

Clinical evaluation of 292 Genesis II posterior stabilized high-flexion total knee arthroplasty: range of motion and predictors

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Abstract The primary aim of the study was to evaluate the range of motion and complications after Genesis II total knee arthroplasty with high-flexion tibia insert (TKA–HF). Furthermore, difference in knee flexion between high flexion and standard inserts was compared. The hypothesis was that knee flexion is better after high-flexion TKA. A total of 292 TKA–HF were retrospectively reviewed. Mean follow-up was 24.3 months. The range of motion was compared between TKA–HF (high-flexion group) and a comparable cohort of 86 Genesis II TKA with a standard tibia insert (control group). Surgeries were performed by one experienced knee orthopedic surgeon. Knee flexion in the high-flexion group increased from 114.8° preoperatively to 118.0° postoperatively ($P < 0.01$). Knee extension in the high-flexion group increased from -4.5° preoperatively to -0.4° after surgery ($P < 0.01$). Mean knee flexion was $5.52^\circ (\pm 1.46^\circ)$ better in the high-flexion group compared with the control group ($P < 0.01$). Preoperative range of motion, body mass index, diabetes mellitus and patellofemoral pain significantly influenced range of motion. Few complications occurred after TKA–HF. The Genesis II TKA–HF showed good short-term results with limited complications. Knee flexion after Genesis II TKA–HF was better compared with a standard tibia insert.

Keywords Genesis II · Posterior stabilized high flexion · Total knee arthroplasty · Range of motion · Complications

Introduction

Total knee arthroplasty (TKA) is a successful surgery for end-stage knee osteoarthritis. Pain relief and optimal range of motion are important goals of TKA. These goals are also important for patient satisfaction [1, 2]. Many factors influence the range of motion after TKA: preoperative flexion, surgical indication, coronal alignment, patient age, body weight, Knee Society knee score, wound closure technique and prosthetic design [3–9]. Postoperative pain and knee ligamentous stability are also important factors for a successful TKA [10, 11].

Since January 2005, the senior author (R.J.) uses the Genesis II posterior stabilized TKA with a high-flexion tibia insert (Smith & Nephew, Memphis Tennessee, USA). The high-flexion tibia insert has several design modifications in comparison with the standard insert (Fig. 1). This leads to a decreased impingement potential of both patella and patellar ligament on the posterior stabilized cam in case of deep knee flexion [12]. The primary aim of the present study was to assess the range of motion and complications after Genesis II posterior stabilized TKA with high-flexion tibia insert (TKA–HF, Smith & Nephew, Memphis Tennessee, USA). Furthermore, range of motion was compared between Genesis II posterior stabilized TKA–HF and a comparable cohort of Genesis II TKA with standard tibia insert. The hypothesis was that knee flexion is better after high-flexion TKA.

Materials and methods

We retrospectively reviewed the data of 307 primary cemented Genesis II TKA–HF (282 patients) operated between January 2005 and May 2009.

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Fig. 1 Genesis II posterior stabilized “high flexion” tibial insert. The anterior portion of the polyethylene has been chamfered to decrease impingement of the patellar tendon. The posterior portion has been chamfered anteriorly to prevent impingement of the patella

Inclusion criteria were primary TKA–HF, follow-up ≥ 10 months and surgery by a single surgeon (R.J.).

Exclusion criteria were unknown preoperative range of motion of the knee, follow-up < 10 months, surgery by a different orthopedic surgeon and revision surgery.

Fifteen patients (15 TKA) of the 307 TKA were excluded. Reasons for exclusion were unknown preoperative range of motion (3), follow-up < 10 months [non-related deaths (7), patients who could not be traced or contacted for follow-up examinations (5)]. Mean follow-up period was 24.3 (10–61) months.

In order to compare range of motion outcomes between a posterior stabilized high flexion and standard tibia inserts, the group of 292 Genesis II TKA–HF was compared with a cohort of patients operated by the same surgeon with a Genesis II TKA with standard insert in the years prior to 2005 (control group). The control group consisted of 102 patients. In the control group, 16 TKA were excluded because of a follow-up < 10 months [non-related deaths (2) and patients who could not be traced or contacted for follow-up examinations (14)].

Patient demographics are presented in Table 1. To determine their role in final range of motion after TKA, the following factors were analyzed: gender, age, BMI, tibial–femoral angle, co-morbidity (diabetes mellitus and rheumatoid arthritis) and preoperative range of motion.

