White Paper on Structural Integrity and Safety of Irradiated JRF Ortho Tendon Allografts

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Introduction

The use of allografts in reconstruction and revision surgeries has become more commonplace where additional structural support is needed[2,6]. They are a beneficial tool because unlike autografts they are not associated with donor-site morbidity and also allow for shorter operative time and decreased surgical site pain[5]. Data compared from United States anterior cruciate ligament (ACL) registries illustrates that allograft tissue is used in an estimated 40% of primary ACL reconstructions and 75% of revision ACL reconstructions[3,5]. The FDA, AATB and the public have high expectations regarding the safety of allografts. These grafts need to be processed in a way that decreases the risk of disease transmission while still maintaining structural integrity[1,2,5].

Background/Problems

In processing allografts, it is standard to cleanse tissue to eliminate marrow, lipids and other cellular components through the use of detergents, ethanol and antibiotic rinses[1,2,5]. Further guarantee of tissue safety is done by using gamma irradiation to provide sterilization. However, there has been speculation about the structural integrity of grafts that have gone through irradiation[1,2,5,7]. Kaiser Permanente has conducted the largest retrospective study of its kind consisting of 5,968 primary ACL reconstructions. Outcomes of the study show that BioCleanse graft processing (RTI), younger patient age, BPTB allografts and irradiation over 1.8 Mrad were associated with a higher risk of clinical failure and subsequently a revision surgery[7].

Solution

Tissue distributed by JRF Ortho is minimally processed utilizing aseptic techniques and then cleansed using a proprietary method that does not use hydrogen peroxide to eliminate microorganisms and reduce graft contamination. The FDA accepts a sterility assurance level (SAL) of 10^{-3} as safe for implantable medical devices, including soft-tissue allografts utilized in ACL reconstructions. At this level, there is a one-in-1,000 chance that a microorganism could survive on the tissue[5]. JRF Ortho achieves a SAL of 10^{-6} (one-in-1,000,000) while undergoing temperature controlled, ultra low-dose (.95-1.4 Mrad) irradiation that has minimal impact on the biomechanical integrity of the tissue. The Kaiser Permanente study reinforces positive clinical results for the processing methods of JRF Ortho tissue.

Conclusion

Together, the use of aseptic technique, proprietary cleansing methods and temperature controlled, ultra low-dose irradiation provide a safe, structurally efficient allograft without impacting the integrity of the tissue and reducing potential for case failure[1,2,4,7]. JRF Ortho has no confirmed incidence of disease transmission and continues to deliver safe, high quality allografts. Surgeons should be mindful of the processing methods specific to each tissue vendor in order to make the best choice about allografts to use in surgeries to achieve the best outcome possible.

Works Cited

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