Material properties of various cements for use with vertebroplasty

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The purpose of the current study was to measure the material properties of various cements prepared per manufacturers' recommendations and of cements modified according to compositions developed by clinicians with experience performing vertebroplasty. Cement was prepared, cast to form cylindrical specimens, and tested in compression. The optical density of specimens from the various cement preparations was measured. Batches of Simplex P and Cranioplastic cement were also prepared with increased concentrations of $BaSO_4$ (20% and 30%; and 10%, 20% and 30%, respectively) to evaluate the effect of additional $BaSO_4$. Compressive modulus values for polymethylmethacrylate cements ranged from 2–2.7 GPa; some differences were significant ($p < 0.05$). Compared with polymethylmethacrylate cements, Orthocomp exhibited almost twice the compressive modulus and 2–3 times the strength values. Increasing the $BaSO_4$ concentration in Simplex P and Cranioplastic significantly ($p < 0.05$) affected their material properties; however, it is unknown if these changes in material properties are clinically important. Optical density increased as a function of concentration of the opacifying agent added. The current study provides clinicians with information on changes in the material properties of bone cements when the compositions are altered in a manner consistent with the practice of vertebroplasty.

1. Introduction

Percutaneous vertebroplasty (PVP) is a means of mechanically stabilizing vertebral bodies whose structural integrity has been compromised by compression fractures secondary to osteoporosis [1–3] or osteolytic lesions [4]. The technique typically consists of injecting polymethylmethacrylate (PMMA) cement into the cancellous bone of vertebral bodies via cannula inserted through each pedicle. The formulation of commercially available cements is often altered by clinicians to produce cements that are more amenable for use with vertebroplasty. For example, in an effort to decrease viscosity and increase the working time, clinicians commonly alter the mixture of monomer to polymer recommended by the manufacturer [5–7]. Such alterations significantly affect the material properties of the cement [8]. Clinicians also increase the radiopacity of the cement to increase its visibility under fluoroscopy and thereby minimize the risk of inadvertent extravasation [5–7]. Adding barium sulfate ($BaSO_4$) to PMMA cement to make it radiopaque reportedly affects the cement's material properties [9]. Even in cements that are commercially available with radiopacifiers included, practitioners of vertebroplasty typically increase the opacification by adding more $BaSO_4$ or other agents such as tantalum or tungsten powders. The effect of altering the composition of PMMA cements on the cements' material properties is unknown, as is the combined effect of altering the monomer-to-polymer ratio and adding opacifiers to cement (as practiced clinically in vertebroplasty).

Therefore, the two purposes of the current study were: (1) to measure the material properties of various cements prepared per manufacturers' recommendations and those altered in a manner consistent with the practice of vertebroplasty, and (2) to evaluate the optical density of the various preparations.

2. Materials and methods

Six cements were used: Cranioplastic (CMW, Blackpool, England); Osteobond (Zimmer, Warsaw, IN); Simplex P

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(Stryker-Howmedica-Osteonics, Rutherford, NJ); Chemfix3 (Tecknimed, S. A. Biomateriaux, Vic-en-Bigorre Cedex, France); Fixos (Transysteme, Nimes, France); and Orthocomp (Orthovita, Malvern, PA). Cranioplastic, a PMMA cement, arrives from the manufacturer with no radiopacifier. Osteobond, Simplex P, and Chemfix3, all PMMA cements, each contain 10% by weight $BaSO_4$; Fixos, a PMMA cement, contains 34% by weight ZrO_2. Orthocomp, a bioactive glass (bis-GMA) cement, is naturally radiopaque. We tested the following mixtures: cements mixed according to the various compositions developed by clinicians practicing vertebroplasty (Table I); cements mixed according to manufacturers' instructions; and cements mixed with additional $BaSO_4$ (Cranioplastic prepared with 10%, 20%, and 30% by weight $BaSO_4$ and Simplex P prepared with 20% and 30% by weight $BaSO_4$).

