IMPROVED FLEXURAL STRENGTH OF A NOVEL CRANIOMAXILLOFACIAL CEMENT

Lin J*, Yetkinler DN*, Delaney D*, Nguyen HT*, Constantz BR*[+]
*Skeletal Kinetics, Cupertino CA 95014, [+]Stanford University, Stanford, CA 94305

Introduction

In the past five years, Norian CRS and other calcium phosphate cements have been gradually replacing PMMA as an osteoconductive, biocompatible alternative in the reconstruction of defects of the cranium and facial skeleton from congenital and acquired conditions. Furthermore, calcium phosphate cements have been shown to be safe and effective in a variety of craniomaxillofacial procedures such as replacement of full and partial thickness cranial voids and maxillofacial skeletal augmentations [1].

Despite a low morbidity and complication rate with calcium phosphate cements, these materials do fail. Reported failure modes of craniomaxillofacial calcium phosphate cements include implant loosening, fragmentation, chipping, and multiple fractures [1]. Also, microfragmentation from dural pulsations has been reported by Baker et al [2]. These occurrences may lead to sterile inflammations requiring second procedures to remove debris, thus increasing patient risk.

The principal mode of loading of calcium phosphate cements for craniomaxillofacial applications is flexural, a mechanical property that is dependent on its inherent resistance to fracture and the presence of defects. This property is an important determination for any biomaterial offering treatment for cranio-maxillofacial defects.

This study measured the flexural strength of OsteoVation™, a novel calcium phosphate cement, in order to determine its suitability for craniomaxillofacial applications. The flexural strength of Norian CRS, a well-established calcium phosphate cement, was measured for comparison. Both cements cure isothermically, form a low crystalline carbonated apatite, and are osteoconductive and biocompatible.

Methods

Both Norian CRS (Synthes, Paoli PA) and OsteoVation™ (OsteoMed, Addison, TX) consist of powder and liquid formulations that were mixed in a mortar and pestle until a homogenous paste was obtained. Flexural specimens were prepared by filling an acetal mold with the resultant paste. A cover was clamped onto the mold with minimal pressurization of the material. After curing for one hour, the blocks were cut lengthwise with a diamond tipped blade into flexural specimens measuring 50 mm in length and 8 mm x 8 mm in cross section.

Specimens were cured for 72 hours in phosphate buffered saline at 37°C, pH=7.4 to ensure maximum strength attainment by their complete conversion into carbonated apatite. The edges and faces of the specimens were sanded with 600 grit sandpaper until uniformly chamfered in order to reduce stress risers. Specimens with large voids were excluded from the study.

Testing was performed on a screw-type Instron materials testing machine (Instron Corp, Canton MA). Flexural specimens were tested in a wet environment in a fully articulating four-point bending fixture using a one-half span configuration with an outer loading span of 40 mm. Specimens were loaded under a displacement control rate of 1 μm/s. The following formula was used to calculate flexural strength: $\sigma = 3PL / 4bd^2$

where σ = stress in the outer fiber through load span
P = load at a given point on the load deflection curve
L = outer support span length
b = width of beam
d = height of beam

Care was taken to ensure loading rollers were properly aligned on the sample to prevent non-axial loads. Reported values were obtained by averaging data from at least six samples. Statistical analysis was performed with a two-tailed Student's t-test (α = 0.05)

Results

The flexural strength of OsteoVation™ was 6.87 MPa, while that of Norian CRS was 4.32 MPa. There was also less variation in flexural strength exhibited by OsteoVation™ as compared to Norian CRS bone cement. Flexural strength findings are summarized in Table 1. The difference in flexural strength is statistically significant (p = 0.0002).

Table 1. Comparison of flexure strength of Norian CRS and OsteoVation™ calcium phosphate cements

Sample	P, load (N)	σ (MPa)
Norian CRS	75.3	4.14
	81.7	5.09
	84.2	5.53
	69.3	4.21
	69.7	3.88
	53.6	3.10
Mean		4.32
Standard Devation		0.870
OsteoVation™	128	7.08
	128	7.24
	95.2	6.47
	119	7.66
	138	6.62
	113	6.17
Mean		6.87
Standard Deviation		0.553

Discussion and Conclusions

The flexural strength of OsteoVation™ and Norian CRS calcium phosphate cements was determined in the interest of their use in craniomaxillofacial applications. The flexural strength of OsteoVation™ was found to be 6.87 MPa, 59% greater than that of Norian CRS. This significant difference in strength may be attributed to the different cement reaction chemistry and pore sizes of these materials. This mechanical property, dependant on the material's inherent resistance to fracture, suggests that the occurrence of fragmentation and complications arising from treating defects in the cranium and facial skeleton may be minimized with the use of OsteoVation™ .

References

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