Prosthetic Foot/Ankle Mechanisms:
An Academy State-of-the-Science Conference

Case Study:
Effectiveness of Early Prosthetic Knee Function in Infants and Toddlers

Sponsor’s Educational Editorial:
The Answer2 Improving Orthotic and Prosthetic Patient Care and Clinical Outcomes—SPS/APIS
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Supplement of The O&P EDGE
Are We an Industry or a Profession?

“Hopefully we have to be both. And, are we mechanics, with engineering skills, or are we in the medical field where the structure of anatomy is all important? Again, we have to be both. Therein lies our complicated future.”

—Orthopaedic & Prosthetic Appliance Journal, 1958

And complicated it is! Negotiated rulemaking, qualified provider, minimum education requirements, multiple certification boards, evidence-based practice, declining reimbursement, licensure, competitive bidding, fraud and abuse, Centers for Medicare & Medicaid Services (CMS) quality standards, parity, changing medicine, changing technology, and let’s not forget the FDA.

It seems like such a basic issue that you would think it would have been decided long ago: “Are we an industry or a profession?” Yet we continue to debate this amongst ourselves, nearly 50 years after the concept was last presented.

The question really is this: Can we continue to be both?

Choosing to be both has led to numerous problems. At the very least, we currently display diverging opinions on minimum education requirements, licensure, professional certification and facility accreditation, scope of practice, and encroachment, not to mention how we appear to other healthcare professions and regulators.

It is my personal opinion that we are already a profession—we just don’t know it.

Why is O&P a profession? Well, we are based on problem solving and ongoing management of a person with a disability. We have a relationship with that patient, our services have significant social value dealing with private matters of the person and his or her body, and we focus on the patient’s well-being (do no harm). We also have a unique body of knowledge and skills, we set our own educational standards, we set our own credentialing standards, we set our own ethical standards, and, finally, we are part of a healthcare team.

A profession is defined by a body of knowledge, skills, and an indwelling ethic. Perhaps it is time that we begin redefining what we do from a device focus to a person focus. If we are the only ones who understand the subtleties of materials, alignment, pressure, variable volume control, and their relationship with the human body, why is it that we persist in defining ourselves by components?

So how do we begin to define ourselves as a profession? We begin by raising our minimum education standards. Right away it will attract better students. Better students mean better analytical skills, better rhetorical skills, and an improved ability to handle complex tasks. As the years pass, these students will educate future students in higher-level skills and research, and the cycle continues.

According to the AERTI (Advanced Education Research Training Initiatives) Report, increasing the number of individuals with advanced degrees relevant to P&O will affect the field in the following ways:

- Rapidly increase the knowledge base and science of P&O
- Contribute to the education of the profession, providing academic leaders in P&O
- Enhance the transfer of knowledge from research to clinical practice
- Help create a culture within P&O that values science over marketing and expects clinicians to consume and apply research
- Contribute to research and development in the industry
- Result in the provision of improved patient services and care
- Increase the credibility and parity of the P&O profession within the healthcare realm

Increasing the number of P&O professionals with advanced degrees would facilitate a paradigm shift within the field, emphasizing the importance of self-directed, lifelong learning and creating a culture that values advanced education and scientific research. Such a focus will lead to improved patient care within P&O, and the resulting parity with other health professionals will improve the coordination of care with other disciplines.

I would contend that we are a profession with all of the responsibility and benefits assigned to that role. We need to act like a profession and move toward enhancing our profession for the future of O&P. Let us not look back in 50 years and say, “We should have.”

What do you believe? Write and let me know. Gberke@berkeprosthetics.com. Your letter may be published in The Academy Today.

1. Jean Dietz, PhD, OTR/L on training future O&P educators and scientists.

A copy of the AERTI Report is available at www.oandp.org/grants/AERTI
Replacing the function and appearance of the human foot has long been a goal of prosthetists, engineers, and others involved in the rehabilitation of amputees. Since the 1950s and the introduction of the SACH foot, numerous organizations and individuals have applied the sciences of materials, engineering, biomechanics, and human movement to design innovative prosthetic feet and ankles. Recently, new prosthetic feet designs and enhancements have been introduced at a near dizzying pace. Many features are offered such as energy storage and release, accommodation to all sorts of terrain, powered components, and enhanced appeal through natural appearance, color variations, and even adjustable heel height. Behind these developments are scientists, engineers, manufacturers, and entrepreneurs who often do their own testing or may put their products through rigorous standardized engineering tests of strength, function, and durability. Others, such as prosthetists, physicians, therapists, and biomechanists, have attempted to study, classify, or compare feet through gait labs, energy consumption tests, perceptive analysis questionnaires, or functional outcome measures.

The end users of these prosthetic foot and ankle mechanisms are amputees of all ages and backgrounds worldwide, who represent an extensive array of functional and cosmetic needs and goals. Many patients are now marketed to directly by component manufacturers and distributors. As a result, patients may often have a specific foot in mind when they see their prosthetist. But how do prosthetists and physicians know which feet to recommend to patients that will best meet patients’ needs and best impact their function? Are there resources, publications, comparisons, and outcome studies on which practitioners can rely? How are future developments to be guided in a world where technology is vast but funding sources for providing care to amputees seem to be shrinking?

