The Newest Technology in Transfemoral Socket Interfaces

Photo provided by Martin Bionics

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The past 10 years have seen some of the most significant developments in above-knee (transfemoral) prosthetics. Microprocessor knees, for instance, allow people who use an above-knee prosthesis to walk faster, safer, become more independent and get closer to achieving the activities they performed prior to amputation. Technology continues to evolve, giving amputees the ability to wear the prosthesis longer, do more, and demand more from their prosthesis. Greater comfort, less perspiration, less impinging in uncomfortable areas, adjustability and improved control are concerns of the prosthetic user today. These socket interface concerns are emphasized with newer technology, like microprocessor knees. The ischial containment socket was introduced more than 30 years ago. While the ischial containment socket greatly improved gait and comfort compared to the sockets of that time, it still presents many problems for the user. These problems are mostly related to the inability to adjust to daily volume changes and high trim-lines that are uncomfortable, limit motion, create heat and perspiration and interfere with simple tasks like going to the bathroom and getting in and out of a car.

Past and Present Research on Transfemoral Sub-Ischial Vacuum Socket Interfaces

In 2002, Kahle questioned the need for higher trim-lines with a case study, using a fluoroscope (moving X-ray) to examine the effect of lowering high socket walls (trim-lines). High trim-lines reportedly improve control, but make a socket uncomfortable and limit range of motion. The introduction of vacuum-assisted suspension offers improved control over the socket and prosthesis, which allows the opportunity to

lower the trim-lines and make more comfortable sockets. Kahle and Highsmith were contracted by one of the first companies to make a liner specifically for above-knee vacuum sockets (Southern Bone and Joint) to examine the effect of vacuum and the limits of a sub-ischial socket (low trim-lines well below the groin) compared to ischial containment (high trim-lines well above the groin). The results of these studies have been published in medical journals. In summary, in a properly designed socket, lowering trim-lines can be beneficial and most users prefer it.

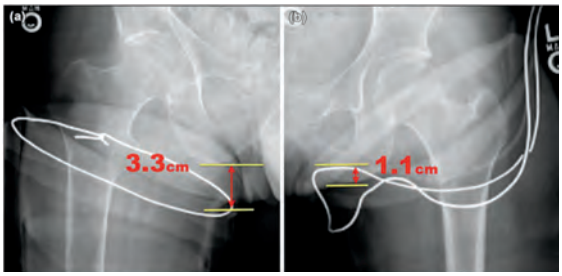
Many companies now make liners that allow your prosthetist to make a vacuum-assisted socket at the above-knee level, and lower the trim-lines, similar to the techniques used in the clinical trials. The traditional ischial containment socket with high trim-lines is being challenged as the "ideal" way to fit amputees by many prosthetists and prosthetic manufacturing companies. The evolution of the above-knee socket is happening right now with the recent introduction of many new advanced technologies.

Cutting Edge Prosthetic Socket Interface Techniques

Several companies and research teams are pushing the limits of traditional above-knee ischial containment socket design. These techniques have been recently introduced and are all currently available for your prosthetist to learn and for you to try if you are a candidate.

biodesigns HiFi Transfemoral Socket Interface

biodesigns CEO Randall Alley, CP, introduced the High-Fidelity (HiFi)™ Femoral Interface System into the field in 2011, after having great success with both his upper- and lower-limb HiFi Interface designs in his own clinic and on DEKA's Luke Arm Project, funded by DARPA. The predominant design differentiation with the HiFi Interface System is Alley's focus on the underlying bone for control, suspension, improved outcomes and overall patient health. While other sockets focus on simple limb encapsulation and ignore the femur's role, Alley's patented and patents-pending compression and tissue release technology recognizes and embraces the critical medical necessity of skeletal loading for delaying the onset of osteoporosis as well as the physiological and neurological benefits of a more direct connection to one's prosthesis. Significant additional clinical benefits include a sub-ischial design, increased comfort, greater propulsion, improved range of motion and proprioception, reduced energy expenditure, improved rotational control, reduced pistoning, improved gait symmetry and stability.



Sub-ischial (a) compared to ischial ramus containment (IRC) (b) and the relation to the pelvis using X-ray. A sub-ischial socket's trim-lines will be significantly below an IRC socket, using vacuum. A lower trim-line will offer improved comfort and range of motion while not compromising function. Courtesy JRRD.

