Title: Significant differences between manufacturer and surgeon ~~The~~ in the accuracy ~~in the prediction~~ of ~~the~~ final component size prediction with CT-based patient specific instrumentation for total knee arthroplasty ~~differs significantly between manufacturer and surgeon~~.

Purpose: Patient specific instrumentation (PSI) for total knee arthroplasty (TKA) may improve component sizing. Little has been reported about accuracy of the default plan created by the manufacturer, especially for CT-based PSI. The goal of this study was to evaluate the reliability of this plan and the impact of the surgeon's changes on the final accuracy of the guide sizes.

Methods: Forty-five patients eligible for primary TKA were prospectively enrolled. The planned implant sizes were prospectively recorded from the initial manufacturer's proposal and from the final plan adjusted in light of the surgeon's evaluation; these two sizes where then compared to the actually implanted sizes. Fisher's exact test was used to test differences for categorical variables. Agreement between pre-operative plans and final implant was evaluated with the Bland-Altman method.

Results: The manufacturer's proposal differed from the final implant in nine (20.0%) ~~of the~~ femoral and 23 (51.1%) ~~of the~~ tibial components, while the surgeon's plan in six (13.3%, ~~(~~ femoral) and 12 (26.7%, ~~(~~ tibial). Modifications in the pre-operative plan were carried out for five (11.1~~1~~%) ~~of the~~ femoral ~~components~~ and 23 (51.1%) ~~of the~~ tibial components ~~ones~~ (p=0.~~029~~03). Appropriate modification occurred in 22 (88.0%) and 19 (76.0%) cases of femoral and tibial changes. The agreement between the manufacturer's and the surgeon's pre-operative plans was poor, especially with regards to tibial components.

Conclusion: The surgeon's accuracy in predicting the final component size was significantly different from that of the manufacturer and changes in the initial manufacturer's plan were necessary to get an accurate pre-operative plan of the implant sizes.

Clinical relevance: Careful evaluation of the initial manufacturer's plan by an experienced knee surgeon is mandatory when planning TKA with CT-based PSI.

Level of Evidence: ~~Prospective cohort study, l~~Level II.

KEYWORDS

Patient-specific instrumentation. Total knee arthroplasty. Size. Reliability. Pre-operative planning.

INTRODUCTION

Patient specific instrumentation (PSI) for total knee arthroplasty (TKA) was initially introduced to improve the accuracy in components' alignment and the efficiency of knee replacement surgery. Theoretical advantages claimed for PSI were the possibility to decrease surgical time and costs of the procedure by reducing the number of surgical steps, instrument trays used and planning time. Initial proponents of this technology also suggested that it could help in minimizing blood loss, and improve clinical outcome [10, 21, 30].

Preliminary studies confirmed that PSI is effective in reducing surgical time [9, 10, 13, 14, 16, 20, 21] and may help to achieve better prosthetic component position and sizes in TKA [10, 21, 30], but recent reviews suggested care when interpreting these initial results [18, 29].

Computer software can indeed facilitate pre-operative planning and help predicting intra-operative resections and component sizes. However, errors made in the initial steps of the planning process can be reproduced and amplified if PSI technology is blindly accepted without verification [28]. Understanding of the reliability of this technology and knowing its limitations is therefore of pivotal importance. Although numerous studies on PSI have been published, little has been currently reported about the accuracy of the default plan created by the manufacturers (manufacturer's plan, MaPl), with some authors advising for care when evaluating these suggestions [24, 28, 31].Most of the studies primarily designed to investigate MaPl accuracy were conducted on Magnetic Resonance Imaging (MRI)-based PSI and reported controversial results, with the accuracy of the MaPl ranging from 38% to 100% across different investigators [17, 24, 26, 28, 32]. With Computed Tomography (CT)-based PSI, a superior dimensional accuracy of bone modelling can theoretically be achieved, but evidence on MaPl accuracy is poor, since no study exists with the sample size necessary to ensure adequate statistical power to the results [11, 14, 34].

Furthermore, no studies were specifically designed to compare the MaPl accuracy with the surgeon's pre-operative plan (SuPl) with CT-based PSI.

