

Musculoskeletal Tissue Retrieval from Deceased Donors in India: Protocols and Challenges

Damini Shah¹, Prasad Bhagunde^{2,3,4,5}, Nihar Modi^{2,4,6}

Abstract

Musculoskeletal tissue donation from deceased donors plays a crucial role in advancing orthopedic and reconstructive surgeries, providing an alternative to autografts and synthetic implants. Despite its clinical significance, the adoption of tissue donation in India remains limited due to challenges such as low public awareness, cultural barriers, and infrastructural constraints. This study analyzes 16 cases of musculoskeletal tissue retrieval conducted in Mumbai between 2022 and 2023, highlighting procedural protocols, ethical considerations, and logistical challenges. The analysis underscores the importance of timely retrieval, adherence to regulatory frameworks like the Transplantation of Human Organs and Tissues Act (THOTA) 1994, and stringent quality assurance measures to ensure the safety and efficacy of allografts. Results demonstrate a high success rate, with over 98% of retrieved tissues meeting bioburden and structural integrity standards. The paper advocates for standardized protocols, improved public awareness, and enhanced training for healthcare professionals to advance tissue donation practices in India. This effort is pivotal for addressing unmet medical needs and fostering a compassionate healthcare system.

Keywords: Allografts, Musculoskeletal tissue donation, Tissue Banking, Orthobiologics, Reconstructive surgeries

Introduction

The modern orthopedic armamentarium has significantly enhanced the success rate of complex procedures. While earlier regenerative surgeries primarily relied on autografts and synthetic grafts, modern ortho-biologics (Fig. 1), including allografts, have repeatedly demonstrated that biology is best replaced by biology. However, the adoption of these advancements has been relatively slow in India. Although ortho-biologics are extensively used in the Western world, their progress in India remains limited.

Allograft options in India continue to face challenges, including the risk of infections and persistent myths surrounding tissue donation. With a population of 1.4 billion and over 5.6 million orthopedic surgeries performed annually [1], India heavily

relies on importing orthobiologics to meet the needs of its healthcare system. While autografts serve as a reliable option, allografts are indispensable for cases such as multi-ligament injuries, severe bone loss, complex trauma in young patients, and situations with poor autograft availability.

Although India has only a handful of tissue banks, significant progress has been made in recent years. These tissue banks aim to provide better healthcare options for the Indian population while instilling confidence among orthopedic surgeons regarding the sterility, safety, and cost-effectiveness of allografts. The retrieval of musculoskeletal tissues, including bones, tendons, and ligaments, from deceased donors is a critical process that must be handled with utmost sensitivity. Figure 2 highlights the types of musculoskeletal tissues that can be retrieved from a deceased donor. It is imperative to maintain high-quality, clinically safe allografts while ensuring respect for the deceased and the sentiments of their families. This article provides a comprehensive overview of the procedural, legal, and quality assurance aspects of musculoskeletal tissue retrieval, as well as the challenges and benefits of this practice.

Legal Framework and Ethical Guidelines

The retrieval of musculoskeletal tissues is strictly regulated under the Transplantation of Human Organs and Tissues Act (THOTA) 1994 India [2] to ensure that all processes are ethical, safe, and for therapeutic purposes. The act mandates

¹Novo Tissue Bank and Research Centre, Mumbai, Maharashtra, India.

²Department of Orthopaedics, Sona Medical Centre, Mumbai, Maharashtra, India.

³Department of Orthopaedics, Saifee Hospital, Mumbai, Maharashtra, India.

⁴Department of Orthopaedics, Jaslok Hospital and Research Centre, Mumbai, Maharashtra, India.

⁵Department of Orthopaedics, Breach Candy Hospital Trust, Mumbai, Maharashtra, India.

⁶Department of Orthopaedics, Criticare Asia Multispeciality Hospital and Research Centre, Mumbai, Maharashtra, India.

Address of Correspondence

Dr. Damini Shah,
Assistant Director of Operations, Novo Tissue Bank and Research Centre, Mumbai,
Maharashtra, India.

