

Potential Arthritis Treatment Advance Blocked by FDA

More than **27 million Americans** currently suffer from debilitating **osteoarthritis**, a progressive and incurable condition with no effective long-term interventions. Pioneering researcher **Dr. Christopher Centeno** of **Regenerative Sciences** has developed a safe, non-surgical therapy shown to eliminate arthritic pain up to **75%** using his patients' own stem cells. But to continue offering this treatment, he must first beat the **FDA in court**.

Start

Scientifically reviewed by **Dr. Gary Gonzalez**, MD, in October 2024. Written by: Delia Wilder.

Painful joint deterioration caused by **osteoarthritis** ranks among the most common, debilitating conditions confronting aging individuals today. It is also rapidly on the rise, in both young and old alike due to excess body weight.

An estimated 27 million Americans age 25 or older currently suffer from osteoarthritis.¹ By 2030, a projected **67 million** people will have doctor-diagnosed arthritis.²

A new therapy might reverse this trend. The technology is called **autologous stem cell transplantation**. It involves using undifferentiated cells that can develop into almost any tissue—*new* cartilage, tendons, ligaments, even bone—to replace damaged, arthritic joints. These cells are taken not from human embryos but from your own body!

At the forefront of this research is Colorado-based regenerative medical expert Dr. Christopher Centeno. His clinical work has already yielded intriguing preliminary results—up to **75% pain reduction** without surgery or side effects in scores of patients.

In this article, the facets of Dr. Centeno's new therapy are detailed. You will then learn of the FDA's inhumane attempt to block Dr. Centeno from using this experimental therapy. In this instance, the FDA is erecting a regulatory barrier to deny patients access to their own stem cells—in all likelihood to protect drug company profits.

Osteoarthritis: The Scourge of Aging Individuals

Osteoarthritis is a *progressive* condition for which no cure exists. Affected joints undergo gradual degradation of cartilage, the natural slippery, lubricated tissue that allows smooth movement and weight-bearing.³ As the cartilage deteriorates, friction increases, leading to severe pain and ultimate destruction of the joint.⁴

In one of nature's seeming cruelties, cartilage is poorly supplied with blood, making it slow to heal. Worse, damaged cartilage will not regenerate itself under normal circumstances.^{5,6} Since osteoarthritis is common in previously physically active people, it can significantly impair quality of life in those who suffer from it, particularly as they age.⁷⁻⁹

Many modern surgical repair procedures are aimed at disrupting cartilage deeply enough to trigger a natural repair response from the bone underlying the cartilage—but the result is often incomplete and inadequate.^{9,10}

Over the past several decades, surgeons have developed techniques for removing small "plugs" of healthy cartilage from uninvolved areas of joints and transplanting them into the damaged areas, sometimes culturing the cells first to increase their numbers.^{4,6} While these techniques have shown some promise, they have the disadvantages of *damaging* otherwise intact cartilage without adequately restoring joint function.^{5,9}

Another challenge osteoarthritis poses for clinicians has to do with aging itself: in the case of knee replacements—one of the most common procedures—the "repair" *does not last for a*

long time, so orthopedists paradoxically delay the first surgery for as long as possible.

For this reason, all too many osteoarthritis sufferers are told to wait until the disease becomes severe enough, or they grow old enough, to warrant full-scale artificial knee replacement surgery. Until then, they must rely on pain relievers or periodic injections of anti-inflammatory steroid drugs while they get older in pain.

When they finally do have the procedure performed, they face yet another lengthy period of debilitation: total knee replacement is major surgery, with patients typically advised to count on up to 6 weeks of limited activity, and 6-12 months of gradual rehabilitation to return to normal function.¹¹ That alone explains orthopedists' keen interest in discovering faster and simpler solutions.

Personalized Therapy Using Your Own Stem Cells

Most people have heard of stem cells—the powerful “precursor” cells that can differentiate, or mature, into virtually every type of tissue in the body. Early work with stem cells involved “harvesting” them from human embryos, which raises a host of ethical issues. Also of concern is the fact that embryonic stem cells, precisely because they are so versatile, carry the risk of transforming into *tumor* cells.¹²

Accordingly, scientific attention has focused of late on alternatives to embryonic stem cell therapies. When it comes to bone and joint regeneration, the most promising approach to emerge in recent years is the use of so-called **mesenchymal stem cells** (MSCs) taken directly *from your own body*.¹³

Unlike embryonic stem cells, mesenchymal stem cells have already differentiated to some extent, “committing” themselves to develop into tissues such as bone, muscle, tendon, ligament, and cartilage.^{13,14} They can be found in abundance in your bone marrow.¹⁴ Under the proper conditions, MSCs can be induced to *differentiate* into each of their potential specific tissue types, making them the ideal “seeds” for implanting into damaged joints and bones.

