Scientific Research Publishing

Open Journal of Orthopedics, 2026, 16(2), 71-81
https://www.scirp.org/journal/ojo
ISSN Online: 2164-3016
ISSN Print: 2164-3008

Effect of Total Knee Arthroplasty Design Evolution on Short-Term Patient Outcomes: A 3-Year Follow-Up Study

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How to cite this paper: Meding, L. and Meding, J. (2026) Effect of Total Knee Arthroplasty Design Evolution on Short-Term Patient Outcomes: A 3-Year Follow-Up Study. *Open Journal of Orthopedics*, **16**, 71-81.
https://doi.org/10.4236/ojo.2026.162008

Received: January 20, 2026
Accepted: February 11, 2026
Published: February 14, 2026

Abstract

Background: Total knee arthroplasty (TKA) is an effective intervention for advanced osteoarthritis, although up to 20% of patients remain dissatisfied postoperatively. Newer implant designs aim to enhance outcomes by mimicking native knee kinematics and improving patellofemoral tracking. This study compares the clinical outcomes of two sequential TKA systems—first-generation (1G) and second-generation (2G)—over a 3-year period. **Methods:** A retrospective review of prospectively collected data was conducted on patients who underwent primary TKA using either 1G (n=121) or 2G (n=123) implants between June 2018 and March 2021. All procedures were performed by a single surgeon using a consistent technique and postoperative protocols. KOOS-JR and Knee Society Scores (KSS) were collected preoperatively and at 6, 12, 24, and 36 months. Complications were documented. Implant survival was determined at 3 years. **Results:** Both groups showed substantial functional improvement from baseline. In the 1G group, KOOS-JR scores rose from 30 ± 15.6 preoperatively to 80.9 ± 15.3 at 6 months, 84.0 ± 13.8 at 1 year, 85.0 ± 14.1 at 2 years, and 92.0 ± 15.2 at 3 years. In the 2G group, scores improved from 33.0 ± 11.9 to 88.0 ± 12.1 at 6 months, 88.0 ± 13.6 at 1 year, 91.0 ± 13.2 at 2 years, and 96.0 ± 9.6 at 3 years. The 2G group had significantly better KOOS-JR at 6 months ($p < 0.05$) as compared to the 1G group, but no significant differences were observed at 1, 2, or 3 years. The implant survival rate was 95% in both the 1G and 2G groups. **Conclusion:** Both TKA systems showed an acceptable safety profile and robust implant survival rate in the short term. The 2G implant showed an early advantage in patient-reported outcomes at 6 months relative to the 1G implants and greater convergence thereafter, suggesting that the new design may promote faster initial clinical recovery and improvement in clinical outcomes.

Keywords

Total Knee Arthroplasty, KOOS-JR, Implant Design, Patient-Reported Outcomes, Knee Society Score

1. Introduction

Total knee arthroplasty (TKA) is a widely performed and highly effective surgical intervention for relieving pain and restoring function in patients with advanced degenerative joint disease [1] [2]. However, up to 20% of patients report persistent dissatisfaction postoperatively, prompting continued efforts to refine implant design and surgical technique [3]-[5]. Prosthetic advancements aim to better replicate native knee kinematics, minimize complications, and improve long-term outcomes [6]-[8].

Historically, the Insall-Burstein (IB) knee system laid the foundation for many modern posterior-stabilized and cruciate-retaining implants [9]. Derivatives, such as the first-generation (1G) system evaluated in this study, incorporated design modifications to reduce patellofemoral complications. More recently, a second-generation (2G) system was introduced with additional enhancements, including improved trochlear groove geometry, asymmetric patellar flanges, and increased tibiofemoral conformity in ultra-congruent inserts [10].

Previous 1-year follow-up data indicated that the 2G system produced superior early functional outcomes compared to its predecessor [10]. This study extends the analysis through 36 months, assessing whether early benefits were maintained or widened over time. Validated patient-reported outcome measures (PROMs), including KOOS-JR and the Knee Society Score (KSS), were used to track clinical progress. Additionally, a detailed analysis of all the complications recorded between the two groups was conducted to determine the implant survival rate.

