Are the long term results of a high-flex total knee replacement affected by the range of flexion?

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Abstract

Purpose The purpose of this study was to examine the effect of deep flexion on the long-term durability of a high-flex ceramic implant in total knee arthroplasty.

Methods Five hundred and five consecutive knees replaced with a Bi-Surface knee system (Kyocera Medical, Osaka, Japan) were divided into two groups according to the range of flexion by 135° postoperatively. Comparison of implant durability was made between the high- and low-flexion groups after a minimum ten year follow-up.

Results With revision for any surgery as the end point, the survival rates at ten years were 95.5 % and 96.2 % in the high- and low-flexion group, respectively ($p=0.63$). With revision for mechanical failure as the end point, survival rates were 98.7 % and 98.5 %, respectively ($p=0.94$).

Conclusion Implant survival rate was similar for both groups. Deep flexion seemed not to affect long-term durability.

Keywords Total knee arthroplasty · Deep flexion · Long-term durability · Clinical results · Bi-Surface knee

Introduction

Total knee arthroplasty (TKA) is a reliable procedure, and good results have been reported by many authors in terms of pain level, walking ability and long-term durability [1–3]. Due to the success of TKA, patients currently receiving TKA are younger and more active than in the past, and postoperative range of flexion has become increasingly important. Furthermore, in Asia and the Middle East, daily activities requiring deep flexion of the knee joint are frequently carried out on the floor for religious and cultural reasons. Knee flexion of up to 111–165° is required for squatting, kneeling and sitting cross legged [4–6]. Deep-flexion activities generate significant net quadriceps moments at the knee. The increase in the extensor force during deep flexion will cause higher stress on the patellar tendon and joint contact forces. In some biomechanical analyses, higher knee forces and polyethylene stresses were shown with increasing flexion angles [7–9]. This higher contact stress suggests that deep flexion activities cause overloads to the polyethylene insert, which might be related to polyethylene wear, component loosening and/or ligament slack [8, 10].

From a clinical standpoint, it has been unclear as to whether or not deep flexion affects long-term durability and clinical results. In some studies from Asia and the Middle East, good clinical results and range of flexion were reported with good durability [11–14]. However, it was not shown whether long-term durability was secured for patients with good range of flexion [11, 12, 14]. Other studies have suggested concerns for deep flexion because a high rate of loosening was observed in deep-flexion patients [15, 16].

We hypothesised that deep flexion might cause problems such as early component loosening and polyethylene wear after a long-term follow-up because higher forces were applied to the knee implant. The purpose of this study was to compare long-term survival rate and clinical results between

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Table 1 Patient characteristics

		High-flexion group (n=207)	Low-flexion group (n=298)	P value
Mean age (years)		67.9	69.4	0.07
Gender	Male	37	39	0.14
	Female	170	259	
Mean body weight (cm)		148.7	148.9	0.88
Mean body height (kg)		53.8	53.9	0.91
Mean body mass index		24.4	24.6	0.77
Diagnosis	Osteoarthritis	139	194	0.53
	Rheumatoid arthritis	66	104	
Follow-up status	Patient death	69	71	0.02
	Lost to follow-up	18	44	0.04
	Available cases	120	183	0.41
Mean follow-up (years)		12.1	12.6	0.15

high- and low-flexion groups and examine the effect of deep flexion on long-term durability and clinical results.

Materials and methods

Five hundred and seven consecutive TKA were carried out in 371 patients using the Bi-Surface knee system (Kyocera Medical, Osaka, Japan) at two different institutions. One patient (two knees) died within one month because of pulmonary embolism, so 505 knees (370 patients) were included in the study. Routine postoperative rehabilitation programmes were carried out for one month, and patients were divided into two groups according to the range of flexion at one month. The high-flexion group consisted of knees with $\geq 135^\circ$ of flexion, and the low-flexion group consisted of knees with $<135^\circ$ of flexion. Two hundred seven and 298 knees were classified into high- and low-flexion groups, respectively. The follow-up period was a minimum of ten years for both groups. No significant difference between groups was identified regarding

Fig. 1 Posterolateral view of the Bi-Surface knee system. The unique ball-and-socket joint is seen in the midposterior portion of the tibiofemoral joint

Fig. 2 Mean range of flexion and standard deviation (SD) over time for both groups. The red line with square dots (■) and the blue line with triangles (▲) indicate high- and low-flexion groups, respectively. Asterisk (*) and dagger (†) indicate statistical significance ($p < 0.05$) for time periods and between groups, respectively

age, gender, body height, body weight, body mass index (BMI), diagnosis and follow-up period. However, there was a significant difference in follow-up status (Table 1).

The Bi-Surface knee system was designed to improve knee flexion and long-term durability. In terms of materials, the femoral component consists of alumina ceramic to reduce polyethylene wear [17]. In terms of design, it has a unique ball-and-socket joint in the midposterior portion of the tibiofemoral joint, which works as a posterior stabilising cam mechanism and shares a load together with medial and lateral condyle in flexion [18, 19]. In addition, this ball-and-joint system allows a greater degree of rotational freedom during deep knee flexion. In several previous studies analysing the in vivo kinematics, larger axial rotation was exhibited during deep flexion [6, 20] (Fig. 1).

