High ten-year implant survivorship and low patellofemoral complication rate for S-ROM rotating-hinge implants in revision total knee arthroplasty

A SINGLE-CENTRE STUDY

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Aims

The aim of this study was to evaluate medium-term outcomes and complications of the S-ROM NOILES Rotating Hinge Knee System (DePuy, USA) in revision total knee arthroplasty (rTKA) at a tertiary unit.

Methods

A retrospective consecutive study of all patients who underwent a rTKA using this implant from January 2005 to December 2018. Outcome measures included reoperations, revision for any cause, complications, and survivorship. Patients and implant survivorship data were identified through both local hospital electronic databases and linked data from the National Joint Registry/NHS Personal Demographic Service. Kaplan-Meier survival analysis was used at ten years.

Results

A total of 89 consecutive patients (89 knees) were included with 47 females (52.8%) and a median age of 74 years (interquartile range 66 to 79). The main indications were aseptic loosening with instability (39.4%; n = 35) and infection (37.1%; n = 33) with the majority of patients managed through two-stage approach. The mean follow-up was 7.4 years (2 to 16). The overall rate of reoperation, for any cause, was 10.1% (n = 9) with a rate of implant revision of 6.7% (n = 6). Only two cases required surgery for patellofemoral complications. Kaplan-Meier implant-survivorship analysis was 93.3% at ten years, using revision for any cause as an endpoint.

Conclusion

This implant achieved high ten-year survivorship with a low complication rate, particularly patellofemoral complications. These can be avoided by ensuring central patella tracking and appropriate tension of the patellofemoral joint in this posterior hinge design.

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Keywords: Revision total knee arthroplasty, Rotating-hinge component, Case series, Clinical outcomes, Survivorship

Introduction

The indications for a rotating-hinge implant in revision total knee arthroplasty (rTKA) practice are well-established. These include gross multidirectional instability or flexion-extension mismatch, bone loss that compromises ligament attachments, and collateral ligament deficiency, particularly of the medial collateral ligament, among others. Early hinged designs only allowed for flexion-extension motion. This high level of constraint led to high failure and complication rates. Varus-valgus motion and axial rotation were introduced in second-generation designs, reducing the level of prosthetic constraint and subsequently the torque stresses on the implant-cement and implant-bone interfaces. More
Contemporary third-generation implants saw the introduction of an improved rotating-hinge mechanism, improved patellofemoral biomechanics, increased component modularity, and improved fixation techniques leading to significant improvements in survivorship and clinical outcomes.\(^8\)\(^-\)\(^{11}\)

Survivorship ranges from 51% to 92.5% at up to ten-year follow-up with complication rates ranging from 9.2% to 63%, as reported in a systematic review of rotating-hinge implants in rTKA.\(^12\) Patellofemoral complications remain high, with patella subluxation reported in 29.6% of cases in a recent contemporary series.\(^13\) Patellofemoral instability following a rotating-hinge implant is multifactorial with patient-, surgical-, and implant-related factors. The mobile bearings in contemporary hinges allow rotation with varying degrees of constraint, shapes, and mechanisms in different prostheses, with some having a long rotating tibiofemoral axis, a short and intra-articular one, or with a fixed longitudinal axis.\(^14\)

The S-ROM NOILES Rotating Hinge Knee System (DePuy, USA) is well-established and widely used. However, high rates of patellofemoral complications have been reported with this prosthesis.\(^15\)-\(^{18}\) The mobile-bearing insert in this system is congruent with the femoral component with a flat undersurface where rotation occurs at the insert-tibial tray interface. The aim of this study was to evaluate the outcomes of this prosthesis at medium-term follow-up in rTKA at our tertiary unit.

