The Knee 26 (2019) 838–846

Contents lists available at ScienceDirect

The Knee

Genesis 1 posterior cruciate-retaining total knee arthroplasty with asymmetric tibial tray: An 18-to-26-year long-term clinical outcome study

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ARTICLE INFO

Article history:
Received 30 March 2018
Received in revised form 10 February 2019
Accepted 16 April 2019

Keywords:
Asymmetric tibial tray
Cruciate-retaining
Genesis I
Long-term outcome
Total knee arthroplasty

ABSTRACT

Background: To present the long-term clinical and radiological outcomes of the Genesis I posterior cruciate-retaining total knee arthroplasty (TKA) (Smith & Nephew Orthopaedics, Memphis, TN, USA) (one of the first designed with an asymmetric tibial tray).
Methods: Prospectively collected data from 117 cemented TKAs performed on 95 patients were evaluated using this design, with a mean follow-up of 21.5 years (range, 18–26). Failures, complication rates, and clinical (both subjective and objective) and radiological outcomes were assessed for all patients.
Results: Seven failures occurred (wear and structural failure of the polyethylene insert) and six revision surgeries were performed at a mean of 10 years (range, three to 14) from the index operation. No revision of either the femoral or tibial components for aseptic loosening was performed. Survivorship analysis showed a cumulative success rate of 93.53% (95% CI, 92.75–94.32%) at 20 and 25 years, with revision for any reason as an end point. All patients showed a statistically significant improvement ($P = 0.001$) in the Knee Society and Oxford knee rating scores.
Conclusions: This study demonstrated satisfactory long-term clinical outcomes for this TKA design, with revisions being related to polyethylene wear structural failure.

1. Introduction

Total knee arthroplasty (TKA) is a successful surgical procedure for end stages of knee disease, with satisfactory survival rates at 15–20 years reported in several large series [1–3]. It is a standard orthopaedic procedure providing patients with pain relief and improved function [4,5].

The development and clinical use of effective TKA designs were delayed for at least 15 years, when compared with total hip arthroplasty, due to the complexity of knee joint biomechanics and kinematics [6]. An impressive design cascade of innovative prosthetic resurfacing TKAs followed the pioneering attempts of the 60s and 70s [7]. In the early 90s, the so-called third-generation TKAs were introduced, and Genesis I, with an asymmetric tibial tray, became available for clinical use.

The aim of this study was to present long-term clinical outcomes of Genesis I, evaluating possible failures, complication rates, objective and subjective clinical outcomes, and radiological scores.

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https://doi.org/10.1016/j.knee.2019.04.014
0968-0160/

2. Patients and methods

From 1992 to 2000, 95 non-consecutive patients (117 knees) underwent cemented Genesis I TKA at the current department and were included in this study. There were 85 (89.5%) women and 10 (10.5%) men (compatible with the female to male patient ratio with knee OA in this region). The mean age at surgery was 69 years (range, 58–83). Sixty (51.3%) procedures were performed on the right and 57 (48.7%) on the left knee. Twenty-two patients underwent staged bilateral procedures. Patients had a mean body mass index (BMI) of 32.5 kg/m^2 (range, 21.5–43.4).

The criteria for patient selection were primary knee osteoarthritis (OA) of moderate severity, varus angular deformity <15°, and flexion contracture <10° (deformity criteria for the use of a posterior cruciate-retaining design in the current department in the early 90s). Exclusion criteria were patients with inflammatory arthritis, post-traumatic arthritis, severe knee deformities (varus deformity >15°, fixed flexion >10°, and valgus deformity >10°), and both femoral and tibial bone defects requiring reconstruction. During this period of time, posterior-stabilised (PS) and rotating hinge implants were used for those patients not fulfilling the above selection criteria, at a rate of 200 TKAs per year. Written informed consent forms were obtained from all patients and the study was approved by the authors need to include study number from Institutional review board.

