Adjustable Prosthetic Sockets: Fit and Form Merge

Leonard Brown: Pedaling Through Recovery Process

Ability, Freedom Innovations Help Patient Return to the Slopes
Meet Erin Meyers, CPO

ABILITY LOCATION:
Hagerstown, Maryland

INTERESTS: Enjoying the outdoors, kayaking, backpacking, art, and travel

FAVORITE THINGS ABOUT HAGERSTOWN: “I love that we’re so close to the culture of the big city, but still close to the great outdoors. Also, our patients are very grounded and very caring.”

ADVICE TO FELLOW CLINICIANS: “Involve the patient in his or her care. It’s important to educate patients about what you are doing and why you are doing it.”

While at a dinner party, Erin had a conversation with a prosthetist that led her to a career in the orthotics and prosthetics (O&P) profession. She found the subject fascinating and felt that with her studies and previous work in television special effects and animatronics, she could bring a valuable point of view and skillset to the field.

Erin completed the Prosthetic Technology program at Century College, White Bear Lake, Minnesota, in 2008, and then entered the prosthetics program at California State University, Dominguez Hills, that same year, and the orthotics program in 2011. She is certified to provide the BiOM powered ankle-foot device; the Freedom Innovations Plie 3 microprocessor-controlled knee (MPK); the Myomo MyoPro myoelectric limb orthosis; the Ottobock C-Brace, C-Leg, Genium MPK, Michelangelo Hand, and E-MAG Active stance-control knee brace; and the WillowWood One System vacuum suspension. Even though Erin is trained and certified in both disciplines, the patients she sees at Ability Prosthetics & Orthotics, where she’s worked since 2011, are mostly those who need orthotic devices.

Learning new things and meeting new people motivates and inspires Erin. “With every patient I see, I gain more experience and exposure to new diagnoses,” she says. “I’m always ready to learn from my patients.” She expects that the rapid technological advances in the O&P profession will continue to provide her with plenty of opportunities to learn new techniques and improve those she already uses. Erin predicts that the adoption of 3D printing and new scanning technologies will allow orthotists and prosthetists to work more efficiently and enhance their patient care. She plans to continue building her professional expertise and maintaining passion for her career and the care she provides. Part of the passion and appreciation Erin has for her work comes from the satisfaction she gets from witnessing the positive impact that the devices she designs have on patients’ lives and abilities.

After growing up in a small town in Ohio, wanderlust led Erin to travel throughout the United States. During those travels, she discovered the Cacapon River, an American Heritage River in West Virginia, where she hopes to build a home one day.
Ability, Freedom Innovations Help Patient Return to the Slopes

Ability Prosthetics & Orthotics and Freedom Innovations, Irvine, California, know that providing care to amputees extends beyond just fitting the patient with a prosthesis. That’s why the two companies joined forces to help Robert Haulbrook return to skiing.

Haulbrook lost his left leg below the knee in an auto accident about a year ago. His motivation and hard work have allowed him to make a full recovery and resume work and family activities. He has done very well with his prosthesis, which was designed and fitted for him by Brian Kaluf, BSE, CP, at Ability’s Greenville, South Carolina, patient care facility. Kaluf used an innovative prosthetic socket design to overcome some initial difficulties he experienced while fitting Haulbrook with a prosthesis. “Mr. Haulbrook had a bone spur on the end of his amputated tibia bone, which caused unbearable pain when he tried to walk with his early prototype prostheses,” Kaluf explained. “To solve this problem, I created a unique socket design that allowed for increased height of his socket trim lines to disperse the pressures while still allowing an acceptable amount of knee range of motion…. [I also added] pressure-reducing channels in the layered socket design to reduce the stiffness of the socket wall where Mr. Haulbrook was experiencing pain from the bone spur.”

Since then, Haulbrook has been challenging himself to return to every activity that he did prior to his accident, including skiing. However, the prosthetic foot that he uses every day is designed for level-ground walking and does not allow him to do the difficult movements required for skiing.

