Knee Surg Sports Traumatol Arthrosc
DOI 10.1007/s00167-014-3345-2

KNEE

Patient-specific instrumentation improved mechanical alignment, while early clinical outcome was comparable to conventional instrumentation in TKA

Werner Anderl · Leo Pauzenberger · Roman Kölblinger · Gabriele Kiesselbach · Georg Brandl · Brenda Laky · Bernhard Kriegleder · Philipp Heuberer · Eva Schwameis

Received: 10 April 2014 / Accepted: 18 September 2014

Abstract
Purpose The aim of this prospective study was to compare early clinical outcome, radiological limb alignment, and three-dimensional (3D)-component positioning between conventional and computed tomography (CT)-based patient-specific instrumentation (PSI) in primary mobile-bearing total knee arthroplasty (TKA).
Methods Two hundred ninety consecutive patients (300 knees) with severe, debilitating osteoarthritis scheduled for TKA were included in this study using either conventional instrumentation (CVI, $n = 150$) or PSI ($n = 150$). Patients were clinically assessed before and 2 years after surgery according to the Knee-Society-Score (KSS) and the visual-analog-scale for pain (VAS). Additionally, the Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) and the Oxford-Knee-Score (OKS) were collected at follow-up. To evaluate accuracy of CVI and PSI, hip-knee-ankle angle (HKA) and 3D-component positioning were assessed on postoperative radiographs and CT.
Results Data of 222 knees (CVI: $n = 108$, PSI: $n = 114$) were available for analysis after a mean follow-up of 28.6 ± 5.2 months. At the early follow-up, clinical outcome (KSS, VAS, WOMAC, OKS) was comparable between the two groups. Mean HKA-deviation from the targeted neutral mechanical axis (CVI: $2.2° \pm 1.7°$; PSI: $1.5° \pm 1.4°$; $p < 0.001$), rates of outliers (CVI: 22.2 %; PSI: 9.6 %; $p = 0.016$), and 3D-component positioning outliers were significantly lower in the PSI group. Non-outliers (HKA: $180° \pm 3°$) showed better clinical results than outliers at the 2-year follow-up.
Conclusions CT-based PSI compared with CVI improves accuracy of mechanical alignment restoration and 3D-component positioning in primary TKA. While clinical outcome was comparable between the two instrumentation groups at early follow-up, significantly inferior outcome was detected in the subgroup of HKA-outliers.
Level of evidence Prospective comparative study, Level II.

Keywords Patient-specific instrumentation · Total knee arthroplasty · MyKnee · CT-based cutting block · Clinical and radiological outcome · 3D-component positioning

Introduction

Neutral mechanical limb alignment and adequate component positioning are primary intra-operative goals thought to be essential for satisfactory long-term outcome after total knee arthroplasty (TKA) [17, 24, 49]. Various studies showed that coronal limb alignment is an important factor in implant durability as outliers in the frontal plane had a significantly higher risk for early loosening and polyethylene wear with decreased overall implant survival [17, 49]. Mechanical malalignment and component malpositioning have also been identified as influencing factors for unsatisfactory clinical outcome [3, 34]. Although the impact of neutral mechanical alignment on implant longevity is still a

Electronic supplementary material The online version of this article (doi:10.1007/s00167-014-3345-2) contains supplementary material, which is available to authorized users.

W. Anderl (✉) · L. Pauzenberger · R. Kölblinger · G. Kiesselbach · G. Brandl · B. Laky · B. Kriegleder · P. Heuberer · E. Schwameis
Department of Orthopedics, St. Vincent Hospital, Stumpergasse 13, 1060 Vienna, Austria
e-mail: werner.anderl@bhs.at

Published online: 19 October 2014

matter of discussion, there is currently no better parameter to aim for when performing TKA [7, 32, 46].

Despite adequate surgical technique, improvements, and simplifications in manual instrumentation systems, malalignment remains a common issue in conventional TKA [10, 14]. A contemporary method to potentially optimize accuracy of alignment in TKA is the use of patient-specific instrumentation (PSI). For patient-specific methods, computed tomography scans (CT) or magnetic resonance images (MRI) are used for preoperative planning and production of patient-matched pin guides or cutting blocks. Early investigations were predominantly reporting on patient-matched systems based on preoperative MRI [2, 4, 8, 9, 11, 22, 40–45, 48, 61, 64, 67], while recently more authors reported on CT-based systems [5, 13, 16, 20, 26, 29, 30, 50, 61, 66]. However, providing a unique fit on the distal femur and proximal tibia, these jigs are used for exact bone resection and component positioning. Potential benefits, such as reduced surgical time and increased accuracy of TKA, come at the cost of increased economic and logistic expenses. Thus, there is great scientific and practical interest in the actual advantages and reliability of these systems [4, 43, 55–57].

At present, there is no consensus in literature regarding accuracy and reliability of patient-matched instrumentation as current studies showed controversial and inconsistent radiological results of various PSI systems; while some authors reported improved alignment and component positioning [2, 14, 22, 26, 40–42, 45], others described comparable [9, 20, 50] or unsatisfactory results [1, 8, 11, 18, 35, 44, 51, 52, 63, 66, 67].

Despite increasing numbers of reports regarding radiological results with PSI systems, investigations focusing on or additionally addressing clinical outcome are scarce, and currently, they are limited by short follow-up periods and small sample sizes [1, 47, 48, 64, 66, 67]. Since the impact of radiological alignment is still controversial and clinical results with PSI are not often reported, clinical combined with radiological assessment becomes more relevant.

Thus, the purpose of the present study was to compare clinical results, as well as radiological limb alignment, and three-dimensional (3D)-component positioning between conventional instrumentation (CVI) and a CT-based PSI in primary mobile-bearing TKA. We hypothesized that (a) clinical outcome would be comparable between PSI and CVI and (b) PSI would be superior regarding mechanical alignment restoration, number of outliers, and 3D-component positioning compared with CVI.

Materials and methods

Included were all patients, regardless of preoperative varus or valgus deformity, scheduled for primary TKA with a mobile-bearing TKA system (GMK® Primary, Medacta International S.A., Castel San Pietro, Switzerland). Initially, the aim of the present single-center study was to evaluate this new TKA system using standard instrumentation regarding clinical outcome, accuracy and reliability of 3D-component positioning, and mechanical alignment restoration. However, in 2010, a PSI method (MyKnee®, Medacta International S.A., Castel San Pietro, Switzerland) for the same mobile-bearing TKA system was introduced and became the preferred method for performing TKA at our institution. Consequently, we expanded the aim of our study toward a comparison between the two methods of instrumentation, to determine additional benefits of the patient-specific method. The same protocol was used for both study groups.

