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Satisfactory medium- to long-term outcomes of cemented rotating hinge prosthesis in revision total knee arthroplasty

A SPECIALIST CENTRE STUDY WITH MINIMUM FOUR YEARS' FOLLOW-UP

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Aims

The aim of this study was to evaluate medium- to long-term outcomes and complications of the Stanmore Modular Individualised Lower Extremity System (SMILES) rotating hinge implant in revision total knee arthroplasty (rTKA) at a tertiary unit. It is hypothesized that this fully cemented construct leads to satisfactory clinical outcomes.

Methods

A retrospective consecutive study of all patients who underwent a rTKA using the fully cemented SMILES rotating hinge prosthesis between 2005 to 2018. Outcome measures included aseptic loosening, reoperations, revision for any cause, complications, and survivorship. Patients and implant survivorship data were identified through both prospectively collected 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

Overall, 69 consecutive patients (69 knees) were included with a median age of 78 years (interquartile range 69 to 84), and there were 46 females (66.7%). Indications were septic revisions in 26 (37.7%), and aseptic aetiology in the remining 43 (62.3%). The mean follow-up was 9.7 years (4 to 18), and the overall complication was rate was 7.24%, all with patellofemoral complications. Failure rate with 'any cause revision' was 5.8%. There was one case of aseptic loosening of the femoral component. At ten years, 17/69 patients (24.63%) had died, and implant survivorship was 92.2%.

Conclusion

In our experience, the SMILES rotating hinge prosthesis achieves satisfactory long-term outcomes with ten-year implant survivorship of 92.2% and a patellofemoral complication rate of 7.24%.

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Introduction

The demand for primary total knee arthroplasty (TKA) continues to rise worldwide with projected increase in revision TKA (rTKA).[1-3] In its 19th annual report, the UK National Joint Registry (NJR) reported re-revision rate of 3.54% at one year, rising to 15.4% at ten years, and 18.98% at 15 years following first rTKA, with aseptic loosening, infection, and instability accounting for the majority of re-revisions.[1] With re-revisions, the complexity increases, as does the use of rotating-hinge prostheses.[4] In a recent systematic review of rotating-hinge implants

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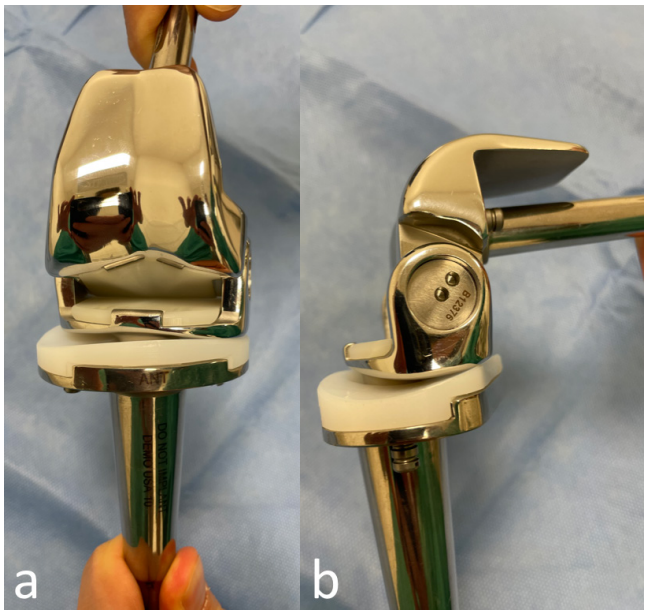

Fig. 1

Photograph of the Stanmore Modular Individualized Lower Limb System (SMILES) prosthesis; the polyethylene insert is bevelled placed on the tibial plate and limits rotational motion to ± 5°.

Table I. Patients' baseline characteristics and indication for surgery.

