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First long-term analysis of survival and clinical outcome in patient-specific instrumentation for total knee arthroplasty: follow-up of a prospective cohort study

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Patient-specific instrumentation (PSI) was introduced to improve post-operative alignment, and consequently the revision rate and clinical results after total knee arthroplasty (TKA). Short- to mid-term data are conflicting regarding these theoretical advantages of PSI. The purpose of this retrospective analysis was to evaluate the survival rate and clinical outcome in PSI TKA 8.4 years after initial surgery. To our knowledge, no other study investigated long-term follow-up of TKA procedures using PSI. From a total cohort of 184 consecutive patients (200 TKA) 136 patients (144 TKA, 72%) were prospectively analysed at a mean follow-up of 8.4 years (±0.4). A survival analysis with all-cause revision of TKA as endpoint was performed. Patient-reported outcome measures (PROMs) were obtained preoperatively and after 1-, 2-, 5-, and 8.4-years of follow-up. Differences between these moments of follow-up were analysed. At final follow-up, 4 TKAs (2%) had undergone revision, all between 2-4 years after primary surgery. Reasons for revision were late infection, aseptic loosening, instability and polyethylene insert breakage. The median score of certain PROMs (WOMAC, VAS, EQ-index, EQ-VAS) decreased compared to previous follow-up scores but were significantly higher than preoperative scores. After 8.4 years of follow-up, no additional revision surgery was performed compared to 5-years postoperatively. Certain PROMs at 8.4-year follow-up decreased compared to earlier moments of follow-up, but all PROMs improved compared to preoperative PROMs.

Keywords Total knee arthroplasty, patient-specific instrumentation, implant survival, patient-reported outcome measures.

INTRODUCTION

Correct alignment of the femoral and tibial components in total knee arthroplasty (TKA) has a positive effect on the survival of the implant and short-term clinical results[1,2]. Malalignment of the components is associated with a reduction of the prosthesis' lifespan[2].

Over the past decade, as surgical techniques have evolved, patient-specific instrumentation (PSI) in TKA gained interest among orthopaedic surgeons as an alternative to traditional alignment instrumentation. With this technique, the patient's ideal prosthesis positioning is calculated based on magnetic resonance imaging (MRI) or computed tomography (CT) images of the patient's affected knee. This method was introduced in order to improve post-operative alignment, and consequently the revision rate and clinical results[3]. Despite the theoretical advantages, recent data are conflicting regarding the alignment accuracy and short-term clinical follow-up improvements of the PSI method as compared to conventional instrumentation[4,5]. Short to midterm results show similar good clinical outcomes of PSI guided as compared to conventionally instrumented TKAs[4,6,7].

To our knowledge, there is only limited evidence reporting on implant survival and long-term clinical outcomes up to 5 years after a PSI procedure[8]. Additionally, no studies have been performed observing these patients for a follow-up period of over 5 years. Multiple authors emphasized the importance of long-term analysis of clinical outcome and implant survival after PSI TKA[4,6,8]. This is even more relevant given the substantial rise in TKA procedures performed in a younger, and therefore, more active patient population[9,10].

This study is a continuation of previously published articles that evaluated surgical data, radiological alignment, implant survival and clinical outcomes at earlier follow-up moments in a cohort of 184 patients (200 TKAs) who received TKA using PSI[1,12].

MATERIALS AND METHODS

A total of 200 PSI TKAs were performed in 184 patients with end stage osteoarthritis. Data were collected prospectively and consisted of the following parameters: revision incidence and clinical functioning scores preoperatively and postoperatively at 1-, 2-, 5-, and 7-to-9 (mean= 8.4 ±0.4) years. Criteria for exclusion in this patient cohort are described in a previous study[12]. Patients were operated between July 2009 and March 2011. Baseline characteristics are listed in Table I.

The Signature™ system (Biomet Inc., Warsaw, IN) was used in this cohort and Vanguard™ (Biomet, Inc., Warsaw, IN) implants were inserted. Pre-operative preparation, operative procedure and postoperative management was performed as described previously by Boonen et al.[13].

