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No difference in mid-term survival and clinical outcome between patient-specific and conventional instrumented total knee arthroplasty: a randomized controlled trial

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Abstract

Purpose The purpose of this multicentre prospective randomized controlled trial was to compare the survival rate and clinical outcome in total knee arthroplasty (TKA) after MRI-based patient-specific instruments (PSI) and conventional instruments 5 years after initial surgery.

Methods At a mean follow-up of 5.1 years (0.4), 163 patients (90.6%) with a mean age of 71.8 years (8.7) were analysed. A survival analysis with revision of the TKA as endpoint was performed. The Knee Society Score (KSS), evaluations on plain radiographs and patient-reported outcome measures (PROMs) were obtained preoperatively and at each FU.

Results At final follow-up, one TKA in the PSI- (1.2%) and 3 TKAs in the conventional group (3.8%) had undergone revision surgery (n.s.). No radiological abnormalities were noted at any time point. Postoperatively, the KSS and PROMs significantly improved within each group compared with the preoperative values. There were no clinically relevant differences for the KSS [PSI: 77.4, 9.8 (95% CI 75.0–79.7) vs. conventional: 77.3 10.5 (95% CI 74.9–79.8)] and the PROMs between both groups (n.s.) at 5 years follow-up.

Conclusion There is still a lack of reliable data on the survival of TKA and clinical evidence, when using PSI for TKA. Longer follow-up studies are, therefore, needed.

Level of evidence I.

Keywords Patient-specific instruments · Conventional instruments · Total knee arthroplasty · Mid-term · Survival · Randomized controlled trial · PROMS · TKA · RCT · PSI

Introduction

One of the key factors that can improve the longevity of the implant after total knee arthoplasty (TKA) is a correct alignment of the individual femoral and tibial components [2, 11, 19, 22]. Malalignment is associated with poor implant survivorship [19, 23, 24, 29]. Alignment of the TKA can be done in several ways. During the conventional technique, the TKA position is defined during surgery with use of alignment rods. Several studies reported results of postoperative malalignment using conventional alignment rods in TKA [6, 14, 28]. Patient-specific instruments (PSI) are already in relatively common use to align the TKA. The method of image acquisition and preoperative planning is not standardized among different manufacturers [33]. Published results on PSI are contradictory. PSI's early 2 years clinical results are equal to conventional instrumented TKA [5, 27, 36]. There is still a lack of reliable data on the survival of TKA and long-term clinical outcome with the use of PSI. To our knowledge, there are no randomized controlled trials (RCT) comparing the implant survival and clinical outcome between PSI TKA and conventional TKA at 5-year follow-up.

This multicentre RCT is a continuation of previously published studies that compared intra-operative results, the radiological outcome of the component alignment and the short-term clinical follow-up in 180 patients who were

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randomly assigned to be operated with PSI or conventional TKA [3]. The results in terms of obtaining a neutral mechanical axis and a correct position of the prosthesis components did not differ between groups [3]. A significant reduction in operation time and blood loss was found in favour of the PSI aligned TKAs [3], however, without any significant or clinically relevant differences at 2 years follow-up (e.g., clinical outcome measures and complication rate) between the two groups [4].

These same patients have now been followed-up for 5 years to address the following hypothesis [4]. It was hypothesised that there would be no difference in revision rate and clinical outcome between PSI and conventional TKA.

Materials and methods

This multicentre, prospective, randomized double-blind study with an allocation ratio of 1:1 was conducted from September 2010 till March 2013 at the Zuyderland Medical Center, Sittard-Geleen and St Anna Hospital, Geldrop, both in the Netherlands. One hundred and seventy-eight TKAs were implanted in 180 patients. Patients were allocated via a computer random number generator (http://www.randomizer.org) to one of the two parallel groups to receive either TKA alignment with PSI (Signature, Zimmer Biomet Orthopaedics, Warsaw, IN, USA) or conventional intramedullary instruments (Zimmer Biomet Orthopaedics, Warsaw, IN, USA). The TKA implant was identical in both groups (cemented CR Vanguard system, Zimmer Biomet Orthopaedics, Warsaw, IN, USA). All surgical procedures were performed by one of three experienced orthopaedic knee surgeons (N.K. at Zuyderland Medical Center and R.D. and H.H. at St Anna Hospital) who had > 10 years' experience with conventional TKA and had undertaken at least 100 TKAs using PSI before the start of the trial.