Between January 2007 and September 2011, patients with osteoarthritis of the knee joint (Kellgren–Lawrence [28] grading II, III, or IV) scheduled for TKA at our institution were assessed for their eligibility as study participants. The first 150 cases of each group meeting the inclusion criteria were enrolled in the study. Criteria for exclusion were previous open surgeries of the knee joint, major trauma or debilitating comorbidities influencing mobility, inability to complete the questionnaire due to cognitive difficulties, and patient refusal for participation. Informed consent was provided by all included patients. A flow chart of patient enrollment is presented in Fig. 1.

Preoperative PSI workflow and surgical technique

Preoperative CT scans according to the standardized MyKnee® protocol (Medacta International S.A., Castel San Pietro, Switzerland) were taken. Cutting blocks and 3D bone models of the knee were produced according to the preferences of the surgeon aiming for a postoperative neutral mechanical axis, a physiological joint line, an anatomical tibial slope (0° to 6° depending on the preoperative condition), and a flush fitting of the femoral component to avoid anterior notching (0° to 4° flexion), together with a femoral component rotation parallel to the transepicondylar axis.

All patients underwent implantation of a standard mobile-bearing total knee prosthesis (GMK® Primary, Medacta International S.A., Castel San Pietro, Switzerland) without patella resurfacing. After a midline skin incision, followed by a medial or lateral parapatellar approach, bone cuts were performed in the CVI group using the standard GMK® instrumentation system assisted by an extra-medullary guidance rod for the tibia and an intra-medullary guidance rod for the femur and spacer blocks. In PSI, the tibial and femoral footprint areas were carefully cleaned of the remaining cartilage for an exact fit of the cutting blocks, and after pinning, bone cuts were performed in accordance to the preoperative planning. Tibial rotation was determined

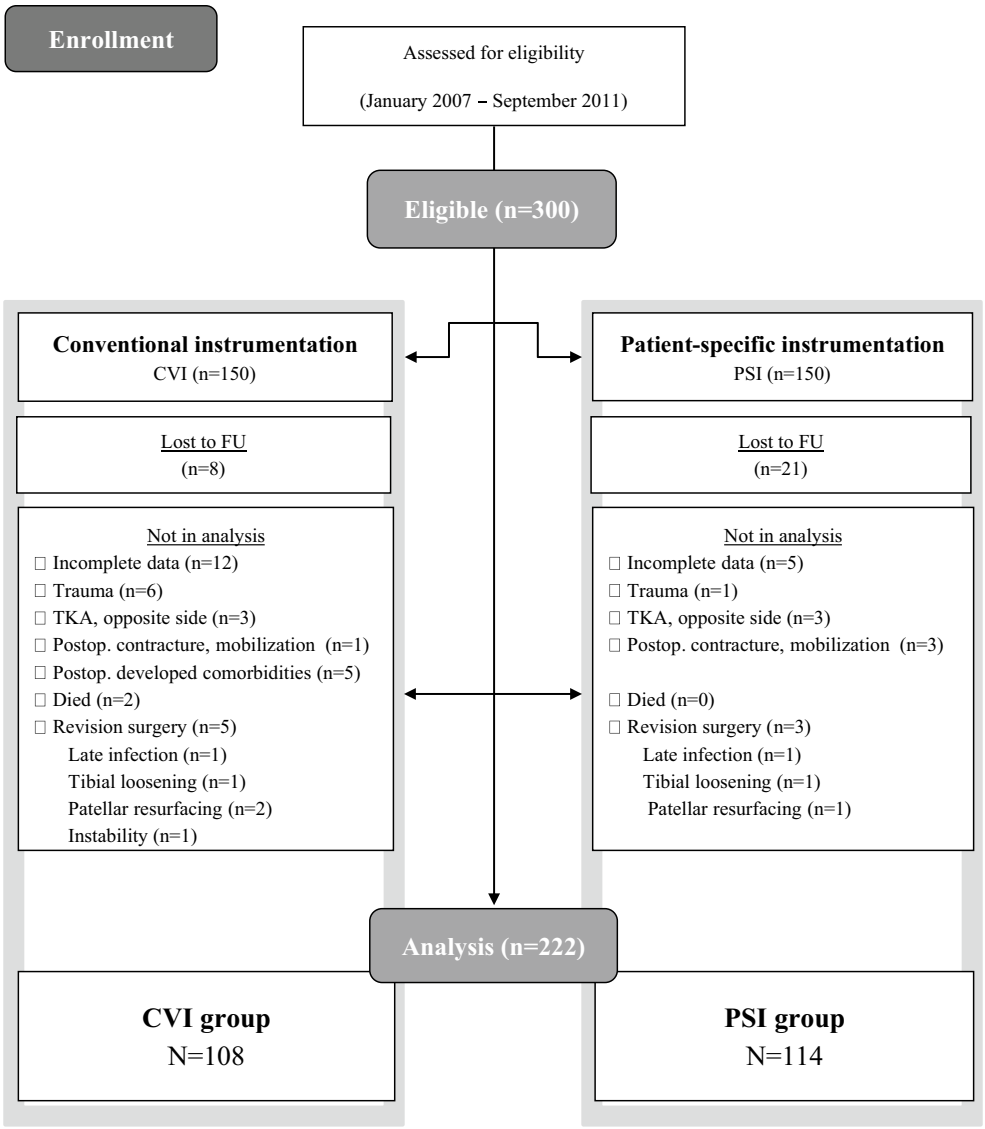

Fig. 1 Flowchart of patient enrollment

clinically according to bony structures in both groups. Fixation of components was either cemented or cementless. Ligament balancing and removal of osteophytes were performed carefully in both groups. Four senior orthopedic surgeons experienced in TKA performed all surgeries, each with both techniques. Postoperative treatment was the same in both groups with respect to pain relief and mobilization.

Clinical assessment

Preoperative data and data collected at a minimum of 2 years after surgery were evaluated. Patient characteristics such as age, gender, body mass index (BMI) were recorded. Clinical assessment included the Knee-Society-Score (KSS) [25] comprised of its two subscales: knee- and function-score. The range of motion (ROM) was recorded. The subjective knee questionnaire included a visual analog scale (VAS) for pain, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [6, 53, 54], and the Oxford-Knee-Score (OKS) [15, 39]. All clinical follow-ups were performed by the same independent examiners (L.P., R.K., G.K., G.B.), who were blinded regarding the used method of instrumentation.

