



Tibial Plateau Coverage in UKA: A Comparison of Patient Specific and Off-The-Shelf Implants



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ARTICLE INFO

Article history:

Received 24 October 2013

Accepted 24 March 2014

Keywords:

unicompartmental knee arthroplasty
patient specific implants
tibial component
overhang
CT-based imaging
ConforMIS

ABSTRACT

Poor tibial component fit can lead to issues including pain, loosening and subsidence. Morphometric data, from 30 patients undergoing UKA were utilized; comparing size, match and fit between patient-specific and off-the-shelf implants. CT images were prospectively obtained and implants modeled in CAD, utilizing sizing templates with off-the-shelf and CAD designs with patient-specific implants. Virtual surgery was performed, maximizing tibial plateau coverage while minimizing implant overhang. Each implant evaluated to examine tibial fit. Patient-specific implants provided significantly greater cortical rim surface area coverage versus off-the-shelf implants: 77% v. 43% medially and 60% v. 37% laterally. Significantly less cortical rim overhang and undercoverage were observed with patient-specific implants. Patient-specific implants provide superior cortical bone coverage and fit while minimizing overhang and undercoverage seen in off-the-shelf implants.

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Numerous anatomical studies have demonstrated a wide range of variability in size and shape of the medial and lateral tibial compartments [1–3]. Despite the high degree of differentiation between individual patients, most unicompartmental knee arthroplasty (UKA) tibial component systems offer a range of 5 or 6 tibial tray sizes. Typically, each system has a predefined shape, differing based on the manufacturer, which is up or downsized during surgery to attempt to best fit the cut tibial plateau. Most of the sizing arrays have been designed for the medial compartment, due to the relative frequency of medial osteoarthritis (OA), as compared to confined lateral OA. The fit of the tibial component has been shown to impact the success of UKA procedures. Implant overhang can lead to issues such as increased pain and impingement of the soft-tissue [4,5]. Conversely, undercoverage of the cut tibial surface has been attributed to component loosening and subsidence [1,3,4].

Patient-specific implants have been recently introduced as an option for patients undergoing UKA. The iUni® (ConforMIS, Inc., Bedford, MA), offers patient-specific femoral and tibial implants, as well as patient-specific instrumentation for all bone cuts. All implants and instrumentation are manufactured utilizing CT-based imaging obtained pre-operatively that is converted into a CAD model to provide the patient-specific geometry for the implants.

The objective of this study was to utilize morphometric data in order to compare size, match and fit between patient-specific implants and incrementally sized off-the-shelf (OTS) UKA implants from several different implant manufacturers. We hypothesized that patient-specific implants would reduce the incidence of overhang and undercoverage of the tibial surface and additionally provide significantly better fit on the cortical rim.

Methods

CT images of 20 knees undergoing medial UKA and 10 knees undergoing lateral UKA were prospectively obtained. Off-the-shelf tibial implants, of 5 different brands (Triathlon, Stryker®, Mahwah NJ; Oxford®, Biomet, Warsaw, IN; ZUK, Zimmer®, Warsaw, IN; Journey® Uni, Smith & Nephew, Memphis, TN; Restoris®, MAKO, Ft. Lauderdale FL), were modeled in CAD, utilizing sizing templates to determine implant shape and size. The patient-specific implants utilized the CAD designs that are generated during the implant manufacturing process. The sagittal cut was made in the AP direction either lateral or medial (depending on type of UKA) to the insertion points for both ACL and PCL to avoid compromising the ligaments and resection depth was calculated individually to utilize a 6 mm poly insert while maintaining the joint line. All tibial osteophytes were removed, to best represent the final resected tibial cut and to ensure accurate and consistent measurements.

We then performed virtual surgery on all 30 knees in both the medial and lateral cohorts for each off-the-shelf implant, with a resultant 180 virtual surgeries performed (30 for each implant

The Conflict of Interest statement associated with this article can be found at <http://dx.doi.org/10.1016/j.arth.2014.03.026>.

