PROSTHETIC LINERS AND SLEEVES

By Miki Fairley

Reaching New Levels of Comfort, Control, and Suspension

Photograph courtesy of Ottobock.

The issues that challenge prosthetic liner and sleeve manufacturers are age-old: durability, residual-limb volume fluctuations, temperature and moisture control, and skin health. The solutions that are in development, however, are entering a whole new world. Innovations range from elegantly simple advances to amazingly sophisticated breakthroughs involving embedded computerized sensor systems. As elevated vacuum prosthetic technology grows in popularity, liners and sleeves will undoubtedly play a significant role. New, "smart" materials that can repair themselves or change their shape, thickness, softness, or durometer in response to changes in the socket environment to maintain fit and comfort may also step forward.

Some of the developments under way are so new, in fact, that several major manufacturers were unable to divulge many details at the time of this writing.

Although it is not possible to include all liner and sleeve manufacturers or research projects, this article reviews some of the newer liners, sleeves, and related products that are available on the market, previews what's coming soon, and provides a glimpse of what's on the horizon.

Addressing Liner Slippage

Ottobock's Anatomic 3D PUR Liner, introduced in 2011, combines several innovations to solve common problems such as liner slippage when skin moisture builds up. The liner uses a textured inner surface to maintain good skin contact despite moisture. Moisture collects in the "valleys" of the textured material while the "peaks" maintain good contact, explains **Scott Weber,** senior market manager for Ottobock, Minneapolis, Minnesota.

The nonstick outer surface, a Parylene coating bonded to the urethane using a chemical vapor deposition (CVD) process, allows easier donning and doffing. The liner's Anatomic Specific Geometry (ASG) design strategy addresses the problem of comfort and range of motion during knee flexion by having thicker gel walls in areas needing more protection and thinner gel walls in areas requiring greater flexibility; the liner also provides 20 degrees of pre-flexion for ease of bending and reduced wrinkles in the popliteal area. The liner is also available with SKINGUARD® antibacterial additive, Weber says.

Aligning the Liner Pin

The Ottobock MagnoFlex® Shuttle Lock helps solve the difficulty that individuals with amputations, especially those with vision or dexterity problems, sometimes have in aligning the locking liner pin with the socket hole. The device was shown at the 2012 National Assembly of the American Orthotic & Prosthetic Association (AOPA) and is expected to be released in the United States this year, according to Weber. The MagnoFlex features a flexible pin and a magnet in the shuttle lock. "As the amputee is settling into the socket, if the pin doesn't hit exactly in the middle, the magnet will help guide the tip toward the center, and the pin can flex and slide to align the liner…properly with the socket," Weber explains.

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Photograph of the Anatomic 3D PUR Liner courtesy of Ottobock.

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Eliminating Sleeves

The Aura and Echo Locking Seals from Evolution Industries, Orlando, Florida, are designed to work with expulsion or vacuum systems. The Aura, released in late 2011, is designed for soft tissue density, and the Echo, introduced in July 2012, is designed for medium to firm tissue density. "Using the locking seals with an elevated vacuum system provides a very secure system that doesn't require a knee sleeve," says **Craig MacKenzie, CP, RTP(c).** "The durability of most knee sleeves is terrible; bump against something and you can get a hole in them. But with Össur's off-the-shelf seal-in liners [Evolution Industries is an Össur company] or the customizable Aura and Echo, the seal is internal to the socket and can't be damaged."

MacKenzie continues, "With the Aura and Echo, we can put the seal anywhere you want. For instance, for a really long [residual] limb, such as with a Symes patient, we can put the seal 13 inches from the distal limb and use all that surface area for sealing and suspension."

Össur's Iceross® Seal-In® V and volume adaptive blades. *Photograph courtesy of Össur Americas.*

Taming Volume Changes

Technology and design developments from Össur, headquartered in Reykjavik, Iceland, tackle longstanding prosthetic fit and comfort problems, including daily residual-limb volume fluctuations, skin sensitivity, and sufficient liner and sleeve flexibility for comfort and range of motion.

The new Iceross® Seal-In® V transtibial liner, introduced in January, combines the best features of its previous iterations, the single-seal Iceross Seal-In liner and the five-seal Iceross Seal-In X5, according to **Diane-Marie "Mardi" Herte,** Americas product manager, prosthetics, Össur Americas, Foothill Ranch, California. The latest version incorporates volume adaptive blades (hence, the "V" in the product name) behind the seal, which can accommodate up to an eight-ply volume change. "The volume adaptive blades adjust to limb shape as it fluctuates in volume throughout the day," Herte explains. "In the morning, when the amputee's residual-limb volume fills the socket, the volume adaptive blades lie flat. However, as the volume shrinks with activity during the day, the blades stand up and push, maintaining contact to ensure that the seal is adhering to the socket wall to provide a secure and safe suspension."

Both the Seal-In V and Össur's Iceross Comfort® Wave S Liner, introduced in the fall of 2012, offer the Wave design innovation: horizontal "waves" that allow more stretch over the patella while reducing bunching in the popliteal area for pressure relief and easier knee flexion.

The Iceross Comfort Wave S liner is designed for patients with thinner or more sensitive skin such as geriatric or dysvascular patients. The liner doesn't include skincare ingredients, "since some patients prefer different options," Herte explains. "However, the silicone formulation provides a smoother surface that is only a tad tacky with its silky inner surface for skin comfort and integrity."

Controlling Temperature, Enabling Self-Repair

Stan Patterson, CP, owner and president of Prosthetic & Orthotic Associates of Central Florida (POA), Orlando, is sharing in a $4 million U.S. Department of Veterans Affairs (VA)-funded project along with several universities and other entities. The project primarily targets ways to improve prosthetic socket comfort and function for individuals with transfemoral amputations.

