

REGENERATIVE MEDICINE IS GROWING UP:

From Promise to Evidence



For years, regenerative medicine has existed in an unusual position.

Patients have reported remarkable experiences. Physicians have seen outcomes that have encouraged them to continue exploring the field. Scientists have identified compelling mechanisms through which mesenchymal stromal cells (MSCs) may influence inflammation, tissue environments and repair.

But medicine does not ultimately advance on anecdotes.

It advances on evidence.

And an important new study is providing exactly the kind of evidence the regenerative medicine field needs.

A Phase III Trial Worth Paying Attention To



Published in the March 2026 issue of *Osteoarthritis and Cartilage Open*, researchers reported two-year results from a randomized, double-blind, multicenter, placebo-controlled Phase III study evaluating allogeneic bone marrow-derived mesenchymal stromal cells in patients with grade 2 and grade 3 knee osteoarthritis.

The study enrolled **146 patients**, randomized equally between two groups.

Patients in the treatment group received a single ultrasound-guided intra-articular injection of **25 million cultured bone marrow-derived MSCs**, followed by hyaluronic acid. The control group received placebo followed by the same amount of hyaluronic acid.

Researchers then followed the patients for **24 months**. That matters.

Regenerative medicine needs more than short-term reports of whether someone simply “feels better.” We need controlled studies that ask harder questions over longer periods of time.

Does pain improve?

Does function improve?

Does that improvement persist?

And perhaps most importantly:

What is Actually Happening Inside the Joint?



The Results Were Significant.

At 24 months, researchers reported significantly better WOMAC composite scores—a widely used measure of pain, stiffness and physical function—in the MSC group compared with placebo.

The differences were statistically significant at **$p < 0.0001$** .

The study also incorporated advanced MRI evaluation, including **T2 mapping**, which can provide information about cartilage composition and quality.

Researchers reported no worsening of cartilage T2 mapping measurements in the medial femorotibial compartment of the MSC-treated group, while the placebo group demonstrated progressive worsening. Cartilage volume also increased in the MSC group.



A biomarker associated with type II collagen degradation, urinary CTX-II, decreased in the MSC group while increasing in the placebo group at measured time points.

And by the end of 24 months, **four patients in the placebo group had undergone total knee replacement compared with one patient in the MSC group.**

The safety findings were also encouraging: five adverse events were considered possibly related to the study treatment, all involving local administration-site effects.

These are not testimonials.

They are measurable clinical, imaging and laboratory findings from a randomized, controlled Phase III study.

Source: Gupta PK, et al. *Two years efficacy and safety outcomes of using allogeneic, pooled mesenchymal stromal cells for osteoarthritis of knee in a double-blind randomized placebo-controlled phase 3 study.* Osteoarthritis and Cartilage Open. 2026;8(1):100723.

What This Study Does, And Does Not, Prove





Scientific credibility requires us to be equally interested in the limitations of a study as we are in its exciting findings.

This trial evaluated a **specific bone marrow-derived MSC product, dose, patient population and administration protocol**. It should not be interpreted as proof that every stem cell product, every source of MSCs or every regenerative medicine protocol will produce the same result.

Nor does one study settle the broader scientific debate surrounding cell-based therapies for osteoarthritis.

That distinction is important.

In fact, another large, randomized Phase 2/3 study involving **480 patients** compared several cell-based interventions, including allogeneic umbilical-cord-tissue-derived MSCs, with corticosteroid injections for knee osteoarthritis. At one year, investigators did not find superiority of the cell therapies over corticosteroid for the study's primary pain outcome.

That study, published in *Nature Medicine*, is an equally important part of the scientific conversation.

Source: Mautner K, et al. *Cell-based versus corticosteroid injections for knee pain in osteoarthritis: a randomized phase 3 trial*. Nature Medicine. 2023.

Good science requires us to look at both.

And we are all learning that the quality of the biolocs is the defining factor of success and positive outcomes.

And that is precisely why the maturation of regenerative medicine is so important.

The Question Is Changing



For much of the last decade, the public conversation surrounding stem cells has been reduced to an overly simplistic question:

“Do stem cells work?”

That may increasingly be the wrong question.

A more sophisticated scientific conversation asks:

Which cells? From what tissue source? How were they isolated and manufactured?

How were they characterized? At what dose? At what passage?

For which condition? Delivered by what route? To which patients?

And measured against what clinical endpoints?

Those questions move regenerative medicine away from hype and toward something far more valuable: **precision.**



This Is Where the Field Needs to Go



At Auragens, we welcome this evolution. Regenerative medicine should be held to a high scientific standard.

Claims should be tested. Outcomes should be measured. Protocols should evolve as evidence evolves.

And cellular products themselves should be manufactured, characterized, tested and controlled with rigor.

That philosophy is one reason Auragens has invested not simply in providing regenerative treatments, but in building an integrated regenerative medicine and research platform.

Our physicians and scientists work across cellular biology, orthobiologics, clinical medicine and research. Our laboratory and clinical teams operate within the same ecosystem. Our cellular therapy operations have undergone the independent scrutiny required for AABB accreditation.



And through the Auragens Orthobiologics Division, we are working to contribute to the scientific conversation through research, clinical observation, publication and continued protocol development.

Because the future of regenerative medicine should not depend upon who can make the biggest promise.

It should depend upon who can produce the best evidence.

A New Era of Regenerative Medicine



There is still much we do not know.

There will be studies that produce extraordinary results. There will be studies that disappoint.

There will be protocols that ultimately prove valuable and others that science leaves behind.

That isn't a weakness of regenerative medicine. **That is how medicine progresses.**



What is exciting is that regenerative medicine is increasingly entering the arena where promising medical ideas ultimately have to prove themselves: randomized trials, objective imaging, biomarkers, longer follow-up and peer-reviewed publication.

For patients suffering from osteoarthritis—and for anyone watching the evolution of regenerative medicine—that should be encouraging.

Not because one study has provided the final answer.

But because researchers are beginning to ask better questions.

And increasingly, we are getting better data with which to answer them.

That is how a promising field becomes a serious medical discipline.

Sources

Gupta PK, Maheshwari S, Cherian JJ, et al. *Two years efficacy and safety outcomes of using allogeneic, pooled mesenchymal stromal cells for osteoarthritis of knee in a double-blind randomized placebo-controlled phase 3 study.* **Osteoarthritis and Cartilage Open.** 2026;8(1):100723. DOI: 10.1016/j.ocarto.2025.100723.

Gupta PK, et al. *Efficacy and Safety of Stempeucel in Osteoarthritis of the Knee: A Phase 3 Randomized, Double-Blind, Multicenter, Placebo-Controlled Study.* **The American Journal of Sports Medicine.** 2023. PMID: 37366164.

Mautner K, et al. *Cell-based versus corticosteroid injections for knee pain in osteoarthritis: a randomized phase 3 trial.* **Nature Medicine.** 2023. PMID: 37919438.

This article is intended for educational purposes and should not be interpreted as a claim that the investigational product studied is equivalent to Auragens cellular products or that the study establishes efficacy of any Auragens treatment or protocol.