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Research Article

Mechanical Failures of Rotating Hinge Total Knee Arthroplasty - 15% rate of Hinge Mechanism Fracture at mean of 31 Months

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Abstract

Background: The introduction of rotating hinge knee replacements was intended to reduce the frequency of mechanical complications associated with early hinge designs. This study will assess the survival of the LegionTM rotating hinge system, a third-generation system from Smith and Nephew, undertaken by 6 surgeons at a tertiary arthroplasty centre in the UK. **Methods:** Data was collected for consecutive patients between 2013 and 2021 undergoing total knee arthroplasty (primary or revision) using the LegionTM system by reviewing electronic patient records, radiographs, and operative records. Survival of the hinged implants was compared with lesser constrained Legion implants. **Results:** There were 34 rotating hinge knees implanted among 31 patients with median follow up 75 months. There were 15 complex primary TKAs, 13 single stage revision, and 6 two stage revisions. There were 6 instances of subsequent revision between 4 patients, 5 failures were due to mechanical failure of the hinge mechanism, one patient experienced recurrence of prosthetic joint infection. Among lesser constrained Legion implants, the revision rate was 6%. **Conclusion:** This series has demonstrated a high rate of mechanical failure for this implant. We hypothesise a method of failure and would recommend a high index of suspicion for patient with this implant experiencing pain or instability. We advise caution when considering this implant for patients with gross instability or a severely attenuated soft tissue envelope, and we would advise caution when considering limited revision of the hinge mechanism in the setting of early mechanical failure.

Keywords: Failure; Legion; Rotating Hinge; Mechanical Failure; Total Knee Arthroplasty

Introduction

Total Knee Arthroplasty (TKA) is a common treatment for patients suffering from end-stage knee arthritis, and modern knee implants have a low complication rate and long survivorship. Hinge-Linked Total Knee Arthroplasty (HTKA) was developed to address severe knee instability, deformity, and ligamentous or extensor mechanism insufficiency and can be used in the primary or revision setting. Initial HTKA designs were prone to complication, primarily due to aseptic loosening or hinge failure due to high forces transmitted across the hinge or at the bone prosthesis interface, [1,2] because these designs did not allow any axial rotation. Modern hinge designs typically allow axial rotation around the axis of the tibia and so are called rotating hinge TKA (rHTKA), this additional degree of freedom reduces force transmission resulting in lower rates of aseptic loosening and mechanical failure, while also improving patellofemoral dynamics reducing the rate of instability. [3] At our UK institution (a tertiary revision arthroplasty centre), the LegionTM Hinge Knee System (Smith and Nephew, Memphis, TN, USA) is the rHTKA used when a high level of constraint is required, be that for complex primary arthritis, or in the revision setting with septic or aseptic loosening of previously implanted TKAs with associated severe bone loss, deformity or ligamentous incompetence. In this linked implant, the femoral and tibial components are connected by a metal and polyethylene bush. This bush allows for flexion/extension by rotating around an axel through the condyles of the femoral component, while also allowing axial rotation around a tibial post which is fixed to the tibial component via a morse taper supplemented with a bolt. The sleeve also allows a small amount of longitudinal translation of the bush along its length (Figures 1 and 2). There is little published data on the survivorship of this implant. After local anecdotal evidence of mechanical failures of this prosthesis were noted, a retrospective review of our results was undertaken.

Methods

Design

This is a retrospective review of electronic patient records for all patients who had undergone total knee replacement at our institution utilising the rHTKA Legion system (between implant introduction in our department in January 2013, and December 2021). For comparison, we also undertook a limited review of surgeries utilising less constrained Legion implants. Figures 1 and 2 demonstrate schematics of the Legion implant with correct nomenclature used in this paper.

