Patient-reported outcomes after fixed- *versus* mobile-bearing total knee replacement

A MULTI-CENTRE RANDOMISED CONTROLLED TRIAL USING THE KINEMAX TOTAL KNEE REPLACEMENT

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We compared patient-reported outcomes of the Kinemax fixed- and mobile-bearing total knee replacement in a multi-centre randomised controlled trial. Patients were randomised to the fixed- or the mobile-bearing prosthesis via a sealed envelope method after the bone cuts had been made in the operating theatre. Randomisation was stratified by centre and diagnosis. Patients were assessed pre-operatively and at eight to 12 weeks, one year and two years post-operatively. Validated questionnaires were used which included the Western Ontario MacMasters University, Short-Form 12, Mental Health Index-5, Knee Injury and Osteoarthritis Outcome Score for Knee-Related Quality of Life and Function in Sport and Recreation scales and a validated scale of satisfaction post-operatively. In total, 242 patients (250 knees) with a mean age of 68 years (40 to 80) were recruited from four NHS orthopaedic centres. Of these, 132 patients (54.5%) were women.

No statistically significant differences could be identified in any of the patient-reported outcome scores between patients who received the fixed-bearing or the mobile-bearing knee up to two-years post-operatively.

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Younger and more active patients are now undergoing total knee replacement (TKR) due to widening criteria for surgery and changing demographics of the patient population.¹ By providing a dual-surface articulation, allowing mobility of the bearing surface and enhancing the conformity of the polyethylene insert, the theoretical advantage of the mobile-bearing implant is a reduction of stress at the bearing surface and thereby a reduction in failure due to polyethylene wear.² These design features should also follow a closer reproduction of normal knee kinematics, thereby producing an arthroplasty that feels more natural to the patient. The Kinemax Plus mobile-bearing prosthesis (Stryker-Howmedica, Limerick, Ireland) is an evolution combining the Kinemax Plus (Stryker-Howmedica) and an established mobile-bearing system from the Interax ISA (Stryker-Howmedica) system.

To date, there is no clear consensus on whether the mobile-bearing knee produces better outcomes than the fixed-bearing knee replacement. Previous research³⁻⁹ has failed to resolve the ongoing debate, and a Cochrane Review on the subject criticised the methodology of previous studies, describing the quality of the research as 'silver',¹⁰ meaning it was found to be poor.

Many of the previous trials comparing outcomes after fixed- and mobile-bearing implants have used surgeon-based outcome tools, such as the Knee Society score (KSS),¹¹ to assess clinical outcomes. However, tools such as the KSS are limited because there is a well-documented discrepancy between clinician and patient ratings of health status, particularly in subjective domains such as pain and quality of life.^{12,13} To address this deficiency, patient-reported outcome measures, such as the disease-specific Western Ontario and McMaster University Osteoarthritis Index (WOMAC)¹⁴ and the general health Short form (SF)-12,¹⁵ have been developed which can be supplemented by validated measures of joint-related quality of life such as the knee injury and osteoarthritis outcome score (KOOS) quality of life scale¹⁶ and a satisfaction scale.¹⁷

The aim of this randomised controlled trial was to compare patient-reported outcomes, including satisfaction and knee-related quality of life, after Kinemax Plus fixed- *versus* mobile-bearing TKR up to two years after surgery.

Patients and Methods

This prospective, multi-centre randomised controlled trial involved four NHS orthopaedic centres in the United Kingdom (Avon Orthopaedic Centre, Bristol; Weston General

Fig. 1

CONSORT flow diagram.

Hospital, Weston-super-Mare, United Kingdom; Freeman Hospital, Newcastle upon Tyne; Woodend Hospital, Aberdeen, United Kingdom). Ethical approval for this study was gained from South West Multi-Centre Research Ethics Committee as well as the local ethics committees for each of the participating centres. Patients undergoing primary TKR, aged 80 years or younger and with a diagnosis of osteoarthritis or rheumatoid arthritis, were eligible for the study. Exclusion criteria included refusal of consent, a history of infection involving the knee, instability of the knee preventing insertion of an unconstrained prosthesis, augmentation with wedges and/or structural bone grafting at the time of operation, or an inability to complete the questionnaires for either cognitive or physical reasons.