E-mail: daminirshah@gmail.com

Submitted Date: 14 Aug 2024, Review Date: 27 Aug 2024, Accepted Date: 14 Oct 2024 & Published Date: 10 Dec 2024

Journal of Clinical Orthopaedics | Available on www.jcorth.com | DOI:<https://doi.org/10.13107/jcorth.2024.v09i02.686>

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License (<https://creativecommons.org/licenses/by-nc-sa/4.0/>), which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

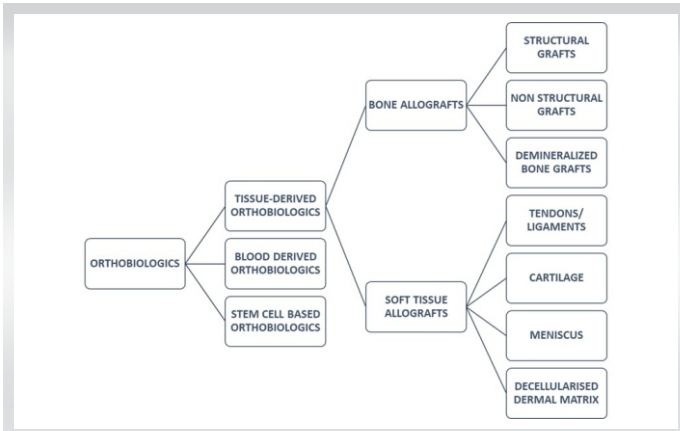


Figure 1: Classification of Orthobiologics

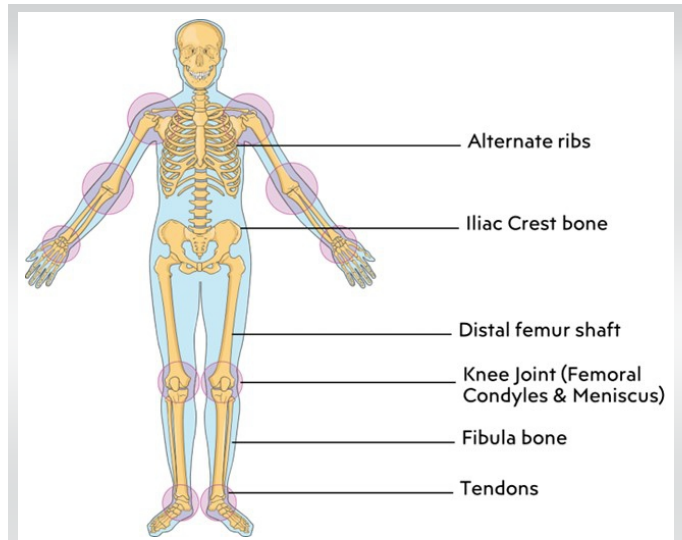


Figure 2: Musculoskeletal tissues that can be retrieved from deceased donors through minimally invasive procedures

mandatory consent from the next-of-kin, and requires tissue retrieval organizations and banks to be licensed. National and state organizations such as National Organ and Tissue Transplant Organization (NOTTO) and Regional cum State Organ and Tissue Transplant Organization (ROTTO-SOTTO) oversee the compliance of retrieval practices. Ethical considerations include ensuring respect for the donor and transparent communication about the donation process. This ensures trust and respect between the donor’s family and the tissue retrieval team.

All procedures were conducted by a registered team from a licensed tissue bank approved by the Directorate of Health Services (DHS) India, fully compliant with ROTTO- SOTTO guidelines [3], and in accordance with the provisions of the THOTA Act 1994 and international best practices [4, 5]. All retrievals were performed following informed consent from the next-of-kin fostering transparency and respect for donor families.

Methodology

This analysis is based on data from 16 musculoskeletal tissue retrieval cases conducted across Mumbai between 2022 and 2023. Cases included diverse demographics and a range of retrieval scenarios, such as refrigerated and non-refrigerated bodies, hospital and mortuary retrieval sites, and donors with varying medical histories. These cases provided a representative sample to evaluate procedural outcomes and challenges.

Selection of Donors

Eligibility Criteria for Donors

Donors were selected based on criteria such as age (typically 18-75), medical history, and physical condition. Donors were excluded on the basis of not having any transmissible diseases, malignancies, or conditions compromising tissue quality.

Screening Procedures

Screening involved reviewing the donor’s medical and social history, conducting serological tests for infectious diseases, and

Donor inclusion criteria	Donor exclusion criteria
<ul style="list-style-type: none"> • Donor is brain stem dead and certification of brain stem death and death certificate is available OR • Donor is circulatory dead and their death certificate is available. • The donor’s treating registered medical practitioner has evaluated and approved the donation process • The donor’s next-of-kin is informed about tissue donation and they have provided written consent for skin donation • Donor age is above 18 years, any gender (No upper age limit) • Donor’s tissue retrieval is scheduled within 15 hours of asystole when the body is not refrigerated OR • Donor’s tissue retrieval is scheduled within 24 hours of asystole when the donor body is refrigerated. 	<p>History, or presence of, or suspicion of, or risk factors for the following</p> <ul style="list-style-type: none"> •Hepatitis B or C, HIV 1 or 2, Septicemia, systemic viral disease or mycosis or active tuberculosis •central degenerative neurological diseases of possible infectious origin •autoimmune or connective tissue disease •use of all native human pituitary derived hormones •history of dura-mater allograft, including unspecified intracranial surgery •malignancy •any immunosuppressive treatment •exposure to a toxic substance that may be transferred in toxic doses or damage the tissue •infection or prior irradiation at the site of donation •COVID in the last 1 month •unknown cause of death

performing physical examinations to ensure tissue suitability.

