

**B. L. Kaptein,
P. den Hollander,
B. Thomassen,
M. Fiocco,
R. G. H. H. Nelissen**

*From Leiden University
Medical Center, Leiden,
Netherlands*

■ KNEE

A randomized controlled trial comparing tibial migration of the ATTUNE cemented cruciate-retaining knee prosthesis with the PFC-sigma design

Aims

The primary objective of this study was to compare migration of the cemented ATTUNE fixed bearing cruciate retaining tibial component with the cemented Press-Fit Condylar (PFC)-sigma fixed bearing cruciate retaining tibial component. The secondary objectives included comparing clinical and radiological outcomes and Patient Reported Outcome Measures (PROMs).

Methods

A single blinded randomized, non-inferiority study was conducted including 74 patients. Radiostereometry examinations were made after weight bearing, but before hospital discharge, and at three, six, 12, and 24 months postoperatively. PROMS were collected preoperatively and at three, six, 12, and 24 months postoperatively. Radiographs for measuring radiolucencies were collected at two weeks and two years postoperatively.

Results

The overall migration (mean maximum total point motion (MPTM)) at two years was comparable: mean 1.13 mm (95% confidence interval (CI), 0.97 to 1.30) for the ATTUNE and 1.16 mm (95% CI, 0.99 to 1.35) for the PFC-sigma. At two years, the mean backward tilting was -0.43° (95% CI, -0.65 to -0.21) for the ATTUNE and 0.08° (95% CI -0.16 to 0.31), for the PFC-sigma. Overall migration between the first and second postoperative year was negligible for both components.

The clinical outcomes and PROMs improved compared with preoperative scores and were not different between groups. Radiolucencies at the implant-cement interface were mainly seen below the medial baseplate: 17% in the ATTUNE and 3% in the PFC-sigma at two weeks, and at two years 42% and 9% respectively ($p = 0.001$).

Conclusion

In the first two postoperative years the initial version of the ATTUNE tibial component was not inferior with respect to overall migration, although it showed relatively more backwards tilting and radiolucent lines at the implant-cement interface than the PFC-sigma. The version of the ATTUNE tibial component examined in this study has subsequently undergone modification by the manufacturer.

Level of Evidence: 1 (randomized controlled clinical trial)

Cite this article: *Bone Joint J* 2020;102-B(9):1158–1166.

Introduction

It is estimated that more than one million total knee prostheses are implanted worldwide annually and that these numbers will increase significantly because of our aging society.¹ As prosthetic loosening is one of the main reasons for long-term

failure,² it is crucial that the local mechanical environment at the joint enables good primary fixation of the prosthesis which remains in the long term. Therefore, a rigorous analysis into the mechanical failure modes at the bone-implant fixation interface of newly introduced implants is necessary.³

Correspondence should be sent to B. L. Kaptein; email: B.L.Kaptein@lumc.nl

©2020 Author(s) et al.
doi:10.1302/0301-620X.102B9.
BJJ-2020-0096.R1 \$2.00

Bone Joint J
2020;102-B(9):1158–1166.

Long-term mechanical loosening can be predicted within two years by assessing sub-millimetre migration of the prosthesis relative to the bone using radiostereometric analysis (RSA).^{4,6} Ideally innovative new designs should be compared with the good performing designs in a randomized RSA study to permit to a phased introduction.^{3,7,8}

The pressed fit condylar (PFC)-sigma prosthesis (DePuy Synthes, Warsaw, Indiana, USA) has good clinical results in elderly patients with ten year survival of 97%⁹⁻¹¹ and minimal early migration of the tibial component as measured with RSA (0.5 mm maximum total point motion (MTPM) at two-year follow-up).¹² The ATTUNE prosthesis (DePuy Synthes) was developed to improve patellofemoral kinematics as well as mid flexion stability of the knee by an increased congruence between femoral and tibial articulations.¹³ However, greater congruence might also effect the forces on the implant-bone interface and thus implant migration. Additionally some concerns with cementing of the tibial baseplate have been reported.^{14,15}

The primary objective of this study is therefore to compare tibial baseplate migration of the cemented ATTUNE fixed bearing cruciate retaining (CR) design with the cemented PFC-sigma fixed bearing CR design. The secondary objectives are to compare clinical, radiological, and patient-reported outcome measures (PROMs) between the two groups.

Methods

A single-blinded randomized, noninferiority study on all consecutive patients who were eligible for elective total knee arthroplasty (TKA) between 2014 and 2015 was conducted. Patients diagnosed with symptomatic osteoarthritis or rheumatoid arthritis of the knee, aged between 21 and 90 years, requiring TKA, and willing and able to give informed consent, were invited to participate in this study.

After providing informed consent, the patients were randomized, using a computer-generated randomization list, in one of the two study groups, a week before surgery. The surgeon was told to which group the patient was assigned on the day of surgery.

Three experienced surgeons (PH, EA, RF) at the Haaglanden Medical Centre, The Hague, Netherlands used identical surgical techniques to implant both designs. All surgeons had experience with the PFC-sigma knee system and were trained to use the ATTUNE knee system. Prior to starting this study, they operated on ten patients using the ATTUNE knee system to obtain experience and confidence with the design and instrumentation. Surgery was performed under regional or general anaesthesia. A standard midline skin incision with a medial parapatellar arthrotomy with standard bone referenced and measured resection balancing techniques were used, retaining the posterior cruciate ligament (PCL). After pulsed lavage, bone cement was put into the proximal tibia and on the osteotomy surface. A tourniquet was used during cementing. Local infiltration analgesia (LIA) was used in addition to prophylactic treatment against postoperative nausea and vomiting to ensure a fast rehabilitation. Indication for patellar resurfacing was grade 4 arthrosis of the patella, or rheumatoid arthritis. Mobilization with physiotherapy began four to six hours after surgery and followed a fast-track protocol.

During enrolment, 191 patients were eligible to be included in the study, 74 patients were randomized, and 62 patients completed the two-year follow-up (Figure 1). Patient characteristics were similar in both groups (Table I). Operating time was a mean of seven minutes longer for the ATTUNE prosthesis than for the PFC-sigma prosthesis ($p = 0.011$, Welch modified two-sample *t*-test), which was related to the learning curve. Patellar resurfacing was done in more knees for the PFC-sigma group, than in the ATTUNE group (($N-1$) $p = 0.034$, chi-squared test).