Because HiFi Interfaces are sub-ischial, wearers report increased walking/sitting comfort, increased range of motion and greater freedom of movement.

The HiFi Imager is a key to the success of the system as patients are able to provide feedback during the casting/scanning of their socket.

Another key component to the HiFi Interface System is the use of the patented HiFi Imager. The Imager allows patients to provide critical feedback during the casting/scanning of their limb, in essence partnering with the clinician in the design of their interface. Finally, HiFi Interfaces are unique because the design can be used with all suspension techniques and can be adjusted on both a macro and micro level, enabling patients to precisely adjust not only their volume, but also their bone position. The HiFi Interface is available for both upper- and lower-limb wearers.

LIM Infinite Transfemoral Socket Interface

LIM Innovations is an orthotic and prosthetic design company that has set out to improve comfort, freedom and access to care. Their foundation is built upon improved socket design to improve outcomes and pressure distribution by providing a socket that can be fit quickly and can adjust in size, shape, alignment, suspension system and tension. The Infinite Socket™ is a custom-molded four-strut design combined with an advanced textile brim and tensioner to contain/control the skeleton and soft tissues across a varying volume. Adjustments can be made by both clinicians and patients to manage long-term and day-to-day fluctuations. The pivoting and sliding connection between the struts and base provides even greater flexibility in adjustability as well as shock absorption and energy response. The Infinite Socket's dynamic frame, together with a textile interface that is low in friction, anti-microbial, durable and washable, has led to hundreds of enthusiastic users.

The Infinite Socket achieves biomechanical control and appropriate pressure distribution through multiple custom components, including an ischial seat, proximal brim, four struts, and a flexible inner distal cup. Selective zones of compliance, shock absorption, and structural support are designed to optimize pressure distribution while providing dynamic control. Improved pressure distribution of the system is engineered to provide better function, control and safety while maximizing comfort across different activities and volume change.

Showing the anatomical fit of the custom-molded Infinite Socket TF C1. This illustration shows one embodiment but an advantage of this dynamic modular socket system is to have various suspensions and fitting shapes or approaches that can be applied, such as a sub-ischial brim option.

Suspension options include pin lock, lanyard, seal-in suction, and seal-in elevated vacuum. The carbon fiber used in the Infinite Socket is 0-90 twill weave carbon in a thermoplastic acrylic (PMMA) matrix, which allows the clinician to reheat, reshape and remold the struts to accommodate major changes in shape or volume of the residual limb.

Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket

The Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket (Figure A) was developed with funding from the DOD to provide above-knee prosthesis users with

Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket

a more comfortable socket. The NU-FlexSIV Socket has lower proximal trim lines that do not impinge on the pelvis (Figures B-E); is flexible so muscles can move comfortably within the socket as they contract during activity and splay during sitting (Figure F); and is held securely to the residual limb by active vacuum as well as compression of an undersized liner and socket. Using undersized compressive silicone liners helps to stiffen the residual limb soft tissue for effective force transfer between the limb and prosthesis. Active vacuum helps to further eliminate relative motion between the socket and limb, in part, by stabilizing residual limb volume. Socket stability during walking has been confirmed in preliminary gait analyses by lack of excessive lateral trunk flexion during prosthetic limb mid stance (Figure G). Preliminary evidence also confirms improved socket comfort compared to ischial containment sockets. Clinical experience fitting this socket to nearly 150 patients confirms these research findings. A clinical trial to further assess the NU-FlexSIV Socket, also funded by the DOD, is currently underway.

WillowWood One System

Initiated through a Veterans Administration grant, the WillowWood® One transfemoral socket system was designed and developed over a three-year period and included clinical testing with over 40 amputees. The system includes a fabric-less Alpha SmartTemp® liner, a gel sock, a seal, an optional LimbLogic® vacuum system, and a definitive socket with removable brim. A major difference the One System offers is that it seals internally to the socket and limb separately. Current internal sealing mechanisms depend on the residual limb maintaining contact with the socket, which can be disrupted by the position or volume changes of the limb, thus breaking the seal and losing suspension. In the One System, a brim is used to maintain one end of the seal in contact with the socket, while the other end of the seal conforms to the residual limb, enabling consistent suspension. Subjective data collected from questionnaires revealed that users were able to put the prosthesis on in the morning and did not have to repeatedly adjust throughout the day.

