The Hinnant Prosthetics Quarterly

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Vacuum Socket Suspension Comes of Age

Nothing is more important to an amputee wearing a prosthetic leg than keeping the prosthesis firmly anchored to the residual limb. The more the residuum moves around inside the socket, the less effective the ambulation, the greater the stress on limb tissues, and the higher the chance the limb will come off entirely, often precipitating a fall.

With conventional suspension methods (atmospheric suction, pin, anatomic, belt, etc.), prosthesis wearers typically experience 6-12 percent residual limb volume loss during the day, caused by alternating weight-bearing pressure during stance and gravity pulling during swing phase. As a result, an intimate socket fit at the beginning of the day deteriorates to a loose attachment in a few hours, either requiring bothersome addition of limb socks or resulting in increased pistoning with reduced proprioception and accelerating fatigue. A majority of lower-limb amputees who wear prosthetic limbs face this reality every day.

Making Strides

The 1999 introduction of a vacuum-assisted suspension system promised a better way. By removing air molecules from the sealed air space between a total surface weight-bearing socket and a prosthetic liner covering a residual limb, the vacuum holds the liner firmly against the socket wall, creating a vastly superior extraction force—the force required to create separation between the liner and socket—to any other current suspension method.

Testing with the system confirmed its effectiveness: For the average size limb (13 inches proximal circumference), an extraction force exceeding 150 pounds was required to separate liner from socket under vacuum. (For reference, extraction forces encountered in daily activities seldom exceed 20 pounds.) By comparison, less than one pound extraction force can cause separation with all other suspension methods.

LimbLogic VS opens vacuum suspension to above-knee amputees.
Courtesy Ohio Willow Wood

Vacuum systems such as the Harmony® give wearers unparalleled "attachment" to their prostheses.
Courtesy Otto Bock HealthCare

Not only does vacuum suspension create a secure bond between limb and socket at the beginning of the day, but by eliminating the pressure fluctuations within the socket normally encountered during ambulation, the system prevents daily residual limb volume loss altogether, thus maintaining the strong limb-socket bond morning to night.

Vacuum Suspension Benefits

- Superior linkage to prosthesis
- Reduced pressure on load-bearing areas
- Minimal residual limb volume fluctuations
- Improved proprioception
- Enhanced residual limb health

The intimate socket fit produced by vacuum assist also enhances the wearer's spatial awareness (proprioception) and control of the prosthesis. The leg responds immediately to residual limb movement and feels lighter, thereby reducing energy expenditure and improving endurance.

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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 75 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**

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Keeping Diabetic Patients On Their (Own) Two Feet

The occurrence of diabetes, already the leading cause of limb loss in the United States, is growing...by 13 percent in just two years (see accompanying statistics). Prosthetists, orthotists and pedorthists in the United States see more patients with diabetes than any other presenting condition. If any patient type can be described as the foundation of O&P practice in this country, it would be the older diabetic individual with peripheral sensory neuropathy.

Despite decades of progress in managing the disease, the course of diabetes still frequently culminates in varying degrees of lower-limb morbidity and ultimately amputation (see statistics). An estimated 90,000 lower-limb amputations were performed on diabetic patients in 2007 with vascular insufficiency secondary to diabetes as the predominant cause.

Ankle-foot orthosis with patellar tendon-bearing support.

With other types of practitioners usually involved in diabetic limb care, we frequently do not see a diabetic patient until an infection, lesion or deformity has progressed to the point that amputation has become the best option, and we are engaged to provide prosthetic management. However, be assured our team is well-prepared to help at-risk patients preserve their intact limbs, be it one limb following amputation of the other...or both.

Another disturbing diabetes statistic reveals that up to 50 percent of surviving diabetic amputees will lose their contralateral limb within five years of an initial amputation. Our goal is not to add to that number. In the case of unilateral diabetic amputees, it is not uncommon to have rigorous orthotic-pedorthic management under way for the non-amputated leg while active prosthetic care is in progress. Such is particularly the case during the period of extensive gait training that accompanies the recent amputee's transition to prosthetic ambulation when considerable additional loading is applied to the remaining foot's plantar surface.