For migration analysis with RSA at least five tantalum spheres (1 mm diameter) were inserted well-scattered around the prosthesis during surgery, with a specially designed insertion instrument (Baat Medical Products, Hengelo, Netherlands).¹⁶

The first postoperative RSA examination, made after weight bearing but before hospital discharge, served as the reference baseline for migration analysis. Subsequent RSA examinations were made at three, six, 12, and 24 months postoperatively using a standard RSA set-up, with the patient in supine position. For calibration, either a uniplanar carbon calibration box (Medis Carbon Box; Medis Specials, Leiden, Netherlands) or a uniplanar acrylic calibration box (UmRSA – Calibration Cage No 43; RSA Biomedical, Umeå, Sweden) was used. Computed radiology cassettes (35 × 43 cm) recorded the RSA images. Computer-aided design (CAD) implant models allowed for implant migration analysis with model-based RSA software (RSAcore, Leiden, Netherlands)¹⁷ following the guidelines on RSA.^{18,19} This technique facilitated examination of implant migration without recourse to attaching markers to the prostheses.

The main outcome parameter was MTPM, which represents the length (mm) of the translation vector of the point on the prosthesis component model that moved the most. Translations (mm) and rotations (°) of the prosthesis components were calculated using a coordinate system with its origin in the geometrical centre of the prosthesis in the baseline evaluation and of which, for a right-sided implant, the transverse axis is medial translation (Tx), longitudinal axis is proximal translation (Ty), and sagittal axis is anterior translation (Tz). Rotations (Rx, Ry, Rz) are defined about these axes following the right hand screw rule.¹⁹ Migration of left-sided prostheses were recalculated in order to describe the migration in anatomical terms for a right-sided prosthesis.¹⁸

Long-leg standing radiographs were made to measure the two years postoperative hip-knee-ankle (HKA) angle, presence and thickness of radiolucent lines along tibial zones were measured in mm at anteroposterior (AP) and mediolateral (ML) short knee radiographs at two weeks and at two years on long-leg standing radiographs.^{14,20} Measurements were conducted under supervision of the senior authors (PH, RN) using the standard PACS viewer (Vital Images, Minnetonka, Minnesota, USA).

Preoperatively, and at all RSA reviews, the Knee Society Score (KSS)²¹ and PROMS were recorded in agreement with the recommendations by the Netherlands Orthopaedic Association: General Health; EuroQol-5D (EQ-5D),²² Knee Function; Knee Injury and Osteoarthritis Outcome Score (KOOS),^{23,24} Oxford Knee Score (OKS)²⁵, and pain score after activity and during rest; (Visual Analogue Scale 0, no pain to 10, worst pain imaginable).

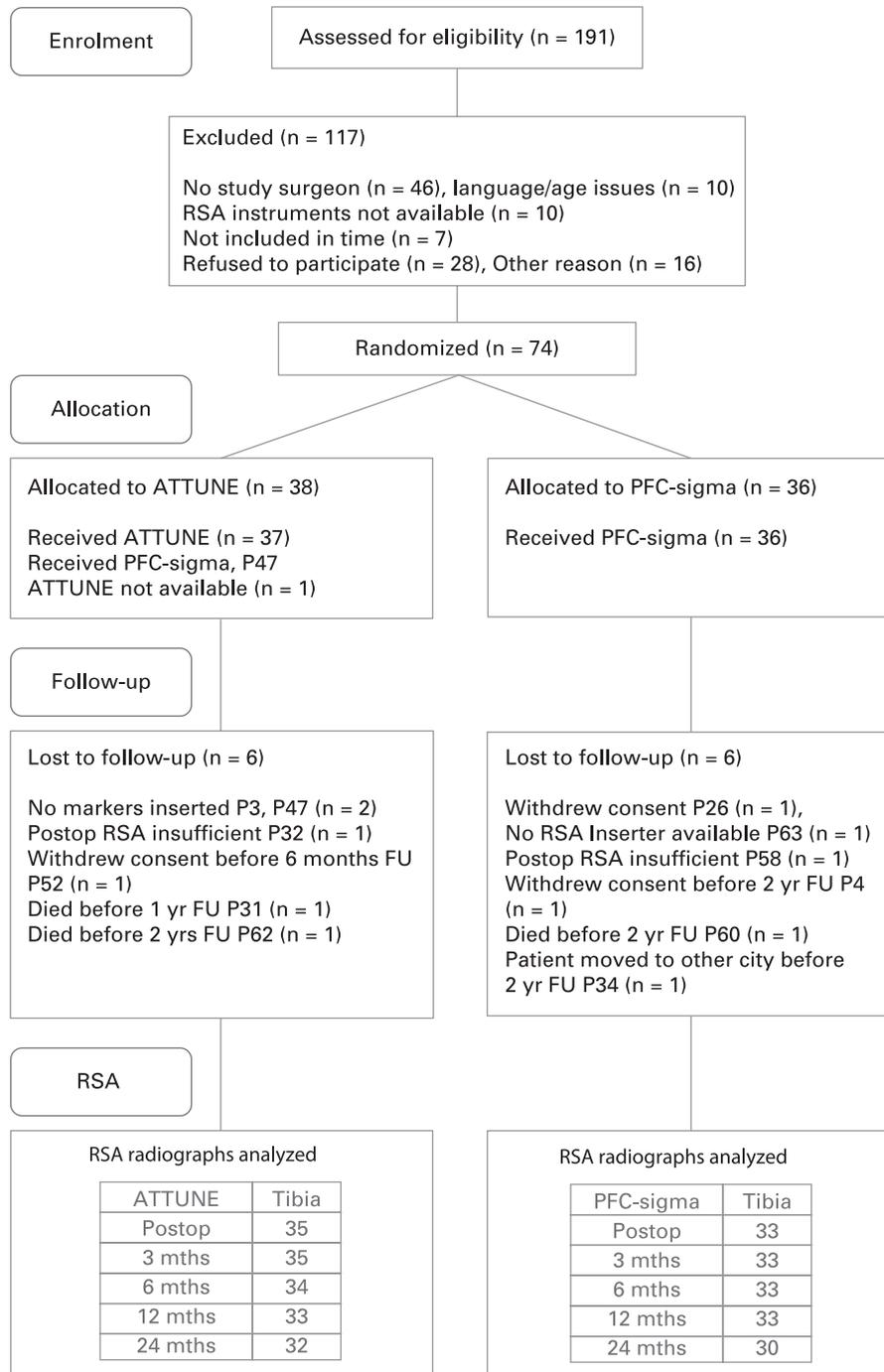


Fig. 1

Flow diagram of participants through each stage. 2Y, two-year; FU, follow-up; PFC, press-fit condylar; RSA, radiostereometric analysis.

