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A Retrieval Analysis of High Flexion versus Posterior-stabilized Tibial Inserts

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Abstract

Background High flexion (HF) implants were introduced to increase ROM and patient satisfaction, but design changes to the implant potentially have deleterious effects on polyethylene wear. It is unclear whether the HF implants affect wear.

Questions/purposes We therefore examined whether the design changes between HF and posterior-stabilized (PS) tibial inserts would affect overall damage or damage on their articular surface, backside, and tibial post and whether flexion angle achieved related to damage.

Methods We matched 20 retrieved HF inserts to 20 retrieved PS inserts from the same implant system on the

basis of duration of implantation, body mass index, and age. Inserts were divided into 16 zones and a microscopic analysis of surface damage was carried out. Five inserts were scanned using micro-CT to further quantify instances of severe post notching. We determined overall damage with a scoring system.

Results We found greater backside and post damage in the HF group but no difference in the articular surface or overall damage scores. Backside and post damage scores correlated to flexion angle in the HF group. There was no flexion/damage correlation in the PS group. Notch depths around the post in both groups ranged from 0.6 to 1.9 mm. **Conclusions** HF inserts are more susceptible to post damage, possibly as a result of higher contact stresses from greater flexion. The increased backside damage was unexpected because the two groups have the same tibial component, locking mechanism, and sterilization method. **Clinical Relevance** The introduction of a highly cross-linked HF insert will require close scrutiny as a result of the potential for post damage demonstrated in this series.

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Introduction

Implant designs for TKA continue to evolve to increase function and provide better resistance to polyethylene wear [16]. The introduction of the posterior-stabilizing tibial post was established to increase flexion through femoral cam articulation with the back of the post to facilitate stable femoral rollback and prevent posterior subluxation [24]. It is well documented that the cam-post is not an innocuous articulation [14, 26]. Tibial post wear is a major factor in the production of osteolytic polyethylene particles and can ultimately lead to catastrophic failure including post fractures [1, 2, 4, 10, 17–19, 26]. The creation of a

high flexion tibial insert design was introduced with the intent of allowing deeper flexion, particularly in patients with high preoperative flexion. With the maintenance of a good flexion arc and resulting functional outcomes, patients are more inclined to have their expectations met after surgery [3]. The high flexion inserts are similar to the conventional posterior-stabilized design with several design changes to the articular surface geometry that vary across manufacturers [22].

The polyethylene tibial inserts from the Genesis® II (Smith & Nephew, Inc, Memphis, TN, USA) implant system are machined compression-molded sheets of GUR 1050 (posterior-stabilized) or 1020 (high flexion) resins (Mediatech, Fort Wayne, IN, USA) and sterilized using ethylene oxide [24]. The design changes (Fig. 1) in the high flexion insert include a cutout in the anterior portion of the insert and tibial post to accept the patellar tendon and minimize impingement in deep flexion [24]. Additionally, the radius of curvature on the posterior surface of the insert is modified to allow increased femoral rollback [24]. These design changes are noteworthy, because even minor adjustments within the confines of a particular model reportedly alter the survivorship and susceptibility to wear of tibial inserts [6]. For example, the original Insall-Burstein I posterior-stabilized knee had a long-term survivorship of 94% at 18 years [8]. However, its successor, the Insall-Burstein II posterior-stabilized, altered the location and height of the tibial post to increase flexion, which resulted in a dislocation rate greater than twice the original [8]. The tibial post of the Genesis® II posterior-stabilized insert was previously determined to have less total damage in comparison to the posts of other contemporary posterior-stabilized designs but was also the most prone to damage to the posterior side [8]. Concerns have been raised that the design changes to the high flexion implant might also have deleterious effects on polyethylene wear as a result of altered femoral/tibial contact and removal of material posteriorly [24]. High flexion inserts were introduced at our

institution in 2004, and since that time, we have revised a number of these implants, providing an opportunity to study the retrieved tibial inserts.

We therefore examined whether the design changes and altered kinematics between high flexion and posterior-stabilized tibial inserts would affect their (1) overall damage profile and more specifically the damage on their (2) articular surface; (3) backside; and (4) tibial post. We also examined the relationship between flexion angle and damage at each of these locations.

