Lower-Limb Prosthetics Outcome Measures:
An Academy State-of-the-Science Conference

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Bilateral Transtibial Amputation and Delayed Wound Healing in Patient with Peripheral Vascular Disease: Walking with Prosthesis or Re-Amputation?

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September 2008

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Continuing the Tradition of Preparing Future Leaders

As I begin my duties as president of the Academy, the change is somehow anticlimactic. The reason is that as Wendy Beattie, CPO, FAAOP, completes her term as your president and I begin mine, the transition will be seamless and perhaps almost unnoticed. Why?

Academy leadership long ago recognized the importance of continuity in the sense that leadership changes do not necessarily signal changes in direction or priority.

The Executive Committee some time ago made a commitment to ensure that future leaders would be mentored by the previous leaders in preparation for their opportunity to serve. We are confident in our positions, where you, our members, want us to be, and what ultimately distinguishes the Academy professional from the rest of our profession. That stability reduces the significance of the “changing of the guard.” I look ahead with excitement as I begin my term and we move forward to what will be a great year.

The Academy views the challenges faced by our profession through the filter of the five pillars contained in our mission statement. I’d like to revisit those pillars, but first I’d like to differentiate who we are. We are “professionals advancing care through knowledge.” In this world, where knowledge is available virtually anywhere, we commit to improve the service we offer our patients through a continuous search for knowledge. In the midst of paying salaries, going through the accreditation process, and dealing with shrinking reimbursement, we strive to improve care. This is the hallmark of a professional and what distinguishes us from others. The Academy’s mission is “to promote high standards in patient care through advocacy, education, literature, research, and collaboration.”

As professionals, we advocate for the rights of our patients to receive care from qualified individuals and to choose who those individuals are. We believe payers should cover prosthetic and orthotic devices as necessary medical care because maximizing functional independence is not only good for the individual, but it is also good for our communities, our society, and our nation. Education is the cornerstone of who we are and what we do. Our Annual Meeting is the preeminent educational conference in the profession and continues to elevate the standards of education. The Paul H. Leimkuehler Online Learning Center (OLC) offers excellent education opportunities without the travel and expense required of more traditional models and creates a perpetual personal reference library for the professional seeking to learn. Go to an Academy chapter meeting and you’ll experience more of the same with a local flavor and have the opportunity to network with local professionals like yourself, sharing your struggles and successes.

If the body of knowledge defines a profession, literature is vital to our continued existence. The Academy, through publication of the Journal of Prosthetics and Orthotics (JPO), brings orthotic and prosthetic literature to your doorstep. The JPO is the only journal dedicated to the scientific publication of literature from and for our profession. Our new editor, David Boone, PhD, CP, LP, and the editorial staff at the JPO look forward to another strong year and more successes through strategic collaborations. Since the inception of the federal grant, the Academy has completed eight State-of-the-Science Conferences and published the findings. We have collected and reviewed the relevant literature on each specific topic and posed the questions still unanswered for future research in each specialty. With evidence-based practice on the horizon, our profession is faced with the challenge to develop and document its body of knowledge through effective research and publication. The establishment of the Orthotic and Prosthetic Education and Research Foundation is a first step. Intended as an independent entity to support research and education in O&P, this foundation will help to fulfill the future needs of orthotic and prosthetic students, educators, and researchers. In the meantime, we continue to work with the other organizations in our profession to support and develop meaningful research in O&P and maintain an ongoing dialogue with the research community.

As with any small organization, a key strategy for success is collaboration. The Academy’s involvement in the O&P Alliance allows effective communication and collaboration with other organizations within our profession in pursuit of our mutual goals. Collaboration with other allied health professionals remains a strategy to ensure that the Academy professional is well represented and recognized.

Recently the Academy Board of Directors attended a strategic planning retreat. During this exciting weekend, we envisioned the next three years and beyond of Academy initiatives. As these visions make their way into the council structure and begin to take root, I look forward to keeping you informed of our progress.

As I look to the year ahead, I do not know who will emerge as future Academy leaders, but I am confident that they will be capable and prepared to guide our organization through to its mission. I thank you for the confidence you have shown in me and pledge to continue the tradition of preparing future leaders.
Lower-Limb Prosthetics Outcome Measures: An Academy State-of-the-Science Conference

Introduction by Laura A. Miller, PhD, CP

With the expanded attention being placed on evidence-based practice, especially by insurers, there is a greater need to find effective ways to show efficacy of treatment and care. This State-of-the-Science Conference (SSC) was convened to examine the body of scientific knowledge related to lower-limb prosthetic (LLP) outcome measures. The meeting was held September 7–9, 2005, in Chicago, Illinois, and funding for this conference was provided by the American Academy of Orthotists and Prosthetists (the Academy) through a grant from the U.S. Department of Education (H235J040017). Experts in the field were invited to offer their insight and expertise in summarizing the evidence and identifying key areas for future research. It was the goal of the conference to examine, debate, and answer the following key questions.

