A cemented mobile-bearing total knee replacement prevents periprosthetic loss of bone mineral density around the femoral component

A MATCHED COHORT STUDY

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Bone mineral density (BMD) around the femoral component has been reported to decrease after total knee replacement (TKR) because of stress shielding. Our aim was to determine whether a cemented mobile-bearing component reduced the post-operative loss of BMD. In our study 28 knees receiving a cemented fixed-bearing TKR were matched with 28 receiving a cemented mobile-bearing TKR. They underwent dual-energy x-ray absorptiometry, pre-operatively and at three weeks and at three, six, 12, 18 and 24 months post-operatively. The patients were not taking medication to improve the BMD.

The pre-operative differences in the BMD of the femoral neck, wrist, lumbar spine and knee in the two groups were not significant. The BMD of the femur decreased post-operatively in the fixed-bearing group, but not the mobile-bearing group. The difference in the post-operative change in the BMD in the two groups was statistically significant ($p < 0.05$) at 18 and 24 months.

Our findings show that a cemented mobile-bearing TKR has a favourable effect on the BMD of the distal femur after TKR in the short term. Further study is required to determine the long-term effects.

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After total knee replacement (TKR), the bone mineral density (BMD) decreases around the cemented and cementless femoral component.¹⁻⁷ Stress shielding is thought to be the main cause of this bone loss⁷ and it has been reported that the design of the articulating surface affects the change in BMD.³ TKRs with posteriorly stabilised inserts have more reduction in BMD than those with other types of insert, such as cruciate-retaining implants.³ The mobile-bearing TKR is designed to maximise conformity between the articulating components and to minimise constraint. It has been suggested that the mobility of the polyethylene insert reduces transmission of stress to the prosthesis-bone interface.^{8,9} However, there have been no studies which have focused on the changes in BMD after implantation of a mobile-bearing posteriorly stabilised TKR. Our hypothesis was that a cemented mobile-bearing TKR would decrease the post-operative loss of BMD around the femoral component. We compared the post-operative BMD of a group of patients who underwent a conventional cemented fixed-bearing posteriorly stabilised TKR (NexGen LPS-flex; Zimmer, Warsaw, Indiana) with a group who

underwent cemented mobile-bearing TKR (PFC Sigma RP; Depuy, Warsaw, Indiana).

Patients and Methods

Between June 2004 and September 2005, 32 primary TKRs were performed in 32 patients using a cemented fixed-bearing (NexGen LPS-flex) posterior-stabilised prosthesis. Three patients died of unrelated causes during the follow-up period and one failed to have measurement of his BMD at two weeks after the operation. This left 28 patients in this group who were available for clinical and radiological reviews.

At the same time 76 patients who had undergone a primary TKR using a cemented mobile-bearing PFC Sigma RP posteriorly stabilised prosthesis were identified. From this series, 28 (28 knees) were matched with respect to gender, age, body-weight, height, diagnosis and date of surgery with the patients with a fixed-bearing prosthesis to obtain matched pairs. We compared the BMD around the femoral component in both groups. Our study was approved by our Institutional Review Board and all the patients gave informed consent.

All the TKRs were performed by the senior author (AK) through a standard midline incision with a medial parapatellar approach. The posterior cruciate ligament was resected. Tibial resection was performed, with an attempt to remove 10 mm from the articular surface perpendicular to the shaft of the tibia in the coronal plane. According to the manufacturer's recommendation, the intended posterior slope of the resection was 0° for the PFC Sigma RP and 7° for the NexGen LPS-Flex implant. Distal femoral resection removed a thickness of bone equal to that of the femoral component perpendicular to the mechanical axis of the femur. The size of the femoral component was determined using a sizer with an anterior reference system. The femoral component was introduced in 3° of external rotation in relation to the posterior condyles. Osteophytes on the posterior aspect of the femur were removed. Ligamentous balancing was then performed. The patella was resurfaced in all the knees. All the femoral components were inserted with cement (Simplex P; Stryker, Mahwah, New Jersey) after thorough pulsed lavage. The drain was removed and patients were mobilised on the first post-operative day.

