Randomized controlled trial comparing traditional versus enhanced-fixation designs of a novel cemented total knee arthroplasty tibial component

Cite this article:
Bone Jt Open 2024;5(1):
20–27.

DOI: 10.1302/2633-1462.
51.BJO-2023-0121

Correspondence should be sent to T. R. Turgeon
tturgeon@cjrg.ca

T. R. Turgeon,[1,2,3] E. Vasarhelyi,[4] J. Howard,[4] M. Teeter,[4,5] C. H. Righolt,[2,3] T. Gascoyne,[3] E. Bohm,[1,2,3] on behalf of the Canadian RSA Network

[1]Concordia Joint Replacement Group, Winnipeg, Manitoba, Canada
[2]Department of Surgery, University of Manitoba, Winnipeg, Manitoba, Canada
[3]Orthopaedic Innovation Centre, Winnipeg, Manitoba, Canada
[4]London Health Sciences Centre, London, Ontario, Canada
[5]Lawson Health Research Institute, London, Ontario, Canada

Aims

A novel enhanced cement fixation (EF) tibial implant with deeper cement pockets and a more roughened bonding surface was released to market for an existing total knee arthroplasty (TKA) system.This randomized controlled trial assessed fixation of the both the EF (ATTUNE S+) and standard (Std; ATTUNE S) using radiostereometric analysis.

Methods

Overall, 50 subjects were randomized (21 EF-TKA and 23 Std-TKA in the final analysis), and had follow-up visits at six weeks, and six, 12, and 24 months to assess migration of the tibial component. Low viscosity bone cement with tobramycin was used in a standardized fashion for all subjects. Patient-reported outcome measure data was captured at preoperative and all postoperative visits.

Results

The patient cohort mean age was 66 years (SD seven years), 59% were female, and the mean BMI was 32 kg/m^2 (SD 6 kg/m^2). Mean two-year subsidence of the EF-TKA was 0.056 mm (95% confidence interval (CI) 0.025 to 0.086) versus 0.006 mm (95% CI -0.029 to 0.040) for the Std-TKA, and the two-year maximum total point motion (MTPM) was 0.285 mm (95% upper confidence limit (UCL) ≤ 0.363) versus 0.346 mm (95% UCL ≤ 0.432), respectively, for a mean difference of -0.061 mm (95% CI -0.196 to 0.074). Inducible displacement also did not differ between groups. The MTPMs between 12 and 24 months for each group was below the published threshold of 0.2 mm for predicting early aseptic loosening ($p < 0.001$ and $p = 0.001$, respectively).

Conclusion

Both the enhanced fixation and the standard tibial implant design showed fixation with a predicted low risk of long-term aseptic loosening.

Take home message

- The two-year migration of Attune S (standard total knee arthroplasty (TKA)) and Attune S+ (enhanced fixation TKA) tibial components was similar.
- The one- to two-year migration of both tibial components was below published thresholds of "at risk" early loosening.

Bone & Joint Open

Introduction

Total knee arthroplasty (TKA) offers significant improvement in quality of life for patients with end stage degeneration of their knee. Over the years, surgical implants and techniques have evolved in an effort to improve patient outcomes and prothesislongevity. Unfortunately, the introduction of new technologies and devices is not a benign process, and even subtle changes to existing implants can affect patient outcomes.[1-5] In order to minimize negative outcomes from implant design innovation, many orthopaedic researchers advocate for the phased introduction of new technologies.[6]

Radiostereometric analysis (RSA) completed early in the process of the clinical evaluation of a new component is a key part of phased introduction of a new implant.[6-8] RSA is a highly accurate radiological technique that is the gold standard for assessing the stability of implants within bone. This precise radiological technique can accurately evaluate fixation of new implants by exposing a relatively small number of patients to the new implant. The pattern of micromotion exhibited by an implant within the first two postoperative years is predictive of the long-term fixation of the component to bone.[9-12] Implant migration of less than 0.2 mm between one- and two-year follow-up examinations indicates solid primary fixation of an implant in host bone.[9]

One knee implant manufacturer recently released a new version of their tibial baseplate as an update to their existing total TKA system. The new baseplate incorporates several features aimed at improving implant-cement fixation of the tibial component. It features a novel backside surface design with deepened, undercut cement pockets and greater surface roughness to mitigate lipid infiltration, and improve the mechanical bonding strength to cement.

The primary objective of the study was to evaluate the effect of the design change on tibial baseplate migration, through comparison of the standard TKA (Std-TKA) and enhanced fixation TKA (EF-TKA) implants up to two years post-surgery using model-based RSA (MBRSA). Our secondary objective was to assess potential difference sin patient-reported outcomes between the study groups.

Methods

This study was a two-centre (Concordia Joint Replacement Group and London Health Sciences Centre, Canada) randomized controlled trial (RCT) involving 50 patients who underwent posterior-stabilized, fixed-bearing, TKA using the ATTUNE Knee System (DePuy Synthes, USA) with either the ATTUNE S (Std-TKA) or Attune S+ (EF-TKA) cemented tibial components. The study had ethical approval at both centres and was registered at ClinicalTrials.gov (NCT03554720). Inclusion criteria were patients with symptomatic osteoarthritis of the knee, aged between 21 and 80 years, with a BMI of < 45 kg/m^2, and who were able and willing to give written informed consent and to comply with the study protocol. Those with active or previous infection and medical contraindications for surgery were excluded. Patients were randomized via sequential, sealed envelopes selection after consent was obtained and prior to their surgical date. Patients and the RSA analyst were blinded to group assignment, but the surgeon and operating room staff could not be blinded.

