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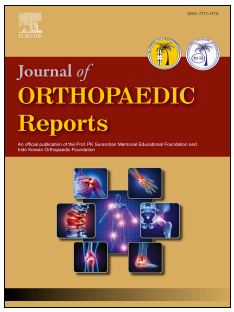

The uncemented ATTUNE Knee Outcome study (ATKOS); short-term clinical improvements in advanced knee osteoarthritis

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I.N. Sierevelt: Methodology, Formal analysis, Data curation, Writing – Review & Editing, Supervision
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The uncemented ATTUNE Knee Outcome study (ATKOS); short-term clinical improvements in advanced knee osteoarthritis

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The uncemented ATTUNE Knee Outcome study (ATKOS); short-term clinical improvements in advanced knee osteoarthritis

Abstract

Background The functional patient-reported outcome measures (PROMs) of the newly introduced uncemented cruciate-retaining rotating-platform ATTUNE total knee arthroplasty (TKA) have not yet been documented. This preliminary study aims to evaluate the short-term functional PROMs. Secondary objectives include evaluating the clinical outcomes, and rates of revisions and reoperations.

Method Preliminary data from an ongoing 10-year multi-center observational study on patients with osteoarthritis receiving an uncemented ATTUNE were analyzed. Surgeries were performed with mechanical alignment and without patellar resurfacing. PROMs (Oxford-knee-score [OKS], Forgotten-joint-score [FJS], Anterior-Knee-Pain-Scale [KUJALA], EQ-5D-5L, NRS-pain-scale, TEGNER and UCLA) and clinical examination results were collected at 6 weeks, 6 months, and 1 year. Linear-mixed-models analyzed PROMs and clinical data, while revision rates were estimated using Kaplan-Meier survival analysis.

Results After excluding 171 knees with less than one year of follow-up, a total of 260 knees were included in the analysis. The cohort comprised 57% women, of 67 years (standard deviation [SD]= 9.5) old, with a follow-up of 2.0 years (SD 0.9). All measured PROMs showed significant improvements at 6 months and 1 year compared to baseline. At 1 year postoperatively, the scores were as followed: OKS 36.8 (CI 35.7–38.0), FJS 53.1 (CI 49.7–56.6), KUJALA 71.7 (CI 69.5–73.8), EQ-5D-5L index 0.88 (CI 0.86–0.90), NRS at rest 1.2 (CI 0.9–1.4), NRS during movement 2.2 (CI 1.8–2.5), TEGNER 3.4 (CI 3.1–3.6), and UCLA 5.6 (CI 5.3–5.9). The revision rate was 1.9% (CI 1.9–1.9) at 1 and 2 years, and 2.8% (CI 2.8–2.8) at 3 years. Revisions included one case of aseptic loosening of the tibial component.

Conclusions The results suggest that the uncemented cruciate-retaining rotating-platform ATTUNE TKA provides substantial short-term functional improvements compared to the preoperative state, which are at least equivalent to other well-established TKAs. Longer

follow-up is necessary to determine if these findings are sustained, particularly regarding revision rates.

Level of evidence Level II (prospective cohort study).

Keywords Total knee Arthroplasty; Uncemented; Cementless; ATTUNE; Patient-reported outcome measures; revision

Introduction

To date, 10–20% of patients remain dissatisfied after total knee arthroplasty (TKA), driving manufacturers to develop new implant designs with enhanced biomechanics to better meet the needs of a growing population of younger, more active patients anticipated in the coming years. [1,2] Uncemented TKA rely on biological fixation through osseointegration, which is thought to benefit this changing patient demographic by preserving bone stock and potentially reducing risks associated with cement wear debris and loosening in the mid-to-long term. [3,4]

In response to dissatisfaction rates, the ATTUNE TKA (DePuy Synthes, Warsaw, Indiana, USA) was introduced to replace its predecessor, the Low Contact Stress (LCS) TKA (DePuy Synthes, Warsaw, Indiana, USA), which had an excellent clinical track record of low revision rates and good patient-reported outcome measures (PROMs). [5] The cemented version of the ATTUNE was launched in 2012, followed by the uncemented version in 2017, which differs in fixation methods, surgical techniques, and potential reasons for revision, all of which could impact clinical and functional outcomes. [6–8]