In an effort to answer these and other related questions, the Academy has embarked on a bold new venture to investigate the state of scientific literature that details the development, evaluation, and future of prosthetic foot/ankle mechanisms and multiple other topics related to the provision of prosthetic and orthotic services. The State-of-the-Science Conference (SSC) on Prosthetic Foot/Ankle Mechanisms was held in April 2005 at Texas Scottish Rite Hospital for Children in Dallas.

An SSC is designed first to provide a systematic review of literature and ranking of evidence on a conference topic. A panel of experts is asked to evaluate this literature and develop statements that advance understanding in a way that will be helpful to health professionals and the public. The conference may also serve to document clinical belief systems in O&P care based on sound research or from expert opinion. The end goal of the conference is to publish a document that identifies and ranks the available evidence and defines the current status of patient care. If possible, the group may develop consensus on controversial issues and identify future research priorities.

The SSC on Prosthetic Foot/Ankle Mechanisms was called to examine the body of scientific evidence that supports the clinical prescription and use of prosthetic foot and ankle mechanisms. For purposes of simplicity and focus, “add-ons” such as torsion or vertical shock absorbers were excluded from emphasis and may be studied at a later time. Studies regarding foot/ankle components that included vertical shock or torsion absorption features as part of their mechanical design were included.
Key Questions
The conference was developed around four key questions posed to the panelists:

**Question 1:** What scientific methods have been used to determine the functional performance of prosthetic feet and ankle systems in current use?

**Question 2:** What is the correlation between the available scientific measurements and the clinical methods used to recommend ankle/foot systems for specific amputees?

**Question 3:** What is the correlation between prosthetic foot/ankle systems and prosthetic outcomes (performance, patient acceptance, durability, etc.)?

**Question 4:** In light of the literature review and the panel’s discussion, what are the primary future research priorities?

Panelists reviewed the literature applicable to one or more of these questions, wrote papers on the subject, and presented their perspectives to the group. All participants were asked to consider the relevance and validity of the following key areas:

- Time-distance parameters as a measure of prosthetic performance
- $O_2$ consumption/energy consumption studies
- Comparisons to normal gait and normal foot/ankle function
- Comparisons to other prosthetic feet
- Patient preference studies
- Other methods used to evaluate or compare foot/ankle function

The topics of focus and contributors to the SSC on Prosthetic Foot/Ankle Mechanisms included the following:

- **Preface/Key Questions/Methods**, Donald R. Cummings CP(LP), Susan Kapp, CPO(LPO)
- **Clinical Prescription and Use of Prosthetic Foot and Ankle Mechanisms: A Review of the Literature**, Brian J. Hafner, PhD
- **Terminology in Prosthetic Foot Design and Evaluation**, Nasreen F. Haideri, PhD
- **Perspectives on How and Why Feet are Prescribed**, Gerry Stark, BSME, CP, FAAOP
- **Scientific Methods to Determine Functional Performance of Prosthetic Ankle-Foot Systems**, Andrew H. Hansen, PhD
- **Clinical Perspectives on the Prescription of Prosthetic Foot/Ankle Mechanisms**, Donald Shurr, CPO, PT
Clinical Perspectives on Prosthetic Foot/Ankle Designs, Terry J. Supan, CPO, FAAOP, FISPO
Research and Clinical Selection of Foot/Ankle Systems, Joseph M. Czerniecki, MD
The Functional Value of Prosthetic Foot/Ankle Systems to the Transtibial Amputee, Robert Gailey, PhD, PT
Perceptive Evaluation of Prosthetic Foot and Ankle Systems, Brian J. Hafner, PhD
Prosthetic Feet for Low Income Countries, John Craig, CPO
Future Trends in Prosthetic Foot/Ankle Research for Soldiers with Amputations, Joseph A. Miller CP, MS, 1st Lieutenant, Medical Services Corp, U.S. Army Reserves

Research and Clinical Selection of Foot-Ankle Systems

By Joseph M. Czerniecki, MD

It is important to realize that the “recommendation of ankle-foot systems for specific amputees” in today’s climate of evidence-based medicine would require that there is scientific evidence (a double-blind, placebo-controlled trial using well-established and validated outcome measures) that shows enhanced function when a given component is provided compared to other suitable components. No studies have been done that would meet this standard. This is supported by a systematic review of the literature between 1966 and 2001 by van der Linde et al. Of the reviewed studies, only one achieved a methodological level of A, and only 15 achieved a methodological rating of B. The majority of these studies addressed outcome variables of metabolic oxygen consumption, stride kinematics, ground reaction forces, or more sophisticated joint movement and joint power output characteristics. These studies generally showed few significant differences between feet. Three B-level studies did show an increase in self-selected walking speed with different energy-storing feet compared to the solid ankle cushioned heel (SACH) foot. Additional studies showed that the increase in walking speed was accomplished by a greater stride length and reduced cadence. In addition to kinematic measures, three of nine B-level studies showed a reduction in metabolic oxygen consumption with the Flex or the Re-Flex VSP compared with the SACH foot.