Statistical analysis. A minimal relevant difference of 0.55 mm MTPM at two-year follow-up between two types of knee prostheses was considered important. Thus, with a power of 80%, (alpha 0.01, SD 0.6 mm) a minimum of 29 patients per group were needed in this non-inferiority study. To accommodate for loss of follow-up a minimum of 32 patients suitable for RSA analysis were included in each group (Figure 1).

Clinical data of excluded patients were evaluated on an intention-to-treat policy. Migration data were evaluated on a per-protocol policy.

A linear mixed-effects model²⁶ was used to analyze migration data and comparison between groups. MTPM was log-transformed during statistical modelling to obtain a normal distribution, computed as log(MTPM + 1). Significance was set

Table I. Baseline and surgery characteristics.

Number of patients	ATTUNE (n = 38)	PFC-sigma (n = 36)
Sex (male/female)	18/20	11/25
BMI, mean (SD) kg/m ²	29 (4.2)	28 (4.0)
ASA grade		
I	9	5
II	23	28
III	6	3
Age, mean (SD) years	69 (9.5)	68 (8.2)
Surgeon		
1	7	5
2	16	15
3	15	16
Smoking		
Yes	7	5
No	31	31
Operating time, mean (SD) mins*	84 (12.3)	77 (11.2)
Postoperative HKA		
Varus (< 178°)	1	1
Neutral (178° to 182°)	30	32
Valgus (> 182°)	1	2
Not measured	6	1
Patellar resurfacing†		
Yes	2	8
No	36	28

*p = 0.011, Welch modified two-sample t-test.

†p = 0.034, (N-1) chi-squared test.

ASA, American Society of Anesthesiologists; BMI, body mass index; HKA, hip-knee-ankle angle; PFC, press-fit condylar.

Table II. Precision of the RSA set-up, mean, and SD of 61 double examinations.

Value	Tx, mm	Ty, mm	Tz, mm	Rx, °	Ry, °	Rz, °	MTPM, mm
Mean	0.02	-0.02	0.06	0.08	0.04	-0.03	0.56
(SD)	(0.13)	(0.14)	(0.33)	(0.51)	(0.57)	(0.15)	(0.50)

MTPM, maximum total point motion; RSA, radiostereometric analysis; Rx, Ry, Rz, rotations; Tx, Ty, Tz, translations.

at a p-value ≤ 0.05. All statistical analyses were performed in the R-software environment (R Foundation, Vienna, Austria).

Results

The RSA precision was calculated by acquiring ‘double examinations’ (Table II).¹⁹ The bone markers had a good distribution (mean condition number 54 m⁻¹) and were stable over time (two years mean error of rigid body 0.22 mm).

Tibial migration (MTPM) stabilized after an initial settling (Figure 2). The mean MTPM at two years was comparable between both types of knee implants: mean 1.13 mm (95% confidence intervals (CI) 0.97 to 1.30) for the ATTUNE and mean 1.16 mm (95% CI 0.99 to 1.35) for the PFC-sigma (Table III), although there were large variations between patients (Figure 3).

Two years postoperatively, the ATTUNE tilted backwards, more than the PFC-sigma: The mean transverse axis rotation (Rx) was -0.43° (95% CI, -0.65 to -0.21) for the ATTUNE and 0.08° (95% CI -0.16 to 0.31), for the PFC-sigma (p = 0.002, linear mixed-effects model). The mean longitudinal axis rotation

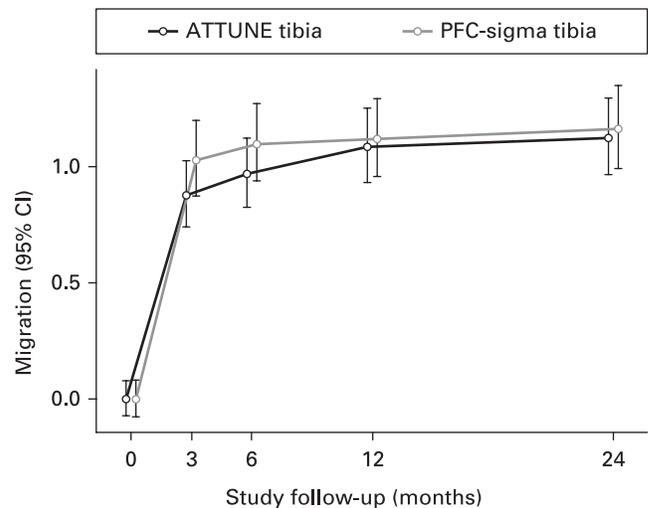


Fig. 2

Mean maximum total point motion (MTPM) migration (mm) for the tibial component.

Table III. Tibial component migration and migration rate at two-year follow-up for the ATTUNE (n = 32) and the PFC-sigma (n = 30).

Tibia prosthesis	ATTUNE	PFC-sigma
Migration, two years postoperative	Mean (95% CI)	Mean (95% CI)
Tx, mm	0.00 (-0.12 to 0.12)	-0.11 (-0.23 to 0.01)
Ty, mm	-0.01 (-0.07 to 0.05)	-0.06 (-0.12 to 0.00)
Tz, mm	-0.22 (-0.39 to -0.04)	0.04 (-0.14 to 0.22)
Rx, °	-0.43 (-0.65 to -0.21)	0.08 (-0.16 to 0.31)
Ry, °	0.31 (0.08 to 0.54)	-0.13 (-0.37 to 0.11)
Rz, °	-0.08 (-0.20 to 0.05)	0.04 (-0.09 to 0.18)
MTPM, mm	1.13 (0.97 to 1.30)	1.16 (0.99 to 1.35)
Migration rate, second postoperative year		
Tx, mm/yr	0.01 (-0.04 to 0.07)	0.04 (-0.02 to 0.10)
Ty, mm/yr	-0.04 (-0.09 to 0.02)	-0.06 (-0.12 to -0.01)
Tz, mm/yr	-0.01 (-0.18 to 0.16)	0.07 (-0.11 to 0.24)
Rx, °/yr	-0.02 (-0.20 to 0.17)	0.24 (0.04 to 0.44)
Ry, °/yr	0.09 (-0.12 to 0.30)	0.02 (-0.2 to 0.24)
Rz, °/yr	-0.06 (-0.13 to 0.01)	-0.05 (-0.12 to 0.03)
MTPM, mm/yr	0.02 (-0.06 to 0.09)	0.02 (-0.07 to 0.10)

CI, confidence interval; MTPM, maximum total point motion; Rx, Ry, Rz, rotations; Tx, Ty, Tz, translations.