Timeframe for Retrieval

Timing was crucial for tissue viability. Tissues were retrieved within 15 hours post-death if the body is uncooled and within 24 hours if refrigerated.

Required Approvals

Consent from the donor’s next-of-kin and a signed death certificate were mandatory before proceeding with retrieval.

Surgical Retrieval Process

The surgical retrieval of musculoskeletal tissues is conducted by registered and trained orthopedic surgeons, ensuring adherence to strict medical and ethical standards. The process begins with the careful preparation of the donor’s body in a relatively clean environment to minimize contamination risks and ensure the safety of allografts. The use of a Betadine scrub (povidone-iodine) is a standard practice in this process. Various tissues, including the iliac crest, tendons, knee joint condyles and meniscus, and fibula, were meticulously isolated. These tissues were retrieved using minimally invasive techniques to preserve their structural and functional integrity while minimizing trauma to the donor’s body.

Iliac crest was procured by incising along the bony prominence of the pelvis and exposing the bone through skin, subcutaneous

tissue and periosteum retraction. The desired portion typically 4x4 cm of the iliac crest was carefully excised using an oscillating saw or osteotome hammering. After excision, the site was closed using sutures and staples ensuring anatomical restoration. Tendons such as the Achilles and patellar were retrieved through a longitudinal incision made over their anatomical locations. Blunt dissection was used to isolate the tendon from the surrounding soft tissues all the while preserving its structural integrity, followed by excising it at the proximal and distal ends. For tendons like the tibialis anterior, tibialis posterior, peroneus longus, peroneus brevis, and extensor hallucis longus, a 2 cm transverse skin incision was made over the respective tendons. The distal end was transected using a sterile blade, while the proximal end was released using sutures and a tendon stripper, ensuring precise retrieval with minimal tissue damage. Knee joint tissues, including the femoral and tibial condyles and the meniscus, were retrieved via a midline incision (~7cm) over the knee under aseptic conditions. The structures were excised using an oscillating saw followed by reconstruction and closure. The fibula struts were isolated through a longitudinal incision (~4-5cm) along the lateral aspect of the lower leg. The periosteum was stripped using a rib stripper to expose the bone, and the desired segment (6-8 cm) was excised using an oscillating saw. Care was taken to maintain the structural integrity of the harvested bone while preserving surrounding soft tissues.

Following retrieval, the donor's body was respectfully reconstructed using wooden and metal prostheses to ensure no disfigurement and to maintain dignity through a compassionate approach (Fig. 3). The entire procedure was carried out under clean and controlled conditions to minimize the risk of contamination and ensure the safety and quality of the retrieved tissues. (Fig. 4)



Figure 3: Tendon retrieval through minimal incisions

Transportation and Preservation

Retrieved tissues were transported to tissue banks in sterile, temperature-controlled containers and preserved following the tissue bank Standard operating procedures (SOPs).

Ensuring safety in the use of donated tissues

Testing for microbial contamination was conducted using tissue sample analysis and smear tests to assess the inherent bioburden load (6). These evaluations guided the implementation of effective bioburden reduction standard operating procedures (SOPs) and sterility protocols. Detailed records were meticulously maintained, including donor documentation,

