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ORIGINAL STUDY

Small interprosthetic gaps do not increase femoral peri-prosthetic fracture risk. An in vitro biomechanical analysis.

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It has been hypothesized that the interprosthetic gap between ipsilateral hip and knee replacements acts as a stress riser affecting bone fracture behaviour. The aim of this study was to quantify femoral strength and fracture morphology for a wide range of interprosthetic gaps. Seven interprosthetic gaps (0-20cm) were created in artificial femora (N = 6-9/group). All specimens were loaded to failure following a compressive loading protocol. Fracture load and fracture morphology were recorded. Outcomes were compared to femora with a hip implant only (N = 6; reference group). Fracture load was highest for 0 cm gaps. All other interprosthetic gaps had fracture loads similar to that of the reference group. Fracture occurred most frequently with a medial butterfly fragment located at the tip of the hip stem.We conclude that small gaps do not act as stress risers. The specific fracture morphology may benefit from different treatment than peri-prosthetic hip fractures.

Keywords : Femur, biomechanics, interprosthetic fracture, peri-prosthetic fracture

INTRODUCTION

The growing number of THA and TKA placements and revisions combined with a greater susceptibility to falls in the aging population cause a rise in the incidence of peri-prosthetic and inter-prosthetic fractures (*5, 13, 17, 19, 20, 24, 25, 41*). Incidence of these peri-prosthetic femoral fractures is estimated between 0.3 to 5.5% after TKA placement (*31*) while peri-prosthetic fractures after THA placement vary between 0.1-3.2% for primary and 2.1-24% for revision arthroplasty respectively (*1, 5, 15, 25, 28, 30, 37, 39*).

The number of patients with a total hip arthroplasty (THA) and ipsilateral total knee arthroplasty (TKA) is increasing as well. THA and TKA revision surgery for various reasons often requires the use of long stems (*15, 17*). As a consequence, the inter-prosthetic (IP) gap between the tip of both components may become substantially small.

It has been hypothesized that small inter-prosthetic gaps induce higher stresses in the bone, hence, will lead to failure of the femoral bone at lower loads (*36, 40*). Furthermore, considering the

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deterioration of bone quality that is associated with the aging population in combination with osteolysis due to aseptic loosening, elderly people may experience an even higher susceptibility for peri-prosthetic fractures. Indeed, patients with severe osteoporosis are more prone to inter-prosthetic fractures of the femur (*11, 18*). The incidence of inter-prosthetic fractures in patients with ipsilateral prosthesis placement is 1.25% (*18*). Treatment of an inter-prosthetic fracture of the femur, especially in the presence of an IP gap, remains a challenge. Due to the presence of the two rigid prostheses the remaining bone volume, needed for fracture fixation, is limited and obtaining a stable construct after osteosynthesis may become a serious challenge (*15, 36*).

However, it is not well understood how IP gaps affect local bone stresses and strains (*16, 21, 22, 35*) and little is known about fracture morphology and the resulting specific fracture management and reconstruction strategies (*10, 26, 29, 32, 36, 37*). Better understanding the alterations in fracture strength of the femur with an inter-prosthetic gap will help the surgeon minimize the risk of jeopardizing the fracture strength of the femur.

Therefore, the aims of this study were (*1*) to evaluate the effect of the inter-prosthetic gap distance on the fracture strength of the femur and (*2*) to describe the inter-prosthetic fracture morphology.

MATERIALS AND METHODS

Six primary THA stems of 14 cm length (C-stem, Depuy J&J, Warsaw, Indiana) and six revision THA stems of 20 cm length (Exeter, Stryker, Kalamazoo, Michigan) were cemented into 12 medium sized (45.5cm length) 4th generation artificial femora (Sawbones, Pacific Research Laboratories, Mälmo, Sweden). Both prosthesis types have a tapered design and were placed with a fixed depth of 1 cm from the shoulder of the stem to the tip of the greater trochanter. Prosthesis placement was performed by trained surgeons (O.S. and H.F.) and based upon prosthesis markings. The Sawbones were mounted into a 250kN mechanical testing machine (Instron, Norwood, Massachusetts) and loaded along the mechanical axis of the femur (*6*). This axis has 7° of valgus inclination and a neutral position in the sagittal plane to simulate the femoral position during single-leg-stance, which resulted in a combined compression and bending (Fig. 1).