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type). The junior surgeon (DC) selected the best size and position of each of the OTS implant in order to maximize coverage of tibial plateau while minimizing implant overhang. Placement was then confirmed and adjusted if needed by the senior surgeon (CLB) in order to ensure optimal fit. Often implants were downsized in the off-the-shelf group during the virtual surgical process, as particular attention was paid to avoiding overhang, specifically anteriorly, per the senior surgeon's typical technique. It should be noted that optimizing fit was completely relegated to the treated tibial compartment. There were no considerations made for the femoral component and the congruency of the femoral implant to the tibial implant was not factored into any placement decisions. Once virtual implantation was complete and confirmed, we were then able to precisely measure the amount of overhang or undercoverage of the implant relative to the tibia in the CAD environment (Solidworks, 64 Edition).

Each off-the-shelf implant was then evaluated to examine fit on the cortical rim. Per Fitzpatrick et al, we defined the cortical rim as a continuous area 1.5 mm from the edge of the resected tibial plateau [6] (Fig. 2). Fit on the cortical rim was examined by two methodologies. First the area of the cortical rim was established in CAD and a total surface area (mm^2) for the zone (indicated in Fig. 2) was identified. Once the implant positioning was finalized, per the above methodology, the area of the implant that rested within the borders of the cortical rim area was calculated (Fig. 1A and B). The second metric utilized was a linear measurement of the arc length of the implant edge. The arc length was defined as the curved portion of the outer edge of the implant; it did not include the edge along the tibial spine that rests parallel to the sagittal cut. The length (mm) of the arc resting within the previously identified cortical rim was then calculated in CAD.

The results for the off-the-shelf implants were then compared to the patient-specific implant for each of the parameters above.

Statistical Analysis

In order to determine the significance between data in each group, a statistical analysis was performed either by using inbuilt or custom functions in Microsoft Excel 2010 (Microsoft Corp, Redmond, WA). Due to the sample sizes between the patient-specific and off-the-shelf (as a whole) being unequal, a two-tailed student's t-test assuming unequal variance (heteroscedastic t-test) was conducted to determine significance ($P < 0.05$), for data comparing patient-specific and the entire cohort of the OTS group. Additionally, each OTS group was compared individually to the patient-specific cohort, to determine

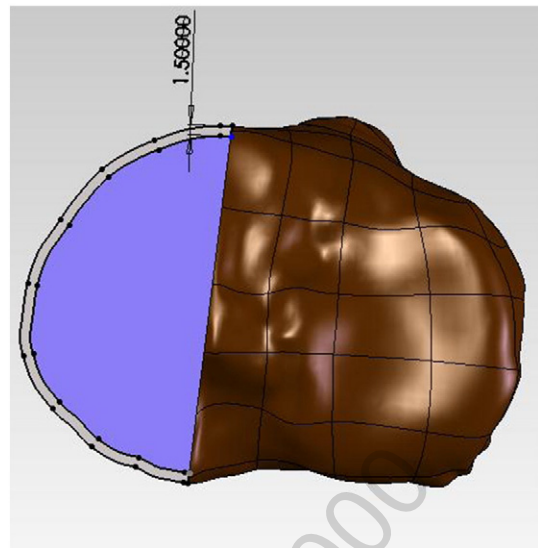


Fig. 2. Resected tibial plateau displaying cortical rim area (shaded) 1.5 mm from edge.

significant differences ($P < 0.05$), with the help of a two-tailed matched pair student's t-test for the numerical variables and a two-tailed Fisher's exact test for frequency count variables.

Results

Overhang and Undercoverage

A significant difference in the average amount of both overhang and undercoverage of the tibia was observed in both medial and lateral implants when comparing patient-specific and OTS designs (Table 1). For the medial implant cohort, the patient-specific group had an average maximum overhang (any zone) of 0.24 mm v. 0.46 mm for the OTS group, ($P = 0.002$) and 0.87 mm v. 3.01 mm of maximum undercoverage ($P < 0.0001$). In the lateral cohort, the patient-specific group had an average maximum overhang of 0.14 mm v. 0.59 mm, ($P < 0.0001$) and 1.19 mm v. 2.26 mm maximum undercoverage laterally ($P = 0.002$). The presence of anterior overhang was observed in an average of 55% of the OTS medial implants (range 25–75%, dependent on implant manufacturer) and 52% of the OTS lateral implants (range 30–80%, dependent on

