



Early results with the Genesis II Posterior Stabilized High Flexion knee prosthesis A one year follow-up study

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The aim of this prospective study was to assess the range of motion (ROM) achieved with the Genesis II Posterior Stabilized High Flexion knee prosthesis. The ROM was compared with that of a historical study group with the standard PS insert and an identical study design.

Sixty three patients with primary knee osteoarthritis (37 female, 26 male ; average age : 67.0 years, average BMI 31.2) underwent primary cemented TKA with a PS high flex insert. The surgery was performed by one senior author using a mini-midvastus approach.

During the follow-up no statistically significant difference in maximal flexion was found between 14 weeks (average flexion = 120°, SD = 11.2) and 65 weeks post-operatively (average flexion = 122°, SD = 8.9).

The radiographic evaluation showed no influence of the implant positioning on the final flexion.

Compared to the results obtained in a 5 year follow-up study of 100 cases in combination with the PS standard insert, the improvement in final flexion range found in this study did not appear not to be great enough to generally recommend the PS high flex insert in terms of a proven higher flexion result.

Keywords : Genesis II Posterior Stabilized High Flexion knee system ; total knee arthroplasty ; deep flexion ; range of motion.

INTRODUCTION

The range of motion (ROM) is an important measure of outcome in Total Knee Arthroplasty

(TKA). The postoperative flexion after TKA results from various factors, some of which are well defined while others are still unknown.

Taking into account the results of a number of studies, consideration should be given to pre-operative factors (maximum flexion, deformity, age, gender, height, weight and body mass index), surgical technique (approach, flexion-extension gap balancing, patella resurfacing and tracking, management of the posterior cruciate ligament,

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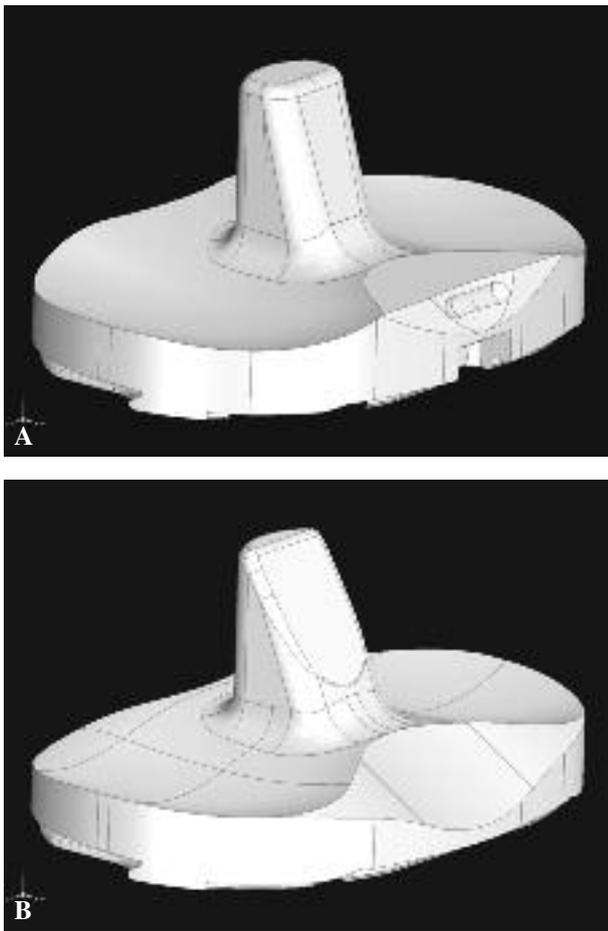


Fig. 1. — A : Genesis II posterior-stabilized tibial insert. B : Genesis II high-flex posterior-stabilized tibial insert. The anterior portion of the polyethylene has been chamfered to prevent potential impingement with the patellar tendon in deep flexion. Likewise, the post has been chamfered anteriorly to prevent potential impingement with the patella in deep flexion (Courtesy Smith&Nephew).

component sizing and position, posterior osteophytes, tibial slope and wound closure), postoperative rehabilitation and of course, prosthetic design (3,16,18,20,21,23,26,27,30,32,34,40,42).

The flexion achieved after TKA using a conventional design rarely exceeds 120° (19,30,36).

It is widely accepted that deep flexion, defined as flexion in excess of 120° could improve the ability to carry out certain important activities in daily life. This has been linked to a better functional outcome (30,32,36).

