In the long run, amputees of varying ability levels will all enjoy some benefits from the technology and scientific knowledge that helped a few to excel.

Armed conflict has always been a substantial contributor to surgical amputation. Yet, in the two thousand years between the Punic Wars and the Civil War, there were surprisingly few improvements in the makeshift substitutes fashioned for missing limbs.

A wooden peg leg remained a wooden peg leg for more than two millenia.

In the intervening centuries, a clever armorer or woodworker might craft a better prosthesis. But, due to isolation and limited communication, only a few amputees in the immediate area would benefit. And the innovation usually died with its inventor.

It took two World Wars and their resulting global mayhem before prosthetics entered the modern world. Shortly after World War II, an intensified program of government-led and financed research focused on improving the design, materials, and fabrication of artificial limbs. Within the past three decades, prosthetic technology has advanced at warp speed giving hope that one day artificial devices may truly mimic the wonderful coordination of natural limbs.

Explore with us what's happening today in prosthetic research. Of necessity, this is merely a glimpse. However, these next six articles will help us appreciate progress made to date, potential marvels on the verge of introduction, and the incredible promise that lies ahead...

The Road Always Under Construction

by David A. Boone, C.P., Prosthetics Research Study

Government and industry address a public need

World War II produced thousands of young amputees. Unfortunately, the prosthetic components available were primitive. The challenges of the second world war led to new appreciation of science as a power that could be harnessed and organized to solve difficult problems. Following the war, the National Academy of Sciences and the National Research Council recommended courses of federally funded prosthetics research. Government research laboratories sponsored by the Army, Navy, and the Veterans Administration each instituted intensive programs of prosthetics research to aid the multitude of war amputees. Universities were enlisted to research the biomechanics of limbs, and educational standards for prosthetists were adopted.

Just as the government had contracted with outside private firms to develop the materiel of war, federal agencies turned to university scientists and the engineers of companies like Northrop and IBM to create better artificial limbs. Under contract to the government, these researchers developed dozens of improvements for artificial limbs. Federal, university, and private cooperative arrangements led to the development of the SACH foot, hydraulic knee and ankle mechanisms, and electric-powered arms. Improved methods for the construction and fitting of prostheses such as suction socket suspension were made broadly available.

Since the 1970s, governmental prosthetics research laboratories within the VA and the armed forces have been almost entirely eliminated. Independent researchers continue to work with government support in the form of grants and contracts. A prime example of the dedicated scientists working in this field is Ernest M. Burgess,
M.D., an orthopedic surgeon active in surgical and prosthetics innovation since the 1940s. With the development of the highly functional Seattle Foot, he increased public awareness of the real benefits prosthetics research brings to the lives of amputees.

**Prosthetics research in the present**

Now, as we approach the end of the century, the legacies of past public/private collaborative efforts in prosthetics research seem as if they will be difficult to match. Government is reconsidering its support of the broad range of fundamental studies and development which might help the amputee. Funding agencies and research institutions are both looking at the need for and value of measurable short term success, and the transfer of research technology to practical applications. Far-ranging, forward-looking projects are encountering considerable competition from studies with relatively easily attainable short-term research goals. Now is clearly a time of transition in the conducting of research.

Federal expenditures for all needs are being re-evaluated, and there are many questions regarding how much public support will be available for research. A few agencies still strive to maintain research into aiding amputees as part of their basic mission most notably the Rehabilitation Research and Development Service of the Department of Veterans Affairs, the National Institute on Disability and Rehabilitation Research, and the National Center for Medical Rehabilitation Research of the National Institutes of Health.

The Paralympics movement has provided impetus for further advances in high performance prosthetics. The private sector is running for the gold with innovative components that enable amputees to achieve goals of higher, faster, stronger. Advanced technology which helps individuals exceed the bounds of their abilities also increases our collective knowledge of precisely how the physical process of amputee running occurs. Just as the introduction of the Seattle Foot made it possible for others not just athletes to run, so too, subsequent advances will expand functional capabilities for all.

Of considerable impact on commercial manufacturers is the adoption of new international testing standards for prosthetic components. Private research and development resources are being used to test existing designs of prosthetic components and to create new designs which measure up to the tougher standards. Amputees and prosthetists will benefit from the incentive that companies have to create better designs. As each company increases its knowledge of function and performance, new features will inevitably be incorporated into its products.

**What the future holds**

As we move through this transition period, what will future innovation bring?

Basic research in areas not necessarily earmarked as prosthetics may have a profound influence on the structure and function of artificial limbs. Investigations into how wounds heal may help prevent many amputations caused by vascular disease or diabetes, particularly in the elderly. Improved biological understanding of the interface between the skin and the prosthesis will result in prosthetic sockets which are more comfortable and less likely to lead to problems such as blisters. Eventually, techniques being pioneered in Sweden may radically alter the interface by direct skeletal attachment of the prosthesis. While still in an early experimental phase, these surgical methods have the potential to eliminate the socket for some amputees by attaching the prosthesis directly to the bones in the residual limb.

