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Patient-specific implants for lateral unicompartmental knee arthroplasty

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Abstract
Purpose The lateral compartment of the knee is biomechanically and anatomically different from the medial compartment. Most commercially available unicompartmental implants are not designed specifically for the lateral compartment. Patient-specific custom-made unicompartmental knee arthroplasty (UKA) are designed to provide optimal fit on both femoral and tibial surfaces. This study aimed to determine if the use of patient-specific lateral unicompartmental implants provide better bone coverage than standard, off-the-shelf commercially available unicompartmental implants in lateral unicompartmental knee arthroplasties. As a secondary question, we wished to determine if patient-specific unicompartmental implants provide good clinical outcomes in surgical treatment of lateral unicompartmental osteoarthritis.
Methods We prospectively evaluated 33 patients who underwent lateral unicompartmental arthroplasty using patient-specific implants and instrumentation with a minimum of 24 months of follow-up. We analysed bone coverage observed in plain radiographs in 33 patient-specific lateral unicompartmental arthroplasties and compared to 20 lateral unicompartmental arthroplasties performed with commercially-available, standard off-the-shelf unicondylar implants.
Results The mean tibial implant lateral coverage mismatch in the patient-specific implant group was 1.0 mm (S.D. 1.2, range 0–5.7 mm) versus 3.3 mm (S.D. 2.43, range 0.4–7.8 mm) in the conventional implant group ($p<0.01$). In the patient specific cohort, pre-operative limb alignment was 3.3 (valgus) and post-operative limb alignment was −0.9 (varus). The Knee Society score improved from 48 (S.D. 16.2) to 95 (S.D. 7.6). Survivorship in the patient-specific implant group was 97% at an average follow up of 37 months, versus 85% at a follow-up period of 32 months for the standard implant group.
Conclusions Patient-specific lateral unicompartmental knee replacements demonstrated better tibial coverage and provide excellent short-term clinical and radiological results as compared to a standard lateral UKA.

Keywords Knee · Osteoarthritis · Unicompartmental arthroplasty · Patient-specific implants · Tibia · Lateral · Custom-made

Introduction

Isolated unicompartmental osteoarthritis (OA) is approximately ten times less common in the lateral than the medial compartment [1], with previous studies indicating that only 5–10% of unicompartmental knee arthroplasty (UKA) is performed in the lateral compartment [2]. This number might be artificially low, since a majority of surgeons reported preferring total, rather than lateral unicondylar knee replacement for the treatment of lateral compartment OA [3]. Accordingly, fewer and smaller series have reported the results of lateral compartment arthroplasty [2, 4–7].

Technically, lateral UKA is more challenging than medial UKA, due to difficulties with exposure, as well as shortcomings of traditional unicompartmental implants, which do not address the anatomical differences between the medial and lateral compartments. Typically, the lateral tibial plateau is rounder than the medial plateau, the lateral femoral condyle

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is smaller than the medial femoral condyle, and the screw-home mechanism is far more significant on the lateral side [8, 9]. Generally, commercially available unicompartmental implants are designed for the medial compartment, due to the much larger surgical volume in this location. Modifications and compromises in the surgical technique are required to compensate for the mismatch between implants designed for the medial compartment and the anatomy of the lateral compartment [4, 10, 11]. Due to the surgical compromises required, the use of standard medial unicondylar implants for a lateral compartment indication may lead to inadequate rotational alignment of the tibial component and suboptimal bone coverage or overhang of either the tibial or femoral components [8, 12]. Femoral components with significant (i.e. greater than 3 mm) overhang have been demonstrated to nearly double the risk for post-operative knee pain and the corresponding amount of overhang on the tibial plateau has shown significantly worse knee scores, pain scores [13, 14] and increased MCL load [15].

Recently, patient-specific implants have been described as increasing the match between shape and size of the lateral compartment and the implants (Fig. 1) [8, 11]. Additionally, pre-navigated patient-specific custom-made cutting jigs may facilitate implant placement in a more anatomic position and alignment in lateral UKA (Fig. 2) [11].