All surgeries were performed by one of four fellowship-trained arthroplasty surgeons (TRT, EV, JH, EB). A medial parapatellar approach was used and the patella was resurfaced in all patients. Between six and ten tantalum RSA beads (Halifax Biomedical, Canada) of 1.0 mm diameter were dispersed around the proximal tibial metaphysis during the operation. As per usual surgical technique, care was taken to avoid contaminating the inferior surface of the tibial component with blood, fluids, or fat. A standardized cementing technique was employed between sites, involving Simplex cement (Stryker, USA) with tobramycin for all cases, and was applied to the cut surface of the bone as well as the under-surface of thetibial (including the keel), femoral, and patellar components. Implants were seated into bone in the listed cementing order. The standardized one-stage cementing technique consisted of pulse lavage and pressurization of cement. There were no procedural or technique differences between the Std-TKA and EF-TKA device surgeries.

In order to compare migration of the tibial components, the primary outcome, a baseline MBRSA examination was undertaken six weeks postoperatively with further examinations at three, six, 12, and 24 months postoperatively. Radiographs were taken with patients in a supine position. Duplicate baseline examinations were undertaken at six weeks, with the patients repositioned between exposures to calculate intraobserver errors.[13] Additional imaging was performed at 24 months postoperative at one centre (London Health Sciences Centre), which enrolled approximately half of all patients, in which patients were weightbearing on the affected limb with negligible load on the opposing limb.

The RSA suite differed between the two clinical sites (Concordia Joint Replacement Group and London Health Sciences Centre), but have previously been validated for combined data collection and analysis.[14] One clinical site used a carbon-fibre uniplanar calibration box (Halifax Biomedical) with ceiling-mounted radiograph sources aimed at opposing 30° angles, crossing at the patient's knee. The other clinical site used a biplanar calibration box (RSA Biomedical, Sweden) and ceiling-mounted radiograph sources at perpendicular angles crossing at the patient's knee. MBRSA software (version 4.1; RSAcore, Netherlands) was used for analysis, using computer-assisted design models of the implants provided by the manufacturer and using the beads to represent the bone. Halifax Biomedical performed all analyses.

Migration was assessed using maximum total point motion (MTPM) and subsidence (superior/inferior movement) of the tibial component relative to the bone. The six-week RSA examination was used as baseline, and migration was assessed at each of the subsequent follow-up time points. Migration between 12 and 24 months was calculated with reference to the baseline value.[9] Migration between the supine and weightbearing examinations at 24 months was calculated to determine the tibial component displacement under full body weight.

Patient function, the secondary outcome, was assessed using the Oxford Knee Score (OKS),[15] EuroQol five-dimension five-level questionnaire (EQ-5D-5L),[16] visual analogue scales (VAS) for pain and satisfaction, University of California at Los Angeles (UCLA) Activity Score,[17] Pain Catastrophizing Scale (PCS),[18] Patient Knee Implant Performance (PKIP),[19] and the Knee Replacement Expectation Survey (KRES).[20] The VAS for pain was recorded with 0 representing no pain and 100 representing the worst pain imaginable, and the VAS for