1. What validated instruments are available in English to measure global lower-limb prosthetic outcomes?
2. What do these instruments attempt to measure?
3. What are the relative strengths and weaknesses of current instruments?
4. What are the barriers to clinical application of these tools?
5. In light of the literature review and the panel’s discussion, what are the primary future research priorities?

Conference participants contributed the following topics of focus for the SSC:

- Measurement of Health Outcomes: Reliability, Validity, and Responsiveness, Kathryn E. Roach, PhD, PT
- Lower Limb Prosthetics Outcome Measures: A Review of the Literature 1995 to 2005, Elizabeth Condie, Grad Dip Phys, FCSP
- Improving Health Care Quality with Outcomes Management, Allen W. Heinemann, PhD
- Predictive Outcome Measures Versus Functional Outcome Measures in the Lower-Limb Amputee, Robert S. Gailey, PhD, PT
- Tools to Measure Outcomes of People with a Lower Limb Amputation: Update on the PPA and LCI, Christiane Gauthier-Gagnon, MSc
- Use of the Prosthesis Evaluation Questionnaire (PEQ), David Alan Boone, BS, CP, MPH
- Development and Application of the Orthotics and Prosthetics User Survey: Applications and Opportunities for Health Care Quality Improvement, Allen W. Heinemann, PhD
- Use of a Step Activity Monitor in Determining Outcomes, David Alan Boone, BS, CP, MPH, PhD
- Use of Quantitative Gait Analysis for the Evaluation of Prosthetic Walking Performance, Steven A. Gard, PhD
- Overview of Outcome Measures for the Assessment of Prosthetic Foot and Ankle Components, Brian J. Hafner, PhD
- Outcomes from the Surgeon’s Perspective, Michael S. Pinzur, MD
- Special Challenges in Outcome Studies for Amputation Surgery and Prosthetic Rehabilitation, Douglas G. Smith, MD
- The Walter Reed Experience: Current Issues in the Care of the Traumatic Amputee, LTC Paul F. Pasquina, MD
- Barriers to Clinical Application: A Prosthetist’s View, Jack E. Uellendahl, CPO
- The Development of Coverage Policy for Lower-Extremity Prosthetics: The Influence of the Payer on Prosthetic Prescription, Deanna Fish, MS, CPO

The discussion was facilitated by an extremely thorough and comprehensive written review of the literature that was completed by Elizabeth Condie, PT, FCSP, and colleagues, and which was provided to the participants prior to the meeting and is included in the final proceedings.

Outcome measurement tools can evaluate either the actual level of performance or perceived performance and can also be generic or population specific (e.g. for lower-limb amputees). Although there was a general preference for population-specific outcome measurement tools, which may be more responsive, one primary conclusion that emerged from the discussion regarding the strengths and weaknesses of outcome measures in LLP was that although there are many tools that have been validated in one situation, this does not mean they can be used in any situation. The tool must be validated for the specific application (that is, for the question to be answered and population to be studied). Other than the outcome measurement tools summarized by Condie, there were also presentations and discussion about the use of gait analysis and about the findings of the Academy SSC on the evaluation of prosthetic foot/ankle mechanisms.
In addition to discussing the tools themselves, there was an assessment of the general challenges to the use of outcome measures in a clinical setting. One of these challenges was the general selection of the tool and whether it should evaluate overall function or the patient’s subjective perception of this function, which may not always coincide. Additional discussion included the challenges of administering these outcome measurements in a clinical setting where time is already limited.

However, there was no question that there is a need to continue the implementation of these tools in the tightening healthcare market. To better justify new components, it is important to show not only how this technology can improve function or quality of life, but also how optimal care can reduce the need for more expensive healthcare overall. However, to show an “improvement,” it is necessary to have a well-defined and well-designed study that accurately identifies which changes in function and/or quality of life are expected and clearly chooses an appropriate outcome-measurement tool based on this hypothesis.

Overall, five research priorities and their order of importance were agreed on by the participants. The primary future research questions were then categorized into these five priority areas: (1) healthcare economic impact; (2) rehabilitation guidance tools; (3) activity limitation/performance measures; (4) pain and comfort; and (5) quality of life.

