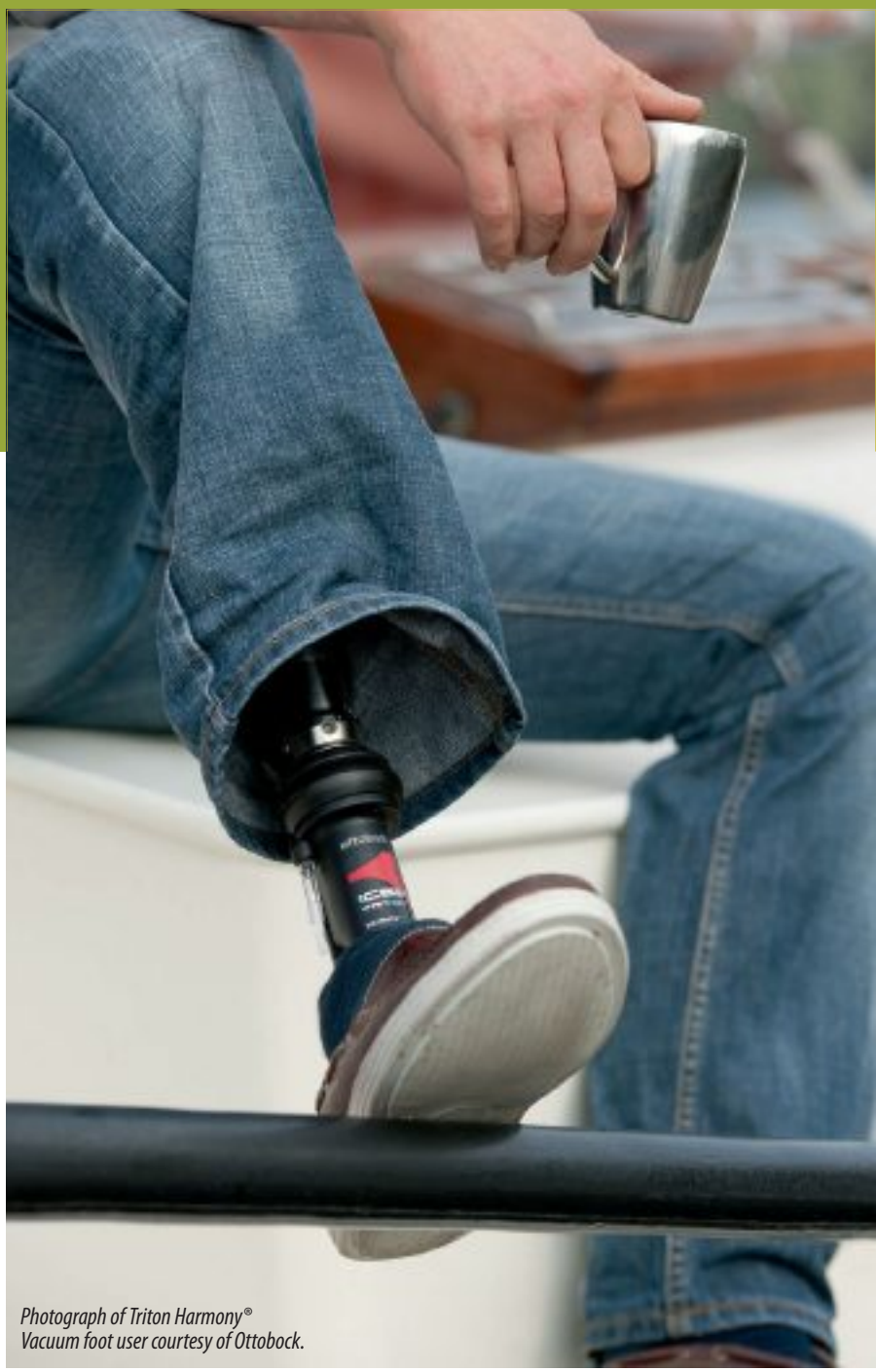
# Sub-Atmospheric **Socket Technology** Gains momentum

Since its introduction in the late 1990s, there has been a significant increase in the clinical application of sub-atmospheric (elevated vacuum) prosthetic suspension.

By Miki Fairley



*Photograph of Triton Harmony® Vacuum foot user courtesy of Ottobock.*

"When I began teaching…sub-atmospheric technology around ten years ago, only about 1 percent of the clinicians were using it; now I'd say the percentage is about 30–40 percent," says **Stan Patterson, CP,** president of Prosthetic & Orthotic Associates, Orlando, Florida. "More and more practitioners are realizing its great potential for their patients."

