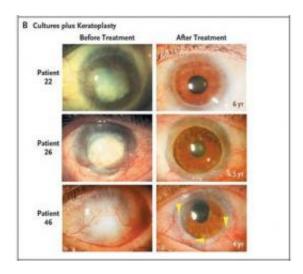


## Adult stem cell research far ahead of embryonic

August 2 2010, By MALCOLM RITTER, AP Science Writer



This image from an Italian study published June 23, 2010 by the New England Journal of Medicine shows the eyes of three patients with alkali burns before and after successful stem cell transplants. Dozens of people blinded or injured by chemical burns had their sight restored by transplants of stem cells from their own bodies \_ a stunning success for the growing cell therapy field, Italian researchers reported Wednesday. (AP Photo/New England Journal of Medicine) MANDATORY CREDIT NEW ENGLAND JOURNAL OF MEDICINE, NO SALES, EDITORIAL USE ONLY

(AP) -- A few months ago, Dr. Thomas Einhorn was treating a patient with a broken ankle that wouldn't heal, even with multiple surgeries. So he sought help from the man's own body.



Einhorn drew bone marrow from the man's pelvic bone with a needle, condensed it to about four teaspoons of rich red liquid, and injected that into his ankle.

Four months later the ankle was healed. Einhorn, chairman of <u>orthopedic surgery</u> at Boston University Medical Center, credits "adult" stem cells in the marrow injection. He tried it because of published research from France.

Einhorn's experience isn't a rigorous study. But it's an example of many innovative therapies doctors are studying with adult stem cells. Those are stem cells typically taken from bone marrow and blood - not embryos.

For all the emotional debate that began about a decade ago on allowing the use of <u>embryonic stem cells</u>, it's adult stem cells that are in human testing today. An extensive review of stem cell projects and interviews with two dozen experts reveal a wide range of potential treatments.

Adult stem cells are being studied in people who suffer from multiple sclerosis, heart attacks and diabetes. Some early results suggest stem cells can help some patients avoid leg amputation. Recently, researchers reported that they restored vision to patients whose eyes were damaged by chemicals.

Apart from these efforts, transplants of adult stem cells have become a standard lifesaving therapy for perhaps hundreds of thousands of people with leukemia, lymphoma and other blood diseases.

"That's really one of the great success stories of <u>stem cell biology</u> that gives us all hope," says Dr. David Scadden of Harvard, who notes stem cells are also used to grow <u>skin grafts</u>.

"If we can recreate that success in other tissues, what can we possibly



imagine for other people?"

That sort of promise has long been held out for embryonic stem cells, which were first isolated and grown in a lab dish in 1998. Controversy over their use surrounded the 2001 decision by former President George W. Bush to allow only restricted federal funding for studying them.

Proponents over the past decade have included former first lady Nancy Reagan and actors Michael J. Fox and the late Christopher Reeve. Opponents object that human embryos have to be destroyed to harvest the cells.

Embryonic cells may indeed be used someday to grow replacement tissue or therapeutic material for diseases like Parkinson's or diabetes. Just on Friday, a biotech company said it was going ahead with an initial safety study in spinal cord injury patients. Another is planning an initial study in eye disease patients later this year.

But in the near term, embryonic stem cells are more likely to pay off as lab tools, for learning about the roots of disease and screening potential drugs.

Observers say they're not surprised at the pace of progress.

As medical research goes, the roughly 10 years since the embryonic cells were discovered "is actually a very short amount of time," said Amy Rick, immediate past president of the Coalition for the Advancement of Medical Research. The group has pushed for embryonic stem cell research for about that long.

Hank Greely, a Stanford University law professor who works in bioethics and has followed stem cells since the 1990s, said: "Give it another five years and I'll be surprised if we don't have some substantial



progress" beyond initial safety studies.

The Pro-Life Secretariat of the U.S. Conference of Catholic Bishops continues to oppose embryonic work. Deirdre McQuade, an official there, said that compared to adult stem cell research, work on embryonic cells is proving "fruitless."

Adult cells have been transplanted routinely for decades, first in bone marrow transplants and then in procedures that transfer just the cells. Doctors recover the cells from the marrow or bloodstream of a patient or a donor, and infuse them as part of the treatment for leukemia, lymphoma and other blood diseases. Tens of thousands of people are saved each year by such procedures, experts say.

But it is harnessing these cells for other diseases that has encouraged many scientists lately.

In June, for example, researchers reported they had restored vision to people whose eyes were damaged from caustic chemicals. Stem cells from each patient's healthy eye were grown and multiplied in the lab and transplanted into the damaged eye, where they grew into healthy corneal tissue.

A couple of months earlier, the Vatican announced it was funding adult stem cell research on the intestine at the University of Maryland. And on Friday, Italian doctors said they'd transplanted two windpipes injected with the recipients' own stem cells.

But these developments only hint at what's being explored in experiments across the United States.

Much of the work is early, and even as experts speak of its promise, they ask for patience and warn against clinics that aggressively market stem-



cell cures without scientific backing.

