

Long-term results of posterior-cruciate-retaining Genesis I total knee arthroplasty

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Abstract

Background Long-term results of Genesis I modular total knee system are not well known.

Methods We analyzed data from 345 patients with 393 primary total knee arthroplasties (TKA) using the Genesis I prosthesis. In all cases, the posterior cruciate ligament (PCL) was retained, and the patella was not resurfaced. The minimum follow-up was 10 (range 10–16) years.

Results Preoperative range of motion improved from 89° preoperatively to 105° at the time of the most recent follow-up ($p < 0.001$). Mean preoperative Knee Society pain and function scores increased from 29 and 25 points to 91 and 85 points, respectively ($p < 0.001$). Tibiofemoral angle shifted from 2.40° of varus before to 4.8° of valgus after the operation ($p < 0.001$). Early postoperative complications occurred in 34 knees (8.6%). Manipulation under general anesthesia was done in six knees (1.5%). Nonprogressive radiolucent lines were seen around the femoral component in 16 knees (4%) and at the tibial bone–cement interface in 101 knees (25%). However, in only five cases (1.3%) was there significant progression leading to implant loosening and revision surgery. Eight more revisions were performed due to infection (three knees), stiffness (three knees), excessive wear and fracture of polyethylene liner (one knee), and instability (one knee). The overall survivorship of knee replacement reached 96.7%.

Conclusions In the long term (up to 16 years), PCL-retaining Genesis I total knee prosthesis is associated with good functional outcomes and low failure rates.

Introduction

The number of total knee arthroplasty (TKA) procedures performed each year is predicted to gradually increase [1]. As indications grow and younger patients are becoming candidates for this type of operation, the demands for a better and newer prosthesis that will fulfill all expectations are steadily increasing [2]. The Genesis I modular total knee system (Smith & Nephew Orthopedics, Memphis, TN, USA) consists of an anatomically designed chrome–cobalt femoral component and an asymmetric semiconstrained titanium-alloy (6A1-4V) tibial component with a short central stem. Also, it has a minimally conforming polyethylene bearing surface, which is made up of ultra-high molecular weight polyethylene and a dome-shaped polyethylene patellar component with a central fixation peg [3–6]. Modular components, such as optional stems, wedges, and augments, allow great intraoperative versatility in both primary and revision situations.

Few trials have been published presenting midterm results of Genesis I prosthesis in knee osteoarthritis [3–8]. Both posterior-cruciate-ligament-retaining (PCLR) and PCL-substituting (PCLS) designs were associated with good functional scores and high survivorship rate. The aim of this study is to present the long-term clinical and radiological results (minimum 10-year follow-up) of Genesis I PCLR system in primary TKA.

Materials and methods

Study design

This study was a retrospective cohort analysis (level III, therapeutic study). The arthroplasty database of the hospital

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was used to identify all patients who had undergone a primary TKA using the Genesis I total knee prostheses. Between 1994 and 2000, 453 consecutive primary TKAs (Genesis I, Smith & Nephew) were performed in 386 patients by two senior surgeons. Forty-one patients (10%) were excluded due to insufficient data, death, or inadequate follow-up (<10 years), leaving for examination 345 patients and 393 knees. The study was approved by the hospital ethical committee. Data collection consisted of age; sex; side; indication for knee replacement; preoperative and postoperative extension, flexion, and total range of motion (ROM); preoperative and postoperative Knee Society (KSS) pain and function score [9, 10]; occurrence of closed manipulation (performed when <80° of flexion had not been achieved by 6 weeks postoperatively); wound complications; implant failure; infection; reoperation(s); and follow-up from the time of surgery. Furthermore, anteroposterior (AP) and lateral knee radiographs were reviewed by two independent observers (one for each patient) to measure limb and prosthesis alignment and detect radiolucent lines [9]. Interobserver agreement between investigators was not assessed. The Knee Society total knee arthroplasty roentgenographic evaluation system [9] was used to determine any radiolucent lines around the femoral and tibial components. Radiolucency around the tibial component was determined from both AP and lateral knee views. From the AP view, zones 1 and 2 represent the area beneath the medial plateau, zones 3 and 4 the area beneath the lateral plateau, and zones 5, 6, and 7 the keel area. In the lateral view, radiolucent zone 1 is anterior, zone 2 is posterior, and zone 3 is at the tip of the keel. Radiolucency around the femoral component was determined in seven zones on the lateral X-ray. Zones 1 and 2 represent the area behind the anterior flange; zones 5, 6, and 7 represent the stem or central area; zones 3 and 4 represent the posterior part of prosthesis. No intraobserver or interobserver analysis of radiographic findings was performed.