One advantage of using MSCs from your own body (autologous) is there is zero risk of transplant rejection. There is even evidence that transplanted MSC's exert *anti-inflammatory, immune-modulating* influences within the joint.^{4,15} This means they can theoretically outperform more traditional transplants, which run the risk of destruction by inflammation.

For years, the burning question among researchers in the field has been: will MSC (mesenchymal stem cell) transplants prove effective in *human* patients with osteoarthritis?

Thanks to the work of Dr. Christopher Centeno, an international expert and specialist in regenerative medicine, the answer may be *yes!*

Dr. Christopher Centeno's Healing Approach

Based at Regenerative Sciences in Westminster, Colorado, Dr. Centeno first became interested in applying what was known about the powers of stem cells to solving problems in orthopedics roughly a decade ago. Because *orthopedics* is the practice of medicine devoted to the health of bone, joint, muscle, and connective tissue, **mesenchymal stem cells** (MSCs) were the obvious choice for his research.

Centeno was aware of the rapidly growing success of MSCs in animal studies, and the failure rate of existing therapies for osteoarthritis and similar diseases.¹⁶ He knew that human bone marrow contained an adequate supply of MSCs that could readily be “harvested” from a patient's own hip bone. He theorized the patient's own tissue growth factors, obtained from a “puree” of their own platelets—the clotting factors contained within the blood—could be used to trigger MSCs to develop functional cartilage and bone to repaired damaged joints.¹⁶

Once the cells had been “amplified” in culture with activated platelets, they could be injected into a diseased joint. Animal studies had demonstrated that such cells would proceed to further differentiate into the proper cell types based on local tissue factors produced by the surrounding healthy structures.

In two seminal 2008 papers, Centeno presented the results of his first human patient, an individual with a long history of chronic knee pain that proved unresponsive to surgery.^{13,16}

Centeno's patient underwent successful harvest, expansion (through platelet-derived tissue factors), and transplant of his own MSCs into his damaged knee joint. The results were compelling—just one month after the injection the patient's cartilage surface had expanded by approximately **20%**, a gain that was maintained at three months. And the meniscus (the lower cartilage that actually bears weight) was nearly **29%** larger in volume at 3 months, indicating vigorous growth and remodeling of previously damaged tissue. Just as critically, the patient's pain level dropped from 4 out of 10 to less than 1 out of 10, and his range of motion, previously limited, returned close to normal.

WHAT YOU NEED TO KNOW: STEM CELL TRANSPLANTATION

- An estimated 27 million Americans 25 and up currently suffer from osteoarthritis—a number expected to rise rapidly in the coming decades.
- An experimental therapy called autologous stem cell transplantation can arrest and *reverse* the progression of osteoarthritis, using stem cells safely drawn from a patient's own body to grow new cartilage in affected joints.
- Pioneered in part by one researcher, Dr. Christopher Centeno, this novel, non-surgical intervention has yielded up to 75% pain reduction in osteoarthritis patients.
- The FDA has responded to this new therapy by attempting to assume regulatory *control* over these stem cells—and block the use of this therapy.
- Dr. Centeno and his research organization, Regenerative Sciences, hope to defeat the agency's efforts in court.

Since that time, Dr. Centeno and his colleagues have completed hundreds of autologous MSC transplants in patients with both knee and hip joint disease. Their most recent outcome data shows that for knee pain, more than 60% of their patients report a greater than 50% reduction in pain, and fully 40% report more than a 75% reduction.²⁰ Hip pain patients report greater than 50% relief in about 42% of cases, with more than 75% relief in about 23%. Those numbers are impressive on their own, and much more so in the context of the simplicity and ease of doing the transplant procedures compared with major surgery.

Centeno has been rigorous in following up with his patients to determine short- and long-term outcomes, both functional and safety-related. He has recently submitted a paper reporting on 339 patients, focusing on those with knee osteoarthritis.^{21,22}

Nearly all of these individuals had been told by their physicians that they would need a total knee replacement. But over the entire observation period, only **4%** of Centeno's patients wound up actually requiring surgery! The rest achieved real, lasting relief after their stem cell procedures.

YOUR PLATELETS: MASTER REGULATORS OF JOINT REPAIR

Platelets, best known for their role in blood clotting, also contain key growth factors required for tissue repair. When an injury occurs, platelets become activated by newly-exposed tissue proteins, and release their cargo of growth factors, which become available to all cells involved in the healing process.¹⁶ Among the cells stimulated by these platelet factors are MSCs, which proceed to differentiate into some or all of their potential tissue types following exposure.¹⁷⁻¹⁹ That's how wounds heal naturally, forming tissue that "belongs" in each specific part of the body. So it makes sense to turn to activated platelets to provide growth factors that tell MSCs in culture to "grow up" into the precursors of cartilage, bone, or ligaments.