The ATTUNE system is designed to provide smooth knee flexion and enhance anteroposterior stability through its gradually reduced femoral radius. [6] As for the cemented ATTUNE, it demonstrated equal to slightly better PROMs compared to previous designs. [9] For the uncemented design, only 3 studies have investigated PROMs: one investigated the cruciate-retaining (CR) mobile-bearing (MB) design, but had an insufficient sample size due to it focusing on implant migration, another solely investigated the Knee Injury and Osteoarthritis Outcome Score (KOOS-PS) of the CR MB design, and the third studied only the Forgotten-joint-score (FJS) of the posterior-stabilized (PS) MB design. [10–12] All three studies reported equal to slightly better scores compared to their respective comparisons in national registries after 1 year. Moreover, it is of utmost importance to thoroughly evaluate the early

functional outcomes of newly introduced implants, regardless of their fixation method, as poor outcomes identified at later term comes at the expense of patients' well-being.

This study aims to report the preliminary short-term outcomes of the "follow-up uncemented ATTUNE Knee Outcome Study" (ATKOS) [6] with a primary focus on assessing a broad overview of different 6-month and 1-year PROMs to provide a thorough evaluation of patient outcomes. Secondarily, it evaluates the clinical and functional outcomes, revision rates, and complications in patients with end-stage primary or secondary osteoarthritis who received the uncemented CR MB ATTUNE total knee system.

Methods

Study design

This study reports short-term findings from the multicenter ATKOS study [6], adhering to STROBE and AQUILA guidelines [13,14]. Ethical approval was obtained from the Amsterdam UMC (CME NL71274.029.19), and the protocol was preregistered on ClinicalTrials.gov (NCT04247672) and published. [6]

Settings

The ATKOS study aims to assess revision and reoperation rates of the uncemented ATTUNE knee system over 10 years, with a target enrollment of 900 patients. [6] Recruitment began in 2019 and is ongoing across four hospitals in the X, namely:

- X, X (4 surgeons)
- X, X (2 surgeons)
- X, X (3 surgeons)
- X, X (2 surgeons)

According to the ATKOS protocol, all recruited patients undergo physical examinations and complete questionnaires at predefined intervals: at 6 weeks (physical examination only, except at X X), 6 months, 1 year, 5 years, and 10 years. [6]

Implant and surgical procedure

This study investigates the uncemented, MB (rotating platform), CR ATTUNE total knee system by DePuy Synthes, designed for anatomic patellar tracking and enhanced anteroposterior stability up to 150° flexion. The cobalt-chromium-molybdenum alloy tibial tray features radially positioned pegs and a central keel for fixation, with a spherical bead coating to minimize micromotion and support bone ingrowth. The polyethylene insert incorporates antioxidants for wear resistance and stability. Patella resurfacing was not performed.

Surgical techniques followed manufacturer guidelines, including medial arthrotomy without a tourniquet and mechanical alignment via intramedullary femoral and extramedullary tibial guides. Rotational alignment adhered to Akagi's line for the tibia and the transepicondylar axis and Whiteside's line for the femur. To minimalize bias, all surgeons were uniformly trained in the ATTUNE system. Further implant and surgical details are available in the published study rationale. [6]

Participants

All patients between 21 and 90 years, with end-stage primary or secondary osteoarthrosis of the knee that necessitates a primary TKA, and able to comply with the study schedule, were consecutively asked for participation. Patients were excluded from the ATKOS study if they withdrew prior to surgery or if surgery with the uncemented ATTUNE could not proceed, or when there was an indication for a cemented fixation (e.g., decreased bone stock or quality of

the cancellous bone), a stemmed component or a fixed posterior-stabilized insert. For the current short-term study, patients were secondarily excluded if their follow-up was less than 1 year. Demographic details on included patients were presented in Table 1.