Variable	Data
Patients/knees, n	69
Median age, yrs (IQR)	78 (70 to 82)
Female sex, n (%)	46 (66.7)
BMI, kg/m2	
Median (IQR)	30 (27 to 33)
Mean, (SD; range)	30.7 (5.3; 20 to 51)
ASA grade, n (%)	
I	4 (5.8)
II	23 (33.3)
III	38 (55.0)
IV	4 (5.9)
Indications, n (%)	
Septic	26 (37.7)
Two-stage	15 (21.7)
Single-stage	11 (16)
Aseptic	43 (62.3)
Loosening with ligamentous instability	22 (31.9)
Instability (incompetent MCL)	14 (20.3)
Subluxation/dislocation (posterior capsular failure)	6 (8.7)
Stiffness	1 (1.4)

ASA, American Society of Anesthesiology; IQR, interquartile range; MCL, medical collateral ligament; SD, standard deviation.

in rTKA, survivorship was reported from 51% to 92.5% up to ten years' follow-up, with complication rates ranging from 9.2% to 63%.[5] Notably, patellofemoral complications remain high, with patella subluxation reported in 29.6% of cases in a recent contemporary series.[6]

Since the introduction of the rotating-hinge mechanism, contemporary hinge implants have seen improved outcomes and survivorship. However, common complications with hinges remain high with early loosening and patellofemoral issues.[7-9] The indications to use a rotating-hinge implant in rTKA practice are well-established, including collateral ligament deficiency, severe bone loss that compromises ligament attachments, gross flexion-extension mismatch, recurvatum, and gross multidirectional instability.[10]

Patellofemoral instability with a hinge construct is multifactorial with patients', surgical and implant-related factors. Based on the specific hinge design, the mobile bearings allow rotation with varying degrees of constraint.[4] The Stanmore Modular Individualized Lower Limb System (SMILES) was first introduced in 1990. In this design, there is some rotational control built in the under-surface of the tibial component, so as it rotates it rides upwards providing some resistance to rotation which is advantageous for the patellofemoral mechanics (Figure 1). This system is fully cemented and of relatively low cost.

In this study, we aim to evaluate the medium- to long-term outcomes of SMILES rotating hinge prosthesis in rTKA at our tertiary unit. We hypothesize that this fully cemented system leads to satisfactory clinical outcomes.

Methods

This was a retrospective consecutive study of all patients who underwent a rTKA using SMILES rotating hinge knee system between 2005 to 2018. Local study ethical approval was obtained. We use this system in elderly patients with collateral ligament failure, posterior capsular failure, or Anderson Orthopaedic Research Institute classification system III (AORI-III),[11] with significant femoral condylar bone loss where augmented condylar revisions are inadequate to provide durable fixation. Patients were identified using a local prospective database and linkable data obtained from the NJR for rTKA. Demographic, clinical, and surgical data were collected from patients' electronic health records. We excluded patients that required endoprostheses with distal femoral replacements.[12,13] All patients underwent routine preoperative anaesthetic assessment and received a spinal anaesthetic with upper thigh sterile tourniquet and perioperative prophylactic antibiotics.

Implant. SMILES is a fully cemented hinged knee made from a cast cobalt-chromium-molybdenum and titanium alloy. The rotating-hinge articulation includes a bevelled polyethylene bearing surface placed on the tibial plate and limits rotational motion to ± 5°. Hyperextension is constrained by a bumper that acts as a secondary bearing surface (Figure 1). This system offers three tibial options in two sizes; a rotating-hinge all-polyethylene tibia, a rotating-hinge metal cased tibia with short (140 mm), and long stem (180 mm) options, and a fixed hinge tibia with short and long stems. In our practice, we use the

Table II. Outcomes and ten-year implant survivorship.

Variables	Data
Patients/knees, n	69
Mean follow-up, yrs (range)	9.7 (4 to 18)
Median follow-up, yrs (IQR)	8.4 (4.5 to 10.7)
Any cause revision, n (%)	4 (5.8)
Patellofemoral complications, n (%)	5 (7.24)
Patella dislocation/subluxation, n	4
Extensor mechanism failure, n	1
Ten-year implant survivorship (any cause revision), %	92.2

IQR, interquartile range.