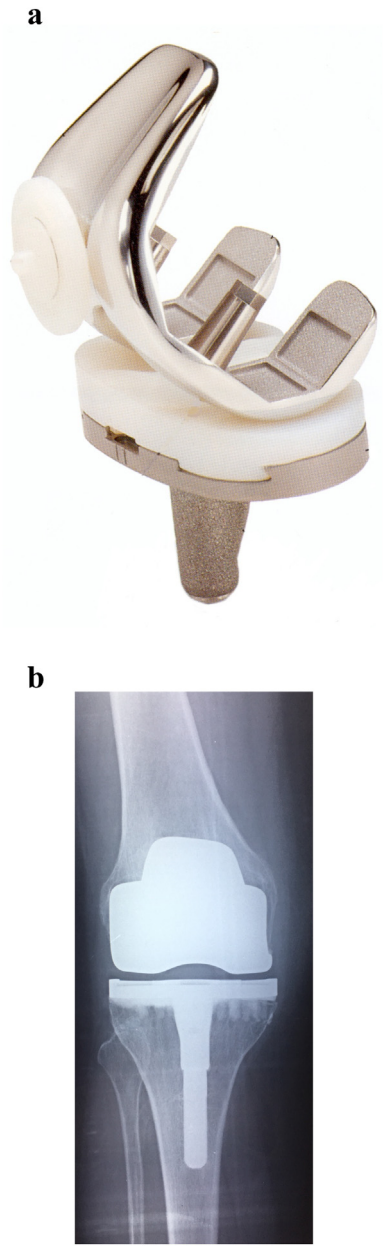

Figure 1. a. A Genesis I photograph. b. Satisfactory anteroposterior radiological outcome at 22-year follow-up.

The Genesis I TKA (Smith & Nephew Orthopaedics, Memphis, TN, USA) was used for all patients (Figure 1). This is a modular system consisting of an anatomical cobalt-chrome femoral component (made for both cemented and cementless fixation) and an asymmetric titanium alloy tibial component with a short (four centimetres) or extended (10 cm) central stem. A polyethylene insert (minimally conforming) was made of ultra-high-molecular-weight polyethylene, sterilised with gamma radiation in air [8,9]. A semi-constrained variant of the implant for posterior cruciate ligament (PCL) retention was used. In 113 out of 117 TKAs, the extended (10 cm) stem was used. A bi-convex-shaped polyethylene patellar component with a central fixation peg was also available.

All procedures were performed by two orthopaedic surgeons (TKA specialists) via a standard anterior midline and medial parapatellar incision. Cemented fixation of both components (including the tibial stem) was carried out for all patients using antibiotic-loaded high-viscosity Palacos® cement (Biomet, Warsaw, IN). The patella was resurfaced in seven (six percent) TKAs. All patients had preventive pre-operative and postoperative intravenous antibiotics for two days, suction drains for two days, and low-molecular heparin administration for 30 days. Full weightbearing as tolerated, with the use of a walking frame, started from the second postoperative day and all patients followed a standard rehabilitation protocol.

Objective and subjective clinical and radiological data were prospectively collected pre-operatively and at three months, six months, one year, and five years postoperatively, and then every five years thereafter; data were stored in a computer database. The following validated scoring systems were used: [10] the Knee Society system (KSS, Knee score and Function score) [11], and the original (60–12) Oxford Knee Score (OKS) [12]. The active range of movement (ROM) when sitting was recorded using a goniometer. At the third and fifth postoperative time intervals, patients were also asked to subjectively judge pain relief, their expectations of surgery, and if they would like to repeat the same operation on another joint. Standardised standing short anteroposterior and lateral radiographs were taken. The KSS was used for radiological evaluation [13]. Changes in alignment and migration (femoral valgus (α), tibial (β), femoral flexion (γ), tibial slope (σ), and tibiofemoral angles) of the components were analysed; angles on the first and last available radiographs were compared. Three surgeons (VG, KM, SB) examined all radiographs for progressive radiolucent lines (RLLs) according to Ewald [13], and if all three found RLLs, this was defined as a consensus. The presence of RLLs measuring >2 mm, subsidence or change in alignment of a component were considered to indicate loosening. Acute or progressive asymmetric radiological joint space narrowing combined with late-onset instability was considered as a criterion of polyethylene liner wear and structural failure. Criteria for failure were the need for revision, either performed or planned, because of aseptic loosening, infection, patellar resurfacing and dislocation, or ligament instability.

2.1. Statistical analysis

Data were analysed for normal distribution using Kolmogorov–Smirnov analysis. Clinical scores (KSS, and OKS) and α, β, γ, σ, and tibiofemoral angles were normally distributed. In order to evaluate possible statistical differences at different time intervals, Student's *t*-test was used for paired samples. Kaplan–Meier analysis with calculation of 95% CIs was performed to calculate survivorship [14–16]. Revision of either component for aseptic loosening, and all other revision operations for any reason were considered as end points. All statistical analyses were performed using SPSS version 12.0 (SPSS Chicago, Illinois) at the Biostatistics Department of the University of Thessalia. A *P*-value of ≤0.05 was considered significant.

3. Results

The patients in this series were followed for a mean of 21.5 years (range, 18-26 years). Between December 2017 and February 2018, a final evaluation was performed and 74 (77.9%) patients with 91 (77.8%) TKAs were available for study. Eight (8.4%) patients (eight TKAs) were lost to follow-up and 13 (13.7%) patients (18 TKAs) had died for reasons unrelated to the surgery, with their TKAs performing well. Seven (six percent) failures were observed and six (5.13%) revision procedures were performed. Three TKAs were revised at five, 12 and 14 years, respectively, due to polyethylene wear (implant-related failure) (Figures 2 and 3). One TKA was revised at 10 years, due to knee trauma and polyethylene damage (implant-related and patient-related failure) (Figure 4). Another patient (BMI 40 kg/m^2) had a knee injury and polyethylene damage (implant-related and patient-related failure) at 14 years. A revision was proposed, but the patient refused it because the knee was asymptomatic. Two patients who were unable to tolerate anterior knee pain underwent additional surgery. The patella was replaced at three years in one of them, and the patella component was revised due to wear and loosening (implant-related failure) at 12 years in the other. No signs of polyethylene liner backside wear were observed. There was 74% compliance with the intervals of follow-up evaluation.

Kaplan–Meier survivorship analysis showed a cumulative success rate of 96.45% (95% CI, 96.10–96.81%) at 10 years, and 93.53% (95% CI, 92.75–94.3%) at 15, 20 and 25 years, with revision for any reason as an end point (Figure 5). Kaplan–Meier survivorship analysis showed a cumulative success rate of 96.50% (95% CI, 95.99–97.01%) at 10 years, and 91.67% (95% CI, 90.64–92.69%) at 15, 20 and 25 years, with all operations as an end point (Figure 6). Kaplan–Meier survivorship analysis showed a cumulative success rate of 98.29% at 10, 15, 20 and 25 years, with revision for aseptic loosening as the end point.

Minor wound healing problems were recorded in nine (7.7%) knees. Deep vein thrombosis was detected in four (3.4%) knees of four patients who fully recovered. In three (2.6%) knees, manipulation under anaesthesia was performed in order to improve postoperative flexion after the fourth postoperative week.