Radiological assessment

In both groups, long-leg, anterior–posterior, lateral of the knee joint, and tangential patella radiographs were taken before surgery and before hospital discharge. In addition, patients of the PSI group underwent preoperative CT scans

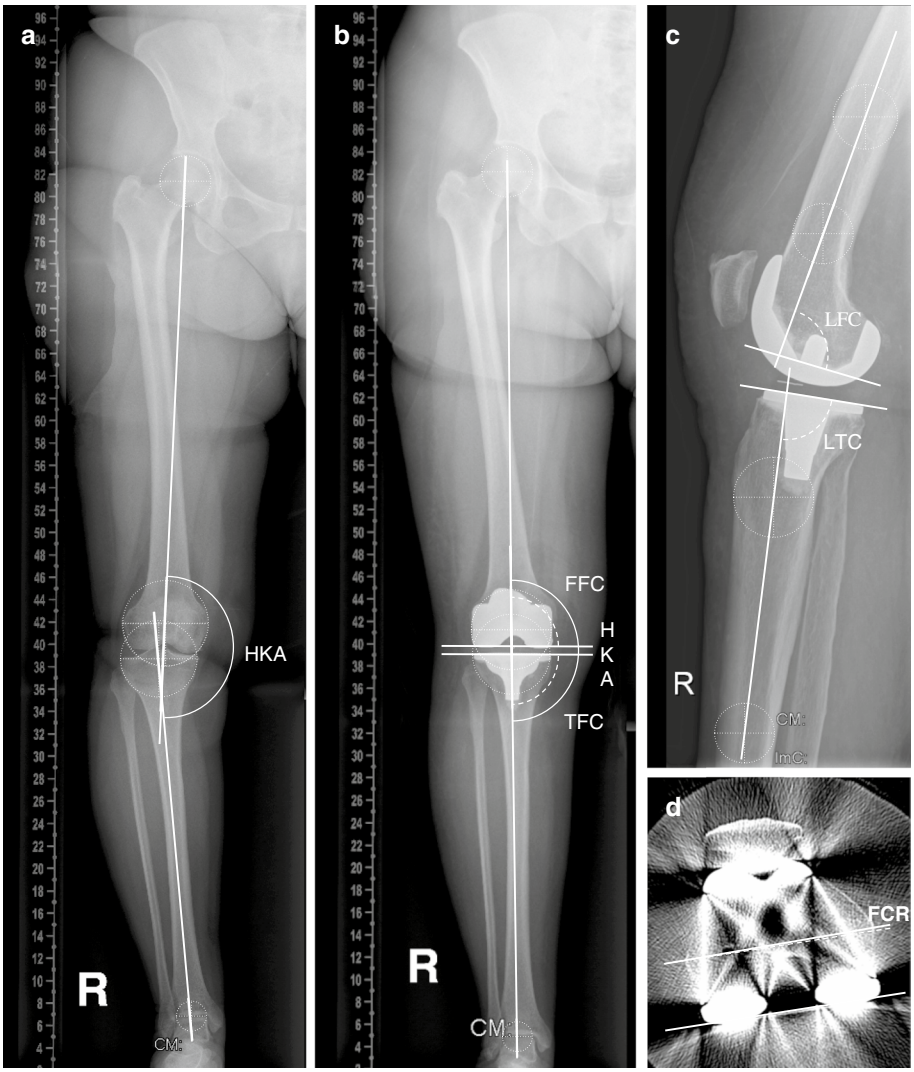

Fig. 2 Pre- (**a**) and postoperative (**b**, **c**, **d**) radiographic evaluations of hip-knee-ankle angle (HKA) and postoperative frontal femoral (FFC) and tibial (TFC) component angle on long-leg weight-bearing radiographs. Evaluation of lateral femoral (LFC) and tibial (LTC) component angle on sagittal short view radiographs. Femoral component rotation (FCR) measured on CT scans of the knee

at a minimum of 4 weeks before scheduled surgery according to the standardized MyKnee® protocol for planning and production of the individual cutting blocks.

For frontal mechanical alignment, the hip-knee-ankle angle (HKA) was measured on long-leg radiographs. Frontal femoral component (FFC) position was defined as the angle between the femoral mechanical axis and the tangent formed by the distal femoral condyles. Frontal tibial component (FTC) position was measured as the angle between the mechanical axis and the tibial plateau. Lateral component position was defined as the angle between the femoral or tibial axis and the respective implant surfaces (lateral femoral component angle, LFC; lateral tibial component angle, LTC). Femoral component rotation (FCR) was assessed on postoperative CTs of the first 25 patients of each group to limit radiation exposure and costs (Fig. 2).

Radiographic measurements were performed twice at two different time points by two independent examiners (L.P., G.B.). Intra- and inter-rater comparisons revealed measurement errors less than one degree for all examined parameters.

In order to analyze accuracy of mechanical axis restoration and 3D-component positioning between the CVI and PSI group, deviations from neutral mechanical alignment and targeted 3D-component positioning in degrees were calculated. Outliers were defined as deviations from the intra-operative goals (HKA 180° ± 3°, FFC 90° ± 2°, FTC 90° ± 2°, LFC [86° to 90°] ± 2°, LTC [84° to 90°] ± 2°, FCR 0°).

This trial was approved by the institutional review board and was carried out as a single-center study.

Statistical analysis

A power analysis showed that a sample size of 100 knees per group is required to detect a mean difference of 10 points and an assumed standard deviation of 25 points in the KSS between the CVI and PSI group with a power of

Table 1 Group characteristics

Preoperative	CVI group ($n = 108$)	PSI group ($n = 114$)	p value
Age* (years)	67.7 ± 9.6	68.7 ± 8.2	n.s.
Female/male† (n)	63/45	73/41	n.s.
Body mass index* (kg/m^2)	29.8 ± 5.4	29.9 ± 5.2	n.s.
Right/left knee† (n)	57/51	60/54	n.s.
Varus/valgus† (n)	81/27	89/25	n.s.
Kellgren–Lawrence grading II/III/IV (n)	20/62/26	25/58/31	n.s.
Mediolateral instability ≤5°/6–9°/≥10° (n)	30/11/1	30/5/1	n.s.

CVI conventional instrumentation, *PSI* patient-specific instrumentation

* The values are given as the mean and the standard deviation

† The values are given as numbers

80 % at an α-level of 0.05. To account for possible drop-outs, we enrolled 150 knees in each group for a total of 300.

Descriptive statistic was used to present patients characteristics. Distribution of the data was assessed by a visual inspection of histograms and the Kolmogorov–Smirnov test. For normally distributed variables, the independent t test and the Mann–Whitney U test for nonparametric variables were used to compare differences in means between CVI and PSI, as well as between HKA-outliers and non-outliers. Fisher's exact or chi-square tests were employed to examine the relationship between counts of binary variables and treatment groups. Statistical significance was reported at a p value of <0.05 level (two sided). All statistical analyses were performed in SPSS 21® (IBM® Corporation, Armonk, USA).