2. Materials and Methods

This study was a retrospective review of prospectively collected consecutive samples by a high-volume, fellowship-trained joint arthroplasty surgeon. Patients were included if they were undergoing a primary TKA for one or both knees using the StelKast Proven GenFlex or GenFlex2 knee system as part of their standard of care (*i.e.*, the surgeon had already selected the StelKast Proven GenFlex knee system for patients without considering his/her participation in this study). All patients included in the study were treated for end-stage osteoarthritis that was refractory to conservative management between June 2018 and March 2021. During the study period, the surgeon transitioned from using the 1G implant to the 2G implant upon its availability, with no changes in surgical technique, patient selection criteria, or postoperative rehabilitation protocols during this transition.

Patients with a history of metabolic bone disorders, inflammatory arthritis,

prior knee infection, or significant contralateral limb dysfunction were excluded. All procedures were performed using a medial parapatellar approach with cemented fixation of both tibial and femoral components. Tibial alignment was achieved with an extramedullary guide, while femoral alignment was performed with an intramedullary guide. All patients received similar perioperative care, including prophylactic antibiotics, deep vein thrombosis (DVT) prophylaxis, and standardized physical therapy starting on the day of surgery.

The primary outcomes were KOOS-JR and KSS, collected preoperatively and postoperatively at 6, 12, 24, and 36 months during scheduled clinic visits with the attending surgeon. Intraoperative events and postoperative adverse outcomes, including revision procedures, secondary operations, and unplanned returns to the operating room, were systematically recorded throughout the study period. The implant survival rate was defined as the total number of patients who did not require implant revision surgery for any cause divided by the total number of patients who completed 3-year follow-up.

Implant Design

The PROVEN TKA implant is the 1G system developed and launched by Stelkast in 2013. The system came in cruciate retaining (CR) and posterior stabilized (PS) options. Based on feedback from 1G users and deep analysis of the components from revision retrieval through years of clinical use, a 2G system called GenFlex2 was launched in 2016. It also came in CR and PS options. The 2G system design improved tibio- and patellofemoral contact consistency between CR and PS implants, resulting in more similar wear patterns. Key femoral changes include debulking, asymmetric patellar flange and trochlear groove, reduced anterior flange width, shorter posterior condyles, and a trapezoidal profile. Tibial insert updates include patellar tendon relief, a rounded PS post, reduced posterior lip, and increased CR slope (6˚). This updated insert was called ultra-congruent (UC), providing greater femoral conformity, a higher posterior lip, better subluxation resistance, and an elevated anterior wall (Refer Figures 1-3 in Toossi *et al.* 2023).

Statistical Analysis

Statistical analysis was performed using JMP software (version 18.1.0, JMP Statistical Discovery LLC). Group comparisons for continuous variables were performed using unpaired two-sample t-tests, preoperative to postoperative differences were evaluated using paired t-tests, and categorical variables were analyzed using chi-square tests. Attrition analysis was done by comparing the baseline demographics of 1G+2G patients with and without 3-year follow-up data to evaluate potential selection bias given the high drop-out rate; the results of these are reported as loss-to-follow-up p-values in Table 1. To account for differences in gender and Body Mass Index (BMI) between the two groups, multivariate linear regression analysis was utilized to assess the independent effect of the 1G and 2G groups on clinical outcomes. For each post-operative time point, the KOOS-JR score and KSS sub-scores served as the dependent variables. A p-value of <0.05 was considered statistically significant.

3. Results

A total of 244 patients were included in this retrospective review (121 in the 1G group; 123 in the 2G group). There were no significant differences between the groups in terms of age, racial distribution, or treated side (Table 1). There were statistically significant differences in gender distribution (male: 1G = 32; 2G = 49; p = 0.016) and BMI (1G: 35.5 ± 9.23 kg/m^2; 2G: 38.0 ± 9.17 kg/m^2; p = 0.032). In both groups, there was similar loss of follow-up as the postoperative timepoint increased, changing from 121 at preoperative to 104 at 6 months postoperative, 90 at 1 year postoperative, 62 at 2 years postoperative, and 42 at 3 years postoperative in 1G, and from 123 at preoperative to 99 at 6 months postoperative, 87 at 1 year postoperative, 27 at 2 years postoperative, and 41 at 3 years postoperative in 2G.

Table 1. Patients' demographics.