The innovative purpose of this prospective study was to fill this gap in the available literature and evaluate the accuracy of the MaPl and the impact of surgeon's changes on the final accuracy of CT-based cutting guide sizes. Primary goal of this study was to compare the proportion of appropriate planning (with respect to the actually implanted size) between the MaPl and the SuPl. ~~The study was designed to test the hypothesis that the proportion of appropriate tibial planning by the surgeon (with respect to the actually implanted sizes) differs from that of the manufacturer by at least 25%, assuming an average accuracy in manufacturer's sizing of 50%; power analysis and cut-off values were based on the published data at the time of study design [24, 28].~~ Secondary goals were to measure the frequency of surgeon's modifications to manufacturer's planned sizes and to evaluate their appropriateness, with respect to the actually implanted components.

The study was designed to test the hypothesis that the proportion of appropriate tibial planning by the surgeon (with respect to the actually implanted sizes) differs from that of the manufacturer by at least 25%, assuming an average accuracy in manufacturer's sizing of 50%~~; power analysis and cut-off values were based on the published data at the time of study design [24, 28]~~.

MATERIALS AND METHODS

Institutional review board approval was obtained prior to study initiation (Ethical Committee of ASL Milano 2, Protocol nr. 2782). Patients younger than 80 years and eligible to receive a TKA were prospectively enrolled (D.C.); exclusion criteria were the presence of any metal devices within 8 cm from knee articular surfaces or of any fixed deformities greater than 15° in varus, valgus, flexion or tibial slope. All patients underwent clinical examination, long leg knee radiographs and a CT scan from the hip to the ankle, according to the manufacturer's requests. CT scan, demographic and morphometric data were submitted for instruments design and production. A default pre-

operative plan based on patient's bony morphology, implant design, surgical specifications and bony landmarks was generated by the company (MaPl). No specifications concerning implant size were suggested by the surgeon at this stage.

The first part of this study was dedicated to the evaluation of the MaPl: the surgeon was able to change the MaPl, modifying the proposed size of the implant components. Every variation to the initial proposal was noted.

A new, modified pre-operative plan was hence delivered from the manufacturer to the surgeon for a new modification or final approval (SuPl).

A cemented, posterior stabilized prosthesis with patellar resurfacing was implanted using a medial parapatellar approach. PSI cutting guides (Trumatch®, DePuy Orthopaedics, Inc. Warsaw, IN, USA) were used to perform proximal femur and distal tibial cuts and to guide the axial positioning of the four-in-one cutting block. According to the manufacturer's instructions, osteophytes were not removed unless explicitly indicated on the pre-operative plan. Before positioning the femoral four-in-one cutting block and the tibial keel reaming instrumentation, the implant sizes were checked with conventional instrumentation. The same surgeon, with extensive experience in TKA and four years experience with PSI, performed all interventions (P.R.).

The second part of this study was dedicated to the evaluation of the SuPl: the surgeon was able to follow or discard the SuPl suggestions, modifying the proposed size of the implant components. The appropriate size was then chosen and implanted.

In both evaluative steps of this study, the optimal component size was defined as that leading to the best congruence of the prosthetic component to the bony surfaces, without mediolateral overhang. The surgical transepicondylar axis was chosen as reference for the femoral component rotation and Akagi's line for the tibial one [1]. Cases in which an intra-operative change of the implant size was requested to correct ligamentous balance, were not included in this series.

According to the institution's standard operating procedure after TKA, four days after surgery all patients underwent a post-operative radiographic control with lateral and anteroposterior weight-

bearing views, in which five parameters were evaluated: femoral component mediolateral overhang, femoral component flexion, tibial component mediolateral overhang, tibial varus/valgus, and tibial slope [15]. This internal quality control was performed by two independent examiners (R.C, P.F.), neither involved in the surgical procedures nor in statistical analysis.

The implanted sizes were then compared to the sizes planned in the MaPl and in the SuPl.

Statistical analysis

Statistical analysis (A.M.) was performed using GraphPad Prism v 6.0 software (GraphPad Software Inc.) and Microsoft Excel (Microsoft Corporation). The Shapiro-Wilk normality test was used to evaluate the normal distribution of the sample. Continuous variables were expressed as median and interquartile range [first and third quartiles] or mean ± standard deviation as appropriate. Dichotomous variables are expressed in numbers of cases and frequencies. The differences for categorical variables were tested using the Fisher's exact test. Agreement between results for pairs of planned and implanted sizes was evaluated by use of the Bland-Altman method [6]. Bland-Altman plots were produced to show the agreement between the two measurements of planned and implanted sizes: the differences between measurements were plotted on the y-axis against the mean of the measurements, plotted on the x-axis. The Limits of Agreement (LOA) were defined as the 95% confidence interval (CI) of the mean difference between the sizes.

