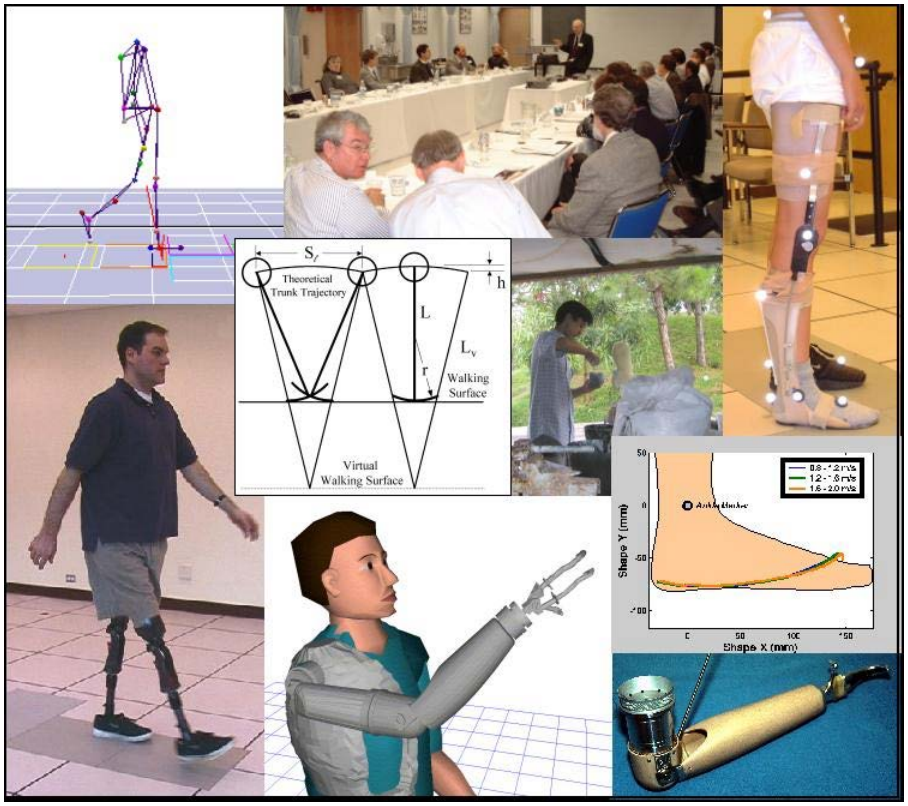
REHABILITATION ENGINEERING RESEARCH CENTER IN PROSTHETICS AND ORTHOTICS

REPORT ON THE STATE-OF-THE-SCIENCE MEETING IN PROSTHETICS AND ORTHOTICS

17-18 May 2002



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Northwestern University Prosthetics Research Lab
and Rehabilitation Engineering Research Center

NORTHWESTERN UNIVERSITY
FEINBERG SCHOOL OF MEDICINE

EXECUTIVE SUMMARY

Overall, the key themes/needs arising from the State-of-the-Science Meeting in P&O may be summarized as follows:

- There needs to be more orthotics research.
- There exists a need for the development and implementation of meaningful outcomes measures.
- There is a need for science and quantification in prosthetics and orthotics.
- There are benefits to revisiting previous research.
- There is a need for better materials science application to prosthetics and orthotics.
- There is a need to re-establish the medical/clinical/engineering team.
- There is a need to address the effect of managed care on education, practice, and research.

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INTRODUCTION:
ART, SCIENCE, or ENGINEERING:
or all the above

By Dudley S. Childress, Ph.D.
Director, Northwestern University Prosthetics Research Laboratory
and Rehabilitation Engineering Research Center

It might logically be asked why this meeting is called the State-of-the-Science Meeting on Prosthetics and Orthotics and not the State-of-the-Art Meeting on the same topic. Presumably the decision to use "science" in the name rather than "art" was to emphasize the importance of science in the advancement of the prosthetics and orthotics (P&O) field. Yet many of those present at the meeting were engineers.

Thomas S. Kuhn, in his classic book, *The Structure of Scientific Revolutions* (1970) suggests that crafts such as medicine, calendar making, and metallurgy played an important role in the emergence of new sciences. These early crafts were sources of facts and technologies that had been developed through empirical means. As such, they were fertile grounds from which sciences could grow. P&O did not participate much in this process until about 1945. The 1959 book, *Human Limbs and their Substitutes,* edited by Klopsteg and Wilson, more or less documents the arrival of science in P&O in the United States.

NCMRR Meeting on Science in P&O

In 1992 I was asked to make a presentation entitled, "Applying Science to Prosthetics and Orthotics," at a National Conference on Prosthetic/Orthotic Research for the 21st Century that was held in Bethesda, Maryland and sponsored by the National Center on Medical Rehabilitation Research (NCMRR) of the National Institutes of Health (NIH). In 2002, I updated that presentation for an editorial in the Journal of Prosthetics and Orthotics (Vol.14, No.3). In the presentation and in the editorial I tried to define and describe science and to show its application to P&O. Kuhn' book, *The Structure of Scientific Revolutions* formed the basis for many of my thoughts in the article.

Relationships Between Science and Engineering

Since writing the editorial, two related books have come to my attention. They are: *What Engineers Know and How They Know It (Analytical Studies from Aeronautical History)* by Walter G. Vincenti (1990) and *Pasteur's Quadrant*, by Donald E. Stokes (1997). Both of these books discuss the fallacy of a linear model that shows basic science as the fundamental source of knowledge flowing to applied science and hence to practical applications. Vincenti particularly faults the line of thought that has engineers receiving their knowledge from scientists and then somehow transferring this knowledge into material artifacts (Applied Science). He suggests that engineers know from experience that this view is incorrect. Vincenti brings out that engineers develop their own engineering knowledge, which they use, along with other knowledge (scientific) to design artifacts. The main difference between engineers and scientists is, in his opinion, that engineers want to turn knowledge into artifacts (devices, mechanisms, instruments, etc.). Vincenti's diagram of knowledge generation and use by scientists and engineers is shown in Figure 1.

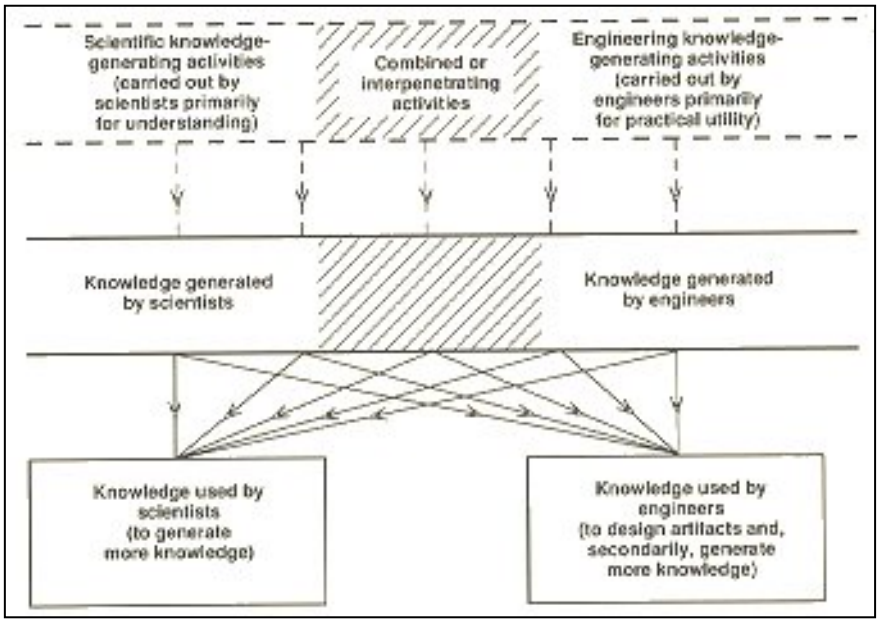

Figure 1 Diagram of knowledge and its generating activities. (Taken from Vincenti W.G. (1993) *What Engineers Know and How They Know It: Analytical Studies from Aeronautical History*. The John Hopkins University Press, Baltimore, MD.)

Stokes has a figure in his book similar to Figure 1 but he speaks of applied research and technology rather than about engineers and engineering. Stokes' idea is that some scientists, like Pasteur, solve(d) practical problems while at the same time developing scientific knowledge. He believed this was an efficient, cost effective way for scientists to work. Instead of a one-dimensional model for research progress (from basic to applied), Pasteur's quadrant provides two dimensions for the model. Applied work was shown on the abscissa of the quadrant and basic science on the ordinate. Pasteur's work generally fell within the quadrant where he had a practical objective and where, by the way he worked, he obtained scientific results. Stokes suggests that more researchers should work in this way, which is somewhat the way research engineers do in Vincenti's model shown in Figure 1. This approach seems to me to be a good way to work in P&O research—to try to make practical advances and at the same time to produce basic knowledge that may be useful for further advances in P&O or other fields. One of the deficits of P&O research often seems to be the development of an artifact without corresponding knowledge that enlarges the body of knowledge and thereby enables further progress (e.g. science).

The State-of-the-Engineering in P&O

The book by Vincenti helped me conclude that it might be appropriate for this document to be called the State-of-the-Engineering of Prosthetics and Orthotics. In society the tendency of many people is to rank scientists above engineers. For example, if a probe to the planet Mars is successful it is a scientific success, but if the probe fails, it is an engineering failure. Anyway, in Vincenti's view scientists and engineers share the knowledge pool and are, in many ways, closely related in what they do. Both are puzzle solvers and problem solvers but with different primary objectives. The scientist seeks knowledge. The engineer also seeks knowledge, but knowledge to the engineer is not considered an end in itself but a means to a utilitarian aid. The kinds of knowledge engineers seek

may be different from that sought by scientists. Some observers may feel that in engineering "tacit knowledge" is of more importance than in the sciences but Kuhn writes that much of the scientist's success depends upon tacit knowledge that is acquired through practice and that cannot be articulated explicitly.

It is not uncommon for scientists to end up as engineers or engineers as scientists, particularly at the knowledge generation level. Irving Langmuir, a General Electric scientist/engineer made many advances in lighting products with GE and received many engineering awards. He also received the Nobel Prize in chemistry for his scientific accomplishments. Examples such as this demonstrate the similarities between engineers and scientists. David C. Simpson, from the University of Edinburgh influenced me greatly with his prosthesis designs and with his ideas about extended physiological proprioception. Simpson was a physicist who became one of the best designers of upper-limb prostheses for children with limb loss.