Centeno also compared his patients' procedure-related complication rates with those of patients undergoing traditional knee replacement surgery. Among his patients, no serious complications were attributed to the procedure. But based on published data for knee replacement surgery, Centeno calculates that in a similar sized group of surgical patients^{23,28,37} would have had serious surgical complications, including 1-2 deaths, and so

group of surgical patients,²⁰ would have had serious surgical complications, including 1-2 deaths, and as many as 16 hospital re-admissions for serious infections.²¹

Of course, safety is also a concern in stem cell therapy because of the theoretical risk of tumor development with embryonic stem cells. Dr. Centeno and his group have recently published the largest safety study to date in patients undergoing autologous bone-marrow-derived stem cell transplants for orthopedic conditions.²² They followed 227 patients for up to 2 years following the procedure, including a large group in whom high-definition MRI scans were available. They found no cancer-like complications at any stem cell transplant site!

You would think these results would enjoy recognition not only within the research and medical communities, but *also* among those regulatory agencies charged with overseeing such innovative therapies.

You would be wrong.

Battling the FDA's Attempt to Hijack Your Own Cells!

The Food and Drug Administration responded to these therapeutic improvements by making it *illegal* for Centeno and all other clinicians to initiate therapy using their patients' own stem cells. The agency is persecuting Centeno's practice and prosecuting an entire branch of potentially life-saving medical research.

The FDA argues that since cells taken from the patient's own body can be cultured by the millions in the laboratory, they're somehow equivalent to drugs that can be *manufactured* by the millions in chemical plants. Extending this pretzel logic, the agency contends that each stem cell is the equivalent to a single dose of a drug, just like a pill or a capsule. Therefore the agency asserts it can and should assume regulatory jurisdiction over these cells—cells taken from your own body—just as it does with drugs.

This unconscionable, *insane* effort is likely to cost patients millions of dollars *and* inflict needless suffering on millions of current and future osteoarthritis patients.

"If physician practices and hospitals must now use the same standards as drug manufacturers, expect medical care costs to skyrocket without any measurable impact on safety," says Centeno, who is taking the FDA to court.

"The FDA finally will answer our questions, in court, about their claims and jurisdiction as opposed to doing everything in their power to avoid the issue that we are not a drug manufacturer, but simply a medical practice," says Centeno. "This is an important case for everyone that suffers from any type of illness, not just patients with orthopedic problems. It will decide, once and for all, if the government has the right to restrict a patient and their doctor from using a person's own stem cells to treat disease. Regenerative Sciences believes that stem cells are body parts and not the property of the government or big pharma."

In fact, there's precedent supporting his position. "What we're doing in our medical practice is no different, in principle, than a fertility clinic that uses the in-vitro fertilization technique," says John Schultz, MD, Centeno's colleague and co-founder of the clinic. "The only difference is that we're using the patient's own stem cells and fertility clinics use fertilized eggs."

For the time being, Centeno and his colleagues have been forced to halt all therapies involving cultured cells to enrich the population of MSCs prior to transplantation—the part of the procedure the FDA believes it can regulate.

One small consolation for victims of osteoarthritis: Centeno's team has developed a same-day procedure that involves no cell culture, and therefore can be performed legally. MSCs are harvested from the hip bone marrow space, purified, and directly injected into the damaged joint. This procedure delivers fewer activated MSCs to the site, but it is free of the bureaucratic muddles of the more intensive treatment.

Centeno remains optimistic, confident that he and his colleagues will prevail. He cites David Audley, director of the International Cellular Medicine Society, who has stated, "The Centeno-Schultz Clinic meets our strict criteria for the safe therapeutic use of adult autologous stem cells. There is more medical and scientific evidence supporting this type of medical therapy for orthopedic conditions, for example, than there is for many approved drugs that the FDA allows to be used in off-label or unconventional applications."

Christopher J. Centeno, MD is an international expert and specialist in regenerative medicine and the clinical use of mesenchymal stem cells in orthopedic medicine.

Summary

An estimated 27 million Americans 25 or older currently suffer from osteoarthritis—a number expected to rise rapidly. Existing treatments—including heavy reliance on drugs and replacement surgery—have proven costly, inadequate, and sometimes dangerous. A novel therapy called **autologous stem cell transplantation** holds the potential to arrest and reverse the progression of osteoarthritis, using stem cells safely extracted from the patient's own body to grow new cartilage in arthritic joints. This non-surgical approach, pioneered in part by one researcher, Dr. Christopher Centeno, has yielded intriguing preliminary results in clinical trials, producing up to 75% pain reduction in osteoarthritis patients. In an unconscionable and flagrant move to protect conventional medicine profits, the FDA has responded to this experimental therapy by attempting to assume regulatory *control* over these stem cells—and block their use. Dr. Centeno and his research organization, Regenerative Sciences, hope to thwart the agency's efforts in court. If you have any questions on the scientific content of this article, please call a Life Extension® Health Advisor at 1-866-864-3027.

orthopedics. He is board certified in physical medicine as well as rehabilitation and in pain management through the American Board of Anesthesia.

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