Comparison of high-flex and conventional implants for bilateral total knee arthroplasty

Abstract
Clinical and radiographical outcomes of conventional versus high-flex implants were compared in a prospective study in twenty patients one year after bilateral total knee replacement. First, a conventional posterior stabilized total knee arthroplasty (TKA) was implanted in one limb. Six to eight months later, the contralateral knee of each patient was replaced with a high-flexion design TKA. Clinical and radiological parameters including Knee Society objective and functional Scores (KSS), range of motion, tibial slope, position of the femoral component, angles between the components and the anatomical axis of femur and tibia and final varus or valgus alignment were evaluated one year after the operation. One year after surgery, for PS implants mean knee score and mean functional score were 79 points (range 72 to 93 points) and 81 points (range 70 to 100 points), whereas for RPF knees they were 86 points (range 76 to 93 points) and 91 points (range 75 to 100 points) respectively. Mean maximal flexion 97º in the PS group and 118º in the RPF knees. These results were significantly better for the High flex implants. No differences were found in the radiological results. We conclude that the high flexion TKA is associated with a higher range of motion of the knee resulting in better functional outcomes.

INTRODUCTION
Patient satisfaction after total knee arthroplasty (TKA) depends not only on pain relief but also on the range of motion [1,2]. A knee flexion of 90º to 100º is enough to allow most activities of daily living for elderly people in western countries. Climbing up and down the stairs and sitting on a chair requires 90 to 120º. This range of motion can be achieved with conventional TKA designs whose maximal flexion angle has been reported to range between 100 and 110º [3]. Apart from being influenced by the condition of the patient and surgical technique, the final outcome of a TKA, depends also on the implant design. Therefore, implant manufacturers have attempted to design TKAs that better accommodate knee mechanics in high flexion up to 155º [4,5] to allow patients activities such as squatting and sitting cross-legged which require knee flexion of 110 to 130º [6]. High-flexion implants were initially designed thinking of people who need more flexion in their professional, cultural and religious environments, specially in Asian countries. Nowadays, the demands made on TKA implants are increasing due to a reduction in the age of patients undergoing this procedure, thus high flexion designs are now more often implanted.

The aim of this study was to compare the early clinical outcome and radiological results after bilateral total knee replacement first using in each patient a conventional posterior stabilized implant and later on a high flexion TKA in the contralateral side.

MATERIALS AND METHODS
In 2007, we included 20 patients (7 men and 13 women) who underwent total knee replacement in a prospective study. Mean age of the patients was 75 years (range 65 to 81 years). All patients in this study were diagnosed with bilateral degenerative arthritis, had a body mass index (BMI) less than 30, no previous joint infection, no inflammatory disease, a varus deformity of less than 10º or a valgus deformity less than 5º. Knee function according to the Knee Society objective and functional Scores (KSS) was recorded before the operation. Anterior, lateral, axial and long standing x-rays views were performed preoperatively. Patients were first operated on of one knee with a conventional posterior stabilized (PS) implant (Depuy PFC Sigma PS). Six to eight months later, surgery was performed
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on the contralateral knee of each patient with a high flexion (RPF) TKA (Depuy PFC Sigma RP Flex).

All surgeries were done by two well-trained surgeons. The operative procedures were the same for both the knees in each patient. In all procedures, a medial parapatellar approach was used. Both the anterior and posterior cruciate ligaments were resected in all the cases. Both femoral and tibial components were cemented. The patella was always resurfaced with a cemented implant. Tourniquet was used in every patient. Drains were removed 48 hours after surgery. The rehabilitation program during admission was the same for all the patients. Immediately after surgery they were encouraged to begin quadriceps strengthening exercises. Weight bearing and active ROM exercises were started 24 hours postoperatively and the patients were discharged 8–9 days after surgery. Follow-ups were scheduled 3 weeks, 3 months and one year after surgery.Clinical and radiological examinations were done in each visit. Clinical parameters including KSS, range of motion, maximal extension and flexion were finally evaluated one year after the operation.

Preoperative and postoperative maximal flexion and extension were determined with a goniometer on the lateral side of the knee on supine position.

