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Total knee replacement using the Genesis II prosthesis: a 5-year follow up study of the first 100 consecutive cases

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Abstract

One hundred consecutive patients with osteoarthritis undergoing knee replacement using a prosthesis with asymmetrical posterior condyles and an asymmetrical tibial base plate (Genesis II) were followed for a minimum of 5 years after surgery. Mean flexion was 118°. Seventy nine percent of the patients could ascend and descend stairs in a reciprocal manner. A lateral retinacular release was required in only three patients. Post-operative patellar tracking was excellent as determined by both patellar displacement and patellar tilt. There was excellent flexion space stability using this prosthesis configuration without having to resort to external rotation of the femoral component. Tibial coverage was obtainable in >95% of the knees due to the asymmetric configuration of the base plate. Kaplan Meir Survivorship was 98% at 5 years.
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Keywords: Total knee replacement; Genesis II; Osteoarthritis

Total knee replacement is one of the most successful interventions in orthopaedic surgery. Over the 30 years since its inception, advances in implant design and surgical technique continue to improve the outcomes and make the operation applicable to overwhelming numbers of patients with advanced gonarthrosis.

Beginning in 1994, the author started evaluating a new tricompartmental implant, for patients who were candidates for primary knee replacement. The prosthesis had components which would allow performing the surgery with and without the presence of the posterior cruciate ligament. The prosthesis was modular with the ability to customize the implant with intramedullary stem extensions and augments if required. The tibial component was asymmetrical. The femoral component was likewise asymmetrical with a thicker postero-lateral femoral condyle than postero-medial femoral condyle.

This paper describes the results in the first 100 consecutive knee replacements performed for patients with osteoarthritis and with a minimum follow up of 5 years.

1. Materials and methods

Ninety-six consecutive patients with osteoarthritis (100 knees) underwent a primary knee tricompartmental replacement using the Genesis II (Smith and Nephew, Memphis, TN) cemented prosthesis. In four patients, bilateral knee replacements were performed under the same anesthesia.

The average patient age was 67.5 years, with a range from 52 to 94 years. The average patient weight was 90 kg with a range of from 54 to 125 kg. The mean BMI was 30.1 with a range of from 21.5 to 42.7. The pre-operative clinical and radiographic data is noted in Table 1.

During the 5-year period, four patients were lost to follow-up, and four died of causes unrelated to their total knee replacement. Two patients required a revision procedure for an infection which occurred 4 years after the index surgery. Two additional patients required revision of the arthroplasty, one for a periprosthetic femur fracture which loosened the femoral component, and another for tibial component loosening 5 years after the index procedure. This left 88 knees in 86 patients that could be evaluated with a minimal follow-up of 5 years. The average follow-up for this group was 5.8 years.

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Table 1
Pre-Operative Findings

Age	(range 52–94 years) (m=67.5 years)
Weight	(range 54–125 kg) (m=90 kg)
BMI	(range 21.5–42.7) (m=30.1)
Tibio-femoral angle (36″ standing roentgenograms)	
27 knees	Normal alignment +3° to +9°
56 knees	Varus (range −20° to +3°)
17 knees	Valgus (range +10° to +35°)
Fixed flexion contracture	(range 0° to 30°) (m=3°)
Maximum passive flexion (patient supine and hip flexed)	(range 80–135°) (mean=113°)

All of the surgeries were performed using a combined spinal epidural anesthetic. The epidural catheter remained in place for 48 h after surgery. Patients began on parenteral antibiotics ½ h prior to the skin incision. The antibiotics were continued for 24 h after surgery. First generation cephalosporin was used in all patients other than those with documented cephalosporin allergy, in whom Vancomycin was used.

All the patients in this series had their knee replacement through a standard midline skin incision and median parapatellar capsular approach with eversion of the patella. Cutting blocks were guided using intramedullary tibial and femoral alignment guides. Anterior referencing femoral blocks were used to guide the anterior and posterior femoral resections.

