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New step forward?

Technology using stem cells from bone marrow could help save limbs in danger of amputation

PHOTOGRAPHS BY GRACE BEAHM/STAFF

Lynn Menges encourages her father, Tom Fisher, before he heads into an experimental stem-cell therapy trial under the care of Dr. Jeb Hallett, medical director at the Roper St. Francis Heart and Vascular Center.

BY JILL COLEY
The Post and Courier

Tom Fisher, who turned 83 last week, walks the cusp of medical science. In July, doctors amputated his right leg, oxygen-choked and ulcerous with gangrene. Five months later, a stem-cell therapy trial could save Fisher's left leg from the same fate.

"In American medicine, this is a landmark event," said Dr. Jeb Hallett, medical director at the Roper St. Francis Heart and Vascular Center. "People have been looking at how to use stem cells in treating diseases."

The disease under fire is the severe obstruction of the arteries, blocking blood flow to the extremities. The condition is called critical limb ischemia and is the end result of the hardening of blood vessels, which can be related to hypertension, smoking and diabetes.

Hallett and Dr. George Geils Jr., who leads the Roper St. Francis Blood and Marrow Transplant Program, are co-principal investigators of the trial that includes six U.S. medical centers.

Fisher was among the first three patients – all of whom faced amputation – to participate in the blind trial, which began Nov. 28 at Roper Hospital.

The randomized trial is among a wave of studies vying to be the first stem-cell therapy in the U.S. The Food and Drug Administration currently has no approved stem-cell therapies, spokeswoman Karen Riley said.

Stem-cell research has been controversial in the U.S. because many people associate stem cells with embryonic stem cells, which are

Doctors mark the injection sites on Tom Fisher's leg for the trial procedure. "In American medicine, this is a landmark event," Dr. Jeb Hallett said of the study, which is designed to help determine how stem cells can be used.

What are stem cells?

Stem cells, when coaxed in certain directions, have the potential to develop into different types of cells. People carry around stem cells in their bodies that repair injuries. Stem cells also are found in embryos.

The trial at Roper Hospital uses stem cells from a patient's own bone marrow, not embryonic stem cells.

What is peripheral arterial disease?

Peripheral arterial disease is a buildup of fatty material, called plaque, inside arteries that carry blood to limbs.

Blocked blood flow can result in critical limb ischemia, which is marked by numbness, pain, or, in severe cases, death of tissue.

Patients in late stages may face amputation.

How does the procedure work?

A patient's bone marrow is harvested from his pelvis. Then a centrifuge-type machine, the size of a desktop computer, concentrates the stem cells.

Doctors inject the stem-cell concentrate into the patient's leg that has poor circulation. There, the cells hopefully will respond to the low-oxygen environment and help build new vessels, improving blood flow.

-Jill Coley

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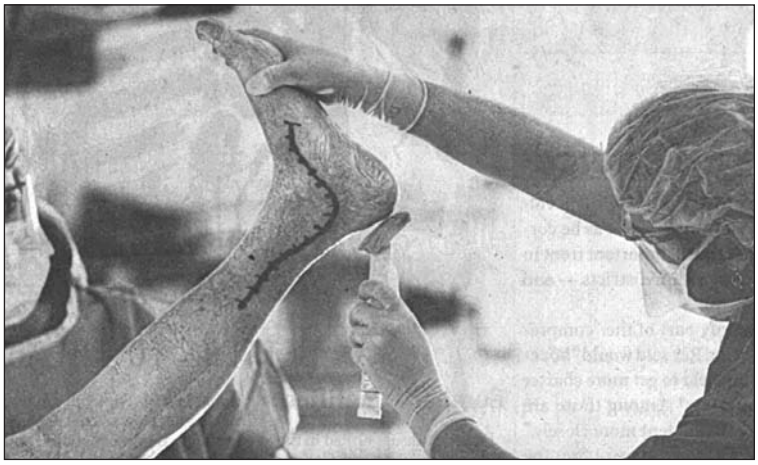
Dr. George Geils, Jr., leads the Roper St. Francis Blood and Marrow Transplant Program

Technology could help save limbs in danger of amputation

derived, as their name suggests, from embryos.

