Reducing the Risk of Bone Cement Implantation Syndrome During Femoral Arthroplasty

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abstract

Patients with pathologic hip fractures or impending pathologic proximal femur fractures are at a high risk for developing bone cement implantation syndrome during cemented femoral arthroplasty. Comorbid conditions of patients who sustain these fractures, including cardiopulmonary compromise and permeable, highly vascular bone related to metastatic disease, put them at risk for sudden death. Reducing intraoperative intramedullary pressure, a modifiable intraoperative intervention, may decrease this risk. The goals of this study were to determine the pressure generated by low- and high-viscosity cement during femoral implantation and the pullout strength of the bone-cement-implant interface.

Ten pairs of cadaveric femurs were divided into 2 groups: those receiving low-viscosity cement and those receiving high-viscosity cement during femoral arthroplasty. Pressure was recorded with sensors implanted in the lateral femoral cortex at proximal, middle, and distal implant positions in both groups during cement insertion and prosthesis implantation. Each construct underwent pullout failure testing after thorough cement curing. Significantly higher pressures were generated with high-viscosity cement for implant fixation, whereas the pullout force to failure was similar between groups.

Low-viscosity cementation may be used to reduce the risk of bone cement implantation syndrome in high-risk patients with pathologic hip fractures or impending pathologic proximal femur fractures. The proposed mechanism of risk reduction is through lower intramedullary pressure with no bone-cement-implant interface pullout strength reduction. Further clinical trials are needed to prove this biomechanical effect.

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Cemented hip hemiarthroplasty is the most common procedure performed for proximal femoral pathologic hip fractures and impending pathologic fractures. The comorbid condition of patients sustaining these fractures, including cardiopulmonary compromise and permeable, highly vascular bone related to metastatic disease, puts them at risk for sudden death secondary to bone cement implantation syndrome during femoral implant cementation. Bone cement implantation syndrome comprises systemic hypotension, hypoxemia, pulmonary hypertension, cardiac arrhythmias, and cardiac arrest. It is rare in patients presenting for routine total hip arthroplasty (THA),\(^1\) but can lead to mortality rates as high as 4.3% in patients with pathologic bone related to metastatic disease.\(^2\) Patients with metastatic disease are at the highest risk for bone cement implantation syndrome. Risk factors include metastatic disease, older age, osteoporotic bone, and increased cementation pressure.\(^3\)

Cementation pressure is a modifiable intraoperative risk factor. High-pressure cementation techniques have increased implant longevity but also increase the risk of marrow extrusion.\(^4\)\(^5\) Patients with metastatic disease are at the highest risk for bone cement implantation syndrome and may not require a cement technique that requires high pressure to increase implant longevity because they have a shortened life expectancy. These patients are also more likely to have osteoporotic bone. Osteoporotic bone has had a better bone-cement interface than nonosteoporotic bone.\(^6\)\(^7\) The current hypothesis was that using cement in its low-viscosity state early after mixing would decrease intramedullary pressure during cementation and femoral implantation without compromising the pullout strength of the bone-cement-implant interface when compared with the routine cementation technique.

**Materials and Methods**

**Preparation**

Ten matched pairs of fresh cadaveric femurs (provided by the Musculoskeletal Transplant Foundation, Edison, New Jersey) were prepared for femoral arthroplasty. All femurs were cleaned of soft tissue and a femoral head resection was performed with a 15-mm neck cut. The femurs were then reamed and broached, and the canals were cleaned to accept a femoral prosthesis (Answer Hip stem; Biomet, Warsaw, Indiana). A commercially prepared distal restrictor (Biomet) was placed in the canal 2 cm below the stem tip. Three 5-mm holes were drilled and tapped in the lateral femoral cortex to allow the insertion of 3 pressure transducers (Model 147-500 psi, 5-mm thread; Precision Measurement Company, Ann Arbor, Michigan). The placement of pressure transducers remained constant by using a template femoral prosthesis marked at the proximal, middle, and distal stem. Epoxy was applied to the transducer threads to maximize bonding between the thread-bone interface and the transducers were inserted at a depth flush to the broached canal. The prepared femur was then placed vertically in a tree mount and secured to the authors’ standard Instron mount testing platform (Instron, Norwood, Massachusetts).

**Cementation**

One femur from each pair was assigned to the low- or high-viscosity group, and the contralateral femur received the alternate technique. The same cement (Biomet Cobalt MV Cement; Biomet) was used for both techniques, after being mixed in a temperature-controlled lab at 66°F. A low-viscosity state was defined as having been mixed for 30 seconds and implanted 2 minutes later, whereas a high-viscosity state was defined as having been mixed for 30 seconds and implanted 4 minutes later. At implantation, the low-viscosity cement was in a liquefied state, and the high-viscosity cement had a doughy consistency. The cement was mixed under standardized conditions; it was loaded into the cement gun and inserted retrograde into the femoral canal. Femoral components were placed in the femur using 2 methods: the low-viscosity cement was placed by hand, whereas the high-viscosity cement was placed using light mallet blows. Pressure readings were recorded at 2 intervals: cement placement during retrograde filling and at femoral component insertion.