Pioneered by Carl Caspers, CPO, a transtibial amputee, sub-atmospheric socket technology was initially developed for the transtibial amputation level. However, clinicians soon saw its applicability for other amputation levels as well and are successfully using it for transfemoral, partial foot, hip disarticulation, hemipelvectomy/transpelvectomy, and transradial prostheses.

Enthusiasts of the technology now have their own information-sharing and networking group, the Sub-Atmospheric Technology Group (SATG), under the auspices of the Lower Limb Prosthetics Society of the American Academy of Orthotists and Prosthetists (the Academy) and chaired by **Michael Leach, CPO,** clinical specialist, prosthetics, Professional and Clinical Services, Ottobock Manufacturing, Salt Lake City, Utah.

## Benefits for Ambulation, Limb Health

A growing body of clinical and research studies as well as anecdotal experience indicates that vacuum technology not only often enables easier, more comfortable ambulation, but it also provides health benefits not available in other prosthetic systems.

Leach summarizes these benefits in his article, "Pressure Principles and Benefits of Providing a Sub-Atmospheric Transtibial Prosthetic Socket" (*The Academy TODAY,* February 2012):

- Daily volume loss is minimized because osmotic pressures in the capillaries are improved, encouraging fluid back into the limb.
- Limb health is improved by increased hydration and blood flow. Clinical experience, as well as a large body of anecdotal evidence, reports a reduction of common limb issues; e.g., skin abrasions and callus formation. Healing of open wounds may be achieved as a result of improved limb health even while continuing to wear the prosthesis.
- Movement of the bony anatomy within the socket can be reduced to less than 1mm when vacuum pressure is maximized within the socket. This, in turn, minimizes acceleration forces between the socket, liner, and residual limb.
- Proprioception, control of socket movements, and the resulting biomechanics are improved and are more symmetrical compared to other socket systems.
- The limb and socket system are connected at all times. This provides unmatched suspension in the swing phase and excellent support in the stance phase.

"A nearly universal observation with vacuum suspension is the reduction or elimination of minor skin problems such as folliculitis and recurring cysts," says **Glenn Street, PhD,** in an article, "Vacuum Suspension and its Effects on the Limb," (*Orthopädie Technik,* IV 2006). "More impressive are the cases where open wounds heal and remain healed upon switching to vacuum suspension."

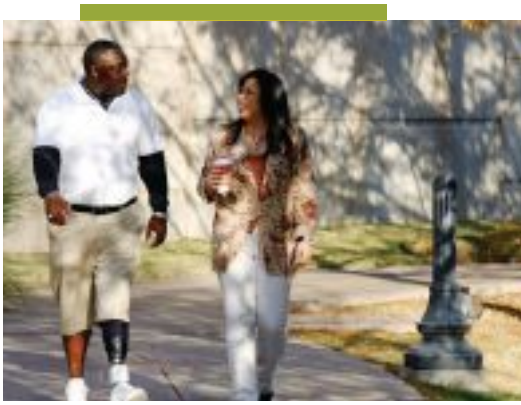
"The presence of oxygen ($O_2$) is one of the most important indicators of healthy tissue, with higher levels correlating with infection resistance and faster wound healing, **Glenn Klute, PhD,** et al., point out in a paper, "Vacuum Suspension and In-Socket Tissue $O_2$," presented during the 2012 Academy Annual Meeting & Scientific Symposium. Lower-limb prosthetic use can compress residual-limb tissue, restricting blood flow and reducing tissue oxygen, which can result in harmful consequences for amputees with poor circulation. The study found that although prior to walking or standing, no vacuum provided a higher tissue oxygen level, standing and walking with vacuum produced higher levels than no vacuum. The authors concluded, "Vacuum suspension systems with activity- and history-dependent control may improve residual-limb health."

## Componentry Advances

The increasing popularity of the technology has resulted in the availability of a plethora of improved componentry, and there are more developments in the pipeline. Although it's not possible to cover all of them in this article, this overview shows some of the exciting developments now occurring.

### *Edison: A Silent, "Smart" System*

The recently introduced Edison™ Adaptive Vacuum Suspension System from Orthocare Innovations, Oklahoma City, Oklahoma (www.orthocareinnovations.com), was designed as part of the U.S. government's Defense Advanced Research Projects Agency (DARPA) Revolutionizing Prosthetics program to elevate the level of technology available for wounded warriors and civilian amputees. "It was created to provide new and different functions specifically engineered to improve patient quality of life in many ways," says **David Boone, PhD, MPH, CP,** chief technology officer and company co-founder.



