

The Rotaglide+ total knee replacement: a comparison of mobile versus fixed bearings

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Abstract

Purpose Mobile-bearing knee replacements were introduced as an alternative to their fixed-bearing counterparts. Movement of the polyethylene insert relative to the tibial tray has been shown to decrease contact stresses, wear and polyethylene-induced osteolysis. The aim of this study is to compare outcomes between mobile and fixed-bearing surfaces of the Rotaglide+ total knee prosthesis.

Methods A prospective, *partially randomised twin cohort study* of 149 Rotaglide+ total knee arthroplasties performed in one unit between September 2000 and January 2005, was carried out. The patients were allocated to a mobile or fixed bearing. The patients were assessed using a pain visual analogue score (VAS), the American Knee Surgeons Score (AKSS) the range of movement, the Oxford Knee Score (OKS) and walking time. Seventy-five patients had mobile-bearing surfaces, and 74 had fixed bearings.

Results At 5-year follow-up, there was no significant difference between the fixed- and mobile-bearing implants with respect to range of movement [104.7(SD 17.0) vs. 103.6(SD 15.7) degrees]; AKSS [146.6(SD 23.9) vs. 144.1(SD 32.4)]; VAS [3.3(SD 1.2) vs. 3.4(SD 1.3)]; OKS [30.8(SD 9.7) vs. 29.6(SD 10.9)], respectively.

Conclusion This study is the first of its kind to outline the medium-term (≥ 5 years) outcomes in Rotaglide+ total

knee replacements. Its findings reinforce previous research which has shown no discernible difference in clinical outcomes between the 2 groups.

Level of evidence II.

Keywords Total · Knee · Replacement · Fixed · Mobile · Bearing

Introduction

Total knee replacement is well established as the gold standard treatment for end-stage knee arthritis. Traditionally, the polyethylene-bearing surface is fixed to the tibial component. This has been used successfully in total knee replacement surgery with survival rates of at least 97 % at a minimum 10-year follow-up [4, 5, 18]. However, retrieval studies of fixed-bearing implants have identified high-grade wear patterns [7] including delamination, pitting and scratching [13, 17].

Mobile-bearing knee replacements were introduced as an alternative to their fixed-bearing counterparts [3]. They allow movement of the polyethylene insert relative to the tibial tray. This has been shown to decrease contact stresses [15, 22], resulting in less wear and subsequently less polyethylene-induced osteolysis [10] as well as decreasing patello-femoral contact stresses [19, 20].

Despite the theoretical advantages of using mobile bearings, it is unclear whether these ‘advantages’ become clinically significant, or improve patient outcomes. Previous comparative studies have identified little or no clinical benefit of using a mobile bearing [6, 11, 16].

The Rotaglide+ total knee replacement was introduced onto the market in 2000, as an ‘amalgamation’ of the Nuffield (fixed bearing) and Rotaglide (mobile bearing)

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total knee replacements, both of which were manufactured by the same company (Corin Medical Ltd. UK). The new Rotaglide+ total knee replacement came with the option of either fixed- or mobile meniscal-bearing surfaces using the same tibial base plate and instrumentation. To date, there have been no published studies comparing outcomes using the different bearing surfaces in the Rotaglide+ prosthesis.

The aim of this study is to compare the outcomes of fixed- versus mobile-bearing Rotaglide+ total knee replacements within a single-surgeon series in a prospective parallel study. The null hypothesis is that there is no difference in outcome between the 2 bearing surfaces.

Materials and methods

All patients had end-stage arthritis that had failed non-operative treatment. Patients who had had a previous unicompartmental knee replacement; high tibial osteotomy; distal femoral osteotomy; or those with an active infection were excluded.

Surgical procedure

An antero-medial approach to the knee was utilised in all cases. The patella was everted to facilitate access to the distal femur. There was no learning curve for instrumentation, as the Nuffield instruments (which were familiar to the senior author) were used, and extra-medullary alignment was utilised. The patella was usually resurfaced. Five patients had no resurfacing, because the state of the patella was not arthritic, or because it was not feasible, the patella being too thin to accept a prosthesis.

The two cohorts were prospectively studied in parallel. Allocation to one group or the other was at operation depending upon how the trial prostheses moved intra-operatively. Twenty-eight procedures were randomised as a part of a national knee arthroplasty trial in the mobile-versus fixed-bearing arm of the study. The preliminary results of which have been published [8]. Random allocation was carried out via a centralised telephone randomisation service. These patients were not analysed separately. They are included in the study, as they were part of the individual surgeon's series, and the data used were different.

