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REVIEW

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Patient-specific instrumentation in total knee arthroplasty: a review of the current literature

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Total knee arthroplasty (TKA) is one of the most frequently performed interventions in the field of Orthopaedic surgery. Over the last decades the implantation technique has improved continuously. The majority of patients is satisfied with the clinical outcome of TKA. However in various clinical follow-ups, up to 20% of unsatisfied patients can be observed. Periprosthetic infection and aseptic loosening seem to be the most common reasons for failure. Malalignment has been discussed as a cause of aseptic loosening and often leads to revision surgery. In order to increase the precision of implant positioning and alignment, new technologies such as patient-specific instrumentation (PSI) have been developed. Since the introduction of PSI, multiple clinical studies have been performed analyzing the clinical and radiological outcome of TKA with PSI technique. This review covers the recent literature of PSI in respect to surgical accuracy, clinical outcome, time- and cost-effectiveness.

Keywords: total knee arthroplasty, limb alignment, patient-specific instrumentation, cutting block, conventional instrumentation.

INTRODUCTION

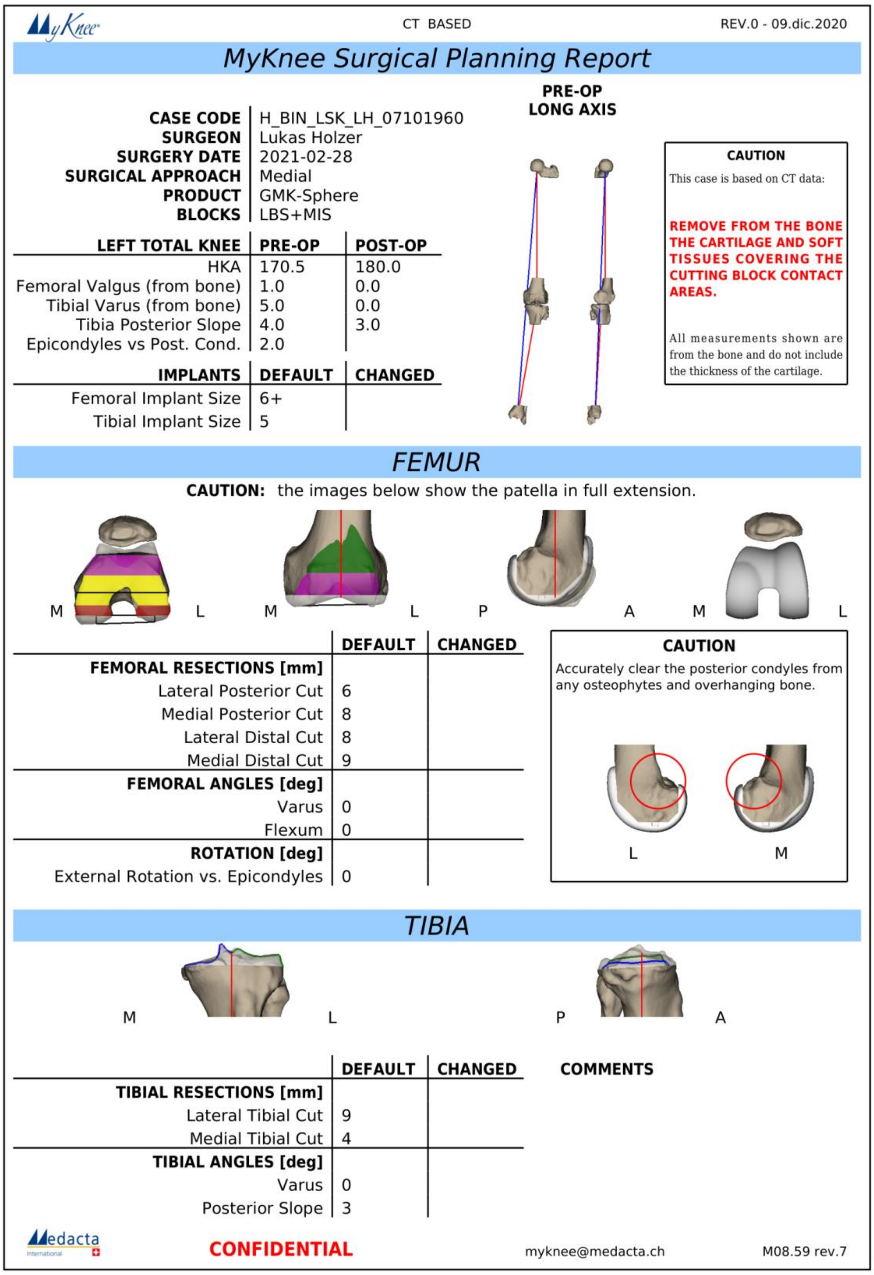
Total knee arthroplasty (TKA) is an effective and well-studied procedure for the treatment of symptomatic osteoarthritis of the knee [1-3]. Studies show excellent clinical and radiological outcomes and long implant survivorship rates. Nevertheless, about 20% of the patients are unsatisfied with the clinical result[1-3]. The most common reasons for failure and subsequently revision surgery are periprosthetic infection and aseptic loosening. Aseptic loosening is mostly the consequence of a malalignment of the hip-knee ankle angle[4-6]. Several types of alignment strategies in TKA are described in the literature ranging from mechanical to kinematic alignment. To enclose the individual anatomy and alignment of the patients and to optimize the positioning of TKA additional novel techniques such as patient specific instrumentation (PSI) and computer- assisted surgery (CAS) were developed.

