PREPARATION AND REHYDRATION EFFECTS ON COMPRESSIVE PROPERTIES OF CORNERSTONE ASR CERVICAL SPINE ALLOGRAFTS

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ABSTRACT

This study investigates the compressive properties of an anterior cervical interbody allograft subject to two preparation processes: (1) freeze-dried and (2) frozen, and three rehydration durations T_R: (1) none, (2) 30 s, and (3) 24 hours (h). Experimental data showed a similar behavior for the 24 h rehydrated freeze-dried and all frozen specimens. Freeze-dried specimens with no or 30 s rehydration time showed a very brittle behavior and large data variation. The influence of grain orientation on failure behavior and strength has been also statistically evaluated. The clinical implications are that either method of preparation results in graft strengths that are from four to forty times greater than loads experienced on joints in the cervical spine under activities of daily living, even without the added benefit of supplemental surgical instrumentation.

INTRODUCTION

Allografts are typically subjected to various processing techniques to ensure their safety to the public health and for storage purposes. Questions remain as to the effect of two methods of preparation, in particular (freeze drying and freezing) on the compressive properties of these and similar allografts assembled from cortical and trabecular bone.

METHODS

Cornerstone^{TM} ASR (Assembled Special Reserve) cervical spine allografts were supplied by their manufacturer (Regeneration Technologies (RTI); Alachua, Florida, USA). Each ASR is comprised of a trabecular bone center assembled between lateral cortical bone plates via two transverse interference-fit cortical bone pins. Machined ridges augment the cranial and caudal faces, and the anterior face is machined into a portion of a cylindrical surface Each specimen was randomly assigned to either the no, the 30 s, or the 24 h rehydration group. The dimensions of each specimen were measured with digital calipers prior to rehydration and/or mechanical testing. Rehydration was accomplished by placing each specimen in phosphate buffered saline for the prescribed duration.

Compression testing was performed in a displacement controlled materials testing machine (InstruMet). Each specimen was placed between a fixed caudal platen and a self-leveling cranial platen within a "guided" compression fixture. The base of a linear extensometer was magnetically mounted to the crosshead, and the extensometer tip was placed in contact with the fixture near the caudal platen to eliminate fixture and test machine compliance. Each specimen was centered on the platen and then pre-loaded to 50 N prior to the application of a quasi-static crosshead displacement rate of 0.01 mm/s to failure. Load, extensometer displacement, and crosshead displacement was acquired at 1 Hz throughout each test.

The extensometer modulus E_e for each specimen was determined from the applied compressive load as measured by the load cell and the graft compression as measured by the extensometer. The ultimate load F_U for each specimen was determined as the maximum load achieved for specimens that exhibited brittle behavior and as the load at the end of the elastic portion of the stress-strain curve (the onset of trabecular bone consolidation; see **Figure 1**). An ultimate strength σ_U for each specimen was determined by dividing the ultimate load by the original total graft area in the transverse plane. Appropriate statistical tests were conducted.

RESULTS

Compression test data results are summarized in **Table 1**. The extensometer moduli were significantly different depending on preparation and rehydration duration. The 24 h rehydrated freeze-dried and all frozen specimens regardless of rehydration duration possessed similar compressive behavior including extensometer moduli and strengths. The mean extensometer moduli and ultimate strengths were greater for the no and 30 s rehydration freeze-dried specimens than the other specimen groups.

Typical stress-strain behaviors are shown in **Figure 1**, in which the "DL & F*" curve typifies that of the 24 h rehydrated freeze-dried (DL) and all of the frozen (F*) specimens, and the "DN & DS" curve typifies that of the no (DN) and 30 s (DS) rehydrated freeze-dried specimens. The 24 h rehydrated freeze-dried specimens exhibited compressive behavior typical of many porous materials, i.e., an initial mostly elastic region, followed by compaction of the pores over a large strain range, and ending in a compaction region of rapidly increasing stress (cut off in this curve). The no and 30 s rehydration freeze-dried specimens exhibited brittle behavior (rapid load drop post-failure shown in this curve).

Failure modes for 24 h rehydrated freeze-dried and the frozen specimens were determined post-test using the failed specimens. For the no and 30 s rehydration freeze-dried specimens, it was not possible to determine precisely the failure mode since they completely disintegrated at ultimate failure.

Preparation	T_R	**Designation**	E_e **[MPa]**	σ_U **[MPa]**
	0	DN	430 (120)	54 (12)
Freeze-Dried	30 s	DS	420 (100)	46 (11)
	24 h	DL	290 (70)	37 (8)
	0	FN	330 (50)	36 (4)
Frozen	30 s	FS	320 (60)	35 (6)
	24 h	FL	360 (60)	37 (6)

Table 1. Mean (standard deviation) values of extensometer moduli E_e and ultimate strengths σ_U for the freeze-dried and frozen specimens split by rehydration duration T_R.