*Photograph of Edison user courtesy of Orthocare Innovations.*

The Edison integrates microprocessor technology to provide not only mechanical solutions but also underlying software and communications capabilities for establishing a patented "smart" technology platform approach. Orthocare's products are "designed to work together and provide more information to clinicians and patients than previous generations of prosthetic devices," Boone says. "They are not static devices, but rather dynamic, providing feedback for optimizing performance."

The Edison operates silently, solving a major issue for amputees who use electronic vacuum pumps. Another helpful aspect of the system is its "set-and-forget" feature. It automatically adapts vacuum as the user's daily activities require increased or reduced pressure for comfort. The onboard memory enables prosthetists to verify system performance and identify excessive socket air leakage, thus avoiding slippage and excessive battery drainage.

The device's ability to dynamically lower and raise vacuum levels may help patients with diabetes and other dysvascular conditions, since they may not tolerate constant high vacuum levels. The Edison also helps maintain healthy skin-tissue oxygen levels in the residual limb. Some of Boone's earlier research with the late orthopedic surgeon Ernest Burgess, MD, PhD, and dermatologist John Olerud, MD, professor and chief of the Division of Dermatology at the University of Washington, Seattle, School of Medicine, developed his awareness of the importance of skin-tissue oxygen levels to maintain residual-limb health. In developing the Edison, Boone believed fluctuating socket vacuum levels would enhance skin-tissue oxygen perfusion. Referring to Klute et al.'s paper on tissue-oxygen effects of vacuum suspension, referenced earlier in this article, Boone says, "Completely independently, without knowing we were developing the Edison, they built a laboratory-controlled, very precise version of the Edison for their experiment, which validated the value of the Edison's oxygen-perfusion effect with unquestionably good measurement techniques."

#### *Clinical Trials*

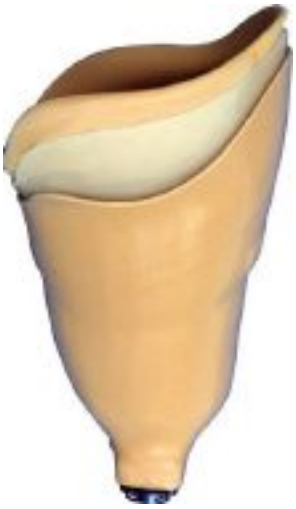
Westcoast Brace & Limb, Tampa, Florida, was among several facilities that participated in a pre-commercial release clinical trial of the Edison early this year. Westcoast had previously

participated in trials of other Orthocare products, notes lead prosthetist **Vern Swanson, CP, LP.**

Participating patients included Medicaid specialist and consultant Tim Case, 60. Case underwent a left transtibial amputation in 2004 just before scheduled surgery to correct Charcot foot deformity because an infection and gangrene had set in. Case had previously used a mechanical pump sub-atmospheric system.

Case is enthusiastic about the Edison, noting that he especially appreciates that the Edison (and some other electronic pumps) warns if there is vacuum loss. Since Case has peripheral neuropathy due to diabetes, he was unable to feel socket slippage when he lost vacuum in his mechanical system and suffered a large, painful blister.

Swanson says that patient presentations such as Case's can often be helped by a recent innovation, the Shock Absorbing Cushioned Socket™, which uses a customized cushioned insert to provide comfort and protection while maintaining a total contact socket. While this socket and insert turned out to be ideal for use with the Edison system, the cushioned socket can also be applied with other types of suspension.



*Photograph of Shock Absorbing Cushioned Socket courtesy of Westcoast Brace & Limb.*

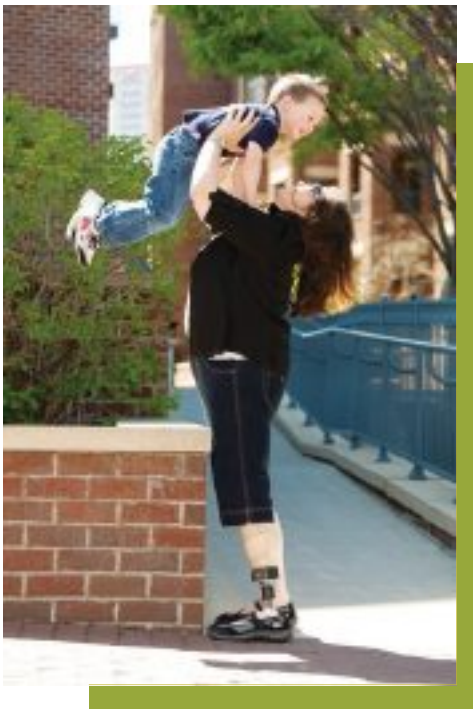
Steve Budd, 46, another trial participant, is at the opposite end of the spectrum from Case. Budd underwent a right transtibial amputation due to trauma but is otherwise healthy. He says he prefers the Edison to his previous mechanical system because its automatic vacuum adjustments throughout his highly active day leave him less fatigued. "It exceeded my expectations," he says in a YouTube video interview.