What is Engineering? Who are Engineers?

The utilitarian end in P&O is usually a prosthesis or an orthosis. In some countries (e.g. Sweden) prosthetists and orthotists are referred to as prosthetics engineers and orthotics engineers. How they compare with traditional engineers is not known to the author. In the United States the terms "engineer" and "engineering" are used in many different ways. Vincenti uses a quote by a British engineer, G.F.C. Rogers, to define engineering. According to Rogers, *"Engineering refers to the practice of organizing the design and construction [and, I would add, operation] of any artifice which transforms the physical world around us to meet some recognized need."* Vincenti takes "organize" to mean the sense of "bringing into being" or "devising" or "planning." To Vincenti the word "organizing" is all important. He says, *"This word selects engineering out from the more general activity of 'technology,' which embraces <u>all</u> aspects of design, production and operation of an artifice. Draftspersons, shop workers, and pilots, for example, though all technologists, do not organize in the engineering sense and are therefore not engineers. All engineers, that is, count as technologists, but not all technologists count as engineers."* Whether prosthetists and orthotists may ultimately become, or want to become, recognized as engineers with specialized abilities, is yet to be determined.

Engineering in Society

The State-of-the-Science (Engineering) Meeting on Prosthetics and Orthotics contained many comments and opinions that were directed at social, economic, and personal needs. In fact, these issues frequently dominated over engineering and scientific issues. Such a condition would not be surprising to Vincenti, who writes, *"Engineering knowledge reflects the fact that design does not take place for its own sake and in isolation. Artifactual design is a social activity directed at a practical set of goals intended to serve human beings in some direct way. As such, it is intimately bound up with economic, military, social, personal, and environmental needs and constraints."* Engineering is sometimes defined as design under constraint conditions. For example, with prostheses and orthoses there are often constraints of cost, weight, size, noise, appearance, reliability and energy. In other applications there are environmental constraints.

Analogies

Analogies, like metaphors or like engineering models can be carried too far. Nevertheless, if used judiciously analogies can greatly assist with understanding. Before reading Vincenti's book on engineering in the aeronautical field, I often compared P&O with the field of aviation. The first human flight by machines that were heavier than air took place 100 years ago. Nevertheless, for its first 30 years the advancement of aviation was haphazard and slow. In my presentations, I

suggested that the DC-3 was the first aircraft design that moved aviation out of the barnstorming days and into the modern flight era, which is heavily influenced by engineering knowledge. Vincenti illustrates the changeover with Consolidated's B-24, which first flew in 1939. I probably like to use the DC-3 analogy because it was the first airplane I ever flew in.

I believe use of the aviation analogy is helpful in understanding many aspects of the State-of-the-Science Meeting on Prosthetics and Orthotics. We could equally use analogies of the development of the radio, electric lighting, bicycles, automobiles, skyscraper architecture/engineering, or many other artifacts. However, most everyone today has some knowledge of aircraft that they can relate to.

National Advisory Committees

It is interesting to me how helpful the National Advisory Committee for Aeronautics (NACA) was to American aircraft design during the 1930s. Prosthetics was initially assisted by the National Advisory Committee on Prosthetics, which later became the Committee on Prosthetics Research and Development (CPRD). CPRD had a planning meeting in 1969 that I attended. It is interesting that the conclusions and recommendations of that meeting were very similar to those that came out of this State-of-the-Science meeting.

The NACA examined and tested over 100 wing airfoils during the early 1930s. Some of these are shown in Figure 2. The shapes of these airfoils reminded me that it has been reported that there are over 100 prosthetic feet worldwide and that some people in the artificial foot industry may be interested in the roll-over shapes of these feet. The foot shapes may be as important to human locomotion as wing airfoils are to flight travel. Unfortunately, in the 1930s the uncertainties about airfoil performance were considerable because of a lack of theoretical and experimental data (science/engineering knowledge) that could permit evaluation, selection, and criticism so that the best airfoils could be selected or further developed. There was no airfoil paradigm at the time. This condition is not unlike our knowledge today about foot roll-over shapes or the shapes of transfemoral sockets around the region of the pelvis. Unfortunately, we don't have a CPRD today to help with evaluations and clinical trials of new shapes and new ideas. As a result there are many uncertainties that make it difficult to be able to evaluate good designs from better ones and better designs from the best ones.

ROLL-OVER SHAPES

We have been examining the effective rocker (cam) shapes that various lower limb systems conform to between heel contact and opposite heel contact events of walking. We call these effective rockers roll-over shapes since they are the shapes that develop as the body rolls over, or rotates over, the stance leg. Our studies of non-disabled walking have shown that the ankle-foot and knee-ankle-foot systems adapt to various conditions of level ground walking, such as speed, added weight, and shoe heel height, to maintain similar roll-over shapes. We believe this knowledge is useful for design and alignment of prostheses and orthoses. To this end we have developed a prosthetic foot (the *Shape&Roll*® Prosthetic Foot) and an automated alignment system for different kinds of prosthetic feet (Roll-over Shape Alignment System, or ROSA™ System). The roll-over shapes of non-disabled ankle-foot and knee-ankle-foot systems also change in predictable ways on ramped surfaces. We hope to use our findings from non-disabled ramp walking studies to develop prosthetic and orthotic devices that are more auto-adaptive to various terrains.

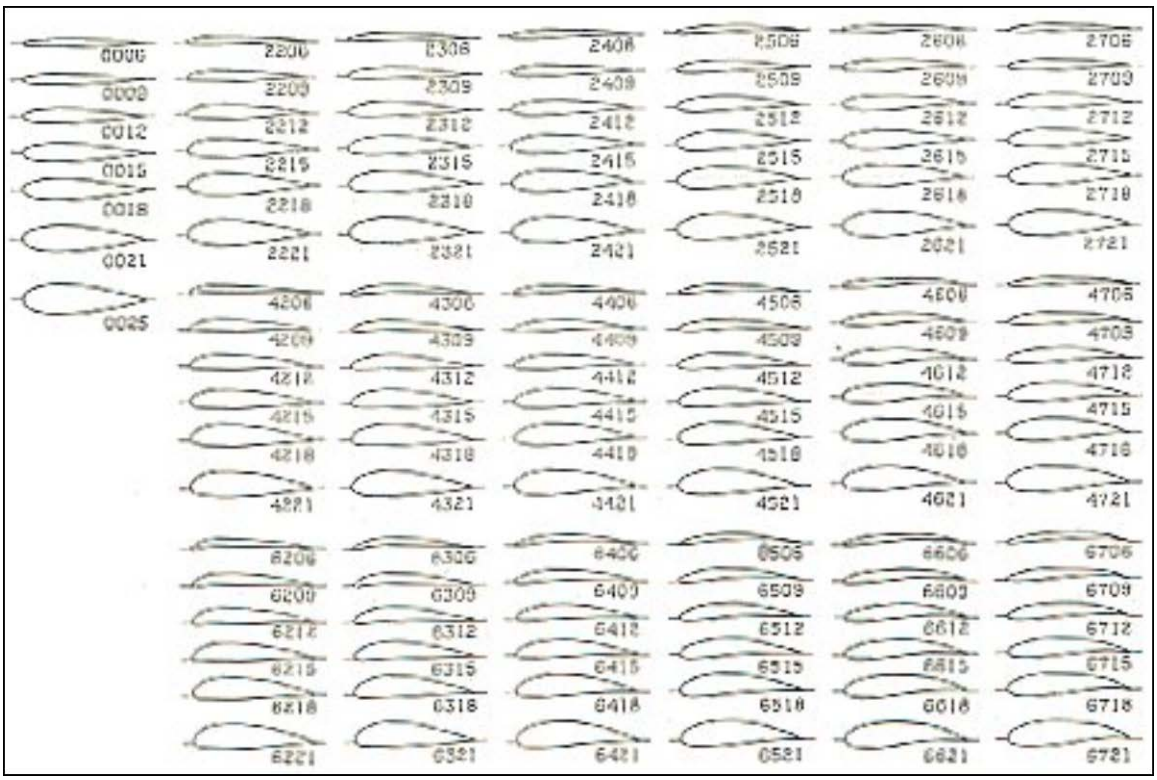

Figure 2 NACA four digit airfoil family from early 1930s. (Taken from Vincenti W.G. (1993) *What Engineers Know and How They Know It: Analytical Studies from Aeronautical History.* The John Hopkins University Press, Baltimore, MD.)

NORTHWESTERN UNIVERSITY
REHABILITATION ENGINEERING RESEARCH CENTER
IN PROSTHETICS AND ORTHOTICS

The Northwestern University RERC in P&O is located on the14th floor of the Rehabilitation Institute of Chicago (RIC), one of the top comprehensive rehabilitation programs in the country. The RIC is on the Chicago Campus of Northwestern University, adjacent to the Feinberg School of Medicine. We are well positioned from a prosthetics and orthotics (P&O) standpoint. The Clinical Services Program in P&O for the RIC, directed by Marty Kacen, C.O. and Robert Lipschutz, C.P., is on the 17th floor above us. The Prosthetics Education Programs, directed by Mark Edwards, C.P., and the Orthotics Education Program, directed by Bryan Malas, C.O., are also on the 17th floor. There are few places where this triad of clinical services, research and development, and P&O education are found in the same building, let alone where they are integrated closely and collaborate routinely. All-in-all, we believe our RERC is in a good setting for "closing gaps" between the disciplines that are involved in P&O care and in enlarging communication with disciplines tangentially related to P&O. We believe this is an excellent setting for an RERC on prosthetics and orthotics.

Our RERC in P&O is comprised of faculty, staff, post-doctoral fellows and graduate students representing diverse backgrounds. Faculty includes Dr Dudley Childress, Ph.D. (Director), Dr Steven Gard, Ph.D. (Assistant Director), Richard Weir, Ph.D., Joshua Rolock, Ph.D., Margrit Meier, Ph.D., P/O, Allen Heinemann, Ph.D., Todd Kuiken, M.D./Ph.D., Bryan Malas, C.O., and Mark Edwards, C.P. Research staff includes Edward Grahn, B.S., Craig Heckathorne, M.S., Kerice Tucker, B.S., Jan Little, M.S., Sophie Lambla, M.S. and Kelly Lim, B.A. Post-doctoral fellows include Stefania Fatone, Ph.D., P/O and Andrew Hansen, Ph.D. We currently have eleven students in the graduate program both at the Ph.D. and M.S. levels. All are enrolled in the Department of Biomedical Engineering at Northwestern University.

