REHABILITATION ENGINEERING RESEARCH CENTER IN PROSTHETICS AND ORTHOTICS

Research in P&O: Are We Addressing Clinically-Relevant Problems?

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

February 28, 2006

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FEINBERG SCHOOL OF MEDICINE

FOREWORD

This report summarizes the findings and recommendations from a meeting to critically assess the status of research and explore new directions in the field of prosthetics and orthotics (P&O) held on February 28, 2006 in the Northwestern University Prosthetics-Orthotics Center on the 17th floor of the Rehabilitation Institute of Chicago. This meeting was hosted by the Rehabilitation Engineering Research Center (RERC) in P&O (see Appendix F), which is supported by the National Institute on Disability and Rehabilitation Research (NIDRR).

The field of prosthetics and orthotics lacks the necessary knowledge base that is expected of a discipline to establish a legitimate science. Currently, the practice of P&O is very much an art form, typically requiring years of practice by prosthetists and orthotists to develop the necessary skills and expertise to become a proficient, well-respected and knowledgeable practitioner. Unfortunately, much of the evidence that practitioners rely on for making decisions about component selection, fitting and fabrication of prostheses and orthoses is anecdotal and undocumented. For this reason, we are hesitant to regard our meeting as an assessment of the "state-of-the-science", recognizing that the "science" of P&O is severely immature and that much work remains to be done. Therefore, we decided to change the emphasis of this meeting in order to make it more relevant and beneficial to the field by addressing a significant need, focusing less on the science of P&O (or lack thereof), and instead concentrating on clinically-relevant areas of research of immediate concern to prosthetists and orthotists.

Prosthetists and orthotists are in an ideal situation for identifying clinically-relevant research problems because they deal with the current prosthetics and orthotics technology and procedures on a daily basis. Additionally, they regularly communicate with prosthesis and orthosis users who provide them with feedback about their devices. In my informal interactions with clinicians, I have found that they often have many excellent ideas for research projects, but don't necessarily have the time or the resources to conduct the research themselves. Some of these proposed projects are long-recognized problems in the field, but they have never been systematically investigated. Therefore, we decided that the purpose of our meeting should be to gather information from practitioners about those areas in P&O that have not received sufficient attention in research to date. Clinically-relevant problems should be identified and investigated in order to provide the knowledge base required of a science and that would be necessary to advance the field.

Our meeting consisted of six sessions that focused on different areas of P&O. Each session began with brief presentations by two speakers, the first providing a research perspective and the second providing a clinical point of view. The research perspective provided an overview of published studies that highlighted ongoing investigations in the field, while the clinical perspective focused on patient/practitioner issues and concerns. The formal presentations were merely intended to stimulate thought and set the stage for open discussion by all participants for the remainder of the allotted time during that session. Ensuing discussion by the group was intended to create subcategories of major topic areas and make recommendations for further research. The last session, entitled "Open forum", enabled participants to make short presentations on additional topics of research interest that may not have been previously mentioned or discussed in the formal sessions. The meeting was attended by approximately 50 prosthetists, orthotists, user representatives and research engineers from across the U.S. and from our own RERC (see Appendix A for a list of participants).

In actuality, this meeting represents only one mechanism that our RERC used to identify clinically-relevant areas of P&O research. We began gathering information for this meeting in the fall of 2005 when we launched an online survey and forum, the results of which are also summarized in this report.

It is our hope that the importance of the information gleaned from our meeting, survey and forum will be recognized and addressed by investigators in the field, and that it will prove to be useful for guiding future direction, establishing a science, and steering funding priorities in the field of P&O research.

Steven A. Gard, Ph.D.
Director

ACKNOWLEDGEMENTS

The State-of-the-Science meeting and this report would not have been possible without the efforts of the following people: Rosemary Collard and Elizabeth Schreiber for their administrative and organizational assistance; Pinata Sessoms, M.S., Sara Koehler, M.S., and Kiki Zissimopoulos, B.S., for taking the notes during the meeting that much of this report is based on; Craig Heckathorne, M.S. for the photos shown in the following pages and on the cover; the staff of the Northwestern University Prosthetics-Orthotics Center for use of their facilities; and all the speakers who spurred the discussions. Photos of the State-of-the-Science meeting participants appear in this report with their permission. This report was edited by Stefania Fatone, Ph.D., and Steven Gard, Ph.D.

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INTRODUCTION

The concept behind the meeting's agenda was to try to stimulate thinking by having two presenters give research and clinical perspectives on a general topic area, and then to follow the two presentations with in-depth discussions by meeting participants. Each of the two presenters gave short back-to-back presentations (seven minutes each) that were followed by a 30-minute discussion period. Our desire was to provide participants with ample time to discuss issues connected with seven major research areas within P&O. The topic sessions for presentation and discussion were:

- Lower-Limb Prosthetics I: Foot/ankle mechanisms
- Lower-Limb Prosthetics II: Sockets, knees, shock absorbers
- Upper-Limb Prosthetics I: Electric prostheses
- Upper-Limb Prosthetics II: Body-powered prostheses
- Orthotics I: Lower-limb
- Orthotics II: Spinal
- CAD/CAM
- Open Forum: Miscellaneous topics

Participants were encouraged to express their views, identify current clinically-relevant problems, and speculate on future research directions. The meeting ended with an "open" session that enabled participants to bring up additional topics thought to be important.

This report consists of summaries of the presentations and discussions, followed by the conclusions and recommendations related to these sessions.

A number of appendices with additional information are also included in this report: Appendix A is a list of participants; Appendix B is the meeting's agenda; Appendix C is a copy of the online survey; Appendix D presents an overview of the structure of the online forum; Appendix E contains the Executive Summary from our previous State-of-the-Science Meeting that was held in 2002; and Appendix F provides the one-page abstract and mission statement of our Rehabilitation Engineering Research Center in P&O.

ONLINE SURVEY AND FORUM

In anticipation of the State-of-the-Science meeting, we held an online survey and forum in order to investigate the opinions of the P&O community regarding the direction that research in the field of P&O should take over the next 5-10 years. The results of the survey and forum were compiled and presented for discussion at the State-of-the-Science Meeting held February 28, 2006.

Summary of Survey Results

The survey was available online at http://www.medschool.northwestern.edu/depts/repoc/ from November 21 to December 30, 2005. The survey was advertised on the oandp-l list server, which had 3,300 subscribers during that period, the Clinical Gait Analysis (CGA) list server, and amp-l, the Amputee Coalition of American list server as well as their web site http://www.amputee-coalition.org/. E-mail invitations were also sent to colleagues in the field. Survey questions are included as Appendix C.

There were a total of 224 responses received and 172 (77%) respondents provided their name and e-mail addresses. The majority of respondents (78%) were aged 30-59 years (Figure 1) and 60% identified themselves as either Certified Prosthetists (CP), Certified Orthotists (CO) or Certified Prosthetist/Orthotist (CPO) (45.5% CO; 49.6% CP) (Figure 2).

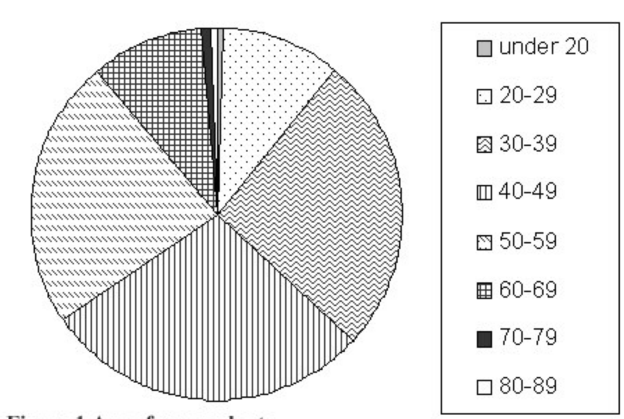


Figure 1 Age of respondents.

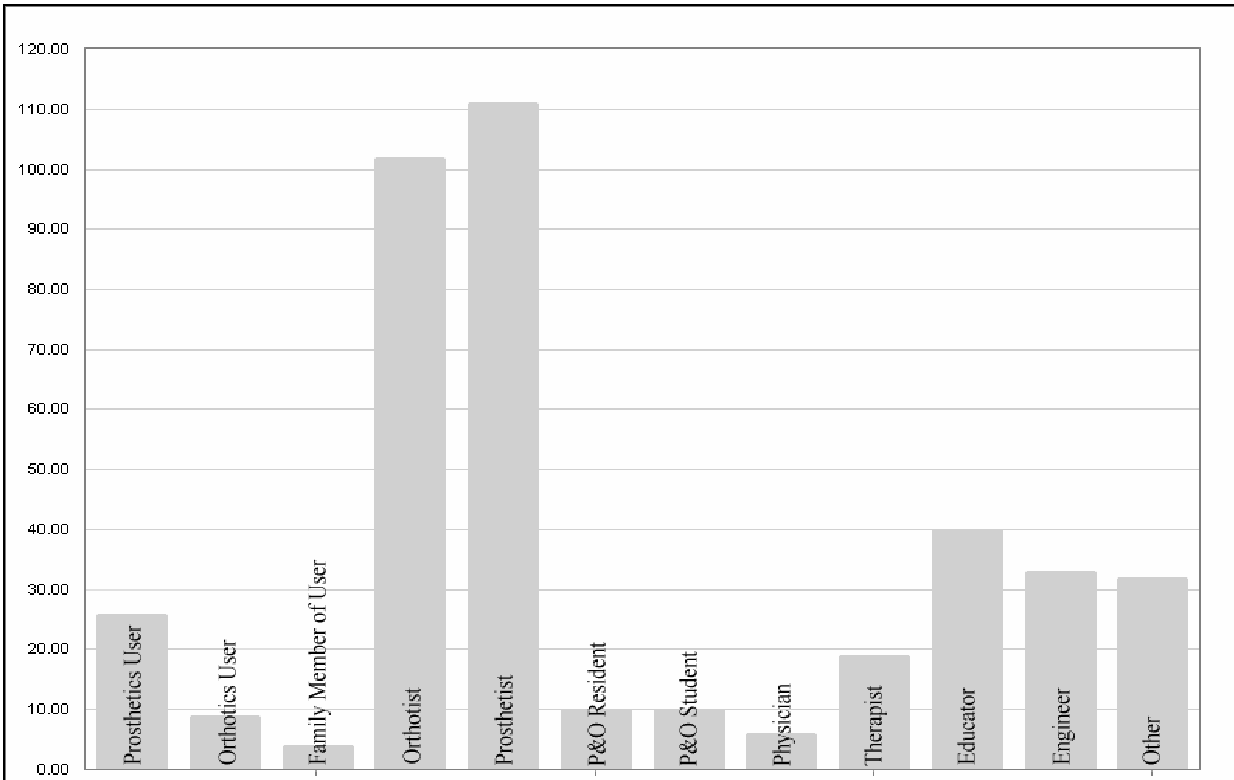


Figure 2 Association with P&O.

When asked if they conduct research in the field of prosthetics and orthotics, 54% of respondents indicated that they do not conduct research. Of the respondents that indicated that they did participate in research, 44% (98) specified a percentage of time devoted to research. It appears that when involved in research, the majority of Prosthetists/Orthotists spend less than 20% of their time on research (Figure 3). Those respondents spending more than 80% of their time on research tended to identify themselves as Engineers.

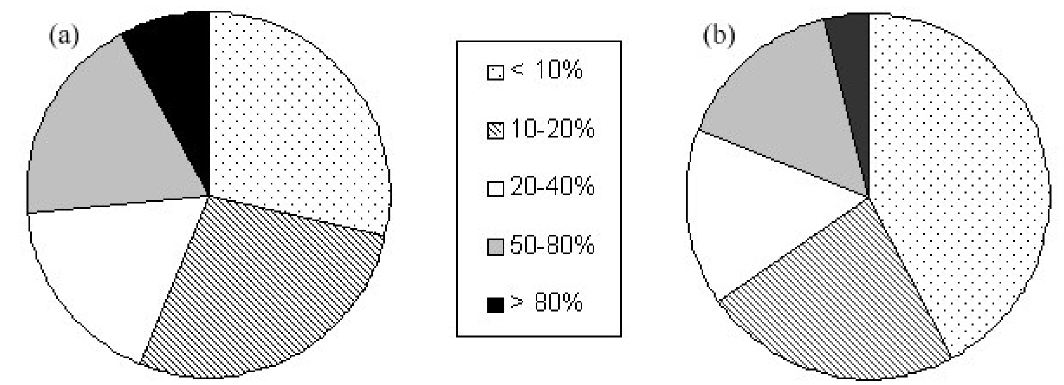


Figure 3 Percentage research time of (a) all respondents and (b) CO, CP and CPOs.

When asked what journals they read on a regular basis to stay abreast of the latest prosthetics- and orthotics-related research, 66-68% of respondents indicated they read O&P Edge, Journal of Prosthetics and Orthotics, and O&P Business News (Figure 4). In answer to "Other", 33 additional reading sources were cited, most only once. "Other" reading sources cited more than once included: O&P Almanac (6), InMotion (4), Challenge (DS/USA) (2), Alignment - Canadian magazine (2), Advance - for Directors in Rehab (2), Journal of Bone and Joint Surgery (2), Journal of Pediatric Orthopedics (2), Developmental Medicine and Child Neurology (2), Clinical Biomechanics (2), and the internet (2). (Number in parentheses indicates number of responses.)

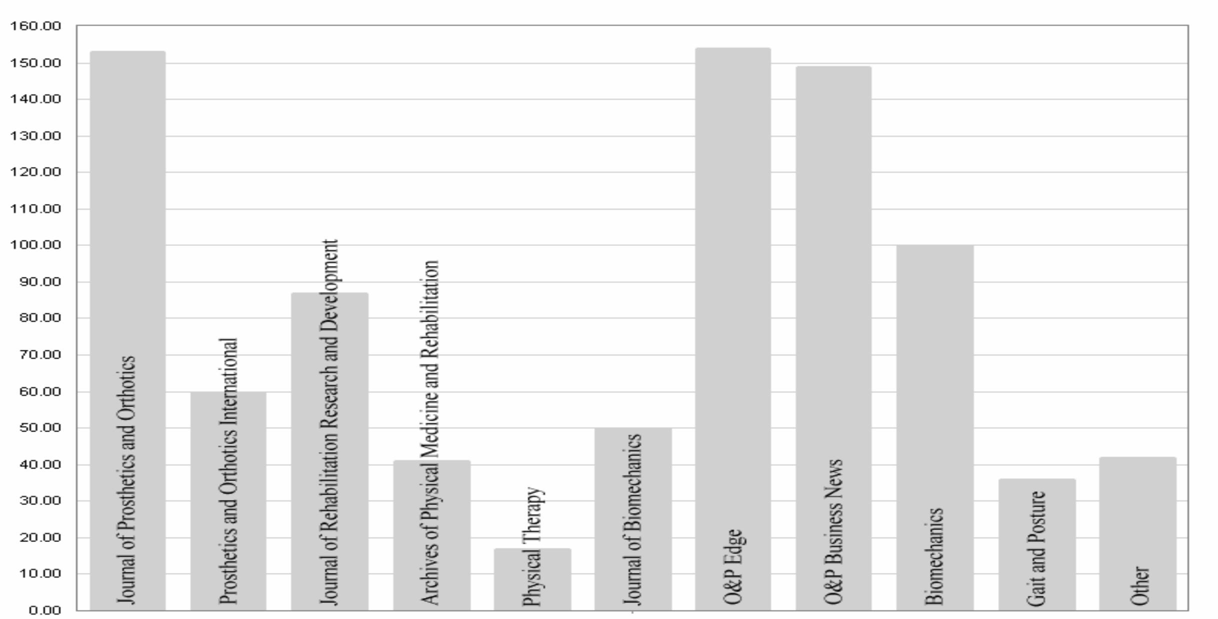


Figure 4 Journals read by respondents.

Almost all respondents (98.2%) felt that research was important. When asked if they feel that a sufficient amount of research is being conducted in the field of prosthetics and orthotics and if the emphasis of current prosthetic and orthotic research is appropriate, 79.9% of respondents indicated that the amount of research was lacking (Figure 5a) and 61.2% indicated that the current research emphasis was lacking (Figure 5b).

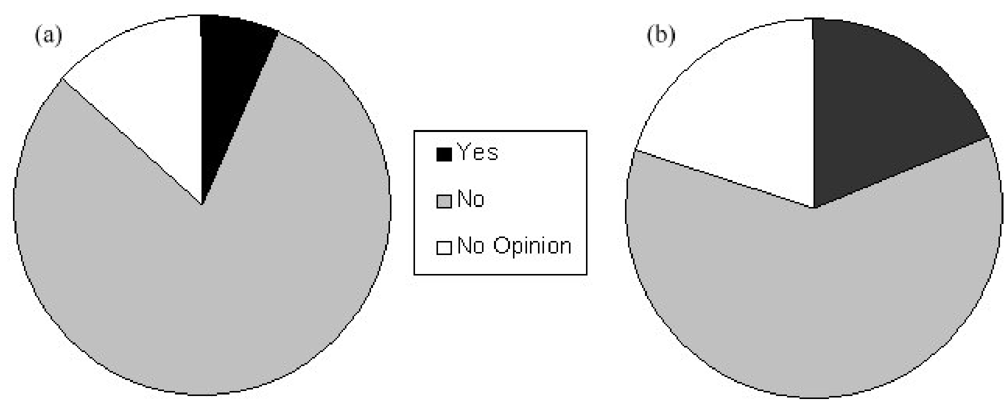


Figure 5 Amount (a) and emphasis (b) of research by percentage of respondents.

80% of respondents identified specific areas that they believed were lacking sufficient research: outcomes/evidence/efficacy (56), orthotics research (16), funding (15), statistically significant studies with strong design (12), objectivity/independence of research (7), time to do research (6), quantity of research being conducted (6), quality of research being conducted (5), and involvement of Prosthetists and Orthotists in research (5). (Number in parentheses indicates number of responses.)

61% of respondents identified areas of research that they believed were currently lacking emphasis: outcomes/evidence based practice (23), funding (11), study design and size (11), orthotics research (8), contribution to research by prosthetists and orthotists (5), time to conduct research (4), and cost effective P&O solutions (4).