Materials science and advanced engineering design promise not only components of lighter weight and greater strength but, ultimately, improved function. The human body moves with great fluidity, and some future advancements in prosthetics will certainly make prostheses perform more naturally. Improvements to date have eliminated many of the telltale limps and sways that some amputees experienced not from their own physical restrictions, but from the inadequacies of older prosthetic designs. Improved transmission of power and better component mechanics will help upper extremity amputees more easily grasp and move their arms. New materials and techniques are also improving the appearance of the prosthesis.

Advancements in gait analysis are beginning to provide objective feedback as to whether prosthetic components actually do what they are designed to do. Continuing study of basic human locomotion will result in new feet and ankles which will provide more natural function. Future feet and ankle components will better help
Sophisticated instrumentation that more precisely guides assessing and adjusting the prosthesis will become a normal adjunct to the specialized training and skills of the clinical prosthetist. Future instruments will measure, verify, and document more facets of performance. Fit, alignment and patient satisfaction will be measured by the prosthetist and accomplished with assurance. Eventually, the measures of function will be integrated into improved design and fitting methods.

Already, computer-aided design and fabrication (CAD/CAM) systems have been adopted by many prosthetists. Advanced design and fabrication technology will increase fabrication efficiency and enable prosthetists to provide greater customization.

For example, the Squirt Shape project underway at Northwestern University illustrates the potential for making prosthetic sockets directly from computerized measurements and analyses. This major step in fabrication eliminates the intermediate casting procedure, decreasing the cost of labor and materials and saving the practitioner's valuable time. With help from the computer, the prosthetist can customize not only the shape of the socket, but also the strength and flexibility of the entire limb.

The nature of public/private cooperation in prosthetics research will continue to change. In the past 50 years, war amputees have represented a public need which encouraged governmental and private prosthetics research and development. In the next century, as the aging population of our nation encounters the many physical processes that can lead to amputation, we will be presented with a research mission not unlike that earlier challenge. While technical advances are being pursued by the private sector, there remains a place for research and development outside of considerations for a company's product line or strategic marketing. Public funding of prosthetics research should continue.

**The amputee's voice in research**

The needs of the amputee will always be the researcher's best motivator. With new amputees questioning how and when they will regain function, and long-time amputees seeking better devices with which to compensate for limb loss, the researcher continues to face demanding goals. Research exists to answer questions, and it is the first task of the researcher to respond. By listening to those we are striving to help, prosthetics researchers find the direction to guide future work, and discover the seeds of solutions which will enhance the comfort, function, and appearance of the prosthesis.

**About the Author...**

Certified prosthetist David Boone is a Masters of Public Health candidate at the University of Seattle and director and co-principal investigator of Prosthetics Research, Seattle. He serves as technical director of the Prosthetics Research Center in Hanoi, Vietnam, and on the board of directors of the U.S. Member Society of the International Society for Prosthetics and Orthotics. A clinical instructor in the Departments of Rehabilitation Medicine and Orthopaedics at the University of Washington, he has written and presented a number of professional papers on computer automated fabrication and the VA/Seattle Limb system for lower extremity amputees.

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**Research: Lofty Goals, Not Ivory Tower Isolation**

Eighteen stories above the streets of downtown Chicago rises a sleek column of concrete, glass and steel. Windows on the 14th floor sweep the dramatic Windy City skyline in one direction, and the blue sparkle of Lake Michigan in the other. Pedestrians and cars seem tiny from here, but the sky goes on forever.

While the view is compelling, few people spend time gazing.

This is no "ivory tower." Instead, residents of the 14th floor maintain a bustling pace. The objective is doing not
idly dreaming. Yet their efforts will ultimately reward, and someday fulfill, the dreams of those who have experienced amputation.

There is a hum of activity everywhere.

The gleaming structure is the famed Rehabilitation Institute of Chicago, and its 14th floor is home to Northwestern University's prosthetics and orthotics research laboratories. On the 17th floor is the school's graduate level certificate programs for candidates studying toward certification as orthotists and prosthetists.

Both the research and education components are directed by Dudley Childress, Ph.D., and function within the Orthopedic Surgery Department of Northwestern University's Medical School. But, there is nothing austerely academic and musty here.

**Dusty? Yes.**

The O & P school's nearby fabrication laboratory, with its constant assaults on plaster casts, ensures "dusty." In fact, trails of white footprints on the dark hallway carpets readily lead visitors to the series of classrooms and labs that constitute the practitioners' learning center. There, Director of Prosthetic Education Mark Edwards, CP, and Director of Orthotic Education Bryan Malas, CO, preside over the oldest and largest O & P school in the country.