MISSION STATEMENT

The Northwestern University Rehabilitation Engineering Program is dedicated to the improvement of prostheses and orthoses, to the improved fitting and manufacturing processes for prosthesis/orthosis systems, and to the improved basic understanding of human interactions with these systems. The research, applied, and technical in nature, is conducted in a rehabilitation environment that fosters direct clinical interactions and applications.

We are dedicated to develop and provide—through science, engineering, prosthetics and orthotics and other related disciplines—limb replacements (prostheses) and structural and movement aids (orthoses) that help humans affirm their lives with enthusiasm, wholeness, and hope.

STATE-OF-THE-SCIENCE MEETING IN P&O: SESSION SYNOPSES

The State-of-the-Science meeting in P&O was held on May 17-18, 2002, at the Northwestern University Prosthetics-Orthotics Center (NUPOC), Chicago, IL. Participants included prosthetists and orthotists, engineers, researchers, physicians, and other respected members of the P&O community from across North America, as well as people from our RERC and NUPOC. A listing of participants is provided as Appendix A.

The meeting format facilitated much discussion. The agenda for this meeting is included as Appendix B. Six major topic areas in P&O were highlighted:

- Interface Mechanics, Attachment and Alignment;
- Enhancement and Evaluation of Functional Performance;
- International Issues/Low-Income Countries;
- Reaching and Manipulation;
- Fabrication, Materials and Safety;
- Long Range Research and Clinical Practice.

Two 'raconteurs' introduced each major topic and discussed issues concerning state-of-the-science in that particular area. A moderated discussion time immediately followed in which participants were encouraged to express their views, identify current problems, and speculate on future directions. Additionally, each day ended with an 'open' session that enabled participants to expound on subject matter related to any of the prior sessions of the day.

The following sections of this report provide synopses of the discussion that occurred in each session over the two days. The gray-boxed text, or 'side-bars', highlights areas of research and education currently being conducted at the Northwestern University RERC in P&O. They are intended to clarify the contribution our RERC is making towards areas of research discussed by participants during the course of the State-of-the-Science meeting in P&O.

The State-of-the-Science Meeting and this report would not have been possible without the efforts of the following people: Rosemary Collard, Doreene Wierzgacz and Elizabeth Schreiber for their administrative and organizational assistance; Pinata Hungspreugs and Stefania Fatone for taking the notes during the meeting that much of this report is based on; Craig Heckathorne for taking the photos shown in the following pages; the staff of NUPOC for use of their facilities; Andrew Hansen, Kerice Tucker, Pinata Hungspreugs, Steven Gard, Rebecca Stine, Allen Heinemann, Camille O'Reilly, Margrit Meier and Stefania Fatone for contributing the 'side-bars'; and all the raconteurs and moderators who spurred the discussions.

SESSION 1: INTERFACE MECHANICS, ATTACHMENT AND ALIGNMENT

Raconteur I: Robert "Skip" Meier, M.D.
Dr Meier began this session with the idea that 'interface' means more than a connection between the patient and prosthetic and orthotic hardware. He felt that with new technology and new techniques of rehabilitation we have begun to expect subjects to achieve a level of function, all things being equal, that is the same as someone their own age who doesn't have a disability. However, this is not always the reality. Dr Meier suggested that Prosthetics and Orthotics (P&O) and Physical Medicine and Rehabilitation (PM&R) should do more to educate the public about what to expect in terms of functional outcomes.

Dr Meier emphasized the importance of 'systems of care' and the need for adequate and appropriate rehabilitation. For example, he indicated that a quality interface starts with the surgery and that it is important that we impress on the surgeon how important what they do is for the rehabilitation outcome. Dr Meier was concerned with the fact that as rehabilitation has evolved, transformed from inpatient to outpatient care, patients are falling through the cracks because they are rushed through the health care system so quickly. He was also concerned that many practitioners were substituting technological innovations and improvements for adequate rehabilitation. He suggested that we don't see people today prepared to use a prosthesis before receiving one. For example, receiving preparatory aerobic training.

ORTHOTICS AND PROSTHETICS USERS' SURVEY (OPUS)
The Center for Rehabilitation Outcomes Research at the Rehabilitation Institute of Chicago is developing a comprehensive set of clinical outcome instruments for P&O referred to as OPUS: Orthotics Prosthetics Users' Survey. The objectives of this project were to develop a set of self-report instruments that assess functional status, quality of life, and satisfaction with devices and services that can be used within an orthotics and prosthetics clinic. Selecting items from a variety of existing instruments, we developed and revised four instruments that differentiate patients with varying levels of lower extremity function, quality of life, and satisfaction. These four components of OPUS provide clinicians with a useful tool to evaluate individual client and program outcomes. The psychometric properties are promising as the instrument demonstrates the ability to detect a wide range of function, quality of life and satisfaction, and possesses good internal consistency and construct validity. The usefulness of the OPUS should be manifest as orthotic and prosthetic practitioners evaluate the quality and effectiveness of their services or as programs fulfill accreditation requirements that mandate outcomes assessment. The next steps are to evaluate the instruments' sensitivity to change over time and differences across patient groups defined by impairment and prescribed device. Funding for this project was provided by the National Institute on Disability and Rehabilitation Research through the RERC on P&O.

Dr Meier indicated that today we seem to have lost the idea of teamwork and the ability to work as a team because in today's health care environment we are not reimbursed for it. He emphasized that the person with the disability should be the leader of the team. That we should focus on *their* needs and desires. That we need to work out how we can gain adequate information about what they need from us. Also, we need to be measuring outcomes to ascertain if what we've done is of any benefit to the individual and society in general.

Raconteur II: Joshua Rolock, Ph.D.
Dr Rolock reviewed the process of tissue loading in sockets and how we as clinicians define and assess those loads. He discussed the distinction between pressure and stress. Dr Rolock emphasized that tissue health is of great importance and that it is affected by stresses. However, we

still don't know what it is about stress that is important or how it affects tissue abrasion, or what other factors may also be involved, e.g. PH, temperature, biochemistry, humidity, vascular occlusion, etc. Dr Rolock commented that materials, such as liner materials, might be used to affect stress, however he questioned our understanding of these materials. He suggested that in future we might be able to combine science and engineering. For example, characterizing tissue geometry using Magnetic Resonance Imaging (MRI), plugging in information about typical loading and stress limits through a computational engine, and coming out with a socket shape and alignment automatically manufactured. However, there is still a lot of basic understanding lacking in these areas.

Dr Rolock also commented on the current limitations of socket alternatives such as osseous integration. With respect to alignment, Dr Rolock commented that it is affected by the socket but that our understanding of that coupling is limited and that quantitative measures aren't yet providing much help with alignment since we either don't know what we are looking for or what is important may be too small to measure. Dr Rolock concluded that although empiricism still reigns (for now), he felt that science and engineering knowledge had the capacity to advance the field.

Discussion

There was some discussion regarding the similarities and differences between prosthetics and orthotics and the relative attention they receive with respect to research and the literature available. Some participants felt that we need to acknowledge that State-of-the-Science in prosthetics is very different to that in orthotics. That the starting point for research is quite different for each discipline. This was countered by the notion that there are a lot of similarities between the two disciplines such as in the area of mechanics of walking, issues of shape taking and pressure on tissues. That we should look for more similarities rather than separating the two disciplines. Dr Childress pointed out that things haven't changed much: 25 years ago recommendations were made regarding the direction prosthetics and orthotics research should take: there was 2 pages on prosthetics and ½ a page on orthotics.

The need for quantitative criteria was emphasized by a number of the participants. That we need to apply science to art and be more quantitative instead of using rules of thumb. That there are those in this field who are good at this but don't necessarily have a way of communicating how they do this to the newcomer in the field.

Recommendations of the Workshop on "The Current Status of Prosthetics and Orthotics and Trends for Future Research and Development", University of Miami, April 1-3, 1977 (Orthotics and Prosthetics, 1977, Vol. 31, No. 4).

This workshop covered both upper and lower limb prosthetics and orthotics as well as spinal orthotics. There were a number of general observations and recommendations (8) arising from the panel discussions on all these areas. These focused primarily on issues of research coordination and direction in P&O; education and continuing education of P&Os; and the need for improved cosmesis, sensory feedback and connection between patient and appliance. Additionally, there were 13 recommendations each in the upper and lower limb prosthetics, but only 7 in upper limb orthotics, 3 in lower limb orthotics and 5 in spinal orthotics. This reflects the imbalance that has since persisted with respect to the research attention focused on the areas of prosthetics and orthotics. Many of the issues and needs discussed at this workshop are echoed here at this State-of-the-Science Meeting, for example, the need for more orthotic research, the need to educate P&Os regarding research and evaluation, the need to educate 3rd party payers, the need for methods of objective evaluation, etc.

SESSION 2: ENHANCEMENT AND EVALUATION OF FUNCTIONAL PERFORMANCE

Raconteur I: Kelly James, P.Eng

Dr James presented on the development of the prototype of the Otto Bock C-Leg and the process of taking the prototype through to a finished product.

Raconteur II: Hugh Herr, Ph.D.

Dr Herr presented on the theme of 'Robots to Rehab'. So far his lab has built machines with legs that can walk and run but still remain balanced. The focus of the lab is to attempt to build robotic legs to attach to prostheses. They are attempting to transfer technology of legged robotics to P&O and develop models of animal and human locomotion and apply that science to the control of P&O systems. To step towards the next generation of P&O systems in our world, we need better sensors, better control algorithms, and a better understanding of how we walk. We need to integrate robotics, machine learning, and P&O, combining it all in a useful way.

Discussion

Dr Gard set the tone for the discussion by highlighting Jacqueline Perry's 4 conditions for obtaining a normal gait pattern:

1. forward progression & propulsion,
2. stability in stance phase,
3. shock absorption,
4. energy conservation.

He pointed out that the raconteurs touched on a number of these issues and proposed the following questions:

- What are we currently doing in P&O to meet these objectives?
- What needs to be done to better address these?
- How do we go about evaluating these in P&O devices?

