Biomechanical Integrity of Freeze-Dried vs. Frozen Allografts

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Background:
The key functions of structural allografts, such as those used for spinal fusion, are to provide sufficient strength and stiffness to accommodate human body weight and to encourage bony union. Allografts used in spinal fusion procedures are typically subjected to several types of forces including impact forces during implantation, and compression forces in the early postoperative period, before graft incorporation.

There are two primary methods for the preservation and storage of allografts: freezing and freeze-drying. Frozen tissue is stored at or below -40°C and requires thawing before use. Alternatively, freeze-dried tissue is first frozen to -80°C, then the frozen water content is sublimated into water vapor. The vapor is removed during a process called lyophilization. The result of this process is freeze-dried tissue that has a residual moisture content below 6%. Freeze-dried tissue has the advantage of convenient and economical room temperature storage, shipping and handling. In addition, the process of freeze-drying bone has been shown to reduce antigenicity, while maintaining the osteoinductive ability of the graft. However, freeze-dried tissue should be rehydrated in saline or water before implantation.

The purpose of this paper is to compare the effects of each of the preservation methods described above on the strength and stiffness of allograft tissue.

Results:
Previous studies described in the literature reported the results from biomechanical evaluation of human bone grafts subjected to freezing versus freeze-drying. The authors tested the human bone samples after in vivo rehydration in water or saline for a minimum of 1 hour, most commonly after 24 hours of rehydration. The authors conclude that rehydrated freeze-dried cortical, cancellous, and iliac crest wedge bone has statistically equivalent compressive strength compared to frozen bone. However, due to limitations in the operating room, a rehydration period of 24 hours is unrealistic, and in fact, many surgeons do not rehydrate freeze-dried tissue for 1 hour.

A recent study was completed by Dr. Andrew Rapoff to examine freeze-dried tissue at rehydration times that mimic what is performed in the operating room. Assembled Smith-Robinson type cervical interbody allografts were tested to compare stiffness and ultimate compressive strength of frozen versus freeze-dried treatment groups. Three groups of samples were tested: freeze-dried samples rehydrated for 30 seconds in buffered saline (FD 30s), freeze-dried samples that were not rehydrated (FD 0s), and frozen samples that were thawed, but not rehydrated (FZ). The stiffness was significantly greater for both freeze-dried treatment groups compared to the frozen specimens (Figure 1). The ultimate strength was also significantly greater for the freeze-dried bone grafts compared to the frozen bone grafts, Figure 2.
Conclusion:
While surgeon preference may dictate choice, research has shown that the strength of freeze-dried Smith-Robinson allografts, rehydrated for 30 seconds, is greater than the strength and stiffness of frozen Smith-Robinson allografts. The mean ultimate strength was greater for both freeze-dried treatment groups compared to the frozen groups. Long-term rehydration (24 hour rehydration period), as would occur in vivo, demonstrates that the mean ultimate strength was greater for the frozen specimens compared to freeze-dried specimens for a rehydration duration of 24 hours, but the variance was not statistically significant.

References: