

Patients With Osseointegrated Implants:

Challenges and Possibilities for Prosthetists

By Maria St. Louis-Sanchez



Mark Schaal adjusts components on Fred Hernandez's prosthesis. *Photographs courtesy of Fred Hernandez.*



As technology continues to adapt and change, prosthetists may soon have to add a new skillset: working with patients whose prostheses connect to their residual limbs via titanium implants inside their bones. Osseointegration (OI) for prosthetic attachment is growing in popularity around the world as patients with amputations seek alternatives to sockets.

“As media awareness and peer-to-peer interest develops, we do find ourselves discussing this surgical procedure more frequently,” says **Jamie Gillespie, HCPC Registered Prosthetist/Orthotist**, Pace Rehabilitation, Chesham, England, who has treated several patients after they underwent OI. “It is certainly causing debate within amputee social media sites.”

Recently, the technology was approved for limited use in the United States. In July 2015, the U.S. Food and Drug Administration (FDA) approved the humanitarian use of Integrum’s Osseoanchored Prostheses for the Rehabilitation of Amputees (OPRA) device for people with transfemoral amputations.

While the technology is promising, it still carries risks and can only be used for a fraction of patients with amputations, experts say. However, for those patients who are candidates, the role of the prosthetist will be as important as ever.

“Patients will still need prosthetists to make sure the connections to the limb and the alignment is optimal,” says **Sarina Sinclair, PhD**, who works with research and clinical teams to help develop OI implant technology at the University of Utah (U of U) and the George E. Wahlen Department of Veterans Affairs Medical Center’s Bone and Joint Research Lab (BJRL), Salt Lake City. “We are not making changes to what needs to be provided to the patients for their legs, knees, ankles, and feet. In some ways it will open up new components that they will need and prosthetists will have to learn about or develop.”

A Possible Solution for Socket Discomfort

While socket technology has improved greatly through the years, there will always be some patients for whom sockets are not ideal, experts say. For these people, the OI procedure might be a good solution.

“In most cases, we can provide comfortable and effective sockets, but the residual limb is a constantly moving target with daily [volume] fluctuations, limb maturing, weight gain or loss, and environmental factors such as heat and cold influencing socket comfort and fit,” Gillespie says. “For many, this is manageable. Others struggle and look to osseanchored prostheses as a possible solution. For some, especially bilateral transfemoral amputees, we have seen it make the difference between being able to walk with prostheses or not.”

A direct connection of the prosthesis to the bone means the patient is more sensitive to the surfaces he or she traverses and, for example, can tell the difference between walking on carpet versus rocks. This will mean fewer falls, experts say. Plus, comfort may be increased because bones, by design, are better able to bear weight than the soft tissue of the residual limb.

“Biomechanically, they can use what they have left of their limbs,” says Sinclair. She adds that because of their improved ability to ambulate without the use of walking aids after the surgical procedure, OI may also help patients who have worn out their shoulders because of their continual use of crutches.

“We certainly don’t think this will replace the socket system,” she says. “We want to offer it as an alternative to people.”

Researchers continue to study the benefits and risks associated with OI. In fact, long-term risks are still being discovered even for the more established methods, Gillespie says.

“We do not have enough historical data to fully understand the long-term risks of the current procedures,” he

says. “For those who have opted to receive this surgery, there are obvious short- to mid-term benefits. It certainly looks encouraging, and we believe that these techniques will continue to play a part in our work in the future.”

Promising Technology, But Not for All

While osseanchored implants have been used and tested for more than 25 years in Sweden and for more than 30 years in Germany, researchers around the world are still working to perfect the technology and gain peer-reviewed acceptance of their methods.

Thus far, the OPRA implant system is the most widely accepted and researched system. This system requires two surgeries. In the first, a titanium implant called a fixture is

inserted into the bone of the residual limb; in time, the bone will grow to attach to the fixture. In general, the patient can’t put weight on the bone for six months as the bone heals, and then he or she must gradually apply more and more weight until the bone is capable of bearing the patient’s weight. In the second surgery, an extension known as an abutment is attached to the bottom of the fixture. The abutment sticks out of the skin and is used to attach the prosthesis.