Surgical technique management

All patients were placed in the supine position, and a tourniquet was applied in the ipsilateral thigh. Routine antibiotic prophylaxis with intravenously administered cefuroxime (1.5 g) was given 20 min before tourniquet inflation and was continued for 48 h (750 mg three times per day). A midline skin incision of approximately 18–24 cm and a medial parapatellar arthrotomy were used. The retropatellar fat pad was sharply excised along with the menisci and anterior cruciate ligament (ACL). Overhanging osteophytes were removed from the femur and tibia. Distal femurs were cut at a 5° valgus angle using an intramedullary cutting guide; tibias were cut perpendicular to tibial anatomic axis using an extramedullary rod. In all cases, the PCL was maintained,

and the patella was not replaced. However, detailed patellar debridement, removal of unstable cartilage fragments or drilling of subchondral bone in case of complete cartilage absence, thorough peripatellar synovectomy, and circumpatellar cauterization were performed. The femoral component was intended to be placed in 5° of valgus and 3° of external rotation. The tibial prosthesis was aimed to be positioned in 90° at the frontal plane, with a 3° posterior slope at the sagittal plane. Trial implants then were placed over the resected bone surfaces, and joint stability, ligament balance, and ROM were subsequently assessed. In case of persistent flexion contracture, PCL and posterior capsular release at the femoral side were performed. All tibial components were cemented, whereas femoral components were fixed with or without cement. The issue of cementing or not cementing the femoral prosthesis was at surgeon's discretion according to bone quality and trial component stability. Suction drains were routinely used, and the tourniquet was released before wound closure. Postoperative physiotherapy was identical for all patients. Continuous passive motion was initiated on day 1. Full weight bearing was commenced on day 2 postoperatively under physiotherapist's supervision. After hospital discharge, low molecular weight heparin (LMWH) was prescribed for 1 month. Patients were reviewed clinically and radiographically after 6 weeks, 3 months, 1 year, and then annually.

Statistics

Statistical analysis was carried out with SPSS software package (SPSS 17.0, Chicago, IL, USA). Data are presented as number of cases with percentage or as mean and range. The *t* test was used to compare parametric variables. For the purpose of survivorship analysis, three Kaplan–Meier survivorship curves were created. The radiographic probability of the survival curve was referred to revision surgery due to gross evidence of component loosening, change of implant position, or progression of radiolucent lines. The clinical probability of survival curve was estimated taking into account all other reasons responsible for TKA failure, such as infection and stiffness. The total probability of survival curve summed up all conditions that led to prosthesis revision. Statistical significance was assumed for $p < 0.05$.

Results

Clinical findings

There were 62 men and 283 women, with a mean age of 69 (range 58–85) years (208 right and 185 left knees). Average body mass index (BMI) was 28.8 (range 21–38.6). Mean follow up was 13.6 (range 10–16) years. Primary

osteoarthritis (363 knees) was the most common indication for TKA, followed by rheumatoid arthritis (18 knees), posttraumatic arthritis (eight knees), hemophilic arthropathy (one knee), and osteonecrosis (three knees). The PCLR femoral prosthesis was introduced with cement in 330 (84%) and without cement in 63 (16%) knees. Lateral release was performed in 17 knees (4%) to optimize patellar tracking. Mean preoperative ROM improved from 89° (range 58°–112°) preoperatively to 105° (range 95°–128°) at the time of the most recent follow-up ($p < 0.001$, t test). Mean preoperative KSS pain and function scores increased from 29 (range 17–41) and 25 (range 0–50) points to 91 (range 70–100) and 85 (range 65–100) points, respectively ($p < 0.001$, t test).