The purpose of this study was to determine whether using a patient-specific UKA implant results in more precise component positioning and better tibial bone coverage than standard commercially-available medial implants for the treatment of lateral unicompartmental arthritis. As a secondary outcome, we asked whether these patient-specific lateral unicompartmental implants could effectively restore the patient's coronal alignment and provide significant improvement in postoperative range of motion and in the American Knee Society score. Additionally, implant survivorship was tracked for all patients in both cohorts.

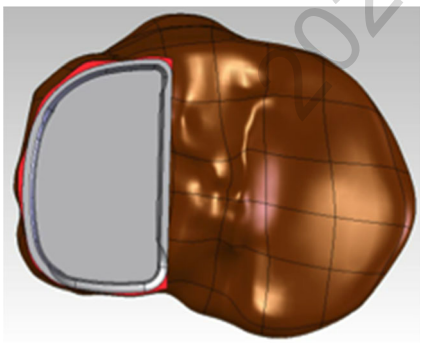

Fig. 1 CAD designs demonstrating patient-specific implant design (*left*) and a standard design sizing array (*right*). Placement was optimized for a standard implant to maximize coverage while minimizing overhang; a larger size could have been chosen to increase coverage, at the cost of overhanging the resected tibia

Fig. 2 Pre-navigated patient-specific custom-made cutting jigs

Materials and methods

From June 2007 to December 2009, a consecutive series of 32 patients (33 knees) underwent lateral unicompartmental knee arthroplasty with the iUni G1 implant (ConforMIS, Burlington, Massachusetts), performed by two senior surgeons at our institution. The device is completely patient specific. Each device is made on the basis of data from a pre-operative computed tomographic scan [16]. The individualized iUni (ConforMIS, Burlington, Massachusetts) implant has been cleared under the 510(k) process (i.e., pre-market notification) by the United States Food and Drug Administration. For comparison, we also reviewed a consecutive series of 19 patients (20 knees) who had undergone lateral UKA previously, by the same surgeons, with commercially available medial implants (Miller-Galante Unicompartmental System; Zimmer, Warsaw, Indiana) between September 2003 and September 2009. All knees had a diagnosis of isolated osteoarthritis of the lateral compartment, verified through MRI or CT arthrogram to assure the medial compartment did not have degenerative disease. This was an IRB approved retrospective review of the results from those two patient cohorts.

Our indications for lateral UKA for all patients included non-inflammatory osteoarthritis with symptoms isolated to the lateral compartment, no disease attributable to the medial or patellofemoral compartments and a ligamentously stable knee with intact anterior/posterior cruciate and collateral ligaments. Additionally, patients had at least 90 degrees of knee flexion, a flexion contracture of less than 10 degrees, a maximum valgus deformity of 20 degrees and a BMI of less than 40 kg/m^2, with the exception of one patient in each cohort that exceeded the BMI . The patient-specific implant cohort was slightly older (mean 59 years vs 56 years), weighed less on average (BMI 28.7 kg/m^2 versus 32.7 kg/m^2), and had a shorter mean duration of follow-up (37 months versus 75 months) given the only recent introduction of the patient-specific implant system (Table 1).

Radiographic assessment with preoperative weight-bearing anteroposterior (AP), lateral, skyline view and long-length

Table 1 Characteristics for patient-specific implant and conventional implant groups

Characteristic	Patient specific implant	Conventional implant	p-value
Mean age in years (range) <SD>	59 (44–88) <10.9>	56 (36–71) <6.9>	$p=0.21$
Mean BMI[a] (range) <SD>	28.7 (20.7–41.7) <5.3>	32.7 (26.5–46.5) <7.2>	$p=0.08$
Gender	11 male, 21 female	9 male, 10 female	
Mean follow-up in months (range) <SD>	(24–53) <8.6>	75 (26–109) <20>	$p<0.05$

[a] One patient in each group had a BMI over 40

films were obtained. Furthermore, we performed either MRI or CT arthrography preoperatively to evaluate the patellofemoral and medial compartments.

