



A comparison of SanatMetal Sanat Swing and Zimmer NexGen® total knee implants: 10-year postoperative follow-up results

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One of the most significant achievements in orthopedic surgery in the 20th century was the introduction and further development of total knee arthroplasty (TKA). The continuously increasing arthroplasty rates have led to increasing expectations for the long-term performance of implants.^[1-4] Different manufacturers have developed systems of different shapes, surfaces, stabilizations, and fixation methods to increase the long-term survival of the prostheses.^[5] Several articles have been published in the literature demonstrating excellent mid- to long-term results of the NexGen® (Zimmer Biomet Inc., Warsaw, IN, USA) knee replacement system.^[6-10] There are no significant differences in the design between the two products (Sanat Swing® [SanatMetal Ltd., Eger, Hungary] vs. NexGen®); both have a high flex design, but one of the goals in the development

ABSTRACT

Objectives: In this study, we present our 10-year postoperative follow-up results of Sanat Swing® and NexGen® total knee implants.

Patients and methods: A total of 189 patients (93 males, 96 females; mean age: 68 years; range, 48 to 86 years) who underwent total knee replacement between January 2008 and September 2010 were retrospectively analyzed. A total of 105 patients (Group A) were implanted a cemented Sanat Swing knee prosthesis and 84 patients (Group B) were implanted a cemented NexGen knee prosthesis. Operation time, range of motion (ROM), pain level, Knee Society Score (KSS), distance of painless walking, and the ability to climb stairs were evaluated between the groups.

Results: The mean follow-up was 10.8 (range, 9.8 to 12.3) years. No significant difference was observed in the survival of the prostheses, ROM, pain level, KSS, walking distance, and in the ability to climb stairs between the two groups at 10 years. With an experienced team, the operation time was about 4 to 5 min shorter in the Sanat Swing implantation group. In selected cases, Sanat Swing was superior to the NexGen system; however, there was no statistically significant difference. Complication rates were also low and comparable between both groups.

Conclusion: Based on the 10 years of follow-up evaluation, Sanat Swing total knee replacement system seems to yield comparable clinical results with the NexGen. Experiences with the operative technique and comparative evaluation, the Sanat Swing system is a safe and reliable alternative for total knee replacement, providing a user-friendly operative technique and shorter operation time.

Keywords: Cemented, functional outcome, knee prosthesis, NexGen, Sanat Swing total knee replacement.

Received: June 08, 2020

Accepted: October 01, 2020

Published online: January 06, 2021

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Doi: 10.5606/ehc.2021.76756

Citation: Abonyi B, Pap K, Gal T, Vasarhelyi G, Udvarhelyi I, Hangody L. A comparison of SanatMetal Sanat Swing and Zimmer NexGen® total knee implants: 10-year postoperative follow-up results. Jt Dis Relat Surg 2021;32(1):10-16.

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of the Sanat Swing knee prosthesis was to make a more user-friendly instrumentation kit, presumably allowing for a shorter operation time.

In the present study, we aimed to compare the results of the two products in a 10-year follow-up and to analyze the differences between the long-standing

and well-established NexGen knee prosthesis and the recently introduced Sanat Swing knee prostheses.

PATIENTS AND METHODS

This single-center, retrospective study was conducted at Uzsoki Hospital Department of Orthopedics and Traumatology, Semmelweis University Department of Traumatology between January 2008 and September 2010. A total of 189 patients (93 males, 96 females; mean age: 68 years; range, 48 to 86 years) who underwent TKA were included (Table I). Of these, 105 received a Sanat Swing (Figure 1a) cemented knee prosthesis (Group A), and 84 patients received a NexGen (Figure 1b) cemented knee prosthesis (Group B). In this study, we followed the 10-year survivorship of the implants based on radiographic imaging. A total of 105 patients of the Sanat Swing group were included in the analysis, as they all had their TKA implantations for ≥ 10 years. The inclusion of NexGen patients was adapted to the inclusion time period of the Sanat Swing patients to have cases from the same time period. Exclusion criteria were as follows: missing follow-up data, death or implant removal for any reason. A written informed consent was obtained from each patient. The study protocol was approved by the Uzsoki Hospital Ethics Committee. The study was conducted in accordance with the principles of the Helsinki Declaration.