Hafner et al. suggest that one of the important factors that have limited the achievement of statistical significance in these biomechanical and metabolic studies is the small sample sizes. As expected, some of the discussions were lively, and there were understandably areas of controversy, but the group was able to arrive at agreement on the responses, which are summarized in the Proceedings on Prosthetic Foot/Ankle Mechanisms published in October 2005 and mailed to all Academy members.

The Academy continues to share and update the results through certificate programming, and an online course is under development.

The Academy has also developed a continuing education opportunity from the results of this SSC. Reading the following paper by Joseph M. Czerniecki, MD, titled “Research and Clinical Selection of Foot-Ankle Systems” and completing the quiz will earn you PCE credits. This quiz is available on the Paul E. Leimkuehler Online Learning Center (OLC). Simply read the paper, take the quiz by visiting www.oandp.org/olc, and earn ABC-approved PCE credits.
laboratory relevant to real-world mobility? Hofstad et al. use the term “ecological validity” from Mulder. An example of the first issue is that a drug may cause a statistically significant 10 percent reduction in cholesterol but have no effect on the development of clinical atherosclerosis. An example of the second issue is that the metabolic costs may be reduced while walking in linear constant-speed ambulation on a linoleum floor, but these conditions are rarely seen in day-to-day ambulation. Walking in real-world conditions with stopping, starting, inclines, and stairs may in fact result in increased metabolic oxygen consumption and have an adverse effect on functional mobility. These questions should not be interpreted as a rejection of the need for fundamental biomechanical research. This research will be necessary to further understand the response of the amputee to changes in design and to assist in the development of novel prosthetic designs.

Along with laboratory measurement, an additional approach used to quantify the effect of prosthetic feet is through subjective analysis. That is, amputees, through a variety of mechanisms, are asked to provide their subjective perceptions or define, in a quantifiable way, their subjective impressions in various domains. Hafner et al. have reviewed the literature in this regard, and unfortunately, few studies have met adequate quality standards to be interpreted as to their relevance. In the systematic literature review of van der Linde et al., only one level-A study and two level-B studies were acceptable. One showed no particular benefit of energy-storing feet over conventional feet, and the other two showed some benefit of the Flex-Foot® over the SACH foot; however, these studies were not conducted in a double-blind fashion. Blinding of subjects and investigators is clearly an essential part of studies that include a subjective evaluation.

**Conclusion**

There is limited useful research to aid the clinician in the recommendation of specific foot-ankle mechanisms for specific patients.

**Important Future Directions**

**Better Define Patient Needs**

The majority of the research on prosthetic feet has classified the subject population with a fairly “coarse mesh.” That is, the populations have been defined on the basis of age, amputation level, and etiology of amputation. Part of the reason that the research on subjective evaluation of prosthetic components has been inconsistent is that the needs and priorities of subjects in these populations may be different. If we are going to get to the point where we can use scientific evidence to help in the prescription of the prosthetic feet, we must be able to more clearly define the needs, requirements, and priorities of individual patients so that we can better fit the prosthetic component to the patient.

There are a number of outcome tools available that measure the level of mobility of patients, such as the Medicare K levels, the Stanwood, the Locomotor Capability Index, or the Special Interest Group in Amputee Medicine (SIGAM) mobility grades. These are typically general mobility scales but do not allow one to measure, for instance, the intensity of mobility and the potential need for impact absorption or torsional activities that the patient might experience in his or her day-to-day functional tasks. For example, Medicare K levels divide the functional mobility status of the amputee into five levels, K0–K4, but they should not be used to prescribe a prosthetic foot. This is illustrated by the K2 level description: “has the ability for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.”

Would you prescribe the same prosthetic foot to someone who lived in an apartment in an urban environment and walked exclusively on level surfaces as you would to someone who lived in a doublewide mobile home in a rural environment with extensive irregular terrain, and also enjoyed fishing? The clinical history, in contrast, attempts to identify special patients’ needs and priorities when arriving at a prosthetic prescription. Unfortunately, as it is used in the clinical context, it cannot be quantified and used for scientific investigation.

The approach used by Postema et al. may provide the foundation for a needed future direction—the development of a tool that quantifies a patient’s mobility in key domains and also quantifies the importance of function within each of the domains for an individual patient. Postema et al. developed two questionnaires. The first questionnaire was an evaluation of the prosthetic foot measure that included 27 questions grouped into four separate domains. The amputee rates how well the prosthetic foot performed on a 0–10 scale for each question. The second questionnaire included 12 factors that relate to prosthetic foot function. The subjects then were presented with 66 pairs of these 12 factors and were asked to rank the importance of the factor of each presented pair.

These questionnaires allow you to define a patient’s needs and priorities in a more comprehensive way and then measure...
the effect of differences in prosthetic feet on their function. For example, if you were doing a research investigation on impact-absorbing pylons in transtibial amputees, you might find no beneficial effect with conventional subjective or objective biomechanical measures. But if you used the approach Postema et al. described, you might find that an impact-absorbing pylon benefited those who walked over irregular terrain or on inclines and who prioritized comfort as an important criterion. This would then suggest that a clinician could administer a questionnaire at the time of clinic visits to assess the needs and priorities of a given patient and then provide a prosthetic foot that had been shown to be beneficial in that population.

