The Effects of an Alternate Preservation Method on the Biomechanical Strength of Allograft Tissue

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Introduction: Allograft tissue is traditionally stored in either a freeze-dried or frozen state. An alternative storage method has been developed using a proprietary glycerol-based solution, Preservon®, which allows allograft tissue to be stored at ambient temperatures in a fully hydrated state. The benefits of this new storage method include convenient graft shipment and storage at ambient temperature with minimal preparation required prior to use. Traditional frozen allografts require shipment on dry ice and storage in mechanical freezers, while freeze-dried allografts require lengthy rehydration times prior to use. The purpose of this study was to determine the effects of Preservon treatment on the axial compressive strength of representative allograft tissue and also to determine the biomechanical integrity of Preservon-treated allograft tissue over time.

Materials and Methods: Allografts representative of the cortical, cancellous, and cortico-cancellous tissue types were chosen to be tested. 20 mm fibular shaft segments were processed from 9 donors with an average age of 42.0 ± 12.6 yr, 14 mm Cloward dowels were processed from 12 donors with an average age of 49.5 ± 13.2 yr, and 9 mm iliac crest wedges were processed from 12 donors with an average age of 46.9 ± 10.8 yr. Test samples were donor matched over the groups in order to account for donor-to-donor variation in mechanical properties. The control groups were processed to represent currently provided allografts and were treated per the AllowashXG® process (a patented cleaning, disinfection, and sterilization technology for allograft tissue1), freeze-dried using current manufacturing processes which results in residual moisture < 6%, and packaged in PETG trays. The experimental groups were treated per the AllowashXG process, Preservon-treated (a patented preservation method for bone tissue2), and packaged in conformable peel packaging. Allografts were tested at time zero and after accelerated aging of three and five years at 50°C (with 53 days at 50°C being equivalent to one year at 22°C). A minimum of twelve replicates were tested for each treatment per time period.

Cross-sectional area was determined for each graft. Cloward dowel average cross-sectional area was calculated as πDL/4, where L is the length of the cylinder, D is its diameter, and πD/4 is the average chord length of its circular face. The average cross-sectional area of the iliac crest wedge and fibular segment was measured with a planimeter due to its irregular shape. Because the opposite surfaces may differ slightly in size, both surfaces were measured in triplicate and averaged together. The average cross-sectional area was 3.7 ± 0.7 cm² for iliac crest wedges, 2.6 ± 0.5 cm² for Cloward dowels, and 1.0 ± 0.2 cm² for fibular segments.

Cloward dowels were tested on custom milled compression platens that allowed the graft to lay longitudinally in rounded grooves, insuring the load was applied evenly across the length of the dowel. The iliac crest wedges and fibular segments were tested in standard compression platens. Each allograft was tested using a dual column, 3360 series, Instron mechanical testing machine, equipped with a 30 kN load cell. The allografts were pre-loaded to 20 N and loaded to failure at a rate of 35 mm/min. The property compared was compressive strength which was calculated by dividing the load to failure by the cross sectional area.

Results: All data are presented as average ± the standard deviation (Tables 1, 2, and 3). The data were compared between treatment groups and time points using a one way ANOVA. While some changes were noted, no significant differences between the control and treatment groups existed for any allograft types tested (p>0.05).

Discussion: The data presented here indicate that Preservon treatment is a suitable alternative to freeze-dried preservation in respect to biomechanical strength. The use of Preservon as a preservation method allowing for fully hydrated graft storage at ambient temperature thus may prove a viable alternative to the time and temperature constraints present with current preservation methods for bone grafts.

References: 1. US Patents 5,556,379; 5,820,581; 5,977,034; 6,024,735. 2. US Patents 6,293,970; 6,544,289; 6,569,200; 7,063,726.