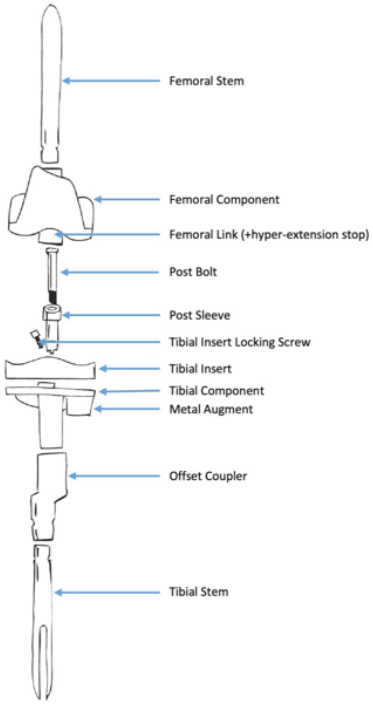


Figure 1: Schematic of Legion rHTKA with component nomenclature (modified from the Legion Surgical Technique [4]).

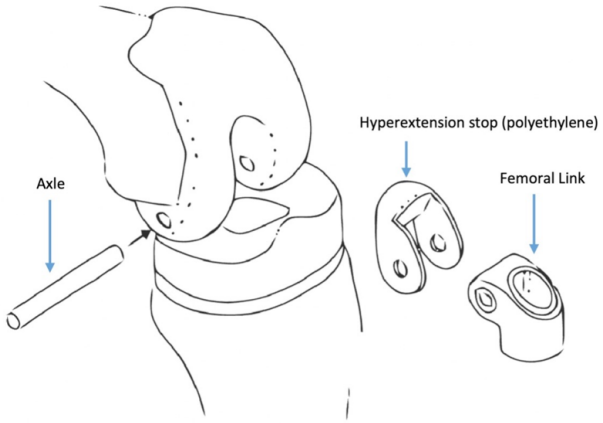


Figure 2: Femoral link assembly (modified from the Legion Hinge disassembly & rebuild Technique [5])

Patients

Electronic theatre records were interrogated for the terms: “revision total knee”, “Legion total knee”, “complex primary total knee”. Patient’s electronic records were reviewed including indication for surgery, imaging, biochemistry and microbiological samples, and clinic letters. An initial search returned 248 surgical

procedures. Patients were excluded if the implant used was not the Legion system (n=18), if it was an isolated liner exchange (n=4), if the procedure undertaken was part of a DAIR (debridement, antibiotics and implant retention) for infection (n=2), or if they had registered with the National Data Opt Out service (NDOO) (33). In all there were 34 instances of patients undergoing TKA using the Legion hinge system (between 31 patients, 11M:20F). Median age was 72 (range 56 to 92), mean body mass index (BMI) was 31.2 (range 22.1 to 45.9). There were 157 instances of patients undergoing TKA with less constrained legion implants (between 151 patients).

Surgical Procedure

Patients underwent standardised pre-operative workup and screening. Prophylactic antibiotics were given prior to incision and variations of medial parapatellar approach was used to expose the knee (as per individual surgeon preference). In cases of revision surgery, all patients had undergone a clinical work up to exclude infection as the cause for failure of the primary implant or, in the case of a second stage for revision surgery, to exclude persistent infection after first stage. Procedures were performed in accordance with the surgical technique and all surgeons had undertaken training with the Legion implant. During revision procedures, multiple joint samples were taken for microbiological assessment to exclude infection. Antibiotics were continued post operatively as a matter of routine, until microbiological samples had been reported as negative for infection on extended cultures.

Ethical Considerations

This project was registered with the hospital's information governance department as a service evaluation project, and Caldicott approval was granted on the basis that any patient's data be excluded if they had registered with NDOO.

Results

Median radiographic follow up was 24 months (IQR 13-47). Median time since implantation was 75 months (IQR 49-96). Indications for Legion rHTKA can be seen in table 1, along with numbers subsequently revised. There were 7 instances of further surgery involving revision of four rHTKA patients. Five of 7 were for mechanical failure of the hinge mechanism, The other two were a staged revision for a single patient due to recurrence of periprosthetic infection, this is counted as a single revision. This gives an overall revision rate of 18% (6/34) among the rHTKA implants, and 15% (5/34) for mechanical failure. The mean time to revision was 30.8 months. Characteristics can be seen in table 2.