For the sake of economy, we prepared small batches of the PMMA cements, typically consisting of 10 g of powder, to which the desired volume of monomer and the desired mass of opacifying agent were added. The cement powder and desired mass of opacifier were weighed on a balance (Mettler Instruments Corp., Heightstown, NJ) accurate to $\pm$ 0.001 g and then placed in a Teflon mixing bowl. $BaSO_4$ was added mechanically by the manufacturer for Simplex P with 20% and 30% $BaSO_4$. The desired volume of monomer, measured with a glass pipette, was added to the powder. Each batch was mixed manually until the powder was completely wetted by monomer (about 30 s), and then the batch was immediately poured into a Teflon mold pretreated with silicone spray mold release (Solder Seal, Radiator Specialty Company, Charlotte, NC). Unlike the PMMA cements, Orthocomp is manufactured in a double-barreled cartridge that must be loaded into a device that forces the cement through a mixing tip. Because mixing occurs in the tip, the cement was directly injected into the Teflon mold. The mold consisted of 48 cylindrical holes, each 6 mm in diameter and 12 mm high. Remaining preparation and testing were performed per the American Society for Testing and Materials (ASTM) standard F451 [10]. The Teflon mold was then placed between two stainless steel plates and compressed using a C-clamp. The mold was placed in a saline (0.09%) bath maintained at 37 °C for 1 h. The stainless steel plates were separated from the mold, and the cement specimens were sanded flush with the mold with 240-grit wet sandpaper.

The specimens were pressed out of the mold, placed in a perforated plastic bag, and returned to the bath to polymerize completely for a period of 24 h. The specimens were then removed from the bath and visually inspected for defects. Any specimen containing a defect greater than 10% of its cross-sectional area was discarded [10]. The diameters and heights of the specimens were measured using digital calipers (Mititoyo Corp., Japan) accurate to $\pm$ 0.01 mm. The specimens were then individually placed between

TABLE I Compositions for cement preparation[a]

Batch	N	Opacifier/ powder (g/g)	Monomer/ polymer (ml/g)	Compressive yield strength (MPa)	Ultimate compressive strength (MPa)	Compressive modulus (GPa)	Optical density
Cranioplastic-based cements							
Cranioplastic							
0% $BaSO_4$	43	0	0.56	61.2 $\pm$ 2.4	64.2 $\pm$ 2.7	2.28 $\pm$ 0.09	—[b]
10% $BaSO_4$	46	0.10 $BaSO_4$	0.56	58.2 $\pm$ 2.9	60.8 $\pm$ 2.8	2.15 $\pm$ 0.07	75
20% $BaSO_4$	47	0.20 $BaSO_4$	0.56	54.9 $\pm$ 1.8	57.2 $\pm$ 1.8	2.04 $\pm$ 0.10	100
30% $BaSO_4$	39	0.30 $BaSO_4$	0.56	56.4 $\pm$ 1.7	59.9 $\pm$ 1.0	2.15 $\pm$ 0.10	175
Jensen[c]	20	0.28 $BaSO_4$	0.73	49.9 $\pm$ 3.2	52.9 $\pm$ 3.0	2.02 $\pm$ 0.12	167
Mathis[d]	32	0.26 $BaSO_4$	0.73	51.0 $\pm$ 1.4	53.8 $\pm$ 1.3	2.07 $\pm$ 0.07	165
Osteobond-based cements							
Osteobond	48	0.10 $BaSO_4$	0.56	72.4 $\pm$ 4.3	75.8 $\pm$ 4.5	2.64 $\pm$ 0.17	NA[e]
Murphy	37	0.31 $BaSO_4$	0.86	66.6 $\pm$ 2.8	71.0 $\pm$ 2.4	2.51 $\pm$ 0.16	195
Simplex-P-based cements							
Simplex P							
10% $BaSO_4$	47	0.10 $BaSO_4$	0.56	65.9 $\pm$ 2.0	69.8 $\pm$ 2.2	2.34 $\pm$ 0.08	100
20% $BaSO_4$	47	0.20 $BaSO_4$	0.56	71.6 $\pm$ 2.8	75.9 $\pm$ 3.1	2.53 $\pm$ 0.20	165
30% $BaSO_4$ (I)	46	0.30 $BaSO_4$	0.56	72.9 $\pm$ 2.9	80.2 $\pm$ 2.7	2.74 $\pm$ 0.21	NA
30% $BaSO_4$ (II)	47	0.30 $BaSO_4$	0.71	68.2 $\pm$ 2.2	73.8 $\pm$ 2.6	2.42 $\pm$ 0.18	195
Deramond	26	0.10 $BaSO_4$, 0.18 tantalum powder	0.80	61.8 $\pm$ 2.1	65.5 $\pm$ 2.4	2.26 $\pm$ 0.07	206
Olan[f]	27	0.10 $BaSO_4$, 0.05 tantalum powder	0.56	65.6 $\pm$ 2.8	69.8 $\pm$ 2.0	2.37 $\pm$ 0.08	185
Chemfix3	27	0.10 $BaSO_4$	0.47	70.6 $\pm$ 3.4	74.6 $\pm$ 1.9	2.25 $\pm$ 0.19	105
Fixos	10	0.34 ZrO_2	1.20	56.9 $\pm$ 2.2	61.0 $\pm$ 1.7	2.54 $\pm$ 0.05	216
Orthocomp	38	—[g]	—[g]	112.6 $\pm$ 12.1	162.0 $\pm$ 33.0	5.51 $\pm$ 0.54	204

