

VACUUM INFUSION PACKAGING RAPIDLY HYDRATES AND REDUCES BRITTLINESS OF FREEZE-DRIED ALLOGRAFT BONE IMPLANTS

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Abstract: Vacuum Infusion Packaging (VIP) rapidly rehydrates and improves the mechanical properties of freeze-dried allograft bone. A dye penetration test into porous bone grafts resulted in deeper and more uniform distribution of fluid compared to conventional soaking methods. Mechanical testing resulted in improved yield displacement and mechanical toughness properties for femoral ring allograft bone grafts in comparison to traditionally soaked grafts. In addition, VIP decreased the stiffness of the freeze-dried graft which may result in fewer fractures during impaction. VIP proved to be an effective and rapid means to uniformly deliver liquids into porous grafts and reducing the brittleness of freeze-dried bone grafts.

Introduction

In order to optimize shelf life and reduce antigenicity of allograft implants, they are commonly freeze-dried prior to storage.^[1] The freeze-drying process renders the implant completely dehydrated increasing brittleness. Allograft implants often require impaction during implantation and the implants may fracture as a result. One method of reducing the brittleness of freeze-dried bone grafts is to reduce stiffness by rehydration.^[2] Often, the high density of allograft bone makes fluid penetration difficult. Conventional rehydration of these implants typically involves lengthy periods of soaking the implants so that the collagen regains some of the moisture. Surgeons are reluctant to allot extended periods of time to rehydrate bone in the OR. Often the grafts are not hydrated but simply splashed with saline, rinsing its surface. The soaking time required to rehydrate bone to effectively restore its inherent flexibility is unknown. A more efficient means of reducing the brittleness of allograft bone is needed. Vacuum infusion packaging (VIP) seals a dehydrated implant under an extremely strong vacuum (>29" Hg) evacuating the air within the pores of the implant. The vacuum is released with fluid infusing into the pores rehydrating the implant very quickly.

Experimentation

Dye penetration testing was performed to determine the difference in fluid penetration depth and uniformity between conventional soaking methods and vacuum infusion packaging (VIP). Eight PLIF allograft spinal implants from different donors were cut in half laterally resulting in 16 similar cortical bone blocks. Ten cortical 7mm dowels were recovered and machined out of individual donors. Both groups were completely dehydrated for a period of three days in a lyophilizer. Each sample was labelled in individual flasks.

Eight cortical bone blocks and five cortical dowels were soaked in methylene blue dye for twenty minutes. The other eight blocks and five dowels were infused with dye using VIP. Each of the allograft implants and dowels were cut in half and labelled.

A qualitative survey from five individuals was conducted utilizing a rating scale from one to five. The survey rated the dye penetration and dye uniformity of each sample along the face of the cut. A one reflected poor penetration depth and nonuniform distribution while a five reflected complete penetration and uniform distribution. Dye penetration results were plotted according to the average rating of the two different hydration methods.

A mechanical test was performed to evaluate the effect of hydration levels and methods on the mechanical properties of femoral rings. The study consisted of 40 femoral ring allograft bone samples split into 10 donor matched sets of four. Each sample in the group consisted of the same donor, but each group differed in donor. Each sample was machined to have the same geometric dimensions in height and inner diameter.

One of the four grafts in each group was kept fresh frozen and the rest were freeze-dried (FD). Each of the grafts were rehydrated using different soaking methods, with specified time points; fresh frozen conventional 30 second soak, FD conventional 30 second soak, FD conventional 20 min soak, FD VIP for 30 seconds. A 30 second soak was chosen to simulate non-rehydrated or a rinsed graft.

The samples were impact tested on an MTS Bionix machine. A compressive displacement of 2mm was applied at a rate of 1 m/sec. Force and displacement data was recorded at 10kHz. Stiffness was also

calculated to help quantify the brittleness differences of the rehydration method.

Results and Discussion

Figure 1 illustrates the dye penetration results for the cortical bone dowels and the cortical bone blocks. The VIP produced 4 and 4.8 ratings for the cortical dowels and cortical blocks, respectively. The conventional soaking method produced ratings of 1.6 and 2.6 for the cortical dowels and cortical blocks, respectively. The results indicate that with the use of the VIP, superior penetration depth and uniformity was achieved. Figure 2 illustrates the differences of VIP over conventional soaking rehydration. Both blocks (a) and (b) are from the same PLIF graft to eliminate donor to donor variability and density differences within the same donor.

