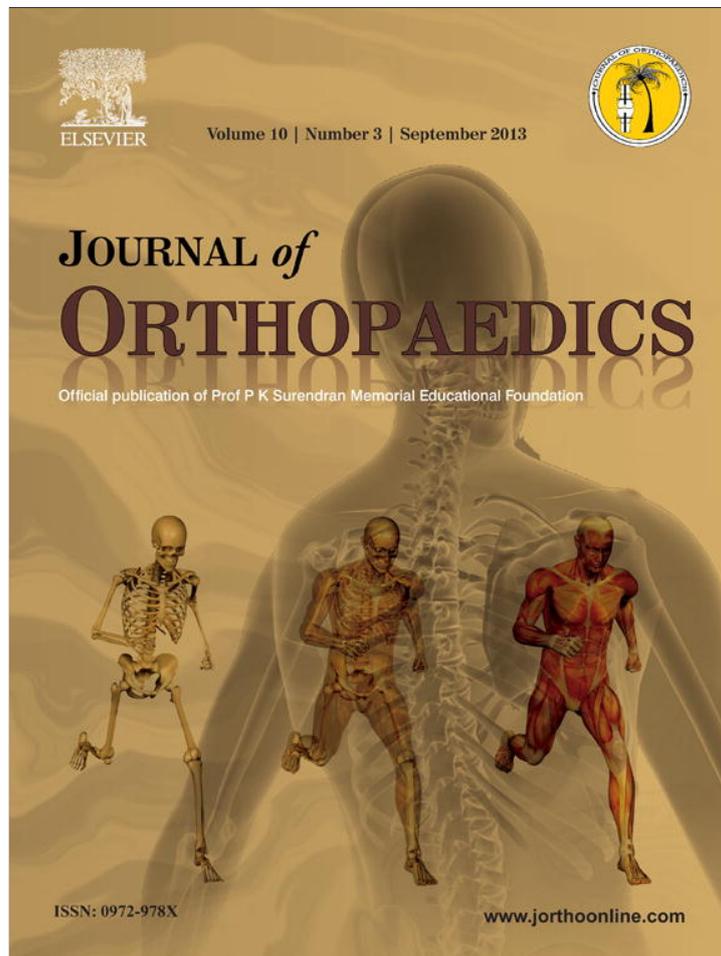


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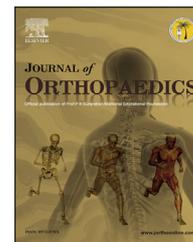
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Original Article

Comparable short-term results seen with standard and high-flexion knee arthroplasty designs in European patients



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ABSTRACT

Purpose: In a prospective study we evaluated outcomes of total knee arthroplasty (TKA) procedures in 62 patients with a follow up of 12 months to test our hypothesis that high-flexion CR (cruciate retaining) TKA provides a better range of motion and better outcome than standard CR design in Central European patients with their special problems and demands.

Methods: Patients were randomly divided into two groups (high flex vs. standard). The outcome was determined by measuring maximum knee flexion and using the KS-score and the SF-36 score.

Results: After 12 months ability to flex the knee significantly improved in both groups to 115° (SD 11) in the high flex group versus 119° (SD 12) in the standard group. There was no difference between the designs regarding maximum flexion ($p = 0.78$). Overall clinical rating scores significantly improved in both groups, but there was no difference between groups at one year after surgery (p (KSS) = 0.7 and p (SF-36) = 0.63). KS-score values improved from 25 points to 89 points for standard TKAs and from 20 points to 90 points for high flex TKAs. SF-36-score "Physical Functioning" values improved from 33 points to 66 points for standard TKAs and from 27 points to 63 points for high flex TKAs.

Conclusion: Our results confirm known good results of the procedure and suggest that the benefit of high flex knee designs is similar to standard knee designs one year after index surgery. Further studies are required to evaluate long-term results of both designs.

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1. Introduction

In the last few years the functional outcome of knee arthroplasty has gained greater importance, including range of motion (ROM). Therefore, modifications of femoral designs were introduced to accommodate knee mechanics in deep

flexion, i.e. modification of condylar offset and increased posterior conformity. ROM is influenced by many factors, as patient condition, surgical technique, and socio-cultural background. Furthermore, the design of the prostheses might also influence postoperative flexion. Although high flex designs are widely distributed in the market, only few data are

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available for European patients in combination with a cruciate retaining, fixed bearing prosthesis.¹

We compared the functional outcomes of knee arthroplasty using a standard CR (cruciate retaining) design and a high-flexion CR design to test the hypothesis that high-flexion CR knees provide better outcomes than standard CR knees.