Clinical and radiological evaluation was performed pre-operatively and at 24 months post-operatively by an author (YM) who was not involved in any of the operations. Clinical evaluation was performed using the Knee Society score¹⁰ and measurement of the range of movement of the knee.¹¹ Radiological evaluation was performed using anteroposterior, lateral and skyline views with the knees flexed to 45°. Radiolucent lines were evaluated.

Dual-energy x-ray absorptiometry (DXA; QDR 4500A; Hologic, Waltham, Massachusetts) was used to measure the BMD. Standard scans of the L2-4 vertebrae, the ipsilateral femoral neck and the ipsilateral forearm were obtained pre-operatively and scans of the lumbar spine were also obtained at 24 months after the operation. The density in the distal part of the femur was measured at two weeks pre-operatively and at two weeks and at three, six, 12, 18 and 24 months after the operation. The distal part of the femur was divided into three regions of interest (ROI) as follows: the anterior (ROI 1), the central (ROI 2) and the posterior (ROI 3) (Fig. 1).

Statistical analysis. The age, body-weight, height, pre- and post-operative Knee Society score¹⁰ and the pre-operative BMD in the lumbar spine, hip, forearm and knee in the two groups were compared using the Mann-Whitney U test. Gender and the pre-operative diagnosis in the two groups were compared using the chi-squared test or Fisher's exact test. The Mann-Whitney U test was also used to compare the relative changes in the BMD at three, six, 12, 18 and 24 months in the two groups in each stratum. The BMDs in each ROI at two weeks and at three, six, 12, 18 and 24 months after the operation in all the knees was compared using the paired *t*-test. A *p*-value ≤ 0.05 was considered to be significant.

For the evaluation of reproducibility, DXA measurements were repeated twice in ten patients with an interval of one to seven days. The mean absolute value of the

Fig. 1

Radiograph showing the bone mineral density measurements performed in the lateral projection in the distal part of the femur. Range of interest (ROI) 1 is the anterior third of the distal femur, ROI 2 the central third and ROI 3 the posterior.

difference was 0.05 g/cm² (95% confidence interval (CI) -0.03 to +0.13) at ROI 1, 0.08 g/cm² (95% CI 0.01 to 0.15) at ROI 2 and 0.05 g/cm² (95% CI -0.02 to +0.12) at ROI 3. Intraclass correlation coefficients were 0.90, 0.89, and 0.99 for ROIs 1, 2 and 3, respectively. Power analysis showed that a sample size of 20 would be required to establish significance with $\alpha = 0.05$ and with a power of 0.8.

Results

None of the differences in pre-operative data (gender, age, body-weight, height, diagnosis, Knee Society score, range of movement) or the pre-operative BMD of the lumbar spine, hip, forearm and knee in the two groups was significant (Table I). In addition, at 24 months after operation, the differences in the Knee Society score, the range of movement of the knee, and the BMD in the lumbar spine in the two groups were not significant (Table II). No knee exhibited radiolucent lines.

In the fixed-bearing group, the BMD around the femoral component (ROI 1 to 3) decreased significantly post-operatively, but in the mobile-bearing group it did not (Table III). In ROI 3, the BMD was significantly increased at 12 months post-operatively ($p = 0.047$) in the mobile-bearing group. The difference between the pre-operative and the 24-month post-operative BMD in the lumbar spine was not

Table I. Details of the pre-operative parameters in both groups

Parameters*	Fixed-bearing	Mobile-bearing	p-value
Mean (range) age at operation in years	74.1 (57 to 85)	71.6 (57 to 83)	0.136
Gender			
M:F	6:22	6:22	1.000
Mean (range) body weight in kg	55.6 (33 to 79)	59.1 (42 to 79)	0.198
Mean (range) height in cm	149.6 (135 to 169)	151.8 (137 to 172)	0.255
Diagnosis			
OA:RA	26:2	26:2	1.000
Mean (range) Knee Society score (points)			
Knee	37.6 (20 to 51)	40.6 (20 to 60)	0.186
Function	43.5 (20 to 70)	44.3 (20 to 65)	0.094
Mean (range) range of movement (°)			
Extension	-10.5 (-30 to 51)	-11.6 (-40 to 0)	0.518
Flexion	120.5 (80 to 140)	121.4 (80 to 145)	0.682
Mean (range) BMD in g/cm ²			
Lumbar spine	0.937 (0.629 to 1.332)	0.874 (0.681 to 1.169)	0.359
Hip	0.746 (0.453 to 1.018)	0.772 (0.558 to 1.108)	0.579
Forearm	0.445 (0.351 to 0.604)	0.433 (0.328 to 0.575)	0.533
Knee (ROI 1)	0.718 (0.360 to 1.348)	0.724 (0.366 to 1.500)	0.736
Knee (ROI 2)	0.747 (0.356 to 0.910)	0.755 (0.370 to 0.869)	0.966
Knee (ROI 3)	1.160 (0.263 to 0.841)	1.063 (0.236 to 0.868)	0.156

