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ORIGINAL ARTICLE

Onlay Tibial Implants Appear to Provide Superior Clinical Results in Robotic Unicompartmental Knee Arthroplasty

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Abstract *Background:* Unicompartmental knee arthroplasty (UKA) is an increasingly popular option for the treatment of single-compartment knee osteoarthritis (OA) in adults. Two options for tibial resurfacing during UKA are (1) all-polyethylene inlays and (2) metal-backed onlays. *Questions/Purposes:* The aim of this study was to determine whether there are any differences in clinical outcomes with inlay versus onlay tibial components. *Patients and Methods:* We identified 39 inlays and 45 onlays, with average 2.7- and 2.3-year follow-up, respectively, from a prospective robotic-assisted surgery database. The primary outcome was the Western Ontario and McMaster University Arthritis Index (WOMAC), subcategorized by the pain, stiffness, and function subscores, at 2 years postoperatively. The secondary outcome was the need for secondary or revision surgery. *Results:* Postoperative WOMAC pain score was 3.1 for inlays and 1.6 for onlays ($p=0.03$). For 25 inlays and 30 onlays with both preoperative and postoperative WOMAC data, pain score improved from 8.3 to 4.0 for inlays versus from 9.2 to 1.7 for onlays ($p=0.01$). Function score improved from 27.5 to 12.5 for inlays versus from 32.1 to 7.3 for onlays ($p=0.03$). Four inlays and one onlay required a secondary or revision procedure ($p=0.18$). *Conclusions:* We advise using metal-backed onlays during UKA to improve postoperative clinical outcomes.

Level of Evidence: Level III

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Introduction

Unicompartmental knee arthroplasty (UKA) is becoming an increasingly popular option for the treatment of single-compartment knee osteoarthritis (OA) in adults. The procedure involves the selective resurfacing of the arthritic area (medial or lateral), while preserving the unaffected side, cruciate ligaments, and other soft tissue structures [11]. While UKAs comprised only 1% of all knee implants in 1997, this number expanded to 6% of all knee implants in 2000, and the use of UKA is projected to increase [10].

Although initial studies of UKA reported failure rates as high as 35% [7], subsequent reports have been encouraging. Foran et al. recently reported their long-term results of fixed-bearing UKA and found survivorship rates comparable to total knee arthroplasty at 10-, 15-, and 20-year follow-up [4]. However, little is known about what factors may be contributing to the improvement in UKA durability, particularly implant-related factors.

Two primary fixed-bearing designs have been historically used for tibial resurfacing when performing a UKA: (1) inlay and (2) onlay. Inlay components are polyethylene-only implants cemented into a carved pocket on the tibial surface, thereby relying upon the subchondral bone to support the implant (Fig. Fig. 1a) [10]. Onlay components commonly have a metal base plate and are placed on top of a flat tibial cut, supported by a rim of cortical bone (although all-polyethylene designs are also available with some systems) (Fig. Fig. 1b). Previous research has suggested that metal-backed onlay components exhibit superior biomechanics [12]. However, to our knowledge, there is no published report that compares the clinical outcomes of these two implants.