Although a long way from being a perfect solution, a key question that needs to be answered is whether or not it is possible to develop some simple instrumented quasi-static load deflection evaluations that all manufacturers will be required to perform on their prosthetic feet before bringing them to the marketplace.

Better Validated Tools for Evaluation and Measurement of Function That Have Adequate Sensitivity to Detect Change in Function Over Time As Well As Psychophysioligc Measures

Currently, the tools that are available to the investigator to measure the effect of prosthetic components on key functional parameters are limited. We need measurement tools that have adequate sensitivity and specificity, adequate ability to detect change in function over time, and adequate floor and ceiling characteristics for the population under study. For example, some key domains that could be measured are perception of exertion, fatigue, mobility, and stability.

Development of Tools That Can be Used in Biomechanical or Metabolic Measurement During Real-World Functional Tasks

The majority of the scientific biomechanical research has been done in a laboratory and oftentimes walking on a treadmill. This is inadequate to comprehensively quantify the effects of prosthetic feet on function. Equipment is available to accurately and reliably measure VO2 in the field. Techniques to measure impact transients, residual-limb torque, forces, and activity are needed. This should help better quantify the influence of prosthetic feet on function in a more “ecologically valid” way.

Additional Concerns

Prosthetic Foot Evolution and Rate of Production

The current practice of prosthetic foot development and introduction to the marketplace will pose significant challenges to the development and utilization of patient-specific criteria for prosthetic foot prescription. New prosthetic feet are being introduced regularly. These prosthetic feet are introduced without any published quantification of even their most basic functional characteristics. Any research done on evaluation and quantification of performance will always lag behind the marketplace. Although a long way from being a perfect solution, a key question that needs to be answered is whether or not it is possible to develop some simple instrumented quasi-static load deflection evaluations that all manufacturers will be required to perform on their prosthetic feet before bringing them to the marketplace, such as a heel-strike simulation, a forefoot keel dorsiflexion and release, and a medial and a lateral foot load to simulate the effect of walking on irregular terrain. These would allow some objective measurement that a clinician could understand so that new feet could be viewed in the context of feet available in the marketplace. So if a new foot was developed and its loading characteristics were quantified, you might be able to say, “It is better than a Seattle Lightfoot in absorbing energy at the heel but stores and returns less energy in the forefoot keel than a Renegade, and is about as stiff in the medial lateral plane as a LuXon® Max.” Ultimately new clinical studies would need to be done, but this could be used in the interim to help a clinician predict the utility of a foot for a patient with a given constellation of functional needs.

Time Delays in Funding, Conducting, and Publishing Research

Currently, the average time delay required to design and write a research proposal may span two to three months. Subsequently, there are additional delays from submission of the research grant through review, and, if successful, waiting for funding to arrive. After receipt of funding, depending on the study design, it will then take two to three additional years to complete the study. There will then be an additional 12- to 18-month delay before it is in print. Thus from inception to completion, five years may pass. This is incompatible with the rate of prosthetic foot development and testing. The use of modeling of different gait activities and the effect of foot design may ultimately allow the prediction of the effect of a novel foot without needing to conduct a three-year clinical trial. The development of these models will, of course, take time, and so will their validation.
References


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Interested in Submitting a Relevant Topic for Consideration for a State-of-the-Science Conference?

Topics for a State-of-the-Science Conference may be suggested by clinicians, educators, researchers, and other organizations associated with or engaged in the O&P profession. Final selection of a topic is made when agreement is reached by the Academy’s Planning Committee and with confirmation from the Academy Board of Directors.

1. Go to www.oandp.org/grants/MasterAgenda and review the conference guidelines.
2. Use the online topic suggestion form.
3. Topics should show the following:
   a. Relevance to current clinical practice
   b. Influence on a significant number of patients
   c. Importance to improving patient outcomes
   d. Controversy or lack of widespread consensus
   e. Presence of gaps between knowledge and practice
   f. Emerging or evolving concepts
   g. Quantity and quality of available peer-reviewed literature
   h. Degree of public interest
4. List three to six key questions to be specifically addressed about this topic.
   a. Questions should address efficacy, risks, benefits, and clinical applications of this topic, as these questions will determine the scope and substance of the conference.
   b. Questions should be straightforward and concise and framed so answers might be derived from scientific information and not based solely on subjective judgment or expert opinion.