[a] All cements are PMMA, except for Orthocomp, which is bis-GMA.
[b] —, this composition is radiolucent; therefore, no optical density measurements could be obtained.
[c] Dr Jensen routinely adds 1.2 g of tobramycin. We did not include tobramycin in our test batches.
[d] Dr Mathis no longer uses his Cranioplastic formulation; he now uses Simplex P with an additional 6 g of $BaSO_4$.
[e] NA, not available.
[f] Since the current study was conducted, Dr Olan no longer adds 1 g of tantalum powder; he now uses Simplex P as it arrives from the manufacturer (unaltered).
[g] —, not applicable.

TABLE II Summary of significant differences among cement preparations[a]

Mixture	Deramond	Fixos	Olan	Orthocomp	Osteobond	Simplex P	Jensen	Mathis	Murphy	Chemfix3	Cranioplastic
Deramond											
Fixos	M										
Olan		Y									
Orthocomp	M/Y/U	M/Y/U	M/Y/U								
Osteobond	M/Y/U	Y/U	M/Y	M/Y/U							
Simplex P	Y	Y	—	M/Y/U	M/Y						
Jensen	M/Y/U	M/Y	M/Y/U	M/Y/U	M/Y/U	M/Y/U					
Mathis	M/Y/U	M/Y	M/Y/U	M/Y/U	M/Y/U	M/Y/U					
Murphy	M/Y	Y	—	M/Y/U	Y	—	M/Y/U	M/Y/U			
Chemfix3	Y/U	M/Y/U	Y	M/Y/U	M	Y	M/Y/U	M/Y/U	M/Y		
Cranioplastic	—	M	Y	M/Y/U	M/Y/U	Y	M/Y/U	M/Y/U	M/Y	Y/U	

[a] The abbreviations used are: M, significant difference for modulus; U, significant difference fort ultimate strength; Y, significant difference for yield strength. The use of a dash (—) or the absence of a letter indicates no significance difference.

loading platens on an Instron model 8521 materials testing machine (Instron, Canton, MA) and compressed to failure at a rate of 0.01 mm/s. The compressive load was measured using a 8896-N load cell (Sensotec Inc., Columbus, OH). Load and deformation data were recorded at 10 Hz.

Stress and strain data, obtained by dividing the load and deformation data by a specimen's cross-sectional area and initial length, respectively, were plotted for each specimen. Ultimate compressive stress was defined as peak (maximum) stress. Compressive modulus was determined as the slope of the linear (Hookean) portion of the stress versus strain curve. Compressive yield strength was determined using the 2% offset method [10], in which a line is drawn parallel to the Hookean portion of the stress versus strain curve but offset along the strain axis a distance equal to 2% of the specimen's initial height.

After mechanical testing, three specimens were randomly selected from each batch and radiographed. Optical density of the specimen images was measured from digital radiographs.

We evaluated the effect of $BaSO_4$ content on the parameters of interest (ultimate strength, yield strength, and compressive modulus) for Simplex P and Cranioplastic using a one-way repeated measures ANOVA. We also evaluated the effect of composition on parameters of interest (ultimate strength, yield strength, and compressive modulus) using a one-way ANOVA with repeated measures. Differences were analyzed for statistical significance $(p \leq 0.05)$ using Tukey's post-hoc comparison test.

3. Results

3.1. Compositions

Compressive modulus values for PMMA cements ranged from 2.0–2.7 GPa (Table I) with some significant differences between the various cements (Table II). Orthocomp exhibited compressive modulus almost twice that for the PMMA cements. Similarly, for compressive yield strength and ultimate compressive strength, PMMA cements ranged from 50–73 MPa and from 53–80 MPa, respectively, but Orthocomp exhibited strength values 2–3 times those values.