Results

Demographics

Of 290 study participants (300 knees), 29 patients were lost to follow-up (follow-up rate 90 %), 39 patients were not included from analysis due to the following reasons: died during the follow-up period ($n = 2$), incomplete data ($n = 17$), debilitating comorbidities that developed during the follow-up period ($n = 5$), traumatic (periprosthetic) injuries of the operated leg or debilitating injuries to other body parts ($n = 7$), total joint arthroplasty of the opposite knee or other major orthopedic surgery within 6 months of follow-up ($n = 6$), severe postoperative contracture with consecutive mobilization ($n = 4$), and secondary patellar resurfacing ($n = 3$). Sub-analyses of baseline data including all group characteristics revealed no differences between cases included versus not included in analysis (Suppl. Table 1) and cemented versus cementless fixation (Suppl. Table 2). There was no necessity to intra-operatively abandon PSI in any case. Revision surgery for knee infection was indicated in two cases: for aseptic loosening of the tibia component in one case and for knee instability in the other case (Fig. 1).

A total of 222 knees (five patients underwent bilateral TKA) were followed for 28.6 ± 5.2 months. The study cohort consisted of 108 cases in the CVI group and 114 cases in the PSI group. No significant differences in group characteristics were detected (Table 1).

Clinical and radiological outcome

Clinical (KSS knee, KSS function, ROM, VAS) and radiological parameters (HKA, HKA of preoperative varus and valgus knees) improved significantly from pre- to postoperative in both groups (Tables 2, 3). At the early follow-up, clinical outcome was comparable between the two groups, whereas KSS function and VAS for pain were significantly better in the PSI group (Table 2). No significant differences between the CVI and PSI group were detected with the

Table 2 Clinical outcome between conventional (CVI) versus PSI after total knee arthroplasty

	CVI group ($n = 108$)	PSI group ($n = 114$)	p value
KSS knee (0–100 points)			
Preoperative	44.3 ± 18.6	42.8 ± 23.3	n.s.
2-Year follow-up	92.7 ± 10.7	92.2 ± 11.8	n.s.
p value	<0.001	<0.001	
KSS function (0–100 points)			
Preoperative	53.1 ± 22.6	47.4 ± 26.5	n.s.
2-Year follow-up	80.9 ± 20.4	86.8 ± 16.3	0.017
p value	<0.001	<0.001	
Range of motion (°)			
Preoperative	109.6 ± 16.2	110.9 ± 16.4	n.s.
2-Year follow-up	116.6 ± 12.1	116.9 ± 11.8	n.s.
p value	<0.001	0.001	
VAS pain (0–10 points)			
Preoperative	7.5 ± 1.5	7.0 ± 2.0	n.s.
2-Year follow-up	2.4 ± 2.2	1.8 ± 2.0	0.038
p value	<0.001	<0.001	

All values are given as the mean and the standard deviation

CVI conventional instrumentation, *KSS* Knee-Society-Score, *PSI* patient-specific instrumentation, *VAS* visual analog scale for pain

WOMAC (85.7 ± 17.9 vs. 86.7 ± 15.4, respectively) and the OKS (35.9 ± 10.3 vs. 35.8 ± 9.3, respectively).

While the mean postoperative HKA was not significantly different between the groups, the mean deviation from a neutral mechanical alignment was significantly lower in the PSI group (Table 3). Additionally, the accuracy of femoral and tibial component positioning was significantly higher in all planes, except for LFC (Table 3).

More than half of all PSI cases (57 %) reached postoperative HKA of 180° ± 1°. Mechanical alignment restoration grouped by degrees of deviation from the targeted neutral axis is presented in Fig. 3.

Further radiological evaluation showed significant reductions of outliers regarding HKA (outlier >3° and >5°) and 3D-component positioning (Table 4) in the PSI group. All clinical parameter, except ROM, were significantly better in HKA non-outliers compared with HKA-outliers (Table 5).

Discussion

In this prospective single-center study, the most important findings were that (a) PSI showed significantly superior accuracy in mechanical alignment restoration and 3D-component positioning compared with CVI in primary TKA and (b) clinical outcome was comparable between the two instrumentation groups at early follow-up, whereas KSS, VAS, WOMAC, and OKS were significantly better in the subgroup of knees within ±3° of deviation from a neutral mechanical axis compared with outliers.

As patient-specific cutting or pin-positioning blocks are still relatively new, but potentially feasible methods to aid the surgeon in reaching satisfactory component positioning and overall limb alignment, efforts are made to improve accuracy and reliability of such methods. Current studies have found controversial results regarding mechanical alignment with reported outlier rates (deviation >3°) from 3 to 49 % [2, 4, 8, 9, 11, 14, 30, 40, 44, 61]. Interestingly, studies using even the same PSI technique reported inconsistent results ranging from 7 to 45 % [16, 37, 47, 61]. While on one hand the outlier rate in one of the only two studies evaluating the same PSI system as in the present study was with 12 % [29] comparable with our findings, the other study [16] with a 37 % outlier rate was not. A possible reason for such variances might be a considerable difference in sample size (291–23, respectively). Furthermore, the authors [16] reported that according to intra-operative navigation control and postoperative X-ray assessment, single component measurements for the coronal plane

Table 3 Radiological outcome between conventional (CVI) versus PSI after total knee arthroplasty

	CVI group[a] ($n = 108$)	PSI group[b] ($n = 114$)	p value
HKA (°)			
Preoperative	176.4 ± 6.3	175.6 ± 6.4	n.s.
Postoperative	180.0 ± 2.8	179.6 ± 2.0	n.s.
p value	<0.001	<0.001	
Preoperative varus knees (°)	173.7 ± 4.3	172.8 ± 3.6	n.s.
Preoperative valgus knees (°)	184.6 ± 3.9	185.3 ± 4.1	n.s.
HKA-deviation from neutral (°)	2.2 ± 1.7	1.5 ± 1.4	<0.001
Of preoperative varus knees (°)	2.2 ± 1.7	1.4 ± 1.4	0.002
Of preoperative valgus knees (°)	2.3 ± 1.7	1.6 ± 1.3	n.s.
FFC (°)	91.1 ± 2.2	90.2 ± 1.5	<0.001
FFC deviation from 90° (°)	2.0 ± 1.4	1.1 ± 0.9	<0.001
FTC (°)	88.8 ± 1.7	89.6 ± 1.4	0.001
FTC deviation from 90° (°)	1.5 ± 1.4	1.2 ± 0.9	0.019
LFC (°)	88.5 ± 2.5	86.7 ± 2.7	<0.001
LFC deviation from 86°–90° (°)	0.7 ± 1.2	0.8 ± 1.5	n.s.
LTC (°)	85.2 ± 2.8	86.2 ± 2.3	0.004
LTC deviation from 84°–90° (°)	0.6 ± 1.2	0.2 ± 0.7	0.002
FCR deviation from 0° (°)	2.3 ± 1.5	1.7 ± 0.9	0.046

