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Stem cells mature

You've heard the controversy, now get the facts: No human clinical trials use embryos. But researchers are making huge strides in developing therapies with adult cells

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Stem cells may have repaired Steve Nemeth's heart, building a network of new vessels to route blood around a blocked artery.

But ask the 64-year-old Solon retiree how he feels about research that plucks stem cells from five-day-old embryos, and he says, "I'm against it. I'm a Catholic, a very devoted Catholic. I have some real reservations about it."

Sound contradictory?

Not at all.

The stem cells used to repair Nemeth's heart were harvested from the bone marrow in his own hip, purified in a lab, then infused into his heart to help grow new blood vessels.

No embryos were harmed, used or even thought about in Nemeth's treatment. In fact, today's disease-treating promise of stem cells has virtually nothing to do with embryonic stem cells; not a single clinical trial in humans has been undertaken with embryonic stem cells in the United States.

"Some see (embryonic stem cells) as the ultimate," said Dr. Daniel Simon, chief of cardiovascular medicine at University Hospitals Case Medical Center. "They have a better potential to make vessels and capillaries and everything else that goes into heart muscle, so there's something there.

"But it's so far away from clinical application that, for us, we don't even think about it. We just follow it with great interest."

Full of possibilities

The reality is that the bulk of today's stem-cell research relies on adult stem cells taken from bone marrow, blood, skeletal muscles, body fat and umbilical cord blood. Scientists have even managed to coax adult skin cells to mimic the versatility of embryonic stem cells, which can grow virtually any cell or tissue in the human body.

Unlike embryonic stem cells, though, these adult stem cells are being tested in humans right now, with very real possibilities to change the way various diseases are treated in the next five to 10 years. Stem cells may be used to grow new blood vessels or muscle to heal damaged hearts; to make chemotherapy more effective and less harmful; to encourage new bone growth to mend hard-to-heal

fractures; to regenerate neurons in the brain or spinal cord to treat multiple sclerosis, Huntington's or Lou Gehrig's disease and to retrain the immune system to treat autoimmune diseases.

The only kind of stem-cell therapies commonly used today are bone-marrow transplants to treat leukemia and lymphoma. That's been the gold standard of treatment for about three decades.

A bone-marrow transplant "is actually a stem-cell transplant," said Debra Grega, executive director of the National Center for Regenerative Medicine in Cleveland. "That's something that I think a lot of people don't realize. Most people say, 'Stem cells, oh, that's 10 years in the future,' but it's here now."

And she suspects there's a lot more to come.

"Easily in the next five to 10 years . . . we'll get to where one of the routine things your doctor does is store your own stem cells," she said. "You'll have some personalized stem cells in the freezer someplace, so if you're in an accident, they'll be able to pull them out and treat you effectively.

"Stem-cell therapy will be more like being treated with a drug. It's on the shelf and you pull it off when you need it."

Controversy confuses

To many people, "stem cells" mean "controversy," with talk centering on the morality of embryonic stem-cell research, debates about when life begins and whether taking cells from a five-day-old embryo is murder.

Dr. Mary Laughlin runs into that problem constantly when she visits expectant mothers at Hillcrest Hospital in Mayfield Heights to see if they're interested in saving their newborn's umbilical cord blood.

"All they read about in the newspapers is the controversy surrounding embryonic stem cells, so they presume once you mention the word 'stem cells,' it's embryonic," said Laughlin, founder of the Cleveland Cord Blood Center. "We find almost uniformly that the American public is confused and misinformed about stem cells in medical research and therapy. The average American public does not understand the distinction between embryonic stem cells and umbilical cord stem cells."

Embryos are still being used in research, though their use is limited by federal law. Proponents argue that those limits have let other countries jump ahead of the United States in stem-cell research.

The result may have been, however, that scientists have found a way to work around the controversy.

Last year, three research teams — one in Japan and two in the United States — manipulated skin cells from mice to act like embryonic stem cells, without creating or destroying embryos. The genetically modified cells can take on the characteristics of embryonic stem cells, growing any tissue in the body.

The finding was "the biologic equivalent of an alchemist's dream of turning lead into gold," a British researcher wrote in February's *New England Journal of Medicine*.

Dr. Stanton Gerson, director of the Ireland Cancer Center at University Hospitals Case Medical Center, called the research "pretty intriguing."

Gerson works exclusively with adult stem cells, but he said, "There are still some things we're not good at getting adult stem cells to do. There are many areas where we're just scratching at the surface."

Both embryonic stem cells and reprogrammed skin cells, however, present a similar danger from tumors.