Patterson is part of a team that is investigating various types of sensors and nanotechnologies to create a liner that is capable of controlling temperature inside the socket, as well as a computerized feedback system to help amputees know as they don the prosthesis whether they need to remove or add socks. *(Editor's note: For more information, read "Outcome Measures: Are We There Yet?" on pg. 38 and "Walk This Way" on pg. 48.)*

"Being able to control the temperature within the socket environment can eliminate a lot of issues," Patterson says. "Besides discomfort, hot temperatures can cause the skin to sweat and macerate, leading to skin breakdown and possible infection. On the flip side, controlling socket temperature to provide more warmth in cold weather can prevent further circulation impairment for dysvascular amputees. We know that if we can keep the temperature close to the 98.6-degree body temperature, the skin is much less susceptible to breakdown."

Patterson's prosthetic team has patented and is utilizing a silicone liner that features a pleated, accordion-type design in the popliteal area that prevents material from bunching as the knee is flexed and eliminates tension from the distal part of the tibia.

Patterson is also developing a sleeve that amputees can repair themselves. "Sleeves are something that just drove me nuts!" he exclaims. "Just like many other facilities, for every sleeve we get reimbursed for, we probably have two that we don't get paid for. Extremely active patients can go through two or three sleeves a month…. Are we going to say, 'Well, our prosthetic care has helped you get to this level of activity; now stop being so active and tearing up those sleeves?'"

Users can repair holes, "not big slashes," Patterson points out, in the sleeve by mixing a formula that enables the gel material to be added into the hole and then curing the material by heating the liner in a microwave oven for four to five minutes.

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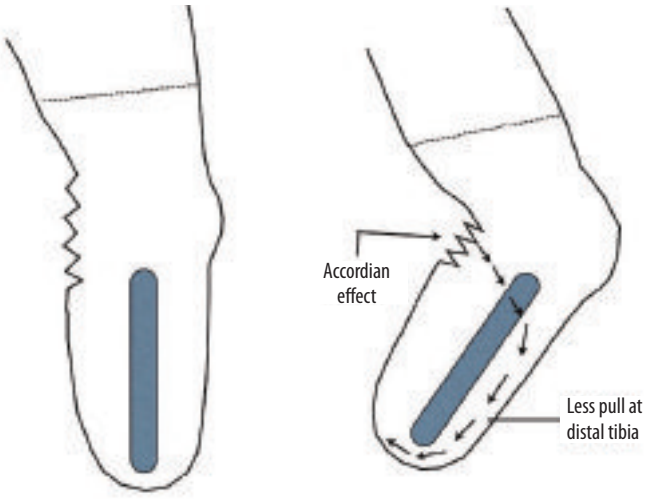
Patterson's liner design incorporates a pleated accordian-type design in the popliteal area. *Illustration courtesy of Stan Patterson.*



As they say, 'If the socket don't fit, you want to quit.'

— Stan Patterson, CP

"As an industry, we've made great strides with prosthetic feet, knees, and other componentry, but when we look at sockets and interfaces, we haven't done a good job of utilizing the technologies and materials that are out there," Patterson observes. "As they say, 'If the socket don't fit, you want to quit.'"

Reducing Shear

Shear within a prosthetic socket can be a big problem for prosthesis users. "If the shear is not addressed, it can cause skin breakdown, which can limit overall function," says **Charles Kuffel, CPO, FAAOP,** owner of Arise Orthotics & Prosthetics, Blaine, Minnesota. "Some of the areas of most concern include the patella during knee flexion, the fibular head during ambulation, and the distal anterior tibia."

Most interface liners are fabricated in a linear fashion but undergo multiple plane disfigurations during dynamic prosthetic use, he explains. This pushing and pulling between the skin, liner, and socket can create areas of shear. Although lubricated gels, socks, and sheaths can be helpful when used beneath the liner, they don't always provide adequate relief from shear. They can also cause distal migration of the liner and possible loss of suspension.

Tamarack Habilitation Technologies, Blaine, recently developed GlideWear™, a low-friction interface technology that is successfully being used on wheelchair cushions to reduce shear and tissue breakdown beneath the ischial tuberosities. Prosthesis users are using a scaled-down version of this technology, the GlideWear patch, to reduce shear on affected areas of the residual limb. Placed between the skin and prosthetic liner,

The GlideWear Patch (right) is placed on the residual limb to spot reduce areas of shear (left). *Photographs courtesy of Charles Kuffel.*

the GlideWear patch is used to spot-reduce shear by creating a gliding motion between the two layers of fabric that otherwise cause the skin to absorb the motion and disrupt skin integrity, explains Kuffel, who is helping Tamarack test the technology. The patch has been used on all areas of the residual limb that are prone to skin breakdown with positive patient responses and outcomes, he says, adding, "The use of the GlideWear patch by prosthesis wearers has also resulted in reduced incidences of follow-up for socket modifications and adjustments."

According to Kuffel, studies of the patch and its effectiveness are currently under way.

Chillin' Out

Columbia, South Carolina-based SCRA Applied R&D and Porticos, Research Triangle Park, North Carolina, have developed an affordable socket-cooling sleeve that uses a water-bottle-size canister of liquid carbon dioxide (CO_2), such as that used in paintball guns.

The cooling sleeve is being tested at the Georgia Institute of Technology (Georgia Tech), Atlanta. "We are excited about this concept although there is a way to go before commercialization,"

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Photograph of the SCRA cooling system courtesy of SCRA Applied R&D.