All values are given as the mean and the standard deviation

CVI conventional instrumentation, *FCR* femoral component rotation, *FFC* frontal femoral component angle, *FTC* frontal tibial component angle, *HKA* hip-knee-ankle angle, *LFC* lateral femoral component angle, *LTC* lateral tibial component angle, *PSI* patient-specific instrumentation

[a] The CVI group consisted of 81 varus and 27 valgus knees. FCR was evaluated in a subgroup of 25 patients in each group

[b] The PSI group consisted of 89 varus and 25 valgus knees. FCR was evaluated in a subgroup of 25 patients in each group

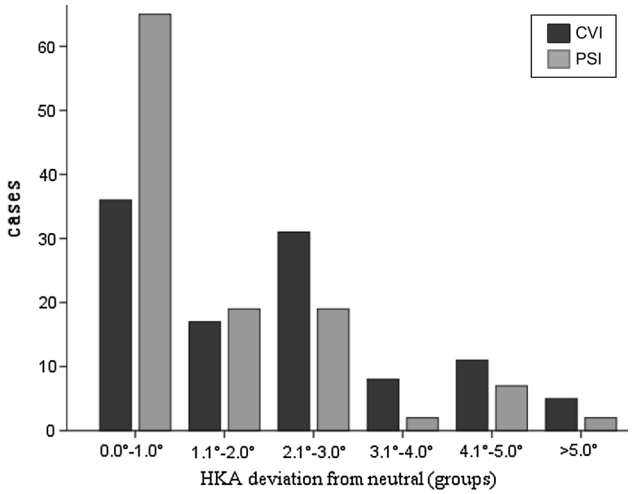

Fig. 3 Hip-knee-ankle angle (HKA) grouped by degrees of deviation from the targeted neutral axis after total knee arthroplasty with conventional (CVI) and PSI

Table 4 Comparison of outliers between conventional (CVI) versus PSI after total knee arthroplasty

	CVI group	PSI group	*p* value
HKA-outlier (<177°; >183°)	22.2 % (24/108)	9.6 % (11/114)	0.010
HKA-outlier (<175°; >185°)	7.4 % (8/108)	1.8 % (2/114)	0.042
FFC outlier (<88°; >92°)	42.6 % (46/108)	12.3 % (14/114)	<0.001
FTC outlier (<88°; >92°)	28.7 % (31/10)	10.5 % (12/114)	0.001
LFC (<84°; >92°)	14.8 % (16/108)	6.1 % (7/114)	0.034
LTC (<82°; >92°)	14.8 % (16/108)	3.5 % (4/114)	0.003
FCR (<−2°; >2°)	32.0 % (8/25)	4.0 % (1/25)	0.010

CVI conventional instrumentation, *PSI* patient-specific instrumentation, *HKA* hip-knee-ankle angle, *FFC* frontal femoral component angle, *FTC* frontal tibial component angle, *LFC* lateral femoral component angle, *LTC* lateral tibial component angle, *FCR* femoral component rotation

showed satisfactory results, whereas the overall mechanical alignment was unsatisfactory. Despite the fact that we also performed long-leg radiographs for early evaluation after surgery, which Ensini et al. [16] blamed to be a possible reason for malalignment, we are not able to confirm their findings, since we detected a mean of less than 2° deviations from targeted component position in all planes as well as in HKA. Although Koch et al. [29] did not include a CVI group, PSI results of 291 patients were comparable with the present HKA-outliers (12 vs 10 %, respectively). However, the overall mechanical alignment outlier rate of our PSI group is among the lowest currently reported.

Victor et al. [61] recently reported in a randomized controlled trial no improvements regarding accuracy of mechanical axis restoration and three-planar component positioning with four different PSI systems compared with CVI. These findings are in contrast to the results of the present study. Possible reasons for such differences may include the fact that four different PSI technologies with only 16 patients in each group were evaluated, from which a total of 22 % PSI cases were considered as outliers because intra-operative navigation control measurement exceeded alignment targets. Furthermore, it is difficult to compare our data with values from a combination of intra-operative navigation and postoperative full leg radiograph data. It is well accepted that accurate alignment measurements with navigation are superior to CVI [19, 58], but a recent meta-analysis [21] comparing CVI with computer-assisted surgery reported a HKA-outlier rate of 13 % in large population; thus, it is also not warranted that with navigation, surgeons are able to achieve their targets in every single case. Two studies [29, 41] compared their PSI findings with data from meta-analyses of navigation procedures and found no superiority of one or the other technique. However, instead of intra-operative navigation control and possible abandoning PSI, we verified the tibial and femoral cutting block position and cut height with an extramedullary guidance rod and sickle finger, and planned resection was checked with the 3D model. To our experience, a perfect cutting block positioning was only given,

Table 5 Comparison of clinical outcome between non-outliers and outliers of mechanical alignment

	HKA non-outlier (≤3°) ($n = 187$)	HKA-outlier (>3°) ($n = 35$)	*p* value
KSS knee* (0–100 points)	93.2 ± 9.9	88.6 ± 16.3	0.027
KSS function* (0–100 points)	85.8 ± 16.7	74.0 ± 24.3	<0.001
Range of motion* (°)	117.2 ± 11.7	114.4 ± 13.0	n.s.
VAS pain* (0–10 points)	1.9 ± 1.9	3.0 ± 2.9	0.003
WOMAC score* (0–100 points)	87.8 ± 14.5	77.4 ± 23.5	0.001
Oxford-Knee-score* (0–48 points)	36.8 ± 9.2	30.9 ± 11.4	0.001

KSS Knee-Society-Score, *VAS* visual analog scale for pain, *WOMAC* the Western Ontario and McMaster Universities Osteoarthritis Index

* The values are given as the mean and the standard deviation

if all remaining cartilage was precisely removed from foot print areas. Indeed, we found similar HKA alignment and favorable 3D component accuracy with PSI compared with a computer-assisted surgery group of Hetaimish et al. [21].