Healthcare economic impact was agreed to be the most important category, with rehabilitation guidance tools second. After determining the list of five research priorities, the group discussed the current outcome measurement tools and categorized them according to priority. Specific topic areas of research in each of the priority areas were recommended.

This group, with experience and training in many areas, brought a rich contribution to the areas of discussion. Given the breadth of the topic, final conclusions on the “best” outcome measure were not found, but recommendations for the use of certain existing tools were made, as were recommendations for future research. These recommendations are summarized in the State of the Science Conference Findings on Lower Limb Prosthetics Outcome Measures, published in 2006.

The Academy continues to share and update the results through certificate programming and an online course that was recently released.

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**Improving Health Care Quality with Outcomes Management**

**Allen W. Heinemann, PhD**

**William P. Fisher Jr.**

**Richard Gershon, PhD**

More than one million people in the United States have sustained loss of a limb caused by injury, diabetes, cancer, vascular disease, infection, congenital conditions, or other diseases. In 1996, most persons losing limbs were male (69.5 percent) and white (92.5 percent). The leading causes of limb loss between 1988 and 1996 were dysvascular (82.5 percent), followed by traumatic (16.5 percent), and cancer-related (1 percent), with most amputations (86 percent) involving lower extremities. Almost 200,000 persons in the United States used an artificial limb in 1994, and about 87 percent of those limbs involved a lower extremity.

A significant increase in the number of persons requiring orthoses and prostheses is expected in the coming years, just as the number of professional orthotists and prosthetists (O&P) declines significantly. The divergence in O&P supply and demand requires a paradigm shift in the service-delivery system and enhanced quality improvement efforts.

Health tracking has been shown to provide returns on investment of $1.44 to the federal government alone for every federal dollar invested. The American public and economy would be likely to obtain a considerably higher return when potential insurance-cost reductions, saved workplace productivity, and the human value of improved health are considered. The need to measure and evaluate rehabilitation practice in general, and orthotics and prosthetics practice specifically, has received growing recognition in the past several years. Fuhrer outlined recommendations for medical rehabilitation outcomes research generated at a 1994 conference organized by the National Center for Medical Rehabilitation Research (NCMRR). Critical to NCMRR’s agenda, and reiterated throughout the report, is the need for valid, reliable,
and change-sensitive outcome measures to evaluate the efficacy and effectiveness of rehabilitation practices. The American Board for Certification in Orthotics, Prosthetics & Pedorthics (ABC) echoes this call by encouraging outcomes measurement and clinical pathways within the context of a continuous quality-improvement process.\(^6,7\) ABC’s quality assessment and improvement standard states: “There is an ongoing quality assessment and improvement program designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve orthotic and/or prosthetic care, and resolve identified problems.”\(^9\)

Despite the ongoing quality efforts and interests of providers and accreditation agencies, healthcare has not yet reproduced the quality revolution provoked in the automobile industry by Toyota in the 1970s.\(^10\) “Executives within healthcare organizations, both health plans and providers, generally view quality improvement as an ethical responsibility or a social good, rather than as a business strategy for improved financial performance and competitive market positioning” (p. 764).\(^11\) There are four reasons healthcare executives find it difficult to make a business case for quality and to “pursue perfection” in the manner of other industries. First, other industries pursue perfection as an ideal or heuristic goal, that is, by computing mathematical parameters for quality and engineering performance relative to those parameters. These parameters have been proposed in a significant body of research in healthcare but have not yet moved beyond isolated research applications.\(^12,13\)

Second, other industries produce their desired outcomes, their products, by directly managing their measures. That is, the measures are not indicators separate from the product, something different and apart that represents the outcomes in certain contexts such as accreditation. Rather, the measures themselves are managed. The measuring instrument is the medium of the outcome message. Managing the message and telling the outcome story is then a matter of managing the measure.

Third, other industries, in contrast with healthcare, share a common frame of reference for evaluating quality. This common frame of reference stems largely from industry-wide shared product definitions. Unfortunately, healthcare is a $1 trillion per year industry “without a clear measure or definition of its main product.”\(^14,15\) Without a shared product definition, it is impossible to coordinate industry-wide efforts into focused quality assessment and improvement. Historians of science illustrate how widespread availability of standardized instrumentation is usually a prerequisite for advances in theory and practice.\(^16,17\) We have the mistaken perception that technology is a product of science, whereas “historically the arrow of causality is largely from the technology to the science.”\(^18,19\) The availability of a common language implemented in a stable frame of reference effects a qualitative transformation in our ability to think together in a distributed but collective manner, multiplying and magnifying the impacts of individual ideas by making them more readily accessible and comprehensible.\(^20-22\)