Surgery was performed in a uniform manner at both institutions. The posterior cruciate ligament (PCL) was sacrificed, and bone cut was carried out with a measured resection technique. All implants were fixed with bone cement, as follows: First the cement was divided into two equal parts. One half was used to cover the entire bone surface and the other half was spread on the back side of the component. Next, the patellar, femoral and tibial components were impacted and fixed in order with the same technique. For the tibial component, the stem was fixed with cement. Aggressive knee-flexion exercises were performed under physical therapist supervision for the month-long, routine rehabilitation programme, following which patients were free to carry out activities, including deep-flexion activities, without restriction.

Physical examination and knee scoring were performed pre-operatively, one month and one year after surgery and annually thereafter and were assessed using the Knee Society Score (KSS) for knee score and knee function score [21]. Range of flexion was measured passively with a goniometer with the patient in a supine position. Radiographic evaluation

Table 2 Knee Society Score (KSS)

Knee society score		High-flexion group	Low-flexion group	<i>P</i> value
Knee score	Preoperation	43.0±16.9	37.1±16.7	0.03
	Final	95.1±5.8	92.5±8.7	0.04
Function score	Preoperation	39.0±20.2	31.9±18.4	0.02
	Final	51.8±21.2	53.1±26.1	0.75

was also carried out annually. All clinical and radiographic data from the follow-up examinations were recorded and compiled by observers who were not part of the operating team. For survival analysis, all knees were divided into smaller increments (<104°, 105–114°, 115–124°, 125–134°, 135–144°, >145°), as well as the high- and low-flexion groups to evaluate the effect of range of flexion in detail.

Statistical analysis was performed using student *t* test to compare pre-operative demographics (age, body weight, body height, BMI), follow-up period, range of flexion and KSS between groups. Post hoc test was used to compare range of flexion among the four follow-up periods. Chi-square analysis was used to compare patient demographics (gender, diagnosis and follow-up status) and complication rates between groups. Kaplan–Meier survivorship analysis was used to determine the cumulative rate of survival during the period of the study. Log-rank test was used to compare the survival rate between groups. Values of *p*<0.05 were considered significant for the Student *t* test, chi-square test, post hoc test and log-rank test. Post hoc power analysis was conducted to assess durability.

Results

In the high-flexion group, average range of flexion was 133.0° pre-operatively, which was maintained until final follow-up. In the low-flexion group, average range of flexion was 111.6°

pre-operatively, which increased significantly at final follow-up (Fig. 2). Twenty-one knees in the high-flexion group lost their range of flexion <135° at final follow-up, whereas 22 knees in the low-flexion group gained range of flexion ≥135° at final follow-up. Comparing groups, there were significant differences between at any time (*p*<0.01).

KSS knee and function scores were significantly improved in both groups (*p*<0.01). When comparing groups, there were significant differences in knee score between pre-operation and final follow-up and preoperative function score, whereas no significant difference was found in function score at final follow-up (Table 2). In terms of improvement pre-operatively to final follow-up, there were no significant differences in either knee (*p*=0.22) or function (*p*=0.08) scores between groups.

Revision surgeries were performed in 20 knees, components were removed or replaced from 12 knees and one femoral component in the low-flexion group was defined as radiographically loose, which was not revised because the patient refused. This case was included in the revision and removal group in subsequent analysis. Mechanical failure was defined as a case being revised because of instability, aseptic loosening or polyethylene wear. There were no significant differences in any factor between groups (Table 3). Comparing postoperative range of flexion after one month between knees revised due to any surgery or radiographic failure and nonrevised knees, average angles were 122.1±23.3° and 125.4±16.8°, respectively. Comparison between knees revised because of mechanical failure and nonrevised knees, average angles were 122.5±21.0° and 125.3±17.1°, respectively. There were no significant differences between revised and nonrevised knees (*p*=0.40 and *p*=0.65), respectively.

With revision for any surgery or radiographic failure as the end point, there was no significant difference in the survival rate between groups (*p*=0.63, power=0.65) (Fig. 3a). With revision for mechanical failure as the end point, no significant difference was observed in survival rate between

Table 3 Reasons for revision surgery

Reasons	High-flexion group (<i>n</i> =207)		Low-flexion group (<i>n</i> =298)		<i>P</i> value	
	Revision	Removal	Revision	Removal	Revision	Removal
Infection	5	2	4	2	0.37	0.71
Instability	1	1	3	3	0.51	0.51
Aseptic loosening	1	1	2	2	0.78	0.78
Fracture	1	1	1	0	0.80	0.23
Polyethylene wear	0	0	1	1	0.40	0.40
Patellar tendon rupture	0	0	1	0	0.40	
Arthrofibrosis	0	0	1	0	0.40	
Total	8	5	13	8	0.78	0.85
Mechanical failure	2	2	6	6	0.37	0.37

Mechanical failure was defined as a case which was revised because of instability, aseptic loosening or polyethylene wear.

