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Similar early migration when comparing CR and PS in Triathlon™ TKA: A prospective randomised RSA trial

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ABSTRACT

Objectives: The objective of this study was to compare the early migration of the cruciate retaining and posterior stabilising versions of the recently introduced Triathlon™ total knee system, with a view to predicting long term fixation performance.
Methods: Sixty patients were prospectively randomised to receive either Triathlon™ posterior stabilised cemented knee prosthesis or Triathlon™ cruciate retaining cemented knee prosthesis. Tibial component migration was measured by radiostereometric analysis postoperatively and at three months, one year and two years. Clinical outcome was measured by the American Knee Society Score and Knee Osteoarthritis and Injury Outcome Score.
Results: There were no differences in rotation around the three coordinal axes or in the maximum total point motion (MTPM) during the two year follow-up. The posterior stabilised prosthesis had more posterior–anterior translation at three months and one year and more caudal–cranial translation at one year and two years. There were no differences in functional outcome between the groups.
Conclusion: The tibial tray of the Triathlon™ cemented knee prosthesis showed similar early stability.
Level of evidence: Level I.
Article summary: Article focus:
This was a prospective randomised trial aiming to compare the single radius posterior stabilised (PS) Triathlon™ total knee arthroplasty (TKA) to the cruciate retaining Triathlon™ TKA system with regard to fixation.
Strengths and limitations of this study:
Strength of this study was that it is a randomised prospective trial using an objective measuring tool. The sample size of 25–30 patients was reportedly sufficient for the screening of implants using RSA [1].
Trial registration:
ClinicalTrials.gov Identifier: NCT00436982.

1. Introduction

In the healthy knee, the posterior cruciate ligament (PCL) causes posterior translation of the femur onto the tibia or "roll back" during knee flexion [2,3]. At high flexion the anterolateral bundle of the PCL is thought to constrain the mediolateral translation of the tibia, whilst the posteromedial bundle constrains the anteroposterior translation of the tibia [4]. In patients having a total knee replacement (TKA), the stabilising action of an intact PCL can assist in maintaining the natural knee movements [5,6] and therefore there is some controversy over whether it is best to retain the PCL and use a cruciate retaining (CR) prosthesis or to remove it and use a posterior stabilising (PS) prosthesis during TKA. Currently there is limited scientific evidence to assist surgeons in deciding whether to use a CR or a PS design and the main factors influencing this choice are the degenerative status of the ligament, the type of implant available and the preference of the surgeon [7].

The presence of micromotion, as measured by radiostereometric analysis (RSA) of prostheses within the first two years, can serve as a predictor of late mechanical loosening and long-term failure [1]. In a study comparing a PS design with a mobile bearing (MB) design, a higher variability in subsidence and rotation about the transverse axis was found for the PS group [8]. An increase in varus–valgus tilting of the tibial component has also been reported for PS designs [9]. There is little data available in the literature describing difference in micromotion between the CR and PS concepts.

The purpose of this study was to compare the amount of short-term three-dimensional micromotion of the tibial component between the