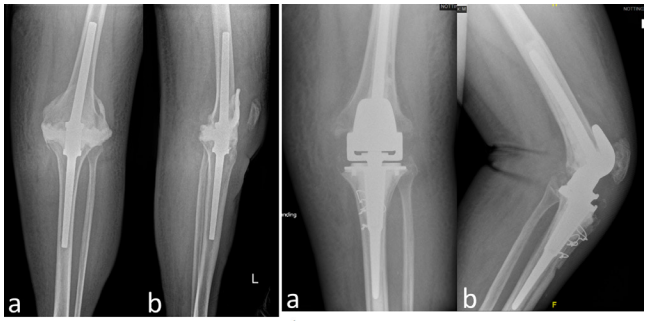

Fig. 2

a) Preoperative anteroposterior and lateral radiographs of left knee in a 79-year-old female with a fusion nail following first-stage revision for infection. b) Anteroposterior and lateral radiographs at three-year follow-up using Stanmore Modular Individualized Lower Limb System (SMILES) rotating hinge, with no loosening and satisfactory clinical outcomes.

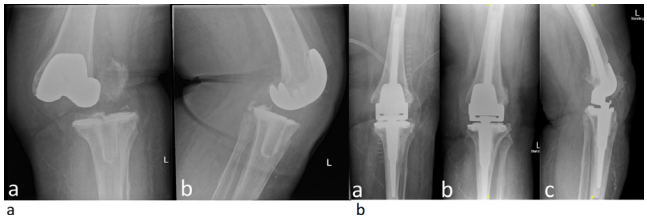

Fig. 3

a) Preoperative anteroposterior and lateral radiographs of a failed infected and dislocated total knee arthroplasty (TKA) in an 83-year-old female. b) Immediate postoperative, a) and two years follow-up; b-c) following revision TKA with a rotating hinge Stanmore Modular Individualized Lower Limb System (SMILES) prosthesis and satisfactory clinical and radiological outcomes.

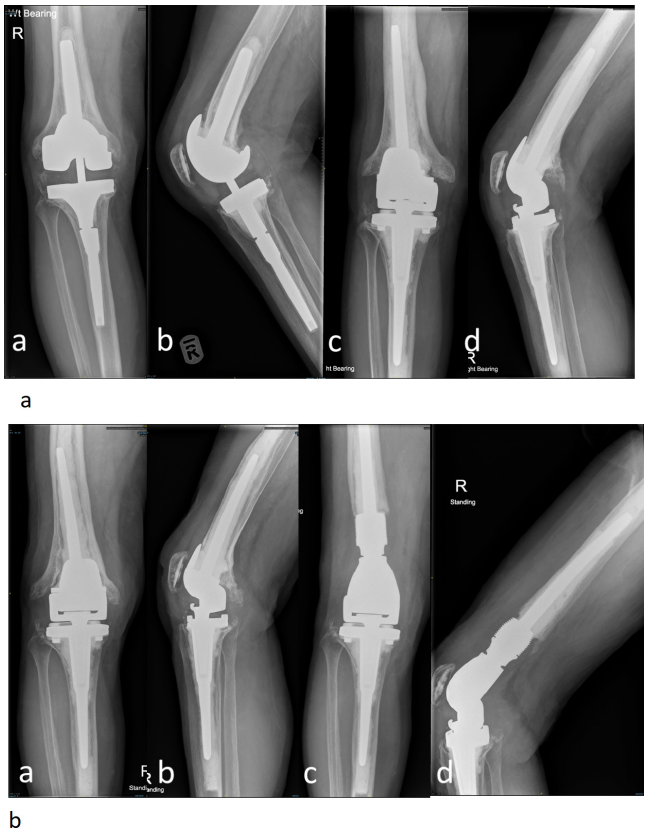

Fig. 4

a, b) Preoperative anteroposterior and lateral radiographs of right revision knee in a 75-year-old female with aseptic loosening and instability. c, d) Postoperative radiographs following re-revision total knee arthoplasty with a rotating hinge Stanmore Modular Individualized Lower Limb System (SMILES) prosthesis. b) Anteroposterior and lateral radiographs at 5.6 years follow-up with loosening around the femoral component with well-fixed tibial component. c, d) Anteroposterior and lateral radiographs following single component revision to a distal femoral replacement of the same system retaining the tibial component.

rotating-hinge metal cased tibia. The femoral component is either small or standard size with a 140 mm long femoral curved titanium stem of 13 mm diameter for standard components and 12 mm for small components. The hinge mechanism is assembled with an axle, a pair of polyethylene bushes, and a titanium circlip.