* OA, osteoarthritis; RA, rheumatoid arthritis; BMD, bone mineral density; ROI, range of interest

Table II. Details of the post-operative parameters at 24 months after operation in both groups

Parameters	Fixed-bearing	Mobile-bearing	p-value*
Mean (range) Knee Society score			
Knee	95.8 (78 to 100)	93.8 (83 to 100)	0.144
Function	80.1 (45 to 100)	86.3 (65 to 100)	0.114
Mean (range) range of movement (°)			
Extension	-2.0 (-10 to 0)	-2.5 (-30 to 0)	0.857
Flexion	125.0 (105 to 140)	125.5 (100 to 140)	0.676
Mean (range) BMD [†] in g/cm ²			
Lumbar spine	0.881 (0.636 to 1.462)	0.946 (0.690 to 1.165)	0.903

* Mann-Whitney U test

† BMD, bone mineral density

significant or in the fixed-bearing ($p = 0.892$) or the mobile-bearing group ($p = 0.604$).

The relative change in the BMD in ROI 1 at 24 months was -14.9% (SD 17.2) in the fixed-bearing group ($p < 0.001$) and 10.5% (SD 26.0) in the mobile-bearing group. The relative change in the BMD in ROI 2 at 24 months was -8.7% (SD 19.9) in the fixed-bearing group ($p = 0.027$) and 8.1% (SD 30.7) in the mobile-bearing group. In ROI 3 at 24 months it was -0.7% (SD 18.9) in the fixed-bearing group ($p = 0.037$) and 9.7% (SD 23.9) in the mobile-bearing group (Fig. 2). The difference in the relative change in the BMD between the two groups was

statistically significant in ROI 1 at 18 and 24 months, in ROI 2 at 12, 18 and 24 months and in ROI 3 at three, six, 12, 18 and 24 months (Fig. 2).

Discussion

Previous studies have shown a decrease in the BMD in the distal femur after TKR, regardless of the method of fixation (cemented or cementless) or if posteriorly stabilised or cruciate-retaining design were used.¹⁻⁷ This decrease is most obvious during the first six months with a magnitude as high as 57%,⁷ especially around the anterior femoral flange.^{5,7} It remains substantial with a mean of 5% per year, up to two

Table III. Details (mean, SD) of post-operative bone mineral density (g/cm²) values in the distal femur in both groups

	Fixed-bearing	p-value*	Mobile-bearing	p-value
ROI 1				
2 wks	0.92 (0.19)		0.99 (0.21)	
3 mths	0.88 (0.21)	0.113	0.98 (0.19)	0.757
6 mths	0.80 (0.18)	0.014 [†]	0.95 (0.20)	0.665
12 mths	0.81 (0.17)	0.002 [‡]	0.95 (0.17)	0.314
18 mths	0.78 (0.19)	< 0.001 [§]	0.95 (0.20)	0.650
24 mths	0.77 (0.19)	< 0.001 [§]	1.05 (0.18)	0.184
ROI 2				
2 wks	1.16 (0.32)		1.09 (0.26)	
3 mths	1.06 (0.23)	0.145	1.11 (0.27)	0.347
6 mths	0.95 (0.23)	0.019 [†]	1.06 (0.20)	0.882
12 mths	0.88 (0.27)	< 0.001 [§]	1.11 (0.24)	0.451
18 mths	0.93 (0.22)	< 0.001 [§]	1.06 (0.21)	0.451
24 mths	1.03 (0.17)	0.034 [†]	1.12 (0.27)	0.539
ROI 3				
2 wks	1.45 (0.26)		1.29 (0.23)	
3 mths	1.35 (0.27)	0.006 [‡]	1.33 (0.28)	0.223
6 mths	1.22 (0.26)	< 0.001 [§]	1.31 (0.21)	0.638
12 mths	1.19 (0.27)	< 0.001 [§]	1.37 (0.23)	0.047*
18 mths	1.32 (0.25)	0.010 [†]	1.34 (0.21)	0.583
24 mths	1.42 (0.26)	0.527	1.39 (0.26)	0.120