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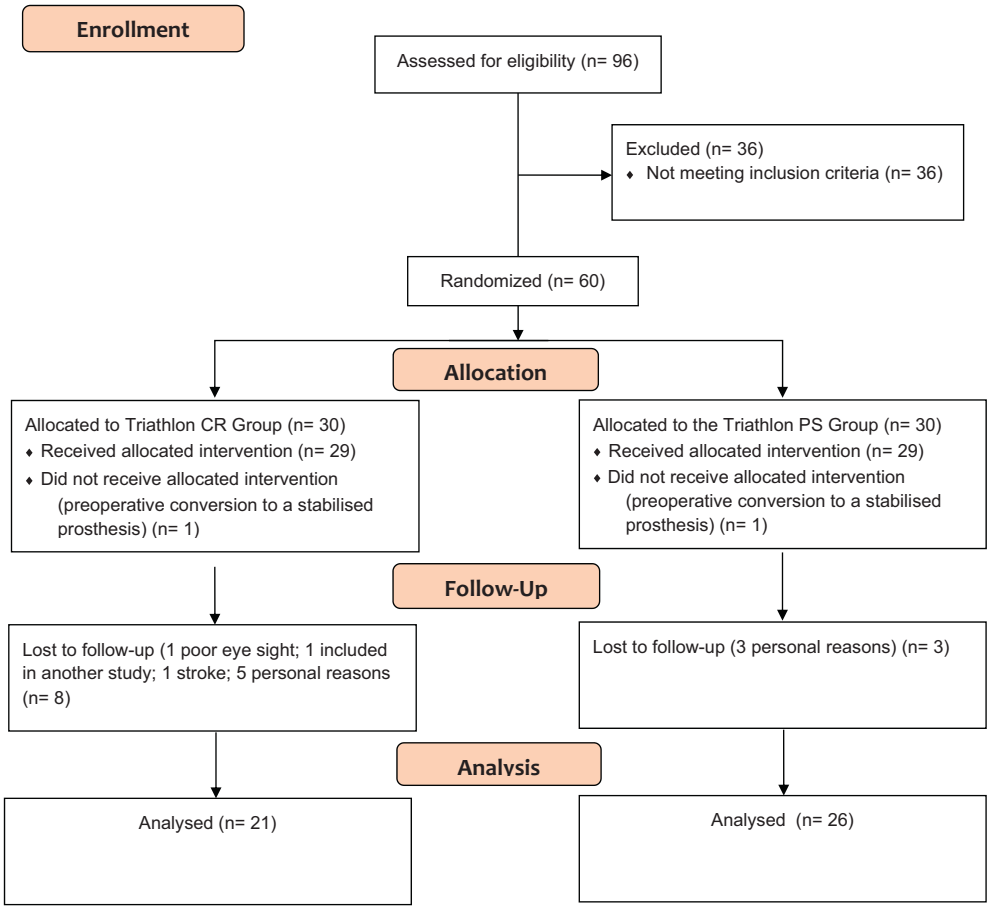

Fig. 1. CONSORT recruitment and follow-up chart.

PS and CR variants of a recently introduced total knee system using RSA. This study provides data for a new TKA design for which there is currently very limited information on function and likely long-term prosthetic fixation.

2. Patients and methods

2.1. Design

This study was a prospective randomised study of patients receiving a TKA for treatment of osteoarthritis of the knee. Patients were recruited from a single centre and were prospectively randomised to receive either a Triathlon™ PS or Triathlon™ CR (Stryker, Mahwah, New Jersey, USA) total knee system.

2.2. Participants

Randomisation was achieved using a sealed envelope technique. Three surgeons (MM, CFN and STL) were involved in both the selection and operation of the patients. During the period of trial 96 total knee replacements were performed in 96 patients using either the Triathlon™ PS or Triathlon™ CR total knee system; of these, 36 patients were excluded from the study due to long travelling time for follow up or for not having met the inclusion criteria. Therefore, 60 patients (24 men and 36 women) were included in the study, with 30 patients randomised to each group (Fig. 1).

Patients were blinded to the treatment allocated. Ethics Committee approval was obtained from the local medical ethics committee prior to initiation of the study. Patients were considered for enrolment according to their clinical findings and subject to gaining their written informed consent according to International Conference on Harmonisation Good Clinical Practice (ICH GCP) requirements. The inclusion criteria for selection to participate in the study are provided in Table 1. The exclusion criteria are provided in Table 2.

At two years, 26 patients were available for RSA follow-up in the Triathlon™ PS group and 21 patients were available for follow-up in the Triathlon™ CR (Fig. 1). In the Triathlon™ PS group one patient left the study due to perioperative conversion to a stabilised prosthesis; and three patients left the study due to personal reasons. In the Triathlon™ CR group, one patient left the study prior to the three month follow-up due to poor eyesight; one patient was excluded because they were already included in another study; one patient left the study due to perioperative conversion to a stabilised prosthesis; one patient left the study prior to the second year follow-up due to a stroke; and five patients left the study due to personal reasons (Fig. 1).

Table 1
Inclusion criteria.

Inclusion criteria
1. Patient suffering exclusively from OA; stages II–V (Ahlback 1968)
2. Patient requiring knee prosthesis is suitable for the use of either the Duracon or Triathlon Knee System.
3. Patient understands the conditions of the study and is willing and able to comply with the scheduled post-operative clinical and radiographic evaluations and the prescribed rehabilitation.
4. Patient has signed the Ethics Committee approved Informed Consent Form prior to surgery.