For all analyses, the significance level was set at p-value lower than 0.05.

Power analysis and cut-off values to define the sample size were based on the published data at the time of study design [24, 28], in order to test the hypothesis that the proportion of appropriate tibial planning by the surgeon (with respect to the actually implanted sizes) differs from that of the manufacturer by at least 25% (assuming an average accuracy in manufacturer's sizing of 50%).

RESULTS

Records were available for 45 knees (left knee: 24 cases; females: 30 cases; median age: 73.3 [66.9 – 76.2] years; mean Body Mass Index: 28.7 ± 3.9 Kg/m^2).

The femoral size in the MaPl was modified by the surgeon in the pre-operative phase in 5 cases (11.1%) and the tibial size in 23 (51.1%); altogether, in 24 knees (55.6%) pre-operative modifications were performed (Figures 1 and 2). The most frequently requested modification to the MaPl was an upsizing of the tibial tray (23 cases, 51.1%); in no cases the surgeon requested to downsize the implants.

Further intra-operative modifications from the SuPl were needed in 6 femoral components (13.3%) and 12 tibial trays (26.7%), with at least one modification in 16 cases (35.6%). In comparison, the MaPl differed from the final implant in 20% of the femoral components (p: n.s.) and 51.1% of the tibial trays (p=0.~~0299~~03) and at least one modification occurred in 62.2% of cases (p=0.~~0199~~02). In no cases a change greater than one size was required. The proportion of intra-operative changes from the SuPl was significantly smaller than that from the MaPl when considering the tibial tray alone and both components together (Figure 1 and Table 1).

For the femoral components, agreement between MaPl and final implant was poorer than agreement between SuPl and final implant. On the contrary, for the tibial components, the overall agreement was poorer between SuPl and final implant, but the SuPl appeared to approximate more precisely the final implant than the MaPl (SuPl: 73%, MaPl: 49%, p=0.~~0299~~03). The MaPl showed a tendency to underestimate the tibial tray size, throughout the spectrum of different sizes available; the SuPl, on the contrary, overestimated the sizes of some tibial trays, especially among the larger ones (Figure 2). The agreement between MaPl and SuPl was poor, especially for the tibial components (Figure 3).

In some cases, the surgeon, after modifying the MaPl, returned to the initially suggested size intra-operatively. We evaluated how often the surgeon's modifications from MaPl were inappropriate: in 12.0% of the femoral and 24.0% of the tibial components, the surgeon returned to the

manufacturer's size, meaning appropriate approval of 88.0% and 76.0% for femoral and tibial components, respectively. In none of the 45 procedures the use of PSI instrumentation was stopped due to an excessive mismatch between pre-operative planning and intra-operative observations. Internal quality control of the post-operative radiographs revealed correctness of the investigated parameters in 97.3% of the measurements.

DISCUSSION

The main finding of our study was that the surgeon's accuracy to predict the final component size is significantly different from that of the manufacturer and a poor agreement between planning and implant exists. The proportion of intra-operative changes form the SuPl was significantly smaller than that form the MaPl when considering the tibial tray alone and both components together. These results indicate that role of the surgeon is critical in evaluating the planning provided by manufacturer in CT-based PSI, in which deviations between the suggested and appropriate component size may occur. In our series, this was especially notable for the tibial tray.

Few other studies presented data on differences between MaPl and SuPl, mainly with MRI-based PSI systems, and controversial results were reported in the six available studies which indicated the accuracy of the pre-operative plan as primary goal. Stronach et al. prospectively evaluated the templating outcomes (Biomet Signature) in 60 patients, and recorded a sizing accuracy of the MaPl to the final components of 47% for tibial components and 23% for femoral ones [28]. In the same year, Issa et al. (ShapeMatch - Stryker Orthopedics) ~~reported sizing accuracy values of 97% (tibia) and 95.5% (femur)~~reported sizing accuracy values of 93% (tibia) and 95.5% (femur) [17], whereas Pietsch et al. (Zimmer PSI) reported that the proportion of implanted sizes comparable to the SuPl (tibia: 84%; femur: 100%) was significantly superior to that of implanted sizes comparable to the MaPl (tibia: 38%; femur: 84%); surgeon's changes to the MaPl occurred in 48% of the tibial and 16% of the femoral components [24].