Although prosthesis design is only one of several factors influencing the postoperative flexion, there are studies suggesting that a high flex design may result in a increased ROM (16,30,36,41,42).

We report the clinical outcome and ROM of TKA with the Genesis II Posterior Stabilized High Flexion System™ (Smith & Nephew Inc, Memphis, TN, USA).

MATERIAL AND METHODS

In a prospective cohort study without a randomized control group, 63 patients (37 right and 26 left knees, average age 68 ± 9.8 years, average BMI 31.2 ± 4.9) underwent 64 primary cemented TKAs using the Genesis II™ prosthesis with the PS High Flex insert for primary osteoarthritis of the knee (fig 1). The implant was used in a continuous series as a standard implant.

As an exclusion criterion, the use of this unconstrained bicondylar TKA was deemed to be contraindicated if correct tissue balance could not be achieved intraoperatively and a higher degree of constraint was therefore necessary. In terms of inclusion criteria there was no limitation with respect to the BMI, the preoperative ROM or the patient's activity level.

In one patient a bilateral TKA with the PS High Flex Insert was performed as a two-stage procedure.

All procedures were performed by the senior author (RL) at the Hospital for Special Surgery (HSS), New York, via a mini-midvastus incision using standard instruments, under regional epidural anaesthesia supplemented by a femoral nerve block (27).

Intramedullary guides and anterior referencing cutting blocks were used for positioning of the femoral cutting jig. For the femoral component, 6° valgus in the coronal plane and 180° in the sagittal plane were regarded to be the target positions. The femoral size was selected so as to replicate the anteroposterior dimension of the distal femur.

An intramedullary tibial alignment rod which was placed for at least 80% of the tibial length was used for placement of the tibial resection jig.

In the Genesis II prosthesis the posterior stabilized high flexion insert features a built-in 4° posterior tibial slope, and a tibial cut with 3° posterior downslope is required. In the coronal plane the tibial plateau was resected at 90° to the anatomical axis of the tibia.

A high-flex posterior-stabilized insert was implanted in all cases.

The patella was displaced laterally, but was not everted. A symmetrical inset patellar implant was implanted in all cases, in an attempt to restore the preoperative patellar thickness.

All patients were put on parenteral antibiotics for 24 hours after surgery. Coumadin (Bristol-Myers Squibb, Princeton, NJ, USA) was used as an antithrombotic medication for 4 weeks after surgery.

A combined epidural and femoral nerve block was performed for anaesthesia in all patients. Postoperatively, a closed suction drain was left for 24 hours.

The epidural block was continued for 2 days. Patients received a basal level of analgesics and were allowed to increase this amount by using a self-administered patient - controlled analgesia (PCA) pump (CADD-PRIZM™, Simos Delta, St. Paul, MN, USA).

All patients received standard physiotherapy. They began performing flexion exercises using a controlled passive motion machine in the post-anaesthesia care unit, set initially at 70° and then increased as tolerated. The passive motion machine was used twice a day for one hour throughout the hospital stay. This was supplemented by sitting flexion exercises supervised by a physiotherapist. Patients were allowed to walk, bearing weight on the affected leg, the day after surgery. External support was initially a walker, replaced by crutches from the third or fourth day.

Clinical follow-up was planned 1 month, 3 months and 1 year postoperatively. All preoperative and follow-up assessments were performed by the senior author following the American Knee Society (AKS) scoring system (17).

In addition a radiographic evaluation was performed, consisting of measuring the joint line position, the patellar height, the patellar displacement and tilt pre- and postoperatively as well as the implant positioning (tibial slope, varus- valgus positioning of tibial implant, extension/flexion of femoral implant), on average 43.2 ± 17.7 days postoperatively (11,12). Anterior/posterior translation of the femoral prosthesis was also measured. Posterior translation was defined as anterior notching of the distal femur. Anterior translation was present if a (cement-filled) gap of more than 1mm could be detected in the lateral radiograph between the distal part of the anterior femoral cut and the femoral implant.

Noted was the presence of a postoperative ossification and/or remained overhanging dorsal femoral osteophytes, which were measured in width and length (fig 2) (38).

