



ASSURING CEMENT FIXATION: ALL MIXING SYSTEMS ARE NOT THE SAME

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INTRODUCTION

Aseptic loosening attributed to cement fracture and the subsequent disruption of fixation interfaces remains a major long-term failure mode of cemented arthroplasty. Knowledge of the fracture strength of bone cement, especially in fatigue, is an important indicator of cement integrity and the potential for fixation failure. Several manufacturers have advocated mixing devices to increase the strength of bone cement by reducing its porosity or pore diameter.

This study evaluates different mixing methodologies as they influence cement porosity and the diametral tensile strength of cement specimens in both single cycle and fatigue. This serves as a means of establishing the effectiveness of these methods in producing optimal bone cement for use in joint arthroplasty.

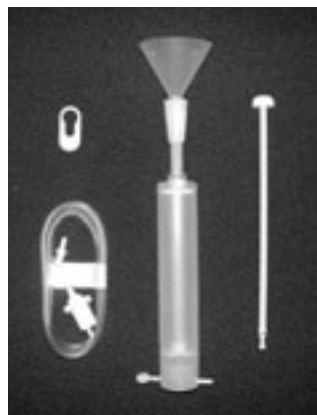
MATERIALS

A single, surgical quality and commercially available surgical bone cement (Surgical Simplex® P, Stryker® Howmedica Osteonics, Rutherford, NJ, USA) was used for all tests. The polymer and monomer components from two hundred (200) single dose units were unified to remove intra-batch variability.

Four vacuum mixing system designs were acquired directly from their respective manufacturers, the ACM® (Stryker® Howmedica Osteonics, Rutherford, NJ, USA) the Cemvac® (DePuy Orthopedics, Warsaw, IN, USA), the Prism™ II (DePuy Orthopedics, Warsaw, IN, USA), and the *twistOR*™ (Immedica, Chatham, NJ, USA). All systems were sterile and approved for human use.



ACM®



Cemvac®



Prism™ II



twistOR™

METHODS

Vacuum mixing was in precise compliance with the specific manufacturer's instructions. In addition, for comparative purposes, two mixing methods, hand mixing and hand mixing with centrifugation (Control), were evaluated. For all methodologies studied, a double dose of bone cement was retro-filled into 10 mm DIA x 75 mm long flint glass tubes.

After the tubes were filled, all specimens were handled identically. 1) Tubes were immediately suspended without immersion in 37°C water for 24 hours and allowed to cure. 2) The glass tubes were broken and the cement sectioned with a diamond wire saw into 20 mm \pm 0.5 lengths. 3) The cut faces were wet polished to a surface finish of \sim 7 μ m with 600 grit silicon carbide abrasive paper. 4) Specimens were labeled and their length and diameter measured within \pm 0.01 mm. 5) Specimens were stored in 37°C, aerated saline for 7 days before testing.

Specimens were drawn randomly for each test from available populations.

Porosity

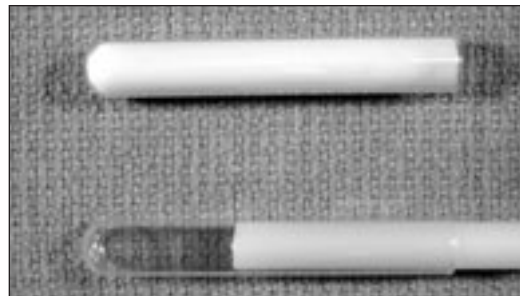
Surface porosity was calculated by optical analysis for a minimum of 10 dry test specimens sectioned into half cylinders with a diamond wire saw and wet polished. The sectioned surfaces were then stained with India ink and dry polished. The surface was digitally photographed and a functional accuracy was achieved to identify voids down to 0.001 mm². The area percent of voids was calculated using image analysis software.

Diametral Tension Strength

Ultimate Diametral Tension Strength (DTS) was measured on a minimum of ten test specimens per ASTM D3967. Specimens were compressed in a 25 kN, closed-loop, servo-hydraulic testing machine (MTS Mini-Bionics, model 358.1, MTS Corporation, Eden Prairie, MN, USA) at a rate of 5 mm/s until fracture. This rate corresponds to a strain rate of 50% per second.