Distally, the specimens were placed in a V-shaped holder constraining the movement in the sagittal plane. Proximally, forces were applied to the femoral stem through a polyethylene socket that was potted in the Instron testing machine with neutral version relative to the stem. A compressive pre-load of 100N was applied, followed by progressive compression displacement of 8 mm/minute until failure. Failure was defined as a 10% decrease in the measured force (*42*). The fracture pattern was documented with a high definition camera (Sony HDR-CX560VE) to allow for evaluation of the failure morphology. The measured parameters were fracture load (Fmax), the deflection of the specimens at failure (δmax), measured in the direction of the applied force, and the work to failure calculated as the area under the force-deflection curve.

In 51 additional femora, seven inter-prosthetic gap distances were created by combining either primary or revision total hip replacements with revision total knee replacements (Profix, Smith&Nephew, Memphis, Tennessee) (Fig. 1). Stem length for the hip prostheses varied from 14 to 26 cm, whereas the stem length for the knee prostheses varied from 10 to 20 cm, leading to interprosthetic gaps ranging from 0 cm to 20 cm (Table I).

As to create the inter-prosthetic gap distances of 1.5 cm and 5 cm, the TKA stems were not placed flush with the intra-condylar fossa. The small part of the TKA stem that protruded from the intra-condylar fossa did not impact the testing set-up. The IP gap specimens were tested in an identical way as described above.

The Mann-Whitney-U test was used to analyse the difference between primary and revision hip prosthesis regarding fracture load, work to failure and ultimate deflection in the primary THA vs revision THA group, when no TKA was present. One-way ANOVA was used to evaluate the effect of gap size on fracture load, work at failure and ultimate deflection. In case of a significant effect, the gap size was compared to all other gap sizes

