A Method for Reducing Variability in Bending Strength

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Statement of Purpose: PMMA bone cement is considered the gold standard for use in arthroplastic procedures of the hip, knee, and other joints to fix metallic and polymeric prosthetic implants to living bone. Recently, new bone cement formulations have been used to stabilize painful osteoporotic compression fractures of the spine. In testing new bone cements, specimen preparation methods can affect mechanical behavior [1,2]. The focus this study was to identify a method to reduce variability in measured bending strengths of polymerized cement per ISO 5833-02, Annex F, using different mold materials and finishing methods. The ultimate goal is to facilitate comparison of mechanical properties of bone cements by identifying a reproducible and consistent sample preparation method.

Methods: ISO 5833-02, describing the preparation of molds for bone cement bend test specimens, states that Teflon, poly(ethylene terephthalate), Delrin, high density polyethylene and aluminum molds have been found to be suitable. The standard specifies that the specimen's bottom surface (the tensile surface in bending) should be polymerized in contact with a polyester film. We examined two deviations from the ISO standard: 1) using an open mold, and 2) testing mold materials other than those listed. SpinePlex ½ Dose (Stryker, Kalamazoo, MI) was mixed using the manufacturer's instructions and poured into an open mold. Aluminum dividers were inserted through the curing cement to separate and create 5 specimens. Once exothermic curing was complete, specimens were removed and the top surfaces machined with a fly cutter. The top and side surfaces were wet-ground to size using 400 grit SiC paper. The bottom surface (contacting the mold) was not altered for one group, while in the other group, the sample's bottom was wet sanded with 600 grit SiC paper in the longitudinal direction. Surface roughness of the bottom surface was determined using stylus profilometry. Specimens were X-rayed to determine internal porosity and identify large agglomerates of $BaSO_4$. Specimens were maintained at room temperature for at least 48 hours prior to testing. Ten specimens from each mold material were tested and analyzed per ISO 5833 using an MTS Alliance universal testing machine with cross head speed of 5mm/min. Force at break was recorded and the bend strength was calculated. The fracture surfaces were examined using light microscopy to observe the fracture pattern and identify any agglomerates of $BaSO_4$. The fracture location was identified on the X-ray micrographs. Differences in mean bend strength were tested by ANOVA and a Tukey HSD post-hoc test for pairwise comparisons.

Results: The five tested mold materials differ in bottom (tensile) surface roughness, 4pt bending strength, and the variation in bending strength (standard deviation) (Table 1). When the bottom surface was sanded to a uniform Ra of 0.13µm, bend strength increased for Delrin, Aluminum, and Teflon, and decreased for PE and Glass; however, only the changes for Teflon and PE were significant. The overall range of bend strength for the different mold materials decreased with bottom sanding from 44 to 55 MPa to 48 to 53 MPa. In addition, the standard deviation decreased for all sanded groups except for Teflon, which showed a slight increase. Delrin showed the largest decrease in standard deviation (8.28 to 2.48). The surface roughness of the specimen reflects the surface roughness of the mold material. Surface roughness of the mold also dictates the number and nature of nucleation sites that may influence surface porosity. Surface irregularities, such as macro roughness, influence fracture initiation; the smoother the surface, the higher the material's strength because there are fewer stress concentrators and hence fewer crack initiation sites. The specimens with the lowest surface roughness had the highest bending strengths (Glass and thick Polyester film, Table 1, #1, & #3) but had large standard deviations. Specimens that were sanded after molding (Table 1) exhibited lower variation in bending strength compared to the same mold material alone (except for Teflon). For PE and Glass, the surface roughness increased from 0.06 µm and 0.05µm, respectively, to 0.13µm for both. There were fewer surface crack initiation sites, such as small scratches, for both PE and Glass, and therefore a greater probability that failure originated at random subsurface imperfections. In addition, soft mold materials may not be suitable for repeated use because scratches may add additional irregularities to the specimen's surface and may lead to greater variation in bending strength.

Table 1. Bending Strength For Different Mold Materials

Mold Material	Surface Roughness: specimen bottom, µm	Average (n=10) Bend Strength, MPa (standard deviation)	Significantly Different from ($P<0.05$):
1. Polyester film, 0.01"	0.06	55.1 (3.68)	2, 3, 8
2. Polyester film, 0.01" $^+$	0.13	52.3 (2.90)	1, 3, 4, 6, 8
3. Glass	0.05	54.8 (6.17)	1, 2, 8
4. Glass$^+$	0.13	51.8 (1.43)	2, 5*, 6, 8
5. Teflon	1.18	48.6 (3.41)	4*, 6, 7, 10
6. Teflon$^+$	0.13	50.2 (3.60)	2, 4, 5, 10
7. Aluminum	0.28	46.8 (5.07)	5, 9, 10
8. Aluminum$^+$	0.13	53.3 (2.76)	1, 2, 3, 4, 7
9. Delrin	0.13	44.0 (8.28)	
10. Delrin$^+$	0.13	48.0 (2.48)	5, 6, 7

NOTES: $^+$ specimen's bottom uniformly sanded, * Significant at ($p<0.10$)

Conclusions: The results demonstrated that bending strength variations (standard deviation) of molded bone cement specimens depends on the specimen preparation procedure. When samples from different mold materials were sanded, the variability in bend strength between the different mold materials was reduced. Materials loaded in tension (for instance in bending or fatigue) are sensitive to material flaws and therefore both mold material and sample processing can significantly affect the measured material behavior. We observed that, independent of mold material, specimens that were sanded after molding showed the lowest variation in bending strength (smallest standard deviation). Any mold material will provide suitable test specimens if post-molding processes standardize the surface finish. Sanding is recommended for any molded specimens tested using ISO 5833 to reduce variability in the reported bend strength values.

References: [1] Demian HW. and McDermott, K. Biomaterials. 1998;19:1607-1618.
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