Standardized weight-bearing long leg radiographs were obtained to measure the mechanical tibial–femoral angle. A single independent researcher (M.F.) performed all examinations. Range of motion of the knee was measured

Table 1 Demographic variables

Insert	High flexion	Standard	<i>P</i> value
Number of prostheses (patients)	292 (271)	86 (78)	
Side (right–left)	153–139	44–42	0.841
Age at operation (years)	71.39 (43.5–94.0)	69.79 (42.8–83.6)	0.145
Gender (male–female)	84–208	19–67	0.203
Body mass index (kg/m ²)	29.0 (15.7–44.0)	29.0 (21.23–35.7)	0.942
Diagnosis			
Osteoarthritis	277	76	0.503
Post-traumatic osteoarthritis	3	4	
Rheumatoid arthritis	12	6	
Tibial–femoral angle			
Varus	171	58	0.353
Valgus	92	23	
Straight	27	4	
Unknown	2	1	
Resurfacing patella (TKA)	4	16	< 0.001
Co-morbidity			
Diabetes mellitus (TKA)	46	9	0.222
Rheumatoid arthritis (TKA)	12	6	0.272
Preoperative flexion	114.78 (80–140)	111.16 (50–140)	0.025
Preoperative extension	–4.52 (–30 to 5)	–6.22 (–30 to 0)	0.056

using a goniometer. Patients were placed supine. Center of rotation was determined as the lateral femur epicondyle. One arm of the goniometer was placed parallel to the shaft of the femur in line with the greater trochanter of the hip, and the other arm was placed parallel to the shaft of the tibia in line with the lateral malleolus at the ankle.

Surgical technique

A combined spinal and epidural anesthesia was preferred in all patients. Prophylactic parenteral antibiotics (first generation cephalosporin) were administered 30–60 min prior to the skin incision, continued for 24 h after surgery. A tourniquet was inflated with the knee in maximum flexion prior to the surgery.

An anterior midline incision was followed by a medial mid-vastus arthrotomy. After lateral subluxation of the patella, the anterior cruciate ligament and menisci were dissected. The valgus angle for the intramedullary femur guidance can be set between 5° and 7° of valgus. The

amount of valgus of the femoral component was measured on the weight-bearing long leg X-ray, as the angle between the mechanical and anatomical femoral axis. On the same X-ray, the point of intersection of the anatomical femoral axis and the distal femoral joint line determined the entry point of the femoral guidance rod at the distal femur. The rotation of the femoral component was determined by the A–P axis (Whiteside's line) marked during surgery. Posterior femoral offset was restored as much as possible by choosing the largest femoral component if in between sizes, never exceeding the femoral medial–lateral size. Anterior referencing femoral blocks were used to guide the anterior and posterior femoral resections. After all femoral chamfer cuts were made, the tibia was exposed and osteophytes removed. The extramedullary tibial alignment guide was mounted on the lower leg. The distal portion of the guide was centered over the ankle and the proximal part aligned with the tibial crest in a frontal plane. A second long straight rod was held parallel to the fibula in the sagittal plane to set tibial slope. Rotation of the tibial resection guide was set over the medial third of the tibial tubercle. This technique has previously been reported as reliable by the senior author [13]. The tibial resection was made using the correct right or left resection guide, after sizing the amount of tibial resection by means of a 9 mm stylus. Finally, trial component implantation and ligament balancing in flexion and extension were performed. A high flexion- or standard posterior stabilized tibial component was inserted in all patients. Final rotation of the tibial component was set in full extension, aligning the tibial and femoral components after range of motion control. Both femoral and tibial components were cemented. The patella was not routinely resurfaced.

Tourniquet was released, and patellar tracking evaluated. Wound closure was performed in 90° of knee flexion. A closed drainage system was left in situ for 24–48 h after surgery. A compressive bandage of the leg was removed on the first day after surgery.

The epidural anesthesia was continued for 48 h after surgery. Thereafter, patients received oral analgesia. Low molecular heparin was used as thrombosis prophylaxis for 6 weeks after surgery. The first day after surgery, patients started with exercises on the continuous passive motion machine (OrthoRehab, Oakville, Ontario, Canada). The second day, patients started walking with crutches or walker and continued active and passive range of motion exercises. Weight-bearing was allowed as tolerated. In severe valgus osteoarthritis, patients were instructed to 50 % weight-bearing for 6 weeks. After discharge, mostly after 4 days, patients received outpatient physiotherapy for a minimum of 6 weeks. Clinical and radiological evaluations were done at 6 weeks, 3–6 months, and yearly thereafter, and collateral ligamentous stability and

postoperative patellofemoral pain were identified as possible factors affecting range of motion.

