Gulf Coast Orthotics & Prosthetics

FIRST STEP

Current Developments in Orthotics & Prosthetics — Winter 2014

You Can See the Future from Here!

O&P Tomorrow

For most of the last year, news about the health care industry has been dominated by insurance and reimbursement issues, notably so in our orthotics and prosthetics (O&P) specialty.

From the halting implementation of the Affordable Care Act to unprecedented limitations on Medicare funding for more-than-basic O&P componentry, media attention in our field has been much more focused on financial problem-solving than advances in the rehabilitative care we provide.

That's unfortunate, for we are on the verge of some remarkable breakthroughs in O&P technology that can markedly improve lifestyle horizons for different populations of physically challenged patients...some in the near future.

For that reason, we are devoting this issue of our newsletter to a preview of some of the most exciting projects currently under development.

We hope you find the coverage interesting and worthwhile.

Portable powered AFO; see page 2.

C-Brace a Leap Forward in KAFO Design

The new C-Brace® KAFO (knee-ankle-foot orthosis) applies much of the same advanced technology used in the groundbreaking C-Leg® prosthetic limb to the needs of patients contending with lower-limb dysfunction, notably partial paralysis, post-stroke issues, spinal cord injury and post-polio syndrome. It is the first orthosis to prove both swing- and stance-phase support through hydraulic control of the knee joint.

Like its prosthetics forbear, the C-Brace utilizes electronic sensors and microprocessors to perform real-time gait analysis and hydraulics to provide the correct knee response for safe, energy-efficient ambulation. By continually sensing movements of the patient's knee and ankle, the C-Brace is able to deliver immediate compensatory reactions to enable the wearer to proceed confidently throughout the gait cycle, climb and descend stairs, and change walking speed on all types of terrain.

Courtesy Otto Bock Health Care.

Key features include:

• Stumble control – Resistance to uncontrolled knee flexion when sensors detect a moment of instability gives the wearer the ability and time necessary to recover and avoid a fall.

• Real-time gait analysis – Each segment in the gait cycle is controlled dynamically and in real time, allowing the patient to walk with greater ease, reduced concentration and considerably less compensation of the sound side and torso...and therefore less fatigue.

• Standing and second mode – Selectable modes allow for comfortable static standing and specific settings for therapy or other activities.

• Stance extension damping – Progressive resistance allows natural movement without uncontrolled and early knee and hip extension at terminal stance, resulting in a more natural movement without abrupt changes to the center of gravity, lower back and lower limb joints.

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Congress, We Have a Problem

Friends, as outlined in our previous newsletter, changes in Medicare reimbursement rules are inhibiting our ability to continue providing our patients the absolute best orthotic and prosthetic outcomes we can deliver. Here's how you can help:

If you are a health care provider to patients who require prosthetic or orthotic care, or a Medicare-eligible patient who receives that care, we encourage you to express your concerns to your senators and district representative in Washington, D.C.

Please let your elected officials know the future of your health care is in jeopardy and urge them to action.

The Hon. Bill Nelson
716 Senate Hart Office Building • Washington, DC 20510

The Hon. Marco Rubio
284 Russell Senate Office Bldg. • Washington, DC 20510

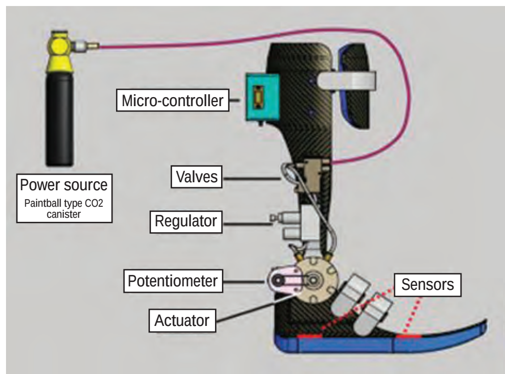
The Hon. Jeff Miller (District. 1)
336 Cannon House Office Bldg. • Washington DC 20515

It's Coming: The Portable Power-Assisted Ankle-Foot Orthosis

Someday in the not-too-distant future, individuals with significant lower-limb motor impairment will ambulate successfully and efficiently aided by a power-assisted ankle-foot orthosis using a compact, portable source of fluid (pneumatic or hydraulic) energy.

That development will open new lifestyle options to a patient population historically limited by impaired ankle function secondary to stroke, trauma, incomplete spinal cord injury, cerebral palsy, polio, muscular dystrophy, and multiple sclerosis, among others. Such a device could be applied in daily use to enhance walking function and as a physical therapy tool for gait training and building strength and range of motion.

Normal ambulation requires proper function of both dorsiflexor and plantarflexor muscle groups. Traditional AFO designs, consisting predominantly of fixed or articulated passive devices providing motion control and joint stability only, often fail to restore normal ankle function because they are incapable of generating any sort of propulsion assist. Unlike current functional electrical stimulation units, which induce the peroneal nerve to activate the dorsiflexors but generate no plantarflexion help, a power-assisted AFO would provide both.