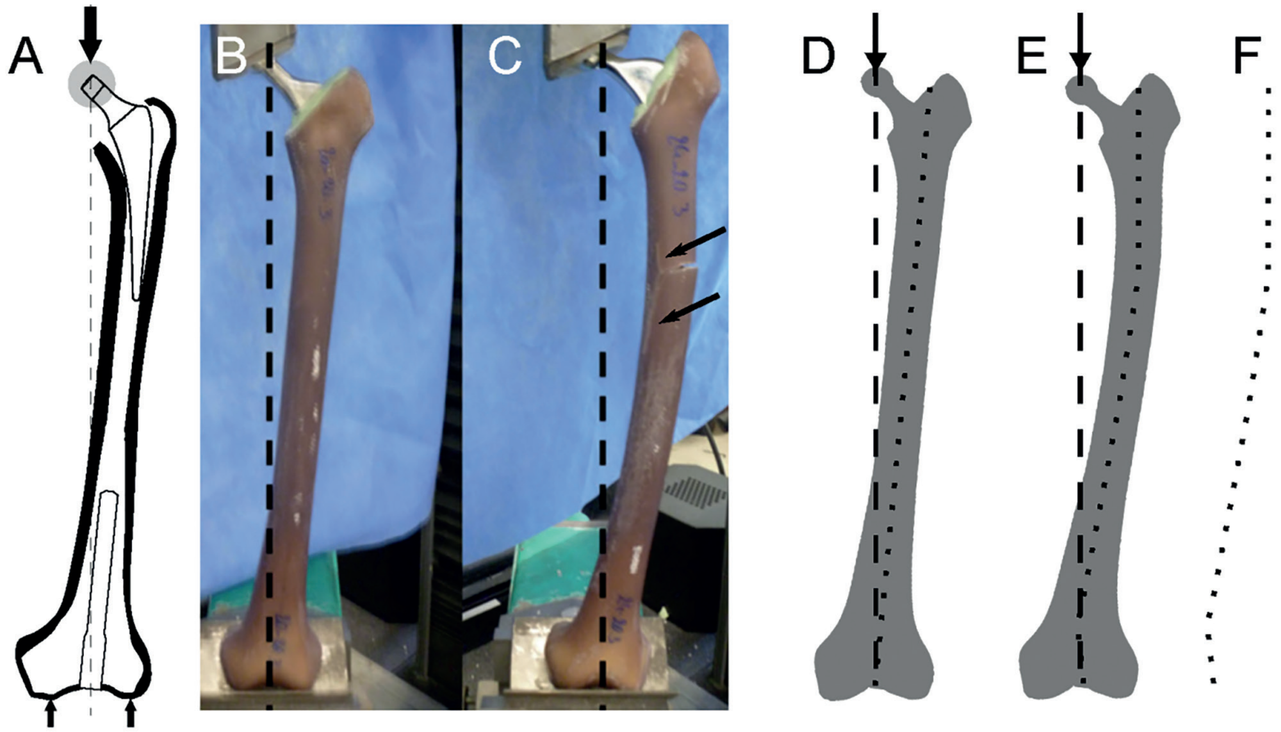

Fig. 1. — (A) Schematic and (B) actual representation of the set-up with indicated load axis (dashed line) as described by the single-leg-stance protocol. Arrows on the image on the right indicate the fracture lines during medial butterfly fracture. Deflection (δmax) is measured along the loading axis (dashed line). (C) Specimens were loaded until failure. (D) Schematic representation of the s-shaped bending. The line from the trochanteric region to the intracondylar region on the figure on the right is deformed into an s-shape under load (E & F).

Table I. — Overview of all specimens used in this study. The different combinations of total hip arthroplasty (THA) and total knee arthroplasty (TKA) lengths are shown, together with the resulting gap distance. The name of the groups reflects the gap size.

	THA Only		IP Gaps						
	THA Primary	THA Revision	Gap 20	Gap 15	Gap 10	Gap 5	Gap 3	Gap 1.5	Gap 0
Specimens per group	6	6	6	9	9	9	6	6	6
Primary THA stem (cm)	14	/	14	14	14	/	/	/	/
Revision THA stem (cm)	/	20	/	/	/	20	26	22	24
Revision TKA stem (cm)	/	/	10	15	20	20	15	20	20
Interprosthetic gap (cm)	/	/	20	15	10	5	3	1.5	0

in a pair-wise fashion using the Tukey-Kramer test. Correction for multiple testing was applied; all significance levels were set to 5%. All analyses were performed using Matlab 2014b's Statistics toolbox for Windows.

RESULTS

For the reference measurements consisting of THA prostheses only, the fracture load (Fmax) was 8407 +/- 463 N and 8435 +/- 459 N, for the primary and revision THA respectively (p = 0.937; Fig. 2). The femur with only a cemented THA revision stem demonstrated similar work to failure to the femur with only a primary THA stem, 49.0 +/- 12 J versus 43.1 +/- 11.9 J respectively (p = 0.394; Fig. 2). Mean ultimate deflection (δmax) was 8.852 +/- 1.785 mm and 9.698 +/- 1.357 mm for the primary and revision THA respectively (p = 0.240). For these specimens with a THA only, 9 of 12 fractures occurred with a lateral butterfly fragment.

The fracture load after the insertion of a TKA revision stem was 8155 N (range 6759 N to 9796 N). The lowest fracture load (7346 +/- 519 N) was found with a 15 cm gap size. The highest fracture load (9415 +/- 206 N) was found with a gap size of 0 cm. The fracture load increased with decreasing gap size when the distance between both stems was smaller than 5 cm (Fig. 2). Gap size had a significant influence of fracture load (p<0.001). The fracture load of the 0 cm gap was significantly higher than all other gap sizes (p<0.05). The fracture load of the 15 cm gap was lower than the 0.5 and 3 cm gap sizes (p<0.05).