The current literature shows that the primary goal, to improve the alignment, accuracy and implant positioning, can be achieved by the use of CAS[7-9]. The positive side effects of CAS have been reported to be a lower blood loss and lower embolization rates due to failure to open the medullary canal[10]. However, no benefit has been found in terms of complication rates, clinical outcome, patient satisfaction and implant survivorship[8,11-13]. The cost-benefit ratio should be questioned in case of a significant additional surgical effort and longer operating time. An economic advantage would only be given with a significantly lower revision rate[14]. However, long term effects on clinical and functional outcomes are still to be evaluated[7,9,11].

The PSI technique is another system with the goal to increase the accuracy of implant positioning and limb alignment. A patient specific 3D computer model of the patient's knee is developed by either a computer tomography (CT) or a magnet resonance imaging (MRI) scan (Figure 1). After the approval of the surgeon, personalized cutting blocks are designed by the use of a 3D printer and delivered before surgery.

METHODS

Literature search was performed using Pubmed, ScienceDirect, Scopus and Google Scholar databases on articles between 1990 and March 2022. The following key words were used: "knee", "arthroplasty", "joint replacement", "total knee arthroplasty", "total



CT BASED REV.0 - 09.dic.2020

MyKnee Surgical Planning Report

CASE CODE	H_BIN_LSK_LH_07101960
SURGEON	Lukas Holzer
SURGERY DATE	2021-02-28
SURGICAL APPROACH	Medial
PRODUCT	GMK-Sphere
BLOCKS	LBS+MIS

LEFT TOTAL KNEE	PRE-OP	POST-OP
HKA	170.5	180.0
Femoral Valgus (from bone)	1.0	0.0
Tibial Varus (from bone)	5.0	0.0
Tibia Posterior Slope	4.0	3.0
Epicondyles vs Post. Cond.	2.0	

IMPLANTS	DEFAULT	CHANGED
Femoral Implant Size	6+	
Tibial Implant Size	5	

PRE-OP LONG AXIS

CAUTION

This case is based on CT data:

REMOVE FROM THE BONE THE CARTILAGE AND SOFT TISSUES COVERING THE CUTTING BLOCK CONTACT AREAS.

All measurements shown are from the bone and do not include the thickness of the cartilage.

FEMUR

CAUTION: the images below show the patella in full extension.

M L M L P A M L

	DEFAULT	CHANGED
FEMORAL RESECTIONS [mm]		
Lateral Posterior Cut	6	
Medial Posterior Cut	8	
Lateral Distal Cut	8	
Medial Distal Cut	9	
FEMORAL ANGLES [deg]		
Varus	0	
Flexum	0	
ROTATION [deg]		
External Rotation vs. Epicondyles	0	

CAUTION

Accurately clear the posterior condyles from any osteophytes and overhanging bone.

