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Midterm clinical and radiographic outcomes of 115 consecutive patient-specific unicompartmental knee arthroplasties

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ABSTRACT

Background: Poor implant positioning has been identified as a factor in early failure of unicompartmental knee arthroplasty. The aim of this study was to report the accuracy of component positioning, and midterm clinical, functional and radiological outcomes following patient-specific instrumented (PSI) unicompartmental knee arthroplasty (UKA).

Methods: A total of 115 PSI-UKA were included. The primary outcomes were UKA survival, complication, and failure rates. Tibial implant positioning was determined using plain radiographs. Functional assessment included Oxford Knee Score (OKS), Forgotten Joint Score (FJS), patient satisfaction, and range of motion (ROM).

Results: The survival rate of PSI-UKA was 92% after a mean follow-up of 55 months. The complication and failure rate was 13% and eight percent, respectively. The tibial component was accurately implanted in the desired frontal and sagittal alignment with a minor deviation of 0.3° (SD 1.9°) and 0.4° (SD 2.6°) to the preoperative planning. OKS increased from 24 (SD eight) points to 44 (SD six). FJS was 87 (SD 23) and 89.6% of all patients reported to be satisfied at the final follow-up. Patient satisfaction was negatively correlated with patients' age ($p < 0.05$).

Conclusion: Excellent accuracy regarding component placement in UKA can be achieved with PSI. However, despite excellent survivorship and clinical outcomes, these data indicate that the PSI system is not superior to conventional UKA implantation methods.

1. Introduction

Isolated medial or lateral degeneration is encountered in 30% of patients suffering from knee osteoarthritis (OA) [1]. Advantages of unicompartmental knee arthroplasty (UKA) over total knee arthroplasty (TKA) include preserved knee kinematics [2], faster recovery, reduced mortality, and fewer complications [3]. Nevertheless, despite the excellent functional outcomes, the reported long-term survival rates of UKA are still inferior to TKA [4,5]. The higher incidence of failure in UKA, leading to early revision, has been associated with poor patient selection and errors in surgical technique [6].

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Regarding surgical technique, Chatellard identified several factors associated with low implant survivorship [7]. In particular, the tibial component obliquity and tibial slope should not exceed a deviation of three degrees and five degrees, respectively, relative to the pre-operative value. High rates of early implant failure – due to unequal polyethylene wear, mechanical loosening, and OA progression in the contralateral compartment – have been reported in the literature [8–10], of which most revisions were attributed to component malpositioning.

Current evidence suggests that the recently introduced patient-specific implant (PSI)-UKA could improve the accuracy of component positioning and therefore positively influence UKA survivorship [11–16]. Although excellent short-term outcomes following PSI-UKA in a small cohort have been published [11], there are no available data in the literature regarding the midterm outcomes of PSI-UKA on a larger scale. Therefore, the purpose of this study was to report on 1) the accuracy of component placement and 2) midterm clinical and functional outcomes in 126 consecutive PSI-UKA.

2. Materials and methods

This study was approved by the Institutional Review Board and the Ethical Committee (Project-ID 2018-01079). It was conducted entirely at the authors' institution.

2.1. Inclusion criteria

Inclusion criteria were: adult patients who underwent primary UKA (MyKnee UNI®, Medacta International, Castel San Pietro, CH) for symptomatic, medial unicompartmental knee OA stage III–IV according to the Kellgren–Lawrence classification (primary or secondary), and who completed at least two years of follow-up at the time of data collection. Patient's informed consent was obtained.

2.2. Patient characteristics

From May 2011 to April 2016, a total of 116 medial PSI-UKA were performed in 114 patients (male: 50, female: 64), with an average age of 69 years (range, 56–86). The average follow-up was 55 months (range, 33–83; standard deviation (SD) 16). Mean body mass index (BMI) was 29.5 kg/m^2 (SD five). Mean patients' physical status according to the American Society of Anesthesiologists (ASA) was two (SD one) and mean hospital stay was six days (SD four).