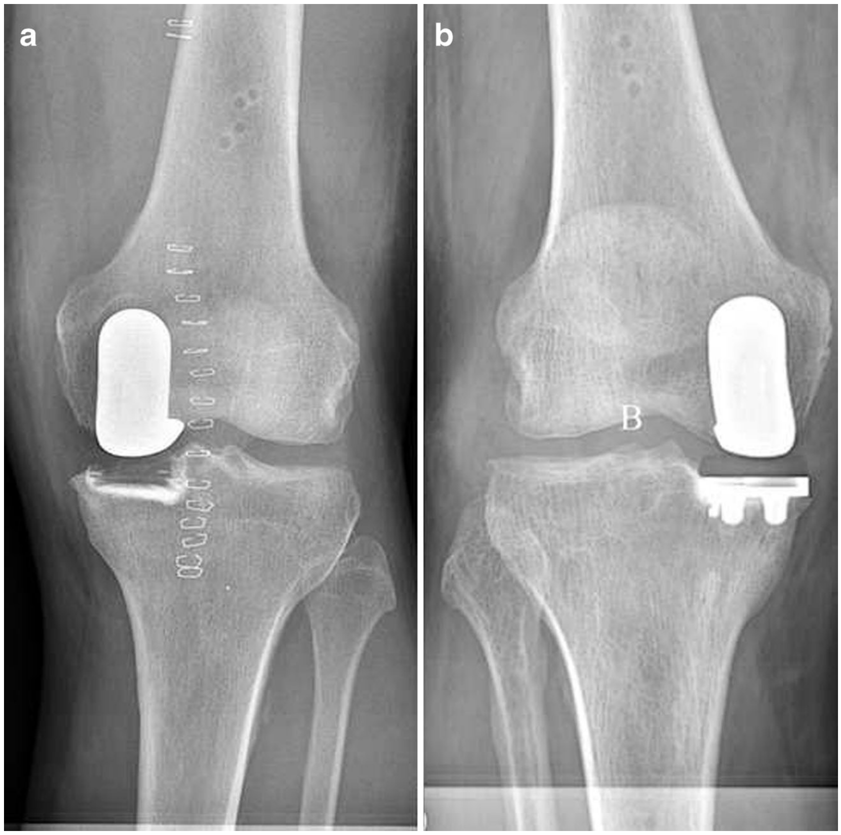

Fig. 1. Anteroposterior radiographs of **a** all-polyethylene inlay and **b** metal-backed onlay tibial components for unicompartmental knee arthroplasty.

Therefore, the objective of this study was to review a single surgeon's prospective database to determine the following: (1) whether there are any differences in clinical outcomes between patients undergoing robotic-assisted medial UKA with inlay versus onlay tibial components and (2) the rate of revision or secondary surgeries associated with these two implant options.

Patients and Methods

Study Population

This study was approved by the institutional review board prior to its undertaking. The prospective surgical database of the senior author (ADP) was retrospectively reviewed for all consecutive patients who underwent robotic-assisted UKA between November 2008 and June 2011. UKAs were considered for inclusion if the patient (1) had preoperative varus mechanical alignment with isolated medial compartment OA, (2) had undergone medial robotic-assisted UKA (MAKO Tactile Guidance System [TGS], MAKO Surgical Corporation, Fort Lauderdale, Florida), and (3) agreed to complete a research questionnaire regarding their clinical status. A total of 158 UKAs were initially available for analysis; however, 54 patients did not agree to complete a clinical questionnaire and therefore were not considered for inclusion. Thus, a total of 104 UKAs met the inclusion criteria for our study. We then excluded any patients that did not have available clinical data from the 2-year follow-up visit or were not able to be contacted by telephone in order to determine their clinical status. Because of appointment scheduling considerations, we allowed patients to be included in the study if they were seen for the customary 2-year follow-up visit at a minimum of 1.8 years from the surgical date. Application of these inclusion and exclusion criteria yielded a total of 84 UKAs in 75 patients for final analysis, of which 39 UKAs used an all-polyethylene inlay tibial component and 45 UKAs used a metal-backed onlay tibial component. Of these 84 UKAs, there were five (four inlays, one onlay) that required a secondary or revision procedure prior to the 2-year follow-up date and were considered separately for the final analysis.

The electronic medical record and paper charts of the 84 UKAs that met the inclusion/exclusion criteria were then reviewed. Patient demographic data including gender, age, body mass index (BMI), laterality, and alignment were collected and are displayed in Table 1. Clinical outcome data were also recorded for each patient. The primary outcome was the Western Ontario and McMaster University arthritis index (WOMAC), subcategorized by the pain, stiffness, and function subscores, at 2 years postoperatively (higher subscores correlate with worse outcomes). The secondary outcome was the need for secondary or revision surgery.