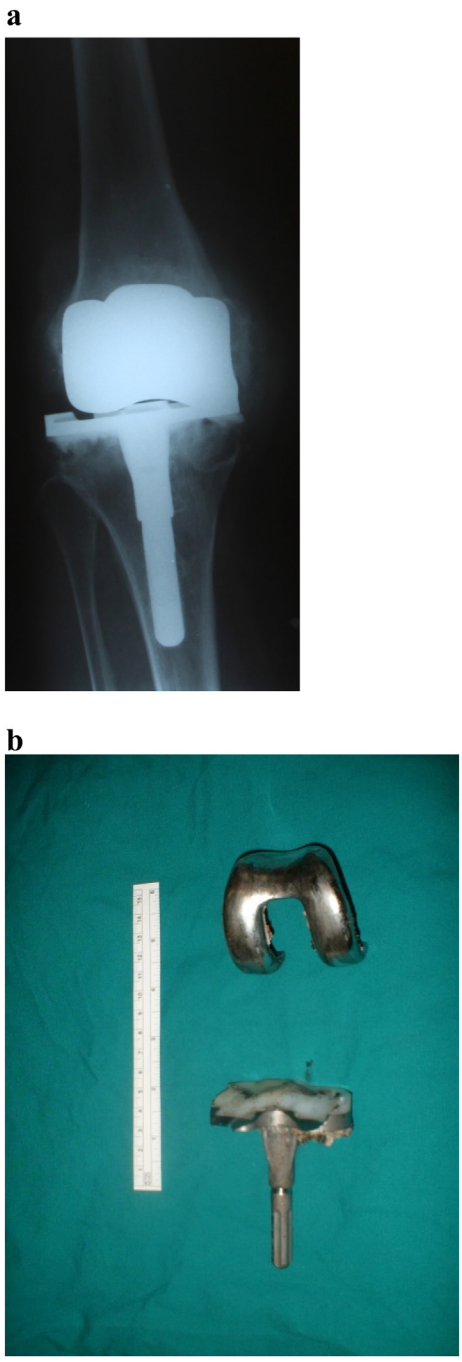

Figure 2. a. Anteroposterior radiographs of a right total knee arthroplasty showing severe polyethylene wear and structural damage of the insert at 12-year follow-up. b. Photograph showing the retrieved damaged implants during surgery.

3.1. Clinical evaluation and knee function

Pre-operative, final follow-up values, and statistically significant differences (s.s) of the KSS, Function Score, Total Score, and OKS are shown in Table 1. Statistically significant improvement in all scores was observed (*t*-test $P = 001$). Excellent results were observed in 72 (79.1%) TKAs, good results in 12 (13.2%), fair in six (6.6%), and poor in one (1.1%). Pain relief was excellent in 64% of the patients, very good in 28%, good in six percent, and fair in two percent. Surgery fulfilled patients' expectations at an excellent level in 57% of the patients, at a very good level in 31%, at a good level in nine percent, and at a fair level in three

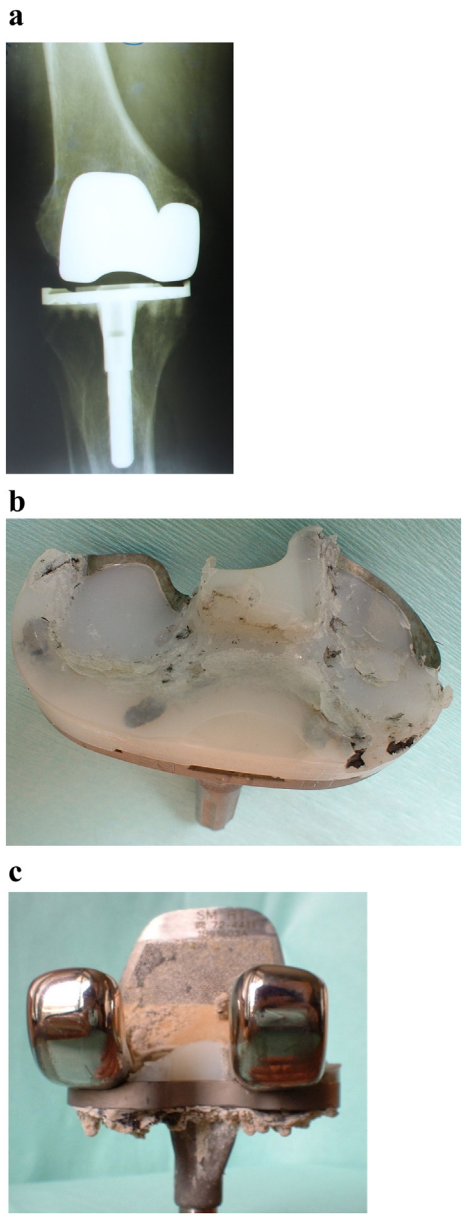

Figure 3. a. Anteroposterior radiographs of a right total knee arthroplasty showing severe polyethylene wear without tibial bone-implant interface radiolucent lines at 14-year follow-up. b. Photograph showing severe polyethylene wear of both compartments. c. Photograph showing the worn but matching femoral and tibial surfaces.

percent. Finally, when patients were asked if they would like to repeat the same surgery in another joint, 72% of them replied definitely yes, 24% possibly yes, one percent probably not, and three percent certainly not. The range of movement rose from a pre-operative mean of 98.8° (range, 75–12°) to a final mean of 105° (range, 85–135°) and postoperative fixed flexion deformity, up to 10°, was found in three (3.3%) TKAs. Seven (9.5%) patients (nine TKAs) reported mild to moderate anterior knee pain.