In all patients the pre- and postoperative ROM and femorotibial angle were measured clinically using a stan-

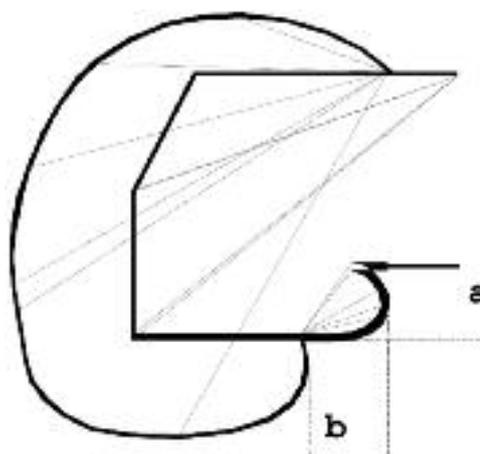


Fig. 2. — Measurement of overhanging dorsal osteophytes of the femur.

dard 2-arm goniometer (30 cm arms with 1° markings) by the senior author (5,10).

The soft tissue balancing was assessed in 0°, 60° and 90° of flexion for mediolateral stability and in 90° flexion for AP stability. This evaluation was performed by the senior author following the AKS criteria (17).

Statistical analysis

Statistical analyses were performed using SPSS for Windows Release 15.0 (SPSS Inc.).

For comparisons between normally distributed paired groups we used Student's t-test.

In order to measure the degree of linear relationship between two variables the Pearson Product Moment Correlation (PPMC) was performed.

Multilinear regression analysis was used for the modeling and analysis of numerical data consisting of values of a dependent variable (response variable) and of one or more independent variables (explanatory variables). A p value of less than 0.05 was considered significant.

RESULTS

Clinical evaluation and ROM

Assessment of the ligament balance showed no postoperative mediolateral or AP-instability.

According to the definition used for this study (varus deformity : > 180° femorotibial angle ; valgus deformity : < 175° femorotibial angle) 46 knees

had a varus alignment (mean : $10^\circ + 4^\circ$) while 15 had a valgus alignment (mean : $14^\circ + 3^\circ$) preoperatively.

Table I shows the results of the preoperative evaluation and follow-up visits for flexion contracture, maximal flexion and AKS.

Sixty two patients (98.4%) returned for the first follow-up 6 weeks after TKA. During the time interval since operation, manipulation was necessary in two patients because of insufficient postoperative flexion which could not be improved by physiotherapy.

No correlation was determined between either the difference between pre- and postoperative flexion contracture or the difference between pre- and postoperative flexion and age, body height, body weight, gender and BMI (PPMC, $p > 0.05$).

The preoperative joint line position and patellar height had no influence on postoperative flexion contracture and flexion, as we found no significant correlation (PPMC, $p > 0.05$).

In addition no correlation was found between the flexion contracture or the maximum flexion and the postoperative patellar height or joint line position determined radiographically (PPMC, $p > 0.05$).

Sixty patients (95.2%) returned for the second postoperative visit 14 weeks after operation. A correlation was found between maximal flexion preoperatively and 14 weeks after operation, (PPMC : $r = 0.27$, $p = 0.034$) and between maximal flexion 6 weeks and 14 weeks after operation (PPMC : $r = 0.655$, $p < 0.001$).

Interestingly we noted a negative correlation between the differences in flexion between preoperative and 6 weeks postoperative and between 6 and 14 weeks after operation (Pearson Product Moment Correlation, $r = -0.43$, $p < 0.001$). This suggests that the main improvement in flexion is achieved within the first 6 weeks after surgery.

This is supported by the finding of a positive correlation between the flexion noted 6 and 14 weeks after surgery (PPMC : $r = 0.34$, $p = 0.008$).

Forty seven patients (74.6%) returned for the third follow-up, on average 65 weeks after operation. Despite considerable effort the missing 16 patients could not be convinced to return for this third visit ; all were available for a telephone evalu-

ation. We noted no revision in this group, all patients were satisfied with their clinical result. Furthermore all seemed to bend at least to 90° or more, as the question relating to perpendicular bending of the operated knee was positively answered.

Preoperative flexion below 90° was noted in 2 patients (3.1%) while a flexion equal to or more than 120° was measured in 16 of 64 knees (25%).

Among the 47 patients who returned for a one year follow-up examination, we measured a flexion equal to or more than 120° in 32 knees (68%, and 50% of 64). Flexion below 90° was found in only one case.

No statistically significant correlation was found between the flexion range after one year and the pre- and postoperative joint line position, the pre and postoperative patellar height, the slope of the tibial prosthesis and the flexion of the femoral prosthesis in the lateral radiograph (PPMC : $p > 0.05$).

During the follow-up we observed a significant improvement of the Knee Score and Function Score to a high level at 65 weeks (table I).

