Does Femoral Component Loosening Predispose to Femoral Fracture?

An In Vitro Comparison of Cemented Hips

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Abstract The incidence of femur fracture around total hip arthroplasties continues to increase at substantial cost to society. These fractures are frequently associated with a loose femoral component. Consequently, we sought to test whether femoral component loosening predisposes to periprosthetic femoral fracture. Because many periprosthetic femoral fractures are spiral in nature, we evaluated the torsional characteristics of the implanted femur in which the only design variable was instability of the femoral component. We used synthetic (polyurethane) ($n = 15$) and paired cadaveric femora ($n = 10$) with specimens divided into two groups: well-fixed and loose cemented stems. Each specimen was tested mechanically in internal rotation until failure. For the synthetic specimens, torque to failure was reduced by 38%, whereas stiffness was decreased 54% for the loose group compared with the well-fixed group. For the cadaveric specimens, torque to failure was reduced by 58%, whereas stiffness decreased 70% for the loose group compared with the well-fixed group. Fracture patterns were similar between synthetic and cadaveric femora with a proximal spiral pattern in loose specimens and more distal fracture patterns with

well-fixed stems. Based on our data, patients with loosened femoral components are at risk for fracture at a substantially lower torque than those with well-fixed components.

Introduction

By 2030, the demand for primary THAs is estimated to grow by 174% to 572,000 per year [14]. Although periprosthetic fracture is a relatively rare complication affecting less than 5% of all hip arthroplasties [3, 8, 10], it is associated with increased morbidity and mortality compared with aseptic revision surgery [6, 14, 19, 20, 31], decreased functional return, and substantial cost to the individual and society. Treatment usually requires open reduction and internal fixation with a wide exposure (well-fixed stem) or a difficult revision arthroplasty (loose stem) with or without allograft struts/bone grafting [16]. Roughly one in five patients treated for periprosthetic fracture has a major complication, a higher mortality rate compared with primary and revision THA, and half have a poor clinical outcome [19, 20, 28, 31]. In 1998, a 78% increase in cost and in increased hospital stay from 6¾ days to 12¾ days for treatment of periprosthetic fracture compared with early femoral revision surgery was reported for clinically silent osteolysis [15]. In a series of patients treated for nonunion of a periprosthetic femur fracture, it was concluded that the treatment was exceedingly difficult and not always successful and that periprosthetic fractures should be avoided if possible by regular radiographic surveillance and elective revision of aseptically loosened femoral components [9]. Moreover, the incidence of periprosthetic fractures around the hip has been estimated as between 0.1% and 2.4% [3, 4, 16] and this figure appears to be increasing [3, 7, 12], making it an important health policy issue.

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Recent analysis of data from large numbers of patients in national registries has suggested etiologic factors that predispose to periprosthetic fracture, including increased age of the patient, osteoporosis, and osteolysis [7, 8, 10, 17, 19]. One of the most consistently mentioned predisposing factors is aseptic loosening of the femoral component. One study reported that 75% (22 of 35) of their patients had prefracture evidence of femoral component loosening [5]. Another study reported almost 50% of their patients had evidence of femoral component loosening as did other groups [11, 13]. Beals and Tower reported 25% of their patients (22 of 93) had loose femoral components before fracture [1]. In an analysis from the Swedish hip registry, 230 periprosthetic fractures were recorded of which 70% were associated with pre-existing femoral component loosening [18].

Despite this association, it is unknown which factor(s) dominate the biomechanical function to support this clinical observation. Furthermore, the majority of these fractures result from lower-energy trauma than is commonly associated with fractures of the femur. Only 7% of the fractures in patients with primary hip arthroplasty are the result of major trauma, whereas 75% reportedly occurred from a fall at the same level (sitting or standing), and 18% occurred “spontaneously” [19]. Another study reported 66% of their fractures occurred from a fall at home, and 8% occurred spontaneously [1]. Thus, it is fair to say many of these fractures could be classified as “pathologic.” The causes of this “pathologic” state have been attributed to osteoporosis (both age-related and prosthesis-related) and wear debris-related osteolysis [10]. However, the fractures could also be due to the mechanical state of the implant, and in particular that of a loose implant.

Our aims were therefore to (1) create reproducible instability (loosening) of a femoral component within the femur; (2) examine the biomechanical behavior of these femurs to failure in torsion in comparison to a well-fixed component; (3) and qualitatively assess any difference in fracture profile between a group of well-fixed femoral components and a group of components with torsional instability.