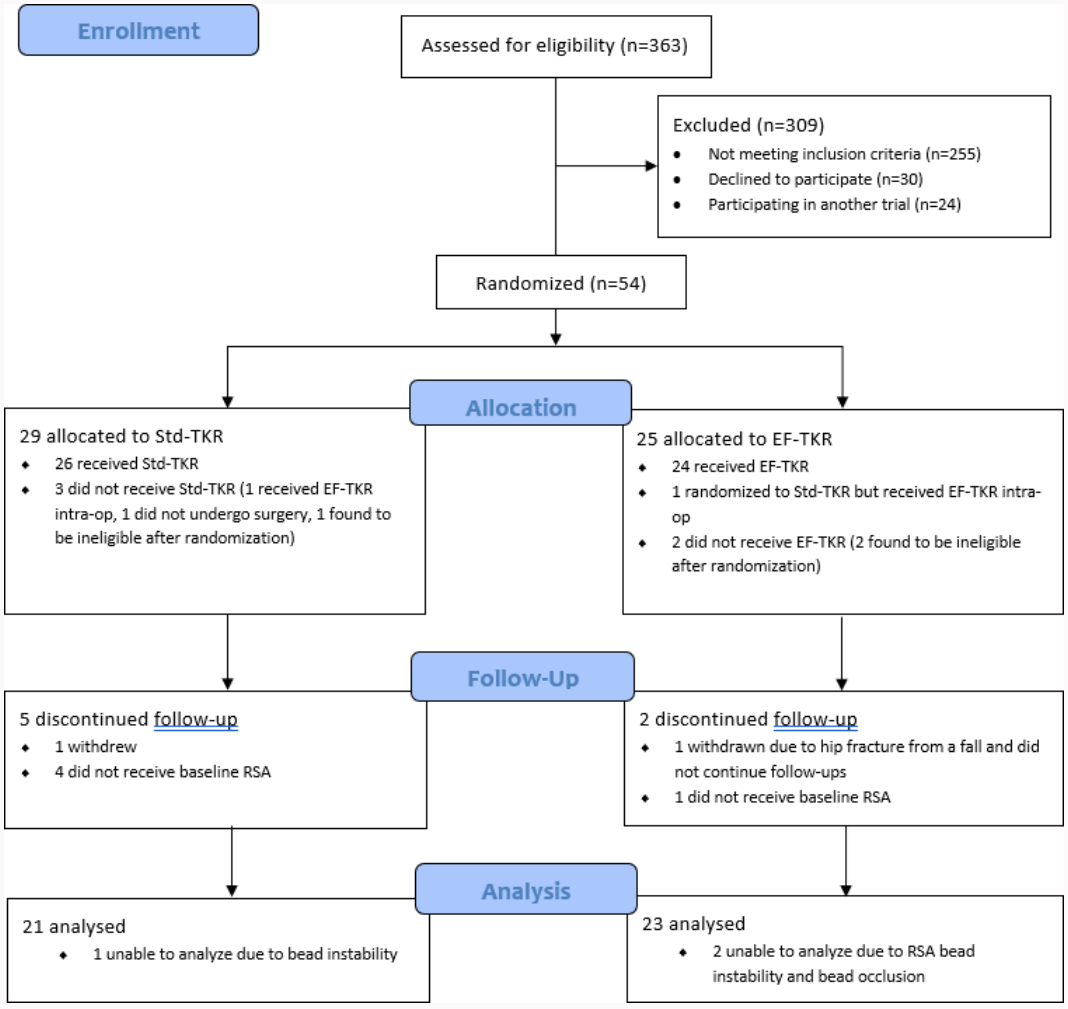

Fig. 1
CONSORT flowchart of patient screening and enrolment.

satisfaction was recorded with 0 representing "unsatisfied with my knee" and 100 representing "completely satisfied with my knee".

Statistical analysis

A sample size of 25 patients per arm was chosen, which is typical for RSA studies. With 25% loss to follow-up, an upper limit to the 12- to 24-month MTPM of 0.2 mm to be clinically important for each device,[9] a standard deviation (SD) of 0.12,[21] and $\alpha = 0.05$, which would lead to power of 1.000 for a 0 mm null hypothesis, 0.971 for a 0.10 mm null hypothesis, and 0.549 for a 0.15 mm null hypothesis. Two-sample *t*-tests were used to compare patient-reported outcome measures (PROMs), the secondary outcomes, between study groups with statistical significance defined as $p < 0.05$. One-sample *t*-tests and 95% confidence intervals (CIs) were used to compare migration of the study groups with published migration thresholds.

Results

The surgeries were performed at each site between August 2018 and November 2019 (Figure 1). The first patient at one centre was randomized to the Std-TKA group, but received an EF-TKA due to an administrative error. No other study patients received the incorrect device. All analyses were performed on as-treated study groups. Three patients were withdrawn from the study; this included one patient who fell and suffered a hip fracture five weeks after surgery, was treated with open reduction internal fixation, and did not return for study follow-up visits. In all, five patients were excluded from migration analysis due to missed baseline RSA examinations as a product of local COVID-19 pandemic restrictions on research. Characteristics of the final patient cohorts are shown in Table I.

The mean subsidence between the first and second year was -0.001 mm (95% CI -0.023 to 0.021) for Std-TKA and 0.017 mm (95% CI 0.006 to 0.029) for EF-TKA. The mean MTPM between the first and second year was 0.066 mm (95% CI -0.013 to 0.145) for Std-TKA and -0.003 mm (95% CI -0.054 to 0.047) for EF-TKA. The difference in the means of one- to two-year MTPM for EF-TKA and Std-TKA was -0.069 mm (95% CI -0.163 to 0.024). The mean MTPM between the first and second year was significantly lower than the published threshold of 0.2 mm for both Std-TKA ($p = 0.001$) and EF-TKA ($p < 0.001$), using the *t*-test with a fixed reference.

There were no statistically or clinically significant differences detected in subsidence or MTPM between the two study groups at any time point (Table II). The mean subsidence at two years (Figure 2) was 0.006 mm (95% CI -0.029 to 0.040) for Std-TKA and 0.056 mm (95% CI 0.025 to 0.086) for EF-TKA.

Table I. Demographic and BMI characteristics of both patient cohorts.

Study group as treated	N	Sex, M:F	Mean age at surgery, yrs (SD)	Mean height, cm (SD)	Mean weight, kg (SD)	Mean BMI, kg/m^2 (SD)
Attune	21	9:12	65.8 (6.3)	168.1 (11.2)	91.7 (23.1)	32.1 (6.2)
Attune S+	23	9:14	66.1 (7.2)	168.2 (11.5)	91.9 (21.4)	32.3 (5.6)
Total	44	18:26	66.0 (6.7)	168.1 (11.3)	91.8 (22.0)	32.2 (5.8)

SD, standard deviation.

Table II. Tibial baseplate subsidence (superior/inferior movement) and maximum total point motion in mm.

	Std-TKA			EF-TKA		
Variable	**Mean**	**SD**	**N**	**Mean**	**SD**	**N**
Baseline, precision						
Subsidence	-0.009	0.028	18	0.007	0.035	17
MTPM	0.205	0.183	18	0.187	0.111	17
3 months						
Subsidence	-0.011	0.051	20	0.018	0.063	19
MTPM	0.249	0.124	20	0.250	0.210	19
6 months						
Subsidence	0.001	0.062	21	0.060	0.152	21
MTPM	0.286	0.176	21	0.447	0.540	21
1 year						
Subsidence	0.009	0.046	20	-0.002	0.151	20
MTPM	0.284	0.192	20	0.402	0.453	20
2 years						
Subsidence	0.006	0.074	20	0.056	0.065	20
MTPM	0.346	0.221	20	0.285	0.202	20
1 to 2 years						
Subsidence	-0.001	0.046	19	0.017	0.024	18
MTPM	0.066	0.164	19	-0.003	0.102	18
2 years weightbearing						
Subsidence	0.000	0.028	13	-0.007	0.037	13
MTPM	0.212	0.146	13	0.209	0.158	13

EF-TKA, enhanced fixation total knee arthroplasty; MTPM, maximum total point motion; SD, standard deviation; Std-TKA, standard total knee arthroplasty.