Materials and Methods

We retrieved 108 Genesis® II cruciate-sacrificing tibial inserts from our Institutional Review Board-approved implant retrieval laboratory between 1996 and 2011. This group consisted of 76 posterior-stabilized and 32 high flexion tibial inserts. Inserts that had been implanted for less than 3 months were excluded from analysis. The remaining cohort included 20 high flexion inserts, which we then matched to a similar cohort of posterior-stabilized inserts on characteristics including duration of implantation, body mass index (BMI), and age (Table 1). The 40 retrieved specimens had a mean duration of implantation of 1.7 years (range, 0.3–3.6 years, and the mean patient BMI was 33.7 kg/m² (range, 17–47 kg/m²). The majority of implants in both groups were revised as a result of infection. The average age at revision was higher in the posterior-stabilized group than in the high flexion group (67 ± 9 years versus 62 ± 9 years, respectively). As a newer insert design, the high flexion group included a greater proportion of knees with an Oxinium femoral component (10 versus two). Other demographic data were approximately equal in both groups. Patients' maximum knee flexion angle was higher in the high flexion group by an average of approximately 10° ($110.9^\circ \pm 19.3^\circ$ versus $99.9^\circ \pm 24.3^\circ$; Mann-Whitney $p = 0.24$). Combined femoral and tibial component flexion angle (as measured in the sagittal plane from radiographs) was also higher in the high flexion group by less than 1° on average ($6.7^\circ \pm 2.0^\circ$ versus $5.8^\circ \pm 2.3^\circ$; Mann-Whitney $p = 0.25$). The posterior-stabilized group had a greater degree of component valgus alignment (8.1 ± 2.3 versus 4.6 ± 3.8 ; Mann-Whitney $p < 0.01$).

Two examiners (NRP, MGT) were blinded to implant demographic details (such as duration of implantation) and carried out a modified damage analysis based on the protocol described by Hood et al. [13]. Inserts were inspected under low-power magnification (up to $10\times$) by dissecting light stereomicroscopy (SZ-CTV; Olympus, Tokyo, Japan). We assessed each tibial insert individually for damage mode and severity and gave an appropriate score. The damage modes assessed included burnishing, abrasion,

Fig. 1 Design of the high flexion (left) and posterior-stabilized (right) Genesis® II tibial inserts. The three-dimensional geometries were acquired from micro-CT scanning.

Table 1. Patient demographics

Variable	Genesis® II PS	Genesis® II HF
Total number of patients	20	20
Sex	5 female, 15 male	5 female, 15 male
Age (years)	67 ± 9 (47–82)	62 ± 9 (48–85)
Length of implantation (years)	1.7 ± 1.0 (0.3–3.5)	1.7 ± 1.0 (0.3–3.6)
Body mass index (kg/m ²)	33.8 ± 6.6 (17.0–43.0)	33.6 ± 6.2 (25.0–47.0)
Reason for revision	65% (13) infection 10% (2) aseptic loosening 25% (5) other/unknown	55% (11) infection 10% (2) instability 35% (7) other/unknown
Revision history	80% (16) implanted as primary 15% (3) implanted as first revision 5% (1) implanted as second (+) revision	65% (13) implanted as primary 30% (6) implanted as first revision 5% (1) implanted as second (+) revision
Oxinium bearing surface	10% (2)	50% (10)
Insert size	4.4 ± 1.6 (1/2–7/8)	4.6 ± 1.2 (3/4–7/8)
Insert thickness (mm)	14.0 ± 3.1 (11–21)	14.3 ± 3.78 (9–25)
Maximum flexion angle (degrees)	99.9 ± 24.3 (45–125)	110.9 ± 19.3 (70–145)

PS = posterior-stabilized; HF = high flexion. Reason for revision, revision history, and Oxinium bearing surface are listed as percentage of total (number). All others are listed as mean ± SD (range).

deformation, scratching, pitting, embedded debris, and delamination. We divided the tibial insert surfaces into 16 zones (Fig. 2). Both lateral and medial condylar articulating surfaces were divided into four quadrants with the tibial post divided into anterior, medial, lateral, and posterior zones. We also divided the backside (inferior) surface into four quadrants. For each damage mode, scores ranging from 0 to 3 were ascribed to each zone depending on the area covered by the damage. A score of 0 represented no damage to the zone, whereas scores of 1, 2, or 3 represented less than 10%, between 10% and 50%, or greater than 50% coverage area of the zone, respectively. The final score was calculated from an average of the two examiners. If a score discrepancy of two or greater occurred, reexamination by both assessors was performed. Articular surface damage was calculated from the eight articular zones, backside surface damage was calculated from the four backside zones, post surface damage was calculated from the four post zones, and total surface damage was calculated from all 16 zones.