(Ry) was 0.30° (95% CI, 0.08 to 0.53) for the ATTUNE, and -0.13° (95% CI, -0.37 to 0.11) for the PFC-sigma (p = 0.013, linear mixed-effects model). For the ATTUNE, this backwards tilting also resulted in a mean sagittal axis translation (Tz) of -0.22 mm (95% CI -0.39 to -0.04) (Table III).

Migration rate (MTPM/year) in the second postoperative year was negligible; mean 0.02 mm/year (95% CI -0.06 to 0.09) for the ATTUNE, and 0.02 mm/year (95% CI -0.07 to 0.10) for the PFC-sigma. Mean component tilting in the second postoperative year was larger for the PFC-sigma: the mean transverse axis rotation (Rx) of the ATTUNE was -0.02°/year (95% CI -0.20 to 0.17), while the PFC-sigma tilted forward: 0.24°/year

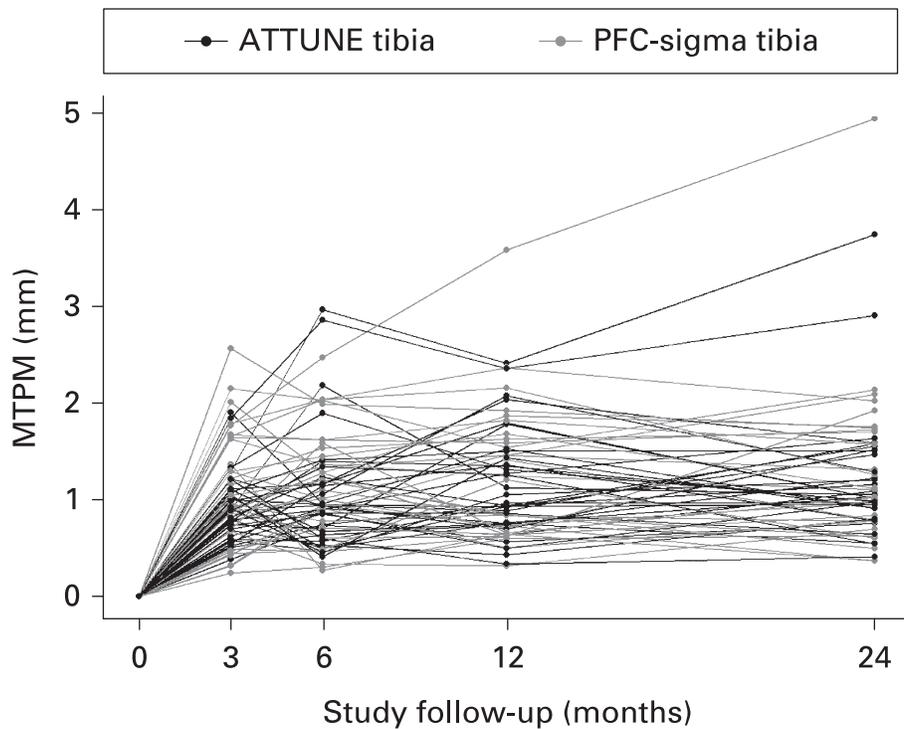


Fig. 3

Maximum total point motion (MTPM) tibia migration for each patient showing the individual variation.

(95% CI 0.04 to 0.44) ($p = 0.025$, linear mixed-effects model) (Table III, Figure 4, and Supplementary table i).

One PFC-sigma patient was successfully treated for a periprosthetic infection in the second postoperative year, by arthrotomy, debridement, liner exchange, and six weeks of antibiotics. Another PFC-sigma patient was treated by a release of the posterior tibial nerve in the tarsal tunnel in the second postoperative year, which was unrelated to the TKA. Apart from the liner exchange, no patients required revision surgery. Three patients died due to causes unrelated to the study.

Postoperatively, the clinical outcomes and PROMs improved compared to the preoperative period in both groups (Table IV). The majority of the knees were reconstructed to the neutral position (Table I). At two weeks postoperatively, medial implant-cement interface radiolucent lines were 17% and 3% for the ATTUNE and PFC-sigma respectively ($p = 0.052$, (N-1) chi-squared test) (Table V). Most were progressive and were 42% for the ATTUNE and 9% for the PFC-sigma at two years postoperatively ($p = 0.002$, (N-1) chi-squared test). All implant-cement interface radiolucencies were less than 2 mm thick (Table V). At the lateral cement-bone interface, radiolucencies were found at two weeks for one ATTUNE case (2.8 mm) and one PFC-sigma case (1.6 mm), both radiolucencies were not visible at two-year follow-up (data not shown).

As a post-hoc analysis, the ATTUNE group was separated into a group without radiolucencies ($n = 22$) and a group with radiolucencies underneath the medial or lateral baseplate at

two-year follow-up ($n = 13$). There was no difference in any of the migration parameters between these groups.

Discussion

Comparing the MTPM migration profiles of the ATTUNE with the PFC-sigma tibial components confirms our hypothesis that with respect to overall migration, the ATTUNE is at least as good as the PFC-sigma. Even though the ATTUNE had relatively large backward tilting and a relatively high incidence of radiolucencies at the implant-cement interface below the medial baseplate. There was no relation between these radiolucencies and any of the migration profiles (translations, rotations, MTPM). Similar to other studies,^{13,27-29} differences in the secondary outcome parameters such as clinical outcome and PROMS were not found, but the study was not powered for these parameters.

