according to Iverson, from the field of robotics and watching people eat and what they had to do to eat.[520] Water and dirt resistance, also elements of human hands, also had to be pushed into the market, according to Iverson.[521]

Improvements to the Utah Arm 3 have also come from advances in other fields. Microprocessors offered reduced current consumption, increased bandwidth, and decreased size, as well as simultaneous control of both the elbow and hand.

According to Sears, this is how innovation in the field has changed since the 1970s, not by new innovation practices, but improved materials and electronics (e.g. lighter battery packs, shorter and more powerful charging systems, improved connectors, brushless motors, and transistors). But it has also changed as a result of increasing interdisciplinary approaches. The field of mechatronics, combining mechanical, electrical, computer, software, and systems-design engineering, was virtually non-existent in the early 1970s, and only emerged as these separate branches of engineering began to work together on projects. As well, the statements by Motion Control about its novel, user-oriented approach to development of the Utah Arm in the early 1980s makes explicit a third change in innovation since the mid-1940s.

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[519] E. Iverson, author telephone interview, June 21, 2010.
[520] Ibid.
[521] Ibid.

One change Sears is not fond of is the move by universities into the space occupied by centres for engineering design. He said:

> There is a challenge for a university to make a contribution in the commercial arena. That is a big leap. When I was a student I didn't realize how big a leap it is. Now I do. To develop something new and have it work commercially, it is important to know that is what you are doing and to do the things necessary to address the manufacturing needs and the needs of the user. Effective marketing for us is developing and making products, and making them available to clients, the prosthetists. Universities are not structured to incentivize people to do this. Faculty report to committees and the customer is the last thing on their mind. The model of a think tank for new technology than spins off into company is unusual, as is the technical person who grows a head for business. Why don't other universities make products? It is because they are not set up to do this. [522]

For Sears, research at universities has its role, and it is important not to confuse the roles of research with product development. Research proposals that list how many amputees will have their lives revolutionized by a new development are particularly irksome because of their frequency and lack of results, which he calls a kind of mispresentation at the expense of the prosthetics community. Universities, according to Sears, are getting more and more greedy about intellectual property. As a result, Motion Control has moved away from participating in university projects because of their intellectual property rules and design for patent ownership.

In terms of the forces at play in the development of Motion Control's products, Sears did not emphasize the availability of federal funding (of which he sees a dearth), national science policy initiatives (same as previous factor), nor changes in the practice of innovation and collaboration, but rather technological advances in other fields, as mentioned above, and the marketplace. As an example

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[522] H. Sears, author telephone interview, June 21, 2010.

of the latter, he cited the i-Limb (the world's first commercial electronic prosthesis with finger individually controlled digits, profiled in the last case study). "The patients and amputees wanted the i-Limb more than we imagined. They are not good for heavy work. I am surprised by the amount of money spent on these multiple degree of hands. But the patients kept beating up their insurers and the Army to buy them. This was very surprising. The market is the most important driving force."[523]

Likewise, for Iverson the major advances in myoelectric upper limb prosthetics since 1960 are improvements in reliability, accessibility, batteries and motors, and this has been driven by advancements in other fields. Computer aided design has, for instance, revolutionized the field. Iverson also credits the small business innovation research program (SBIR).[524] Motion Control has done well by the program. From 1992 to 2009, the company was awarded thirteen SBIR Phase I awards for a total of almost $900,000 and seven SBIR Phase II awards worth more than $3.5 million.[525] Commercial partners have also had an important influence. Advanced Arm Dynamics and Hanger Orthopedic Group were important collaborators, the former in design engineering and the latter in clinical services. Hangar was especially important because Motion Control's customers are clinicians, not patients. Hangar both confirmed interest in the electric hook and also became a big purchaser of the product. Last, Iverson stated insurance companies

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[523] Ibid.

[524] Federal agencies with extramural R&D budgets that exceed $100 million are obligated to allocate 2.5 percent of their R&D budget to the SBIR program. The SBIR program provides grants to encourage US small businesses to engage in US federal government R&D that has the potential for commercialization. Phase I grants are often under $100,000 and Phase II grants under $1 million. The program website is: http://www.sbir.gov/about/about-sbir.

[525] Website: http://www.sbir.gov/sbirsearch/detail/240127 (June 5, 2010).

have influenced a move to “research outcomes” and a convergence of definitions of “quality R&D results” among prosthetists, physicians, clinicians, manufactures, and users.[526] According to Iverson, this has resulted in more devices being provided to research users and standardization of tests.

Looking back, Jacobsen says his contributions to the Utah Arm stopped because of commitments to others to apply Sarcos’ robotics technology, such as Disney, starting in the 1980s. However, that has not dampened his interest in trying new approaches to assistive technologies. One of Jacbosen’s enduring interests has been the development of a human exo-skeleton system, illustrated below.

**Figure 41: Test engineer plays soccer during a demo at the Raytheon Sarcos research lab in Salt Lake City, Utah. Photo courtesy of Raytheon Company.**

Although he did not find interest for the system in the prosthetics industry, its use in military application was compelling enough to obtain a grant from DARPA to develop a powered version of the exoskeleton system. This led to prototypes in

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[526] E. Iverson, author telephone interview, June 21, 2010.

2006. Raytheon's purchase of Sarcos in 2007 was reportedly driven by their desire to expand into robotics research and production.

Jacobsen's metaphor for innovation comes from sailing. He says innovation is like tacking a sailboat into the wind, moving forward by moving right and then left against the headwind. Consistent with both his admiration of fellow MIT graduate Vannevar Bush, Jacobsen says it can look linear if you stand back far enough.[527]

Reflecting on the factors behind the success of the Utah Arm, Jacobsen said it was a combination of federal funding for R&D, national science policy initiatives, scientific and technological advances in others fields, close proximity of researchers to patients, prosthetists, technicians and collaboration among these groups. But these are also sources of problems. For instance, developing projects that are agreeable to the scientists, technologists and clinical representatives is not easy. There are also issues in having the project financier being a different party than the one that pays for the prosthetic device, such as loss of focus on customer feedback.

For Jacobsen the great resource for his projects are the students he calls "obsessible," those who get joy from creating new things, whether musical instruments or prosthetics. Like himself, they sometimes cause problems. According to Jacobsen, the kids from farms come with an advantage, having had the opportunity to "think with their hands" and practice fixing equipment with limited resources.

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[527] S. Jacobsen, author telephone interview, June 28, 2010.

And on this subject of the student as the driver of innovation, Jacobsen's thoughts turn to public policy and his concern with the potential loss of America's endless frontier of science and engineering. In his view, one of America's greatest economic challenges is in competing against nations with large rural populations whose children are, for the first generation ever, entering higher education institutions, modeled on Western or American universities and staffed by instructors educated at institutions like his University of Utah. These are not just the students returning to China and India, but those who go to work at German companies like Otto Bock that have "focus, focus, focus," according to Jacobsen.[528] Likewise, he wonders what good has come from his long publication record: "When we published the work we created competition."[529]

Motion Control seems to be both the prototypical and exceptional university start-up company. It is a company of its times in that it did what the contemporary innovation system asked. Motion Control moved products from the laboratory to the market, created value from university intellectual property, employed graduate students, created local employment, generated tax dollars for governments, and improved the lives of amputees. It has even resisted the forces of globalization and remained an American company[530] and has continued to operate in Salt Lake City. But Motion Control seems more exceptional than prototypical. As of 2011, it was one of four start-up companies that Jacobsen helped develop, which have gone on to successful acquisitions, rare for university faculty inventors. Most of the product

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[528] Ibid.

[529] Ibid.

[530] Although its ownership changed in 1997, the acquisition was by an orthotic and prosthetic firm headquartered in Chattanooga, Tennessee: Fillauer Companies, Inc.

development for the first iteration of the Utah Arm was done at the University of Utah. And Jacobsen, with more than 359 projects (as of 2011) in industry areas ranging from medical to entertainment, commercial and military, and more than 200 patents to date, is the exceptional university professor involved in technology transfer and commercialization, not the rule.

## Utah Case Analysis

The linear model does not appear to be a good fit with the Utah Arm case for the simple reason that it was an engineering design and product development project, without basic or applied research. As mentioned in the case, there was a survey undertaken of academic research, although it found no general principles for application, but rather systems that were poorly received by amputees and plagued by problems. Where promising methods were found, such as from MIT and Liberty Mutual, UNB, and the University of Edinburgh, the design team found they typically involved systems too complex for implementation. What was needed instead was a system that addressed "simple" problems, used more limited control methodologies, and addressed with considerable importance the hardware problems that had plagued previous developments. This was instead a project of the second mouse to the cheese, which followed after the diffusion of knowledge from the Boston Elbow project. It may tack like a sailboat in the wind, but it was step-wise engineering: design, build, test, and repeat as necessary.

If it was not the linear model, then was it an early example of the move from mode 1 to mode 2 science? The University of Utah design group was clearly self-conscious that this was to be a different kind of university project: practical and commercially successful. It was not technology transfer where the university handed off proof-of-concept stage designs and tests results to a company. The design group considered economic and industrial factors at the outset of the project, as well as considerations of cost and performance of fittings, production, maintenance, repairs, government regulatory affairs, payment terms, project financing, marketing material, and the establishment and training of distributors of the product. In mode 2 speak, there was change in motivation, from publishing reliable knowledge to creating a robust product.

Its three phases would take the project and university personnel beyond typical university involvement in the commercialization process. The project's first phase, development, was a point where many universities hand off projects to industry (i.e. it was no longer research and thus the capabilities of the academic personnel to contribute to the project were marginal). The first phase of the project covered a term of six years, going well beyond the period of most research grants. The second and third phases, field trials and third party evaluation of the Utah Arm, would take the group even further beyond the traditional boundaries of the university's three-fold mission.

But if the project met with requirements of mode 2 theory in terms of its interdisciplinary activities, was there a move from university laboratory-based research to generation of problems and methodologies, dissemination of results in the context of application (i.e. hospitals and clinics)? It may be a form of "weak" or "mid-range contextualization." The design, building, and testing of the first ten artificial arms were done mostly in the university's design engineering laboratory, with some limited experience in the field. The design group did, however, actively seek out patients and during and after the Phase (ii) field trials, allowing the designers to appreciate electromechanical problems that they might not have seen in the laboratory. The experience of going on the road and meeting with patients, occupational therapists, and others involved in fittings was also a transformative experience for future Motion Control president, Sears; especially after having spent years in the laboratory engaged in doctoral studies. He learned to listen and communicate with the customer and others who would influence buying decisions for the Utah Arm.