Survival of prosthesis at 8.4-year follow-up was collected from electronic patient files. Additionally, specific questionnaires were sent to all patients by mail to prevent missing data due to possible revision treatments in other institutions. All revision or implant removal interventions were recorded together with the reason for revision and the revised component (insert, femoral component, tibial component or total revision). An overview of the number of patients at each of the analysed follow-up moments and the reasons for exclusion, is presented in Figure 1.

The clinical functioning scores consisted of the following questionnaires: the Western Ontario and McMaster Osteoarthritis Index (WOMAC; 0 to 100, 0 being the worst and 100 the best possible outcome)[14], the Oxford Knee Score (OKS; 12 to 60, with 12 being the worst and 60 being the best possible outcome)[15], the Pain Visual Analogue Score (VAS; 0 to 10, 0 representing no pain and 10 representing the worst pain imaginable), the EuroQol (EQ-5D-3L; 1 to 3 on all 5 domains and combined into one calculated index value), and the EQ-Visual Analogue Scale (EQ-VAS; on a vertical VAS, 0 representing worst imaginable health state and 100 representing the best imaginable health state)[16].

The same array of questionnaires was used pre-operatively and at the other postoperative follow-up time points. The scores were evaluated and compared between the different moments of follow-up. Additionally, for the 8.4-year follow-up the Forgotten Joint Score-12 (FJS-12; 0 to 100, 0 being the worst and 100 being the best possible outcome) has been evaluated to assess the degree of patients' awareness of their artificial joint[17].

Table I. — Baseline characteristics

Characteristics	Value
Females, n (%)	80 (55.6%)
Median age at surgery date, years (Range)	66 (48-84)
Median follow-up, years (range)	8.3 (7.7-9.1)
ASA1, n (%)	77 (53.5)
ASA2, n (%)	62 (43.1)
ASA3, n (%)	5 (3.5)
BMI median (range)	29.1 (19.8-45.0)
Prosthesis side left/right	56/88

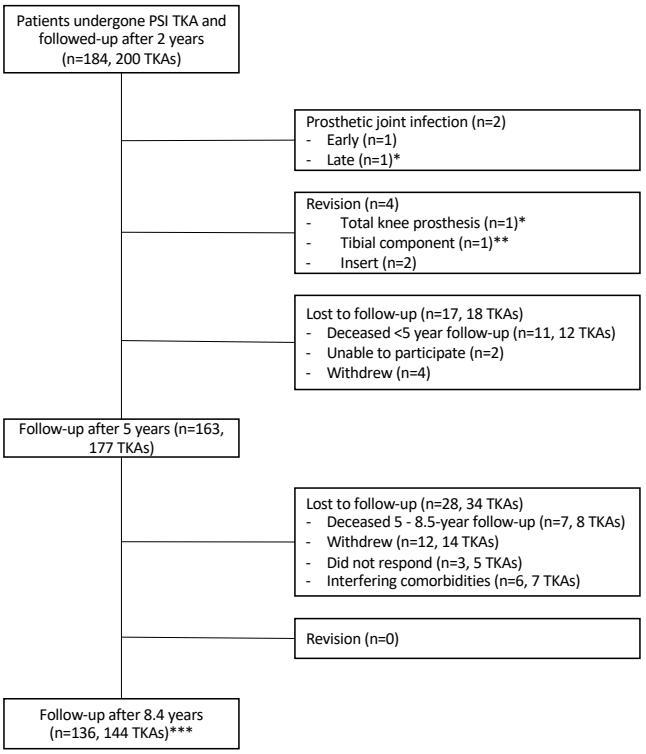

Figure 1. — Diagram of the included patients at the 2-, 5- and 8.4-year follow-up.
**Occurred in same patient. **Patient still included for prosthesis of contralateral knee. ***One patient excluded at 5-year follow-up was successfully included at the 8.4-year analysis.*

This study was approved by the hospital's ethics committee (METC Z, Heerlen, the Netherlands; trial number 13-N-102).