Robotic Arm-Assisted UKA Technique

All surgeries were performed by the senior author using a previously described technique [10]. In this series of patients, inlay tibial implants (MAKO Surgical Corporation, Fort Lauderdale, Florida) were used initially because this was the only implant option available at the senior author's institution. Once onlay implants became available, all patients thereafter received an onlay implant (MAKO Surgical Corporation, Fort Lauderdale, Florida). Thus, inlays and onlays in this study represent two consecutive series of patients, the first of which received inlays and the second received onlays. Prior to surgery, a preoperative plan was created from three-dimensional reconstructions (3D recon) of a computed tomography (CT) scan of the patient's operative extremity. This process uses computer-assisted design (CAD) models of the implanted components, which are templated onto the 3D recon images using computer software (Fig. Fig. 2). At the time of surgery, standard surgical navigation markers are placed on the femur, tibia, and the robotic arm. The virtual modeling of the patient's knee and intraoperative long leg alignment (LLA) tracking allows real-time adjustments to be made in order to achieve correct alignment and soft tissue balance. The robotic arm is equipped with a 6-mm burr, which is used to resect the templated amount of the bone from the specified compartment. When the burr is physically within the volume of the bone to be resected, the robotic arm is operated freely without resistance. However, as the burr approaches the pretemplated boundary of resection, the robotic arm resists the motion and contains the burr within the accepted region. Thus, the robotic arm effectively acts as a three-dimensional virtual instrument that precisely executes the operative plan.

Statistical Analysis

All data were collected and analyzed using Microsoft Excel software (Microsoft Corporation, Redmond, Washington) and GraphPad software (GraphPad Software, Inc, La Jolla, California). Continuous variables were analyzed using the two-tailed Student's t test. Categorical variables were analyzed using Fisher's exact test. In all cases, statistical significance was set at $p=0.05$.

Results

Of the 84 UKAs that met the study inclusion/exclusion criteria, 39 had an all-polyethylene inlay tibial component, and 45 had a metal-backed onlay tibial component. Average follow-up was 2.7 years (range 2.0–4.2 years) for inlays and 2.3 years (range 1.8–3.7 years) for onlays, a significant difference ($p=0.009$). There were no significant differences found between inlay and onlay groups with respect to the patient demographic variables analyzed: gender, age, BMI, laterality, and alignment (Table 1).

At the time of final follow-up, the WOMAC pain subscore was 3.1 for inlays and 1.6 for onlays ($p=0.03$). The stiffness subscore was 1.8 for inlays and 1.4 for onlays ($p=0.20$). The function subscore was 10.1 for inlays and 6.7 for onlays ($p=0.14$) (Fig. Fig. 3).

We identified a subgroup of 55 patients (25 inlay, 30 onlay) for whom there was both preoperative and postoperative WOMAC data available. There were no differences in the preoperative pain, stiffness, or function subscores between inlays and onlays. In this subgroup, the pain subscore improved from 8.3 to 4.0 for inlays versus an improvement from 9.2 to 1.7 for onlays ($p=0.01$) (Fig. Fig. 4a). The stiffness subscore improved from 4.0 to 2.2 for inlays versus an improvement from 4.3 to 1.5 for onlays ($p=0.08$) (Fig. Fig. 4b). The function subscore improved from 27.5 to 12.5 for inlays versus an improvement from 32.1 to 7.3 for onlays ($p=0.03$) (Fig. Fig. 4c).