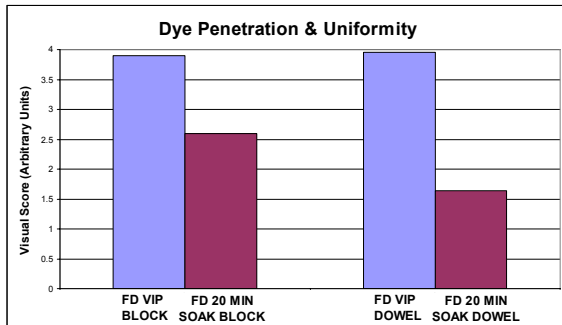


Figure 1: Dye Penetration Survey Results

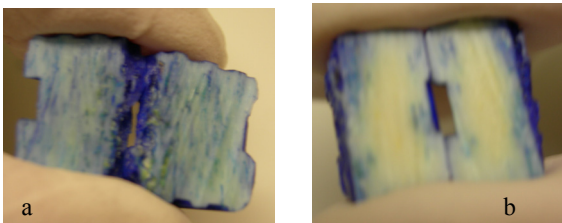


Figure 2. (a) FD VIP Block (b) FD 20 Min Soak Block

The mechanical testing results are shown in Figures 3 & 4. The results were plotted in terms of yield displacement, toughness, and stiffness.

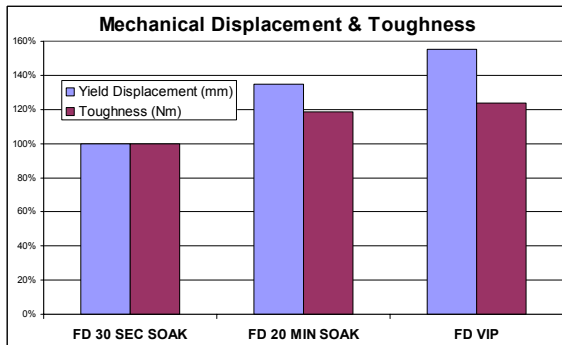


Figure 3: Mechanical Displacement & Toughness

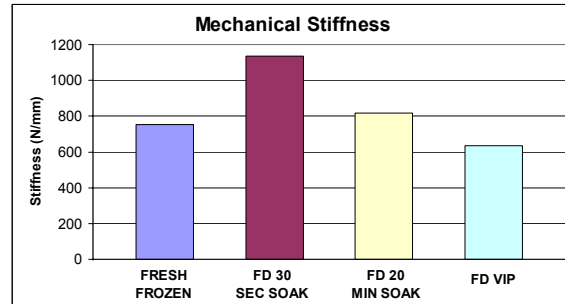


Figure 4: Mechanical Stiffness

The graphs in Figure 3 demonstrate that each hydration method proved to have a significant effect on yield displacement and toughness. All graft data in figure 3 was normalized to the freeze dried 30 second soak samples. The twenty minute hydration increased 35 % and VIP increased 55 % in yield displacement. Toughness increased of 19 % in twenty minute soak and 24% for VIP.

Mechanical stiffness data was plotted for all four hydration states in Fig 4. The soaked FD allograft displayed a decrease in stiffness with increased soak time. This confirms data previously reported that increased hydration reduces stiffness. The VIP grafts resulted in less brittle implants out performing the other soaking methods.

Figures 3 & 4 present the difference in toughness and stiffness between all the hydration methods tested. With the rationale that hydration increases mechanical toughness; the results confirmed that VIP rehydration delivery to be a superior method for rehydration.

Conclusions

VIP was found to hydrate freeze-dried bone implants more efficiently. The dye penetration testing demonstrated deeper uniform penetration of fluid in 30 seconds than samples soaked for 20 minutes. The mechanical testing of the femoral rings quantified the benefits of the increased hydration. The increase in toughness and decrease in stiffness show that VIP will help a freeze-dried bone implant be less brittle and bend before it breaks. As a result, the VIP allows the implant to absorb more energy prior to fracture than a soaked implant. Application of the VIP into medicine may result in fewer implant fractures during implantation and result in fewer complications for the patient.

References

- [1] E.U. CONRAD, ET AL., (1993): 'The Effects of Freeze-Drying and Rehydration on Cancellous Bone', *Clin. Orthop. Rel. Res.*, **290**, pp. 279-284
- [2] C.H. TURNER, D.B. BURR., (1993): 'Basic Biomechanical Measurements of Bone: A Tutorial', *Med. Biol. Eng. Comput.*, **38**, pp. 339-47