The surgical technique for the conventional implants utilized a midline incision and standard lateral parapatellar arthrotomy. The patella was subluxed medially and the knee hyper flexed. A metal cutting jig is pinned into place on the femoral condyle and three faceted cuts are made: a distal cut, a posterior cut, and an anterior cut. Component trials are inserted and the knee is taken through a full range of motion with careful attention paid to avoid overcorrection of any valgus deformity. After the trials are removed, the final components are cemented in place using standard techniques. The same surgical approach was performed for patient-specific unicompartmental arthroplasty. Since the patient-specific implant is a resurfacing implant, cartilage posterior to the femoral sulcus terminalis and on the lateral tibial plateau was removed with curettes to ensure proper implant seating on subchondral bone. Then peripheral osteophytes were removed to ensure proper seating of the anatomic cutting jigs, which determine the posterior cut on the femur, as well as the tibial resection. No anterior or distal bone is removed from the femur; rather, the implant sits directly on the subchondral bone plate, which is perforated with the drill several times to improve cement inter-digitation. Final implant components are placed as usual.

Postoperatively, patients from both groups received standard of care anti-coagulation treatment with Coumadin for three weeks, were allowed immediate full weight-bearing and range of motion on the day of surgery and followed similar discharge and rehabilitation protocols.

The lateral fit, or lateral coverage mismatch, of the tibial tray component on the tibial cut surface were analysed in postoperative AP radiographs in both patient-specific and conventional groups by an independent musculoskeletal radiologist(Fig. 3a and b). Lateral undercoverage was defined as the distance on the tibial surface between the implant and the lateral edge of the tibial plateau on the AP radiograph (Fig. 3a). Lateral overhang was defined as the distance along the implant edge from the edge of the tibia to the lateral edge of the tibial tray. All image analyses were performed on a digital picture archiving and communication system (PACS) on calibrated DICOM radiographs. For purposes of this study, clinically significant overhang was defined as greater than 3 mm [14] and in order to assess undercoverage, cortical bone was defined as an area within 1.5 mm of the edge of the resected tibia [8].

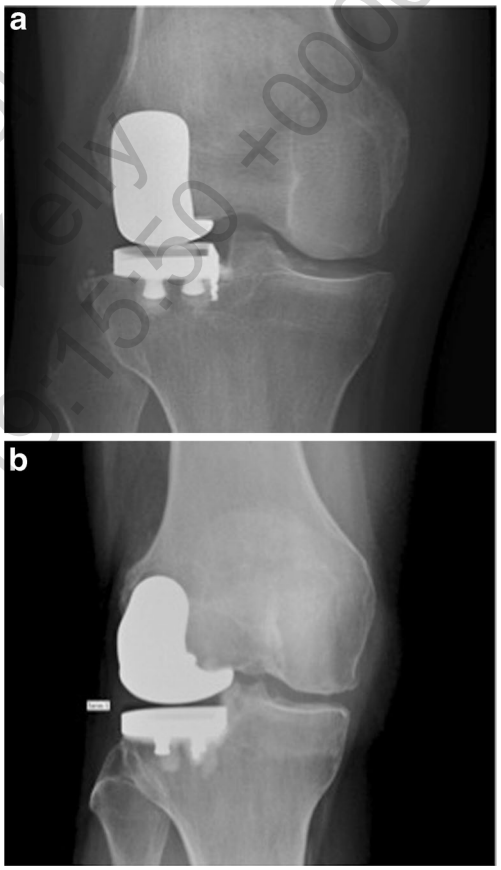

Fig. 3 (**a**) Conventional implant: In order to avoid anterior/posterior overhang, the implant needed to be sized smaller, causing lateral undercoverage and necessitating lateralizing the implant to match femoral position. (**b**) Patient specific implant: Full tibial resection coverage with no mismatch on the tibia laterally. Femoral component designed to shape of lateral condyle which obviates the need to lateralize the implant on the tibia to align components. Note that the geometry of the patient-specific implants is different from the conventional implant as it covers the entire lateral condyle to match the patient's geometry. As the patient-specific implant has a small amount of M/L curve, it may look like an impingement of the tibial spine in a radiograph view when in actuality it doesn't impinge and will in fact follow the patient's normal tibio-femoral rotation through ROM, providing better contact with the poly inserts throughout ROM, without ever impinging

Pre- and postoperative long-leg radiographs were evaluated for mechanical alignment; however, long-leg X-rays were not available for the conventional implant group and a large percent of the patient-specific group, as this was not part of our institution's standard practice until more recently. Both preoperative and postoperative long limb radiographs were obtained from 15 of the 32 patients (40%) who received the patient-specific implant. Mechanical alignment was measured using the centre of the hip joint, the centre of the knee joint, and the centre of the ankle as reference points; varus knees were recorded as negative values and valgus as positive. Postoperative lateral and AP images were also evaluated for evidence of loosening of the implants.