When all 84 patients in the study were considered, 4/39 inlays (10.3%) underwent a secondary or revision procedure during the follow-up period. The mean time elapsed from the index inlay until revision for these patients was 2.4 years (range 1.1–4.1 years). Two of the inlays were converted to a total knee replacement (TKR), one for tibial pain with aseptic loosening and the other for tibial pain with aseptic loosening and subsidence in a patient with reflex sympathetic dystrophy. The third

Table 1 Patient demographic data

	Inlay (n=39)	Onlay (n=45)	p Value
Gender (n, %)			0.198
Female	23 (59%)	20 (44%)	
Male	16 (41%)	25 (56%)	
Age (mean, range)	62.8 (45.5–84.1)	63.3 (45.3–85.3)	0.828
Body mass index (mean, range)	29.8 (15.2–40.7)	28.9 (19.0–46.5)	0.487
Laterality (n, %)			0.198
Right	14 (36%)	25 (56%)	
Left	21 (54%)	20 (44%)	
Bilateral	4 (10%)*	0 (0%)	
Alignment (°)[a]			
Preoperative	7.6 (1.4–14.2)	7.2 (2.0–15.0)	0.642
Postoperative	3.2 (−3.7–13)	2.4 (0.0–8.4)	0.602

*Two patients in the inlay group had a bilateral procedure (total 4 UKAs)

[a] Positive values indicate varus alignment; negative values indicate valgus alignment. Preoperative films (hip-knee-ankle standing anteroposterior radiographs) were available for 21/39 inlays and 40/45 onlays. Postoperative films were available for 37/39 inlays and 43/45 onlays

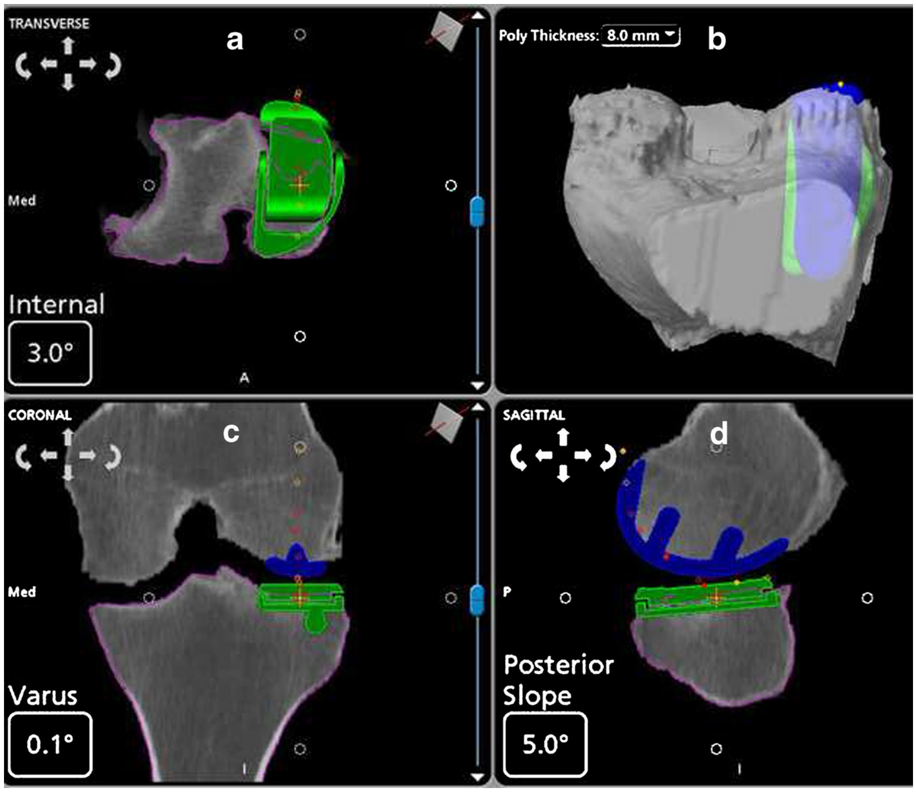

Fig. 2. Computer-assisted design (CAD) models of the implanted components are virtually templated onto the patient's computed tomography scan prior to surgery. Variables such as component rotation (**a**), polyethylene thickness (**b**), coronal alignment (**c**), and posterior slope (**d**) can be virtually templated and trialed with this software.

inlay patient had unexplained persistent tibial pain under the implant and was converted to an onlay. The fourth inlay patient had pain under the tibial component secondary to a subchondral compression fracture and underwent subchondroplasty. In the onlay group, 1/45 patients (2.2%) underwent a revision procedure, a conversion to TKR at 1.3 years postoperatively, in a medically complicated patient with unexplained persistent knee joint pain. The difference in rates of secondary surgery between the two groups was not statistically significant ($p = 0.18$).