All statistical analyses were performed using SPSS software (SPSS inc., Chicago, Illinois). Descriptive statistics were used to evaluate the baseline characteristics and the data regarding patient reported outcome measures (PROMs). Baseline data were not normally distributed; therefore, the observed PROMs

Table II. — Characteristics of the individual revision cases

Side	ASA	BMI	Age (years)	Time until revision (years)	Type of revision	Cause of revision
Left	2	30	73	2.1	Tibial component revision	Aseptic loosening
Left	2	25	77	2.2	Total revision	Secondary prosthetic join infection
Right	1	28	54	2.5	Insert exchange	Collateral instability
Left	2	31	71	3.7	Insert exchange	Posttraumatic polyethylene insert breakage

Table III. — Results at follow-up time points presented as median scores and range

	Preoperative	1-year postoperative	2-year postoperative	5-year postoperative	8.4-year postoperative
WOMAC	57.0 (0-93)	90.5 (23-100)	90.0 (27-100)	90.0 (18-100)	82.3 (4.2-100)*
OKS	39.0 (21-56)	19.5 (12-47)	19.0 (12-45)	18.0 (12-55)	18.0 (12-53)
VAS	7 (0-10)	2 (0-10)	2 (0-9)	1 (0-10)	1 (0-8.5)***
EQ-index	0.788 (0.615-1.000)	0.874 (0.638-1.000)	0.874 (0.593-1.000)	0.874 (0.595-1.000)	0.874 (0.600-1.000)*
EQ-VAS	60 (0-100)	80 (0-100)	80 (0-100)	80 (0-100)***	75 (0-100)**
FJS12	-	-	-	-	67.75 (0-100)

*WOMAC, Western Ontario McMaster Universities Osteoarthritis index; OKS, Oxford Knee score; VAS, Pain Visual Analogue Score; EQ-index and EQ-VAS, EQ-5D-3L; FJS12, Forgotten Joint Score. *Significant difference compared to all previous follow-up moments (1-, 2-, and 5-year follow-up). *Significant difference compared to 1- and 2-year follow-up moments. ***Significant difference compared to 1-year follow-up moment*

are presented as median including the range. Wilcoxon signed-rank tests were performed to determine whether significant differences are present between follow-up observations. *p* values below 0.05 were considered statistically significant.

RESULTS

At a mean follow-up of 8.4 years (± 0.4), 144 patients (72%) with a mean age of 73.7 years (± 7.8) were analysed. Additional baseline characteristics are presented in Table I. Figure 1 shows detailed information of evaluated patients at final follow-up.

At final follow-up, four patients (4 TKAs, 2%) had undergone revision surgery (Table II). All revisions occurred in a follow-up range of 2 to 4 years. Indications[11] for the revisions are described by Schoenmakers et al.[11]. Summarized description of the individual revision cases is shown in Table II.

PROMs measured preoperatively and at each follow-up time point are shown in Table III. The medians of all observed PROMs showed significant improvement at the 8.4-year follow-up compared to preoperative values ($p<0.005$). The median of the WOMAC, VAS, EQ-index, and EQ-VAS at final follow-up differed compared to one or more previous follow-up observations, as described in Table III. The OKS did not significantly change between individual follow-up time points.

DISCUSSION

The main finding of this study was that all-cause revision of TKA occurred in 4 patients (2%). All implant revisions occurred during the period between 2- and 4-year follow-up. PROMs at final follow-up significantly improved compared to the preoperative values.

To keep loss to follow-up to a minimum and still have a substantial follow-up period, the cohort was analysed at this time point instead of waiting until the 10-years follow-up. Increase in decease rate and invalidating comorbidities is expected due to an ageing cohort.

