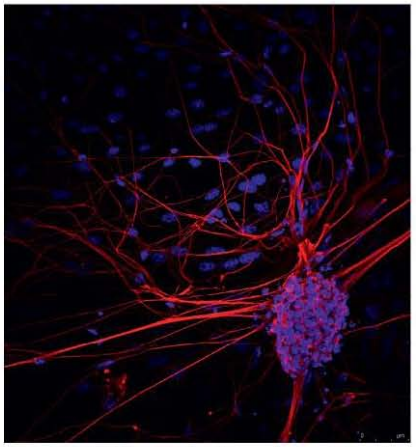
repairing life

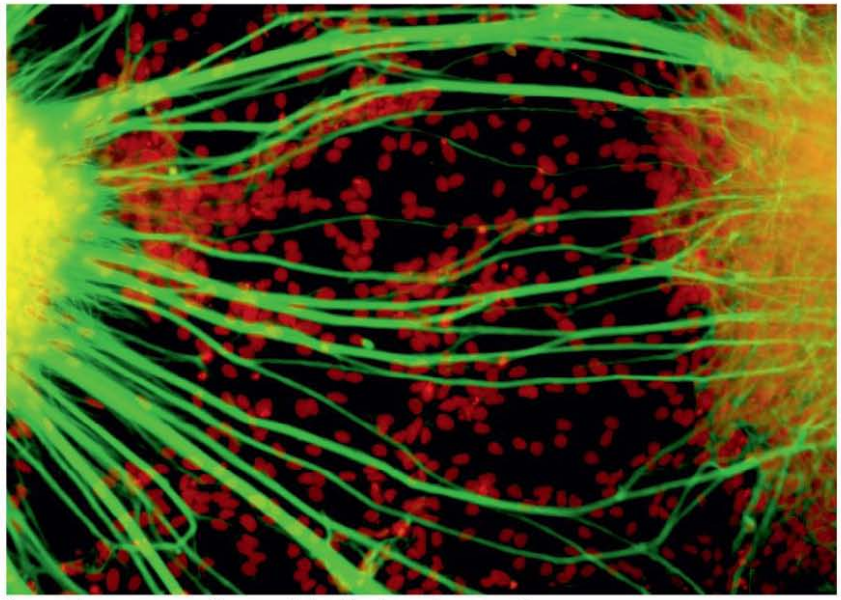
Stem cells are the fundamental building blocks of our bodies, present in every human at every age. Why then is it so controversial to use them in medicine? Glass examines the facts



Neurosphere: a ball of human embryonic stem cells giving rise to repairing nerve cells

Imagine the human body as a house. Think of cells as the bricks that compose the walls and then picture stem cells as the clay that the bricks are made of. The body is like a building that, over a period of years, will suffer from the effects of the weather and gradually fall apart. But, as with a house, this degeneration can be slowed with sufficient care and replacement of the worn out materials. Stem cells are the basic building blocks that can morph into the necessary tools to repair any damage. Two types of stem cells are used in medicine, and one in particular, embryonic stem cells (which are taken from an embryo and grown for mass production) has attracted huge speculation and media attention in recent years. As a result though, it has overshadowed, misconstrued and impeded a much less controversial and ethically charged form of treatment, that of adult stem cells which are already present in everybody throughout our life.

A quick run around the block, a workout at the gym, or just daily use causes *micro* damage to virtually all tissues of the body. Micro damage doesn't necessarily cause pain or dysfunction, but rather acts like a small crack in a foundation that can then get bigger and bigger until it does cause problems. It turns out that we have billions to trillions of tiny little repairmen in all tissues of our body, called adult stem cells, whose job is to find foundation cracks and fix them before they get bigger. There are a number of different types of adult stem cells; one example is called a mesenchymal stem cell (MSC). MSCs live in virtually all tissues and are put to work once damage is detected. They can act as a general contractor in the repair response, giving signals to the body to bring in the other subcontractor cell types that are needed for the repair job. They can also *differentiate* or turn into a particular cell type needed for the repair job. For example, to repair cartilage in your knee, MSCs can differentiate into these cartilage cells.



Two neurospheres, compact masses of precursor cells, derived from human embryonic stem cells

As we get older or sometimes when we get an injury, our stem cells can't keep up with repair of all of the foundation cracks like they used to when we were younger. This is where the technique of taking stem cells from one part of the body (usually from the bone marrow or fat) and putting them where our body needs them most comes in.

While the public eye has been largely transfixed by the ethical concerns surrounding embryonic stem cell use, promising breakthroughs in therapies involving adult stem cells have gone largely unnoticed; for example, a medical facility in Italy in which cases of burn induced blindness have been treated successfully. Dozens of people who were blinded or otherwise suffered severe damage to the lens of the eye by caustic chemicals have had their sight restored with transplantation of their own adult stem cells. A study, published in the New England Journal of Medicine, described how the authors took a small number of stem cells from the healthy eye, grew them for a few weeks in culture so there were more cells, and then implanted them into the burned eye. The majority of patients who regained their sight are still doing well, many years after the treatment.

This remarkable result is only one of many recent stories of success with adult stem cell therapy; and new studies are published virtually every week. Another example is a placebo-controlled trial published in a respected cardiology journal that showed that adult stem cells could be used to help heart attack victims recover by growing new blood vessels to bring more oxygen to the heart. With more than 1.2 million heart attacks every year in the US alone, the possibilities with this kind of treatment can't be understated. Up until now, once the heart muscle was damaged there was no way it could be repaired. So while many people might survive a first heart attack, their quality of life was poor, as their damaged heart usually struggled to keep up with the demands of normal daily activities. If stem cell therapy for this condition becomes readily available in the near future, the capacity to improve lives is immeasurable.