3.2. Radiological evaluation

Postoperative and final follow-up mean values of implant alignment parameters of α, β, γ, and σ angles, and knee alignment in both groups are shown in Table 2. No statistically significant changes developed when postoperative and final follow-up values were compared. At the first-year and third-year time intervals, on anteroposterior radiographs of the tibial component, non-progressive and <2 mm RLLs were recorded in 14 (12%) TKAs (zones 1 and 5). At the same time intervals, on lateral radiographs of the femoral component, non-progressive and <2 mm RLLs were recorded in two (1.7%) TKAs (zones 1, 2, 3). At final follow-up, there was no radiological evidence of progressive RLLs or osteolysis due to polyethylene wear debris in all available TKAs.

Figure 4. Anteroposterior radiograph of bilateral total knee arthroplasties (TKA) of an overweight patient, showing structural damage of the left TKA insert at 14-year follow-up and moderate wear of the right TKA insert.

4. Discussion

The evolution of TKA has been rapid and impressive. Better understanding of knee kinematics, advancements in surgical techniques, and improved polyethylenes have all led to extensive development of TKA designs [17–22]. Despite satisfactory long-term cemented TKA clinical outcomes, aseptic loosening remains one of the most common indications for revision [23]. The effects of various factors related to patient selection, surgical approach, abnormal artificial joint kinematics, optimum biomaterials, and ligament resection or preservation still remain controversial. The risk of TKA failure at 10 years is currently five percent. The most common indications for revision are aseptic loosening, infection, and pain [24–27]. Loading of polyethylene inserts has been extensively investigated and the distribution of peak contact stresses has been calculated in different knee designs [28–31]. Femoral component geometry, polyethylene thickness and surface geometry, as well as motion constraint kinematic principles, are crucial parameters influencing the durability of polyethylene inserts [32–34]. Polyethylene insert sterilisation has been extensively studied and is considered an important factor in determining the mechanical properties and wear characteristics of the inserts [8,9,35]. Patellofemoral joint symptoms are a common complication after a TKA. Femoral component design characteristics (trochlea groove), patella kinematics, patella instability and, most importantly, both femoral and tibial component malrotation are all related to the development of anterior knee pain [36–39]. Patient satisfaction with TKA outcome is increasingly being adopted as a measure of the patient's perception of TKA outcome. Moreover, there is a well-documented discrepancy between clinician and patient ratings of health status [40,41], and, despite recent advances, dissatisfaction rates following TKA range from 5.5–19% [42,43].

Satisfactory long-term survival of Genesis I prosthesis was recorded in this series. The seven failures that occurred are considered low for this generation of implant and length of follow-up. Five failures were related to polyethylene insert wear and structural damage. The other two were due to patellofemoral joint complications. The lack of septic complications is considered a coincidental finding. No cases of aseptic loosening, structural failure of either component, or late TKA instability were recorded. Current available data do not allow conclusions to be drawn on whether the lack of aseptic loosening failures was due to tibial tray design, stem length, and appropriate cementing technique. It cannot be certain whether the fact that there was no aseptic loosening was due to the stability afforded by the stem or the cement or both.

The Genesis I system has an anatomical bi-concave, externally rotated, femoral component, and an asymmetric anatomical tibial tray for improved coverage of the tibia and a deep and lateralized trochlear groove for improved patella tracking. This system was one