It was suggested that there was a distinction between prosthetics and orthotics. In orthotics we still have muscles in the leg contained within the orthosis. So we have the option of stimulating those muscles to produce the power needed to walk with the orthosis. However, the response from stimulated muscles is often too great and requires an external skeleton to dissipate the excess energy. Also, we need to be able to distinguish between eccentric and concentric contractions.

It was pointed out that in designing controllers, we have a wonderful opportunity to produce any wanted motion. We can produce algorithms based on normal motion. However, we don't know what the optimal outcome is and, although we are striving for normal, a prosthesis doesn't have the same behavior as biological legs. It was then pointed out that disabled people want to walk normally, or more accurately, not to walk abnormally. The reality at present is that to meet this need we have to make acceptable compromises. It was suggested that the level of disability predicts how much abnormality patients will put up with.

It was noted that the devices described by the raconteurs are exquisite passive devices. They don't use information from the patient's own body, e.g. myoelectric signals, to ensure volitional control of gait. Volitional control is important especially in going down stairs or stumbling. We have a long way to go to achieving this. We need further research to improve functionality of these essentially

passive devices to make them more functional. It was pointed out that at present, with respect to control, we do as much as possible locally. We get as much function out of a local system as possible, but the aim is to use a distributive system. However, we need to start somewhere. This notion that we require powered devices to walk was countered with the idea that the normal human body doesn't put a lot of power into walking. For example, non-powered devices walk like humans with only the aid of a gravitational slope and that studies of the roll-over shape of normal feet also support this idea. It was pointed out that although smart parts are the state-of-the-art at the moment, currently available EMG controlled products haven't been much better than available passive devices. Multiple controls science needs to be improved.

SHOCK ABSORBING COMPONENTS

Shock absorbing pylons (SAPs) are components that increase prosthetic compliance and provide shock absorption during walking, running, and other high-impact activities in persons with leg amputations. The RERC in P&O conducted a study to investigate the effect of SAPs on the gaits of persons who walk with trans-tibial prostheses. Two gait analyses were performed on ten subjects walking with and without an Endolite TT (Telescopic-Torsion) Pylon. Comparison of kinematic and kinetic gait parameters indicated that there were few quantitative changes in the way people walked with and without the SAPs. The most consistent change among subjects was a reduction in the magnitude of an isolated force transient that occurred during the prosthetic loading response phase, an effect that was more evident at higher speeds. Results from a questionnaire that was administered to subjects indicated they generally preferred walking with the SAP for reasons related to comfort. We concluded that SAPs may provide significant benefit for persons with trans-tibial amputations who are able to routinely walk at speeds above approximately 1.3 m/sec. We are currently involved in an investigation comparing the shock absorbing properties of SAPs and stance flexion knee units in transfemoral amputees.

The discussion moved on to methods of achieving shock absorption in prostheses. It was pointed out that, with respect to shock absorbing pylons, we don't have 'pogo sticks' in our normal anatomy. Rather, we control shock with the ankle. So, why does the shock absorbing pylon need to be there? A foot with better control of ankle motion would eliminate the need for a shock pylon. In response, it was pointed out that many mechanisms act as shock absorbers. Northwestern University's gait studies show that the knee and pelvis contribute greatly to shock absorption. It was suggested that gait efficiency drops when shock pylons are compared to a stiff system. When the shank is vertical, there is a lot of stiffness in the vertical shock system, but at the same time there is a lot of shock absorption in the normal body.

A participant asked when is the technology ready to transfer to commercial application? This process is dictated somewhat by big company politics and the fear of litigation. Extreme exercises are undertaken to make sure devices doesn't fail. We need the same attitude in research, but should be very careful because failures are discouraging. It was pointed out that we should get gait analysis labs, practitioners, and designers working together to identify patients' need and generate specifications for the design. Research ideas can be developed a long way, but if the specifications are wrong, the idea gets discarded.

Another participant asked whether the science existed that allows us to do stuff "a little less well but cheaper?" Pointed out that research and design is striving towards perfection, but that there exists a need to accommodate the population that cannot afford State-of-the-Art components. Perhaps we need to simplify things. From a practical point, patients see things on TV and want them. But socio-economics dictate that they cannot afford them. It was pointed out that function is predicated on more than technology. Training and preparation play a big part and aren't being provided to the same extent as they once were.

SESSION 3: REACHING AND MANIPULATION

Sam Landsberger, DSc Director, RERC on Technology for Children with Orthopedic Disabilities

Raconteur I: Sam Landsberger, D.Sc.
Dr Landsberger talked about some of the innovative work that has been done at the Shriner's hospitals since the late 1960's. He commented that whenever you add something to a patient, the motivation of the patient has to be at least equal to the nuisance of the device. He discussed a number of functionally useful devices that are either not being used much because of problems with reimbursement, e.g. the mobile arm support, or where nothing similar exists today, e.g. birdcage suspension.

Raconteur II: Robert Lipschutz, C.P.
Robert discussed his thoughts on upper limb prostheses based on his involvement in the fitting of upper limb prosthetics. He asked what is going to allow patients to accept devices? To use them? What is going to make devices comfortable to wear and use (weight, suspension, binding)? He touched on issues to do with:

- Weight: Use bypass rings to decrease weight on one side. What else can we do? How binding is the harness? E.g. during bending?
- Suspension: How is the device holding on? Does better suspension imply better fit? Can we transmit some power to the device so it's more comfortable? Can we perform direct skeletal attachment to the upper limb?
- Ease of donning: Can we make it easier? For the bilateral amputee, will they use a device if it's too difficult? Must let the user don the device. We need to train them and make donning devices if needed.
- Independent finger movement: See if it is feasible for the patient. This is dependent on the devices the user needs.
- Gloves: One of the biggest areas of complaint among those with upper limb prostheses. Vinyl gloves get stained and the stains don't come out. Gloves need to be durable and cleanable.
- Other considerations: Functional. Cosmetic. Affordable (Will it be paid for?). Efficiency (With and without glove or other cosmesis). Sensory feedback (Spontaneity of patient utilizing the device. So far not much is being utilized).

Robert mentioned that training is the vital piece of the puzzle that is missing in the area of upper limb prosthetics. The weeks or months of training that used to be undertaken are not happening today. Prosthetists have little time to train patients and Occupational Therapists have little education in upper limb prosthetics to effectively train patients.

Robert discussed the types of movements needed in upper limb devices:

- What type of grasp is needed? Does it need to conform to the object?
- Powered wrists are very functional tools. Why can't we create coordinated movements of hand and wrist motion in body-powered prostheses?
- Need to work more on coordinated movement. Will this be more feasible for externally powered devices?

With respect to upper limb orthoses, Robert pointed out that many patients see an occupational therapist before they seen an orthotist. An orthotist may try and find a better device for the patient, but it may not always be more comfortable.

Discussion

A few other points were raised for comment. In science we need:

- Measurements: What's important to measure?
- An experimental environment that will essentially model the complete environment for those patients needing an upper limb prosthesis.
- Subject pools for controlled studies.
- Acknowledge the constraints of health care. Should we limit research to what exists now?
- Understand how the expectations of persons with congenital deficiencies versus persons with acquired injuries or diseases may differ.

Another participant noted that the upper limb deficient child is challenging to fit. There is very little in the literature regarding psychosocial issues of family, age, the changing needs of the child, education, etc. Would no prosthesis be sometimes better? For research, small patient numbers requires multi-center cooperation to pool information.

One participant mentioned the concept of 'natural control': that the amputee does with the muscles of the amputated side the same thing as those of his sound side, while the prosthesis duplicates the control.

PROSTHETIC ARM DESIGN AND SIMULATION SYSTEM (PADSS)

The prosthetic fitting process can be time and cost consuming, especially for clients with high levels of amputation, such as shoulder and hip disarticulations. In 1992, the Prosthetics Arm Design and Simulation System (PADSS) was developed to assist prosthetists with selection of upper limb prosthetic components that would fit their clients' needs. This software program was updated in 2000 using a commercially available 3D human simulation program called Jack by Electronic Data Systems (EDS). By using a modified version of Jack, a prosthetist would be able to create a 3D computer model of his or her client by specifying sex, weight, and applicable measurements from the residual limb needed to perform a prosthetic fitting. Once the human model is created on the computer, the desired prosthetic components are chosen and placed on the human model in the desired configuration. The PADSS is then able to show the prosthetist areas on the body that the client can touch (contact map) and volume in space that the client can reach (workspace volume). This program allows prosthetic students to practice fittings virtually, acts as a visual communication tool between the client and prosthetist, and can be used to assess new prosthetic designs or configurations. Currently this software is being tested and modified. Future plans include obtaining feedback from prosthetists on its design and interface, comparing results from the PADSS to that of actual fittings by prosthetists, and making the program more robust.

There was some discussion as to whether it might be appropriate to return to old research and control methods. Some ideas need to be revisited, such as pattern recognition, angulation osteotomy, and cineplasty. We need more surgeons interested in these types of modifications and then we need to match new technology with old control ideas. It was noted that at Otto Bock there are many failed research/design/development ideas but that the company keeps a record of why the device failed and every now and then they revisit these dead ends and determine if they can be brought back to life.

It was pointed out that we are experiencing changes in health care funding. Patients are being diffused away from centers of excellence to standard hospitals. There was some concern about whether they are getting the care they need.

It was pointed out that there is a disparity between the engineer who tries to replicate lost function and the clinician whose first priority is comfort.

There was also some discussion as to what should drive research ideas. Participants asked whether constraints in health care should be a constraint on research? Cost shouldn't limit what research we do as the cost of devices may go down eventually. However, it helps to approach research with some consideration of both cost and available technology although we shouldn't limit our research based on what we know today. If researchers fail to dream, the platform from which we do research will be lost. Dreaming allows us to come up with new research ideas. Technology shouldn't drive research, but sometimes engineering research is impractical when we don't think through how it will be used. It might be helpful to piggyback on other ideas and industries.

SESSION 4: INTERNATIONAL ISSUES/LOW-INCOME COUNTRIES

Raconteur I: John Fisk, M.D.
Dr Fisk shared his experiences working with polio patients in Korea and South America. He discussed needs with respect to types of disabilities, resources and education available and required, research activities being conducted, and future directions. From the point of view of disabilities in other countries, there is a huge population with polio disabilities and a huge population affected by land mines. Although the World Health Organization has global eradication initiatives that are slowly being met, they are complicated in countries where poverty and conflict limit the use of vaccinations.

