

The early radiological follow-up of a medial rotational design of total knee arthroplasty

A. Amin^{a,*}, A. Al-Taiar^b, A.P. Sanghrajka^a, N. Kang^a, G. Scott^a

^a Royal London Hospital, Whitechapel Road, Whitechapel E1 1BB, United Kingdom

^b School of Medicine Health Policy & Practice, University of East Anglia, NR4 7TJ, United Kingdom

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Abstract

The objective of this study was to investigate the hypothesis that the increased constraint of a medial rotational knee promotes earlier loosening of the prosthesis. All patients with a Freeman-Samuelson 1000 knee arthroplasty (medial pivot design), (group 1), or a Freeman-Samuelson Modular knee arthroplasty, (group 2), with a minimum follow-up of 2 years (mean follow-up 4 years) were identified from our unit's arthroplasty database, and matched as closely as possible for age, length of follow-up and pre-operative diagnosis. Standardised anteroposterior and lateral radiographs were analysed for component migration and radiolucent lines as recommended by the Knee Society.

There were 48 knees in each group. There were no failures in group 2. There was one failure requiring revision of the tibial component in group 1. There was no significant difference in overall radiolucent line scores between the two groups ($p=0.66$, at 5 years). Progressive radiolucent lines were detected in similar numbers of patients in both groups (FS1000 8/48, FSM 7/48, $p=0.84$). Our early radiological survey suggests that the increased constraint of the medial pivot knee prosthesis does not result in an increased incidence of radiographic loosening.

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Most modern total knee replacements have minimal constraint created by the conformity between the femoral and tibial articular geometry. Theoretically, this will limit the stresses at the interfaces between the prosthesis and the bone and accommodate any physiological roll back of the femur on the tibia that may be present in the replaced knee. In overload in such designs, mild subluxation of the femoral component on the tibial insert can be tolerated without compromising the fixation of the prosthesis. Fluoroscopic study of posterior cruciate-retaining knee implants has shown that paradoxical anterior sliding of the femur on tibia can sometimes occur [1,2]. This could result in clinically significant gait abnormalities and might produce accelerated wear.

Recent magnetic resonance studies of six normal cadaver knees demonstrated that during unloaded knee motion, the

medial side remained stable like a ball-in-socket joint, with only a few millimetres of posterior translation of the femur relative to the tibia as the knee was flexed, whilst the lateral femoral condyle moved in a posterior direction of up to 19 mm, with the centre of rotation located at the medial femoral condyle [3]. Similar investigation with fluoroscopy of normal knees found a mean lateral translation of 12.7 mm [4]. The Medial Rotation Knee (MRK, Finsbury Orthopaedics, Leatherhead, United Kingdom) has been designed to complement these kinematics through the interaction of a spherically shaped medial condylar portion of the femoral component and a matched concave medially conforming tibial component, whilst retaining the concept of a coronally aligned cylinder in a shallow trough that rotates in the sagittal plane in the lateral compartment. Gait analysis of the normal knee reveals that at heel strike with the knee in full extension, and at load acceptance, the forces producing anterior sliding of the femur on the tibia are at their greatest [4]. In the replaced knee it might be reasonable to assume that these anteriorly directed forces would be resisted by

* Corresponding author. 39 Church Drive, North Harrow, Middx, HA2 7NR, United Kingdom. Tel.: +44 7813 211 395.

E-mail address: amitam@doctors.org.uk (A. Amin).

the anterior elevation of the tibial insert. These features might lower the contact stresses on the articular surface of the tibial component and enhance long-term durability of the polyethylene but at the risk of the increased constraint transferring forces to the interface between the tibial component and the host bone, thus increasing the risk of component loosening.

The aim of this study was to investigate the hypothesis that the increased constraint of the Medial Rotation Knee prosthesis could promote earlier loosening of the components. We used the development of radiolucent lines (RLLs) and specifically the progression of these as a surrogate end-point to compare outcomes between groups.

1. Patients and methods

1.1. Background

A retrospective radiographic observational cohort study was conducted comparing the outcome of the Freeman-Samuelson 1000 (FS1000) prosthesis (the pre-market version of the MRK design) and the Freeman-Samuelson Modular (FSM) prosthesis (Zimmer-Centerpulse, Winterthur, Switzerland), the traditional roller in a trough design from which the FS1000 was developed. The FSM design had an ultra high molecular weight polyethylene (UHMWPE) tibial insert with a single radius shallow trough that articulated with a cobalt-chromium femoral component with a matching 24 mm radius in the sagittal plane and flat in the coronal plane, remaining fully congruent throughout the range of flexion and extension. The maximum distance from the lowest point in the tibial insert to the highest portion of the anterior aspect of the insert was between 3 and 4 mm. The prosthesis was therefore minimally constrained. The FS1000 medial rotating knee had a concave medial tibial surface conforming to the 25 mm radius of curvature of the medially spherical femoral component (Fig. 1). This allowed the maximum distance from the lowest part of the UHMWPE tray to its highest anterior lip to be increased to 11 mm. Laterally, the femoral condyle remained a portion of a cylinder with the traditional 24 mm radius articulating in a matching tibial trough. The geometrical differences



Fig. 1. FS1000 (MRK) total knee replacement showing the highly conformed medial articulation.