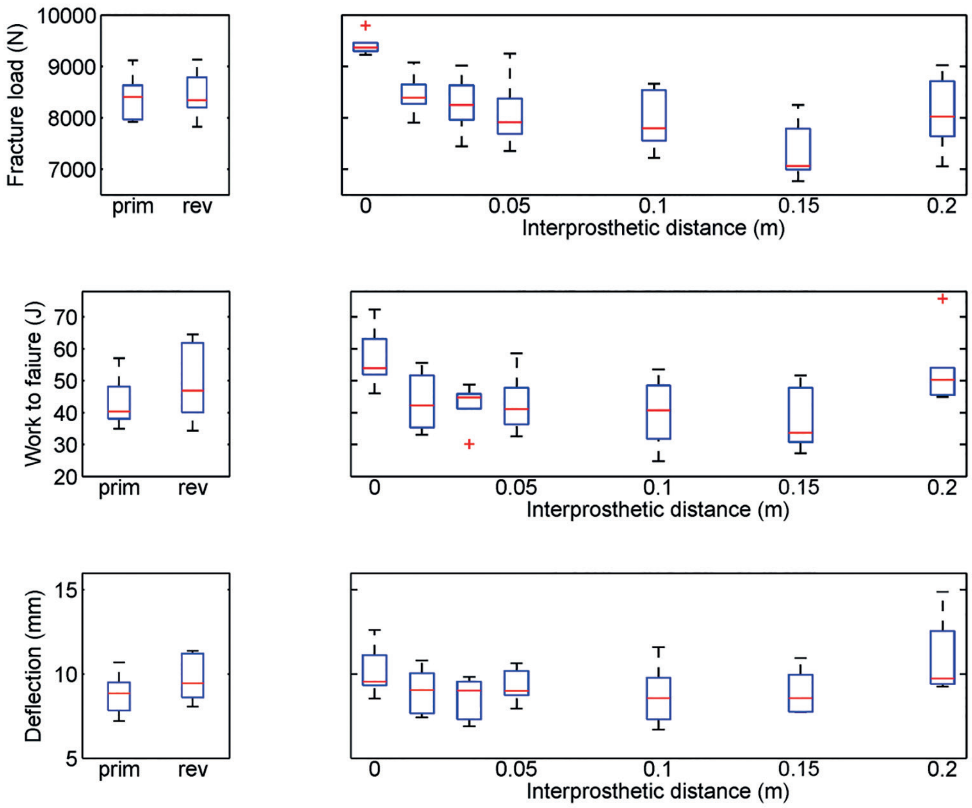

Fig. 2. — Results of (prim)ary and (rev)ision THA tests and IP gap variation are shown in boxplot format. Fracture load, work to failure and deflection at failure are shown. 0 cm gaps had a significantly higher Fmax than all other gap sizes (p<0.05). Fmax of 15 cm gaps was significantly lower (p<0.001), than 0.5 and 3 cm gaps. 0 cm gap required significantly higher work to failure than the 10 and 15 cm gaps (p<0.05). 20 cm gaps required significantly higher work at failure than 15 cm gaps (p=0.049).

The mean ultimate deflection (δmax) was 9.1 mm (range 7.3 to 16 mm). The highest deflection (11.1 +/- 2.6 mm) was found with the 20 cm gaps. The lowest deflection (8.6 +/- 1.2 mm) was found for the 3 cm gaps. No significant correlation between the gap size and δmax was found (p = 0.056).

Work to failure was smaller with gap sizes between 5 cm to 15 cm than with 0 or 20 cm gaps. Gaps smaller than 5 cm required more work to failure (Fig. 2). There was a trend of higher work to failure with gap sizes of 0 cm and 20 cm when compared to other gap sizes. A 0 cm gap required significantly higher work to failure compared to the 10 and 15 cm gaps (p<0.05) respectively. The 20 cm gaps required significantly higher work to failure compared to the 15 cm gaps (p = 0.049).

Both the THA and TKA stems remained well fixed to the bone in all cases. All femurs failed at the level of the interprosthetic gap, close to the tip of the hip prosthesis (Fig. 3). Gap fractures had a typical medial butterfly fragment in 34 of 51 specimens (67%). A lateral butterfly fragment was present in 12 specimens (23.5%): none of the 0 cm gaps, 17% of the 1.5 cm gaps and the 3 cm gaps, 55% of the 5 cm gaps, 11% of the 10cm gaps, 33% of the 15 cm gaps and 17% of the 20 cm gaps.

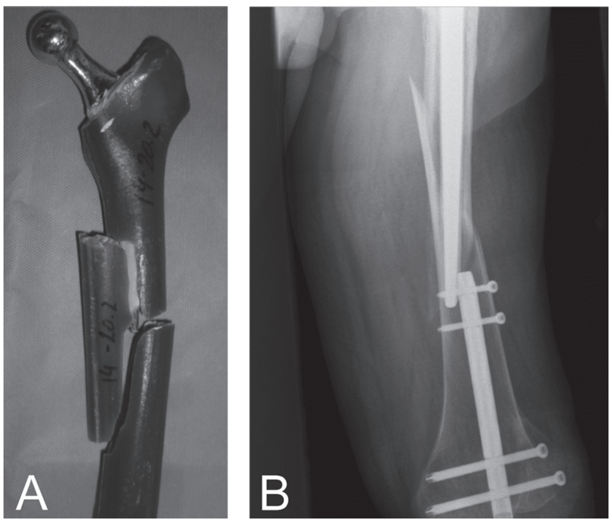

Fig. 3. — Typical medial butterfly fracture at location of the interprosthetic gap, at the tip of the THA prosthesis. (B) As correlation to the clinical situation, an X-ray showing a similar fracture between a long revision THA and an intramedullary nail is shown as well.

