# THE INFLUENCE OF ANTIBIOTICS ON THE FATIGUE LIFE OF ACRYLIC BONE CEMENT: *ASSURING CLINICAL STRUCTURAL INTEGRITY*

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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.

In current practice, orthopaedic surgeons may choose to utilize antibiotics in bone cement for prophylaxis or treatment of a known infection. However, the antibiotics, bone cements and mixing methodologies employed lead to variability in the quality of the end product.[1-3,5]

During 2003, several orthopaedic manufacturers received Food and Drug Administration (FDA) 510[k] clearance for their pre-packaged antibiotic-loaded bone cement for use in the second stage of a two-stage revision situation where the initial infection has been cleared. This availability provides a more uniform cement mix with known mechanical and elution characteristics at the 0.5 to 1.0g level of antibiotic per 40g of polymer powder.

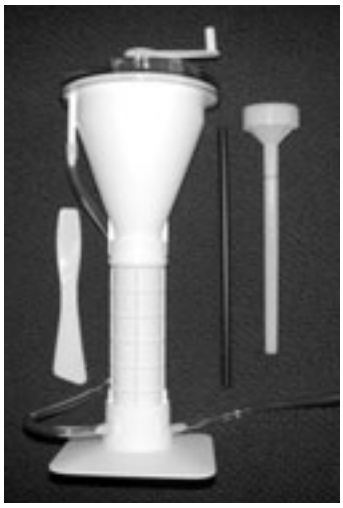
This study evaluates the influence of antibiotic inclusion on the porosity, strength and fatigue life of Surgical Simplex® P bone cement when employing both vacuum and hand mixing techniques.

## MATERIALS

Two surgical quality and commercially available surgical bone cements were evaluated: Surgical Simplex® P and Simplex™ P with Tobramycin (Stryker® Howmedica Osteonics, Mahwah, NJ, USA). Additionally, ten 1.2g doses of Tobramycin were acquired (Pharma-Tek, Huntington, NY, USA), which is the base quantity supplied to the operating theater.

The ACM® vacuum mixing system (Stryker® Howmedica Osteonics, Mahwah, NJ, USA) was utilized in these experiments.

ACM®



# METHODS

Vacuum mixing of the Surgical Simplex® P and Simplex™ P with Tobramycin bone cements was in precise compliance with the manufacturer's instructions. Further, to simulate a standard operating room procedure, 1.2g of crystalline Tobramycin was hand blended with 40g of Surgical Simplex® P powder and then vacuum mixed. For all cements 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 ± 0.5 lengths. 3) The cut faces were wet polished to a surface finish of ~7 µm with 600 grit silicon carbide abrasive paper. 4) Specimens were labeled and their length and diameter measured within ± 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*

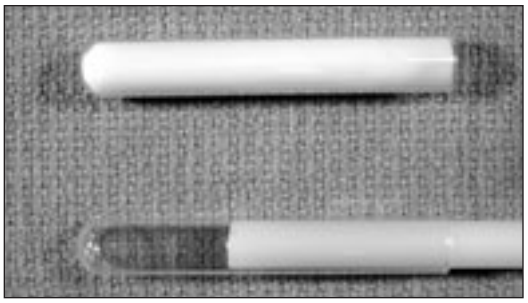
Surface porosity was calculated by optical analysis for a minimum of 10 dry test specimens sectioned into half cylinders with a diamond wire saw and wet polished. The sectioned surfaces were then stained with India ink and dry polished. The surface was digitally photographed and a functional accuracy was achieved to identify voids down to 0.001 $mm^2$. 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.