Throughout the evaluation of insert surface damage, it became apparent that several inserts in both the high flexion and posterior-stabilized groups demonstrated notching damage and/or deformation of the tibial post. To better visualize and quantify the damage, we scanned these inserts using micro-CT and analyzed them by using a previously described approach [29, 30]. The inserts with the most severe anterior and posterior post notching in each group were selected for scanning, along with a high flexion insert with severe post deformation, for a total of five scanned inserts. Inserts were individually scanned and

Fig. 2 The retrieved tibial inserts were divided into 16 zones for damage scoring. A left-sided insert is shown with four divisions each for the lateral condyle of the articular surface (1–4), tibial post (5–8), medial condyle of the articular surface (9–12), and backside surface (13–16).

reconstructed using a laboratory micro-CT scanner (eXplore Vision 120; GE Healthcare, London, Canada). Scans were completed using an isotropic resolution of 50 µm over 1200 views with 10 frames averaged per view at an exposure time of 16 ms. The x-ray tube voltage was 90 kV and used a current of 40 mA. Image volumes were reconstructed at the full isotropic resolution (50 µm). We then used three-dimensional micro-CT analysis software (MicroView v2.2; GE Healthcare) to segment the insert from the image volume and generate a three-dimensional surface model of the insert geometry. The depths of the post notching were measured from planar views of the inserts using the software's line measurement tool.

We determined differences in damage scores (for the overall score, articular surface, backside surface, and tibial post) between the high flexion and posterior-stabilized groups using the Wilcoxon matched-pairs signed rank test. When a difference was found for one of these analyses,

further differences in damage scores by damage type and damage quadrant location between the high flexion and posterior-stabilized groups were determined using the same test. We determined the correlation between flexion angle and damage score using the Spearman correlation, recording both the correlation coefficient (r^2) and whether the slope was significantly nonzero.

Results

We found no difference ($p = 0.09$) in the total damage score between the high flexion and posterior-stabilized groups. From a maximum possible total damage score of 336, the high flexion group had a mean score of 55.1 ± 15.4 , whereas the posterior-stabilized group had a mean score of 49.2 ± 12.3 . All 40 tibial inserts demonstrated evidence of damage across the various regions of the inserts. Burnishing, pitting, and scratching were the

primary damage modes found for both high flexion and posterior-stabilized groups (Fig. 3A). There was no correlation between patients' maximum degree of flexion and total damage score in the high flexion group ($r^2 = 0.46$, $p = 0.06$) or in the posterior-stabilized group ($r^2 = 0.31$, $p = 0.26$). Similarly, there was no correlation between component flexion and total damage score in the high flexion group ($r^2 = 0.26$, $p = 0.27$) or in the posterior-stabilized group ($r^2 = 0.22$, $p = 0.49$).

We found no difference between the high flexion and posterior-stabilized groups for the lateral articular surface damage score ($p = 0.56$), the medial articular surface damage score ($p = 0.36$), or the overall articular surface damage score ($p = 0.71$). There was no difference between the lateral and medial condyles for either the high flexion ($p = 0.69$) or posterior-stabilized ($p = 0.89$) groups. From a maximum possible overall articular surface damage score of 168, the high flexion group had a mean score of 39.5 ± 12.8 , whereas the posterior-stabilized group had a

Fig. 3A–D Graphs of mean damage scores for the different damage modes in each of the high flexion (HF) and posterior-stabilized (PS) groups for overall score (A), articular surface (B), backside surface (C), and tibial post (D).

mean score of 37.4 ± 10.2 . The primary damage modes on the articular surface were burnishing, scratching, and pitting for both the high flexion and posterior-stabilized groups (Fig. 3B). There was no correlation between patients' maximum degree of flexion and articular surface damage score for either the high flexion group ($r^2 = 0.31$, $p = 0.22$) or the posterior-stabilized group ($r^2 = 0.42$, $p = 0.12$). There was also no correlation between component flexion angle and articular surface damage score for either the high flexion group ($r^2 = 0.26$, $p = 0.27$) or the posterior-stabilized group ($r^2 = 0.17$, $p = 0.60$).

We observed greater ($p < 0.01$) backside damage for the high flexion group in comparison to the posterior-stabilized group. From a maximum possible backside surface damage score of 84, the high flexion group had a mean score of 8.3 ± 3.6 , whereas the posterior-stabilized group had a mean score of 6.3 ± 2.7 . The damage was greater only in the anterolateral quadrant, 2.0 ± 1.1 versus 1.2 ± 0.7 ($p = 0.01$). The primary damage modes on the backside surface were burnishing and scratching for both the high flexion and posterior-stabilized groups (Fig. 3C). Burnishing was greater in the high flexion group ($p = 0.03$). There was moderate correlation between patients' maximum degree of flexion and backside damage score in the high flexion group ($r^2 = 0.50$, $p = 0.03$) but no correlation in the posterior-stabilized group ($r^2 = -0.20$, $p = 0.46$). However, there was no correlation between component flexion angle and articular surface damage score for either the high flexion group ($r^2 = 0.06$, $p = 0.79$) or the posterior-stabilized group ($r^2 = 0.35$, $p = 0.27$).