Unlike college life, studies continue all day, five days a week. The school graduates four classes per year, two in each specialty, and each certificate course is five months long with tuition set at $10,500. An occasional softball game is about all that lightens the intensive pace.

One exceptional advantage these students have, however, is access to some of the field's foremost biomedical engineering specialists and advanced prosthetics research studies underway in the nation. Some students participate in Northwestern's research program, contributing to highly technical projects. School faculty members lend a prosthetics expertise to various research efforts and, conveniently, research staff lecture O & P students in their specialty areas.

The educational component provided by the university's O & P certificate programs is just one of three factors that enhance research at Northwestern. Another vital aspect is the clinical relationship researchers maintain with the Rehabilitation Institute of Chicago. RIC's amputee patients relate their prosthetic needs and evaluate experimental components and technology. The third important element is consumer input. This comes from varied sources including the research program's Consumer Advisory Panel and Technical Advisory Panel as well as RIC patients and amputee groups. It's a tremendously effective and mutually supportive use of talent and knowledge.

"The result is a constant exchange of ideas and information so that our work isn't isolated. It's anything but an 'ivory tower' situation," stressed Edward C. Grahn, associate director of the Prosthetics Research Laboratory.

"Northwestern is one of the centers for prosthetic and orthotic research nationwide. We've been designated a Rehabilitation Engineering Research Center in this area by the National Institute of Disability and Rehabilitation Research," he added.

NIDRR and the Department of Veterans Affairs are the two major funding sources for O & P research at Northwestern.

"The NIDRR-supported program started in 1972," Ed continued. "Its purpose is to improve internal joint replacements and help severely disabled people achieve better control over their environment. Research funding went beyond improving wheelchairs and prosthetic systems to devising technology that will enable people with quadriplegia to answer doors and telephones, and operate computers and other electronic equipment," he noted.

The VA emphasis is on improved prosthetic systems that make amputees more independent. Both funding sources encourage the transition from pure research to functional products.
"In the earlier years, there was a feeling that researchers couldn't charge for technology or prototypes developed through government grants that public funding meant this information belonged in the public domain," Ed continued.

"Now, however, we are able to have licensing agreements with manufacturers who market our innovations. One such product under Northwestern's license is a synergetic prehensor an electric hook that's the only prehensor on the market that approximates the physiological force and speed of the hand of an adult male. It is licensed to Hosmer Dorrance, which pays a royalty to Northwestern," he said.

**From concept to prototype**

"A major plus is that our facilities allow us to go from a concept to actually fabricating a prototype. We have a full machine shop within the department," he noted with pride.

Meanwhile, down the hall, other research staffers were anxious to show off their endeavors.

In the Human Mechanics Measurement Laboratory, the focus is on improving the technology for conducting gait analysis. Explained Steven Gard, Ph.D., "One of our aims is to develop instrumentation to measure gait parameters in real time.

"We have devised our own equipment and software for gait measurement," noted Richmond Chan, Ph.D., as he displayed a "butterfly" diagram on the computer screen. "During the past five years, we have also developed a camera system that overlays ground reaction forces on video displays of walking. This helps to visualize how forces act on the body during walking."

Janet Jhoun, a doctoral candidate in biomedical engineering, stood on a force plate while delicate instruments recorded her body movements although to all appearances she remained completely still.

"My research shows that standing is actually an extremely dynamic activity that there's a lot of involuntary motion, although it's very small. My studies," she explained, "are directed toward improving an amputee's posture and balance and demonstrating that being upright allows potential energy to be greater."

Across the lab, away from the high-tech computer hookups and cameras, doctoral candidate Laura Miller adjusted a homemade testing fixture consisting of boards, springs, and weights secured by miles of duct tape.

She explained how the simple yet effective device was used to reveal various characteristics of the major types of energy storing feet presently on the market. A report on the study was recently published.

"This project was spearheaded by Erick Knox when he was a grad student here. It's been underway the past five years," she noted.

Down the hall, Keith Oslakovic, a mechanical engineer more fascinated by robotics and bioengineering than designing cars, peered intently at a computer screen. Its colored graphics portrayed "hot spots" on a socket design, revealing areas of greater stress.

"We're trying to take CAD/CAM to the next level using math formulas to study the stress a socket puts on different areas of the residual limb. The present CAD system indicates contact, but doesn't really reflect stress levels that's intuitive information supplied by the prosthetist," Keith explained.

"The idea is to make a PTB socket more comfortable but we may end up finding the PTB isn't the best design after all. We also want to incorporate other variables besides comfort. The socket actually is a new 'joint' introduced between the ankle and knee. Our goal is to identify what's important in socket design, describe it numerically, and then let the computer search all the various shapes that could produce the characteristics we want," he continued.