Patients were assessed pre-operatively. The primary outcome measure was the American Knee Surgeons Score. Other parameters measured included type of arthritis, Oxford Knee Score, range of movement, pain score (visual analogue score).

The Knee Society Score uses walking distance as measured by 'blocks' as part of the functional score. For the purposes of this study, walking distance was replaced with

'walking time' (minutes), as 'block' is not a commonly used measurement of distance within the United Kingdom.

It was attempted to follow-up all patients post-operatively annually, and the same parameters were reassessed. Clinical and radiographic evaluation was also performed by the senior author or a member of the surgical team. Complications and revision surgery were noted. For the purposes of this study, patients who had not attended recently were contacted by post and asked to either attend for review or complete an Oxford Knee Score. Fourteen knees were assessed by this method, but clinical data obtained earlier were available. Radiographic assessment was not possible due to 3 changes of systems for storing radiographs, resulting in the loss of many originals.

Statistical analysis

The data were stored and analysed on an Access Database (Microsoft). Statistical analysis of the data was performed using the StataIC 11™ computer programme (StataCorp, USA). A standard two-sample mean comparison test (*t* test), Kruskal–Wallis rank test and ANOVA were used.

The cohorts, although assessed prospectively, were analysed retrospectively. The collection of data, and the close of the study, occurred when the senior author stopped performing knee surgery.

Using a two-sample comparison of means test, in order to have a pain score difference of 1 point, and using the standard deviations obtained in this series, it is estimated that the sample size should be 48 in each arm. For a 5 point difference in the Oxford Knee Score, the sample size is estimated at 60 in each arm. For a 10 degree change between the 2 groups in the degree of flexion, or the range of movement, the sample size is estimated at 48 in each arm.

Results

One hundred and forty-one patients (149 procedures) underwent primary total knee replacement between 2000 and 2005.

Only a small number of patients are available in either group after 7 years. Thus, there are no significant results available for comparison.

Seventy-five primary mobile-bearing total knee replacements were inserted in 71 patients (4 had bilateral surgery). Seventy-four primary fixed-bearing total knee replacements were inserted in 70 patients (4 had bilateral surgery). The demographics of both groups are outlined in Table 1.

Proportionately, there are almost twice as many men within the fixed group (0.8: 1) compared with the mobile

Table 1 Patient demographics

	Mobile	Fixed
Sex	Female 53 Male 22	Female 41 Male 33
Age (mean)	66 (31–88)	67 (35–91)
Diagnosis	Osteoarthritis 48 Rheumatoid arthritis 26 Psoriatic arthritis 1	Osteoarthritis 50 Rheumatoid arthritis 22 Psoriatic arthritis 2

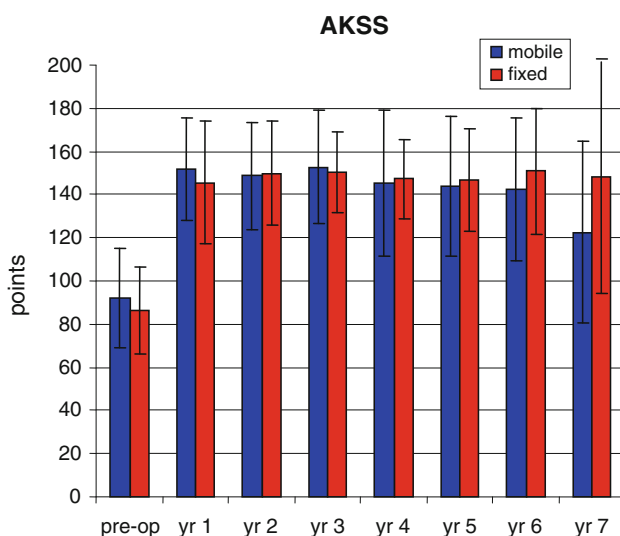
group (0.42: 1), a statistically significant difference. There is no statistically significant difference between the 2 groups regarding any other demographic variables. This series contains a large proportion of patients with rheumatoid arthritis, reflecting the senior author's practice.

There was no significant difference in operation time between the 2 groups as measured by tourniquet time: mobile: 70 min, SD 14, range 44–105; fixed: 69 min, SD 17, range 44–129.