Protecting the Neuropathic Foot

O&P concern for diabetic patients, whether or not they have already undergone an amputation, stresses sound foot management through regular careful observation, patient education and orthotic-pedorthic support. The goal is to prevent elevated plantar pressures and trauma, which unresolved can quickly lead to plantar ulcerations, often the first insult in a series of events leading to amputation.

Charcot Restraint Orthotic Walker
Courtesy Orthomerica Products Inc.

The primary weapon against plantar ulcers for the diabetic patient is properly prescribed and fabricated therapeutic footwear—including specially constructed shoes, modifications, and custom-molded inserts.

Other orthotic measures include supportive and protective componentry for specific conditions, such as a custom-molded ankle-foot orthosis (AFO) or Charcot Restraint Orthotic Walker (CROW). Charcot deformities of the foot and ankle often beset diabetic patients. Appropriate treatment consists of joint immobilization using total-contact casting, a solid-ankle AFO or CROW boot.

The CROW is sometimes a nice alternative to casting because it provides the needed total contact, immobilization and pressure relief but can be removed periodically for bathing and dressing changes.

Diabetic footwear

While amputation of a part of a lower limb may be a sound therapeutic decision, it does not resolve the host of conditions that likely prompted the amputation in the first place for the aging diabetic patient: ischemia and/or neuropathy in the lower limb, generalized muscle weakness, lack of coordination and balance, and visual and cognitive impairments. Thus, continuing aggressive management of these conditions with the O&P practitioner as an involved participant remains an important management strategy.

Sobering Stats

Recent American Diabetes Association and Centers for Disease Control statistics relating to the incidence and outcomes of diabetes in America and around the globe indicate a still-growing health issue:

- The CDC estimates that 23.6 million Americans—8% of the population—have diabetes, 5.7 million of whom are undiagnosed. Diabetes prevalence increased 13.6% from 2005 to 2007.
- Nearly 30% of diabetics age 40 and older have impaired sensation in their feet. An estimated 15% of people with diabetes will develop foot ulcers.
- Diabetes was the underlying cause in an estimated 90,000, primarily lower-extremity, amputations in the U.S. last year. Worldwide, diabetes is linked to one million foot and leg amputations annually.
- More than 60% of non-traumatic lower-limb amputations occur in people with diabetes. The amputation rate for people with diabetes is 10 times higher than for people without diabetes.
- 1 of every 10 health care dollars in the U.S. is spent on direct and indirect costs of diabetes.

Prosthetic Implications of Diabetes

Complications of diabetes frequently also complicate prosthetic rehabilitation of the new diabetic amputee. Common issues include ischemia and/or neuropathy in both the amputated and contralateral limb; poor muscle strength, coordination and endurance; visual impairment; balance problems; cognitive difficulty; and desire to resume an active lifestyle.

The first determination is whether the patient can indeed benefit from a prosthetic limb. The recuperating amputee must possess certain prerequisite capabilities to advance to prosthetic use, notably the ability to rise from bed or chair and pivot on the contralateral limb and sufficient hand and arm strength to maneuver prosthetic components. These prerequisites also require an adequate level of balance and cognition.

Prosthetic Timing

Slow wound healing is a hallmark of advanced diabetes, especially in the lower limb. A commonly accepted guideline is to begin the transition to a prosthesis about six weeks post-op, barring lingering complications.

One approach is to provide a preparatory, or training, limb when the wound has sufficiently healed and all edema and infection issues have been resolved. A preparatory limb is a relatively simple and inexpensive device that enables the rehabilitative team to assess the patient's ambulation potential. When the amputee's strength returns and the diabetes is under reasonable control, transition to a definitive prosthesis can begin.

