GULF COAST ORTHOTICS & PROSTHETICS

FIRST STEP

Current Developments in Orthotics & Prosthetics Winter 2007

The Prosthetic High-Tech Explosion

Prosthetics Tomorrow

Prosthetic science—long a rather docile entity characterized by periodic improvements making momentary headlines—has suddenly discovered steroids.

Generated by new applications of space-age materials and digital technology, fresh thinking about how to enhance prosthetic outcomes, and America's experience in rehabilitating its amputee casualties in Iraq and Afghanistan, prosthetics in the 21st century has become downright exciting, and a bright future of continuing innovation awaits.

This momentum swing might well be traced to the introduction of the C-Leg® microprocessor-controlled knee-shin component for transfemoral prostheses in 1997. The C-Leg has become the poster child for adaptation of computer technology to limb prostheses, having now been fitted on more than 13,000 people worldwide.

Rheo Knee™

Courtesy Össur

But fame is fleeting: The C-Leg has been eased off the front page by some remarkable new upper-extremity components, the first powered lower-limb prostheses to reach the market, and the promise of a whole new way of attaching prosthetic limbs to the body.

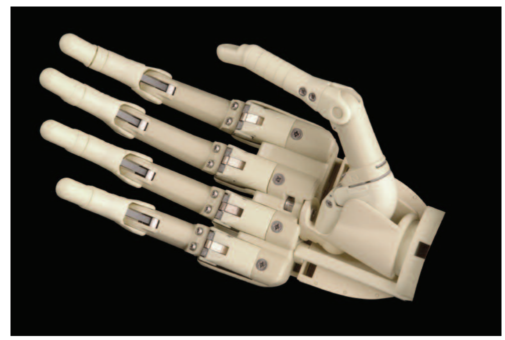
We're not yet to the time of Steve Austin, TV's Six Million Dollar Man, but led by some inspiring research initiatives (see page 3), we're getting there.

C-Leg® epitomizes prosthetic advances.

Courtesy Otto Bock Health Care

Microprocessor-Controlled Knees

Otto Bock's C-Leg and its recently introduced competitor, the Össur Rheo Knee™, use an on-board microprocessor to adjust prosthetic leg swing in real time in response to the wearer's cadence, toe and heel loading, and other gait variables. As a result, the leg is ready for heel strike at just the right instant, providing above-knee amputees with unprecedented security, gait flexibility, greater freedom of movement, natural swing motion and reduced walking fatigue.



i-LIMB—Hand of the future? See page 3.

Courtesy Touch Bionics

Microprocessor-controlled knee systems enable wearers to change walking speed, negotiate uneven terrain, walk up and down slopes, and descend stairs step-over-step.

(Continued on page 2)

Now Serving Gulf Breeze

Gulf Coast O&P is pleased to announce the opening of our new facility in Gulf Breeze. We are located opposite Gulf Breeze Hospital and the Andrews Institute at 1157 Gulf Breeze Pkwy.

Our new 2200 square foot facility is open from 8:30 a.m. to 5 p.m., Monday through Friday and offers all of our services—orthotics, prosthetics and pedorthics—provided by certified, licensed practitioners.

We have opened in Gulf Breeze to better serve this growing area and save patients from the drive into Pensacola. Please call our Gulf Breeze office at 934-8850 for more information.

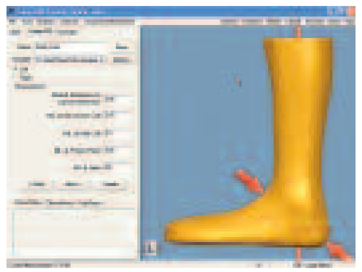
We hope you enjoy this issue of *First Step*, focusing on the latest technology in prosthetics, and welcome your inquiries, comments, and referrals.

Prosthetic Limbs of Tomorrow Making Preview Appearances Today

(Continued from page 1)

The C-Leg now incorporates several new enhancements that improve its performance even further, including:

- a new standing mode, which stabilizes the knee, taking weight off the sound limb and allowing the user to relax while standing;
- a wireless remote control, which enables users to switch easily between modes as well as fine tune swing phase dynamics for different activities; and
- a widened scope of application that now includes transfemoral, knee-disarticulation, hip-disarticulation, and hemipelvectomy amputees.



Typical CAD-CAM software display.

Courtesy Ohio Willow Wood

Sockets and a New Attachment Method

Technologically advanced distal componentry demands comparable improvement at the crucial point of integration between prosthesis and biological limb. Typically this connection is achieved by a socket suspended from the residual limb.

BioScanner™ portable CAD-CAM scanner

Courtesy BioSculptor

Among the advances in socket design and fabrication are new and improved CAD-CAM systems, through which more precise, more functional and more comfortable sockets can be provided than ever before in substantially less time.

CAD-CAM systems include a measurement device, or digitizer, to input the residual limb topography; design software on which to create the unique socket shape that will address the patient's physical capabilities, residual limb anomalies and functional desires as closely as possible; and a carving machine to render the finished socket from the finished digital design.