Kim Dell with Freedom Innovations learned about the limitations of Haulbrook’s prosthesis and his goal of returning to a full and active lifestyle, and garnered a company sponsorship to provide him with Freedom Innovations’ Slalom Ski Foot. This is the first prosthetic foot designed to be quickly and easily inserted directly into a ski binding—just step in and go. The Slalom can be configured to fit most standard ski bindings. It provides flexibility, shock absorption, and fluid motion without the rigid shock normally experienced by amputee skiers. Dell also helped Haulbrook return to skiing for the first time as an amputee by working with the ski shop where he would pick up his skis and bindings.

Haulbrook’s first attempts on the ski slopes were made possible by an Ability-sponsored adaptive ski event that was organized by Jeff Quelet, CPO, through Two Top Mountain Adaptive Sports Foundation at Whitetail Resort, Mercersburg, Pennsylvania, on February 6. He was accompanied by several wounded warriors, trained adaptive ski instructors, and certified prosthetists from Ability. After a few adjustments and improvements to his ski prosthetic setup, Haulbrook made 12 runs down the slopes—with no detour to the bunny hills. His first experience skiing with the Slalom Ski Foot from Freedom Innovations was a success, and he looks forward to skiing next winter, with hopes for snowy conditions closer to his home in South Carolina.

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On October 7, 2014, Leonard Brown of Hagerstown, Maryland, planned to ride his new three-wheel recumbent bicycle from Williamsport to Clear Spring, Maryland. As Brown approached Williamsport, he had to ride over a short concrete bridge with two wide expansion seams that traveled lengthwise, making it difficult for bicycles and motorcycles to maneuver.

As Brown, 64, reached the end of the bridge, he failed to navigate a bend in the road and collided with the left rear wheel of a dump truck. The impact shattered his right tibia and fibula, causing “a pain level I had never before felt,” he remembers.

Brown says he lost consciousness for a few moments, and when he opened his eyes, he saw his bike helmet had been split in two. “My glasses were crooked, and my left cheek was against the truck’s right rear tire,” he says.

He was transferred by helicopter to the University of Maryland Medical Center’s R Adams Cowley Shock Trauma Center, Baltimore. Physicians determined that Brown’s lower leg was so badly broken it had to be amputated immediately. “The first amputation needed to be done quickly to stabilize my condition,” says Brown. The next day, physicians performed an above-knee amputation so his leg could be prepared for a prosthesis.

Brown, an engineer, spent ten days in the hospital before being transferred to Meritus Medical Center, Hagerstown. After that, he spent one week in rehabilitation. While in rehab, Brown says he realized he needed a new car with an automatic transmission. He contacted a Volkswagen dealership, which had the car he wanted. “I had them drive it to the hospital, where I purchased it and spent one rehab session practicing putting the walker into the rear seat and starting the engine,” Brown says.

His surgeon and the nurses, Brown says, were amazed at how quickly he was recovering from his injuries. Brown’s surgeon told him his recovery was going faster than “most 20-year-old patients.”

Brown met prosthetist Chris DiGioia, CP, with Ability Prosthetics & Orthotics while still in rehab. DiGioia says because Brown was so physically fit and strong before his accident, it has helped with his recovery. “Right out of the gate, his balance was good and his core was strong. He has a great attitude. He’s constantly pushing himself.”

Brown received his preparatory prosthesis in early December, an ischial containment socket with an Össur Total Knee and an Ability Dynamics Rush87 foot. By late January, Brown was able to walk several hundred feet for the first time using just his cane. “Up until [then] I had to use crutches when walking with my prosthetic leg,” he says. “Now I needed to build up the hours of wearing the prosthetic. My [residual limb] needed to build up tolerance to the pressures and weight.” And that’s what Brown has spent these last few months doing.

DiGioia says he has had between eight and ten appointments with Brown, and he continues to be impressed by his recovery. “The first few times he came with his walker, then his cane,” he says. “The last few months with his prosthesis, he just strolls in.”

Within the next month or so, Brown will receive his definitive prosthesis, a microprocessor-controlled knee (MPK); he is going to be trialing Freedom Innovations’ Plié 3 at his next appointment, DiGioia says.

Now that Brown’s bike has been repaired and he has a new helmet, he has also returned to cycling. And he’s not just pedaling around the block—he has steadily progressed from 25 to 35 to 50 miles.
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Adjustable Prosthetic Sockets: Fit and Form Merge

In this issue of Lifenhanced, we present two mini features about adjustable prosthetic sockets. The first is LIM Innovations’ Infinite Socket, and the second is Click Medical’s RevoFit Lamination Kit featuring the Boa Closure System.