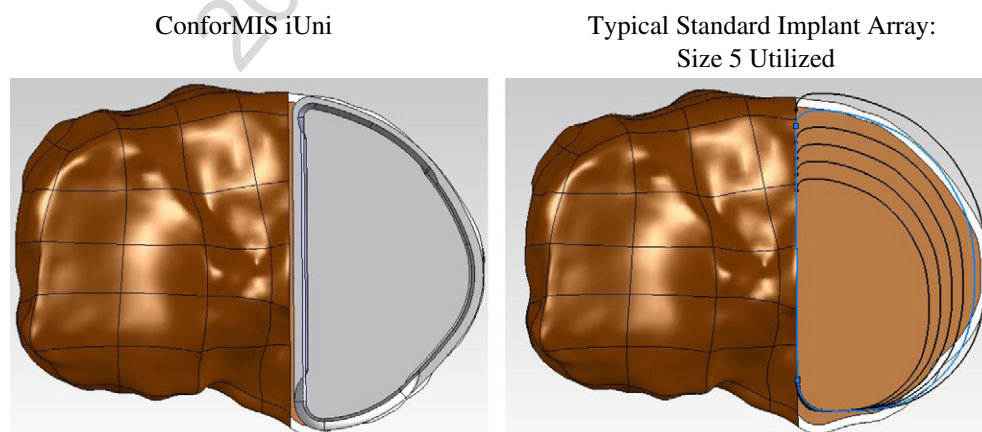


Fig. 1. (A) Patient-specific unicompartamental CAD image. (B) Typical overlay of an off-the-shelf unicompartamental implant sizing array CAD image, a size 5 was determined to provide best fit and coverage.

Table 1
Overhang and Undercoverage of Resected Tibiae.

Implant Type	Medial Implants		Lateral Implants	
	Ave. Maximum Overhang	Ave. Maximum Undercoverage	Ave. Maximum Overhang	Ave. Maximum Undercoverage
Patient-specific	0.024	0.87	0.14	1.19
Standard	0.46	3.01	0.59	2.26
off-the-shelf				
P-value	0.002	<0.0001	<0.0001	0.002

implant manufacturer). Anterior overhang was not observed in any of the implants in the patient-specific group (Fig. 3).

Cortical Rim Coverage

Patient-specific implants provided significantly greater cortical rim surface area coverage, defined as the percentage of cortical rim area covered by the tibial tray, versus incrementally sized OTS implants: 77% coverage in medial knees v. 43 for OTS implants (range 41–46%) ($P < 0.0001$) and 60% in lateral knees v. 37% for OTS implants (range 29–41%) ($P < 0.0001$). The arc length of the patient-specific and OTS implants was also evaluated to determine the percentage of implant edge resting on cortical bone, 84% in patient-specific v. 55% in OTS medial implants (range 48–59%) ($P < 0.0001$) and 79% v. 57% laterally (range 53–60%) ($P < 0.0001$) (Fig. 4A and B) (Table 2).

Discussion

The hypothesis that patient-specific implants for a unilateral indication would provide significantly less overhang and undercoverage as well as superior coverage of the cortical rim of the cut tibia compared to standard OTS implants was supported by this study. Specifically, the standard OTS implants demonstrated a nearly two-fold increase in overhang medially and more than a four-fold greater average overhang laterally. The medial group of standard OTS implants averaged three times and the lateral group nearly twice the amount of undercoverage. Additionally, despite our best efforts to avoid this during implant placement, we noted a much higher than expected prevalence of anterior overhang in the OTS group. The shape of the OTS implants led to compromises during positioning and necessitated decision making on either increasing cortical

coverage at the expense of overhang, or inversely undercovering to avoid tibial overhang.

There are some limitations of this study that must be noted. This study removed the added surgical variability of having to match tibial tray placement to femoral implant placement in the OTS group. The typical surgical step to gain congruency and proper rotational alignment between the femoral component and tibial polyethylene surface often leads to additional compromises with fit and tibial coverage. Oftentimes the OTS tibial trays need to be moved off the sagittal cut along the tibial spine in order to achieve this maximum congruency. This warrants additional decision making and compromises with fit. This compromise is obviated by the patient-specific implants, due to the CT-based design of the implant which aligns tibial and femoral implants pre-operatively into ideal congruency and rotational alignment. Importantly, this is also a study of virtual surgery, where all dimensions can be easily visualized and optimal placement achieved. The constraints of live surgery present additional difficulties with visualization, specifically posteriorly, which were not accounted for in the present study. Lastly, the positioning of the implants was decided by a single surgeon, which could introduce error, which was mitigated by having a more senior surgeon, who performs unicompartmental surgery routinely, verify and modify implant positioning as needed.