This cutaway model shows how the WillowWood One system creates two seal points for secure vacuum suspension.

This close-up of a prosthesis using the WillowWood One System shows that the prosthetic knee can be placed more closely to the position of a natural knee when the LimbLogic pump is placed on the side of the socket instead of at the bottom.

The system's Alpha SmartTemp® liner is made with material that absorbs heat from the limb. The liner's ability to control heat and perspiration

The Newest Technology | continued from previous page

was tested in a recent double blind randomized clinical trial and found to significantly reduce both. The results were published in the October 2015 issue of the *Journal of Prosthetics and Orthotics*. Additionally, research conducted as part of the VA project found that elevated vacuum improved residual limb blood flow and skin health compared to non-vacuum suspension methods.

Left: The Socket-less Socket uses compliant fabric-based materials, enabling it to truly conform to the user. No more static socket shape. No more rigid ischial seat. And no more loss of suction.

Right: The Socket-less Socket can be micro-adjusted in real-time to the user, allowing for immediate patient feedback during the fitting process.

Martin Bionics Socket-less Socket

In 2012, Martin Bionics was invited by NASA to transition its fabric-based socket designs into the space program to help them mesh exoskeletal robotics and astronauts. The program's success resulted in the discovery and creation of fascinating new materials and methods for meshing man and machine. Using the NASA-based hammock-fit technology, the Socket-less Socket uses lightweight compliant fabric-based materials to replace the rigid plastics conventionally used to make prosthetic sockets. This eliminates a rigid ischial seat and static socket shape, allowing the Socket-less Socket to truly conform to the user. "The uncomfortable areas that have plagued traditional sockets are now eliminated, and users find the brim and adjustability of this socket to be ultra-comfortable," says creator Jay Martin, CP, FAAOP.

The Socket-less Socket allows a prosthetist to custom fit a transfemoral socket typically in just one appointment, eliminating the need for antiquated casting, modification and iterative test socket fitting methods from the past. It can be micro-adjusted to the user in real-time with direct patient feedback, giving more control over how the socket fits. Its design provides excellent femoral capture and control for both long and short limbs. Donning no longer requires the limb tissue to be pressed or pulled into a static socket shape; instead, the fabric-based socket can now be wrapped *around* the limb, making donning much simpler, especially for seniors.

Science, Evidence and Evolution

The absence of evidence is not the evidence of absence. While these companies have introduced technology, in prosthetic and amputee research the science of a new technology usually lags behind the commercial-ability. Research is expensive and not all prosthetic manufacturing companies have the resources to invest in high-dollar research programs and clinical trials.

While they all need to strive to support research around proving the effectiveness of their product, it is important to be patient with that process. Using mechanical logic and clinical experience to invent and test a product is common in prosthetics. Unfortunately, the largest funding agency of research (NIH) has fallen short of delivering the money necessary for prosthetics research. The DOD recently funded Kahle and Highsmith, as well as the Northwestern group, to examine alternative socket designs. Many of the companies mentioned above are also pursuing self-funding research into the effectiveness of their products. Knowing the science and evidence behind a product is important; while the user's preference still seems to be the strongest evidence we have in prosthetic and amputee research.

Conclusion

New technology is needed, as we are still far away from truly replacing a limb. New prosthetic socket interface technology offers the potential of improving your use of an above-knee prosthesis. To learn more about each of these transfemoral socket interfaces, start by speaking to your prosthetist. Some of this technology has only recently been introduced, so if your prosthetist is unfamiliar with the technology, that's OK – you can learn together. These companies are developing training programs and disseminating their knowledge, technique and technology to prosthetists all over the world. A qualified prosthetist will be trained in anatomy, biomechanics, engineering aspects, gait and the knowledge of fitting any transfemoral socket. The specific technology discussed in this article may be good for you as a user. However, there is still no recognized "gold standard" for fitting prosthetic interface sockets; it may take some trial and error on your prosthetist's part and patience on yours.

If you're interested in trying these new technologies, it's important to remember that there has to be a medical necessity as defined by your physician. This means that just because it sounds good, it doesn't mean your insurance will cover it. The time to discuss alternatives with your prosthetist is when you are having problems with your current socket interface. It is then your responsibility to explain to your physician why you require a new socket interface, for which he will write the prescription. Your prosthetist will help you communicate with your physician.