Keith believes biomedical engineering has much to offer amputees and orthopedic surgeons.

"We can show surgeons how the shape of the residual limb they create affects socket design and comfort," he said.
While Keith struggled with improvements to the CAD element of socket design, Kerice Tucker and Joshua Rolock showed off a nifty new piece of technology that vastly updates the CAM, or socket fabrication aspect. Fascinating to watch, Northwestern’s advanced “Squirt Shape” was spinning out narrow ribbons of polypropylene to build a socket “in thin air.” It was done by computer measurements alone with no intermediate cast to use as a model. Tirelessly, the Squirt Shape formed the sleek socket without human guidance or intervention.

“This machine is a research prototype that can save considerable time and cost for the prosthetist," stressed Joshua. "It can also eliminate intermediate steps in socket fitting and enhance socket properties since the machine can create sockets that are impossible to build by hand," he added.

"We have used amputee volunteers to test these sockets. One person has worn our prototype socket for two years and it has proven to be as durable as a traditional socket," the researcher volunteered. "Time-saving is a major factor the practitioner presses a button and can walk away. Although we’re working primarily with BK sockets, there is also a potential for orthotics!"

All Northwestern staff members acknowledge that the clinical association with RIC amputee patients is crucial to their work. Jack Uellendahl, CPO and director of the Prosthetic - Orthotic Service of the Rehabilitation Institute of Chicago, noted that both facilities have collaborated particularly in upper extremity and above knee prosthetic research, since the 1960s.

"One of our recent projects has been the study of 4-bar linkage knees to give bilateral AK amputees more normal and efficient gait patterns," he reported.

**RIC focus is clinical**

Of particular benefit is that RIC's outstanding reputation as a rehabilitation facility attracts many people with severe amputations, especially those who have failed to find adequate technology via traditional components.

"In the last ten years, we've fit 36 bilateral arm amputees, 23 of them high level missing both elbows," said Jack. "That's probably more than any rehab hospital in the country."

"Many practitioners might see only one bilateral above elbow amputee in a whole career," interjected Northwestern researcher Craig Heckathorne. "These people impart a personal approach to our research. They tell us what they want a prosthesis to accomplish and they give us vital feedback," he continued.

In a lab devoted to improving prosthetic hands and prehension devices, he gestured toward a series of photos on the wall above a table littered with components. The pictures, Craig said matter of factly, were of RIC patients, one of whom had an electrical accident resulting in amputation and paralysis.

"The charge entered his hands, burning off his arms above the elbows, and exited through his feet, destroying his legs below the knees. He was on a ladder when he was struck and the electrocution knocked him off, injuring his spine and leaving him paralyzed below the waist," Craig related.

"He told us he wanted to accomplish three things feeding himself, washing his face, and writing. We were able to develop a prosthesis that enabled him to perform those activities," the engineer added.

"There used to be criticism that research didn't produce products. That isn't true a lot of the knowledge and principles basic to product development were discovered by researchers. And research is intrinsic to product design and function.

**Research is basic to design**

"However," he paused thoughtfully, "This misconception has fed into a greater emphasis on funding clinical services. My concern is that, without education, this misperception may drain funds needed for research, and place most of it in clinical projects. If that happens, we won't have new products that truly work for people. You still need researchers to create the body of knowledge that is the foundation of product development," Craig stressed.
Further, research provides the documentation that justifies high-tech components or substantiates the value of a certain component. By sharing our research findings, we will ensure continuing advances in prosthetic design for coming generations.

It would seem that the collegiality and professional cooperation displayed by Northwestern's staff and RIC clinicians amply demonstrates the worth of such collaboration. Certainly, the amazing advances in the field of prosthetics and orthotics in the past few decades owe a substantial debt to such dedicated researchers.

Tomorrow's technology will exist thanks to the questions those men and women ask and answer in the lab today.

Research Evolves Into Technology
Northwestern's Dudley Childress

"Most people don't see much of a connection between a high-performance Indy racer and the car they drive to the grocery store," suggested Dudley S. Childress, Ph.D., director of prosthetic and orthotic research programs at Northwestern University.

Upon first consideration, the distinguished researcher explained, the comparison may be something of a stretch. But the revamped engine designs, experimental parts, and grueling road testing that produce customized racers also contribute to refining factory-made vehicles. Eventually, there is a trickle-down benefit of better engineering / better performance when high-tech innovations are incorporated into new car models.