Fourth, manufacturing and service industries typically seek to control every aspect of the products and services they deliver. In contrast, healthcare is restricted in dealing (1) with a limited set of the total number of factors that ultimately influence an individual’s health; and (2) with sequential and usually non-overlapping samples of the total population of relevant patients. Because patients may live in environments that reinforce negative health behaviors, healthcare providers may feel powerless about their ability to promote population health. Thus, the return-on-investment (ROI) model most relevant to healthcare is not the usually assumed quality-improvement focus, but one of facilitating cost-avoidance while maintaining, and less often improving, quality.\(^23\)

Quality improvement is fundamentally a matter of determining which resource investments make a difference and which do not.\(^24\) Resources invested in producing outcomes, but which cannot be shown to contribute to those outcomes, may, in effect, be wasted resources. However, an overly narrow focus on clinical indicators tends to devalue and disregard vitally important human and social outcomes. The historical difficulty associated with measuring the qualitative and intangible human outcomes of healthcare has been reduced considerably by advances in fundamental measurement theory and practice.\(^25,26\) It is now possible for survey-based instruments to provide objective measures that have the veracity of temperature, time, weight, and length.\(^6,27,28\)

**Centrality of Patient Satisfaction in Health Outcomes**

Accordingly, patient perspectives on the benefits of devices and services and satisfaction with services are widely recognized as important areas of rehabilitation and in healthcare generally. Donabedian\(^29\) states that “patient satisfaction may be considered to be one of the desired outcomes of care, even an element in health status itself.…. Information about patient satisfaction should be as indispensable to assessments of quality as to the design and management of healthcare systems” (p. 1746). Ware et al.\(^30\) state that health status and patient satisfaction are the primary outcomes of interest for rehabilitation care. The greatest challenge, they argue, is the lack of standardization in measures that would allow outcomes to be compared across programs.

Patient satisfaction reflects expectations, prior healthcare experiences, and quality of healthcare. Patients might measure high on a satisfaction scale less as a result of quality care than as a result of being impressed with a prosthetist’s authoritative opinion, an orthotist’s caring touch, or an expensive device. The relevant question to ask is this: To what extent will managing
this measure contribute to the quality of the processes and outcomes produced? It is possible that a focus on satisfaction could produce high measures bearing no relationship to the quality of the relevant processes and outcomes.

Patients who are active participants in their care, ask informed questions, and contribute to the decision-making process tend to have better outcomes than do those who do not. Measures of patient-centeredness or of patient “activation,” as it is also called, may be fundamentally important in quality improvement, as was noted by the O&P industry.

A survey sponsored by the Amputee Coalition of America (ACA) and reported by the Amputee Resource Foundation of America suggests that many persons needing O&P care feel excluded from the care process, with 75 percent of the respondents saying they needed more educational materials than were provided and 57 percent saying they received no educational materials. For the 43 percent who received materials, only 15 to 20 percent of those materials were deemed helpful. It seems that satisfaction with quality of care should not be operationalized so much as a function of patients’ opinions as much as a function of the extent to which they have been engaged by the provider in the process of care.

Measurement of patient satisfaction typically focuses on patients’ opinions in such a way that the objects of concern are not integrally intertwined with the process of care itself. That is, patients are not made the center of concern; consequently, quality is disconnected from anything of importance to the actual outcomes of care. Instead, the clinic or the staff is made the object of concern in the name of facilitating an administrative focus that conflates the care process with the care outcome. However, focusing on the relationship with the patient tracks the established association between patient participation in the care process and the quality of the outcome. Hibbard et al. show that the activation continuum is defined by four distinctive aspects of attitude and behavior: (1) belief in the importance of taking an active role; (2) confidence in one’s ability to take action; (3) active participation; and (4) persistence in staying the course under stress. These four domains fall in a relatively invariant order across healthcare providers and consumers. Patients with higher activation measures are more likely to engage in appropriate disease-management tasks and are less likely to access the healthcare system.

Patients are more likely to be activated when their providers encourage them to be activated. Thus, a patient activation measure ought to function as a tool by which healthcare providers can effectively locate, engage, and move patients along the activation continuum. This kind of functionality is beyond the scope of satisfaction measures in providing a means of embedding assessment in the practice of care, following the recently established models of integrated assessment and instruction that are becoming commonplace in education.

Rigorously scaled and universally uniform patient-centered outcome measurement has the potential to inform both the valuation of care quality in the most relevant human terms and the evaluation of care quality in the strictest economic terms. For the healthcare economy to function more in accord with the economies of other industries, common currencies for the exchange of human and monetary value must be scientifically calibrated and deployed.