Recruitment. Independent trained research assistants following a standard protocol, recruited patients for the study. All patients gave written informed consent.

A total of 242 patients (250 knees) were recruited from the four centres: Avon Orthopaedic Centre, 85 knees in 85 patients; Weston General Hospital, 23 knees in 23 patients; Freeman Hospital, 92 knees in 84 patients, and Woodend Hospital, 50 knees in 50 patients. Eight patients had bilateral TKR. The mean age of the patients was 68 years (40 to 80) and 132 patients (54.5%) were women. The full

details of patient recruitment are shown in the Consort¹⁸ diagram (Fig. 1).

Assessment times. Patients were assessed within six weeks prior to surgery and at eight weeks, one year and two years after surgery.

Pre-operative data included demographics and socioeconomic status. In order to assess function, knee pain, quality of life, general health and satisfaction with the outcome of surgery, patients completed questionnaires pre-operatively and at each post-operative assessment. Knee status was assessed using the WOMAC questionnaire.¹⁴ Scores for the pain and function domains of the WOMAC were transformed to a 0 to 100 scale, with 100 indicating no pain/functional difficulty and 0 indicating extreme pain/functional difficulty. Physical health was assessed using the Physical Component Score of the SF-12,¹⁵ which ranges from 0 to 100, 100 being best. Mental health was assessed using the five-item Mental Health Index from the SF-36,¹⁹ which has been shown to have good psychometric properties in the general population.²⁰ Quality of life in relation to the knee was measured using the KOOS knee-related quality of life scale.¹⁶ This indicates how much patients are aware of their knee problem, and how much it affects their life, on a scale of 0 to 100, 100 being best. Higher function

Table I. Baseline sociodemographics, clinical characteristics and pre-operative scores

	Fixed (n = 132)	Mobile (n = 118)	p-value
Number of knees per centre			
Avon Orthopaedic Centre	43	42	
Weston General Hospital	13	10	
Freeman Hospital	48	44	
Woodend Hospital	28	22	
Mean age in years (range)	67.6 (40 to 80)	68.9 (41 to 80)	0.20*
Number of women (%)	64 (49)	68 (58)	0.15†
Socioeconomic factors (%)			
Education: College or University	27 of 123 (22)	24 of 102 (24)	0.23†
Income: > £21,000 per annum	10 of 105 (10)	10 of 91 (11)	0.85†
Clinical characteristics			
Mean number of comorbid conditions (SD)	1.7 (1.4)	1.6 (1.4)	0.45*
Diagnosis: osteoarthritis (%)	118 (89)	109 (92)	0.42†
Mean pre-operative patient-reported scores (SD)			
WOMAC [‡] pain	37.2 (17.9)	36.8 (18.7)	0.86*
WOMAC function	37.5 (16.6)	39.0 (18.2)	0.50*
KOOS [§] knee-related quality of life scale	19.1 (14.5)	19.7 (14.6)	0.70*
Physical component score	28.1 (7.2)	27.5 (7.8)	0.37*
Mental Health Index-5	77.2 (18.5)	77.8 (15.7)	0.83*

* Mann-Whitney U test

† chi-squared test

‡ WOMAC, Western Ontario McMasters University

§ KOOS, knee injury and osteoarthritis outcome score

Table II. Frequency of completed questionnaire booklets and reasons for missing data

	Pre-operative	8 to 12 weeks	1 year	2 years
Total number of booklets missing	2	16	17	39
Reasons for missing booklets				
Questionnaire not completed but patient still in study	2	15	8	17
Withdrew from study	0	0	4	11
Revised	0	0	1	2
Deceased	0	1	3	5
Lost to follow-up	0	0	1	4
Completion rate (%)	99.2	93.6	93.2	84.4

was measured using the KOOS function in sports and recreation scale,¹⁶ which measures how much difficulty patients experience when performing five activities: squatting, running, kneeling, jumping, and twisting/pivoting their knee. Response categories range from no difficulty to extreme difficulty. An additional category was added so that patients could indicate if they did not perform the activity. The number of comorbidities was recorded using a validated self-administered comorbidity questionnaire.²¹ Post-operatively, satisfaction data were recorded using a validated measure of satisfaction.¹⁷ This questionnaire includes four questions asking about satisfaction with overall outcome, pain relief, ability to perform activities of daily

living and ability to participate in leisure activities. Responses are on a four-point Likert scale, which ranges from very satisfied to very dissatisfied. A global satisfaction score was calculated as the mean of these responses and then transformed on to a scale ranging from 0 to 100 with 100, being the best.