All operations were performed in the same manner by five consultant orthopedic surgeons experienced

with a high number of surgeries performed per year. They were allowed to choose which product to implant in each patient individually, and the surgical indication did not affect their decision.

The mean age at the time of surgery was 69 ± 18 years (Group A), and 67 ± 19 years (Group B). A total of 50/49 left and 55/35 right knees were included. The mean body mass index (BMI) was 28.5 (range, 20.1 to 40.3) kg/m^2 in Group A and 28.8 (range, 19.8 to 41.7) kg/m^2 in Group B. Tourniquet was used in all cases and the patients were given cefuroxime axetil 1,500 mg intravenously 1 h before inflation. An anterior midline skin incision was followed by a modified mini-midvastus capsular approach. Cemented fixation was used for all three components (normal bone cement in 83/67 cases, gentamicin-loaded bone cement in 21/18 cases). Decision for the use of gentamicin-loaded bone cement was based on comorbidities of the patients (e.g., diabetes mellitus or prior infection). All patients received a cruciate-retaining (CR) insert and, in all cases, patella components were used, as well. The operation time was calculated. Postoperative anteroposterior (AP) and lateral X-rays were done to check the implant positioning. On the first postoperative day, the suction drain was removed in all cases, the patients stood up and began several steps full weight-bearing with the use of walking frame or crutches, and continuous passive motion exercises were initiated. On the second or third

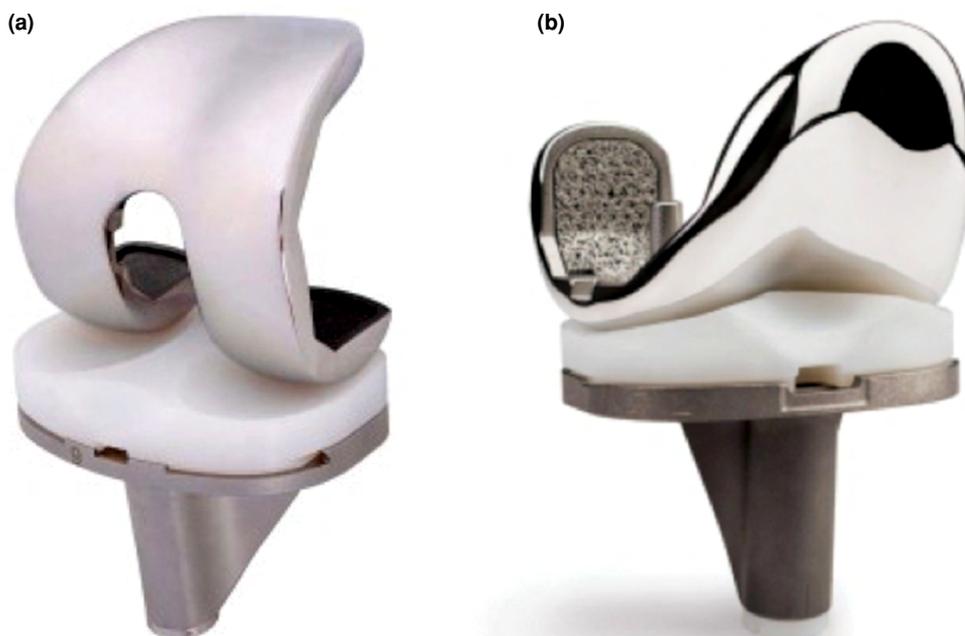


FIGURE 1. (a) SanatMetal Sanat Swing, (b) Zimmer NexGen

Group	Sanat Swing (Group A)		NexGen (Group B)	
	Left	Right	Left	Right
Male	23	16	18	12
Female	27	39	31	23
Total	50	55	49	35
Mean age (year)	69.5		67.8	

postoperative day, the patients began walking up and down stairs under the supervision of a physiotherapist. The patients were discharged home or to a rehabilitation facility on the fourth or fifth postoperative day. At each follow-up visit, radiographic examinations were performed at six weeks, six months, 12 months, and biennially thereafter. All radiographs were evaluated by an independent examiner. Bilateral views - AP and lateral X-rays were taken, the independent examiner examined alignment and possible signs of loosening. During the follow-up examinations, range of motion (ROM), intraarticular effusion, level of pain, and the ability to walk and climb stairs were recorded. Additionally, the Knee Society Score (KSS)-function was used for the follow-up at 10 years.