**Principles of Quality Improvement Measurement**

Four principles of a technically sound, diagnostically relevant, and clinic-based quality-improvement system incorporating patient self-assessments can be traced from recent work in measurement theory and alternative assessment methods gaining increasing use in education. The four principles assert (1) the value of clear expectations routinely checked against observations; (2) the need for therapeutic validity; (3) that assessment and care must be patient-centered, but the system must be clinic-based and clinician-managed; and (4) that the evidentiary basis of decision making is rigorously consistent, unbiased, and comparable across cases.

The first principle is the basic principle of management. We manage what we measure, and what we measure establishes clear expectations as to what should be happening when and where and with whom. Measurement is most clearly meaningful when numbers consistently represent the same amounts of the construct measured across patients, instruments of a type, clinicians and clinics, time, and space. When expectations are confirmed or refuted by observations, management relies on measurement to indicate what comes next in the order of things. Instruments that are valued by the O&P industry must define continua of more and less functional status, quality of life, and patient activation, with the therapeutic goal being to raise the measures to their optimum levels and the quality goal being to optimize the cost/benefit ratio.

Thus, it is essential for the measures to be therapeutically valid, taking us to the second principle. What is assessed must match what is being diagnosed and prescribed. This is, of course, the often overemphasized basic tenet of content validity. We must ascertain that the items included on the patient self-report surveys are relevant and representative of the entire population of items, tasks, and problems that a patient might conceivably encounter. But ensuring representative content must be balanced with construct and consequential validity. Highly content-valid items may not work together to produce the consistent quantitative evidence required for interpretable and manageable measures. So in addition to covering the relevant content domain, the items on an instrument must fall in a theoretically meaningful and empirically supported order capable of indicating when a better outcome and higher quality care are achieved.
Clinically valid patient-reported measures require clinicians to be responsible for managing them, our third principle. Clinicians, not patients, are the ones best prepared and situated to make the fullest use of the assessment information in the process of guiding diagnosis and treatment. The interpersonal contact established at the point of care involves the clinician and patient in the context of the need for care. Neither the patient nor any third party has the degree of involvement or the background of training and experience required for responsibly managing these patient-based quality indicators. If quality measurement is to be practical, it must be an integral part of the practice.\textsuperscript{42, 43}

To meet the demands of this responsibility, clinicians require interpretable feedback at the point of care, bringing us to the fourth principle. One of the most common and longstanding criticisms of patient reports concerns the quality of the evidence provided. Not only are patients’ perspectives on their own conditions variable and of questionable comparability, the instruments representing those perspectives to clinicians are themselves often poorly designed and inadequately evaluated. As noted above, fundamental measurement theory\textsuperscript{12, 13, 25, 26} can provide clear and effective guidance in instrument design and calibration, such that data quality and comparability are based on mathematically sound principles of invariance, statistical sufficiency, and parameter separation.

**Summary**

Continuous quality improvement requires that we must first measure to manage care processes and outcomes. Healthcare quality instruments in general, and O&P instruments in particular, are rarely developed with the kind of care and precision taken for granted in other industries. New technologies for precision measurement in healthcare have recently emerged, creating new opportunities for informing quality improvement efforts. Orthotics and prosthetics could be one of the first areas of healthcare to employ these technologies, take advantage of the new opportunities, and establish common product definitions and comparable outcome measures, en route to rebalancing the cost/quality equation.

**References**


18. Ihde D. Instrumental Realism: The Interface Between Philosophy of Science and Philosophy of Technology. The Indiana Series in the Philosophy of Technology.


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Bilateral Transtibial Amputation and Delayed Wound Healing in Patient with Peripheral Vascular Disease: Walking with Prosthesis or Re-Amputation?

Anton Johannesson, CPO

Abstract

This article presents a case study to introduce an alternative to a re-amputation at a higher level when dealing with delayed wound healing after transtibial amputation in patients with peripheral vascular disease (PVD).

Despite a large wound after transtibial amputation, a prosthetic fitting was performed. By mobilizing the patient with a vacuum-suspended prosthesis and a total-surface-bearing (TSB) socket, the rehabilitation was started. This method provides an alternative to prolonged rehabilitation or re-amputation at a higher level, both with a risk of poor functional outcome.