Indications for Legion rHTKA, and number of subsequent revisions		
Indication	**Number of cases**	**Subsequently revised**
Complex primary	15	2 (13%)
Single stage revisions	13	1 (8%)
Two stage revisions	6	3 (50%)

Table 1: Indications for Legion rHTKA, and number of subsequent revisions.

Legion rotating hinge revision cases				
Identifier/ Age / BMI	**Date of index procedure**	**Indication**	**Implants**	**Further management**
Patient A 74 26.2	04-04-2016	Single stage revision of Legion (constrained) for cam jump instability	4 tibia 11x160 stem 5 femur 15 5 femur 15x160 stem 155mm poly, 15mm bolt/sleeve	Revision of hinge mechanism with the same size bolt and sleeve June 2022 (6yr2m)
Patient B 62 30.8	21-04-2016	Complex primary, valgus arthritis with incompetent medial collateral ligament	Size 2 tibia, 9x120 stem Size 4 femur, 13x120 stem 15mm poly, 15mm bolt/sleeve	Limited revision of femur and hinge mechanism with thicker (21mm) poly Nov 2017 (19 months) Ongoing instability demonstrated on subsequent radiographs, further revision to a different implant Jun 2018 (7 months)
Patient C 65 26.2	19-09-2019	2nd Stage revision for infection (Propionibacterium acnes)	size 3 tibia 12x160 press fit stem size 5 femur (+50mm augment wedge) 15x160 cemented stem 11mm poly, 11mm bolt/sleeve	2 stage revision for recurrence of infection September 2021(24 months)
Patient D 69 23.6	16-03-2017	2nd Stage revision for infection (Propionibacterium acnes)	size 3 tibia 13x220 press fit stem size 5 femur 18x160 cemented stem21mm poly, 21mm bolt/sleeve	Limited revision of hinge mechanism Jan 2022 (4yr10m) Tibia insert size 2-3 18mm 18mm bolt/ sleeve Further revision to knee arthrodesis April 2022 (3 months

Table 2: Legion rotating hinge revision cases

Patient A

A patient with a constrained Legion knee with a posterior stabilised insert presented with cam-jump instability. Patient A underwent revision to a Legion hinge in April 2016. There were no immediate post operative complications. They were discharged from follow up in September 2017 but re-presented acutely in April 2022 with several instances of knee locking and instability. Plain radiographs demonstrated anterior tilt of the hinge sleeve (Figure 3). Treatment with a brace was trialled with no improvement, the patient ultimately opted for re-revision (6 years after index Legion rHTKA). Limited revision of the hinge mechanism in was performed, retaining the tibial insert and replacing the post bolt/sleeve components and femoral link/axel. At revision, it was noted that the sleeve was loose within the tibial component, there was excessive wear within the polyethylene lining of the femoral link (Figure 4a, top right) and of the hyper-extension stop (polyethylene liner between the femoral link and the femoral component, (Figure 4a top centre). Additionally, the small location tab at the distal end of the sleeve had fractured off (Figure 4b). The patient was happy with the outcome of the revision surgery at follow up after 3 months and has not undergone any further procedures.

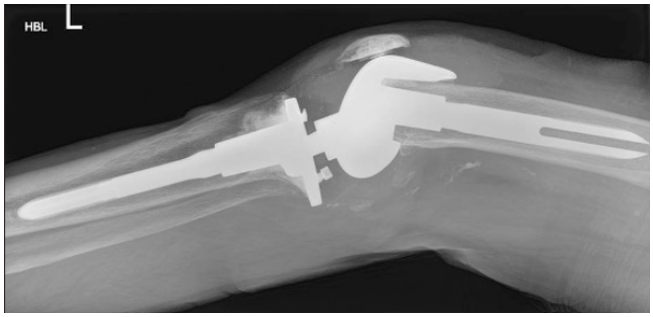


Figure 3: Lateral view of the left knee of patient A demonstrating clear anterior tilt of the hinge sleeve relative to the tibial baseplate