There are elements of the triple helix concept that fit with the case, although the core concept is missing: basic research linked to utilization through a series of intermediate processes involving government, university and industry collaboration. Basic research was not part of the University of Utah project. Government was not a significant player in the initial development of the Utah Arm. The US federal government did not support R&D at Motion Control after the initial launch of the Utah Arm, although by that time the University of Utah was no longer involved, and key university personnel had moved over to full time positions at the company.

Where the triple helix fits is with its concept of a "second academic revolution," "entrepreneurial university," and "knowledge production." Jacobsen's Centre for Engineering Design, with its hundreds of projects and spin-off companies, is consistent with these concepts. The Centre routinely created inventions that become commercial products, and, in doing so, expanded the university mission of "service." Presumably there is the potential for significant third-stream revenue sources. It also offers Jacobsen and his colleagues new motivations for university labour, beyond publications and presentations, to extensive collaborations with industry and government, the reduction to practice of inventions, development of new companies, and even development of new industries.

To Forman's argument that there has been a reversal in primacy in science and technology and a move to anti-disciplinarity, the focus of the Center is clearly on design engineering within a variety of fields, which seems not out of place given its name. Indeed, the existence of a design centre says something about the changing position of technology in the university. As well, Jacobsen's curriculum vitae suggests a different kind of academic, more focused on technology development and entrepreneurial in outlook. It includes an impressive record of university teaching, research, and services, but with a strong emphasis of both Sarcos and Center for Design Engineering projects that "push technology limits, and lead to pioneering commercial products."[531]

How did R&D and innovation change in this case? University personnel designed and implemented a product development project according to best practices in commercial product development. The driver of the change was initially Stephen Jacobsen, but as the project progressed Sears and Iverson came to play important roles in integrating the role of the customer and market actors (i.e.

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[531] http://www.mech.utah.edu/people/faculty/jacobsen/CV.html (June 5, 2010).

interdisciplinary groups) into the R&D process. Likewise, technological advancement in microprocessors, electronics, motors, and batteries played an important role in the improvement of the Utah Arm. There is also the interest of Jacobsen in "trying new approaches to assistive technologies"[532] and his ability to find obsessible students for projects.

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[532] S. Jacobsen, author telephone interview, June 28, 2010.

## 6.6 The i-Limb

The i-Limb is the world's first commercial prosthetic hand with five independently powered fingers and thumb. It was conceived and initially developed by David Gow at a Scottish National Health Service (NHS) hospital in Edinburgh from the mid-1980s to the early 2000s, and subsequently made into a commercial product by the start-up company he created in 2002, Touch EMAS. Brief versions of the i-Limb story have been published by both the NHS and Touch Bionics (the new name for Touch EMAS).

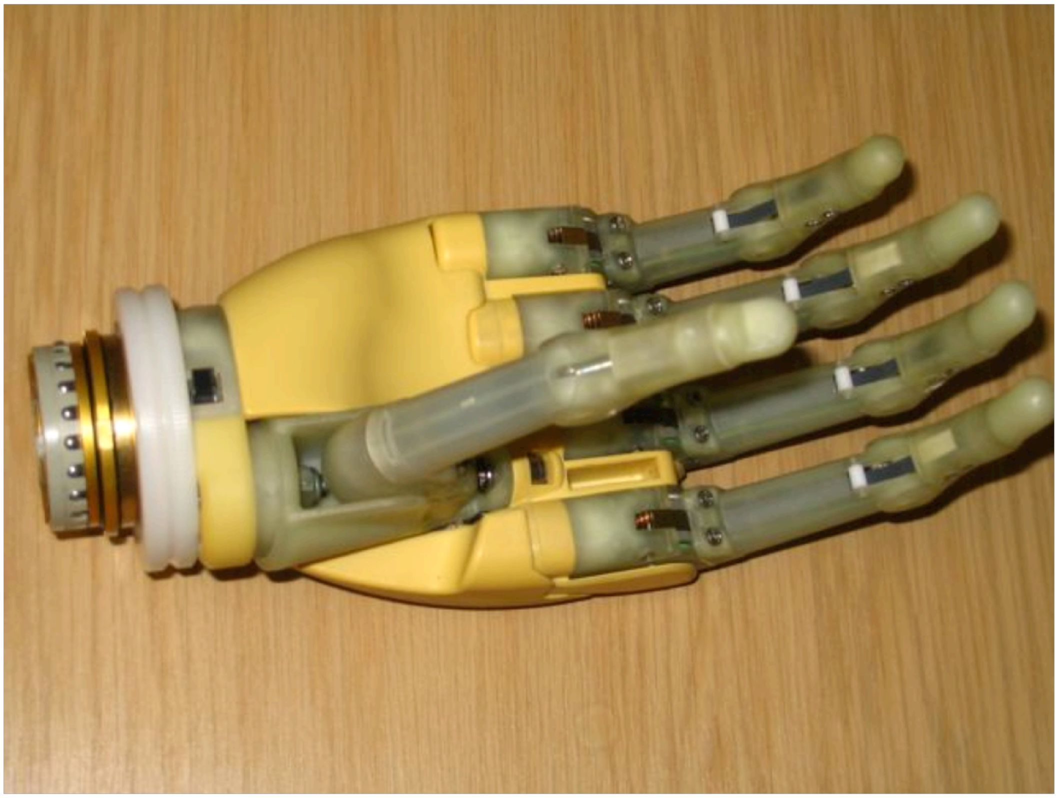

**Figure 42: The i-Limb has five independently powered digits, controlled by a traditional myoeletric system. (Image source: David Foord)**

The Edinburgh Astley Ainslie Hospital story connects the development of the i-Limb at its SMART (South-east Mobility and Rehabilitation Technology)

Centre to research on upper limb prosthetics at two predecessor NHS hospitals in Edinburgh, the Princess Margaret Rose Orthopaedic Hospital (Princess Margaret Rose) from 1963 to 2000, and then the Eastern General Hospital from 2000 to 2007.[533] Like UNB's IBME and Bloorview Research Institute, a bioengineering centre was established to conduct R&D into powered prostheses for children affected by thalidomide. Also like the IBME and the Bloorview Research Institute, its founding director, Dr. David Simpson,[534] developed an international reputation for the Centre. The Edinburgh case differs from US and Canadian institutions in using carbon dioxide canisters as the power source in the 1960s and 1970s, not batteries and myoelectric systems.

**Figure 43: Southeast Mobility and Rehabilitation Technology (SMART) Centre (Image source: NHS)**

The hospital's telling of the story focused on the Centre's third director,

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[533] The new SMART Centre was build with a budget of £7.5 million. It was specifically designed to house a range of services for disabled people at the Astley Ainslie Hospital.

[534] Like R. N. Scott, David Simpson is not a medical doctor, but is at home in orthopedic hospitals and works closely with patients in designing and fitting upper limb prosthetic devices. Both men share a patient-oriented motivation. Simpson's proudest moment occurs in seeing a child feed herself with the use of an arm system he has designed and fitted.

David Gow. Gow in the 1980s and 1990s built on the work performed at the Princess Margaret Rose in the 1960s and 1970s, although he changed the power source from $CO_2$ to the now dominant electric control systems. This work resulted in the development of the world's first electrically powered shoulder-arm-wrist-hand prosthesis in 1998[535] and a partial hand system in 2000. Gow then incorporated in 2002 the NHS's first spin-off company, TouchEMAS Ltd. In 2007 the company officially launched its i-Limb product and, and then in 2009 its ProDigits partial hand system.

The company's story also began with the work conducted at the Princess Margaret Rose in 1963, emphasizing the comprehensive research that went into developing prosthetic solutions for children. It then moved to 1986 when David Gow joined the Bioengineering Centre at the hospital (he was actually hired earlier, in 1984). In 1988, Gow started work on electronic shoulders, wrists and hands. This resulted in a partial hand system in 1993. In 1997 the first i-Limb fitting occurred with a patient. In early 2003, Gow led in the creation of a spin-off company from the NHS. Scottish Health Innovations Ltd. (SHIL) was mentioned as playing a role in the transaction, as did the regional development corporation, Scottish Enterprise, which provided financing to get the company started. Subsequently Archangel Informal Investments, TriCAP, Clydesdale Bank and the Scottish Co-investment Fund invested in the company. In 2005 the company was rebranded Touch Bionics, dropping reference to EMAS, an acronym for "Edinburgh Modular Arm System." In 2007, the i-Limb hand was launched, followed by launch

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[535] Otto Bock, LTI, Motion Control, and VASI had all previously manufactured elbows and hands, but not had integrated it with an electronically controlled shoulder.

of i-Limb digits in 2009, and thereafter, continuous improvement of the product lines.

There are also some fundamental differences in the two narratives. In the NHS story there is mention of the founding director, David Simpson. First development of the partial hand system occurs in 1993 in the company narrative, 2000 in the hospital narrative. The company story emphasizes role of the first customer, technology-transfer organization, investors, as well as product improvement work. In the NHS narrative the primary forces are NHS's founding of a bioengineering centre in light of the thalidomide tragedy, David Simpson and David Gow. In the company's telling, there is a longer list of actors, with more emphasis on those that post-date the design of the first hand system.