An oblique fracture occurred in 3 cases (6%) (1 of the 3 cm, 10 cm and 15 cm gaps) and a multi-fragment fracture occurred in 1 case (5 cm gap). One specimen (10 cm gap) had an antero-medial butterfly.

Images from the high-definition video showed that, for the THA-only specimens, the single-leg loading protocol combined with fixed knee condyles caused an s-shaped bending. This bending shape is characterized by a lateral outward bending in the proximal part of the femur, followed by an inward bending in the femoral shaft starting just above the knee condyle. Insertion of the distal TKA stem led to a less pronounced s-shaped bending (Fig. 1) which influenced the bending deformation as well.

DISCUSSION

The aims of this study were (*1*) to evaluate the effect of the inter-prosthetic gap distance on the fracture strength of the femur and (*2*) to describe the inter-prosthetic fracture morphology. These aims of this study have been achieved. We demonstrated that small inter-prosthetic gaps do not hamper the load-bearing capacity of the femur. Furthermore, we found that most femora fractured with a medial butterfly fragment.

Multiple sizes of THA were used, but these did not influence the maximal force at fracture. Inter-prosthetic gaps smaller than 5 cm were associated with an increased fracture load and work to failure compared to gaps larger than 5 cm. Even more, when the inter-prosthetic gap is decreased to a gap size of 0 cm, the fracture load and work to failure increased significantly when compared to larger gap sizes.

Single-leg-stance loading, or so-called isometric loading (*27*) was applied since it is a well-accepted testing protocol which represents the major compressive loading at the hip joint (*2*, *8*, *23*, *33*, *35*, *42*). In our study, both the distal and proximal ends were free to rotate in the V-shaped holder and acetabular cup, respectively. As such, a more physiologically relevant loading was obtained.

Previous experimental studies investigating the IP gap used cantilever bending (*16*) or four-point bending (*22*). Cantilever bending only simulates the bending forces, whereas four-point bending leads to a constant moment over the specimen between the two supports. Neither of these represents an anatomical loading condition. Furthermore, in both the cantilever bending and four-point bending studies the specimen ends were embedded in steel pots (*16, 22*), which limits the deformation of the specimen. We do acknowledge that addition of the abductor force, which is not included in our study, can change the bending moment at the interprosthetic gap, but do not believe that this would change the outcome of this comparative study.

In this study we tested a wide range of gap sizes. The effect of IP gap size has been tested before on cylindrical, idealized, prosthetic stems through cantilever bending in Sawbone femora by Iesaka et al. (*16*). They found that when stems remained fixed to the bone, gap length variation did not influence the peak tensile stress on the femur, nor did stem tips act as stress risers, which is similar to the results of our study. The smallest gap of 1 mm showed a lower stress than all other larger gaps, which concurs with our findings of a significant higher fracture load for 0 cm gaps. Another study evaluated the impact of adding a stemmed TKA prosthesis or a distal retrograde nail to hip stem placed in a human cadaveric femur (*22*) ; yet, only one IP gap size was evaluated. They found that adding the stemmed knee prosthesis did not increase the risk for fracture. Our study showed similar results, where TKA implantation did not lower the fracture load compared to THA-only specimens. The role of IP gap size has been evaluated in more detail in a finite element study where the femora were loaded under gait conditions (*35*). Gap size did not influence the risk for fracture, nor did stem tips act as stress risers, similar to the results of our study. Yet, the THA stem length was fixed, and the smallest gap was 5 cm only.