**Pullout Testing**

After the cement cured overnight in a controlled environment set to 66°F, the femurs underwent pullout testing. The femoral component was secured to the Instron Universal Testing Machine arm and an increasing axial pullout force of 1 kN/s was placed on the construct until component failure occurred, which was defined as implant pullout or femur fracture. Force and direction were measured throughout the testing (Figure 1).

**Data Analysis**

Because the data represented paired specimens with either low- or high-viscosity cement assigned to a given side, viscosity comparisons were made using a paired \(t\) test. To account for 3 comparisons of insertion force at 3 positions along the specimen, the \(P\) values from the paired \(t\) tests were adjusted for multiple comparisons using the Hochberg multiple comparison procedure.

To compare the 3 positions along the same specimen, a likelihood ratio test from mixed effects linear regression was used. This approach provided a within-specimen comparison among the means of the 3 repeated measurements (3 positions), analogous to extending the paired \(t\) test to the 3 repeated measurements.

**Results**

**Pressure Results**

In the low-viscosity group, the pressure created by injecting cement into
the canal was negligible, whereas the high-viscosity group had consistent pressure readings across all specimens, with pressure reading values averaging 20±9 psi (P=.001). Average pressure readings in the low-viscosity group during prosthesis implantation were 4±1 psi (95% CI, 2-6 psi), 7±1 psi (95% CI, 5-9 psi), and 9±1 psi (95% CI, 7-10 psi) at the proximal, middle, and distal positions, respectively. In the high-viscosity group, the average values were 70±12 psi (95% CI, 42-98 psi), 108±19 psi (95% CI, 65-152 psi), and 155±23 psi (95% CI, 101-209 psi) at the proximal, middle, and distal positions, respectively. Pressures were significantly higher for the high-viscosity group compared with the low-viscosity group for all 3 positions (P=.001) (Figure 2).

Average force of each hammer blow used to implant the femoral prosthesis in the high-viscosity group was 2.4±0.2 kN (95% CI, 2-2.8 kN), as measured by load cells mounted on the Instron Universal Testing machine. This was not measured in the low-viscosity group because the implants were placed by hand.

**Pullout Results**

Nine specimens in each group failed at the bone-cement-implant interface. The remaining specimen in each group failed due to fracture at the cortical rim. The 2 fracture specimens were not a matched pair. Average pullout force required to cause femoral implant failure was 7.8±1.5 kN (95% CI, 4.2-11.4 kN) in the low-viscosity group compared with 9.7±1 kN (95% CI, 7.3-12.1 kN) in the high-viscosity group. This difference was not statistically significant (P=.29) (Figure 3).

**Discussion**

Intraoperative death related to cemented femoral arthroplasty is a well-described complication, with an incidence as high as 4.3% in patients with pathologic proximal femur fractures. Medical comorbidities and pathologic bone in patients with a pathologic hip fracture or impending pathologic proximal femur fracture increase the likelihood of cardiopulmonary collapse. Bone cement implantation syndrome accounts for the majority of intraoperative deaths and is characterized by systemic hypotension, hypoxemia, pulmonary hypertension, cardiac arrhythmias, or cardiac arrest around the time of cementation, prosthesis insertion, or joint reduction. Decreased cardiac contractility and tone, cardiopulmonary embolic showers, and clotting cascade activation in the lungs are pathologic findings of bone cement implantation syndrome, and the causes are multifactorial, related to cement monomer, increased intramedullary pressure, and increased bone porosity in these patients. The goals of advanced cement techniques are to increase cement penetration and quality; however, concerns exist as to the relative benefit of pressurized cementation practices in high-risk patients with pathologic fractures or impending pathologic proximal femur fractures. To reduce high-pressure–related morbidity, cementation techniques, such as low-viscosity cementation, vacuum venting, drill-hole venting, and canal lavage, have been reported.