When asked if they had identified areas where further research is needed, but lacked the ability and resources to carry out the work, 78.1% of respondents responded "yes" (Figure 6a). 74.6% felt that insufficient research funding prevents more research from being conducted (Figure 6b).

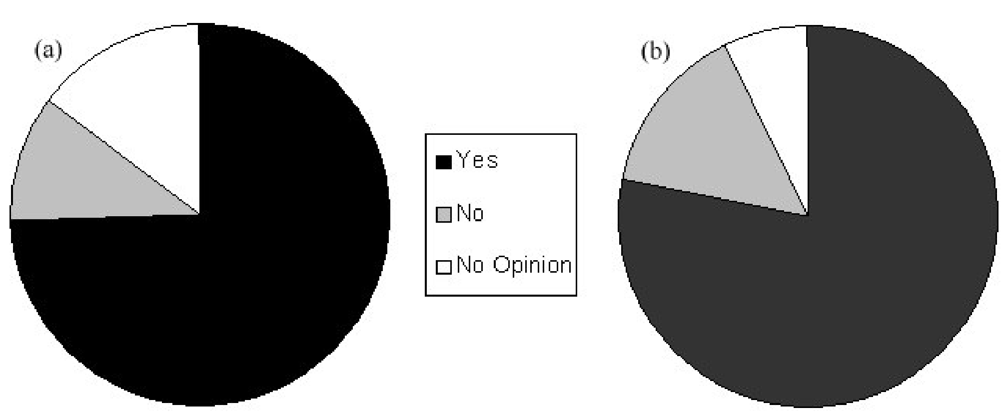


Figure 6 Insufficient funding for P&O research (a) and lack resources/ability to do research (b).

Respondents were also asked to rank in order of importance the top five problem areas of prosthetics and orthotics where they believe research should be directed (ranked from 1 to 5 with 1 being the most important). Results for prosthetics are shown in Figure 7 and orthotics in Figure 8.

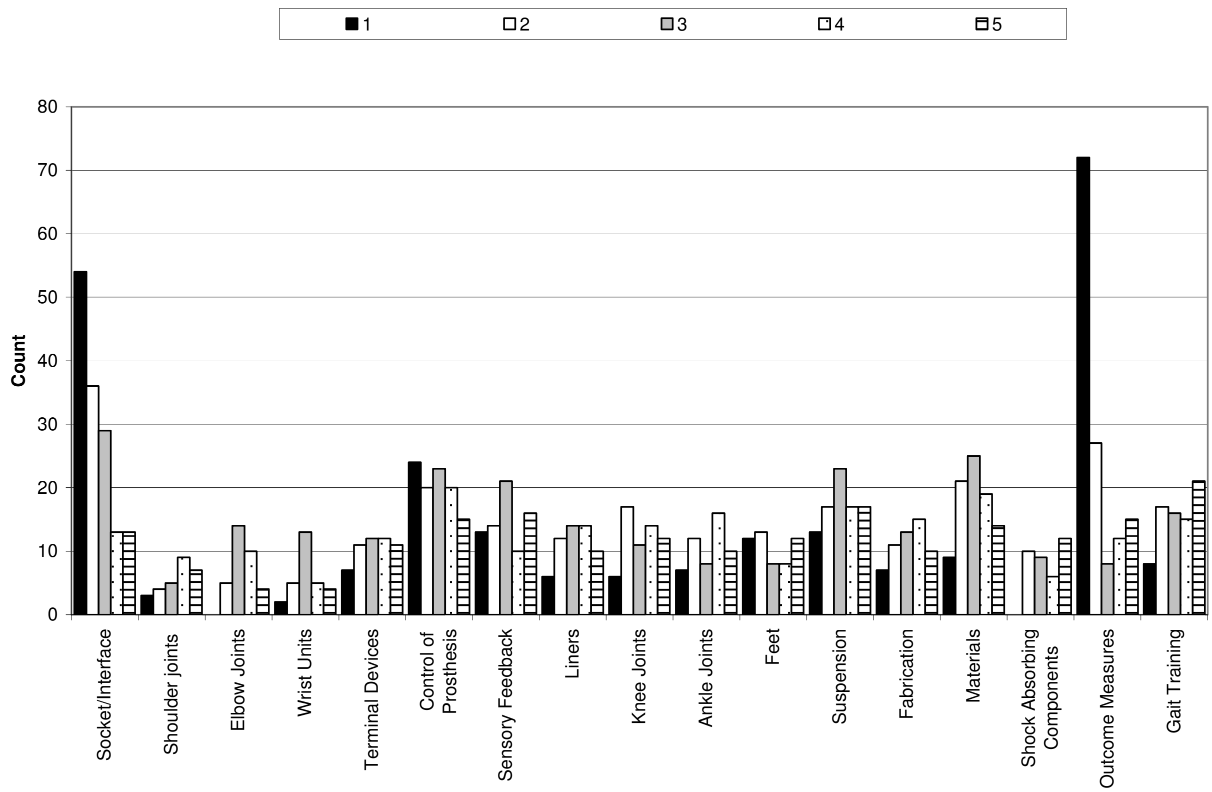


Figure 7 Ranking of prosthetic topics.

Overall, the topics ranked number one by most respondents for prosthetics were outcome measures and socket/interface. The topic ranked most often at each level was:

1. Outcome Measures
2. Socket/Interface
3. Socket/Interface
4. Control of Prosthesis
5. Suspension

"Other" topics included clinical decision-making (5), alignment (5), education (4), and practitioner accuracy/precision (4). (Number in parentheses indicates number of responses.)

Overall, the topic ranked number one by most respondents for orthotics was outcome measures. The topic ranked most often at each level was:

1. Outcome Measures
2. AFOs
3. Fabrication
4. Materials
5. Materials

"Other" topics included prescription principles (6), comfort (4) and alignment (4). Materials was rated most often as 4 and 5, hence the repetition.

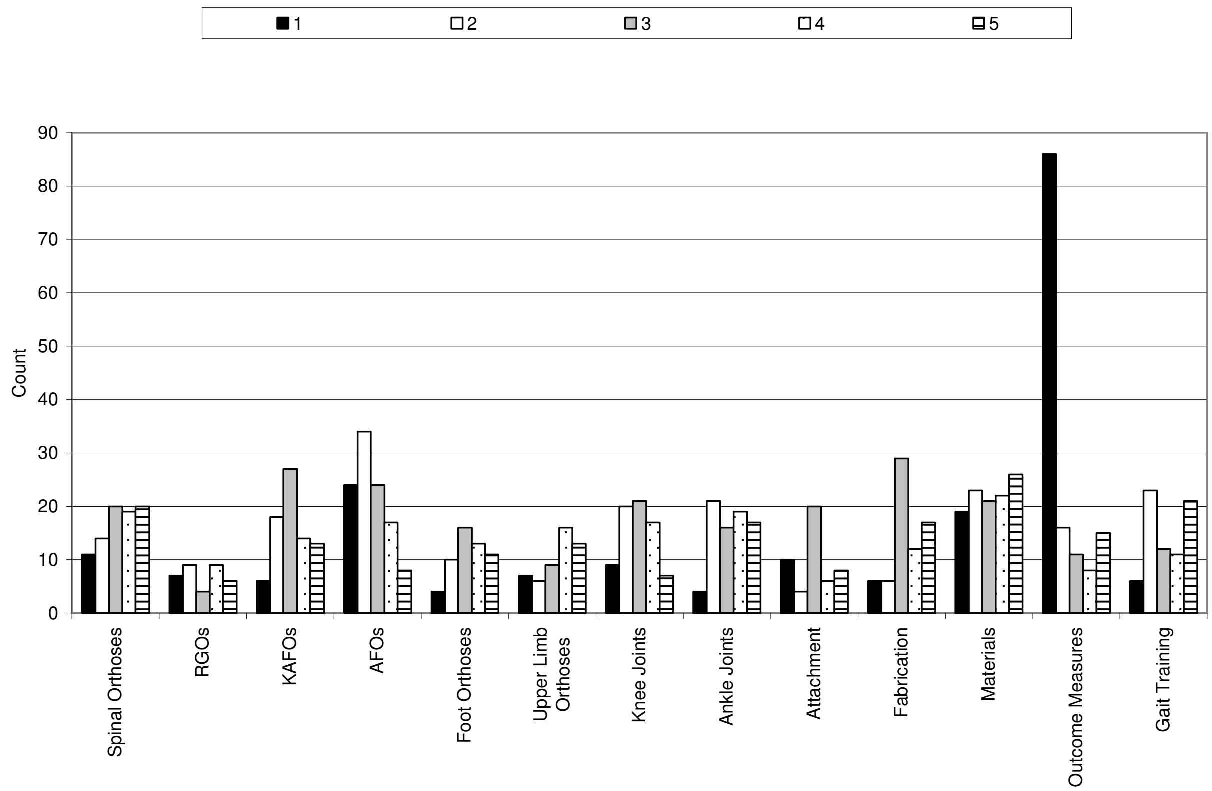


Figure 8 Ranking of orthotic topics.

Respondents were asked the open ended question, "What do you consider to be the 3 most important questions to be addressed by prosthetics and orthotics research in the next five to ten years?" Summarized below are the most common topics that were mentioned in answer to this question:

- Outcome Measures – efficacy of P&O service, Evidence-Based Practice
- Cost-benefit analysis of P&O services/technologies
- Develop low cost alternatives
- Development of materials for P&O applications
- Develop light weight components
- Develop fabrication processes: ease and quality
- Develop prescription principles for better decision making, e.g. component and device choice
- Long term and real-world functional analyses, application of motion analysis to P&O
- Interface/socket design and comfort
- Development of control options for prostheses
- Education and qualifications: standards, continuity, quality

Summary of Forum Discussion

The forum was opened online at http://www.medschool.northwestern.edu/depts/repoc/ on November 21, 2005. The forum was advertised in the same manner as the survey. Forum structure is outlined in Appendix D.

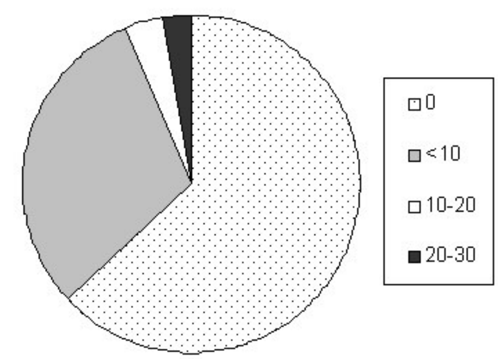
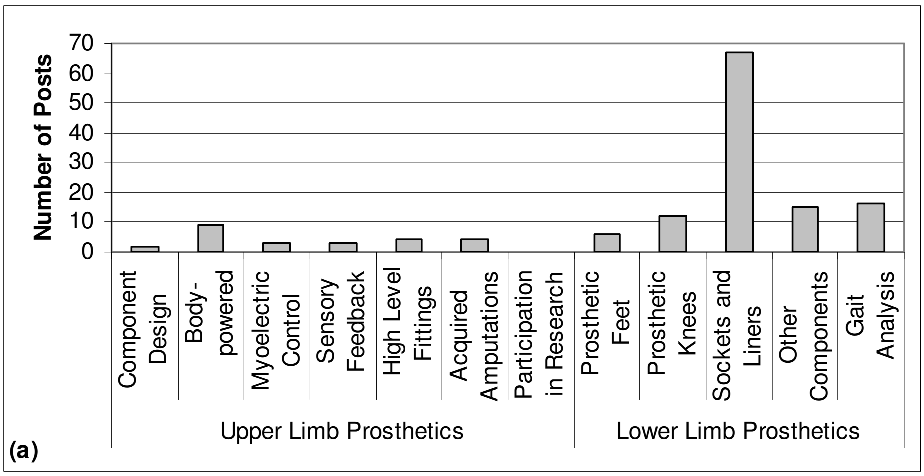
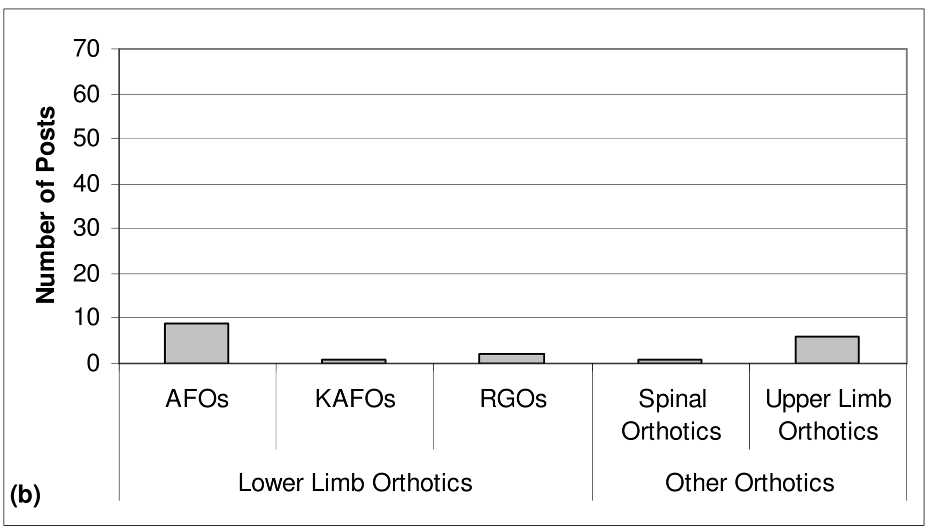


Figure 9 Number of posts per registered user.

As of February 16, 2006, there were 108 registered members. Although the forum remained open for a few months beyond the date of the State-of-the-Science Meeting, there was little activity after mid-January. The majority of registered users did not post any comments (Figure 9). Of the remaining users who posted comments, most posted less than ten. The topics that received the most posts were "Lower-limb Prosthetics: Sockets and Liners" and "Research and Development Wish-list: 'Lack of Science in P&O'". Overall, there was greater discussion with regards to prosthetic topics than orthotic topics. Figures 10a-c (below and on next page) summarize the number of posts per discussion topic.





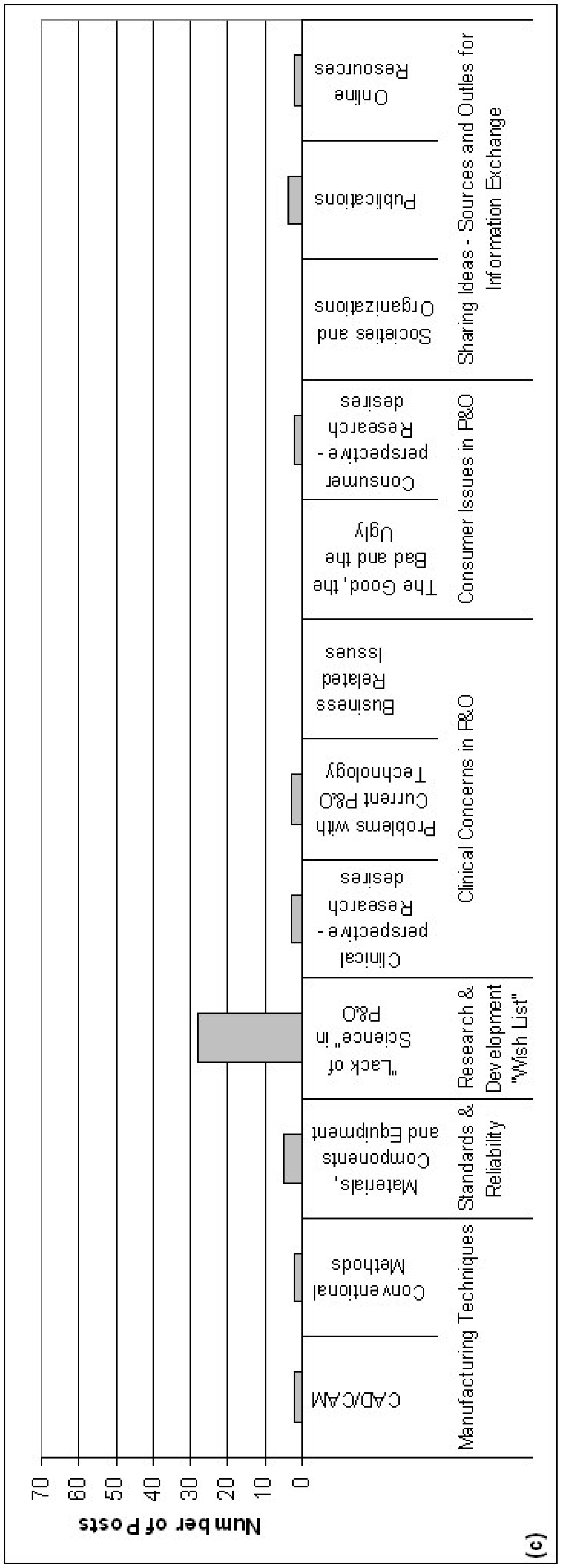


Figure 10 (and previous page) Number of posts per topic:
(a) prosthetics, (b) orthotics, and (c) "other".

From the discussion in the forum it was possible to identify many potential research questions. Overall, 70 individual issues were identified, but many were related to two primary topics: 17 directly from the topic "Research Desires" and 14 with regards to "Sockets and Liners". Within the topic "Research Desires" it was suggested that we need to determine function and efficacy of different technologies, improve current technologies and develop new ones. With regards to the topic "Upper-limb Prostheses" most of the suggestions were directed at improving function through reductions in weight and weight distribution, and improving control processes and sensory feedback. With regards to the topic "Lower-limb Prostheses" most of the suggestions were directed at improving function particularly in real world conditions, developing better prescription principles, improving and better understanding alignment, establishing the cost-benefit of new technologies, and developing a better understanding of the socket-limb interface and its effects on tissue health. Finally, it was suggested that we need to determine the efficacy and function of orthoses; the role of CAD/CAM in P&O; and improve the selection criteria and determine the life span of materials and components used in P&O.