Discussion

UKA remains an increasingly popular option for treating single-compartment OA of the knee. Although early studies of UKA survivorship demonstrated failure rates as high as 35% [7], recent data from the Finnish register reports UKA survivorship of 80% at 10 years and 70% at 15 years[8]. Additionally, studies from tertiary referral centers involving high-volume surgeons have demonstrated 10-, 15-, and 20-year survivorship as high as 98, 93, and 90%, respectively

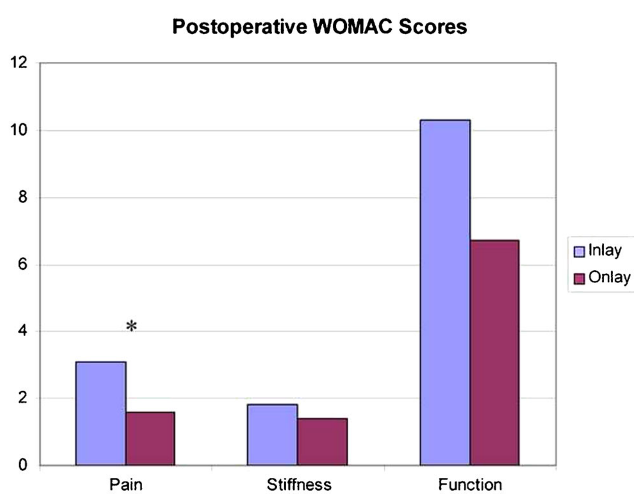

Fig. 3. Postoperative WOMAC subscores. Statistically significant differences ($p \leq 0.05$) are indicated by an *asterisk* (*).