In theory, a cemented tibial component should have no migration, but the transverse- (Rx) and longitudinal-axis (Ry) rotations of the ATTUNE were statistically significant and larger than for the PFC-sigma indicating more backward tilting and more external rotation of the ATTUNE tibial component. The increased backwards tilting, which even continues between six and 12 months, may be the consequence of the increased congruency of the ATTUNE articulating surfaces. The latter should also give more rollback of the ATTUNE prosthesis seen intraoperatively,³⁰ although this has to be confirmed by in vivo fluoroscopy studies. It might also be that this backwards tilting

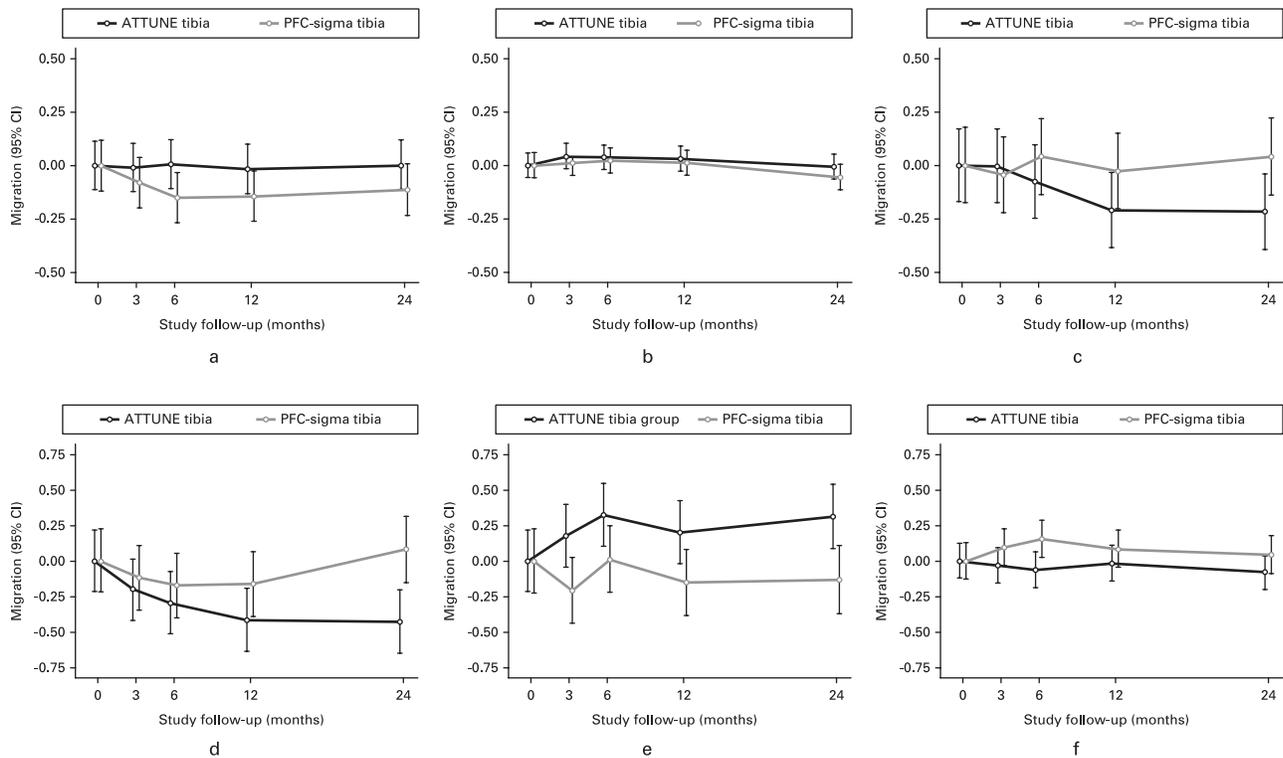


Fig. 4

Translations (mm): a) Tx, b) Ty, c) Tz, and rotations (°): d) Rx, e) Ry, f) Rz for the tibial component.

Table IV. Patient-reported outcome measures (PROMs) data for the preoperative and all follow-up timepoints.

PROM	ATTUNE					PFC-sigma				
	Preoperative mean (SD)	3 mths	6 mths	12 mths	24 mths	Preoperative mean (SD)	3 mths	6 mths	12 mths	24 mths
KOOS symptoms	53 (15.8)	71 (16.9)	76 (13.8)	80 (13.8)	82 (15.6)	49 (18.1)	76 (16.7)	78 (16.4)	85 (11.7)	88 (10.4)
KOOS pain	46 (13.4)	77 (19.0)	76 (21.6)	84 (16.9)	87 (14.8)	47 (16.2)	79 (17.1)	82 (18.3)	87 (14.8)	89 (16.5)
KOOS sport/rec	20 (19.0)	54 (24.9)	63 (25.2)	62 (24.8)	65 (27.9)	18 (23.3)	48 (27.7)	53 (30.1)	50 (26.7)	62 (27.2)
KOOS ADL	52 (15.2)	79 (17.5)	78 (21.1)	86 (15.9)	89 (14.4)	53 (20.0)	82 (14.9)	83 (16.9)	87 (15.1)	88 (16.6)
KOOS QOL	29 (13.9)	60 (18.0)	62 (21.1)	69 (19.4)	74 (22.3)	28 (18.4)	64 (16.1)	69 (22.5)	77 (18.5)	77 (22.7)
Pain at rest	5 (2.3)	2 (2.5)	2 (2.1)	1 (1.6)	1 (1.5)	5 (2.4)	1 (1.8)	1 (2.2)	1 (1.2)	1 (2.0)
Pain during activity	7 (2.0)	3 (2.6)	2 (2.4)	2 (2.1)	2 (1.8)	7 (2.2)	2 (1.9)	2 (2.6)	2 (2.1)	1 (2.2)
EQ5D	70 (15.7)	77 (19.0)	80 (11.1)	76 (17.4)	82 (10.5)	69 (16.8)	80 (10.4)	70 (21.7)	78 (12.9)	81 (14.2)
KSS*	51 (12.4)	80 (13.2)	85 (13.9)	91 (9.6)	93 (8.0)	54 (13.3)	85 (9.8)	89 (11.2)	93 (10.0)	95 (8.3)
OKS	15 (8.6)	25 (7.9)	26 (7.2)	28 (7.5)	31 (7.1)	13 (8.2)	27 (7.1)	28 (10.2)	31 (6.6)	31 (7.4)

*Combination of knee and function score.