The reasons for the heterogeneity of reported accuracy in contemporary PSI systems are yet not clear. Nonetheless, published studies mainly focus on PSI systems relying on MRI-based manufacturing of cutting blocks [4, 8, 35, 43, 61], whereas reports of CT-based PSI are relatively rare [29, 61]. In general, MRI may be better in defining cartilage surface, and CT scans have the advantage of a distinct visualization of femoral and tibial bone–cartilage interface. Therefore, degeneration and mechanical properties of the cartilage surface, especially in severe osteoarthritis, can alter correct cutting block or pin-guide placement. Such imprecision can easily be avoided by relying on bony landmarks [62, 65]. At the initial phase of the present study, we decided to use CT scans as it was considered to be the ultimate precision tool in measuring lower limb alignment [10]. A recently published randomized clinical trial reported slightly better accuracy with MRI-based compared with CT-based PSI [47], whereas another randomized clinical trial comparing three different MRI- and one CT-based PSI system showed inconsistent results [61]. Further investigations comparing a CT-based with an MRI-based PSI version of the same system would be of interest, but was beyond the scope of the current study.

To our knowledge, we are the first to present clinical data 2 years after TKA using PSI. Few clinical outcome studies comparing PSI and CVI in TKA have shown heterogeneous results, but follow-up periods were less than one year [48, 64, 66, 67]. While Pietsch et al. [48], Woolson et al. [66], and Vundenlickx et al. [64] reported no difference in clinical outcome between PSI and CVI, and Yaffe et al. [67] reported significant improvements with PSI, we detected subtle clinical differences between the instrumentation groups at the 2-year follow-up. Interestingly, we found significant differences between CVI and PSI regarding VAS for pain, but not with the pain-emphasized standardized WOMAC score. Both scores are patient generated and therefore influenced by various subjective conditions (e.g., depression) and expectations [23]; thus, it remains unclear how to interpret such differences. The other significant difference was detected with KSS function, which is known to have a poor correlation with the function part of the WOMAC score [31, 59]. However, it is still not clear if the two detected as significant differences are of clinical relevance; therefore, further long-term clinical investigations are required.

The influence of limb alignment on clinical outcome is not yet clear. Various studies showed an association between malalignment and decreased clinical outcome [12, 27, 33], whereas more recent studies suggested no negative effect of residual deformity on clinical results [36, 38, 60]. In contrast to the weak clinical differences between the two instrumentation cohorts of our study, a comparison of HKA-outliers and non-outliers (assuming a $\pm 3^\circ$ target) showed significantly better clinical outcome in the group of non-outliers. These findings not only confirm the importance of accurate limb alignment and component positioning, but also that a combination of clinical and radiological assessment is of additional value.

The present study has some limitations. One limitation of the study is that it was not randomized. However, the two consecutive groups were not significantly different regarding demographics and preoperative limb alignment. A further possible influencing factor is that we used either medial or lateral parapatellar surgical approach according to varus or valgus, which might influence clinical and radiological outcome, but the deformity distribution was not significantly different in both groups. Nonetheless, to our knowledge, the current study is the first reporting on clinical outcome of PSI versus CVI in primary mobile-bearing TKA with a follow-up of 2 years. Furthermore, it is among the largest studies currently available that compared radiological outcome between PSI and CVI in primary TKA.

Conclusion

The importance of this study lies in the findings that CT-based PSI compared with CVI improved accuracy of alignment restoration and 3D-component positioning in primary TKA. Such a reduction could be a feasible way to further improve patients' outcome and satisfaction in TKA. Although clinical outcome was similar in both instrumentation groups at early follow-up, significantly inferior outcome was detected in the subgroup of HKA-outliers. However, further long-term studies are necessary to evaluate clinical and radiological outcome as well as implant survival after TKA using PSI.

Acknowledgments The authors want to thank XX, XX, and XX for their assistance and participation in this study.

Conflict of interest The TKA system GMK® Primary was designed by Medacta International S.A., Castel San Pietro, Switzerland, in cooperation with the senior author, who will receive royalties for his contribution regarding the design of the implant. XX is a consultant for Medacta. However, Medacta had no influence on study design, data collection, interpretation of the results, or the writing of the final article. There was no external funding source for this study.