Patients and Methods

Synthetic femora were used initially in this study to evaluate the experimental protocol before applying the protocol to human bone. Sixteen polyurethane foam/cortical shell left femora (Sawbones Model 1121-3; Pacific Research Laboratories, Vashon, WA) were prepared in standard fashion for a conventional cemented total hip prosthesis (Endurance; DePuy Inc, Warsaw IN). A femoral neck

osteotomy was performed 1 cm proximal to the greater trochanter using an alignment guide. Each specimen was then reamed and broached in a standard fashion, reaming to 15 mm. The canals were thoroughly cleaned and an intramedullary plug was placed distally. Femora were then cut to a standard 30-cm length from the tip of the greater trochanter and the distal shaft potted in 2-inch polyvinyl chloride (PVC) piping with polymethylmethacrylate. Two 1/8-inch transfixing pins were drilled across the PVC to help secure the femoral shaft in the fixture.

Cement was then injected into the canal in a retrograde fashion (Endurance bone cement; DePuy Inc) and a Size 5 Endurance stem that had been coated in a thin layer of silicone lubricant was inserted. Once the cement had cured and was no longer warm to the touch, the prosthesis was gently tapped out of the cement mantle. In the well-fixed group, the same Size 5 stem was tapped back into the cement mantle and fully seated for testing. In the loose group, a customized Size 3 stem was placed. This stem was milled from a 200-mm long-stem Size 3 to match the length and distal profile of the standard Size 5.

The size difference between the two prostheses was selected to ensure a consistent cement mantle defect averaging 1.5 mm between the cement and stem in the loose group and allow for the stem to “bottom out” when inserted. Several studies of clinically well-functioning femoral components have commented on the development of implant-cement radiolucencies (“debonding”). In a long-term followup of cemented Charnley femoral components Berry et al found radiolucencies of 2 mm or less along the implant-cement interface of the lateral shoulder of the prosthesis were associated with satisfactory clinical function of the prosthesis [4]. It was previously demonstrated that radiolucencies greater than 0.7 mm are required to be discernable on plain radiographs [32]. Consequently, we selected an implant-cement defect to be consistent with that published in the clinical literature.

The specimens were then mounted in a 1321 Instron biaxial servohydraulic testing machine (Instron Corp, Canton, MA) outfitted with a TestStarII system for digital control and data acquisition (MTS Systems, Eden Prairie, MN). A custom mounting vise ensured collinear alignment between the femoral shaft and the Instron actuator. Six 5/16-inch screws were inserted uniformly around the circumference and proximally/distally through the metal fixation cup and into undersized holes previously drilled in the PVC/PMMA to rigidly hold the specimen to the Instron base (Fig. 1). A custom jig was used to hold the tapers on the proximal aspect of each stem onto which flats had been milled for securing purposes. A small compressive load (approximately 5 lb) was applied; axial position was then held constant while the stem was manually rotated both internally and externally until a torque of 2 N-m was

Fig. 1 Typical specimen setup for torque to failure testing shows the base for rigidly holding the distal femoral shaft while the proximal stem was rotated to simulate internal rotation.

reached as the stem engaged the femur. This was repeated three times in each direction and the angular position was noted at each extreme. The average of this “toggle” was used as the start point to consistently place the stem within the center of the mantle. The femoral stem was then rotated through a 90° arc over 1 second to simulate internally rotating on a planted foot with a fixed distal aspect of the femur.

For the cadaveric specimens, 10 fresh-frozen human upper legs (five pairs), age range 46 to 67 years (average, 60 years), were used. No specimen had a history of a malignant lesion or known bone disease. Bone mineral density in the femoral neck region was determined for each specimen using dual-energy absorptiometry with a Hologics QDR-4500A (Hologics Inc, Waltham, MA). The bone mineral density ranged from 0.66 to 1.06 gm/cm² (mean, 0.79 gm/cm²) for all cadaveric specimens. We observed no difference ($p = 0.128$, power = 0.313) between the femora for well-fixed stems (0.81 ± 0.15 gm/cm²) and loose stems (0.77 ± 0.13 gm/cm²). The legs were sealed in airtight bags for storage at 20°F (−7°C) until testing. Specimens were thawed at room temperature followed by removal of soft tissues. Each specimen was prepared as for the synthetic femora with the exception that

femoral canals were thoroughly washed and dried before cementing, with one femur of each pair well fixed and the other “loose.” All specimens were tested to failure as previously described.

