Fiber Loaded Calcium Phosphate Cement Improves the Structural Integrity of Defect- Filling Cement Mass under Simulated Dural Pulsation

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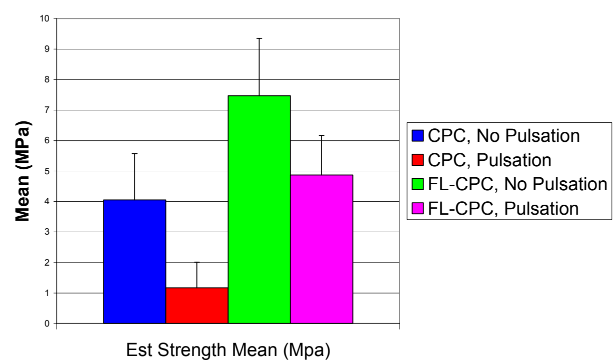
Statement of Purpose: Calcium phosphate cements (CPC) have been used as bone graft substitutes for over ten years with variable success. CPC repairs of cranial defects usually require reinforcement with a titanium or absorbable mesh on the intracranial surface, in order to protect against the effects of dural pulsation. Although there are anecdotal reports that dural pulsation is associated with the development of micro and macro cracks in cement reconstructions, this has not been studied in a systematic fashion. The specific aim of the current study was to determine whether dural pulsation has any negative effect on the mechanical or structural properties of CPC placed within a cranial defect. Additionally, we sought to determine whether a novel polylactide-co-glycolide fiber-loaded CPC (Synthes Biomaterials, West Chester, PA) was stronger and more resistant to the effects of dural pulsation as compared with non-reinforced CPC.

Methods: Specimen preparation was performed using a custom dural pulsation simulation fixture, developed at Synthes Biomaterials, West Chester, PA. The fixture provides an anatomically correct skull model with simulated dural pulsations. The model includes a cranial defect measuring 25cm^2. The amplitude of pulsation was adjustable, with a frequency of 67 beats/min. The skull model was housed in an environmental chamber that maintains constant in-vitro conditions of 37°C and 95-100% relative humidity.

The CPC and fiber-loaded CPC (FL-CPC) cements were each loaded for 24 hours with dural pulsation or 24 without dural pulsation. A total of 7 specimens were created in each of the four test conditions (CPC with pulsation, CPC without pulsation, FL-CPC with pulsation and FL-CPC without pulsation). Once the testing was complete the specimens were carefully removed and were loaded in 3-point bend until failure. The span of the 3-point bend fixture was constant at 45mm.

Results/Discussion: Biomechanical parameters including peak force, energy to peak force (area under force-displacement curve) and stiffness were measured to quantify the structural integrity of the defect mass. The material strength of the specimens was then calculated using beam theory. The highest energy to peak force was seen in FL-CPC without dural pulsation (109.129 N-mm) while CPC with dural pulsation showed the least energy to peak value (3.941 N-mm). FL-CPC with dural pulsation and CPC without dural pulsation followed respectively at 44.871 and 15.964 N-mm. The mean estimated strength for FL-CPC without pulsation, FL-CPC with pulsation, CPC without pulsation and CPC with pulsation was calculated at 7.471, 4.871, 4.057 and 1.171 MPa, respectively (Figure 1). Using ANOVA, it was determined that the non-pulsation group was significantly stronger than the pulsation group ($p<0.0001$). Similarly, specimens prepared using FL-CPC were significantly stronger ($p<0.0001$) than those created using CPC. These results show that dural pulsation negatively impacts the strength and other structural parameters of both CPC and FL-CPC defect-filling masses. FL-CPC consistently outperformed CPC and had a higher resistance to failure in the presence of dural pulsation. In fact, the strength of FL-CPC with dural pulsation was higher than that of CPC without dural pulsation, perhaps indicating that it may be feasible to use FL-CPC without any form of mesh reinforcement for the repair of cranial defects.

Figure 1



Conclusion: Our results confirm the observation of many surgeons that dural pulsation negatively impacts the structural and mechanical properties of calcium phosphate cement. Polylactide-co-glycolide fiber loaded calcium phosphate cement is more resistant to dural pulsation and may reduce or even eliminate the need for augmentation with titanium or absorbable mesh.