**Methods**

This was a retrospective consecutive study of all patients who underwent a rTKA using S-ROM implant between January 2005 and December 2018. Local institutional study approval was obtained. Patients were identified using a local prospective database and linkable data obtained from the National Joint Registry (NJR) for rTKA. Surgeries were performed by two authors (BVB, PJJ). We excluded patients that required endoprostheses with distal femoral arthroplasties and patients with periprosthetic fractures.\(^19\),\(^20\) Demographic, clinical, and surgical data were collected from patients’ electronic health records. All patients underwent routine preoperative anaesthetic assessment and received a spinal anaesthetic with upper thigh sterile tourniquet and perioperative prophylactic antibiotics. Postoperatively, full weight-bearing was commenced as tolerated with routine physiotherapy. Follow-up was performed regularly at six weeks and three months, and every 12 months thereafter.

**Implant.** The S-ROM Rotating Hinge Knee System is a third-generation modular mobile-bearing prosthesis that

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**Table I.** Baseline characteristics and indication for surgery.

| Characteristic                      | Total |
|-------------------------------------|-------|
| Patients/knees, n                   | 89/89 |
| Median age, yrs (IQR)               | 74 (66 to 79) |
| Female, n (%)                       |       |
| Median BMI, kg/m² (IQR)             | 30 (28 to 33) |
| ASA grade, n (%)                    |       |
| I                                   | 3 (3.4) |
| II                                  | 49 (55.0) |
| III                                 | 36 (40.4) |
| IV                                  | 1 (1.2) |
| Indication                          |       |
| Aseptic loosening with ligamentous instability, n (%) | 35 (39.4) |
| Instability (incompetent MCL), n (%) | 15 (16.8) |
| Subluxation/dislocation (posterior capsular failure), n (%) | 3 (3.4) |
| Stiffness, n (%)                    | 1 (1.1) |
| Implant fracture, n (%)             | 1 (1.1) |
| Malalignment, n (%)                 | 1 (1.1) |
| Infection, n (%)                    | 33 (37.1) |
| Two-stage                           | 31 (34.8) |
| Single-stage                        | 2 (2.2) |

ASA, American society of Anesthesiologists; IQR, interquartile range; MCL, medical collateral ligament.

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**Table II.** Complications, reoperations, and ten-year implant survivorship results.

| Outcome                        | Total |
|--------------------------------|-------|
| Patients/knees, n              | 89    |
| Mean follow-up, yrs (range)    | 7.4 (2 to 16) |
| Reoperation, n (%)             |       |
| Any cause                      | 9 (10.1) |
| Component revision             | 6 (6.7) |
| Ten-year implant-survivorship, %| 93.3  |
Table III. Reoperation for any cause.

| Pt | Age (yrs), sex | BMI, kg/m² | ASA grade | Indication | Time to reoperation, yrs | Cause | Component revision | Outcome       |
|----|----------------|------------|-----------|------------|------------------------|--------|-------------------|---------------|
| 1  | 77, M          | 31         | II        | Second stage; PJi | 0.5                | PJi, DAIR | No                | 1.4 yrs, death |
| 2  | 81, F          | 32         | III       | Second stage; PJi | 0.6                | PJi, DAIR | No                | 9.5 yrs, no further surgery |
| 3  | 78, M          | 27         | II        | Second stage; PJi | 2.8                | PJi instability, no component revision | No | 6.6 yrs, no further surgery |
| 4  | 81, M          | 30         | II        | Second stage; PJi | 3.0                | PJi, extensor mechanism failure | Yes | Implant-arthrodesis |
| 5  | 50, F          | 30         | III       | Aseptic loosening, instability (Ehlers-Danlos) | 5.0                | Instability, revised with change of poly, then revised to fixed hinge SMILES | Yes | 5.5 yrs, no further surgery |
| 6  | 70, M          | 29         | II        | Second stage; PJi | 8.7                | PJi, two-stage DFR | Yes | 4.7 yrs, no further surgery |
| 7  | 63 M           | 32         | II        | Repeat two-stage for presumed PJi | 1.5                | Repeat two-stage DFR | Yes | 2.6 yrs, no further surgery |
| 8  | 75, F          | 32         | II        | Aseptic loosening, instability | 2.2                | PJi, two-stage DFR | Yes | 10.9 yrs, no further surgery |
| 9  | 80, M          | 27         | II        | Aseptic loosening, instability | 6.2                | Aseptic loosening femur, revised to DFR | Yes | 5.3 yrs, death |

DAIR, debridement, antibiotics and implant retention; DFR, distal femoral arthroplasty; PJi, periprosthetic joint infection; SMILES, Stanmore Modular Individualised Lower Extremity System.