2.3. Surgical technique and perioperative care

The unicompartmental knee prostheses were implanted through a minimally invasive approach with patient-specific cutting blocks for the tibial component (MyKnee UNI ®, Medacta Switzerland). Surgery was performed or supervised by two experienced knee surgeons with a caseload of >100 knee arthroplasties per year (approximately 40 UKA and 80 TKA). A pre-operative computed tomography (CT) scan was acquired in all the patients for pre-operative planning, and a CT-based three dimensional (3D) bone model was produced by the manufacturer. The amount of tibial resection was set to a maximum of six millimetres in all patients. Slope and varus obliquity of tibial component were set to a standard of five degrees and three degrees, respectively. A correction of >3° to the pre-operative value was necessary in 21 cases with a varus alignment of >10°. Through this intervention, postoperative excessive residual varus was prevented. Consequently, a suggestion of implant size was provided according to the 3D bone model. After validation by the surgeon, a sterile, tibial patient-matched cutting block was supplied to perform the horizontal and vertical tibial cuts. The femoral cut was carried out parallel to the tibial cut in spacer-based technique for implant congruency [8]. Soft-tissue balancing was avoided. All implants were cemented, and a fixed bearing was used.

All patients followed a standardised physiotherapy protocol, with immediate mobilisation out of bed on the first postoperative day. Patients' discharge criteria included safe self-mobilisation, controlled pain, and dry wounds. Enoxaparin 40 mg subcutaneously was prescribed for 30 days once daily as deep venous thrombosis prophylaxis.

2.4. Clinical evaluation

The patients were clinically and radiographically followed-up at three months, one year and five years following surgery. For a final follow-up, all patients were interviewed by phone and invited to the outpatient clinic for clinical and radiographic examination for the purpose of this study between August and September 2018. Three patients refused but completed questionnaires. Medical records were retrospectively reviewed – including outpatient clinic notes, operative reports, and hospital records for readmission – and searched for complications or reoperations. Independent of any medical staff, pre-operative and postoperative Oxford Knee Score (OKS) was carried out by patients.

At the final follow-up, the Forgotten Joint Score (FJS) was acquired and patient satisfaction was assessed using the subjective knee value as a five-point Likert Scale for responses: excellent, very good, good, poor, and terrible. Postoperative range of motion (ROM) was measured using a handheld goniometer with the patient in the supine position and with knee stability. An orthopaedic surgeon from the clinic, but not involved in the study, performed the clinical examination in a standardised manner. Significant complications were considered to be superficial or deep periprosthetic infection, according to the criteria of the Musculoskeletal Infection Society [17], and wound dehiscence or postoperative haematoma that required additional intervention.

Failure was defined as conversion to TKA, revision of any UKA component, or UKA of the unaffected compartment due to disease progression.

2.5. Radiographic measurement

Frontal alignment of the tibial component was assessed on a long-leg standing view and was defined as the angle between the tibial component undersurface and the anatomical tibial axis (positive values indicated varus) (Figure 1). The tibial slope was defined as the angle between the proximal tibial anatomical axis and the tibial component undersurface in the sagittal plane, on the lateral x-ray (Figure 2) [18]. Hip–knee–ankle (HKA) angle was measured on a long-leg standing x-ray 12 weeks following surgery and compared with a long-leg standing x-ray radiograph taken pre-operatively. Postoperative tibial slope and varus obliquity were compared with pre-operatively set values. Also, all radiographs were compared with the initial postoperative radiograph to evaluate for component loosening. Component loosening was defined as subsidence of >2 mm or an angular change of >3° relative to previous radiographs [19].

Figure 1. Component position in frontal plane, defined as the angle between the tibial anatomical axis (A) and the component's undersurface (CU).

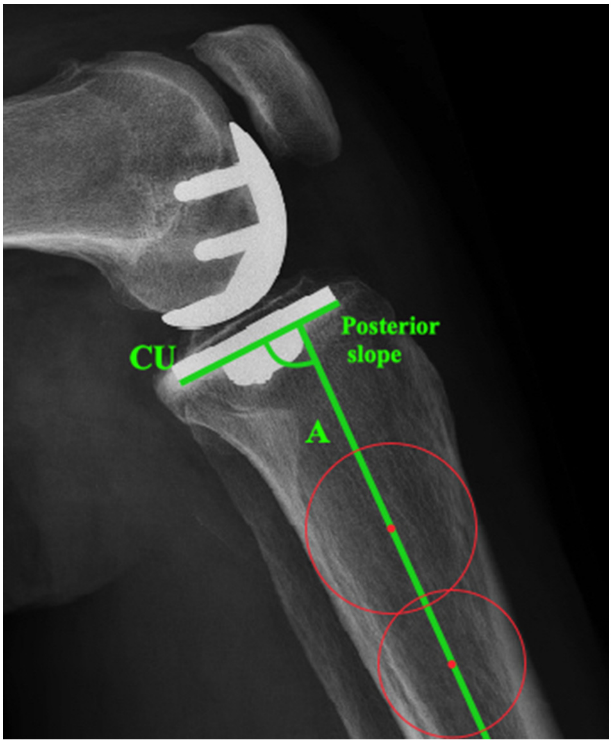

Figure 2. Tibial slope, defined as the angle between the proximal tibial anatomical axis (A) and the component's undersurface (CU) in the sagittal plane.