Multi-linear regression analysis showed that the final flexion was not correlated with age, body height, body weight, gender or BMI in this study.

Results of radiographic evaluation

The radiographic evaluation could be performed in preoperative films of 64 knees and in postoperative films of 61 knees (95.3%) (table II).

We found an AP position of the tibial implant of $92.4^\circ \pm 2.8^\circ$, a tibial slope of $90.3^\circ \pm 2.66^\circ$ and an extension/flexion position of the femoral implant of $87.5^\circ \pm 3.7^\circ$.

No significant difference was noted between pre- and postoperative measurement values of the joint line position, patellar height, patellar tilt and patellar displacement (Student's t-test, $p < 0.05$).

There was no case of an anterior notching of the femoral prosthesis and therefore no posterior translation. No anterior translation was detected either.

No significant ossification of the dorsal capsule or sign of component loosening could be identified on the radiographs at 65 weeks follow-up.

Table I. — Extension, Flexion and AKS

	Preop	First Postop Visit (6 ± 2.5 weeks)*	t-test (between preop & first postop visit)	Second Postop Visit (14 ± 6.5 weeks)*	t-test (between second & first postop visit)	Third Postop Visit (65 ± 28 weeks)*	t-test (between second & -third postop visit)
Flexion Contracture	5.0 ± 4.0°	1.7 ± 3.5°	p < 0.001	0.9 ± 2.4°	p = 0.114	0.1 ± 0.7°	p = 0.020
Flexion	114 ± 9.2°	110 ± 12.9°	p = 0.007	120 ± 11.2°	p < 0.001	120.7 ± 11.8°	p = 0.211
Knee Score	52.2 ± 12.2	79 ± 9.8	p < 0.001	87.4 ± 11.4	p < 0.001	91.7 ± 15.5	p < 0.287
Function Score	51.8 ± 17.6	59 ± 16.5	p = 0.019	75.0 ± 18.1	p < 0.001	88.0 ± 14.0	p < 0.002

(mean, standard deviation, Sig. = significance of Student's t-test, preop = preoperatively, postop = postoperatively, * weeks after TKA).

Table II. — Positioning of tibial and femoral implant

	Joint Line Position (cm)	Patellar Height (cm)	Patellar Tilt (degrees)	Patellar Displacement (mm)
Preop	2.86 ± 0.54	4.79 ± 0.76	3.06 ± 4.43	1.9 ± 2.79
Postop	2.77 ± 0.57	4.78 ± 0.73	3.29 ± 5.08	2.17 ± 4.25

(mean, standard deviation).

Posterior osteophytes were found in 16 (25%) knees. None of the osteophytes exceeded the thickness of the posterior condyle of the femoral implant in the lateral view.

The mean flexion of patients with dorsal osteophytes was 117 ± 11.9° while the mean flexion of patients without dorsal osteophytes was measured at 121 ± 10.8° (Student's t-test, p = 0.2213).

Complications

No wound healing problems or infection were noted in this series. Manipulation was necessary in two patients. No symptomatic postoperative deep vein thrombosis was observed. There was evidence of one pulmonary embolism which did not require intensive care.

DISCUSSION

Range of motion after TKA is an important determinant of the clinical outcome, as the results achieved with most modern TKAs are usually very

good in terms of pain relief and walking ability. As the average age of patients who undergo TKA continues to decrease, implant designers have attempted to modify their prostheses to allow more flexion as would be required for many low-impact sporting activities. There has also been an attempt to obtain higher degrees of flexion for those patients whose culture requires sitting or kneeling on low surfaces.

It is widely accepted that a deep flexion, defined as flexion beyond 120°, could improve the ability to carry out important activities of daily life and would be linked to a better functional outcome (29,32,36).

Most clinical studies report final flexion after TKA between 110 and 120° (30,32,36). Furthermore the results of many studies suggest that one cannot expect a significant improvement of flexion beyond the first year after operation (1,3,4,8,15,21,24,33,35,37). Schurmann *et al* therefore concluded that studies of factors influencing the range of movement do not require follow-ups extending beyond one year (34).

A variety of factors influence the final flexion. Prosthesis design is only one of those factors. On the other hand, experience has shown that the

flexion achieved after TKA using a conventional design rarely exceeds 120° (1,3,8,13,15,19,30,35-37).