	1G	2G	p-value	Loss to Follow-up p-values*
N	121	123		
		Age (Years)		
Mean ± SD	68.5 ± 10.00	68.0 ± 9.39	0.695	0.533
Min - Max	41.0 - 91.0	44.0 - 90.0		
		Gender - n (%)		
Female	72 (29.51)	91 (37.30)	0.016	0.512
Male	49 (20.08)	32 (13.11)		
		BMI (kg/m^2)		
Mean ± SD	35.5 ± 9.23	38.0 ± 9.17	0.032	0.416
Min -Max	21.3 - 71.6	19.7 - 67.6		
		Race - n (%)		
Asian	1 (0.41)	1 (0.41)		
Hispanic	0 (0.00)	2 (0.82)	0.252	1.000
White	120 (49.18)	120 (49.18)		
		Side - n (%)		
Right	65 (53.72)	65 (52.85)	0.891	0.324
Left	56 (46.28)	58 (47.15)		

*Comparing 1G+2G patients with 3-year follow-up and 1G + 2G patients without 3-year follow-up.

Both KOOS-JR and KSS demonstrated significant improvements from preoperative baselines at 6-month, 1-year, 2-year, and 3-year follow-ups in patients who underwent either 1G or 2G TKA (Table 2). KOOS-JR outcomes were compared between patients treated with the 1G and 2G implants by quantifying both absolute improvements in mean scores and the proportion of patients in each group achieving the minimum clinically important difference (MCID; >14-point improvement) [11] from preoperative to postoperative timepoints. For the 1G group, mean

KOOS-JR scores increased from 30.0 ± 15.5 preoperatively to 80.9 ± 15.3 at 6 months, 84.3 ± 13.8 at 1 year, 85.3 ± 14.1 at 2 years, and 91.6 ± 15.2 at 3 years, with 95.2%, 98.9%, 100.0%, and 97.4% of patients meeting the MCID threshold across the respective intervals. For the 2G group, KOOS-JR scores improved from 33.3 ± 11.9 preoperatively to 88.0 ± 12.1 at 6 months, 88.2 ± 13.6 at 1 year, 90.9 ± 13.2 at 2 years, and 95.8 ± 9.6 at 3 years, with 99.0% of patients achieving the MCID at 6 months and 100.0% at all subsequent timepoints.

Table 2. KOOS-JR score over time.

	1G	2G	p-value 1G vs 2G*	p-value Preop vs Postop 1G	p-value Preop vs Postop 2G
Preoperative					
N	121	123			
Mean ± SD	30.0 ± 15.57	33.3 ± 11.87	0.1		
6 months post-op					
N	104	99			
Mean ± SD	80.9 ± 15.27	88.0 ± 12.11	<0.001	<0.0001	<0.0001
1-year post-op					
N	90	87			
Mean ± SD	84.3 ± 13.78	88.2 ± 13.60	0.1	<0.0001	<0.0001
2-year post-op					
N	62	27			
Mean ± SD	85.3 ± 14.07	90.9 ± 13.15	0.15	<0.0001	<0.0001
3-year post-op					
N	40	39			
Mean ± SD	91.6 ± 15.18	95.8 ± 9.57	0.2	<0.0001	<0.0001

*Adjusted for baseline differences in gender and BMI using linear regression analysis.

In both 1G and 2G groups, all components of the KSS—such as functional activity, objective knee, patient satisfaction, and patient expectations—also showed substantial gains from preoperative assessments to the 6-month, 1-year, 2-year, and 3-year postoperative intervals (Table 3).

Table 3. KSS score over time.

	Timepoint		1G (N = 121)	2G (N = 123)	p-value* 1G vs 2G	p-value Preop vs Postop 1G	p-value Preop vs Postop 2G
Objective Knee Score	Preoperative	n	121	123			
		Mean ± SD	40.1 ± 16.44	42.1 ± 17.56	0.341		