ADL, activities of daily living; EQ5D, EuroQol 5 Dimensions; KOOS, Knee Injury and Osteoarthritis Outcome Score; KSS, Knee Society Score; QOL, quality of life; OKS, Oxford Knee Score; rec, recreation.

is an early sign of loosening, as it has been suggested that rotations about the transverse (Rx) axis have a better predictive power than MTPM for loosening of tibial components.³¹ The stabilization in the second postoperative year is a positive sign for the long term durability of the ATTUNE prosthesis,^{5,32} while the PFC-sigma prosthesis shows forward tilting in the second postoperative year.

Although MTPM values are often used as cut-off points for performance of orthopaedic implants,^{5,32,33} for an absolute (unsigned) measure such as MTPM, this is difficult as, for

mathematical reasons, mean MTPM will be larger with lower precision. For that matter, the two-year mean MTPM migration of the cemented PFC-sigma tibial prosthesis in this study was 1.16 mm, while von Schewelov et al¹² reported 0.5 mm for the same prosthesis. The overall migration rate in the second postoperative year was negligible for both components, which we consider more important than the absolute migration values.

As the ATTUNE was launched in 2013, the first five years of data are now available in the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man

Table V. Number (%), mean, and range of the radiolucencies at the implant-cement interfaces in mm at two weeks (number of patients = 36/35) and two years (number of patients = 33/35) postoperatively for the ATTUNE and PFC-sigma tibial components.

Location*	ATTUNE		PFC-sigma		p-value*
	n (%)	Mean (range)	n (%)	Mean (range)	
AP Z1, 2 wks	6 (17)	0.7 (0.4 to 0.9)	1 (3)	1.3	0.052
AP Z1, 2 yrs	14 (42)	0.9 (0.4 to 1.4)	3 (9)	1.1 (0.5 to 2.0)	0.002
AP Z2, 2 wks	2 (6)	1.3 (0.6 to 2.0)	1 (3)	0.5	
AP Z2, 2 yrs	2 (6)	1 (0.6 to 1.4)	1 (3)	0.8	
LAT Z1, 2 wks	1 (3)	0.2	0 (0)		
LAT Z2, 2 wks	3 (8)	0.9 (0.7 to 1.2)	1 (3)	0.5	
LAT Z3A, 2 wks	1 (3)	0.9	0 (0)		

*(N-1) chi-squared test.

AP, anteroposterior; LAT, lateral; LZ1 (anterior baseplate); LZ2 (posterior baseplate); LZ3A (anterior stem); Z1 (medial baseplate); Z2 (lateral baseplate).

(NJR) and the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). According to the AOANJRR, the five years' cumulative revision percentage for the cemented ATTUNE CR and PFC-sigma CR are similar: 2.3% (95% CI: 1.9, 2.7) for the ATTUNE and 2.5% (95% CI: 2.2, 2.7) for the PFC-sigma.³⁴ In the NJR, there seems to be a difference: 2.67% (95% CI: 2.09, 3.41) for the cemented ATTUNE and 1.96% (95% CI: 1.91, 2.01) for the cemented PFC-sigma, although these numbers are for the CR and posterior stabilized versions combined.

Recently some worrying reports have been presented on potential problems with up to 35.1% radiolucencies in 276 cemented ATTUNE knee prostheses, compared to 7.5% in 253 PFC-sigma knee prostheses at 12 months postoperatively.¹⁴ These data are not confirmed by a study by Ranawat et al,¹³ but data from our study confirm these results; at two years postoperatively, 42% radiolucencies were seen between the ATTUNE medial baseplate and the cement, compared to 9% for the PFC-sigma ($p = 0.001$).

One paper reported more revisions supposedly related to cement implant debonding for the ATTUNE,¹⁵ however this was a case series without reporting the size of the series in which the findings were made, making it of limited scientific value.^{35,36} Potential problems with cement adherence to the undersurface of the tibial plateau have also been presented by others,^{37,38} and for other modern tibial components of TKA implants.³⁹ Although the undersurface of the ATTUNE tibial plateau has increased roughness compared to the PFC-sigma, it is not equipped with a cement pocket area with an undercut.³⁸

In 2017, a redesign of the tibial plateau with an undercut and even more surface roughness to facilitate extra cement bonding was launched by the manufacturer. An RSA migration study for this new ATTUNE S + tibia design has been started (clinical trial number NCT04037735).

Based on the results of this paper showing increased backwards tilting, the relatively large number of radiolucencies, confirmed by the literature, worrying reports about increased revision rates as a result of cement debonding, the larger revision rates in one of the registries and the fact that the manufacturer changed the design of the implant only four years after its first introduction, we would like to raise concerns about the further widespread use of this specific ATTUNE tibial implant design.

Turgeon et al⁴⁰ reported good implant stability measured with RSA for the ATTUNE PS design, both for MTPM as well as for translations and rotations. Comparison with the Turgeon study is difficult since they used a PS design and used a baseline of six weeks postoperatively, while we studied a CR design and a directly postoperative baseline. Turgeon et al⁴⁰ found mean (SD) values below 0.02 (0.08) mm for translations, 0.06° (0.18°) for rotations, and 0.21 (0.12) mm for MTPM, which is remarkably small compared to our data. This indicates that most migration (if any) occurred before six weeks postoperatively. We found backward tilting of the ATTUNE tibial component between three months (-0.20°) and 12 months (-0.42°) postoperatively (Supplementary table i).

A limitation of this study is that only 74 out of 191 eligible patients were randomized. More than half of the 117 excluded patients had surgery by non-study surgeons or refused to participate. Other reasons are described in Figure 1.

Another limitation of this study is that even for model-based RSA, the precision of the migration calculations in this study is relative low.¹⁷ Reasons for this might be the use of computer radiology which is less accurate than digital radiology,⁴¹ inaccuracy of the CAD models, and the use of two different calibration box designs. For that matter, the precision results in our study are about two times worse compared to other clinical model-based RSA studies.⁴² As the Haaglanden Medical Centre has three different locations, the use of two calibration boxes for this study was inevitable. Even though the randomized controlled trial design of the study makes it unlikely this will have an effect on the interpretation as there was no bias in the use of calibration box by prosthesis group.

Another limitation is that the two-year radiolucencies were measured in long-leg standing radiographs. Nevertheless, most of the radiolucencies that were detected at two weeks' regular AP radiographs progressed and were also measured at two years.