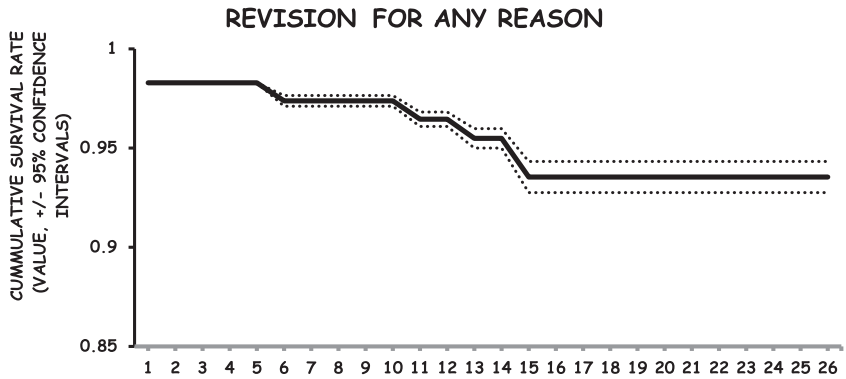

Figure 5. Kaplan–Meier survivorship, with revision for any reason as an end point (95% CIs shown).

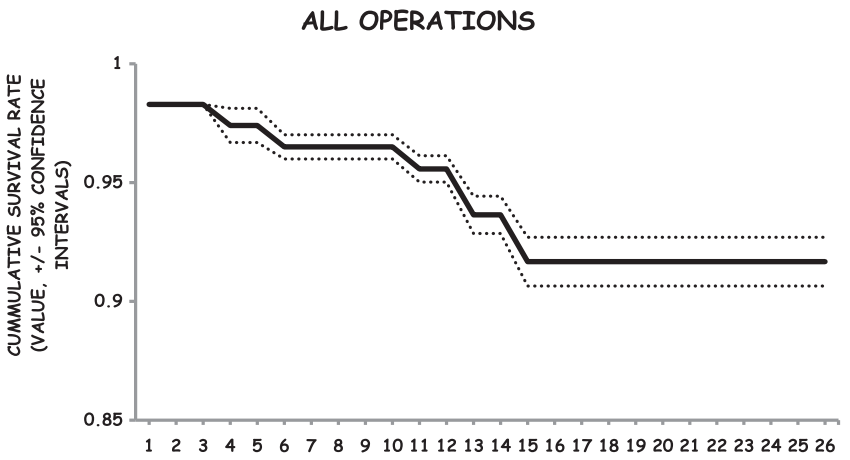

Figure 6. Kaplan–Meier survivorship, with all operations as an end point (95% CIs shown).

of the first introducing the 'patella friendly' femoral component principle. It has recently been suggested that tibial asymmetric components result in a lower incidence of tibial tray malrotation, and this may partially explain favourable patella kinematics [44]. Genesis I TKA has passed the test of time, being durable and clinically reliable with low rates of anterior knee pain and patella complications. Polyethylene insert failures have reflected the mechanical and wear characteristics of this generation of polyethylene. Of the four retrieved polyethylene inserts, three showed clear signs of rapid abrasive and linear wear of the surface and subsurface area, and were considered to be a material-related failure since there was no implant malalignment or other risk factors to justify this damage. Concerning the third insert, there was a history of repetitive falls and it was found to be fractured (structurally damaged). Functional recovery, as assessed by the Function score (objective) and the OKS (subjective) was also satisfactory, with patients being satisfied concerning pain relief, fulfilment of expectations, and possible performance of a TKA in the contralateral knee. This system also had a simple, comprehensive and easy-to-use instrumentation set, which allowed for easy and reliable performance of the surgical procedure [45–47].

Limitations of the study were the relatively small number of patients, the high rate of loss to follow-up, and the lack of a control group. During this period of time other implants with asymmetric tibial trays did not exist, and including a control group from a different period of time was not possible due to methodology problems (improved surgical technique, length of follow-up, scoring rating scales, etc.). The fact that all operations were performed in one hospital by dedicated surgeons could be considered a weakness of the study. Moreover, patients in this cohort had knee OA of moderate severity and the inclusion criteria did not represent current everyday practice. Also, the data presented in this study did not indicate if the satisfactory outcomes were implant, surgeon or OA-severity related. The results of this paper may not, given the severity of the OA treated and the surgeons' expertise, be achievable in a normal arthroplasty practice in a general setting. It could also be argued that the Genesis I TKA system is not currently in use. However, the low rate of patient loss to follow-up and the length of the observation period (>20 years) strengthen the findings of the study. There are limited data concerning TKA clinical outcomes >20-year follow-up. Lessons learned from such studies are of considerable value in the assessment of newer devices, both in terms of quality and performance [48,49].