References

1. Abdel MP, Parratte S, Blanc G, Ollivier M, Pomero V, Viehweger E, Argenson JN (2014) No benefit of patient-specific

instrumentation in TKA on functional and gait outcomes: a randomized clinical trial. Clin Orthop Relat Res 472(8):2468–2476
2. Bali K, Walker P, Bruce W (2012) Custom-fit total knee arthroplasty: our initial experience in 32 knees. J Arthroplasty 27(6):1149–1154
3. Bargren JH, Blaha JD, Freeman MA (1983) Alignment in total knee arthroplasty. Correlated biomechanical and clinical observations. Clin Orthop Relat Res 173:178–183
4. Barrack RL, Ruh EL, Williams BM, Ford AD, Foreman K, Nunley RM (2012) Patient specific cutting blocks are currently of no proven value. J Bone Joint Surg Br 94(11 Suppl A):95–99
5. Barrett W, Hoeffel D, Dalury D, Mason JB, Murphy J, Himden S (2014) In-vivo alignment comparing patient specific instrumentation with both conventional and computer assisted surgery (CAS) instrumentation in total knee arthroplasty. J Arthroplasty 29(2):343–347
6. Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW (1988) Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. J Rheumatol 15(12):1833–1840
7. Bonner TJ, Eardley WG, Patterson P, Gregg PJ (2011) The effect of post-operative mechanical axis alignment on the survival of primary total knee replacements after a follow-up of 15 years. J Bone Joint Surg Br 93(9):1217–1222
8. Boonen B, Schotanus MG, Kerens B, van der Weegen W, van Drumpt RA, Kort NP (2013) Intra-operative results and radiological outcome of conventional and patient-specific surgery in total knee arthroplasty: a multicentre, randomised controlled trial. Knee Surg Sports Traumatol Arthrosc 21(10):2206–2212
9. Chareancholvanich K, Narkbunnam R, Pornrattanamaneewong C (2013) A prospective randomised controlled study of patient-specific cutting guides compared with conventional instrumentation in total knee replacement. Bone Joint J 95-B(3):354–359
10. Chauhan SK, Clark GW, Lloyd S, Scott RG, Breidahl W, Sikorski JM (2004) Computer-assisted total knee replacement. A controlled cadaver study using a multi-parameter quantitative CT assessment of alignment (the Perth CT Protocol). J Bone Joint Surg Br 86(6):818–823
11. Chen JY, Yeo SJ, Yew AK, Tay DK, Chia SL, Lo NN, Chin PL (2014) The radiological outcomes of patient-specific instrumentation versus conventional total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc 22(3):630–635
12. Choong PF, Dowsey MM, Stoney JD (2009) Does accurate anatomical alignment result in better function and quality of life? Comparing conventional and computer-assisted total knee arthroplasty. J Arthroplasty 24(4):560–569
13. Chotanaphuti T, Wangwittayakul V, Khuangsirikul S, Foojareonyos T (2014) The accuracy of component alignment in custom cutting blocks compared with conventional total knee arthroplasty instrumentation: prospective control trial. Knee 21(1):185–188
14. Daniilidis K, Tibesku CO (2014) A comparison of conventional and patient-specific instruments in total knee arthroplasty. Int Orthop 38(3):503–508
15. Dawson J, Fitzpatrick R, Murray D, Carr A (1998) Questionnaire on the perceptions of patients about total knee replacement. J Bone Joint Surg Br 80(1):63–69
16. Ensini A, Timoncini A, Cenni F, Belvedere C, Fusai F, Leardini A, Giannini S (2014) Intra- and post-operative accuracy assessments of two different patient-specific instrumentation systems for total knee replacement. Knee Surg Sports Traumatol Arthrosc 22(3):621–629
17. Fang DM, Ritter MA, Davis KE (2009) Coronal alignment in total knee arthroplasty: just how important is it? J Arthroplasty 24(6 Suppl):39–43
18. Fu H, Wang J, Zhou S, Cheng T, Zhang W, Wang Q, Zhang X (2014) No difference in mechanical alignment and femoral component placement between patient-specific instrumentation and conventional instrumentation in TKA. Knee Surg Sports Traumatol Arthrosc. doi:10.1007/s00167-014-3115-1
19. Fu Y, Wang M, Liu Y, Fu Q (2012) Alignment outcomes in navigated total knee arthroplasty: a meta-analysis. Knee Surg Sports Traumatol Arthrosc 20(6):1075–1082
20. Hamilton WG, Parks NL (2014) Patient-specific instrumentation does not shorten surgical time: a prospective, randomized trial. J Arthroplasty 29(7):1508–1509
21. Hetaimish BM, Khan MM, Simunovic N, Al-Harbi HH, Bhandari M, Zalzal PK (2012) Meta-analysis of navigation vs conventional total knee arthroplasty. J Arthroplasty 27(6):1177–1182
22. Heyse TJ, Tibesku CO (2014) Improved femoral component rotation in TKA using patient-specific instrumentation. Knee 21(1):268–271
23. Hirschmann MT, Testa E, Amsler F, Friederich NF (2013) The unhappy total knee arthroplasty (TKA) patient: higher WOMAC and lower KSS in depressed patients prior and after TKA. Knee Surg Sports Traumatol Arthrosc 21(10):2405–2411
24. Insall JN, Binazzi R, Soudry M, Mestriner LA (1985) Total knee arthroplasty. Clin Orthop Relat Res 192:13–22
25. Insall JN, Dorr LD, Scott RD, Scott WN (1989) Rationale of the Knee Society clinical rating system. Clin Orthop Relat Res 248:13–14
26. Ivie CB, Probst PJ, Bal AK, Stannard JT, Crist BD, Sonny Bal B (2014) Improved radiographic outcomes with patient-specific total knee arthroplasty. J Arthroplasty. doi:10.1016/j.arth.2014.06.024
27. Kamat YD, Aurakzai KM, Adhikari AR, Matthews D, Kalairajah Y, Field RE (2009) Does computer navigation in total knee arthroplasty improve patient outcome at midterm follow-up? Int Orthop 33(6):1567–1570
28. Kellgren JH, Lawrence JS (1957) Radiological assessment of osteo-arthrosis. Ann Rheum Dis 16(4):494–502
29. Koch PP, Muller D, Pisan M, Fucentese SF (2013) Radiographic accuracy in TKA with a CT-based patient-specific cutting block technique. Knee Surg Sports Traumatol Arthrosc 21(10):2200–2205
30. Kotela A, Kotela I (2014) Patient-specific computed tomography based instrumentation in total knee arthroplasty: a prospective randomized controlled study. Int Orthop. doi:10.1007/s00264-014-2399-6
31. Lingard EA, Katz JN, Wright RJ, Wright EA, Sledge CB (2001) Validity and responsiveness of the Knee Society Clinical Rating System in comparison with the SF-36 and WOMAC. J Bone Joint Surg Am 83-A(12):1856–1864
32. Lombardi AV Jr, Berend KR, Ng VY (2011) Neutral mechanical alignment: a requirement for successful TKA: affirms. Orthopedics 34(9):e504–e506
33. Longstaff LM, Sloan K, Stamp N, Scaddan M, Beaver R (2009) Good alignment after total knee arthroplasty leads to faster rehabilitation and better function. J Arthroplasty 24(4):570–578
34. Lotke PA, Ecker ML (1977) Influence of positioning of prosthesis in total knee replacement. J Bone Joint Surg Am 59(1):77–79
35. Lustig S, Scholes CJ, Oussedik SI, Kinzel V, Coolican MR, Parker DA (2013) Unsatisfactory accuracy as determined by computer navigation of VISIONAIRE patient-specific instrumentation for total knee arthroplasty. J Arthroplasty 28(3):469–473
36. Magnussen RA, Weppe F, Demey G, Servien E, Lustig S (2011) Residual varus alignment does not compromise results of TKAs in patients with preoperative varus. Clin Orthop Relat Res 469(12):3443–3450

