The Hinnant Prosthetics Quarterly

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Mobility Technology Pushes Forward

The majority of orthotic and prosthetic devices today are focused on helping people overcome deficiencies of the lower extremities—ankle-foot orthoses, below-knee and above-knee prosthetic limbs, and diabetic footwear being the most prevalent. Thus it comes as no surprise that the lion's share of O&P research and development addresses improving the mobility of amputees and individuals with various other lower-limb deficiencies.

This article reports on two emerging concepts that, though not yet in the rehabilitation mainstream, show promise for helping physically challenged patients return to their former active and pain-free lifestyle.

What's Coming

Push-off Power for Amputees

Perhaps the most significant barrier to full mobility for lower-limb amputees is fatigue resulting from the considerable effort and energy-expenditure of powering a prosthetic limb through the gait cycle. Even with a dynamic-response prosthetic foot, amputees use substantially more effort to position their leg and propel themselves forward than their non-amputee counterparts.

The iWalk **BiOM** is the world's first leg prosthesis to provide powered plantar flexion as well as real-time terrain adaptation. In so doing, the system delivers a near-normalized symmetrical gait for amputees at roughly the same metabolic demand of non-amputees... an important breakthrough.

In place of the passive spring core of the typical contemporary prosthetic foot, the battery-powered BiOM incorporates microprocessors, gyroscopes and motors to sense the wearer's ambulatory purpose and respond with the appropriate positioning and force, effectively replacing the function of the absent calf muscle and Achilles tendon.

iWalk BiOM prosthesis

Another important feature is the BiOM's ability to absorb ground impact at heel strike. An estimated 80 percent of lower-limb prosthesis-wearers experience significant back pain and encounter joint deterioration within five years. The BiOM's engineering reduces unnatural impact stress, pain, pressure within the prosthetic socket and joint trauma. At the end of the day, BiOM users report they have more energy, less pain, and the feeling of having their leg back.

The BiOM is now available for above- as well as below-knee applications.

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Promise and Challenge in O&P

We are living in a time of significant change in American orthotic and prosthetic practice. Even as technological advances increase mobility and lifestyle horizons for physically challenged individuals to levels thought impossible just a few years ago, growing government medical insurance "red tape" is denying those very advances to many of the patients who need them.

This newsletter reports on two exciting new developments in O&P componentry, as well as the "elephant sitting in the living room," the recently implemented Medicare requirement that physicians bear the burden of documenting medical necessity for their patients' lower-extremity prosthetic care...a role long handled by the prosthetists who delivered that care. We also review the inspiring participation of bilaterial amputee Oscar Pistorius in the 2012 Olympic Games.

Hinnant Prosthetics Quarterly is a professional newsletter published since 1998 by Hinnant Artificial Limb Co. to keep physicians, therapists and other rehabilitation professionals abreast of the latest trends and technology in prosthetics.

Hinnant has been serving the needs of amputees and patients with congenital limb deficiencies for more than 81 years. We specialize in applying the latest proven technology commensurate with each patient's capabilities, lifestyle and personal desires.

We hope you find our newsletter to be interesting and professionally relevant and encourage your comments, questions and referrals. We also encourage you to visit our website at **www.hinnantprosthetics.com**

Our Staff

Kale Hinnant, CP, FAAOP

Danny Ellis, CP — Jeff Haskett, CPO, FAAOP

Thong Chanthaboury, CTP — Tim Martin, CTP

Michael Franz, CTP

CMS Documentation Mandate Disrupts Prosthetic Care

An August 2011 pronouncement by the Center for Medicare and Medicaid Services (CMS) has upset the long-accepted methodology for determining and providing reimbursement for prosthetic care rendered to amputees.

Departing from the practice of accepting the clinical judgment of prosthetists for assessing the type and level of care required after an initial determination of need by the referring physician, CMS now mandates all essential documentation for Medicare coverage and payment, including justification of medical necessity and a detailed prosthetic prescription, appear in the physician's patient record.

Prosthetic Documentation

If that documentation is missing or deemed incomplete, the reimbursement for the prosthetic limb already delivered and related patient services already rendered is summarily denied.

The result has been turmoil, an avalanche of denied claims for prosthetic services with resulting financial hardship for many O&P practices and significantly reduced access to care by the patients who need it.

Less-active amputees are usually rated K-1/K-2.
Courtesy Fillauer Inc.

Functional Levels

Center for Medicare and Medicaid Services reimbursement criteria now require *physician* clinical assessment of patients' rehabilitation potential based on the following classification levels (commonly referred to as K levels):

Functional level 0: The patient does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance his/her quality of life or mobility.

Functional level 1: The patient has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.

Functional level 2: The patient has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.

Functional level 3: The patient has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.