In conclusion, in the first two postoperative years the initial version of the ATTUNE tibial component was not inferior with respect to overall migration (MTPM), although it showed relatively more backwards tilting and radiolucencies at the implant-cement interface than the PFC-sigma. The version of the ATTUNE tibial component examined in this study has subsequently undergone modification by the manufacturer.



Take home message

- Short-term implant migration is predictive for long-term aseptic loosening, therefore we compared migration of the new ATTUNE cemented fixed bearing cruciate retaining tibial component with the established press fit condylar (PFC) sigma cemented fixed bearing cruciate retaining tibial component that has good long-term clinical outcomes.

- In the first two postoperative years the ATTUNE tibial component was not inferior with respect to overall migration, although it showed relative more backwards tilting and radiolucent lines at the implant-cement interface than the PFC-sigma.

- This is the first randomized controlled RSA study on the ATTUNE tibial component. The version of the ATTUNE tibial component examined in this study has subsequently undergone modification by the manufacturer.

Twitter

Follow the authors @LUMC_Leiden

Supplementary material



Overview table of all migration results for the tibial component.

References

- Kurtz S, Ong K, Lau E, Mowat F, Halpern M.** Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. *J Bone Joint Surg Am.* 2007;89-A(4):780–785.
- Lum ZC, Shieh AK, Dorr LD.** Why total knees fail-A modern perspective review. *World J Orthop.* 2018;9(4):60–64.
- Nelissen RGHH, Pijls BG, Kärrholm J, et al.** Rsa and registries: the quest for phased introduction of new implants. *J Bone Joint Surg Am.* 2011;93-A(Suppl 3):62–65.
- Pijls BG, Nieuwenhuijse MJ, Schoones JW, et al.** Rsa prediction of high failure rate for the uncoated Interax TKA confirmed by meta-analysis. *Acta Orthop.* 2012;83(2):142–147.
- Pijls BG, Valstar ER, Nouta KA, et al.** Early migration of tibial components is associated with late revision: a systematic review and meta-analysis of 21,000 knee arthroplasties. *Acta Orthop.* 2012;83(6):614–624.
- Laende EK, Richardson CG, Dunbar MJ.** Predictive value of short-term migration in determining long-term stable fixation in cemented and cementless total knee arthroplasties. *Bone Joint J.* 2019;101-B(7_Suppl_C):55–60.
- Malchau H.** On the importance of stepwise introduction of new hip implant technology: assessment of total hip replacement using clinical evaluation, radiostereometry, digitized radiography and a national hip registry. Göteborg, Sweden: Göteborg University, 1995. <https://gupea.ub.gu.se/handle/2077/12932> (date last accessed 25 June 2020).
- Faro LMC, Huiskes R.** Quality assurance of joint replacement legal regulation and medical judgement. *Acta Orthop Scand.* 1992;63(sup250):1–33.
- No authors listed.** Annual Report 2018. Hip, Knee & Shoulder Arthroplasty. Australian Orthopaedic Association. National Joint Replacement Registry (AOANJRR). <https://aoanjrr.sahmri.com/annual-reports-2018> (date last accessed 25 June 2020).
- The NJR Editorial Board.** National Joint Registry for England, Wales, Northern Ireland and the Isle of Man. 15th Annual Report 2018. 2018. <https://reports.njrcentre.org.uk/Portals/7/PDFdownloads/NJR%2015th%20Annual%20Report%202018.pdf> (date last accessed 14 July 2020).
- Robertsson O, W-Dahl A, Lidgren L, Sundberg M.** Annual Report 2018. Swedish Knee Arthroplasty Register. http://myknee.se/pdf/SVK_2018_Eng_1.0.pdf (date last accessed 25 June 2020).
- Schewelov T, Besjakov J, Sanzén L, Carlsson Åke.** A Clinical and Radiostereometric Study of the Cemented PFC-Sigma Prosthesis – A 5-Year Study of 29 Cases with a Fixed Bearing. *J Knee Surg.* 2009;22(03):231–236.
- Ranawat CS, White PB, West S, Ranawat AS.** Clinical and radiographic results of Attune and pFC sigma knee designs at 2-year follow-up: a prospective matched-pair analysis. *J Arthroplasty.* 2017;32(2):431–436.
- Staats K, Wannmacher T, Weihs V, et al.** Modern cemented total knee arthroplasty design shows a higher incidence of radiolucent lines compared to its predecessor. *Knee Surg Sports Traumatol Arthrosc.* 2019;27(4):1148–1155.
- 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(05):435–439.
- Selvik G, stereophotogrammetry R.** A method for the study of the kinematics of the skeletal system. *Acta Orthop Scand Suppl.* 1989;232:1–51.
- Kaptejn BL, Valstar ER, Stoel BC, Rozing PM, Reiber JHC.** A new model-based RSA method validated using CAD models and models from reversed engineering. *J Biomech.* 2003;36(6):873–882.
- Valstar ER, Gill R, Ryd L, et al.** Guidelines for standardization of radiostereometry (RSA) of implants. *Acta Orthop.* 2005;76(4):563–572.
- No authors listed.** Implants for surgery - Roentgen stereophotogrammetric analysis for the assessment of migration of orthopaedic implants. International Standard. 2013 2013-10-01. Contract No.: ISO 16087:2013(E). International Organization for Standardization (ISO). <https://www.iso.org/standard/55662.html> (date last accessed 25 June 2020).
- Meneghini RM, Mont MA, Backstein DB, et al.** Development of a modern knee Society radiographic evaluation system and methodology for total knee arthroplasty. *J Arthroplasty.* 2015;30(12):2311–2314.
- Insall JN, Dorr LD, Scott RD, Scott WN.** Rationale of the knee Society clinical rating system. *Clin Orthop Relat Res.* 1989;248:13–14.
- Fransen M, Edmonds J.** Reliability and validity of the EuroQol in patients with osteoarthritis of the knee. *Rheumatology.* 1999;38(9):807–813.
- Roos EM, Lohmander LS.** The knee injury and osteoarthritis outcome score (KOOS): from joint injury to osteoarthritis. *Health Qual Life Outcomes.* 2003;1(1):64.
- de Groot IB, Reijman M, Terwee CB, et al.** Validation of the Dutch version of the hip disability and osteoarthritis outcome score. *Osteoarthritis and Cartilage.* 2007;15(1):104–109.
- Murray DW, Fitzpatrick R, Rogers K, et al.** The use of the Oxford hip and knee scores. *J Bone Joint Surg Br.* 2007;89-B(8):1010–1014.
- Ranstam J, Turkiewicz A, Boonen S, et al.** Alternative analyses for handling incomplete follow-up in the intention-to-treat analysis: the randomized controlled trial of balloon kyphoplasty versus non-surgical care for vertebral compression fracture (free). *BMC Med Res Methodol.* 2012;12(1):35.
- Chua JL, Goh GS-H, Liow MHL, et al.** Modern TKA implants are equivalent to traditional TKA implants in functional and patellofemoral joint-related outcomes. *Knee Surg Sports Traumatol Arthrosc.* 2019;27(4):1116–1123.
- Behrend H, Zdravkovic V, Bösch M, Hochreiter B.** No difference in joint awareness after TKA: a matched-pair analysis of a classic implant and its evolutionary design. *Knee Surg Sports Traumatol Arthrosc.* 2019;27(7):2124–2129.
- Molloy IB, Keeney BJ, Sparks MB, et al.** Short term patient outcomes after total knee arthroplasty: does the implant matter? *Knee.* 2019;26(3):687–699.
- Takagi H, Asai S, Sato A, et al.** Case series report of navigation-based *in vivo* knee kinematics in total knee arthroplasty with a gradually reducing femoral radius design. *Annals of Medicine and Surgery.* 2017;17(17):33–37.
- Gudnason A, Adalberth G, Nilsson K-G, Hailer NP.** Tibial component rotation around the transverse axis measured by radiostereometry predicts aseptic loosening better than maximal total point motion. *Acta Orthop.* 2017;88(3):282–287.
- Pijls BG, Plevier JWM, Nelissen RGHH.** Rsa migration of total knee replacements. *Acta Orthop.* 2018;89(3):320–328.
- 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.
- No authors listed.** Annual Report 2019. Hip, Knee & Shoulder Arthroplasty. Australian Orthopaedic Association. National Joint Replacement Registry (AOANJRR). <https://aoanjrr.sahmri.com/documents/10180/668596/Hip%2C+Knee+%26+Shoulder+Arthroplasty/c287d2a3-22df-a3bb-37a2-91e6c0b0fcf0> (date last accessed 25 June 2020).
- Mont M.** Isolated group of failures without denominator. *J Knee Surg.* 2018;31(06):591–592.
- 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(08):811–814.
- Maag C, Peckenpaugh E, Metcalf A.** Influence Of Intraoperative Lipid /Marrow Infiltration And Intraoperative Motions Upon Cemented Tibial ImplantFixation. [Abstract]. *18th EFORT Congress.* Vienna, Austria, 2017.
- Cerquiglini A, Henckel J, Hothi H, et al.** Analysis of the Attune tibial Tra backside: a comparative retrieval study. *Bone Joint Res.* 2019;8(3):136–145.
- Arsoy D, Pagnano MW, Lewallen DG, Hanssen AD, Sierra RJ.** Aseptic tibial debonding as a cause of early failure in a modern total knee arthroplasty design. *Clin Orthop Relat Res.* 2013;471(1):94–101.