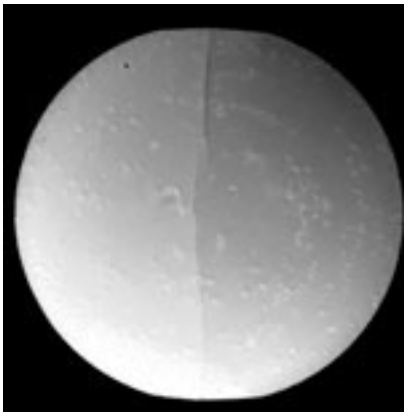
### *Diametral Tension Fatigue Life*

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*

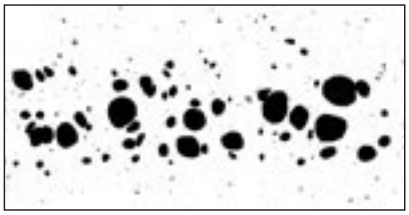
# RESULTS

## *Porosity*

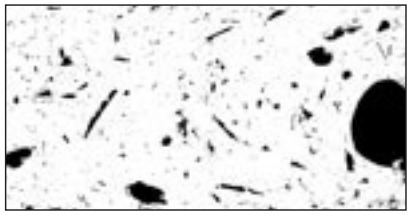
These images represent the median porosity specimen for each bone cement evaluated.

*Hand Mixed Surgical Simplex® P with Centrifugation (Control)*

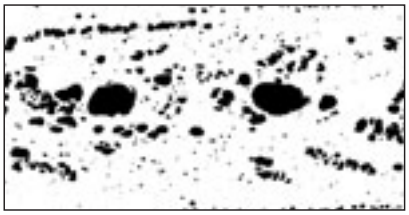
*Vacuum Mixed Surgical Simplex® P*



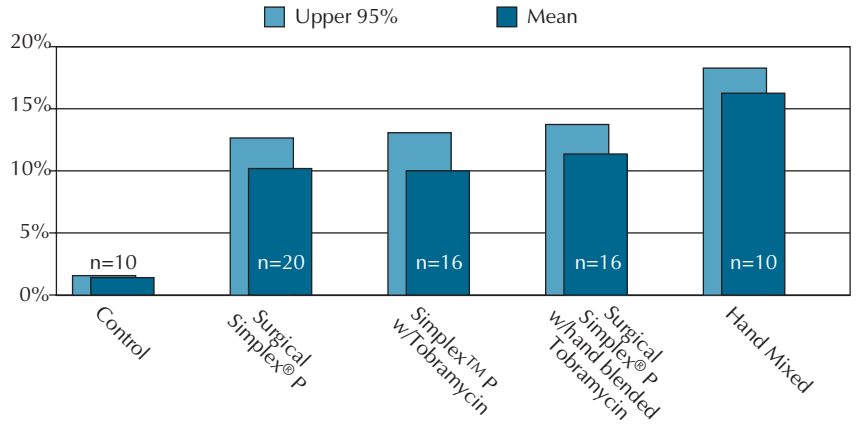
*Vacuum Mixed Simplex™ P with Tobramycin*



*Vacuum Mixed Surgical Simplex® P with hand blended Tobramycin*



*Hand Mixed Surgical Simplex® P*

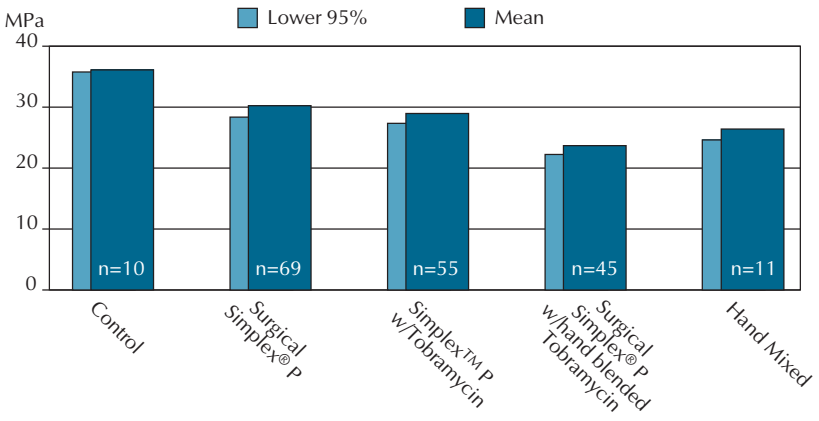



*Percent Porosity for each bone cement evaluated. Bars depict the mean porosity and the upper 95% confidence interval.*