The Academy will acknowledge receipt of all completed submittals and provide you with the Planning Committee’s recommendation or disposition. Unfortunately, not all topics will be approved or funded for a State-of-the-Science Conference. Approval of a specific topic does not ensure conference participation, as a national, multidisciplinary team of subject-matter experts will be developed by the conference chair and co-chair in collaboration with the Academy’s Planning Committee.
Effectiveness of Early Prosthetic Knee Function in Infants and Toddlers

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Brian Giavedoni, CP, MBA

Abstract
This case study describes the results of fitting of an articulating knee component in a child’s first prosthesis with respect to early mobility, crawling, and functional activities. Conventional wisdom suggests that children with limb loss at or above the knee should not receive an articulating knee component in their first prostheses. Some suggest waiting to fit a knee component until the child reaches four or five years of age. New data indicate that children may develop more natural motor patterns and demonstrate improved biomechanics when an articulating knee is placed in the first prosthesis, sometimes before the first birthday. A 12-month-old was monitored in crawling and functional activities in a biomechanics lab with and without an articulating prosthetic knee. The articulating knee joint improved biomechanical parameters associated with symmetry, efficiency, and typically developing motor performance in crawling and functional activities and is expected to promote more normal ambulation.

Background
Infant and toddlers with limb loss or deficiency who require a prosthetic knee joint present a unique rehabilitation challenge to clinicians. Historically, clinical protocols have placed the goal of stability over the goal of neuromotor development. With a prosthetic knee joint that locks into full extension during locomotion, or no knee unit incorporated in the prosthesis, stability is assured; however, gait deviations to achieve swing-phase clearance are known to develop, and other age-appropriate activities are hindered. In addition, in past years, prosthetic knee joints were not manufactured in sizes appropriate for infants and toddlers. Recently, however, appropriately sized knee joints have been developed to allow for flexion and extension during gait. Children’s Healthcare of Atlanta and Georgia State University have investigated the ability of infants and toddlers, 11–36 months, to control prosthetic knee functions during crawling with an articulating prosthetic knee and during age-appropriate activities. The central hypothesis guiding this work is that these subjects will demonstrate knee flexion function paralleling their non-amputee peers if provided with an articulating prosthetic knee at the first prosthetic fitting compared to diminished knee flexion functions if fitted with a non-articulating knee component.

Case Study
This case study involves a male congenital high right-side unilateral transfemoral amputee. At 12 months of age he received his first prosthesis, which included a modified quadrilateral socket, total elastic suspension belt, Otto Bock 3R38 pediatric prosthetic knee, and SACH foot. The analysis was conducted six days after prosthesis delivery to avoid the development of habitual motor patterns associated with the articulating knee.

Methods
Analysis of crawling and functional activities occurred at the Georgia State University Biomechanics Laboratory. Informed consent was obtained, and the protocol was approved by relevant Institutional Review Boards. For crawling, ten spherical markers were attached to landmarks on the torso and legs and
tracked using eight 120-Hz cameras and Peak Motus software (ViconPeak, Englewood, Colorado). Crawling trials were recorded with the knee articulating and repeated with the knee locked into full extension. Markers were removed and functional activities including tall kneel, crawl-to-sit, stair climbing, and climbing and descending a toddler slide were videotaped. Functional activities were also repeated with the knee locked.

**Results and Discussion**

Several differences were noted in the crawling patterns when the infant used an articulating knee versus a locked knee. While locking the prosthetic knee into full extension naturally limited prosthetic knee range of motion, increased motion and excursion was found in other joints. Contralateral knee flexion (Figure 1) increased by more than 18 degrees, perhaps in an attempt to increase step length, since step-through crawling was impossible with the locked knee (Figure 2). Hip abduction also increased in the contralateral limb by 10.9 degrees, a factor that might be associated with increased pelvic motion in the plane of the floor. Trunk motion was also affected, with increased rotation of the shoulders relative to the pelvis. Perhaps most important, crawling velocity was reduced substantially when the knee was locked. Figure 1 shows three complete crawling cycles. In the unlocked condition, the infant completed the cycles in two seconds. When the knee was locked, the infant required five seconds to complete three cycles. The knee flexion patterns for the locked condition reveal hesitation and higher frequency content indicative of an uncertain motor pattern.

Success in functional activities was reduced when the knee was locked (Figure 3). Several activities that are part of typical toddler development either became biomechanically impossible or were refused by the infant when the knee was locked. Functional activities were also repeated with the knee locked, were successfully completed with the articulating knee. During other activities, the subject used an abnormal posture or motor pattern to complete the task. For example, tall kneeling was achieved with the knee locked, but the child kneeled on only the contralateral limb, abducting the ipsilateral hip substantially to rest the prosthetic foot to the side.

These results suggest that the inclusion of an articulating prosthetic knee component in perambulatory infants will allow more normal motor patterns to emerge and will promote success in the development of walking and age-appropriate functional activities.

**References**

The Answer 2 Improving Orthotic and Prosthetic Patient Care and Clinical Outcomes

In 1960, Theodore Levitt published a paper in the Harvard Business Review titled “Marketing Myopia.” Its publication marked a paradigm shift in how companies and industries assessed their products and services, and what they needed to do to remain competitive in an ever-changing marketplace brought about by new competitive forces and product innovation. Levitt believes that most “organizations endanger their futures because they improperly define their purposes, and they too narrowly define the businesses they are in.” Levitt emphasizes that most companies tend to so narrowly focus on their products, services, and “know-how,” they create a culture that almost guarantees their premature senescence. By focusing primarily on a company’s core competencies, the company inherently limits not only the size of the potential market for the company’s products and services, but also future growth opportunities. It is for this reason that many companies have seen their opportunities for growth stalled—not because a particular market segment has become saturated, but rather due to a failure to see the opportunities that exist to meet potential customer wants and needs.