Possible reasons for this wide variability in the outcomes include differences in the templating software or in the type and manufacture of the cutting blocks, with margins of error differing between manufacturers. Three more recent studies, which have been conducted with the same PSI technology (Biomet Signature), show a tendency towards similar results, and none of them could confirm the disappointing results published by Stronach et al. [28]: Schotanus et al. retrospectively analysed a cohort of 293 TKA implanted with either CT- or MRI-based PSI systems, and observed that the sizes in MaPl were comparable to the implanted ones in 82.6% of the tibial and 78.8% of the femoral components; the surgeon modified the MaPl in 15.4% of the tibial and 17.1% of the femoral components and obtained a superior proportion of plans comparable to the final implant (91.1% for tibial and 93.9% for femoral components) [26]. De Vloo et al. indicated a 79% MaPl accuracy for the tibial component and 100% for the femoral one [32]. Similarly, Okada et al. recorded a 78% MaPl accuracy for the tibial size with a 2% intra-operative correction rate, whereas for the femoral size a 49% MaPl accuracy with a 7% intra-operative correction rate was documented [22]. Other authors reported variable sizing accuracy of PSI guides as secondary finding of their researches, conducted in most cases on MRI-based PSI [17, 22, 24, 26, 28, 32].

CT-based PSI provides advantages over MRI-based PSI in terms of superior dimensional accuracy of bone modelling and reduction of procedure-related costs and scanning time [33]. On the other hand, CT-scans have limitations in visualizing cartilage and expose patients to ionizing radiation [26]. Data on CT-based PSI is lacking, and no study specifically investigated the performance of the MaPl and SuPl for this kind of PSI. The series published by Schotanus et al. included 28 patients who underwent CT-based planning: the proportion of sizes from MaPl comparable to the implanted components (71.4% tibial, 67.9% femoral) appeared lower than that from SuPl (96.4% tibial, 85.7% femoral). Surgeon's changes to the MaPl occurred in 25% of the tibial and 14.3% of the femoral components.

For what concerns the specific PSI analysed in this study (Trumatch®, DePuy Orthopaedics), few studies cited sizing accuracy among the secondary goals, and in none a comparison between

manufacturer and surgeon's planning was provided [11, 14, 34]. Woolson et al. randomized 64 patients to receive a conventional or a PSI-assisted TKA. In the study group, the size of the component was changed in 9 of 22 knees (41%): the femoral component appeared inadequate in 3 cases (14%), the tibial one in 4 (18%), and both components in 2 (9%). These figures are similar to what observed in our study for the femoral components (23% versus 20%), but are smaller for the tibial ones (27% versus 51%); however, the authors describe that in 7 of the 22 PSI procedures the tibial cutting blocks were abandoned due to overt malalignment, and the final cut was made with a standard extramedullary alignment guide, a procedure which may have favourably biased the sizing accuracy of the cutting guide [34].

Chotanaphuti et al. stated that the size of the planned femoral component matched the implanted component in 38 of 40 knees (appropriate MaPl: 95%), whereas that of the tibial one in 36 (appropriate MaPl: 90%). However, the authors measured the expected femoral size also with a conventional instrumentation jig and observed that this size was different than the pre-operative plan in 45% of the cases; nevertheless, they indicated that the only two changes in femoral size that occurred were performed to balance the flexion gap, whereas in all other cases manufacturer suggestions were accepted [14].

Briffa et al. also agreed on figures of 95% and 90% of correct MaPl size planning, but obtained this result after performing an intra-operative double-check of the cutting blocks positioning with a pin-less computer navigation system [11].