We also found greater ($p = 0.01$) post damage for the high flexion group in comparison to the posterior-stabilized

group. From a maximum possible post damage score of 84, the high flexion group had a mean score of 7.4 ± 2.3 , whereas the posterior-stabilized group had a mean score of 5.5 ± 1.9 . The damage was greater in the high flexion group on the posterior side (4.2 ± 0.9 versus 3.2 ± 1.0 ; $p = 0.02$) and medial side (1.1 ± 0.6 versus 0.5 ± 0.5 ; $p = 0.02$) of the post. The primary damage modes on the post were burnishing and deformation for both the high flexion and posterior-stabilized groups (Fig. 3D). Burnishing was greater in the high flexion group ($p < 0.01$). There was moderate correlation between patients' maximum degree of flexion and post damage score in the high flexion group ($r^2 = 0.48$, $p = 0.04$) but no correlation in the posterior-stabilized group ($r^2 = 0.16$, $p = 0.56$). There was no correlation between component flexion angle and articular surface damage score for either the high flexion group ($r^2 = 0.33$, $p = 0.16$) or the posterior-stabilized group ($r^2 = 0.07$, $p = 0.69$). Micro-CT was able to visualize the anterior (Fig. 4A–B) and posterior (Fig. 4C–D) notching of the post in both the high flexion and posterior-stabilized inserts along with the severe deformation of the high flexion post (Fig. 4E–F). The depths of the notching measured with micro-CT ranged from 0.6 to 1.9 mm.

Discussion

Implant design remains an evolving area of orthopaedics that has the ability to shape patient outcomes and the patient's evaluation of a surgery's success. High flexion inserts were designed to provide increased ROM; however, concerns have also been raised that these design changes

Fig. 4A–F Micro-CT images of tibial post notching (arrows) and deformation: anterior high flexion post (A), anterior posterior-stabilized post (B), posterior high flexion post (C), posterior posterior-stabilized post (D), top view of deformation of a high flexion post (E), and front view of deformation of a high flexion post (F).

may have deleterious effects on polyethylene wear [24]. We therefore examined how the design changes and altered kinematics between high flexion and posterior-stabilized tibial inserts would affect their (1) overall damage profile and more specifically the damage on their (2) articular surface; (3) backside; and (4) tibial post. We also examined the correlation between flexion angle and damage score.

We acknowledge several limitations with this study. First, like with any retrieval study, the components removed at revision surgery may not be representative of well-functioning implants. Second, while matching groups to be as similar as possible, we were confined by a sample of convenience available at our institution. The efforts made to ensure that the duration of implantation, BMI, and age were identical between groups resulted in a difference between bearing surfaces (Oxinium). Although this may seem like an obvious confounder, recent retrieval literature of Genesis® II inserts with Oxinium versus cobalt-chromium femoral components suggests that the Oxinium group would be expected to have less damage [11], whereas the group in this study with more Oxinium bearings demonstrated either no difference or greater damage than the group with more cobalt-chromium bearings. These contrary results lead us to believe that Oxinium did not have a major role in the findings of greater backside and post wear in the high flexion group. Furthermore, there was a slightly higher percentage of high flexion inserts implanted as (and subsequently retrieved from) a revision surgery. More data regarding patients' knee flexion were available for the high flexion group than the posterior-stabilized group with data available for 18 of 20 patients in the high flexion group versus 15 of 20 in the posterior-stabilized group. In addition, the flexion angle measured was only available preoperatively to the revision surgery for five of 20 patients in the posterior-stabilized group versus two of 20 in the high flexion group. This may have affected the relationship we determined between the patients' maximum degree of flexion and damage score, particularly in the posterior-stabilized group, in which no correlation was found. Similarly, radiographs were not available for eight of 20 patients in the posterior-stabilized group, so component flexion/extension and varus/valgus alignment could not be measured. Radiographs were available for all 20 patients in the high flexion group. Third, we did not collect details regarding patient activity levels. Increased activity and demand on the joint could potentially result in increased damage attributable to increased contact stresses. If the high flexion group had greater activity levels, this could also have contributed to the greater backside and post damage seen in that group. Lastly, although the duration of implantation for the implants is relatively low because of matching for the high flexion implants, it mirrors the time in which these

implants have been commercially available and remains the first reported retrieval study to look at these contemporary inserts. A major strength of the study is that although the bearing type may have been different between groups, all other design aspects (ie, the tibial baseplate and femoral component) were identical between groups.