2.6. Statistical analysis

Descriptive statistics used frequencies and percentages to present the data. Intra-observer and inter-observer reliabilities of the radiographic measurements performed by two orthopaedic residents blinded to the study were evaluated using single-measure intraclass correlation coefficients (ICC) with a two-way random-effects model for absolute agreement. All parameters were tested with the Shapiro–Wilk test for normality. When the criteria for normality were met, a two-tailed paired *t*-test was used. Otherwise, the Wilcoxon signed-rank test was applied. The mean differences between planned and final implant position were calculated. The Spearman correlation was used to identify a potential relationship between patients' functional outcome, failure or patient satisfaction and patient demographics or postoperative implant alignment. The level of significance was set at $p = 0.05$. All the statistical analyses were performed using SPSS, version 23 software (SPSS Inc., Chicago, IL).

3. Results

One patient declined to participate in this study, leaving 115 UKA for clinical and radiographic evaluation.

Table 1
Summary of complications.

Complication	Knees (n = 115)
Infection (n)	0
Wound dehiscence (n)	0
Haematoma needing revision (n)	1 (0.9%)
Arthroscopic adhesiolysis and mobilisation under anaesthesia	4 (3.5%)
Failure (n)	9 (7.8%)
• Aseptic loosening (n)	5 (4.3%)
• Pain, but no obvious reason (n)	4 (3.5%)
• Re-operation prior to failure (n)	0 (0%)
Progression of disease (n)	1 (0.9%)
Total complications (n)	15 (13%)

Values are given as mean and percentage.

3.1. Intraobserver and interobserver reliabilities

The intraobserver ICCs for tibial varus/valgus and tibial slope were 0.91 and 0.95, respectively. The interobserver ICCs for tibial varus/valgus and tibial slope were 0.89 and 0.93, respectively.

3.2. Complication and Failure Rate

At a mean follow-up of 55 months, the survival rate of all 115 PSI-UKA was 92.2%. The total complication and failure rates were 13% and 7.8%, respectively (Table 1). No infection requiring revision surgery was observed in this cohort. Four patients (3.5%) underwent arthroscopic adhesiolysis and mobilisation under anaesthesia at a mean of seven months postoperatively, due to pain and decreased ROM. At final follow-up, those four patients reported a mean OKS of 45.5/48.

All UKA failures (n = 9, 7.8%) occurred within the first two years after surgery. Five patients (4.3%) presented with aseptic loosening. Two were treated with loosened component exchange (femoral component only in one patient, and both femoral and tibial components in the second patient), whereas three were converted to TKA at an average of 1.3 years following the primary surgery. Before revision, mean OKS of all failures was 32/48. At the latest follow-up, all five patients with aseptic loosening were satisfied, reported no pain, had a mean OKS of 44/48, and did not undergo any further re-operation. Four patients (3.5%) suffered from constant pain and functional limitations without any apparent reason (OKS 22/48) and underwent conversion to TKA at another institution.

One patient showed OA progression in the primarily unaffected knee compartment six years following UKA implantation. Due to her age (89 years) and satisfactory ambulation, she declined revision surgery; therefore, this case was not considered as a failure.

3.3. Clinical outcomes

The nine patients with UKA failure (7.8%) were not included in the analysis of the clinical outcomes. For the remaining 106 patients, mean OKS increased from 24 (SD eight) pre-operative to 44 (SD six) postoperative ($P < 0.05$). The FJS was 87 (SD 20). Mean subjective knee value was 4.6, with 89.6% of all patients being satisfied (four points) or very satisfied (five points). Mean active ROM increased from 118° (SD nine degrees) to 124° (SD eight degrees) (Table 2). At final follow-up, all knees were stable with restored soft-tissue balancing.