Operative technique. 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. The knee was then reconstructed with flexion first approach.[14] Tibial preparation was then performed, and the canal reamed to accept a cemented stem. Attention was then turned to femoral preparation. A trial was then assembled and the joint line level was restored in flexion and extension and checked using a combination of anatomical markers and soft-tissue tension, particularly extensor apparatus and length measurements, including patellofemoral articulation.[15] Once satisfactory trial positioning was obtained, definitive implants were assembled and cemented using Palacos R+G cement (Hereaus Medical, Germany). Routine closure was then performed in layers over a drain which was removed in 24 hours. Full weightbearing was encouraged, as tolerated with routine physiotherapy. Follow-up was performed regularly at six weeks, three months, and 12 months thereafter.

Outcome measures. The primary outcome measure was implant survivorship and mechanical failure, which was defined as the presence of progressive radiolucent lines

Table III. Revision for any cause.

Patient no.	Age, yrs; M/F	BMI, kg/m²	ASA grade	Indication	Time to revision, yrs	Cause of reoperation	Outcome following re-revision
1	76; M	35	III	Aseptic loosening, instability	1.1	Periprosthetic fracture	4.3 yrs/ no further surgery
2	60; M	43	III	Second stage; PJI	1.5	PJI, repeat two-stage	Implant-arthrodesis
3	72; M	29	III	Second stage; PJI	7.9	PJI, repeat two-stage	4.6 yrs/ no further surgery
4	75; F	25	III	Aseptic loosening of rTKA (Figure 4)	5.6	Femoral component aseptic loosening and failure	2 yrs/ no further surgery

ASA, American Society of Anesthesiologists; DFR, distal femoral replacement; PJI, periprosthetic joint infection; rTKA, Revision total knee arthroplasty.

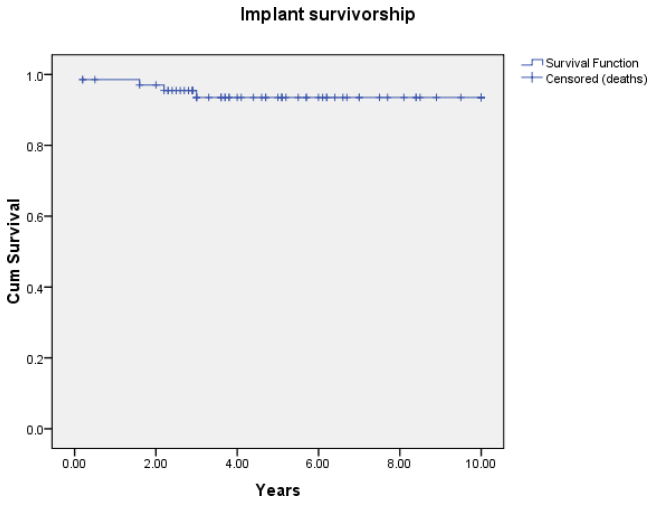

Fig. 5

Kaplan-Meier implant survivorship plot at ten years.

around either component on serial anteroposterior and lateral radiographs assessed by two authors (HEM, BVB), or the need for revision surgery for aseptic loosening. The secondary outcome measure was complications, particularly patellofemoral complications. Reoperations and revision for any cause were also collected. Death was identified through both local hospital electronic databases and linked data from the NJR/NHS Personal Demographic Service.

Statistical analysis. Values of all parameters are presented as percentages and Kaplan-Meier survival analysis were performed for implant survivorship using SPSS 16.0 software (SPSS, USA).

Results

There were 69 consecutive patients (69 knees) during the study period, which were all included in the analysis. These included 46 females (66.75%) and 23 males (33.25%) with a median age of 78 years (interquartile range (IQR) 70 to 82), and a mean BMI of 30 kg/m² (27 to 33). The majority of patients (88.4%) had American Society of Anesthesiology (ASA) grade II/III. The indications were second stage reconstruction for infection (37.7%), and aseptic aetiology in the remining patients (62.3%) (Table I).