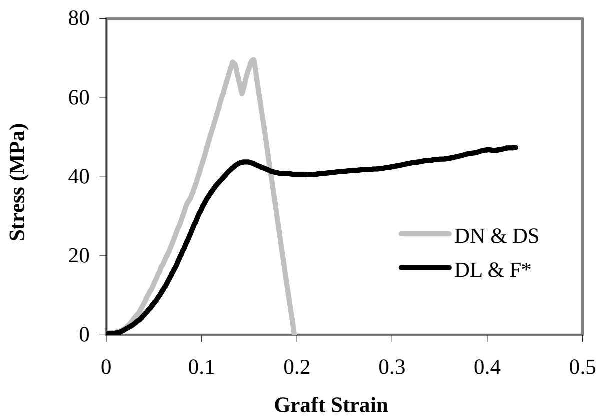

Figure 1. Typical stress-strain curve observed.

We found the failure mode to correlate highly with "grain" orientation (i.e., osteonal orientation and the first principle material direction) of the cortical bone of the lateral plates. The convention used for defining the grain direction on the cortical plates and the corresponding failure modes is shown in **Figure 2**. For the specimens with a predominate vertical (V) or diagonal (D) grain orientation, we observed multiple cracks that propagated in the grain direction. For specimens with a predominate horizontal (H) grain orientation, We observed multiple cracks on planes of maximum shear stress; a detachment between the cortical plates and trabecular center was also often observed.

We pooled the 24 h rehydration freeze-dried and all of the frozen specimens (DL and F*) for further analysis. This pooling was done for two reasons: (1) these groups exhibited similar compressive behaviors, and (2) their hydration is more representative of *in vivo* conditions compared to the essentially dry no and 30 s rehydration freeze-dried specimens. The DL and F* specimens possessed a pooled mean ultimate strength of 36 MPa (standard deviation 6 MPa). However, those in which both cortical plates had a vertical (V) grain orientation possessed a mean strength of 42 MPa (3 MPa). Those in which both cortical plates had a horizontal (H) grain orientation possessed a mean strength of 35 MPa (6 MPa). Specimens with a diagonal (D) or mixed orientation of their cortical plates possessed intermediate strengths. This behavior most likely reflects the fact that cortical bone is strongest in compression and weakest in shear. For the specimens with horizontally oriented grain, failure occurred along the 45° planes of maximum shear stress, while the specimens with vertical orientations failed along vertical planes.

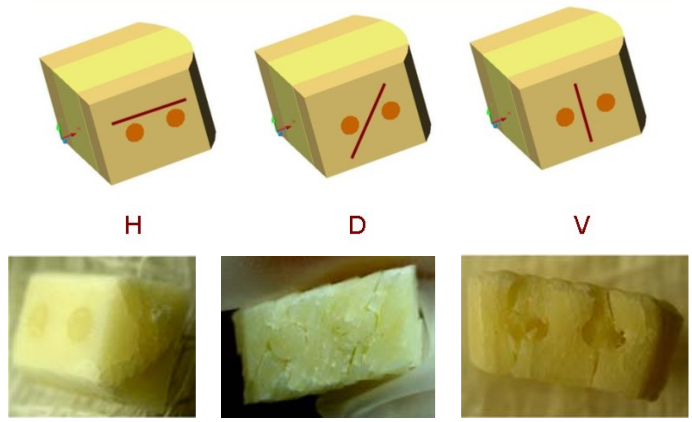

Figure 2. Grain orientation types and corresponding failure modes.

DISCUSSION

Analysis of the experimental data yields the following conclusions:

- Freeze-dried specimens with a 24 h rehydration duration and all of the frozen specimen exhibited similar compressive behavior, including failure modes.
- Specimens with both cortical plates having a vertical grain orientation possessed an ultimate strength at least 16% greater than that of the specimens with other grain orientations.
- Freeze-dried specimens with no or 30 s rehydration durations exhibited brittle behavior. They possessed a greater ultimate strength than the 24 h freeze-dried and frozen specimens, but the large variation in strength makes their strength poorly predictable.
- The 24 h freeze-dried and frozen specimens continued to bear load after cracking for high values of graft compression, whereas the no and 30 s rehydration freeze-dried specimens failed catastrophically.
- The brittleness of the no and 30 s rehydration freeze-dried specimens perhaps made them more sensitive to the initial presence of small cracks that may have been generated during manufacture of the allografts.

In summary, this study demonstrated that there was only a slight effect of time of rehydration on the elastic moduli and ultimate strengths for the frozen allografts. Conversely, rehydration time was crucial in reducing the inherent brittleness of the freeze-dried allografts.

ACKNOWLEDGEMENT

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