Another strength of this study that it is the first study on inter-prosthetic gaps where fracture location and fragment type were investigated. We found that 67% of the specimens failed with a diaphyseal medial butterfly fragment, as this is the location where the highest stresses and strains are located. This may be surprising at first sight, because several clinical studies reported supra-condylar inter-prosthetic fractures, located proximal to the TKA component (*26, 36*). Yet, this discrepancy can be explained by the fact that we used a stemmed TKA component, while previous reports referred to non-stemmed TKA components. In more detail, due to the presence of a THA and TKA stems the rigidity and resistance to fracture of the proximal and distal region of the femur are higher than in the native case. The diaphyseal bone at the location of the gap will absorb most of the energy during loading. Due to the nature of the single-leg-stance loading protocol, the bending component of the load decreases from proximal to distal (Fig. 1A). As such, the largest bending in the bone is located at the tip of the THA stem. As a consequence, the fracture will originate at the lateral side of the IP gap, where high tensile stresses will occur that co-locate with the lowest strength (tensile strength lower than compressive strength (*38*). When the crack grows in the transverse direction, the failure mode will switch to compressive failure, causing an oblique (shear) fracture line. As a consequence, a butterfly-shaped bone fragment is created. We attribute the variability of fracture morphology in one gap group to slight variations in prosthesis placement.

There are several limitations of this study. First, the *in vitro* nature can be questioned. However, measuring fracture strength in a patient is not possible and the quantification of fracture morphology would be very complicated, if possible at all. Additionally, advanced age of these patients, many with existing co-morbidities, will undoubtedly make it difficult to reach clear conclusions. The *in vitro* nature also excluded taking bone remodelling into account. Yet, to the best of our knowledge, there is no single clinical study indicating that bone-remodelling would be of greater concern in patients with small interprosthetic gaps. We hypothesize that bone remodelling will lead to weakening of the bone. Yet, based on the fact that bone fracture will occur close to the distal end of the hip stem, and considering that bone remodelling close to the tip will be limited (if at all), it is questionable whether bone remodelling would result in reduced failure loads. Second, to construct the different gap distances, several THA sizes have been used. Even though larger revision THA stems seem to lead to a smaller deflection as compared to primary THA, the difference was not significant, neither was the difference in force at failure. Third, while IP gap fractures are prevalent in osteoporotic patients, Sawbones are not representative for osteoporotic bone quality, remodelled bone after prosthesis placement, or for hip fracture simulation (*3*, *16*, *34*, *36*). Yet, as the inter-prosthetic gap is located at the femoral isthmus, which is less affected by osteoporosis than the metaphyseal regions, Sawbones can be used as a relevant model for human bone, especially since it was our goal to perform a comparative study where cadaveric-bone variability had to be avoided. Furthermore, validation studies have shown that Sawbones display stiffness and strains curves very similar to those of natural femurs but have a much lower variability thereby allowing them for utility in comparative tests (*9*, *12*, *14*, *42*). In addition, the analogue cortical bone used in fourth generation sawbones also displays fracture toughness and tensile strength similar to human cortical bone (*7*). Fourth, we did not consider cortical thickness, even though it plays a dominant role in fracture load (*40*). We believe that, even for bones with a thinner cortex, the findings of our comparative study still apply. Fifth, in this study we evaluated cemented prostheses. The use of bone cement will only slightly influence the bending rigidity as compared to uncemented specimens, since the cement is located close to the force-transmission line; hence, the findings of this study can be extrapolated to uncemented, press-fitted or ingrown prostheses. And sixth, only one loading condition was used. As we used a physiologically relevant load case along the mechanical axis of the femur (*6*), and as we used the data in a comparative way only, we do not expect to find different conclusions when more complicated loading would have been applied. Furthermore, the measured failure load was substantially higher than the peak forces that arise in a variety of loading conditions (*4*). Torsional loads will be largely carried by the bone; hence, strong effects of the IP gap size were not expected and were not tested experimentally.

In summary, we conclude that this is the first study that experimentally evaluated the biomechanical influence of small (< 35 mm) inter-prosthetic gaps between the femoral components of hip and knee prostheses, using a relevant single-leg-stance loading protocol. Our findings confirm earlier studies indicating that, during the immediate post-op situation, inter-prosthetic gaps do not act as stress risers. In fact, small gaps require higher forces to fracture, thus do not have increased fracture risk. Due to the presence of the THA and TKA stems the typical failure will result in the creation of a medial butterfly fragment. Such fractures may warrant specific reconstruction techniques.

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