The reasons for the higher templating accuracy registered in previous reports with the same PSI system as compared to our study could either lay in a very zealous instrumental intra-operative control of the cutting guides position, which might have corrected minimal component malpositioning that our study setting was not designed to verify [11] or be related to the blind acceptance of the MaPl by the surgeon, which can have produced undetected over- or undersizing of the components and therefore an overesteem in MaPl accuracy [14]. The paucity of studies

primarily designed to investigate the MaPl accuracy with CT-based PSI does not yet permit an unbiased comparison to MRI-based PSI concerning templating accuracy.

Determination of appropriate component size plays a crucial role in ensuring successful TKA: errors in femoral sizing negatively affect ligamentous balance and patellofemoral kinematics, since an oversized femoral component can lead to patellofemoral overstuffing with persistent anterior knee pain and create stiffness and joint tightness, especially in flexion [8, 19, 27]. Excessive bone resection due to undersizing of the femoral component may result in notching on the anterior femoral cortex or create a wider flexion gap, requiring correction via additional distal resection with joint line elevation, additional soft tissue release and increased insert thickness to obtain a stable joint [23, 35]. An oversized, medially or laterally protruding tibial component can lead to decreased flexion and persistent pain due to distension of the medial collateral ligament medially or the ileotibial band laterally, while anteriorly or posterior overhang may lead to impingement with the patellar tendon or damage the popliteus tendon [3, 4, 7]. Finally, undersized tibial component can lead to insufficient bone coverage, periprosthetic fractures, subsidence and premature prosthesis failure [2, 5].

Therefore, correct match between the pre-operative plan and intra-operative observations is a key factor in PSI-assisted TKA: if a poor match is noted, the surgeon may consider the cutting guide unreliable, decide to abort the PSI procedure and switch to a conventional instrumentation system for alignment and sizing, increasing however operative time and procedure-related costs. This critical aspect, already reported in previous reports, was not observed in our series [12, 25, 31, 34].

However, we observed a tendency of the MaPl to underestimate the tibial trays sizes, throughout the spectrum of different sizes available and we noted that the agreement between MaPl and SuPl was poor, especially for the tibial components (Figure 3). This study has some limitations. The surgeon could neither be blinded to the manufacturer's planning nor to the modified planned. Implant sizing was considered as sole variable in this study; this indeed may be also affected by other surgical needs uncontrollable by planning software, as ligamentous balancing and patellar overstuffing or

tracking issues. In our series, no size changes were necessary due to unmatched bony gaps or patella-related issues. Furthermore, the planning and operating surgeon was the same; this could represent a bias on the choice of the final implant size, but nevertheless reduces variability in implant sizing strategies. Finally, a single type of PSI was tested (Trumatch®, DePuy Orthopaedics); other systems may perform differently and these results may then not be representative for all different custom-fit technologies available.

The results of this study question the reliability of the MaPl in CT-based PSI, showing that frequent pre- and intra-operative modifications are required to obtain the ideal component size: therefore, a careful evaluation of the initial MaPl by an experienced knee surgeon is recommended in the clinical setting when using these planning systems.

CONCLUSIONS

The surgeon's accuracy in predicting the final component size is significantly different from that of the manufacturer; furthermore, intra-operative modifications are significantly inferior when comparing the surgeon's to the manufacturer's plan. The role of careful evaluation by an experienced surgeon in both planning phase and PSI guides positioning is of utmost importance when dealing with CT-based cutting guides, and blind acceptance of manufacturer's plans is discouraged.

FIGURES AND TABLES

Table 1: Number of cases and proportion of appropriate implant size planning. Data are expressed in numbers of cases and frequencies.

Table 1: Number of cases and proportion of appropriate implant size planning					
	Manufacturer, No. (%)		Surgeon, No. (%)		p-value
Femoral component	36	(80.0)	39	(86.7)	n.s.
Tibial component	22	(48.9)	33	(73.3)	0.0299 03
Femoral or tibial component	17	(37.8)	29	(64.4)	0.02199

Figure 1: Comparison between the manufacturer's planning, the surgeon's planning and the implanted component size (in millimetres) for the 45 study patients. A) Femoral component anteroposterior (AP) sizes. B) Tibial tray mediolateral (ML) sizes.