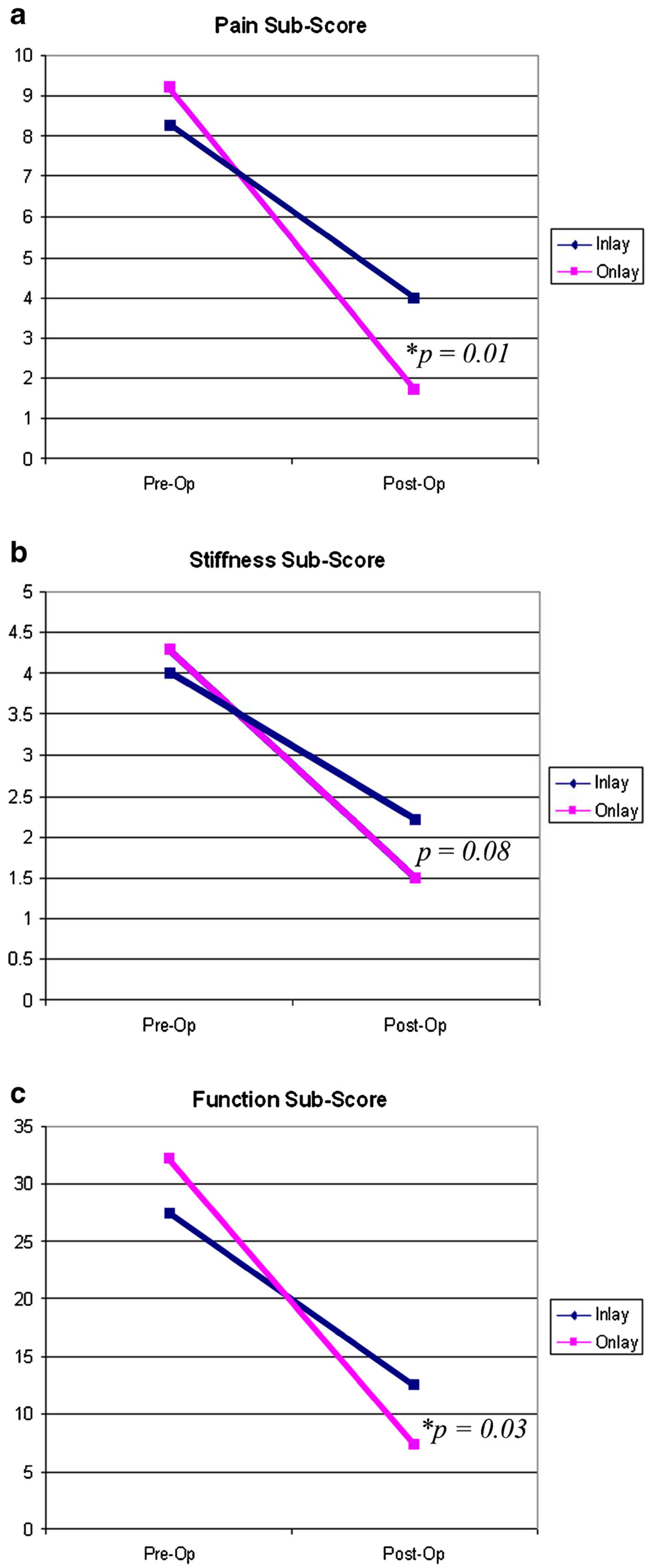

Fig. 4. Change in WOMAC scores after surgery. Statistically significant differences ($p \leq 0.05$) are indicated by an *asterisk* (*). **a** Pain subscore, **b** stiffness subscore, **c** function subscore. *Pre-Op* preoperative, *Post-Op* postoperative.

[4], which is comparable to that reported for total knee arthroplasty [1, 6]. However, relatively, little is known about the factors responsible for this improving survivorship, particularly implant-related factors. The purpose of this study therefore was to determine whether two commonly used tibial component options, the all-polyethylene inlays and the metal-backed onlays, differ in terms of (1) clinical performance and (2) rate of revision or secondary surgery.

There are several limitations to this study. First, it is a retrospective review of prospectively collected data, and therefore has the potential for selection bias which is inherent to any retrospective study. A second limitation is that 54 out of a possible 158 patients did not agree to complete the clinical questionnaire and participate in the study; thus, this could potentially create a selection bias. An attempt was made to blunt the effect of selection bias by using predefined inclusion/exclusion criteria and by enrolling consecutive patients from the senior author's prospective database over a discrete time period. Additionally, patient demographic variables were analyzed, which showed no differences between the two groups, further mitigating the effect of selection bias. A third possible limitation is that the follow-up period was slightly longer for the inlay group (mean 2.7 years) than that for the onlay group (mean 2.3 years). Thus, there exists the possibility that the longer follow-up period for inlays may have allowed capture of more failures, or negative clinical results, than if the follow-up periods were similar. However, while it was statistically significant, the absolute difference of mean follow-up time between the groups (5 months) is unlikely to result in a clinically meaningful difference in the performance of the two implants. A final limitation is that the inlay group of patients underwent UKA earlier during the study period than did the onlay group. Thus, it could be argued that the learning curve of the procedure could have affected the difference in outcome between the two groups. However, we feel that this limitation is blunted by two important points. First, at the time of study commencement, the senior author had already performed more than 30 robotic UKA cases, dampening the potential effect of a learning curve. Second, the use of a robotic-controlled protocol in performing UKA has been shown to allow even less experienced surgeons to implant UKAs with superior accuracy to conventional methods [5]. Thus, we do not feel that a learning curve effect played a vital role in the difference in outcomes between the two groups.