In addition to validated questionnaires, patients were also asked whether they would undergo the operation again, and how much the TKR had improved their quality of life. Responses were on a 6-point Likert scale, which ranged from “more improvement than I ever dreamed possible” to “the quality of my life is worse”. At each post-operative assessment, data on complications were recorded

on standardised complication forms. All patients lost to follow-up were documented, with reasons for loss recorded.

Randomisation. A computer-generated sequence was used to randomise patients to either the Kinemax Plus fixed- or the mobile-bearing prosthesis. Randomisation was stratified by centre and diagnosis within the centre, so that each centre had two boxes of sealed envelopes, one for patients with a diagnosis of osteoarthritis and one for those with rheumatoid arthritis. After the bone cuts had been made in the operating theatre and it was deemed suitable to implant an unconstrained prosthesis, patients were randomised to either the mobile-bearing or the fixed-bearing prosthesis. A theatre nurse opened a sealed envelope containing the randomisation card to indicate which was to be used, so that the surgeon was not part of the selection process. Both the surgeons and the research nurses were blinded to the treatment allocation until the envelope was opened.

Surgical technique and post-operative rehabilitation. All components were implanted with either Palacos (Biomet, Merck, Darmstadt, Germany) or Simplex (Stryker-Howmedica) cement. Soft-tissue release was performed as required. The patella was resurfaced at the discretion of the surgeon. Post-operative rehabilitation followed the standard protocol for each centre.

Sample size calculation. Assuming a type I error of 0.05 and power of 0.80, the number of patients required to detect a difference between the fixed-bearing and mobile-bearing knee was calculated using the WOMAC function score as the primary outcome measure. An effect, size of 0.4 on the WOMAC function scale is equivalent to an eight-point difference, which is the minimally-perceptible clinical difference to patients.²² Based on this effect, size with a power of 80%, 99 patients would need to be recruited into each group. Accounting for a loss to follow-up of 10% at eight to 12 weeks, one year and two years, it was calculated that a total of 250 knees would need to be recruited (125 in each group).

Statistical analysis. In order to determine whether the data were significantly different from the normal distribution, a Kolmogorov-Smirnov test was used. If $p < 0.05$, the data were treated as non-parametric. To compare continuous variables between the fixed- and mobile-bearing implants, two-sample *t*-tests were used for parametric data and Mann-Whitney U tests for non-parametric data. Chi-squared tests were used to compare categorical data between the two implant groups. All tests were two-tailed, and a significance level of $p < 0.05$ was maintained throughout.

Results

The baseline sociodemographic factors, clinical characteristics and pre-operative scores of the patients by prosthesis type are shown in Table I. There were no significant differences in any of the baseline factors between the two groups. The number of missing questionnaire booklets at each

assessment, and reasons for missing data, are given in Table II. Excellent follow-up was obtained at one year, with questionnaires completed for 233 knees (93.2%), and at two years for 211 knees (84.4%).

Surgery and randomisation. In total, 132 knees were randomised to receive a fixed-bearing prosthesis and 118 to receive a mobile-bearing prosthesis. A total of 57 knees (43.2%) randomised to the fixed-bearing prosthesis had a patellar resurfacing, compared with 44 (37.3%) randomised to the mobile-bearing prosthesis. There was no significant difference in the rate of patellar resurfacing between the fixed- and mobile-bearing groups (chi-squared 0.90, $p = 0.34$).

Patient-reported outcome scores. Overall, the mean WOMAC function scores improved from 38.2 (SD 17.3) pre-operatively to 74.6 (SD 20.8) two-years post-operatively. Greater improvements were observed in pain, from a mean of 37.0 (SD 18.3) before surgery to 80.8 (SD 19.9) at two years' follow-up. The knee-related quality of life mean score of 58.2 (SD 25.4) at two years was markedly lower than the WOMAC pain and function scores at the same stage, but given that this score was also lower pre-operatively with a mean of 19.4 (SD 14.5), the magnitude in change was similar to the WOMAC pain and function scores.