Figure 2: Bland-Altman plot depicting agreement of values for femoral and tibial sizes. A) Agreement between implanted femoral sizes and MaPl; B) agreement between implanted femoral sizes and SuPl. C) Agreement between implanted tibial sizes and MaPl; D) agreement between implanted tibial sizes and SuPl. Differences between measurements are plotted against the mean of measurements. The pointed line indicates 0 difference, the solid line represents the mean difference in measurements and two dotted lines represent the 95% confidence intervals (CIs) for the mean difference (LOA).

Figure 3: Bland-Altman plot depicting agreement of values between MaPl ans SuPl. A) Femoral sizes; B) Tibial sizes. Differences between measurements are plotted against the mean of measurements. The pointed line indicates 0 difference, the solid line represents the mean difference in measurements and two dotted lines represent the 95% confidence intervals (CIs) for the mean difference (LOA).

Authors contributions:

DC: study design, patient recruitment and data collection, original draft preparation; AM: statistical analysis, figures and tables, draft revision; RC, PF, CF: discussion, manuscript correction; PR: study design, surgical procedures, manuscript correction.

Compliance with Ethical Standards

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317 **References**

318 1. Akagi M, Oh M, Nonaka T, Tsujimoto H, Asano T, Hamanishi C (2004) An anteroposterior
319 axis of the tibia for total knee arthroplasty. Clin Orthop Relat Res 366:213–219

320 2. Altintas F, Sener N, Ugutmen E (1999) Fracture of the tibial tray after total knee arthroplasty.
321 J Arthroplasty 14:112–114

322 3. Argenson J-NA, Scuderi GR, Komistek RD, Scott WN, Kelly MA, Aubaniac J-M (2005) In
323 vivo kinematic evaluation and design considerations related to high flexion in total knee
324 arthroplasty. J Biomech 38:277–284

325 4. Barnes CL, Scott RD (1995) Popliteus tendon dysfunction following total knee arthroplasty.
326 J Arthroplasty 10:543–545

327 5. Berend ME, Ritter MA, Hyldahl HC, Meding JB, Redelman R (2008) Implant migration and
328 failure in total knee arthroplasty is related to body mass index and tibial component size. J
329 Arthroplasty 23:104–109

330 6. Bland JM, Altman DG (1986) Statistical methods for assessing agreement between two
331 methods of clinical measurement. Lancet 1:307–310

332 7. Bonnin MP, Saffarini M, Shepherd D, Bossard N, Dantony E (2016) Oversizing the tibial
333 component in TKAs: incidence, consequences and risk factors. Knee Surg Sports Traumatol
334 Arthrosc 24:2532–2540

335 8. Bonnin MP, Schmidt A, Basiglini L, Bossard N, Dantony E (2013) Mediolateral oversizing
336 influences pain, function, and flexion after TKA. Knee Surg Sports Traumatol Arthrosc
337 21:2314–2324

338 9. Boonen B, Schotanus MGM, Kerens B, van der Weegen W, van Drumpt R a M, Kort NP
339 (2013) Intra-operative results and radiological outcome of conventional and patient-specific
340 surgery in total knee arthroplasty: a multicentre, randomised controlled trial. Knee Surg

Sports Traumatol Arthrosc 21:2206–2212

10. Boonen B, Schotanus MGM, Kort NP (2012) Preliminary experience with the patient-specific templating total knee arthroplasty. Acta Orthop 83:387–393

11. Briffa N, Imam MA, Mallina R, Abdelkafy A, Adhikari A (2016) Verification of in vivo accuracy of Trumatch^{TM} patient-specific instrumentation in total knee replacement using pin-less computer navigation. Eur J Orthop Surg Traumatol 27:1–8

12. Cavaignac E, Pailhé R, Laumond G, Murgier J, Reina N, Laffosse JM, Bérard E, Chiron P (2015) Evaluation of the accuracy of patient-specific cutting blocks for total knee arthroplasty: a meta-analysis. Int Orthop 39:1541–1552

13. 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:354–359

14. 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 21:185–188

15. Dejour H, Bonnin M (1994) Tibial translation after anterior cruciate ligament rupture. Two radiological tests compared. J Bone Joint Surg Br 76:745–749

16. Fu H, Wang J, Zhou S, Cheng T, Zhang W, Wang Q, Zhang X (2015) No difference in mechanical alignment and femoral component placement between patient-specific instrumentation and conventional instrumentation in TKA. Knee Surg Sports Traumatol Arthrosc 23:3288–3295