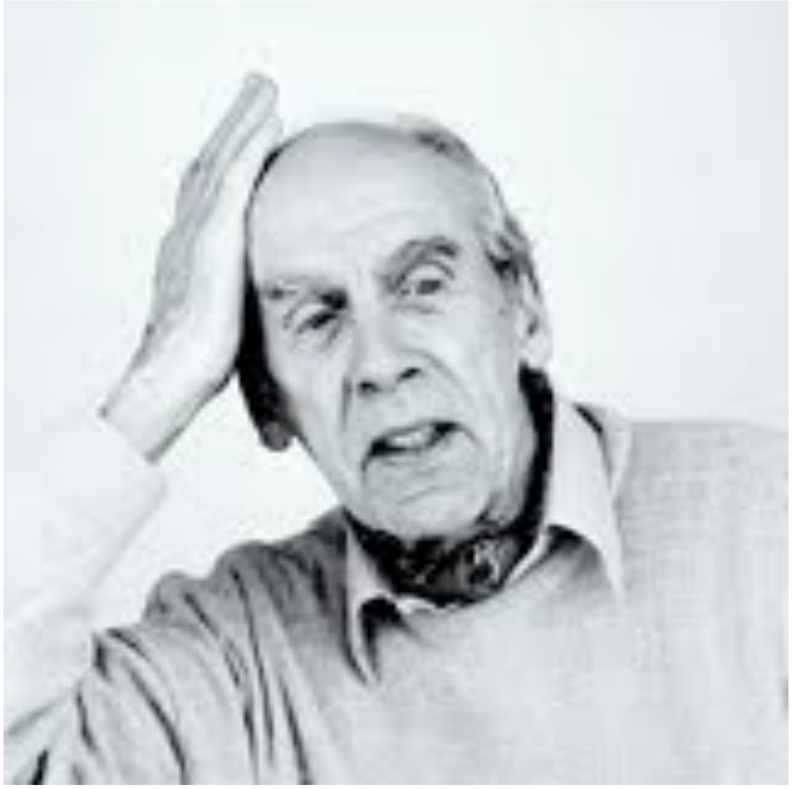

**Figure 44: David Simpson (Image source: University of Edinburgh)**

The story appropriately begins with David Simpson. Germans were to have a profound influence on his life. He was born in 1920, and had originally trained to be an accountant. But these plans were changed when war broke out and he volunteered for the Royal Scots. From the summer of 1944 to the spring of 1945 Simpson fought with the Highland Light Infantry in Belgium and the Netherlands. Only weeks before the war ended he was badly injured during combat in Germany; shrapnel cut into his right shoulder and neck, severely damaging the network of nerves responsible for control of most of his right upper limb.

Injured and traumatized by the war, and without the use of his right arm (he was right handed), he nevertheless entered the University of Edinburgh.[536] He studied physics under Max Born, the father of a childhood friend he had first met in Germany in 1938. Graduating with a bachelor's degree in science in 1945, he then obtained a PhD in medical physics in 1952. He stayed on at the University of Edinburgh after receiving his PhD and designed monitoring equipment for use in transplant surgery and a fetal heart monitor.

As in Canada, it was 1963 when major institutional funding programs were begun in light of the thalidomide tragedy. In Scotland, the NHS created and funded a new powered prosthetic unit (PPU) at the Princess Margaret Rose. And also like Canada, the technical and research organization concepts came from elsewhere. For the Scots, the influence for both the organization of the PPU and its research program came from Germany. In 1963 Simpson visited the University of Heidelberg's Orthopedic Clinic. The Heidelberg clinic, originally established in the

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[536] After a series of operations Simpson regained most of the use of his right arm shortly after completing his undergraduate degree.

1890s, had become internationally recognized as one of the world's foremost orthopaedic clinics. It had also been confronted by greater numbers of children affected by thalidomide than anywhere else. Simpson spent a few days with the University of Heidelberg's Ernst Marquardt, who had developed carbon dioxide gas powered prostheses in the 1950s, and was now applying it to children whose mothers had taken thalidomide. Although still at an early stage of development, Simpson was sufficiently impressed to accept the generous offer from Marquardt to take some of the prostheses back to Edinburgh for fittings of Scottish patients.

According to Gow, the other significant idea brought back from Heidelberg was the location of the clinic at a hospital. It was conventional for Marquardt to work in a hospital. He was a medical doctor as well as a researcher. Simpson's doctorate, however, was in medical physics. Employment in industry or academia was the more typical career path. Indeed, this was the path Simpson was on at the University of Edinburgh. The idea Simpson adapted in Edinburgh was the location of a group of physicists and engineers not in a university electrical engineering department, but in a hospital, close to patients and other professionals such as occupational therapists, prosthetists, and others.

But it did not start this way, and it appears the concept was less imported from Heidelberg than grown incrementally in Edinburgh as patient relationships become more and more central to the work of PPU staff. The first home for the PPU was in the basement of a (now demolished) house on the campus of the University of Edinburgh, five miles from the Princess Margaret Rose. This was from 1963 to 1965, when Simpson and four technicians of the PPU moved into what Gow refers to as a hut at the Princess Margaret Rose. The hut was the home of three workshops: mechanical, plastics, and electronics. This was to last four years, from 1965 to 1969.

Growth in the PPU's patient services load and staff meant that more space was needed. The next move, in 1969, coincided with a name change, from Powered Prosthetics Unit to the Orthopaedic BioEngineering Unit (OBU), indicating an expanded mandate, now including the design of beds, wheelchairs, and other biomedical devices. Funding from the Medical Research Council and the Scottish Home and Health Department was provided to build and equip new facilities in the Princess Margaret Rose to accommodate the now approximately 25 people in the OBU. There was also a change in relationships to patients. The PPU provided services to other hospital departments. Increasingly, the OBU provided services directly to patients. What this meant was that physicists, engineers, and technicians were forced to deal with patients on a daily basis, the users of their devices, and had to learn how to combine the performance of R&D at the same time as staying ahead of the needs of their patients.

The next major changed occurred in 1976 when Simpson resigned as director of the OBU to accept the post of assistant dean of the University of Edinburgh's Faculty of Medicine. As at UNB, with the second director there was an expansion in the range of services offered, as well as a focus on developing relationships both within and outside the host institutions. With the departure of Simpson there was a decline in the pneumatically powered prostheses work that he had championed during his time at the OBU. The R&D programme in body powered prosthetics continued, and there was a branching out into electrical powered devices and control systems. The OBU's mandate expanded into areas of service for surgeons, clinicians, and patients. This included the development and testing of surgical instrumentation for surgeons and clinicians, mobility aids for child patients, fracture fixation and healing.

One of the results of this increasing focus on patient services was another organizational change. In 1987, the "Orthopaedic BioEngineering Unit" became "Rehabilitation Engineering Services" (RES), formalizing the Centre's patient service activities. It was another step in the direction of clinical practice.

**Figure 45: David Gow (Image source: Touch Bionics)**

It was into the orthopaedic bioengineering unit that David Gow was hired. Born in 1957, Gow studied mechanical engineering at the University of Edinburgh, graduating with an honours degree in engineering science in 1979. Like Simpson, shortly after obtaining his degree (undergraduate, not doctorate) he was hired at the University of Edinburgh to study control systems for artificial limbs. He began his doctorate shortly thereafter, in 1981, on pneumatic upper limb prosthetics, working at the University from 1981 to 1984, when he left to join the Orthopaedic BioEngineering Unit.

A peculiarity of Gow's career path is that he did not complete his doctoral degree, nor acquire a professional teaching and research mentor, resulting in an education that more resembles that of Scott than Gow's contemporaries. Although his position at the OBU, and subsequently at the RES, allowed him to pursue doctoral studies during his employment, he only completed one course on research methods. There was, according to Gow, not the mentorship available that he felt he needed for the doctoral program, and decisively, there was the allure of prosthetic arm and hand development projects.[537] What covered the surfaces of his home were not readings for graduate courses, but sketches of what was to become Pro-digits. Gow, Like Scott, identified himself as an engineer first, although one who did R&D.[538]

Even though Gow and Simpson did not work together at the OBU, Gow nevertheless felt an influence from Simpson given the way he had structured the OBU.[539] According to Gow, Simpson wanted the OBU to be an engineering unit, not a clinical department. Simpson developed the OBU on this model, despite being

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[537] D. Gow, author interview, November 19, 2010.
[538] Ibid.
[539] Ibid.

immersed in the hospital's clinical environment, and provided with funding oriented to research, not product development. Simpson struggled against the forces that pulled the OBU into the mainstream of the hospital clinical culture. Simpson's development of a low-pressure bed for prevention of bed sores fit into that engineering/production development model, as did its commercial development, production and sales by a third-party licensee. Gow saw himself similarly, a system developer working in an engineering department, not a clinical or research unit.[540]

Two years after being hired, in 1986, Gow became responsible for the service and research areas of the OBU. His initial work in this new role was funded by government research grants and focused on development of more cosmetic prostheses. But the actual work he did was varied. He led a team doing some research, some technical work, and development of cosmetic coverings. What was obvious to Gow in doing this work was that improving the aesthetics of the prosthetic hand was not just about the cosmetics, but the overall design.[541] It was not about "pliers on wires," but creating something that looked and functioned like a human hand.

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[540] Ibid.
[541] Ibid.

**Figure 46: ProDigits are the self-contained fingers, individually powered fingers for partial-hand patients. The i-Limb Hand is effectively a chassis for five ProDigits. (Image source: Touch Bionics)**

The work to develop the Edinburgh Modular Arm System (EMAS) and ProDigits (the basis for the subsequent i-Limb) occurred over a period of twenty years, beginning in 1984, according to Gow.[542] The major milestones at the RES were the initial patenting of ProDigits in 1995 and EMAS in 1998, development of the first ProDigits prototype in 1998, first development and fitting of the EMAS in 2000, incorporation of the start-up company Touch EMAS in 2002, and a SMART Award in 2003.

According to Gow, the R&D process was highly linear, although with backwards steps. Gow characterizes it as a “journey of faith,” faith in a revolutionary product. The conceptualization of the technology that was the basis for ProDigits and the i-Limb, occurred during what Gow calls the “two years of indolence,” from 1993 to 1995, a period when grant funding had dried up and ironically “he had time to think.”[543]

The design work initially focused on a partial hand for children as young as nine years. This was different than the conventional approaching of first designing

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[542] Ibid.
[543] Ibid.

an adult device and then scaling it down for a children's hand. The power digit was the basic module, and then adapted for the specific finger or thumb. According to Gow, the initial prototype design, building, and testing of the first individual digits occurred over a period of two years, from 1996 to 1998. OBU staff did most of the work as part of the twenty percent of their time that was permitted for other projects. Gow was the project manager, applying what he called a benign dictatorship management style, keeping in touch on a daily basis with work being performed by the team.[544] The overall costs from initial design to filing of the first patent were incredibly modest for this sort of venture, about fifty thousand pounds (approximately USD$80,000)[545] for materials and supplies to produce a prototype.[546]

A patent application for the prototype prosthetic finger was filed in 1995. Gow was named as the sole inventor. Its title was "Motor drive system and linkage for hand prosthesis."[547] Its novelty was a motor and gear-box inside the prosthetic finger, and the ability of the finger joint to move up and down at the knuckle. The two additional joints of the finger and the one in the thumb did not move. The patent cites six earlier patents, including two from industry (one filed by Otto Bock in 1989), two from US government researchers, and two from university researchers, one of which was authored by Dudley Childress. In 1998 another NHS patent application naming Gow as sole inventor was filed. This one was for an

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[544] Ibid.

[545] Currency conversion made using XE Currency Converter website on May 6, 2012. Website: http://www.xe.com/ucc/.