Table 1 summarizes the research-related issues that were mentioned on the forum:

Upper-limb Prostheses	Body Powered	• reduce friction • decrease weight, explore weight distribution • improve cosmesis • improve mechanical efficiency
	Myoelectric Prostheses	• improve quality, consistency, and reliability of signals through a full range of motion • transfer new control algorithms (fuzzy logic, neural networks) to commercially available products
	Sensory Feedback	• allow proprioceptive control without hindering movement • improve sensory feedback
	High Level Fittings	• reduce weight, explore weight distribution • develop telescoping components similar to adjustable tripod legs
Lower-limb Prostheses	Prosthetic Feet	• compare feet in real world situations • establish functional requirements to guide classification, evaluation and prescription • Can we establish a "benchmark" of desired mechanical qualities that when met would give us the "best" prosthetic foot? • combine the principles of 2 or more alignment methods
	Prosthetic Knees: Transfemoral	• determine the importance of alignment process • How is bench alignment determined for a given component? • Can we improve our alignment techniques?
	Prosthetic Knees: Microprocessor	• determine the importance of active dorsiflexion • consider performance in different conditions (inclines, turning) not just level walking • What are the attitudes of prosthetic users about these knees? • Does the increased complexity and cost significantly improve function?

Table 1 (continued)

	Sockets and Liners	• develop transtibial socket designs appropriate specifically for older or younger amputee populations • develop adjustable sockets • better understanding of the socket-limb interface • explore provision of systems with adjustable cushiness at the socket-limb interface • examine the benefits of gel liners alone over the PTB socket with or without a Pelite liner • develop a reactionary interface that could alter the impact of forces experienced by the user • examine the causes of long term limb volume loss • examine whether denervation atrophy is the reason for excessive muscular atrophy in short residual limbs • examine whether a routine exercise program that includes isometric contraction might prevent disuse atrophy or even increase muscle mass • develop a better understanding of socket pressures • develop understanding of how vacuum and traction on tissues affects interstitial fluid volume • examine if applying an elevated vacuum to the residual limb mimics natural physiologic mechanisms • explore effects of pins and/or suction on tissue pressures and atrophy • determine minimal vacuum level needed to maintain volume • determine effect and amount of liner preload required for optimal outcome
	Education	• Is the "prosthetics" education we are providing students in our profession what is needed to understand the issues presented by new technologies?
	Prosthetic Ankles	• design a foot or ankle that increases stability while walking on uneven terrains
	Shock Absorbing Components	• Do prosthetists routinely fit these devices? • What are the perceived benefits for the user?
	Suspension	• develop more durable suspension systems for transtibial prostheses • determine whether a certain amount of play in suspension is acceptable • determine how much play might be acceptable
	Gait Analysis	• determine accuracy of hip kinetic data for transfemoral amputees • find a better way to measure hip moments so that it accounts for any migration of the femur inside the socket • examine contribution of gait training and physical therapy to amputee function with a prosthesis • explore effects of orthoses on fall prevention and prevention of foot deformities
Orthotics	AFOs	• develop consensus on a modern biomechanical design of the UCBL, along with prescription criteria and outcomes • use research to support or refute the many "old rules" that exist in orthotics

Table 1 (continued)

CAD/CAM	• incorporate fuzzy logic into the next generation of CAD software so that successful socket design outcomes can be learned by the system to improve upon future socket designs and outcomes • establish whether CAD/CAM produces better sockets, faster ones, or both
Materials, Components and Equipment	• improve ability to select the appropriate materials for fabrication of orthoses • determine the true life span of today's endoskeletal components that meet ISO standards of manufacture
Research Desires	• explore the value of active dorsiflexion in transfemoral amputees • incorporate microprocessor technology into an ankle that will dorsiflex after toe-off • develop improved versions of the Hydracadence, perhaps 4-bar versions. • determine the relationship between 4-bar dynamics and type of residuum (length and strength) • determine whether there are benefits of stance knee flexion in prostheses • determine who are candidates for stance knee flexion • determine what extra training is necessary to use stance flexion knee joints • develop variably flexible feet or ankles to accommodate for changes in terrain, or loads a person carries • improve durability of suspension sleeves • develop a light weight dynamic response foot with good plantar flexion for transfemoral amputees • determine the advantages and disadvantages of pin suspension • develop a system that improves on the ICRC system and is available in an unrestricted way for the US as well as the rest of the world • develop a non-contact laser digitizer that scans the inside of a cast or the outside of a model that is relatively low cost, table top in size and can be used with current software • investigate and explain the mechanism that causes limb volume stability under elevated vacuum conditions • unbiased assessments of component performance that are functionally oriented • develop a lower extremity orthosis that absorbs shock at initial contact, then conforms to the surface, and once single stance is achieved turns into a rigid lever arm for third rocker • develop an electromagnet controlled socket with thinly mounted metal strips on the outside of a gel interface, allowing for complete limb encapsulation circumferentially and eliminating socket rotation

SESSION 1: LOWER-LIMB PROSTHETICS I
Foot/Ankle Mechanisms

Research Perspective: Andrew H. Hansen, Ph.D.

Dr. Hansen began his presentation by listing seven general areas within the literature that summarize the various approaches that have been used to investigate prosthetic foot/ankle mechanisms: (1) movement analyses (usually gait on level ground), (2) subjective data on prosthetic foot preferences, (3) mechanical testing of ankle-foot components, (4) modeling considerations for prosthetic foot/ankle mechanisms, (5) new prosthetic foot designs, (6) reviews of prosthetic foot papers, and (7) general information on current components. The focus of Dr. Hansen's talk was on movement analyses of persons using the devices (item 1 above) and mechanical testing of the ankle-foot systems (item 3 above). The advantages and disadvantages of both approaches were outlined and the results of both approaches were summarized.

The advantage of movement analysis studies is that they provide direct measures of the components in use, and therefore represent the most clinically-relevant approach. The disadvantage of movement analysis studies is that the measurements indicate the overall behavior of the component and the user together, and it is difficult to separate the user's actions from those of the component.

The advantage of mechanical testing is that it eliminates the human from the system and gives a better indication of the true mechanical differences between components. The disadvantage of mechanical testing is that it can be difficult to transfer the results from these tests into clinically useful information.

In general, movement analyses have shown few consistent differences in user performance when using different types of prosthetic feet. However, mechanical tests have demonstrated vast differences in mechanical properties of prosthetic feet. The reason for these differences is not perfectly clear, although alignment of the devices may offer some explanation of these findings. In mechanical testing, all devices are connected with their attachment surfaces in the same orientation as the other components being tested. The same alignment is used in mechanical testing to allow more stringent comparisons between the mechanical characteristics of the different feet. However, when prosthetic feet are investigated in movement analysis studies they are usually individually aligned (and likely differently aligned) to help give the best performance for the user. This alignment step is necessary to reflect what happens in practice, although it may actually serve to minimize differences in gait that may otherwise be detected based on the different mechanical properties of the devices.

Research on prosthetic foot/ankle mechanisms has been largely exploratory thus far (e.g., have several prosthesis users walk with various devices and measure their gait, obtain their opinions of each component, etc.). Findings that occur simultaneously are sometimes linked with one another using causal relationships, and these relationships may be used to formulate additional hypotheses for further investigation. However, these hypotheses are rarely explored through follow-up research. An example was given regarding sound limb loading results and various hypotheses that have resulted from this rather consistent finding, but that have never been followed-up.

The idea of using experimental prosthetic feet that can be systematically altered to investigate a particular mechanical property was proposed. These feet could be used in movement analysis studies in order to give the most clinically-relevant results. While this approach may have a reduced clinical impact in the short term, it may give a better core knowledge and understanding of prosthetic foot properties and their effects on gait, which will hopefully be transferred to commercially available prosthetic foot/ankle mechanisms. A better core knowledge may be more easily transferred to prosthetic foot components that become available in the future, as current devices quickly become obsolete.

In closing, Dr. Hansen called for a better "marriage" of mechanical testing and clinical studies of prosthetic foot/ankle mechanisms and suggested the research triangle shown in Figure 1.1.

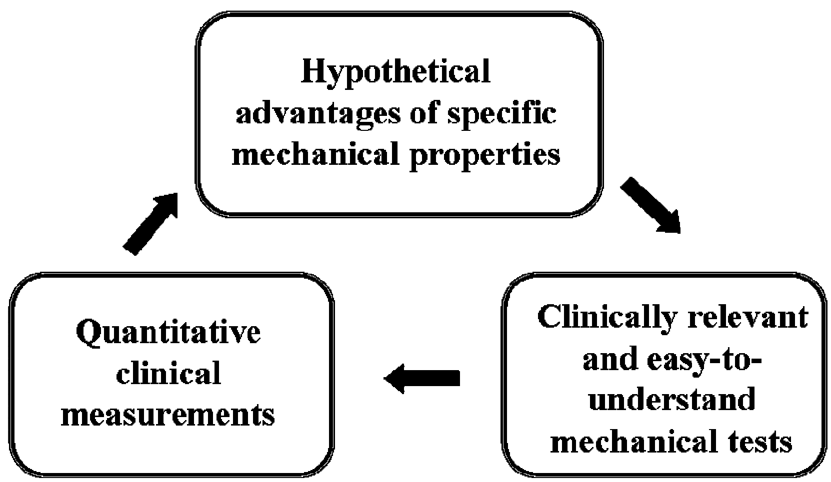


Figure 1.1 Research triangle proposed by Dr. Hansen for investigating prosthetic foot/ankle mechanisms. Hypothetical advantages of specific mechanical properties can first be explored using clinically-relevant and easy-to-understand mechanical tests. These mechanical tests will help to identify particular prosthetic feet that can be used to study the particular property of interest and thereby reduce the number of independent variables. These feet can then be used in quantitative clinical measurements of gait and assessment of the subjective preference of users. The results of clinical measures can be used to support or refute the hypothetical advantages of specific mechanical properties and/or be used to create new hypotheses.

Clinical Perspective: Donald G. Shurr, CPO, PT, MA

The presentation given by Mr. Donald Shurr addressed two main topics: (1) Unresolved Clinical Issues, and (2) Future Research Directions.

Mr. Shurr began his talk by urging everyone to read the findings of the American Academy of Orthotists and Prosthetists (AAOP) State-of-the-Science Conference concerning "Outcomes in Lower Limb Prosthetics", which is available in the published proceedings. He pointed out that of 340 published studies on the topic of outcome measures in lower-limb prosthetics, only 28 met the inclusion criteria. Mr. Shurr also quoted Liz Condie, who wrote: "…*generic, nonamputee specific measures of function and quality of life are inappropriate for lower limb amputees*." [1]

Mr. Shurr raised questions regarding residual limb liners, with or without pins, and socket designs. Specific questions asked were, "Do they [the liners or socket designs] alter the gait or the action(s) of the foot/ankle?" or "Does the foot/ankle complex affect the interface between the liner and the skin?"

Mr. Shurr also posed the question, "Would the addition of an articulated ankle in concert with an energy storing and return foot (ESAR) provide a more functional and efficient gait?" Also, Mr. Shurr asked, "Would the addition of an appropriate roll-over shape allow more controlled loading during stance phase?"

The possibility of creating clinical gait observation systems that could be taught to physical therapists, prosthetists, and orthotists was proposed. Such a system would hopefully bridge the gaps that exist between researchers and clinicians when describing amputee gait, and could potentially be jointly linked electronically so that both parties could observe and describe the same person's gait simultaneously.

Mr. Shurr stated that, "We now have little hands but few little feet!", speaking to the importance of developing more pediatric prosthetic foot/ankle components. Along with this, Mr. Shurr asked "Are there designs that will allow little ones to develop and walk more normally?" and "Are there developmental issues and/or milestones that may be enhanced by more anatomic and kinesiological foot designs?"

In closing, Mr. Shurr recommended that the following areas be considered for future research directions: (1) Develop amputee-specific outcomes studies, (2) Examine the interactions between liners and foot/ankle systems and between sockets and foot/ankle systems, (3) Address the need for an articulated prosthetic ankle, (4) Develop a clinical gait system for use by the amputee care team, and (5) Develop more, and better designed, pediatric feet.

Discussion

Many of the concerns and issues raised by Dr. Hansen and Mr. Shurr were echoed by the meeting attendees. Some additional discussion arose as to the best method of studying prosthetic foot components. On one side of the discussion, it was noted that testing commercially available feet is most useful in the short term for clinicians. The data that results from these types of tests can possibly be implemented immediately into clinical practice. On the other side of the discussion, it was noted that careful clinical trials take a long time to perform. Time is needed to find funding for a project, to collect the data for the project, to process the data, and then to publish the data. By the time all of these steps have been accomplished, the components that were tested may no longer be commercially available. A problem with using commercially available prosthetic feet in research studies is that there are many mechanical differences between them and it is difficult or even impossible to distinguish which properties are affecting the gait characteristics of the users. The prosthetic foot market tends to be unpredictable and rapidly changing, with many new components entering the market every year and many being abandoned. A majority of the attendees agreed that, at this time, we need well-controlled prosthetic foot studies that systematically vary one particular mechanical parameter at a time. These types of tests can give a better core knowledge of mechanical properties of prosthetic foot/ankle systems and their specific effects on the gait of their users. Additionally, prosthetic feet may be categorized by their mechanical properties, e.g., using the roll-over shape, and these categories may be useful for clinical fitting and billing/coding.

Other topics of discussion included the realization that we are in an exploratory phase of research and we must prioritize such research in a way that gives us incremental progress. A plea was made for more studies of components in the "real world", meaning studies conducted outside of a research laboratory and ones that incorporate a prosthesis user's everyday activities. Additionally, it was stated that better models are needed of the overall 'system' that take into account user function/capabilities and their interaction with the components. The panel agreed that improved communication and collaboration is needed between clinicians and researchers to make researchers' work more clinically-relevant and to make clinicians' work more scientifically (i.e., evidence) based.

Other suggested topics included:
(1) Improvements in patient education about their prosthesis socket fit and alignment (i.e., what should prosthesis users expect as an outcome?).
(2) Identification of appropriate outcome measures with consideration for patient capabilities.
(3) Development and utilization of consistent subjective outcome measures—patient feedback and perception.
(4) The need for the development of prosthetic feet that return more energy and provide "push-off".

Lastly, the attendees agreed that the main objective of research should be to facilitate good outcomes for prosthesis and orthosis users. In particular, we should continue to ask ourselves, "Are prosthesis and orthosis users able to accomplish what they desire on a daily basis?"

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Section Summary provided by Andrew Hansen, Ph.D.

SESSION 2: UPPER-LIMB PROSTHETICS I
Electric-Powered Prostheses

Research Perspective: Richard Weir, Ph.D.

Dr. Weir provided an overview of current research on electric-powered upper-limb prostheses. The problem of developing functional and effective electric-powered prostheses is multifaceted, involving physical and control interfaces, deciphering of the user's intent, powered actuators, and sensory feedback. The physical interface suspends and stabilizes the prosthesis on the user's body. Newer alternatives to prosthesis suspension are osseointegration and the Subfascical Implant Supported Attachment (SISA).

Osseointegration of limb prostheses provides for direct skeletal attachment of the prosthesis to the transected bone at the amputation site. Under development for over fifteen years, osseointegrated limb prostheses remain experimental though promising.

The SISA implant is an inverted T-shaped structure implanted in the cut end of the humerus at the trans-humeral amputation level to create artificial condyles. The goal is similar to that of the Marquardt angulation osteotomy. In the Marquardt procedure, a distal portion of the humerus is cut and fused to the remaining end of the humerus at an angle. Proper design of the humeral socket then captures the angled bone, which provides supplemental suspension and transfer of physiological rotation of the humerus to controlled internal and external rotation of the prosthesis. The Marquardt procedure is best applied to long transhumeral amputation levels. The SISA implant provides the same function but can be applied effectively to shorter transhumeral amputations.

Silicone sleeve suspension is not new and has been used to great effect for aesthetic and body-powered prostheses. With improvements in materials and fabrication, sleeve suspension is gaining popularity in the fitting of electric-powered systems. Even myoelectrically-controlled prostheses can be fit using new electrode designs that attach to the sleeve.

Research into improved control interfaces is exploring the creation of new control sites and access to control signals from within the body. One approach to the surgical creation of control sites is targeted muscle reinnervation. A muscle, for example the pectoralis muscle of a person with a shoulder disarticulation, is surgically divided into sections of muscle. Each section is denervated and an arm nerve, transected by the amputation, is sutured to a section of muscle. Over the course of months, the sutured nerve reinnervates the piece of muscle, causing the muscle to contract in response to signals generated through the nerve. In the case of the pectoralis, it is possible to create four independent and separate muscle signal sources using the remaining lengths of the four nerves that had passed into the arm before the amputation.

Implantable electrodes and electrode arrays that access signals from within the body are under development. Implanted Myoelectric Sensors (IMES) placed within a muscle would detect that muscle's individual myoelectric signal. In the case of a transradial amputation, where it is generally possible to get only two good signal sources at the skin surface, implanted electrodes would make it possible to detect many more signal sources. Electrode arrays being used experimentally for peripheral nerve interfaces and for brain-machine interfaces could eliminate the need for sections of muscle by accessing nerve signals directly. Such access could further increase the number of potential control signals.

With more signal sources comes the need for better processing of those signals to achieve reliable multi-functional control. Principal Component Analysis (PCA) and pattern recognition through neural networks are two possible approaches to processing more complex signals.

Considerable work is needed to develop higher performance mechanisms and actuators. The CyberHand project of the Dario Group and the Touch Bionics' hand are examples of multi-actuator hand mechanisms currently under development. A current initiative by the Defense Advanced Research Projects Agency (DARPA) of the U.S. Department of Defense has the goal of developing a twenty-two degree of freedom arm with neural interface within four years.

DC electric gearmotors are commonly used in powered prosthetic components. However, DC motors are stiff and do not produce movements that are very physiological. Series Elastic Actuators, which incorporate a spring in series with the motor, are compliant and considered biomimetic, meaning that they can produce human-like movement. However, making DC electric motors act biomimetically may not be enough and higher performance hands and arms may require actuators using significantly different technology. Actuators based on monopropellant fuel sources, pneumatic or hydraulic power, and electro-active polymer gels are being investigated for application to limb prostheses.