Variables and measurements

Since the main study commenced in 2019 and is still ongoing, the primary outcomes of the current preliminary study include the PROMs measured preoperatively, and at 6 months and 1 year postoperatively. The PROMs include:

1. Knee and health-related PROMs, assessed preoperative, 6 months and 1-year post-surgery.
   - Oxford Knee Score (OKS): assessing the pain and function of the knee; 0 = most severe problems; 48 = least severe. [15]
   - Forgotten Joint Score (FJS): assessing artificial knee joint awareness during daily living, by use of a 5-point Likert scale, with a score of 0 = most aware; 100 = least aware. [16]
   - Anterior Knee Pain Scale (KUJALA) assessing patellofemoral function and pain; 0 = worst; 100 = best. [17]
   - EuroQol 5-dimension 5-level (EQ-5D-5L): assessing general health; 0 = worst; 1 = best. [18]
   - Numerical rating scale (NRS-rest; NRS-activity): assessing pain at rest and during activity; 0 = no pain; 10 = worst pain imaginable).
   - Anchor scales by 3 likert-cales, assessing satisfaction (0 = not satisfied; 10 = very satisfied), change in pain and daily function since the index surgery (0 = much deteriorated; 7 = much improved).

2. Return to sport and work, assessed preoperative and 1-year post-surgery.

- University of California Los Angeles activity scale (UCLA): an ordinal rating scale from 0 to 10; 0 = no physical activity or dependency on others; 10 = regular participation in impact sports.
- Tegner rating scale, an ordinal rating scale from 0 to 10; 0 n= o physical activity or disability; 10 = participating in highly competitive sports.

The secondary outcomes of the study encompass the clinical outcomes from physical examination, performance-based measurements (PBMs), complications, and the rate of planned or performed revisions and reoperations. Clinical outcomes were registered during physical examination, including measurements of range of motion (ROM), anteroposterior and mediolateral stability, and anteroposterior alignment. The anteroposterior alignment was measured by use of full-leg, full weight-bearing conventional radiographs preoperatively and 1 year postoperatively. PBM measurements were performed preoperatively and at 1-year, including the 30-second chair stand test (30-CST), 40-meter fast-paced walk test (40-FPWT), and the stair climb test (SCT). [19] Patients performed as many repetitions of standing up and sitting down in 30 seconds for the 30-CST, walked 40 meters while timing was recorded for the 40-FPWT, and ascended and descended a set of stairs while timing was recorded for the SCT. Additionally, planned or performed revision and reoperation surgeries were registered. A major revision was defined as the implantation, explantation, or exchange of at least the femoral or tibial component, and a minor revision in case if only the insert was exchanged and/or patella was added. A reoperation was defined as all interventions or procedures that did not qualify for a minor or major revision. Complications encompass any adverse events related to knee surgery occurring during the postoperative period. All data were collected on paper or electronically, by using Research Manager (Cloud9 software, Deventer, Netherlands) and exported for analysis to SPSS Statistics 26.0 (IBM SPSS, New York, USA).

Statistical methods

Baseline characteristics were presented as means with standard deviations (SD), medians with interquartile ranges (IQR), or frequencies with proportions, depending on the data distribution. PROM scores and clinical outcomes were presented as means with corresponding 95% confidence intervals (CI) or frequencies with proportions. The mean and CI of PROMs and clinical outcomes were calculated using a linear mixed-effects model (LMM) to effectively account for missing values and within-patient correlations. In the LMM, postoperative time was set as a fixed effect, while patient cases were treated as random effects. Since PROMs were the primary objective, the CI of scores were compared with those from previous follow-up moments (i.e., baseline vs. 6 months and 1 year, 6 months vs. 1 year). Non-overlapping CIs indicate a significant difference between PROM values at the different follow-up moments, whereas overlapping CIs indicate non-significance. [20,21] To assess the potential impact of attrition bias, PROMs of patients excluded due to missing 1-year follow-up data but with available 6-month scores were compared to those of included patients. Cumulative crude revision incidences were assessed using Kaplan-Meier survival analyses for major and minor revision for any reason. Time was characterized from primary TKA to first revision, patient death, or the date of data export (April 5, 2024). Deaths were censored observations, assuming independence from the risk of revision. Revision rates were presented with corresponding CIs. Complications and adverse events were described.

A post-hoc sample size calculation was performed to determine whether the study had adequate power to evaluate the PROMs. Based on a minimal important clinical difference of 5 points and a SD of 9.74 for the Oxford Knee Score [22], the current study with 260 knees had 99% power to detect a 5-point difference at a significance level of 0.05.