There was no difference in the average absolute superior/inferior movement of EF-TKA compared to Std-TKA (0.015 mm (95% CI -0.015 to 0.045)). The mean MTPM at two years (Figure 2) was 0.346 mm (95% one-sided upper confidence limit (UCL) ≤ 0.432) for Std-TKA and 0.285 (95% UCL ≤ 0.363) for EF-TKA. There was no difference in the average MTPM of EF-TKA compared to Std-TKA (-0.061 mm (95% CI -0.196 to 0.074)). Similarly, there was no difference detected between study groups in the weightbearing inducible displacement exams at two years for subsidence (mean inter-group difference 0.005 mm; 95% CI -0.012 to 0.023) or MTPM (mean inter-group difference -0.003 mm; 95% CI -0.123 to 0.117).

Two outlier subjects, both in the EF-TKA group, were observed with high values for subsidence and MTPM (Figure 3) at year one. One subject was found to have a high mean error of rigid body fitting of 0.23, and the other had a high condition number of 131. In both cases, error in model fit was likely the cause of these outlying values as opposed to actual migration of the implant. Both subjects indicated scores of 100 satisfaction VAS, ≤ 5 pain VAS, and ≥ 44 OKS at two years. Of those subjects with acceptable mean error and condition number, no subject experienced > 0.2 mm of subsidence or MTPM (Figure 3) between 12 and 24 months post-operation.

Mean error of rigid body fitting for all patients averaged between 0.04 to 0.09 throughout the study with all patients below 0.20, except for the aforementioned outlier. Condition number for all patients averaged between 26 to 32 throughout the study, with all patients below 102 except for the aforementioned outlier.

There were no differences detected between the study groups for the patient reported outcome measures at any time

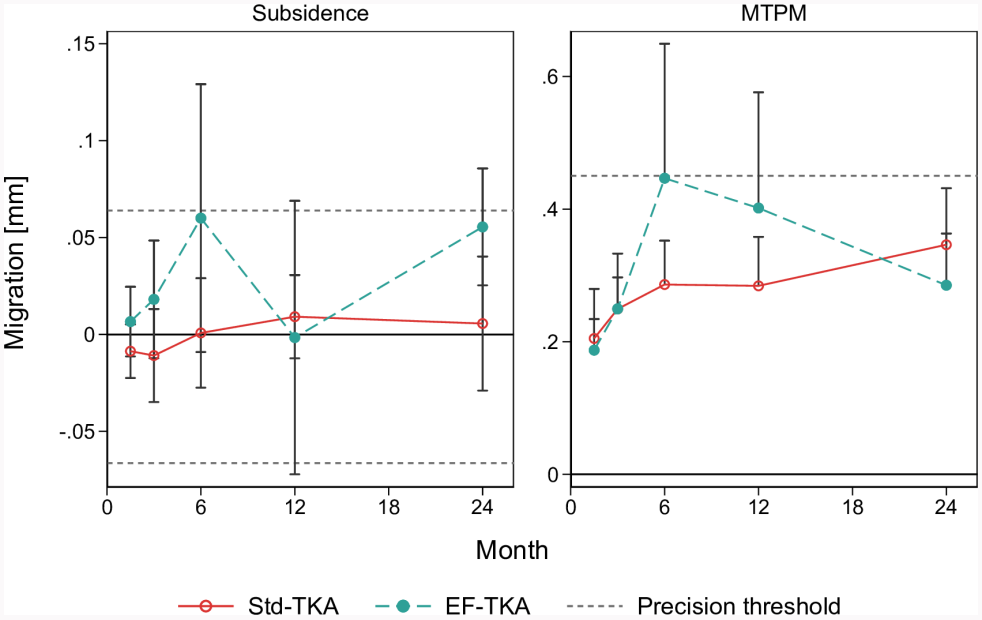

Fig. 2
Mean and 95% confidence intervals of the subsidence and maximum total point motion (MTPM) for the standard total knee arthroplasty (Std-TKA) and and enhanced fixation TKA (EF-TKA) tibial component over time. The precision threshold represents the detection limit of the radiostereometric analysis system.