Table 2
Exclusion criteria.

Exclusion criteria
1. Previous major knee arthroplasty
2. Significant disabling problems from the muscular–skeletal system other than in the knees
3. Obese patients where obesity is severe enough to affect subject's ability to perform activities of daily living (body mass index, kg/m^2: BMI ≥ 35).
4. Patients with active or suspected infection
5. Patients with malignancy — active malignancy
6. Patients with severe osteoporosis, Paget's disease, renal osteodystrophy
7. Patients who are immunologically suppressed, or receiving steroids in excess of physiologic dose requirements
8. Patients with a neuromuscular or neurosensory deficit which would limit their ability to assess the performance of the device or which interferes with the patient's ability to limit weight bearing or places an extreme load on the implant during the healing period
9. Female patients planning a pregnancy during the course of the study
10. Patients with systemic or metabolic disorders leading to progressive bone deterioration
11. Patients who, as judged by the surgeon, are mentally incompetent or unlikely to be compliant with the prescribed post-operative routine and follow-up evaluation schedule
12. Patients with other severe concurrent joint involvements which can affect their outcome
13. Patients with other concurrent illnesses, which are likely to affect their outcome such as sickle cell anaemia, systemic lupus erythematosus or renal disease requiring dialysis
14. Patients under the protection of law (e.g. guardianship)

2.3. Prosthesis

All patients received a chrome–cobalt femoral component. Both the Triathlon™ PS and Triathlon™ CR had chrome–cobalt tibial components with a delta-shaped stem and were prepared for cemented fixation with Refobacin® Bone Cement R (Biomet Inc., Warsaw, Indiana, USA). No patellar components were used in either group.

2.4. Interventions

Each patient was given preoperative antibiotics (2 g cloxacillin iv. 15 to ~45 min before surgery) and tranexamic acid (100 mg per kg administered as preparing for cementation of components). The surgeries were performed via a midline incision with a parapatellar medial entrance to the joint using appropriate guide instruments and according to the surgical-technique manual supplied with each knee system. At the time of surgery eight tantalum markers (0.8 mm diameter; RSA Biomedical, Umeå, Sweden) were inserted into the proximal tibial metaphysis and five markers were inserted in the polyethylene tibial insert. [10–12] Post-operatively low molecular weight heparin (enoxaparin 100 mg/ml, 0.4 ml sc. for 10 days, starting at 4 to 8 h post-operatively was used for thromboembolic prophylaxis. Mobilisation was similar for both groups and included full weight bearing.

Table 3
Demographic data.

Demographic data	Triathlon™ PS	Triathlon™ CR
Age (mean years ± SD)	67 ± 8	67 ± 8
Female:male	17:13	19:11
Weight (mean kg ± SD)	88 ± 14	83 ± 11
Mean body mass index (kg/m^2 ± SD)	30.8 ± 4.5	29.1 ± 3.5
Left:right	16/14	20/10
Ahlbäcks grade (n, %)		
I	0 (*0*)	0 (*0*)
II	18 (*60*)	8 (*27*)
III	12 (*40*)	22 (*73*)
IV	0 (*0*)	0 (*0*)
Mean operating time (mins ± SD)	66 ± 9	62 ± 9
Hospital stay duration (days ± SD)	5.1 ± 2.7	4.7 ± 0.9

Italic values indicate significance at $p < 0.01$.

Table 4
Hip–knee–ankle index.

HKA (°)	Triathlon™ PS	Triathlon™ CR
N (preoperative)	28	25
N (three months postoperative)	27	28
Mean ± SD (preoperative)	176 ± 8	172 ± 5
Mean ± SD (three months postoperative)	178 ± 3	179 ± 4
Range (preoperative)	159–192	161–188
Range (three months postoperative)	173–184	173–190

2.5. Evaluation

Migration of the tibial component was measured using RSA. The first RSA investigation was performed within three days of the operation after weight bearing had been achieved, and then at three months, one year and two years postoperatively. RSA was performed with the patient in a supine position, with the knee of interest inside a calibration cage (Cage 10, RSA Biomedical, Umeå, Sweden). The three-dimensional (3D) tibial component migration was measured using UmRSA software (v6.0, RSA Biomedical, Umeå, Sweden).