Patient-reported outcome scores by prosthesis type are shown in Table III. As the patient-reported data are skewed for some measures, medians as well as means are presented for all outcome measures at each follow-up assessment. There were no significant differences at any post-operative assessment for the mean scores for pain, function, knee-related quality of life, physical health, mental health, or satisfaction with the outcome of surgery between patients who received a fixed-bearing TKR and those who received a mobile-bearing TKR.

Because reporting means can mask those patients with an excellent or poor outcome, the percentage of patients with each prosthesis that reported no pain/functional limitations or moderate-extreme pain/functional limitations were plotted at each post-operative assessment (Figs 2 and 3). Overall, 23 of the 211 patients (10.9%) had moderate-extreme pain and 34 (16.1%) had moderate-extreme functional limitations at two years post-operatively. There was no significant difference (chi-squared test, function $p = 0.51$; pain $p = 0.09$) in the proportion of knees with either excellent or poor outcomes between the groups.

Satisfaction. A comparison of patient satisfaction with overall outcome, pain relief, ability to perform activities of daily living and ability to partake in leisure activities two years post-operatively is shown in Figure 4. Based on the results from the validated satisfaction scale and Likert scale, in total, 87% (94 of 108 knees) of those with a fixed-bearing TKR and 88.2% of patients (90 of 102 knees) with a mobile-bearing TKR were satisfied with the outcome two years post-operatively. There were no significant differences in satisfaction rates between the groups for any aspect of this outcome. For both prostheses, more patients were

Table III. Patient-reported outcome scores at each follow-up interval

	8 to 12 weeks			1 year			2 years		
	Fixed	Mobile	p-value*	Fixed	Mobile	p-value*	Fixed	Mobile	p-value*
WOMAC[†] pain									
Mean score (SD)	69.1 (20.1)	67.0 (21.4)	0.49	78.6 (22.3)	78.9 (19.8)	0.73	80.0 (20.0)	81.7 (19.9)	0.46
Median score (range)	75 (10 to 100)	70 (0 to 100)		85 (15 to 100)	85 (20 to 100)		85 (25 to 100)	90 (20 to 100)	
WOMAC function									
Mean score (SD)	64.8 (20.2)	62.3 (20.9)	0.44	71.5 (22.5)	72.2 (21.2)	0.91	74.6 (21.0)	74.5 (20.8)	0.92
Median score (range)	67 (16 to 100)	63 (0 to 100)		77 (10 to 100)	77 (13 to 100)		81 (12 to 100)	81 (13 to 100)	
KOOS[‡] knee-related quality of life									
Mean score (SD)	42.9 (21.1)	40.0 (20.3)	0.37	55.2 (27.8)	53.1 (24.8)	0.80	57.7 (25.3)	58.8 (25.6)	0.98
Median (range)	44 (0 to 100)	44 (0 to 94)		56 (0 to 100)	56 (0 to 100)		59 (6 to 100)	56 (0 to 100)	
Satisfaction scale									
Mean score (SD)	72.7 (27.9)	69.5 (25.0)	0.18	79.6 (27.4)	77.8 (23.4)	0.13	78.5 (26.3)	78.2 (26.2)	0.66
Median (range)	83 (0 to 100)	67 (0 to 100)		91 (0 to 100)	83 (0 to 100)		92 (0 to 100)	92 (0 to 100)	
Physical component score									
Mean score (SD)	33.9 (9.8)	32.3 (8.5)	0.22	37.1 (12.2)	37.0 (10.1)	0.96	38.2 (11.4)	36.5 (12.4)	0.32
Median (range)	32 (17 to 55)	30 (17 to 51)		37 (14 to 58)	34 (19 to 57)		39 (16 to 60)	35 (14 to 64)	
Mental Health Index-5									
Mean score (SD)	77.1 (18.0)	75.4 (17.3)	0.35	80.5 (16.6)	78.0 (16.3)	0.20	81.1 (17.3)	77.3 (18.2)	0.76
Median (range)	84 (20 to 100)	76 (24 to 100)		84 (16 to 100)	82 (32 to 100)		88 (12 to 100)	84 (16 to 100)	

* Mann-Whitney U test

† WOMAC, Western Ontario McMasters University

‡ KOOS, knee injury and osteoarthritis outcome score

Fig. 2

Graph showing the percentage of patients with Western Ontario McMasters University pain and function scores of 100 (no pain or functional difficulty) by type of prosthesis at each assessment.