The femoral prosthesis used was asymmetrical with a thicker posterior-laterally than poster-medially. This permitted filling of the flexion space [1] in most patients without externally rotating the femoral component.

For those patients in whom there was a flexion and/or fixed varus or valgus deformity greater than 15° to 20° (38 knees), the posterior cruciate ligament was released and posterior stabilized femoral and tibial components were used. In the remaining 62 knees, posterior cruciate retaining implants were chosen. After the trial implants had been inserted, the knee was ranged from flexion to extension. If there was excessive rollback or anterior lift-off of the tibial component with knee flexion, the ligament was recessed at its tibial insertion until lift-off or abnormal rollback no longer occurred.

After the distal femur and proximal tibial were resected, the knee was evaluated for fixed coronal deformities. If present these were released in a standard manner [2]. Flexion and extension space balancing was assured before implantation of the final components.

The femoral components (Fig. 1) were fabricated of a cobalt–chrome–molybdenum alloy. The trochlear flange was angled laterally to maximize capture of the patellar component. The tibial components were modular with a Ti alloy baseplate, a short intramedullary stem with anti-rotational fins, and a modular polyethylene bearing surface. The capture mechanism of the metal base plate extended around 80% of the polyethylene. The tibial baseplate was asymmetrical to maximize coverage of the asymmetrically resected tibial surface. In all cases, the patella was resurfaced with an inset symmetrical polyethylene implant. The goal was to restore the pre-resected thickness of the patella and to avoid over stuffing.

Before implantation of the final components, flexion extension balancing and stability, and proper component tracking were ascertained. A final evaluation of patellar tracking was made after the permanent implants were cemented in place and the tourniquet released. If necessary, a lateral parapatellar release was performed from inside the joint. A closed drainage system was left in situ for 24 h after surgery.

Parenteral Coumadin supplemented by mechanical foot compression pumps were used as anti-thromboembolic measures. The Coumadin was continued on an empiric basis for 4 weeks after surgery with neither routine venography nor ultrasonography used. Patients were begun on range of motion exercises beginning on the day of surgery using a continuous passive motion machine. Gait training, allowing weight bearing as tolerated was begun the day after surgery with a walker. On the third post-operative day, patients were allowed to ambulate using a cane in the contralateral hand. At 1 month after surgery, patients were allowed to return to driving a car, but encouraged to continue to use the cane when walking outdoors for another month.

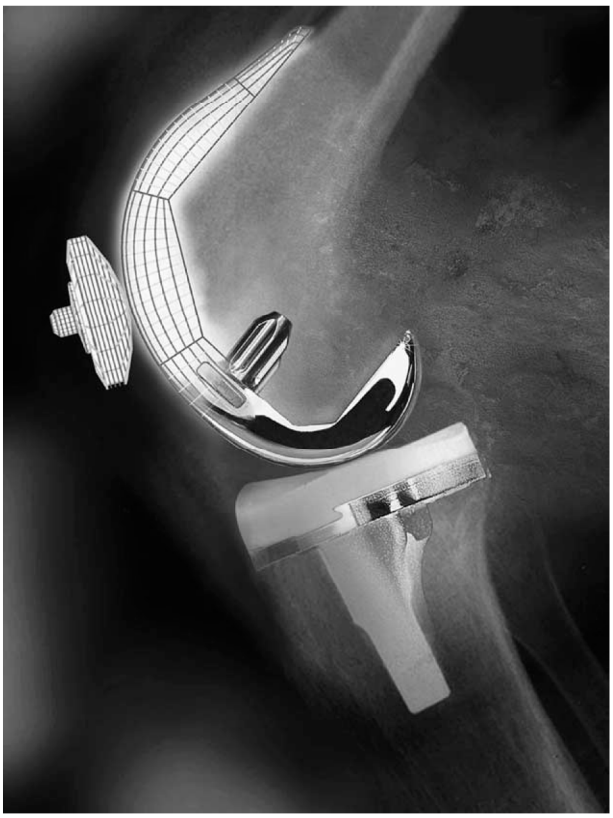

Fig. 1. Genesis II total knee prosthesis.