## *Diametral Tension Strength*

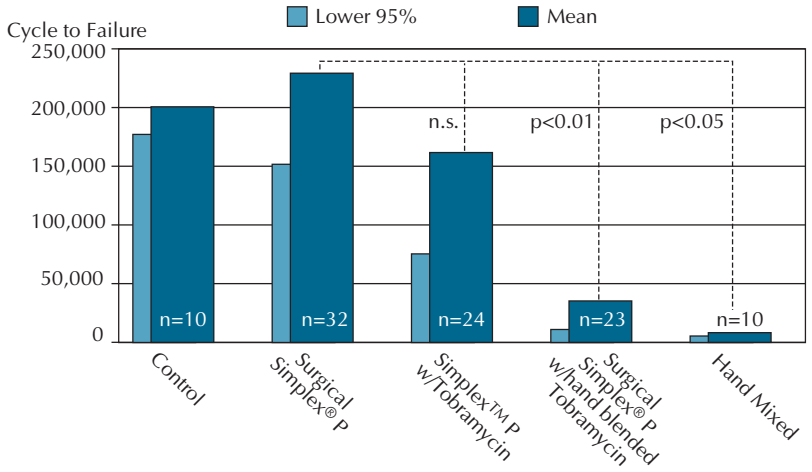
All specimens fractured in classic DTS manner with the crack forming in a plane containing the long axis of the cylindrical specimens and the loading axis.

*Ultimate Diametral Tension Strength for each bone cement evaluated. Bars depict the mean strength and the lower 95% confidence interval.*



### *Diametral Tension Fatigue Life*

*Fatigue Life in diametral tension for each bone cement evaluated. Bars depict the mean life and the lower 95% confidence interval.*




# DISCUSSION

For historical and comparative purposes, hand mixing and hand mixing with centrifugation (Control) of Surgical Simplex® P are included in the data presentation.[4]

Vacuum-mixed Surgical Simplex® P results in specimens with the greatest fatigue life, while hand-mixed Surgical Simplex® P produces the weakest cement ($p<0.05$). The pre-packaged antibiotic-loaded bone cement, Simplex™ P with Tobramycin, demonstrates a decrease in fatigue life from Surgical Simplex® P, but this is not statistically significant ($p>0.05$). However, the hand blending of 1.2g of Tobramycin crystals in the simulated operating room procedure results in a significantly weaker cement ($p<0.01$) than the latter, despite vacuum mixing.

With the recent FDA 510[k] clearance of several pre-packaged antibiotic bone cements, it is important to appreciate the influence of antibiotic inclusion on the mechanical characteristics of the bone cement, especially in fatigue. This study, although limited to one approved pre-packaged antibiotic bone cement, strongly suggests that antibiotic hand blending as well as open hand mixing at the time of surgery are practices that should be avoided. Additionally, a continual finding of these evaluations is that neither porosity nor static strength is a consistent predictor of bone cement fatigue life, as indicated by rank order.[4]

# EPILOGUE

- This laboratory study demonstrates that the vacuum mixing of Simplex™ P with Tobramycin is structurally superior to hand blending this antibiotic at the time of surgery with subsequent vacuum mixing.
- Further, it affirms that vacuum mixing using the ACM® system with Surgical Simplex® P produces cement of superior structural integrity when compared to hand mixing.
- It is recommended in the strongest terms that the practice of hand mixing should be abandoned in joint arthroplasty procedures.

# REFERENCES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2. Duncan CP, Masri BA: The role of antibiotic-loaded cement in the treatment of an infection after a hip replacement. Instr Course Lect 44:305-313, 1995.
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*4. Postak PD, Greenwald AS: Assuring cement fixation: All mixing systems are NOT the same. Proc Amer Acad Ortho Surg 4:656, 2003.

5. Sterling GJ, Crawford S, Potter JH, Koerbin G, Crawford R: The pharmacokinetics of Simplex-tobramycin bone cement. J Bone Joint Surg 85-B:646-649, 2003.




*Papers available via the Orthopaedic Research Laboratories website: http://orl-inc.com