Twenty-seven patients have died from non-surgery-related illness, and 3 other patients have been lost to follow-up. Of these 30 patients lost to follow-up 15 were in each study group. Twenty-two had the diagnosis of osteoarthritis, and 8 had a diagnosis of rheumatoid disease.

American Knee Society Score

At 5-year follow-up, the mean AKSS was 147 (standard deviation (SD) 24) in the fixed group versus 144 (SD 32) in the mobile group. There was no statistically significant difference (n.s.) between the 2 groups at any stage pre- or post-operatively as shown in Fig. 1.

**Fig. 1** American Knee Society Scores of fixed and mobile bearing total knee replacements at annual follow-up

Oxford Knee Score

At 5-year follow-up, the mean OKS was 31 (SD 10) in the fixed group versus 30 (SD 11) in the mobile group (n.s.). There was no statistically significant difference between the 2 groups at any stage pre- or post-operatively as shown in Fig. 2.

Movement

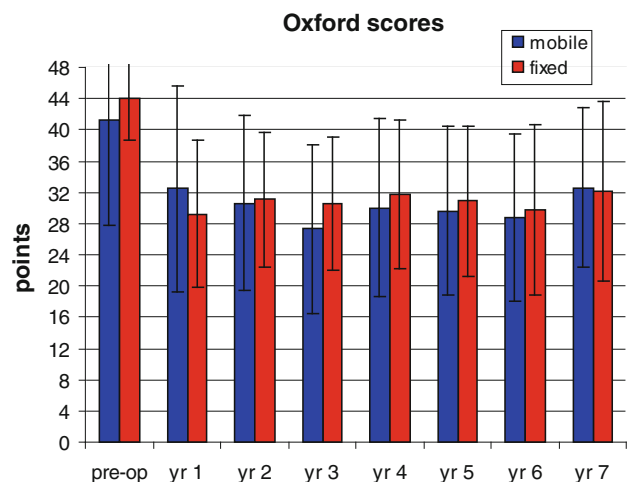
At 5-year follow-up in the mobile-bearing group, the mean range and maximum flexion were 104 (SD 16) and 104 (SD 15) degrees. In the fixed-bearing group, range and maximum flexion were 105 (SD 17) and 105 (SD 17) degrees at 5 years. There was no statistically significant difference between the 2 groups at any stage pre-operatively or post-operatively with regard to range or maximum flexion as shown in Figs. 3 and 4.

Pain score

At 5-year follow-up, the mean pain scores were 3 (SD 1.2) in the mobile group and 3 (SD 1.3) in the fixed group (n.s.). There was no statistically significant difference in pain scores between the fixed and mobile groups pre-operatively or post-operatively as shown in Fig. 5.

Survival

Kaplan–Meier survival charts have been plotted using revision as the endpoint. There is little difference between the two bearing surfaces as shown in Fig. 6. The Nelson–Aalen cumulative risk estimate indicates that there is little difference between the two bearing surfaces as demonstrated in Fig. 7.

**Fig. 2** Oxford Knee Scores of fixed and mobile bearing total knee replacements at annual follow-up

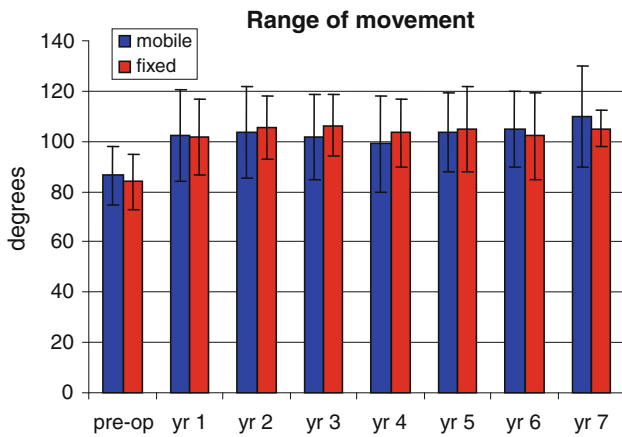


Fig. 3 Range of motion of fixed and mobile bearing total knee replacements at annual follow-up