In like manner, it isn't always apparent how sports prostheses can help the average amputee. Nor is it always obvious how university-led research into improving prosthetic technology or understanding biomechanical interactions translates into more functional rehabilitation devices. Certainly, the route from research lab to rehab clinic can be lengthy and occasionally roundabout. Nevertheless, Dr. Childress pointed out, clinical, experimental, or theoretical research is usually behind most advancements.

As head of Northwestern's two major O & P research programs in the university's Departments of Biomedical Engineering and Orthopedic Surgery, Dr. Childress has logged some 30 years helping to improve the quality of components for amputees.

With a doctorate in electrical engineering, Dr. Childress oversees both Northwestern's Prosthetics Research Laboratory (PRL) funded by the Department of Veterans Affairs Rehabilitation Research and Development Service through Lakeside VA Medical Center, and Northwestern's Rehabilitation Engineering Research Center in prosthetics and orthotics, which is funded by the National Institute of Disability and Rehabilitation Research (NIDRR), a part of the Department of Education.

"We are one of the older if not the oldest continuous programs of prosthetics research in the country," Dr. Childress noted.

The staff consists of approximately 15, and between eight and ten graduate students at a given time. These talented specialists have advanced degrees in mechanical, electrical, or biomedical engineering, or in prosthetics/orthotics. Physical and occupational therapists have participated in the past, and orthopedic surgeons and physiatrists contribute on an advisory basis, Dr. Childress explained.

Northwestern's involvement in prosthetics research started shortly after World War II when responsibility for developing better artificial limbs was transferred from the Surgeon General of the Army to the Veterans Administration, he related. In 1946, the VA arranged research contracts with 16 universities among them Northwestern and with industrial laboratories and foundations.

As stipulated by the VA, Northwestern's Prosthetics Research Laboratory emphasizes developing more functional components for amputee veterans. By 1954, the government realized that improved artificial limbs were also needed for the general population. Eventually, this civilian prosthetics focus became the province of
Both the VA and NIDRR periodically determine general areas for research and then issue requests for specific proposals. Accepted projects are usually funded for three-year periods, and participating institutions report annually on research efforts.

"Accountability is an important aspect of research," Dr. Childress stressed. "We need to show progress within the grant period. Often, representatives of the funding agency come here to view what we're doing. We publish project results and report ongoing progress in various research periodicals as well as in our own newsletter, Capabilities. And we also have a web site that outlines our activities," he continued.

Within the guidelines established by funding sources, Northwestern staffers determine the specific route their research will take. Decisions are based on a number of factors. A major source is requests from practicing professionals prosthetists and orthotists who see a need for a particular device or better system. Practitioners also relate needs expressed by their amputee clientele. And, consumer advisory boards provide practical commentary on research directions.

"Then, based on the scientific information we have, we must determine what type of project is feasible and what isn't," Dr. Childress pointed out. "One of the biggest issues of research and development is to know when to work on a project. Is the work commensurate with our abilities? Do we have adequate personnel and resources? Is the proper technology available for what we're trying to accomplish?"

Another aspect of the selection process is what size population would benefit from the research.

"Do we want to tackle something that will have impact on a substantial number of people below knee amputees, for example? Yet, we are also sensitive to the fact that a small percentage of consumers have extremely severe amputations and, therefore, greater needs. Again, our decision is based on our experience as a research facility," he added.

**Varied populations benefit**

Happily, Northwestern University has pursued research projects that have benefited a range of amputee populations. Currently, its Rehabilitation Engineering Research Program (RERP) is following research in three major areas: upper limb prostheses, enhanced ambulation, and computer-aided engineering. RERP also delivers research data directly to amputees, their families, professionals, and care-givers through publications and electronic information systems.

Recent projects on the different characteristics of the most popular lines of energy-storing feet, and experiments in improving the technology used in gait analysis will aid the majority of amputees, those minus lower limbs. Multiple projects are also underway to improve prosthetic function for the much smaller segment of bilateral above elbow and shoulder disarticulation amputees. Still other studies focus on improving design and fabrication tools from computer software to socket-forming equipment to help prosthetists create more comfortable, affordable, and better performing sockets.

"Perhaps about 25 of our innovations have become commercial products," Dr. Childress noted. "We've had long-term involvement with Hosmer Dorrance in developing upper limb prosthetics, and now we also are working with Flex-Foot and M+IND on certain projects."

"Indirectly," he continued, "We stay in touch with manufacturers through our students. Alan Sandifer, one of our graduates, is now director of research at Becker Orthopedic. Gerald Stark, who was one of our faculty members last year, heads development at Hosmer. As these and other graduates move into industry, we often retain our relationship with them.

"Moreover," he added, "We attend national AOPA and AAOP meetings and contact manufacturers and practitioners."

"Another very important mission of Northwestern research is to create knowledge and scientific information," Dr. Childress emphasized. "Our report on comparisons of energy-storing feet will help prosthetists accurately
select the component needed for each patient and, ultimately, it may translate into new and better foot designs that will improve gait.