37. Marimuthu K, Chen DB, Harris IA, Wheatley E, Bryant CJ, MacDessi SJ (2014) A multi-planar CT-based comparative analysis of patient-specific cutting guides with conventional instrumentation in total knee arthroplasty. J Arthroplasty 29(6):1138–1142
38. Matziolis G, Adam J, Perka C (2010) Varus malalignment has no influence on clinical outcome in midterm follow-up after total knee replacement. Arch Orthop Trauma Surg 130(12):1487–1491
39. Naal FD, Impellizzeri FM, Sieverding M, Loibl M, von Knoch F, Mannion AF, Leunig M, Munzinger U (2009) The 12-item Oxford Knee Score: cross-cultural adaptation into German and assessment of its psychometric properties in patients with osteoarthritis of the knee. Osteoarthr Cartil 17(1):49–52
40. Nam D, Maher PA, Rebolledo BJ, Nawabi DH, McLawhorn AS, Pearle AD (2013) Patient specific cutting guides versus an imageless, computer-assisted surgery system in total knee arthroplasty. Knee 20(4):263–267
41. Ng VY, DeClaire JH, Berend KR, Gulick BC, Lombardi AV Jr (2012) Improved accuracy of alignment with patient-specific positioning guides compared with manual instrumentation in TKA. Clin Orthop Relat Res 470(1):99–107
42. Noble JW Jr, Moore CA, Liu N (2012) The value of patient-matched instrumentation in total knee arthroplasty. J Arthroplasty 27(1):153–155
43. Nunley RM, Ellison BS, Ruh EL, Williams BM, Foreman K, Ford AD, Barrack RL (2012) Are patient-specific cutting blocks cost-effective for total knee arthroplasty? Clin Orthop Relat Res 470(3):889–894
44. Nunley RM, Ellison BS, Zhu J, Ruh EL, Howell SM, Barrack RL (2012) Do patient-specific guides improve coronal alignment in total knee arthroplasty? Clin Orthop Relat Res 470(3):895–902
45. Parratte S, Blanc G, Boussemart T, Ollivier M, Le Corroller T, Argenson JN (2013) Rotation in total knee arthroplasty: no difference between patient-specific and conventional instrumentation. Knee Surg Sports Traumatol Arthrosc 21(10):2213–2219
46. Parratte S, Pagnano MW, Trousdale RT, Berry DJ (2010) Effect of postoperative mechanical axis alignment on the fifteen-year survival of modern, cemented total knee replacements. J Bone Joint Surg Am 92(12):2143–2149
47. Pfitzner T, Abdel MP, von Roth P, Perka C, Hommel H (2014) Small improvements in mechanical axis alignment achieved with MRI versus CT-based Patient-specific Instruments in TKA: a randomized clinical trial. Clin Orthop Relat Res. doi:10.1007/s11999-014-3784-6
48. Pietsch M, Djahani O, Zweiger C, Plattner F, Radl R, Tschauner C, Hofmann S (2013) Custom-fit minimally invasive total knee arthroplasty: effect on blood loss and early clinical outcomes. Knee Surg Sports Traumatol Arthrosc 21(10):2234–2240
49. Ritter MA, Davis KE, Meding JB, Pierson JL, Berend ME, Malinzak RA (2011) The effect of alignment and BMI on failure of total knee replacement. J Bone Joint Surg Am 93(17):1588–1596
50. Roh YW, Kim TW, Lee S, Seong SC, Lee MC (2013) Is TKA using patient-specific instruments comparable to conventional TKA? A randomized controlled study of one system. Clin Orthop Relat Res 471(12):3988–3995
51. Russell R, Brown T, Huo M, Jones R (2014) Patient-specific instrumentation does not improve alignment in total knee arthroplasty. J Knee Surg. doi:10.1055/s-0034-1368143
52. Stronach BM, Pelt CE, Erickson JA, Peters CL (2014) Patient-specific instrumentation in total knee arthroplasty provides no improvement in component alignment. J Arthroplasty. doi:10.1016/j.arth.2014.04.025
53. Stucki G, Meier D, Stucki S, Michel BA, Tyndall AG, Dick W, Theiler R (1996) Evaluation of a German version of WOMAC (Western Ontario and McMaster Universities) Arthrosis Index. Z Rheumatol 55(1):40–49
54. Stucki G, Sangha O, Stucki S, Michel BA, Tyndall A, Dick W, Theiler R (1998) Comparison of the WOMAC (Western Ontario and McMaster Universities) osteoarthritis index and a self-report format of the self-administered Lequesne-Algofunctional index in patients with knee and hip osteoarthritis. Osteoarthr Cartil 6(2):79–86
55. Thienpont E, Bellemans J, Delport H, Van Overschelde P, Stuyts B, Brabants K, Victor J (2013) Patient-specific instruments: industry's innovation with a surgeon's interest. Knee Surg Sports Traumatol Arthrosc 21(10):2227–2233
56. Thienpont E, Bellemans J, Victor J, Becker R (2013) Alignment in total knee arthroplasty, still more questions than answers. Knee Surg Sports Traumatol Arthrosc 21(10):2191–2193
57. Thienpont E, Fennema P, Price A (2013) Can technology improve alignment during knee arthroplasty. Knee 20(Suppl 1):S21–S28
58. Tingart M, Luring C, Bathis H, Beckmann J, Grifka J, Perlick L (2008) Computer-assisted total knee arthroplasty versus the conventional technique: how precise is navigation in clinical routine? Knee Surg Sports Traumatol Arthrosc 16(1):44–50
59. Torres-Claramunt R, Leal J, Hinarejos P, Pelfort X, Puig L (2013) Correlation study between KSS, WOMAC and SF-36 scores in patients undergoing total knee arthroplasty in a Spanish speaking population. J Arthroplasty 28(6):950–953
60. Vanlommel L, Vanlommel J, Claes S, Bellemans J (2013) Slight undercorrection following total knee arthroplasty results in superior clinical outcomes in varus knees. Knee Surg Sports Traumatol Arthrosc 21(10):2325–2330
61. Victor J, Dujardin J, Vandenneucker H, Arnout N, Bellemans J (2014) Patient-specific guides do not improve accuracy in total knee arthroplasty: a prospective randomized controlled trial. Clin Orthop Relat Res 472(1):263–271
62. Victor J, Van Doninck D, Labey L, Innocenti B, Parizel PM, Bellemans J (2009) How precise can bony landmarks be determined on a CT scan of the knee? Knee 16(5):358–365
63. Voleti PB, Hamula MJ, Baldwin KD, Lee GC (2014) Current data do not support routine use of patient-specific instrumentation in total knee arthroplasty. J Arthroplasty. doi:10.1016/j.arth.2014.01.039
64. Vundelinckx BJ, Bruckers L, De Mulder K, De Schepper J, Van Esbroeck G (2013) Functional and radiographic short-term outcome evaluation of the Visionaire system, a patient-matched instrumentation system for total knee arthroplasty. J Arthroplasty 28(6):964–970
65. White D, Chelule KL, Seedhom BB (2008) Accuracy of MRI vs CT imaging with particular reference to patient specific templates for total knee replacement surgery. Int J Med Robot 4(3):224–231
66. Woolson ST, Harris AH, Wagner DW, Giori NJ (2014) Component alignment during total knee arthroplasty with use of standard or custom instrumentation: a randomized clinical trial using computed tomography for postoperative alignment measurement. J Bone Joint Surg Am 96(5):366–372
67. Yaffe MA, Patel A, Mc Coy BW, Luo M, Cayo M, Ghate R, Stulberg SD (2012) Component sizing in total knee arthroplasty: patient-specific guides vs. computer-assisted navigation. Biomed Tech (Berl) 57(4):277–282