3.2. Adding $BaSO_4$

Material properties for Cranioplastic decreased as $BaSO_4$ was added up to 20%, after which the trend reversed. There were no significant differences in material property values between Cranioplastic without $BaSO_4$ and Cranioplastic with 10% $BaSO_4$, but once the $BaSO_4$ content increased to 20%, the differences compared with Cranioplastic without $BaSO_4$ were significant (Table II). For Simplex P, the trend was opposite that for Cranioplastic. Material properties significantly increased as a function of increasing $BaSO_4$ for all parameters, except for the difference in ultimate strength between Simplex P with 20% and 30% $BaSO_4$, which was not significant. Material properties were significantly less for Simplex P containing 30% $BaSO_4$ mixed with a 0.71 monomer/polymer ratio compared with that mixed with a 0.56 monomer/polymer ratio (Table II).

3.3. Optical density

Optical density was greatest for Fixos (Fig. 1) and was generally a function of the quantity of opacifying agent

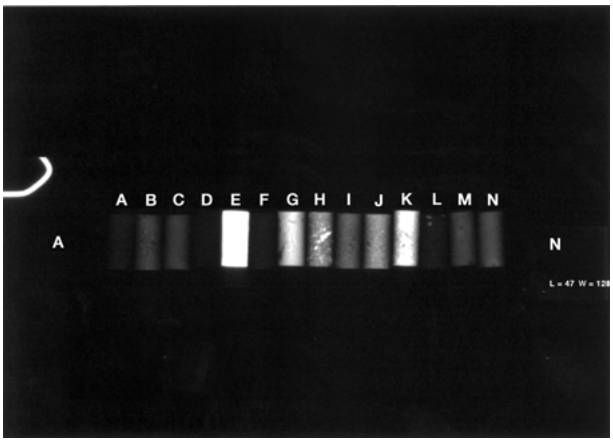

Figure 1 Radiograph of various cement preparations from which optical density measurements were made. Specimens are organized alphabetically, although only the first and last specimens in each row are labeled. A = Simplex P; B = Simplex P plus 20% by weight $BaSO_4$; C = Mathis; D = Cranioplastic plus 10% by weight $BaSO_4$; E = Fixos; F = Chemfix3; G = Orthocomp; H = Murphy; I = Olan; J = Simplex P plus 30% by weight $BaSO_4$; K = Deramond; L = Cranioplastic plus 20% by weight $BaSO_4$; M = Jensen; N = Cranioplastic plus 30% by weight $BaSO_4$.

within each cement (Table I). Cranioplastic without $BaSO_4$ exhibited no optical density.

4. Discussion

In the current study, we report the mechanical properties of various compositions developed and used by clinicians with extensive clinical experience with vertebroplasty. Each of these variations is a clinician's attempt to modify PMMA to facilitate percutaneous injection and visualization using real-time fluoroscopic monitoring.

We sought to evaluate a variety of preparations that used different base cements, but our selection was not all inclusive. We also sought to duplicate the modifications to cement composition as described by the selected clinicians. However, minor variations may have occurred for two reasons. First, we endeavored to eliminate additional variables. For example, Dr Jensen typically adds 1.2 g of tobramycin. Although adding tobramycin to PMMA reportedly does not affect strength [11], we chose to eliminate the variable of adding an antibiotic to our test compositions. Second, the clinicians typically base their compositions on volumetric measurements [5, 6] Because some inaccuracies may exist when powders are measured volumetrically (i.e., the amount may vary slightly depending on whether the powder is tightly or loosely packed), we converted the volumetric measurements to mass measurements to allow consistent reproduction for testing purposes. Doing so may have introduced some minor differences in the makeup of these compositions. The current report focuses on the changes in material properties as a function of cement composition; it is not intended as an endorsement of any given composition. In fact, some practitioners have altered their compositions since the initiation of the current study.