We found a significant difference in flexion between 6 and 14 weeks after TKA but not between 14 weeks and 65 weeks. We assume that the maximum of postoperative flexion was reached between one and three months postoperatively, in contrast to other authors who conclude that there is an increase in flexion beyond one year postoperatively (25,39). On the other hand several studies have concluded that the postoperative flexion will not increase (9, 28,34) or will even decrease (42) after 1-3 months postoperatively.

Parallel to this we found a significant difference between knee extension after 6 weeks and 65 weeks, even though the difference (decrease from 0.9° to 0.1° on average) is not clinically relevant. On the other hand we found a positive correlation between the flexion contracture at 6 and 14 weeks (PPMC : $r = 0.34$, $p = 0.008$). This suggests that a higher flexion contracture tends to persist after six weeks of follow-up. The low value of the flexion contracture noted directly after operation could be an important reason for this observation.

We tend to support the findings of others who believe that the final extension does not differ significantly from that obtained at operation and that improvement should be achieved at the time of surgery by soft-tissue release or increased bone resection (34).

One limitation of this study is the absence of a randomized control group. Therefore the postoperative measurement of flexion can only be compared with the average reported by other studies (table III).

It must be noted that some studies report a postoperative flexion which is superior to what we observed : Kim *et al* (19) 138.5° , Seon *et al* (36) 130.7° , Huang *et al* (16) 138° . The remaining high flexion design studies show a ROM comparable to what we found : Wohlrab *et al* (41) 122.5° and Yamazaki *et al* (42) 122.1° .

One strength of this study is the prospective design with accurate data collection and the high level of standardisation (one experienced surgeon, same approach, same anaesthesia and postoperative

management). This made it possible to compare our results with those obtained in a 5 year follow-up study of 100 consecutive cases with the same study design and operating technique, performed by the same surgeon utilizing the Genesis II prosthesis in combination with the standard PS insert (22). The final flexion values were compared statistically and showed no difference.

The preoperative parameters of both study groups such as age (mean 67.5 years), BMI (mean 31.5), flexion contracture (mean 3°) and the maximum preoperative passive flexion (mean 113°) are similar to those we found in the present study with the high flexion insert (22).

The results presented here are up to date and more comprehensive than those which were published in smaller series by the senior surgeon (RL) who likewise operated the patients in this study. The mean flexion of 133° in the high flex insert group versus 120° in a control group with the standard PS insert (21) could not be confirmed by this study. Because of the unexpected death of the senior author, we are not in a position to explain these differences comprehensively. It remains unclear to which extent the previous results reflect a form of patient selection and if the control group represents a form of matched pairs.

Another limitation of this study is the follow-up of 75% at the one-year follow-up. Although we think that we could exclude missed complications or inferior flexion results by our telephone interview, we are aware that this limited information influences the relevance of the result. On the other hand we found no increase in flexion range after 14 weeks. For these reasons, we would not expect to significantly influence our final flexion result if we had the chance to include the missing patients for the one-year follow-up.

The usefulness of high-flexion designs is underlined by a variety of clinical outcome studies. However, these studies are heterogenous with respect to the preoperative parameters, the study design, the operating technique and the conditions under which the follow-up was carried out.

If we look for instance at the preoperative flexion contracture which was $5.0^\circ \pm 4.0^\circ$ in our series, we note a difference from other studies with a high-

Table III. — Studies with High-Flexion Design

Authors	Number of TKAs	Design	Patellar implant	PCL	approach	dg	Preop Contract	Preop Flexion	Postop Flexion (highflex/ conventional)	Follow-up	Average age	BMI
Wohlrab (41)	30	NexGen LPS vs LPS Flex (Zimmer)	yes	removed	midvastus	OA	n/a	108.5°	122.5° 120.5°	2.91 years	66.5	24.1
Seon (36)	100	ibidem	no	removed	medial parapat	OA	13.1°	127.5°	130.7° 128.5°	2 years	66.5	26.8
Huang (16)	25	ibidem	yes	removed	medial parapat	OA	n/a ROM only	n/a ROM only	138° 126°	2.5 years	69.5	n/a
Yamazaki (42)	114	Hy-Flex II (DePuy)	yes	removed / retained	n/a	RA	13.6°	113.6°	122.1°	1 year	58.4	n/a
Kim (19,42)	100	NexGen LPS vs LPS Flex (Zimmer)	yes	removed	subvastus	OA RA	5°	126°	138.5°	2.1 years	68	n/a
Mean	53.8						10.6	119	130.4	2.1	65.8	