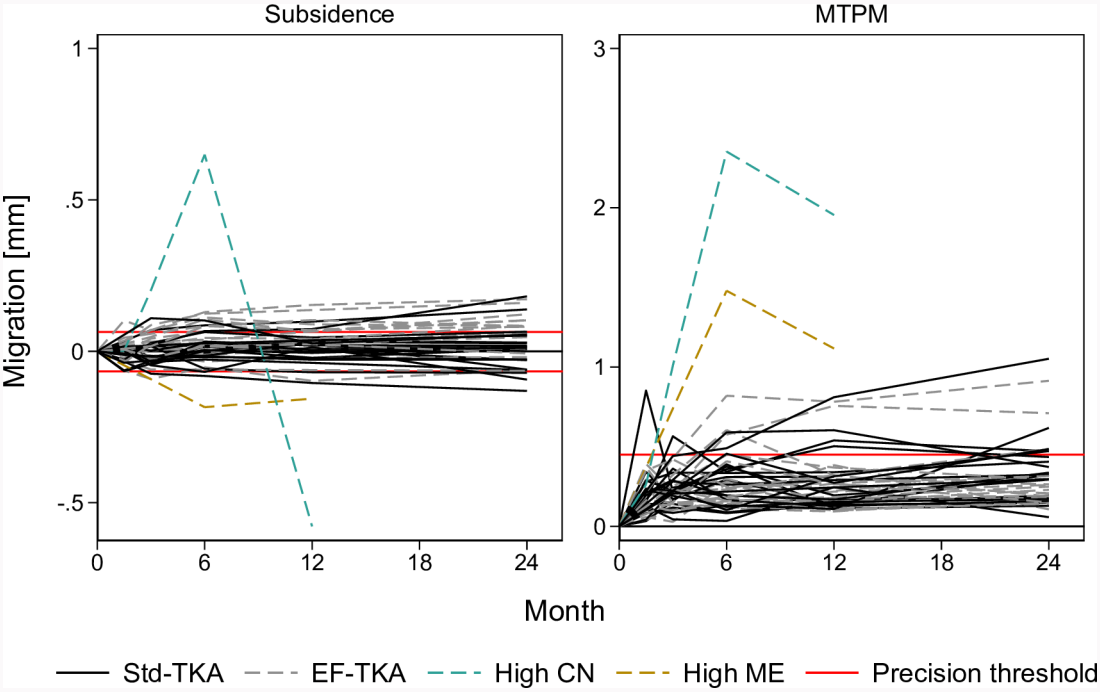

Fig. 3
Subsidence and maximum total point motion for individual patients in both study groups over time. The precision threshold represents the detection limit of the radiostereometric analysis (RSA) system. One enhanced fixation total knee arthroplasty (EF-TKA) patient displayed tightly clustered RSA beads resulting in a condition number (CN) which exceeded the standardized limit of 120. One EF-TKA patient's RSA data had an elevated mean error (ME) of rigid body fitting, but this value did not exceed the standardized limit of 0.35.[22]

point (Table III), though the sample size is insufficient to rule out clinically relevant differences.

Discussion

This study demonstrated excellent implant stability of the tibial component of both the standard and enhanced fixation variants of the assessed knee system. No statistically significant or clinically relevant differences were found between the standard and enhanced fixation tibial implant variants. Although not powered to detect such a difference, clinical outcome metrics also did not appear to differ between the two designs. Both knee designs also demonstrated migra-

Table III. Patient-reported health and function outcome measures according to implant.

	Preoperative			1 year			2 years			Improvement at 2 years		
PROM	Std-TKA	EF-TKA	p-value*	Std-TKA	EF-TKA	p-value*	Std-TKA	EF-TKA	p-value*	Std-TKA	EF-TKA	p-value*
Mean KRES (SD)	34.9 (8.0)	34.4 (8.6	0.842									
Mean PCS (SD)	15.6 (12.2)	14.1 (10.7)	0.640	4.1 (6.2)	9.3 (11.7)	0.090				12.9 (11.0)	5.6 (13.2)	0.064
Mean EQ-5D-5L (SD)	0.729 (0.091)	0.676 (0.143)	0.130	0.822 (0.133)	0.837 (0.103)	0.695	0.900 (0.096)	0.831 (0.115)	0.051	0.155 (0.121)	0.155 (0.125)	0.998
Mean OKS (SD)	25.6 (6.1)	22.5 (7.0)	0.110	41.8 (4.1)	38.8 (7.6)	0.129	42.7 (5.4)	40.8 (7.3)	0.353	16.5 (5.8)	18.1 (7.2)	0.458
Mean pain VAS (SD)	55.2 (22.3)	52.7 (22.9)	0.701	6.6 (12.2)	17.3 (21.8)	0.066	6.4 (11.0)	11.0 (14.9)	0.275	50.0 (19.5)	41.6 (26.7)	0.266
Mean satisfaction VAS (SD)	30.0 (19.7)	31.5 (25.3)	0.832	88.8 (14.9)	82.6 (15.7)	0.218	90.2 (15.9)	85.2 (19.4)	0.389	57.2 (17.7)	56.8 (34.7)	0.960
Mean PKIP (SD)	51.4 (7.4)	51.2 (7.9)	0.943	57.1 (7.4)	56.7 (7.3)	0.862	59.2 (13.8)	60.3 (14.1)	0.800	7.9 (14.7)	8.3 (13.9)	0.919
Mean UCLA (SD)	4.6 (1.8)	4.6 (1.9)	0.888	5.8 (1.7)	5.8 (1.6)	0.893	6.3 (1.8)	6.0 (1.7)	0.697	1.5 (2.0)	1.5 (1.8)	0.997

*Two-sided *t*-tests between the study groups at each study interval.
EF-TKA, enhanced fixation total knee arthroplasty; EQ-5D-5L, EuroQol five-dimension five-level questionnaire; KRES, Knee Replacement Expectation Survey; OKS, Oxford Knee Score; PKIP, Patient Knee Implant Performance; PROM, patient-reported outcome measure; SD, standard deviation; Std-TKA, standard total knee arthroplasty; UCLA, University of California at Los Angeles Activity Score; VAS, visual analogue scale.

tion that was significantly less than the published reference point for 'at risk' migration. This indicates a low risk of aseptic loosening for both designs at ten years. This finding is supported by five-year reported revision rates of 3.1% in the Australian Orthopaedic Association National Joint Replacement Registry and 2.1% in the National Joint Registry (NJR),[23,24] although registry data out to ten years will be required to fully validate the finding.

As mentioned in the results, two subjects were outliers with subsidence or MTPM recorded that were greater than published thresholds. Outliers are commonly documented in RSA studies and do not affect the conclusions of the long-term risk of loosening for the group as a whole.[25,26] In the current study, these subjects had either a high mean error of rigid body fitting (bead instability) or high condition number (inadequate bead spacing) of the RSA bead model, calling into question the accuracy of the measurement for these two subjects. To be conservative, both subjects were kept in the group analyses, and despite their inclusion, no differences were found between groups and both groups showed migration patterns predictive of low risk for aseptic loosening at ten years.