Flex-Foot Assure
Courtesy Össur Americas

Another method is to provide definitive limb components from the outset, then provide a new socket when the residual limb matures, 4-8 months later. This course enables the use of more advanced components up front and eliminates the need to retrain the patient in the use of a different prosthesis after the preparatory period.

Component Selection

Light weight, durability and ease of use are particularly important attributes in prosthetic legs for diabetic patients. Because sores and infection occur so frequently in insensate limbs, optimal socket design and appropriate liners are vital to prosthetic success. Flexible, dynamic sockets help prevent undue pressure over sensitive skin or nerve areas and bony prominences. Gel liners help reduce friction and skin irritation and increase tolerance for forces within the socket.

Courtesy Ohio Willow Wood

For above-knee diabetic amputees, a lightweight knee component providing a high degree of stability is usually prescribed. Polycentric designs are a frequent choice with some incorporating a locking device to prevent knee buckling while standing.

Lightweight foot components appropriate to the amputee's activity level will help maximize the benefit the older diabetic patient receives from a prosthetic limb. Good options for seniors with diabetes include the new Flex-Foot Assure, Endolite Senior, and the still-reliable SACH (solid ankle, cushion heel) foot, among others.

Our practitioners are dedicated to providing the best possible outcome for our diabetic patients. We are available to help with patient education, resolve componentry issues as they occur, and assist patients in achieving the compliance necessary for success. For additional information, give us a call.

Electronic Vacuum Innovations Foretell Better Sockets for Above-knee Amputees

(Continued from page 1)

Yet another benefit of vacuum suspension is substantially better limb health. By subjecting residual limb tissues to abusive pistoning with resulting excessive pressure and shear forces, other suspension methods frequently produce pressure sores and skin breakdown. Conversely, a vacuum socket environment is so limb-friendly that open sores have been observed to heal while the patient continues daily prosthesis use.

The substantial advantages of vacuum suspension can be achieved only with careful design and fabrication of a total surface weight-bearing socket that closely matches residual limb shape, a carefully selected roll-on gel liner, and for a transtibial socket an airtight flexible knee sleeve.

Componentry Options

Since the introduction of the breakthrough Harmony Vacuum-Assisted Socket System a decade ago, various new innovations have expanded vacuum opportunities for amputees.

• **Harmony®**—The original Harmony system has been enhanced with the introduction of two improved vacuum pump models. The Harmony is a mechanical in-line pump actuated by alternating weight-bearing pressure and swing-phase relief during ambulation to maintain negative pressure within the socket while cushioning each step. A plastic tube connects the pump to a valve on the back of the socket.

E-pulse in transfemoral application
Courtesy Otto Bock HealthCare

The Harmony mechanical system also features an integrated torsion adapter, which effectively replaces the normal ankle rotation of the human leg during ambulation. The Harmony mechanical units are appropriate only for transtibial applications and cannot be used with a long residuum.

• The **LimbLogic™ VS** is a battery-powered system that can be mounted either in-line directly below the socket or external to the shaft for long residual limbs. The controller unit weighs less than a half-pound and requires no external tubing.

Perhaps the most noteworthy advantage of the LimbLogic system is that it opens the door to vacuum suspension for above-knee amputees. As a result transfemoral sockets can be designed with lower trimlines, leading to significant improvements in range of motion and comfort, both standing and sitting.

Once set by the prosthetist, LimbLogic continually monitors and maintains the desired vacuum pressure within preset limits; the wearer can adjust the pressure within those limits using a small wireless remote unit. Both the controller and remote are water-resistant.

LimbLogic VS system built into a transtibial prosthesis
Courtesy Ohio Willow Wood

• The **Harmony e-pulse** adds the benefits of an externally mounted, battery-powered vacuum unit to the original Harmony system, replacing the in-line mechanical pump. Like the LimbLogic, the e-pulse can work with any residual limb length and thus can be used for both above-knee and below-knee patients.

The e-pulse offers four preset vacuum levels, easily selected by the wearer. The e-pulse is small, lightweight, quiet, and provides audio and visual feedback.

