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Editorial

The stem cell clinic problem in India: what do orthopaedic surgeons owe their patients?

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1. Introduction

Orthopaedic out-patient clinics across the Indian sub-continent are increasingly encountering a familiar clinical scenario, i.e. a geriatric age group woman in her late 50s, with Kellgren-Lawrence grade 3 osteoarthritis of the knee, who had been advised for total knee arthroplasty (TKA). However, they come with a print-out or video from a private clinic advertising a single stem cell injection capable of regenerating the cartilage, which is offered at a cost of several lakhs of rupees. Faced with the prospect of surgery and the promise of cartilage regeneration, they seek the orthopaedic surgeons' advice on whether this treatment is worth pursuing.

This is a question that warrants a response grounded in scientific evidence rather than non-critical enthusiasm or outright dismissal. Cell based therapies represent a promising frontier in Musculo-skeletal research and advancing this field remains a key objective of this journal. However, many interventions marketed to patients as 'stem cell therapy (SCT)' lack regulatory approval, trial registration or credible supporting evidence. Online surverys have identified India as one of the countries with the highest numbers of clinics advertising SCTs directly to consumers.[1]

In 2026, the regulatory landscape governing this market underwent a significant shift, with the Supreme Court of India and the Union Ministry of Health issuing unequivocal clarifications on the permissible and impermissible use of SCTs.[2,3] This editorial examines these developments in the context of the available orthopaedic evidence and addresses a more fundamental question, i.e. what are the ethical and professional responsibilities of orthopaedic surgeons when patients seek advice about these commercially marketed interventions?

1.1. What Indian regulators actually permit

The regulatory framework governing stem cell research in India is not new. The National Guidelines for Stem Cell Research (NGSCR), jointly issued by the Indian Council of Medical Research (ICMR) and the Department of Biotechnology in 2017, recognise haematopoietic stem cell transplantation for a defined set of indications as the only established standard-of-care application of stem cells.[4] All other uses remain investigational at the moment. The guidelines explicitly state that administering SCTSs outside an approved and monitored clinical trial is unethical and constitutes malpractice.[4] Clinical studies must obtain clearance from an institutional stem cell committee, an ethics committee and the Central Drugs Standard Control Organisation (CDSCO), be registered with the Clinical Trials Registry–India and incorporate a minimum follow-up period of two years.[4,5]

On 30 January 2026, the Supreme Court of India reinforced this regulatory position in *Yash Charitable Trust v. Union of India*, addressing the use of SCT for autism.[2] The honorary Court had stated that such interventions cannot be offered as a routine clinical service and may only be

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administered within approved and monitored clinical trials. It further has rejected the proposition that the patient or parental consent could even legitimise an unproven intervention and has called for a stronger national oversight.[2] Although the judgment had concerned autism, its underlying principles regarding scientific evidence, professional accountability and informed consent have broader implications across the various clinical indications.

Subsequently, the executive action further had clarified the regulatory position. In September 2026, the Ministry of Health and Family Welfare had advised State governments that SCT could be offered as standard care only for approved the indications, 18 in adults and 14 in children as specified.[3] The advisory explicitly stated that the mesenchymal stem cell transplantation is not a recommended standard care for any disease. It also identified unauthorised administration, prescription, promotion and advertisement of such interventions as potential professional misconduct, subject to action by the respective State Medical Councils.[3] The National Medical Commission had issued a corresponding advisory.[3,6] In addition to these, amendments to the Drug Rules, 1945, in 2026 brought cell-based and stem cell-derived products within the scope of central licensing requirements.[3]

An important distinction nevertheless remains for orthopaedic practice. Stempeucel, an allogeneic, pooled, bone marrow-derived mesenchymal stromal cell preparation, received CDSCO marketing approval in 2022 for the treatment of Kellgren–Lawrence grade II–III knee osteoarthritis following a phase III randomised controlled trial (RCT).[7,8] A regulated product authorised for a specific indication is fundamentally different from an inadequately characterised cellular preparation administered in a private clinic without appropriate regulatory oversight. For patients, however, this distinction is not always apparent. The commercial incentives surrounding regenerative medicine may further obscure the boundary between an authorised therapeutic intervention and an unproven treatment.

1.2. Where the orthopaedic evidence stands

The current evidence for cell-based therapies (CBT) in orthopaedics presents a cautiously optimistic but far from conclusive picture. Although knee osteoarthritis has generated the largest body of randomised clinical evidence, the reported benefits remain modest and inconsistent. Pooled analyses suggest improvements in pain and function compared with placebo at approximately 12 months. However, a 2025 meta-analysis of eight placebo-controlled trials involving 467 patients estimated that much of the symptomatic improvement following intra-articular injection could be attributed to contextual and placebo effects, with only a small additional benefit attributable to the cells themselves.[9,10] More importantly, convincing evidence of structural cartilage regeneration in humans remains lacking. Even in earlier trials of Stempeucel, whole-organ MRI (Magnetic Resonance Imaging) scores did not differ significantly between the treatment and placebo groups.[8]

Osteonecrosis of the femoral head presents a similar evidentiary challenge. Core decompression augmented with bone marrow concentrate has attracted considerable interest, supported by long-term cohort data from its proponents.[11] Nevertheless, small RCTs have failed to demonstrate a clear advantage over core decompression alone, including a double-blind trial involving patients with stage III disease.[12,13] Larger multicentre trials remain ongoing. The evidence supporting CBTs for fracture non-union, articular cartilage defects and tendinopathies is even less mature.

