Ten-year Results of the First 100 Genesis II Total Knee Replacement Procedures

R.B. BOURNE, MD, FRCSC; RICHARD S. LASKIN, MD; J.S. GUERIN, BMATH

abstract

The first 100 consecutive Genesis II (Smith & Nephew; Memphis, Tenn) total knee replacements (TKR) procedures performed in 97 patients by the senior investigators (RBB, RSL) had a Kaplan-Meier survivorship of 96% ± 2% at 12 years with any reoperation as the endpoint. Significant improvements in health-related quality-of-life outcome measures were noted. There were no revisions for implant-related factors (ie, polyethylene wear, osteolysis, or aseptic loosening). No implant demonstrated radiographic loosening. The features of this device are discussed as well as its long-term performance.

Total knee replacement (TKR) has revolutionized the care of patients with end-stage knee arthritis.[1-4] Much of this success has been attributed to stepwise improvements in TKR design, instrumentation, and surgical technique. The Genesis II TKR (Smith & Nephew; Memphis, Tenn) was introduced more than 10 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.[5-12] The purpose of this study is to assess the outcomes of the first 100 Genesis II TKRs performed by two of the design surgeons (RBB, RSL).

MATERIALS AND METHODS

The first 100 consecutive Genesis II TKRs with a minimum 10-year follow-up performed by the two senior investigators were included in this study (Figure 1). The Genesis II TKR was available in eight femoral and tibial component sizes. All implants were secured with bone cement fixation. Each patella was resurfaced with a cemented biconvex inset patellar button. The device was inserted using built-in femoral component rotation, rather than the traditional technique of externally rotating the cutting block and femoral component to achieve equal flexion and extension spaces.[8] Built-in femoral component external rotation has been reported to have several advantages in optimizing patellofemoral tracking, minimizing the risk of femoral notching, and preventing tibiofemoral shear forces in extension and flexion.[6,9,10]

An asymmetric anatomic tibial base plate was also used to provide optimal tibial surface coverage and to guide accurate tibial component rotatory positioning.[11,12] The tibial base plate was polished on its upper surface, which, when combined with a durable locking mechanism, was developed to minimize backside wear of the tibial polyethylene insert.[9] The modular, tibial, ultra-high molecular weight polyethylene tibial inserts were sterilized with ethylene oxide to avoid the oxidation, wear, and osteolysis associated with gamma-in-air sterilization.

Optimized instrumentation that allowed interchangeable anterior and posterior femoral referencing to minimize the risk of femoral notching was used. The femoral instrumentation used an intramedullary rod, whereas the tibial instrumentation was available in intramedullary or extramedullary modes.

Patient demographics included sex, age at the time of surgery, diagnosis, Charnley class, and body mass index (BMI). Intraoperative data on anesthetic used, surgical approach, instrumentation used, and implant selected (ie, posterior cruciate ligament retaining versus sacrificing) were collected. Patients were followed at

Dr Bourne and Mr Guerin are from the London Health Sciences Center, University of Western Ontario, Ontario, Canada, and Dr Laskin is from the Hospital for Special Surgery, Weill Cornell Medical College of Cornell University, New York, NY.

Dr Laskin and Dr Bourne are consultants for and have received compensation. Mr Guerin has received research support from Smith & Nephew.