[546] D. Gow, author interview, November 19, 2010.

[547] D. Gow, "Motor drive system and linkage for hand prosthesis" Website: http://www.google.com/patents/US5888246

"Upper limb prosthesis," consisting of a mechanical pivoting wrist, elbow and shoulder joint.[548] The most recent from Gow is a 2005 application, called "Prostheses with mechanically operated digits members." It is an improvement patent to the first filing, protecting a finger that bends at each joint, thereby allowing three grips with a finger.

Patents, along with press releases and news stories, were the major sources of information about the new arm and hand products. Consistent with the engineering design model, Gow published very few academic articles on his development activities.

With the news stories Gow had help, initially with a patient, Mr. Campbell Aird, and subsequently with staff at Touch EMAS.

**Figure 47: Campbell Aird and David Gow (Image source: Trinity University)**

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[548] D. Gow, "Upper limb prosthesis" Website: http://www.google.com/patents/US6361570 (June 5, 2010).

**Figure 48: Campbell Aird (Image source: Trinity University)**

In 1998 newspaper stories announced an EMAS fitting of a local hotelier, Campbell Aird, whose right arm was amputated after he was diagnosed with muscle cancer.[549] Aird, according to Gow, turned out to be a major force in the initial development of both the EMAS and prodigit technologies because of his persistence in seeking improved prostheses from the NHS and his skills in generating press for what he wanted. In companies it would be called "customer led innovation." Aird, according to Gow, went so far as to announce dates for his

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[549] "Field trials under way on revolutionary bionic arm" *The Scotsman*. August 26, 1998.

arm and hand system fittings, before even consulting with Gow. Gow elected to go along with it and was able to meet the deadlines. It was the resulting international press in 1998 that marked the turning points for Gow, as it was then that the investors became interested in the products. This initially occurred with the fitting of the first prototype arm/hand system in 1998. Additional press followed in 2000 when the results of the first trial with children were announced.

To secure the investment meant forming a company and in-licensing technology from the NHS.[550] In June 2002 the company, Touch EMAS, was incorporated. External government grant funding was sought with support from the NHS commercial development group, including Roger Stuart and Monica Flynn who helped write the SMART award. The NHS legal office was the biggest impediment. The licensing of the technology to the company was, according to Gow, painful, bureaucratic, and slow.[551] It was a novel transaction for the NHS and the first company to be spun out of the Scottish NHS. Scottish Health Innovations Ltd. (SHIL) became a significant shareholder because of its investment of patents, technology, and other intellectual property into the company.

Touch EMAS became the first SHIL spin-out to receive significant funding. It came from a variety of sources. An initial SMART award to the RES of sixty thousand pounds (approximately USD$97,000)[552] was granted by Scottish Enterprise, which was matched by a fifteen-thousand dollar award from the NHS. The funding was used to develop a version of the i-Limb with fingers that bent both

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[550] Real property is sold and leased. Intellectual property is assigned and licensed. Licenses, like leases, grant property rights and obligations for specific periods.

[551] Ibid.

[552] Currency conversion made using XE Currency Converter website on may 6, 2012. Website: http://www.xe.com/ucc/.

at the knuckle, as well as the two finger joints (and which was subsequently patented in 2005). Angel funding organization Archangel Informal Investments and a local regional development body Scottish Co-investment Fund, both invested directly in Touch EMAS. The funding was used to develop shoulders, elbows, wrists and hands of the modular system, and to fund the two-year secondment (two days per week) of David Gow into Touch EMAS to serve as its first president. In this role, Gow oversaw the work by external engineering design firms and subcontractors that took his clinical systems and developed prototype products for clinical trials. He also oversaw the development of a business plan, calling for recruitment of a CEO with commercial experience.

In July 2005 the new CEO was recruited and hired: Stuart Mead. Mead directed the early development work in consultation with Bill Dykes, SRPros MBAPO, a senior lecturer at the National Centre for Prosthetics and Orthotics at the University of Strathclyde, Glasgow, one of the biggest prosthetic centres in the United Kingdom. Touch EMAS used some of its expertise to get the product to a point where it could introduce it to some of its partners in the United States.

Knowing that a successful commercial launch would require introduction into the US market, Mead also developed partnerships with several US-based clinical companies. During this period the company also partnered with Livingskin from Middletown, New York; and ARTech Laboratories in Midlothian, Texas to develop durable, lifelike cosmetic solutions. Mead and Phil Newman, the head of sales and marketing at Touch Bionics, developed a market study group made up of a dozen patients, a mix of civilian, military, and ex-military patients from the UK and the US

In October 2006 the European launch of the i-Limb occurred, followed by the world launch in July 2007. The i-Limb could now be bought off the shelf for about £8,500 (approximately USD$11,100).[553] By the start of 2008 Touch Bionics had annual sales of more than $2 million, an expanding network of clinics around the world, patients in twenty-five countries (70% in the US driven by sales to soldiers wounded in the war in Iraq, 5% in the UK and 25% spread across twenty-two countries), and was closing in on its two hundredth sale. It also had the confidence of its existing investors, Archangel and TriCap business angel networks and the Scottish Co-investment fund, and projections of £5 million (approximately USD$8 million)[554] in sales in calendar 2008.

In May of 2008, Touch Bionics acquired Livingskin. The acquisition gave Touch Bionics ownership of intellectual property in an artificial skin production to use with its i-Limb and an increase in its presence in the important US market. Touch Bionics also needed the gloves for its i-Limb warranty.

By April of 2009 the company reported sales of more than 500 i-Limb hands, and expansion into the Chinese market through a prominent distributor. In that same year, Gow left the company after two years as director of technology. He considered that, by then, his services had become obsolete.[555]

Replacing Gow was Gordon McLearly, who came to the position with years of experience in product development for large multinational firms. He started

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[553] Currency conversion made using XE Currency Converter website on May 6, 2012. Website: http://www.xe.com/ucc/.

[554] Ibid.

[555] D. Gow, author interview, November 10, 2010.

after production had begun and after the third-party design had occurred, but nevertheless saw a need for a redesign of the products to address input from customers and to fit better with the production process. According to McLearly he saw two approaches to product development in the company. Initially the hand was designed with Otto Bock components. This was subsequently replaced by a design by Touch Bionics of its own components. According to McLearly this allowed the company to move to both a higher level of design, and expand its product offerings to other upper limb components.

McLearly suggested that the growth from 2007 to 2009 was almost too fast and exceeded planning.[556] He, for instance, was hired in late 2007 as employee number twenty or thereabouts. Two years later there would be two hundred on staff. Initially all of the staff at the Livingston location (approximately 15 minutes by taxi from the suburbs of Edinburgh) could fit into one of the modular buildings in the industrial park. By 2010 there were three buildings, one for administrative, corporate offices and the clinic, a second for R&D, and a third for production.[557]

For a first Scottish NHS start-up and upper limb prosthetics company, Touch Bionics had been wildly successful. It is also a bearer of the legacy that Gow inherited from Simpson, even down to the laboratories that Gow designed to facilitate the kind of work he did at the Princess Margaret Rose and Eastern General hospitals. But as Touch Bionics developed its product development and clinic business, the laboratory model that placed an electrical engineering department in a hospital, in between research and clinical cultures, had been diminished. The

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[556] G. McLearly, author interview, November 10, 2010.
[557] Ibid.

upper limb prosthetic development work that emerged as an integral function of Edinburgh hospitals from the 1960s to the first decade of the 2000s, had moved on to industry.

## Edinburgh Case Analysis

David Gow's comments on the linear model were similar to those from Scott, and like Scott, based on the assumption that this was an engineering design process, beginning with user needs, and not a research-based process. As a result, Gow found the process highly linear, although with backwards steps (Scott called them feedback loops).[558] As with Scott's initial work on myoelectric systems, Gow's ProDigits arose from conceptualization of a technical system, not through a program of fundamental research that he directed. Indeed, Gow came up with the concept for ProDigits during his "two years of indolence," from 1993 to 1995.[559] Gow, who refers to himself as an engineer, not a "lab rat,"said: "This was production, not new knowledge. We combined old things in new ways."[560] As such, the project does not fit well with the linear model. Rather, it is a design, build and test project, albeit with a novel underlying design concept.

Mode 2 offers a better fit for the case study. Over the course of David Simpson's career there was a move from University of Edinburgh's laboratory-based research to generation of problems and methodologies, and dissemination of results at the Princess Margaret Rose, Eastern General and Edinburgh Astley

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[558] D. Gow, author interview, November 10, 2010.
[559] Ibid.
[560] Ibid.

Ainslie hospitals (including the SMART Centre), and then subsequently in user homes and workplaces, and finally the clinic housed by Touch Bionics. In contrast with the theory, there was no basic research in this new context of application, but it was where products were conceptualized, developed, designed, built and demonstrated. With the change in context, presumably, it was easier to involve occupational therapists, users, company managers, and others in the development process, as well as gain access to different theories, methods, experience, and tacit knowledge to solve problems. This was also a case where "users talked back to science," in particular, Campbell Aird, who provided Gow with the features of and delivery dates for the new prosthetic hand. The definitions of quality that emerged from the development of pro-digits and the i-Limb arose not just from Gow, but also patients and colleagues at Touch Bionics. Although the case did not give rise to a "new social vision of scientists as working outside of their laboratory and engaged in the public and private realms," Gow has been recognized for his innovative work.

The triple helix concept does not appear to apply as there is no "basic research linked to utilization through a series of intermediate processes involving government, university and industry collaboration." Missing is both basic research and university involvement during the period of development of ProDigits and the i-Limb.

To the question of whether there has been a reversal in primacy in science and technology, as with the UNB and Toronto cases, there was significant research funding for upper limb prosthetics research in the 1960s and 1970s, then a dearth of funding for prosthetic research in the 1980s and 1990s, and a rise in new funding programs in the 1990s and 2000s for patenting, innovation projects and start-up of new companies. Gow said that as the funding dried up in the 1970s the Centre moved from research projects to design of devices. With the diminishing research funding the choice for Simpson was whether he wanted the department to be an engineering department or a clinical department. It was no choice; Simpson's strong interest was for an engineering department.

There is also Gow's attitude, and his interests. He wanted to see his work proceed past proof-of-principal studies and into commercial production and use. He was a keen partner for the innovation-funding program. He also appreciated the mixture of theory and practice, and was suspicious of fundamental research by itself. He said: "Theory without practice is intellectual play, and practice without theory is blind."[561] Gow also said that he considered the conceptualization of ProDigits, the design, development and testing activities, and the commercial implementation to be equally important.

