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Comparative Fixation and Subsidence Profiles of Cementless Unicompartmental Knee Arthroplasty Implants



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ABSTRACT

Background: Aseptic loosening is the primary cause of failure for both cemented and cementless unicondylar knee replacements (UKRs). Micromotion and subsidence of tibial baseplate are two causes of failure, due to poor fixation and misalignment, respectively.

Methods: Stair ascent activity profiles from Bergmann et al and Li et al were used. Biphasic Sawbones models were prepared according to the surgical techniques of traditional and novel cementless UKRs. Implants were tested for 10,000 cycles representing post-operative bone interdigitation period, and micromotion was observed using speckle pattern measurements, which demonstrated sufficient resolution. Additionally, the test method proposed by Liddle et al was used to measure subsidence with pressure sensors under increasingly lateralized loading.

Results: Mean displacement due to micromotion for mediolateral and anteroposterior plane was consistently greater for traditional cementless UKR. Mean displacement for axial micromotion was significantly higher for traditional UKR at the anterior aspect of the implant; however, values were lower for the medial periphery of the implant. Subsidence was significantly lower for the novel design with increasingly lateralized loading, and indentation was not observed on the test substrate, when compared to the traditional design.

Conclusion: Our findings demonstrate that the novel cementless design is capable of fixation and elimination of subsidence in laboratory test settings. Both designs limit micromotion to below the established loosening micromotion value of 150 μ m. The L-shaped keel design resists both micromotion and subsidence and may prevent failure modes that can lead to aseptic loosening for UKRs. These findings are highly relevant for clinical application.

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Aseptic loosening is a primary failure mode of unicondylar knee arthroplasty (UKA) [1-4]. Most loosening cases involve the tibial component, which is prone to instability through two mechanisms [1,5]. First, micromotion under shear stress may prevent adequate fixation at the bone-implant interface [6]. Repeated micromotion stimulates ingrowth of fibrous tissue that may prevent subsequent osseointegration [2,6]. Second, component misalignment may result in eccentric loading of the tibial component by the femoral component [1]. The resulting abnormal force distribution may lead to tibial baseplate subsidence, insert dislocation, or polyethylene fracture [7-10].

Cementless UKA was introduced in the 1980s, in an effort to reduce the incidence of revision [2]. Three dimensional printed porous structures provide a surface which interdigitates with surrounding cancellous bone [11]. This technology permits secure implant fixation while avoiding potential pitfalls of cementation such as mantle failure, extrusion, loose bodies, and particle-induced osteolysis [1,2]. Studies have demonstrated equivalent outcomes between cementless and cemented UKA [3,12]. However, the former has the potential to remain susceptible to aseptic loosening and tibial baseplate subsidence. Optimizing biological fixation and maintaining a uniform load distribution therefore

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Fig. 1. Oxford Cementless (left) and Tritanium UKR (right) designs.

represent 2 key objectives toward the advancement of cementless UKA prostheses.

Recent advances in additive manufacturing have allowed the production of porous materials that accurately reproduce the structure of cancellous bone [13]. This may influence both the biological fixation and load-bearing properties of cementless implants. We hypothesized that a novel cementless UKA design implementing an additively manufactured porous titanium surface would exhibit equivalent or less micromotion and tibial component subsidence under physiologic loading conditions.

Materials and Methods

Implants

Two cementless UKA implants were directly compared in this study. The fixed bearing Stryker Tritanium UKR (Stryker Orthopaedics, Mahwah, NJ) incorporates a porous technology at the tibial baseplate (Fig. 1). The porous technology refers to a trabecular microstructure consisting of titanium alloy (Ti-6Al-4V), produced by an additive manufacturing process similar to processes outlined previously [11]. A right-angled tibial keel resists shear forces in both the coronal and sagittal planes (Fig. 1). The implant is inserted via a robotic arm—assisted technique according to the manufacturer's instructions similar to the process outlined previously in detail [14].

The mobile bearing Oxford Cementless (Zimmer Biomet, Warsaw, IN) is a modification of the cemented Oxford III. The tibial baseplate features a plasma-coated titanium and calcium hydroxyapatite coating [2,15]. This implant uses a straight keel with a longitudinal slot (Fig. 1) [2]. The Oxford Cementless is inserted with a manual technique, which has also been previously described [16].

Micromotion Testing

Biphasic bone models were constructed to measure implant micromotion under cyclical loading conditions. Each implant was tested 6 times with an individual specimen. Each specimen consisted of a new tibial construct, based on Sawbones (Pacific Research Laboratories Inc, Vashon Island, WA). Sawbones tibial block density was selected to replicate severely osteoporotic bone, featuring a 12.5 PCF polyurethane cancellous shell and 40 PCF cortical shell [17].

Tibial implants were inserted into the medial aspect of the Sawbones tibias using the manufacturer recommended surgical technique. Although the system is not cleared for use as bicompartmental UKR, implants were also inserted into the lateral aspect to balance the joint loads obtained from published total knee arthroplasty (TKA) data [18,19]. Manual placement of the Oxford

Cementless implant required an implant-specific preparation consisting of burring an oval shape on the Sawbones surface ^{1/2} millimeter deep under the medial cut of the tibial baseplate due to a proud plasma coating region (Fig. 2). This was performed to ensure optimal implant seating and circumferential cortical contact. Tibial assemblies were spray painted with a black and white speckle pattern coating to track micromotion (Fig. 3A,B). Femoral constructs consisted of the femoral component cemented into an arbor positioned overhead (Fig. 3A).