Recent improvements in prosthetic-orthotic CAD-CAM systems have made the limb measurement process considerably easier and faster for patients. With one of the new non-contact optical devices, such as Ohio Willow Wood's Omega Tracer T-Ring™ II or BioSculptor's hand-held BioScanner™, a test socket for an amputee patient can be fabricated in less than an hour, shortening the pre-prosthetic period by days and giving prosthetists more time to spend with their patients.

Omega Tracer T-Ring™ II captures residual limb shape in moments.

Courtesy Ohio Willow Wood

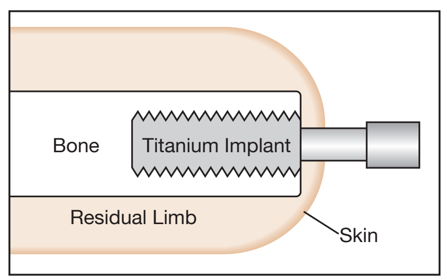
Among emerging socket designs, the Marlo Anatomical Socket (MAS) stands out for its innovation and potential benefits to appropriate above-knee amputees. This socket features a markedly lower posterior brim than other A/K designs and a pronounced medial alignment, which facilitates a more normal and more energy-efficient gait than provided by other ischial containment or quadrilateral sockets.

MAS socket's pronounced adduction alignment facilitates more normal prosthetic gait.

Courtesy Marlo Ortiz, P.O.

MAS users generally demonstrate an increased range of hip motion and report the socket is more comfortable to wear, whether standing, walking, or sitting down.

Perhaps the greatest potential development in prosthetic attachment does away with the socket altogether, instead anchoring the prosthesis to the residual limb by a titanium bolt surgically implanted directly into the distal residual bone. Though not yet approved by the Food and Drug Administration for use in the United States, this process of *osseointegration* has been used successfully with more than 100 lower-limb and more than 30 upper-limb patients in Europe.



Osseointegration cross section

Osseointegration shows the potential to eliminate most if not all of the problems inherent in prosthetic socket attachment for appropriate patients:

- End weight-bearing is restored;
- prosthetic limb control is greatly enhanced while energy expenditure is substantially reduced;
- risk of sudden prosthesis detachment from the body is minimized;
- user perception of the limb's place in space is much improved; and
- residual limb pain and skin breakdown caused by constant contact with the socket environment are virtually eliminated.

Osseointegration, already approved for dental and maxillofacial applications, is expected to be approved for orthopedic use in the United States within five years.

Upper-Limb Innovation

For several decades, upper-extremity prosthetics has led the way in high-tech prosthetic applications with myoelectric control of battery-powered hand, elbow and wrist actuators. Leading systems such as Motion Control's Utah Arm series continue to improve through upgraded components, while new offerings, such as the Otto Bock Dynamic Arm, help to raise the performance bar.

Like many newly introduced products, the Dynamic Arm offers certain advantages over the field, including faster elbow actuation, greater lifting capacity (13 pounds) and a more natural swing motion.

An intriguing new entry into upper-limb componentry is a new terminal device developed in Scotland that features five distinct fingers, each powered by separated motors. The i-LIMB Hand (see photo, page 1) is still in its infancy at this point—the fingers, though individually powered, can only move together. However, individual finger actuation is anticipated in the next few years with the development of improved control systems.

Powered Lower Limbs

Until now, powered components have been limited to upper-extremity applications. That all changed with the recent introduction by Össur of its Power Knee and Proprio Foot prostheses. These components, and others like them that will undoubtedly follow, promise to significantly reduce the effort and energy expenditure of walking while enabling appropriate amputees to ambulate confidently over uneven terrain and on stairs and providing a major assist for sitting and rising.

Proprio Foot

Courtesy Össur

These, like many of the other products described in this newsletter, are not yet ready for the general amputee population. Some are still in the research and development stage; others carry a whopping price tag well beyond the budget of the average American.

But the good news is that the innovation we're seeing today will become the reality of tomorrow. Prospects for improved prosthetic capabilities have never been brighter.

Dynamic Arm offers new capabilities to transhumeral amputees.

Courtesy Otto Bock Health Care

Walter Reed, DARPA Pushing Prosthetic Horizon

Research Report

Recent componentry breakthroughs like those discussed in this newsletter give testimony to new efforts to develop markedly improved prosthetic solutions for people with congenital and acquired limb deficiencies. As encouraging as these new systems might be, two major research initiatives now under way suggest "You ain't seen nothin' yet!"

One program has evolved from efforts to provide a new level of restored function to military personnel who have lost a limb in the ongoing U.S. campaigns in Afghanistan and Iraq. Most of these typically young and vital men and women are treated at Walter Reed Army Medical Center (WRAMC), an acknowledged world leader in amputee rehabilitation.

WRAMC's determination to carry out a grateful nation's desire to provide the maximum possible rehabilitation to more than 300 combat amputees is contributing valuable new insights into the management of younger men and women with a traumatic limb loss. This growing body of knowledge, dubbed the "Walter Reed Experience," will likely influence amputee care in both military and civilian sectors for years to come.