3.4. Radiographic outcomes

Measurement of HKA showed a mean value of 175.1° (SD 2.8°) varus pre-operative compared with 176.3° (SD 2.6°; $P > 0.5$) postoperative. Mean pre-operative angles were 7.0° (SD 2.5°) and 7.5° (SD three degrees), and planned angles 2.8° (SD 0.7°) and 4.5° (1.1°), for coronal and sagittal alignment, respectively. Mean difference of final implant position compared with pre-operative planning was 0.3° (SD 1.9°; $P = 0.09$) for tibial varus/valgus and 0.4° (SD 2.6°; $P = 0.2$) for tibial slope (Table 3).

There was no correlation between failure and postoperative tibial component alignment or other parameters. A weak but statistically significant negative correlation between patients' satisfaction and age was found (Spearman Correlation coefficient $r = 0.27$, $P = 0.0002$).

3.5. Accuracy of pre-operative planning

The PSI guides fitted to the patient's anatomy in all cases. To be able to insert a bearing with a minimal thickness of 3.0 mm, intraoperative adjustments to the pre-operative planning were performed in 17 patients (14.8%), consisting of additional or less resection of the tibia. No additional posterior femoral resections were necessary. In 50 patients (43.5%), one or more components

Table 2
Clinical outcomes.

Characteristics	Pre-operative	Postoperative
ROM (°)	118 (9)	124 (8)
Oxford Knee Score	24.2 (8)	44.2 (6)
Forgotten Joint Score		87.3 (20)
Subjective Knee Score		4.6 (0.8)
5 (n)		78 (73.6%)
4 (n)		17 (16%)
3 (n)		6 (5.7%)
2 (n)		4 (3.8%)
1 (n)		1 (0.9%)

Values are given as mean and standard deviation.
ROM, range of motion.
For functional scores, all failures (n = 9) were excluded (remaining n = 106).

Table 3
Radiographic outcomes.

	Pre-operative alignment	Planned alignment	Final implant alignment	Δ Final implant to planned alignment	Significance between planned and final implant alignment (*P*)
Tibial varus/valgus (°)	7.0 (2.5)	2.8 (0.7)	3.2 (2)	0.3 (1.9)	0.09
Tibial posterior slope (°)	7.5 (3)	4.5 (1.1)	4.9 (2.8)	0.4 (2.6)	0.2
HKA (°)	175.1 (2.8)	–	176.3 (2.6)	0.9 (1.8)	–

Values are given as mean and standard deviation.
HKA, hip–knee–ankle.
P-value is between the planned and final implant alignment.

were changed intraoperatively to another size than previously planned, but the sizes were accurate to within one implant size in 100%.

4. Discussion

The current study aimed to report the complication and survival rates, as well as the midterm clinical and radiographic outcomes at an average follow-up of 55 months following a PSI-UKA. The results of the present study showed excellent accuracy in component placement, high patient satisfaction, and good midterm clinical, functional and radiographic outcomes of PSI-UKA. There was also a negative correlation between patients' satisfaction with PSI-UKA and age.

Recent evidence has suggested that PSI in UKA implantation could reliably and accurately translate pre-operative planning into an in vivo situation. Kerens et al. prospectively compared their first 30 cases of UKA implanted using PSI with conventional outlining [20]. Except for the femoral component in the frontal plane, they found no statistical difference in radiological component positioning between the two groups. They highlighted a smaller range of measured alignment for PSI, but a similar number of outliers between the groups. Outliers were defined as being positioned outside the safe zone described in the Oxford partial knee phase III manual (® Zimmer Biomet), specifically ±5° for varus/valgus and slope. They reported 10% and three percent outliers in the frontal and sagittal planes, respectively. Applying similar definitions for the safe zone, the current study reported a lower percentage of outliers in the frontal plane (0.9%; n = 1), whereas there were similar numbers of outliers in the sagittal plane (4.3%; n = 5). Kerens et al. reached the same conclusion in another study, where they determined component position with a postoperative CT scan [14]. With a median absolute deviation from the pre-operative plan of 2.5° and three degrees in the frontal and sagittal planes, respectively, angular positions were not significantly different than planned. These findings were mirrored in the current study, as final component position did not significantly differ from pre-operatively set values in frontal or sagittal planes. Therefore, patient-specific implant in UKA surgery allows reliable and accurate translation of pre-operative planning into an in vivo situation. A previous study from the current institution, which used the same methodology as Kerens et al. in 28 patients who are included in the presented study, also reported good results regarding component rotation [12,14].

