The Devil Is In The Details

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With a growing amputee population, two firms partner to design artificial limbs that use vacuum pumps to increase circulation, comfort, and quality of life.

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A new system for prosthetics eliminates excess motion and, since the vacuum pressure is high enough, converts perspiration from the socket to a vapor that seeps out through the pump back into the atmosphere—curing another ailment of the below-knee amputee community.

Until recently, artificial limbs were held on via archaic methods, such as straps, sleeves, or pins. All of the former methods allowed for certain types of motion, motion that creates sores and pressure. Ray McKinney, certified prosthetist orthotist (CPO) of McKinney Prosthetics, and his partner in design, William Flemming, president of Dynaflo, have developed a vacuum suspension system to create a seal that securely holds the prosthesis to the limb.

The new system eliminates excess motion and, since the vacuum pressure is high enough, it converts perspiration from the socket to a vapor that seeps out through the pump back into the atmosphere—curing another ailment of the below-knee amputee community.

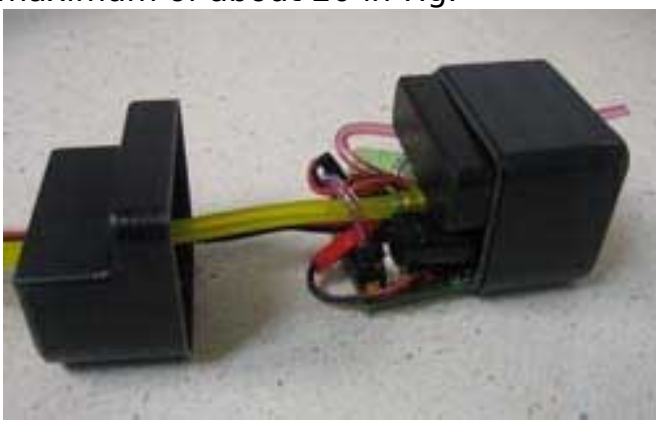
The vacuum not only holds the leg on, but it also makes the prosthetic feel lighter and stabilizes the bind between the limb and prosthesis.

“Normally, as amputees will tell you, when they put the leg on in the morning it will usually fit fine, but it shrinks and continues to shrink all day as a result of the positive pressure of the prosthesis,” says McKinney. “But with elevated vacuum, if it’s higher than 15 in-Hg, which these pumps are, it keeps the limbs from shrinking.”

According to McKinney, limbs normally shrink anywhere from seven to 12 percent of their limb volume in the course of the day. In vacuum, they shrink less than one percent, and problems typically don’t occur until four percent. The seal between the socket and the limb and liner is not perfect. Over the course of several hours, the vacuum will diminish and the pump has to be able to reestablish the vacuum.

The pump was Flemming’s brainchild and was designed specifically for this application.

“What’s unique about the pump itself is the fact that it’s very small, but it’s capable of generating a relatively high vacuum level [up to 25 in-Hg] and that compares to an absolute vacuum level of about 29 in-Hg,” says Flemming. “In most actual installations, nowhere near 25 in-Hg is required. They typically run up to a maximum of about 20 in-Hg.”



The key attribute of the pump is its ability to start against a relatively high vacuum. Pumps of this type are characteristically capable of running against a higher load, whether it be pressure or vacuum, but they’re capable of running against a higher load than they can start against.

Flemming had to develop a system that was capable of starting at a relatively high load to suit this application.

In a diaphragm-type pump, such as this one, the pump seals the media/fluid path from the outside environment. This is advantageous in this particular application

because a number of things, including sweat and/or lubricants, are used to put the sockets on.

“A number of things can go wrong in the context of a system that is electronically controlled,” says Flemming. “It’s good to have a pump that seals the fluid path and can be exhausted externally to the rest of the system.”

Without the vacuum, the remaining limb continually shrinks all day. When it shrinks, it gets loose and it bobbles up and down, which causes sores. With a vacuum, it prevents that shrinking from taking place.

“If they’re nice and comfortable at the beginning of the morning [with the vacuum], they’ll still be comfortable if they’re dancing at midnight,” McKinney says.

Pain & Suffering

McKinney is currently on the clinical end of the design, but it has been demonstrated that, by virtue of the cycling of the vacuum load, circulation in the residual limb is promoted. This encourages healthier tissue, better healing, and far fewer problems for amputees.

The device is installed as part of the prosthetic, so it has to be small, lightweight, and portable. In most of the devices, the source of power is a lithium-ion battery. Lithium-ion cells have a nominal cell voltage of about 3.7 VDC. As a result, the pump must be capable of operating at a really low applied voltage.

The motor that drives the pump is a Maxon Motor RE-14 series ironless core motor which can provide high torque output in a relatively small diameter.

“It stands to reason that torque output on a small DC motor goes hand in hand with its diameter,” says Flemming. “The diameter of the motor is 15 mm, yet it puts out a solid amount of torque. That is a key part in our ability to generate a high level of vacuum, but start against a high level of vacuum. They are top-shelf motors.”

Having been in the pump business since the 1980s, Flemming has been aware of the different types of motor technologies available in smaller, subtractional horsepower DC voltage motors. He built the entire 2102x pumps around the motor. The pump is optimized around the motor’s capability and the whole package is optimized around the requirements of the application.

“We’re still advertising this pump as the smallest diaphragm pump capable of these vacuum levels,” says Flemming. “The next step would be to try and reduce the size even more, but the smaller you go, the less throughput you can make available. If we went with a smaller pump, we’d have to go with a smaller pumping diaphragm in order to generate the same vacuum levels, but that essentially means that it would take longer to evacuate the socket. There is a trade off, but the driver here is the motor technology.”