Are your stem cells body parts or drugs?

All cells are technically tiny body parts and stem cells are no different. Despite this common sense analysis, regulatory bodies in the U.S. and Europe have thus far considered the removal of stem cells from a person's body, growing the cells, and then putting them back in the same person, to be the same as the development of a new antibiotic or other drug, thus requiring many years of research before clinical use. Not everyone shares this view. "Stem cells are body parts and should be treated as such by regulators", says David Audley, executive director of the International Cellular Medicine Society (ICMS), a professional organisation representing 1,200 physician, scientist, and patient members from 35 countries. The debate is over how risky adult stem cell therapy really is. One thing is certain; unlike the manufacture of drugs, the risk of a "bad batch" of adult stem cells would only affect the patient getting the treatment. In comparison,

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a defective batch of drugs can injure or kill hundreds or thousands of people. Many consider the risk of stem cell treatment to be like any other medical procedure (one doctor to one patient), and medical procedures are not subjected to federal regulation. Doctors are trained and licensed to treat patients as they believe is best for their patient.

A key legal case in the U.S. courts may decide this issue once and for all. A Colorado company which has been using adult stem cells to treat wear and tear conditions in joints (like the knees and hips) is currently involved in a legal battle with the U.S. Food and Drug Administration over whether those cells are body parts or drugs. "Cells taken from the patient and used in that same patient to help arthritis are body parts and can't be reasonably regulated the same way as drugs", states John Schultz, M.D., one of the clinic physicians. "There is no benefit to society in treating the cells in your body the same as a new antibiotic," continues Schultz. In fact, with more than 5,000 deaths every year in the U.S. from knee replacement surgeries, there may be a very significant detriment to society by not allowing access to a stem cell procedure that has been shown to be both safe and to keep patients away from this surgery.

Stem cell tourism

The debate over stem cells as body parts or drugs is further clouded by the recent phenomenon of 'Stem Cell Tourism'. In the past several years, the internet has been filled with ads for stem cell clinics offering cures for everything from autism, stroke, and multiple sclerosis, among many others. The validity of the claims ranges from reasonable to pure 'snake oil'. The clinics target what are often the most desperate patients: people faced with a choice between almost certain death or ineffective or nonexistent medical alternatives. This fact alone does not mean that the therapies are worthless; in fact, some of them may be effective, safe and reasonable alternatives to more traditional but less effective and potentially less safe therapies that are readily available. The ICMS is attempting to help those who are interested in travelling out of country to receive stem cell therapy by creating a means of describing and ranking these clinics. The organisation has put forth professional guidelines and begun to register patients into a international database so that possible complications and outcomes of the therapies can be tracked. Rather than "cherry picking" miracle cure cases, the ICMS hopes to report on the outcomes of all cases so that patients can make informed decisions before they seek this type of care. The concept being used by ICMS is similar to that used for decades by fertility clinics practising in vitro fertilisation.

"The idea of ICMS bringing strict standards to these off-shore stem cell therapy clinics is sorely needed. It's really the wild, wild west out there," states Stephen Coles, M.D., Ph.D., Co-founder of the Los Angeles Gerontology Research Group, an academic research practice dedicated to figuring out why some of us live longer than others. Coles believes that stem cells may ultimately play a big role in helping to repair the damage we all accumulate as we age. "Furthermore, we need to ensure that stem cell clinical trials in the future, even if they are off-shore, are carried out under the auspices of an Institutional Review Board or IRB. That way, not only the successes, but also the failures will be reported. Therefore, deceptive advertising of *only* the before-and-after successes will be prohibited and we will have a more accurate assessment of the state-of-the-art," states Coles.

Several companies have begun offering a higher standard of stem cell care, using strict international guidelines. One is New York based Neostem, who are working with hospitals in China to implement stem cell therapies following the guidelines set forth by the ICMS. Neostem scientifically vets and licenses credible stem cell technology before agreeing to offer a particular therapy. "Neostem China is already offering mesenchymal stem cell therapy for orthopaedic conditions and will soon be offering advanced very small embryonic stem cell (VSEL™) therapy as part of several clinical trials," says Robin Smith, M.D., Neostem's CEO. VSELs are like embryonic cells in that they can become many other cell types, but unlike embryonic stem cells, they are derived from the adult patient in which they'll be used, not from embryos. Neostem will be submitting their cases to the ICMS registry so that both efficacy and safety can be tracked.

The future of adult stem cell therapy and what such therapies may be able to do to relieve human suffering is still undecided and largely mistrusted, due to the misinformation propagated by media and oppositional groups. First, the governing bodies who determine the medicines we take must decide whether a person's stem cells are parts of their own bodies to do with as they wish, or if they are drugs – to be legislated and controlled. Meanwhile the debate goes on and the research continues, much like the work of the stem cells themselves, quietly and assuredly trying to fill the missing pieces.

by Christopher Centeno MD
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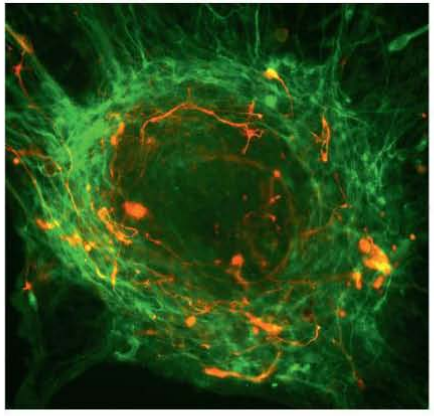

Images courtesy of the California Institute of Regenerative Medicine

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Image left: Hundreds of human embryonic stem cells in various stages of development. Some cells have become neurons (orange), while others are still precursors of nerve cells (green)