Experts say that many patients who have used the system have reported less pain and greater mobility, but there is also a higher chance of infection than with traditional sockets and a danger of a bone fracture if a patient has a bad fall.

Roy Bloebaum, PhD, an orthopedics research professor and bioengineering →



From left: Schaal, Hernandez, and Rudy Nunez, Schaal’s former employer who made Hernandez’s first prosthesis more than 30 years ago.

Schaal checks the alignment of Hernandez's prosthesis.



and biology adjunct professor at U of U and the codirector of the BJRL, says researchers are working to improve the technology.

His team, which includes Sinclair, received full FDA approval in July 2012 for an early feasibility study to implant their device into ten patients, and in December 2015 two Iraq war veterans underwent the first stage of the surgery. The BJRL team hopes the porous titanium material with which their implant is coated will be better at helping the bone form a secure bond with the implant which will prevent infections and have a better interface with the skin.

However, all OI implant technology should be approached with caution since there are still risks, Bloebaum says. "If a patient is content with the socket system, we'd encourage them to keep using it," he says. "Right now there's about a 50 percent infection rate."

In truth, most patients with amputations won't be candidates to get an osseanchored implant. "I'd say that 60 percent of amputees are diabetic and have neurovascular disease," Bloebaum says. "Those patients have compromised immune systems or have vascular problems that will limit the use of these

devices for at least a decade."

Of the rest of the people with amputations, viable candidates would be limited to those who have a transfemoral or trans-humeral amputation. "I'd be shocked if in the next five years there are more than a couple of thousand who had implants," Bloebaum says.

For those who are good candidates, Sinclair stresses the necessity of the prosthetist's role.

"The implant is worthless without a prosthetic limb," she says. "You still have to make sure that the alignment for that prosthetic limb is correct [and] make sure the components are correct for the activities [the users] want to perform. Everything from the implant down is still going to need service and care, and the people who provide that care are the prosthetists."

Prosthetist and Patient Partnership

Patients with OI implants are already working with prosthetists in the United States.

The OI procedure has meant a whole new lifestyle for Fred Hernandez, who prompted his prosthetist, **Mark Schaal, BOC**, owner of Quality Care Prosthetics & Orthotics, Anaheim, California, to learn about the new possibilities.

In 1985, at age 17, Hernandez fell asleep behind the wheel of his car and steered into a semi-trailer truck, leaving him crushed and trapped in a burning car. Emergency crews saved his life, but medical complications left him with an amputated right leg and a left leg so burned and damaged that a large amount of skin and muscle had to be removed from it. When he had healed enough to wear a prosthesis, the road to walking was slow and painful. His injured left leg and an injured pelvis from the crash made it much more difficult, he says, and for 28 years he never felt comfortable in a socket.

"When you wear a socket, specifically

an above-knee, everything revolves around the socket and your comfort," Hernandez says. "Just sitting on a chair, you are sitting on the socket."

When he heard about OI implant technology and did his research, he says he knew he had to try it. He sold everything he had and temporarily moved to Australia for the procedure.

The process was difficult, he says, but worth it in the end. "It's as if you have your limb back again in a lot of ways," says Hernandez.

The continual pain from the socket is gone, he says, and his mobility has improved. Since he's recovered, he's become a spokesman of sorts for OI and is always trying or testing new prosthetic components to find even better solutions.

His search has meant even more work for Schaal, who initially thought Hernandez having the implant would make his job simple. "At first I thought, 'This is easy, all I have to do is put a knee on and that's it,'" says Schaal. "But it's much more technical than that."

Getting the correct alignment was a challenge at first, especially since the angle of the adaptor Hernandez used initially was not adjustable, so there was no way to slide the knee forward or backward to adjust it. Since then, however, Schaal says there have been some improvements in the adaptors. Also, he says, with the implant, Hernandez is better at sensing the differences in componentry and thus had a harder time finding the components that work best for him.