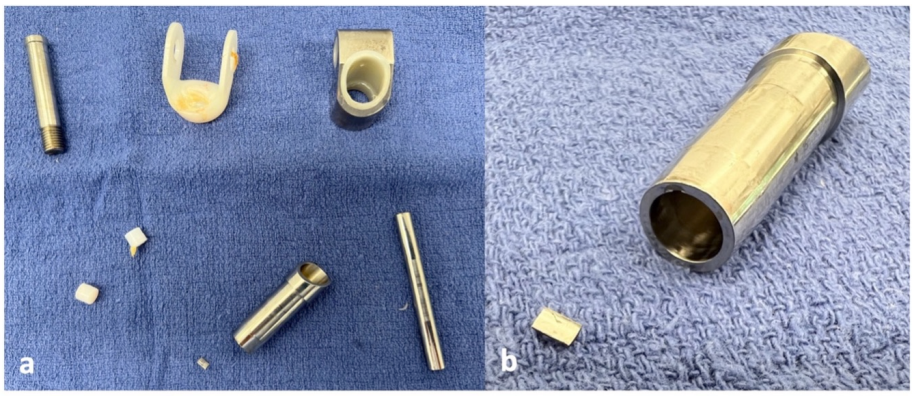


Figure 4: (a) photograph of explanted hinge mechanism from Legion Hinge of patient A, note wear of the polyethylene within the femoral link bushing, (b) photograph of hinge post sleeve part demonstrating small location tab fractured from main body.

Patient B

A patient with valgus knee OA and debilitating pain. They underwent complex primary right TKA with the Legion rHTKA to address a MCL deficiency, with no immediate complications. They were very happy with the outcome initially and went on to have a simple primary TKA on the contralateral knee. In August 2017 the patient came back to clinic for routine follow up with a complaint of increasing valgus deformity of the right (Legion hinge) knee, radiographs showed gapping between the tibial insert and the medial femoral condyle (Figure 5). Stress radiographs under anaesthetic (Figure 6) confirmed instability and gapping of the implant. There were no biochemical or arthroscopic features of infection. Revision surgery was undertaken November 2017 it was noted that axle was loose within the femoral component. The knee was trialled with a new hinge mechanism and remained unstable so the femoral component was revised, and the construct was felt to be stable with a thicker tibial insert. Almost immediately post operatively the patient reported that the knee felt unstable and had coronal plane instability on examination. The Legion hinge was ultimately revised to another implant in June 2018 (after allowing a period for the soft tissues to settle). At revision, it was noted that there was abnormal play of the post within the tibial component (i.e. the post sleeve/bolt was loose and the morse taper had disengaged).

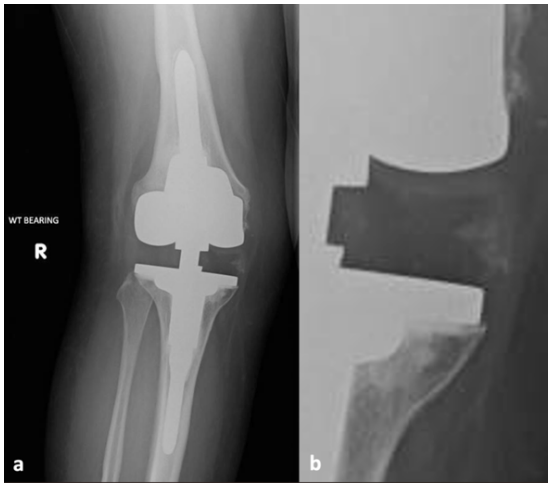


Figure 5: (a) AP view of right rHTKA of patient B at follow up 18 months. (b) magnified view of medial joint line showing gapping between medial femoral condyle and tibial insert.