"So much focus has been on the embryonic stem cell and all the ethical issues," Geils said. "This bypasses that completely. These are bone marrow stem cells."

Two of the three patients in the trial received their own bone marrow concentrate and one received his own blood. All patients had both types of samples drawn, so they couldn't tell which they received.



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Nurse Lisa Pritcher (right) preps Tom Fisher's leg for surgery at Roper Hospital.

Similar procedures have been used successfully in Europe and Japan for about the past five years. Abroad, the treatment has saved nearly 70 percent of limbs, Hallett said. Patients' blood pressure and oxygen levels improved and they suffered less wound pain.

The technology to condense the stem cells from the bone marrow varies. Hallett and Geils are working with a system manufactured by **Plymouth, Mass.-based Harvest Technologies**. The machine takes 15 minutes to process the marrow, much less time than the three- to five-hour lab process many doctors use abroad, Hallett said.

Hallett and Geils said they feel the veil lifting after Japanese researchers and researchers at the University of Wisconsin reported in November they could reprogram human skin cells into cells very similar to embryonic stem cells.

Scientists announced Thursday that they had successfully treated sickle-cell anemia in mice using stem cells derived from the rodents' tissue.

Geils - who has performed countless bone marrow transfusions for leukemia, lymphoma and other diseases - has long been aware of the plasticity of stem cells.

"You can biopsy someone's heart who's had a brother-sister-type bone-marrow transplant and find the other gender (in the DNA)," he said. Stem cells travel from the bone marrow throughout the body and go where they are needed - to heal a broken bone, or maybe build a new blood vessel.

But in patients with poor circulation, the cells have no way of travelling to the injury.

GRACE BEAHM/STAFF

Doctors amputated Tom Fisher's right leg in July. Hoping to save his left leg, Fisher is taking part in a clinical trial for a therapy using stem cells taken from bone marrow in the pelvis. He won't know if he received his own stem cells or a placebo injection of his blood.

On the Web

For more photos, go to **charleston.net.**

The concept of the study is simple, Hallett said: Bridge blockages with new blood vessels created by stem cells.

Saving limbs from amputation started with general anesthesia in the mid-19th century, Hallett said. The first bypass was performed in Germany in 1915. Bypass surgery grafts a harvested vein or man-made tube to go around the blockage and it became popular in the U.S. in the 1950s. By the 1960s doctors turned to stents and angioplasty to open clogged vessels.

"The use of cell biology to heal people is new," Hallett said. "It's been in the last five to eight years."

Technology might be catching up with Fisher.

After he retired from the Navy, where he served as a submarine officer, he took to the stage and acted in 15 Dock Street Theatre plays.

"I had stage fright terrible," he said. But he embraced the invigoration and earned a bachelor's degree in theater from the College of Charleston.

Fisher first noticed pain in his feet a couple of years ago. When doctors told him he would lose his right leg, he said, "I thought they could do something magical to save it." But they couldn't.

He took the challenge of his prosthesis head-on and has returned to his beloved rose garden. The most fragrant variety is Abraham Lincoln, he said, pointing to a dense, velvet bloom in a glass vase.

As treatment options ran out for his left leg, Hallett approached Fisher and told him to hold on, don't let anyone cut your leg off, the technology is coming.

A week after the injections, Fisher's pain tested at a lower level, and he showed no side effects at the injection site.

GRACE BEAHM/STAFF

The blind study is designed to determine whether stem cells can encourage growth of new blood vessels in oxygen-starved limbs.

It takes about a month before more blood vessels could be expected to grow, Hallett said. "If (the procedure) doesn't work, eight out of 10 of these patients may face amputation in the future. It's very difficult if you've lost one leg to walk with two artificial legs."

Even if Fisher does not receive the stem-cell concentrate in the trial, he said he is eager to advance the technology that will bring him closer to the treatment. "I not only think of saving my leg but many thousands of legs," he said.

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