- For example, lower-limb amputees are routinely evaluated at the center's gait laboratory to analyze and optimize their prosthetic ambulation. Their outcomes could conceivably help justify Medicare and private insurance coverage of computerized gait analysis, currently not reimbursed in most instances. Walter Reed clinicians have found gait and motion analysis particularly helpful for making component choices and as an educational tool for both patients and rehab team members.
- Another finding reveals that a microprocessor knee system such as the C-Leg can be used throughout a new above-knee amputee's progression from initial prosthetic intervention to final definitive prosthesis, saving weeks of lost time and progress while adjusting to periodic applications of sequentially more capable knee units as the patient becomes stronger and more functional. The microprocessor knee system can be programmed to accommodate the user's abilities at any stage of rehabilitation.
- Upper-extremity amputees, who generally require a period of postoperative healing before prosthetic application, are being prepared for rehabilitation by early identification of myoelectric control sites on intact muscles in the residual limb, which the recovering patient is trained to use through video games. In learning to generate the right electromyographic signals to operate the games, amputees thus become ready to control a myoelectric prosthesis when cleared to do so, while enjoying a therapeutic, competitive activity.

Meanwhile, the Defense Advance Research Products Agency (DARPA) has launched a major drive to produce a better prosthetic arm for soldier amputees, and ultimately civilians as well. In a two-phase, four-year $70 million program, DARPA is involving leading engineers, prosthesis developers, neuroscientists and others to develop a replacement limb that is:

- highly functional (capable of 22 independent movements as compared with a maximum of three in today's prosthetic arms);
- lightweight (weighing no more than a typical human arm);
- "sensitive" to pressure, heat and cold; and
- "aware" of where it is in space.

Lofty ambitions? Perhaps, but this is the same country whose innovation put a man on the moon within eight years of its first manned space flight. With the proper attention and resources now being devoted to the effort, don't be surprised at what might develop.

Is 'Prosthetic Parity' a Good Thing?

Never far from any discussion of advanced prosthetics and orthotics is the companion topic of cost and reimbursement. Like most new products providing new and improved capabilities, breakthrough prosthetic components like the C-Leg, Proprio Foot and Advanced Arm discussed in this issue typically come with a hefty price tag and thus may be financially viable for only a small percentage of individuals with congenital or acquired limb loss. Obtaining insurance coverage for advanced prosthetic systems is usually a long and arduous process, which often doesn't bear fruit.

The difficulty of obtaining adequate third-party reimbursement for a prosthesis of any type has been a growing challenge in our business for years. Whereas the federal government has mandated full prosthetic coverage for military personnel with limb casualties sustained in war, Medicare maintains significant coverage limitations, and many private insurance companies offer far less, in some worst cases limiting amputees to reimbursement for one prosthetic limb in a lifetime...or providing no coverage at all.

Courtesy Ohio Willow Wood

In early 2006, an Amputee Coalition of America poll of 660 users on the ACA web site—amputee-coalition.org—revealed that of the 423 respondents who reporting having private insurance:

- 62 percent reported their prosthetic coverage had remained the same in the past three years;
- 31 percent said it had been reduced, and
- 7 percent stated it had been eliminated altogether.

ACA has since championed an advocacy program to promote passage of "prosthetic parity" legislation that would ensure an appropriate minimum level of prosthetic care for Americans with limb loss. Subsequently, the Orthotic & Prosthetic Alliance, a coalition of national organizations representing the O&P profession, began advocating "for fair and equitable coverage and reimbursement policies so that patients have access to technology and can continue to receive high quality orthotic and prosthetic services."

By the end of 2006, six states—Colorado, New Hampshire, Maine, Rhode Island, Massachusetts and California—had passed parity bills, most of which mandate that private insurers in the state provide coverage for prosthetic devices at least equal to federal laws and regulations for the aged and disabled. Another 11 states, possibly more, reportedly will consider similar legislation in 2007.

Nevertheless, the push for parity is not without controversy. Among qualified prosthetic practitioners is a serious concern that less-than-specific language in different state bills with regard to provider credentials may lead insurers to direct policyholders to underqualified providers. At the end of 2006, only 10 states required prosthetists to be licensed.

In concept, however, prosthetic parity laws are a step in the right direction. As supporters of such legislation in various states continue advocating for services to be provided by appropriately credentialed prosthetists, we make progress toward an acceptable level of care for all individuals with limb loss.

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:

BioSculptor • Ohio Willow Wood • Marlo Ortiz, P.O.
Össur • Otto Bock Health Care • Touch Bionics

First Step
A publication of
Gulf Coast
Orthotics & Prosthetics

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

1157 Gulf Breeze Pkwy.
Gulf Breeze, FL 32561
(850) 934-8850
Fax (850) 934-8851

www.gulfcoastoandp.com

Steven L. Gavin, CPO

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