Effect of Simulated Early Weight Bearing on Micromotion and Pullout Strength of Uncemented Distal Femoral Stems

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abstract

The effect of simulated early weight bearing on both micromotion and pullout strength of uncemented distal femoral stems was evaluated in this study. The effect of stem endosteal contact and bone quality on implant pullout strength was also analyzed. A randomized matched-pair study was performed using 8 bilateral pairs of fresh human cadaveric femoral specimens. Each specimen pair was dual-energy x-ray absorptiometry scanned, uniformly implanted, fluoroscopically imaged, and randomly assigned to the cycled or uncycled group. The cycled group received 5000 cycles of axial compressive loading (to 700 N) and the contralateral side was not cycled. Micromotion was monitored during cycling and compared with a failure threshold (150 μm), and all implants underwent direct axial distraction (pullout) testing. During cycling, minimal micromotion was observed with an asymptotic decrease in differential motion between the first and last 50 cycles. Both cycled and uncycled groups demonstrated no statistical difference in average pullout force (4888±2124 N vs 4367±1154 N; \( P = .43 \)). The percentage of cortical contact for each implant was determined from panoramic fluoroscopy images using digital image analysis software. Contact area for the distal third of the stem showed the highest correlation with pullout force and with predicting pullout force. Bone quality did not correlate with pullout force (\( r^2 = 0.367 \)) or stem contact area (\( r^2 = 0.394 \)). In sum, press-fit uncemented femoral stems did not loosen or demonstrate decreased pullout strength with early weight bearing simulated by cyclical axial compressive loading. [Orthopedics. 2015; 38(5):e417-e422.]

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Primary osseous sarcomas typically occur in a relatively young population, with a primary peak incidence during adolescence. Ewing’s sarcoma and osteosarcoma are commonly found in the distal femur and proximal tibia, where approximately two-thirds of lower-extremity tumors occur. Many patients are surgical candidates for limb salvage, where efforts focus on the re-creation of a functional limb and planning for a life expectancy that exceeds average implant survival. Allograft and modular oncologic implant reconstructions are both viable options, but implant reconstruction is commonly preferred for osteoarticular resections. This reconstruction method, along with patient age and improved survival rates that range from 65% to 75% at 5 years, places an increasing importance on implant longevity.

Oncologic total knee arthroplasty (TKA) has traditionally relied on cement for immediate stem fixation; however, results have been less than ideal. Cemented implant failure rates have previously been reported to be 16% at 2 years, 27% at 5 years, and 41% at 10 years, with aseptic loosening being the most common mode of failure. Surgical revision is possible to correct fixation and other mechanical failures; however, each surgery is associated with increased difficulty and risk of infection, prompting movement toward a more durable construct.

The press-fit stem was introduced as a durable alternative to the traditional cemented stem. Although aseptic loosening may occur with uncemented press-fit stems, osseointegration commonly develops between implant and host bone under adequate conditions, namely primary stability and minimal micromotion (<150 μm). However, excessive micromotion will occur if the implant is initially unstable, resulting in the formation of fibrous tissue between stem and host bone. Anchoring the distal femoral stem in diaphyseal bone and obtaining an adequate press-fit maximizes endosteal contact and, ideally, implant stability and bony ingrowth. The total hip arthroplasty literature shows ingrowth fixation occurred in 93% of patients in which a press-fit of the stem at the bony isthmus was obtained, compared with 69% of those patients without press-fit (fibrous ingrowth accounted for remaining specimens).

Biomechanical studies have confirmed rotational stresses as one of the primary causes of press-fit stem instability. The rotating surface with hinged-knee designs in current megaprostheses attempts to account for these high stresses. Traditionally, limb salvage patients at the current authors’ institution are protected from immediate postoperative weight bearing, with the idea that osseous integration into the implant’s porous surface will occur prior to advanced weight-bearing status, decreasing the exposure of the knee to high stress. Immediate weight bearing on an oncologic TKA remains controversial.

A previous study by the authors tested the torsional stability of 3 different uncemented distal femoral components using the Stryker Global Modular Replacement System (GMRS), specifically the short cloverleaf, short curved, and long curved stems (Stryker Corp, Kalamazoo, Michigan). Of the 3 implant designs, the short cloverleaf stem was found to have superior stability in resisting axial torsion moments in the transverse plane.

The purpose of the current study was to determine the effect of simulated early weight bearing on micromotion and fixation strength of uncemented distal femoral stems. The effect of stem endosteal contact and bone quality on implant fixation strength was also analyzed. Micromotion was evaluated using cyclical compressive loading of the stem to simulate axial weight-bearing forces, and axial pullout was used to examine fixation strength. Although torsional failure has traditionally been used to evaluate implant stability, axial distraction examines another load that occurs during gait (from gravitational and inertial axial forces) against which the implant must maintain primary stability.