The migration was described as segment motion (translation and rotation) of the geometric centre of the prosthetic markers and as the maximum total point motion (MTPM). MTPM describes the 3D motion of the prosthetic marker moving the most between examinations, and was used as a simplistic way to denote the magnitude of the micromotion enabling the micromotion between the tibial insert and the tibial bone to be described.

Positive directions for translations along the orthogonal axes were: transverse (medial to lateral), longitudinal (caudal to cranial), and sagittal (posterior to anterior). Positive directions for rotations about the coordinate axes were anterior tilt (transverse axis), internal rotation (longitudinal axis), and varus (sagittal axis). An increase in MTPM of more than 0.2 mm between the first and second year follow-up was considered continuous migration [13] and these patients were classified as "at risk" of future implant loosening. In order to ensure accuracy of the measurements, stable fixation of the tantalum markers within the bone was essential. The upper limit for mean error (ME) of rigid body fitting (a measure of marker stability) was 0.2 mm, and the upper limit for condition number was 100. The upper limits for ME of rigid body fitting and condition number are generally proposed to be 0.35 mm and 150, respectively [14]. The precision of the RSA system according to the double exams were 0.12 mm, 0.21 mm, and 0.14 mm for x−, y−, and z−translations, respectively and 0.12°, 0.11°, and 0.09° for x−, y−, and z−rotations, respectively [15].

2.6. Clinical assessment

Clinical evaluation took place preoperatively and at three months, one year and two years postoperatively and consisted of the American Knee Society Score (AKSS) [16] and the Knee Injury and Osteoarthritis Outcome Score (KOOS) [17] questionnaires. Hip–knee–ankle measurements were made preoperatively and at the three-month radiographic follow-up; varus was classified as being <180° and valgus was classified as being >180°. The severity of osteoarthritis was graded according to the Ahlbäck classification [18]. The patients were evaluated by unbiased observers during the follow-up period.

2.7. Statistical analysis

2.7.1. Sample size

From previous studies the migration during the first two years for total knee prostheses has been about 1.0 ± 0.5 mm (MTPM), if this migration will decrease by 50% to 0.5 ± 0.5 mm. Considering an alpha level of 0.05 and a beta level of 0.20 (power ≈ 80%) this will require 17 cases in each group. With a ß of 0.75, 15 patients in each group will be needed. Continuous migration between the 1st and 2nd year follow-up has been

Table 5
The mean translation and rotation of the tibial component measured by RSA at three months, one year and two years. Positive directions for translations along the orthogonal axes were: transverse (medial to lateral), longitudinal (caudal to cranial), and sagittal (posterior to anterior). Positive directions for rotations about the coordinate axes were anterior tilt (transverse axis), internal rotation (longitudinal axis), and varus (sagittal axis).

RSA assessment	3 months			1 year			2 years		
	Triathlon™ PS	Triathlon™ CR	p-Value	Triathlon™ PS	Triathlon™ CR	p-value	Triathlon™ PS	Triathlon™ CR	p-Value
Mean (95% CI) translation (mm)									
Medial–lateral	0.05 (0.09)	−0.05 (0.08)	0.100	0.01 (0.12)	0.01 (0.12)	0.925	0.01 (0.14)	0.05 (0.12)	0.699
Caudal–cranial	0.06 (0.08)	0.01 (0.08)	0.341	0.14 (0.10)	−0.02 (0.12)	0.043	0.12 (0.10)	−0.07 (0.12)	0.011
Posterior–anterior	−0.10 (0.11)	0.08 (0.12)	0.022	−0.15 (0.13)	0.06 (0.12)	0.021	−0.18 (0.24)	0.06 (0.13)	0.090
Mean (95% CI) rotation (°)									
Anterior tilt	−0.13 (0.13)	0.03 (0.12)	0.080	−0.21 (0.21)	−0.09 (0.17)	0.278	−0.23 (0.23)	−0.12 (0.16)	0.450
Internal rotation	0.10 (0.15)	0.07 (0.52)	0.752	0.16 (0.19)	0.01 (0.16)	0.256	0.13 (0.21)	0.09 (0.18)	0.761
Varus	−0.06 (0.10)	0.09 (0.17)	0.110	0.03 (0.14)	0.03 (0.19)	0.958	−0.01 (0.14)	−0.06 (0.25)	0.676
Mean (95% CI) MTPM (mm)	0.49 (0.10)	0.49 (0.13)	0.945	0.66 (0.15)	0.62 (0.15)	0.873	0.77 (0.21)	0.67 (0.18)	0.445