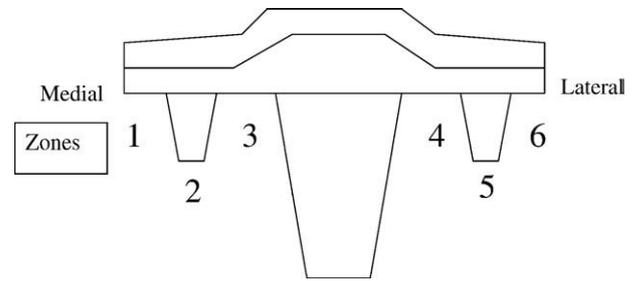


Fig. 2. Modification of tibial zones analysed for RLL (from Knee Society Scoring System [5]).

between the two designs enabled the contact area of the FSM prosthesis to be increased from 510 mm³ to just over 1000 mm³ for the FS1000 [manufacturer's data]. Whilst these features allowed rotation of the femur relative to the tibia around the centre of the medial femoral condyle in flexion when the lateral collateral ligament was relaxed, they also increased to the constraint of the replacement. The allocation of the prostheses was not randomised but was determined by availability of the appropriate size implants as the FS1000 was initially produced in only one size.

1.2. Study group

Using our unit's database, all patients with osteoarthritis or rheumatoid arthritis who had undergone knee replacement with an FS1000 (MRK) or a FSM knee replacement between November 1994 and September 2001 with a minimum clinical follow-up of 2 years were identified. Forty patients (48 knees) were identified with a FS1000 total knee replacement, who were matched for diagnosis, gender and age to within 5 years with 42 patients (48 knees) from the FSM list.

1.3. Surgical technique

All operations were performed or directly supervised by the same surgeon (GS). A standard midline incision with a medial parapatellar approach splitting the quadriceps tendon and everting the patella was performed in every patient. Both cruciate ligaments were excised. The instruments used were the same for both designs with intramedullary femoral alignment and extramedullary tibial alignment. Soft tissue releases were controlled using a tensor to produce a balanced knee aligned at 7° of valgus. Both designs were inserted with surface-cement fixation of the tibial and femoral components.

1.4. Radiographic technique

Standardised supine anteroposterior radiographs in extension, lateral radiographs in extension and at 90° of flexion and skyline patellar views were taken post-operatively, at 6 months, 1 year and at the second post-operative year with the intention that the patients would be reviewed again at 3, 5, 7 and 10 years, subject to their continued attendance. The exposures were made by experienced radiographers, without fluoroscopic assistance, who were required to produce true interface views. The multiplicity of films allowed us to assess accurately the bone–cement interface in all patients.

1.5. Outcome measures

All the available radiographs were examined systematically and independently of the senior surgeon (GS). Authors (AA, NK, APS) examined all the radiographs independently and where discrepancies were found the radiographs were re-examined and the mean response was used. Component migration and radiolucent lines (RLLs) identified were scored according to the system recommended by the Knee Society [5]. Modifications to the scoring system were required as the tibial components analysed in this study had two pegs and an 80 mm stem (Fig. 2). As the tibial stem was not cemented a specific zone was not allocated to the main stem. On the lateral radiograph of the tibia the pegs and stem prevented an adequate view of the interfaces to permit assessment of RLLs

Table 1
Demographic data of the study groups

	FS1000 (MRK)	FSM
No of patients/knees	40/48	42/48
Gender M:F	10:30	14:28
Diagnosis OA:RA	36:4	38:3
Mean age (years, range)	70.4 (52–90)	70.3 (52–84)
Mean follow-up (years, range)	4.3 (2–9)	4.5 (2–10)

so that only osteolytic lesions and component migration were studied. Coronal component migration was also assessed using the anteroposterior radiograph [5]. The RLLs at the femoral interface were demonstrated on the lateral radiograph. The femoral component migration was based on angular change measured on both anteroposterior and lateral radiographs adapting a system previously used in FSM knees [6]. In this earlier report component migration identified at 3 years post-operatively was a poor predictor of failure but the absence of adverse radiological features conferred confidence that loosening was unlikely to occur.