The variability of tibial plateau anatomy can result in difficulty with optimizing coverage and preventing significant implant overhang or undercoverage with off-the-shelf unicompartmental implants. Even with the patient-specific implants, it is impossible to achieve 100% coverage of cortical surfaces, unless the surgeon is willing to accept significant overhang, due to the variable shape of the outer edge of the cut tibia. Several previous studies have demonstrated that overhang of the tibial tray can cause significant clinical issues with pain and impingement. Chau demonstrated that in partial knees, patients with significant overhang have an increased risk for worse knee and pain scores post-operatively [4]. In addition only a very small percent (3%) of the patients he studied demonstrated perfect fit. Gudena has shown the medial collateral ligament load almost doubles when there is greater than 2 mm of overhang and further suggests that this excess strain may be a potential cause for chronic pain issues, which ultimately can lead to revision [5].

Subsidence and aseptic loosening of the tibial tray are among the most common reasons for revision with UKA, with some reports having as much as 25% of failures attributed to aseptic tibial loosening [7–9]. Though to our knowledge, no studies exist showing a direct causal link between undercoverage, which could lead to tibial implant fixation on softer cancellous bone, to tibial loosening or subsidence, it has been suggested as a contributing factor to aseptic loosening in both UKA [4,6,10] and TKA [11–13], as cancellous bone is less able to support the loads placed on the implant [13].

Fitzpatrick performed an analysis of theoretical designs of unicompartmental implants versus known shapes of commercially available implants on 34 tibiae [6]. The analysis concluded that the theoretical design where both shape and size could be altered provided significantly better cortical rim coverage than commercially available implants regardless of shape (teardrop or D-shaped). In this analysis theoretical implants had 79.2% medial and 72.9% lateral cortical bone coverage, as opposed to 74%, 52% medial and 60%, 63% lateral cortical bone coverage for teardrop and D-shaped OTS implants respectively, utilizing a methodology similar to the cortical rim arc length metric employed in this study. The results we gathered showed better results for the patient-specific design (84% medial and 79% lateral) than the best case theoretical implants for the Fitzpatrick study, while the standard off-the-shelf implants in our study performed similarly or worse (55% medial, 57% lateral) than the teardrop and D-shaped implants in the Fitzpatrick study. Because our current study was performed using actual tibial template dimensions from all implant manufacturers, rather than the generic designs

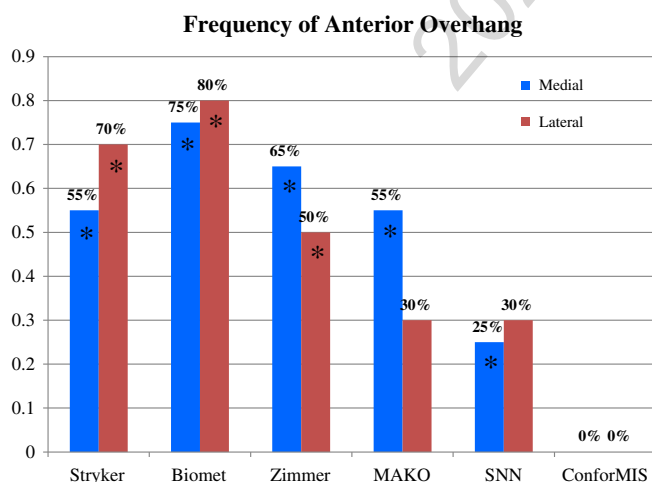


Fig. 3. Analysis of frequency of anterior overhang (* indicates statistical significance).