L M

TIBIA

M L P A

	DEFAULT	CHANGED
TIBIAL RESECTIONS [mm]		
Lateral Tibial Cut	9	
Medial Tibial Cut	4	
TIBIAL ANGLES [deg]		
Varus	0	
Posterior Slope	3	

COMMENTS

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Figure 1. — Patient-specific preoperative template based on CT scans.

knee replacement", "patient-specific instrumentation". All references were exported from the databases to a reference management tool.

DISCUSSION

Surgical Technique – Patient Specific Instrumentation

The surgery is performed under general anaesthesia or spinal anaesthesia and perioperative antibiotic prophylaxis. The surgical approach follows a standard medial skin incision and a parapatellar capsulotomy. After exposure of the joint all soft tissue and cartilage is removed from the contact points of the cutting blocks to ensure exact positioning. The osteophytes are spared. After the tibial guide is positioned and fixed the surgeon should check the level of resection and the tibial alignment with the use of an extramedullary guide. After the resection, the resected bone has to be measured and should be compared to the template.

The distal femoral resection follows the same principle. After the distal femoral resection, the medio-lateral extension gap has to be checked with a spacer block. If additional resections are necessary the surgeon hast to switch to conventional cutting blocks.

Table I. — Current literature on patient-specific instrumentation in total knee arthroplasty

Author	Number of participants (PSI/CI)	Imaging techniques	PSI system	Percentage of outliers (%)		p value
				PSI	CI	
Gemalmaz et al. [21]	40 (20/20)	CT	Zimmer PSI	5	35	0,04
Mehdipur et al. [22]	24 (12/12)	CT	Fanavaran Jarahyar Sharif Ltd.	8,3	41,7	0,077 (n.s.)
Zahn et al. [28]	225 (75/150)	MRI	Visionaire	18,7	10	-
Randelli et al. [25]	60 (31/29)	CT	Trumatch	-	-	n.s.
Boonen et al. [45]	180 (86/82)	MRI	Signature	30	18	n.s.
Chareancholvanich et. [46]	80 (40/40)	MRI	Zimmer PSI	2,5	7,5	n.s.
Hamilton et al. [47]	52 (26/26)	CT	Trumatch	35	31	n.s.
Parratte et al. [48]	40 (20/20)	MRI	Zimmer PSI	20	10	n.s.
Roh et al. [49]	100 (42/48)	CT	Signature	12	10	n.s.
Kotela A. and Kotela I. [50]	112 (49/46)	CT	Signature	49	30	n.s.
Victor et al. [51]	128 (61/64)	MRI CT MRI + LLR MRI	Signature Trumatch Visionaire Zimmer PSI	25	28	n.s.
Woolson et al. [52]	60 (22/26)	CT	Trumatch	41	38	n.s.
Abane et al. [53]	140 (59/67)	MRI + LLR	Visionaire	33	32	n.s.
Gan et al. [54]	70 (35/35)	CT	Stryker	3	23	< 0,001
Yan et al. [55]	90 (30/30)	MRI	Zimmer PSI	27	43	n.s.
Huijbregts et al. [56]	140 (69/64)	MRI + LLR	Visionaire	13	22	n.s.
Vide et al. [57]	100 (47/48)	MRI + LLR	Visionaire	13	35	0,011
Maus et al. [58]	157 (59/66)	MRI	Imprint	26	12	0,04
Van Leeuwen et al. [59]	94 (42/49)	MRI	Signature	26	22	n.s.

Then the 4-in1 cutting block is positioned to perform the anterior, posterior and oblique femoral resections. After checking the flexion gap and the femoral rotation the positioning of the cutting block can be adapted. After these resections, the final trial implants are used to check alignment, range of motion and stability.

Under the use of the tourniquet the definitive tibial and femoral components are cemented. The wound is closed in respect to the various layers and the skin by the use of staples.

Accuracy

The alignment of components seems to be the most important factor considering clinical outcome and patients' satisfaction. Therefore, one of the primary aims of the PSI technique is to improve the accuracy of tibial and femoral cutting and subsequently implant positioning. Although the aim of achieving the axis of 180° in the coronal plane raised some doubts, it is still the target to accomplish a neutral mechanical axis. Most authors defined an axis deviation of 3°≤ as an outlier and failure.