17. Issa K, Rifai A, McGrath MS, Callaghan JJ, Wright C, Malkani AL, Mont MA, McInerney VK (2013) Reliability of templating with patient-specific instrumentation in total knee arthroplasty. J Knee Surg 26:429–433

18. Jiang J, Kang X, Lin Q, Teng Y, An L, Ma J, Wang J, Xia Y (2015) Accuracy of patient-specific instrumentation compared with conventional instrumentation in total knee arthroplasty. Orthopedics 38:e305-313

19. Lo C-S, Wang S-J, Wu S-S (2003) Knee stiffness on extension caused by an oversized femoral component after total knee arthroplasty: a report of two cases and a review of the literature. J Arthroplasty 18:804–808

20. MacDessi SJ, Jang B, Harris IA, Wheatley E, Bryant C, Chen DB (2014) A comparison of alignment using patient specific guides, computer navigation and conventional instrumentation in total knee arthroplasty. Knee 21:406–409

21. Noble JW, Moore CA, Liu N (2012) The value of patient-matched instrumentation in total knee arthroplasty. J Arthroplasty 27:153–155

22. Okada Y, Teramoto A, Suzuki T, Kii Y, Watanabe K, Yamashita T (2017) Preoperative corrections are required for planning of patient-specific instrumentation in total knee arthroplasty. Knee 24:1492–1497

23. Pagnano MW, Hanssen AD, Lewallen DG, Stuart MJ (1998) Flexion instability after primary posterior cruciate retaining total knee arthroplasty. Clin Orthop Relat Res 39–46

24. Pietsch M, Djahani O, Hochegger M, Plattner F, Hofmann S (2013) Patient-specific total knee arthroplasty: The importance of planning by the surgeon. Knee Surgery, Sport Traumatol Arthrosc 21:2220–2226

25. 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 knee. Clin Orthop Relat Res 471:3988–3995

26. Schotanus MGM, Schoenmakers DAL, Sollie R, Kort NP (2017) Patient-specific instruments for total knee arthroplasty can accurately predict the component size as used peroperative.

389 Knee Surg Sports Traumatol Arthrosc 25:3844–3848

390 27. Seil R, Pape D (2011) Causes of failure and etiology of painful primary total knee
391 arthroplasty. Knee Surg Sports Traumatol Arthrosc 19:1418–1432

392 28. Stronach BM, Pelt CE, Erickson J, Peters CL (2013) Patient-specific total knee arthroplasty
393 required frequent surgeon-directed changes. Clin Orthop Relat Res 471:169–174

394 29. Thienpont E, Schwab P-E, Fennema P (2017) Efficacy of Patient-Specific Instruments in
395 Total Knee Arthroplasty: A Systematic Review and Meta-Analysis. J Bone Joint Surg Am
396 99:521–530

397 30. Tibesku CO, Hofer P, Portegies W, Ruys CJM, Fennema P (2013) Benefits of using
398 customized instrumentation in total knee arthroplasty: results from an activity-based costing
399 model. Arch Orthop Trauma Surg 133:405–411

400 31. Victor J, Dujardin J, Vandenneucker H, Arnout N, Bellemans J (2014) Patient-specific
401 guides do not improve accuracy in total knee arthroplasty: a prospective randomized
402 controlled trial. Clin Orthop Relat Res 472:263–271

403 32. De Vloo R, Pellikaan P, Dhollander A, Vander Sloten J (2017) Three-dimensional analysis
404 of accuracy of component positioning in total knee arthroplasty with patient specific and
405 conventional instruments: A randomized controlled trial. Knee 24:1469-1477

406 33. White D, Chelule KL, Seedhom BB (2008) Accuracy of MRI vs CT imaging with particular
407 reference to patient specific templates for total knee replacement surgery. Int J Med Robot
408 4:224–231

409 34. Woolson ST, Harris AHS, Wagner DW, Giori NJ (2014) Component Alignment During
410 Total Knee Arthroplasty with Use of Standard or Custom Instrumentation. J Bone Jt Surg
411 96:366

412 35. Zalzal P, Backstein D, Gross AE, Papini M (2006) Notching of the anterior femoral cortex

during total knee arthroplasty characteristics that increase local stresses. J Arthroplasty 21:737–743