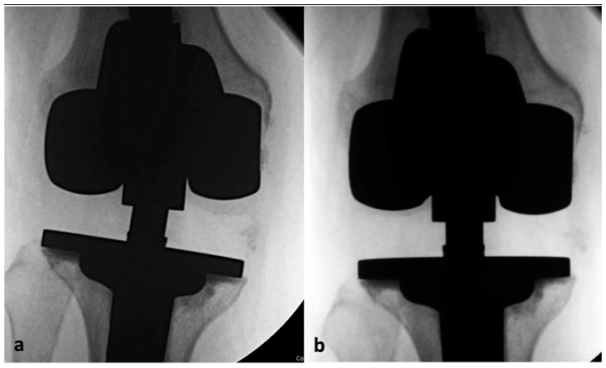


Figure 6: Fluoroscopy of right rHTKA of patient B with (a) valgus stress in extension demonstrating gapping medially, and (b) with varus stress demonstrating more subtle gapping laterally.

Patient C

This patient had a history of previous revision TKA, presented with a recurrence of infection. First stage revision was performed with implantation of a temporary antibiotic spacer in February 2019, and after treatment with IV antibiotics and a period of quiescence while not taking antibiotics, the second stage was completed in September 2019. At that time due to bone loss and flexion–extension imbalance a Legion rHTKA prosthesis was used. In July 2020 the patient was seen with worsening pain in the knee in the absence of trauma. The knee had evidence of recurrence of infection clinically and biochemically and so underwent a repeat staged revision procedure at another unit.

Patient D

A patient with a previously revised TKA (2 stage revision for infection) in 2006. He developed some progressive tibial subsidence so underwent 2 stage revision to a Legion rHTKA, the second stage in March 2017, without any complications. At the one year follow up a check x-ray suggested that the tibial insert retaining screw may have backed out. The patient was entirely asymptomatic, so the situation was monitored. At the 2 year follow up there was no change in the screw position and the patient remained asymptomatic. The patient re-presented in June 2021 with worsening left knee pain and swelling affecting his gait. There was no history of trauma. Check radiographs of the knee were unchanged, and the patient was placed on regular review. Four months later the patient complained of worsening pain and instability in the knee, and radiographs clearly showed fracture of the femoral link (Figure 7). In January 2022 a limited revision of the hinge mechanism was performed, using a thinner tibial insert in an attempt to reduce the stress over the construct. The femoral and tibial components were found to be well fixed at the time of revision. At the one month post operative review the patient was experiencing symptoms of instability and repeat radiographs showed anterior tilting of the post sleeve (Figure 8) similar to that seen in patient A, indicating failure of the hinge mechanism. The patient subsequently underwent knee arthrodesis.



Figure 7: lateral radiograph of rHTKA of patient C demonstrating fracture of the link bush



Figure 8: lateral radiograph of rHTKA of patient C taken 4 weeks post revision of hinge mechanism, demonstrating anterior tilting of the hinge sleeve relative to the tibial baseplate, indicating further mechanical failure of the hinge mechanism.

Lesser Constrained Implants

For comparison, during the same time period we identified 157 legion implants performed within the unit that were not hinge linked. These had an overall revision rate of 6% (n=9), revisions according to indication can be seen in table 3. A Kaplan Meier graph comparing the hinged and non-hinged prostheses can be seen in figure 9, a Log-Rank test showed this difference to be statistically significant (p=0.033).

Indications (and revisions) for non-hinge Legion cases		
Indication	**Number of cases**	**Required revision**
Complex primary	26	0
Single stage revision	76	4
Second stage revision	55	5