Prostheses in these parts of the world may be very inexpensive by our standards. They may cost approximately $120, but when the annual income is $200, this is a huge financial burden.

Resources available include practitioners, schools, materials, and componentry. Materials available are based on consistency, availability and pricing and there is much less diversity. Resource needs include the availability of practitioners, cost, durability and access to data.

There are only 5 P&O schools outside of the Western world and Japan. Many educational programs are funded by foreign money, e.g. the Cambodia Trust, which is largely funded by Japanese money. ISPO has a traveling course (e.g. for polio in Cambodia). The enthusiasm of students is important for education. Practitioners want to know more about patient evaluation, since there is often an absence of medical support.

With respect to research:

- Outcomes research needs to be patient oriented and on sight.
- Need appropriate technologies for particular areas.
- Need to gather appropriate data.
- Need to do educational research to identify the best process of developing Category I practitioners.
- We need to know the numbers of people with disabilities in order to work out how many practitioners are needed.

Most facilities are run by NGO's that are mostly funded by international organizations. We need to determine what is the responsibility of the nation.

Recommendations:

- Need a coordinated effort in data collection.
- Need to determine what practitioners need to ply their trade.
- Need to determine what componentry works best, what techniques work best for the needs of the local population.

"The most noble question in the world is: What good can I do here?"
—Ben Franklin

Raconteur II: William K Smith, M.D.
Dr Smith discussed the activities of the Center for International Rehabilitation in developing countries. He identified the problem: over 70 million land mines in 70 low-income countries; more than 80% of victims are civilians. Patterns of injury from landmines, which are designed to have a specific effect:

- Standing on a land mine: leg amputation, loss of blood, intensive rehab.
- Near an exploding land mine: random penetrating injuries of lower limbs, abdomen, and/or thorax.
- Handling mines: severe upper limb injuries, blindness, and facial injuries.

There is an increase in the rate of amputation in the presence of land mines, e.g. USA 1 per 22,000, Cambodia 1 per 236 people.

Dr Smith discussed the effects of relief agencies entering and exiting a country and defined 5 stages of service delivery (service delivery is a resource driven area):

- conflict
- post-conflict (influx of money and an international community)
- recovery (training local service providers)
- development (prevent corruption, continue to train locals)
- sustained program activity (how to keep funding going).

In June 2001, CIR_OAS held a Consensus Conference on "Ongoing medical and rehabilitation needs of Landmine Survivors in Central America" in Nicaragua, which was attended by 30 local rehabilitation experts and consumers. The participants identified five areas requiring attention:

- Planning and coordination: the need for a national rehabilitation plan.
- Decentralization: need to develop an integrated community based rehabilitation strategy (can we make prefabricated devices, e.g. the mono-limb which incorporates alignment in the manufacturing process); organize outreach programs using mobile units; link rehabilitation and primary health care services; provide equipment and rehabilitation training to existing health facilities.
- Education: needs include a multidisciplinary approach, medical school curriculum, community leaders, continuing education, short-term courses.
- Pediatric Programs: need to development of community-based rehabilitation programs for children.
- Research/Development

Session on International Issues/Low Income Countries
Speaker: Hector Casanova, C.P., Director of Rehabilitation Program, CIR

Discussion

The process of technology transfer and field-testing in developing countries was discussed. Developers sometimes want to test products in the developing world, in an area that does not have care. However, these people can't afford failure since they can't be tested again for many years. We need to do the research here, in a controlled environment. Once we've tested the technology here, we need to expose new technology to the field where it will be used and expose patients to the device and see how it will work in their environment.

Do we use standards such as those of the International Standards Organization (ISO) when using these devices internationally and under different environments? We really need to test under appropriate conditions.

Care in other countries is different than that in the US. We can't impose our views on them. We must find out their needs. However, there is often no concept of follow-up. We need to introduce this and teach the value of this. Dr Smith pointed out that international groups need large amounts of money to generate infrastructure. How do you switch from emergency assistance to a long-term solution not tied to cycles of emergency? There are a lot of reasons why practitioners might not be able to intervene long-term as much as they would like. We need to find incentives for people to do long-term follow-up.

Design and Development of Appropriate Technology for Low-Income Countries: An Overview of Development and Preliminary Field Testing of the *Shape&Roll*® Prosthetic Foot

The *Shape&Roll*® prosthetic foot was developed by the RERC in P&O in cooperation with the Center for International Rehabilitation (CIR), Chicago, the National Institute on Disability and Rehabilitation Research - Rehabilitation Engineering Research Center (NIDRR-RERC) for Improved Technology Access for Land Mine Survivors. The design of the *Shape&Roll*® foot incorporates biomechanical principles of the unimpaired physiological foot/ankle complex, yet it is simple and allows for easy manufacturing by non-prosthetic/orthotic-trained personnel. Care has been taken to use material that is easily available in low-income countries. In early summer 2002 we conducted a preliminary field trial in El Salvador, Central America. Twelve persons with unilateral transtibial amputation participated in the field trial. They were requested to wear a test prosthesis mounted with a *Shape&Roll*® foot for three weeks. The *Shape&Roll*® foot increased significantly walking distances, facilitated fast walking, improved the ability to keep up with walking speeds of non-amputees, and enabled better handling of uneven surfaces. The roll-over characteristics of the *Shape&Roll*® foot were perceived by the participants as natural and very smooth.

The need to identify the specific needs of developing countries was raised. Who is going to do this? The bottom line is that we need better-trained health care providers, consistent long term funding, and devices that are affordable and durable.

"How do you eat an elephant? You eat it piece by piece."

SESSION 5: OPEN SESSION

One participant commented that his overwhelming impression from the morning's discussion was that people are very interested in outcome measures and issues of how managed care is forcing out training. Should the constraints of the health care system limit research? No it shouldn't. Science operates in advance of it ever reaching the commercial stage or the patient. Another participant suggested that education of P&Os is being brought down because of the health care environment: you can pay less for a device provided by someone with less education. It was then suggested that this type of 3rd party problem might be solved if we had quantitative data to back up what we are saying as a profession. We need to inject science into the profession and educate new clinicians so that they can understand the science and use it. We also need to educate the 3rd party payers because they are being more critical of what they are paying for.

One participant noted similarities in the development of P&O to that of nursing where there are the same difficulties with quantifying caring; where it is cheaper to have less well-trained nurses by the bedside; where standardization of training is a problem. P&O is considered a profession. One hallmark of being a profession is having a unique body of knowledge. P&Os need to take their science back. Like nursing science. Lots of things nurses did as a tradition without knowing why. Nurses went back and worked out why by taking measurements. This goes back to the education of new clinicians. This is what will make it a science. What nursing has done is the process of benchmarking. Dr Childress suggested that we're already seeing this happen in P&O with the presence of people with both P&O and PhD degrees. Also encouraging are the students who come from bioengineering, then take the prosthetics course and then go out into the P&O industry. They have a body of knowledge; a set of skills; and an indwelling ethic: qualifications, schooling, exams, ethical standards, etc. All of which are the hallmarks of a profession.

One participant, a chairman of the National Commission on Orthotic and Prosthetic Education (NCOPE), agreed that we're seeing better education in this country. Before we had people with technical skills, now we have baccalaureate degrees. Even residency research is improving as the caliber of people improves. This is the future of P&O. However another

P&O EDUCATION

Our RERC in P&O has an active education program:

- We currently have eleven students in the **graduate program**. Six are at the Ph.D. level, and five are at the M.S. level. All are enrolled in the Department of Biomedical Engineering at Northwestern University.
- We currently have two **post-doctoral fellows.** Stefania Fatone, Ph.D., from Australia, is a prosthetist/orthotist with a Ph.D. in biomechanics. She is working predominantly on orthotic research. Andrew Hansen, Ph.D., is continuing work on foot roll-over shape that he undertook for his doctoral dissertation.
- Our RERC is actively involved in the **NIDRR Young Scholar Program**, hosting an annual research internship for a student with a disability. Recent participants in the program include Brian Ruhe (now a graduate student in our RERC), Kelly Lim (who continues to work as a research assistant in our RERC) and Allison Boynton, C.P. (a recent graduate of NUPOC).
- For the last two years, in conjunction with the American Academy of Orthotists and Prosthetists, we have convened and taught a three-day instructional course entitled **Advanced Training Course: Overview of Gait Analysis for Prosthetists and Orthotists.** The course is aimed at Certified Prosthetists and Orthotists interested in continuing education.
- Members of our RERC routinely contribute to **P&O education for physicians and therapists** at Northwestern University. This course is offered four times each year.
- Members of our RERC teach and collaborate with the **Prosthetics and Orthotics Education Programs** in the Northwestern University Prosthetics and Orthotics Center (NUPOC).

participant suggested that in his experience teaching P&Os, we still haven't instilled in the students that science is important. Educators are still being told people need to learn more about billing. Why are you teaching them moments? That's not what they need. There is still a lot of reluctance in the field.

Participants noted the value of revisiting old research.

One participant suggested that in the absence of professionals, we could introduce the idea of getting experienced amputees to teach new amputees how to do things. There was agreement that we don't involve the users enough in this process and that peer counseling and support groups are invaluable. Peer groups are mostly used for psychological benefits, but by pulling people together they also learn from each other.

How do we apply what we know, mostly from prosthetics, to orthotics? In orthotics there is no space to work. In prosthetics, the segment is removed and there is space to put components. One participant contended that the problem is not analogous to prosthetics. Another suggested that there are parallels between prosthetics and orthotics. Biomechanics are very similar in both areas and advancements in prosthetics can be applied to orthotics.

The need for clinicians to quantify their practice was raised again. Clinicians may feel they 'know' something with their hands, but numbers don't necessarily mean the same thing to them. There is a whole other area of technology and education required: education of how to interpret numbers. It was noted that measuring things is complex, e.g. gait labs. At Northwestern, we think our motion lab is very important. Before we had it, we had hypotheses about what would happen if we did this or that, but we couldn't test them. Measurements are necessary to test hypotheses. These devices need to be available for research and ours is dedicated to P&O research. Another participant commented that what they'd learnt from their gait lab had made them a better clinician. It was suggested that a major challenge in terms of gait lab utilization is to produce information that is clinically digestible. As a research tool it has been valuable, e.g. modeling, predicting surgical outcomes. Another participant suggested that if you combine data with pictures and video, communication between engineer and clinician would improve.