How did R&D and innovation change in this case? Among the drivers was the government response to thalidomide, the influence of the Heidelberg Orthopaedic Institute, David Simpson's development of the NHS rehabilitation engineering program, and David Gow's desire to make a better electronic prosthesis, and to take the SMART Centre further into the clinical practice and device development. Government funding programs and private investors also

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[561] Ibid.

played an important role in financing and developing the technology, and Touch Bionics.

# 7. CONCLUSION

## Linear Model of Innovation

In brief, the linear model is applicable in the field history in you take a long view, for example from the UCLA study in the 1950s selecting myoelectric signals as the most promising for prosthetic device control to the late 1970s when the vague line between been crossed from pre-commercial to commercial products. Or better still, measured in centuries, from Galvani's 1791 discovery of the relationship between electricity and muscle contraction as a result of experiments with frog's legs at the University of Bologna.

The linear model did not fare so well in examination against the case studies. None of the cases met all of the criteria of the model. After reviewing with interview subjects a definition of the linear model, only a few agreed the model reflected their experience in making prosthetic devices, although, I suspect, those who agreed with the model had in mind the classic engineering design model (not the linear model of innovation), beginning with user need and proceeding through basic and detailed design to construction and testing. Martin Mifsud and Al Timmen from the Toronto case were two of the interview subjects who saw the process as mostly linear, and explicitly stated that it began with the identification of user needs, followed by design, production of prototype devices, testing and user trials. It was repeated based on user feedback and available funding. Once the final design was approved, it was released for production. R. N. Scott, Greg Bush, and David Gow from, respectively, the UNB and Edinburgh cases, saw a similar engineering process, although all spoke about feedback loops or backwards steps. As mentioned, neither Scott nor Gow was the recipient of research grant funding nor directed a program of fundamental research before conceptualizing their technical systems. Jacobsen's concept of tacking is similar, in that concepts and designs eventually make it through the steps in the process, and like Scott and Gow, it is a design-centred approach, albeit with very innovative concepts.

There was a third group of engineers/researchers interviewed for this study who distinguished between basic and applied research, found these concepts useful in explaining their work, but saw the linkages between basic research and applied research and design engineering as not straightforward. Phil Parker appeared to take Scott's comment about the feedback loop a step further in his statement that basic and applied research move back and forth over issues, and only after the proof-of-concept stage does the process appear to be linear. Biden said a spaghetti-on-the-plate model is closer to the truth.

Hudgins commented not on the performance of research, but rather on the funding of research. In his experience basic research that had been supported in the 1980s was now being bypassed by new funding agencies that focused on technology and product development, a symptom of mode 2 tendencies.

The cases where the linear model appeared to have the closest, but far from exact fit, were those in which technology or knowledge were generated by one group and then transferred for more research or engineering design activities. But it is not a stepwise process: research continues throughout the development of products. In the Boston Elbow history, concepts from Norbert Wiener and basic concept designs from Germany and Russia were known to Robert Mann when he was designing prototypes. The designs were in turn transferred to Liberty Mutual and used by Robert Jerrard and T. Wally Williams at Liberty Mutual in the redesign and improvement of the prototype device to produce a commercial product. Likewise, Scott's provision of "low tech" assistance to quadriplegic patients to improve control of their wheelchairs used knowledge from research at UCLA that he learned about at the CPRD conferences he attended in the early 1960s.

For Otto Bock there was research that went back to 1919, as well as the R&D directed by Hannes Schmidl of the INAIL, and Zemann for Viennatone. The specifications from INAIL were likely useful in the design of the prosthetic hand hardware. Likewise, Todd Kuiken's groundbreaking work on TMR was conceptualized in reading a survey article on existing methods for recording of electrical activity in nerves and muscles. This in turn allowed Otto Bock to apply and test TMR at its facility in Vienna.

There are gradations of linearity. In one version of the strong model, fundamental research provides a major concept for testing in an applied research project, and the concept then provides the primary novel features in a prototype product, which is then diffused to other producers through technology transfer. Bernie Hudgins's doctoral research on pattern recognition approximates this first two-steps model in the move to a prototype system that was coded and tested at UNB in the 1980s. However, diffusion appears to come before production in the transfer of the code to groups at the RIC and Deka in order to apply the pattern recognition system with TMR. In one version of the weak model, broad theoretical concepts influence the development of a prototype system, although they do not provide solutions to major problems that must be solved to develop a product. This was the case with the Boston Elbow. Concepts from Norbert Wiener influenced Mann's design, although the major design issues were resolved during redesigns at MIT and Liberty Mutual. Select cases in this dissertation approximate, at most, a weak version of the linear model of innovation.

## Triple Helix

I asked these questions of the triple helix model in the introductory section Is basic research linked to utilization through a series of intermediate processes involving government, university and industry collaboration? Is this biomedical R&D field part of a "second academic revolution," which involves a move to an entrepreneurial university? Are the universities that host these biomedical and bioengineering programs "entrepreneurial universities?" Can the biomedical research at these universities be characterized as "knowledge production?" Did the development of these programs expand the university mission of "service?" What were significant "third steam" revenue sources? For biomedical researchers were there new incentives in academic life during the fifty-five year period of this study? Or were the motivations of faculty in the 1950s and 1960s similar to those of today?

The answer to most of the questions is no, with the exception of Jacobsen's Center for Engineering Design at the University of Utah, which in general appears to be an anomaly within universities. The triple helix concept does not appear to apply to the European cases given the lack of universities in the Edinburgh (at least after the move by Simpson) and Otto Bock cases. In the case of UNB, the triple helix concept was illuminating for the UNB hosted Myoelectric Control Symposium, but less so for its R&D projects, where the linkages have less to do with industry than with patients, hospital staff, and other researchers. The same can be said of development activities at the OCCC and the Bloorview Centre. There was collaboration between these entities and the University of Toronto and UNB, as well as the successful partnership with the Variety Club or Toronto in the creation and operation of VASI. But there was not significant industry collaboration, although VASI did collaborate with other parties in its commercialization activities. For the Boston Elbow, there was university and industry collaboration, but government appeared to be a minor player.

### Mode 2

Was there a move from university laboratory-based research to generation of problems and methodologies, dissemination of results in hospitals and clinics, as well as user homes and workplaces? Has R&D changed from being the sole domain of electrical engineers to involving occupational therapists, users, company managers, and others involving their own theories, methods, experience, and tacit knowledge to solve problems? Do amputees talk back to engineers? Have definitions of quality emerged that are judged not just by research disciplinary peers, but also by companies, patients and others? Do researchers see laboratory tests as most important, or patient feedback?

Although the simple answer to each question is yes, for the cases the question of applicability of the mode 2 model is complicated by movement in the other direction, from mode 2 to mode 1, during the 1970s to the present. In some cases, such as the UNB case, design engineering, product development and sales, and the fitting of limbs by a university precedes mode 1 type activities. Scott, Biden, Milner, and Hubbard all spoke about this transition. Max Nader and Hans Deitel commented on the enduring research in upper limb prosthetics that does not make an impact on clinical practice (i.e. interestingly, that appears to be work, which is neither mode 1 or mode 2). A major reason for the countermove (from a design engineering focus to an applied research orientation) was the dissemination of the applied science research model to engineering schools, the resultant growth in doctoral engineering programs, and the termination in the 1970s of clinically oriented R&D programs for veterans, and children affected by thalidomide. As a result, those engineers/researchers who remained in the field from the late 1970s and onward sought a greater portion of their funding from research programs during the 1980s and 1990s. This supported the growth of research programs in this period. Although funding for research continued to be available in the first decade of the 2000s, new innovation funding for upper limb prosthetics grew as a result of the US-led gulf wars, and separately, as commercialization-funding programs were launched in the 1990s and 2000s. It is these sorts of funding programs that I suspect the mode 2 authors had in mind when writing about the new production of knowledge. And although there are signs of a transition to something like mode 2, the “context of application” requirement of mode 2 – if taken to mean being in the place of patients or customers or users of products and services made from university research – raises a very high bar for university faculty members. Indeed, how many university researchers are like those at UNB's IBME, having patients fitted with UNB designed products come and go on a daily basis?

The second major conclusion is that the mode 2 concept of "context of application" is a common and important element of the case studies.  In most of the cases there was a move from university laboratory-based research to generation of problems and dissemination of results in the context of application, such as hospitals and clinics, as well as user homes and workplaces. And within this context of application, R&D appears to have changed from being the sole domain of electrical engineers to involving occupational therapists, users, company managers, and others involving different approaches to solving problems. At MIT, UNB and the OCCC it began in the 1960s. At Motion Control in the 1970s, Sears sought out this environment and brought this context to bear on the development of the Utah Arm. For David Gow, whose office and laboratory is in a clinic and who is immersed in the daily demands of a clinical practice, the challenge was not to seek out occupational therapists and patients, but rather to not be consumed by his clinical practice. The development of methodologies and concepts to solve problems confronted in the clinic is another matter. It appears that development of concepts used in creating designs for new prosthetics systems occurred elsewhere, either in laboratories or places away from the demands of a clinical practice of the hospital and clinic. For David Gow the drawings of what became the ProDigits were made at his residence. Indeed, it is easy to see the need for a closed door to reflect on experiences in the clinic and with patients.

A third conclusion is that mode 2 appears to be, at least with respect to this study, a theory of exceptional cases of academic or university based research. Most of research projects in the field of upper limb myoelectric prostheses over the past half century did not result in a product like the Boston Arm. Indeed, the two cases that best fit with the mode 2 concept are the exceptional cases of the Utah Arm and i-Limb. That they are both success stories is one limiting factor. Even more limiting for the Edinburgh case is that David Gow worked in a clinic that purchased prosthetic devices, and provided him with access to the buyers and users of the devices. How many university professors work in facilities that also have customers coming and going on a daily basis? Likewise, Jacobsen appears to be quite exceptional in his abilities to generate technology-based products, inventions, and spin-off companies.

As a corollary to this conclusion, given the apparent smallness of mode 2 knowledge production in the field and the widespread rise in innovation funding programs, one obvious question is whether there exists a kind of interzone between mode 1 and mode 2. This interzonal science is neither fish, nor fowl. It is neither what the research groups really want to do, which is seeing where the research will take them, nor what the innovation funding body wants, which is local jobs and tax revenue from commercialization. In trying to do both, it does neither. It is tempting to speculate that this is a real problem, in that government sponsored R&D funding programs designed to have researchers create commercially oriented technology, whether solely or in collaboration with companies, are instead resulting in technologies that are rarely incorporated into products. However, neither the field history essay nor the field essays provide a good basis to answer this question.

