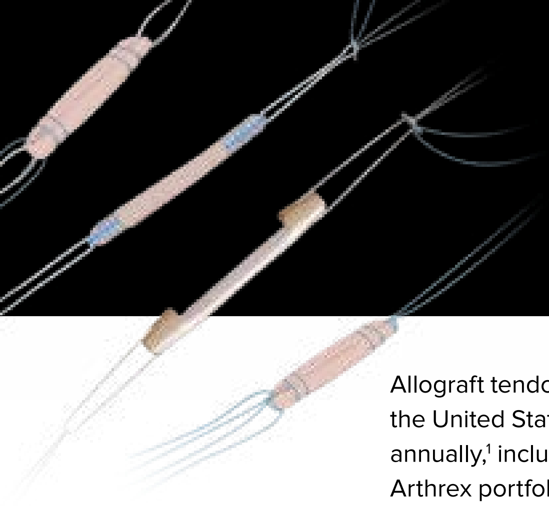

Allograft Tendons – Sterilization

Scientific Update

Allograft tendons provide surgeons with an invaluable tool for treating a variety of injuries. In the United States, it is estimated that there are 500,000 knee ligament procedures performed annually,[1] including an estimated 300,000 anterior cruciate ligament (ACL) surgeries.[2] The Arthrex portfolio of tendons provides surgeons with the largest selection of presutured and standard allograft tendons on the market.

Tissue processing methods from our partners balance safety and quality by ensuring the preservation of the tissues' inherent biological properties. These methods result in terminal sterilization of tendons and renders a sterility assurance level (SAL) of 10^{-6}. However, questions have recently arisen as to whether terminal sterilization at all intensities may negatively impact the mechanical integrity of tendon allografts, thereby compromising their use as structural components. This scientific update addresses these concerns and discusses counterclaims heavily supported by scientific literature.

Allograft Tendon Landscape

Roberson TA, Abildgaard JT, Wyland DJ, Siffri PC, Geary SP, Hawkins RJ, Tokish JM

"Proprietary processed" allografts: clinical outcomes and biomechanical properties in anterior cruciate ligament reconstruction. *Am J Sports Med*. 2017;45(13):3158-3167. doi:10.1177/0363546516687540

- Allograft tendons are increasingly becoming the top choice for ACL reconstruction and revision. One hospital system reported that, out of 16,000 reported cases, 42.4% of primary ACL reconstructions and 78.8% of ACL revisions were completed with allograft tendons.
- An AOSSM survey on ACL reconstructions completed by 833 surgeons found that 31% of these reconstructions had no documentation on the processing techniques of the allografts used. In addition, 80% of the surveyed surgeons were concerned about the clinical performance of sterilized allograft tissue.
- While 69% of the reported cases had available processing data, 57% of the surgeons responsible for those cases did not personally research the clinical records of their chosen allografts.
- BioCleanse®, AlloTrue™, and Allowash XG® are the most common proprietary tendon processing techniques. There are hundreds of studies that outline the advantages and shortcomings of each process.

Takeaway

Processing techniques for allograft tendons have long been discussed in literature, often including whether these cleaning processes may impact the mechanical and clinical performance of grafts. While this study emphasizes the need for larger, longer-term trials for more confident and reproducible conclusions, there is an abundance of research available to successfully mitigate common concerns and educate users on the basics of tendon processing techniques.

Basics of Tendon Allograft Sterilization

Arthrex Research
and Development

Low-dose irradiation of allografts for ligament and tendon reconstruction. LA1-0872-EN_A. Naples, FL; 2013.

- Terminal sterilization—the final processing step of cleaning allograft tissue of bacterial and immunocompromising components—is completed via gamma radiation.
- Allografts irradiated at intensities from 0.5-2 mrad showed successful terminal sterilization and maintained structural integrity.
- Allografts irradiated at intensities greater than 2 mrad may experience decreases in stiffness and maximum elongation at break. However, these changes may be mitigated if tendons are irradiated in a frozen environment.
- Allograft mechanical properties are characterized by the levels of healthy collagen within the tissue. Testing revealed that allografts irradiated between intensities of 0.5 and 2 mrad had levels of healthy tissue equal to nonirradiated allografts.