The mean follow-up was 9.7 years with a median 8.4 years (4 to 18). The overall complication rate was 7.24%, all with patellofemoral complications (Table II), and have not had operative interventions. These were one case of extensor failure that required extensor mechanism reconstruction in an elderly frail patient who opted for nonoperative management. Similarly, three cases of patella instabilities were managed nonoperatively. Only four cases were revised (5.8%); infection in two cases, one periprosthetic fracture, and one case for mechanical failure and aseptic loosening of the femoral component (Figures 2 to 4; Table III). There were no other cases of mechanical failure or progressive radiological loosening around either the tibial or femoral components.

Survivorship analysis. At ten years, 17/69 patients (24.63%) had died. Implant survivorship analysis, using "revision for any cause" as an end point, was 92.2% at ten years, with estimated mean implant survivorship of 9.2 years (95% confidence interval (CI) 8.97 to 9.97) (Figure 5).

Discussion

In this study, we report satisfactory ten-year survivorship and low complication rate of SMILES rotating hinge prosthesis in rTKA patients. Although this implant has been in use for many years, little has been published on the long-term clinical outcomes in non-tumour patients. Here, rTKA patients are often elderly, female, and invariably with osteoporotic bone. A fully cemented prosthesis is therefore beneficial, offering the ability to immediately weightbear and mobilize.

In their meta-analysis of 17 studies of condylar rTKA, Wang et al[16] found no significant differences in failure for any reason, reoperation, aseptic loosening, or infection between rTKA with cemented or cementless stem fixation. However, little is known about the effects of stem fixation on long-term outcomes of rotating hinge implants.[17] To our knowledge, this is the largest series of this prosthesis in rTKA patients. Back et al[18] reported on their series of SMILES prosthesis (29 patients/29 knees) over 4.5 years to 11 years. The authors reported one patient with evidence of aseptic loosening on radiographs and an overall failure rate of 13.8%. However, they reported a low rate of patellofemoral complications of 6%.

We also report a low patellofemoral complication rate of 7.24% over the entire 18-year study period, which were managed nonoperatively. In contrast, in their recent series of the S-ROM (DePuy Synthes, USA) rotating hinge in rTKA, Panesar et al[19] reported their outcomes at a mean seven years' follow-up. They reported a 26% complication rate, particularly with patellofemoral disorders and 19% revision rate. Notably, the S-ROM design has no inherent resistance to rotation, as the rotating hinge is delivered with a flat poly on a flat metal tibial tray, compared to the SMILES system, which does attempt to limit the degree of rotation, which can occur to ± 5° (Figure 1). It is possible that the increased rotational freedom, while having benefits for protecting tibial fixation, may increase the risk of patellofemoral instability.[20] Further, the one case of mechanical failure in this study was around the femoral component in a previously multiply revised knee. Here, it appears that cement interdigitation into a sclerotic femoral bone was not achieved which led to early failure. However, the tibial component was well-fixed, which allowed for a single component revision into a distal femoral replacement with good outcome.

A number of studies on contemporary rotating-hinge implants in rTKA have been published, although most with short- to medium-term outcomes with various implants.[9,20-25] Our study has long-term follow-up with low complication and revision rates for any cause. However, our study is limited by retrospective nature of its design and lack of clinical scores. In addition, our data was collected prospectively for all patients in a mandated national registry adding to its internal validity. Furthermore, our unit is a specialist tertiary centre with a multidisciplinary team approach ensuring standardization of care.

To conclude, in our experience, the SMILES rotating hinge knee achieves satisfactory long-term outcomes with ten-year implant survivorship of 92.2% and a low patellofemoral complication rate of 7.24%. The latter is achieved by ensuring central tracking of the patella with appropriate soft-tissue tension. There appears to be a protective role of the rotating hinge design in the SMIELS system against patellofemoral complications with its inherent resistance to rotation. However, further comparative studies are needed to further clarify role of insert design in rotating-hinge implants.

Take home message

- The Stanmore Modular Individualized Lower Limb System (SMILES) cemented rotating hinge prothesis has 92% survivorship in revision total knee arthroplasty patients.
- Aseptic loosening is usually seen more on the femoral side, and a well-fixed tibia can be revised to SMILES distal femoral replacement, keeping the same tibial component.

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