Functional level 4: The patient has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

The irony of this situation is that physicians now bear the responsibility of documentation for prosthetic limbs but in most cases have not the time, resources or training to perform a thorough prosthetic assessment. Meanwhile, the O&P providers on whom physicians have traditionally relied to evaluate, design, deliver, and document their patients' prosthetic needs are now wholly dependent on the perceived acceptability of the notations in the physician's medical record to be compensated for their work.

As recently as this summer, reports to the American Orthotic and Prosthetic Association indicated 90 percent or more of initial lower-limb prosthetic claims submitted to CMS were denied. As a result, many O&P providers have become cautious about providing care without first obtaining reasonable assurance that the referring physician is aware of the new requirements and agreeable to adhering to the new documentation standard.

The new requirement has become so onerous, in fact, that some suppliers will not deliver prosthetic services until they receive copies of the physician's documentation they believe will be acceptable to the Durable Medical Equipment Medicare Administrative Contractor in their area.

Courtesy Willow Wood

Predictably, this hesitation has led to significant delays in delivery of service for many Medicare patients, notably new amputees, for whom early prosthetic intervention is often a key component of a successful rehabilitation outcome. In some cases, the dilemma has resulted in new amputees still not receiving a prosthetic limb many months after their surgery.

It is the position of our practice that we will do everything possible to continue to deliver the most appropriate prosthetic componentry to our Medicare patients in a timely and efficient manner. However, we need the cooperation of our referring physicians and patients to meet that goal.

Efforts spearheaded by national O&P organizations have been under way for many months to rectify this situation, but short-term relief is far from assured. Meanwhile, we are dedicated to work closely with our referring doctors and their staff personnel to obtain the best possible outcomes for their (and our) patients.

CMS prosthetic limb documentation guidelines, spelled out in an August 2011 letter to physicians, require that "The prosthetist's records must be corroborated by the information in your patient's medical record." We will be happy to make the full text of the CMS letter available to any physician practice or patient by request.

As before the CMS change in policy, we are fully prepared to evaluate any patient's functional capability and recommend a prosthetic course of treatment to any of our referring physicians.

Amputees capable of walking with a variable cadence rate a K-3 or K-4 assessment.
Courtesy Otto Bock Health Care

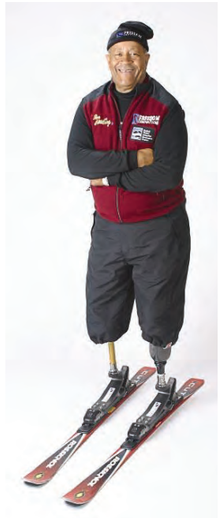
This information may be inserted into the physician's patient record but should be date-stamped and corroborated by a separate physician entry restating the patient's functional capabilities and the physician's concurrence or disagreement with the prosthetic assessment.

The physician's documentation must include a statement of the patient's functional capabilities based on the "K-level" classification system (see box at lower left)—pre-surgery, current, and anticipated with prosthetic support, including an explanation for differences.

It is important that the physician record not understate the patient's potential function with a properly designed prosthetic limb. For example, a patient capable of walking with a variable cadence should be classified at the K-3 or K-4 level to ensure he or she receives limb components capable of providing that variable gait. Moreover, with an uncomplicated surgery the patient's pre-amputation level of function is generally the best indicator of potential function with a prosthesis.

In many instances, inclusion of physical therapy notes in the physician's record may be helpful in supporting the medical necessity of a prosthetic limb prescription. We encourage therapists to include in their notes specific assessment of the patient's ambulatory capacity using the K-level classifications. We also encourage ongoing dialogue between physicians and their amputee patients regarding their ambulatory function and any problems they may be having with their prosthesis.

We look forward to continue working with physicians and patients alike to achieve the best possible prosthetic results for both new and "experienced" amputees.



Athletes and active amputees should be classified K-4.
Courtesy Freedom Innovations

Note to Our Readers

Mention of specific products in our newsletter neither constitutes endorsement nor implies that we will recommend selection of those particular products for use with any particular patient or application. We offer this information to enhance professional and individual understanding of the orthotic and prosthetic disciplines and the experience and capabilities of our practice.

We gratefully acknowledge the assistance of the following resources used in compiling this issue:

Fillauer Inc. • Freedom Innovations
Otto Bock Health Care • Willow Wood

What Constitutes Acceptable Physician Documentation?

The following excerpt from the August 2011 CMS letter to physicians regarding Documentation of Artificial Limbs provides guidelines for establishing medical necessity for a limb prosthesis.