The current data regarding the accuracy of PSI technique is controversial. On one hand authors attribute clear advantages of the PSI over the conventional instrumentation (CI)[15-19]. On the other hand some others did not find any effect of the PSI on the accuracy of implant positioning[20].

An overview of the clinical trials comparing PSI and CI can be seen in table I.

Gemalmaz et al. compared postoperative mechanical alignment of 40 patients that had TKA with either PSI or CI technique. No significant differences respective femorotibal angles (mFTA), femoral coronal angles (FCA) and tibial coronal angles (TCA) were found. 5% outliers were seen in the PSI group compared to 35% in the CI group (p = 0,04). The authors concluded that PSI may improve TKA alignment by improving the ratio of the outlier patients with marked malalignment[21].

Mehdipur et al. reported a higher number of outliers in the CI group in comparison to the PSI group, even if the result was not significant (41,7% vs. 8,3%). They argued that the small number of study participants (n = 24) could be the reason for the missing of statistical significance. They concluded that PSI may result in the improved postoperative mechanical alignment of the limb, but future investigations should investigate, if the results support considerably higher costs of this technique[22].

Tibesku et al. examined 94 patients, who received an MRI preoperatively for the development of the cutting blocks. 48 were treated with the CI, in 46 PSI technique was used. The rotation of the femoral components was determined by MRI postoperatively and axis deviations over 3° were defined as outliers. 11 versus 1 outliers resulted in a significant better result in the PSI group[23].

Nizam et al. and colleagues measured all femoral and tibial resections in 201 knees operated with patient specific instrumented knee replacement systems and compared them to the preoperative CT predicted bone resection surgical plan. 94% of all collected resection readings were below the error margin of ≤1.5 mm. The authors concluded that the accuracy of the predicted bone resection of the 3D printed cutting blocks with slots for jigs would directly affect component positioning[19].

Turgeon et al. did not find any significant difference between CI and PSI in respect to the coronal alignment ($p = 0{,}79$) or in the number of mechanical alignment outliers ($p = 0{,}40$). The tibial sagittal angle was found to be more accurately reproduced to the preoperative target of 3° with PSI ($p < 0{,}001$)[24].

Randelli et al. compared 31 patients, in which PSI technique was used, to 29 patients, who had surgery with the CI. The aims of their study were to study if PSI improves the rotational alignment of the femoral component and the sagittal alignment of the tibial component. Comparing the two techniques in terms of rotation of the femoral component and the slope of the tibial component no significant differences between the groups were seen. Also, no variance respecting the outliers were found. Furthermore, the number of tibial recuts was significantly higher in the PSI group. Randelli et al. summed up that their results did not support the routine use of PSI during standard TKA [25]. Giannotti did not find any difference in respect to the postoperative femorotibial angle between the PSI and the CI (178,9° vs. 178,8°). They reported some difficulties with the positioning of the preconstructed cutting guides[20].

To optimize evaluation of PSI, Yamamura et al. were the first ones to superimpose postoperative three-dimensional (3D) CT image onto the preoperative 3D CT plan and measure the absolute difference in the prosthetic alignment[26]. This type of measurement was used to compare the accuracy of a conventional PSI with that of a newly designed PSI. Several points are improved in comparison to the old design: larger contact points between bone and PSI; a rotational marker to optimize the reproduction of the preoperative plan; prolongation of the hole for the extramedullary rod to support attachment of the ankle cramp; inclusion of the hole of the anteroposterior marker pin in the tibial cutting jig. The new PSI showed significant less outliers in the tibial prosthesis than the conventional design and the differences between the pre- and postoperative 3D CT image was significantly lower in the coronal and axial planes[27].

Zahn et al. examined 300 patients to compare conventional and innovative techniques in total knee arthroplasty. The participants were divided into 4 groups: two conventional groups (extramedullary and intramedullary) and two innovative groups (PSI and navigation). The medial proximal tibial angle (MPTA) and the tibio-femoral axis were measured three months postoperatively and compared between the groups. Intramedullary and computer navigated techniques showed significantly better results than the other two groups. The PSI group produced the highest number of outliers (18,7%)[28].