Patient dossiers were used for the present study. If the patients did not attend the regular follow-up examinations, they were contacted by telephone or letter. In these patients, new X-rays were obtained and all follow-up examinations were done.

Statistical analyses

Statistical analysis was performed with IBM SPSS Statistics 19.0. Normal distributed scores were compared with the paired *t* test or ANOVA test. Not normally distributed scores were compared with the Wilcoxon test or the Kruskal–Wallis *H* test. Distribution was tested with skewness and kurtosis. Significance was set at <0.05. Regression analysis was used to correct for demographic factors and to analyze the factors that influenced postoperative range of motion.

Results

In the TKA–HF, the flexion and extension increased significantly postoperatively compared with preoperative values (Table 2).

After correcting for the preoperative flexion and patellofemoral resurfacing, there was still a significant increase in mean flexion of 5.52° ($\pm 1.46^\circ$, $P < 0.01$) of the high-flexion group compared with the control group [mean postoperative flexion of 111.7° (35°–140°)]. There was no significant difference in extension -0.35° (-10° to 0° , $P = 0.75$).

In the present study, several factors significantly affected final range of motion after TKA: preoperative flexion and preoperative extension (Table 3), diabetes and obesity (Table 4) and patellofemoral pain (Table 5). For obesity, comparison was made between the postoperative results of non-obese (BMI < 30) versus obese (BMI > 30) patients [14].

For preoperative flexion contracture, there was a significant difference between the patient group without a flexion contracture and the patient group with a contracture more than 10° (Table 4). There was no significant

Table 2 Comparison of pre- and postoperative range of motion in the TKA–HF

	Preoperative	Postoperative	<i>P</i> value
Flexion	114.8° (80°–140°)	118.0° (40°–140°)	<0.01
Flexion contracture	4.5° (-30° to 5°)	0.4° (-5° to 10°)	<0.01

Table 3 Preoperative flexion and extension as determinant of postoperative flexion

Group	N (TKA)	Mean preoperative flexion	Mean postoperative flexion	P value
1. 0°–90°	20	89.50° (80°–90°)	106.50° (40°–130°)	*
2. 90°–120°	202	112.15° (95°–120°)	118.61° (90°–140°)	
3. 120°–140°	70	129.57° (125°–140°)	119.64° (90°–130°)	
		Mean preoperative extension	Mean postoperative extension	
4. 0°–5°	157	0.03° (0°–5°)	–0.25° (–10° to 5°)	0.03
5. –30° to 10°	33	–18.48° (–30° to 15°)	–0.91° (–5° to 0°)	

* P value: group 1 versus group 2: $P < 0.01$, group 1 versus group 3: $P < 0.01$, group 2 versus group 3: $P = 0.51$

Table 4 Diabetes mellitus (DM) and BMI as determinant of postoperative flexion and extension

Group	N (TKA)	Flexion	P value	Extension	P value
No DM	246	118.80° (40°–140°)	<0.01	–0.35 (–10 to 5)	0.23
DM	46	113.91° (90°–140°)		–0.65 (–10 to –0)	
BMI < 30 [26.30 (15.7–30.0)]	188	119.39° (90°–140°)	<0.01	–0.45 (–10 to 5)	0.40
BMI > 30 [33.81(30.1–44.0)]	104	115.58° (40°–140°)		–0.29 (–10 to 0)	

Table 5 Patellofemoral pain as a determinant of postoperative flexion

Group	N (TKA)	Mean preoperative flexion	Mean postoperative flexion	P value
1. No pain	245	115.06° (80°–140°)	118.75° (40°–140°)	0.01
2. Pain	47	113.30° (90°–130°)	114.15° (90°–140°)	

Table 6 Postoperative complications

Complication	Number (%)
Delayed wound healing	5 (1.7)
Deep infection	1 (0.3)
Deep venous thrombosis	3 (1)
Peroneal nerve palsy	2 (0.7)
Dislocation of insert [15]	1 (0.3)
Manipulated under anesthesia	3 (1)

difference between patients without a flexion contracture and patients with a contracture between 0° and 5° ($n = 61$ TKA, $P = 0.52$) or 5° and 10° ($n = 41$ TKA, $P = 0.40$).