Radiographic findings

Mean tibiofemoral angle shifted from 2.40° of varus (range –15° to 10°) before to 4.8° of valgus (range 1°–7°) after ($p < 0.001$, t test) the operation. The femoral component was positioned in 95.4° (range 92°–97°) at the coronal plane and

in 89.6° (range 86°–92°) at the sagittal plane. Angles for the tibial component were 89.4° (range 86°–95°) at the coronal plane and 87.6° (range 85°–91°) at the sagittal plane. Femoral radiolucencies were seen in 16 knees (4%) involving only zone 1 (anterior). On the other hand, 125 tibial bone–cement radiolucencies were found in 101 knees (25%) (Table 1) (Fig. 1). However, in only five cases (1.3%) (one femur, three tibia) was there significant progression that led to implant loosening and subsequent revision surgery. Radiographically, none of these five patients had component malalignment. However, two patients were obese (BMI 37.6 and 40.3) and one reported some posterior knee aching during deep flexion, probably due to a tight flexion gap. Another revision TKA (0.3%) was made to a male patient due to excessive wear and fracture of the polyethylene liner 9 years after its implantation. Although no injury was mentioned, the patient ignored the instructions to avoid strenuous and intense farming activities.

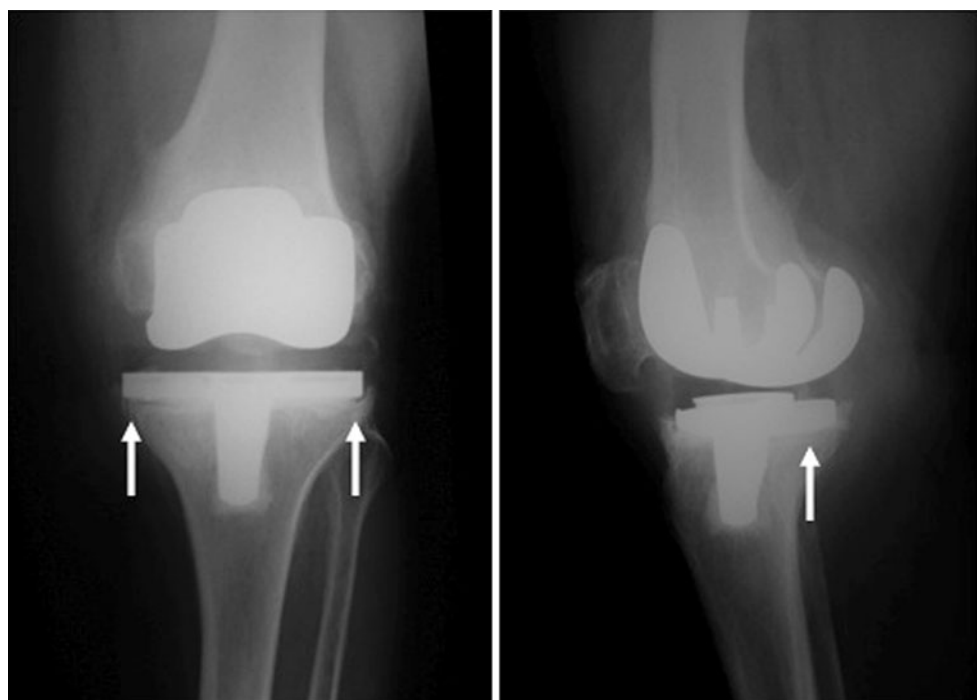
Clinical complications

Early postoperative complications (<4 weeks) occurred in 34 knees (8.6%). These included persistent wound drainage [12 cases (3%)], blistering [five cases (1.3%)], erythema [six cases (1.5%)], deep venous thrombosis (DVT) [ten (2.5%) cases], and nonfatal pulmonary embolism [one case (0.3%)]. Manipulation under general anesthesia due to poor flexion (<90°) was done in six knees (1.5%); three of these (0.8%) required a revision arthroplasty due to persistent knee stiffness and pain. One TKA revision (0.3%) was also

Table 1 Radiolucent lines around Genesis I knee components

Location	Plane	Zones	Number
Femur	Coronal plane	Zone 1 (anterior)	16
Tibia	Coronal plane	Zone 1 (medial)	77
		Zone 4 (lateral)	34
	Sagittal plane	Zone 1 (anterior)	10
		Zone 2 (posterior)	4

Fig. 1 Anteroposterior (AP) and lateral knee views showing Genesis I total knee system 15 years after implantation. Radiolucent lines are evident at tibial zones 1 and 4 (coronal plane) and tibial zone 2 (sagittal plane). The patient was asymptomatic (range of motion 105°, Knee society (KSS) pain score 89 points, KSS function score 90 points)



