Introduction: Soft tissue allografts are commonly employed as an alternative to autograft tissue for primary, complex, and revision ligamentous reconstruction of the knee. Allograft reconstructions are advantageous because their use avoids donor site morbidity, decreases operative time, decreases cost, and provides greater utility for multiple reconstructions or revision surgeries. Clinical studies of allograft repairs have reported very good results compared to autograft repairs without other associated morbidities. These reported morbidities include fewer activity limitations, less pain postoperatively, and improved function at one year. The use of allografts, however, does carry the risk of infectious disease transmission. Some current sterilization modalities such as ethylene oxide adversely affect graft properties. Sterilization by irradiation preserves the mechanical properties of the tissue but may not achieve 100% sterilization. The Biocleanse tissue sterilization process has been shown to effectively eliminate all viruses, spores, bacteria, and fungi. This process has been shown to preserve the biomechanical properties of allograft bone; however, there is no data of its effect on soft tissue allografts. The study purpose was to determine the biomechanical properties of soft tissue allografts treated with the Biocleanse tissue sterilization process as compared to fresh frozen allograft samples.

Methods: Soft tissue grafts allografts were harvested from the bilateral tibialis anterior tendons of human cadaveric donors. A total of thirty six grafts were harvested and randomly allocated to one of three groups. Fresh frozen (n=12), irradiated (n=12) and Biocleanse (n=12) grafts were stored frozen following sterilization until the time of testing. For mechanical testing, all grafts were thawed and tested at room temperature, taking care to maintain hydration. Grafts were looped in order to create double thickness constructs. The trailing ends of the grafts were sutured with #5 non-absorbable Krackow suture. The trailing ends of the looped grafts were then clamped rigidly using custom designed soft tissue clamps. This device has been used previously for soft tissue fixation for in-vitro sports medicine biomechanical studies (Petit, 2003; Bynum, 2005). The leading edge of the clamps was fixed to the tendon construct ten cm from the transverse rod in order to standardize the length of soft tissue that was subjected to the loading protocol. Once placed within the machine, specimens were pre-tensioned to 10N for two minutes prior to testing to normalize all specimens to input stress and to simulate a surgical pre-tensioning event. Data for displacement (mm) and force (N) was sampled at 0.5Hz for a total of 1000 cycles. Following cyclic testing, data for failure load (N) was sampled at 10Hz during the pre-tensioning phase to evaluate the biomechanical properties of soft tissue sterilization process as compared to fresh frozen allograft samples. From cycle 10 to cycle 100 and cycle 1000 demonstrated small increases in the range of 9% to 17%.

Discussion: Data from the pre-conditioning test seem to indicate that creep associated with surgical preparation and handling prior to insertion is not affected by sterilization technique. While the first cycle stiffness was significantly greater for both sterilization techniques, stiffness data for all groups stabilized within 10 cycles. As all remaining data were not significantly different between groups, the data indicate that the Biocleanse system effectively eradicates infectious organisms without changing the biomechanical properties of the ACL allograft material. Issues related to tissue healing and in-vivo biomechanical stability with the Biocleanse process have been reported elsewhere and were not incorporated into this “time zero” in-vitro study.

References:

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