Background

When a major amputation is unavoidable, it is essential to select the lowest level that will allow both healing and optimal function. Delayed or failed healing at more distal amputation levels is known to increase morbidity and prolong hospitalization. The choice of a more proximal amputation level benefits wound healing, but lowers the odds of the patient becoming a prosthetic user.1 This may lead to more social isolation, less independence, and other negative effects regarding the quality of life of the patient.2 Traditionally, an individually made prosthetic socket is not provided until the wound is completely healed, especially in elderly PVD patients. Vacuum-assisted closure for chronic non-healing wounds is a well-known method of treatment today.3 Creating sub-atmospheric pressure within a prosthetic socket is possible by using an airtight suspension sleeve. The weight of the prosthesis creates a negative pressure within the socket in the swing phase. During full load, a positive pressure is produced. It is hypothesized that this enhances the circulation at the distal end of the residuum and promotes the healing process.

Case Study and Methods

A left-side transtibial amputation was performed on a 65-year-old female with PVD. After rehabilitation with a TSB socket, good functional status was obtained although circulation in the right leg was poor. One year later, after unsuccessful vascular surgery, a transtibial amputation was performed on the right side, leaving a short residual limb. The tissue cover was poor due to previous surgery, which resulted in a necrotic area distally around the suture line (12 x 8 centimeters). Fifty-five days after the surgery, the wound was clean and showed good signs of healing (figure 1). The cavity of the wound was filled with highly absorbing bandages and covered with thin plastic film. A silicone liner without a distal adapter was rolled on. A prosthesis was provided using a pressure-casting socket (ICEX™, Össur Inc., Reykjavik, Iceland) with a distal valve, lightweight pylon, and foot. An airtight suspension sleeve was used to provide vacuum suspension. The dressings were changed at intervals depending on the amount of leakage from the wound to avoid wound fluid coming into contact with healthy skin. The amount of weight put on the leg and the walking distance was increased during this period, and the patient was in charge of the speed of progress. The prosthesis was used most of the day (minimum eight hours), and the patient stayed at home during the entire healing period. During the first three weeks, the patient came in three times a week for wound inspection and training; after that, the patient only came in once a week. After four weeks, the size and the depth of the wound was reduced to half (figure 2). After eight weeks, a three-ply sock was added for better fit and comfort (figure 3). After 12 weeks, the wound was totally healed (figure 4).

Discussion

In this case, a higher-level amputation was not an option if walking ability was to be reestablished. The traditional practice of delaying the prosthetic fitting until the wound is completely healed would not only have prolonged the healing time but presumably the patient would have adjusted to a wheelchair, risking knee and hip contractures. This case study shows favorable results demonstrating that a TSB vacuum suspension socket can enhance the wound healing through better distal blood circulation. This shortens the rehabilitation time and helps avoid a re-amputation at a higher level. Further research is warranted to explore the approach.
author has now used this method for ten years in more than 20 cases of delayed wound healing without any setbacks. The method requires good teamwork between the doctor, the wound specialist nurse, the physiotherapist, the prosthetist, and, most of all, the patient.

References


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The first exploration of CAD/CAM in the O&P industry began in the 1970s with applications targeted at lower-limb prosthetics, with a transtibial focus. Until recently, development continued to be concentrated on lower-limb prosthetics. The technological requirements for capturing most residual limbs, which are typically cylindrical, are not quite as complicated as they are for most orthotic shapes; for example, an AFO, which is not a simple cylinder but, instead, a bent cylinder. However, recent advancements in technology, accompanied by a decrease in the cost of this type of technology, have opened the door for orthotic applications to be developed much more aggressively. In the last two years, more development has been focused on the expansion and advancement of orthotic applications, with the greatest emphasis on the challenge of shape capture/acquisition.

Shape Capture

In prosthetic CAD applications, it is common to take an electronic image of the limb without the need for any plaster at all. When a foot and ankle are brought into the equation, though, the process is not as straightforward. Different approaches are required according to factors such as anatomy, pathology, and the amount of detail required in the final device.

If the patient has little or no deformity or contracture, scanning the patient directly is an appropriate clinical application. This process actually involves two scans. The foot is placed in a foam impression box to provide an impression of the plantar surface and to aid in the stabilization of the limb during scanning. Reflective markers on the patient identify landmarks to be transferred into the 3D image. Reference landmarks are also placed on the flat surface of the foam impression box and are included in both scans. For the first scan, the entire lower leg, including the ankle region and dorsum of the foot, is scanned. Once the first scan is complete, the limb is removed from the foam impression box and the plantar imprint is scanned. The software uses the reference landmarks to assemble a complete model from the two scans.

For patients with moderate to severe contractures or little muscle tone who require a significant amount of manual correction in order to return the leg to a more functional and anatomically normal position (preferably subtalar neutral if functionally possible), an intermediate step is required. A cast is taken, and then the cast—not the patient—is scanned. This is accomplished by scanning the outer surface in a single step, or by splitting the cast in half and scanning the inner surface.