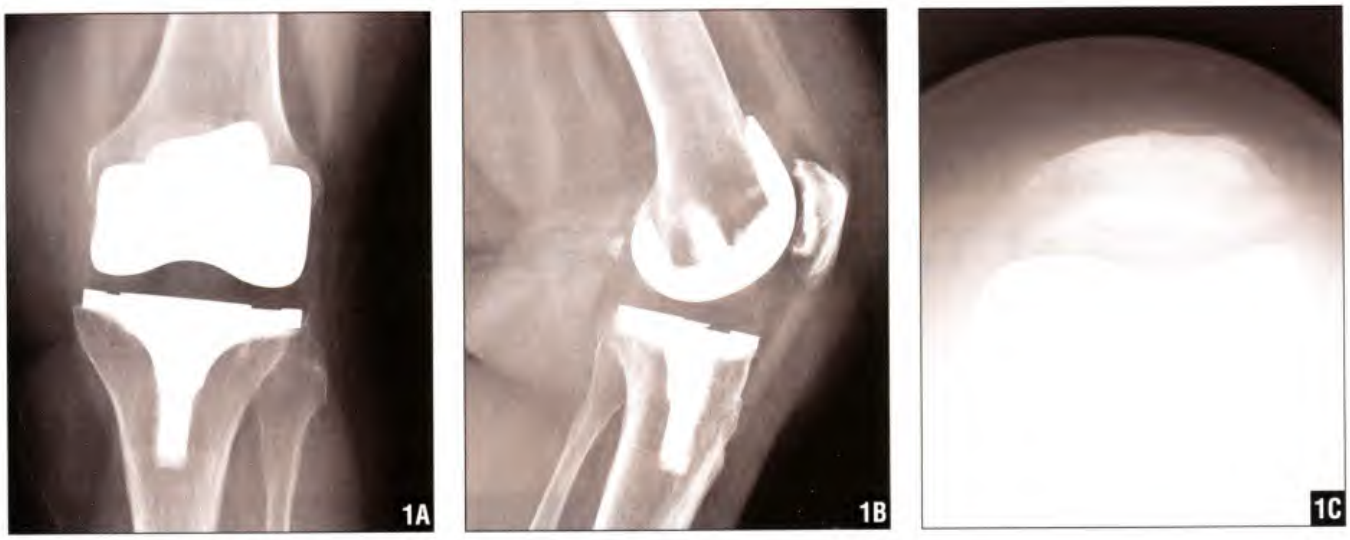


Figure 1: AP (A), lateral (B), and axial patellofemoral (C) of a posterior cruciate-preserving Genesis II TKR at 11 year follow-up.

Table 1

		Pre-Op Rom	Post-Op Rom
	'N'	Mean	Mean
60° – 90°	11	75°±9°	100°±13°
91° – 120°	74	104°±8°	113°±12°
>120°	15	124°±6°	117°±13°

Table 2

	Knee Scores		Function Scores	
	Pre-Op	Post-Op	Pre-Op	Post-Op
60° – 90°	30±18	78±19	37±15	57±30
91° – 120°	38±13	92±9	48±12	64±19
>120°	48±13	94±7	53±14	68±23

6, 12, and 52 weeks and annually thereafter. Postoperative assessments included health-related quality-of-life outcomes (ie, Knee Society clinical score, Western Ontario and McMaster Osteoarthritis Index [WOMAC], and Short form-12, as well as radiographic assessments [anteroposterior, lateral, and axial patellofemoral radiographs]). All data were collected on a computerized database allowing analysis of the data.[13-16]

Results

Institutional review board approval was given for the analysis of this prospectively generated database of 100 consecutive Genesis II TKRs in 97 patients (58 women). No patient was lost to follow-up. Mean age at the time of surgery was 69±8 years (range: 47-88 years). There were 93 patients with osteoarthritis, 1 patient with inflammatory arthritis, and 3 patients with osteonecrosis. There were 47 patients with unilateral knee disease (Charnley Class A), 33 patients with bilateral knee arthritis (Charnley Class B), and 17 patients with multijoint or significant other comorbidities (Charnley Class C). Mean BMI of the patient population was 30±5 (range:18-43 years). All but 18 TKR devices were posterior cruciate-retaining implants.

Mean Kaplan-Meier survivorship of the first 100 Genesis II TKRs at 11.9 years follow-up was 96%±2%.[17] Three knees were reoperated on for deep sepsis (3%) and 1 (1%) for stiffness, but none for implant-related failure mechanism (ie, wear, osteolysis, aseptic loosening, or component fracture).

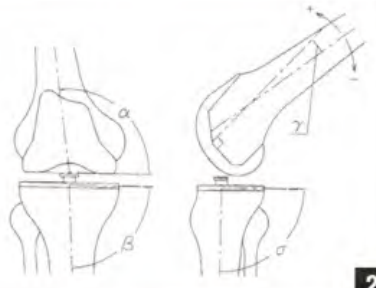
Significant improvements in preoperative health-related quality-of-life outcome measures were noted. Knee Society clinical ratings improved from 38±14 preoperatively to 91±11, 10 years postoperatively for the Knee Society score ($P<.001$) and from 47±13 to 64±21 for the Knee Society function score ($P<.001$). Similar improvements were noted for the WOMAC scores, with the pain score improving from 40±18 to 63±25 ($P=.002$), the joint stiffness score from 42±19 to 63±27 ($P=.002$) and the function score from 42±17 to 60±24 ($P=.001$). The SF-12 physical component scores improved from 28±5 to 34±11 ($P=.031$), but the mental component scale remained unchanged at 51±12 preoperatively and 50±12 postoperatively.

Improvements in mean preoperative (103°±15°) to postoperative (112°±13°) knee range of motion (ROM) were noted ($P<.001$). In Table 1, preoperative patients were divided into those with <60° of flexion, 60° to 90° of flexion, 91° to 120° of flexion, and over 120° of flexion. Knee ROM was a indicator of patient disability in patients with less preoperative ROM and poorer Knee Society scores ($P=.003$). The most significant improvements occurred in those patients with the stiffest knees (Table 2).

Patients were also assessed for anterior knee pain. Ninety-five percent of patients reported no anterior knee pain. In the 5% of patients who reported anterior knee pain, 2 patients reported mild anterior knee pain (visual analog scale of 1-3) and 3 patients reported moderate anterior knee pain (visual analog scale of 4-6). Only 4 (4%) knees required a lateral retinacular release.