MOTION ANALYSIS LAB

The VA Chicago Motion Analysis Research Laboratory (VACMARL) housed alongside the RERC in P&O is equipped with state of the art motion measurement instrumentation including an eight camera real-time, digital motion capture system for kinematic measurements, six force platforms for measuring ground reaction forces, an eight-channel telemetered EMG system for recording muscle activity, and a pedobarograph system that uses insoles for measuring pressures between the foot and the shoe during walking. VACMARL also has a digital video subsystem comprised of two digital camcorders, a VCR, a monitor, and a video editing board that is used for recording split screen displays of two simultaneous views from the digital recorders. All of the measurements systems in VACMARL are integrated to allow a complete picture for the characterization of human movements. VACMARL is being used to increase understanding about normal human ambulation, and to study pathological gaits in an attempt to determine how improvements to prosthetic and orthotic devices can be made.

The utility of Functional Electrical Stimulation (FES) in prosthetics and orthotics was raised. It was noted that we lack objective data as to the carry-over benefit of FES: there is functional input when 'on' but we are not sure of the long-term benefit. Other benefits though include improved bone

health. There are problems though with movement of surface electrodes. One participant noted that regardless of efficacy there is no coding system for P&Os to supply it. Just like serial casting where P&Os can't bill for the service but physical therapists can. Another participant pointed out that there are numerous examples of FES being applied in multidisciplinary teams, e.g. in Cleveland and Scotland. However, there is currently no consensus that FES is better than a conventional AFO for foot drop. Someone suggested that it won't replace the orthosis but is an aid to it. However, there is not a big enough market for companies to develop these products.

SESSION 6: FABRICATION, MATERIALS AND SAFETY

Raconteur I: John Michael, C.P.O.

John began by saying that he wasn't trying to be overly critical of us as P&Os but that we should be brutally frank in this forum. We should assess where we are, where we might go and how to best to get there. John commented that since A.A. Marks wrote his book in 1906, not much has changed. As P&Os it is difficult for us to articulate what we think we know because it is based on collective experiences and there is no documentation.

Fabrication:

- Empiricism rules. What we do is rational, but we are eager for more science in our art.
- Cost containment pressures limit available time for fabrication. Time efficient but more costly materials have hope but anything that takes more time is hard in today's market.
- CADCAM is mostly hyperbole. It hasn't yet lived up to its promise. Very immature at this stage. With better inputs CADCAM may make sense. Great interest, but no great advance yet.

Central fabrication:

- Generally cheaper but slower and less versatile than having an on-site technician. Also as clinicians, we have to think the process through all the way from the beginning rather than as a step-by-step process such as we can take when working with a technician on-site. Shipping adds time to the process even though it is cheaper.

Materials:

- Pragmatism predominates.
- Low cost, low tech, versatile methods predominate.
- One-off "prototypes" make production costly.
- Materials science methods from high volume industries do NOT transfer directly to P&O products.

We need to adapt existing information for the niche we are working in.

Safety:

- No comprehensive data on US P&O failures. Cost of litigation is increasing.
- More comfortable, more functional devices = need for greater durability.
    - Bar for fabrication is slowly rising.
    - Real need to improve materials science and fabrication.
- Workplace hazards are becoming more widely recognized and regulated.
- ISO prosthetic standards have increased our awareness of manufacturer's component failures.
- Failures of custom-made structures are still largely invisible.
- Functional failures often unrecognized.

Problems:

- No benchmarking = no established standards.
- We are vulnerable to "bad science". To make us better consumers of science would be invaluable.
- Catastrophic product failures uncommon = not "on the radar screen".

- Generic guidelines are rarely better than real world experience.

Evolution of P&O practice:

1. technical training = how to do it…
2. clinical experience = when to do it…
3. scientific evidence = why to do it…underpin what we have learned through collective experience.

Raconteur II: Joshua Rolock, Ph.D.

Joshua began by saying that he would restrict his comments to engineering materials rather than biological ones.

- Materials science is well established with a wealth of information available on material chemistry, properties, and processing.
- Industrial fabrication utilizes process control to ensure quality, e.g. taking periodic samples, and testing them to ensure quality.
- P&O is (somewhat) at the mercy of the material suppliers. As clinicians we don't know the quality control standards of our suppliers unless undertaking some form of testing ourselves.
- In P&O practice there is limited understanding of materials science, "strength of materials", or stress analysis. We don't know how these are affected by material processing. We get by on rules of thumb, doing it the way it has always been done and over-engineering to keep in the safety zone. There is a resistance to materials education in P&O.
- Fabrication techniques: not all polymers can be worked by hand.
- Fabrication parameters are subject to variability. There is no quality control.

Advanced fabrication methods can enable us to explore new (and old) materials. Devices such as rapid shape can increase consistency and quality control by heating material in a standard way every time, controlling the pull/strain of material and controlling the vacuum application. Squirt Shape, for example, can further increase quality control by maintaining consistent processing

SQUIRT SHAPE

The "Squirt Shape" process developed by our RERC in P&O provides a new method for the computer-aided manufacturing of sockets in a fully-automated, single-step operation directly from three-dimensional coordinate data. The technique borrows principles from industrial rapid prototyping and manufactures sockets by the continuous deposition of multiple layers of extruded plastic. This technique differs from other means of prosthetics Computer Aided Manufacture in that the separate steps of socket mold carving and socket molding are now eliminated. The machine uses standard thermoplastics already common to prosthetics fabrication and can fabricate a typical below-knee socket in roughly 45 minutes. The strength and durability of the sockets are sufficient for long-term clinical use in lower-limb prostheses. Using Squirt Shape, we are investigating the possibility of building below-knee sockets with pylons and alignment built in. Since these prostheses will be a single unit (i.e., socket/pylon complex built on a foot), alignment prior to fabrication is necessary. A three-dimensional, graphic software package, Squirt Shape 3D (SS3D), that allows the prosthetist to perform static alignment directly on the computer image has been created. SS3D displays the image and gives the prosthetist the option of attaching a pylon of desired length and a virtual foot of specific size. After adding a pylon and a virtual foot, the prosthetist performs static alignment by inputting values for rotations, translations, and other alignment parameters. The software then calculates the transformations and redisplays the modified image. Once the alignment process is finished, the modified data is sent to the Squirt Shape system for fabrication. Currently, the strength between the pylon and the foot is being tested.

parameters and geometric tolerances. For example, thickness varies with hand fabrication, but Squirt Shape can control for this.

Joshua concluded by saying that while the State-of-the-Science is promising, application of the science is (at present) poor!

Discussion

One participant pointed out that both presentations focused primarily on prosthetics, but that orthotic patients frequently sustain breakages, especially since the choice of materials used in devices is limited. Dr Childress pointed out that anything will break eventually. You probably can't put a device on someone that won't fail in some circumstance. It was suggested that we need a recall system. Preventive maintenance. Benchmarking would help us learn the intervals that we need to inspect devices and components and allow us to estimate their life. There are some things we can do to avoid failures such as better monitoring and replacing devices and components at frequent intervals to avoid fatigue failures. Another participant indicated that prosthetists have criteria such as activity level and weight to guide them, but orthotists don't. If orthotists had something to go by initially they'd be better off.

One participant commented that there aren't a lot of plastics suppliers in this field and that perhaps we should work towards certification of suppliers. Perhaps material should come with specific data about application to our field. We know fabrication techniques can affect material properties, so data sheets informing of the right way to use particular materials would be useful. Another participant commented that this information is already available but that it's application to this industry is lacking. We need to look at how to convey/share this information.

It was suggested that educational research was required to ensure that our industry is sufficiently standardized. There is an incredible variability in knowledge among P&O professionals. There is a movement within NCOPE to include materials science in the education of P&Os but there is resistance to this. One participant suggested that web-based education might be used to help educate P&Os about materials science. Dr Childress pointed out that orthopedics has a history not unlike P&O with respect to bad materials choices leading to failures, e.g. in total hip replacements. He suggested that if you have failures, it is a valuable practice to collect and document them. It would build up knowledge. It was suggested that P&Os need a quality assurance process to use failures to improve the quality of future products.

It was pointed out that it used to be that the limitation to the number of patients being seen was room, but now it is time. We're on an outcomes based system. The point is that there is data out there whether it is in your form or not, but it is out there. Combining data would solve a lot of problems. However, no one wants to share data. The cost of entering data needs to be acknowledged. We need to push the value of prospective data collection with non-specific protocols. How can we share data on failures? We have regulations that preclude access to patient information. If this data forms part of an internal quality assurance program, lawyers are kept away from it. This sort of data CAN NOT be subpoenaed. How to share data safely is something the Academy should teach. One participant commented that our IRB information from last fall was that you need patient consent to share data even in a retrospective study. Camille O'Reilly however asserted that if the data is stripped of all identifiers, you can share that data. There are all kinds of data out there for sharing, e.g. the Research Data Assistance Center (RESDAC), where researchers will strip data for you if you request it specifically.

"…the highest application of technology in rehabilitation is not the same as the application of the highest technology."—Forscheimer

"My goal in life is to be two fads behind."

"Forthright dogmatism is better than conclusions propped up by shaky statistics."
—Sir Herbert Seddon (hand surgeon from England).

SESSION 7: LONG RANGE RESEARCH AND CLINICAL PRACTICE

Raconteur I: Hugh Herr, Ph.D.
Dr Herr began by saying that he would speak about his personal views on what may emerge in this field, i.e. Hugh's wish list!

Dr Herr discussed a hypothesis regarding conservation of angular momentum, which gives us transformations from one state space to another. He talked about Virtual Model Control language and how it is being used. He talked about the role the Center of Mass (COM) plays.

Dr Herr introduced attendees to a robotic knee that has a 'virtual' prosthetist and biomechanist programmed in and attempts to account for user intent. User intent might be measured using Bions. Bions may in the future help us measure EMG. The Defense Advanced Research Projects Agency (DARPA) is interested in this type of work. They would like researchers to work on measuring neural signals to control robots.

Dr Herr suggested that 50 years from now we may have Actin-Myosin Machines. Artificial muscle (using synthetic materials to act as muscle) is currently being researched, but can we get real muscle to work? If you denervate muscle by cutting the nerve, can you keep the muscle alive? It may be possible to build devices *with* muscle, i.e. hybrid machines. The long-term objective would be to have muscle-driven robots (e.g. fish) that feed on glucose. But why strive to have muscle actuators? Muscle actuators have excellent functional characteristics. They are functionally adaptive, scalable, quiet (unlike mechanical or electric motors), biocompatible, and biodegradable. There are two approaches: cell culture muscle (grow muscle from cells) or organ culture approach (take muscle from animal).