Radiographic evaluation included both knee standing AP and lateral projections and lateral views in maximal flexion.

In the lateral x-rays, the tibial slope, the position of the femoral component (angle between femoral axis and implant axis) and the maximal knee flexion degree were recorded. For long standing x-rays we analysed the accuracy of component position with respect to the anatomical references. We also recorded the alignment of the tibial component with respect to the centre of the ankle, the alignment of the femoral component with respect to the mechanical axis of the femur and the final varus or valgus limb alignment. All these measurements were performed by an independent radiologist.

The data were analyzed using paired Student t test and Student t test. Differences were considered statistically significant at P<0.05.

RESULTS

Preoperatively, the mean knee score was 41 points for the PS knees (range 11 to 60 points) and 40 for the RPF group (range 60º to 115º).

Mean maximal flexion was 85º before the operation in the PS knees (range 60º to 120º) and 87º in the RPF group (range 60º to 115º).

Preoperative alignment for PS knees was a varus deformity in 19 cases (mean 12°, standard deviation 3.5°) and a 7° valgus in one case. In the RPF group, the alignment was varus in 19 cases (mean 12.5°, SD 3.5°) and a 6° valgus in one case.

Postoperative clinical results are summarized in table 1. One year after surgery, mean knee score and mean functional score were 86 points (range 74 to 90 points) and 81 points (range 70 to 100 points) for PS implants, whereas for RPF knees they were 88 points (range 76 to 93 points) and 91 points (range 75 to 100 points) respectively. There were no statistical differences in the KSS objective score (P=0.3), but the functional score was significantly higher in the PFC knees (P=0.0036). No flexion contractures were found after surgery. Maximal flexion was significantly higher in the RPF group (mean 119º, range 90º to 140º) (Fig.1) than in the PS group (mean 97º, range 80º to 120º) (Fig 2.) P=0.0007.

Postoperative radiological data are presented in table 2. No statistical differences were found between both types of implant.

Figure 1

Table 1. KSS scores and range of flexion
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**DISCUSSION**

The amount of flexion a patient with a TKA can obtain depends on several factors including preoperative ROM [7], pain control and implant design [8]. It is well known that the range of motion after TKA is important for a patient’s overall functional outcome [9]. ROM after TKA using conventional implants has been reported to be about 110° [10]. This range of motion allows most of the activities of daily living in elder people, such as climbing up and down the stairs or sitting and getting up from a chair. High-flexion implants were initially designed in an attempt to obtain higher degrees of flexion for those patients whose culture requires squatting, kneeling or sitting cross-legged [11]. Nowadays, as the average age of patients who undergo TKA continues to decrease, it is desirable for knee prosthesis to allow more flexion as it would be required for many low-impact sporting activities.

Results using high-flex implants are controversial. Huang et al [12] reported no difference in KSS results. However they found an average flexion 10° higher than using a conventional PS implant. Bin et al [13] also found a significantly higher maximal flexion in the high-flex TKA but no differences in the clinical or radiographical outcomes. To the contrary, Kim et al [14] did not find any differences in the flexion obtained in a prospective randomized study after bilateral TKA.

In our study, the objective KSS score showed no differences between the two implants. This may be due to the fact that the knee score is only increased by only one point for each five degrees of flexion. To the contrary, we found a statistically significant difference in functional KSS scores when comparing high-flex and conventional PS TKA. These results were mainly determined by a better ability to climb up and down the stairs.

In all the patients except for one, RPF implants resulted in greater flexion of the knee joint than the PS implants.

In concordance with the majority of reports, we did not find radiological differences when analysing the component position and alignment between our TKR groups.

The main advantage of this study is that both kinds of implant were tested in the same patient, avoiding that demographic, body weight and subjective parameters could affect the results. The limitation is that the prosthesis were not implanted simultaneously, thus slight variations in the rehabilitation protocols could modify the outcomes.

**CONCLUSION**
We conclude that the high flexion TKA is associated with a higher range of motion of the knee resulting in better functional outcomes.

References
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