Table 3: Indications and subsequent revisions of non-hinge Legion TKA cases

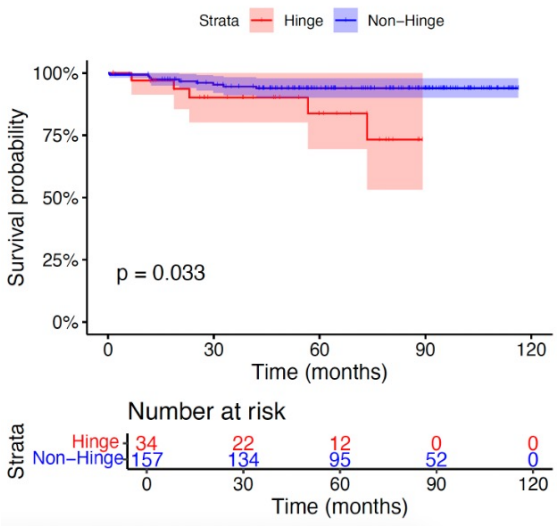


Figure 9: Kaplan Meier graph comparing hinged and non-hinged Legion implants

Discussion

This case series demonstrates a revision rate of 18% for the Legion rHTKA system, and a 15% rate of early mechanical failure of the hinge mechanism at mean of 30.8 months from implantation. The management of instability and bone loss in knee arthroplasty is a challenge which may be met with a number of different reconstruction methods. These include cementing techniques, bone grafting, metal augmentation, metaphyseal fixation with cones or sleeves, custom-made implants and prosthesis of increasing constraint, which include hinge-type implants. [6] Hinged rotating knee replacements, if used in the management of non-tumour associated reconstruction, have reported good clinical results and improved quality of life for patients. [7,8] The Legion rHTKA is utilised in our centre for patients, in both complex primary and

revision settings. Instability and early mechanical failure in rHTKAs, though infrequent, have been reported and pose a clinically significant complication as it often necessitates further intervention. [9,10] Other authors have previously reported instability with the Legion rHTKA. Van Laarhoven et al observe a 3.5% incidence of instability in their cohort of 169 patients. [11] On stress testing the Legion rHTKA in varus/valgus they observed excessive tilting of the link-bush mechanism. They also observed that if the joint is under distraction (when not under axial load) the force distribution between condyles and tibial liner is lost. The stress is therefore, placed purely upon the short link-bush system. This mechanism of failure is the same as was seen in patient B, as demonstrated by the varus/valgus tilt and condylar lift-off seen in figures 3 and 4. In their cohort, they managed this instability successfully with a brace in 50% of cases, and the remaining were managed with limited revision of the liner and hinge mechanism, with no mention of further revisions. Limited revision of the sleeve/bolt connection was attempted in 2 cases, and both rHTKAs went on to rapidly fail. In both patients B and D a liner exchange was performed as well to alter tension in the soft tissue envelope and offload the hinge mechanism, but the outcome was unsuccessful. Van Laarhoven did not report their duration of follow up although it can be inferred that it could be up to 6 years and there was no stated follow up for those who had undergone limited revision. In their conclusion, van Laarhoven et al do not recommend the use of the Legion rHTKA in specific patients (multidirectional instability, posterior capsule insufficiency, grossly imbalanced flexion extension gaps, extensor mechanism insufficiency, or revision of a more rigid rHTKA system) due to the tilting and wear observed by the less rigid design of the Legion compared to other devices such as the RT-PLUS (Smith and Nephew). Perrin and Turgeon report on their experience with the Legion rHTKA system [12] in 39 implants with 2 years follow up. They report a 2-year survival of 90.7%, with only one patient (2.5%) experiencing early failure of the hinge mechanism after a fall. There were no traumatic events documented for any of the failures in our study, and in 2 of the 3 patients who experienced hinge failure (the first time) the time to failure occurred several years after implantation. Perrin et al do not record their long term results. Failure of the hinge mechanism in rHTKAs is reported to be exceedingly rare. [13] Bornes et al [14] report on outcomes of 115 rHTKAs with a mean follow up of 3 years and only report one episode of hinge component failure out of 115 (0.9%). The rHTKA in their series are various designs, 35 of which were Legion rHTKAs, however, the authors do not specify which model of rHTKA experienced mechanical failure. In another series of 86 rHTKAs [15] with a mean follow up of 5 years there was only one hinge related failure (Link rotating hinge, Waldemar LINK GmbH and Co, Hamburg, Germany). Cottino et al [16] report on 408 rHTKAs (varying models, no Legions included) with mean follow up 4 years and identified 10 mechanical failures (2.5%), although they do not elaborate on the nature of the failure. Bruce et al report on 53 NexGen rHTKAs with a mean follow up of 7.6 years with only one hinge failure, treated successfully with revision of the modular hinge components [17]. Several case series for other implants do not report on any instances of hinge failure for implants including NexGen (Zimmer Biomet) [18-20]. Modular Rotating Hinge System (Stryker) [12], MUTARS GenuX MK, (Implantcast GmbH) [21] GMK Hinge (Medacta international) [22]. One reported method of failure of rHTKAs is dislocation of the hinge mechanism [23,24] indeed in some rHTKA designs the femoral and tibial components are not technically connected, but linked by a post that can rotate and piston within a barrel on the opposing part such as with the S-ROM NOILESTM (DePuy Synthes). Dislocations are avoided by ensuring a large 'jump distance' however with a severely compromised soft tissue envelope, this jump distance can be exceeded. Other rHTKA designs have avoided this complication by incorporating a mechanical link between the femoral and tibial components, as is seen in the Legion.