Today's electric-powered prostheses offer very little to the user by way of sensory feedback. The Otto Bock SensorHand Speed and the Motion Control Utah Arm use internal feedback to improve the performance and enhance the function of these devices; however, the user is not part of the feedback loop. Targeted reinnervation applied to patches of skin rather than muscle may provide sensation of touch, force, and temperature associated with the fingertips of a prosthetic hand. Proprioception, the perception of a limb's movement and position in space, may be essential for effective control of multi-joint arm prostheses.

Clinical Perspective: Troy Farnsworth, CP, FAAOP

Mr. Farnsworth provided a clinical perspective on electric-powered upper-limb prostheses, stating that the ultimate goal of applying upper-limb prostheses is to benefit the end user. To appreciate what needs to be done, it is helpful to consider where we are now, clinically. In terms of fitting methods, so-called “new” designs are often simply old designs that utilize new materials. CAD/CAM techniques, once full of promise, have yet to make any significant inroad in the application of upper-limb prostheses. Surgical intervention to improve prosthetic use or function is limited.

With respect to components, controllers can be adjusted in real time through tethered and wireless computer interfaces while accepting multiple inputs and providing multiple outputs. Yet, electric hands have only one degree of freedom forming a three-jaw chuck grasp, the gripping surfaces of hands are not conformable and fingers are not compliant. Non-hand grippers or work terminal devices (TD) provide other grasp patterns, hook-shaped "fingers", and water resistance. Electric-powered wrist rotation is slow and low torque. Multi-position wrists are mechanical and manually positioned. Electric elbows are primarily used to position the TD and rarely to perform dynamic work. Shoulder components are manually positioned, with only one model available that can be locked in flexion and extension.

The principal manufacturers of electric-powered components used in the U.S. are Animated Prosthetics, Hosmer, Liberating Technologies Inc., Motion Control, Otto Bock, RSL Steeper, and VASI.

Among routinely encountered clinical problems is the perception that the prostheses are heavy, which is influenced by fitting and surgical considerations and certainly by component weight. Patient education and training is often problematic. Component choices are limited in number and function. Most systems are not "user friendly" (i.e., not natural to use) and need to provide more reliable and repeatable performance. Funding can be difficult to achieve and limiting. And while prosthetic fitting gives users function, the question remains, are they getting value appropriate to the price?

Mr. Farnsworth mentioned the following research considerations: 1) Alternatives to traditional fitting protocols are needed to improve function. 2) The perceived prosthesis weight must be drastically reduced. 3) Systems need to be easier (more natural) for users in terms of fitting, control, function, and maintenance. 4) Documented outcomes are needed to justify choices and validate the effectiveness of devices.

Discussion

Much of the discussion among meeting attendees supported or expanded upon comments made within the research and clinical perspectives. Particular areas of comment included surgical intervention, device control, and outcome measures.

With regard to surgical intervention, the present day clinical situation was characterized as "we take what we get" with respect to the physical aspects of the client. However, limb shape, neuromas, bone spurs and other physical attributes that might negatively impact prosthetic fitting could be resolved surgically before proceeding to the fitting. It was generally thought that advancements in surgical procedures and techniques were not being adequately applied to persons with amputations and that appropriate surgical intervention could have a significant positive impact on the outcome of prosthetic fitting.

It was expressed that device control needed to be close to or 100% reliable to be acceptable for day-to-day use. Control commands should produce the desired function and no device should become active in the absence of a control command. Near perfect reliability was felt to be particularly problematic to achieve, but necessary for higher-level fittings that involve several controllable joints and multiple control sources. In addition to being reliable, the control also needs to be subconscious to reduce the mental loading experienced by users of multi-joint prostheses. Greater use of physiological proprioception as a pathway for sensory feedback could reduce the degree of conscious effort required when positioning a prosthetic arm. In general, it was believed that advances in sensory technology will be important to advancing upper-limb prosthetics

On outcome measures, discussants indicated that there is not enough information to identify factors that can facilitate success in a prosthetic fitting. A study of long term users was suggested as one method for identifying these factors. Further study might establish the relative importance of various factors and help concentrate efforts to improve the fitting process and its outcome. Comprehensive studies might also lead to defining function levels for users of upper-limb prostheses, similar to the function levels established for users of lower-limb prostheses.

Other areas of research that were identified included the development of flexible or adaptive materials for socket interfaces, the reduction of device weight, development of improved aesthetic coverings and more dynamic hands. It was also noted that primary education in upper-limb fittings is less than it was twenty years ago, but that devices are now more complicated and that knowledge and skill in fitting upper-limb prostheses will affect the outcome.

Section Summary provided by Craig Heckathorne, M.S.

SESSION 3: ORTHOTICS I
Lower-Limb

Research Perspective: Stefania Fatone, Ph.D., BPO(Hons)

Dr. Fatone began her presentation with an overview of the literature on lower-limb orthoses based on an Ovid Medline search of 470 citations (Figure 3.1) that demonstrated that the majority of the available literature has focused on Ankle Foot Orthoses (AFO) (compared to other orthoses such as Foot Orthoses (FO), Knee Ankle Foot Orthoses (KAFO), Hip Knee Ankle Foot Orthoses (HKAFO), etc.). Using Ovid Medline's search engine, further analysis of study design (with ranking based on the rigor of the study design[1]) indicated that most of these studies were clinical trials and case reports (Figure 3.2) with the majority of publications in the last two decades. It was also noted that although publications regarding FOs were mostly on adults, a much larger proportion of publications regarding AFOs and KAFO/HKAFOs were on children.

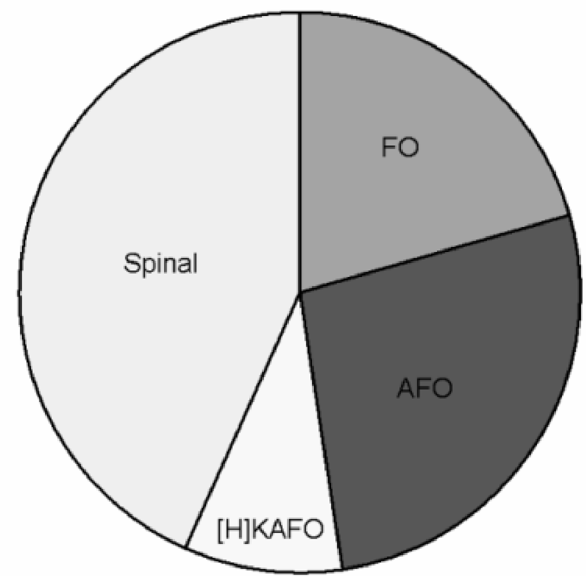

Figure 3.1 Distribution of lower limb orthotics articles based on Ovid Medline search of 470 citations.

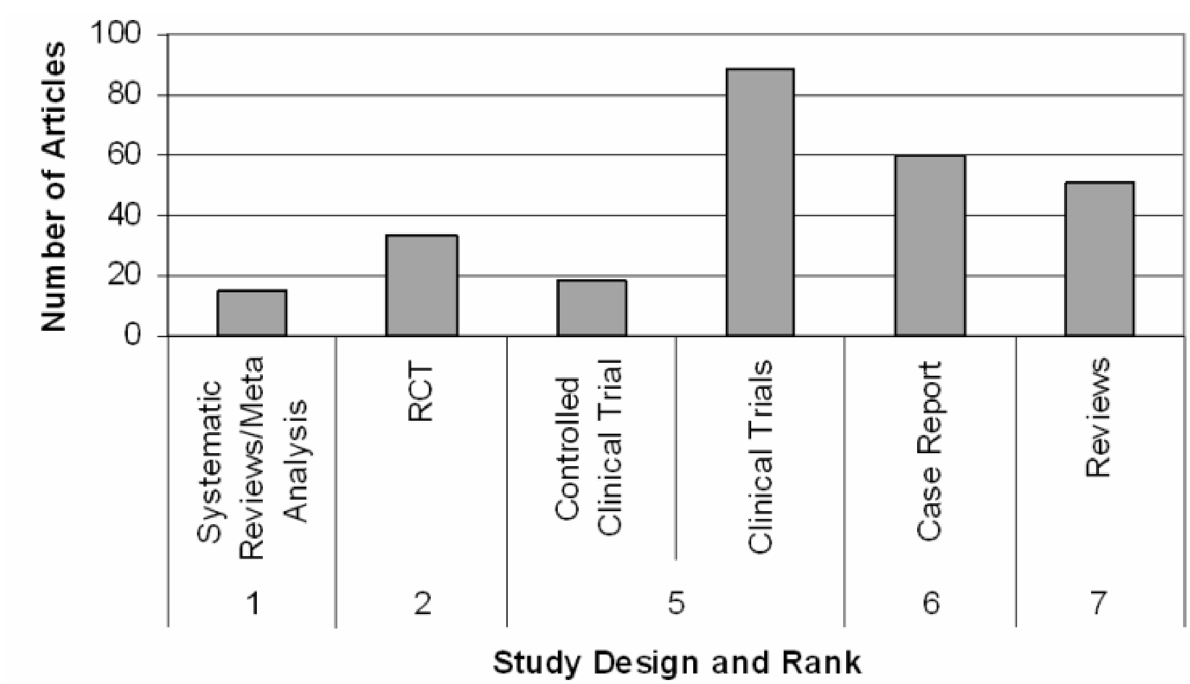

Figure 3.2 Distribution of lower limb orthotics articles based on study design.

Dr. Fatone then proceeded to give an overview of the literature pertaining to three categories of lower-limb orthoses: FOs, AFOs and [H]KAFOs (i.e., KAFOs and HKAFOs).

Foot Orthoses: Dr. Fatone commented that studies of FOs have been characterized by clinical heterogeneity, in particular due to the wide variety of pathologies that have been treated with FOs. For example, plantar fasciitis, heel pain, rheumatoid arthritis, juvenile idiopathic arthritis, knee osteoarthritis, patella femoral pain syndrome, runners, overuse injuries, and excessive pronation have all been studied in conjunction with FOs. Further variability in the literature appears to arise from the highly subject-specific responses that occur with use of FOs[2]. However, the need for research regarding FOs is increasing: as Americans above age 65 have become healthier and remain physically active, there is an increasing incidence of lower extremity and foot problems[3]. Dr. Fatone pointed out that epidemiologic studies provide strong support for the clinical advantages of FOs, yet explanations of foot orthotic mechanisms remain incomplete and sometimes contradictory[4]. The clinical efficacy, mechanical effects, and underlying mechanism of action of FOs has not been conclusively determined making it difficult for practitioners to agree on a reliable and valid clinical approach to their application and fabrication[5].

Ankle Foot Orthoses: Dr. Fatone acknowledged the "ISPO Report of a Consensus Conference on the Orthotic Management of Stroke Patients" as providing a recent overview of literature in the area of AFOs. Bowers[6] pointed out that there are more studies of the application of AFOs in the cerebral palsy population than stroke. In a ranking of studies regarding non-articulated AFOs and stroke, Bowers[6] reported that there were two randomized control trials, 16 cross-sectional and three case studies, while Hoy and Reinthal[7] reported that there was one systematic review, one randomized control trial, 11 case-control studies and 5 case studies regarding articulated AFOs and stroke. Both authors commented on a paucity of literature, especially at higher levels of evidence and that the orthoses investigated were often poorly described, making it difficult to generalize or interpret the clinical relevance of results. Hoy and Reinthal[7] also reported that the data regarding articulated AFOs and stroke was inconclusive due to heterogeneity in various aspects of study design. With regards to AFOs and cerebral palsy, many studies over the last 10-15 years have compared different kinds of AFOs using gait analysis (e.g., hinged AFO, solid AFO, posterior leaf spring, dynamic AFOs, supra-malleolar orthoses) with the main outcome measures including gait kinematics/kinetics, energy expenditure, analysis of sit-to-stand, ankle-foot alignment, balance, and stair negotiation. A single randomized control trial confirmed that Botulinum Toxin-A reduced spasticity and improved functional performance in standing and walking in children with CP, and that in association with casting, Botulinum Toxin-A provided more marked and enduring results than use of AFOs[8]. In general the literature would suggest that AFOs ameliorate the gait pattern in patients with spastic hemiplegia[9]; that children with spastic diplegia seem to prefer articulated AFOs[10]; that there is little indication of a carry-over in effect between periods when AFOs are worn and when they aren't[11]; that there is value in monitoring the moment arm of the AFO[12]; and that AFO alignment may be important to outcome[13].

[Hip] Knee Ankle Foot Orthoses: Dr. Fatone acknowledged the "AAOP State-of-the-Science Conference 7: [H]KAFOs for Ambulation" for providing a recent overview of literature in the area of [Hip] Knee Ankle Foot Orthoses. A review of 240 articles in RECAL and Medline indicated that the majority of publications regarding KAFOs and HKAFOs for ambulation involved patients with Spinal Cord Injury. Although Hip Guidance Orthoses (HGO) and Reciprocating Gait Orthoses (RGO) were originally designed for ambulation by children with paraplegia, the RGO in particular has been evaluated more often in adults with paraplegia. While a reasonable amount of literature has been written about [H]KAFOs, more so about HKAFOs than KAFOs, the level of evidence regarding [H]KAFOs for ambulation is generally low. There is some evidence from longitudinal studies and retrospective reviews that use of HKAFOs diminishes with time in both adults and children with paraplegia[14-16]. When orthoses are used, they are used mostly for therapeutic purposes[16-18]. However, regardless of orthotic device used walking speed is slow and energy cost high in people with paraplegia[19]. There is some suggestion that the HGO is more mechanically efficient than the RGO because of greater rigidity especially during single limb support[20,21]. Although reciprocal gait can be achieved with both the HGO and RGO and is probably more efficient in the HGO, patient preference has reportedly favored the RGO due to better cosmesis[20]. There is some evidence that treadmill training with an RGO may improve function during over ground walking with an RGO[22]. Overall, with regards to these orthoses, inter subject differences were much greater than inter orthosis differences[20].

Dr. Fatone concluded that there is a reasonable quantity of literature on lower-limb orthotics, but quality could be improved.

Clinical Perspective: Tom DiBello, CO

Mr. DiBello proposed that the goal of AFOs is to "improve stance phase mechanics for patients with spasticity or paresis of the lower-limbs" and identified two primary problems related to this goal:

1. Patients with spasticity and paresis secondary to cerebral palsy, stroke, spinal cord or traumatic brain injury have often had only marginal improvements in the functional kinematics of their gait after orthotic intervention.
2. The study of this large population of patients has not previously been allocated appropriate resources to determine the most effective ways to positively improve the orthotic outcome.

Figure 3.3 Tom Di Bello.

Mr. DiBello proposed some hypotheses and questions that he believed warranted research attention:

1. In the sagittal plane, appropriate motion control and effective alignment of the limb through the shoe and the shank to floor angle can positively impact limb kinematics in stance and swing.
    a. Can we define the appropriate amount of ankle motion control needed to achieve optimal kinematics at the end of second rocker?
    b. Does normalizing terminal stance and pre-swing mechanics improve swing phase mechanics?
2. The coronal and transverse plane alignment of the foot and ankle within the orthosis is critically important and optimal alignment will vary based upon clinical presentation.
    a. Does the position of the foot within the orthosis impact the function of the device?
    b. Do the molding position, mold modifications and trim-lines of the orthosis affect foot and ankle alignment?

Mr. DiBello also provided some background and rationale for these proposed hypotheses and questions. He noted that the motion of the swing leg has been found to be the manifestation of the interaction of all of the mechanical swing phase variables and that the overall dynamics of the swing leg are dependent upon the initial angular velocity of the thigh[23]. He also commented that there appears to be a relationship between the lateness of heel rise and the amount of knee flexion achieved in swing. Stiff-legged gait in patients with spastic paresis appears to be strongly related to quadriceps activity during pre-swing or initial swing[24]. Increasing hip flexor torque resulted in increased knee flexion in swing for each of five subjects but further work needs to be performed to assess the potential effects of altering torques during the stance period before toe-off[25]. Precision of tuning the AFO–footwear combination is vital as even small changes can make significant changes to the alignment of leg segments and the ground reaction forces at the knee and hip joints[26].

Discussion

The ensuing discussion raised a number of additional issues:

- It was acknowledged that orthoses provide greater potential to impact the quality of life for a large number of people than prostheses.
- We need to explore the ability of orthoses to prevent further complications and future surgeries.
- We need to establish treatment algorithms for orthotic management.
- We need to focus on particular populations of patients to obtain general guidelines for different types of orthoses.
- We need to explore the effect of orthosis use on joint problems in the contralateral limb.
- We need to investigate the importance of joint alignment in orthoses.
- There is a need for real-time evaluation of joint motion in the clinic.
- We need to improve the cosmetic appeal of orthoses, e.g., for children.
- We need more orthotic studies on able-bodied persons to answer fundamental questions—the advantages of this model include larger numbers of subjects, uniformity of population.
- We need to consider feasible, practical study designs for orthotics, e.g., within subject cross-over studies since randomized control trials are often not feasible.
- We need baseline studies of orthotic effects on users to document outcome potential.
- We need better justification for earlier fitting (and funding) of orthoses.

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Section Summary provided by Stefania Fatone, Ph.D.

SESSION 4: CAD/CAM

Research Perspective: Joshua Rolock, Ph.D.

History: Computer-Aided Design and Computer-Aided Manufacture (CAD/CAM) were originally developed as a way to increase the efficiency of product development in the industrial marketplace. The earliest implementations of industrial CAD/CAM were in the early 1960s, and it was at that time that the notion of applying similar techniques to the fabrication of prosthetic sockets was first suggested. However, at that time the personal computer did not exist, and the availability, the cost, and the power of computers were not suitable for development of prosthetics CAD/CAM.

With the introduction of mini-computers in the early 1970s some research laboratories around the world began to investigate and test the feasibility of applying CAD/CAM principles to prosthetics. At that time there was considerable debate over how to approach the problem of data input and socket design particularly since products for three-dimensional digitizing did not exist and since graphics computers were neither well developed nor affordably available.