found in up to 50% of the cases. Suppose that an improvement will have to yield a decrease in continuous migration to 10% in order to be clinic relevant, an alpha level of 0.05 and beta level of 0.20 (power = 80%) would require 25 cases in each group. Due to the risk of patient dropout, 30 patients were included in each group. The statistical analyses were performed using SPSS statistics 17.0. Depending on the nature of the study variables, frequencies (for qualitative variables) or descriptive (for continuous variables) have been presented. For qualitative variables, Chi square tests were used and for continuous variables, independent *t*-test/Mann–Whitney test and Paired sample test/Wilcoxon Rank test. Significance level was assumed to be 0.05.

3. Results

3.1. Demographics

The two groups were similar in terms of patient demographics and severity of osteoarthritis except for grades II and III ($p < 0.01$) (Table 3).

3.2. RSA and roentgen

The hip–knee–ankle (HKA) angle measurements were similar between the two groups and are presented in Table 4.

The migration of the tibial components in millimetres and degrees is presented for each of the time points in Table 5. The graphs of maximum total point motion are presented in Figs. 2 and 3. There were no differences in rotation around the three coordinal axes (all p values > 0.08). At three months there was a difference in posterior–anterior translation between the groups ($p = 0.022$). At one year there was a difference in caudal–cranial and posterior–anterior translation between the groups ($p = 0.043$ and $p = 0.021$ respectively). At two years there was difference in caudal–cranial translation between the groups (p–0.01). There was no difference in maximum total point motion (MTPM) during the two year follow-up (Table 5, Figs. 2 and 3). There were two patients in the Triathlon™ PS group and one patient in the Triathlon™ CR group who had a large increase in MTPM between the first and second year follow-up.

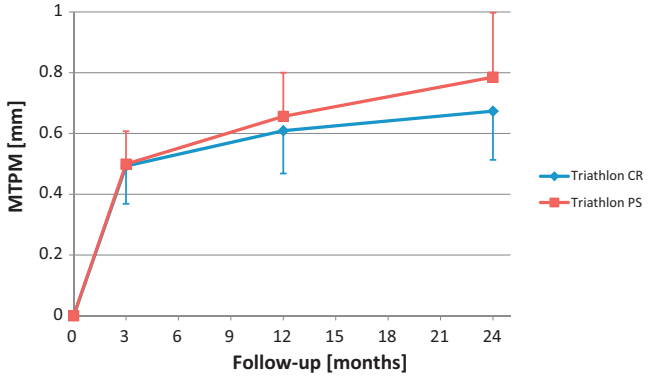

Fig. 2. Graph showing the mean maximum total point motion (MTPM) for both the Triathlon PS and Triathlon CR groups over the two-year follow-up. Error bars denote the 95% CI.

In total there were four, out of 26, tibial trays that demonstrated continuous migration (increase in MTPM > 0.2 mm) between the first and second year follow-up in the Triathlon™ PS group, and there were a total of four tibial trays, out of 21, in the Triathlon™ CR group that demonstrated continuous migration.

3.3. Clinical assessment

Both groups showed an improvement in clinical outcome score postoperatively; however, there was no difference in the clinical outcome scores between the two groups at any time point (Table 6; Fig. 4).

3.4. Adverse events

In the PS group one patient had a superficial infection. In the CR group one patient had a superficial infection, one patient had a stroke, and one patient had a pulmonary emboli.

4. Discussion

There was no major difference in our study in migration for the CR or the PS Triathlon™ total knee prosthesis. Nor was there any difference in the patient related outcome measurements.