Operating technique. Using the pre-existing midline incision, whenever possible with appropriate proximal and distal extensions, knees were approached through a standard medial parapatellar arthrotomy with subluxation of the patella following complete synovectomy. Components were then removed in the standard fashion with minimal bone loss. The tibia was prepared and the canal was reamed to accept an appropriately sized stem with press-fit metaphyseal sleeve. Attention was then turned to the femur, and the canal was similarly prepared using a press-fit cementless stem with femoral metaphyseal sleeve. We posteriorized the sleeve to ensure central stem position in the femoral canal. A trial was then assembled and articulated with the tibial component. The joint line level was restored in flexion and extension and checked using a combination of anatomical markers, soft-tissue tension (particularly extensor apparatus), and length measurements, including patellofemoral articulation. We routinely resurfaced the native patella in revision cases. However, if the patella had been resurfaced at time of primary surgery and was tracking well with minimal wear, it was left in situ and selectively revised in cases of button wear to mitigate risk of patellar fracture or fragmentation. Once satisfactory trial positioning was obtained, definitive implants were assembled to match the trials. For surface cementing, Palacos R+g (Hereaus Medical, Germany) was used. Additional antibiotics can be added to the cement as required. Routine closure was then performed in layers over a drain, which was removed in 24 hours. Full weightbearing was commenced as tolerated with routine physiotherapy.

Outcome measures. Clinical outcomes including surgical complications, reoperations, revision for any cause, loosening, and mortality data were collected. Revision was
Fig. 3
Immediate a) anteroposterior and b) lateral radiographs in the same 81-year-old female patient, and c) and d) at seven-year follow-up using S-ROM mobile rotating-hinge with cementless metaphyseal sleeves on both femoral and tibial sides with satisfactory clinical outcomes.

defined as removal or exchange of any component; debridement, antibiotics and implant retention (DAIR) was also considered a revision procedure. Death was identified through both local hospital electronic databases and linked data from the NJR/NHS Personal Demographic Service.

Statistical analysis. The values of all parameters are presented as number and percentage. Power calculation for sample size was calculated using average reported rate of complications (22%). A minimum of 63 knees were required to detect a statistically significant difference (power: 0.8, α = 0.05). Kaplan-Meier survival curves were used for survivorship analysis. Statistical analyses were performed using SPSS 16.0 software (SPSS, USA).

Results
There were 89 consecutive patients (89 knees) during the study period and were all included in the analysis. These included 47 female (52.8%) and 42 male patients (47.25%) with median age of 74 years (interquartile range (IQR) 66 to 79) and median BMI of 30 kg/m² (IQR 28 to 33; Table I). The main indications were aseptic loosening with instability (39.4%; n = 35) and infection (37.1%; n = 33), with the majority of patients managed through two-stage approach (Table I).

The mean follow-up was 7.4 years (2 to 16). The overall rate of reoperation for any cause was 10.1% (n = 9) with rate of implant revision of 6.7% (n = 6; Tables II and III). There were three reoperations (two infection, one patella instability) and six component revisions: three infections, one extensor mechanism failure, one instability, and one aseptic loosening (Table III).

Patellofemoral-specific complications. As above, there were one reoperation for patellar instability and one revision with extensor mechanism failure for an overall 2.25% rate of patellofemoral complications requiring surgery.