Statistical analysis

Statistical analysis was performed using the SAS version 9.4 software (SAS Institute Inc., NC, USA). Descriptive data were expressed in mean \pm standard deviation (SD), median (min-max) or number and frequency, where applicable. The normality test of the variables was performed. A paired t-test was used to compare the groups. A *p* value of <0.05 was considered statistically significant.

RESULTS

Baseline demographic data of the patients are shown in Table I. In Group B, the mean operation time was 53.25 ± 15.5 min from the incision until the skin closure. The surgical team was well-familiarized with the instrumentation. At first, in Group A, the mean operation time was 10 to 12-min longer; however, after the learning curve was surpassed, as the scrub nurses became more familiar with instrumentation, the operation time gradually decreased. The difference in the mean operation time was -4.25 (57.50 ± 12.25 min), which may have been even less, if the learning curve was excluded (Figure 2), indicating no significant difference between the groups ($p=0.92$).

The independent radiologist involved in examining the radiographs observed signs of loosening in both groups. Revision surgery was performed in these cases where signs of radiological loosening (i.e., lysis or radiolucent zones) was accompanied with clinical symptoms. These cases were further examined based on the Philadelphia consensus and were presumed as low-grade infections, which were treated with two-stage revision surgery (Table IIb). Radiological signs of loosening not accompanied by any complaints were followed more frequently.

In the Sanat Swing group (Group A), four patients did not attend to follow-up examination after the removal of sutures. Two patients died (nine months and five years after surgery, respectively); at the final examination before death, no complaints were reported related to TKA. In three patients, early loosening was observed. Low-grade septic complication was suspected; therefore, these cases were treated with two-stage revision surgeries (1.0, 1.2, and 2.2 years after primary arthroplasty). However, none of these cases had positive microbiological test results. In one case in the Sanat Swing group, mechanical loosening was observed. Revision was performed seven years after the primary implantation (Table IIa, b). In five patients, contralateral TKAs were done at a later

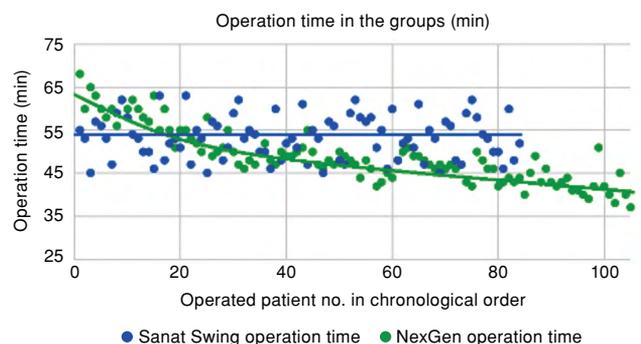


FIGURE 2. Operation time.

TABLE II (a) Total knee arthroplasty survivorship					
Group	Sanat Swing (Group A)		NexGen (Group B)		p
	n	%	n	%	
No loosening	95		72		0.91
Septic loosening	3		2		0.89
Aseptic loosening	1		0		0.93
Could not be followed up					0.32
Died	4		4		
Lost for follow up	2		6		
Survivorship		95.96		97.30	0.92

TABLE II (b) Summary table of revised total knee arthroplasty					
Revised TKA	Time of revision after the primer TKA (year)	Revision method	Intraoperative microbiologically test result	Inflammatory lab tests	Patient status now
Sanat Swing 1	1	Two step revision	Negative	CRP >15; <25	No complaint related to TKA
Sanat Swing 2	1.1	Two step revision	Negative	Negative	No complaint related to TKA
Sanat Swing 3	1.2	Two step revision	Negative	CRP >5; <15	No complaint related to TKA
Sanat Swing 4	7	Two step revision	Negative	CRP >5; <15	No complaint related to TKA
NexGen 1	1	Two step revision	Negative	CRP >15; <25	No complaint related to TKA
NexGen 2	3.6	Two step revision	Negative	Negative	No complaint related to TKA

TKA: Total knee arthroplasty; CRP: C-reactive protein; Sanat Swing 1-4 are the revision cases; NexGen 1-2 are the revision cases.

date. The follow-up of the contralateral prosthesis was excluded, due to the shorter follow-up period. One patient suffered from a perthrochanteric femoral fracture on the ipsilateral side of the total knee replacement; this patient was treated with a Synthes proximal femoral nail antirotation nail. In one patient, fever and joint effusion were observed following a dental procedure at one year. Due to

the signs of inflammation of the prosthetic knee, arthroscopic lavage was performed and the patient became free from knee complaints. In two patients, open arthrolysis was done at nine and 12 weeks postoperatively and the microbiological cultures obtained were negative.