Although underpowered for analysis of PROMs data, the metrics in this study appear consistent with findings from other publications. Giaretta et al[27] reported clinical results on 228 primary knees using the same implant as the present study with mean follow-up of 3.2 years reporting an OKS of 35 (SD 14.6). The present study found slightly higher OKS results in both the standard (42.7) and enhanced fixation groups (40.8) that do not differ statistically from the Giaretta et al[27] study due to the SDs and sample sizes involved. A pain numeric rating scale of 2/10 was reported, almost identical to the VAS score in this study of 19.5/100 at twoyears.

An institutional database review assessed 742 uses of the investigational system, with ten cases of aseptic tibial loosening in the first three years for a rate of 1.35% with a minimum two-year follow-up.[28] The authors found that all ten events occurred with the standard design with high viscosity cement products (2.1% of high viscosity cement cases), and that loosening occurred with 15.1 greater odds with low volume arthroplasty surgeons (< 50 cases per year). Additional cadaveric and benchtop research has shown movement and implant surface contamination during cementing to reduce implant pull-out strength.[29,30] A change in practice from low-viscosity to high-viscosity cement has also been implicated in cement debonding,[31] even though the exact viscosity when using the cement depends on the details of its handling. The current study used low-viscosity cement with high-volume surgeons, and did not see any cases of loosening. A prior study that included both low and high viscosity cement, did not detect any migration difference, or find evidence of loosening between cement types using the standard tibial implant.[32]

In 2017, Bonutti et al[33] published a case series of 15 patients with described cement debonding suggesting implant design as the underlying cause. In a response letter to the editor, the lead author implied that the development of the enhanced fixation design was evidence of cement debonding.[34] Both this study and a previous study by Turgeon et al[32] appeared to go against the Bonutti et al[33] study findings, giving no signs of loosening or increased risk of long-term aseptic loosening with the standard design in either study. This is further supported with a review of NJRs, which found the assessed implant to demonstrate survivorship consistent with other knee system designs.[35] Cementing technique is important for long-term fixation of the implant; surgeon experience and volume likely affect this technique.

Strengths of this study include a randomized controlled design, with subjects in both arms of the study being enrolled at two geographically disparate centres.

The surgical team could not be blinded to the implant as they needed to be prepared for the surgery. All cases were done with the same low-viscosity cement from the same vendor using a standardized cement technique that involved coating both the tibial component, including the keel, as well as the cut surface of the tibia. There was a small differential loss to follow-up: four Std-TKA patients and one EF-TKR patient did not receive their baseline RSA examination. This differential loss to follow-up was due to staff turnover at one of the study sites leading to missed exams, which was unlikely to be related to the investigational devices as there is a 37.5% (12/32) probability that five people lost to follow-up would not be lost at 2:3 or 3:2 ratio. RSA gives a highly accurate and precise measure of early migration of implants, making it far more likely to detect cement debonding with the relatively short time frame of two years from surgery. Due to the RSA at our centres, we were only able to do baseline examinations at six weeks rather than immediately postoperative, this means we only capture the migration after this six-week mark. While both a strength and a weakness, all cases were performed by high-volume fellowship-trained arthroplasty surgeons. While this improves the consistency of the surgical procedure required for a RCT, it does not reflect the variable nature of surgical experience in real-world surgical care delivery. The relatively small sample size, while being appropriate for RSA studies, precludes definitive analysis of the clinical outcome metrics of the study.

In conclusion, this study found stable fixation with both the standard and enhanced fixation version of the ATTUNE tibial baseplate. This indicates low probability of aseptic revision at eight to ten years, regardless of design variant when used with proper cement and implant handling techniques.