The authors hypothesized the following: (1) obtaining a tight isthmic press-fit prevents early failure of distal femoral implants, and stem press-fit is determined by the endosteal contact with the implant at the proximal third of the implant (near the stem collar); (2) immediate weight bearing (simulated by cyclic axial compression) results in axial instability and thereby early (pullout) failure of distal femoral implants; and (3) decreased bone density correlates with early implant (pullout) failure.

**Materials and Methods**

Specimens

Eight matched pairs of fresh (unembalmed) human cadaveric whole femoral specimens were obtained and stored frozen at -20°C until ready for implantation and testing. Average age of the study specimens was 58.6±7.7 years; 5 specimens were from males and 2 were from females (1 study specimen did not have demographic information available). Whole-femur dual-energy x-ray absorptiometry (DEXA) scans were performed to assess the bone quality of all specimens.

Before testing, each femur was thawed in a room temperature water bath, and all extraneous muscle tissues were sharply dissected. A 13-cm distal femoral osteotomy, measured from the medial femoral condyle, was performed to accommodate the implant. A second osteotomy 18 cm proximal to the distal osteotomy site was made to produce the final testing specimen.

Each study specimen was implanted by the same orthopedic surgeon (J.S.B.). Using the Stryker GMRS system, each pair of femoral specimens was reamed to the same diameter of chosen implant size or, depending on implant “fit,” oversized by 0.5 mm. Stem selection consisted of Stryker GMRS short straight fluted designs 11 to 15 mm in diameter. All attempts were made to achieve the tightest press-fit possible by reducing the
variation of underreaming vs line-to-line reaming. The end-facing reamer was used to obtain a flush fit with the implant collar, and the stem was placed according to the Stryker implantation manual. Care was taken to ensure that both sides of each matched pair received the same size of implant guided by endosteal fit.

Following implantation, each specimen was potted to facilitate biomechanical testing. Within the proximal 6 cm of bone, two 70-mm wood screws were placed bicortically and perpendicular to each other to enhance potting strength. Each specimen’s proximal end was potted in bone cement (polymethylmethacrylate) using a 63.5-mm-diameter × 38-mm-long PVC tube as a potting mold (Figure 1).

Experimental Protocol

Prior to testing, each implant underwent fluoroscopic imaging to document bone-stem contact area. Panoramic fluoroscopy images were obtained for each implant at 15° increments, providing 12 images per specimen (Figure 2).

The 8 pairs of femurs were randomly assigned to either the cycled (treatment) or uncycled (control) group, with the cycled group receiving a 700 N axial compressive load applied at 1 Hz for 5000 cycles to simulate 1 week of early postoperative full weight bearing of a 71-kg adult. This level of activity (ie, 5000 steps per week) was established based on data collected from postoperative limb salvage patients at the authors’ institution. During cycling, a linear variable differential transformer (LVDT) (model 500 DC-D; Schaevitz, Pennsauken, New Jersey) was used to monitor micromotion between the stem and the femur (Figure 3). The resolution of the LVDT was found to be 5 µm when sampled with a 16-bit data acquisition board (model 6033E; National Instruments, Austin, Texas).

Cyclical and pullout testing were performed on an MTS servohydraulic test system (model 318.10S; MTS Corp, Eden Prairie, Minnesota), with a load cell (model 4526; Robert A. Denton, Inc, Rochester Hills, Michigan) used to measure the applied axial forces. The treatment group was cycled for 5000 cycles immediately before pullout testing. All implants underwent direct axial distraction (pullout) testing at 0.5 mm/s while recording the load and LVDT displacement at 100 Hz.

Data Analysis

After testing, the peak micromotion observed during cyclical loading (for the cycled group), the peak pullout force during axial distraction, and the measured force recorded at 150 µm of micromotion were determined for each specimen. One hundred fifty microns was chosen as a micromotion endpoint because it has been shown to be an accepted threshold known to cause fibrous ingrowth instead of osseous ingrowth.

Statistical comparisons between the cycled and uncycled group results were made using paired t tests, with a P value less than .05 representing significance.

Image Analysis

The percent of cortical contact for each implant was determined from the panoramic fluoroscopy images using ImageJ digital image analysis software (National Institutes of Health, Bethesda, Maryland). To ensure consistency in the analysis, a protocol was established to normalize the image intensity of all images by adjusting the brightness/contrast to achieve the same background grayscale level (30:255). Once this adjustment was
applied to all 12 images acquired for each specimen, the total edge length of the implant in contact with the bone was then computed on each image using the same threshold grayscale value (10:255) to ensure sample consistency. Only contiguous contact areas greater than 1% of the overall stem length (3 pixels or more) were included in the summed contact length for each slice, eliminating random image artifacts (Figure 4). This protocol was repeated for every specimen. In an effort to determine whether a particular zone was more influential in estimating the pullout force of the uncemented distal femoral stem, each stem edge was subsequently divided into 3 zones: proximal, middle, and distal.