"Other information that results from our research may have to wait until technology catches up sufficiently for it to have practical applications. Nevertheless, it is vital that the knowledge be available for future studies."

"Like my example of the Indy cars, technology that helps amputee athletes perform better will trickle down and also aid the geriatric amputee."

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**Improving Life Through Rehabilitation Research**

*By Louis A. Quatrano, Ph.D.*

National Center for Medical Rehabilitation Research

The National Center for Medical Rehabilitation Research (NCMRR) brings the health-related problems of people with disabilities to the attention of America's best specialists in the biological, behavioral, and engineering sciences. As the medical rehab research arm of the National Institute of Health, NCMRR provides funds and coordinates research and research training assigned to various institutions, and releases the resulting information to scientists, rehabilitation service providers, and to persons with disabilities.

The Center's first request for prosthetic and orthotic research proposals was issued in February, 1992, after recommendations from a task force organized in 1990. The NCMRR's announcement for applications emphasized maximizing function, comfort and support, cost effectiveness, and obtaining the highest possible degree of replication of natural function. Fifty-seven proposals were received and nine awards made in 1993.

Of nine grants awarded, five addressed prosthetics concerns. One project, directed by Dr. Lawrence E. Carlson at the University of Colorado in Boulder, focused on improving prosthetic prehension for both body-powered and externally-powered terminal devices, including the design, fabrication and laboratory testing of prototype prehensors.

The second project was directed by Harold H. Sears, Ph.D., at Motion Control, in Salt Lake City, Utah. It concerns an advanced above knee prosthesis which is more natural to walk with, requires less effort, and increases capabilities for walking on slopes and at higher gait speeds. Implementing this involves development of a practical variable impedance knee mechanism and an adaptive controller. Both components have been produced and are being integrated.

Dr. William H. Donovan at The Institute for Rehabilitation Research (TIRR) in Houston, Texas, directed the third project, a two-year comprehensive survey of people with upper limb loss to evaluate past use, current needs, and preferences. This information identifies research areas for future upper limb prosthetic development and design. Survey results are now available from TIRR.

The fourth project, directed by Dr. Ronald R. Riso at Case Western Reserve University in Cleveland, Ohio, explored providing sensory feedback and improved control of artificial limbs, particularly hands. This is done by electrically stimulating the ends of the sensory nerves that once were part of the natural hand and remain within the residual limb. Since these nerves are viable and still maintain connections to the brain, it's possible to "fool" the brain into thinking that resulting touch sensations are coming from the fingers of the artificial hand, just as if the terminal device were an exact replacement for the user's natural hand.

**Independent fingers**

Dr. Riso's project further sought to improve control of the prosthetic hand by having fingers operate independently, the wrist rotate, and grasping operations simplified all by having wearers imagine they are using the artificial hand exactly as they did the former natural hand.

The fifth project, directed by Dr. Michael Vannier at Washington University in St. Louis, Missouri, concerns the development of a 3-D imaging system and comparison of data obtained from this system to let prosthetists
subjectively evaluate the quality of fit.

Another request for proposals followed a July, 1992, NCMRR conference on prosthetic/orthotic research. Its focus was the reaction of skin to contact with rehabilitation devices. As a result, six studies began in 1994, three of which have implications for persons with limb loss. The first project, directed by Dr. Michael J. Mueller at Washington University in St. Louis, concerns restoring walking function for people with transmetatarsal amputation. Research was to determine how footwear (full shoe or short shoe), a rigid rocker bottom sole, and ankle-foot-orthoses affect skin, overall stability, and prescription acceptance by those with partial foot amputations.

The second project, by Dr. Joan E. Sanders at the University of Washington in Seattle, is developing new prosthetic liners and therapeutic treatments to enhance healthy skin and soft tissue for prosthesis wearers. Basic studies on skin adaptation will also enhance the skin's ability to become more load-tolerant. The third study, by Dr. Stephen Sprigle at the Center for Rehabilitation Technology in Albany, New York, concerns measurement of the mechanical loading conditions that damage soft tissues of diabetic amputees. The research promotes better technology for measuring residual limb/socket interface pressures and tissue response immediately after fitting the first permanent prosthesis.

A further request for research proposals in 1995 focused on chronic pain experienced by people with spinal cord injury, amputation, cerebral palsy, spina bifida, or traumatic brain injury. Multidisciplinary research approaches to alleviating chronic pain were encouraged; three programs were funded that began this year. One project, directed by Dr. Mark Jensen at the University of Washington in St. Louis, surveys pain and evaluates the use of biofeedback and various medications.