Development and validation of prosthetics CAD/CAM occurred in the early 1980s at the time when micro-computers and personal computers were becoming available. These early implementations of CAD/CAM in prosthetics reflected the limitations in available technology but gave a clear indication that this approach could work. By the mid 1980s functional research prototypes were demonstrated and by the late 1980s commercial systems were available for sale to the clinical community.

Research: The basic research that was involved in the early development of prosthetics CAD/CAM was focused on finding a way to replicate the prosthetist's art using technology. Chief among this, was developing an on-screen approach to socket rectification that paralleled the well-established process of modifying plaster limb models using rasps or plaster build-ups.

An expanded avenue of research that began in the mid 1980s was directed at developing a fundamental understanding of socket interface mechanics and how the shape of a socket affects these mechanics. One of the goals of these investigations was to enable the CAD portion of socket CAD/CAM to become "smart" so that the computer could suggest an appropriate rectified socket shape; one that might not need any further tweaking by the prosthetist.

Development of "smart" prosthetics CAD/CAM will require development of basic knowledge and understanding of the mechanics of socket fitting as well as technological advancements in soft tissue characterization (digitizing) and computer software and hardware. There seems to be reluctance in the United States to fund this area of research and development, and as a result there has been no real progress on this front in the past decade. The reason for this reluctance is unclear.

Corporate Research & Development: At the time of commercialization of prosthetics CAD/CAM, continued research and development shifted from university laboratories to corporate research and development (R&D) departments. The unfortunate difficulty with this was that the companies producing prosthetics CAD/CAM equipment and software had little or no experience with equipment or software development and/or marketing. As a result, some systems were released that failed to meet promises or expectations; this phenomenon continues to plague the P&O profession.

In the early implementation years, a number of companies began offering CAD/CAM systems with the expectation of large profits from expensive equipment and software. The market quickly became flooded, particularly since adoption by the clinical community was slower than anticipated. The consumer's unease with product reliability and the slow adoption of the technology by the consumer resulted in company closures and further unease by the consumer as to the stability of the CAD/CAM marketplace.

Added to all this has been a misunderstanding or a misrepresentation of the importance of education and skills development to successful CAD/CAM implementation. Companies have falsely stated or implied that transformation from conventional skills to CAD/CAM usage can be quickly and seamlessly accomplished with a minimum of effort. Consequently, consumers that do not invest in skills development will often feel that CAD/CAM technology cannot match conventional practice. A clinician who has spent years honing the skills for conventional socket production must understand that a new set of tools (i.e., CAD/CAM) requires a new set of skills and that a commitment of time and effort is required to develop those skills.

Future Prospects: At this juncture the future of prosthetics CAD/CAM is somewhat uncertain. Among those clinical practitioners who have taken the time to learn to use these new tools, there is consensus that CAD/CAM is a useful and valuable approach to producing sockets.

There is a lack of stability among the companies that provide CAD/CAM equipment and software; this situation must be stabilized. First and foremost, the products marketed by those companies must meet the clinical needs of the consumer as well as meeting basic expectations of performance and reliability. Product testing is not the job of the consumer; it should occur prior to a product release.

Education and skills development are essential and companies have a responsibility to communicate this fact to the consumer. Prosthetics education programs need to provide courses to teach CAD/CAM skills to practitioners. Companies that provide training must be clear that a one or two day training course is not sufficient for adequate skills development.

Finally, research and development is still needed to advance the functionality of prosthetics CAD/CAM. "Smart" CAD/CAM systems have the potential to greatly increase the capability of the technology, but will require a commitment to research and an understanding that many years' work will be required for that development.

Clinical Perspective: Michael Brncick, MEd, CPO

CAD/CAM Overview: The production of prosthetic sockets using CAD/CAM directly parallels conventional manual techniques for socket production. The 5-step process can be compared between the conventional approach and the CAD/CAM approach as follows: (1) instead of taking a plaster impression of the limb, the limb is digitized; (2) instead of making a positive plaster model from the impression, the digitized shape is displayed on a graphics computer; (3) instead of physically modifying the plaster model by shaving off or adding plaster, software templates are applied to rectify or modify the digitized shape; (4) instead of fabricating a socket by forming a plastic shell over the plaster model, a positive model is carved using a computer-controlled machine tool and then the plastic shell is formed; and finally (5) fitting and assembly of the prosthesis, which is the same for either approach.

In the short history of prosthetics CAD/CAM, some things have stayed the same and some things have changed. The three basic steps have stayed the same: digitizing, software-based rectification, and manufacturing. The most significant changes are that some systems no longer exist or are no longer supported, and some companies no longer exist or no longer sell or service CAD/CAM. The economics of producing prostheses and orthoses have also changed, particularly within the third-party payer system. Under these pressures, prosthetics CAD/CAM provides a viable alternative to conventional prosthetics practice for producing high quality sockets quickly and economically.

Digitizing: A number of different tools are now available to directly digitize the three-dimensional shape of a limb. Among these are hand-held, laser-based optical scanners (e.g., Biosculptor Scorpion), tripod-mounted optical scanners (e.g., Orten), and application-specific laser scanners (e.g., Canfit Yeti). Unfortunately, these digitizing options still fall short of the ideal. Ideally, we want:

- Instant digitization
  - Difficult for patients to remain "still" during the process
- Portability
  - Take anywhere: office, hospital, homes
  - Set up with minimal effort or time
- Reliability
  - System needs to be robust
  - Calibration should be quick and effortless

Software: Except for graphic enhancements and easier user interfaces, the software has generally remained unchanged. Shape rectifications are accomplished by means of defining modification regions either freehand or by template, and then either 'bumping out' or 'bumping in' the selected regions while maintaining feathered borders. Just as with the earliest research and commercial software systems, the limb shapes can either be digitized or can be estimated using tape and caliper measurements. Some software applications have been expanded to include such applications as spinal orthotics and shoe lasts for pedorthics.

However, several software features are still missing, including:

- Need to accept all possible input
  - MRI, X-ray, CAT Scan, Ultra Sound
  - All other available digitizing equipment
- The ability to utilize for orthotic management

- AFO, KAFO, Hip Orthosis (HO), Wrist Hand Orthosis (WHO)
- Algorithm to change shape and maintain anatomical shape/volume characteristics

Manufacturing: Carving has undergone minimal advancements. The size of the carvers has increased. Some carvers have more controlled axes, enabling more detailed carving of non-cylindrical surfaces. What is really needed, however, is to avoid the carving stage entirely since this is time intensive, requires blanks to be purchased or manufactured, and requires "break out". Furthermore, as the software is expanded to include more orthotic applications, the manufacturing equipment needs to be expanded to enable those shapes to be produced.

State of CAD/CAM: A brief and informal survey of CAD/CAM companies has revealed some interesting information. Ohio Willow Wood, perhaps the most popular supplier of CAD/CAM equipment and software, reports that they have 470 licensed systems in 270 different facilities. About 20% of these facilities own their own carvers and 80% use central fabrication. Prosthetics applications represent 50-60% of the use with 40% transtibial, 60% transfemoral, and a "*small percentage of upper limb*" applications.

Alan Finneston of Biosculptor, one of the oldest CAD/CAM companies, believes that some of the current problems with prosthetics CAD/CAM have arisen because some companies have sold "*equipment* [that] *didn't do what it said it would do*", that "*practitioners made a financial commitment* [to CAD/CAM] *but did not make a commitment to the technology*", and that "[there is] *minimal exposure* [to CAD/CAM] *at the basic education level*."

Finally, although not a lot has changed with the technology, there are pressures on practitioners that will make this technology more and more appealing.

Discussion

There was division among the participants as to the value of CAD/CAM in prosthetics and orthotics. In particular, one individual, while admitting that he has never tried or used CAD/CAM, stated that he had never seen a good CAD/CAM fitting. He feels that CAD/CAM results in compromises that lower the overall quality compared to what can be obtained using conventional socket production methods. Another participant had the exact opposite experience, stating that he felt that many conventional fittings that he sees are sub-standard and that CAD/CAM "raises the bar" on the quality of those fittings, improving the overall results for all but the best prosthetists.

It was stated that there is nothing magic about current CAD/CAM technology—bad prosthetists will produce bad sockets with either approach, and likewise for good prosthetists. It was also stated that there needs to be a balance between CAD/CAM and hand production. Each approach will have applications to which they are best suited and the skilled practitioner will recognize which tool (manual or CAD/CAM) is best for each application.

A comment was made that CAD/CAM can provide a "diagnostic style socket" that will give clinicians a good start, and that CAD/CAM may provide greater consistency to socket design. It was felt that we really need to figure out what parameters make a socket more comfortable and move forward from there.

Section Summary provided by Joshua Rolock, Ph.D.

SESSION 5: LOWER-LIMB PROSTHETICS II
Sockets, Knees, Shock Absorbers

Research Perspective: Margrit Meier, Ph.D., CPO

Dr. Meier provided an overview of current research involving prosthetic sockets, knee joints and shock absorbing components. Due to the nature of the State-of-the-Science meeting, Dr. Meier decided to limit this review to the most recent publications, i.e., publications from the years 2000 until the beginning of the year 2006, to keep the focus on the most current developments. This review is not comprehensive or conclusive as only one resource–Ovid Medline–was used. Nevertheless, it provides a sufficient overview of the most recent research activities in the given domains.

Figure 5.1 Kevin Carroll and Margrit Meier.

<u>Prosthetic Sockets</u>

Successfully interfacing the residual limb with a prosthesis remains one of the biggest challenges in the field of prosthetics. It becomes evident that this challenge has not been met yet by analyzing literature regarding prosthesis use: Sixty to 74% of prosthesis users report problems with heat and excessive sweat as well as sores and skin irritations because of the prosthetic socket[1,2]. For most users these problems interfere with their performance of daily activities, negatively impacting their quality of life[3,4].

<u>Transtibial Sockets:</u> Several research groups are developing models of the residual limb that allow the analysis of prosthetic socket fit[5-8]. Such models will permit a better understanding of the interactions between the prosthetic socket and the residual limb. Due to the complexity of these interactions, the current models are recognized as having significant limitations.

Interface pressure and shear stresses have been assessed by either direct measurement techniques using specially developed sensors [9-11] or by Finite Element Analysis (FEA) models[12-15]. The limitation of these analyses lies in the model restrictions as well as in the complicated and complex measurement techniques. These analyses are only in their infancy and further development is required to gain a complete picture.

Little is known about how transtibial prosthetic sockets affect fit, suspension and comfort. Only two studies were identified that compared Patellar Tendon Bearing (PTB) and Total Surface Bearing (TSB) sockets[16,17]: Yiğiter, et al.[16] concluded that results with TSB sockets were as good or better than PTB sockets, concurring with Sewell, et al.'s review[17]. However, Sewell, et al.[17] mentioned that despite the fact that TSB sockets have gained a lot of acceptance, there is insufficient scientific evidence regarding precisely how these socket systems work and how the interface stresses compare with traditional PTB sockets. So far, only one of the newly developed vacuum-assisted socket suspension systems has been investigated, but the results indicate that it reduces pistoning and minimizes overall residual limb volume change during swing and stance phase[18-20]. An interesting attempt has been undertaken by Hanspal, et al.[21] to develop a comfort score for prosthetic socket fit in order to have a survey instrument for use in the clinic that would allow objective assessment of the fit of a prosthetic socket.

Transfemoral Sockets: The fit of transfemoral sockets and the effect on the underlying soft tissue has been studied even less than that of transtibial prosthetic sockets. Studies have shown that muscle activation and underlying changes in the vascular system within a transfemoral residual limb seem to contribute to increased pressure and shear stresses and poor tolerance of prosthesis use[22,23].

An alternative approach to transfemoral prosthetic socket design, the MAS socket, has been developed by Marlo Ortiz. The MAS sockets seem to provide greater hip range of motion (ROM) and very good suspension that reportedly result in increased comfort and superior cosmetic appearance (Figure 5.2). Although there is plenty of anecdotal evidence illustrating the benefits of the MAS socket, it must still be objectively tested and validated through well-designed research studies.

Figure 5.2 Amputee demonstrating ROM of MAS Socket. Full suspension seems to be present even through these large movements. Source: http://www.opga.com/MAS

Osseointegration as a way of suspending transfemoral prostheses has been investigated[24-26]. Although very successful in other areas of medical practice, this procedure is still in its infancy within the field of lower-limb prosthetics. Careful patient selection is of utmost importance. If successful, it provides unrestricted range of motion and the best comfort as no residual limb interface (i.e., a prosthetic socket) is required.

Prosthetic Knee Joints

Recent research on prosthetic knee joints has concentrated on microprocessor-controlled joints. A variety of microprocessor knees are now available that demonstrate different characteristics, thus expanding the possibilities for both users and prosthetists (Figure 5.3). However, results from energy expenditure studies of subjects walking with these knee joints are mixed, ranging from some improvements, to no improvements, to higher energy expenditure than passive knees[27-29]. Also, studies of performance during gait and user cognitive demand have produced mixed results[30-36]. In contrast, participants' satisfaction with microprocessor knee joints are generally favorable, suggesting that these components may make it easier to negotiate uneven terrain, ascend and descend stairs, and change speed[35,37].

Figure 5.3 Examples of microprocessor-controlled knee joints. Source: Various company websites.

Shock-absorbing Components

Knowledge about the effect of shock absorbing components on the gait of prosthesis users is lacking. Studies have shown that prosthetic feet incorporating shock absorption do not seem to have an effect on metabolic parameters[32,38]. However, there remain discrepancies between user perception and measured variables: Shock-absorbing pylons have been observed to produce changes in timing and magnitude of the vertical ground reaction force[39]. Reduction in oxygen consumption has been reported, particularly when participants walk at higher speeds[40,41]. But biomechanical gait variables reveal few differences between rigid pylons and pylons with shock-absorbing units. However, participants generally express a preference for shock-absorbing units. Results of studies analyzing prosthetic knee joints that provide shock absorption show that the magnitude and the timing of the stance knee flexion is asymmetrical when compared to the non-amputated side[32,42].

Clinical Perspective: Kevin Carroll, M.S., CP, FAAOP

Professionals are at the forefront of prosthetic care and thus encounter first-hand the challenges of rehabilitating prosthetic users. Mr. Carroll demonstrated that there is still a lot of room for improvement in prosthetic care and thus plenty of areas to be addressed by research.

Dynamic Response Socket: Residual limb volume fluctuation occurs not only during the day and over the course of the week because of fluid changes, but also due to muscle contraction/relaxation. This is a challenge for rigidly-constructed prosthetic sockets that do not conform to different residual limb shapes. Mr. Carroll introduced the idea of a "Dynamic Response Socket", a frame construction with flexible inner socket made with a material that conforms with body heat. The socket has an open frame posteriorly that permits flexibility of the inner socket for sitting as body heat makes the socket material pliable. Anteriorly, cut-outs in the frame over the rectus femoris allow for additional adaptation of the flexible inner socket during walking. Currently, the life span of the material used in the dynamic response socket is roughly three months, after which the material loses sufficient elasticity in response to the body's heat.

Socket Comfort: Mr. Carroll indicated that increased knowledge about the principles underpinning current socket techniques is needed in order to better understand their characteristics. This would eventually lead to prosthetic sockets that are more comfortable, thus reducing irritation and pain that often occurs in the residual limb. Different materials are also needed that allow for a smooth transition between soft and hard materials and that are more resistant to lotion applied to the residual limb.

Gel Liners: Mr. Carroll commented that gel liners can affect proprioception and prosthesis control if their wall thickness is too great, and yet we don't know what thickness is appropriate for both comfort and control.

The Seal-In-Liner is a relatively new liner that works well for users with a transtibial amputation, but can be problematic for users with transfemoral amputations. The advantage of the Seal-In-Liner is that good suspension can be achieved without the use of a pin. According to Mr. Carroll, roughly 60-70% of users with transtibial amputations use a pin-lock system for their prosthesis suspension. Yet, it is not the suspension that is a challenge, but the pin and its correct alignment in the locking mechanism. These issues are eliminated with the use of a Seal-In-Liner. In addition, cosmesis with the Seal-In-Liner is improved.

Joints with Stance Knee Flexion: The overall question regarding all prosthetic knee joints that provide stance knee flexion is whether users are utilizing this specific feature. Mr. Carroll suggested that several points should be addressed in order to insure proper functioning (Figure 5.4): (a) Is the therapist aware that the knee joint has a stance knee flexion feature? (b) Is the user aware of it and have they received the correct training on how to use it? Both the therapist and the user should be educated on the features and function of stance flexion joints so that therapy can specifically address proper function with this component. Mr. Carroll felt that knee joints with stance knee flexion are over-prescribed since, in his opinion, only very active users are able to benefit from stance knee flexion units and that they add unnecessary weight. Mr. Carroll encouraged researchers to develop lightweight shock-absorbing units instead.

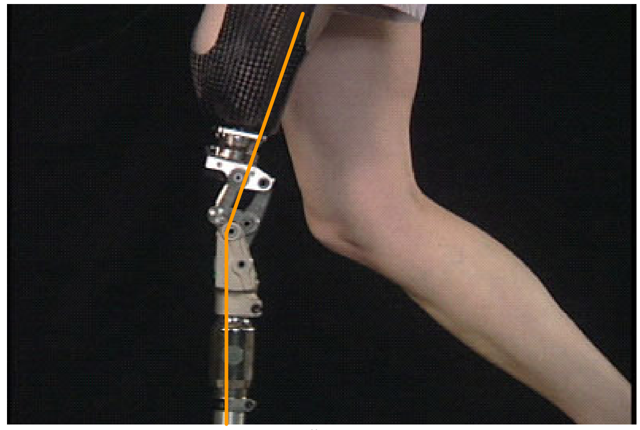

Figure 5.4 Total Knee Joint, Össur
Source: www.ossur.com/template110.asp?PageID=597

Dynamic Response Feet: It is very important that consumers be well educated about the availability and characteristics of different dynamic response feet. The shock absorption provided by these feet is especially needed for running. It is possible that older persons might benefit more from a lightweight foot than one that incorporates shock absorption.

Discussion

During the discussion it was pointed out that for a successful pin system fitting the overall shape of the residual limb must be taken into account. Not every limb shape is suitable for use with pin suspension. Objective quantification of limb shapes and types were proposed in order to assist practitioners with component selection.