Torque (N-m) versus angular rotation (degrees) curves were generated to determine torque to failure (greatest torque before a sharp decline) and total rotation to failure. Stiffness (N-m/degree) was determined on the basis of the slope of the linear portion of torque versus angular rotation curve from 5 to 20 N-m for synthetic and 5 to 40 N-m for cadaveric specimens. Additionally, the “toggle” (rotation to engagement of the stem to the cement mantle in both CW and CCW directions) between groups was compared as well as rotation to failure after engagement (ie, total rotation minus toggle). At a significance level of 0.05 and 80% power, a sample size of five was sufficient to detect statistical differences on the order of twice the standard deviation in the primary torsional properties (stiffness, torque at failure, rotation at failure). With standard deviations typically on the order of 10% to 20% of the mean value for a given biologic property, this would reduce the factor of safety inherent in biologic systems for the typical loads encountered in activities of daily living and imply that failure could occur within limited cycles of loading.

We compared the torsional properties for well-fixed versus loose prostheses individually for the synthetic and cadaveric specimens using a two-sample Student’s *t*-test with SAS analysis software (SAS Institute, Cary, NC). One synthetic loose specimen was eliminated from statistical analyses postexperimental testing because the fractured surface revealed a large air pocket from manufacturing that may have compromised calculated properties. Because the cadaveric specimens were matched pairs, a two-sample paired Student’s *t*-test was used to compare these data.

Results

Both synthetic and cadaveric specimens demonstrated increases in the rotational instability (“toggle”) of a loose prosthesis compared with a well-fixed stem (Fig. 2). The loose synthetic specimens demonstrated a greater mean rotation ($p = 0.0013$; power = 0.999) within the cement mantle compared with that for well-fixed implants. There was less “toggle” in the cadaveric specimens than the synthetic femora; however, loose specimens continued to show an increased rotation ($p = 0.0085$; power = 0.943) of the prosthesis within the cement mantle compared with the well-fixed stems. These differences are also evident in the loading curves to failure for loose and well-fixed specimens (Fig. 3). Once engagement of the stem to the cement mantle occurred, specimens exhibited linear behavior before abrupt failure.

Fig. 2 Internal/external manual rotation to 2 N-m, representing initial instability (“toggle”), was larger for loose versus well-fixed femoral components in both synthetic and cadaveric specimens.

Fig. 3 Typical torque versus total rotation curves to failure is depicted for well-fixed and loose stems in both synthetic and cadaveric specimens. Overall, loose components demonstrated inferior torsional characteristics compared with well-fixed specimens.

Total rotation to failure was greater for the loose stems (Fig. 4). Mean angular rotation to failure in synthetic specimens increased ($p = 0.0008$; power = 0.998) by 48% with loose compared with well-fixed stems. Cadaveric specimens similarly showed a 72% increase in rotation to failure ($p = 0.0119$; power = 0.898) for loose stems. Once the rotation to engagement of the stem to cement mantle, or “toggle,” was taken into account, however, no difference was observed in the rotation to failure after engagement between loose and well-fixed groups for either synthetic ($27.2^\circ \pm 4.9^\circ$ versus $23.7^\circ \pm 2.8^\circ$, respectively; $p = 0.1488$; power = 0.294) or cadaveric tests ($14.2^\circ \pm 2.7^\circ$ versus $10.8^\circ \pm 5.4^\circ$, respectively; $p = 0.2493$; power = 0.182).

The stiffness of synthetic specimens decreased ($p < 0.0001$; power = 0.999) 54% in the loose specimens over a well-fixed prosthesis for the torque range of 5 to 20 N-m (Fig. 5). Similarly, with the cadaveric specimens, stiffness decreased ($p = 0.0023$; power = 0.999) 70% in

Fig. 4 Total rotation to failure was increased for loose versus well-fixed femoral components in both synthetic and cadaveric specimens.

Fig. 5 Torsional stiffness was calculated from 5 to 20 N-m for synthetic and 5 to 40 N-m for cadaveric specimens. We observed greater stiffness in well-fixed compared to loose femoral components.

Fig. 6 Torsional strength at failure was larger for well-fixed versus loose femoral components in both synthetic and cadaveric specimens.

the loose specimens compared with a well-fixed prosthesis for the torque range of 5 to 40 N-m (Fig. 5).

Torque to failure was decreased with a loose prosthesis (Fig. 6). Synthetic femora with loose implants failed at a torque 38% lower ($p < 0.0001$; power = 0.999) than those with well-fixed stems. Cadaveric specimens demonstrated

Fig. 7 Different fracture patterns resulted from loose versus well-fixed femoral components, with the fracture beginning in the proximal/calcus region in loose constructs compared with the mid- to distal stem region for well-fixed components. However, fracture patterns were similar for synthetic and cadaveric specimens tested.

a 58% decrease in torque to failure ($p = 0.0147$; power = 0.862) for loose specimens versus well-fixed stems.