Do some O&P professionals today have myopic vision where footwear is concerned? Based on the profession’s reluctance to embrace and provide new products or product extensions, such as footwear, many patients and healthcare professionals would say yes. With a growing patient demand for providers of comprehensive footwear, many O&P professionals have failed to recognize patient needs and the potential market opportunities that are now available to them through the dispensing of specialty footwear. Most O&P professionals have remained on the sidelines as other healthcare professionals and non-healthcare providers have stepped in to fill the demand for footwear created by a growing diabetic patient population, an active aging population, and an underserved pediatric population.

Every day, orthotists and prosthetists fit patients with advanced custom orthotic and prosthetic devices. Utmost care is given by orthotists and prosthetists to ensure that the best possible orthotic or prosthetic devices are provided to their patients and that the fit and function of these devices meets the highest possible standards of care. However, once these devices are fit, most practitioners delegate the fitting of the footwear to someone else. In many instances, O&P patients are left on their own to find the appropriate footwear. O&P patients who are in need of accommodative footwear usually purchase their shoes at outlet malls, off the rack at a Wal-Mart, or are fit by a shoe salesperson at a department store. In each of these cases, patients are not receiving the same attention to their footwear needs that qualified orthotists and prosthetists provide in the delivery of the patients’ orthoses and prostheses. A publication of the National Shoe Retailers Association estimates that only 5 percent of all persons who sell shoes have any significant training or experience in fitting footwear. The number of individuals with specialty training for the fitting of accommodative footwear for patients with unique pathologies is significantly less than the 5 percent within the overall shoe fitter category. These statistics only serve to emphasize the need for orthotists and prosthetists to take on the responsibility of providing appropriate footwear for their patients.

While the O&P profession continues to ignore the needs and opportunities that currently exist within the accommodative footwear market, demand for footwear and footwear products is increasing dramatically within the United States. Today, there are more than 18 million Americans who have diabetic conditions, and that number is expected to skyrocket to more than 30 million over the next three decades. Approximately 15 percent of patients with diabetes will develop a foot ulcer during the course of the disease. Of those people with ulcerations of the foot, approximately 15 percent will require amputations. The three-year survival rate for diabetic patients who sustain foot amputations is 50 percent.

Prosthetists routinely fit diabetic lower-limb amputee patients with prostheses, and in many cases the prosthetists, during their patient evaluations, ignore the footwear their patients are wearing on their non-prosthetic limbs. One of the primary concerns of a lower-extremity diabetic amputee patient is making sure that he or she does not become a bilateral lower-extremity amputee. However unilateral diabetic amputee patients have a high probability of losing the other limb if appropriate education is not provided to them regarding the management of their diabetes, and no one makes sure that they are wearing appropriate footwear. In research conducted by Dr. Peter R. Cavanagh, PhD, DSc, there is evidence to support that inappropriate footwear is the cause of many foot ulcers in patients with diabetes and that appropriate footwear can significantly reduce the incidence of primary and secondary ulcerations. Based upon Cavanagh’s research, and the studies conducted by other researchers, every prosthetist should include foot exams and footwear evaluations as standard protocols in prosthetic patient clinical evaluations.

Orthotists routinely fabricate and fit patients with uniquely designed custom lower-extremity orthoses. However, after the
fitting of the orthoses by an orthotist, patients are oftentimes sent out into the marketplace to find footwear to fit over their AFOs, KAFO, or foot orthotic that has been provided to them. Trying to find appropriate footwear can be an extremely frustrating experience for patients, as they go store to store or log on to the Internet in an attempt to find footwear that will fit over their orthoses. Listed below are several quotes from patient postings on Internet chat boards that exemplify both the frustration experienced by patients trying to find appropriate footwear, and the joy when they find a solution to their footwear problems.

The Challenges and Frustrations

- “Just wondering if anyone would be able to help me at all. Laney just got her first pair of AFOs yesterday, and I can’t find any type of shoes to put the AFOs in. I was ready to pull my hair out at the stores today. I tried the less pricey shoes to expensive shoes, and I still couldn’t find a pair of shoes that worked with her AFOs. Can anyone offer any wonderful advice on getting a pair of children’s shoes that will work with AFOs?”
- “It made me so upset looking for shoes. There’s a market for this, and I wish I had the resources to do something about it.”
- “Hi, my son has some neurological problems that are similar to CP, and he also wears two-step AFOs. It has been a pain to find shoes that will fit over them.”