References

1. **Wedderkopp N**, **Andersen-Ranberg F**, **Andersen MB**, **Termansen NB**. Aseptic loosening of BonelocR cemented hip prostheses. *Int Orthop*. 1997;21(2):87–90.
2. **Nilsson KG**, **Dalén T**. Inferior performance of Boneloc bone cement in total knee arthroplasty: a prospective randomized study comparing Boneloc with Palacos using radiostereometry (RSA) in 19 patients. *Acta Orthop Scand*. 1998;69(5):479–483.
3. **Howie DW**, **Middleton RG**, **Costi K**. Loosening of matt and polished cemented femoral stems. *J Bone Joint Surg Br*. 1998;80-B(4):573–576.
4. **Ohlin A**, **Persson PG**. Failed Christiansen total hip arthroplasty. A radiographic and histologic study. *J Arthroplasty*. 1989;4(3):207–215.
5. **Sudmann E**, **Havelin LI**, **Lunde OD**, **Rait M**. The Charnley versus the Christiansen total hip arthroplasty. A comparative clinical study. *Acta Orthop Scand*. 1983;54(4):545–552.
6. **Nelissen R**, **Pijls BG**, **Kärrholm J**, **Malchau H**, **Nieuwenhuijse MJ**, **Valstar ER**. RSA and registries: the quest for phased introduction of new implants. *J Bone Joint Surg Am*. 2011;93-A Suppl 3:62–65.
7. **Gross M**. Innovations in surgery. A proposal for phased clinical trials. *J Bone Joint Surg Br*. 1993;75-B(3):351–354.
8. **Gross M**. A critique of the methodologies used in clinical studies of hip-joint arthroplasty published in the English-language orthopaedic literature. *J Bone Joint Surg Am*. 1988;70-A(9):1364–1371.
9. **Ryd L**, **Albrektsson BE**, **Carlsson L**, **et al**. Roentgen stereophotogrammetric analysis as a predictor of mechanical loosening of knee prostheses. *J Bone Joint Surg Br*. 1995;77-B(3):377–383.
10. **Ryd L**. Micromotion in knee arthroplasty. A roentgen stereophotogrammetric analysis of tibial component fixation. *Acta Orthop Scand Suppl*. 1986;220:1–80.
11. **Ryd L**, **Lindstrand A**, **Rosenquist R**, **Selvik G**. Tibial component fixation in knee arthroplasty. *Clin Orthop Relat Res*. 1986;213:141–149.
12. **Ryd L**. Roentgen stereophotogrammetric analysis of prosthetic fixation in the hip and knee joint. *Clin Orthop Relat Res*. 1992;276:56–65.
13. **Valstar ER**, **Gill R**, **Ryd L**, **Flivik G**, **Börlin N**, **Kärrholm J**. Guidelines for standardization of radiostereometry (RSA) of implants. *Acta Orthop*. 2005;76(4):563–572.
14. **Laende E**. Formation of a National RSA Network for Standardized Multicentre RSA Research. In: *4th International RSA Meeting*. Bologna, Italy: 2015.
15. **Dawson J**, **Fitzpatrick R**, **Murray D**, **Carr A**. Questionnaire on the perceptions of patients about total knee replacement. *J Bone Joint Surg Br*. 1998;80-B(1):63–69.
16. **EuroQol G**. EuroQol--a new facility for the measurement of health-related quality of life. *Health Policy*. 1990;16(3):199–208.
17. **Zahiri CA**, **Schmalzried TP**, **Szuszczewicz ES**, **Amstutz HC**. Assessing activity in joint replacement patients. *J Arthroplasty*. 1998;13(8):890–895.
18. **Osman A**, **Barrios FX**, **Kopper BA**, **Hauptmann W**, **Jones J**, **O'Neill E**. Factor structure, reliability, and validity of the Pain Catastrophizing Scale. *J Behav Med*. 1997;20(6):589–605.
19. **Lewis S**, **Price M**, **Dwyer KA**, **et al**. Development of a scale to assess performance following primary total knee arthroplasty. *Value Health*. 2014;17(4):350–359.
20. **Mancuso CA**, **Sculco TP**, **Wickiewicz TL**, **et al**. Patients' expectations of knee surgery. *J Bone Joint Surg Am*. 2001;83-A(7):1005–1012.
21. **Turgeon TR**, **Gascoyne TC**, **Laende EK**, **Dunbar MJ**, **Bohm ER**, **Richardson CG**. The assessment of the stability of the tibial component of a novel knee arthroplasty system using radiostereometric analysis. *Bone Joint J*. 2018;100-B(12):1579–1584.
22. **Association, I.S**. Implants for Surgery - Roentgen Stereophotogrammetric Analysis for the Assessment of Migration of Orthopaedic Implants, Geneva 20, CH: ISO: 1211. 2013.
23. **No authors listed**. Hip, Knee & Shoulder Arthroplasty: 2022 Annual Report. Australian Orthopaedic Association National Joint Replacement Registry. https://aoanjrr.sahmri.com/en-GB/annual-reports-2022 (date last accessed 12 December 2023).
24. **No authors listed**. 19th Annual Report 2022. National Joint Registry. https://www.njrcentre.org.uk/njr-annual-report-2022/ (date last accessed 12 December 2023).
25. **van Hamersveld KT**, **Marang-van de Mheen PJ**, **Tsonaka R**, **Valstar ER**, **Toksvig-Larsen S**. Fixation and clinical outcome of uncemented peri-apatite-coated *versus* cemented total knee arthroplasty: five-year follow-up of a randomised controlled trial using radiostereometric analysis (RSA). *Bone Joint J*. 2017;99-B(11):1467–1476.
26. **Schotanus MGM**, **Pilot P**, **Kaptein BL**, **et al**. No difference in terms of radiostereometric analysis between fixed- and mobile-bearing total knee arthroplasty: a randomized, single-blind, controlled trial. *Knee Surg Sports Traumatol Arthrosc*. 2017;25(9):2978–2985.
27. **Giaretta S**, **Berti M**, **Micheloni GM**, **Ceccato A**, **Marangoni F**, **Momoli A**. Early experience with the ATTUNE Total Knee Replacement System. *Acta Biomed*. 2019;90(12-S):98–103.
28. **Torino D**, **Damsgaard C**, **Kolessar DJ**, **et al**. Tibial baseplate-cement interface debonding in the ATTUNE total knee arthroplasty system. *Arthroplast Today*. 2022;17:165–171.
29. **Martin JR**, **Wronski PT**, **Schilkowsky RM**, **Orfanos AV**, **Fehring TK**, **Mason JB**. Chitranjan S. Ranawat Award: Motion during total knee cementing significantly decreases tibial implant fixation strength. *J Arthroplasty*. 2022;37(6S):S12–S18.
30. **Kelly BC**, **Owen JR**, **Shah SC**, **Johnson AJ**, **Golladay GJ**, **Kates SL**. A biomechanical comparison of the effect of baseplate design and bone marrow fat infiltration on tibial baseplate pullout strength. *J Arthroplasty*. 2021;36(1):356–361.
31. **Kopinski JE**, **Aggarwal A**, **Nunley RM**, **Barrack RL**, **Nam D**. Failure at the tibial cement-implant interface with the use of high-viscosity cement in total knee arthroplasty. *J Arthroplasty*. 2016;31(11):2579–2582.
32. **Turgeon TR**, **Gascoyne TC**, **Laende EK**, **Dunbar MJ**, **Bohm ER**, **Richardson CG**. The assessment of the stability of the tibial component of a novel knee arthroplasty system using radiostereometric analysis. *Bone Joint J*. 2018;100-B(12):1579–1584.