Diametral Tension Fatigue Life

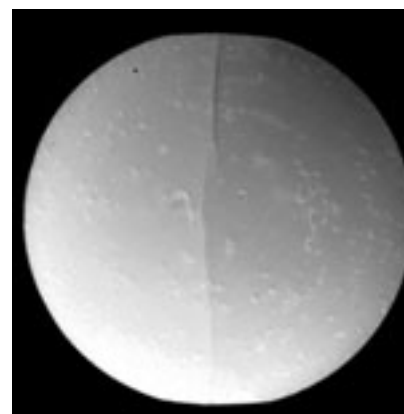
Diametral Tension Fatigue Life was measured on a minimum of ten test specimens per ASTM D3967 by modifying the loading profile. A sinusoidal fatigue load of -3.80 ± 0.02 kN was applied in compression to the test specimens at 3 Hz and R=10. This corresponds to peak DTS of 11.6 ± 0.3 MPa.



Creation of bone cement specimens through retro-filling.



Environmental Test Chamber

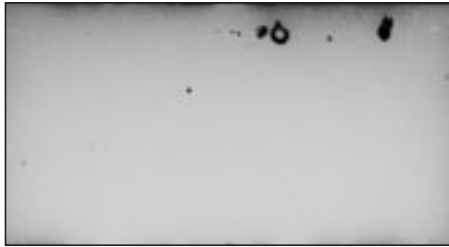


Classic Diametral Tension Fracture

RESULTS

Porosity

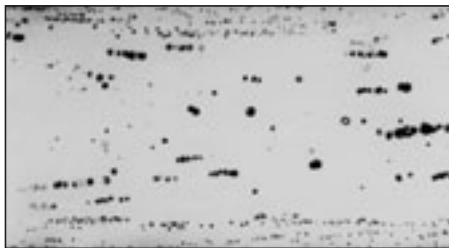
The images below represent the median specimen for each mixing methodology. All specimens demonstrated complete polymer powder incorporation and polymerization.



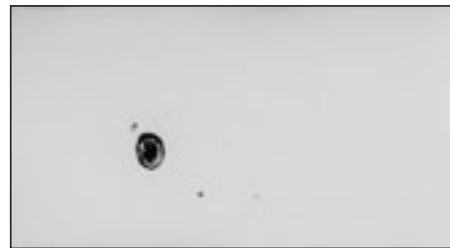
Cemvac®



Hand Mixed with Centrifugation (Control)