Medical records were reviewed to identify postoperative complications. Range of motion and the Knee Society knee and function scores (KSS) were assessed for the patient-specific implant group.

Due to the relative infrequency of the procedure, no power analysis was conducted to pre-determine sample size, rather we utilized the data from a consecutive series of surgeries for both respective cohorts. To compare pre-operative and postoperative results for both groups, we performed a two-tailed paired Student's t-test. To compare the results between the two groups (patient-specific and conventional implants) we performed a Kolmogorov-Smirnov test to evaluate the normality of the results distribution. For the parametric distribution results, we performed a two-tailed non-paired t-test, and for the non-parametric distribution results we performed a Mann–Whitney test.

Results

The mean tibial implant lateral coverage mismatch, expressed as the absolute value of overhang/undercoverage, with the patient-specific group was 1.0 mm (S.D. 1.2, range 0–5.7) versus 3.3 mm (S.D. 2.43, range 0.4–7.8 mm) in the conventional group ($p=0.02$). In the patient-specific implant group, there was lateral tibial overhang of over 3 mm in one of the 33 patients and only one had greater than 1.5 mm of undercoverage laterally. Additionally, 25/33 of patients demonstrated perfect fit, defined as 1 mm or less of lateral overhang/undercoverage (Figs. 4 and 5). Of the 20 knees analysed in the conventional implant group there were 19 evaluable postoperative films. In the standard group there was no lateral tibial overhang greater than 3 mm. Lateral undercoverage of greater than 1.5 mm was present in 12/19 of the cases and only 4/19 of patients demonstrated perfect fit (Figs. 4 and 6).

The long-leg radiographs (patient-specific group only) demonstrated a mean correction angle of 6 degrees (S.D. 1.9, range 3.4–9.2). The mean pre-operative alignment was 3.3 degrees of valgus (S.D. 4.9, range −5.4 to +8.5) versus a mean postoperative alignment of 0.9 degrees of varus (S.D. 3.8, range from −8.0 degrees to 3.4 degrees) ($p<0.05$). There was no sign of radiographic loosening in the study patients from both the conventional and the patient-specific implant groups.

Knee Society knee scores for the patient-specific implant group are described in Table 2 and show statistically significant improvement and an overall excellent result with a postoperative score of 94. KSS survey results were

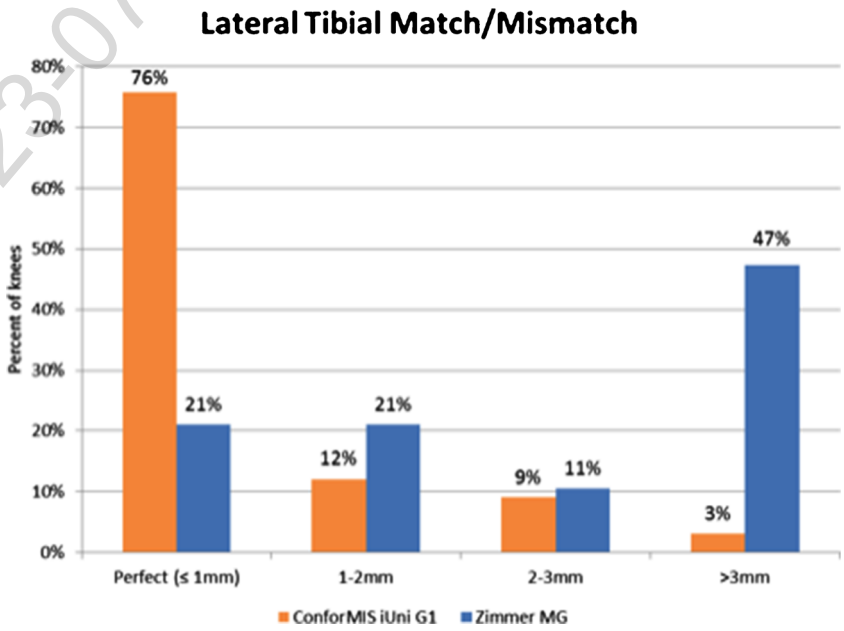

Fig. 4 Tibial lateral match/mismatch distribution for the conventional and patient-specific implant groups as a percentage of cases