Fig. 3

Graph showing the percentage of patients with Western Ontario McMasters University pain and function scores < 50 (moderate to extreme pain or functional difficulty) by type of prosthesis at each assessment.

very satisfied with pain relief than with return to normal activities of daily living (65.6% (137 of 209 knees) *vs* 52.2% (109 of 209 knees), and were less likely to be very satisfied with their ability to perform leisure activities (43.7%, 90 of 206 knees).

At two years after surgery, 73.8% (79 of 107 knees) of knees that underwent a fixed-bearing implant and 70% (70 of 100 knees) of those that underwent a mobile-bearing implant stated that they would undergo surgery again. Although 12.1% (13 of 107 knees) of the fixed-bearing

Fig. 4a

Fig. 4b

Fig. 4c

Fig. 4d

Individual response to questions from the validated satisfaction scale at two-years post-operatively: a) Overall, how satisfied are you with the results of your knee replacement? b) How satisfied are you with the results of your knee replacement for relieving pain? c) How satisfied are you with the results of your knee replacement for improving your ability to do household or gardening work? d) How satisfied are you with the results of your knee replacement for improving your ability to do leisure activities?

group and 6% (6 of 100 knees) of the mobile-bearing group said that they would not repeat the operation, there were no significant differences between the two groups (chi-squared value 4.97, $p = 0.08$). Overall, 26 of the 210 knees (12.4%) were somewhat or very dissatisfied with the overall outcome of their surgery. A small amount of missing data has meant the totals are slightly different each time, this occurred if a patient missed a question.

Quality of life. A breakdown of the KOOS knee-related quality of life scale at two-years post-operatively is given in Figure 5. There were no significant differences in any of the questions between patients who received a fixed-bearing prosthesis and those who received a mobile-bearing prosthesis.

When the two-year results were combined for patients in both groups, 60.3% (117 of 194 knees in 189 patients) were daily or constantly aware of their knee problem, and 60.2% (118 of 196 knees in 190 patients) also had to moderate or totally modify their lifestyle to avoid potentially damaging their knee. However, 63.2% (124 of 196 knees in 190 patients) of patients were not at all or only mildly troubled by a lack of confidence in their knee and 61.9% (122 of 197 knees in 191 patients) had none or only mild difficulty with their knee.

When patients were asked how much the TKR had improved their quality of life at two years after surgery,

89.2% (91 of 102 knees, in 102 patients) of patients with a fixed-bearing TKR and 82.4% (89 of 108 knees in 100 patients) of those with a mobile-bearing TKR indicated that they had experienced at least a moderate improvement in quality of life.

Higher function. There was no significant difference at two-years' follow-up in the percentage of patients with the fixed-bearing or the mobile-bearing prosthesis who had difficulty squatting (chi-squared 6.2, $p = 0.28$), running (chi-squared 8.29, $p = 0.14$), jumping (chi-squared 5.97, $p = 0.31$), twisting (chi-squared 2.5, $p = 0.77$) or kneeling (chi-squared 1.3, $p = 0.93$). However, most patients did not perform the activities on the KOOS function in sports and recreation scale, with between 61.7% (121 of 196 knees in 190 patients) and 84.2% (166 of 197 knees in 191 patients) of patients not performing the activities at two-years post-operatively.

Complications. Details of complications at each post-operative assessment are given in Table IV. Two patients, both with a fixed-bearing TKR, had revision surgery during the study period, for an inadequate range of movement in one patient and loosening of the tibial component in the other.