These current limitations should not be interpreted as an argument against further investigation. Rather, they actually underscore the distinction between the scientific promise and established clinical benefits. Current evidence suggests that patients cannot reliably be assured that a commercially available cellular preparation will completely regenerate articular cartilage or prevent hip replacement. This disconnect between what the evidence supports and what is promised in commercial advertising lies at the heart of our concern at present.

1.3. The harms are not only physical

CBTs that are not yet proved are frequently shown as safe inherently, but this pre-emptive assumption is quite tough to defend. Preparations made or instiled outside appropriately regulated facilities may expose patients to infection, contamination and unpredictable biological effects. In the United States of America, three patients experienced vision loss following injections of autologous adipose-derived cells at a commercial clinic, which emerged as one of the most widely cited warning till date.[14] In general orthopaedic practice, an intra-articular infection following an injection can have devastating consequences, potentially necessitating repeated surgery and prolonged antimicrobial treatment. The true incidence of such complications associated with commercially marketed CBTs remain difficult to establish, particularly when adverse events are reported inadequately.

The financial burden can be substantial, with patients spending several lakhs of rupees on repeated injections without established clinical benefits, often without insurance coverage. Pursuing these unproven treatments delay evidence-based interventions, including physical therapy, corrective osteotomy and replacements, potentially prolonging the disability and compromising subsequent treatment outcomes.

More than the individual patients, exaggerated therapeutic claims to threaten public trust in regenerative medicine and legitimate scientific research. Commercially available, unproven treatments may also divert patients from properly structured RCTs, which can hinder recruitment and further delaying reliable evidence generation. Ultimately, regenerative medicine is threatened not by innovation itself but these commercial practices that actually invoke scientific progress without meeting the literature evidence standards required to support their claims.

1.4. What orthopaedic surgeons owe their patients

Orthopaedic surgeons have a central role in addressing this issue, as musculoskeletal conditions are among the most frequently publicised indications for CBTs worldwide.[1,15] With few clinics operated by orthopaedic surgeons themselves, professional accountability is paramount. Therefore, we put forward five fundamental obligations:

1. **Honest and empathetic counselling:** Communicate the available evidence, acknowledge its limitations and discuss realistic alternatives to ensure informed patient decision-making.
2. **Distinguishing research and accountability:** To restrict unproven CBTs appropriately registered and ethically approved RCTs, with transparent disclosure of their investigational status and uncertain benefits.[2,4] Informed consent cannot legitimise an otherwise unproven intervention.[2]
3. **Clinical restraint and accountability:** To ensure appropriate regulatory oversight, accurate treatment documentation, systemic outcome monitoring and transparent reporting of adverse events and treatment failures. The 2026 regulatory advisories identify the promotion or advertisement of unauthorised SCTs as potential professional misconduct.[3]
4. **Professional and institutional action:** To document and report suspected misconduct and adverse events to the appropriate regulatory authorities, while professional bodies develop evidence-based guidance and accessible patient education.
5. **Strengthening clinical evidence:** Promote adequately powered, placebo-controlled trials with standardised cellular characterisation, transparent protocols, clinically relevant outcomes and long-term follow-up to establish the safety, efficacy and durability of cellular interventions.

2. Conclusion

The regulatory advisories have substantially clarified the professional and legal boundaries that govern SCT in India. Outside approved indications and appropriately authorised RCTs on SCT cannot be legitimately marketed or administered as established clinical treatments. What remains uncertain is enforcement and that depends partly on the profession policing itself.

Returning to our patient with the printout: she deserves to hear that cell therapy for her knee is an active area of research, that one approved product exists with modest benefit and that no clinic can honestly promise to regrow her cartilage. She deserves to hear about a trial if one is open to her. She also deserves a clear plan for the treatments that work.

Regenerative medicine will earn its place in orthopaedics through evidence, not marketing. As a young journal of the Indian stem cell community, *Stem Cells and Cellular Therapy International* is well placed to insist on that standard in what it publishes and to give clinicians the evidence they need to have honest conversations with their patients.

3. Authors Contributions

1. **Manish Khanna:** Conceptualization, data curation, formal analysis, investigation, methodology, software, visualization, writing – review and editing.
2. **J S R G Saran:** Conceptualization, data curation, formal analysis, investigation, methodology, software, visualization, writing – original draft.

4. Conflict of Interest

None.

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