The results on prosthesis survival at final follow-up are in line with literature on conventional TKA. The 2% failure rate is minimally lower than results reported for conventional TKA after comparable follow-up[18,19]. Specified for similar prosthesis design, the failure rate does not differ from our results, ranging between 2.2% and 3.3%[18,20,21]. These findings suggest no alteration in long-term survival with the use of PSI. Long-term follow-up of RCTs are necessary to clarify these findings. A randomized analysis by Schotanus et al.[8] reported no significant difference in survival

after 5 years comparing conventional- to PSI TKA. Additionally, multiple short-term radiographic RCTs[22-24] and case series[25] analysing PSI have been published. Unfortunately, mid- to long-term follow-up of these cohorts have not yet been published. The absence of additional implant revisions after 4 years in our cohort is as expected since these findings seem to follow a general course of prosthesis failure after conventional TKA[18]. During the first 3 postoperative years infection and instability cause a strong increase in revisions, while in the following few years the failure incidence stabilizes relatively. After 10 years the incidence increases again, mainly due to an increase in aseptic loosening and polyethylene wear[18].

In conventional TKA, septic and aseptic loosening are the most common reasons for revision, ranging between 15-30% of all revision cases[26,27]. The septic and aseptic loosening cases in this study, representing both 25% of the total number of revisions, are as expected. However, revision caused by instability and insert breakage has been observed much less in the literature compared to this study[26,27]. The authors believe that this cohort can be too small to adequately compare revision after PSI TKA with conventional TKA. With only 4 revisions, the impact of a single revision is disproportionate and could over-represent a less common cause of revision.

Boonen et al.[12] published the radiographic alignment analyses of this cohort, and discussed that the number of outliers using PSI are in line with literature on PSI TKA. In this study, 2 out of 4 revisions had postoperative malalignment of the prosthesis (>3° deviation from planned alignment). One of these patients, with a mechanical axis malalignment of 7.2° varus, suffered a broken insert after trauma. The insert was exchanged after which the patient was satisfied regarding its clinical functioning. The other patient had a mechanical axis malalignment of 3.6° valgus and suffered from lateral instability postoperatively. Although the insert was replaced with a larger size, the stability did not improve. Eventually, a total system revision to a semi constrained prosthesis was considered but not performed for this patient.

The observed results on clinical functioning are in line with results described in literature on conventional TKA[28-30]. The decrease of the WOMAC and EuroQol scores could be a consequence of the ageing cohort, since aging and an associated health decline are correlated with lower PROMs[31]. The marginal decrease in VAS is considered as not clinically significant.

PSI was introduced to improve alignment after TKA, and therefor result in better clinical functioning with less revisions[3,32]. Regarding prosthesis survival and clinical outcomes, in the current literature PSI does not seem to show advantages over conventional TKA. Studies with short- to mid-term analyses show similar results with no difference in postoperative alignment, clinical functioning or prosthesis survival[8,33,34,35,36]. Moreover, PSI is more expensive compared to conventional TKA. The pre-operative MRI scan and fabrication costs of the patient-specific cutting jigs are higher than the costs saved by reduction of operation time[37,38]. Slover et al.[39] calculated that a revision reduction of 50% would be necessary for PSI to be cost-effective. To date, this criterium is not met. Currently, studies are launched to assess patient-specific cutting jigs designed from x-ray images. This method has the potential to greatly reduce costs compared to MRI- or CT-based PSI [40]. Future studies are needed to analyse the accuracy of this technique and whether or not this could lead to a better cost-effectiveness.

The most important strength of this study is the well-described cohort with analysis of clinical outcome and prosthesis survival over 3 successive time points, with relatively little lost to follow-up. Moreover, this study is the first to report results of over 5 years follow-up and is among the largest study currently available on follow up of PSI TKA.

The most important limitation was the absence of a control group. This makes it challenging to compare this PSI cohort with conventional instrumented TKA. A randomized controlled design would be preferable in future research. Secondly, only one PSI system was used. It is unclear if our results automatically apply to other PSI-systems. At last, although no new revisions were performed between the last two follow up moments, x-rays were not assessed for the presence of radiolucency which could be a predictor for future revisions.

CONCLUSIONS

After 8.4 years of follow-up, no additional revision surgery was performed compared to 5-years post-operatively. Certain PROMs at 8.4-year follow-up decreased compared to earlier moments of follow-up, but all PROMs were significantly higher compared to the preoperative values. Future research is needed to evaluate possible advantages of PSI TKA compared to conventional TKA, preferably with a randomized controlled design.

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