Results

Out of 444 cases enrolled in the ATKOS study by April 2024, 431 knees met the inclusion criteria (Figure 1). Thirteen cases were excluded post-recruitment for various reasons (Figure 1). Additionally, 145 knees were secondarily excluded as they had less than one year of follow-up (of which 51 patients had 6-monthts values). Ultimately, 241 patients (260 knees) with at least one year of follow-up were included (Figure 1). Missing PROM scores were noted for 24 preoperatively and 47 at both 6-month and 1-year follow-ups.

Patient-reported outcomes measures

All mean PROM scores measured at 6 months and 1 year significantly improved compared to the preoperative scores (Table 2). Additionally, all PROM scores, except for the EQ5D-5L index, EQ5D-5L VAS scale, and NRS for pain at rest, showed significant improvement between the 6-month and 1-year postoperative periods (Table 2). Majority of scores improved the most during the first 6 months following surgery. Patients rated their satisfaction on a 0 to 10 scale, with scores of 7.8 (CI 7.6–8.1) at 6 months and 8.2 (CI 7.9–8.5) at 1 year.

The risk of attrition bias was deemed minimal. Assessment of attrition bias showed that the 51 patients with 6-month data but excluded due to missing 1-year follow-up had a mean OKS of 27.1 (CI 21.8–32.9), which was significantly lower than that of the included patients (34.5 [CI 33.4–35.6]). All other PROMs were comparable between the two groups.

Clinical outcomes

The mean range of motion reached was 119.3 (CI 117.7–120.3) at 1-year, which was comparable to the preoperative range of motion (Table 3). The proportions of patients with deformations (e.g., extensor lag, mediolateral and anteroposterior instability) decreased after

surgery (Table 3). The mean coronal mechanical alignment was corrected from 180.1 (CI 179.3–181.0) preoperatively to 182.1 (CI 181.1–183.1) after 1 year.

All 3 PBM exercises demonstrated significantly improved 1-year scores compared to preoperatively (Table 3).

Survival and adverse events

As for the survival, 9 revisions (3 major, 6 minor) and 12 reoperations were planned or performed (Table 4). The minor revision rate was 1.5% (CI 1.5–1.5) at 1 year, and 2.1% (CI 2.1–2.1) at 2 and 3 years. For major revisions, the rates were 0.8% (CI 0.8–0.8) at 1 and 2 years, and 1.6% (CI 1.6–1.6) at 3 years. The overall revision rate was 1.9% (CI 1.9–1.9) at 1 and 2 years, and 2.8% (CI 2.8–2.8) at 3 years. A total of 243 patients were at risk at 2 years, and 130 at 3-years. Additionally, a total of 18 cases withdrew and 2 patients died. As for reoperations, a total of 11 manipulations under anesthetic (MUA) were performed after an average of 6.1 months (SD 5.9), with a 1-year incidence of 3.9% (CI 3.9–3.9). Nine serious adverse events occurred, excluding revisions and reoperations, all listed in Table 5.

Discussion

The most important finding of the current study was that all PROMs, including the OKS, FJS, KUJALA, EQ5D-5L, NRS scores, and Tegner and UCLA activity scores, improved significantly at 6-months and 1-year postoperatively, compared to baseline. This was the first study with a sufficient sample size that was able to provide insight into the short-term functional outcomes of the uncemented CR MB ATTUNE TKA. These findings suggest that the uncemented ATTUNE TKA can deliver short-term substantial functional benefits and pain relief to patients with end-stage primary or secondary osteoarthrosis of the knee.

Due to the recent introduction of the uncemented ATTUNE TKA system, literature and available PROMs on the device are limited. This scarcity makes it challenging to compare scores accurately and assess the generalizability of our findings.