The physician's assessment of a patient's physical and cognitive capabilities typically includes:

- **History of the present condition(s) and past medical history that is relevant to functional deficits**
- **Symptoms limiting ambulation or dexterity**
- **Diagnoses causing these symptoms**
- **Other co-morbidities relating to ambulatory problems or impacting the use of a new prosthesis**
- **What ambulatory assistance (cane, walker, wheelchair, caregiver) is currently used (either in addition to the prosthesis or prior to amputation)**
- **Description of activities of daily living and how impacted by deficit(s)**
- **Physical examination that is relevant to functional deficits**
- **Weight and height, including any recent weight loss/gain**
- **Cardiopulmonary examination**
- **Musculoskeletal examination**
  - **— Arm and leg strength and range of motion**
- **Neurological examination**
  - **— Gait**
  - **— Balance and coordination**

The assessment points above are not all-inclusive, and physicians should tailor their history and examination to the individual patient's condition, clearly describing the pre- and post-amputation capabilities of the patient.

The history should paint a picture of your patient's functional abilities and limitations on a typical day. It should contain as much objective data as possible. The physical examination should be focused on the body systems that are responsible for the patient's ambulatory or upper-extremity difficulties or impact on the patient's functional ability.

Note that when physicians are unable to provide the requested documentation to the supplier, the suppliers receive denials for the items billed, which could result in your patient being financially responsible for all or part of the charges for the items/service received. If a supplier contacts your office to request additional clinical documentation, please partner with the supplier to establish what clinical records are needed to support that the service/item you ordered is medically necessary.

Courtesy Willow Wood

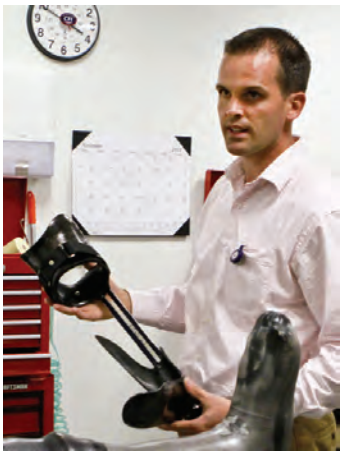
W. T. Hinnant Artificial Limb Co.
120 E. Kingston Ave. • Charlotte, NC 28203

Limb-Salvage Breakthrough

(Continued from page 1)

A remarkable success story is being written at the Center for the Intrepid at San Antonio's Brooke Army Medical Center, where many of our country's wounded warriors come to put their lives back together.

One of the cruel realities of "modern" warfare is the IED—improvised explosive device—which has turned hundreds of U.S. warriors into amputees, both lower- and upper-extremity. But thanks to America's commitment to help its wounded servicemen and women regain a positive quality of life and research connected to that effort, some legs that almost assuredly would have been amputated are now being saved by a unique brace called the IDEO — Intrepid Dynamic Exoskeletal Orthosis.



Center for the Intrepid prosthetist and device developer Ryan Blanck holds an IDEO.

Through advanced surgical techniques, doctors now are able to save combat-damaged limbs that formerly would have been amputated on the spot. Yet, the lost muscle function, nerve damage and joint immobility that often follow the initial surgery have produced pain and mobility limitations that caused many warriors to opt for subsequent amputation anyway. The IDEO is not only changing that outcome, but also helping return many warriors to active duty.

The lightweight IDEO consists of a footplate connected to a leg cuff by carbon-fibre rods incorporating the energy-storing properties of contemporary leg prostheses. The construction offloads the limb during ambulation, allowing the wearer to move in a way that avoids pain. Energy stored at heel strike is released at toe-off to propel the foot forward, helping the patient to walk, run, even jump out of airplanes again.

Statistics reported in May 2012 showed that 97 of 219 warriors fitted with the IDEO were returned to active duty...quite a story!

Pistorius Pierces Olympic Barrier For Physically Challenged Athletes

2012 will be remembered as the year the great divide between Olympic and Paralympic competition became narrow, when "fully able" and "partially able" athletes first competed head-to-head on the Olympic stage, and when the differences between these two communities were found to be small indeed.

The trailblazer, now widely recognized around the world, is South Africa bilateral amputee sprinter Oscar Pistorius, who in 2008 was turned away in his bid to compete in the Olympics because the powers-that-be feared his Cheetah prosthetic running blades would give him an unfair advantage over mere human competitors.

Cleared at last to compete in 2012, Pistorius was himself found to be merely human, as his best efforts produced also-ran finishes in the finals of the 400 meters and 4x400 relay, and in fact he later was defeated by another "blade runner" in the subsequent Paralympic Games. But those results don't really matter.

What does matter is that this remarkable athlete who asked only the opportunity to compete on a level playing field (make that running track) through determination and perseverance broke down the barrier separating physically challenged competitors from the rest of the athletic world. In so doing, he has become a most worthy inspiration and role model, not only to athletes with a disability, but to *anyone* going through life with a disability.

Oscar Pistorius has proved that life's, and society's, obstacles can be overcome. We applaud his great accomplishment.