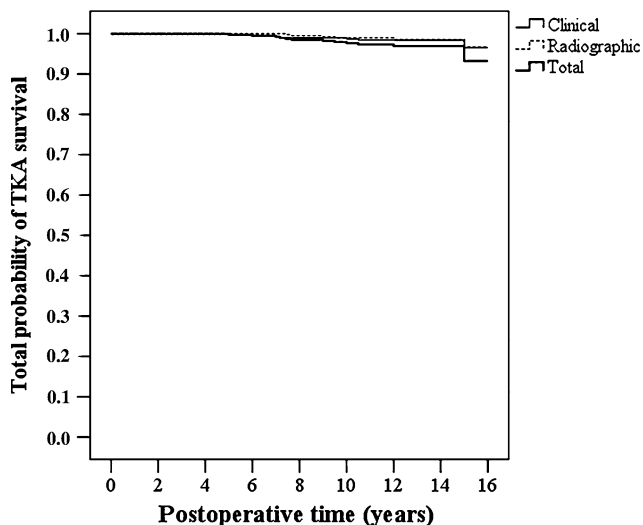


Fig. 2 Kaplan–Meier survivorship curves of clinical probability (*thin line*), radiographic probability (*dotted line*), and total probability (*thick line*) of total knee arthroplasty (TKA) survival. Postoperative time was used as the continuous numeric variable, and revision was defined as the event on the curves

made due to PCL insufficiency and significant AP instability. Delayed-onset infection treated with two-stage revision arthroplasty was reported in three knees (0.8%). Two osteoporotic women patients (0.5%) also sustained a periprosthetic fracture just above the stable femoral component due to falls. Both fractures were treated with internal fixation via a 95° condylar side plate or a supra-condylar nail. However, no revision was required.

Survivorship analysis

Overall survivorship of knee replacement reached 96.7%, as 13 revisions of 393 TKAs were performed due to radiographic (six of 393 knees, 98.5% survival rate) or clinical failure (seven of 393 knees, 98.2% survival rate). The Kaplan–Meier survivorship curves showing clinical, radiographic, and total probability of TKA are presented in Fig. 2.

Discussion

Genesis I total knee prosthesis achieved satisfactory survivorship rates. Mokris et al. [6] studied 105 Genesis I knee components and found no revisions for any reason during a mean follow-up of 4.25 years. Chen et al. [3] analyzed 110 Genesis I TKAs in 72 patients at a mean 7.2-year follow-up period. Kaplan–Meier survivorship was 97% at 10 years. Laskin [5] reported his results of 56 PCLR and 44 PCLS Genesis I replacements at an average follow-up of 11.2 and 10.4 years, respectively. Survivorship was

96% in patients in whom the PCL was retained and 97% in patients in whom the PCL was sacrificed. Ishii et al. [7] analyzed data from 82 primary Genesis I TKAs (53 PCLR and 29 PCLS) performed in 74 patients over a 7-year mean follow-up period. Two knees were revised due to aseptic loosening of femoral and patellar component at 72 months and deteriorated varus of the tibial component at 15 months after 3° of initial varus implantation (97.6% survivorship). Our study of patients who underwent a Genesis I knee replacement with PCL retention and non-resurfacing of the patella showed a 96.69% survival rate after an average 13.6-year follow-up period. As far as we know, this is the largest study of Genesis I patients with the longest follow-up published so far.

Studies examining the Genesis I design showed significant improvement in pain relief, ROM, and knee function [3–8]. Ishii et al. [7] recorded that the mean Hospital for Special Surgery (HSS) score increased from 39 points preoperatively to 92 points postoperatively. Similarly, mean ROM improved from 82° preoperatively to 108° at the most recent follow-up. Chen et al. [3] reported that the mean postoperative ROM was 112.58°, improved from 96.38° preoperatively. KSS pain and functional scores increased from preoperative averages of 55 and 44 points to 92 and 88 points, respectively. Mokris et al. [6] found a mean postoperative ROM of 116° compared with 104° preoperatively. Laskin [5] showed that >95% of patients had excellent pain relief. Mean flexion was 114° in patients in whom the PCL was sacrificed and 117° in patients in whom the PCL was retained.

The incidence of radiolucency around knee components can be widely varied. Lotke and Ecker [11] advocated that malposition of the tibial component, especially in varus, was a major factor for the presence of radiolucent lines around the tibial component. However, radiolucent lines are not always indicative of implant loosening or poor outcome [3–8]. Mokris et al. [6] found no significant progression of radiolucent lines or loosening of any knee component. Chen et al. [3] found eight knees (7.2%) with tibial radiolucent lines at zones 1, 2, 3, and 4 and two knees (1.9%) with femoral radiolucent lines at zones 1 and 4. Laskin [5] reported eight radiolucent lines (8%) on the tibial component in zones 1 and 4. He hypothesized that the low rate of radiolucency was due to optimum position of the tibial component. Ishii et al. [7] recorded that the overall frequency of radiolucency was 28%. The radiolucent lines were in zones 1 for the femoral component and in zones 1 and 4 for the tibial component. In our study, radiolucent lines were seen in 29% of cases, but progression and loosening were encountered in only 1.3%.

