

## Health Care

### Hopkins is testing new gel therapy that could lead to fewer amputations

KAREN BUCKELEW

Daily Record Business Writer

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It began as just a callous on his toe, but it almost cost John Doody his leg.

Like many diabetics, the 66-year-old Arnold man developed a non-healing, or ulcerated, wound on his foot.

Doody was relatively lucky — his surgeons were able to save his leg, and he lost only two toes and some bones in his foot.

Now, one of Doody's doctors at the Johns Hopkins Wound Center is hoping to be part of a solution for the 100,000 diabetic Americans who lose limbs to non-healing wounds each year.

Dr. Gerald Lazarus, director of the wound center, is testing an experimental drug called Excellerate, a therapeutic gel made by San Diego firm Cardium Therapeutics Inc.

The gel, designed for application directly to the wound, contains a gene known as a growth factor. It's designed to stimulate the cells in a wound to produce a protein that promotes healing.

Lazarus is part of a Phase II clinical trial Cardium's subsidiary, Tissue Repair Co., is sponsoring to evaluate the drug's effectiveness in 210 patients at about 25 medical centers.

Lazarus said the need for a new treatment is great. The wounds become debilitating long before an amputation is necessary.

"It's very isolating for the patients," he said. "They can't function very well. You really desperately want the patient to heal."

About 15 percent of the 21 million Americans with diabetes will develop foot ulcers, according to Barbara Sosnowski, chief operating officer of Tissue Repair Co.

"It's the leading cause for non-traumatic amputation in the U.S.," Sosnowski said.

It's a facet of diabetes that flies under the radar, even for patients like Doody. He said he still can't believe how quickly his wound got out of control.

"It was just a tiny thing at the beginning," he said. "People don't realize the impact of diabetes. If you really want to know, go to the wound clinic. You'll see some of those people coming in, limbs missing, and it'll shake you up. It's terrible."

In addition to Doody's amputation, Lazarus operated to improve blood flow in the patient's leg to help heal his ulcer. It's a common treatment for the condition, in addition to the hyperbaric chamber, debridement — removing tissue from the wound — and regular changing of dressings.

Poor blood flow is one of the problems that prevents healing in diabetics, according to Dr. Thomas Donner, medical director of the University of Maryland Joslin Diabetes Center and an associate professor of medicine at the medical school.

"Once they get an infection in their feet, the immune system, which is carried through the blood stream, is less able to get there," Donner explained.

Diabetics also tend not to notice wounds until they're too severe and infected to be ignored. A form of nerve damage called diabetic neuropathy often causes numbness in their feet, Donner said.

"Patients can have things in their shoes — tacks in their feet, nails and things — because they can potentially lose all sensation," he said.

Patients are instructed to carefully inspect their feet, and correct maintenance of their diabetes through diet and insulin helps control the problem, Lazarus said.

Those tactics help, according to Donner, but they aren't perfect.

"It's lessened," Donner said, "but we still see it, unfortunately, all too commonly."

Patients enrolling in the Cardium study with Lazarus will receive all the ordinary treatments in addition to the gel.

If all goes well, Sosnowski said, Cardium hopes the gel could be on the market in the next two or three years. That would require successful Phase IIb and Phase III trials, and approval from federal regulators.

Doody is hopeful. He still could develop more non-healing wounds in his lifetime.

"It's a vicious disease," he said. "This thing holds promise if it can end the process before it really gets bad."

Lazarus, who is enrolling patients in the study, shares Doody's optimism.

"Just with the things we do now at Hopkins, we can get people healed, and that's good, but this may make the healing process faster," Lazarus said. "If we can get them healed faster, that gets them back to doing the things that are important in their lives."