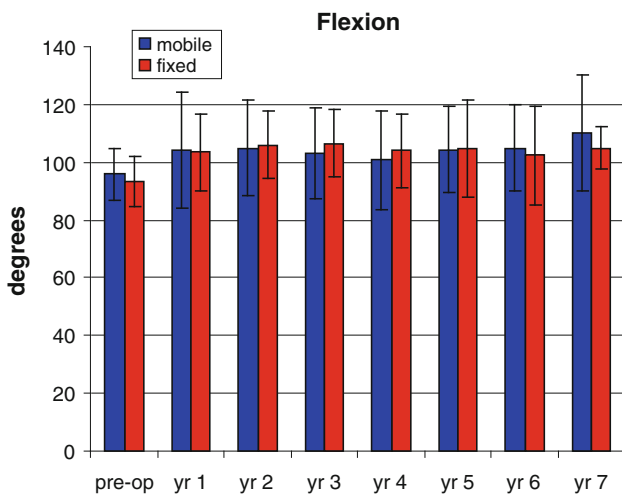


Fig. 4 Knee flexion of fixed and mobile bearing total knee replacements at annual follow-up

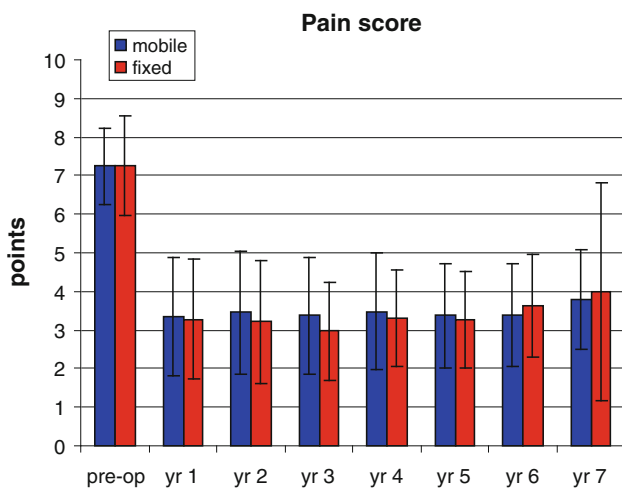


Fig. 5 Pain score of fixed- and mobile-bearing total knee replacements at annual follow-up

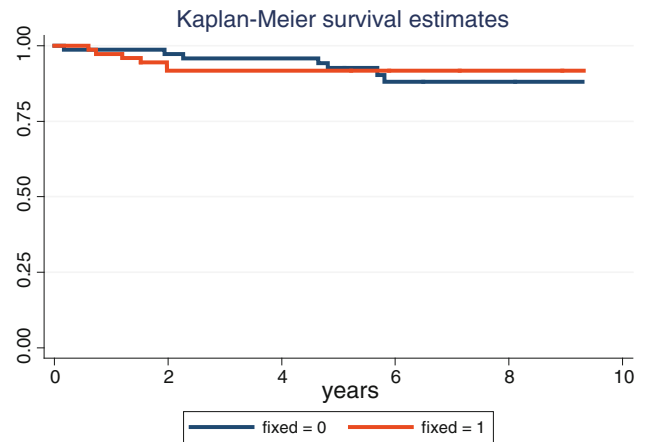


Fig. 6 Kaplan–Meier curve, fixed versus mobile

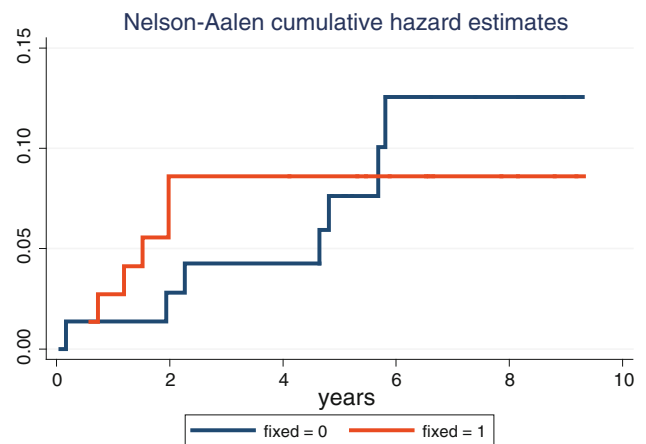


Fig. 7 Nelson–Aalen cumulative hazard estimates, fixed versus mobile

Revision

Seven patients in the mobile group required revision after an average of 44 months (2–71). This was due to aseptic loosening in 4 cases; ligamentous instability which commenced 6 months post-operatively in 1 case; and in 2 cases, the hospital notes were not retrievable. Six patients in the fixed group required revision after an average of 16 months (7–24). This was due to aseptic loosening in 4 cases, ongoing pain in the absence of infection in 1 case; the other patient’s hospital notes were not retrievable.