Flemming has also designed another pump that is 60 percent smaller in order to make it practical to put in a knee brace. The vacuum holds the brace in place and

keeps it from migrating.

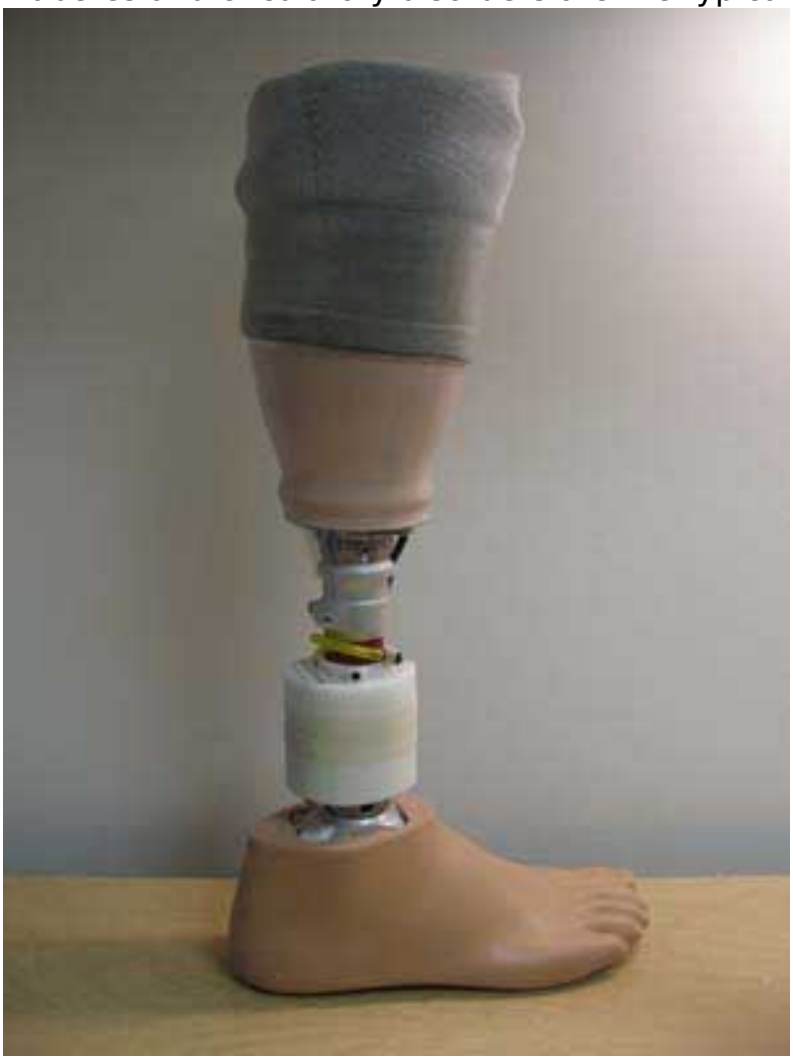
"Our legs are conical," says McKinney, "and with gravity, sweat, and hair on an active patient, knee braces tend to slide down."

On the knee brace, the vacuum pressure reaches 4 ½ in-Hg, more than enough to hold the brace in position.

Fighting Diabetes

Unfortunately, the prosthetic market is a growing one, ushering in 52,000 brand new amputees a year in the U.S. alone. The country currently has millions of existing patients.

Diabetes and circulatory disorders are the typical culprits causing amputation.



"Amputation is at record levels right now," adds McKinney. "You hate to say it, but if you're a prosthetic supplier, it's an unfortunate but vibrant business until they get this diabetes under control."

The cost of prosthesis can range from $15,000 to $70,000. In perspective, the $2,000 pump is not an expensive piece within the frame.

"The pump does make the cost of the prosthetics higher, but the benefits that it

provides far outweigh that cost," says McKinney. "When people are wearing other sockets and they keep having sores and shrinking out of them, the sockets have to be constantly replaced. Now the sockets don't have to be replaced. In the long run, the costs are much less, not to mention the pain and perspiration is gone."

The most important fact is that 95 percent of amputees at McKinney Prosthetics are now fitted with vacuum systems.

First Signs of Hope

The first elevated vacuum system that was put onto a patient was designed by Carl Caspers, a technologist with a unique relation to the market: he too was an amputee.

According to McKinney, Caspers should be given all the credit for designing vacuum systems; however, Caspers designed a mechanical unit.

"His unit was under six inches long, weighed a pound and a half, and had very few places where you could put it," adds McKinney. "It felt like you were dragging around a ball and chain. We went to Bill [Flemming] and he designed a pump that weighs 2 ¾ oz. He was able to put together a system that we could fit in almost any prosthesis."

Flemming's design is a more practical delivery method because it doesn't require ambulation to make it work. According to McKinney, the "old mechanicals had to be stood on, compressed, and moved up and down to create a pumping action to draw vacuum."

Flemming's design is electronic, and pumping occurs when the patient is sitting, standing, or walking.

"I can't tell you how many amputees' lives are better because of what Bill has done," McKinney says.

"We did not invent anything new in the sense that small diaphragm pumps have been around for a long time," Flemming concludes. "But the devil is always in the details, and we paid very close attention to the details in the design to achieve the desired level of vacuum performance."

For more information visit www.mckinneyprosthetics.com [1] and www.dynaflo.com [2].

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