It was not surprising that the overall damage scores between the two cohorts were similar. Wear is caused by a number of factors including implant factors, surgical factors, and patient factors [14, 31]. We attempted to control for these variables with the exception of implant geometry. The native knee achieves flexion past 120° by the lateral femoral condyle rolling back and perching on the edge of the lateral tibial plateau, whereas the medial femoral condyle rides up, losing contact with the tibial plateau [25]. The re-creation of these forces in deep flexion was believed to have implications for wear in the posterior lateral quadrants of high flexion inserts. In general, it has been noted that the lateral compartment of the insert may be prone to greater wear as a result of abnormal flexion kinematics [12]. However, both groups demonstrated equal articular surface damage, suggesting that if patients achieving deep flexion are recreating these forces, it is not affecting the polyethylene. In keeping with the literature [12, 14, 20], the primary modes of damage to the articular surface of our implant series were burnishing, pitting, and scratching.

Backside wear in TKA has long been established as source of polyethylene debris [5, 7, 21]. The moves toward polished tibial trays, improved sterilization, and better locking mechanisms have all served to mitigate the source of the problem [31]. The potential for a high flexion insert to have increased contact stresses in deep flexion may explain our findings that the high flexion cohort had substantially greater overall damage to the backside. Backside damage was correlated to patients' maximum degree of flexion in the high flexion group. Nonetheless, the primary mode of backside damage remained scratching, which can likely be accounted for by third-body cement debris [21]. However, both groups have identical locking mechanisms, tibial trays, and sterilization methods, resulting in an unclear explanation for the greater backside damage in the high flexion cohort. One potential reason for the increased backside damage in the high flexion group is the use of GUR 1020 resin. This resin, which has a lower abrasive resistance than GUR 1050 [27], was used in the posterior-stabilized group. Scratching was the predominant mode of backside damage, and burnishing was also greater in the high flexion group than the posterior-stabilized group. Scratching and burnishing are both types of abrasive wear. The benefit of GUR 1020 over 1050 is increased impact strength [27]. Our findings are consistent with a link established between increased backside damage scores and increased post damage scores [14].

Tibial post damage in TKA remains an important issue [26] with the incidence of failure resulting from post fractures estimated at approximately 1% [17] but recorded as high as 12% in one implant series [2]. One recent study of three contemporary inserts established that tibial post damage was primarily determined by the insert design and to a lesser extent the duration of implantation and revision diagnosis [6]. The PS Genesis® II has performed well against other contemporary inserts, demonstrating overall lower damage scores [6] as well as lower peak contact stress at all flexion angles in neutral tibial rotation [9]. However, the PS Genesis® II was more prone to damage to the posterior aspect of the post than other inserts [6]. Our results indicate the high flexion inserts have greater damage to the post than the posterior-stabilized inserts, particularly on the posterior and medial aspects. These results are interesting, because in one reported series of post fractures, every case occurred in patients with a high flexion arc and took place while patients were performing deep flexion activities [23]. Post damage was correlated to patients' maximum degree of flexion in the high flexion group. However, it is important to note that to date, we have not experienced any post fractures with the Genesis® II implant. These results may be more worthy of note when one considers the use of highly crosslinked polyethylene in posterior-stabilized TKA. Although early reports of simulator testing have reported reduced wear and superior tibial post durability in highly crosslinked inserts [28], it is unclear whether reduced wear and increased durability are achieved in vivo. One early report of crosslinked posterior-stabilized inserts has already documented post fractures in a different implant design [15].

We found that although the overall damage scores remain consistent with the conventional posterior-stabilized group, the high flexion inserts demonstrated increased backside and post wear. This may have been related to greater flexion in the high flexion group. The average patients' maximum degree of flexion tended to be greater (10°, not significant) in the high flexion group, and both backside and post damage were correlated to this flexion angle. However, damage was not correlated to this flexion angle in the posterior-stabilized group, for which less flexion angle data were available. It is therefore difficult to conclusively state whether the differences in damage were flexion- or design-dependent. Although several meta-analyses and randomized controlled trials have concluded that high flexion implants offer minimal or no gains in overall flexion [22, 24], it remains unknown whether the increased contact forces in deep flexion are responsible for the elevated post and backside wear. Our observations shed light on the potential increased vulnerability of the tibial post in high flexion implants. Furthermore, these findings

suggest the introduction of a highly crosslinked high flexion insert will require close scrutiny and monitoring as a result of the increased strain and potential for post damage demonstrated in this series.

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