The Knee Society Rating System [3,4] was used for patient evaluation. Data points were collected prior to surgery, at 6 weeks, 3 months, and then yearly. Knee scores greater than 90 points were considered excellent, 80 to 89 were considered good, 70 to 79 were fair, and less than 69 were considered to be poor.

Radiographs were taken prior to surgery, at 6 weeks and then yearly. The images included an anterior–posterior (AP) view (weight bearing), a lateral, a Rosenberg crouch view, and a patellar skyline view with the knee in approximately 40° to 50° of flexion.

The primary indication for surgery in this group of patients was pain relief. All the patients in his group had pain which they rated as moderate or severe pre operatively. Secondary indications included restoration of stability, increasing ability to walk distances, and correction of flexion deformities.

2. Results

At 5 years after surgery, 77% of the patients had no pain with any activities. Twenty-one percent had mild discomfort usually during inclement weather. Two patients had pain on a daily with weight basis, and were on continuous analgesic medications. No patients had either night or rest pain. The clinical and radiographic findings are noted in Table 2.

Seventy-nine percent of the patients could both ascend and descend stairs in a reciprocal manner. All the remaining patients could ascend stairs foot over foot, but descend stairs, one step at a time. There was no statistical difference in stair walking ability between patients in whom the PCL was retained and those in whom the PCL had been sacrificed and a posterior stabilized prosthesis used.

Table 2
Five-year postoperative demographics for patient after total knee arthroplasty

96 Patients (100 knees) initially implanted
4 Died
4 Lost to follow-up
2 Revision for infection (both 4 years post op)
1 Revision for periprosthetic femur fx
1 Revision for tibial component loosening (5 years post op)
88 Knees for evaluation
Passive flexion: 90–135° (mean 118°)
Flexion contracture: None (85 knees), 5° (1 knee), 10° (2 knees)
Medial lateral instability: None to 5° (84 knees), 5° to 10° (4 knees)
Antero-posterior instability: None to 5 mm (78 knees), 5–10 mm (8 knees), >10 mm (2 knees)
Lateral retinacular release: 3 knees (all had pre-op femoral tibial alignment >12°)
Kaplan Meir survivorship at 5 years: 98.7% (Failure=implant failure, implant loosening, of recurrence of pain)
Knee Society Scores:
>91 (excellent): 69%
80–90 (good): 31%

The tibio-femoral alignment varied between 2° and 9° with a mean of 5.2°. There was no statistical difference in the mean alignment between the patients with PCL retention and those with a PS prosthesis.

The angulation between the undersurface of the tibial component and the tibia in the frontal plane was measured post-operatively on 18″ cassettes. In all but four knees it was 90±2°. In two knees, it was 95° (both knees had a pre-operative valgus deformity), and in two knees it was 86°. In the sagittal plane, all but three knees had a posterior angulation of 3±2°. Of the remaining three knees, one had an upsloping of −5°, and the others a downslope of 8° and 10°, respectively.

The angulation between the femoral component and the anatomic axis of the femur in the frontal plane was 95±2° in all but one knee where it was 92°. The femoral component was parallel to the anatomic axis of the femur (180±2° in the Knee Society Roentgenographic Evaluation) in the lateral plane in all but four knees. In those knees, the component was slightly flexed with angles of 172°, 174° (two knees) and 175°, respectively.

A lateral retinacular release was performed in three knees. The mean patellar tilt of the bony cut on Merchant view X-rays was 1.2° (with a range of from 0° to 15°). The mean patellar displacement laterally was 0.5 mm (with a range from 0 to 7 mm). 82% of the knees had neither lateral displacement nor patellar tilt.

Seven knees demonstrated a bone cement radiolucency, all less than 1 mm in width, usually in Zone I or IV of the tibial component. There were no radiolucencies extending around the entire component. Femoral component radiolucencies were seen under the femoral flange in eight knees, all these lucencies measuring less than 1 mm in thickness.