Future research is required to systematically search parameter space and build autonomous robotic fish platform with reflex feedback systems to demonstrate bioreactor performance.

"The future may bring a great intimacy between human and machine."

Because of that humans may be far more capable (physically and mentally), becoming hybrid machines.

Raconteur II: Dudley Childress, Ph.D.
Dr Childress (pictured right) directed the following comments at Dr Herr's discussion:

- EMG appears a considerable time before force, so you have quite a bit of advanced time to control something.
- Recommended reading Flesh and Machines, just published by MIT.

Dr Childress questioned the 'newness' of devices. For example, a long rod was used as an assist for a paralytic limb in Egypt (circa 1500 BCE) and Africa (circa 1993 CE). Is it an ancient idea or a very good design?

Dudley Childress, PhD Director, RERC on P&O

Dr Childress revisited the idea of cineplasty. The benefits of cineplasty are that pinch force is proportionate to the force in the muscle, so you have a feel for the force that you are applying. You can operate the device in any position in which you can operate your muscle.

Dr Childress charted some of the history of cineplasty beginning with Professor Dr. Ernst-Ferdinand Sauerbruch (1871-1951) and his team. Dr Sauerbruch worked with Aurel Stodola (a world leader in steam power and turbines) who is perhaps the first Rehabilitation Engineer. He discussed the forearm cineplasty with prosthesis where Sauerbruch used agonist/antagonist muscle pairs. In this arrangement, muscle force was very weak; however now we can use electrically powered prostheses to produce more force. Robert Beasley, M.D. introduced the Exteriorized Tendon Cineplasty Surgical Procedure where a loop is made around the tendon. A hand with an amplified control system is then added. The muscle may move a maximum of 3mm, but with the right gain on the amplifier, a prosthesis can be operated (though not as good a sense of position is achieved since the movement is very small). Dr Childress showed an example of combining old and new techniques: modern technique using transfer of toe to hand to get prehension and old technique of separating the radius and ulna to create a prehension device.

Dr Childress also discussed direct skeletal attachment, hand transplants, neural network classifiers, interfacing with the brain, bions and a bion delivery system. A benefit of direct skeletal attachment is that it provides proprioceptive feedback.

Dr Childress introduced Dr Kuiken's experimental technique involving nerve-muscle grafts for shoulder disarticulation. This technique uses nerves in the Pectoralis muscle to control an arm prosthesis. Essentially this technique creates new muscle sites and increases the number of control signals.

"Surgeons, physicians, prosthetists, therapists, scientists, and engineers must work creatively together to advance upper limb prosthetics."

Discussion

One participant suggested that the common unifying theme of this morning's raconteurs was the fusion of flesh and machines. It was thought that exploiting the capabilities of living systems should be very useful.

One participant pointed out that the ideas of different levels/types of control were not addressed: autonomous control, supervisory control, and local control. As we continue to develop powered devices, we need to be aware that not everything needs to be volitionally controlled.

There was some discussion among participants regarding achieving multiple functions from a single EMG sight. This work is in the literature but is not currently being pursued. It was suggested that the mental loading required to keep a device performing the appropriate task is a drawback of single site EMG for multiple functions. One participant suggested that the goal should be 'natural control', where a device can predict what is going to happen based on what you are trying to do. Another participant concurred saying that we need to use muscles that are naturally used for a function.

Dr Herr asked whether by using bions we could harness the phenomenon of phantom awareness and the elaborate firing patterns that occur when attempting to move the phantom limb to control a

prosthesis. Dr James pointed out that you must be careful in selecting muscles for control of the prosthetic device. For example, muscles in a socket may be being used to hold the socket on rather than perform a task. To overcome this sort of problem, maybe EMG data should be used for timing issues, and everything else should be controlled locally.

There was some discussion about the process of turning research into devices for the market. Dr Childress argued that a researcher could be successful without producing products by publishing their work and providing others the information with which to develop products. Another participant suggested that Dr Milner's work in Canada was a very good example of a synergistic way of creating a device and marketing it. It was suggested that creating a commercially available products is usually not mutually exclusive to good quality research. Dr Milner replied that it is often helpful to take products developed in the lab and produce them in short runs so that you can introduce them into the market. But you must be careful that you do not forget about the fundamental ideas in your research.

SESSION 8: ROUND-UP SESSION

Dr Meier began the session with a recap on general topics he noticed over the course of discussions:

1) What are collaborative roles that can occur between commercial industry, manufacturers, providers and clinicians?
2) Is there a way to formally identify consumer priorities? We need to separate out the perceived needs of children and adults.
3) Why is there not more research in orthotics?
4) Is there a way to affect change in education and behavior in surgeons and rehabilitation specialists, and is that a role someone could assume?
5) Are there technologies that are less costly for both national and international applications; and does something that is State-of-the-Science necessarily have to cost more?
6) Criteria for standards of care and prescriptions would allow us to influence the health care system for funding devices and systems of care for training with those devices.
7) Is there a plan of action for the dissemination of these discussions here?
8) Do we understand the demographics of the populations being served? Or is development and technologically commercially driven? e.g. Utah arm.

ORTHOTICS RESEARCH

Research and technological advancements in the field of orthotics has lagged behind prosthetics for many years. Our RERC in P&O is attempting to address this by investigating a number of different aspects of orthosis performance. We currently have three main areas of investigation:

"An Investigation of Foot Alignment and Support in Ankle Foot Orthoses (AFOs)" The purpose of this research study is to increase our understanding of AFO-assisted gait, and to determine if ankle-foot alignment and foot support significantly affects AFO performance in persons with hemiplegia following stroke. We believe that the results from this study may enable us to recommend more appropriate AFO prescription and designs. This is a VA-sponsored study.

"Pilot Investigation of the Functional Benefits of Stance Control Orthotic Knee Joints" Recently, a number of new orthotic knee joint designs have become commercially available which allow stance phase control. We are currently gathering pilot data comparing kinematic and kinetic parameters for locked knee gait to the stance control joints in order to quantify any benefits these new joints may have. We are grateful to Horton's Orthotic Lab. Inc. for their generous loan of a set of SCOKJs. The NIDRR Research Scholar program supported this project.

"Analysis of Able-Bodied Spinal Motion During Walking" This investigation addresses the role of the spine during walking both with and without restriction from a spinal orthosis (a customized fiberglass body jacket similar to a Thoraco-Lumbo-Sacral Orthosis). We are comparing kinematic and kinetic parameters to determine how the restricted spinal motion affects gait patterns. This project forms part of Ms. Regina Konz's PhD dissertation and is funded in part through the Department of Neurosurgery at Northwestern Memorial Hospital.

9) Is there a way to develop important outcome measures that can be used in a scientific manner?
10) What is influencing health care systems with regards to standards of care and do we have any influence?
11) Can this group influence educational systems that would include outcome measures, communication skills, psychosocial aspects, etc.?
12) Is there a way we can influence international systems of demographic studies of disability? Malaria is a big problem in these countries, bigger issue than landmines or polio.
13) Is there a way to influence international funding to move P&O and rehabilitation up the wrung in terms of priority in health service provision?

14) Is there a way to influence commercial fabrication and manufacture?
15) Is there a relationship between State-of-the-Science, this group here, and the banning of landmines and other causes of disability around the world?
16) Can we differentiate low income and national priorities because we've studied them and understand them?

There were a number of participants who wanted to know what was to be done with the information arising from this meeting. Dr Childress clarified that this meeting is a requirement of the funding of our research center by the National Institute on Disability and Rehabilitation Research (NIDRR). We and NIDRR will use information from this meeting as a basis for a planning document. We are a Rehabilitation Engineering Research Center (RERC) on P&O, and it would be hard for us to handle problems like malaria. Because of our area of expertise, we tend to look at technical research problems. We are also educational. Dr Childress commented that his problem with lists like these is that it includes things we can't do. Participants suggested that we don't let that discourage the publication of these ideas since they may, in a different venue, lead to action. This idea was supported since many of the issues brought up are important even though they are not engineering problems and NIDRR has broader interests than just rehabilitation engineering. With respect to non-engineering issues, they are not the sorts of problems any engineering center should or could address. Engineering solutions require engineering problems. The sort of things engineers do well is to address problems that can be defined in terms of engineering issues. However, one participant felt that it was important that engineers enter into the non-engineering world and look for problems outside of their own environment.

Mr Peterson (pictured right) clarified the role of NIDRR and what they are looking for from this process. They are hoping to receive a report that helps the field and helps NIDRR to develop future directions. Although it is intended for the document to be published, where it should be published is not specified. There was a question as to whether NIDRR was in a position to assist with education and training. Mr Peterson suggested that this was the case only to some degree. A Rehabilitation, Research and Training Center (RRTC) could possibly be established in the future to address some of these issues.

William Peterson, MS
Project Manager, NIDRR

It was suggested that a group like the committee on P&O development that existed in previous years is potentially very powerful and would be a good way of advocating for the profession and patients.

One participant asked whether we could develop a better model for product development, to minimize the time it takes to get a product to market. Mr Peterson indicated that this has long been a problem. Things are often developed in the lab in isolation and then when thrown on the market don't succeed. We are missing part of the equation. NIDRR has an RERC on technology transfer that have developed a number of models that may resolve this issue.

It was pointed out that while this meeting had stimulated many people to go back and work in prosthetics, there wasn't as much emphasis on orthotics. One participant suggested that although many of the problems of orthotic design have been identified, we haven't seen any breakthroughs because it is hard, harder than prosthetics.

CONCLUSIONS & RECOMMENDATIONS

The State-of-the-Science Meeting in P&O brought together a diverse range of people with an interest and experience in prosthetics and orthotics. Represented were clinicians, researchers, engineers, prosthetists, orthotists, physicians, educators, students and users. The meeting contained many comments and opinions that were directed at social, economic, and personal needs, not surprisingly informed by the experiences of the particular person. In fact, these issues frequently dominated over engineering and scientific issues. It is important in formulating recommendations arising from this meeting that those problems that can be addressed by an RERC are distinguished from those that are beyond it's scope.