## *Future Directions*

Looking ahead, Boone says, "We want to enhance data recording and communication feedback to the patient, practitioner, and also to our Galileo™ Clinical Outcomes Assessment System. Our strategy is to provide information links and cross-connections with all of our devices for patients and clinicians. Improvements [to the Edison and Galileo systems] include adopting Bluetooth 4.0 low-energy technology."

## *Harmony P3: "Less Is More"*

The Harmony® P3 vacuum system is the newest generation of Harmony vacuum systems from Ottobock, Duderstadt, Germany. The P3 is smaller and significantly lighter than the P2 and P2 HD systems, Leach notes, plus it covers a wider weight range than its predecessors: 88–275 pounds as compared to 100–220 pounds for the P2 and P2HD.



*Photograph of Harmony P3 user courtesy of WillowWood.*

According to Ottobock's U.S. website (www.ottobockus.com), the P3's overall smaller size increases prosthetic foot options while the smaller circumference enhances cosmesis. The P3 uses a functional ring that provides vacuum generation, vertical shock absorption, and torsion in a single component that can be serviced by the prosthetist in minutes rather than being returned to Ottobock for servicing, Leach says. Like all Ottobock mechanical pump systems, the P3 is waterproof.

Ottobock offers the Triton Harmony® prosthetic foot, which combines the Triton carbon-fiber foot with the Harmony P3 pump. "It's a high-performance foot for K3–K4 levels with a mechanical pump, which doesn't restrict the foot's performance quality since it has relatively small build-height space," Leach says.

## *LimbLogic VS: New Version Coming Soon*

Like the Edison, the LimbLogic® VS electronic sub-atmospheric suspension system from WillowWood™, Mt. Sterling, Ohio (www.owwco.com), features "set-and-forget" technology, as well as inline fabrication and wireless remote control to adjust vacuum levels as needed via a handheld fob that uses proprietary wireless technology. The LimbLogic is waterproof in fresh water to a depth of ten feet for up to 12 hours at a time.

WillowWood is preparing to release a new version of its LimbLogic VS system this summer. According to WillowWood Product Development Manager **Steve Byers,** the new product incorporates significant improvements, focusing on reliability and ease of use:

- Battery charging has been changed to inductive charging, such as that used by rechargeable electric toothbrushes.
- The filter access has been reconfigured and relocated so filters can be changed in the field rather than sent back to the factory.
- Body style has been designed to be more aesthetically pleasing and easier to cover cosmetically.
- Electronics have been updated to support future enhancements in data collection and tracking.

## *NPS: High-Level Success*

The Negative Pressure Suspension (NPS) socket system developed by Patterson has been used with considerable success for persons with transtibial, transfemoral, hip disarticulation, and hemipelvectomy/transpelvectomy amputations. POA has successfully fit more than 30 hip disarticulation patients in the past year. Patterson says he often fits two or three hemipelvectomy patients in a single week.

*continued on page 32*

## Sub-Atmospheric Socket Technology...continued from page 30

The NPS includes a patented vacuum chamber that is lighter and has fewer moving parts than most other systems. The NPS system features lower trim lines and a specialized alignment technique to allow for a more natural gait for transfemoral patients.

Developing a successful sub-atmospheric transfemoral system involves much more than the vacuum chamber. Patterson explains that it took quite a bit of trial and error to perfect the socket design. "We struggled for a long time about the length of our inner cup," he says. "At first we used one-third the length of the residual limb for the vacuum cover, but that didn't provide enough vacuum for stability. Then we tried to go way up high and found that we compromised the remaining proximal muscles; the muscles couldn't fire. We finally found the appropriate level at about two-thirds of the residual-limb length, which provides control under vacuum without restraining range of motion. For the outer socket, we have to go higher for more control, especially for really short [residual] limbs."