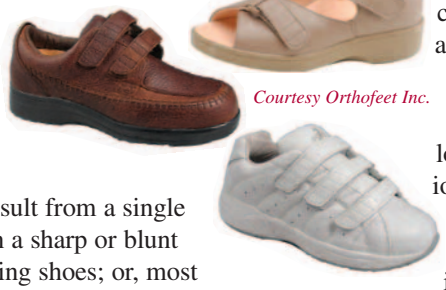
As with most O&P breakthrough technology, widespread insurance coverage for advanced vacuum suspension systems is not yet a reality...it will take time. When the now immensely popular C-Leg® microprocessor knee system was introduced a decade ago, the inevitable patient question "Is it covered by my insurance?" was almost always answered in the negative. Today, C-Legs are frequently covered by insurance, including Medicare, with proper authorization and documentation.

As the performance and comfort benefits of vacuum suspension become more widely appreciated, we may expect that this technology will likewise qualify for reimbursement.

First Line of Defense for Diabetic Feet

Diabetes has appropriately been described as a public health problem of epidemic proportions in the United States. More than 25 percent of the estimated 23.6 million people with diabetes in the U.S. will develop significant foot problems.

People with diabetes are prone to peripheral neuropathy and may have essentially no sensation in their feet. As a result, tissues already overly susceptible to poor circulation, infection and skin damage may give no warning when a developing crisis is being exacerbated with every step.



Courtesy Orthofeet Inc.

In the diabetic foot, skin breakdown can result from a single high-stress event, such as stepping barefoot on a sharp or blunt object; from ischemia, aggravated by tight-fitting shoes; or, most commonly, from the repetitive moderate stress of everyday walking. A common outcome is ulcers on the plantar surface under the metatarsal heads.

Without aggressive treatment, superficial lesions can quickly degenerate to deep ulcers involving tendon and bone. Further deterioration can yield an abscess, osteomyelitis and ultimately gangrene and amputation. Diabetes is also the most prevalent factor in the development of neuropathic arthropathy, frequently leading to foot and ankle deformities.

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:

Apex Foot Health Industries • Ohio Willow Wood
Orthofeet Inc. • Orthomerica Products Inc.
Össur Americas • Otto Bock Health Care

The goals of applying therapeutic footwear are to provide even pressure distribution across the plantar surface, eliminate focused stress areas, afford shock absorption and foster proper foot biomechanics. While foot orthoses can be designed to correct certain deformities, the primary role of special footwear for diabetic patients is to provide an advanced level of protection for the insensate foot.

Shoes

General considerations for diabetic shoes include low heels, a spacious, rounded toe box, well-cushioned heel and sole, and soft uppers that can mold to the shape of the patient's foot. Shoes with extra depth throughout are commonly prescribed to allow insertion of a molded foot (FO) or ankle-foot (AFO) orthosis or to accommodate minor deformities. For advanced diabetes and gross deformities, custom-molded shoes or boots are generally necessary. Therapeutic shoes are available in a wide variety of styles and colors.

Courtesy Apex Foot Health Industries

Inserts and Modifications

Custom-molded orthotic inserts and special modifications are added to shoes to provide for specific anatomical, functional and protective needs. Inserts are foot orthoses formed to a model of the patient's foot to protect against focused stresses and to accommodate minor deformities. They are typically made from lightweight-but-durable materials and can be easily removed and replaced when necessary.

Shoe modifications—arch supports, metatarsal bars, rocker bottoms, toe-fillers, heel counters, and heel and sole wedges—are used to relieve pressures under the metatarsal heads, provide advanced protection for the plantar surface and assist full heel-to-toe gait after a partial foot amputation. Special modifications may also be applied to accommodate Charcot joint deformities resulting from diabetes-related arthropathy.

When it comes to diabetes management, one size definitely does not fit all. We welcome your inquiries about diabetic footwear and recommendations for individual patients.

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