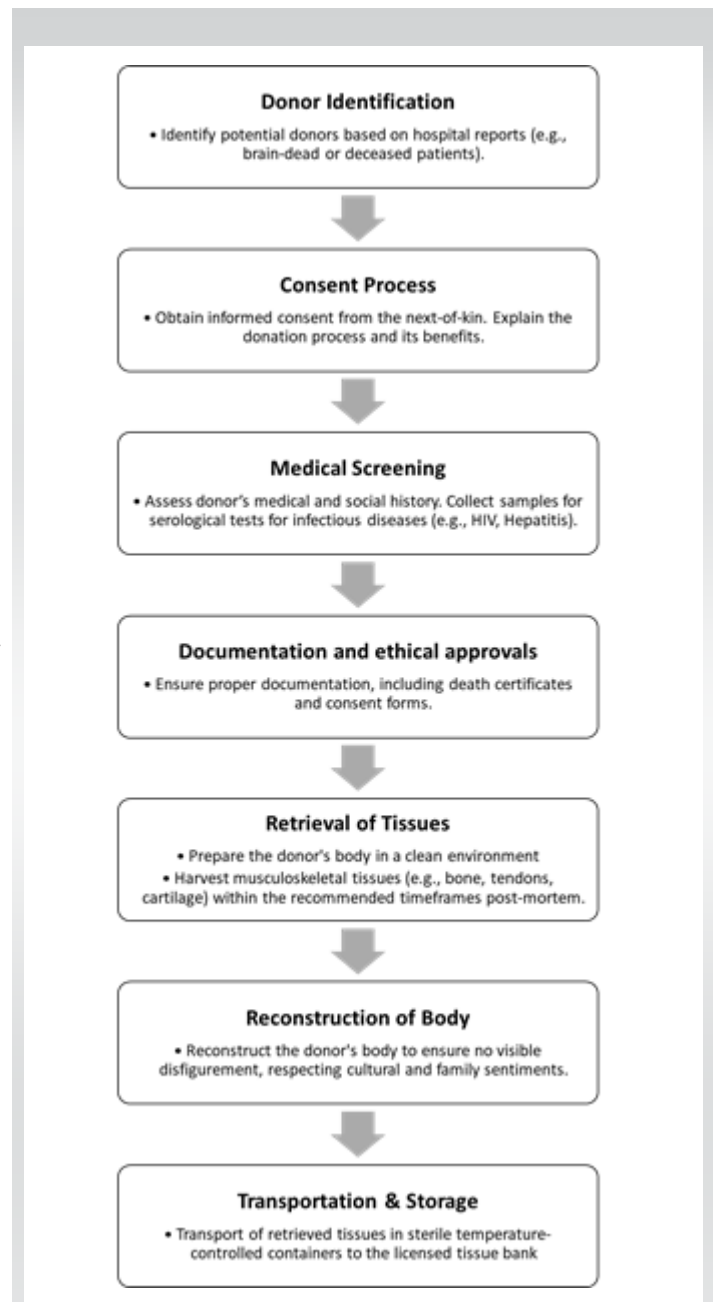


Figure 4: A step-by-step guide for the musculoskeletal tissue retrieval process

screening results, and consent forms. Unique identification numbers were assigned to each donor and their corresponding tissues to ensure robust traceability and compliance with regulatory standards.

Results of Tissue Retrieval: Graft Quality

More than 98% of retrieved tissues met bioburden and structural integrity standards after being retrieved through this procedure. Timeliness of retrieval (within 15 hours post-mortem) was correlated with higher graft success rates, typically achieved within 10 hours. Bodies that were refrigerated allowed for retrieval up to 24 hours post-mortem. However, due to rigor mortis, the retrieval of soft tissues like tendons became more challenging, often resulting in truncated grafts. Despite this, the strength of the grafts was not compromised. Time remained a sensitive factor in the process, given the family's sentiments and the rituals to be followed afterward. Therefore, retrieval was carried out in a systematic and efficient manner, ensuring high-quality grafts while maintaining a rapid pace. The average time for retrieval was between 45 and 60 minutes

Challenges in Musculoskeletal Tissue Retrieval

Musculoskeletal tissue retrieval in India faces several significant challenges. Public awareness of tissue donation remains limited, resulting in a low rate of consent from families. Time constraints also pose a barrier, as retrieval often disrupts rituals, which may be delayed for several hours. In some communities, rituals need to be completed before sunset, further complicating the timing of tissue harvesting.

Additionally, infrastructure for tissue banking and retrieval is still in its nascent stages, primarily concentrated in urban centers, leaving rural areas underserved. Ensuring regulatory compliance across diverse states adds another layer of complexity, as oversight and the implementation of guidelines vary. These challenges are further exacerbated by logistical issues, such as transportation difficulties and the need for skilled personnel to carry out both retrieval and processing procedures effectively.

Benefits of Musculoskeletal Tissue Donation

Clinical Applications

Musculoskeletal tissue donation plays a critical role in modern orthopedic and reconstructive surgeries. Donated tissues, such as bone, tendons, ligaments, and cartilage, are extensively used in procedures like joint reconstruction, spinal surgeries, and trauma repairs helping restore function and improve outcomes in surgeries involving significant bone loss, offering superior results when biological tissue is required for optimal healing. These tissues offer an essential resource for patients requiring complex surgeries, providing alternatives to autografts and

synthetic implants.