It was noted that there seems to be a discrepancy in the understanding of study results between researchers and professionals. Clinical professionals too often assume that study results constitute fact. However, it is important to realize that there are no definitive answers in our field, and that study results depend on the methodology applied. The methodology in turn is based on the research question that is posed at the outset of the study, which should have been chosen carefully and determined to be the most appropriate for answering the desired question. However, resources can restrict a researcher's ability to choose the optimal methodology, thereby affecting the results. It is often not possible to carry out prosthetics research on the same scale as, for example, that of pharmaceutical companies. It is not always possible to conduct placebo-controlled studies since the study participant would nearly always know what type of component s/he is wearing. Given these challenges, we should consider whether it might be appropriate to develop testing protocols that are specific to the O&P field.

Another aspect of the discussion was that of consumer perspective, education and training. An expensive device does not necessarily mean it will automatically be better and thus enhance the user's performance. Also, not every component that becomes commercially available is equally good for every individual. The clinical professional tries to address the wishes and desires of the consumer in addition to their physical needs. But how does a new consumer know what is best for him/her? It is very difficult to find a balance between what we as professionals think the consumer might need and what the consumer thinks will be good for them. It has to be remembered that improved clinical practice is often based upon subjective evaluation, but objective measures are needed to improve our understanding of the field.

Recommendations

Based on the presentations and discussion the following areas of potential research in lower-limb prostheses were identified:

- Determine what we actually know (i.e., what science supports) versus what we think we know. This includes the testing of clinical assumptions.
- Further exploration of the human/prosthesis interaction.
- Investigate pin-lock systems and their correct application based upon considerations of residual limb shape. Cognitive ability is often not considered with different types of sockets/suspension.
- There is a need for thorough research designs that incorporate good research questions, methodical documentation of practitioner's work, and the amount and kind of therapy received.
- Try to establish the end-user's wishes and wants, and determine if products and services are able to meet those needs.
- Subjective versus objective evidence—patient feedback is important and should be methodologically assessed and incorporated into research studies.
- The benefits of the Hydracadence knee joint should be reconsidered, since the active dorsiflexion that it provides during swing phase may improve transfemoral gait patterns.

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Section Summary provided by Margrit Meier, Ph.D.

SESSION 6: UPPER-LIMB PROSTHETICS II
Body-Powered Prostheses

Research Perspective: Craig Heckathorne, M.S.

Mr. Heckathorne provided an overview of research in body-powered upper-limb prostheses noting that the majority of upper-limb prostheses provided to persons with arm amputations are body-powered devices. Their operational design is based on principles that were established in the middle of the 20th century, while some components, such as the split hook and friction wrist, have their origins in the early part of that same century. Over the decades, new components, new materials, and new concepts for interfacing body-powered prostheses and users have continued to be introduced, implemented, and incorporated into standard practice. Yet, there remains a dearth of rigorous, science-based knowledge to guide the application of body-powered systems, especially to discern the difference between "new" and "improved" designs and to understand the biomechanical interaction between the user and the prosthesis during functional activities.

This scientific weakness can be illustrated by a review of the contents of three journals generally considered to be key publications in the field of prosthetics—*JPO: Journal of Prosthetics and Orthotics*; *Prosthetics and Orthotics International*; and *JRRD: Journal of Rehabilitation Research and Development*. From January 2000 to February 2006, the percentage of papers dealing with body-powered prostheses in *JPO* was 3%, in *P&O International* was 1%, and in *JRRD* was 0.3%. Similar results are found in reviewing the content of the last two world congresses of the International Society of Prosthetics and Orthotics (ISPO). Among the courses, workshops, symposia, free papers, and posters, some aspect of body-powered prostheses was the main topic in only 3% of the content of ISPO 2001 and 2% of the content of ISPO 2004.

There exists more research involving body-powered prostheses than is evident in the three journals and two conferences reviewed here, but not much more, and what additional work there is, is scattered across a wide range of journals and conference proceedings. RECAL, an information service of the National Centre for Training and Education in Prosthetics and Orthotics of the University of Strathclyde is an excellent resource for identifying relevant literature. Among conferences, the Myoelectric Control Symposium of the University of New Brunswick Institute of Biomedical Engineering is unparalleled in its focus on upper-limb prosthetics and has continued to broaden its content in the last few decades with more presentations on body-powered prostheses.

There are many aspects to the design of body-powered prostheses that might benefit from scientific research. Foremost is comfort. The most common complaint of users of body-powered prostheses is discomfort, either associated with the manner of suspending the prosthesis on the body or from high forces transferred to the body when operating the prosthesis. Harnesses instrumented with force transducers and sockets lined with pressure transducers can quantify the magnitude of forces distributed over the suspension system. With quantification, different harness configurations can be compared and ranked. Instrumented suspension systems would also benefit and encourage the design of new components, such as the Otto Bock Automatic Forearm Balance (AFB) Unit, that are intended to improve the mechanical efficiency of a component's operation.

The appearance of body-powered prostheses is also of great concern to users. Although the split hook is the most common prehension device used in body-powered systems, many users would readily switch to a hand-like device if it could be operated as efficiently and used as functionally as the split hook. New approaches to designing efficient mechanical hands need further investigation.

The concept of "force directed design" being explored at Delft University of Technology for voluntary closing hand prostheses, the Easy Feed Hand concept developed at the Rancho Los Amigos National Rehabilitation Center, and alternative sculpting, such as used in the TRS Lite Touch Hand, are all examples of new approaches to designing efficient mechanical hands.

New components that improve the ability to position the prosthesis in space or increase the range of motion of the prosthesis are always needed. Multi-axes wrists and shoulder joints have a high priority, as do cable-actuated humeral rotators. New designs can be evaluated with analytical tools similar to the NUPRL & RERP Prosthetic Arm Design and Simulation System (PADSS) that show reach envelopes and contact maps produced with different prosthesis configurations.

More needs to be done to facilitate the design of appropriate upper-limb prosthetic technology for developing countries. Research can support this effort with mechanical and biomechanical analyses of alternative designs produced using low cost indigenous materials and fabrication methods.

Finally, the old dichotomy of body-power versus electric power needs to be put to rest. There are sufficient numbers of persons using and preferring each or both types of prostheses to support the clinical-relevance of both design approaches. It would be better to study why people prefer one or the other or both designs, and use those results as guidelines to improve future prosthetic designs, regardless of power source.

Clinical Perspective: Jack Uellendahl, CPO

Mr. Uellendahl provided the clinical perspective on body-powered upper-limb prostheses, proposing that potential research topics include lighter weight components, functional body-powered hands, updated body-powered elbows, partial hand mechanisms, harnesses designed for comfort, and hybrid power.


Figure 6.1 Jack Uellendahl, CPO

Most users of upper-limb prostheses complain about the weight of their device. There is a clear need to explore materials and manufacturing techniques that drastically reduce prosthesis weight. Reduced weight would also make self-suspending techniques more feasible.

As already mentioned in the research perspective, most persons with arm amputation would prefer an artificial hand if it functioned as well as a split hook. This is particularly true of persons with unilateral arm amputations. Hands should be designed with a conformable grasp. A hand with a relatively stiff surface has a small number of points of contact with a held object and requires high forces to stabilize and retain the object. A hand with a conformable surface has broad areas of contact and can retain and stabilize an object with lower force.

The appearance of mechanical hands can be improved with center-pull actuation and cosmetic gloves that are both durable and natural in appearance. The glove must also be designed to offer little resistance to the movement of the hand mechanism to keep the operating force lower.

New mechanical elbows are needed that are easier to operate and more versatile. Locking and unlocking of the elbow should be automatic and integrated with control of the position of the elbow. The force used to position the elbow should not be transmitted to the prehension device through the common cable. A durable gravity compensator and locking humeral rotation joint should be integrated with the elbow.

Persons with partial hand amputations represent the largest population of upper-limb amputees. Strong, lightweight devices are needed that can be configured to match various finger absences. Off-the-shelf designs that offer kinematic coupling to a physiological finger joint or to the wrist joint for control of positioning would be helpful.

Control and suspension harnesses should be designed with comfort as a primary objective using biomechanical analysis and new materials.

The use of hybrid power should be explored as a way of augmenting body-power while retaining the benefits of body-power, especially proprioceptive feedback. One form of this might be a device that uses body-power when high speed with low prehension force is needed, but uses external power when low speed, high prehension force is needed.

In addition to these research topics, there is a need for education, for effective methods to disseminate best practices. Much of what is known and practiced in the application of body-powered prostheses is based on decades old information. However, there is generally very poor understanding of the basics by most practicing prosthetists.

Discussion

The meeting participants generally agreed with the observations and comments of the research and clinical perspectives. The summation of the discussion that follows emphasizes additional topics and alternate viewpoints.

Many participants commented on the weight of prosthetic devices and its influence on comfort, operational effort, efficiency, and acceptance. There was general agreement that most devices are felt by users to be heavy and that users would prefer them to be lighter. Participants thought that the situation could be improved by reducing both the actual component weight and the perceived weight. Actual weight reduction could be achieved through new component designs that emphasize lighter weight materials. Reducing perceived weight could be achieved through placement of heavier parts more proximal and by suspension systems that better distribute loading on the body. Suspension systems suggested included custom silicone sockets, vacuum assisted suspension designs, and osseointegration.

In discussion of component design, participants encouraged the development of more efficient cable systems, improved endoskeletal systems, and kinematically coupled devices. With respect to cable systems, function could be improved by separating the operating force for the elbow from the force used to operate the prehension device. Cable recovery devices could also improve function by more efficiently using a person's available operating excursion, but such devices would need to be simple, reliable, and durable, unlike previous designs.

Improvements sought for endoskeletal devices include better skin coverings and shape-giving materials, less expensive aesthetic alternatives, and locking elbows with free swing. The problem of having material crossing and encompassing an endoskeletal joint, such as an elbow, was of special concern. Skin coverings and shape-giving materials are needed that appear more natural as the joint moves through its range of motion and don't impair or impede the movement of the joint.

Kinematic coupling of joints was discussed as a means of positioning multiple joints with a common control action. An example given was linked rotation of a prehensor toward the face as a prosthetic elbow was flexed.

Graphic computer modeling of prosthetic systems was encouraged, especially with respect to documenting range of positioning or reach. Having that information would allow testing of any correlation between positioning range and acceptance or rejection of a prosthesis.

Increased application of surgical intervention was seen as necessary to improve the function of body-powered systems. Osseointegration of prostheses for suspension and angular osteotomy of the humerus at the transhumeral level for supplementary suspension and rotation control were two specific examples discussed.

Section Summary provided by Craig Heckathorne, M.S.

SESSION 7: ORTHOTICS II
Spinal

Research Perspective: Bryan Malas, MHPE, CO

Mr. Malas began his presentation with an overview of the literature on spinal orthoses based on a Medline search of 371 citations. Specifically, he reported on the distribution of articles across eight spine content areas (Figure 7.1) noting that the majority of the literature has been focused on spine deformity, in particular scoliosis and kyphosis. Of the remaining seven spine content areas, biomechanical evaluations/comparisons between orthoses and non-operative management of the cervical and thoracolumbar spine have received the most attention. Yet, spine pathology is of considerable future concern: the annual cost of low back pain is reported to be US$20-50 billion and the incidence of osteoporosis in the ageing baby boomers is 15-25% greater than the incidence of idiopathic scoliosis. Mr. Malas then proceeded to give an overview of the literature pertaining to each of the spine content areas (with the exception of spinal deformity).

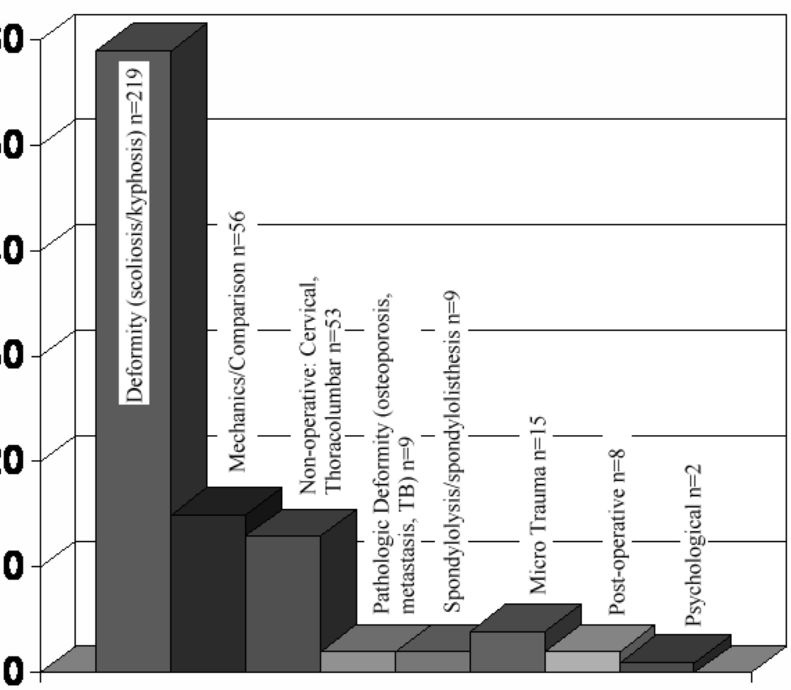

Figure 7.1 Distribution of articles across eight spine content areas.

<u>Spinal Biomechanics/Comparison</u>: Mr. Malas noted that there is a need to evaluate mechanical theories in-vivo; revisit biomechanical principles such as intra-abdominal pressure versus load-sharing or three point hyperextension versus bending moment; and revisit research completed prior to the "follower load" publication that demonstrated that cadaveric/synthetic models could replicate in vivo, physiologic loads.

<u>Non-operative management</u>: With regard to non-operative management, Mr. Malas noted that recent research[1-5] has identified three main types of stable fractures without neurologic compromise that may benefit from non-operative management: Anterior Compression Fracture, Seat Fracture (bony) and Burst Fracture (controversial). Key research questions arising from this research include: Should orthosis design be fracture specific? Can we develop a reproducible impression technique?

<u>Pathologic Deformity</u>: With regard to hyperkyphosis secondary to osteoporosis, research has shown that orthotic management with CASH or Jewett orthoses is ineffective, and that surgical management such as kyphoplasty addresses deformity alone so that the patient may remain symptomatic. Also, kyphoplasty is a high-risk procedure with low reimbursement. Current orthotic

management favors the posterior shell, and early, unpublished results appear positive. Further research is needed regarding orthotic design and dosage for the treatment of pathologic deformity.

Micro Trauma: Micro trauma of the spine commonly manifests itself as low back pain. Orthotic management is usually abandoned if the corset doesn't address the symptoms of low back pain. Successful management appears to be based on appropriate spinal alignment[6,7]. Again, further research regarding orthotic design and dosage and the effects of multiple and simultaneous treatments such as physical therapy and orthotic management is needed.

Post-operative Management: With regard to post-operative management with spinal orthoses, there are a number of potential research questions, e.g. should orthotic design be surgical construct specific? What are the short and long-term effects of post-operative orthotic management versus no orthotic management? What works better: custom, made-to measure or off-the-shelf orthoses? What are the effects of different designs, especially with regards to openings, material and trim-lines? Is there a role for orthotic management in cases of surgical hardware failure?

Mr. Malas concluded by indicating that investigation of patient psyche as a predictor of successful orthotic treatment might be worthwhile, and that it remains unclear what effect there is of clinician knowledge/skills on orthotic outcome.

Clinical Perspective: Don Katz, CO, LO, FAAOP

Mr. Katz began by reviewing the clinical challenges of treating idiopathic scoliosis. Idiopathic Scoliosis was defined as lateral curvature of the spine >10° in the absence of any relevant congenital spinal anomaly or associated musculoskeletal condition. The treatment goals of orthoses are: to alter the natural history of further curve progression, to avoid the need for surgical correction and to provide passive in-brace correction with the predominant corrective force being the transverse loading of the spine. Previous research has established the effectiveness of treatment with a brace in girls who have adolescent idiopathic scoliosis[8]. It has been suggested that transverse load increases the critical load that the spine can carry, rendering the spine more stable with respect to buckling into a greater magnitude of curvature. Although 50% in-brace reduction of the Cobb angle has long been considered the target value, recent work has suggested that the threshold in-brace reduction predictive of success is between 30-40% depending on curve location[9].

Mr. Katz noted that there are competing consequences in treatment with Thoraco-Lumbo-Sacral Orthoses (TLSO): there is a significant positive correlation with strap tension, pad pressure and the immediate reduction of the Cobb angle[10-15]. However, there is also a tendency toward flattening of sagittal contours in an already hypokyphotic spine[15-20]. Investigation of the pathogenesis of Idiopathic Scoliosis resulted in the conclusion that coronal plane curvature is entirely secondary to the sagittal imbalance of growth[21]. It has also been suggested that a linked column, such as the spine, loses stability when it is lengthened and straightened, potentially allowing rotational and coronal plane deformities to develop.

Mr. Katz noted that we need to use good judgment in achieving appropriate in-brace reduction and that "squeezing" out another 5-10° may render the orthosis intolerable. Rather, we should aim to balance both the spine and the forces acting upon it. However, we still don't know how best to apply forces to the spine in order to achieve "adequate" reduction of deformity. We believe that applying force to the apex of the curve is best, but we don't know how that is best translated into orthotic design. In creating a balanced spine, should we try to induce a compensatory curve in the unbalanced spine? It is important that we not make deformity in the sagittal plane worse at the expense of correction applied in the coronal plane. Can we avoid thoracic kyphosis while reducing coronal plane deformity? How do we make an orthosis tolerable to the patient? An orthosis can only help if it is worn and there is mounting evidence of a "dose relationship" and of poor compliance with current treatment regimes. Perhaps we can make orthoses more tolerable by using softer materials that breathe or by developing a better understanding regarding what level of maturity it is safe to discontinue treatment. Skin care is also a challenge when spinal orthoses are used in the treatment of scoliosis, but perhaps framed designs might help.

Mr. Katz concluded by stating that beyond mathematical modeling studies, little evidence exists regarding how best to apply forces to the hypokyphotic scoliotic spine to reduce the amount of deformity in all three planes, while recognizing the heterogeneity of curve presentations. We must continue to strive to produce orthoses that are as tolerable as possible to the patient.

