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Local man's oxygen device able to heal chronic wounds

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Roger Mezger
Plain Dealer Reporter

Mel Burk's father-in-law was 89 when he developed a nasty pressure sore on his foot.

Two years of treatment failed to heal the open wound. Complications set in. The doctor said that without an amputation, Burk's father-in-law would die.

Then Burk told the doctor about a medical device he was developing an oxygen bandage system for treating just that kind of chronic wound.

With nothing to lose, the doctor let him try it. The wound healed, the amputation was canceled, and Burk's father-in-law lived to be 95.

Now, after nine years of work, Burk's brainchild is finally on the market. Limited production of the wound-therapy device, called EpiFLO SD, started this month.

Using technology adapted from fuel cells, the matchbox-size device sends a slow, steady trickle of pure oxygen to the wound site through a spaghetti-thin, flexible tube. In tests, wounds that had been open sores for months or years often healed after treatment.

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"Grandma used to say, If you want the boo-boo to heal, you let air get to it," says Burk, co-inventor of the technology and president of Ogenix Corp., the Cleveland company marketing the device.

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But EpiFLO is aimed at conditions much more serious than boo-boos. Each year more than 4 million Americans are treated for chronic wounds such as leg ulcers, bed sores and diabetic foot ulcers at a cost of about \$9 billion, the National Institutes of Health says. The wounds are hard to heal because poor circulation keeps oxygen-rich blood from reaching them.

Burk, of Beachwood, believes his company's product will cause "market disruption." It is more cost-effective than today's standard therapies for chronic wounds, he says, including oxygen treatments that confine patients to a room for a few hours every day.

The battery-powered EpiFLO, on the other hand, works continuously and does not restrict mobility. The small plastic box attaches anywhere on the patient, while a sterile dressing holds the tip of the flexible tube in place at the wound site. The device lasts seven days, so the patient needs a new one for each week of treatment.

Doctors can't believe the device is so small, Burk says. "You put it in their hand and they say, 'Where's the rest of it?'" But those who have tried it on hard-to-cure patients say it appears to work.

Summa Health System's Wound Care Center in Akron gave a test version of the device to eight patients, who also continued to receive traditional care.

"With eight patients, it's hard to draw any sweeping conclusions," cautions Steven Schmidt, the center's research director, who says a larger-scale study is needed.

Evidence of healing

Still, there are examples of success in other tests. An 80-year-old woman who had a bed sore for several months started healing when her doctor included EpiFLO in her therapy, said Corrine Tanski, a nurse and program director at the Wound Care Center.

Dr. Alan Hirsh recently treated a 65-year-old diabetic woman at University Hospitals Health System's Chagrin Highlands offices. An open foot ulcer that the woman had for at least 14 years closed after about two months of therapy with the device, Hirsh said.

Hirsh also is the doctor who treated Burk's father-in-law. "That got my attention," he says. Now a true believer in the technology, he has invested in privately held Ogenix.

In Florida, Dr. Tamara Fishman, a North Miami Beach podiatrist with no financial stake in the company, said that two months of treatment has nearly healed a stubborn wound on the toe of a 104-year-old man, sparing him a risky amputation.

The secret to EpiFLO is a polymer film membrane, about an inch in diameter, that is like the membrane in some fuel cells. The membrane

is the gatekeeper in an electrochemical process that draws oxygen from the air and concentrates it for delivery to the wound.

ICET Inc. of Norwood, Mass., an Ogenix investor headed by a Case Western Reserve University graduate, makes the membrane. Northeast Ohio suppliers make some of the other parts. Astro Instrumentation LLC, a medical device contract manufacturer in Strongsville, is handling assembly.

For the rest of this year, the prescription-only device will be available only here and in southern Florida, where chronic wounds are a problem for the elderly population. Before rolling out the product to other regions, Ogenix will try to convince health insurers that paying the \$700-a-week bill for EpiFLO is cheaper in the long run than the cost of other advanced wound-care therapies.

Science, business merge

Science has always fascinated Melvyn Burk, 63, a modest man who did not want to be photographed for this story. But his background is in business, not in science and medicine.

"I don't know where the ideas come from," he says, though he admits to poring over science magazines "like some people read novels."

Burk spent 25 years at Predicast Inc., a business information database publisher. He was chief financial officer when the Cleveland company was sold and moved to San Francisco in 1993, leaving him and others behind.

While Burk searched for another job crunching numbers, the government approved a patent that he and a friend had applied for a couple of years earlier.

The friend is Daniel Scherson, a chemistry professor at Case. Their invention, a technology for making concentrated oxygen, grew out of one of their scientific chats.

The technology has many commercial applications, Burk believes, particularly in the \$17.8 billion worldwide industrial gas business. But the inventors wanted to try it first in a field where there was little or no competition. They learned about chronic wounds, and in 1995 Burk started Oxyfast Corp. to develop an oxygen bandage.

"I never realized that patients could get a wound where you could look into the wound and see tissue, muscle, tendon and bone and no blood," Burk says. "The skin just opens up."

More work ahead

The Oxyfast device won Food and Drug Administration approval last year. Worried about being confused with makers of laundry detergent and other consumer goods, the three-employee company changed its name to Ogenix.

Burk is setting up a second company that will use the same technology to build an oxygen concentrator that patients with breathing problems

can use at home. The 5-pound, shoebox-size device will compete with larger, heavier and noisier models available now. That product could be on the market next year.

And that would mean more work for 3-year-old Astro Instrumentation, which has a long-term agreement to build Burk's products.

For now, the advanced manufacturing company's 80 workers would be able to turn out thousands of Epi FLO devices a month in addition to handling jobs for other clients, says Kevin Webb, Astro's marketing and sales manager. But as more products spill out of Burk's oxygen technology pipeline, Astro might add assemblers and engineers and expand the plant it opened last year.

Burk says he never could have guessed that it would take nine years to get the device into the hands of doctors. But despite setbacks and frustrations, there was no walking away from the project.

"Once we knew we could salvage my father-in-law's foot from amputation," he says, "how do you give up?"

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