RLLs were defined by Smith et al. [7], as radiolucent intervals between the cement or the implant and the subjacent bone. RLLs detected on the immediate post-operative radiograph were thought to be the result of poor interdigitation of cement into sclerotic bone, but the progression of such lines were carefully scrutinised and documented. We refer to these lines as index RLLs. The progression of RLLs was documented if a RLL in an involved zone is thickened by 1 mm over the follow-up period. Lytic lesions were diagnosed when there was no reactive sclerosis present and when ballooning extended away from the margins of the implant. The total RLL scores for each implant were recorded and then used to calculate the mean RLL score for each group at regular time intervals, (6 months, 1, 2, 3, 4, 5 years).

1.6. Statistical analysis

The results of the two groups were analysed for statistically significant differences using the Mann–Whitney *U* test and chi-squared analysis as appropriate, with differences that showed $p < 0.05$ (two-sided) deemed to be significant.

2. Results

Demographic data for the study groups are shown in Table 1.

There were no revisions undertaken in the FSM group. There was one failure requiring revision of the tibial component in the FS1000 group at 5 years following primary surgery, which resulted from a fall from an extending ladder. The patient’s leg passed between the rungs of the ladder such that he was suspended upside-down with his full weight transmitted through his replaced knee. The knee became painful immediately afterwards and failed to recover. Subsequently it became apparent that the tibial component had loosened and revision was required.

Table 2 highlights the progression of RLLs (increase by 1 mm over follow-up period) per zone at final follow-up. RLLs occurred most commonly under the medial tibial plateau (zone 1), although only five patients in both groups demonstrated progressive scores in this zone.

Table 2
The number of patients with progression of RLLs by 1 mm per zone at final follow-up

	Tibial component zones					Femoral component zones			
	1	2	3	4	5	6	2	3	4
FS1000 (MRK)	5	–	1	–	–	–	2	1	–
FSM	5	–	–	–	–	2	–	–	–

Table 3
Frequencies of progressive and initial RLLs, and frequency of osteolysis between groups

	FS1000	FSM	<i>p</i> value (chi-squared)
Progressive RLLs	8/48	7/48	0.84
Osteolysis (tibial)	3/48	2/48	0.99
Non-progressive RLL (detected on initial post-operative film)	4/48	2/48	0.68

Table 3 shows the frequencies of progressive and index RLLs and the prevalence of osteolysis. There was no difference in the number of patients with progressive RLLs between the groups (8/48 FS1000, 7/48 FSM) ($p = 0.84$ chi-squared analysis).

Fig. 3 shows the progression of median RLL scores for both groups over time. There were no significant differences between the two groups at any point in the follow-up period ($p = 0.66$, Mann–Whitney *U* test at 5 years).

The small subgroup of patients with initial (index) RLLs on the post-operative film (4/48 FS1000, 2/48 FSM), thought to result from poor cement interdigitation, did not show progression of these RLLs, nor did they develop osteolysis. This difference between the

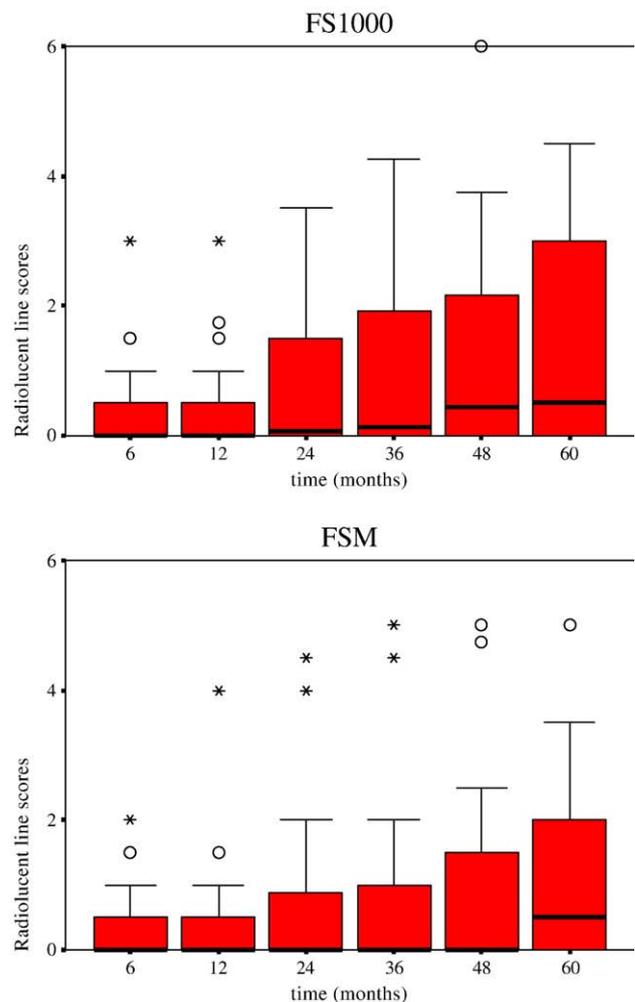


Fig. 3. Boxplot graphs demonstrating progression of RLLs over time in both groups.

two prostheses was not statistically significant (chi-squared analysis, $p=0.68$).

