

Amputee Inventor

Develops New Suction Socket



Rick Greenwald, PhD, is the co-founder of Simbex LLC.

Fluids engineer and amputee **Robert Dean, ScD**, of Norwich, Vt., knows few limits, whether it is inventing new products and processes or biking through Scotland. A transfemoral amputee for 60 years following a farming accident at age 14, Dean wore a quadralateral socket with his prosthesis for nearly 50 years. But a serious heart attack in 1990 caused him to lose weight and require a new prosthesis and socket.

A prosthetist fit him with a more contemporary medial lateral socket, but after seven office visits Dean was dissatisfied with the fit. While the socket fit well in the morning, his residual limb lost volume as he was active during the day, causing the distal end of his femur to painfully hit the bottom of the socket by day's end. Dean, also an adjunct professor of the Thayer School of Engineering at Dartmouth College, knew there had to be a better way and that he wasn't alone in his frustration.

During the next 10 years, with financial assistance from the National Science Foundation's Small Business Innovation Research program and later from the National Institutes of Health, Dean and his fellow researchers undertook a series of experiments to test sockets that would adjust to limb volume changes.

First, they measured hourly volume changes in his residual limb. Then, they built an automatically adjusting socket with a pump, pressure transducers, microcomputers and temperature sensors. But transfemoral and transtibial amputees in

By Joan D. Bennett

the study group found the system too heavy, noisy and power consuming. Next, the research group tried heating thermal gels to control volume change, but the gels produced little pressure.

Inspiration Strikes

In 1998 as he sat at his desk looking at pressure data from people walking on a treadmill, Dean suddenly realized that walking itself is a pumping cycle. During each step, the pressure in an amputee's socket increases as weight is placed on the foot and decreases as the foot leaves the ground. Dean recognized that during this walking cycle, a residual limb in a suction socket lined with a liquid-filled bladder would force liquid out of a reservoir and then "suck" liquid back in, repeating this process with every step and allowing the socket to adjust to limb volume changes.

"We've got a pump that is activated by walking," said Dean. "So we developed a simple hydraulic circuit that requires no electricity, batteries or fancy sensors."

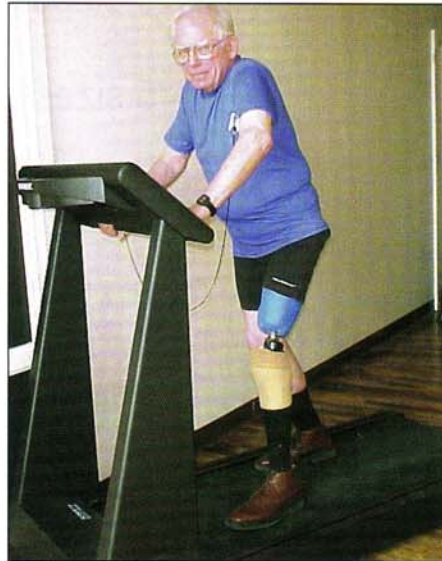
Dean built the first suction socket prototype control circuit in a day and tested it himself, refining its components over time. The device evolved into the Active Contact System, which was unveiled in March 2002 during the Annual Meeting and Scientific Symposium of the American Academy of Orthotists and Prosthetists. Simbex LLC, a research and product development company that sells the device, was co-founded by Dean and **Rick Greenwald, PhD**, a biomedical engineer and president of Simbex. The company, based in Lebanon, N.H., focuses on active life improvement products (see sidebar on page 103).

Energy of Walking

The patent-pending Active Contact System uses the pumping energy created by walking to power a fluid control circuit called the Actiflow Circuit. This circuit

automatically sends incompressible fluid in and out of the bladders in the socket to maintain fit as the limb changes volume during activity or natural body fluid changes, Dean said.

A pressure regulation valve is pre-set by the prosthetist to maintain a comfortable maximum system pressure, and a valve allows the user to drain the fluid into



Dean works out, using the socket he invented.

a reservoir at night for easy morning donning. When a patient first puts on the device for the day, the system returns to the set pressure after approximately 10 steps.

"The key feature is its dynamic and continuous adjustment of volume to maintain comfort," said Greenwald. "It is sensitive to the user's activity level, so when you're highly active, it functions to maintain comfort and stability, and it relaxes when you relax so you don't feel constrained by your prosthesis."

The Active Contact System can be manufactured into a new prosthesis or retrofitted into an existing one. Greenwald said the system is used in combination with other products, rather than replacing

them. Various techniques can be used for the suction socket and frame design, and nearly all commercially available knee components can be used with the device. It weighs less than a pound and a height build-up of approximately one-quarter inch should not affect gait symmetry, he said.

Pilot Trials

Pilot trials of versions of the Active Contact System were conducted at Next Step Orthotics and Prosthetics in Manchester, N.H. **Bob Emerson, PA**, a prosthetist and transfemoral amputee, tested the Active Contact System himself, as did several other clients. These pilot trials provided information on the design, shape and position of the bladders and potential fluid consumption. Parts and devices were also fabricated during the early pilot trials.

"Most amputees can relate to losing volume control," said Emerson. "The goal was to influence this project to make it a workable solution for amputees."

Clinical Trials

The Active Contact System has been on the market for a year now. Simbex is in the process of completing a clinical trial with 40 transfemoral and transtibial amputees in a 20-week crossover study. In the randomized trial, each patient began the trial wearing his or her current suction socket for eight weeks, followed by a four-week accommodation period before wearing the new socket for eight weeks, or began the study with the system and then reversed the process.

Research variables include computerized gait analysis using a Gaitrite walkway, oxygen consumption, Socket Comfort Score (SCS) and a Prosthesis Evaluation Questionnaire (PEQ).

Intermediate results from the transfemoral clinical trial study indicate statis-

Simply Better Exercise

Simbex, a contraction for "Simply Better Exercise," was founded in 2000. This engineering research and product development firm specializes in biomechanical feedback systems. The company's goal is to create marketable products and solutions for active improvement in the areas of human performances, sports injury and rehabilitation.

"In the field of prosthetics, we are evolving from a research to a product development company," said Greenwald. "Our next goal will be to ramp up our sales and distribution efforts so we will be ready for the launch of our transtibial volume management products."

Other products in Simbex's pipeline include the IBEX™ In-Bed Exerciser and Head Impact Recording Technology (HIRT). The IBEX is a portable, interactive exercizer to improve leg strength and prevent muscle wasting in elderly and sedentary patients. The HIRT monitors and records the severity of impacts taken by an athlete during contact sports, such as football and hockey. The miniature impact monitor is worn inside protective equipment, where accelerometers and telemetry can provide vital, real-time, hit-by-hit data (patent pending).

tically significant improvements in SCS. Additionally, several key indices from the PEQ were found with complete data from only nine of 20 patients. Oxygen consumption with the system decreased for most participants.

"One way to look at the PEQ and SCS scores is that they are validated measures of telling whether an amputee is stable and comfortable with their prosthesis," said Greenwald. "We are seeing more than a 10 percent increase in these scores, which is


scientifically relevant."

He also said that comments from the study's patients are clinically relevant and valuable to the researchers.

"Many prosthetists want good scientific information, but they also want to know that changes are important in their clients' daily lives."

The researchers are hopeful the clinical data will help prove the medical necessity of the device, ultimately allowing for Medicare reimbursement.

"We hope the Active Contact System will allow amputees to maintain a more active lifestyle," said Greenwald, "and to improve the comfort and stability of their prosthesis throughout the day, no matter what they're doing."

This is what Dean had in mind when he started experimenting years ago. 

FOR MORE INFORMATION:

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