Continued

	6 months	**n**	**104**	**99**			
		Mean ± SD	92.9 ± 6.65	92.7 ± 5.69	0.753	<0.0001	<0.0001
	1 year	n	88	87			
		Mean ± SD	95.0 ± 4.89	95.4 ± 3.95	0.416	<0.0001	<0.0001
	2 years	n	62	27			
		Mean ± SD	96.1 ± 3.57	95.6 ± 3.88	0.207	0.0002	<0.0001
	3 years	n	42	41			
		Mean ± SD	95.7 ± 7.72	96.5 ± 3.30	0.273	0.001	<0.0001
Functional Activity Score	Preoperative	n	121	123			
		Mean ± SD	21.6 ± 12.87	21.0 ± 11.21	0.732		
	6 months	n	104	99			
		Mean ± SD	69.3 ± 18.15	73.4 ± 15.36	0.081	<0.0001	<0.0001
	1 year	n	90	87			
		Mean ± SD	73.1 ± 15.83	75.5 ± 15.65	0.824	<0.0001	<0.0001
	2 years	n	62	27			
		Mean ± SD	80.6 ± 13.46	77.4 ± 14.72	0.162	<0.0001	<0.0001
	3 years	n	42	41			
		Mean ± SD	81.4 ± 14.80	82.8 ± 17.86	0.993	<0.0001	<0.0001
Patient Satisfaction Score	Preoperative	n	121	123			
		Mean ± SD	4.7 ± 5.25	4.7 ± 4.31	0.912		
	6 months	n	104	99			
		Mean ± SD	33.4 ± 6.40	34.1 ± 7.01	0.556	<0.0001	<0.0001
	1 year	n	90	87			
		Mean ± SD	34.4 ± 6.34	34.6 ± 6.34	0.766	<0.0001	<0.0001
	2 years	n	62	27			
		Mean ± SD	34.7 ± 6.64	34.1 ± 5.84	0.240	<0.0001	<0.0001
	3 years	n	42	41			
		Mean ± SD	36.3 ± 7.01	36.5 ± 4.85	0.795	<0.0001	<0.0001
Patient Expectations Score	Preoperative	n	121	123			
		Mean ± SD	13.6 ± 2.19	13.8 ± 1.97	0.899		
	6 months	n	104	99			
		Mean ± SD	10.9 ± 2.99	11.1 ± 2.77	0.892	<0.0001	<0.0001
	1 year	n	90	87			
		Mean ± SD	11.9 ± 2.74	12.1 ± 2.85	0.929	<0.0001	0.0003
	2 years	n	62	27			
		Mean ± SD	12.3 ± 3.01	10.7 ± 3.31	0.010	0.0002	0.0005
	3 years	n	42	41			
		Mean ± SD	11.9 ± 3.45	11.9 ± 2.72	0.688	0.001	0.0006

*Adjusted for baseline differences in gender and BMI using linear regression analysis.

The differences in clinical outcome measures between the 1G and 2G groups were evaluated at each postoperative time point (Table 2 and Table 3). At baseline, no differences were detected between the two groups across KOOS-JR and all the KSS sub scores. At the 6-month follow-up, the 2G group demonstrated significantly better KOOS-JR as compared to the 1G group (2G = 88.0 ± 12.11; 1G = 80.9 ± 15.27, p = 0.0003), and no meaningful difference in all the KSS sub scores. At 1-, 2-, and 3-year follow-ups, there was no meaningful difference seen in mean KOOS-JR and all the KSS sub scores, except for the mean patient expectation score at the 2-year follow-up, which showed 1G to have a statistically significant difference of 1.6 points more than the 2G group.

The overall complications profile between the 1G and 2G groups showed a total of 8 and 7 patients experienced a complication, respectively. This was broken down into two categories: not requiring any implant revision surgery and requiring partial or total implant revision surgery. Six patients in 1G and 5 patients in 2G experienced complications resulting in not requiring any kind of revision of the knee implant. For more details on its breakdown, please refer to Table 4.

Table 4. Complication Profile between the 1G and 2G groups.

Complications Breakdown		
1. Not Requiring Any Implant Revision Surgery	**1G**	**2G**
Reflex Sympathetic Dystrophy	2	0
Patella Fracture	1	0
Post-op Sciatica	1	0
I&D (due to post-fall wound)	2	2
Manipulation Under Anesthesia	0	2
Draining subcutaneous hematoma at 2 months.	0	1
Sub Total	**6**	**5**
2. Required Partial or Total Implant Revision		
I&D (due to *S. viridans* bacteria) with poly exchange	1	0
I&D (due to MRSA bacteria) leading to TKA explant	1	0
Quad tendon tear repair with poly exchange	0	1
Revision TKA - femoral fracture	0	1
Sub Total	**2**	**2**
Implant Survival Rate (%)	**95.2% (40/42)**	**95.1% (39/41)**
Total Patients with a Complication (1+2)	**8**	**7**

Two patients in 1G and 2G required either partial or total implant revision. Drilling further into this, in 1G, 1 patient experienced *S. viridans* bacterial infection 3 months postoperatively and required irrigation and debridement (I&D)

surgery with polyethylene exchange, and 1 patient experienced late MRSA bacterial infection a little over 2 years postoperatively, requiring staged I&D with explant and revision TKA. In 2G, 1 patient experienced a fall resulting in distal femur fracture requiring revision TKA surgery, while another patient experienced quadriceps tendon rupture after a fall 5 months postoperatively, requiring tendon repair surgery with polyethylene insert replacement. Overall, the implant survival rate from this study was 95.2% (40/42 patients) in 1G and 95.1% (39/41 patients) in 2G at 3 years postoperative.