Baseline conditions, randomization, surgical procedure, perioperative outcome (e.g., operation time, blood loss) and postoperative protocol were described in detail in a previous publication [3]. After completion of the 2-year FU, patients were unblinded for the type of alignment method that was used [4]. An overview of the number of patients at the 5-year follow-up analysed in this study is presented in Fig. 1.

A survival analysis with revision of the TKA (e.g., bearing and/or femur and/or tibia component) as endpoint was performed. All clinical evaluations and patient-reported outcome measures (PROMs) were obtained preoperatively and at each FU by an independent physician (M.S. at the Zuyderland MC and W.W. at the St. Anna hospital), who were blinded to the type of instrumentation which had been used during surgery. Clinical and digital radiographical evaluation on plain radiographs and postoperative knee society evaluation [9] was obtained with use of the clinician-derived Knee Society Score (KSS; 0–100, 100 being the highest score) [18] and patients completed the following four PROMs: the 12-item Oxford Knee Score (OKS; 12–60, 12 being the highest score) [16, 26], the Western Ontario and McMaster University Index (WOMAC; 0–100, 100 being

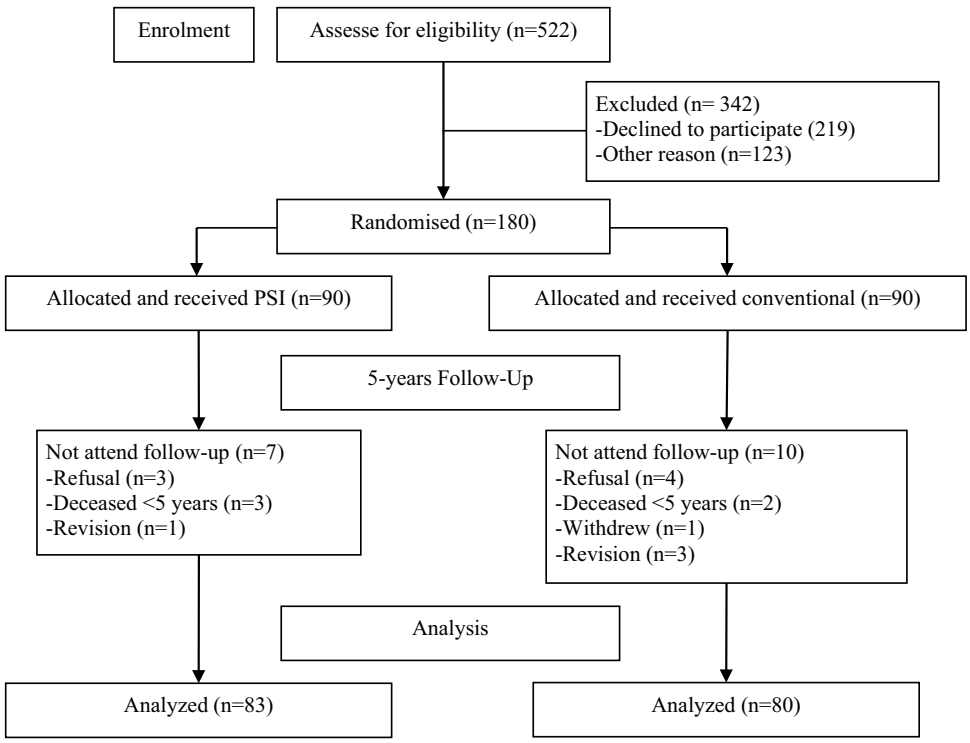

Fig. 1 Patient distribution of the included patients at 5-year follow-up

the highest score) [30], a visual analogue scale (VAS) for pain [12] and the EuroQol (EQ-5D) [10]. For the EQ-5D, a single summary index was calculated, using the value set for The Netherlands [5, 10, 14, 21, 25]. Scores on the questionnaires were compared between both groups at the different follow-up visits. Missing items in the PROMs were treated as described in the literature [16, 18, 30]. Radiolucency was scored at all follow-up moments according to Ewald [9].

The study protocol was approved by the hospital's Independent Review Board (IRB, METC Z; File nr. 10-T-21). The trial was conducted in accordance with the Declaration of Helsinki and CONSORT (Consolidated Standards of Reporting Trials) guidelines. Written informed consent was obtained from all individual participants included in the study.