The Answer to These Challenges

- “There is a new specialty shoe that is made. You can probably get them wherever you got your AFOs. They are awesome. Called Answer2™ shoes. They look just like regular tennis shoes. (The ones we got for Ryan have little lights on the back!) They are extra wide to fit the brace without having to buy a ‘HUGE’ shoe to go over the brace. They stretch over the top and have Velcro to close. They are adorable! Ryan hasn’t been wearing his braces because we had trouble finding shoes for them, so then we had soles put on the bottom, but the rainy season is coming up, and I didn’t like him wearing ‘just braces.’ So anyway, thought I would share the information. We are really excited. Ryan is much more stable on his feet while wearing these. We got them yesterday. He isn’t falling as much!”
- “The shoes are simple! We found a brand called Answer2. We had so much trouble with that for over a year until we found out about these wonderful shoes. They are made for AFOs! You don’t have to buy big elephant shoes at all! They are made extra wide and extra tall. (They stretch at the top—with long Velcro straps. The kids shoes are adorable and have lights that light up...etc.) Several to choose from. They are cute, and you can’t even tell a child is wearing special shoes. They are easy, easy, easy to put on. (The tongue pulls all the way up to the TOES!) They have been such a blessing to us. They are cuter than any other shoes I’ve found, too!”

The Children’s Hemiplegia and Stroke Association (CHASA) devotes a page on its website to purchasing shoes. The website states, “You may think it rather odd to have a page devoted to how to purchase shoes, but it is a major issue for parents of children with hemiplegia. Many children with hemiplegia wear orthotics on their feet, and finding shoes that are attractive, yet fit with the orthotic, is often challenging.”

As exemplified by the Internet postings above, patients who wear orthoses and prostheses are in dire need of assistance in solving their footwear problems. Orthotists and prosthetists need to take the time to educate themselves and their patients on appropriate footwear. Orthotists and prosthetists should have a good understanding of footwear design, construction, and modifications, and they should educate their patients on the need for appropriate footwear in order to achieve the best possible outcomes with their orthotic or prosthetic device. O&P practices should also stock a small fitting inventory of shoes for patient and practitioner convenience. By having a limited inventory of shoes in stock, practitioners can fit the patient without having to special order several pairs of shoes for each patient. Patients appreciate the convenience of not having to shop endlessly for shoes as well as knowing that their practitioner has taken the time to ensure that the appropriate footwear has been provided.

Patients deserve the same attention to their footwear that is provided in the design, fabrication, and fitting of their orthoses or prostheses. Practitioners should not fall victim to becoming myopic in the delivery of O&P patient care. Theodore Levitt’s prescription for success includes expanding a company’s core competencies in the delivery of its products and services. Having the vision to provide patients with accommodative footwear provides O&P practitioners with the opportunity to meet customer expectations and seize upon a commercial niche that can provide a practice with increased financial returns.

References


If you have questions about setting up a footwear program in your practice, please contact Apis Footwear Company or SPS. Apis Footwear Company: 888.937.2747; SPS: 800.767.7776 x 3.
A Report on Ongoing Efforts to Advance the O&P Profession

The Academy’s U.S. Department of Education grant programming has entered its fourth year. The areas of focus remain awareness, education, and research to help advance the O&P profession. Following are some examples of the ongoing work and what we have found.

Using the Academy’s geographic map (www.oandp.org/grants/GeoMap), you can review the ratios of certified practitioners to potential O&P demands in your state and elsewhere in the United States. These results established important baseline data for future planning and identified areas where a qualified provider shortage is most acute.

While year I grant activities identified the ratio of practitioners to Medicare-based demands for each of the states, year II efforts identified and studied metropolitan statistical areas (MSAs) within the U.S. with the greatest need for O&P services. Year II used the same baseline data, but by using the MSA breakdown, it allowed the analysis to cross state lines to better identify metro areas that may be underserved. For example, small states like Delaware or Rhode Island may initially appear to be inadequately served, but with the MSA analysis, it was evident that practitioners who reside in a neighboring state may provide care. The MSA analysis confirmed the same states as being underserved while highlighting the specific underserved areas within each of the 50 states. Year II findings will be formally presented at the Academy’s 2007 Annual Meeting in San Francisco, California, March 21–24.

Year III efforts are focused on identifying the underlying attributes and characteristics that may influence the differences between demand for O&P services and the ability to meet them.

Work on the Academy’s strategic plan for an advanced degree is focused on training the future scientists and academic leaders in the field. As a result of year II’s O&P Education Summit that the Academy held in conjunction with NCOPE, it was decided that the entry-level practitioner education should shift to a master’s level by the year 2010. Armed with this information, a group of academicians and other subject-matter experts gathered in Chicago, Illinois, in December 2006 to develop basic cost estimates that would allow current O&P faculty to advance their education. Once these basic estimates can be determined, the grant team will pursue funding opportunities to meet these needs.

Also in December 2006, subject-matter experts gathered to develop a Research 101 curriculum under the master agenda grant program heading. Led by Mark Geil, PhD, these experts worked on a curriculum and delivery method to help make practitioners better consumers of O&P research. The courses will provide practitioners with the knowledge they need to search the current literature, understand the peer-reviewed publishing process, study designs, classifications, and elements of a peer-reviewed manuscript, and evaluate and assess manuscripts. All the courses are being developed in response to the demands for O&P professionals to better understand evidence-based medicine.

The next in the series of State-of-the-Science Conferences (SSCs) is slated for the spring of 2007. The SSCs’ findings led to the development of online professional continuing education (PCE) courses. Courses based on SSCs #6 (Prosthetic Outcomes) and #7 (KAFOs) will be available in early 2007 (www.oandp.org/OLC).