Surfing Buddies Collaborate on Adjustable Prosthetic Socket
By Betta Ferrendelli

When it comes to designing and producing a comfortable device that can be made quickly and allow greater user adjustability, some would say there is still much room for improvement.

Current methods for fabricating a socket are time-consuming and labor-intensive. The average time from initial evaluation to final delivery is typically one month. Practitioners may be able to fabricate sockets in less than one week, but may only be able to produce a limited quantity for a few patients due to the time commitment. In addition, most sockets are solid structures that lack dynamic change capability.

Colleagues, business partners, and surfing buddies Garrett Hurley, CPO, and Andrew Pedtke, MD, an orthopedic surgeon, have developed a new socket system they hope will change that.

A Literal Board Meeting
Hurley and Pedtke met several years ago at the University of California, San Francisco, when Pedtke was in his first year of orthopedic surgery residency and Hurley was working as a prosthetist. The two worked together closely, and before long, began surfing together and became friends.

“It was during our time surfing when we really started to collaborate and talk about working together,” Hurley says.

Pedtke remembers a particular day when the two met at a café after surfing. “I discussed with him some surgical concepts I had for medical device development, and then we simply said why not pool our ideas, start a company, and develop these concepts over time,” Pedtke says.

Hurley and Pedtke initially recruited an industrial designer and a materials scientist. “Once we had this small core of people, some real turnkey solutions became realized and some traction started to push the business forward…,” Pedtke says.

The end result is LIM Innovations, San Francisco—a company Hurley and Pedtke cofounded in October 2012 to develop what they call the Infinite Socket. Hurley says that the new socket design aims to improve clinical outcomes and versatility through a blend of structural design, manufacturing techniques, and proprietary materials, and could take as little as 24 hours from evaluation to final delivery.

According to the company’s website, the socket is fabricated from a combination of solid components and soft goods. The vertically placed, thermoplastic carbon fiber struts combine with the distal plate to form the dynamic modular frame, and the soft-goods adjustable brim supports the top end of the struts, allows movement of the leg, and optimizes weight distribution. A two-part tensioning system allows the user to adjust for volume management without the need for adding or removing prosthetic socks. And because the dynamic frame is modular, the need for a test socket is eliminated. Additional benefits it offers users are increased comfort, control, heat dissipation, and moisture management.

One of the main values of the socket, Hurley says, is that it “is applicable to many different socket approaches, different suspension mechanisms, as well as different socket shapes. Therefore, practitioners will still be able to apply their skills and preferences to meet the patient’s needs…."

Practitioners need to be a certified LIM clinical partner to order a socket and will have to provide a mold or CAD file plus patient data such as weight and activity level, Hurley says. (Ability Prosthetics & Orthotics currently has four prosthetists who are certified to fit patients with the Infinite Socket; another 13 are slated to receive their certifications in July.)
Fit on the Fly
Though initially intended for people who have transfemoral amputations and knee disarticulations, the socket system is applicable to all amputation levels, says Pedtke, the company’s CEO.

One test patient is Geoff Turner, 49, who lost his right leg at the knee when he was struck by a car one night on an Australian highway about 25 years ago. A long-time patient of Hurley’s, he has worked closely with him on some modified designs and various ideas for improvements to prosthetic sockets, and has since taken on the role of chief operating officer, in addition to being a board advisor and lead product tester.

Turner says that the increased comfort made possible by the modular construction and level of adjustment of the Infinite Socket are “dramatic improvements” over traditional sockets. “The ability to wear my prosthesis all day without even thinking about it—well, that’s probably the most profound difference,” says Turner, a runner and triathlete who competes at local and national levels. Further, he says that the ability to adjust his socket “on the fly” is one of the best advantages of the system. “[T]here is no need to go to the bathroom at work to take off my leg and add or remove a stump sock,” he says. “If I have volume change in my stump during the day, a simple adjustment is all I need.”