Existing clinical outcome data related to Genesis I TKA show promising early to mid-term results [45,50]. Survival rates ranging from 92 to 97%, at the 10-year and 15-year follow-ups, have also been published [46,47,51,52]. However, analysis of failure patterns was not included in their methodology. In the above studies, excellent clinical and functional results, at high rates, were presented mainly using the objective Knee Society rating scale. It is believed that the current study is the first to present survival rates for longer than 20-year follow-up, with patient satisfaction and functional outcomes as they are depicted by the subjective Oxford Knee score. It could be argued that equivalent contemporary scales can provide more useful clinical information, but they were not available when the current study was started.

Long-term TKA outcome data, >15 and 20 years, are sparse in orthopaedic literature. The Natural Knee (introduced by Zimmer in 1985) also had an asymmetric tibial tray and showed satisfactory survival rates at the level of 95% at 14 years in a 25-year long-term follow-up series [2]. The Duracon TKA showed excellent long-term survival, 97.7% after 10 years and 94.8% after 15 years [53]. The total condylar knee, which was introduced during the mid-70s as the ideal knee system, showed a survival rate of 77% at 20-years follow-up in the available 30 (45 TKAs) patients [1]. Font-Rodriguez and Lachiewicz reported survival

Table 1
Pre-operative and postoperative mean values (range) at 18–26 years of objective clinical outcome rating scales used in the study.

Knee Score (objective)	39.7 (10–70)	92.6 (68–99)	$P = 0.001$
Function Score (objective)	42.5 (5–60)	72.9. (33–98)	$P = 0.001$
Total Score (objective)	72.2 (15–120)	157.2 (101–197)	$P = 0.001$
Oxford Knee Score (subjective)	44.4 (36–53)	25.1 (17–41)	$P = 0.001$

Table 2
Pre-operative and postoperative mean values (range) of alignment parameters for both components.

	Pre-operative	Postoperative
Mean femoral valgus angle (α)	96 (93–101)	97 (92–102)
Mean tibial angle (β)	89 (82–93)	88.5 (81–93)
Mean femoral flexion angle (γ)	1 (−3 to 4)	1 (−3 to 4)
Mean tibial slope angle (σ)	87 (82–91)	85 (83–92)
Mean knee alignment	5 valgus (8 valgus to 4 varus)	4.7 valgus (7 valgus to 4 varus)

of 98% at 14 years and 90.6% at 15 years, respectively, using a posterior-stabilised implant design [54,55]. It should also to be stressed that in two recent meta-analyses, similar long-term clinical outcomes regarding knee function and postoperative knee pain were presented when cruciate-retaining TKAs were compared with posterior-stabilised TKAs [56,57]. From a regional UK registry with 4606 primary TKAs of various designs, Roberts et al. reported that the best-case scenario survival at 15 years was 92.2%, and in the worst-case scenario was 81.1% (when all patients lost to follow-up presumed to have failed TKAs) [58]. Finally, Gothesen et al. evaluated three cruciate-retaining fixed modular bearing, two cruciate-retaining fixed non-modular bearing, and two PS mobile-bearing TKA designs from a total of 17.782 primary TKAs recorded in the Norwegian Arthoplasty Register [59]. Ten-year survival rates ranged from 89.5–95.3%, with the Profix cruciate-retaining implant showing superior outcomes [59].

5. Conclusions

Genesis I TKA showed favourable long-term survival rates, satisfactory functional recovery, and low rates of patella complications when implanted in a highly selective patient cohort with mild deformities. No failures due to aseptic loosening of either the femoral or tibial component were recorded. The main recognised failure pattern of this TKA was polyethylene wear and structural damage reflecting the structural properties and wear characteristics of this polyethylene generation. It is also unclear if the achieved results were the result of either patient selection, surgical technique or implant selection, and cannot be considered to be widely applicable in relation to both the cruciate-retaining technique and the use of this particular TKA system.

Conflict of interest statement

All authors state that they have not taken any financial support in order to perform this study, and they have no relationship with the company producing the prosthesis.

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