RESULTS

For the treatment group that received 5000 cycles of simulated weight bearing before pullout, insignificant levels of differential micromotion (loading and unloading between 0 and 700 N) were found. Differential micromotion was highest for the first 50 cycles (average, 39.5±10.6 µm) and asymptotically decreased to an average of 30.1±7.3 µm at the end of 5000 cycles (Figure 5).

When comparing the peak pullout forces between the groups, average pullout force was 4888±2124 N in the cycled group and 4367±1154 N in the uncycled group (Figure 6). There was no significant difference between treatment and control groups (P=.43). Pullout failure was established based on the peak axial distraction force. The peak distraction force occurred simultaneously with the micromotion failure threshold (150 µm) in 6 of 8 cycled implants. Two cycled implants marginally exceeded the micromotion threshold prior to reaching the maximum distraction force and failed at 154 µm (6842 N) and 181 µm (3111 N) of micromotion. At the micromotion threshold (150 µm), these 2 implants already achieved 99.98% (6841 of 6842) and 96.88% (3014 of 3111) of their peak pullout forces. Hence, the pullout occurred nearly simultaneously with reaching the micromotion threshold.

Because little micromotion was observed during cycling, both groups were combined to examine the relationship between pullout force and surface contact area. Pullout force moderately correlated with overall contact area (r²=0.584) (Figure 7). When breaking the stem area into thirds, the contact area for the distal third of the stem (farthest away from the collar) had the highest correlation with pullout force (r²=0.586) and was equally effective in predicting pullout force as the total contact area. The contact area for the proximal stem (nearest the stem collar) displayed the weakest correlation with pullout force (r²=0.475) of the 3 regions.

Finally, the average of only the antero-posterior and lateral fluoroscopic images (2 slices) gave a good estimate of the total contact area when compared with the 12-slice analysis (Figure 8).

When examining the effect of bone mineral density, the DEXA scores did not correlate with either pullout force (r²=0.367) or stem contact area (r²=0.394).
Nevertheless, it appears that comparison of anteroposterior (AP)/r 0.584) and equal pullout force compared with the uncycled group; and (3) bone density did not correlate with pullout force. Based on these data, all 3 hypotheses were rejected.

The overall contact area was not strongly correlated with implant pullout force ($r^2=0.584$). When examining the proximal, middle, and distal thirds, none were strong predictors of pullout force. Of these 3 regions, the proximal third was the weakest predictor and the distal third was the strongest predictor of pullout force. Although implant contact area was not strongly correlated with pullout force, it remains possible that contact area could be a predictor of torsional stability (not tested in this study).

The second hypothesis of this study was that, for uncemented implants, simulated weight bearing would loosen the implant, thus demonstrating increased micromotion and a lower pullout force. This was not the case. Minimal micromotion occurred during cycling, with an asymptotic decrease in differential motion between the first and last 50 cycles. Furthermore, there was no statistical difference between the pullout forces for the cycled and uncycled loads, and the pullout force magnitudes (over 5 times the average adult body weight) far exceeded clinical expectations. This suggests that uncemented press-fit GMRS implant fixation (straight fluted stem) should tolerate early weight-bearing loads without significant micromotion or stem fixation (pullout) failure. Although torsional instability is the most common mode of failure in stems, the authors wanted to examine another potential mode of failure that had not previously been well investigated and that directly opposed the applied cyclic weight-bearing forces. Their results demonstrate that pullout strength is not of concern when good ischial press-fit is achieved.

The authors anticipated that bone mineral density (BMD) might influence the pullout strength of the implants; however, it did not. This may be due to the computed BMD via DEXA being more closely associated with the cancellous bone density in the femoral head/neck and lumbar spine rather than the dense cortical bone where the stems in this study were implanted. Nevertheless, it appears that surface contact area better predicted implant pullout force than BMD.

These findings only apply to the GMRS straight cloverleaf stem design. Due to anatomic variability, the studied implants spanned a range of different sizes (11-15 mm). Although this matched-pair study design enabled a paired analysis, there was still considerable size variability between pairs, which affected implant sizes tested. The small sample size (8 matched pairs) also limits the overall power and generalizability of the findings. Future studies should investigate whether similar findings can be achieved for torsional stability and whether the results of this study can be generalized to other implant designs.

### CONCLUSION

Within the limitations of this biomechanical study, the authors demonstrated that press-fit uncemented femoral stems do not loosen with simulated early weight bearing. Pullout strength was not statistically different from the uncycled (control) contralateral implanted side. Although this study was specifically designed with application to oncological TKA, it has broader implications for other uncemented press-fit stems.

### REFERENCES