* paired t-test

† significantly different at p < 0.005

‡ significantly different at p < 0.01

§ significantly different at p < 0.001

years after TKR.^{2,4} The design of the articulating surface influences the change in the BMD around the femoral component, and reduction in the distal femoral BMD is more pronounced in knees with posteriorly stabilised inserts than in those with other types of insert.³ In our study, the BMD decreased by as much as 20% in the fixed-bearing posteriorly stabilised group, but no prosthetic migration or periprosthetic fractures were detected during follow-up.

The effect of the mobile-bearing mechanism on the BMD after TKR has not been previously determined. Although they did not reach significance except in ROI 3 at 12 months, the post-operative BMD values tended to increase in knees with a mobile-bearing posteriorly stabilised component (Table III). The mobile-bearing mechanism thus appears to prevent loss of BMD even in knees with a posteriorly stabilised insert. Statistically significant differences in the relative change in the BMD, in the two posteriorly stabilised groups were seen from three months and in all ROIs after 18 months (Fig. 2). It has been reported that the design of the articulating surface does not influence the relative change in the BMD around the tibial component, but has an effect on that around the femoral component.^{3,12} The post-operative loss of BMD around the femoral component has been reported to be more pronounced in knees with a posteriorly stabilised insert.³ In our study, the BMD in the distal femur and proximal tibia after TKR decreased even if posteriorly stabilised or

Fig. 2a

Fig. 2b

Fig. 2c

Graph showing the relative changes in bone mineral density (BMD) (mean, standard error). Range of interest (ROI) 1 to 3 (%) in the distal femur. The black dots represent the mobile-bearing component and the white dots the fixed-bearing component. Figure 2a – The differences in the relative change in BMD in ROI 1 were significantly less with the mobile-bearing component than in the fixed-bearing component at 18 and 24 months (* p < 0.05). Figure 2b – The differences in relative change in the BMD in ROI 2 were significantly less in the mobile-bearing component than in the fixed-bearing component at 12, 18 and 24 months (* p < 0.05). Figure 2c – The differences in the relative change in the BMD in ROI 3 were significantly less in the mobile-bearing component than in the fixed-bearing component at 3 to 24 months. (* p < 0.05).

cruciate-retaining design were used. The magnitude of BMD decrease around the tibial component was similar between each design. However, the magnitude of BMD

decrease around the femoral component was larger in the posteriorly stabilised design.

There are some limitations to our study. First, although the improvement in the BMD around the femoral component in the mobile-bearing group was suspected to yield better fixation of the components and to reduce the risk of periprosthetic fracture,^{8,9} the relationship between the loss of BMD in the distal femur and the clinical results has yet to be proven. Secondly, the femoral components used in the two groups were produced by different manufacturers. However, we suspect that the minor differences in these had much less effect on our results than the difference in the type of mechanism for the following reasons. Both types of femoral component were made of a cobalt-chrome alloy, and fixation was performed with the same bone-cement product (Simplex P). The designs of both femoral component were of the posteriorly stabilised type and very similar.

This is the first study on the BMD after cemented TKR which compares fixed-bearing and mobile components. We found that the knees with a cemented mobile-bearing component prevented post-operative loss of BMD around the femoral component compared with a cemented fixed-bearing component. The changes in the BMD in knees with a cemented mobile-bearing component beyond two years are currently unknown. Additional follow-up information would be required to determine the long-term clinical benefits of the use of the cemented mobile-bearing mechanism in TKR.

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