Discussion

- It was noted that idiopathic scoliosis can be held up as a model for systematic investigation of other areas of P&O.
- It was suggested that we need to strike a balance between aggressiveness of treatment and tolerability for the orthosis wearer.
- We need to explore why curves progress.
- We need to investigate the benefits of surgery versus orthotic prescription.
- There is currently little rationale or justification for the treatment of low back pain. It is mostly market driven.
- We need improved education and training for orthotists fitting spinal orthoses.
- We need to explore how to incorporate technology to create "smart" orthoses.
- Do we need to correct all spinal deformities, or let one side go if it doesn't seem to really affect spinal balance?

Figure 7.2 Brian Malas, left, and Don Katz, right.

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Section Summary provided by Stefania Fatone, Ph.D.

SESSION 8: OPEN FORUM

The last session, entitled "Open forum", enabled participants of the State-of-the-Science meeting to make two-minute presentations on additional topics of research interest that may not have been mentioned or discussed in previous sessions. The list below highlights the issues raised by the participants:

- Outcome goals: negative and positive.
- Explore use of CAD/CAM to record and store socket information.
- Develop a model for feasible, higher level research.
- How to improve Clinician-Researcher dialogue?
- Need for predictive modeling of walking with prostheses/orthoses—training, prescription.
- Improve cosmetic appeal of orthoses, e.g. for children.
- Better define what consumers want.
- Technical specifications of different products are required to improve understanding of what they may contribute to function.
- Re-evaluate how to capture biomechanically the power of the body for upper-limb prostheses.
- The need for gas permeable suspension sleeves. Do they eliminate perspiration?
- Explore hybrid systems for upper-limb orthoses.
- Explore alignment in upper-limb prosthetics.
- Determine value of prosthesis or orthosis to the user—what meets their needs and can be paid for by third party payers?
- Apply successful models of spinal research, such as in scoliosis, to other areas of P&O not previously investigated.
- Establish simple, relatively global outcome measures that we can all agree on and then figure out how best to measure them.
- Inclusion of a force sensing system in pylons would provide excellent data.
- Explore the effect of different prosthetic socket trim-lines.

SPECIAL EVENT: ARE WE ADDRESSING CLINICALLY-RELEVENT RESEARCH?
Annual Meeting of the American Academy of Prosthetists and Orthotists
March 1-4, 2006, Chicago IL

To capitalize on the many prosthetists, orthotists, researchers and consumers in P&O who would be attending the American Academy of Orthotists and Prosthetists (AAOP) annual conference, which was held in Chicago during the same week as our State-of-the-Science meeting, we held a symposium as part of the AAOP program.

The purpose of the symposium was to disseminate the key recommendations from our State-of-the-Science meeting and open the floor to public opinion. The symposium consisted of presentations from Steven Gard, Ph.D., on lower-limb prosthetics and CAD/CAM; Stefania Fatone, Ph.D., on orthotics; and Craig Heckathorne, M.S., on upper-limb prosthetics. Findings from the online survey and forum were summarized and key recommendations resulting from the State-of-the-Science meeting presented.

Following these presentations, the floor was opened for discussion. The list below highlights issues and concerns raised by the symposium attendees:

- How many studies need to be done to achieve consensus?
- The P&O profession does not have measurable outcomes to teach evidence-based medicine.
- Identify ways in which practitioners can get research started when they have ideas.
- Can we document experience in some way that is meaningful and may contribute to the body of knowledge?
- Sample size is one of the overwhelming problems in conducting research.
    - Multi-center trials require uniform protocols.
- Basis for developing consensus – should be established based on scientific parameters (e.g. orthopedic model).
- How do we sort out failures?
- Research is driven by what is out on the market, but it should be the other way round.
- Can we use L-codes to look at population size/distribution and determine where research should be targeted?
- Can we use cadaveric studies to examine research questions in P&O?
- Development of CAD/CAM educational tools for training.

CONCLUSIONS & RECOMMENDATIONS

During the course of the on-line survey, forum and State-of-the-Science Meeting, many specific research topics were suggested. Although some of these have been mentioned in the preceding pages, a more comprehensive summary is included as Appendix G. It is difficult, based on the discussion that occurred on February 28, 2006, to objectively stratify the priority that each of the topics raised should be given. However, the following concluding remarks attempt to provide an overview of the main, clinically-relevant problems that were identified.

In all aspects of P&O, outcome measures, including the need to develop evidence-based practice and demonstrate efficacy of P&O treatment, was emphasized as an important area of research priority.

With regard to prosthetics, including both lower and upper-limb, further understanding of the interface between human and device to improve both comfort and function was raised as a priority for research.

Within lower-limb prosthetics, the need for real world functional evaluation of devices and better understanding of prosthetic knees and socket suspension were emphasized. Specifically for prosthetic feet and ankles, understanding of component interaction and alignment, development of improved prosthetic ankles and feet, especially pediatric feet, and development of mechanical and functional classification systems for prosthetic feet, all deserved attention.

In the area of upper-limb prostheses, several needs were emphasized as pertaining to both electric and body-powered systems. These common needs included reduction in the perceived and real weight of devices, improved control systems and strategies, pre-fitting training and surgical intervention to improve the condition and health of the residual limb, and improved performance and a greater variety of components. Sensory feedback was identified as a significant need for electric-powered systems. For body-powered systems, mechanical efficiency was recognized as a major area for improvement.

In all aspects of orthotics, development of better fabrication processes and appropriate materials were considered of high research priority.

With regard to lower-limb orthotics, the need for research into the use and efficacy of AFOs was emphasized. Also of high priority was the need to establish the most appropriate and effective timing of orthotic management. There is also a need to establish the effects of orthoses on many variables such as the contralateral limb, joint alignment, fall prevention, and prevention of foot deformities.

In the area of spinal orthoses, there remains a need to explore appropriateness of surgical and orthotic prescription, curve progression, and management of low back pain. The research that has been conducted on spinal orthotics, particularly in scoliosis, was considered a successful model for systematic investigation within P&O.

The need to further develop CAD/CAM was discussed. Such development must improve the utility and reduce the cost of this technology. We need to establish whether CAD/CAM produces better sockets, allows for more rapid socket fabrication, or both. There is also a need to apply CAD/CAM to orthotics.

Education and the development of specific expertise was an issue in many areas, but was mentioned specifically with respect to spinal orthotics, upper-limb prosthetics and CAD/CAM. It was further acknowledged that there is a broader need to improve education among clinicians about research. It was also suggested that there needs to be improved clinician-researcher dialogue.

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APPENDIX B: AGENDA

Meeting in the Northwestern University Prosthetics-Orthotics Center
Room 1702 of the Rehabilitation Institute of Chicago
345 E. Superior
Chicago, Illinois 60611

Time	Session	Speaker	
8:00 - 8:30	Continental breakfast		
8:30 - 8:45	Greetings/Overview	Steven Gard	
8:45 - 9:00	Overview of Survey & Forum	Stefania Fatone	
9:00 - 9:45	Lower-limb prosthetics I Foot/ankle mechanisms	Researcher: Clinician:	Andrew Hansen Donald Shurr
9:45 - 10:30	Upper-limb prosthetics I Electric prostheses	Researcher: Clinician:	Richard Weir Troy Farnsworth
10:30 - 10:45	Break		
10:45 - 11:30	Orthotics I Lower-limb	Researcher: Clinician:	Stefania Fatone Tom Dibello
11:30 - 12:15	CAD/CAM	Researcher: Clinician:	Joshua Rolock Michael Brncick
12:15 - 1:00	Lunch		
1:00 - 1:45	Lower-limb prosthetics II Sockets, knees, shock absorbers	Researcher: Clinician:	Margrit Meier Kevin Carroll
1:45 - 2:30	Upper-limb prosthetics II Body-powered prostheses	Researcher: Clinician:	Craig Heckathorne Jack Uellendahl
2:30 - 2:45	Break		
2:45 - 3:30	Orthotics II Spinal	Researcher: Clinician:	Bryan Malas Don Katz
3:30 - 4:00	Open forum Miscellaneous topics	Steven Gard	
4:00 - 4:30	Summary & Wrap-up	Steven Gard	
6:00	Dinner		

A primary objective of this meeting will be to facilitate communication between researchers and clinicians with the intent of identifying clinically-relevant research problems in the field.

Each session will begin with brief presentations by two speakers, one providing a research perspective and the other providing a clinical perspective. The formal presentations are intended to stimulate thought and set the stage for open discussion by all participants for the remainder of the allotted time during that session. The research perspective will provide an overview of published studies that will highlight issues of ongoing concern. The clinical perspective will discuss patient/practitioner concerns and conclude with a set of recommendations for new research directions. Ensuing discussion by the group will create subcategories of major topic areas and make recommendations for further research. The last session, entitled "Open forum", will enable participants of the meeting to make two-minute presentations on additional topics of research interest that may not have been mentioned or discussed in previous sessions.

APPENDIX C:
ONLINE SURVEY

The Northwestern University Rehabilitation Engineering Research Center in Prosthetics and Orthotics, funded by the National Institute on Disability and Rehabilitation Research, is conducting this survey in preparation for a State-of-the-Science Meeting to be held in 2006.

The purpose of this survey is to investigate the opinions of the prosthetics and orthotics community regarding the direction that research in the field of prosthetics and orthotics should take over the next 5-10 years.

The results of this survey will be compiled for discussion at the Northwestern University Rehabilitation Engineering Research Center in Prosthetics and Orthotics State-of-the-Science Meeting to be held in 2006, and will be presented at the AAOP Annual Meeting to be held in Chicago, March 1-4, 2006.

It is hoped that the information gathered here will identify clinically-relevant research problems that deserve attention in the near-term, and help guide future research in the field of prosthetics and orthotics.

We thank you for taking the time to complete this short survey.

Age ________

Gender
- ☐ Male
- ☐ Female

Please indicate your association with the field of prosthetics and orthotics (can select more than one):

- ☐ Consumer
- ☐ Family member of consumer
- ☐ Orthotist
- ☐ Prosthetist
- ☐ Prosthetic/Orthotic Resident
- ☐ Prosthetic/Orthotic Student
- ☐ Physician
- ☐ Therapist
- ☐ Educator
- ☐ Engineer
- ☐ Other____________________________

Do you conduct research in the field of prosthetics and orthotics?
- ☐ Yes
- ☐ No

If yes, indicate the percentage of time you devote to research: ______

Which of the following journals do you read on a regular basis to stay abreast of the latest prosthetics- and orthotics-related research? Can select more than one.

- ☐ Journal of Prosthetics & Orthotics
- ☐ Prosthetics-Orthotics International
- ☐ Journal of Rehabilitation Research & Development
- ☐ Archives of Physical Medicine and Rehabilitation
- ☐ Physical Therapy
- ☐ Journal of Biomechanics
- ☐ O&P Edge
- ☐ O&P Business News
- ☐ Biomechanics
- ☐ Gait & Posture
- ☐ Other___________________________

Do you feel that a sufficient amount of research is being conducted in the field of prosthetics and orthotics?

- ☐ Yes
- ☐ No

Do you feel that the emphasis of current prosthetic and orthotic research is appropriate?

- ☐ Yes
- ☐ No

Do you consider research to be important to the continued development of the prosthetics and orthotics field?

- ☐ Yes
- ☐ No

Have you identified areas where further research is needed, but do you lack the ability and resources to carry out the work?

- ☐ Yes
- ☐ No

Do you feel that research funding is a factor that prevents more research from being conducted in the field of prosthetics and orthotics?

- ☐ Yes
- ☐ No

In their order of importance, please rank the top five problem areas of prosthetics where you believe research should be directed (marks 1 through 5 with 1 being most important):

_____ Sockets/interface
_____ Shoulder joints
_____ Elbow joints
_____ Wrist units
_____ Terminal devices
_____ Control of prosthesis
_____ Sensory feedback
_____ Liners
_____ Knee joints
_____ Ankle joints
_____ Feet
_____ Suspension
_____ Fabrication
_____ Materials
_____ Shock absorbing components
_____ Outcome measures
_____ Gait Training
_____ Other ___________________________

In their order of importance, please rank the top five problem areas of orthotics where you believe research should be directed (marks 1 through 5 with 1 being most important):

_____ Spinal orthoses
_____ RGOs
_____ KAFOs
_____ AFOs
_____ Foot orthoses
_____ Upper-limb orthoses
_____ Knee joints/components
_____ Ankle joints/components
_____ Attachment
_____ Fabrication
_____ Materials
_____ Outcome measures
_____ Gait Training
_____ Other ___________________________

What do you consider to be the 3 most important questions to be addressed by prosthetics and orthotics research in the next five to ten years?

____

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APPENDIX D:
ONLINE FORUM

'State of the Science' in Prosthetics and Orthotics

An online Forum managed by the Prosthetics Research Laboratory and the Rehabilitation Engineering Research Program of Northwestern University

FAQ Search Memberlist Usergroups Register
Profile Log in to check your private messages Log in

The time now is Tue Mar 07, 2006 3:50 pm
'State of the Science' in Prosthetics and Orthotics Forum Index View unanswered posts

Forum	Topics	Posts	Last Post
General			
The 'State of the Science' Discussion Board... Purpose of the Forum. Questions, comments and concerns related to the Forum itself (rather than specific Forum Topics.)	4	5	Mon Mar 06, 2006 8:31 am Al Pike, CP
Upper Limb Prosthetics			
Component Design Purpose: To identify components that are needed and not currently available and characteristics of existing components that should have high priority for improvement.	1	2	Sat Dec 31, 2005 11:58 am Mike Brncick
Body-powered Prostheses Purpose: Is there a future for body-powered prostheses? What are the major problems in the design or use of body-powered prostheses? What is needed to make body-powered prostheses more functional?	1	9	Sat Dec 31, 2005 11:07 pm Mike Brncick
Myoelectric Control Purpose: Is there a future for myoelectric control? What are the major problems in the implementation or use of this control method? What is needed to enhance or expand use of myoelectric control?	1	3	Sat Dec 31, 2005 11:48 pm Guest
Sensory Feedback Purpose: What sensations are most missed by persons using upper-limb prostheses: touch, force, temperature, position in space, or something else?	1	3	Sun Jan 01, 2006 10:35 am Mike Brncick
High Level Fittings Purpose: What should be done to improve prosthetic fittings for persons with trans-humeral, shoulder disarticulation, and interscapulothoracic amputations?	2	4	Sun Jan 01, 2006 10:58 am Mike Brncick
Acquired Amputations and Congenital Limb Deficiencies Purpose: Are the research needs of these two groups different?	2	4	Tue Dec 27, 2005 3:58 pm Ted Trower CPO

	Participation in Research Purpose: How can persons with upper-limb amputations or limb deficiencies effectively participate in upper-limb prosthetics research and the establishment of research goals?	0	0	No Posts
Lower Limb Prosthetics				
	Prosthetic Feet	1	6	Sun Jan 01, 2006 5:10 pm Mike Brncick
	Prosthetic Knees	2	12	Tue Jan 03, 2006 10:25 am arjohn
	Sockets and Liners	2	67	Fri Jan 13, 2006 11:29 am gmstreet
	Other Components	3	15	Wed Dec 14, 2005 7:07 pm Mark
	Gait Analysis	1	16	Sat Dec 17, 2005 12:04 pm Marmaduke
Lower Limb Orthotics				
	AFOs	1	9	Wed Jan 04, 2006 8:24 am Stef
	KAFOs	1	1	Wed Nov 16, 2005 8:30 am Stef
	RGOs	2	2	Fri Dec 16, 2005 2:45 am Marmaduke
Other Orthotics				
	Spinal Orthotics	1	1	Fri Nov 11, 2005 3:54 pm Stef
	Upper Limb Orthotics	1	6	Wed Dec 14, 2005 9:38 pm Pharmer
Manufacturing Techniques				
	CAD/CAM	1	2	Wed Dec 14, 2005 7:37 pm Mark

	Conventional Methods e.g Hand Fabrication and Assembly	1	2	Thu Dec 15, 2005 2:40 pm Mark
Standards and Reliability				
	Materials, Components & Equipment	3	5	Tue Jan 17, 2006 7:14 pm wgodoy
The Research and Development "Wish List"				
	"Lack of the Science" in P&O	2	29	Sun Mar 05, 2006 4:34 pm Orestes
Clinical Concerns in Prosthetics and Orthotics				
	Clinical perspective–Research desires	2	3	Tue Dec 27, 2005 10:07 pm Ted Trower CPO
	Problems with Current P&O Technology	1	3	Mon Dec 26, 2005 8:49 am arjohn
	Business Related Issues	0	0	No Posts
Consumer Issues in Prosthetics and Orthotics				
	The Good, the Bad and the Ugly Personal perspectives on prosthetics and orthotics. What works, what doesn't, and what's missing.	0	0	No Posts
	Consumer Perspective–Research Desires	1	2	Sun Dec 04, 2005 4:19 pm Jeff A. Zeller, CP
Sharing Ideas– Sources and Outlets for Information Exchange				
	Societies & Organizations	0	0	No Posts
	Publications	1	4	Thu Dec 15, 2005 3:39 pm Mark
	Online Resources	2	2	Sun Dec 04, 2005 8:52 am WayneR
Toot–Your–Horn				

	Share Personal Research Results Note: Postings of a commercial nature will be deleted.	0	0	No Posts
Forum Trial Area				
	Testing...1...2...3... This is the place to go if you just want to test out how posting and responding works.	4	4	Thu Feb 23, 2006 8:38 pm jagtek1
Moderators				
	Moderator Information	1	1	Mon Nov 21, 2005 1:02 pm rolock

All times are GMT - 6 Hours

Who is Online

Our users have posted a total of **222** articles
We have **123** registered users
The newest registered user is **funnywhidden**

In total there is **1** user online :: 0 Registered, 0 Hidden and 1 Guest [Administrator] [Moderator]
Most users ever online was **11** on Thu Dec 15, 2005 11:36 am
Registered Users: None

This data is based on users active over the past five minutes

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New posts No new posts Forum is locked

Prosthetics Research Laboratory and Rehabilitation Engineering Research Program
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Chicago, IL 60611-4496
(312) 238-6500 / Fax (312) 238-6510

APPENDIX E:
Executive Summary from 2002 State-of-the-Science Meeting

I. General themes and needs arising from the State-of-the-Science Meeting in Prosthetics and Orthotics (P&O) were summarized as follows:

1. Orthotics research needs to be greatly expanded and emphasized.
2. Development and implementation of meaningful outcome measures is needed in P&O.
3. Science and quantification needs to be emphasized in prosthetics and orthotics. The use of science to bring out possible "fusion of flesh and machine" was an emergent theme, as was biomimetics (to mimic nature). Materials science is considered to be of particular value to the advancement of the P&O field.
4. There is value in re-visiting earlier research. Outstanding ideas of the past may be exploited by new technologies and knowledge of the present.
5. The loss of the multi-disciplinary team approach to P&O service in America was lamented. Research teams of the future need to be integrated with clinical service. The active involvement and participation of surgeons in P&O matters seems essential for broad advancement of the field.
6. Elevation of educational programs across the whole spectrum of P&O disciplines is considered vital to advancement of science in P&O
7. The influence that managed care is having on P&O practice, education, and research needs examination.