Osteolysis was detected only around the tibial component in a limited number of knees (3/48 FS1000, 2/48 FSM) and was not statistically significantly different between the two designs ($p=0.99$, chi-squared analysis).

There were no cases of femoral component migration as suggested by the Knee Society [5]. We detected angular change of 4° in the tibial component on the anteroposterior radiograph in two patients from the FS1000 group. Both patients had tibial RLLs evident but these were non-progressive and were not associated with osteolysis. This change was not clinically significant at the time of analysis.

3. Discussion

Many choices of knee implant design are available for contemporary TKR, from cruciate-substituting to mobile bearing designs. Reproducible benefits of total knee arthroplasty include pain relief and subsequent improvement in quality of life. With an increasingly younger population presenting with symptomatic osteoarthritis of the knee, improved function has become of paramount importance.

Improved understanding of knee joint kinematics has meant that previous concepts of a ‘crossed four bar link’ model have been superseded by evidence of relative medial joint stability and lateral joint motion allowing effective axial rotation of the tibia on the femur in flexion [3,4,8,9]. Contemporary cruciate-retaining and -substituting designs have failed to complement these natural kinematics, and anteroposterior instability has been reported with RSA studies [10].

The relatively recent advent of the medial rotational type knee replacement has generated discussion about whether normal knee kinematics can be replicated. A comparable range of post-operative knee flexion at 1 year has been documented when comparing this design to a posterior stabilised implant [11], however the long-term benefit may lie in the improved contact characteristics. Schmidt et al. [12] in a fluoroscopic study revealed a lower lateral femoral condylar lift off with the medial rotational style knee prosthesis when compared to conventional posterior cruciate-retaining implants. In a study comparing variations of the Freeman-Samuelson knee replacement, Saari et al. [13] demonstrated reduced anteroposterior translation when comparing the medial rotational knee design, to the standard fixed bearing design and mobile bearing versions.

This retrospective radiological comparison of two related but different designs of total knee replacement, the FS1000 (medial pivot) and the FSM, found no significant difference between the two designs in terms of radiolucent line progression. Similar numbers of patients developed progressive RLLs over time, which we defined as increase in width in one zone by 1 mm over the follow-up period (FS1000 — 8/48, FSM — 7/48).

Our observation that RLLs detected immediately post-operatively did not lead to osteolysis, corroborates with the findings of Smith et al. [7], who suggested that this accelerated process only occurs when the wear rate is greatly increased. Osteolysis was detected infrequently without obvious predisposition, and we agree with Smith et al., who found that

osteolysis could develop in areas previously appearing to be the site of bone–cement contact, suggesting that debris can penetrate even an intact interface [7].

The presence and extent of RLLs could have been influenced by radiographic technique, including the beam control and limb rotation. We used a standardised technique and protocol, with which all radiographers were familiar, and serial evaluation of the radiographs was performed to minimise significant errors [14]. We used a constant source to plate distance for each knee analysed and unless the patient’s stature changed significantly, the magnification produced was reproducible. We accept that our study cannot match the accuracy of radiostereanalysis (RSA) but our data did not support the hypothesis that the increased constraint of the FS1000 design compromised fixation.

RSA of the femoral [15] and tibial [16] components of the FS1000 at 2 years has not revealed increased migration of this more highly constrained design. The cemented version of the conventional Freeman-Samuelson total knee replacement has a published 10 year survival of 96% [17]. The RSA results and our current findings suggest that the FS1000 now known as the MRK should not experience survival results worse than the design it supersedes but we acknowledge that our study is limited by the lack of randomisation and may not be sufficiently powered to detect small differences. We undertook a post hoc power analysis to see if the lack of significant difference may be due to our small sample size. We calculated that to detect a difference of 15% between the groups, with a power of 80%, we would require 70 patients in each arm to be certain of not failing to identify a difference in the incidence of RLLs. The ability to detect a 10% difference would require 185 patients in each arm. The smaller numbers in this study we feel are offset by the close matching of the groups. Additionally, the more sensitive RSA measurements comparing these prostheses did not identify higher migrations in the FS1000 (MRK) version [15,16] and accordingly we feel are findings that can be relied upon.

Our findings do not support the hypothesis that the increased constraint of the FS1000 design promotes earlier loosening of the components. However, it will require longer follow-up before the enlarged contact area and the more favourable kinematics can demonstrate any improvement in the wear characteristic. Studies with larger numbers and longer-term follow-up are required to corroborate these early findings.

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