Complications

Complications found in present study are presented in Table 6.

Discussion

The most important finding of the present study was a significant increase in flexion and extension after TKA with a high-flexion tibia component. Compared with a cohort with TKA with standard insert, we also found a significantly better flexion. In the present study, preoperative flexion, preoperative extension, BMI > 30, diabetes

mellitus and postoperative patellofemoral pain were significant factors that influenced postoperative range of motion after TKA.

One of the many factors affecting the outcome of the TKA is the implant design. The principal goal of high-flexion TKA is an increase in postoperative flexion. In the present study, there was a significantly better mean flexion in the high-flexion Genesis II TKA compared with the same prosthesis with a standard insert ($5.52^\circ \pm 1.46^\circ$). Murphy et al. [16] have performed a systematic review on high-flexion TKA. Their results showed a variable range of motion: 106°–133° of flexion and –0.7° to 1.0° of extension after a follow-up <35 months. Other authors compared the high-flexion insert with the standard and cruciate retaining insert. Mehin et al. [17] concluded in a meta-analysis of five randomized controlled trials (RCT) that there was no significant improvement in the postoperative range of motion. Hamilton et al. [18] found similar results in a focused review of five prospective RCT. In the reviews, different types TKA were used. Focusing on the Genesis II TKA, McCalden et al. compared, in a RCT study, the range of motion between the TKA–HF (50) and TKA standard insert (50). There was no significant difference in flexion after 2 years ($124^\circ \pm 7^\circ$ vs. $123^\circ \pm 7^\circ$) [19]. Laskin [20] compared a group of 40 Genesis II TKA–HF with a cohort of 40 Genesis II standard TKA. After 2-year follow-up, they found a significant difference in flexion in the TKA–HF group (133° vs. 118°). Compared with the present study, the patient groups in the studies by

McCalden et al. and Laskin et al. were smaller. Other in- and exclusion criteria were used in the study of McCalden. McCalden et al. [19] excluded patients with a preoperative flexion $<90^\circ$. Laskin [20] did not describe their in- and exclusion criteria. Preoperative range of motion is an important factor for postoperative range of motion after TKA [3–5]. This has also been demonstrated in the present study. The differences in flexion after Genesis II TKA–HF in the present study (mean postoperative flexion 118.0°), in comparison with the previous studies with the same prosthesis by McCalden et al. (mean postoperative flexion 124°) and Laskin et al. (mean postoperative flexion 133°), may be explained by these differences.

Zeh et al. [21] evaluated the Genesis II posterior stabilized high-flexion TKA. They found a mean postoperative flexion of 120.7° and extension contracture of 0.1° with mean follow-up of 1.25 years in 64 primary cemented prostheses. In the present study, similar results were found.

Do patients need high flexion after TKA or is pain relief the most important goal for patients? A few studies have evaluated the necessity of knee motion during daily living. They found that different cultures have different requirements regarding knee flexion angles. In the western culture, knee flexion of 110° – 115° is sufficient for most activities of daily living. One needs 90° of flexion to descend stairs, 93° to raise from a chair, and 117° to lift an object [22]. People in Asian or Middle East cultures need a greater degree of flexion for activities such as kneeling or sitting in cross-legged positions in order to eat, pray, or socialize [23, 24]. The average flexion of 118° obtained in the present study may be considered a good result for the western patient population. The studies of Meneghini and Ghandi concluded that there is no significant functional difference between knee flexion of 115° versus a flexion of $>125^\circ$ in the western population [25, 26].

Frosch et al. [27] reported the complications of 512 TKA at 1-year follow-up. Compared with the present study, they found higher complication rates. Cusher et al. [28] described, in a multinational observational study, the complications of 8325 TKA at 3–12 months follow-up. The complications in the present study compare favorably with these findings.

There are limitations to the present study. The retrospective setting of the present study only allowed a descriptive conclusion of the complication rate after TKA–HF. We agree with the conclusion in the study by [27] that comparison of complications after TKA between different publications is difficult. Another possible limitation of the present study is the comparison of results between the study group and a cohort control group. However, comparable demographics between both groups as well as an identical surgical technique by a single surgeon did allow the conclusions as proposed.

In conclusion, the Genesis II TKA–HF showed good short-term results with limited complications. Knee flexion after Genesis II TKA was better with a high-flexion posterior stabilized tibia insert compared with a standard posterior stabilized insert.

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Conflict of interest None.

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