TABLE III Complications			
Complications	Sanat Swing (Group A)	NexGen (Group B)	p
	n	n	
No complication	82	67	0.82
Deep vein thrombosis	6	4	0.76
Blood transfusion	12	10	0.83
Aspiration of the joint	5	3	0.68

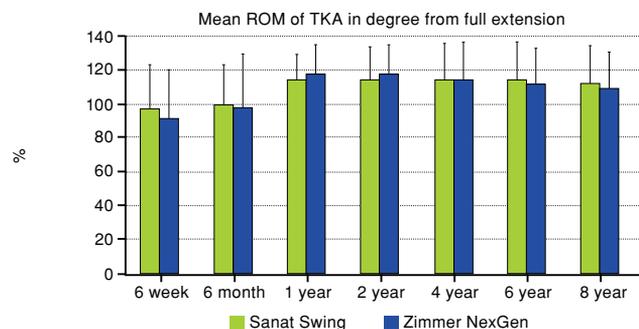


FIGURE 3. Mean ROM of the TKA in degrees. ROM: Range of motion; TKA: Total knee arthroplasty.

Knee Society Score	SanatMetal Sanat Swing		Zimmer NexGen		p
	n	%	n	%	
Excellent	79	83.16	49	68.06	0.45
Good	12	12.63	17	23.61	0.52
Fair	4	4.21	5	6.94	0.80
Poor	0	0.00	1	1.39	0.55

In the NexGen group (Group B), six patients did not attend to follow-up examination after removal of sutures. Four patients died (2 to 3.6 and 8.1 to 9.2 years after surgery); at the final examination before death, no complaints were reported related to TKA. In two patients, early loosening was observed, and low-grade septic complication was suspected. These patients were also treated with two-stage revision surgeries (1.0 to 3.6 years after primary arthroplasty) (Table IIa, b). In one patient, two years after TKA, the patient suffered from a periprosthetic supracondylar femoral fracture, which was treated with an angular stable plate osteosynthesis. When the patient who did not attend to follow-up or died was excluded, the survivorship rate was 95.9% in Group A and 97.2% in Group B.

There were no intraoperative complications in 189 TKA cases. Deep venous thrombosis was detected in 10 patients (Group A: n=6, Group B: n=4). In 22 patients, blood transfusion was required in the postoperative period (Group A: n=12, Group B: n=10). Aspiration of joint effusion was necessary in five patients in Group A and in three patients in Group B (Table III).

After 10 years, the remaining 95 prostheses in Group A had a mean ROM of $114.4 \pm 21.3^\circ$ flexion from full extension, while 72 prostheses in Group B had a mean ROM of $110.7 \pm 17.8^\circ$ flexion from full extension (Figure 3). Both groups reached their maximum flexion at a mean of one year following the operation. The ROM, then, gradually and minimally decreased. No significant difference was observed between the two groups ($p=0.95$).

Excellent results in the KSS-function were achieved in 83.16% of the patients in Group A and in 68.06% of the patients in Group B. Results of 12.63% (Group A) vs. 23.61% (Group B) were good, 4.21% vs. 6.94% were fair, while 0.00% vs. 1.39% were poor (Table IV). Based on the statistical evaluation, no significant difference was observed in long-term results between the two implants ($p=0.07$).

In both groups, two-thirds of the patients had unlimited walking distances, while 25% vs. 20% in Group A and Group B, respectively had a 500-m restriction where they needed to stop, and 11% in both groups needed a walking aid (Figure 4). No significant difference was observed between the two groups ($p=0.71$).

About 69% of the patients had no pain, 15% had pain at the end of the day, 9% suffered from pain while weight bearing, and 7% had persistent pain (Figure 5). No significant difference was observed between the two groups ($p=0.75$).

In both groups, about 50% of the patients were able to walk stairs without restriction (Figure 6). In Group A, 41% of the patients were able to climb and descend the second floors, and 9.5% were only able to use stairs with the help of a walking aid. In Group B, 36% of the patients were able to climb and descend the second floors, and 15% needed the help of a walking aid to use stairs. No significant difference was observed between the two groups ($p=0.60$).