Takeaway

Gamma radiation is the most popular terminal sterilization technique for allograft tissue. However, it must be implemented at moderate intensity and low temperatures to minimize the risk of damaging allograft structural integrity.

Farago D,
Kozma B,
Kiss RM

Different sterilization and disinfection methods used for human tendons - a systematic review using mechanical properties to evaluate tendon allografts. *BMC Musculoskelet Disord*. 2021;22(1):404. doi:10.1186/s12891-021-04296-4

- Analyzed 10 studies that evaluated the impact of gamma radiation on tendon allograft mechanical properties and found that negative impacts depended on radiation intensity, temperature, and tendon type.
- Tendons cooled between -20 °C and -80 °C and kept on dry ice during gamma radiation had minimal mechanical deterioration when compared to samples irradiated at the same intensity at room temperature.
- The 1.5-2.8 mrad radiation range killed all bacteria but not all viruses. Radiation doses above 2.5 mrad are virucidal but may deteriorate tendons' mechanical properties.

Takeaway

Tissues should be irradiated at or below 2.5 mrad to minimize risk of bacterial translation and maintain tendons' mechanical properties. Tendons must be irradiated on dry ice to avoid excess heat, which can cause tendon decomposition that leads to tissue damage.

Arthrex®

Patient Outcomes

Lansdown DA,
Riff AJ,
Meadows M,
Yanke AB,
Bach BR Jr

What factors influence the biomechanical properties of allograft tissue for ACL reconstruction? A systematic review. *Clin Orthop Relat Res*. 2017;475(10):2412-2426. doi:10.1007/s11999-017-5330-9

- Analyzed 48 studies on changes to mechanical strength of human allograft tissue resulting from variations in graft tissue type, sterilization method, and graft preparation process.
- Of the 10 anatomically different allografts tested, quadriceps tendons exhibited superior mechanical strength. Most of the others met or exceeded the ultimate tensile strength of the native ACL regardless of sterilization method.
- High-dose gamma radiation deteriorates the mechanical properties of tendon allografts, unlike low to moderate doses (mrad <2). In the few studies that claimed otherwise, low to moderate doses of gamma radiation caused a maximum 20% reduction in stiffness in vitro. These studies did not address impact on performance in vivo.
- Multiple clinical studies illustrated similar postsurgical performances in patients who received autograft bone-patellar tendon-bone (BPTB) tendons compared to those who received BPTB allograft tendons irradiated at <1.5 mrad. One supporting study drew this conclusion from 477 ACL reconstructions and another from 238 ACL reconstructions.

Takeaway

The internationally accepted SAL of 10^{-6} for allograft tendons can be reached with 0.92 mrad. This value is low-dose gamma radiation, which has been proven to maintain the mechanical properties and clinical performance of allografts while eliminating biohazards for patient safety.

Dashe J,
Parisien RL,
Cusano A,
Curry EJ,
Bedi A,
Li X

Allograft tissue irradiation and failure rate after anterior cruciate ligament reconstruction: a systematic review. *World J Orthop*. 2016;7(6):392-400. doi:10.5312/wjo.v7.i6.392

- While in vitro data indicates negative effects of high-intensity gamma radiation on the mechanical properties of allograft tendons, clinical data does not support this as strongly.
- Study compared the clinical outcomes of nonirradiated autograft tissue to allograft tissue irradiated at 2.5 mrad, both for ACL reconstruction, and found no significant difference in patient outcomes.
- Mechanical strength of tendon allografts irradiated with high-intensity radiation (>2.5 mrad) fell below minimum values required by the body's biomechanics.

Takeaway

Allograft tendons treated with gamma radiation greater than 2.5 mrad may have reduced mechanical properties, but there is a lack of data supporting an increased postsurgical failure rate of these tendons compared to nonirradiated tendons. This study found tendon allografts irradiated at <2.5 mrad had identical functional failure rates and equal clinical performance compared to nonirradiated tendons.

References

1. SmartTRAK Market Research. Tendon Allografts — US, 2018.
2. Garrett WE, Jr, Swiontkowski MF, Weinstein JN, et al. American Board of Orthopaedic Surgery practice of the orthopaedic surgeon: part II, certification examination case mix. *J Bone Joint Surg Am*. 2006;88:660-667. doi:10.2106/JBJS.E.01208

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