Using this specific design in a robotic-assisted protocol, the present study demonstrates that patients with onlay tibial components have better pain relief compared to patients with inlay tibial components. The onlay group had significantly improved postoperative WOMAC pain subscores at the time of final follow-up. In addition, when patients with available preoperative and postoperative data were considered, onlays demonstrated significantly greater improvement in both the pain and function subscores. Inlays (10.3%) in this study were associated with a higher rate of revision or secondary surgery than onlays (2.2%), but this difference did not reach statistical significance. Importantly, all implants in the study were placed using a robotic-assisted, standardized technique. While anatomic landmarks during the initial registration process and soft tissue balancing are controlled by the surgeon and are subject to human error, we feel that the application of a standardized robotic technique theoretically limits variability secondary to surgical technique, implant positioning, or other human-related factors. Thus, any differences noted between the performance of the two implants are more likely to be related to the implants themselves. Taken together, these data suggest that superior clinical outcomes occur with onlay compared to inlay tibial components.

Previous authors have suggested that onlays are superior to inlays for tibial resurfacing in UKA. Using a biomechanical model to compare inlay versus onlay tibial components, Walker et al. reported that the all-polyethylene inlays generate six times more peak stress at the tibial surface than do the metal-backed onlays. Furthermore, inlays were found to produce strain values which exceeded that of onlays by a factor of 13.5, which was attributed to areas of softer bone at the bone-implant interface. The authors concluded that the metal-backed onlay components were a better option when considering load distribution over the tibial surface [12]. The superior load distribution of the metal-backed onlay design may be a mechanistic explanation for the improved pain relief demonstrated by the onlay components as compared to the inlay devices. It is also interesting to note that the reason for secondary procedures in all inlay cases was tibial pain below the prosthesis (with or without implant loosening); the trend toward a higher rate of secondary procedures due to tibial pain in the inlay group may be due to the poorer load distribution and increased strain in this region.

A review of multiple survivorship studies of UKA indicates that onlays may be preferable to inlays for tibial resurfacing. An early study of the Marmor UKA prosthesis, using an all-polyethylene inlay technique, demonstrated 21 failures in 60 UKAs at an average of 10-year follow-up; eleven of these failures (18.3%) were attributed to aseptic loosening of the inlay tibial component alone [7]. Using the same prosthetic design, Cartier et al. reported nine failures (three infections, three femorotibial subluxations, two patients with degeneration of the contralateral compartment, and one patient with severe osteoporosis and subsidence of the implant) in a series of 60 UKAs at an average of 12-year follow-up. Importantly, the authors placed the tibial all-polyethylene component directly on the cortical rim of the plateau (onlay technique), rather than within the cancellous bone (inlay technique), citing improved control of component positioning, a lower risk of subsidence, and decreased occurrence of major bone defects [3, 9]. Using a metal-backed onlay tibial component in a series of 62 patients, Berger et al. reported only two failures (3%) at a minimum 10-year follow-up, both for progression of patellofemoral arthritis [2]. An updated report from this same group recently reported only four failures (6%) at an average of 19-year follow-up (all failures were for progression of arthritis in another compartment) and demonstrated 15- and 20-year revision-free survival of 93 and 90%, respectively[4].

While biomechanical and survivorship data suggest the superiority of onlays over inlays in UKA, we are unaware of any previous comparative clinical studies confirming these data. To our knowledge, the present study is the first direct comparison of clinical performance between these two implant options. In this retrospective review of a single surgeon's prospective database, patients with onlay components had less pain and superior postoperative clinical outcomes when compared to patients with inlay components. We recommend the preferential use of metal-backed onlay components when resurfacing the tibia during UKA.

Disclosures

Conflict of Interest: Brian P. Gladnick, MD, Denis Nam, MD, Saker Khamaisy, MD and Sophia Paul, BA have declared that they have no conflict of interest. Andrew D. Pearle, MD reports personal fees from Pipeline Orthopaedics, stock options from Blue Belt Technologies and research grants from MAKO Surgical, outside the work.

Human/Animal Rights: All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5).

Informed Consent: Informed consent was obtained from all patients for being included in the study.

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