II. Specific mechanisms, methods, knowledge and approaches of high interest to some participants during the State-of-the-Science Meeting in P&O were summarized as follows:

- **Movement Science:** A better understanding of how humans walk is needed. Improved engineering models of walking are necessary to create better mobility aids for P&O. Shock absorption mechanisms and improved foot/ankle systems are of particular importance.
- **Surgical and Medical Sciences:** "Neuromuscular reorganization" methods that surgically create added sites from which to control multi-functional upper-limb prostheses are highly interesting. Tunnel cineplasties and the Krukenberg procedure should not be ignored.
- **Biological Sciences:** Direct skeletal attachment of prostheses to the body is of high interest. New concepts in surface biochemistry suggest that bonding between implants and biological tissue will continue to be improved and made infection resistant.
- **Systems Science and Mechanisms:** Compliant actuators promise to make P&O devices flexible (spring-like) and more resistant to damage. Bions (bionic neurons), miniature muscle implants that can send or receive signals from muscles without using wires, look to be of importance for P&O systems. Microprocessor-controlled reflexes will become common over the next decade. Simplicity of design in P&O devices is considered desirable where possible. High-tech methods, coupled with understanding, can sometimes be used to create design simplicity.
- **Materials Science, Fabrication, and Safety:** Standards for materials and good management of materials during storage and fabrication are highly important in P&O. Rapid prototyping, CAD/CAM and dilatancy methods need to be exploited where they can be shown to be effective.

APPENDIX F:
NORTHWESTERN UNIVERSITY
REHABILITATION ENGINEERING RESEARCH CENTER
IN PROSTHETICS AND ORTHOTICS

Abstract

Through engineering and scientific research, we want to help persons with disability obtain needed limb replacements (prostheses) or assistive systems (orthoses) that are highly functional, comfortable and cost-effective. Therefore, our research and development center in prosthetics and orthotics (P&O) at Northwestern University is requesting the National Institute on Disability and Rehabilitation Research (NIDRR) to consider this competitive application for renewal as the NIDRR-Rehabilitation Engineering Research Center (RERC) in Prosthetics and Orthotics.

Our vision for the Center is to improve the quality of life for persons who use prostheses and orthoses through creative applications of science and engineering to the P&O field. We want to uncover new knowledge and understanding in P&O and to bring more quantification to the field, which we believe will enable us to develop new concepts and devices to improve the quality, cost-effectiveness, and delivery of P&O fittings. Our plans propose ten research projects, of which three are pilot studies. There are six developmental projects.

In the area of human locomotion our objectives are to conduct quantitative studies that include non-disabled gait, modeling of gait, roll-over shape influence on transtibial amputee gait, gait initiation, shock absorption studies, the role of the spine in walking, transfemoral socket design studies, and evaluation of stance-control orthotic knee joints. Pilot studies, where preliminary data was not already available, are proposed on partial foot prothesis/orthosis systems, on evaluation of Ankle Foot Orthoses (AFOs) and on the design of a Shape&Roll™ foot for children. Development projects are proposed for a simple gait monitoring instrument (Direct Ultrasound Ranging System), on development of a new prosthetic ankle joint that will adapt to inclines, and on preparation of a manual through which individuals in low-income countries can make their own artificial feet. In addition, two upper-limb prosthetics development projects are proposed that deal with reaching, manipulation and grasping. Finally, an outcomes measurement tool is to be developed for P&O facilities in their reporting to the American Board of Certification (ABC).

Training and education are unique at Northwestern University where clinical facilities, education facilities, and research facilities are united within one hospital setting, the Rehabilitation Institute of Chicago (RIC). Graduate students enhance our large research effort. Nearly a third of the students come with their own financial aid.

We are collaborating with REHAB*Tech* at Monash University in Melbourne, Australia to develop educational videoconferences on roll-over shape in evaluation of prosthetic feet and to investigate preliminary incorporation of our shape data into their database.

We are involved with transfer of Shape&Roll™ foot technology to traditional markets in the U.S. and plan to coordinate transfer of this technology to low income countries through the RERC on Technology Access for Land Mine Survivors.

Staff continuity, which is aided by a fine professional location and stimulating atmosphere, has been key to building a group that has depth and breadth. A superior research team with demonstrated innovation and productivity has been assembled.

Mission Statement

The Northwestern University Rehabilitation Engineering Research 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.

APPENDIX G:
SUMMARY OF P&O RESEARCH TOPICS

Prosthetics

- Outcome Measures
- Socket/Interface
  - Interface/socket design and comfort
- Control of Prosthesis
  - Development of control options for prostheses
- Suspension
- Clinical decision making
- Alignment
- Education
  - Is the "prosthetics" education we are providing students in our profession what is needed to understand these issues?
- Practitioner accuracy/precision
- Develop more durable suspension systems for transtibial prostheses
- Determine whether a certain amount of play in suspension is ok
  - How much play might be ok
- Gait Analysis
  - Determine accuracy of hip kinetic data for transfemoral amputees
  - Find a better way to measure hip moments so that it accounts for any migration of the femur inside the socket
  - Examine contribution of gait training and physical therapy to amputee function with a prosthesis
- Determine the true life span of today's endoskeletal components that meet ISO standards of manufacture

Lower-Limb Prosthetics I: Foot/Ankle

- Outcomes
  - Amputee-specific outcomes study.
  - Identify appropriate outcome measures with consideration for patient capabilities
  - Development & utilization of consistent subjective outcome measures—patient feedback & perception
  - Good outcome—Are prosthesis & orthosis users able to accomplish what they desire on a daily basis?
- Liner, socket designs, and foot/ankle interactions.
- Combine principles of 2 or more alignment methods
- Prosthetic Ankles
  - Need for an articulated prosthetic ankle.
  - Develop improved versions of the Hydracadence, perhaps 4 bar versions.
  - Incorporate microprocessor technology into an ankle that will dorsiflex after toe-off in the gait cycle
- Prosthetic Feet
  - More and better designed pediatric feet.
  - Prosthetic feet that return more energy and provide "push off"

- Develop variably flexible feet or ankles to accommodate for changes in terrain, or loads a person carries
- Design a foot or ankle that increases stability while walking on uneven terrains?
- Develop a light weight dynamic response foot with good plantar flexion for transfemoral amputees
- Explore the value of active dorsiflexion in transfemoral amputees

- Well-controlled prosthetic foot studies that systematically vary one particular parameter at a time
- Categorize prosthetic feet by function: roll-over shape; useful for clinical fitting & billing/coding
- Establish functional requirements to guide classification, evaluation and prescription
- Can we establish a "benchmark" of desired mechanical qualities that when met would give us the "best" prosthetic foot?
- Exploratory phase of research—how to prioritize? Incremental progress
- Engineering based studies vs. clinical outcome studies—very different types of results
- Gait analysis
  - Clinical gait system for use by amputee care team.
  - Studies of components in the "real world", outside of the research laboratory
  - Compare feet in real world situations
- Improved models of system (user function/capabilities & components)
- Improved communication/collaboration between clinicians & researchers
- Improved patient education about the prosthesis socket fit and alignment

Lower-Limb Prosthetics II: Sockets, Knees, Shock Absorbers

- Human/prosthesis interaction
- Need for good research designs—consistency of the practitioner, amount of therapy, framing of good research questions
- Testing of clinical assumptions
  - Need to determine what we actually know (i.e., what science supports) vs. what we think we know
- Cognitive ability is often not considered with different types of sockets/suspension
- Everything that comes out on the market is not necessarily better for everyone
- Improved clinical practice is often based upon subjective evaluation
  - Subjective vs. objective evidence—patient feedback is important
  - Find out what end-user wants, and determine if products & services are able to meet those needs
- Force sensing system in pylons would provide excellent data
- Suspension
  - Correct application of pin-lock systems based upon considerations of residual limb and patient population
  - Demonstrate the advantages and disadvantages of pin suspension
  - Improve durability of suspension sleeves
- Prosthetic Knees: Transfemoral
  - Importance of alignment process
  - How is bench alignment determined for a given component?
  - Can we improve our alignment techniques?

- Determine relationship between 4 bar dynamics and type of residuum (length and strength)
  - Determine whether there are benefits of stance flexion in prostheses
    - Determine who are candidates for stance flexion
    - Determine what extra training is necessary to use stance flexion knee joints
- Prosthetic Knees: Microprocessor
  - Importance of active dorsiflexion
  - Consider performance in different conditions (inclines, turning) not just level walking
  - What are the attitudes of prosthetic users about these knees?
  - Does the increased complexity and cost significantly improve function?
- Sockets and Liners
  - Develop transtibial socket designs appropriate specifically for older or younger amputees
  - Develop adjustable sockets
  - Better understanding of the interface
  - Explore provision of systems with adjustable cushiness at interface
  - Examine the benefits of gel liners alone over the PTB socket with or without a Pelite liner
  - Develop a reactionary interface that could alter the impact of forces experienced by the user
  - Examine the causes of the long term limb volume loss
  - Examine whether denervation atrophy is the reason for excessive muscular atrophy in short residual limbs
  - Examine whether a routine exercise program that includes isometric contraction might prevent disuse atrophy or even increase muscle mass
  - Develop a better understanding of socket pressures
  - Develop understanding of how vacuum and traction on tissues affects interstitial fluid volume
  - Examine whether by employing elevated vacuum we are mimicking natural physiological mechanisms
  - Explore effects of pins and/or suction on tissue pressures and atrophy
  - Determine minimal vacuum needed to maintain volume
  - Determine effect and amount of liner preload required for optimum outcome
  - Effect of socket trim-lines
  - Develop an electromagnet controlled socket with thinly mounted metal strips on outside of gel interface, allowing for complete limb encapsulation circumferentially and eliminate socket rotation
  - Investigate and explain the mechanism that causes limb volume stability under elevated vacuum conditions
- Shock Absorbing Components
  - Do prosthetists routinely fit these devices?
  - What are the perceived benefits for the user?
- Develop a system improves on the ICRC system and is available in an unrestricted way for the US as well as the rest of the world.
- Unbiased assessments of component performance that are functionally oriented

Upper-Limb Prosthetics

- Alignment in upper-limb prosthetics
- Allow proprioceptive control without hindering movement
- Improve sensory feedback
- High level fittings:
  - Reduce weight, explore weight distribution
  - Develop telescoping components similar to adjustable tripod legs

Upper-Limb Prosthetics I: Electric Prostheses

- Weight
  - Drastic reduction of "perceived weight".
  - Reduce weight of components
- Control
  - Systems that are easy (natural) for the user; fitting, control, function, and maintenance.
  - Reliability of components to control commands
  - Improve quality, consistency, and reliability of signals through a full range of motion
  - Transfer new control algorithms (fuzzy logic, neural networks) to commercially available products – what's the stumbling block?
  - Reduce mental effort to control prosthesis
  - Improved prosthetic hand design & control
- Outcomes documentation to validate / justify effectiveness.
- Identify and measure "success" factors among long-time users of prostheses and try to better implement those among new users
- Sockets/Interface
  - Improvement of the interface between the user & the prosthesis
  - Improved socket designs to maintain contact between body & electrodes
  - Alternatives to "traditional fitting protocols".
  - Improved education for prosthetists who are fitting complex systems
- Greater emphasis on pre-prosthetic training and muscle development prior to delivery of sophisticated prosthesis
- Surgical techniques—Need cultural shift in the field to improve quality of residual limb & eliminate underlying problems that must be accommodated through prosthetic fitting
- Better coordination/communication among members of the patient care team
- Funding issues
- Sensory feedback; tactile sensation—need for more engineering- and physiology-based studies
- Need to attempt to transfer knowledge about upper-limb prosthesis control to lower-limb
- Establish functional levels for UL amputees

Upper-Limb Prosthetics II: Body Powered

- Weight
  - Components with lighter "perceived" weight
  - Decrease weight, explore weight distribution
- Control/Power
  - Re-evaluate how to capture biomechanically the power of the body for upper-limb prosthetics

- Power shift via transmission mechanism to component that is desired to be controlled
  - Separate force and cable recovery
  - Consider separating functional features of body powered harness
  - Synergetic principles of operation
- Correlate reach volume and body-contact mapping with patient satisfaction
- Trade-offs between various conflicting criteria for prosthetic components
- Endoskeletal systems & components have their place
- Joints
  - Consider joint designs with axes of rotation that are not necessarily perpendicular to the long axis of the limb segments
  - Free-swinging elbows
- Utilization of new materials
- Suspension
  - Silicone socket applications for UL prostheses
  - Vacuum assisted suspension systems
  - reduce friction
- Improve cosmesis

Orthotics

- Outcome Measures
- Fabrication
- Materials
  - improve ability to select the appropriate materials for fabrication of orthoses
- Ankle Foot Orthoses
- Prescription principles
- Comfort
- Alignment
- Improve cosmetic appeal of orthoses, e.g. for children
- Explore hybrid systems for upper-limb orthoses

Orthotics: Lower-Limb

- Orthotics provides greater potential to impact the quality of lives for a large number of people
- Use research to support or refute the many "old rules" that exist in orthotics
- Establishment of treatment algorithms for orthotic management
- Need better justification for earlier fitting (and funding) of orthoses
- Baseline studies on users of orthotic effects to document outcome potential
- Ability of orthotic prescription to prevent further complications and future surgeries—earlier intervention
- Explore effects of orthoses on fall prevention and prevention of foot deformities
- Effect of orthosis on contralateral limb
- Joint alignment
- Need for real-time evaluation of joint motion
- Study design
  - Need to focus on particular populations of patients to obtain general guidelines for different types of orthoses

- More orthotic studies on able-bodied persons to answer fundamental questions—larger numbers of subjects, uniformity of population
  - Need to consider feasible, practical study designs for orthotics—cross-over studies; RCTs not easily performed
- Research on AFOs
- Develop consensus on a modern biomechanical design of the UCBL, along with prescription criteria and outcome study
- Develop a lower extremity orthosis that absorbs shock at initial contact, then conforms to the surface, and once single stance is achieved turns into a rigid lever arm for third rocker

Orthotics: Spinal

- Idiopathic scoliosis held up as a model for systematic investigation of other areas of P&O
- Explore why curves progress
- Surgery vs. orthotic prescription
- Currently little rationale or justification for treatment of low back pain—market driven
- Need to strike a balance between aggressiveness of treatment and tolerability for the orthosis wearer
- Incorporate technology to create "smart" orthoses
- Subjective feedback
- Improved education & training for orthotists fitting spinal orthoses

CAD/CAM

- "In its present form, not as good as traditional techniques"; shouldn't be used as a substitute for the development of good hand skills or experience by the practitioner
  - Computer systems should be able to bring consistency to the practice
  - Development of CAD/CAM educational tools for training.
- Use of CAD/CAM to record and store socket information
- Establish whether CAD/CAM produces better sockets, faster ones, or both
  - Comfort vs. ease of fabrication
- Better integration/blending of traditional fabrication and CAD/CAM techniques
- Cost reduction required to increase feasibility
- Need to utilize for more orthotic applications
- Consideration for condition of patient's residual limb
- Incorporate fuzzy logic into the next generation of CAD software so that successful socket design outcomes can be learned by the system to improve upon future socket designs and outcomes
- Develop a non contact laser digitizer that scans the inside of a cast or the outside of a model that is relatively low cost, table top in size and can be used with current software

Miscellaneous Topics

- Outcomes/evidence/efficacy
  - Outcome goals: negative and positive
  - Outcome Measures – efficacy of P&O service, Evidence-Based Practice
  - Simple relatively global outcome measures that we can all agree on and then figure out how best to measure them
  - We don't have measurable outcomes to teach evidence based medicine.
  - How many studies need to be done to achieve consensus?
  - Develop a model for feasible, higher level research

- Follow successful models such as scoliosis

- Research is driven by what is out on the market – it should be the other way round.
- Clinician-Researcher dialogue
- Identify ways in which practitioners can get research started when they have ideas.
- Education and qualifications: standards, continuity, quality
- Can we document experience in some way that is meaningful and may contribute to knowledge?
- Predictive modeling of walking with prostheses/orthoses—training, prescription
- Better define what consumers want
- Value to the user, meets their needs and can be paid for
- Technical specifications of different products are required to improve understanding of what they may contribute
- Basis for developing consensus – should be established based on scientific parameters (eg orthopedic model)
- Gas permeable suspension sleeves—eliminate perspiration
- Sample size is one of the overwhelming problems in conducting research.
    - Multi-center trials require uniform protocols.
    - Can we use L-codes to look at population size/distribution and where research should be targeted?
    - Can we use cadaveric studies to examine questions?
- How do we sort out failures?
- Cost-benefit analysis of P&O services/technologies
- Develop low cost alternatives
- Development of materials for P&O applications
- Develop light weight components
- Develop fabrication processes: ease and quality
- Develop prescription principles for better decision making, e.g. component and device choice
- Long term and real-world functional analyses, applicability of motion analysis to P&O