As previously mentioned, there is no standardised method for the different PSI manufacturers. There are a few studies that examined the radiological difference between MRI based PSI and CT based PSI. Some of them observed more radiological outliers using the CT based PSI[29,30]. On the other hand a meta-analysis with 22 randomized controlled trials indicated, that the accuracy in the CT based PSI group was significantly higher compared to the MRI based PSI group[31].

Thijs et al. observed the two different types of PSI in terms of clinical outcome and implant longevity. After two years of follow up 57 patients in the MRI group and 67 in the CT group were tested. One patient in each group had to undergo revision surgery, due to progressive valgus instability and respectively a broken bearing. In both groups the patient reported outcome measures showed a significant improvement with the preoperative values, but no difference between the groups were found[32].

Blood loss

As blood loss during surgery associated with postoperative anaemia can lead to several complications and the risks linked with blood transfusions. A specific aim of the use of PSI is a reduction of blood transfusions in comparison to the CI.

Attard et al. compared two different types of PSI systems with CI. The PSI methods showed lower blood loss during surgery than the CI, but the results did not reach a statistical significance[33].

Gianotti et al. found a significant difference in relation to the blood loss during surgery between patients operated with PSI and patients operated with CI (p-value < 0,05). A mean blood loss of 657ml was measured in the PSI group compared to 866,5 ml in the CI group[20].

In a meta-analysis by Kizaki et al. that included 38 studies, a decreased blood loss with the PSI method was found, although the effect size was small corresponding to a 0.4 g/dl haemoglobin. No reduction of the transfusion rate was reported[34].

The purpose of the study of Cucchi et al. was to compare the estimated haemoglobin and red blood cell volume losses in patients undergoing TKA with PSI and CI. A significant difference in haemoglobin reduction in favour of the PSI group was found on the last day of stay in hospital. The total blood loss, the red blood cell volume and the transfusion requirement did not differ between the two groups. This study also demonstrated that PSI leads to a significant trend in earlier haemoglobin regain[35].

In a study with 69 patients who were treated with a TKA by Randelli et al. no significant difference in the haemoglobin-reduction could be seen between CI and PSI technique[25].

Li et al. compared conventional TKA with CAS and PSI in terms of perioperative blood loss. The overall intraoperative blood loss of the patients was 6mililiters and no patient received allogeneic blood transfusion. The total blood loss did not differ significantly between the three groups[36].

A recent meta-analysis reported, that in most of the studies that were included a significant decrease of blood loss in patients treated with PSI was seen.

On the other hand some studies did not show a significant difference between CI and PSI in respect to blood loss[37]. In synopsis the PSI seems to be superior to CI concerning intraoperative blood loss.

Clinical outcome

One of the primary aims of TKA is to improve patients' quality of life and increase the level activity without pain. Studies were identified that compared the functional outcome after TKA between PSI and CI.

Anderl et al. examined the knee society score (KSS), the Oxford knee score (OKS) and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and compared them between patients treated with PSI and CI. After a mean follow up from 28,6 months, both groups showed a significant improved clinical outcome in comparison to the preoperative status. No difference between the two groups could be seen. A significant worse outcome became apparent in the subgroup of radiological outliers in the group of patients treated with CI[38].

Attard et al. investigated four different techniques of TKA: CI single use, CI reusable, PSI single use, PSI reusable. In view of the postoperative OKS all groups showed significant improvement. The CI group with reusable instruments showed the best result with a significant difference to the PSI group with reusable instruments (p= 0,05)[33].

No differences in terms of the KSS and Hospital for Specific Surgery (HSS) between PSI and CI were found by Gianotti et al. and Sun et al.[20,39]. The results in the outcomes of TKA based on the KSS and WOMAC were similar between PSI and CI in a study by Mehdipur et al.[22]. Randelli et al. did not report any significance respectively postoperative OKS gain and the Visual Analogue Scale (VAS) reduction[25]. To compare satisfaction between patients treated with PSI and CI Reimann et al. used the Knee Injury and Osteoarthrosis Outcome Score (KOOS) and a modified EuroQol (EQ). No significant difference was shown in respect to these outcome scores. The patients were asked if they were satisfied with the result after surgery using a Likert scale with five answer options (very unsatisfied, unsatisfied, neutral, satisfied, very satisfied). The global satisfaction was significantly higher in patients treated with PSI. In view of the range of motion (ROM) both groups showed similar results. Postoperatively the average flexion decreased by 5°. The PSI group showed significant better results in terms of the KSS[40].