If the patient displays a lack of definition in the foot and ankle, or if the device will not include any highly prominent anatomical features (as, for example, in a posterior-trimmed AFO), then it is clinically appropriate to scan the outer surface of a well-contoured, smooth cast that has uniform wall thickness. Landmarks are identified with reflective markers on the outer surface of the impression.

On the other hand, if the patient’s anatomy is well defined, if significant muscle tone or contractures are present, or if the device will include highly prominent anatomical features (as, for example, in a tone-reducing or articulated AFO), a scan of the outside of a cast does not provide the required anatomical detail. In this case, the most clinically appropriate scanning option is to scan the inner surface of a cast that is split into medial and lateral halves. Landmarks are identified with reflective markers and each half of the cast is marked with three corresponding reference landmarks along the cut edge. After each half is scanned, the software uses the reference landmarks to assemble a complete model.

Modification

Once the model is captured and reassembled (if applicable), the model is modified to achieve the desired design by using a variety of “tools” in the software.

Alignment correction is achieved by using a selection of tools designed specifically for the correction of the foot and ankle. Plantarflexion/dorsiflexion, inversion/eversion, internal/external rotation, pronation/supination, and forefoot adduction can all be adjusted across a user-defined area of the model.

Surface modification is accomplished by using a series of tools designed for the specific modification needs of an AFO. The arch can be raised or lowered, a relief pad can be applied and modified, and freehand builds and carvings.
can be accomplished. The toebox area can be flattened to accommodate a full foot plate and can also be lengthened to allow adequate room for fabrication and finish work.

Finally, a trim line is established to provide a guide during the finishing process. Multiple trim lines can be applied to create a floor-reaction-style AFO; a popliteal shelf can also be applied to create a PTB-style model.

If desired, the user may select a group of tools, arranged in a preferred order, and save it as a custom “modification wizard” for future use. Different wizards can be created for various modification needs. After selecting a modification wizard according to the needs of the patient and the type of device to be fabricated, the user is automatically prompted through each of the steps in that particular group.

Fabrication
The AFO model is then carved from either one block of foam or from two smaller blocks. The two-part process can be utilized by carvers that cannot reach beyond the rotational axis. An average adult-sized AFO will carve from a single block of foam in approximately 17–20 minutes (or 35–40 minutes for higher resolution), while an average two-part AFO will carve in approximately half that time.

Fitting
AFOs created from scanning the outside of a cast may require a radial or global volume reduction depending on the wall thickness of the cast. Additional reduction may be needed in the calf area, depending on the amount of musculature or soft tissue of the patient. If this is the case, a reduction can be made in an isolated area in addition to or instead of a global reduction.

AFOs created from a scan of the inner surface of a cast, as well as those created from a direct scan, typically require a 1mm radial increase to accommodate for the thickness of a sock to be worn under the device.

Documentation
The use of CAD/CAM provides the ability to document changes in a patient’s volume and length over time, as well as the ability to view a model before and after modification. Several of OMEGA® Tracer’s® software tools, such as those that allow two images to be overlaid or compared to each other, provide documentation for changes in length, A/P, M/L, circumference, and volume. All modifications performed to the model are recorded in a non-editable format within the software. These capabilities also provide benefits for applications other than AFOs; for example, these tools allow documentation of the correction over time that is provided by a cranial remodeling helmet.

Future of CAD/CAM
The future of orthotic applications for CAD/CAM continues to be the focus for both short and long-range research and development efforts. The immediate future offers electronic shape capture for spinal applications and the direct milling of insoles.

Summary
CAD/CAM technology, when applied and implemented correctly, affords consistency, repeatability, and standardization of patient care. The utilization of a non-contact method of shape capture establishes a repeatable and consistent method of capturing and tracking shape and volume changes, and generates an electronic record of the patient on demand whenever needed. The customizable modification wizards provide the flexibility and control of creating a specialized modification protocol that can be applied consistently. Advanced comparison capabilities allow us to compare and contrast models before and after modifications, as well as over time, to check for changes. The benefits for the creation of AFOs are significant, but are also applicable to a wide range of orthotic and prosthetic applications.