As a 'raconteur' in the session on **Interface Mechanics, Attachment and Alignment** Dr Meier presented a holistic view of 'interface': between the patient and the device and between the patient and rehabilitation team. He focused on the importance of rehabilitation, the team approach and listening to the patient. Dr Meier's experiences as a physician influence his perspective and perceived needs. As an engineer, Dr Rolock's presentation was more concerned with engineering problems such as defining the process of tissue loading in prosthetic sockets. He felt that science and engineering had the capacity to advance the field in these areas, providing much needed basic understanding.

In the second session, **Enhancement and Evaluation of Functional Performance**, the two raconteurs, both engineers, focused on two very different aspects: Dr James talked about his experiences in the product development process and taking prototypes to market, while Dr Herr discussed the transfer of technology from the realm of legged robots to P&O. He suggested that to advance P&O systems, we need better sensors, control algorithms and a better understanding of how we walk. Dr James' presentation appealed to those who think of research in terms of building better devices, a perspective that isn't unreasonable given that the prosthetist/orthotist must ultimately provide devices. Dr Herr's presentation focused more on the developing an understanding of how to best control these devices. With respect to control mechanisms there are many avenues to explore for example those mentioned during this meeting included electrical stimulation, bions, and virtual model control language. The discussion highlighted the fact that there is still discussion as to the value of powered versus passive control of devices.

The session on **Reaching and Manipulation** focused mostly on devices that had been designed but for many reasons were not being used much (Dr Landsberger's presentation) and the need for devices that met certain criteria with respect to weight or ease of donning, for example, or needs such as cosmetic gloves that don't stain and independent finger movement (Mr Lipschutz presentation). These two presentations emphasized a commonality between the prosthetists and engineering perspectives. Because of their close interaction with patients and their own frustrations in trying to meet client needs within the bounds of the currently available technology, prosthetists and orthotists are able to identify areas in which the devices they provide are lacking or altogether non-existent. This then informs the engineer as to the types of problems they can define and address with respect to designing devices and components. This process, while necessary and an integral part of research and development, contributes only indirectly to the development of a prosthetic and orthotic science.

When it came to **International Issues/Low-Income Countries**, the needs with regards to rehabilitation appeared to be reasonably well defined. Based on his experiences working directly

with patients in low-income countries, Dr Fisk highlighted the need for on-site data collection, education of native clinicians and appropriate technology. From their experience as an organization attempting to improve rehabilitation in low-income countries, Dr Smith and Mr Casanova (from the Center for International Rehabilitation) concurred with Dr Fisk and added the need for low-income countries to have a national rehabilitation plan that included integrated community based rehabilitation and education. To address these issues there needs to be a collaborative effort from a number of different types of organizations and people. An RERC on prosthetics and orthotics can contribute to some of these needs where they are within the scope of defined engineering problems.

In the session on **Fabrication, Materials and Safety**, Mr Michael emphasized that in much of prosthetics and orthotics, empiricism and pragmatism still dominate. He suggested that while what prosthetists and orthotists do is rational, they are eager for more science in their art. Dr Rolock focused on the need for materials science to be better applied within the field of prosthetics and orthotics, suggesting that the science that does exist, while not necessarily specific to P&O, does have applicability. Both presenters appear to be making a case for the education of clinicians so that they may be better able to apply the science that does exist and contribute to the development of a prosthetic and orthotic science.

In the session on **Long Range Research and Clinical Practice** it was suggested by Dr Herr that the future may bring a greater intimacy between human and machine, for example in the form of actin-myosin machines. Dr Childress suggested that looking back at previous ideas, techniques and devices might also help us to advance.

The **Open Session** and the **Round-up Session** highlighted the interest and pressure that exists among clinicians with regards to developing and applying outcome measures and quantifying their practice. The need for education of new and established clinicians to emphasize the value of developing a prosthetic and orthotic science and the skill with which to contribute to this process was emphasized. It was suggested that knowledge gained through scientific evidence allows prosthetists/orthotists to develop and apply their skills in a manner that is professional, quantifiable and ethical. There was also discussion of the effect managed care was having on prosthetics and orthotics with regards to standards of care and funding. While this is a large area of concern in the health care system, it was difficult to identify how an RERC on P&O could contribute directly. One of the recurring themes of the discussion sessions focused on the similarities and differences between prosthetics and orthotics and the relative attention they receive with respect to research. It was generally agreed that the state-of-the-science in orthotics has lagged behind that of prosthetics and that there is a need for this to be addressed.

One further aspect of prosthetics and orthotics research highlighted by this meeting was the need to keep open communication between all the various professionals and users with an interest in P&O. Each has their own unique perspective on the issues and needs that exist. By harnessing these various perspectives, the field of prosthetics and orthotics will not only advance more quickly, but be the richer for it.

Overall, the key themes/needs arising from the State-of-the-Science Meeting in P&O may be summarized as follows:

- There needs to be more orthotics research.
- There exists a need for the development and implementation of meaningful outcomes measures.
- There is a need for science and quantification in prosthetics and orthotics.
- There are benefits to revisiting previous research.
- There is a need for better materials science application to prosthetics and orthotics.
- There is a need to re-establish the medical/clinical/engineering team.
- There is a need to address the effect of managed care on education, practice, and research.

Our experience would suggest that the first five of these needs are within the scope of an RERC on P&O but that the final two points need to be addressed more widely by the health care community and the prosthetics and orthotics profession. Underlying those needs that fall within the scope of and RERC in P&O is a broader need for the development of general principles and knowledge base. We need to know not only what to do, but how and why. Research should not only be focused on building better devices but on developing documented scientific-based prescription rationales. Like most fields, prosthetics and orthotics has so far been based on a foundation of knowledge that originated empirically. It is now time for prosthetic and orthotic science to emerge.

APPENDICES

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APPENDIX B:
AGENDA

Friday & Saturday, May 17-18, 2002
Rehabilitation Institute of Chicago, 17th Floor (1702)
345 East Superior Street, Chicago, Illinois

TIME	ACTIVITY
Friday	
8:15 – 9:00 AM	**Continental Breakfast** Learning Resources Room, 17th floor, RIC
9:00 - 9:15 AM	**Greetings and Brief Overview** Dudley Childress
9:15 AM	**Interface Mechanics, Attachment and Alignment** (comfort and control)
9:15 – 9:30	**Raconteur* I** Robert "Skip" Meier
9:30 – 9:45	**Raconteur II** Joshua Rolock
9:45 – 10:30	**Discussion** (past & present, problems, promising directions, the science)
	Moderator: Michael Brncick
10:30 – 10:45 AM	**Break**
10:45 AM	**Enhancement &Evaluation of Functional Performance** (measurements, modeling, shock absorption, powered/passive, control)
10:45 – 11:00	**Raconteur I** Kelly James
11:00 – 11:15	**Raconteur II** Hugh Herr
11:15 – 12:00	**Discussion** (past & present, problems, promising directions, the science)
	Moderator: Steven Gard
12:00 – 1:00 PM	**Lunch**

"The scientist has no other method than doing his damnedest."
P.W. Bridgman

**Raconteur: One who tells stories and anecdotes with skill and wit.*

TIME	ACTIVITY
Friday	
1:00 PM	**Reaching and Manipulation** (control, mechanisms, suspension)
1:00 – 1:15	**Raconteur I** Sam Landsberger
1:15 – 1:30	**Raconteur II** Robert Lipschutz
1:30 – 2:15	**Discussion** (past & present, problems, promising directions, the science)
	Moderator: Craig Heckathorne
2:15 – 2:30 AM	**Break**
2:30 PM	**International Issues/Low-Income Countries** (education, techniques, materials, appropriate technology)
2:30 – 2:45	**Raconteur I** John Fisk
2:45 – 3:00	**Raconteur II** William K. Smith
3:00 – 3:45	**Discussion** (past & present, problems, promising directions, the science)
	Moderator: Hector Casanova
3:45 – 5:00 PM	**Open Session** (a gathering of the day's ideas and beyond)
	Discussion Leaders: Barbara Silver-Thorn and Richard Weir
5:00 – 6:00 PM	Participants are welcome to visit the P&O educational facilities on the 17th floor and the research facilities on the 14th floor between 5 and 6PM.
6:00 – 7:30 PM	**Reception** in Lowden Hall (NU Law School across Superior St. north)
End of First Day	

"Beware of false knowledge; it is more dangerous than ignorance."
George Bernard Shaw

TIME	ACTIVITY
Saturday	
8:00 – 8:30 AM	**Continental Breakfast** 17th floor of RIC
8:30 AM	**Fabrication, Materials and Safety** (CAM, education, rapid prototyping, central fabrication, failures)
8:30 – 8:45	**Raconteur I** John Michael
8:45 – 9:00	**Raconteur II** Joshua Rolock
9:00 – 9:45	**Discussion** (past & present, problems, promising directions, the science)
	Moderator: Donald Shurr
9:45-10:00 AM	**Break**
10:00 AM	**Long Range Research and Clinical Practice** (things that may not fit within 5 or 10 year time schemes)
10:00 - 10:15	**Raconteur I** Hugh Herr
10:15 – 10:30	**Raconteur II** Dudley Childress
10: 30 – 11:15	**Moderator:** Morris Milner
11:15 – 12:00 Noon	**Round-up Session** (recapitulation and beyond)
	Discussion Leaders: Robert "Skip" Meier and Dudley Childress
End of Meeting	

"Our ignorance may result from the lack of an adequate theoretical framework in the light of which to order and interpret the relevant facts."

Sir John Kendrew (Encyclopedia of Ignorance)

TIME	ACTIVITY
EXPLANATION CONCERNING THE AGENDA	Our goal with the agenda was to try to step back and look at the broad picture of prosthetics and orthotics. We wanted to avoid starting from the particulars such as prosthetic feet or orthotic AFOs and so forth. Therefore, we generalized the topics. Science has the capacity to help solve particular problems through the development of general concepts (e.g. theories and models). Donald Stokes, in his book, *Pasteur's Quadrant* believed that productive people like Pasteur solve practical problems and at the same time advance science (knowledge & understanding). This approach seems like a useful one for P&O. Stokes thought research and development need not be—and frequently is not—a linear process that only moves from basic research to development and finally to use. Our hope is that the agenda, with two short presentations for each topic area and with approximately 45 minutes of general discussion and debate will encourage the group to do some broad conceptual thinking about P&O research. We also reserved time for discussion of other topics that participants may want to bring up.