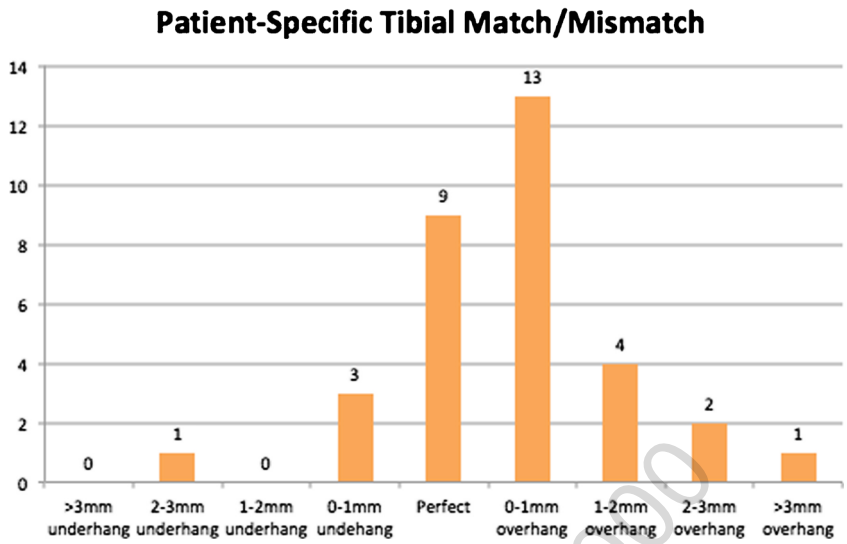

Fig. 5 Tibial lateral undercoverage and overhang distribution in the patient-specific implant group

not available for the standard group.Postoperative range of motion between the two groups was not statistically different, with both types of implants showing good recovery with an average of 125 degrees of motion and a range of 110–140 degrees (Table 3).

There were no intra-operative complications with the use of the implants or the bone cut blocks from either study group. In the custom-implant group, there was one postoperative infection that was successfully treated with two-stage re-implantation of another custom-made implant. In the same group, one implant failed and was revised to a total knee replacement. In the standard implant group, three implants failed at an average of 33 months. One failed due to an infection, the other two due to progression of disease. Thus, survivorship in the patient-specific group was 97% at average 37 months follow-up, and in the standard implant group 85% at an average of 33 months.

Discussion

We hypothesized that performing a lateral unicompartmental arthroplasty with a patient-specific implant would result in superior tibial plateau coverage as compared to conventional, off-the-shelf implants. We also asked whether the patient-specific implants could provide a successful clinical outcome as observed postoperatively with the American Knee Society score, range of motion, and coronal leg alignment. To our knowledge, this is the first report on patient-specific unicompartmental implants for a strictly lateral indication.

There are limitations to our study. First, the limited number of patients and single comparative implant complicates meaningful statistical analyses. However, this is in line with other reported series on lateral UKA, as this remains a comparatively rare procedure. Only a few studies have been published, with subject numbers ranging from 12 to 100, many of them combining different implants designs [5, 6]. Second, this