33. **Bonutti PM**, **Khlopas A**, **Chughtai M**, **et al**. Unusually high rate of early failure of tibial component in ATTUNE total knee arthroplasty system at implant-cement interface. *J Knee Surg*. 2017;30(5):435–439.
34. **Bonutti P**. Response to: Confidence in the ATTUNE knee is driven by real-world scientific evidence: Response to Bonutti et al. article. *J Knee Surg*. 2018;31(8):811–814.
35. **Vasarhelyi EM**, **Petis SM**. Use of National Joint Registries to evaluate a new knee arthroplasty design. *J Arthroplasty*. 2020;35(2):413–416.

Author information

T. R. Turgeon, BSc, MD, MPH, Head of Arthroplasty Research, Head of Surgery, Board Member
E. Bohm, B.Eng, MD, MSc, FRCSC, Professor
Concordia Joint Replacement Group, Winnipeg, Manitoba, Canada; Department of Surgery, University of Manitoba, Winnipeg, Manitoba, Canada; Orthopaedic Innovation Centre, Winnipeg, Manitoba, Canada.

E. Vasarhelyi, MD, MSc, FRCSC, Associate Professor
J. Howard, MD, MSc, FRCSC, Professor of Surgery, Site Chief of Orthopaedics
London Health Sciences Centre, London, Ontario, Canada.

M. Teeter, PhD, Associate Professor, London Health Sciences Centre, London, Ontario, Canada; Lawson Health Research Institute, London, Ontario, Canada.

C. H. Righolt, PhD, Assistant Professor, Director of Clinical Research, Department of Surgery, University of Manitoba, Winnipeg, Manitoba, Canada; Orthopaedic Innovation Centre, Winnipeg, Manitoba, Canada.

T. Gascoyne, MSc, President & CEO, Orthopaedic Innovation Centre, Winnipeg, Manitoba, Canada.

Author contributions

T. R. Turgeon: Conceptualization, Funding acquisition, Methodology, Investigation, Writing – original draft, Writing – review & editing.
E. Vasarhelyi: Conceptualization, Investigation, Methodology, Writing – review & editing.
J. Howard: Investigation, Methodology, Project administration, Supervision, Writing – original draft, Writing – review & editing.
M. Teeter: Conceptualization, Methodology, Writing - original draft, Writing - review & editing.
C. H. Righolt: Formal analysis, Methodology, Writing – review & editing.
T. Gascoyne: Conceptualization, Funding acquisition, Methodology, Project administration, Writing – original draft.
E. Bohm: Investigation, Methodology, Writing - reviewing & editing.

Funding statement

The author(s) disclose receipt of the following financial or material support for the research, authorship, and/or publication of this article: payment to institutions for to conduct this study on a cost-recovery basis from DePuy Synthes. No payments were made to authors, or for authorship or publication of this article.

ICMJE COI statement

The authors disclose payment to institutions to conduct this study on a cost-recovery basis from DePuy Synthes. Each of the authors also disclose the following, each of which is unrelated to the study: E. Bohm declares funding for unrelated studies from Smith & Nephew, DePuy Synthes, Zimmer Biomet, and Hip Innovation Technology; and consulting fees and payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing, or educational events from Stryker Canada; payment for expert testimony for the Government of British Columbia; and a leadership or fiduciary role for the International Society of Arthroplasty Registries, Canadian Joint Replacement Registry Advisory Committee, Canadian Arthroplasty Society, and the Orthopaedic Innovation Centre. T. Gascoyne reports funding for unrelated studies from Smith & Nephew, DePuy Synthes, Zimmer Biomet, and Hip Innovation Technology; and a leadership or fiduciary role for the International Radiostereometry Society and International Standards Organization. J. Howard discloses consulting fees and payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events from Smith & Nephew, DePuy Synthes, Stryker, Sanofi, Intellijoint, and Zimmer Biomet; a leadership or fiduciary role for the Canadian Arthroplasty Society; and stock or stock options for Intellijoint Surigcal. C. Righolt reports funding for unrelated studies from Smith & Nephew, DePuy Synthes, Zimmer, Hip Innovation Technology, and Pfizer Canada; and a leadership or fiduciary role for the Canadian Orthopaedic Association. M. Teeter declares a leadership or fiduciary role for the Canadian Orthopaedic Research Society, International Society for Technology in Arthroplasty, and the Canadian RSA Network. T. R. Turgeon discloses funding for unrelated studies from Smith & Nephew, DePuy Synthes, Zimmer Biomet, and Hip Innovation Technology; and a leadership or fiduciary role for the Orthopaedic Innovation Centre and the Journal of Arthroplasty; and stock and stock options for Precision Advanced Digital Manufacturing. E. M. Vasarhelyi grants or contracts from DePuy Synthes and MicroPort; consulting fees for Zimmer Biomet, DePuy Synthes, and MicroPort; and participation on a data safety monitoring board or advisory board for Hip Innovation Technology.

Data sharing

The datasets generated and analyzed in the current study are not publicly available due to data protection regulations. Access to data is limited to the researchers who have obtained permission for data processing. Further inquiries can be made to the corresponding author.

Ethical review statement

This study was approved by the University of Manitoba Biomedical Research Ethics Board (HS21601 | B2018:024), and the Western University Health Science Research Ethics Board (111837).

Open access funding

The authors report that they received open access funding for this manuscript from DePuy Synthes.

Trial registration number

This trial was registered on ClinicalTrials.gov: NCT03554720.

Twitter

Follow M. Teeter @TeeterLab