The entry-level education program continues to move forward. Grant year III has focused on developing a curriculum guide for the master’s program. Meetings were held throughout 2006 (June, August, and October), and educators will again gather this month in Dallas, Texas, to finalize the curriculum.

For updated reports on the grant and its findings, visit www.oandp.org/grants.
Raising the Standard of Patient Care for Iraqi Amputees

Members of the Iraqi security forces who have lost a limb now have an opportunity for faster, better treatment, thanks to a unique U.S. educational mission that spent five months in Baghdad in the first part of 2006. The five-person team, organized jointly by the Pentagon and the U.S. Armed Forces Amputee Patient Care Program, included Joe Miller, MS, CP, who served on the Academy’s Board of Directors before resigning to join the mission. “It was the first time the military put a rehab mission together to serve in another country,” Miller explained. “The war has shed light on what we prosthetists do. But there’s a different feel working in an actual combat area.”

When he left for Iraq, Miller—a first lieutenant in the Medical Services Corps of the Reserves—was working at Walter Reed Army Medical Center (WRAMC) in the Amputee Care Program, which he had helped overhaul so that it offered topnotch care and rehabilitation to wounded soldiers returning from Iraq. In addition to Miller, the military educational team included a physical therapist, occupational therapist, physical therapy aide, and occupational therapy aide.

After arriving in Baghdad in mid-January, the team began treating Iraqi soldiers and police in a clinic that had been started by two American soldiers (a prosthetist and orthotic technician) and laying the groundwork to expand and improve treatment through intensive education of selected Iraqi prosthetists, PTs, and OTs. The goal of the mission was to help the Iraqis build a self-sufficient prosthetic treatment infrastructure by focusing on four primary areas: education, business practices, workflow, and patient care.

Miller and his colleagues worked closely with two Iraqi prosthetists who had several years of experience as well as previous training in a Fillauer course in Jordan. The Americans taught a four-month course designed to broaden the Iraqis’ technical knowledge and capabilities, enhance their clinical skills, and improve patient outcomes by integrating PT and OT into the rehabilitation process. Mornings were filled with classroom instruction, and afternoons were devoted to treating patients.

To streamline workflow and increase the number of patients served, Miller introduced the 30-30-30 service model, where at any given time, Iraqi prosthetists would be seeing 30 new patients, working on fabricating prostheses for 30 patients, and delivering 30 completed prostheses. “Traditionally, the Iraqis saw a lot of patients, then did castings, then made the prostheses. That meant it could be several months until the first patients received their limbs,” Miller explained. In addition to reducing the fabrication timeline, it was crucial to minimize the number of patient visits, since coming to the clinic required risking their lives to enter the Green Zone.

The U.S. team also provided guidance on ordering supplies more efficiently, shortening the timeline for receiving components, and developing accuracy and accountability systems, as well as meeting the special challenges of working directly in a combat zone. For example, it was critical to arrange a way to get components safely to the clinic in a timely manner—not simply delivered to the airport.

With an eye on the long-term goal of developing a network of prosthetic facilities staffed by highly trained Iraqis, the Americans collaborated with Iraq’s Ministry of Defense and Veteran Affairs agencies. They hosted a three-day, short-term prosthetics course. The Iraqi prosthetists in the four-month training session recruited their colleagues and taught the course, gaining valuable training experience. Miller and the other mission participants provided support and feedback.

Since his return to the United States, Miller helped arrange additional training for the Iraqi prosthetists at a Fillauer course in Sweden. He remains in e-mail contact with them. Actively involved with the Academy during most of his 20-year career in prosthetics, Miller views his work in Iraq as a logical extension of the Academy’s mission to advance the standards of patient care, both domestically and internationally. “It goes hand-in-hand with the educational component,” he noted. “By providing a basic level of training, we can create and sustain programs in other countries based on first-world models versus third-world models.”

Throughout his career, Miller has focused on promoting the field of prosthetics and the highest standards of patient care, both within the military and beyond. In November, he moved from WRAMC to become deputy chief clinical prosthetics officer with the Department of Veterans Affairs (VA). He directly supports Fred Downs, head of the VA’s Prosthetics and Sensory Aids Service (PSAS), which is responsible for providing all prosthetics, orthotics, and sensory aids to disabled veterans across the country. In his new position, Miller plans to continue to build awareness for the need for additional research and high-tech care in both the military and private sectors. As always, he appreciates having the support and expertise of the Academy behind his efforts. “It’s very beneficial to have an organization like the Academy out there to help expand our influence,” he said.
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Answer 2 Shoes have also been the answer to my son’s increased independence. Other shoes just didn’t fit properly, were difficult to remove, and impossible for my son to put on independently. With the Answer 2 Shoes my son is able to completely dress himself in the morning. As a 3-year-old with spina bifida, being able to do something as simple as putting on his own shoes is a huge boost to his self-esteem. It is a milestone of independence; one that I cherish as a mom of a child with special needs. Thank you, SPS, for designing such an incredible shoe and making it available at such a reasonable price.

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