40. **Turgeon TR, Gascoyne TC, Laende EK, et al.** 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.
41. **Honey ID, Mackenzie A.** Artifacts found during quality assurance testing of computed radiography and digital radiography detectors. *J Digit Imaging.* 2009;22(4):383–392.
42. **Nieuwenhuijse MJ, van der Voort P, Kaptein BL, et al.** Fixation of high-flexion total knee prostheses: five-year follow-up results of a four-arm randomized controlled clinical and roentgen stereophotogrammetric analysis study. *J Bone Joint Surg Am.* 2013;95-A(19):e1411–e11.

Author information:

B. L. Kaptein, PhD, Senior Researcher
 R. G. H. H. Nelissen, PhD, MD, Professor, Head of Department, Orthopaedic Surgeon
 Department of Orthopaedics, Leiden University Medical Center, Leiden, Netherlands.

P. den Hollander, MSc, MD, Orthopaedic Surgeon, Department of Orthopaedic Surgery, Haaglanden Medical Center, The Hague, Netherlands.

B. Thomassen, PhD, Coordinator Centre of Expertise Health Innovation, Faculty Health, Nutrition and Sports, The Hague University of Applied Sciences, The Hague, Netherlands.

M. Fiocco, PhD, Statistician, Mathematical Institute, Leiden University, Leiden, The Netherlands; Medical Statistics, Department of Biomedical Data Sciences, Leiden University Medical Center, Leiden, Netherlands.

Author contributions:

B. L. Kaptein: Wrote the paper, Set up the study, Conducted the statistical analysis, Conducted the radiostereometric radiograph analysis.

P. den Hollander: Wrote the paper, Performed the surgery, Collected the data.

B. Thomassen: Reviewed the paper, Collected the data, Analyzed the data.

M. Fiocco: Reviewed the paper, Conducted the statistical analysis.

R. G. H. H. Nelissen: Reviewed the paper, Set up the study.

Funding statement:

The study was investigator-driven; DePuy Synthes provided funds in support of the costs associated with this RSA study, but did not take part in the design, analysis, interpretation, or writing of the manuscript. Although none of the authors has received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article, benefits have been or will be received but will be directed solely to a research fund, foundation, educational institution, or other non-profit organization with which one or more of the authors are associated.

Acknowledgements:

Rudolf van der Flier for performing part of the surgeries, Shaho Hasan for measuring radiolucencies, and Lennard Koster for RSA analysis and HKA measurements.

ICMJE COI statement:

P. den Hollander, B. L. Kaptein, R. Nelissen and B. Thomassen report an institutional grant from DePuy Synthes related to the study.

Ethical review statement:

The trial was performed in compliance with the Declaration of Helsinki and Good Clinical Practice guidelines. The study was approved by the Committee for Medical Ethics (CME) of Leiden University Medical Center (LUMC) (Protocol ID P14.142, ABR No. 48357) and was registered in Clinical Trials (ClinicalTrials.gov ID NCT02256098). Informed consent was obtained from all patients. Reporting of the trial was in accordance with the CONSORT statement.

Trial registration number:

NCT02256098.

Open access statement:

This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial No Derivatives (CC BY-NC-ND 4.0) licence, which permits the copying and redistribution of the work only, and provided the original author and source are credited. See <https://creativecommons.org/licenses/by-nc-nd/4.0/>.

This article was primary edited by G. Scott.