The next step in regenerative medicine for osteoarthritis: Spscs and a new regulatory pathway

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Osteoarthritis (OA) remains one of the leading causes of disability worldwide, burdening health systems and diminishing quality of life for millions

Over the last decade, regenerative medicine has advanced rapidly – from stromal vascular fraction (SVF) and platelet-rich fibrin (PRF) to cell-free therapies such as amniotic-derived exosomes.

Our previous work has contributed to this evolution: first through SVF–PRF combination therapy showing sustained clinical improvements, and later through a large real-world evaluation of exosomes used both locally and systemically. Together, these studies strengthen the case for minimally invasive, biologically active therapies as an emerging pillar in OA care.

Today, a new direction is taking shape – one that may redefine how we think about regenerative cells, manufacturing, and regulation.

Besides the advancements in regenerative medicine, a notable breakthrough came in late 2025: a study demonstrated that inhibiting a “master regulator of aging” can stimulate regeneration of cartilage – even in tissue samples from human joints undergoing replacement surgery [(1)]

This suggests a future in which OA might be treated and healed – at least in part – with pharmacological agents, a very interesting thought is the potential use together with injections or cell- based therapies. If validated in clinical trials, such drugs could represent a paradigm shift: from structural modifications like joint replacement toward true biological rejuvenation.

SPSCs: A new generation of autologous regenerative cells

Earlier this summer, we categorized a new subpopulation of stem cells, the Small Pluripotent Stem Cells (SPSCs). They are an intriguing population of naturally occurring, very small cells found in peripheral blood. Measuring only 1–5 µm, they have demonstrated expression of key pluripotency- associated markers in our laboratory work. Unlike mesenchymal stem cells (MSCs), which typically require expansion, enzymatic digestion, or other manipulations that trigger ATMP classification, SPSCs can be enriched without culturing, additives, or enzymes.

This distinction is critical. SPSCs are:

• Autologous, minimally manipulated, processed only by physical methods, fully compatible with “same surgical procedure” logic.

These factors place SPSCs in a regulatory category far more aligned with already well-established platelet- based therapies than with traditional stem cell products. As health authorities intensify scrutiny of engineered and cultured cells, naturally occurring autologous cells may represent the safest and most compliant form of biological repair [(2)].

To support consistent preparation, we have developed a newly trademarked platform [(3)] designed to enrich and characterize SPSCs while remaining fully aligned with minimal-manipulation standards. This platform provides a structured and reproducible workflow suited for clinical research and clinical implementation.

Building on real-world experience: Why OA is the ideal target

Our earlier studies using SVF+PRF and Exosomes+PRF underline a simple truth: patients with chronic OA benefit from therapies that are minimally invasive yet biologically active. These real-world outcomes support further exploration of next-generation autologous solutions, especially those that avoid the regulatory barriers associated with expanded or allogeneic cell products.

SPSCs may be particularly well-suited for OA because they combine regenerative potential with an attractive regulatory profile – two factors essential for long-term clinical adoption.

A regulatory turning point: Device-enabled cell therapies

One of the most significant shifts in regenerative medicine is the move toward device-based cell preparation, rather than biologic manufacturing. This trend is already visible in the regulation of platelet-rich plasma and autologous bone marrow concentrates, where medical devices – not biologic drug frameworks – govern clinical use.

The new cell platform fits directly within this device-enabled paradigm. And the broader clinical workflow being developed – referred to as Stempheresis™ [(4)] – represents an international, ongoing collaboration focused on integrating SPSC enrichment into established medical-device processes.

Stempheresis™ is a coordinated effort across clinicians, researchers, and technical partners working to create compliant, scalable pathways for autologous cell therapies.

This collaborative model may offer a more sustainable future for regenerative medicine, particularly as regulators tighten oversight of engineered cell products.

Next chapter: A placebo- controlled clinical trial for knee osteoarthritis

To establish robust evidence for SPSCs in OA treatment, we are preparing a placebo-controlled clinical trial – the gold standard for demonstrating efficacy.

The study will evaluate:

- Intra-articular SPSCs prepared via the beforementioned platform
- Primary outcome: WOMAC (pain, stiffness, physical function)
- Secondary outcomes: imaging markers on ultrasound and X-ray

- Long-term follow-up to assess the durability of the response

This trial will be the first controlled evaluation of a minimally manipulated, pluripotent-like autologous cell population for osteoarthritis. Importantly, it will help define whether SPSCs can serve as a reproducible, safe, and regulatorily compliant alternative to MSCs, exosomes, or more invasive regenerative procedures.

The future of OA care may already be circulating in the bloodstream

As regenerative medicine continues to evolve, therapies that combine endogenous biology with regulatory feasibility will define the next decade. SPSCs – small, pluripotent, autologous cells already present in peripheral blood – may represent the safest and most compliant form of cell-based regeneration yet.

SPSCs, prepared through the new platform and eventually delivered through device-supported methods such as the Stempheresis™ method, offer a pathway toward accessible, reproducible, and legally robust OA therapy. With clinical trials on the horizon, the opportunity exists to transform the management of joint disease – not through manufactured biologics, but through the patient's own intrinsic repair system.

The next leap in osteoarthritis care may not come from the lab – but from the bloodstream itself.

Looking forward: Toward accessible, compliant regenerative care

Healthcare systems face mounting pressure to manage OA more effectively and at lower cost. Pharmacological strategies today offer temporary relief; joint replacement remains effective but invasive and expensive. Regenerative medicine continues to promise a middle path – if the therapies can be delivered safely, consistently, and in alignment with regulatory expectations.

References

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