PPAFO components diagram
Courtesy Georgia Institute of Technology

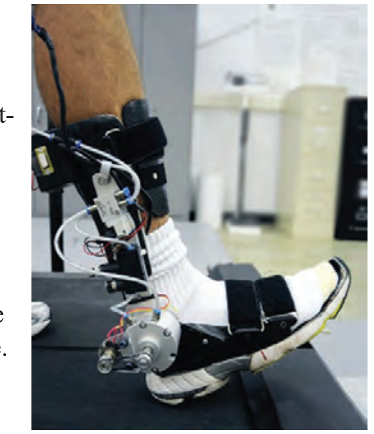
The first step toward a powered orthosis occurred in various laboratories using external power sources to generate torque assistance at the ankle. While these "tethered" prototypes are valuable for laboratory research and clinic-based therapy, they do not enable the wearer to function independently in the outside world.

Since 2006, a multi-disciplinary team funded by a National Science Foundation grant and operating from several major U.S. universities, has been working on a portable powered ankle-foot orthosis (PPAFO), which initially can serve as a rehabilitation aid, both in clinical setting and as a take-home device...and longer-term as an effective daily-wear assist.

To reach that portability goal, the team must overcome two key design challenges:

1. The system requires a compact, lightweight, high-efficiency power source and actuator capable of providing alternating dorsiflexion and plantarflexion assistance for an extended period.

2. The orthosis must incorporate sensors capable of recognizing different gait modes (ambulating on level ground, stairs, ramps, etc.) and a control system that can react promptly to mode changes.



Early generation PPAFO prototype
Courtesy Georgia Institute of Technology

The early generation prototype incorporates a bidirectional pneumatic rotary actuator powered by compressed gas from paintball-style CO2 canisters worn on a belt. Researchers project future iterations will be actuated by hydraulic or pneumatic power generated by a minute engine contained within the PPAFO profile.

In operation the PPAFO assists the wearer through the critical stages of the gait cycle. It provides a dorsiflexion moment to control foot velocity at heel strike to prevent foot slap, permits free ankle plantarflexion up to mid-stance, and generates plantarflexion torque at terminal-stance for propulsion and dorsiflexion assist during swing to prevent foot drop.

Early applications of the PPAFO prototype have been encouraging. Results appear in the Journal of Rehabilitation Research and Development, Vol. 48, No. 4, 2011. (Scan QR code at right to access.)

A New Answer to Residual Limb Volume Change

Ask most any amputee the significant challenges to wearing a prosthetic limb, and residual limb volume change (RLVC) is sure to be part of the discussion. Simply put, changes in the size of the residual limb (stump), whether occurring gradually over time or fluctuating daily in response to lifestyle factors, compound the task of maintaining the secure socket fit essential to prosthetic success.

Proximal view shows details of CJ Socket construction.

The gradual changes, typically resulting from post-surgery edema subsidence, muscle atrophy or significant weight gain or loss, can be managed with a new socket or adjustments. However, the daily fluctuations caused by salt or water intake, rigorous activity, or just routinely using the prosthetic limb must be addressed on the spot if the prosthesis is to continue to perform as intended.

CJ Socket with unique "sail" feature.
Photos courtesy CJ Socket Technologies

As the residual limb loses volume during the day, the socket becomes unstable with resulting increased motion between limb and socket. Hydrostatic lift and weight-bearing efficiency are reduced, and the residual limb moves further into the socket with increased distal pressure, pain, and eventually skin shear and breakdown.

Common methods of dealing with daily volume changes include the flexible socket, consisting of a rigid frame with openings and a pliable interface that can expand to accommodate residual limb expansion; addition and removal of limb socks; pads; inflatable air bladders; fluid-filled bladders; and vacuum-assisted suspension systems. These measures all are intended to keep the residual limb in intimate contact with the socket to enable effective control and propulsion of the prosthetic limb.

All work to some degree, but none has been shown to be a complete or easy solution to daily volume fluctuations. For example, adding limb socks to compensate for lower-limb volume loss requires sitting down, removing the prosthesis, adding several layers of socks, donning the limb again, and re-standing. The process requires both time and effort.

Enter a radical new design, the CJ Socket, which gives the wearer the ability to loosen or tighten socket fit as required for residual limb volume change in seconds.

Transradial CJ Socket

The essential engineering difference in this innovation is a non-elastic but comfortable panel called a "sail" (due to the material's similarity to that used in a Dacron boating sail), which comprises roughly half of the socket circumference, combined with a patient-adjustable Velcro closure. Rounding out the design is a rigid "J" shaped frame, which covers the remaining half of the residual limb, transfers weight-bearing forces from the prosthesis to the residual limb, and provides skeletal control.

Adjusting CJ Socket for limb volume change.

With a CJ Socket, adjustment for daily volume loss requires nothing more than adjusting several Velcro straps to maintain the optimal fit, which can be accomplished in a fraction of the time required for adding socks.

This unique socket was first designed for transfemoral applications with the sail positioned posteriorly. Above-knee amputees experience a particular challenge when sitting down. When a traditional rigid socket contacts a hard chair or toilet seat, the result is usually a combination of (1) discomfort and (2) loss of the total-contact seal that maintains the socket in place on the residual limb.