The 5-year radiostereometric analysis (RSA) RCT by Puijk et al. (2024) compared 30 uncemented ATTUNE implants with 31 uncemented LCS implants. [23] Although underpowered for robust PROM evaluation, their study reported KUJALA scores of 76.9 (SD 15.3) for ATTUNE and 79.9 (SD 17.6) for LCS, both slightly higher than the 1-year score of 71.8 (CI 69.5–74.1) in the current study, suggesting continued improvement beyond 5 years. [23] Their OKS and NRS-rest and NRS-activity scores were significantly better for ATTUNE compared to LCS up to 3 months, with no differences observed at later follow-ups. [23] One possible explanation for ATTUNE's early improvement could be its anatomical femoral design, enhancing anteroposterior stability throughout knee flexion. [12] When comparing their 6-month and 1-year PROM scores to ours, or those (OKS and KOOS) reported by national registries, similar results were observed. [23–26] However, as our study did not assess PROMs earlier than 6 months, we could not verify the results of these early (i.e., <3 months) improvements found in Puijk [23] The OKS and KOOS scores are widely used in studies and registries but are acknowledged to have a high ceiling effect, making them less effective in distinguishing between good and excellent outcomes compared to scores like the FJS and KUJALA. [17,27–29] Unfortunately, these outcomes are not yet registered by national arthroplasty registries. Additionally, this study investigated functional improvement using PBMs, as recommended by previous research. [19] This outcome is rarely explored in other studies, highlighting a unique strength of the current investigation in evaluating patient recovery comprehensively.

We observed an overall revision rate of 1.9% (CI 1.9–1.9) at 3 years, with most revisions due to insert spinout—a recognized complication of TKAs with MB inserts. Keogh [10] (2020)

reported a 2.9% spinout rate in 332 uncemented CR MB ATTUNE implants, with spinouts occurring only in cases using the measured resection technique, not gap-balancing. [10] In contrast, our study exclusively used the gap-balancing technique, which may explain the lower spinout rate observed. One implant in our cohort required revision for aseptic loosening of both components. This aligns with the 5-year RSA RCT by Puijk (2024), which demonstrated equal to superior implant migration stability for the uncemented ATTUNE compared to the LCS, indicating effective long-term fixation. [23] We observed a 1-year MUA rate of 3.9% (CI 3.9–3.9), higher than the 1.7% reported in a Swedish registry study of 64,840 TKAs and 1,061 MUAs. [30] That study highlighted variation in MUA incidence (0–5%) across hospitals, mainly in younger patients (65%), women (64%), and those with ASA scores ≤2 (88%), reflecting a lack of universal indications for MUA. However, the current study lacks the power to assess these factors or rates conclusively. Furthermore, no data exist on MUA rates for the cemented ATTUNE design, underscoring the need for longer-term studies with larger cohorts, including a comparison group.

This study has several limitations. The uncemented ATTUNE TKA is exclusively used for research in the Netherlands and is not the sole implant in each center, potentially introducing selection bias by excluding patients with major deformities requiring cemented, hinge, or PS implants. This may result in a healthier study population compared to the general arthroplasty population. However, the pre- and postoperative demographics and PROM scores were comparable to those in the Dutch arthroplasty registry, suggesting minimal bias. [24] Additionally, The ATKOS study lacks a comparison group, making it difficult to attribute PROM improvements solely to the uncemented ATTUNE, warranting cautious interpretation. Nevertheless, it is the first study with a sufficient sample size, making it valuable for benchmarking to other implants. Further, the study remains small for detecting rare complications, conducting subgroup analyses, or calculating reoperation and revision rates.

However, given the recent adoption of the uncemented ATTUNE, we deemed it essential to evaluate its performance at an early stage to detect any potential issues with failure rates or clinical performance.

Conclusion

The 6-month and 1-year PROMs from this preliminary study suggest that the uncemented CR MB ATTUNE TKA provides substantial short-term functional improvements compared to the preoperative state, which are at least equivalent to other well-established TKAs. The significant improvements in PROMs at 6 months and 1 year postoperatively indicate that it can deliver clinically relevant benefits and pain relief to patients in the short term. The larger follow-up study is necessary to determine if these findings are sustained over the long term, particularly regarding revision rates.

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Table 1. Demographic, clinical and perioperative characteristics of the included population.