However, the clinical relevance of those minor improvements in component positioning due to PSI is unclear, as midterm and long-term outcomes concerning implant survival of PSI are missing. Bell et al. reported promising short-term results with no revisions or complications after a mean follow-up of 24 months (range, 12–30) after 44 PSI-UKA procedures [11]. As the survival rate determines the efficacy of PSI technology, the current study is the first to report the outcome of patients with a mean follow-up of 55 months who received UKA with PSI. However, with a failure rate of 7.8% after a mean follow-up of 55 months, it was unable to show superior survivorship compared with conventional UKA techniques, where survival rates of up to 98.7% at five years, 88% at 10 years, and 91% at 15 years have been reported [21–23]. Similar results have been shown in other studies, where, although navigation contributed significantly to a more accurate UKA component placement compared with the conventional technique, estimated 10-year prosthesis survival rates did not differ between the two groups [24].

Clinical outcomes in this study were comparable with those from other conventionally implanted UKA series [25]. In the current study, OKS was 44.2 at 55 months, and 89.6% of the knees had an excellent or good outcome, whereas, for example, Pandi et al. reported a mean OKS of 40 and 79% excellent or good outcomes after 10 years [23]. Furthermore, soft-tissue balancing was successfully restored in all of the current cases.

In summary, PSI is a useful technique to improve surgical accuracy. Better results were reported in component positioning compared with conventional instrumentation and equivalent to robot-assisted systems, respectively [13]. Nevertheless, this difference was, if present, inconsiderable and therefore unlikely clinically significant [26,27]. In contrast, improved control of surgical technique compared with manual approaches was reported using robotic assistance, explaining a favourable survivorship of 96% in the study by Pearle et al. [28]. However, the robotic system ensured correct tibial component positioning within 1.7° in all directions, which was significantly undercut in this study by patient-specific instruments [28]. In the hands of high-volume UKA surgeons it is doubtful that improvements in clinical outcome and UKA survivorship can be achieved with assistive technologies and therefore be due to correct implant positioning.

One advantage of PSI is simple handling of the system. It has been suggested that the PSI system is particularly useful for low-volume UKA surgeons [29]. A recent laboratory-based study demonstrated the advantages of PSI in TKA by achieving accurate cuts independent of the surgeon's experience and bone mineral density [30]. However, in the current study, manual recuts were performed in 14.8% and a change of implant size was necessary in 43.5% of cases. Attempts to not injure the anterior cruciate ligament insertion during the vertical tibial cut may be one of many possible explanations for this phenomenon, leading to unexpected changes in the size of the tibial tray surface and therefore changes in component size. It is known that very low-volume UKA surgeons obtain the worst results [31]. Thus, the PSI system might not be a key solution for low-volume surgeons, as it does not guarantee a perfect implementation of the pre-operative plan. It might be useful for low-volume UKA surgeons concerning component placement, but its application should not be executed without any reservation. In any case, further development of the PSI technique is warranted to reduce outliers and potentially improve clinical outcomes.

A significant finding of this study was that younger patient age was negatively correlated with satisfaction after UKA. Similar findings were reported by Price et al., where patients aged >60 years showed higher survivorship after 10 years compared with younger patients who received UKA without PSI (96% vs. 91%) [32]. Thus, older age should not be considered a contraindication to UKA [32–34]. A possible explanation could be elderly patients' less active lifestyle and thus lower demand in daily life activities.

The present study should be interpreted in light of its potential limitations. A significant limitation might be the assessment of component positioning on conventional x-ray and not on postoperative CT scans. It was therefore not possible to measure component positioning in the axial plane. Additionally, measurements were restricted to tibial component alignment because patient-specific cutting blocks were only planned and manufactured for the tibial cut, and perpendicular femoral component positioning was achieved in a spacer technique.

In conclusion, this study showed excellent accuracy in implant positioning with the use of PSI in UKA. However, despite excellent clinical outcomes, no superior survivorship was achieved with the PSI system in the hands of an experienced high-volume UKA surgeon. Furthermore, intraoperative adjustments are often necessary and the surgeon should be experienced enough to adequately handle these situations. This study confirmed a significantly negative correlation between younger age and outcome of UKA.

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Declaration of Competing Interest

The authors declare that they have no conflict of interest regarding this study. PD Dr. Näder Helmy is a medical advisor of Medacta International (Switzerland) and receives royalties from Medacta International (Switzerland). Dr. Helmy reports no conflict of interest in relation to this article.

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