Make Fit Happen With Adjustable Socket Technology
To watch Andrew Hale and Dustin Fleming carve turns as they snowboard down the slope, you would be hard-pressed to guess that each has a below-knee amputation—Hale a left, and Fleming a right. The two are Paralympic hopefuls in the sport, and Hale is also a professional skateboarder. Achieving a comfortable and secure prosthetic fit is important for anyone who wears a prosthesis, but even more so when hitting jumps or racing downhill at top speeds. Earlier this year, Click Medical, Steamboat Springs, Colorado, outfitted each athlete with a RevoFit prosthetic socket that uses the Boa® Closure System to adjust socket fit. With this technology, users can adjust fit with a quick click and turn of the dial and accommodate for volume fluctuations in their residual limbs throughout the day.

The closure system, manufactured by Boa Technology, Denver, comprises a steel lace, nylon guides, and a mechanical dial. Developed in the 1990s, the Boa can be found on golf, cycling, athletic, and safety/utility footwear; on snowboard helmets; and on motorsports footwear, knee braces, and gloves. As the product’s popularity has grown, so has interest in using it in new ways—such as on orthotic and prosthetic (O&P) devices, says Jimmy Capra, CEO of Click Medical and the former director of Boa Technology’s medical business unit.

Ability Clinician Keeps Patients’ Comfort in Mind With a New Socket Design
“At Ability Prosthetics & Orthotics, we are always interested in pushing the field forward,” says Brian Kaluf, BSE, CP, managing practitioner of Ability’s Greenville, South Carolina, patient care facility and the company’s clinical outcome and research officer. This is why he welcomed the challenge of mentoring and working with a group of Clemson University bioengineering undergraduates on their senior design project. Their aim was to develop a comfortable prosthetic socket that allows the wearer to adjust for residual limb volume changes by “allowing the circumference of the socket to be altered...throughout the day, over a week, or even over a period of months as the patient’s body weight might fluctuate,” Kaluf explains, and doing so without having to add or remove prosthetic socks or visiting the prosthetist. “[S]ocket interfaces have always been the weakest link in the success of our [prosthetics] patients and the success for outcomes,” Kaluf says. Patients want a better, more comfortable fit than can be achieved with a fully rigid, fixed-volume socket, he emphasizes. “[Sockets] need flexibility and adjustability....”

The students’ design consists of rigid material to provide support for the socket (e.g., carbon-fiber-reinforced polymer, steel, or aluminum) and flexible material that allows the socket to better conform to the wearer’s residual limb (e.g., modified low-density polyethylene, ductile polymer, or fabric). The socket is fabricated in circumferential segments, or bands, Kaluf says, “that the patient can ratchet or make smaller” to achieve the desired fit. The segments are necessary, he says, because volume fluctuations do not necessarily occur uniformly from top to bottom.

Currently, the socket is in the early prototype stage and a provisional patent has been filed. Kaluf and the team have additional goals, including making the socket applicable to all amputation levels and reducing it into something that can be easily custom-fabricated in-house.
From Footwear to O&P

“While at Boa, our efforts were to apply Boa Closure Systems on bracing and supports made by mass manufacturers like Össur, DeRoyal, and Exos Medical,” Capra says. “However, each day we would receive calls from practitioners who were interested in using Boa on their custom-fabricated orthotics and prosthetics. They saw the opportunity for their patients to easily adjust and fit their products, which resulted in improved comfort, better clinical outcomes, and increased patient compliance.”

To service the O&P market effectively, Capra says a new business model that delivers the technology directly to practitioners for single-use application had to be created. With this in mind and with the blessings of Boa Technology, he founded Click Medical, which provides packaged Boa Closure Systems in prepared kits designed for O&P practitioners to integrate into their various products.

Meeting of the Minds
Meanwhile, in Utah, prosthetist Joe Mahon, CP, was working on a prosthetic socket solution to accommodate for changing volume fluctuations in the residual limbs of his patients—one that would not require adding or taking off socks.

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Make Fit Happen

As professional athletes, when Fleming and Hale are training on the slopes or competing, that is where their focus needs to remain—not on prosthetic socket fit.

A benefit of their new socket design, they say, is that when they are freeriding through trees and their sockets are too loose, with a simple twist of the Boa dial they can achieve a better fit without having to take off their pants and prostheses to add or remove socks while on the slope—a cold proposition. At most, they might have to pull up their pant legs to expose the dial. Compounding the former inconvenience, Fleming says, “Most amputees don’t have to do it just once; they’ll probably adjust it and put their stuff back on and 15 minutes later they are going to have to do it again.”