Statistical analysis

The analyses were performed with the use of SPSS version 21.0 software (SPSS Inc., Chicago, USA). Log-rank (Mantel-Cox) test was used to compare the statistical differences of the survival of the TKA between PSI and conventional intramedullary instruments. A generalised linear mixed model (GLMM) approach was used to take into account the repeated-measures design of the study to cope with any missing data collected before and at each follow-up and to cope with the range of variation in relation to the time frame the data was collected [8]. The GLMM contained both random and fixed variables, to estimate the effect of implant design and age on the trend of the different PROMs (dependent variables). The primary study was powered with a 2-sided 5% significance level and a power of 90%. A sample size of 90 patients per group were included to detect a difference in KSS at 2-years postoperatively [4]. For all analyses, a p value was considered to be statistically significant at $p \leq 0.05$. Results are presented as mean, SD and 95% confidence interval (CI).

Results

At a mean follow-up of 5.1 years (0.4), 163 patients (90.6%) with a mean age of 71.8 years (8.7) at FU were analysed. One patient was not able to mobilize due to Parkinson's disease, seven patients did not attend the follow-up (PSI = 3, Conventional = 4) and five patients deceased of causes unrelated to the surgery before the 5-year follow-up (PSI = 3, conventional = 2). Patient distribution is summarized in Fig. 1.

At final follow-up, a total of 4 patients (2.4%) had undergone revision surgery. One TKA in the PSI group (1.2%) and 3 TKAs in the conventional group (3.8%). There was no difference in the survival rates of the PSI and conventional TKA surgery (n.s.). The main reason for revision surgery was persistent knee pain (1 PSI TKA; 2 conventional TKAs). In 2 patients (1 in both groups), both the femoral and tibia component were revised, in 1 patient (conventional TKA), only the tibia plateau was revised to one size smaller due to lateral overhang. In one other patient (conventional TKA), the bearing was revised to one size bigger (size 10–12) due to knee instability and a patellar button was placed to cope with patellofemoral complaints. Kaplan–Meier survival analysis with revision for any reason is shown in Fig. 2.

No radiolucent abnormalities were noted at any time point. Postoperatively, the clinician-derived KSS and PROMs significantly improved within each group compared with the preoperative values. GLMM was adjusted for age and baseline of each outcome. There were no significant differences for the clinician-derived KSS and the PROMs between both groups at 5-year follow-up (Table 1).

Discussion

The main findings of this study were that, at 5-year follow-up, there were no significant differences in the survival between PSI and conventional aligned TKAs, although slightly more implants were revised in the conventionally aligned TKA group. Clinical outcomes between PSI and conventionally aligned TKAs were comparable.

Persistent knee pain (1.8%) was the most common cause of revision in the total study group (1 PSI TKA; 2 conventional TKAs). At the onset of increasing pain after TKA, implant malalignment and/or non-articular causes should be the first consideration [17]. In most cases, pain after TKA is of unknown origin. Spine problems and hip osteoarthritis were the second most common causes of pain after TKA [1]. In this study, a majority of patients were satisfied after revision surgery, except for one patient, where the pain problem was not resolved. A reoperation conducted without identification of a specific reason carries a high risk of failure [7, 25]. Therefore, it is important to perform thorough preoperative evaluations to search for pain resulting from extra-articular causes [17].

Published long-term clinical results on PSI are scarce, since they have relatively recently been released. The available literature on PSI showed that their early 2-year clinical results are equal to conventional instrumented TKA [4, 27, 36]. The used patient-reported outcome measures (PROMs) in this study represent the best subjective measurement of clinical outcome after joint arthroplasty [31]. Although, most of the PROMs did not capture changes between both study groups due to a lack of sensitivity to change [13]. The PROMs in this study failed to detect significant changes after a FU of 5 years.