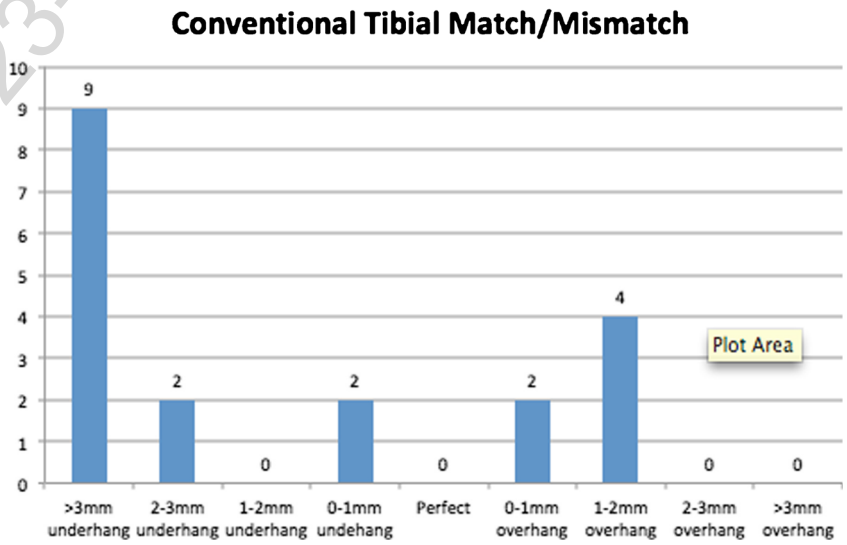

Fig. 6 Tibial lateral undercoverage and overhang distribution in conventional implant group

Table 2 Knee Society score (KSS) for the patient-specific implant group

Score parameter	Preoperative KSS	Postoperative KSS	p-value
Mean	48	94	$p<0.05$
Min	27	67	
Max	64	100	
Standard deviation (SD)	16.2	7.6	

study is a case series and not a randomized clinical trial with Knee Society score results and long-leg radiographs unavailable for the conventional implant. A more comprehensive dataset would have helped strengthen our comparative analysis with supplemental clinical and radiographic outcomes. Third, we consider that postoperative CT would have been advantageous from a research perspective. However, the heightened concerns over radiation exposure specifically from CT scans precluded us from utilizing CT without a clinical indication. Finally, this study was conducted with the first generation of the iUni product ("G1"), prior to the implementation of substantial improvements to the shape-fitting approach for the implant. Cost analyses for patient-specific implants compared to commercially available implants were not performed in this research. It remains unclear whether it will add or decrease cost compared to commercially available off-the-shelf implants. We believe cost analysis is complex as it should also include instrumentation prices, operation room time, sterilization peri-operative period management, pre-operative imaging, and long-term implant revision costs. Also, average cost per surgery and cost-effectiveness of patient-specific implants may be variable comparing high-volume and low-volume unicompartimental arthroplasty centres, especially regarding lateral compartment UKA.

From a surgical technique perspective, UKA is more demanding than TKA, especially on the lateral side. The biomechanics of the lateral compartment are different than the medial compartment; for example, femoral rollback is greater in the lateral compartment [17]. The wear patterns of the original articular surface, as well as that of the polyethylene component after replacement are different in both compartments [9]. The shape of the femoral condyles and the shape of the tibial plateau are different in the medial and lateral sides [18]. Surgeons must therefore modify their technique to perform lateral UKA with conventional implants, which in general are designed for the much more common medial compartment procedure [5]. Sah and Scott advise to shift the femoral component laterally in order to maximize congruency of the tibial and femoral components in extension, which in turn can cause undercoverage or overhang on the tibial plateau. They also suggest a small amount of posterior tibial slope (<5 degrees) to minimize posterior wear [2]. Pennington et al. suggest that the tibial component should be placed in internal rotation (10–15 degrees) to avoid the femoral component overriding the tibial component onto the tibial spine in full extension, as a result of the "screw-home mechanism" [4]. Servien et al. evaluated tibial component rotation using CT in 19 medial and 18 lateral UKA and observed that the component was usually externally rotated. The authors also described that the range of rotational variation was high, with a mean external rotation of 7.3 degrees for the lateral UKA with an SD of 10.3 degrees [12]. To facilitate accurate internal rotation and medial placement of the tibial baseplate, Berend et al. advised performing the vertical cut through a patellar tendon split [6]. These findings collectively demonstrate the increased technical challenges and compromises encountered when performing lateral UKA with conventional implants due to their non-conforming, non-anatomic design.

