Radius Fracture Repair Using Volumetrically Expanding Polyurethane Bone Cement

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Purpose New repair techniques for fragility fractures such as those of the distal radius require biomechanical justification. This study was conducted to investigate a technique using an expanding polymer bone cement to provide strength to a fracture repair.

Methods Distal and proximal ends were isolated from 6 pairs of human radii (mean age 65). Transverse osteotomies were made near the head of each specimen. Paired specimens were repaired using 2 materials of differing polymer chemistries: polyurethane versus polymethylmethacrylate. Repaired specimens were subjected to failure tests in a cantilever beam configuration (distal, n = 6 per treatment) or pure tension (proximal, n = 5 per treatment). Cement penetration tests were conducted using a uniform open-cell model of cancellous bone. Baseline mechanical properties of the polyurethane cement were determined according to ASTM standards.

Results Distal radii repaired with polyurethane bone cement withstood average shear stress 2.9 times as high as polymethylmethacrylate (0.91 vs 0.31 MPa). Peak tensile bending stress was 2.5 times as high in polyurethane (2.57 vs 1.02 MPa). Under pure tension, polyurethane-repaired samples failed at 0.83 MPa versus 0.74 MPa for polymethylmethacrylate. The polyurethane cement expanded to penetrate 49% farther into the trabeculae. The polyurethane cement had mean compressive yield stress of 20.3 MPa, compressive modulus of 754 MPa, ultimate tensile stress of 18.5 MPa, and tensile elastic modulus of 723 MPa.

Conclusions The biomechanical strength data indicate the potential of an expanding bone cement as a candidate strategy for fracture repair. Further evaluation might provide evidence for such an alternative repair strategy for fragility fractures, including those of the distal radius.

Clinical relevance An approach that couples the benefits of closed reduction and internal fixation might prove an attractive paradigm for treatment of distal radius fractures. *(J Hand Surg 2011;36A:1294–1302. Copyright © 2011 by the American Society for Surgery of the Hand. All rights reserved.)*

Keywords Biomechanics, bone cement, fixation, fracture repair, radius.

OSTEOPOROSIS, A DISEASE characterized by imbalanced bone metabolism, resulting in decreased bone mass and strength, is a major public health threat for an estimated 44 million Americans.[1] Among the most severe consequences are fragility fractures and the resulting complications, particularly in the elderly. In the population above age 50, 1 in 2 women and 1 in 4 men will have an osteoporosis-related frac-

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ture in their lifetime.[1] Such injury to the distal radius is the most common upper extremity fracture[2] in individuals over age 65.

Age-related and disease-related changes in bone structure and physiology complicate fracture management. Displacement is more common, and efficacies of some fracture repair techniques decrease relative to younger healthy patients.[3–5] Displaced distal radius fractures typically are repaired by closed reduction and casting or open reduction with internal plate fixation, although this treatment dichotomy can be inadequate for certain elderly patients. Re-displacement rates after closed reduction with splinting[6] approach 50%. Such a clinical failure might require a second closed reduction procedure because open surgery is often left as a last option for the patient. Risks associated with surgical procedures (in general) increase with age and in the face of underlying medical conditions.[7] This conservative approach can result in unions that are functionally adequate; however, deformity remains a common cosmetically undesirable result.[8] Thus, an alternative fixation method that includes the virtues of both closed and open techniques might provide patients and surgeons with a desirable option that could benefit a large percentage of patients.

Alternative approaches to conventional fixation methods have been proposed, including using bone cements and void fillers as a means for providing immediate stabilization and rapid functional recovery, although no approach has gained widespread clinical traction. Polymethylmethacrylate (PMMA) cements have a history of use in a number of procedures in which a grout with high strength is required, such as a filler between metallic implants and bone. Likewise, traditional bone cement has been used to stabilize fragility fractures, such as vertebral body compression fractures[9]; used in osteoporotic patients to reinforce screw purchase[9]; and investigated, for example, as an experimental technique to prevent proximal femoral fractures.[10] Polymethylmethacrylate has also been investigated to stabilize osteoporosis-related fractures of the radius by seeking to leverage the mechanical properties of the cement. Excellent functional and cosmetic results, along with gradual cortical bridging, have been documented[11,12]; however, limitations of the cement and the technique have restricted clinical acceptance.

Although it is widely used, PMMA has potentially fatal health and safety issues, including embolism[13,14] and hypotension[15] related to both the high temperatures developed during curing and the impact of residual monomer levels. Moreover, PMMA volumetrically contracts during curing, increasing the likelihood for gap formation at the interface of cement to trabecular bone.[16] Similarly, a severe material property mismatch between cancellous bone (modulus generally in the 50–500 MPa range[17]) and rigid PMMA (modulus of approximately 2500–3000 MPa[18]) increases the potential for stress shielding, bone resorption, and fracture at the cement–bone interface. Polymethylmethacrylate fails to integrate with host bone, lacking the porosity requisite for bone ingrowth into the material. Calcium phosphate (CaP) cements have been proposed and tested as an alternative, although clinical failures have limited their acceptance. Intended to provide immediate stability with temporal resorption allowing for replacement with new bone, CaP cements failed clinically in mechanically demanding applications such as distal radius repair without hardware fixation. The cements were inadequate to endure the complex loads at the fracture sites,[19] and the inability to maintain reduction[20,21] relative to other techniques has limited CaP use for fixation and has necessitated complementary hardware fixation.

Addressing several limitations of PMMA and CaP cements, a new class of polyurethane bone cements (PBC) has been introduced. Kryptonite bone cement (Doctors Research Group, Inc., Southbury, CT), the PBC selected for this biomechanical investigational study, is currently indicated for use in the United States as a resinous material for repair of cranial defects, although the unique properties warrant investigation into other potential uses. This alternative material is made of castor oil–derived polyols reacted with diisocyanate and mixed with powdered calcium carbonate. It cures exothermically, with temperatures reaching just slightly in excess of body temperature; possesses an inherent porosity in its final form that has been shown to permit bone ingrowth[22]; and, through a volumetric expansion during cure, demonstrates a potential for enhanced integration with the native cancellous bone, possibly increasing fixation strength and stability. Using PBC has shown early clinical and biomechanical success in the fixation of separated cancellous bone after median sternotomy,[23] suggesting adequate mechanical integrity to bear loads, although the application of this approach to (often similarly cancellous) osteoporosis-related fractures of the distal radius has not been examined. By addressing the factors that have limited the utility of existing cements for fracture repair, the PBC class of materials might provide a viable option to surgeons and patients. The objective of the current study was to investigate the feasibility of a PBC to provide biomechanical strength in fracture fixation in