Number of patients	241
Number of knees	260
Performed in hospitals, n (%)	
Spaarne Gasthuis	94 (36.2)
Bergman Clinics	130 (50.0)
Alrijne hospital	18 (6.9)
Maastricht university medical center	18 (6.9)
Duration of symptoms, median years (IQR)	3.5 (2.0 – 6.0)
Secondary osteoarthritis, n (%)	8 (3.1)
Sex, woman, n (%)	149 (57.3)
Mean age, years (SD)	66.6 (9.5)
< 50 years, n (%)	5 (1.9)
50 – 59 years, n (%)	53 (20.4)
60 – 69 years, n (%)	93 (35.8)
70 – 79 years, n (%)	94 (36.2)
80 > years, n (%)	15 (5.7)
Mean BMI, (SD)	29.3 (5.4)
ASA grade, n (%)	
I	40 (15.7)
II	161 (63.1)
III to IV	54 (21.2)
Surgery duration in minutes, mean (SD)	55.0 (18.0)
Follow-up in years, mean (SD)	2.0 (0.9)

Proportions do not add up due to missing values
n Number, BMI Body mass index, IQR Interquartile range, SD Standard deviation

Table 2. Repeated outcome of patient-reported outcome measures 6-months and 1-year postoperative, compared to preoperative values, calculated by use of linear mixed-model analyses.

	Preoperative	Postoperative	
		6-months	1-year
	Mean (95%CI)	Mean (95%CI)	Mean (95%CI) p-value
Cases	236	213	213
OKS score	24.8 (23.7 – 25.9)	34.5 (33.4 – 35.6) [A]	36.8 (35.7 – 38.0) [A, B]
FJS (%)	16.9 (13.6 – 20.2)	44.7 (41.3 – 48.1) [A]	53.1 (49.7 – 56.6) [A, B]
KUJALA score	46.3 (44.3 – 48.4)	66.3 (64.2 – 68.4) [A]	71.7 (69.5 – 73.8) [A, B]
EQ5D-5L			
index	0.64 (0.62 – 0.66)	0.84 (0.82 – 0.86) [A]	0.88 (0.86 – 0.90) [A]
VAS-scale	69.8 (67.6 – 72.0)	78.9 (76.6 – 81.2) [A]	79.4 (77.1 – 81.7) [A]
NRS rest	5.1 (4.8 – 5.3)	1.7 (1.4 – 2.0) [A]	1.2 (0.9 – 1.4) [A]
NRS activity	6.8 (6.5 – 7.1)	2.9 (2.6 – 3.2) [A]	2.2 (1.8 – 2.5) [A, B]
TEGNER	2.4 (2.2 – 2.6)	n/a	3.4 (3.1 – 3.6) [A, B]
UCLA	4.5 (4.2 – 4.7)	n/a	5.6 (5.3 – 5.9) [A, B]

p-values were calculated for values compared to baseline.
[A] Significantly different compared to baseline values, based on non-overlapping 95%CIs.
[B] Significantly different compared to 6-months values, based on non-overlapping 95%CIs.
CI Confidence interval

Table 3. Baseline and repeated measurements of physical examination and performance based measurements.

	Preoperative	Postoperative		
		6-weeks *	6-months	1-year
Number of knees	259	120	210	223
ROM, mean degrees (CI)	119.2 (117.7 – 120.8)	108.0 (105.8 – 110.1) [A]	116.0 (114.3 – 117.8)	119.3 (117.7 – 120.3)
Extension lag, n (%)	92 (35.4)	56 (46.7)	45 (21.4)	33 (14.9)
Anteroposterior stability				
< 5 mm, n (%)	225 (86.5)	112 (95.7)	207 (98.6)	219 (98.2)
5-10 mm, n (%)	25 (9.6)	5 (4.3)	2 (1.0)	4 (1.8)
> 10 mm, n (%)	5 (1.9)	0 (0.0)	1 (0.5)	0 (0.0)
Mediolateral stability				
< 5 degrees, n (%)	174 (66.9)	115 (95.8)	196 (96.6)	208 (94.5)
5 – 9 degrees, n (%)	75 (28.8)	3 (2.5)	7 (3.4)	12 (5.5)
10 – 14 degrees, n (%)	5 (1.9)	2 (1.7)	0 (0.0)	0 (0.0)
> 14 degrees, n (%)	2 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
Performance based measurements				
30-CST, mean reps (CI)	9.3 (8.8–9.8)	n/a	n/a	12.2 (11.7–12.7) [A]
40-FPWT, mean sec (CI)	34.5 (33.2–35.8)	n/a	n/a	27.7 (26.3–29.1) [A]
SCT, mean sec (CI)	14.5 (13.5–15.6)	n/a	n/a	11.7 (10.6–12.8) [A]

n Number, SD Standard deviation, CI Confidence interval, Sec seconds, Reps repetitions, ROM Range of motion

[A] Significantly different compared to baseline values, based on non-overlapping 95%CIs.