Last, to what extent can mode 2 theory offer the "big tent" coverage that the linear model of innovation offered to basic researchers, applied researchers, developers, and producers? Can the players involved in making myoelectric upper limbs fit into mode 2 the way they can be lined up for the linear model? One difference is the terminology used in the mode 2 concept. Instead of basic research, applied research, development, production, and diffusion, the components of the model might instead be said to integrate research with engineering, entrepreneurship, innovation, and commercialization. As mentioned earlier, research, whether undertaken by scientists or research engineers, may be the most difficult to integrate into the model if it must be done at "context of application," (e.g. hospital or shop floor). The "weak contextualization" concept, however, offers a convenient annex to enroll the interests of researchers.

Although entrepreneurship was not included as a specific element of the model, it has many attributes that lend itself to mode 2. The Schumpeterian ideas of entrepreneurial leadership fit well with the cases. The engineers who led the design projects had little glamour, and their work was task focused. They broke off old traditions of making and using prostheses, and created not just new products, but also new ways to make prostheses and fit amputees. It was creative work and there were private kingdoms founded, albeit mostly of the small academic or clinical kind. There was Mark I entrepreneurship in the establishment, development and early growth of Otto Bock. The later Otto Bock and Liberty Mutual can both be seen as examples of Schumpeterian Mark II large firms. Touch Bionics and Jacobsen's Sarcos both fit the Mark I-Mark II "synthesis" model presented in Chapter 2, combining both entrepreneurial leadership from the Mark I model with venture capital financing and professional management from Mark II type companies.

Likewise, various kinds of innovation also appear to be a good fit for the mode 2 "big tent," whether disruptive or incremental, user-inspired, or open. Arguably, incremental innovation fits within the mode 2 model better than disruptive innovation given the assumption that the latter comes from outsiders. In the field history and cases, there is "interpretive flexibility" as to whether or not innovation is incremental or disruptive. In favour of incremental innovation, body powered prostheses remain the dominant upper limb prosthetic device, so if disruption means gaining at least fifty percent market share, myoelectric devices are not yet disruptive. If instead the focus is on technological differentiation, then there may be an argument that development of the myoelectric upper limb market in the 1980s and 1990s constituted a disruption. Likewise, there is an argument that acceptance of the i-Limb disproved the accepted wisdom that amputees did not want an expensive, lightweight, electric hand with five powered fingers, and opened up a market for the bebionic hand from RSL Steeper and the Otto Bock Michelangelo Hand.

In terms of the user innovation, both the user-consumer and user-producer models are found in the field. User consumers had significant roles in all of the cases, although exercised somewhat less influence than users in the famous SCOT "safety bicycle" case study. In terms of user producers, there is an argument that prosthetists are user producers, and play significant roles in the UNB and Toronto cases. The examples of actual amputee user producers, however, lay outside of the myoelectric part of the upper limb device field.[562]

Last, open-innovation also appears to be a good candidate for inclusion in the big tent version of mode 2. Indeed, it seems the most obvious given the collaborative approach to knowledge production within mode 2. It also fits well with the Otto Bock, MIT, UNB, and Toronto case studies.

## Postmodernity

Was there a belief, even if not made explicit, from the 1940s to the 1970s that science was the senior partner in the project to provide veterans and others with powered upper limbs, and followed by a widespread change to the view that science was more a service provider than a guide to technology development, than relationship among equals? The second major question is whether there was a

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[562] One is Bob Radocy of Boulder, Colorado who lost his left arm in an auto accident in 1971. Frustrated by his experience of existing prosthetics devices, he designed a body-powered prehensor during his graduate studies in engineering and biological sciences. In 1980 he formed a company, TRS Inc. and launched his first product. For leg prosthesis, Hanger Orthopedic Group was founded by a confederate soldier and former engineering student, James Edward Hanger, who lost his leg in the 1861 Battle of Philippi and created the first "Hanger Limb" by year-end. I will also ask in the conclusion whether any of the cases fit with the criteria of user-innovation, and whether the concept of user can be expanded from the wearer of the prosthesis to the clinical personnel involved in selecting, fitting and training the amputee to use the prosthesis.

change in values in the field during the second half of the twentieth century, moving away from proceduralism, disinterestedness, autonomy, and socialism?

To the first question the answer appears to be yes, although it is debatable whether it has continued to be a relationship among equals, with each contributing to the purposes of the other group. What is clear, however, is that as early as the 1960s many of the laboratories in the cases were oriented toward technologically or user-defined ends. Specifically, INAIL, Otto Bock, UNB, OCCC, MIT, the University of Utah, and the Princess Margaret Rose were designing, building and testing myoelectric control systems and electronic limbs for clinical and amputee use. In some cases, these activities at universities more resembled new product development projects, such as at the University of Utah, or extended into manufacturing, such as at UNB.

There is also a good argument that what was being designed in these laboratories was done in response to something akin to a demand for "relevance." It came from governments, clinics, and companies to research and develop electric arms for veterans and children. For engineer-researchers in universities, responding to this call for relevance provided them with a narrative other than the dominant research-based enlightenment and emancipation narrative of the university (which has university research in the service of developing an educated and free citizenry). If engineers found this older narrative a difficult fit for their profession, or just plain baffling, then this move to customer oriented design projects offered as a way for engineers to find a place for their work in the narrative of progress.

I argue that the engineering design work was done under the name of research, but was not research. The fundamental question is one of intention. Was it research performed to see where the cybernetics theory may take the investigator, or to input to a device to be designed for potential clinical application, or both? The first is basic research, the second applied research, and, if combined, it is, as mentioned by the authors of *Science and Technology in the Service of the Physically Handicapped*, somewhat blurred.[563] Most of the projects in the case studies fit best with the category of experimental development. Only a few projects appear to meet the criteria for applied research, specifically the Alter doctoral project, much of the research on pattern recognition systems, and investigations of TMR; all were original investigation to acquire new knowledge, directed primarily towards the aim or objective of generating research results for subsequent application in a prosthetic system.

Admittedly, the line between applied research and experimental development is fuzzy, given that both are directed primarily towards a specific practical aim or objective. But with experimental development there is the requirement for systematic work, which may draw on existing knowledge gained from research and/or practical experience, such as Mann's experience in design muscle power systems, prior design of controllers at UNB, or terminal devices at OCCC. There is also a second requirement that it be directed to producing a new device or improving the device. The Rothchild doctoral project appeared to have as its primary purpose the design of devices to meet user needs, as did activities at the

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[563] In Donald Stoke's book *Pasteur's Quadrant*, these are, respectively, the Bohr, Edisonian and Pasteur's Quadrant. Donald Stokes, *Pasteur's Quadrant*.

University of Utah, OCCC, UNB in the 1960s and 1970s and then again in the 2000s, and the Princess Margaret Rose. The names of the centres and institutes in which this work was undertaken is also reflective of the experimental development or product design focus: Scott's technical assistance and research group for physical rehabilitation and then subsequently the Institute for Biomedical Engineering; Robert Mann's engineering design division; Stephen Jacobsen's centre for engineering design, and David Gow's orthopaedic bioengineering unit. The general observation is that given this focus on experimental development, many of the laboratories featured in the case studies were primarily technology, not science, oriented, and had made the change in prioritization at least two decades before 1980.

To the second major question about the change of values in the 1980s, there is good evidence that the field moves away from at least some of the values Forman has identified. The question of changes in proceduralism is complicated by the existence of two procedures in the field, a scientific method and an engineering design method. The Utah case is perhaps the most interesting because the Center for Design Engineering undertook both scientific research and engineering design, and yet also reconfigured some of its project activities to incorporate practices from business. It did not merely extend research in a linear fashion into product development, but reconceived university research projects as product development. This is less "academic capitalism" than just capitalism. Likewise, at UNB and the Princess Margaret Rose, Scott and Gow, respectively, oversaw the move from clinical prototypes to manufacturing of commercial products. On disinterestedness, again the changing motivation can be most clearly seen in the Utah and Edinburgh cases. Changes in autonomy can be seen most clearly in the new practices that came in with the innovation funding programs. Instead of research grants, there were long and detailed funding contracts and multiparty collaborative research agreements that governed the statement of work, deliverables, background and foreground intellectual property and use of funds awarded to the project. The emphasis on commercialization introduced professional managers into projects. And, relevant to Forman's concept of socialism, there was an increase in treatment of research results as private property, whether through use of non-disclosure agreement or in patenting of inventions.

In addition to the changes in values, there was also a change in the relationship of engineering to the other disciplines around it within the field of biomedical engineering. The focus for Forman is the science-technology relationship, and likewise I have focused on the science-applied science relationship within the linear model of innovation. But if we step back from the science and engineering relationship, we also see that the disciplines of art, biology, business, computer science and medicine border engineering in this field. The discipline of art is perhaps the most surprising, although it has the oldest relationship with engineering and a crucial role in the cases. Specifically, the art sub-discipline of drawing was a critical part of the engineering design process. It was, for instance, the sketching of designs at David Gow's home that led to the i-Limb, which subsequently leads to Touch Bionics. The connection to business is more obvious, and, as mentioned, is most clearly seen in the Utah and Edinburgh cases. Medicine, specifically rehabilitation medicine, also pulls at engineering over the period of study, as well as the discipline occupational therapy. In standing back from the science-engineering relationship the overall impression is not of engineering becoming anti-disciplinary, but of engineering moving closer to art and business and the disciplines with rehabilitation medicine, and incorporating practices form these disciplines within engineering.

## Forces

This multidimensional model of how engineering research and design practices changed over the course of the study in relation to its allied disciplines raises a fundamental question of the major forces behind that change.

The forces and model of causation appear to differentiate the field history from the case studies. In the field history the macro-level forces come to the front: war, disease, the thalidomide tragedy, and technological innovation in other fields (lithium ion batteries, transistors and microprocessors) exert strong influences on the research and development of myoelectric devices. In these cases, it is the people who research, design, test, manufacture, sell, and use the devices who come to the fore.