The compositions that exhibited the lowest strength and modulus values were two prepared from Cranioplastic. In previous *ex vivo* studies, vertebral bodies injected with Cranioplastic cement prepared per the Mathis composition were shown to be weaker and less stiff than those injected with other cements [12]. Even so, the Cranioplastic preparations (i.e., the Mathis and Jensen preparations) have been used extensively and without the complications associated with the material properties of the cement [3, 6]. Furthermore, it is currently unknown what magnitude of mechanical stabilization the cement must provide to restore vertebral body strength and stiffness. Recent studies suggest that the volumes of cement needed are less than those once thought necessary [13, 14]. These previous studies, combined with the results from the current study, suggest that if cement preparations with greater material properties than those of the Mathis or Jensen compositions are used, then smaller volumes may be needed to obtain similar clinical results. For example, our results suggest that because Orthocomp was materially stronger and stiffer than PMMA cements, less Orthocomp would be needed to attain mechanical stabilization similar to that of a PMMA cement. This hypothesis is based on data from bench-top studies and needs to be tested clinically in a prospective study. Adding $BaSO_4$ to Cranioplastic to increase radiopacity decreased its material properties, in many cases, significantly so. In the case of Simplex P, material properties increased as the content of $BaSO_4$ increased. This result was contrary to the trend noted with Cranioplastic and in previous reports [9, 15, 16]. One explanation for this unexpected result may be the manner in which the $BaSO_4$ was added. For Cranioplastic, $BaSO_4$ was added manually, which may have resulted in an inhomogeneous distribution or in clumping or settling of the $BaSO_4$. For Simplex P, $BaSO_4$ was added mechanically by the manufacturer.

It is important to note that all material properties reported here were obtained from compression tests. Although the predominant loading mode on vertebral bodies *in vivo* is axial compression, tensile and shear stresses are also present. Cement material properties may be more sensitive to changes in composition, such as adding $BaSO_4$, when the cement is tested in tension or shear.

The significant difference in material properties between Simplex P 30% (I) and Simplex 30% (II) was consistent with that in previous reports (Belkoff SM, Sanders JC: The effect of the monomer/powder ratio on the mechanical properties of acrylic bone cement, *J. Biomed. Mater. Res.* submitted, 2001) [8]. Increasing the monomer/polymer ratio decreases a cement's material properties.

The clinical significance of the changes in material properties of the cements is probably not great. For example, even after adding $BaSO_4$, the weakest and least stiff cement preparation was stronger and stiffer than the Jensen composition, which has been successfully used clinically in the United States for more than six years [6]. Thus, the sacrifice of material properties for better visualization under fluoroscopy seems appropriate. We found no reports in the literature indicating clinical complications resulting from mechanical failure or mechnical inadequacy of the cement. However, although there are obvious risks of complications from cement extravasation, the risk of extravasation may be reduced with the careful practice of vertebroplasty, which includes proper cement opacification and careful monitoring of injection under fluoroscopic guidance.

Radiopacity, as measured by optical density in the current study, was a function of concentration of the opacifying agent. This relationship was not quantitatively analyzed. The senior authors (HD, JMM) believe that opacification should be on the order of 30% by weight to be adequate for fluoroscopic visualization of the cement. Proper opacification is essential for fluoroscopic monitoring of cement injection to prevent extravasation and, thus, the potential complication of pulmonary embolism [6, 17]. In summary, proper opacification may be clinically more important than concern about relatively minor changes in the material properties of cement resulting from alterations in use for vertebroplasty.

Acknowledgments

The authors gratefully acknowledge the following companies for providing samples of cement: CMW (Blackpool, England; Cranioplastic); Orthovita (Malvern, PA; Orthocomp); Stryker-Howmedica-

Osteonics (Rutherford, NJ; Simplex P); Transysteme (Nimes, France; Fixos); Zimmer (Warsaw, IN; Osteobond); and Tecknimed S. A. Biomateriaux (Vic-en-Bigorre Cedex, France; Chemfix3). The authors also thank the following individuals for providing the composition of their cement mixes: Hervé Deramond, MD (Service de Radiologie A, Center Hospitaliere Universitaire, Amiens, France); Mary E. Jensen, MD (Department of Radiology, University of Virginia Hospital, Charlottesville, VA); John M. Mathis, MD (Department of Radiology, Lewis-Gale Medical Center, Salem, VA); Kieran Murphy, MD (Department of Radiology, The Johns Hopkins University School of Medicine, Baltimore, MD); and Wayne J. Olan, MD (Department of Radiology, Suburban Hospital, Baltimore, MD).

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Received 25 April 2000
and accepted 27 February 2001