In the Legion, the rotating hinge mechanism consists of a link-bush mounted on an axle between the condyles of the femoral component. This femoral link has multiple polyethylene linings, sagittally between itself and the femoral component (referred to as the hyper-extension stop), itself and the axle, and axially it rotates around a post-sleeve which engages with the tibial component via a morse taper, and has secondary fixation via a post-bolt which screws into the tibial component using a torque wrench (Figure 1). According to the manufacturer, there is a requirement for 96% of the load through the implant to occur via condylar loading to remove the stress placed upon the femoral link [25]. We hypothesise that for this 96% condylar loading to occur, the soft tissue envelope must be of sufficient competency so as to exert some compression across the tibial insert even during the swing phase of gait. However, if the soft tissue envelope cannot be relied upon to provide such a force, as is possible with multiply revised knees or those without competent collateral ligaments, this condylar loading may not occur. In such a situation excessive forces would be transmitted across the hinge mechanism and in turn lead to stress hardening of the hinge components and ultimately, fracture. This is what we hypothesise happened in the case of patient D when the femoral link fractured (Figure 7).

Patients A, B and D all demonstrated loosening of the post sleeve within the tibial component. For this to occur the fixation must fail in 2 places, the appropriately torqued post bolt must become loose; there is evidence of this in Figure 4a (top centre) with focal wear of the polyethylene bushing between the femoral link and the femoral component. The morse taper must then disengage from the tibial component sufficiently for the small metal tab at its distal aspect to fracture off, and become entrapped such that the morse taper cannot re-engage, allowing the anterior tilt of the post seen

in figures 3 and 8. We suggest that a significantly attenuated soft tissue envelope could allow this at times when the leg is lifted (e.g. during swing phase of gait) and if combined with repeated axial rotations could lead to loosening of the post bolt and ultimately the morse taper.

Limitations

There are several arthroplasty surgeons in our unit performing revision operations and therefore it is difficult to standardise the treatment for all. Patients also have varying indications for revision surgery and therefore their post operative plan and result will vary. Another limitation to our study includes its retrospective study design.

Further prospective work with a standardised approach and post operative stress radiographs at set time intervals could detect any instability or impending catastrophic implant failure. There are no patient reported outcomes measures, however this was outside of the scope of this study.

Conclusion

Despite design advancements and evidence that supports the use of rotating hinge arthroplasty in knee revision surgery, this subset of patients presents complex surgical challenges placing them at risk for complication. Rotating hinge systems such as the Legion have their place in knee arthroplasty both in the complex primary and revision setting but may not have the durability required for some patients. We present five instances of early mechanical failure of the Legion rHTKA in three patients and propose the method of failure. This series emphasises the importance of careful implant selection for patients with gross instability or significantly attenuated soft tissue envelope. Long-term prospective studies with standardized follow-up protocols, including stress radiographs, are warranted to further evaluate the characteristics of rHTKAs in such patients and guide improvement in hinge knee arthroplasty technology and better define its indications for use in this patient cohort.

At present, we believe that major revision units should not rely on a single hinge system to cover all potential hinge cases. Each case requires careful evaluation, and a hinge knee system selected which best fits the patient's needs. We advise caution when considering use of this prosthesis for patients with multiply revised knees or those with gross instability. In cases of mechanical failure, we would recommend caution if considering limited revision of the hinge mechanism. While this is potentially a less invasive option, in this series it was unsuccessful in 2 out of 3 cases.

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