Radiolucencies about the inset patellar implants are difficult to evaluate on standard X-rays. None of the implants, however, demonstrated evidence of loosening or of displacement.

There were no early infections in this group although one patient had a streptococcus infection in the knee occurring 4 years after surgery after she had been treated for a tooth abscess. The implant was removed, a static antibiotic impregnated acrylic spacer inserted, and 8 weeks later a secondary reimplantation performed. There was no recurrence of the infection. Another patient had a septicemia due to an infected gall bladder with secondary seeding to the knee. In this case as well, the implant was removed, a similar type of antibiotic impregnated spacer inserted, and the reimplantation performed 10 weeks later.

One patient required surgery on her knee after a fall. She had suffered a dislocation of the joint and attenuation of the medial capsule. The implant was revised to a super-stabilized implant. The patient subsequently had a stable knee in both sagittal and coronal planes.

The Knee Society Knee Score was excellent (>91 points) in 69% of the knees, and good (81–90 points) in 31% of the knees. The Kaplan Meir survivorship [5] at 5 years, using

revision for any reason, or recurrence of pain as a failure point, was 92.8%. It should be noted, however, that two of the revisions were necessitated for a late bacteremic septicemic infection and one due to the patient having broken her leg. If, more realistically, failure was determined by a failure of the implant or its fixation or the recurrence of pain, that the survivorship was 98.8 %.

3. Discussion

This study documents the results using a fourth generation implant for total knee replacement of the arthritic knee. The prosthesis had provisions made for retention of the PCL or its sacrifice and use of a posterior stabilized bearing surface. The tibial base plate was asymmetrical so as to match the cut surface of the tibia. The femoral component geometry was such that flexion space filling was obtainable without having to externally rotate the component. The trochlear groove permitted patellar tracking in a more anatomical manner.

At the time that these patients underwent surgery, it was the author's preference to retain the posterior cruciate ligament, if this was feasible. In most arthritic knees, the ligament is physically present at the time of surgery, However, retaining the ligament is detrimental in patients in whom there is a fixed angular deformity and or flexion deformity greater than 15° to 20° [6]. Likewise, retaining the ligament yields inferior results in patients with a prior patellectomy [7], in patients with an inflammatory arthropathy (such as rheumatoid arthritis [8]) and those who had undergone a prior high tibial osteotomy. In this study, all except three of the patients in whom a PS prosthesis was used, had this choice based upon the present of the angular and flexion deformity. Rather than have a PCL retaining prosthesis onto which a posterior-stabilized module was affixed, it had been elected to have a dedicated posterior-stabilized implant. In theory, this might prevent any potential fretting corrosion between a posterior stabilized module and the femoral component, although in clinical use this had not been seen when a prior such design (the Genesis I prosthesis) was used and followed for over 10 years [9,10].

The author used intramedullary instrumentation for alignment of the femoral and tibial cutting jigs. For the femur, an attempt was made to pass the rod through the isthmus of the bone. On the tibial side, the rod was inserted for at least 80% of the length of the tibia. On occasion, primarily when there was a very small intramedullary tibial canal (seven knees) or marked tibial shaft bowing (two knees) , an extramedullary tibial alignment rod was used as an alternative [11]. Using these instruments, it was possible to obtain excellent implant alignment in almost all cases.

The tibial baseplate of the implant was asymmetrical. The asymmetric shape was determined based upon a resection specimen analysis of tibial coverage in total knee arthroplasty [12]. Unmagnified roentgenograms of 42 tibial resections taken at the time of knee arthroplasty were digitized. The tibial base plate was then designed so as to achieve at least 95% coverage as determined by these resection analysis specimens. Such asymmetrical shape avoided the often seen postero-medial overhang, or compensatory undersizing of the tibial component which occurred when the Insall Burstein II and Press Fit Condylar symmetrical components had been studied [13].