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Clinical Study to Assess Efficacy of Fat Grafting For Residual Limb Pain

A long-standing challenge for prosthetists and amputees is a bony or irregularly shaped residual limb, which lacks sufficient soft tissue to provide padding around bones resulting in an effective and comfortable prosthetic fit.

A uneven residual limb surface not only makes a total-contact vacuum seal between anatomical and mechanical surfaces difficult but also provides a source of painful irritation and skin wounds, often leading to a poor prosthetic outcome. Various methods and products have been employed over the years to address this problem, but a reliable solution remains elusive.

Now, a new approach involving fat grafting is being investigated at the University of Pittsburgh Medical Center. Active duty military personnel age 18 and above who have undergone a limb amputation with subsequent pain that limits fitting and use of a prosthesis are being sought to participate in clinical trials at the UPMC Center for Innovation in Restorative Medicine.

Minimally invasive fat grafting is nothing new — plastic surgeons performed some 65,000 such procedures in 2011, removing fat from parts of the body where it is unwanted, or less-needed, and replacing it in a more desirable location to replenish lost shape or fullness. In this experimental prosthetic application, that location would be the residual limb to provide additional subcutaneous tissue padding over bony prominences and peripheral nerve trunks.

But there's a problem: Fat has little structure or volume, which makes productive grafting into a residual limb particularly challenging. However, UPMC researchers believe they can overcome this issue by stripping the collected fat down to only the most dense, stem cell-rich component and injecting that refined fat into residual limbs.

Stem cell-rich fat promotes blood vessel growth and blood flow, volume, and lift, crucial factors for the survival of the fat graft and promoting healing and stability.

The study is scheduled for completion in May 2015.

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.

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Gulf Coast
Orthotics & Prosthetics

824 Creighton Rd.
Pensacola, FL 32504
(850) 477-4880
Fax: (850) 477-4766

www.gulfcoastoandp.net

Steven L. Gavin, CPO

Gulf Coast Orthotics & Prosthetics
824 Creighton Rd.
Pensacola, FL 32504

Phantom Pain Aid Comes from Unlikely Origin

Sometimes remedies for complex problems come from unexpected sources.

Katherine Bomkamp is a college political science major whose career goal is to become a corporate attorney. But, oh by the way, she also is developing a potentially breakthrough solution to the widespread amputee phenomenon known as phantom limb pain.

Katherine Bomkamp displays Pain-Free Socket prototype.

Though originally thought to have psychological roots, phantom pain is now understood to be a result of the brain continuing to send signals and commands to a limb no longer present. An estimated 80 percent of the world's 10 million amputees experience this sensation to some degree.

While still in high school, Bomkamp met various military amputees while accompanying her father, a disabled Air Force veteran, on lengthy appointments at the former Walter Reed Army Medical Center.

Upon hearing their lingering issues with phantom pain and simultaneously seeking a project for her school's International Science and Engineering Fair, she set out to develop an alternative solution to the powerful and addictive medications often prescribed.

After interviewing various phantom pain authorities, Bomkamp devised a concept based on thermal biofeedback, in which concentrated, controlled heat applied to severed nerve endings in the residual limb would induce the brain to focus on the heat instead of sending signals to a limb no longer present. (A side benefit is that the heat also relaxes residual limb muscles.)

When her idea sparked initial acceptance, the young student decided to run with it. She engaged a prosthetic consultant to provide professional expertise and build the first prototype of what became known as the Pain-Free Socket. The product consists of thermo-resistive wiring connected to a battery pack incorporated in a below-knee prosthetic socket. After several generations of development, the device is now awaiting patent approval.

Meanwhile, Bomkamp has written a business plan, formed a company (of which she is CEO) to bring the concept to market, and been inducted into the National Gallery for America's Young Inventors, among other honors. She hopes to bring the Pain-Free Socket into a limited clinical trial in 2014.

Quite a start for a college senior who just turned 22!

C-Brace

(Continued from page 1)

• Stance flexion damping – Controlled, partial knee flexion while weight-bearing allows the wearer to exercise knee control when walking down hills and ramps, descending stairs step over step, and when sitting down.

As with the introduction of the C-Leg, the high-tech and not-inexpensive C-Brace is being provided to relatively few patients at the outset, but we anticipate with growing experience and clinical acceptance, this advanced limb orthosis will provide a major lifestyle assist to significantly challenged lower-limb patients in the years ahead.

CJ Socket

(Continued from page 3)

But when sitting in a CJ Socket, the sail, which feels and reacts more like clothing than part of a prosthesis, flattens and conforms to the seat surface, allowing the thigh tissue to spread more naturally and definitely more comfortably. The result is a harmonious interface between anatomy and environment, and sitting on cloth beats sitting on hard plastic any day.

Subsequently, the design was successfully adapted for upper-extremity amputees, including those wearing myoelectric prostheses, who report the socket is lighter, less-restrictive and more comfortable than traditional sockets. The concept is now being extended to below-knee applications as well.