Since Hernandez keeps close tabs on the new technologies, he is always bringing in something new for Schaal to fit him with.

"There are always changes," Schaal says. "Almost every six months there's a new adaptor to try out."

He doesn't mind though. In fact, he says, he's happy because it means he, too, keeps up with the latest technologies. The end result means that his patient is happier, more mobile, and in much less pain.

"He does great now that everything is dialed in," he adds. ➔

The Prosthetist's Role

Gillespie, who has worked with patients with OI implants at his practice, says there are many ways prosthetists can prepare to work with these patients. For the most part, the work is similar to traditional prosthetic work, he says.

“The role of the prosthetist is a slightly different one, but it’s not too far away from normal practices,” he says. “The socket has simply been removed. The prosthetic components still require trial, selection, correct setup, and continual maintenance as we would under a socket.”

and then brought back to the [United Kingdom],” Gillespie says.

Prosthetists should also have contact with the companies that will be providing the connection adaptors for the patients, he says. Prosthetists need to understand the specialized adaptors specifically designed to work with OI implants that they will be working with and also have the tools they will need to make any adjustments.

“Make sure you can access the tooling kits and spare parts at short notice and know how to dismantle and reassemble any sections connecting the implant to the prosthesis,” Gillespie

and tear on other components as well.

“One area which we are monitoring is the durability of standard prosthetic devices used by this group of clients. We have seen some components requiring replacement and inspection under warranty,” he says, noting that knees tend to get worn out. “It’s not clear at this time if increased maintenance/replacement is a result of higher levels of function and use when compared to socket users.”

Continued Patient Care

Prosthetists may have to find new ways to care for their patients with OI implants, but that doesn’t mean their

role is any less necessary in the future, Bloebaum says.

The traditional socket is not going anywhere, he says, since most patients aren’t candidates for OI implants, and even those who get them may have to return to sockets if they get an infection or acquire some other medi-

cal condition that requires removal of the implant.

“Sockets are still going to be universal for decades to come,” Bloebaum says. “I’d probably say centuries.”

And, patients with OI implants will need their prosthetists even without a socket to fit.

“Until more established and durable designs of connection adaptors are developed, it would be wrong to assume this group of patients will walk off into the sunset not to be seen again,” Gillespie says. “There is certainly a need for continual clinical support.”

Instead of seeing this technology as a possible threat, Gillespie says, prosthetists and rehabilitation teams should see it as their next professional challenge.

“This is a new and interesting challenge for us as a profession,” he says. “Like all new concepts, it requires an investment in time to learn how to deal with it well.” **O&P EDGE**

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—Roy Bloebaum, PhD

However, there are a few differences he notes. Many patients travel abroad for the surgery—Sweden and Australia are popular, though it is offered in Africa and other European countries as well—and return to their prosthetists with a variety of adaptors for their OI implants and other componentry that are popular in those areas but not necessarily in their home countries. If possible, prosthetists should try to communicate with their patients and the prosthetic device manufacturers before the surgery to make sure they are all on the same page about the devices patients will be using after their surgeries, Gillespie says. He says the prosthetists at Pace Rehabilitation provide patients with the microprocessor knees they will be using after the surgery to use during the early stages of rehabilitation at their surgery sites abroad.

“This allows for much easier continual maintenance and servicing following surgery rather than devices which may have been purchased overseas

says. “If an issue occurs, you will be under pressure to assist.”

Just like with many other patients, prosthetists will have to work in tandem with physicians and physical therapists. The physicians will be integral in helping manage the opening in the residual limb where the abutment sticks out, called the stoma site, and dealing with any infections that may occur. Physical therapists are key to helping patients reestablish walking and moving patterns—especially working with weakened muscles that have previously been supported by a prosthetic socket, Gillespie says.

For their part, aside from determining correct alignment and componentry, prosthetists will also need to watch the adaptors attached to the OI implant.

“The adaptors will require replacement with time due to wear and tear from normal use,” he says. “The warranty and replacement periods vary, but these can be as little as two years.”

His team has also noticed that prosthetists have to watch out for more wear