The tibial plateau was resected at 90° to the anatomical axis of the bone in the coronal plane, while for the femur, the jigs were set so that the cutting block was perpendicular to the mid-trochlear line. Except for the severe valgus knee with lateral condylar dysplasia, this resulted in equal amounts of bone were removed posteriorly from both condyles. The resultant flexion space is trapezoidal, larger laterally than medially. Faced with this situation if a symmetrical prosthesis had been inserted, it would have been necessary to externally rotate the cutting block resecting extra bone postero-medially to form a rectangular space [14]. It had been clinically noted, however, that such external rotation often caused notching of the femur antero-laterally, or overhang antero-medially, with a mild rotational incongruity in extension. To obviate these problems, the femoral component utilized in this study was specifically designed with a thicker postero-lateral femoral condyle than postero-medial femoral condyle. This permitted filling of the trapezoidal flexion space without femoral component external rotation.

The efficacy of this design was shown in a study measuring the flexion space and flexion stability [15,16]. X-rays were taken with the patient's knee flexed 90° and the tibia hanging down freely with gravity distracting the joint. The medial and lateral "clear spaces" were measured. In over 95% of the cases, these spaces were equal. The knees were then tested for valgus-varus stability in 90° of flexion. There was no instability noted in this testing in 96% of the knees.

One of the advantages of external rotation of the femoral component that was seen in other studies was that it decreased the requirement for a lateral release. Despite the fact that the femoral components in this present study were not externally rotated, the lateral release rate was extremely low. This was accomplished by having a component with a trochlear groove which started laterally proximally and then came to the midline deeper in the notch, in a manner analogous to that seen with the normal patello-femoral groove in the native femur. Patellar tilt and patellar shift were almost non existent in this group of patients, and anterior knee pain was 4%, a level lower than that seen in other reported series of knee replacement. All the patellar implants, at the time of closure, appeared to track well. It is known, however, that this test is done in a static manner and on occasion, active quadriceps power can cause some shift or tilt of the patella. The one patient with 15° of tilt had no anterior knee pain at all.

There was no statistical difference in the eventual flexion between those patients in whom a PCL retaining or a posterior stabilized implant were used. Subsequent to these initial 100 patients, the author began a study of the use of the same implant with a deep dished conforming bearing surface and demonstrate that the range of flexion in that implant was equal to that of a posterior stabilized prosthesis. At that point, the author began to use a deep dished component in those cases where the posterior cruciate ligament was insufficient [17].

At present, the author uses this prosthesis with an Oxidized Zirconium-surfaced zirconium alloy femoral component in patients who are physiologically young (normally less than 68 years of age) [18]. All the patients in this present study, however, had their arthroplasty performed with a femoral component which was fabricated of a cobalt–chrome–molybdenum alloy. Likewise at present, the author inserting this prosthesis primarily through a mini-mid-vastus minimally invasive approach without patellar eversion. All of the patients in this study, however, had their surgery performed through a median parapatellar approach with patellar eversion.

The determination as to whether or not a patient required a lateral retinacular release was made after the tourniquet had been deflated. If a release was required, it was performed from without inward, preserving the integrity of the synovium.

Pagano et al. [19] had reported a high incidence of joint effusion in patients in whom they could demonstrate AP instability after total knee replacement. We found neither repeated joint effusions nor A/P instability in our patients. The polyethylene used in this series was ram extruded and sterilized in Ethylene Oxide. This may have precluded the abnormal polyethylene wear seen by Pagnano in those knees with thin implants, and gamma sterilization in air.

The incidence of radiolucencies either about the femur or about the tibia was low. Tibial malpositioning, especially into varus [19] increases the radiolucency rate; in this series, almost all the tibial components were within 2° of optimal position. Whether this, or the avoidance of thin air-sterilized polyethylene was the protective factor, cannot be proven.

The 5-year survivorship was excellent in this group of patients. At 6 and 7 years, the survivorship remained excellent however the small number of patients at this milestone make true analysis less accurate. All the patients either had no pain, or at worst, mild barometric discomfort.

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