To minimise the exposure of patients to an implant which may have poor long-term survival, the introduction of new systems of arthroplasty concepts to the market is challenging and requires continuous evaluation so that any potential adverse features are recognised early. For these reasons, all new concepts should undergo early evaluation according to a standardised model so that designs can be compared and a more accurate prediction of long-term outcome can be made [19,20]. During the last decades RSA has emerged as a method to assess prosthetic fixation [12]. The method has been used extensively to evaluate both hip and knee arthroplasty [1] as it has been shown that RSA can serve as a predictor of late mechanical loosening of prostheses [13]. So far, the Triathlon™ total knee system has demonstrated good early to mid-term results in a number of joint replacement registries [21,22]. In this study all prostheses had an initial migration with a magnitude as expected from all the experience with different RSA studies. Most prosthesis demonstrated an early stabilisation within two years. There were no differences in the prognostic continuous migration between the two groups.

As expected from other studies [23,24] the major clinical improvements had already been achieved at the three month follow-up, and there were no differences in clinical outcome (AKSS and KOOS) between the groups. This is unsurprising as there are no differences in knee scores reported in the literature comparing CR and PS designs. The only differences between CR and PS designs reported in the literature are for range of motion and AKSS [7]. However, range of motion is hard to assess [25] and the differences were small and have no clinical relevance [7].

The magnitude of the mean MTPM measured at two years for the Triathlon™ prosthesis in this study was 0.67 mm (95% CI 0.18) for CR and 0.77 mm (95% CI 0.21) for PS. This was similar to that measured

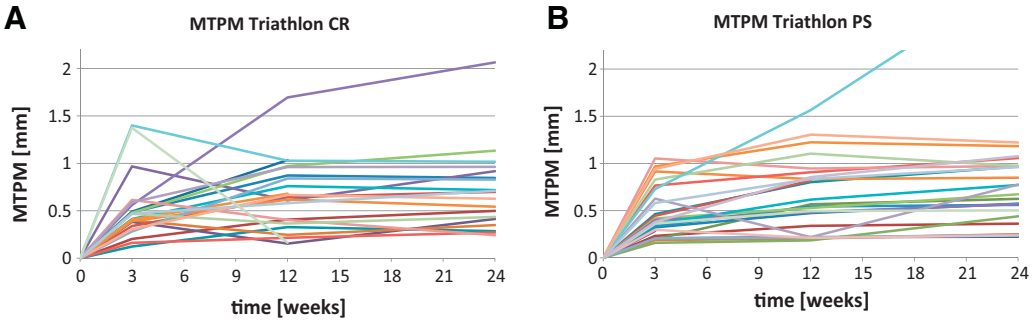

Fig. 3. Graphs showing the individual maximum total point motion (MTPM) for each knee in A) the Triathlon™ PS and B) the Triathlon™ CR Triathlon group. Each line represents the migration pattern for one patient.

for the same CR prosthesis, over two years, in our previously reported studies; 0.63 mm (95% CI 0.26) [15], 0.71 mm (SD 0.64) and 0.53 mm (SD 0.21) [26].

In our study there was no difference between the two prostheses over the two years, except for more posterior–anterior migration at three months and one year and more caudal–cranial migration at one year and two years for the PS prosthesis. Whether this increased translations found have any implications on the long-term prosthetic fixation is too early to determine. However, based on the criteria of Ryd et al. [13], the long-term survival of both prosthesis is very likely to be the same.

The results of this study suggest that the PS and CR variants of the new Triathlon™ total knee system show similar early prosthetic fixation and are likely to have similar long-term mechanical performance.

4.1. Limitations and strengths

A recent discussion of phased introduction of new implants indicates that the mean MTPM of the first year of FU could be used as an early detector of late mechanical loosening [19]. At one year the mean MTPM (95% CI) was 0.66 (0.15) for the PS- and 0.62 (0.15) for the CR-group. The limit for what is described as the first class group is MTPM (<0.5 mm) [19]. In this study the MTPM mean values at one year follow up, almost respectively just, tangents the value of 0.5 mm. Using both the MTPM at one year and the continuously migrating pattern (MTPM between year 1 and year 2) our results indicate that the long term prosthetic fixation for both groups would be equal and good.

A limitation of this study, though, is the small sample size of 21 patients who were followed-up using RSA at two years in the Triathlon ™ CR group; a sample size of 25–30 patients is recommended for the screening of implants using RSA [1,13,14].