2. Material and method

Consecutive patients with primary osteoarthritis and a history of severe pain were included in the period of time between August 2010 and March 2011 after blinded randomization. Excluded from the study were patients not willing to participate, patients with a history of open knee surgery, patients older than 85 and younger than 40 years, patients receiving ongoing corticosteroid medication or suffering from metabolic bone diseases or psychiatric illness, and those with a severe deformity of the leg (deviation $>20^\circ$, flexion contracture $>20^\circ$). Surgery was done by one of the authors (HGS) in all cases using medial standard parapatellar arthrotomy and standard instrumentation. A tourniquet was used for all procedures and was deflated before wound closure to allow surgical hemostasis. In all cases, the posterior cruciate ligament was retained, the patella was resurfaced, and posterior clean out was performed. A PFC Sigma knee was implanted in the standard group (ST) and a PFC Sigma CR 150 knee in the high flex group (HF) (DePuy Orthopädie GmbH, Sulzbach, Germany). The high-flexion design has an extended sagittal curve and the posterior femoral condyles are thicker than those of the standard design (Fig. 1). For all patients we used the same design of tibial base plate. All components were fixed with Palacos cement.

In each case patients were invited to return after 6 weeks and 6 and 12 months for clinical follow up using the Knee Society score (KSS)² and the Short Form-36 score (SF-36).

Our hypothesis was, that the high-flexion design would provide better ranges of motion. Statistical analyses were performed using SPSS for Windows ver. 12.0 (SPSS, Inc, Chicago, Ill.). All analyses were performed with the use of two-tailed tests. Paired Student t-test was used to analyze numerical data. P values <0.05 were considered statistically significant. For estimation of sample size an analysis showed that 27 knees per group were required to detect a clinically relevant difference in the range of motion (assumed to be 15°) with a standard deviation of 15° ($\alpha = 0.05$).

3. Results

Sixty-two consecutive patients were included from August 2010 to March 2011. Two cases were excluded from analysis, one because of intraoperative instability and the necessity to use a semi-constraint component and another case because of severe arthrofibrosis which necessitated the performance of closed mobilization. No infection occurred, and no surgical revision was performed in this series. So, there were 31 patients in the high flex group (φ/δ : 20/11), and 29 patients in the standard group (φ/δ : 18/11). There were no significant differences between the groups regarding mean age at time of surgery (69 years (HF) vs. 71 years (ST)), body weight (BMI 32 (HF) vs. 31 (ST)), preoperative knee score (KSS: 20 pts. (HF) vs. 25 pts. (ST) and SF-36: 27 (HF) vs. 33 (ST)).

3.1. Range of motion

Twelve months postoperatively 56 knees had no flexion contracture, two knees demonstrated a contracture of 5° and in one case there was a contracture of 10° . There was no difference in the postoperative mean flexion contracture ($p = 0.14$). In the HF-group maximum flexion angle improved



Fig. 1 – Standard (left) and high-flexion design (right).

from 99° (SD 15) preoperatively to 116° (SD 11) at 6 months and 115° (SD 11) at 12 months. In the standard group corresponding data were 103° (SD 13) preoperatively, 115° (SD 12) at 6 months, and 119 (SD 12) degrees at 12 months (Table 1). There were no significant differences between the groups ($p = 0.86$ preoperatively, $p = 0.58$ at 6 month, and $p = 0.78$ at 12 month). Twelve months postoperatively average flexion improvement was 16° (SD 19) in the HF patients vs. 15° (SD 13) in ST patients ($p = 0.21$). In both groups a similar percentage of patients achieved a maximum flexion of 125° or more (8 cases in the HF group vs. 10 cases in the ST group).

At last follow up, range of motion (ROM) improved significantly for both groups compared with the preoperative values ($p < 0.05$).

Using our study data for posthoc statistical analysis the initial hypotheses of ROM improvement of 15° or more in high flex knees was not confirmed (power = 0.998).