Component Alignment Angles

	Mean	SD
α angle	95.4°	2.3°
β angle	89.1°	1.6°
γ angle	0.8°	3.1°
δ angle	85.8°	2.5°



2

Figure 2: Radiographic alignment achieved for the femoral, tibial, and patellar components using the Knee Society criteria.

Radiographic assessment confirmed the accuracy of the implant's instrumentation in achieving proper bone cuts and alignment (Figure 2). Radiolucencies within 1 cm of the medial or lateral edges of the tibial plateau and under the anterior flange of the femoral component were common. No implant was considered definitely loose (implant migration), probably loose (100% radiolucencies >2 mm thick), or possibly loose (50%-99% radiolucencies) using the criteria outlined in Materials and Methods.

Clinically and radiographically, no patient had a dislocated patella postoperatively. Using the axial skyline patellofemoral radiographs, 97 knees had normal patellofemoral tracking, and 3 knees had subluxed patellar implants.

DISCUSSION

The first 100 Genesis II TKRs performed by the senior investigators have performed well with 10 or more years, follow-up. This observation confirms results of shorter-term studies of the Genesis II implant reported in the literature.[6,9] Notably, the built-in external rotation of the femoral component seems to have optimized patellofemoral tracking with a low prevalence of complications or the need for a lateral retinacular release (4%).[6] The absence of wear-related failures and osteolysis supports the use of ethylene oxide-sterilized tibial polyethylene, the use of a polished tibial base plate, and the locking mechanism found in the Genesis II TKR. The improvements in the instrumentation for the Genesis II implant seem justified in terms of the accuracy achieved in restoring limb alignment at the time of surgery.[7]

The Genesis II TKR has now been implanted in more than 750,000 patients worldwide and continues to evolve to meet the needs of the active patient. Enhancements to the system since its introduction have included the introduction of 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).

REFERENCES

1. Ethgen O, Bruyere O, Richy F, Dardennes C, Reginster JV. Health-related quality of life in total hip and total knee arthroplasty: a qualitative and systemic review of the literature. *J Bone Joint Surg Am*. 2004; 86:963-974.
2. Harris WH, Sledge CB. Total hip and total knee replacement. *N Eng J Med*. 1990; 323:725-731.
3. Lavernia CJ, Guzman JF, Gachupin-Garcia A. Cost effectiveness and quality of life in knee arthroplasty. *Clin Orthop Relat Res*. 1997; 345:134-139.
4. *NIH Consensus Statement n Total Knee Replacement*. Bethesda, Md: National Institutes of Health; 2003; 20:1-32.
5. Haas SB, Nelson CL, Laskin RS. Posterior stabilized knee arthroplasty: an assessment of bone resection. *Knee*. 2000; 7:25-29.
6. Kaper B, Woolfrey M, Bourne RB. The effect of built-in external femoral rotation on patellofemoral tracking and complications following total knee arthroplasty. *J Arthroplasty*. 2000; 15:964-969.
7. Kotani A, Yonekura A, Bourne RB. Factors influencing range of motion after contemporary total knee arthroplasty. *J Arthroplasty*. 2005; 20:850-856.
8. Laskin RS. Flexion space configuration in total knee replacement. *J Arthroplasty*. 1995; 10:657-660.
9. Laskin RS. Total knee replacement using the Genesis II prosthesis: a five-year follow-up study of the first 100 consecutive cases. *Knee*. 2005; 12:163-167.
10. Ries MD, Salehi A, Laskin RS, Bourne RB, Rand JA, Gustilo RB. Can rotational congruity be achieved in both flexion and extension when the femoral component is externally rotated in total knee arthroplasty. *Knee*. 1998; 5:370-342.
11. Westrich G, Agulnick MA, Laskin RS, Haas SB. Current analysis of tibial coverage provided by total knee arthroplasty systems. *Knee*. 1997; 4:221-226.
12. Westrich G, Laskin RS, Haas SB, Sculco TP. Resection specimen analysis of tibial coverage in total knee arthroplasty. *Clin Orthop Relat Res*. 1994; 309:163-176.
13. Bellamy N, Buchanan WW, Goldsmith CM, Campbell J, Stitt LW. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol*. 1988;15:1833-1840.
14. Hawker G, Melfi C, Paul J, Green R, Bombardier C. Comparison of a generic (SF-36) and a disease specific (WOMAC) instrument in the measurement of outcomes after knee replacement surgery. *J Rheumatol*. 1995; 22:1193-1196.
15. Insall J, Dorr L, Scott R, Scott W. Rationale of the Knee Society clinical rating system. *Clin Orthop Relat Res*. 1989;248:13-14.
16. Ware JE Jr, Sherbourne CD. The MOS 36 item short-form health survey (SF-36), I: Conceptual framework and item selection. *Med Care*. 1992; 30:473-383.
17. Kaplan EL, Meier P. Nonparametric estimation from incomplete observations. *J Am Stat Assoc*. 1958; 53:457-481.