Ethical and Social Impact

Musculoskeletal tissue donation holds profound ethical and social significance. This social contribution enhances the dignity of the deceased, enabling them to leave behind a meaningful legacy and giving new hope to patients in need of these vital tissues. It can bring comfort to donor families, knowing that their loved one's tissue donation has made a positive impact on others, turning a tragic loss into an opportunity for healing. The act of donation also promotes a sense of community responsibility and altruism, creating a positive impact on society as a whole.

Advancing Protocol Standardization

This paper contributes to the development of a standardized protocol for tissue retrieval, ensuring that the process is carried out in a consistent, safe, and ethical manner. By providing clear guidelines for the retrieval and processing of musculoskeletal tissues, it helps set a benchmark for best practices. Standardizing the protocol reduces variability, increases the efficiency of tissue harvesting. This ensures the preservation of tissue quality, minimizes contamination risks, and maintains the structural integrity of grafts, ultimately improving patient outcomes.

Advancing Policy Making

Furthermore, this paper supports the advancement of policy-making in the field of tissue donation by providing evidence-based recommendations. It aims to guide regulatory bodies in ensuring adherence to stringent standards, fostering robust healthcare systems while also highlighting the real time challenges and limitations faced during the process. By addressing the legal, ethical, and medical aspects of tissue donation, it contributes to strengthening tissue banking regulations and ensuring that orthopedic surgeons can rely on Indian tissue banks for their surgical needs.

Education and Training

A crucial aspect of this paper is its role in educating and training orthopedic surgeons across India. As musculoskeletal tissue donation becomes more widely accepted, increasing awareness among healthcare professionals is essential. By providing surgeons with the knowledge and skills needed for retrieval procedures, and the mission to improve patient care is amplified.

In conclusion, musculoskeletal tissue donation offers significant clinical, ethical, and social benefits, providing essential resources for surgical repair and improving patient outcomes. Through the development of standardized protocols and policies, and by educating and training healthcare

professionals, the field of tissue donation and transplantation can be further advanced, ensuring a more effective and compassionate healthcare system.

Conclusion

The retrieval of musculoskeletal tissues from deceased donors in India is a regulated, ethically grounded process. While challenges exist, advancements in tissue banking infrastructure and public awareness hold promise for improving access to

high-quality allografts, ultimately benefiting patients in need.

In conclusion, musculoskeletal tissue donation offers significant clinical, ethical, and social benefits, providing essential resources for surgical repair and improving patient outcomes. Through the development of standardized protocols and policies, and by educating and training healthcare professionals, the field of tissue donation and transplantation can be further advanced, ensuring a more effective and compassionate healthcare system.

Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given his consent for his images and other clinical information to be reported in the Journal. The patient understands that his name and initials will not be published, and due efforts will be made to conceal his identity, but anonymity cannot be guaranteed.

Conflict of Interest: NIL; **Source of Support:** NIL

References

1. India orthopedic procedures count by segments and forecast to 2030. (2024, June 14). Market Research Reports & Consulting | GlobalData UK Ltd.
2. (2011) The Transplantation of Human Organs and Tissues Act, 1994. Gazette of India, Ext., Pt. II, S. 1.
3. Guidelines for Tissue Banking (2021) rottosottokem.in. Available at : <https://rottosottokem.in/downloads/SOTTO%20Tissue%20Guidelines.pdf>.
4. Morales Pedraza, J., Lobo Gajiwala, A. and Martinez Pardo, M.E. (2010) 'A review of the International Atomic Energy Agency (IAEA) international standards for tissue banks', Cell and Tissue Banking, 13(1), pp. 15–25. doi:10.1007/s10561-010-9215-3.
5. Nather, A. et al. (2018) 'Tissue banking in Asia Pacific region: Past, present and future', Cell and Tissue Banking, 19(2), pp. 229–240. doi:10.1007/s10561-018-9697-y.
6. Yusof, N., Shamsudin, A. R., Mohamad, H., Hassan, A., Yong, A. C., & Rahman, M. N. F. A. (2005). BIOBURDEN ESTIMATION IN RELATION TO TISSUE PRODUCT QUALITY AND RADIATION DOSE VALIDATION. In Elsevier eBooks. <https://doi.org/10.1533/9781845690779.5.319>

Conflict of Interest: NIL

Source of Support: NIL

How to Cite this Article

Shah D, Bhagunde P, Modi N. Musculoskeletal Tissue Retrieval from Deceased Donors in India: Protocols and Challenges. Journal of Clinical Orthopaedics July-December 2024;9(2):109-113.