Fig. 3 **a, b** Survival rates with revision for any surgery or radiographic failure as the end point (**a**) and with revision for mechanical failure as the end point (**b**). Red and blue lines indicate high- and low-flexion groups, respectively. No significant differences were found

groups ($p=0.94$, power=0.96) (Fig. 3b). Divided into smaller increments ($<104^\circ$, $105\text{--}114^\circ$, $115\text{--}124^\circ$, $125\text{--}134^\circ$, $135\text{--}144^\circ$, $>145^\circ$), there were no significant differences in survival rate between groups with revision for any surgery or radiographic failure as the end point ($p=0.52$, power=0.84) (Fig. 4a). With revision for mechanical failure as the end point, no significant differences were found in survival rate between groups ($p=0.07$, power=0.74) (Fig. 4b).

Discussion

We hypothesised that deep flexion might cause problems at long-term follow-up because higher knee forces and polyethylene stresses are applied during deep-flexion activities. However, excellent durability and clinical results were secured even in patients with a high range of flexion after a long-term follow-up. Therefore, the hypothesis was denied, and deep flexion seemed not to affect long-term durability and clinical results for implants analysed in this study.

In terms of mechanical properties, deep flexion was considered to be injurious to implanted knees because of the higher loads applied to knee implants and polyethylene and because more axial rotation is demonstrated between femur and tibia. In previous studies, estimated tibiofemoral-joint force in normal knees during full squat were up to seven times greater than body weight in the vertical direction and three times greater than body weight in the posterior direction; also, the force increased with increasing flexion [7, 8, 22]. In the force analysis for implanted knees, results were the same as for normal knees, raising concerns regarding deep flexion after TKA [23, 24]. With respect to knee kinematics for implanted knees, large angular rotation was reported during deep flexion, which might lead to higher load [25, 26]. In some clinical studies, pre-operative range of flexion was positively correlated with postoperative range of flexion [25, 27], and a marked rate of early loosening of the femoral component was reported in deep flexion; squatting, kneeling or sitting cross-legged could be achieved by a higher percentage of patients with loosened knees [15, 16]. In our study, the

Fig. 4 **a, b** Survival rates with revision for any surgery or radiographic failure as the end point (**a**) and with revision for mechanical failure as the end point (**b**), divided into small increments. No significant differences were found

survival rate for high-flexion knees was similar to that in low-flexion knees.

The reasons for revision surgeries are various, and several reasons (infection, fracture, patellar tendon rupture and arthrofibrosis) are considered not to be related to deep flexion [1–3]. In our study, reasons for revision related to deep flexion (instability, aseptic loosening, polyethylene wear) were defined as mechanical failures. In previous studies, the survival rate is 90–97 % at ten years in other types of prostheses with revision for any surgery as the end point; the survival rate is 96–98 % at ten years with revision for mechanical failure as the end point [1–3]. In our study, survival rates with two endpoints for high-flexion knees were comparable with those of other commonly used prostheses.

Characteristics of implants and surgical technique might have contributed to the excellent durability. One feature is that the femoral component is made of alumina ceramic, which showed a lower wear rate than cobalt–chromium (Co–Cr) components [17]. The other feature is that this implant has a unique ball-and-socket joint system, which tolerates large rotation and provides sufficient contact area and lower contact stress in deep flexion [6, 18–20]. As to surgical technique, both the bone surface and the back side of the implant were covered with cement, and all implants, including the tibial stem, were fixed by polymethylmethacrylate (PMMA) cement. This cementing technique reportedly helped the cement to penetrate deeper and the components to be fixed securely [28]. These implant characteristics and the surgical technique might have a positive effect on long-term durability and clinical results.

There were several limitations in our study. The first is that grouping was carried out by range of flexion at one month after surgery. Actually, some knees in the high-flexion group gradually lost their range of flexion; however, though they were included in the study, average range of flexion in the high-flexion group was maintained at final follow-up. In addition, revision operations were performed for five knees from two months to one year after surgery. If the grouping had been carried out at the later period, it would have been difficult to determine how to classify these revised knees. Therefore, grouping was carried out at one month after surgery. The second limitation is that patient activity levels and the frequency of deep-flexion activities were not considered. In Asian lifestyle, deep-flexion activities are frequently required for religious and cultural reasons. The duration of deep flexion might be longer than in Western cultures because patients with good range of flexion might frequently carry out deep-flexion activities on the floor, such as squatting, kneeling and sitting cross-legged. The third limitation is that patients who were lost to follow-up might have undergone revision surgeries in other institutions, and there was a significant difference between groups in patient deaths and those lost to follow-up, which might affect results. The fourth limitation is that the

implant used has been implanted in small numbers worldwide, and patients weighed less, on average, than Western patients. This might have a significant influence on polyethylene wear.

Conclusion

In conclusion, excellent long-term survival and clinical results were obtained for implanted knees that undergo a high range of flexion. Deep flexion seems not to affect long-term durability and clinical results if appropriate implants and surgical techniques are adopted.

Conflict of interest None.

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