Loosening and wear are two important reasons for failure, which can be predicted with RSA, but failure of total joint replacements may have many other causes.

For some types of implants with several interfaces such as cemented prostheses and modular implant designs, motion may occur at different interfaces, which makes the interpretation of migration data complicated [1]. It is known that the polyethylene can move in relation to the tibial metal tray in modular knee arthroplasties. In vitro measurements of the Triathlon™ CS tibial insert rotation have displayed a micromotion of 0.01–0.1° depending on the setup (walking or stair climbing, and torque force) in the test situation [27]. As this could influence especially lift-off, translations and rotation in the horizontal plane, one could theoretically argue that the PS polyethylene may be forced to move more in relation to the tibial tray compared to the CR, and thus that the measured (small) differences do not necessarily represent movements between the tibial metal tray and bone. The tibial tray used, however, had the same design in both groups and the polyethylene quality used, and was the same for both inserts; X3 (Stryker, Mahwah, New Jersey, USA). Then, the randomisation, should minimise the risk for misinterpretation of this problem.

Reasons for inclusion and exclusion in this series have been disclosed in Tables 1 and 2. Approximately 1/3 of the patients undergoing total knee arthroplasty during the period of this series were included, hence the risk for introducing potential bias.

Strength of this study is that both implant designs were screened under the same conditions in a randomised controlled trial.

4.2. Conclusion

The use of either PS or CR technique did not affect the early tibial fixation quality during cemented total knee arthroplasty.

Authors' contribution

STL designed the study and coordinated. MM participated in designing the study. MM prepared the manuscript. Both authors read and approved the final manuscript.

Table 6
Clinical outcome scores according to the Knee Injury and Osteoarthritis Outcome Score (KOOS).

		Preoperative		3 months		1 year		2 years	
		Triathlon™ PS	Triathlon™ CR	Triathlon™ PS	Triathlon™ CR	Triathlon™ PS	Triathlon™ CR	Triathlon™ PS	Triathlon™ CR
KOOS	KOOS mean pain score ± SD	43 ± 19	41 ± 17	71 ± 20	72 ± 17	80 ± 19	86 ± 14	87 ± 14	87 ± 18
	KOOS mean symptom score ± SD	52 ± 20	46 ± 17	66 ± 18	67 ± 18	76 ± 15	76 ± 19	83 ± 15	82 ± 18
	KOOS mean ADL score ± SD	45 ± 15	45 ± 17	72 ± 19	74 ± 14	79 ± 20	86 ± 15	84 ± 16	86 ± 15
	KOOS mean sports/recreation score ± SD	12 ± 13	18 ± 26	29 ± 24	31 ± 22	38 ± 24	39 ± 22	46 ± 22	40 ± 27
	KOOS mean QOL score ± SD	25 ± 15	22 ± 12	58 ± 22	56 ± 19	68 ± 25	68 ± 18	79 ± 20	78 ± 22

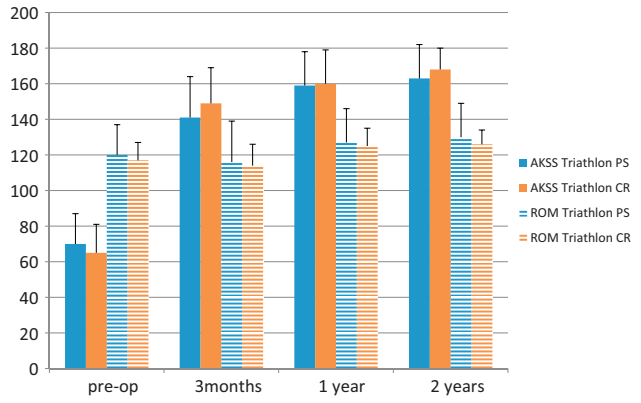

Fig. 4. Bar chart showing the American Knee Society Scores (AKSS; both knee score and mean flexion (°)) for both the Triathlon PS and Triathlon CR groups. Error bars denote the standard deviation.

Conflict of interest

The authors are not supported by, nor maintain any financial interest in, any commercial activity that may be associated with the topic of this study. The authors are not aware of any non-financial competing interest.

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