Once Patterson and his team had found the appropriate length, they had to find the right technique for a proper socket fit. "We used CAD/CAM for a long time, but about a year or so ago we figured out that the double-wall system we use is actually a three-part system. First, we obtain the inner cup and put it under vacuum, then we create a customized brim, then we cast over that. When we tried to fabricate all of the parts all together, often we did not get a well-fitting socket."

Hemipelvectomy patients require a custom liner that fits with no air spaces. "Since these patients, especially cancer survivors, may have a lot of invaginations, often we need to make two or three liners before we achieve the right fit," Patterson says. "Then we custom make a silicone disk to achieve vacuum."

**Jon Batzdorff, CPO, FAAOP,** founder and president of Sierra Orthopedic Laboratory, headquartered in Santa Rosa, California, says he is a believer in Patterson's hemipelvectomy system. "I had a hemipelvectomy patient who wanted a sub-atmospheric suspension socket, and since I didn't know how to do it, she wanted me to go with her to POA to learn the NPS system for follow-up care," he says. "It worked very well for her; she's quite comfortable and functional. I also studied the NPS transfemoral system and have had good results with it." Batzdorff also is the president of ProsthetiKa, a nonprofit organization providing clinical assistance and technical training in developing countries.

### *V-Hold: "Intelligent" Control*

The V-Hold from Innovative Neurotronics, Austin, Texas, is a microprocessor-controlled, "intelligent" sub-atmospheric suspension system that assesses and automatically adjusts to increase or decrease vacuum to provide a stable, comfortable socket environment and keep vacuum within the range set by the practitioner, according to **Aaron Flores, PhD,** V-Hold project head. The V-Hold is set to provide 13 inHg with no programming required; however, it can be programmed to provide up to 21.3 inHg and allows for two settings that can be accessed by the patient through the press of a button. The V-Hold software,

V-Analyst, allows the practitioner to view the vacuum level for the system in real time, thus assisting in diagnosing socket fit, including significant voids and leaks in the socket, Flores adds.

### *AIRPUCK Modular Vacuum Chamber*

A recent entry in the sub-atmospheric market is the AIRPUCK™ from 5280 PROSTHETICS Littleton, Colorado (http://5280prosthetics.com). The AIRPUCK is a low-cost, modular (can be transferred from socket to socket) vacuum reservoir that can be connected to any external vacuum source. The device automatically seals the distal socket aspect and provides negative pressure for eight to ten hours after initial air evacuation, according to 5280 PROSTHETICS owner **Clint Accinni, CPO.** The device is completely self-contained and works well with both thermoplastic and laminated sockets.

Accinni is excited about the upcoming release of the SMARTPUCK, which he says is "the industry's first intelligent electric vacuum system that is installed inside the prosthetic socket. The device requires no holes, ports, or throughways into the socket chamber, thus eliminating the potential for any leaks other than the proximal seal. The SMARTPUCK communicates and is controlled by an iPhone® and provides data collection for K-level justification, computer alignment, and socket diagnostics," Accinni adds.

## Total Contact Socket: Critical for Success

For successful, beneficial sub-atmospheric patient application, the socket is the foundation, Batzdorff says. A total contact socket is essential. "You can't use another type of socket design and simply seal it and put a pump on it. A poorly fitting socket with vacuum will speed development of problems faster than another system. Practitioners and technicians really need to take the training on how to cast for a total contact fit."

"Building the socket is critical with vacuum because vacuum exposes imperfections in a bigger way than traditional sockets," Leach points out in his February 2012 *Academy TODAY* article. He notes that the socket must be total surface bearing. Any voids or spaces resulting from residual-limb shape change or a traditional socket-type relief area create low-pressure air pockets and must be filled to establish a total contact fit. "As the liner, skin, and soft tissue move toward a low air-pressure space, the patient may suffer discomfort, blistering of the skin, and even soft-tissue damage."

## Looking Ahead

As the number of clinical applications of sub-atmospheric suspension systems has increased, the technology has steadily evolved to meet the needs of a wider patient base. In the future, Leach says, "I think we'll see better, smaller, lighter pumps that have longer battery life, and smaller, lighter mechanical pumps," Leach says. As this happens, "Clinical products will expand the range of people we can fit with sub-atmospheric technology, including more upper-limb patients…. Manufacturers are working closely with practitioners to make their products more useful. Clinicians are taking more of a leadership role in the direction of the technology." O&P EDGE

*Miki Fairley is a freelance writer based in southwest Colorado. She can be reached at miki.fairley@gmail.com*

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