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Soft Tissue Allografts Terminally Sterilized with Electron Beam are Biomechanically Equivalent to Aseptic, Non-Irradiated Tissues

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Abstract

Allografts have been proven successful in treating orthopaedic injuries such as rupture of the anterior cruciate ligament, posterior cruciate ligament, and shoulder procedures, but the potential risk of disease transmission calls for effective terminal sterilization techniques to ensure graft safety. Gamma irradiation is the most common sterilization method, but its association with decreased biomechanical strength and higher failure rates in soft tissue allografts has driven our exploration of electron beam (e-beam) sterilization as an alternative in an effort to maintain tissue quality. The objective of this study was to compare e-beam sterilized tendon grafts to aseptic, non-irradiated tendons. Tibialis tendons and bone-patellar ligament-bone (BTB) allografts were aseptically processed and either sterilized with electron beam or left untreated to serve as controls. All specimens were evaluated biomechanically using a test protocol that included both sub-failure (cyclic tensile loading from 0–200 N) and failure (tensile loading to rupture) regimes in a physiologic environment. Structural and material properties were then calculated. Both e-beam sterilized and aseptic tendons displayed similar elongation behavior during cyclic loading. Regarding failure properties, e-beam sterilized tibialis and BTB tendons exhibited structural and material properties that were equivalent to those of aseptic controls. These results illustrate that e-beam sterilization does not alter tendon biomechanical properties and therefore can be a viable alternative for allograft sterilization.

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Introduction

The potential for disease transmission from donor to recipient remains one of the primary concerns regarding allograft use. Consequently, sterilization becomes extremely important for safe transplantation. Gamma irradiation at low dosages has become the most prevalent method used by tissue banks to terminally sterilize allografts[1]. Despite the effectiveness of gamma irradiation in reducing bioburden, the mechanical integrity of the tissue can be compromised with this method[2]. It has generally been accepted that the loss of biomechanical integrity in musculo-skeletal tissue due to gamma irradiation is dose dependent such that greater detrimental effects occur at higher doses[2-4]. However, the effect of "low dose" gamma irradiation on soft tissue biomechanics remains in question. Balsly et al.[3] reported that a low gamma dose (1.83–2.18 mRad) did not significantly reduce the tensile strength or elastic modulus of bone patellar tendon bone (BTB) and semitendinosus tendon allografts. Conversely, Curran et al.[1] found that BTBs exposed to 2.0 mRad of gamma radiation and cyclically loaded from 50 to 250 N elongated 27% more than non-irradiated controls and, when loaded in tension to failure, had a 20% decrease in tensile strength. Other studies reported a 15% reduction in tensile strength for BTBs subjected to 2.0 mRad of gamma radiation compared to controls[5]. Such debate warrants the exploration of alternative methods for allograft sterilization. Electron beam (e-beam) processing is widely used for sterilizing medical products and food packaging materials as well as for disinfestation of unprocessed bulk crops. In this process, an accelerated beam of electrons kills bacteria by directly breaking DNA chains and creating highly reactive compounds or atoms that induce further chemical destruction[6]. E-beam sterilization only requires seconds of exposure for effectiveness compared to hours necessary for gamma irradiation, thus the degradation to tissue can be significantly reduced[7]. Several companies have successfully adopted e-beam to terminally sterilize their tissue-based products due to the benefits of reduced tissue degradation, well-controlled dose ranges, and rapid turnaround[6]. To examine the effects of e-beam on allograft biomechanics, Hoburg et al.[8] exposed soft tissue grafts to 1.5, 2.5, and 3.4 mRad of e-beam sterilization, tested them in cyclic tension followed by tension to failure, and found no significant differences in strain, cyclic elongation or stiffness compared to non-irradiated controls. Additionally, no significant difference was found in failure strength for the 1.5 and 2.5 mRad doses compared to controls, while a minimal decrease was detected for the highest dose.

Study Objective

The purpose of this study was to further elucidate the biomechanical effects of e-beam sterilization at a dose of 1.71-2.10 mRad on tibialis tendons and BTBs in comparison to aseptically processed, non-irradiated tendons. Our hypothesis was that e-beam sterilized grafts would be biomechanically equivalent to non-sterilized controls.

Specimen Preparation

Paired anterior/posterior tibialis tendons and bisected BTBs from 10 research-consented donors were aseptically processed per current soft tissue standard operating procedures as fresh frozen grafts. Tendons were randomly selected and either e-beam sterilized at a 1.71-2.10 mRad dose or left non-irradiated to serve as a control group.