**Evaluating pain controls**

A second program, directed by Dr. Dennis Turk at the University of Pittsburgh, is studying (1) innovations in wheelchair fitting and design to prevent repetitive straining injuries; (2) the pain management value of combining physical therapy and supportive counseling, versus combining physical therapy and cognitive-behavioral therapy; and (3) various methods of evaluating responses to pain therapies.

The third pain management project, directed by Dr. Barbara de Lateur of Johns Hopkins University, Baltimore, Maryland: (1) evaluates the treatment of post-amputation pain by neuroma resection and the administration of adriamycin; (2) assesses the benefits of specific drugs in treating phantom pain; and (3) evaluates the worth of nortriptyline and a cognitive-behavioral treatment in managing pain due to spinal cord injury.

The NCMRR continues its active medical rehabilitation research program focused on improving the health and quality of life of persons with limb loss.

**About the author.....**

Louis A. Quatrano, Ph.D., is Chief of the Applied Rehabilitation Medicine Research Branch at the National Center for Medical Rehabilitation Research within the National Institute of Child Health and Human Development. Dr. Quatrano has been employed for the past 18 years at the National Institutes of Health where he has participated in research review and program development

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**Practicality Drives Product Development**

**Transferring Technology from Lab to Marketplace**

By the very nature of private enterprise, prosthetics manufacturers focus on return on investment when developing new products. They have two options in most cases: introduce a component that will be profitable due to the large number of people who use it; or, introduce a product that will command such a high price that it's profitable even though only a small population benefits.
Traditionally, rehabilitation was considered a charitable endeavor requiring subsidies, but allowing no profitability for a manufacturer. Today, we have shown that rehabilitation is truly of high value actually a good investment for society since people can often return to work or be self-supporting.

Unfortunately in past decades, few practical products that benefit amputees have resulted from government or foundation funded research projects. But this situation seems to be changing. There is a new emphasis on achieving practical outcomes from prosthetics research. Major research units such as the National Center for Medical Rehabilitation Research (NCMRR) are placing increasing focus on turning research into viable prosthetic products. Even the Department of Veterans Affairs (VA) has created a new division, the Office of Technology Transfer, and manufacturers are obtaining some funding through Small Business Innovation Research (SBIR) grants.

Of course, research “for its own sake” is often justified as well. Frequently, studies even if they have no practical applications now or there is insufficient technology to make them feasible may lead toward future applications. Then, when more advanced technology becomes available, findings can be incorporated into product development.

Research paves way

Equally important, the knowledge and experience gained by scientists, students, and staff members may lay the groundwork for practical applications at a later date.

However, it is vital that private prosthetics manufacturers receive funding to help develop market-driven products. Otherwise, these small businesses cannot afford the years of costly research required to bring new devices to consumers.

The generalized flow chart (right) depicts the evolution of a prosthetic product. Orderly progression through all of these elements is necessary to make the transition from concept to finished product. But, before development is even considered, a company must have assurance that certain key factors are present. These factors aren’t steps in the process concept into the first stages.

These basic elements include: a well-researched needs assessment; the availability of adequate technology (equipment and materials) to create the product; a determination that there is a realistic cost/demand for the product; and sufficient financial backing to support product development. Unless all of these factors are in place, a product concept will remain simply that.

In the area of needs assessment, researchers examine the skills a prosthetist would require to fit the device, and estimate how many amputees could benefit from the proposed product.

Before product design is begun, researchers must make choices as to trade-offs between such elements as cost/performance or weight/size. These decisions will define the product in terms of its structure, appearance, and characteristics before the actual design is done. The resulting prototype represents the first approximation of the product.

While initial funding at this stage has paid salaries of scientists and technicians, purchased materials, and financed prototypes, typically, the product will evolve through many versions before it is deemed ready for introduction. Although the secondary stage of evolution i.e; from "development" to "product" could be considered an investment by the manufacturer, most companies don't have sufficient resources to support this phase unless adequate market size and profitability can be predicted with confidence. This is rarely possible, usually because of the inherently small market size in prosthetics.

Furthermore, many prototypes demand improved basic technologies such as more sophisticated electronic or mechanical systems to make them function effectively. At this point, the new product is no longer a short-term project that could conceivably produce an investment return in a realistic period, such as two years. Consequently, many innovative concepts never make it beyond this stage due to prohibitive costs.

An important aspect in the transition from development to product stage is thorough evaluation based on direct
feedback from the amputee population via field trials or in-house testing. Pros and cons of a proposed product should be documented and its advantages identified, even if it is rated negatively. Field study will also yield data on how suitable the product is for various diagnoses as well as how readily it can be fitted, and whether its advantages are likely to justify third party reimbursement. Moreover, such feedback should identify design criteria and help eliminate flaws.