3.2. Knee scores

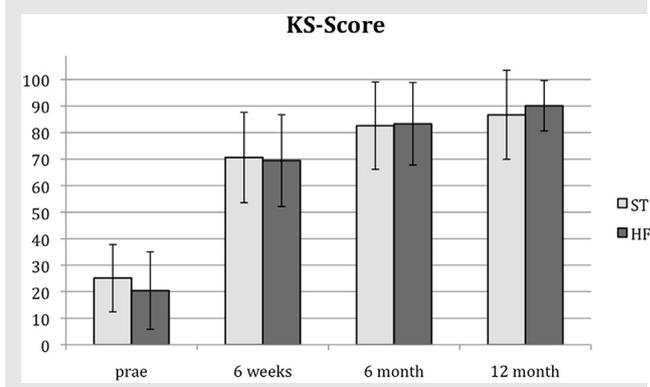
One year after surgery the average postoperative KS-score was 90 points (SD 10) in the HF group versus 89 points (SD 13) in the ST group (Table 2). Mean SF-36-score (“Physical Functioning”) improved to 63 points (SD 23) for HF knees versus 66 (SD 25) points for standard knees. Postoperative score data were similar between the groups ($p = 0.70$, $p = 0.63$). Also SF-36 subscales, i.e. “Bodily Pain” (72 vs. 74 points) and “Change in Health Status” (2 vs. 1.7) were comparable between the study groups ($p = 0.63$, $p = 0.45$).

Twelve months postoperatively both scores improved highly significant for both groups compared with the preoperative values ($p < 0.01$).

4. Discussion

Knee arthroplasty is the end stage therapy of knee arthritis. The goal is long lasting and pain free function of the knee for everyday use. In recent years functional demands of our

Table 2 – Mean KS-score and SD at different time points: There was a significant improvement of postoperative score values compared with the preoperative values, but no difference between the groups (ST: standard, HF: high-flexion).



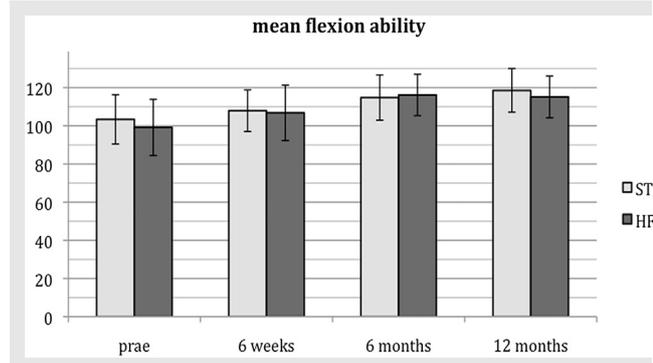
patients have increased and deeper knee flexion may be required, particularly for participating in sport activities in the Western Societies.^{3,4} This resulted in the design of high-flexion prosthesis. Biomechanical studies demonstrated less plastic deformation and contact stress in the high-flexion design with simulated flexion angles beyond 110°. In literature there are inconsistent data regarding functional outcomes of these designs.^{1,6,7} Only few data are available for cruciate retaining arthroplasty designs in combination with Central European patients with their special problems, i.e. high body mass indices.^{8,9}

Our data indicate no significant difference between the high-flexion and standard CR fixed prostheses in terms of range of motion and functional outcome. Hence, we were not able to confirm our initial hypothesis that the high-flexion design would provide better ranges of motion. A limitation of this study might be, that flexion after TKA gradually increases in the second year after index surgery in some cases. Nevertheless, our data indicate good clinical and functional outcomes with both knee designs, although there were negative preoperative predictors, i.e. low levels of preoperative maximum flexion and high body mass indices of >30 in both groups.¹⁰ Our data confirm well known data, that knee arthroplasty reliably results in a marked improvement of life quality.¹¹

It is worth knowing, that high-flexion knees require additional bone resection of the dorsal condyle, because of the thicker dorsal component of the prosthesis. In our series the change in the posterior femoral shape did not improve maximum flexion ability and this design feature does not increase the posterior offset. Increase of posterior femoral condylar offset is known to optimize range of motion.^{12–14}

Although we were not able to detect clinical differences between the groups, for both designs there are potential advantages and disadvantages, respectively. Additional bone loss and increased load in deep flexion might result in early loosening of the femoral component, as demonstrated in Asian patients,¹⁵ and we do not have long-term reports regarding survivorship of high-flexion knee systems. On the

Table 1 – Mean flexion ability and SD at different time points: There was a significant improvement of postoperative maximum flexion ability compared with the preoperative values, but no difference between the groups (ST: standard, HF: high-flexion).



other hand biomechanical data clearly indicate less plastic deformation and contact stress in deep knee flexion for high-flexion designs and a high percentage of our study population achieve maximum flexion ability of 120° or more. In conclusion, our data indicate similar short term results for high-flexion and standard CR fixed prostheses in terms of range of motion and functional outcome. Long-term studies are required to determine whether there are any differences in survivorship between the designs or risks of adverse events for high-flexion designs, respectively. From the clinical point of view, we are not able to recommend one of the both designs with the data available.

Conflicts of interest

None of the authors received payment or services from a third part in support of any aspect of this work. Two authors (HGS, RvE-R) have had a financial relationship, in the thirty-six months prior to submission of this work, with an entity in the biomedical area.

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