(n/a = not applicable, RA = rheumatoid arthritis, OA = osteoarthritis, dg = diagnosis).

flexion design, such as Kim *et al* (19) 6°, Seon *et al* (36) 13.1°, Yamazaki (42) 13.6°. The reported preoperative flexion of high-flexion studies also shows remarkable differences. While a mean preoperative flexion of $114^\circ \pm 9.2^\circ$ was measured in our patients, Kim *et al* (19) reported 126° and Seon *et al* (36) 127.5°. In contrast, Huang *et al* (16), Yamazaki *et al* (42) and Wohlrab *et al* (41) presented preoperative flexion measurement values comparable to our patients (110.3°, 108.5° and 113.6° respectively).

Preoperative flexion is one of the main factors influencing the final flexion result, and we are faced with very different preoperative conditions in these studies (3,14,18,25,31,34), which can affect the comparability of results.

Additionally the studies about the clinical outcome of high-flex designs differ widely regarding the surgical approach, treatment of the patella, duration of follow-up, follow-up intervals, average age, BMI, diagnosis, and the size of study sample and type of implanted prostheses (table III). For example Kim *et al* (19) and Yamazaki *et al* (42) did not report the body mass index of their patients,

while Huang *et al* (16) provided only information about the body weight (mean : 63.3 kg) and excluded patients with a body mass index over 30 from their survey. The body mass index is regarded as one important influencing factor of the final range of motion (25,38).

Another important influencing factor of the final flexion result is the implant positioning.

This was not reported by Huang *et al* (16,42), Seon *et al* (36) and Yamazaki *et al* (42), while Kim *et al* (19) simply stated that in their series no significant aberration of the implant position was found, without reporting the exact measurement method and values.

Wohlrab *et al* (41) reported the positioning of the femoral and tibial prosthesis in their high-flexion study, and Kim *et al* (19) and Yamazaki *et al* (42) stated that there was no significant difference between the pre- and postoperatively measured height of the joint line.

If one analyzes the publications about tibial slope and outcome in TKA it becomes obvious that this is an important aspect of operating technique. Various

publications presented evidence of an influence of the tibial slope on the range of motion (2,3,6,7). While Kim *et al* (19) aimed at a tibial cut with 7° slope, Seon *et al* (36) and Yamazaki *et al* (42) gave no information on this point. Huang *et al* (16) reported that they attempted to match the original posterior slope of the tibial plateau.

In our study the slope of the tibial implant was measured at $90.3^\circ \pm 2.66^\circ$, i.e. a 0.3° posterior slope. This result fails to meet the recommendation of 3° downslope of the tibial prosthesis by Smith & Nephew for the Genesis II PS High Flexion system.

If we follow the results of a study by Bellemans *et al* (3) reporting an extra maximum flexion of 1.7° by 1° extra downslope in a cadaver study of a standard PCL-retaining TKA, we conclude that this could in theory lead to a reduced flexion of 5° . It remains questionable if one can transfer the results by Bellemans *et al* (3) to high flex designs which show different kinematics in flexion.

We believe that the comparability of our recent study with the above mentioned historical 5-year follow-up study is not influenced by the findings of Bellemans *et al* (3) because we strongly assume a very similar tibial slope in that study in which the same type of prosthesis was implanted by the same surgeon using an identical operating technique.

Several authors have reported that parameters such as joint line position, patellofemoral tracking and implant alignment could influence the clinical outcome and particularly the postoperative range of motion (6,7,38). In this study the average postoperative patellar tilt of $3.29^\circ \pm 5.08^\circ$ and the patellar displacement of $2.17 \text{ mm} \pm 4.25 \text{ mm}$ are to be regarded as a minor aberrance (12). Only three patients showed a patellar tilt $> 5^\circ$ (average 7.5°) and 8 patients a patellar displacement $> 5 \text{ mm}$ (average 8.5 mm). In the lateral radiograph no significant difference in the joint line position was noted as compared with the preoperative value.

In addition there was no statistically significant correlation between the final flexion result and the patellar tilt/displacement, nor the patellar height or joint line position. We conclude that these parameters had no influence on the measured flexion result.

The present clinical investigation of the high flexion design shows a mean final flexion of 120.7° while the 5 year follow-up with the Genesis II and standard PS insert showed a mean final passive flexion of 118° . The direct comparison of the final range of flexion of these groups showed no clinically relevant advantage of the high flexion insert in our study.

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