Schotanus et al. examined 163 patients treated with the use of CI technique or PSI assisted TKA. The OKS, KSS, WOMAC, VAS and EQ-5D were analysed preoperatively, three months, one year, two years and five years after surgery. All scores significantly improved within each group. No significant differences between the two treatment groups regarding survival rates, clinical outcome and patient-reported outcome measures (PROMs) were found[41].

Thijs et al. compared MRI- and CT-based PSI. However no significant differences were found in Patient Reported Outcome und Experience Measures (PROM: OKS, WOMAC, VAS, EQ-5D). The PROMs improved significantly within each group compared with preoperative values[32].

Turgeon et al. found a statistically significant difference between CI and PSI in the improvement in the EQ VAS at the one year follow up. All other PROMs were similar in both groups[24].

Leon-Munoz et al. did not find any differences in clinical and functional results in their meta-analysis about studies giving attention to PSI and CI until 2018[37]. Nevertheless, the clinical outcome seems to improve significantly, regardless from the treatment option.

Surgical time and cost-effectiveness

The factor time might become of greater importance within the next years due to an increase in the number of primary TKA and economical pressure on healtcare systems worldwide. The aim of future TKA is to operate as time- and cost-effectively as possible without losing quality of care.

Kizaki et al. did not find any significant difference in their meta-analysis including eighteen studies relating to the surgery time between PSI and CI[34]. In addition, Lin et al. did not see any difference in surgical time in fifteen studies that were observed between PSI and CI However a non-significant benefit in favour of the MRI group in the subgroup analysis of operative time between MRI-based or CT-based image processing was seen[42].

Mehdipur et al. and Menon et al. report a shorter operational time in PSI group, however these results were not statistically significant[22,35].

No significance difference was found by Randelli et al. in terms of total surgical time between PSI and CI[25].

Teeter et al. reported a significant longer procedure time in the PSI group with a difference of 6 minutes (p=0,04). No other differences in surgical resources used or waste generated were found[43].

Turgeon et al., who studied fifty-four patients, who were either treated with PSI or CI, did not see a significant difference in relation to surgical time or length of hospitalization between the both groups[24].

Anderl et al. calculated additional costs for PSI compared with CI comprising due to increase in logistics (CT investigation and production of the cutting blocks). However, reduction of costs could be achieved by shortening the operating time, the length of hospital stay and a smaller demand of blood preservations. In addition, the longer survival time of the implants would lead to a reduction in the additional costs associated with a revision surgery and correction of joint alignment[38].

In order to respond to the growing demand in TKA Attard et al. investigated whether single-use instrumentation would shorten the total operating time. Reusable PSI had a significant shorter procedure time than reusable CI (5min; p<0,054). The significantly improved surgical efficiency by PSI was at the expense of increased costs[33].

Munoz et al. compared PSI and CI based on the length of stay in hospital and objectify differences in cost. The mean duration of hospitalization was 4,22 days respectively 4,29 days and didn´t show any significant difference. The fees per stay were slightly lower for the PSI group. The cost for blood conservation system and transfusions were significant higher in the CI group. Significantly higher expenses for CT scans and higher expenses for instrumentation in the PSI group led to similar overall costs in the two groups[44].

CONCLUSION

The use of PSI did not show any significant difference concerning the radiological and clinical outcome compared to CI in respect to the recent literature focusing on randomized clinical trials. The intraoperative blood loss and haemoglobin reduction is lower in patients who had TKA with the use of PSI. The costs and operating time were not affected due to the use of PSI.

Ethics approval and consent to participate: not applicable.

Consent for publication: not applicable.

Availability of data and material: the datasets during and/ or analysed during the current study available from the corresponding author on reasonable request.

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