Multiple studies have shown a correlation between embolic showers and high intramedullary pressures. Parvizi et al.
al\textsuperscript{2} reported increased sudden death rates secondary to cardiopulmonary collapse in patients treated with cemented THA compared with cementless THA. Postmortem examinations found pulmonary emboli in 11 of 13 patients. During the study, mortality decreased and was attributed to technique improvements, including canal lavage, venting, and reduced use of distal restrictors.\textsuperscript{2} Pitto et al\textsuperscript{6} reported echocardiographic and cardiopulmonary parameter changes in patients undergoing cemented THA with and without the use of a bone-vacuum technique to reduce intramedullary pressure. Significantly more emboli and increased signs of cardiopulmonary compromise were found in the standard cement technique group.\textsuperscript{6} These 2 studies show the usefulness of decreasing intramedullary pressures during femoral arthroplasty cementation by correlating cardiovascular compromise and high intramedullary pressures.\textsuperscript{2,6}

One study reported the effect of bone porosity on fracture strength, which can be used as a correlate with implant fixation strength. Graham et al\textsuperscript{7} reported the mechanical integrity of the bone-cement interface in a bovine model of varying bone porosity. After cementation, the models were subjected to bending forces until fracture occurred. Increasingly porous (more osteoporotic) bone showed greater fracture resistance. The authors reported that strength in bending force improved with greater cement penetration into the porous bone.\textsuperscript{7} This may explain why low-viscosity cement had similar pullout strength as the high-viscosity cement in the current study.

The effect of cement viscosity on cement penetration has been evaluated in multiple studies. Rey et al\textsuperscript{18} reported cement penetration depth in bone with low-viscosity cement and 2 commercially available high-viscosity cements. The intrusion of the 3 cement preparations was evaluated at 20, 40, and 60 psi of intramedullary pressure. The low-viscosity cement had 8 mm of penetration into bone at 20 psi. The penetration depth of the low-viscosity cement was higher than the other preparations at any insertion pressure.\textsuperscript{18} Reading et al\textsuperscript{19} reported cement penetration depth and resultant shear strength of low- and normal-viscosity cement on a femoral arthroplasty model. Low-viscosity cement showed greater penetration depth and greater shear strength than normal-viscosity cement at the proximal femur.\textsuperscript{19} McWilliams et al\textsuperscript{20} reported using timing of femoral implant insertion as a correlate of cement viscosity to show that early (low-viscosity cement) implantation had increased cement penetration depth compared with late (high-viscosity) cementation. All studies\textsuperscript{18-20} reported increased cement penetration depth with low-viscosity cement regardless of testing mode.

Clinical judgment must be used to select the appropriate arthroplasty fixation based on patient profile (ie, bone porosity, medical morbidity/risk of bone cement implantation syndrome, and expected longevity). In the current study, the pressure created in the intramedullary canal was significantly ($P = .001$) lower when using low-viscosity cement and hand insertion of the femoral component. This technique may decrease the risk of bone cement implantation syndrome and mortality in femoral arthroplasty in a high-risk group. The pullout force needed was not significantly different between the 2 techniques ($P = .29$); therefore, using low-viscosity cement may provide adequate fixation of the femoral component in the patients with metastatic disease.

Weaknesses of this study were its inability to correlate laboratory results with actual bone cement implantation syndrome risks, failure to test further clinical methods of implant failure, lack of quantification of cement penetration in the cadaver specimen, and a lack of data regarding bone porosity in the cadaver specimens. The multiple suspected causes of bone cement implantation syndrome make it difficult to correlate specific laboratory findings with the risk of bone cement implantation syndrome. This study controlled the variables of cement viscosity and intramedullary pressure, which can be managed in the operating room. The pullout testing protocol used in the current study cannot account for the biologic stress response and micromotion fatigue failure. Fatigue testing with bone-cement-implant sectioning to assess for cement mantle failures may have given a better estimation of in vivo longevity between the 2 groups.

Figure 3: Pullout force to failure in the low and high-viscosity groups.

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<tr>
<th>Force (kN)</th>
<th>Low Viscosity</th>
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| $P$-value | .29 |

$P$-value indicates the statistical significance of the difference in pullout force between the low- and high-viscosity groups.
The original clinical report on the low-viscosity technique used in patients with metastatic disease showed a poor survivorship of patients secondary to their metastatic disease, with 10 of 27 patients surviving at final follow-up. Implant failure was not reported at a mean final follow-up of 1.9 years. Given the comorbidities of the patient group, using this technique for long-term implant longevity may not be as important as reducing the risk of bone cement implantation syndrome. Cement penetration with varying cement viscosities has been reported in the literature; however, quantifying the cement penetration of the 2 groups was not the goal of this study, but assessing cement penetration may have clarified why the pullout failure force was insignificant between the 2 groups. Lastly, although bone density scanning may have defined bone porosity in the current specimen, using matched pairs helped mitigate this variable.

**Conclusion**

This in vitro study demonstrated that using low-viscosity cement decreased the intramedullary insertion pressure of a femoral implant, which may reduce the risk of bone cement implantation syndrome. In addition, the current results showed that pullout strengths were not significantly different when using high- or low-viscosity cement. The use of low-viscosity cement for femoral arthroplasty should be considered in patients with metastatic disease with pathologic hip fracture or impending pathologic fracture of the proximal femur who are at higher risk of bone cement implantation syndrome.

**References**