The physical characteristics of the induced fractures were examined as well. Typical fracture patterns for both synthetic and cadaveric specimens with loose prostheses showed consistent initiation at the proximal femur/calcus region, whereas the well-fixed stems always involved the mid- to distal stem (Fig. 7). As would be expected with torsional load, fractures were all spiral or comminuted spiral in nature. No fractures occurred exclusively distal to the stem.

Discussion

Periprosthetic fracture has been associated with a preexisting loose prosthesis in many clinical studies. In one study, 75% of patients with periprosthetic fractures had prefracture radiographic evidence of loosening of the implant [5]. In a recent study, 70% of stems were considered loose when the patient sustained the periprosthetic fracture [19]. Patients with a loose prosthesis may not be symptomatic either. One report found up to 80% of patients with radiographic evidence of loosening in their study did not have symptoms [25]. Our aims were therefore to (1) create reproducible instability (loosening) of a femoral component within the femur; (2) examine the biomechanical behavior of these femurs to failure in torsion in comparison to a well-fixed component; (3) and qualitatively assess any difference in fracture profile between a group of well-fixed femoral components and a group of components with torsional instability.

Several limitations influence the interpretation of our study. First, the defect around the stem was between the loose stem and the cement mantle, whereas in vivo, it may be seen between the cement mantle and the femur in addition to the implant-cement interface [23, 25, 27, 29]. However, there is considerable evidence that femoral component debonding is one clinical mechanism of femoral component loosening [3, 8, 19, 20]. Although debonding of the femoral component from the cement mantle is often compatible with good clinical function, in some cases, this debonding progresses to clinical failure [4, 22, 29]. A previous study of clinically successful femoral components retrieved at autopsy noted a common pattern of debonding of the femoral component from the cement mantle and suggested this debonding led to progressive torsional instability culminating in cement fracture and clinical loosening [21]. Second, our study tests only one-stem geometry. The results of the present study may not be universally applicable to all stems in terms of the numeric values, but the import of the results remains. Third, the types of forces that lead to a periprosthetic fracture have not been well-studied. Although the majority of reported periprosthetic fractures have been associated with falls, it is impossible to determine whether these fractures were the result of axial bending loads, direct impact loads, or torsional loads. However, there is evidence that torsional forces may be involved in many periprosthetic fractures, suggesting torsional loading is pre-eminent in causing periprosthetic femur fracture [30]. A review of femoral shaft fractures caused by low-energy trauma treated over a 10-year period found 58% had a spiral fracture pattern, indicating a torsional mechanism for the fracture [26]. Studies have noted high torsional forces

through the proximal femur during activities of daily living and walking [2, 24]. Fourth, we used a cemented femoral component. Although there has been a steady progression toward cementless femoral fixation in primary THA, many patients worldwide have cemented femoral components. A cemented model also provides immediate reproducible fixation for testing purposes.

We developed a model of femoral component loosening that is reproducible as evidenced by the rotational “toggle” and small deviations in the biomechanical data. It also correlates with the clinical description of one mode of femoral component loosening. Our data suggest a loose prosthesis within the cement mantle is associated with decreased torsional characteristics that predispose to periprosthetic fracture in the absence of osteolysis or other bony defects. We found a substantial reduction in the torque to failure in stems not well fixed to cement compared with well-fixed stems (58% less in the cadaveric model and 38% less in the synthetic model). One study [24] compared a press-fit S-ROM prosthesis with tight fixation of both the metaphyseal and diaphyseal components to either loose metaphyseal or diaphyseal fixation for the purposes of evaluating the importance of bonding in a press-fit system. They concluded rotation to failure, defined as either fracture or permanent rotational displacement exceeding 3 mm, was less in either group with either the proximal or diaphyseal region loose, which supports our findings.

Examination of the resultant fracture patterns from a torsional load showed loose cemented prostheses consistently produced spiral fractures involving the proximal femur, whereas well-fixed stems consistently involved the more distal regions. Therefore, a patient presenting with a proximal fracture may be more likely to have a loose implant requiring revision of the prosthesis rather than fracture fixation alone (Vancouver B2 versus B1).

Fracture treatment is associated with substantial patient risk and cost [15, 19, 29, 31]. We believe the data provide biomechanical justification for previous clinical studies that have advocated more regular monitoring of patients and earlier intervention in situations of femoral component loosening even when patients are relatively asymptomatic. The markedly lower torque to fracture levels in our study suggests patients with unstable cemented femoral implants may be at risk for fracture at loads commonly associated with activities of daily living as opposed to the loads from falls and other trauma. Future investigations based on the present study may examine the effects of cementless stem loosening to determine whether this concept may be further extrapolated. Based on our data, we recommend patients with evidence of loosening at followup be counseled that they may be at increased risk of fracture even in the absence of symptoms and that any new symptoms such as startup or thigh pain should not be ignored.

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