Because these cells are immortal, Gerson said, scientists have to figure out how to turn them off once they've accomplished whatever healing task they've been given. If they can't be turned off, they'll continue to divide infinitely — the exact process that forms tumors.

Local research

At the National Center for Regenerative Medicine — a partnership of the Cleveland Clinic, Case Western Reserve University, and University Hospitals Case Medical Center — adult stem cells are the sole focus.

The research involves using stem cells from bone marrow, blood, fat, muscles and umbilical cord blood to treat diseases ranging from cancer to broken bones to heart attacks to diabetes.

Leading the pack is research by Simon (to fight heart disease) and Gerson (to fight cancer).

One of Gerson's projects aims to lessen the side effects of chemotherapy in brain cancer patients.

Chemotherapy causes hair loss and nausea because it kills off healthy cells along with cancerous ones. But Gerson hopes to protect the healthy cells by genetically modifying bone marrow stem cells to withstand the harsh effects of treatment. Though the research is still in its earliest human trials, a Maryland biotech company already has signed an agreement with the center to license, develop and market a stem-cell therapy based on the findings.

Gerson also is using marrow-derived stem cells to lessen a patient's immune reaction to transplants from another donor. In graft-versus-host disease, the patient's body is essentially attacked by the immune cells in the donor's stem cells. The results can be deadly. Gerson hopes that a second transplant using different marrow cells — called mesenchymal cells — can suppress that immune response.

This finding came by accident, when Gerson injected patients with stem cells at the time of the bone-marrow transplant, in hopes of speeding the growth of new blood cells. That didn't happen, he said, but he soon figured out that those who were injected at the time of the transplant "lived better and they lived longer."

Sixty-five-year-old Robert Wise of Geneva was one of those patients. In 1999, he underwent a bone-marrow transplant from his brother, along with the injection of additional stem cells.

"I've been perfect ever since then and that was in 2000," Wise said. "I've been able to watch my grandchildren grow up. Most of them weren't even born then."

The theory is that the mesenchymal cells "have the ability to dampen the immune reaction," Gerson said.

Of the four patients who took part in the early trial, however, Wise was the only one to have long-term success. Two patients had short-lived improvements and one died.

Success story

If you think of the heart as a road map, it has major highways (large arteries) and country roads (smaller blood vessels) to transport traffic (blood flow) through the heart. In Steve Nemeth's case, one of the major highways was clogged, forcing all the traffic onto

country roads too small to handle the task.

In many cases, doctors can open the highway by clearing the blockage and putting in a stent. Nemeth's artery, though, was too clogged and too fragile. A bypass was his only option — unless he wanted to take part in a clinical trial that hoped to show how stem cells could increase the capacity of those country roads to handle more traffic.

"Let's give it a chance," Nemeth told his doctor.

The stem cells were extracted from the bone marrow of his hip, near his lower back. In the lab, a magnetic sorting mechanism sifted through the billions of stem cells to find the ones capable of growing new blood vessels, which were then re-infused back into Nemeth's heart.

It was a small trial, with just eight patients. And as a Phase 1 trial, its purpose was to test the procedure's safety, not necessarily its effectiveness. But of the eight patients in the trial, seven, including Nemeth, showed improvement, as measured by stress tests and heart size.

Before the stem-cell transplant, Nemeth's stress test ended with him "really huffing and puffing," barely able to stay on the treadmill for more than a few minutes. A year later, "the tech kept ratcheting it up and finally he said, 'OK, Mr. Nemeth, you can get off.' "

Now, Nemeth is walking at least six days a week for about a half-hour at the Solon Community Center.

Answers unclear

Was it the stem cells that improved Nemeth's heart health, or was it his increased exercise regimen?

That's unclear, Simon said. Because Phase 1 trials are meant to determine safety, measures of effectiveness aren't given much weight, "so we can't conclude from this trial whether these stem cells worked or not."

In fact, he said, much about stem cells and heart therapy is still unclear.

"We don't know yet what's the right cell and also what is the right way to deliver the cells."

In Nemeth's transplant, the cells were delivered to the heart via a catheter, much like an angioplasty procedure. Some people think that's not very efficient. New systems are allowing doctors to inject the stem cells to the exact area where the heart muscle isn't getting enough blood. And new research by Simon is looking at using stem cells taken from the blood, instead of the hip, making the harvesting procedure much easier.

In these examples, the goal is to grow new blood vessels in the heart. Other research efforts are trying to repair or grow cardiac muscle.

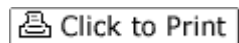
The question is, when stem cells taken from skeletal muscles, like the thigh, are injected into the heart, do they form cardiac muscle?

"Some people say yes, some people say no," Simon said. "It's a field that's in evolution. We are still very early into the clinical trials."

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