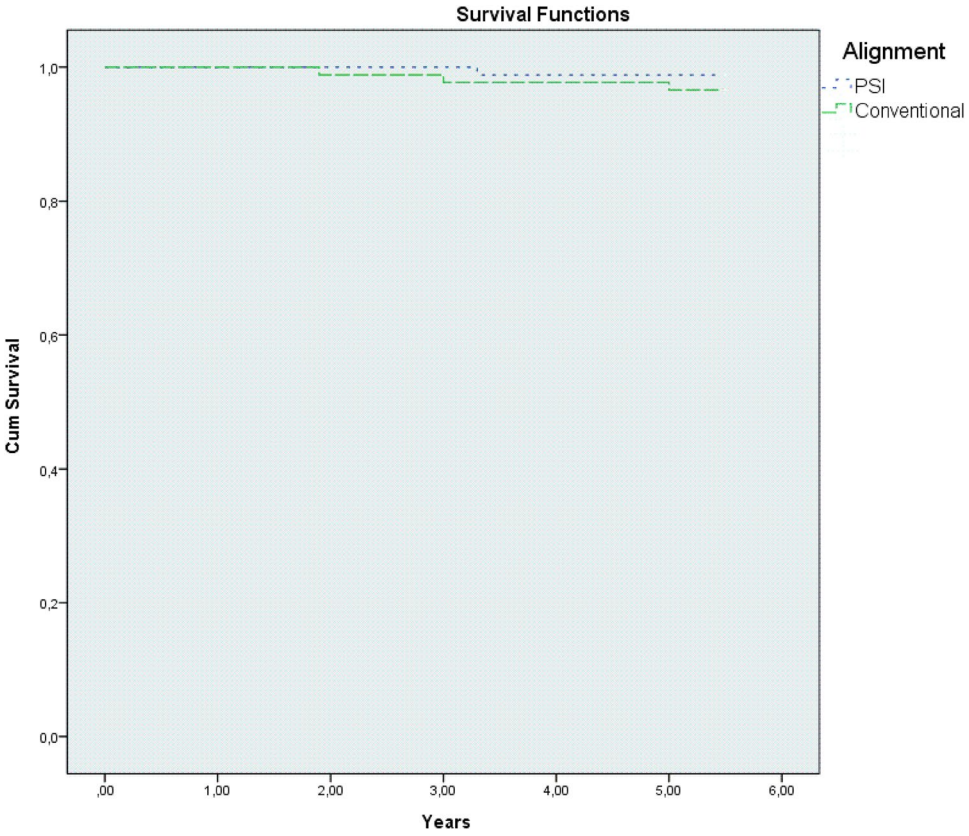

Fig. 2 Kaplan–Meier survival curve of survival to revision for any reason as the endpoint, with a survival of 98.9% (95% CI 96.8–100) and 96.6% (95% CI 92.8–100) for, respectively, the PSI and conventional TKA group after 5 years of FU (n.s.)

It can be discussed that most of the scientific clinical evidence comes from high-volume surgeons [15]. Based on the experience with TKA, the use of PSI and a possible learning curve, implementation of a new implant system may be a potential bias in the outcome [35]. The surgeons operating on patients enrolled in this study were high-volume knee arthroplasty surgeons. Having a TKA in a high-volume hospital is associated with a lower risk of revision surgery [20] and results obtained in this trial might, therefore, not be automatically applicable to low-volume knee surgeons. This also could raise questions about the general applicability of PSI. On the contrary, it has been hypothesised that PSI could be an added value in less experienced surgeons due to their simplicity [15], especially in cases with post-traumatic osteoarthritis and in case of retained metal hardware around the knee joint [32, 34].

The strengths of this study are the number of patients (90.1%) available for this 5-year follow-up. Another particular strength of this study was the multicentre design with good described groups with assessment of multiple clinical outcomes over 5 time points, which allows a more detailed analysis of the different parameters. Furthermore, a mixed model approach was used to analyse the data. This is considered to be more appropriate for assessing repeated measurements in clinical trials [8].

This study had some limitations. The most important limitation were the clinician-derived evaluations and PROMs. It was shown that the KSS and PROMs did not significantly differ between PSI and conventional TKA with a possible floor and/or ceiling effect between the 2- and 5-year follow-up. Ageing and associated health issues over time could be a logical consequence. This emphasizes, that knee arthritis alone only partially determine the overall score. Second, only one PSI system from one manufacturer was used. Therefore, the outcome may be different for other PSI designs provided by other companies.

This is the first RCT comparing longevity and clinical outcome of the TKA implant after a 5-year FU between PSI and conventional TKA. The evaluation of a new alignment method for TKA at mid-term is useful. It provides novel information regarding the TKA survival in daily practice.

Conclusion

In summary, survival rates after a mean period of 5 years between PSI and conventional instrumented TKA were not different. The clinical outcome and PROMs in this study failed to detect subjective changes between PSI and conventionally instrumented TKA after a mean period of 5 years.