* Fewer patients were examined at 6 weeks, as this was not standard clinical practice at one institute.

Table 4. Reasons for revisions and reoperations

Reasons	intervention	n	Mean months, (SD)
Reoperation			
Stiffness or flexion contracture	Manipulation under anesthetic	11	6.1 (5.9)
Periprosthetic fracture	Plate osteosynthesis	1	9.6 (-)
Minor revision			
Insert spinout	insert exchange to thicker size	3	0.5 (0.8)
Patellofemoral osteoarthritis	Adding a patella component	2	10.3 (9.7)
Acute prosthetic joint infection	DAIR with insert exchange	1	1.0 (-)
Major revision			
Femoral fissure and lateral tibial plateau fracture	Revision to cemented sleeved implant	1	1.4 (-)
Expected aseptic loosening	Exchange to cemented sleeved TKR	1	25.8 (-)
Medial collateral ligament rupture	Revision to hinged cemented implant	1	0.7 (-)

Table 5. Adverse events occurred during the study up to April 2024.

Number of knees	Event
1	Direct postoperative collapse resulting from hypotension and bradycardia, requiring an extended hospital stay.
1	Distal patellar fracture, treated conservatively.
2	Hospitalization for bilateral pulmonary embolism.
1	Hospitalization for urosepsis.
1	Shoulder fracture from a fall, requiring total shoulder arthroplasty.
1	Death due to complications of endometrial carcinoma.
1	Hospitalization for treatment of an ankle wound.
1	Endoscopic repair of an inguinal hernia.

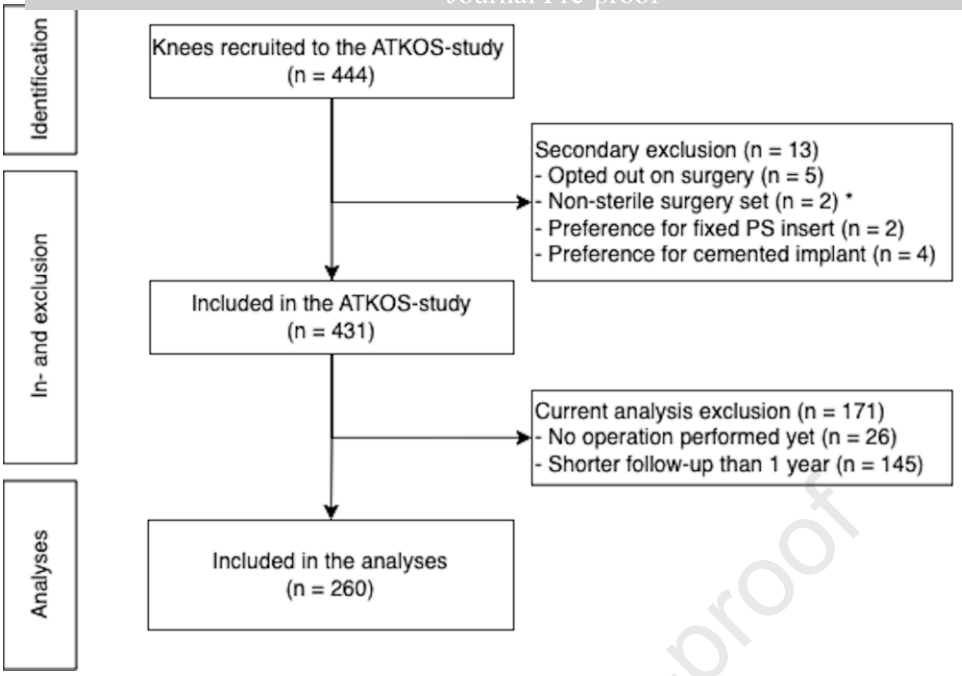

Figure 1. Flowchart of recruitment and inclusion of patients to the AKTOS study.
* Cases where the usual sterile surgical set for the ATTUNE knee system was found to be inadequately packaged, leading to the use of an alternative knee system.

Ethical statement

Ethical approval was obtained from the Amsterdam UMC (CME NL71274.029.19), and the protocol was preregistered on ClinicalTrials.gov (NCT04247672) and published.

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Guardian/patient consent

Not applicable.