Biomechanical Testing

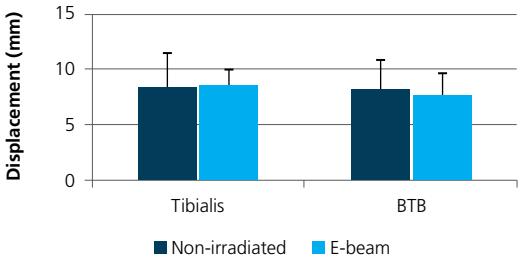
Tissues were stored at -70°C until testing, at which time they were thawed at room temperature and warmed using a water bath set to physiologic temperature (37°C). All specimens were trimmed to a minimum gage length-to-width ratio of 3:1, and the cross-sectional dimensions and initial gage lengths were measured in the unloaded state using a laser micrometer and calipers, respectively. For BTBs, the tibial bone blocks were potted using Bondo® body filler resin in custom molds. For tibialis tendons, the ends were folded in sandpaper to prevent slippage. Both ends of each specimen were secured in pneumatic clamps and testing was conducted using a materials testing system (Instron ElectroPuls E3000; Norwood, MA). Each tendon was preconditioned via cyclic tensile loading from 0-20 N at 0.5 Hz for 10 cycles. The grafts were then subjected to 2000 cycles of cyclic tensile loading at a rate of 2 Hz, with loads sinusoidally ramped between 0 N and 200 N in load control[8]. Specimens were unloaded and allowed to relax for five minutes following the cyclic sub-failure testing. Lastly, the specimens were loaded in tension to failure at a displacement rate of 100% initial gage length per second. All testing was conducted in a custom environmental chamber that maintained physiologic temperature (37 ± 2 °C) and constantly misted the specimens with saline to maintain tissue hydration.

Results

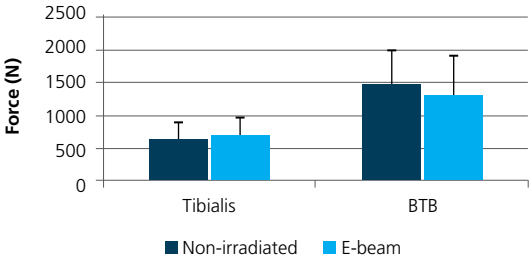
The sub-failure elongation of e-beam sterilized tibialis tendons and BTBs was not different from that of the control group. For both tibialis and BTB tendons, the calculated structural properties of maximum load, maximum displacement, and stiffness were not significantly different from controls. Likewise, the material properties of failure stress, failure strain, and elastic modulus of the e-beam treated tendons was not significantly different from controls. One tibialis tendon in each group and one BTB in the e-beam group failed during the cyclic portion of testing and were consequently excluded from the failure analysis.

Soft tissue allografts sterilized by electron beam were biomechanically equivalent to aseptically processed, non-sterilized tissues.

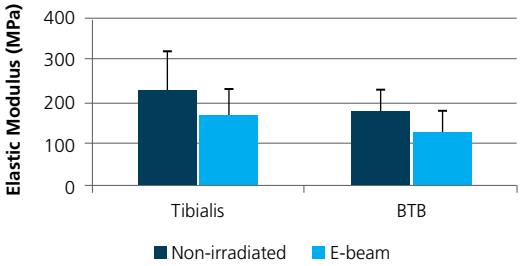
Maximum Displacement



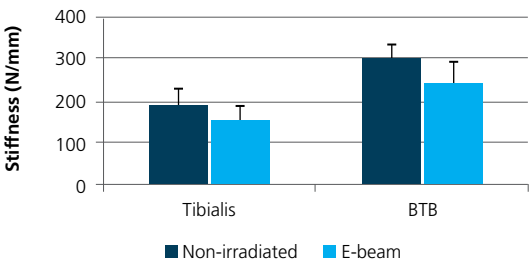
Maximum Load



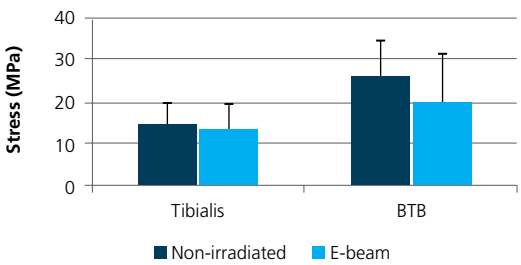
Elastic Modulus



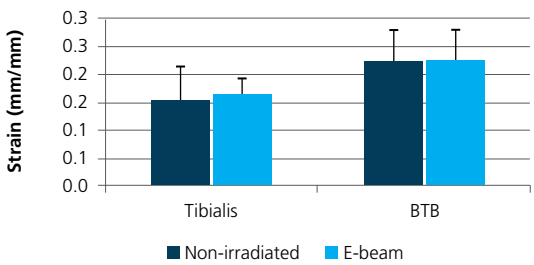
Stiffness



Failure Stress



Failure Strain



Conclusions

The results from this study supported our hypothesis that soft tissue allografts sterilized by electron beam at 1.71-2.10 mRad were biomechanically equivalent to aseptically processed, nonirradiated tissues. The measured structural and material properties hold clinical relevance for several reasons. First, all testing was conducted at physiologic temperature to ensure that the temperature-sensitive measured properties accurately represented the tissues' in vivo behavior. Second, testing was performed in a humidified environment in which the specimens maintained hydration but were not immersed in fluid to avoid potential changes in tissue behavior that can occur due to swelling and altered water content. Finally, all specimens were tested in both sub-failure and failure regimes to provide a more complete representation of biomechanical function. The cyclic loading protocol was chosen to approximate activities of daily living, such as walking or jogging, to evaluate allograft performance under real-life conditions. In closing, the biomechanical equivalence illustrated in this study endorses the use of electron beam sterilization for ensuring the safety of soft tissue allografts without concerns of diminished function.

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