Some of the new approaches, like the long-proven treatments, are based on the idea that stem cells can turn into other cells. Einhorn said the ankle-repair technique, for example, apparently works because of cells that turn into bone and blood vessels. But for other uses, scientists say they're harnessing the apparent abilities of adult stem cells to stimulate tissue repair, or to suppress the immune system.

"That gives adult stem cells really a very interesting and potent quality that embryonic stem cells don't have," says Rocky Tuan of the University of Pittsburgh.

One major focus of adult stem cell work for about a decade has been the ailing heart. While researchers remain committed, much of the early enthusiasm from patients, doctors and investors has slacked off because results so far haven't matched expectations, says Dr. Warren Sherman of Columbia University.

"Everyone, including myself, is impatient and would like to see positive results appear quickly," said Sherman, who hosts an annual international meeting of researchers. But he called for patience.

In treating heart attack, for example, studies show stem cell injections help the heart pump blood a bit better, Sherman said. But the research has not yet established whether injections cut the risk of death, more heart attacks or future hospitalizations, he said.

Sherman said he hopes a large study of those patient outcomes can be done in the next couple of years, and is "very optimistic that patients will benefit."

Similarly, in heart failure, research indicates stem cells can ease



symptoms but larger studies are still needed to show how much good the treatments provide, he said. He noted that current studies are testing stem cells taken not only from bone marrow and leg muscle, but also from fat.

Another heart-related condition under study is critical limb ischemia, where blood flow to the leg is so restricted by artery blockage it causes pain and may require amputation. The goal here is to encourage growth of new blood vessels by injecting stem cells into the leg.

Sherman said limb ischemia research is moving fast and the results "are very, very encouraging."

The injected cells may serve as building blocks while also stimulating local tissue to grow the vessels, said Dr. Douglas Losordo of Northwestern University. His own preliminary work suggests such a treatment can reduce amputation rates.

Dr. Gabriel Lasala of TCA Cellular Therapy also has reported positive preliminary results. One success is Rodney Schoenhardt of Metairie, La.

Schoenhardt had already had surgery on both legs for the disease, and his surgeon was talking about amputating his left leg. Schoenhardt suffered so much pain in his left leg while standing that he used a wheelchair instead.

For Lasala's research, Schoenhardt got 40 shots in each leg about 18 months ago, with stem cells going into his left calf and a placebo dose into the other. Soon, he said, the pain in his left leg was gone.

Schoenhardt, 58, now mows his lawn, and he remodeled his living room to fix damage from Hurricane Katrina. "My wheelchair is in my garage, collecting dust," he said.



"I'm even thinking about taking up a little tennis again."

With all the heart-related stem cell studies, the former president of American Heart Association says, "We should be enthusiastic, but cautiously so." Beyond the promising indications of early studies, researchers need definitive evidence that the treatments not only make patients better but also don't cause unintended harm, says Dr. Clyde Yancy.

Among the other diseases being studied for stem cell treatments:

-Multiple sclerosis. In MS, the body's immune system repeatedly assaults brain and spinal cord tissues, which can cause numbness in the limbs, paralysis or vision loss.

Last year, Dr. Richard Burt of Northwestern reported a small trial in patients with early MS that was aimed at rebooting the immune system to stop the attacks. He removed stem cells from the patient's blood, destroyed their immune systems, and then re-injected them with their own cells to build a new immune system.

To his surprise, most patients actually improved. He's now conducting another trial to provide firmer evidence of improvement.

Dr. Jeffrey Cohen of the Cleveland Clinic is trying a different and less-researched approach. In a preliminary trial he is just starting, he'll use a different kind of stem cell from patients' marrow that he hopes can slow nervous system damage but also promote repair.

Lessons learned from this approach might eventually reveal some clues for treating other conditions like Parkinson's or spinal cord injury, he said.



-Type 1 diabetes. It's also caused by a misguided attack by the immune system, this time on insulin-producing cells. Burt and colleagues reported last year that the "rebooting" strategy allowed some patients to go without insulin for four years. However, some experts call his approach too risky for that disease. Burt is now doing another study in newly diagnosed adults.

Another study, at about a dozen medical centers around the country, is testing whether an off-the-shelf preparation of marrow <u>stem cells</u> can calm the immune system of diabetics. It's still early work, says C. Randal Mills, chief executive officer of Osiris Therapeutics.

-Cancers such as melanoma and kidney cancer. The idea is to transplant cells to produce a new immune system that will attack the diseases. Earlier work around a decade ago failed to give lasting benefit, but new approaches aim for better results, said Dr. Michael Bishop of the National Cancer Institute.

Even as scientists hope <u>adult stem cells</u> will produce new treatments, they are concerned about clinics that make claims about unproven stem cell therapy.

"Clinics have sprung up all over the world ... that are essentially selling snake oil, that are preying on the hopes of desperate patients," said Sean Morrison, a stem cell expert at the University of Michigan.

Morrison suggests patients consult their own doctors about going to a clinic.

**More information:** Stem cell clinic website:

http://www.closerlookatstemcells.org

General stem cell information: <a href="http://stemcells.nih.gov/info/basics/">http://stemcells.nih.gov/info/basics/</a> Adult stem cells: <a href="http://www.isscr.org/public/adultstemcells.htm">http://www.isscr.org/public/adultstemcells.htm</a>



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