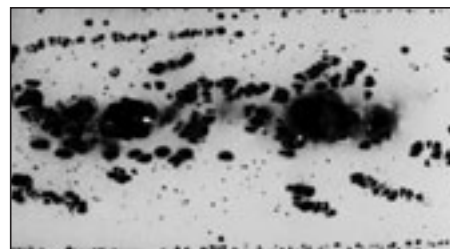
twistOR™



ACM®

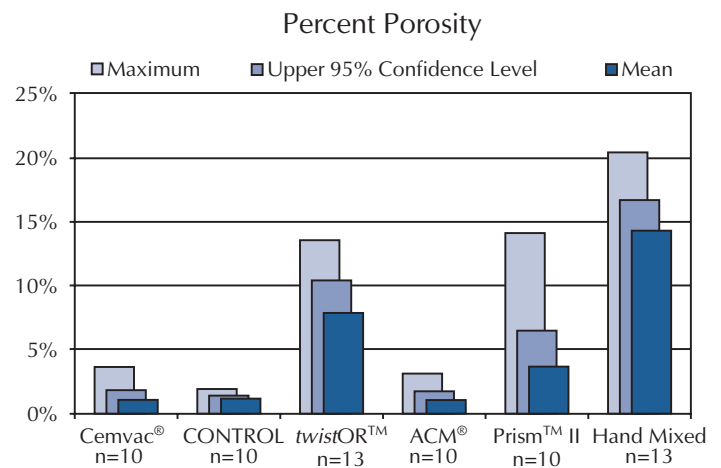


Prism™ II



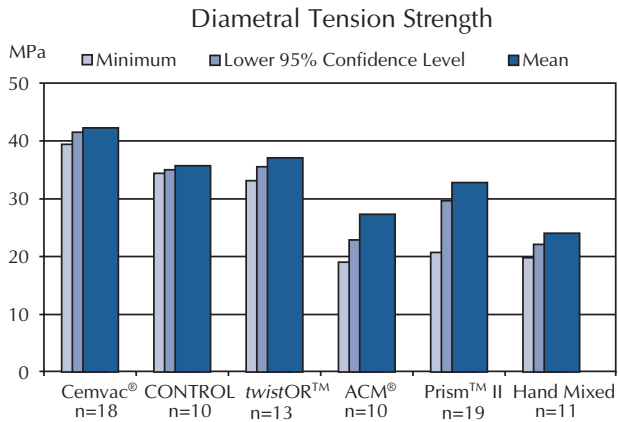
Hand Mixed

Percent Porosity of all mixing methods. Bars depict the mean porosity, the maximum porosity, and the upper 95% confidence interval. Systems are presented in order of their mean fatigue life demonstrating a general lack of correlation between fatigue life and percent porosity.

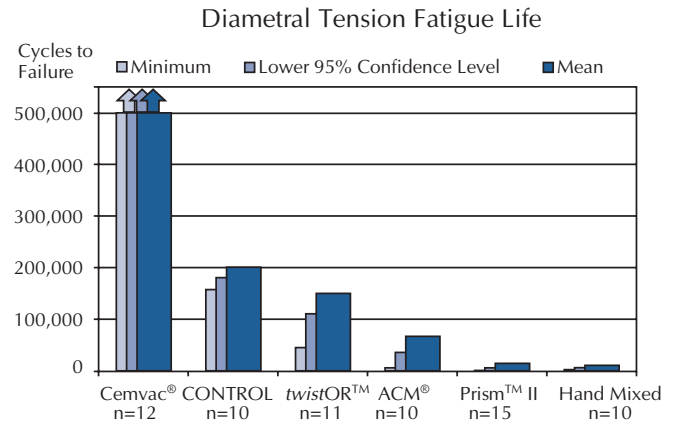


Diametral Tension Strength and Fatigue Life

All specimens fractured in classic DTS manner with the crack forming in a plane containing the long axis of the cylindrical specimens and the loading axis.



Ultimate Diametral Tension Strength of all mixing methods. Bars depict the mean strength, the weakest, and the lower 95% confidence interval. Systems are presented in order of their mean fatigue life demonstrating a general lack of correlation between fatigue life and diametral tension strength.



Fatigue Life in diametral tension of all mixing methods. Bars depict the mean life, the minimum life, and the lower 95% confidence interval. The arrows indicate that testing was stopped without fracture of the specimens.

DISCUSSION

Hand mixing produces the weakest bone cement in this study. Use of this technique should be discontinued in human joint replacement where strength is a concern. Common operating room techniques of shearing, folding, or kneading bone cement while in the dough phase are likely to further decrease its strength.

Cement that was hand mixed and then centrifuged produced the most repeatable specimens. Because centrifugation occurred after retro-filling this technique is not appropriate for the operating room. Centrifuged data is presented in this study only to permit a consistent laboratory control that can be easily repeated by other labs and for analysis of testing variability errors.

The Cemvac[®] system produced the strongest specimens with the greatest fatigue life; all specimens survived greater than 500,000 cycles.

CONCLUSION

Vacuum mixing is an important part of third-generation cement technique. All vacuum systems demonstrated techniques to reduce the exposure of the OR staff to methyl methacrylate monomer, contrary to hand mixing. The bone cement produced by these systems demonstrated significant differences in porosity, diametral tensile strength, and fatigue life with some designs strongly outperforming others. All were superior to open hand mixing. Additionally, neither porosity nor static strength is a consistent predictor of bone cement fatigue strength, as measured by rank order. With proper technique, vacuum mixing produces bone cement of vastly superior fatigue life and should displace open hand mixing as the standard of care in arthroplasty procedures to insure fixation longevity.