In sum, the list of major forces are technological innovation in other fields, especially transistors, microprocessors and batteries, government funding programs, and the design personnel, and changing ideas of technology development. Although technology from other fields was literally and figuratively instrumental, the devices and systems that were developed were hardly inevitable, with government dollars and engineers in the role of mere servants to technological determinism. Governments were motivated by the desire to respond positively to veterans and the thalidomide tragedy (plus, litigation was in the mind of governments from the start), and to make productive citizens. Governments used contemporary conceptions of research to formulate funding programs to make good on these motivations, initially inspired by the linear model of innovation during the period from World War II to the mid-1970s, followed by a period of reduced R&D funding from the mid-1970s to 2000s, and then in the 2000s the emergence of innovation and commercialization funding programs.[564] Engineers and other biomedical professionals were not merely acted upon by technology and funding programs. They exploited them to do research, but also in many cases to work beyond their institutional mandates to do engineering design, prototype development, commercial product design and testing with users in clinics, and in some cases product manufacturing and the fitting of amputees. In doing so they helped legitimate university and hospital activities that went well beyond university missions of teaching and research and hospital missions of clinical care, research and education.

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[564] As with the transition in the 1960s to design of myoelectrically controlled limbs, governments continue to exert control over project activities. The current major US program in upper limb myoelectric prosthetics is the DARPA Revolutionizing Prosthetics Project. The project manager, Stewart Coulter, said of the program: "Commercialization is a big part of that [program] focus. We're very much pushing on the process because we realize that's a very critical part of it. In parallel with the technical work is work on manufacturing-process development—and this is something that we have done a lot with a number of other products. That's a big part of what we're doing, now."[564]

## Utility of the Study

Beyond the assessment of the models, how might this account be applied to understanding or forecasting other cases or areas of technological innovation, or to the design of policies to support the development of new technology-based products? This history will have very limited utility in forecasting, whether for myoelectric, TMR or other technologies, but hopefully will be useful in on-going debates about how biomedical technological innovations occurs. The dissertation points to the importance of context for engineering design projects, and the challenge for similar projects (whether at universities, government labs or elsewhere) that do not have the benefit of this location of users, collaborators, equipment, other professionals, etc. This observation about context of application is also relevant for others fields of engineering research and design. The popularity of the user-innovation and SCOT models and their case studies point to the importance of not just users, but also to the importance of the context in which their users develop and improve medical equipment, scientific instruments, and manufacturing systems.

The study also points the importance of design engineering and trial-and-error testing with users in developing new upper limb devices. Although fundamental studies contributed to the field and realization of devices at MIT, UNB, OCCC and elsewhere, it was in many cases the self-identified design-engineer that led the projects to reduce general concepts to practice in commercial devices. Perhaps if this work did not get described as science and basic research this point would not be so remarkable.

If what policy makers wants are more of these exceptional cases of technological innovation, then finding novel means to locate R&D engineering design teams in "contexts of application" should be a priority. But this is not a simple task as the separation of R&D groups from these contexts is based on major and long-standings concepts, policies and practices. As Gow said, the demands of the clinic are so strong that it is easy to be submerged by this work. We assume there is a need to physically get away from these demands so we can read, think and write creatively. The alignment of research with university teaching and traditional university missions institutionalizes this physical separation, and also supports a cultural separation that until recently was considered socially desirable. This is not necessarily a barrier to the performance of R&D and design projects at hospitals or clinics. At UNB, for instance, the clinic is downstairs from research offices and laboratory. But for many in the field it is a challenge, such as the engineers at the University of Southampton who have no such facility on their fourth floor of their engineering build.

This point is also broadly applicable to government, institute or university researchers and which aspire to contribute to medical or industrial arts. Industrial scale refineries, power plants, manufacturing facilities, and mines are rarely if ever located in engineering faculty buildings or university campuses. These are located elsewhere and for countless good reasons. To move researchers or process developers to contexts of application, grant and contract funding, whether from industry or government, has for decades supported the travel and service costs of research and consulting engineers. More recently, network type funding programs have been created to support longer projects and deeper relationships among the project partners. The Canadian PRTU grants can be viewed as a precursor to these type of network funding programs. But the limitation of these programs is that they often only support a kind of weak contextualization, largely because the researcher often has a full-time job back at the university, institute or laboratory and is only a visitor in the hospital or plant. Rarely, it seems, are researchers like Scott who make it a priority travel to the site over the course of decades and contribute to new design like Gow did at Princess Margaret Rose Hospital.

As mentioned, this is a vexing issue and not easily solved by project funding. It is also an important one as the grounds of legitimacy of research institutions have, if Foreman is believed, shifted from a mission focused on science-based understanding to the advancement of technology. Or instead the change is better described by mode 2 theory, from the pursuit of fundamental to useful knowledge. One of the challenges that these research institutions face, then, is the ability to make good on this mandate with only project funding, and only in exceptional cases.

## Future Research

To further explore the history of the R&D, innovation and commercialization of electronic arms and hands I would like to examine work over the past half century at the RIC and RSL Steeper. There are numerous mentions of the RIC in this study, but I only scratched the surface of the Institute's role in the field. I would have liked to include a case study on the development of the bebionic hand and its commercialization by RSL Steeper. The bebionic hand has in the past few years emerged as the major competitor to the i-Limb. Its development appears to have the makings for a fascinating case study that would fit well with the existing six cases. I would like to investigate the case and try and understand it in light of the theories discussed in this dissertation.

There is also a need for future research to address the broader question of whether the experiences of R&D and commercialization in the field of myoelectric upper limb are unique to electrical or biomedical engineering, or general to certain other areas of engineering. If they are general to other areas of engineering, then there is a stronger argument in favour of the role that engineering faculty members and "little laboratories" played in the emergence of Forman's postmodernity. On the "two transitions" thesis, there are already many histories of engineering that make the case for the transition from a craft to an applied science research culture. The master-narrative is less clear on what has happened since the 1960s. Is it the story of mode 1 to mode 2 and modernity to postmodernity, or is there an alternative narrative structure?

Would a macro, meso, or micro level study be best suited to investigate whether the field of myoelectric upper limb prostheses is particularly unique or generalizable? My preference would be for a series of meso-level studies on perhaps a half dozen engineering sub-fields. The short field history in Chapter 5 would serve as the model, although there would be more of a focus on how the individual engineering cultures changed, and the cultural and other forces at work on that change.

Just as there are many branches of engineering to investigate, so too there are many theories of innovation to use in these social science histories of contemporary technology. One of the tasks in developing new studies is pairing theories with fields of study. One of the areas of theory that would have been interesting to apply to the case studies in this dissertation are evolutionary theories of creativity, in particular Dean Simonton's ideas in *The Origins of Genius*[565] and Teresa Amabile's *Creativity in Context*.[566] These evolutionary theories appear to cut across concepts of basic and applied research, and design engineering, as well as much else. As a result they would provide an alternate way to look at the cases, following trends in the history of technology to move into the minds and creative process developers, but without leaving aside social factors. Indeed, I can almost imagine re-researching my cases to investigate evolutionary theories. But I will instead leave these theories for another field of study.

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[565] Dean Simonton, *Origins of Genius: Darwinian Perspectives on Creativity* (Oxford: Oxford University Press, 1999.)

[566] Teresa Amabile, *Creativity In Context: Update To The Social Psychology Of Creativity* (Boulder, Co.: Westview Press, 1996.)

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# APPENDIX A – INTERVIEW QUESTIONS

The interview questions are premised on knowing the name and title of interviewee, having introduced the goals and plans of the study, provided an introduction to key concepts of mode 2, triple helix and postmodern science theories, and having reviewed the draft narrative of the case.

**Questions for All Interviewees**

1. Personal Information: What is the location of your primary residence, e.g. Fredericton New Brunswick? Who is your employer? What is your age (by decade, e.g. 40-49)? What, if any, post-secondary degrees or diplomas do you have?
2. What are the major advances in myoelectric upper limb prosthetics since 1960?
3. How have research, development, and innovation changed in this field during the period from 1960 to the present? How has the R&D culture changed, if at all?
4. How have you learned about advances in the field (other than those from your projects and centre/institute/business)? Please rank the following sources of information in terms of their use in informing you of advances, and second rate them in terms of usefulness for your work: “5” means extremely useful, “4” means mostly useful, “3” means sometimes useful, “2” means rarely useful, and “1” means not useful. The information sources are:

    a. journals;
    b. conferences presentations;
    c. informal conference discussions;
    d. private correspondence;
    e. patents;
    f. websites/listservs; or
    g. other (please specify).

   Please specify which journals and conferences you read/attend (featuring publications or presentations containing information on myoelectric upper limb prosthetics) and rate them according to the above scale.

5. How do publicly funded researchers in universities and teaching hospitals make their most useful contributions to advances in upper limb prosthetics? Please use the above rating system.
    a. education of undergraduate students in academic programs and upper limb prosthetics related research projects;
    b. education of graduate students in academic programs and upper limb prosthetics related research projects;
    c. development of novel upper limb prosthetic technologies;
    d. collaborative R&D projects with companies;
    e. patenting and licensing of inventions;
    f. delivery of training programs;
    g. publication of research results in journals;
    h. presentation of conference papers; and

   i. hosting of conferences.

Please specify which training programs and conferences you have attended (related to myoelectric upper limb prosthetics) and rate them according to the above scale.

6. What are the major and minor forces behind technological change in the field? Availability of federal funding for R&D following wars and the thalidomide tragedy? National science policy initiatives? Scientific discoveries in other fields? Engineering or technological advances in others fields? Close proximity of researchers to patients, prosthetists, technicians and others? Close cooperation among research laboratories. Close cooperation between hospitals, universities, and companies? Other factors?
7. To what extent has there been a move from research oriented to fundamental understanding to research oriented to use in the field (or vice versa)? If changes occurred, when and where did they occur first?
8. Are there multiple definitions for quality of R&D results, i.e. not just by disciplinary peers, but also by prosthetists, physicians, clinicians, manufactures, users, etc.? How have those definitions changed during your time in the field? How do the definitions differ? To what extent do each of these groups influence R&D activities in the field? How has this influence changed over the period?
9. To what extend has intellectual property been a consideration in the protection of advances in the field e.g. are patent searches done, patent

applications filed, trade-secrets protected, etc.? How has this changed over time?

10. Does technology "evolve" (incrementally changing from earlier work) in the field? Can you provide an example of a new technology that does not evolve, but seems to come from nowhere?
11. Would you characterize research, development, and innovation in the field as linear, i.e. moving from fundamental research to applied research, then to development, design, production, testing, commercialization, and dissemination? If it happens differently, how has it occurred?