Discussion

This prospective randomised controlled trial found that there was no significant difference in any patient-reported outcome

Fig. 5a

Fig. 5b

Fig. 5c

Fig. 5d

Individual response to questions from the knee-related quality of life scale at two-years post-operatively: a) How often are you aware of your knee problem? b) Have you modified your lifestyle to avoid potentially damaging activities to your knee? c) How much are you troubled by a lack of confidence in your knee? d) In general, how much difficulty do you have with your knee?

after the fixed- *versus* the mobile-bearing implant up to two-years post-operatively. Recent prospective randomised trials³⁻⁷ have also failed to find a difference in clinical outcome, radiological analysis or survival between the fixed- and mobile-bearing prostheses. When comparing clinical outcomes of the two implant types in the same patient, no differences were found in the KSS, pain or range of movement between five and 13 years' follow-up.³⁻⁶ In patients undergoing unilateral TKR no significant differences were found in the KSS, at three years post-operatively, although higher maximum flexion was seen in the fixed-bearing knee.⁷ Contrary to other research, Price et al⁸ found that patients with the mobile-bearing implant had significantly better KSS, Oxford knee scores²³ and pain scores than patients with the fixed-bearing implant at one year post-operatively. However, they acknowledged that the findings were likely to be only indirectly related to the type of bearing, because of design differences between the two prostheses. Indeed, the differences in outcome between the fixed-bearing and mobile-bearing knee were not maintained at three-years' follow-up.²⁴

Radiological analysis has failed to find any advantage of the mobile-bearing knee over the fixed-bearing knee. Using the Knee Society roentgenographic evaluation system, similar short-term results were obtained for the fixed-bearing and

mobile-bearing implants.⁷ Long-term radiological follow-up of the two implants has revealed no differences in the presence of radiolucent lines or osteolysis.^{4,5} Excellent survival rates have been reported for both designs, with a survival rate of 97% for the fixed-bearing knee and 98% for the mobile-bearing knee at 14 years.⁴

It is possible that a lack of difference in patient-reported outcomes between the fixed- and mobile-bearing implants in this study was because of participant demographics. The mobile-bearing prosthesis was designed to provide a greater range of movement and allow participation in higher-functioning activities. However, the mean age of participants in this study was 68 years, and the majority were not performing such activities, as demonstrated with the results from the KOOS function in sports and recreation scale. Therefore, it might be argued that the Kinemax mobile-bearing knee implant is not reaching its full potential in the older population that present for TKR in the Health Service, and a randomised controlled trial involving younger, more active patients might be required to reveal any functional advantage of one design over the other.

Other findings from this study that need to be highlighted are that, overall 11% of patients reported moderate to severe pain, and 16.4% of patients reported moderate to extreme

Table IV. Complications

	Fixed	Mobile
8 to 12 weeks		
Medical		
Deep-vein thrombosis	1	2
Cardiovascular complications	0	3
Pulmonary embolism	0	2
Chest infection/pneumonia	1	1
Urinary track infections	1	1
Bowel obstruction	1	0
Surgical		
Superficial wound infection	7	5
Deep wound infection	1	0
Inadequate range of flexion (< 75°)	3	2
Severe unexplained pain	0	1
Fractured patella	0	1
Quadriceps tendon tear	1	0
Fell on ward and dehiscd wound	1	0
1 year		
Inadequate range of flexion (< 75°)	4*	1
Loosening of tibial component	1*	0
Patella tracking laterally	1	0
2 years		
Severe unexplained pain	2	0
Subluxed patella	0	1

* includes one patient revised one-year post-operatively

functional limitations at two years post-operatively. Pain and functional impairment strongly influence patient satisfaction, with those who experience more pain and functional limitations being less likely to be satisfied with the outcome of surgery.²⁵ In the current study, the levels of dissatisfaction reflected those of pain and functional limitations, with 12.4% of patients being somewhat or very dissatisfied with their outcome two years after surgery. Previous research has reported similarly high rates of chronic pain, disability and dissatisfaction after TKR,²⁶ suggesting that it is not achieving its purpose of providing pain relief and restoring functional ability in a substantial proportion of patients.

In conclusion, no statistically significant differences were found in patient-reported outcomes between the Kinemax Plus fixed- and mobile-bearing implants up to two years post-operatively.

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