The two have also discovered a previously unforeseen advantage. When on the line at the start of a race, Fleming says, “Your [prosthetic] leg is fitting better than the guy who didn’t have time to adjust his leg.”

“Patients want a better, more comfortable fit than can be achieved with a fully rigid, fixed-volume socket.”

—Brian Kaluf, BSE, CP

The solution he devised calls for panels to be cut in the prosthetic socket at certain pressure points or areas on the patient’s residual limb that are prone to volume fluctuations. It can also be configured to manage suspension in ways that allows the user to easily don and doff his or her socket. The Boa Closure System is laminated onto the socket and the cable strung in a configuration that allows the user to simply turn the dial to increase or release compression from the panels, as appropriate. After three years of development and testing, the RevoFit lamination kit was released commercially by Mahon’s company, RevoLimb. The system consists of a lamination bayonet, high-power dial, guide tube, HD filament, wire feeder, and T6 tool.

Mahon had been a customer of Capra’s for years. As the idea for Click Medical formed, Capra says it became obvious that a partnership between the two companies would be beneficial to both parties. Therefore, in May, they consolidated into one entity under the Click Medical name.

Similar events are regularly held at other Ability locations. Call your local office for more information or visit AbilityPO.com.
Chuck Baisley underwent an amputation of his left leg below the knee on April 1, 2014. It was the result of residual injuries sustained in a car wreck eight years prior, combined with complications from diabetes. He says there was no time to prepare himself for it either emotionally or through research into what to expect and how to proceed thereafter. “It was one of those things.” He says his physician told him, “You have to do it, no ifs, ands, or buts.”

Thus began the overarching dilemma he encountered after his amputation. “As a new amputee…you don’t know what questions to ask,” he says, which is why he is sharing his insight with Lifenhanced readers.

You Have Options in Prosthetic Care

While in the rehabilitation hospital after the amputation surgery, Baisley says the staff referred him to a prosthetist. “They led me to believe there was only one choice in town,” he says. When he asked why they recommended this particular practitioner, “They said, ‘Well, we’ve never heard anything bad about him.’” Baisley didn’t like this answer, nor did his personality mesh well with that referral, he says, and though he asked the rehabilitation hospital staff about other options, they didn’t offer another name. Fortunately for him, he says, a peer supporter—a woman with an above-knee amputation—came to talk to him. While she couldn’t recommend a prosthetist, she told Baisley where she went for her prosthetic care: Ability Prosthetics & Orthotics in Charlotte, North Carolina.

“I called them on the phone, I liked how they came across on the phone, and one thing led to another,” he says. So, through what he calls “dumb luck,” he came to be a patient of Dara Ross, CPO.

It’s important to research the different prosthetic companies and prosthetists that are in your area and available to you, Baisley stresses, in order to make an informed decision.

Service Matters

When Baisley was still in the rehabilitation hospital, he fell in the shower and landed on his residual limb. “The pain was terrible,” he says. Once Ross heard about this, she drove to the rehabilitation hospital and fitted him with a post-operative protector to keep him from hurting it again. Ross also came to his house several times, including to fit a diagnostic socket before he got his final prosthesis. “I couldn’t ask for better service than I got from her,” he says.

Work With a Practitioner Who Answers Your Questions

Baisley has an inquisitive nature. “Telling me I’m doing well doesn’t cut it for me,” he says. “Why am I doing well? What makes it so well? What are your expectations [of me]? What makes it good that I am walking this way?” Ross takes the time to answer those questions, he says, and guides him on what to strive for in his prosthetic care and rehabilitation.

“For someone who has lost a limb, this is all new territory,” he says. “I expect [my prosthetist] to be able to relate to me and tell me exactly what’s coming down the road.” More so, he says, prosthetists have a good idea about what patients may face given their new situations, and it is valuable for them to share their insight.

Prosthetists are “Erector Set Builders”

“One thing I have learned is that...all prosthetists are basically Erector Set builders,” Baisley says. “They take parts from different manufacturers and put...a custom prosthetic together for you. I didn’t know that. I thought they were all like brand x or brand y. They build it as needed for the individual.” He adds that Ross has done a good job explaining how all the components work together.

All in all, Baisley says, “I feel like [Dara and Ability] have my best interests at heart.”
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