**Case Questions – These questions are only for those people involved in one of the cases being written for the dissertation.**

***Institutions***

1. Which institutions were involved in the case?
2. Who has lead and leads your centre/institute/business?
3. How has the institution been funded? How has the funding changed over time?
4. What is the mission or your centre/institute/business? How has it changed over time?
5. How, if at all, did the history and structure of your centre/institute/business impact on the resulting knowledge and technology?
6. What documents should I read to understand the history of your centre/institute/business? How can I get access to these documents?

### *Technology and Knowledge*

7. What was the technology and knowledge that arose in this case?
8. Where did the ideas come from?
9. How did the new knowledge from you work advance the field? What was new about it?
10. Do you have photos or illustrations you can share with me?
11. Where is the technology and knowledge used today? And how has it influenced the advancement of the field?

### *Project(s) and Activities*

12. What projects and activities make up this case? When did they occur? This may include work to undertake feasibility studies (technical and commercial), obtain funding and overcome regulatory hurdles, as well as work to research, develop, design, prototype, test, patent, market, license, and sell new technologies and products.
13. What documents should I read to understand the project(s)? How, if at all, can I get access to these documents?
14. What, if anything, would you do differently in these projects if you could do it again?

### *Money*

15. What was the cost of the project(s)?
16. Who funded the work and in what amounts?
17. If public R&D funds were involved, was it awarded under a competitive, peer-reviewed process? By what funding agencies?

18. Who covered overhead costs?
19. Were there project budgets?

### *People*

20. What was your role and position in the case?
21. What did you contribute?
22. Where did your work occur?
23. Who were the key people involved in the case and what did they contribute?
24. How was/were the project(s) structured and managed? Was there a project org chart? How often were project meetings held, if at all?

### *Science and Engineering*

25. What theories and methods were used to address the technical problems?
26. Was research oriented to fundamental understanding or oriented to use in the case? Did it advance fundamental research knowledge?
27. Would you characterize new knowledge creation and dissemination in your work as linear or non-linear? If it happens differently, how did it occur?

### *Partnerships*

28. What partnerships and agreements are/were in place for the R&D and commercialization of knowledge and technology arising from the case?
29. How influential were these partnerships on your work?

### *Intellectual Property*

30. Was intellectual property a consideration in the project(s), e.g. were patent searches done, patent applications filed, trade-secrets protected, etc.?

# APPENDIX B – OBSERVATIONAL FORM CHECKLIST

1. Name of Building
2. Address
3. Host
4. Permission to visit and photograph
5. Physical and human geography of locale
6. History of locale
7. History and age of building
8. Owner of building
9. Square footage of building
10. General description of building
11. Knowledge production location(s)
12. Descriptions of knowledge production location(s)
    a. Square footage of location
    b. Equipment, materials
    c. Locked or open doors
    d. Adjacent offices
    e. Number of people working at location
    f. Experience, education and title of people working at location
    g. Other attributes
13. Description of offices of key personnel

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## EDUCATION

2007 to present **PhD**, Interdisciplinary Studies, University of New Brunswick
GPA: 4.2
Thesis: *Making Hands: A History of Scientific Research and Technological Innovation in the Development of Myoelectric Upper Limbs Prostheses, 1945 to 2010*
Supervisor: Dr. Gregory Kealey, Department of History of Vice President, Research

1989 to 1993 **Bachelor of Laws**, Dalhousie University

1986 to 1989 **Bachelor of Arts**, Campion College, University of Regina

## PROFESSIONAL EXPERIENCE

2011 to present **Chief Operating Officer**, Atlantic Hydrogen Inc.

- Responsible for overall company operations, including strategic management, partnerships, and licensing.
- Authored company business plan, carbon white paper, and technology, corporate, marketing and communications, human resources roadmaps.
- Prepared company techno-economic models and business cases.
- Raised over $10 million in company equity and strategic partner financing.

2009 to 2011 **Director, Corporate Development**, Atlantic Hydrogen Inc.

- Authored corporate roadmap and source and use of funds projections as part of a multi-million dollar investment round for Atlantic Hydrogen Inc.
- Authored successful R&D proposal to Atlantic Innovation Fund for a $2 million project entitled “Development of Commercial Carbons”

2003 to 2009 **Director, Intellectual Property**, University of New Brunswick

- Lead transfer transactions with Diaphonics (voice identification computer program), PCI Geomatics (satellite image fusion technology) Green Imaging Technologies (industrial MRI computer programs), HSM Systems (hydrogen storage technology), Inversa Systems (X-Ray-based non-destructive testing technology), and Thomson Nelson (chemistry educational software)

- Authored in May 2008 a successful Tri-Council (CIHR, NSERC & SSHRC) Intellectual Property Mobilization Group Program proposal for $900,000.00
- Co-Authored in April 2008 a successful Atlantic Innovation Fund proposal for $8.5 million
- Authored in May 2005 a successful Tri-Council (CIHR, NSERC & SSHRC) Intellectual Property Mobilization Group Program proposal for $1,545,000.00
- Co-authored in May 2005 a successful Tri-Council (CIHR, NSERC & SSHRC) Intellectual Property Mobilization Training Program proposal for $814,000.00
- Co-authored in May 2005 a successful Tri-Council (CIHR, NSERC & SSHRC) Intellectual Property Mobilization Training Program proposal for $407,000.00
- Authored in September 2004 a successful Atlantic Innovation Fund proposal for $3.6 million

1999 to 2003 **Intellectual Property Manager**, The University of New Brunswick

- Lead technology transfer transactions with Kebony Wood Products (wood polymer treatment technology), Q1 Labs (network security computer program), and PCI Geomatics (remote sensing technology)
- Authored in May 2022 successful Tri-Council (CIHR, NSERC & SSHRC) Intellectual Property Management Program proposal

1993 to 1999 **Contracts Officer**, Simon Fraser University

- Negotiated, reviewed and prepared research agreements, license agreements, confidentiality agreements, service contracts, inter-institutional memoranda, and other related agreements
- Acted as the corporate secretary for SFU's SF Univentures Corporation and its wholly owned companies
- Advised on technology management, commercialization, and transfer issues
- Served as Chair of the Grievance Committee for administrative and professional employees
- Served as negotiator (1994 to 1999) and chair (1998/99) of SFU's Administration and Professional Staff Association negotiating committee

## TEACHING AND RESEARCH INTERESTS

- Strategic Management
- Policy Studies
- Innovation Studies
- Science and Technology Studies
- History of Technology
- Energy Studies

## TEACHING EXPERIENCE

2011 **Student and Graduate**, University of New Brunswick Diploma in University Teaching

- Prepared and delivered sample lecture and examined video of performance and instructor/student critiques
- Prepared teaching dossier

2010 to present **Instructor**, St. Thomas University

- Developed and delivered courses: “Science Technology and Innovation” and “Energy and Society”
- Explained difficult concepts clearly and concisely
- Provided guidance to undergraduate students writing essays on assigned topics
- Counseled students experiencing difficulties in the course
- Graded essays, final examinations, and student tutorial participation

2006 to present **Faculty Member,** University of New Brunswick Shad Valley Program

- Lectured on technological innovation, technology management, and intellectual property
- Supervised students.
- Served as faculty don.

## RESEARCH EXPERIENCE

2007 to present **Doctoral Candidate**, University of New Brunswick

- Synthesized research on R&D of Myoelectric Upper Limbs Prostheses, 1945 to present; prepared and examined case studies on subject
- Completed public policy research project to prepare indicators on education, productivity, gross domestic product, and personal disposable income for the Province of New Brunswick from 1945 to present
- Surveyed research, and collected and analyzed data on Canadian university funding from 1945 to the present

## PUBLICATIONS (REFEREED)

McLaughlin, J., and Foord, D., (2009). "Research- and Development-Based Productivity Indicators." In Boudreau, M., Toner, P., and Tremblay, T. Exploring the Dimensions of Self Sufficiency. Fredericton: New Brunswick and Atlantic Studies Research and Development Centre, pp. 58-73.

## PUBLICATIONS (NON-REFEREED)

Foord, D. (2008). "Education and Human Capital indicators for the Province of Brunswick." In Foord, D., Ruggeri, J., and Watson, B. Indicators of Sustainable Progress for New Brunswick. Fredericton, New Brunswick: University of New Brunswick Policy Studies Centre, pp. 95 to 114.

Foord, D. and Mozboudi, M. (2008). "Productivity Indicators." In Foord, D., Ruggeri, J., and Watson, B. Indicators of Sustainable Progress for New Brunswick. Fredericton, New Brunswick: University of New Brunswick Policy Studies Centre, pp. 65 to 76.

Foord, D. and Subash, P. (2008). "Gross Domestic Product and Personal Disposable Income." In Foord, D., Ruggeri, J., and Watson, B. Indicators of Sustainable Progress for New Brunswick. Fredericton, New Brunswick: University of New Brunswick Policy Studies Centre, pp. 41 to 54.

## CONFERENCES ORGANIZED AND/OR ATTENDED

| | |
|---|---|
| 2010 | Presenter, Alliance for Commercialization of Canadian Technology (ACCT) Directors Forum, Halifax, Nova Scotia |
| 2009 | Attendee, R&D Management, Ottawa, Ontario |
| 2008 | Presenter, Licensing Executives Society Conference, Boston, Massachusetts |
| 2007 | Organizing Committee, ACCT Annual Conference, Toronto, Ontario |
| 2006 | Organizing Committee, ACCT Director's Forum, Montebello, Quebec |
| 2006 | Co-Chair, ACCT Annual Conference, Ottawa, Ontario |
| 2006 | Organizer, Springboard Atlantic Workshop on "Partnerships with Start-Ups", Fredericton, New Brunswick |
| 2005 | Organizing Committee, ACCT Annual Conference, Ottawa, Ontario |
| 2004 | Organizing Committee, "Rendezvous Bioscience", Sackville, New Brunswick |
| 2003 | Organizing Committee, ACCT Annual Conference, Moncton, New Brunswick |
| 2001 | Organizing Committee, "Technology Commercialization Forum", Saint John, New Brunswick |
| 2000 | Organizing Committee, "From Ideas to Marketplace", Fredericton, New Brunswick |
| 1997 | Attendee, AUCC Conference on Commercialization of Research, Ottawa, Ontario |

## MEMBERSHIPS

| | |
|---|---|
| 1999 to present | **Member**, Licensing Executives Society |
| 2009 to present | **Certified Licensing Professional**, Licensing Executive Society |
| 2010 to present | **Member**, Society for Social Studies of Science (4S) |