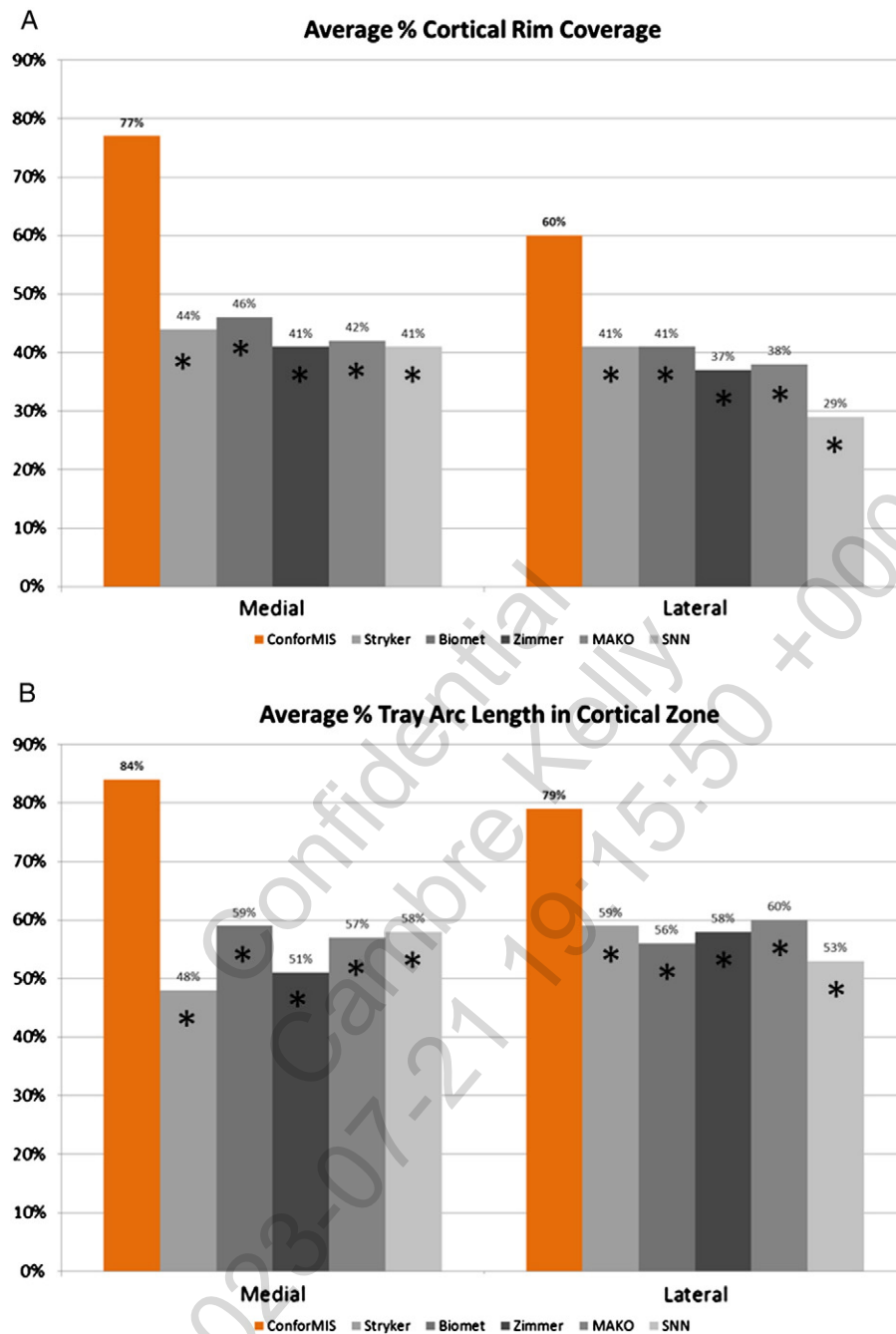


Fig. 4. (A and B) Cortical Rim Congruency (* indicates statistical significance).

utilized in the Fitzpatrick study, these measurements should provide an accurate gauge as to the optimal results that could be expected utilizing both patient-specific and OTS implants.

Table 2
Cortical Rim Surface Area Coverage and Implant Arc Length Within Cortical Zone.

Implant Type	Medial Implants		Lateral Implants	
	Average Cortical Rim Area Covered (mm ²)	Average Tray Arc Length in Cortical Zone (mm)	Average Cortical Rim Area Covered (mm ²)	Average Tray Arc Length in Cortical Zone (mm)
Patient-specific	77%	84%	60%	79%
Standard off-the-shelf	43%	55%	37%	57%
P-value	<0.0001	<0.0001	<0.0001	<0.0001

Conclusions

In this study of virtual implantations in a CAD environment, patient-specific implants provided statistically superior cortical bone coverage and fit while minimizing the inherent issues of overhang and undercoverage seen in standard, off-the-shelf implants.

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