Table 1 Mean, SD, 95% confidence interval (CI) and p values are presented for the KSS and PROMs for both groups for each different follow-up visits tested with a generalised linear mixed model (GLMM)

	PSI ($n=83$) Mean SD (95% CI)	Conventional ($n=80$) Mean SD (95% CI)	p value GLMM
KSS			
Pre	50.7 13.3 (47.4–53.9)	52.0 14.4 (48.6–55.5)	n.s
3-MTS	75.7 18.5 (71.2–80.2)	76.5 14.5 (73.0–80.0)	
1 year	81.6 15.5 (77.8–85.4)	82.2 14.2 (78.8–85.7)	
2 year	81.9 15.7 (78.1–85.8)	82.2 14.8 (78.6–85.8)	
5 year	77.4 9.8 (75.0–79.7)	77.3 10.5 (74.9–79.8)	
OKS			
Pre	30.0 9.3 (27.7–32.3)	29.3 7.5 (27.5–31.1)	n.s
3-MTS	18.5 9.6 (16.2–20.9)	16.4 9.8 (14.0-18.7)	
1 year	16.0 8.2 (14.0–18.0)	15.0 8.2 (13.2–16.9)	
2 year	15.2 8.7 (13.1–17.2)	15.1 8.5 (13.1–17.1)	
5 year	23.5 9.4 (21.4–25.6)	21.6 8.4 (19.7–23.5)	
WOMAC			
Pre	51.5 17.0 (47.9–55.1)	55.8 16.2 (52.4–59.2)	n.s
3-MTS	80.9 16.4 (77.5–84.4)	82.2 14.7 (79.1–85.3)	
1 year	80.6 18.4 (76.7–84.6)	86.0 13.8 (83.1–89.0)	
2 year	80.7 20.2 (76.3–85.0)	86.6 14.8 (83.4–89.8)	
5 year	78.9 19.1 (74.6–83.2)	85.2 16.4 (81.4-88-9)	
VAS pain score			
Pre	60.7 20.1 (52.9–63.8)	61.4 16.9 (57.3–65.5)	n.s
3-MTS	20.0 21.4 (14.8–25.3)	20.6 23.5 (14.9–26.2)	
1 year	21.7 22.3 (16.3–27.2)	19.1 23.6 (13.5–24.8)	
2 year	20.4 24.8 (14.4–26.5)	17.4 21.8 (12.2–22.6)	
5 year	14.9 20.3 (10.5–19.3)	13.6 13.6 (9.5–17.7)	
EQ-5D			
Pre	0.75 0.08 (0.73–0.77)	0.78 0.07 (0.76–0.79)	n.s
3-MTS	0.88 0.10 (0.86–0.91)	0.89 0.10 (0.86–0.91)	
1 year	0.88 0.10 (0.86–0.91)	0.89 0.11 (0.87–0.92)	
2 year	0.89 0.11 (0.86–0.91)	0.90 0.12 (0.87–0.93)	
5 year	0.87 0.12 (0.84–0.90)	0.88 0.12 (0.85–0.91)	
EQ-5D VAS			
Pre	64.9 18.1 (60.4–69.3)	73.6 12.6 (70.6–76.7)	n.s
3-MTS	74.6 14.4 (71.1–78.1)	77.8 11.2 (75.1–80.5)	
1 year	74.5 13.0 (71.3–77.7)	78.0 14.8 (74.5–81.6)	
2 year	72.5 17.9 (68.2–76.7)	76.2 17.9 (71.9–80.5)	
5 year	73.7 15.9 (70.1–77.3)	77.0 16.1 (73.6–80.9)	

Author contributions MGMS: Designed the study, gathered and analysed all the data, wrote the initial draft of the manuscript and managed the study. BB: Ensured the accuracy of the data and the analysis, wrote and revised the manuscript. WW: Gathered and ensured the accuracy of the data and revised the manuscript. HH: Designed the study and revised the manuscript. RD: Designed the study and revised the manuscript. RB: Ensured the accuracy of the data and the analysis, wrote and revised the manuscript. RV: Ensured the accuracy of the data and analysis and revised the manuscript. LR: Ensured the accuracy of the data and revised the manuscript. NPK: Conceived the study and revised the manuscript.

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Compliance with ethical standards

Conflict of interest One author (NK) is a paid consultant on the PSI surgical technique for Zimmer-Biomet, Europe. The other authors certify that they have no commercial associations (e.g., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with the submitted manuscript.

Ethical approval The study was approved by the ethics committee of Zuyderland-Zuyd, Number 10-T-21.

Informed consent For this type of study formal informed consent was obtained from each included patient.

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