The design and shapes of the patient-specific implants are very different for the medial and lateral compartments. Due to the patient-specific shape of the implant with a j-curve designed to mimic the native femur and the full cortical coverage that the femoral implant allows, the need to shift the femoral component laterally as described by Sah and Scott, is obviated. The iUni implant is manufactured for each specific patient utilizing data from a preoperative CT of the knee. The implant is designed using a software algorithm to anatomically match the femur and the tibia for complete cortical bone coverage. The patient-specific disposable cutting jigs are printed using a nylon material on a 3D printing system. Both the tibial metal tray and the polyethylene inserts are made using the patient's specific shape, with two polyethylene-inserts of different thicknesses shipped for intra-operative balancing. The femoral component has a patient-specific sagittal curvature corrected for deformity and a constant curvature in the coronal plane. The constant coronal curvature is matched to a curvature that

Table 3 Range of motion (ROM) in conventional and patient-specific lateral unicompartmental knee arthroplasty (UKA)

ROM parameter	Conventional implant		Patient-specific implant		
	Preoperative	Postoperative	Preoperative	Postoperative	Statistical significance
Mean	122°	127°	125°	125°	NS in either group
Min	110°	110°	110°	110°	
Max	140°	135°	140°	140°	
SD	9.5°	7.5°	8.5°	6.2°	

is applied to the tibial insert to minimize polyethylene wear. This patient-specific design may potentially improve the biomechanical behaviour of lateral unicompartmental arthroplasty as it may recreate more natural biomechanics.

Optimizing anatomic fit, especially of the tibial component, may influence outcomes in two ways: first, by reducing the risk of subsidence by resting on the harder cortical bone [19, 20], and also by decreasing soft tissue impingement. Fitzpatrick analysed 34 tibiae at a depth of 5 mm below the articular surface and compared two commercially available implants (Preservation Uni System and LCS Uni System, DePuy Orthopaedics Inc., Warsaw, IN) against a theoretical symmetric implant regarding their respective coverage of the tibial plateau. The authors described that cortical bone coverage with the theoretical implant design was better for both compartments in comparison to the commercially-available implants [8].

Maximizing tibial coverage may be an important aspect in preventing tibial component failure, especially in heavier patients, as the cortical bone is many times stronger than cancellous or subchondral bone. However, achieving this without introducing overhang is a challenge in unicompartmental procedures, especially so in the lateral compartment. Chau et al. evaluated the effect of tibial component overhang following medial unicompartmental knee replacement in 162 knees. They observed that only five (3.1%) of the knees were deemed to have a perfect fitting tibial component. The authors also described that overhang greater than 3 mm correlates with worse functional scores (Oxford knee score) and pain scores at one- and five-year follow-up [9]. In comparison, Koeck et al. described perfect fit in the anterior-posterior, and within 1 mm in the medial-lateral projection, with the same patient-specific implants used in this study in all of 32 medial unicompartmental replacements evaluated [21]. In this study, the patient-specific implant consistently demonstrated the ability to effectively cover cortical bone, while simultaneously limiting the incidence of clinically-significant overhang. Conversely, the surgical compromises necessitated are well illustrated by the preponderance of undercoverage noted in the conventional group. In order to avoid overhang in the anterior and posterior, it was often necessary to undercover significantly laterally when positioning the standard implants.

Our review of 33 patients treated with a patient-specific lateral unicondylar knee replacement demonstrates high success and function at an average of 37 months post-op. In comparison with a control group of standard unicondylar implants, the patient-specific implant demonstrated significantly better tibial fit and coverage.

In conclusion, we were able to achieve near perfect fit of the tibial components in the lateral compartment utilizing a patient-specific implant in a significantly greater number of cases as compared to the conventional implants. Compared with off the shelf implants, the match of patient-specific implants was significantly better for the tibial component in the anterior-posterior view, which may have positive implications for clinical outcomes as postulated by Chau et al. [14]. Additionally, this result suggests that patient-specific implants and their patient-specific cutting blocks could reduce or eliminate many of the surgical compromises required when performing a lateral unicompartmental arthroplasty with a conventional implant.

Patient-specific implants used in lateral UKA allow for accurate implant positioning, a better anatomic match, a more predictable surgical technique, and good limb axis alignment postoperatively. Importantly, these surgeries were performed utilizing the initial generation of this product; subsequent modifications to both the jigs and implants have been implemented to further improve bone coverage and ease of use and reproducibility of the surgical technique. The benefits of patient-specific implants observed in this study may decrease the technical difficulty for lateral UKA surgery and broaden the appeal of unicondylar knee replacement for isolated lateral osteoarthritis, though further studies are necessary to evaluate longer-term clinical results.

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