About the Author
Jennifer Dowell, CPO, earned a bachelor of science degree in prosthetics and orthotics from the University of Washington, Seattle, in 1990. She spent the first ten years of her practice in traditional clinical care before specializing in the development, testing, and instruction of CAD/CAM technology for the O&P profession. She is the OMEGA research clinician for Ohio Willow Wood, Mt. Sterling, Ohio.
Expanded O&P Online Education

For the past several years, the American Academy of Orthotists and Prosthetists, with funding from the U.S. Department of Education, has advanced the profession in the areas of awareness, research, and education. The grant funding1 made it possible for the Academy to conduct a series of State-of-the-Science Conferences (SSCs) to document the scientific foundation for clinical practice in O&P. Written proceedings of the SSCs are available in print and online at www.oandp.org/SSCs. An array of online professional continuing education (PCE) courses, based on these conference findings, are available through the Paul E. Leimkuehler Online Learning Center (OLC) at www.oandp.org.

The newest addition to the PCE course series is based on SSC #8, The Biomechanics of Ambulation after Partial Foot Amputation (PFA), which was held in March 2007. The multidisciplinary, multinational panel of experts reviewed the scientific literature regarding the biomechanical function during level ground walking of persons with PFA to establish what is known, what is believed to be true, and what needs to be known to optimize ambulation for these patients. It was recognized by the participants that biomechanical analyses of devices used for ambulation with PFAs are only one aspect of the prosthetic/orthotic prescription. Factors affecting protection of fragile skin, prosthesis comfort, and aesthetic value are also of critical importance when selecting the most appropriate prosthetic prescription. This 100-question course carries 22 PCE credits.

Other PCE Courses Developed from SSCs

- Orthotic Treatment of Idiopathic Scoliosis (16 PCE credits)
- Post-Operative Management of the Lower Extremity Amputee (10 PCE credits)
- Orthotic Treatment of Deformational Plagiocephaly, Brachycephaly, and Scaphocephaly (16 PCE credits)
- Orthotic and Pedorthic Management of the Neuropathic Foot (12 PCE credits)
- Prosthetic Foot/Ankle Mechanisms (12 PCE credits)
- Outcome Measures in Lower Limb Prosthetics (32 PCE credits)
- Knee-Ankle-Foot Orthoses For Ambulation (19 PCE credits)

Those who visit the OLC will also see the new course on evidence-based practice (EBP). Through the Academy’s grant, the course was initially presented in the fall of 2007 as a one-day seminar and then again at the 2008 annual meeting. It is now available online as a six-module course designed to define EBP and simplify it. Individuals may take individual modules for credit or complete the full course for a certificate.

The goal of the course is to provide a cohesive guideline to help improve and justify the clinical care for patients. The module topics are listed below.

1. EBP Overview and Evaluate the Problem
2. Form an Appropriate Question
3. Assess the Available Resources
4. Search for Available Evidence
5. Critically Evaluate the Evidence
6. Apply the Gathered Information

Be sure to use these and all the other great resources at the OLC for convenient, 24/7 access to high-quality education.

1SSCs #3–8, the printing and dissemination of the conference proceedings, and the development of all PCE courses were fully funded by grants from the U.S. Department of Education — H235R040001; H235J040017; H235R050001; H235J060001.

‘Best of the Resident Research Series’ Selected

The Academy Research Council’s Research Education Committee reviewed more than 100 resident research papers to narrow down the “Best of Resident Research.” All papers were evaluated based on their originality, method, conclusions, and relevance, as well as the quality of the writing.

Those with top ratings presented original research or an original solution to a clinical problem. The research methods employed were described in detail and were valid, reliable, and appropriate. The conclusions were supported by the results and careful consideration was given to alternative interpretations and limitations. Finally, the study was directly and immediately applicable to clinical, theoretical, or educational problems.

The best prosthetic-related research includes the following:

- “Implementation of a Progressive Resistance Training Exercise Program for Persons with Unilateral...”
Transtibial Vascular Amputation to Show Strength Gains” by Heather Houston, CP

• “Further Study of the Protective Effects of Rigid Removable Dressings for Recent Transtibial Amputation Patients” by Aaron Tarnow, CPO, and Thomas Sorensen

The best orthotic-related research includes the following:

• “A Survey of Current Trends of Pediatricians in Maryland for Screening of Adolescent Idiopathic Scoliosis” by Angela Bryl Swindell, CO

• “Outcomes of Orthotic Treatment of Adolescent Idiopathic Scoliosis: A Gender Comparison Study” by Hailey Smith, CO

Papers that do not qualify as research using the scientific criteria applied by the Research Council, but which may still be of interest to our membership, are posted under the category of Papers of Interest. We encourage you to view papers in this section as well.

• “Design and Use of a New Socket-Adjustment Tool” by Chadwick McCracken

These new research papers and past honorees are posted at www.oandp.org/publications/resident

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