Field testing vital

The worth of adequate field testing cannot be overstated. This is definitely an area which could be greatly expedited by government or foundation funding. The increasing need to produce practical products from research has made it logical to help prosthetics manufacturers introduce new products.

Evaluation is further valuable in conducting failure analysis, narrowing prescription applications, and impartially comparing the prototype to existing and/or other new products.

Traditionally, manufacturers have had three avenues to access prosthetic research. First, they may be requested by researchers to develop a prototype once the basic studies are completed. Second, manufacturers routinely monitor journals for professional papers or requests for research proposals to see if any have potential merit as new products, or as parts of improved prosthetic systems. And, finally, manufacturers may apply for grant funding to explore an unmet need.

In the end, financial contributions toward product development are justified when the amputee population is able to benefit from a broader range of devices that improve productivity, function, and quality of life.

About the Author....

Harold H. Sears, Ph.D., is vice president of Iomed, Inc., and general manager of Motion Control, which manufactures the Utah Arm. He received his doctorate in bioengineering in 1983, and was instrumental in developing the technology of myoelectric controls for upper extremity prostheses. He is a member of the International Society for Prosthetics and Orthotics (ISPO) and the U.S. Executive Committee of the Rehabilitation Engineering Society of North America, as well as a widely published author and frequent lecturer on myoelectrics.

New = Better: When Is It Hype? When Is It A Help??

By John W. Michael, M.Ed., CPO, FISPO

As citizens of a consumption-oriented world, we have all been conditioned since early childhood to eagerly await the latest and greatest "New!", "Improved!!" "Revolutionary Advance!!!" and to try it immediately. This is one of the major reasons why healthcare in the U.S., including prosthetic and orthotic services, leads the world in the clinical application of advanced technologies.

Without the support of such enthusiastic consumers, new developments soon falter and further advances are discouraged. So, the "early adopters" blaze the way for the rest of the population by helping the developers "work out the bugs" in new ideas. This is critical in refining products and services, and to make technology more reliable and less expensive.

But only certain people have the personality to be a "guinea pig" for the latest wrinkle in clinical practice. People who have a low tolerance for frustration are generally poor candidates to try the newest techniques because they tend to give up in disgust at the first complication. Unless they can work with their certified prosthetist to overcome minor problems, they soon become disappointed and discourage the use of new technology because "it doesn't work."

An even higher-risk population for trying emerging technology are those with a history of chronic dissatisfaction. The person who has been bitterly unhappy with each preceding prosthesis and prosthetist may have unrealistic
expectations. Most likely, after a brief and euphoric "honeymoon" period, the latest technology will prove inadequate as well. The chances for long term satisfaction are much higher when the new technology is selected for the specific advantages it offers, rather than simply because it is "the latest."

**Follow-up essential**

Another group who should approach the newest techniques with caution are those people who will have difficulty with follow up visits to their prosthetic facility. If geographical isolation, transportation difficulties, or financial restrictions make consistent return visits a hassle, it is usually best to stick with proven technology. The rural farmer and Alaskan pipeline worker, for example, may value durability and low maintenance features above all else so they can continue working without interruption. Today's "tried and true" technology often serves them better than "what's hot."

A person easily overwhelmed by complexity should also be cautious about demanding advanced technology. Optimal results may require special servicing, meticulous hygiene, and similar attention to details. If learning a new routine seems like an insurmountable challenge, basic technology which is now thoroughly debugged and simplified is usually more successful.

Finally, the colloquialism "If it ain't broke, don't fix it." is usually good clinical advice. Satisfied previous users are almost always best served by continuing with the specific designs that have served them well over the years. They have become so expert at unconsciously adapting to the limitations of their present prosthesis that even a small change in technology can be disconcerting. If they choose to change, and agree to endure the unavoidable adaptation period in which everything will seem "off" to them, fine! Otherwise, the chances for long term satisfaction are diminished.

So, the demand "Gimme the latest thing!" can sometimes lead to dissatisfaction, particularly when people do not fully understand the effort required to master the newest technology.

There are two groups who are most successful with the use of cutting-edge advances. First is the "early adopter" who contributes to the advance of clinical care by volunteering to be among the first to try out a new idea, and then works patiently with the practitioner to identify and overcome any limitations that arise. Second is the new amputee who often masters the latest advance thoroughly and easily because there is no need to overcome behavior learned with previous technology.

**Everyone wins**

And the best news of all: ultimately, every amputee benefits from our investigations of "what's new." Over time today's innovation is refined and becomes the "traditional" solution. As reliability increases, and complexity and costs decrease, all innovative ideas that have clinical merit have more widespread application until they are finally displaced by the next wave of new ideas.

So, the question is not simply, "Is what's new better?" but rather, "Is what's new better for me?" Answering the second question thoughtfully is what separates the hype from the help!

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**About the Author....**

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