After 10-year follow-up, we reached 95.96% survival in Group A (Figure 7b) and 97.3% in Group B (Figure 7b). The septic rate was 2.9% in the case of Sanat Swing knee prostheses and 2.4% in the case of NexGen knee prostheses.

Both types of TKA yielded good-to-excellent outcomes. According to the statistical analysis, none

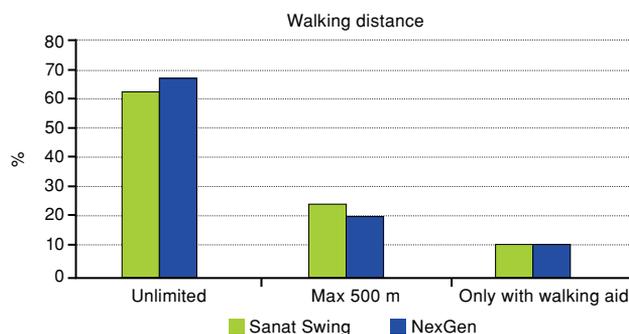


FIGURE 4. Walking ability in Group A and B.

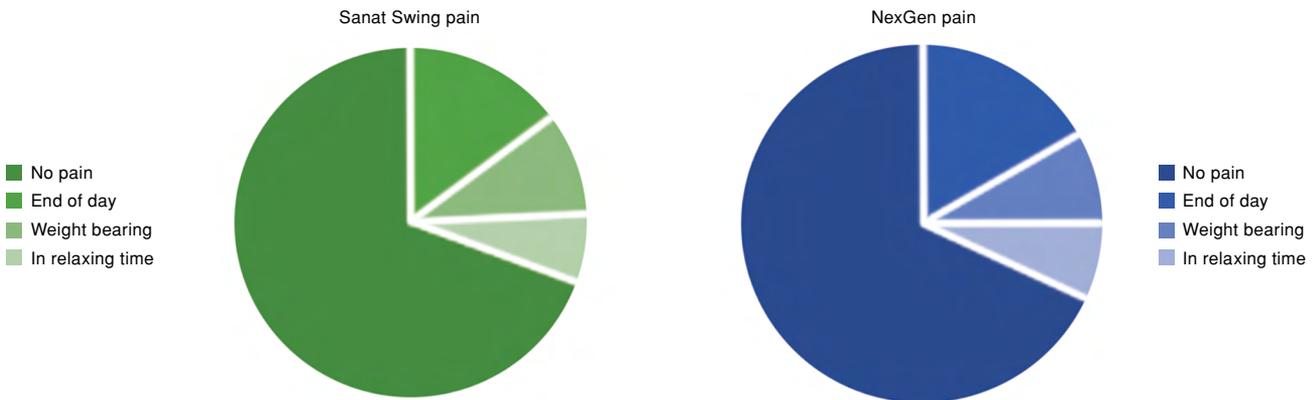


FIGURE 5. Pain levels in the groups.

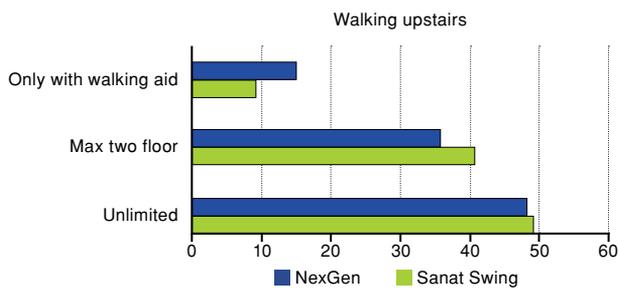


FIGURE 6. Ability to climb stairs, percent ratio in Group A and Group B.

of the measured parameters showed any significant differences between the two groups.

DISCUSSION

Due to the long-term nature of the study and natural attrition of the patients in the study of this duration, the researchers confronted with several unexpected problems. Some of the patients from the beginning of the study did not attend to follow-up,

and some died during the study period; therefore, these cases were unable to be evaluated in the long-term. Nonetheless, the operation time decreased by 4 to 6 min following the learning curve of the surgical team was surpassed and no significant difference was, then, observed between the groups. In the future, it would be worth to follow another group without the learning curve period.