4. Discussion

This study provides a 3-year comparative analysis of clinical and functional outcomes following primary total knee arthroplasty (TKA) using two generations of posterior-stabilized implants from the same design lineage. Both implant groups demonstrated substantial improvement in patient-reported outcomes and functional scores up to 3 years after surgery as compared to the preoperative baseline. A closer comparison between groups revealed that the 2G group achieved significantly higher KOOS-JR improvement at 6 months postoperatively. While the 6-month scores differed significantly between groups (Δ = 7.1 points; p-value = 0.0003), this margin fell short of the established 14-point Minimal Clinically Important Difference (MCID), suggesting limited clinical relevance for the average patient. However, the 2G group had a marginally higher proportion of individuals meeting the MCID, indicating that the 2G implant may have provided more meaningful benefits than the 1G implant.

The initial superiority of the 2G system at 6 months likely reflects the implant's refined trochlear groove design, asymmetric patellar flange, and enhanced femorotibial conformity [10]. These modifications are intended to optimize patellofemoral mechanics and joint stability and better mimic native knee kinematics, potentially facilitating earlier recovery. By 12, 24, and 36 months postoperatively, improvements in patient outcomes continued to be sustained and were largely equal between the two groups, suggesting that the new implant design provides comparable clinical outcomes to the legacy design over the short-term period.

Interestingly, the only significant late difference between groups was observed in the patient expectation sub-score of the Knee Society Score at the 2-year mark, with 1G patients reporting slightly higher scores. While the clinical significance of this isolated finding is unclear, it may reflect subtle differences in preoperative counseling, patient characteristics, or subjective satisfaction that warrant further exploration.

Complication profiles were similar between groups, and most did not require implant revision. Importantly, the introduction of the 2G system was not associated with an increased rate of adverse events, supporting its safety in real-world clinical practice. Moreover, both groups showed an excellent implant survival rate (95%) at 3-year follow-up postoperatively. These results are within the range of 93% - 97.3% published in literature looking at 3-year postoperative revision rates

of total knee arthroplasty from large sample size studies conducted in Iran and Australia [12] [13]. Additionally, when looking at those requiring some type of implant revision, all patients (2/2 patients) in the 1G group had infections caused by *S. viridans* and MRSA bacteria, whereas in the 2G group, all cases (2/2 patients) were related to trauma events such as femur fracture and quadriceps tendon tear.

This study has several strengths, including its use of validated PROMs, a consistent surgical technique by a high-volume arthroplasty specialist, and longitudinal follow-up extending to 36 months [14] [15]. However, limitations include its retrospective nature, single-center design, and baseline differences in gender and BMI between groups, which could introduce confounding variables affecting the comparability of the results. Both groups have high loss to follow-up, with roughly two-thirds of the patients included in both groups not present at the latest follow-up period (3 years postoperative). The substantial loss to follow-up may weaken the robustness of the analyses and introduce uncertainty into the findings, warranting cautious interpretation. Additionally, while all surgeries were performed by the same surgeon, external generalizability may be limited, and the sequential use of the 1G followed by the 2G implant may introduce temporal bias related to increased surgeon experience over time. Moreover, the current study represents a short-term (3-year) follow-up, whereas many landmark TKA studies report outcomes at 15 - 20 years postoperatively [16]-[18]. Long-term data will be essential to determine whether the early comparable implant survival rate between the 1G and 2G implant designs translates into sustained functional benefits and durability over time.

5. Conclusion

The data in this study show that both 1G and 2G posterior-stabilized knee systems yielded substantial and sustained improvements in pain, function, and patient satisfaction over three years as compared to before surgery. The 2G implant demonstrated a modest but statistically meaningful advantage in KOOS-JR scores at six months, suggesting the benefit of design refinements in early recovery. Furthermore, outcomes between the two groups converged by one year and remained comparable thereafter until three years postoperatively. Complication rates were similar, and implant survival rates were excellent between the two groups. Larger, multicenter studies are needed to further verify the sustainability and durability of the favorable short-term clinical results seen from these newer TKA implants.

Acknowledgements

The authors would like to acknowledge the Globus Medical Scientific Affairs team, particularly Dakshith Ragupathi, Fatemeh Nooshabadi and Greg Williams for their support with this study.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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