Survivorship analysis. At ten years, 30 patients had died, leaving a patient survivorship of 70.9%. Kaplan-Meier implant-survivorship analysis, using revision for any cause as an endpoint, showed a 93.3% survival rate at ten years with mean implant survivorship of 9.5 years (95% confidence interval (CI) 9.1 to 9.9) (Figures 2 to 4).
Discussion

In this consecutive series, we present our experience using S-ROM hinge knee implant in rtKA. We report ten-year implant survivorship of 93.3% and approximately 10% complication rate over the entire 17-year study period in this challenging group of patients.

In their recent series, Panesar et al reported their outcomes of 99 rtKAs using S-ROM implant (68% aseptic aetiology and 32% infection) at a mean seven years’ follow-up. They reported a 26% complication rate, particularly with patellofemoral disorders, and a 19% revision rate. In our experience, patellofemoral complications with rotating-hinge implants are multifactorial with tibiofemoral rotation, quads tension, position of the hinge mechanism (posterior vs central) with the resulting stress on the soft-tissue envelope anteriorly, and trochlea groove design all playing a role in patellofemoral complications. In the S-ROM design, the flat undersurface of the insert articulates with the flat metal surface of the tibial tray with no inherent resistance to rotation. From a fixation point of view, this complete rotational freedom is advantageous in protecting the fixation interface. However, if the patella starts to track slightly more laterally, the tibial tubercle will externally rotate through the extensor mechanism and the patella drifts more laterally, leading to subluxation and dislocation.

Furthermore, the S-ROM implant is a posterior hinge. If the patellofemoral joint is overstuffed, this leads to excessive tension on the extensor mechanism and the patella not tracking centrally will lead to patella escape or extensor mechanism failure. These potential complications can be avoided by ensuring patella central tracking and appropriate patellofemoral joint tension.

Our recommendations are: restoring the joint line and to avoid overstuffing the patellofemoral joint; b) during trialling stage, ensure that the patella is central in rest extension (adjustments to component rotation helps to optimize this position), and c) ensure that the quads and extensor mechanism have adequate tension by performing gravity flexion. If it is too tight at this stage despite restoring joint line with adequate rotation and central position, the next step is to downsize the femoral component to detension the extensor mechanism.

We have reported high survivorship at ten years, in keeping with contemporary literature. In their recent biomechanical study comparing stresses of constrained condylar knee (CCK) with rotating-hinge implants, Andreani et al reported interesting findings where rotating-hinge implant induced high stress compared to the CCK, especially in the region close to tip of the stem. However, higher stresses in the proximal tibia were seen with CCK implant due to the post-cam system, leading to higher implant micromotions due to greater torsional constraint. This was also evident in the dramatic reduction in rates of aseptic loosening with a rotating-hinge compared to a fixed-hinge implant, where those high stresses were dissipated by the rotating-hinge mechanism. This has led to improved survivorship of contemporary rotating-hinge implants and have become more widely used in complex rtKA practice.

Most published series on contemporary rotating-hinge implants in rtKA have only reported short- to medium-term outcomes (Supplementary Table). Our study has medium-term follow-up with low complication and revision rates for any cause. However, this study is limited by the retrospective nature of its design and the lack of clinical scores. Finally, although the practice of rtKA in different healthcare systems is variable, this study has a relatively large sample size for this complex group of patients and high internal validity as our data were collected uniformly for all patients and surgical/mortality data was collected nationally, making these findings generalizable. Further, our unit is a specialist tertiary centre with a multidisciplinary team approach ensuring standardization of care.

The S-ROM rotating hinge knee has a high ten-year survivorship and a low complication rate in rtKA. Potential patellofemoral complications can be avoided by ensuring central tracking and appropriate tension of the patellofemoral joint in this posterior hinge design.

Take home message

- High ten-year survivorship can be expected with rotating-hinge implant with metaphyseal sleeve fixation in revision total knee arthroplasty.

- Patellofemoral complications can be avoided by ensuring central patella tracking and appropriate tension of the patellofemoral joint in this posterior hinge design.

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Supplementary material

Summary of published studies on contemporary rotating-hinge implants in revision knee arthroplasty.

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