With the recent advancements in scientific tools for prosthetic knee joints and surgical techniques, the 15 to 20-year long-term survival rate of the knee prostheses is reported as high as 90 to 98% in both young and elderly patients.^[1] Chun et al.^[11] reported that the prosthetic survival rate after a mean follow-up period of 14.8 years was 95.7% with the NexGen CR. The 10-year Kaplan-Meier survival according to the Finnish prosthesis registry was 96% (95% CI, 95-96) for the NexGen CR-Flex.^[12] In our study, the 10-year survival rate was 97.3%, yielding similar results between the two product groups. In another study, Mayne et al.^[13] reported a mean postoperative ROM of 100.7±17.2° at 10 years among the survivors in the NexGen knee prosthesis.

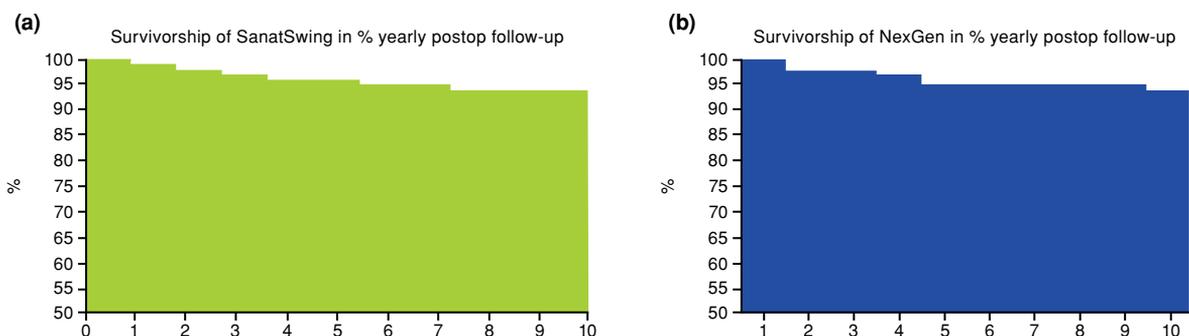


FIGURE 7. (a) Survivorship of SanatMetal Sanat Swing. (b) Survivorship of Zimmer NexGen.

In our study, at 10-year follow-up, the mean ROM was $110.7 \pm 17.8^\circ$ in the NexGen group and $114.4 \pm 21.3^\circ$ in the Sanat Swing group.

In our study, the septic complication rates over the 10-year follow-up period was 2.4% with the NexGen knee prostheses and 2.9% with the Sanat Swing knee prostheses. This rate was 2.8% in the study of Finnish prosthesis registry.^[11]

In the current study, we compared the outcomes of two products which showed correlating results. The NexGen total knee replacement system, which has good results in the literature and which was previously used by the research group yielded good results.^[6-8] The Sanat Swing knee replacement system was first introduced in 2009 and has been used since then in daily practice with similar good results in terms of walking function, KSS, and using stairs. In certain components of the study, the results of the Sanat Swing seemed to be superior to those of the NexGen system, although no statistically significant difference was found between the groups. In our study, the revision rates were also comparable between the groups.

One of the main limitations of the present study is that the Sanat Swing system was first introduced in 2009 and, therefore, a longer follow-up was unable to be done. Since the introduction of the system, our department has performed over seven thousand TKAs with the Sanat Swing total knee replacement system. In general, during follow-up, it was observed that, although there was a slight decrease in the KSS-function, the expectations of the patients also decreased, as they became older and suffered from other comorbidities. Therefore, during the follow-up examinations, not only the patient's knee status affected their walking distance and ability to use stairs, but their general health condition and other chronic diseases also affected the outcomes. The annual increase of total knee replacement surgery would allow for future studies with larger samples. We, as the research group, have already planned a 15-year follow-up study, as well as another 10-year comparison of arthroplasties as of 2015.

In conclusion, based on the actual retrospective evaluation of the first 10-year experiences of the prostheses in our study, we believe that the novel Sanat Swing system seems to be a useful alternative for total knee replacement. However, further large-scale, long-term, prospective, randomized studies are needed to evaluate the mid- and long-term effects of this system.

Declaration of conflicting interests

One of the authors (L. H.) was involved in the development of the SanatMetal Sanat Swing Total Knee Replacement System. All other authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

Funding

The authors received no financial support for the research and/or authorship of this article.

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