Discussion

The most important finding of this study was that there was no statistically or clinically significant difference between the two bearing surfaces in the primary or secondary outcome measures at any stage over a 5-year (minimum) period. Limitations of previous studies comparing fixed-

and mobile-bearing surfaces include the use of different implants, and multiple operating surgeons [11, 16]. Price et al. compared the AGC non-modular, compression moulded fixed-bearing tibial component, with the mobile-bearing TMK modular, mobile-bearing prosthesis [16]. They found slightly better AKSS, OKS and pain scores within the mobile-bearing group at 1 year. Kim et al. have studied simultaneous fixed and mobile-bearing knee replacements in the same patient. Medium- and long-term outcomes comparing a fixed-bearing AMK, with the mobile bearing, modular LCS (both Depuy) have found that total knee score, pain score, mean functional score and range of motion to be comparable in both groups 6 years post-operatively [11]. Longer-term follow-up (13.2 years) confirmed similar outcomes in the 2 groups [12]. The same centre carried out a randomised controlled trial comparing fixed and mobile bearings in the same patient undergoing simultaneous bilateral knee replacement. In this study, the implants (PFC sigma) were similar, (the articular surface of the tibial tray for the mobile bearing is polished, and the surface of the fixed-bearing version is matt). Again no significant difference was found in functional, pain, range of movement or radiographic findings between the 2 groups [9].

Aglietti et al. randomised patients to either a LPS (fixed bearing, PCL sacrificing) or a MBK (mobile bearing, PCL retaining) implant (Zimmer, Warsaw). At 3-year follow-up, the 2 groups had similar knee function and pain scores [1]. A randomised radiostereometric study by Hansson et al. compared the predecessors of the Rotaglide+ prosthesis, that is, the Rotaglide Total Knee System (RTK) and the Nuffield Total Knee System (NTK). There were no differences in HSS knee score, migration or inducible displacement over a 2-year follow-up [6].

More recent studies have used the same implant, with only the bearing surface differing. Wylde et al. [23] found no difference between patients randomised to fixed- or mobile-bearing Kinemax total knee replacements with respect to pain, function and satisfaction. A prospective, randomised, single-blind trial by Ball et al. using the Scorpio knee replacement found that patients' stair-climbing ability was better in the rotating platform group compared with the fixed platform group. Otherwise, there was no difference in Knee Society Scores, range of motion or SF-12 scores between the groups at 2-year follow-up [2]. At an average of 5.9 years, Matsuda et al. [14] found no difference in Knee Society Score, range of motion or radiological results of patients receiving the NexGen LPS-Flex fixed or mobile-bearing prosthesis. A meta-analysis and systematic review carried out by Smith et al. reviewed randomized controlled trials comparing clinical outcomes of fixed and mobile-bearing TKR. It found no significant difference in Knee Society Scores, Hospital for Specialist Surgery Scores or range of motion between the 2 groups [21].

The relatively large sample size of 149 patients and a 5-year follow-up of 79 % compare favourably with other studies and give the results sufficient validity to be of practical use to knee arthroplasty surgeons. The study's main limitations are the process of assigning patients to the fixed-/mobile-bearing surface; the lack of true randomisation; non-blinding of patients and assessors; and the low follow-up numbers beyond 5 years. However, similarities in pre-operative diagnosis and functional scores between the 2 groups are marked and add credibility to the findings. This study uses prospectively collected data from a single-surgeon series, minimising the influence of inter-surgeon variability. The use of a single implant means that the bearing surface is the only implant variable between the two groups. These factors augment the argument that any difference (or lack thereof) between the 2 groups is due to the bearing surface. These findings are clinically relevant as both bearing surfaces are readily available. Surgeons can confidently implant either bearing surface knowing that one is as good as the other.

Conclusion

This study is the first of its kind to outline the medium-term (≥ 5 years) outcomes in Rotaglide+ total knee replacements. Its findings, comparing fixed and mobile-bearing surfaces, reinforce previous research which has shown no discernible difference in clinical outcomes between the 2 groups

Conflict of interest None declared.

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