Debates over whether the PCL should be preserved or the patella should be resurfaced in TKA have been ongoing for several decades. Multiple reviews of the literature have

not found sufficient evidence to recommend evidence-based and consensus guidelines [12–22]. A recent meta-analysis was undertaken to pool the results of randomized controlled trials (RCTs) and to compare the outcomes and postoperative complications after TKA with patellar resurfacing or nonresurfacing [23]. Results indicated that patellar resurfacing would reduce the risk of reoperation after TKA, but the benefits were limited on other aspects, and the analysis of high-quality studies showed no advantage of resurfacing over nonresurfacing, even in the aspect of reoperation risk.

Retaining the PCL is believed to aid in proprioception and AP stability. Also, it may enable better knee function in activities such as climbing stairs and allow normal rollback of the femur on the tibia, thus improving deep flexion. On the other hand, ligament balancing and correction of knee deformity are more difficult with PCL retention. A loose PCL may lead to instability and pain, whereas a tight PCL may restrict knee flexion and lead to high stress concentration in the polyethylene liner [12–16, 18–22]. So far, there is no solid basis for the decision to either retain or sacrifice the PCL during primary TKA. A recent prospective study compared results of 46 PCLR versus 45 PCLS arthroplasties [21]. The outcome was comparable between groups. In the PCLR group, postoperative ROM was 125°, mean KSS pain score 93 points, and mean KSS function score 71 points. In the PCLS group, postoperative ROM was 118°, mean KSS pain score 94 points, and mean KSS function score 73 points.

We found that PCL retention and nonresurfacing of the patella (even in patients with rheumatoid arthritis) provides excellent long-term results and a low complication rate. Although the combination was not associated with a high revision rate, it might influence knee performance. We believe that any flexion instability due to potential PCL insufficiency, or some anterior knee pain due to the non-resurfaced patella, might be underestimated, as we found they did not cause significant disability, particularly in low-demand patients. To what extent meticulous patella preparation and protection of PCL integrity during surgery attributed to good functional outcome, as recorded in this study, is not quite clear. Nevertheless, there is general agreement that more carefully and scientifically designed RCTs are needed to provide definitive answers.

So far, Genesis I TKA has shown favorable mid- and long-term results [3–8]. The Genesis II total knee prosthesis, successor to the Genesis I, was introduced almost 15 years ago. It has built-in external rotation of the femoral component, optimized patellofemoral tracking, an asymmetric anatomic polished tibial base plate, a tibial polyethylene locking mechanism, ethylene oxide sterilization, and improved instrumentation [24]. The system is available in eight femoral and tibial component sizes, and all

implants can be secured with bone–cement fixation [24]. Enhancements to the system since its introduction include minimally invasive instrumentation, optional computer-assisted surgical techniques, the option to use a more scratch-resistant oxidized zirconium metal femoral component (Oxinium; Smith & Nephew) in high-demand patients, and the option to use high-flexion tibial inserts (Hi-Flex; Smith & Nephew). Laskin and Davis [25], in 2005, reported a 5-year follow-up of the first 100 consecutive patients who received the Genesis II prosthesis. Mean ROM was 118° and survival rate 98%. These 100 patients were continued to be followed up, and Bourne et al. [24], in 2007, published the 10-year follow-up results. Postoperative ROM was 112°, KSS pain and function scores were 91 and 67 points, respectively, and the survivorship rate was 96%. It seems that both designs offer comparable outcomes. However, longer follow-up studies are necessary to determine whether the new Genesis is better than the old.

TKA longevity and performance depends on prosthesis design, surgeon's skill, and patient's related variables. Therefore, it is not easy to pinpoint whether a complication or a low function score derives from an imperfect prosthesis design. We found that even older prostheses designs, such as the Genesis I, offers optimum results and high survivorship rates.

Conflict of interest No benefits have been received from a commercial party related directly or indirectly to the subject of this article, there are no conflicts of interest to report.

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