Compressive load parameters were set to model stair ascent. Studies have demonstrated that this activity of daily living (ADL) generates among the highest forces on the knee (3.16-fold body weight) [20]. Implant micromotion is highly probable during stair climbing, secondary to high axial forces at the posterior tibial articulation [6,21]. The load was scaled to 60%, which represents the lower boundary of the standard deviation obtained from clinical data, to avoid damaging the tibial constructs [6,18].

Specimens were subjected to loading at 10,000 cycles using a 4-axis servohydraulic test machine (MTS Systems Corp, Eden Prairie, MN). Run-time corresponded to 13% of all ADL performed over an 8-week postoperative period [19]. Peak-Peak (P-P) micromotion between the baseplate and Sawbones in the coronal, sagittal, and axial axes was recorded at 3 locations (Fig. 4A-4C). Measurements were taken with the ARAMIS optical 3D deformation analysis system (GOM mbH, Braunschweig, DE) at time zero and after 10,000 cycles.

Lateral Subsidence Testing

Lateral subsidence under eccentric femoral loading was measured using the method outlined by Liddle et al [22]. Six specimens were prepared, each using a polyurethane Sawbones block to simulate the tibial plateau. A Tritanium UKR was inserted into the medial compartment of each specimen according to the manufacturer's instructions. The thickest available polyethylene insert (12 mm) was used to generate the largest moment under lateralized loading. Two thin-film pressure sensors (Tekscan Inc, Boston, MA) were inserted between the tibial baseplate and underlying Sawbones block, flanking the tibial keel in a parallel orientation to the anteroposterior (A/P) axis of the baseplate (Fig. 5) [22].

Tibial constructs were positioned in a vice under a servohydraulic test machine (MTS Systems Corp). A 32-mm spherical ball indenter of equivalent diameter to the femoral component was used as the end effector (Fig. 6). The indenter was aligned with the tibial sulcus, and an axial load of 2272 N was applied [18]. Corresponding to the peak force exerted on the knee at 90 degrees of flexion (3.16-fold body weight) during stair ascent, this load was used for dynamic calibration [1].

The loading process was repeated at the tibial sulcus, representing 0 degrees of flexion. Pressure values were retrieved from



Fig. 2. Scanned Oxford implant relative to the flat computer aided design model showing 0.5 mm of deviation (scale in diagram is in inches).

the calibrated Tekscan software. The implant was then removed and the tibial loading area inspected for indentation. The test was then repeated 4 times, sequentially shifting the loading location in 1-mm increments laterally to simulate natural tracking (from 0 to 90 degrees flexion) of the implant during stair ascent (Fig. 6) [6]. Each specimen (n = 6) was tested across the full range of contact points.

Pressure measurements at each location (0, 1, 2, 3, 4, and 5 mm lateral) were compared to historical data for the Oxford

Cementless, which was obtained using the same testing protocol (Fig. 7) [22]. All Tritanium UKR implants were measured 44 mm in the anteroposterior dimension to match the length and width of the Oxford Cementless.

Statistical Analysis

P-P micromotion values were reported as means with standard deviation, obtained from the 6 specimens tested per implant. Values were compared between implants in the A/P, mediolateral (M/L) and axial motion planes at each of the 3 gauge points (GPs), using unpaired *t* tests with unequal variance. Lateral subsidence values were reported as means with standard deviation for each loading location. These were compared qualitatively to historical subsidence data for the Oxford Cementless implant. All analysis was performed using SPSS version 21.0 (SPSS Inc, IBM Corporation, Armonk, NY) at a significance threshold of P < .05.

Results

Micromotion

Mean displacement in the M/L plane was consistently greater for the Oxford Cementless at GP 1 (51 vs 24, P = .056), 2 (33 vs 19, P = .053), and 3 (23 vs 21, P = .035) (Fig. 8). Mean micromotion in the A/P plane was also higher for the Oxford Cementless at GP 1 (33 vs 13, P = .058), 2 (25 vs 9, P = .047), and 3 (18 vs 13, P = .14; Fig. 8). Mean axial displacement was greater for the Tritanium UKR compared to the Oxford Cementless at GP 2 (48 vs 40, P = .39) and 3 (32 vs 20, P = .002) but significantly less at GP 1 (19 vs 99, P = .008; Fig. 8).

Lateral Subsidence

The variation in pressure exerted on the tibial baseplate during eccentric loading was significantly lower for the Tritanium UKR vs the Oxford Cementless (Fig. 7). Mean pressure when loading at the sulcus of the Tritanium UKR was 4.5 (\pm 0.16) MPa. This fell incrementally with increasing lateralization of force to 3.5 (\pm 0.84) MPa at 5 mm. In comparison, mean pressure at the tibial sulcus has previously been reported at 2.0 MPa for the Oxford Cementless



Fig. 3. Initial fixation test setup. (A) Close up of the test setup. (B) ARAMIS dual camera system.

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Fig. 4. (A) Transverse plane showing locations of gages 1, 2, and 3 and anterior (A), posterior (P), medial (M), lateral (L) orientations. (B) Sagittal view. (C) Cartesian sign convention with respect to the implant.

[22]. Loading pressure rose to 12 MPa at 3-mm lateral migration and peaked at 13 MPa at 5 mm in the historical data [22]. Visual inspection revealed no subsidence markings on the tibial Sawbones surface for the Tritanium UKR samples.

Discussion

Our findings demonstrate that the Tritanium UKR achieves initial fixation at a level equivalent to or greater than that of the Oxford Cementless in benchtop testing. Although the Tritanium UKR exhibited relatively greater micromotion in the axial plane at 2 of 3 measurement points, these values were well below the micromotion threshold, established by previous studies, known to prevent bone interdigitation [6]. Peak axial displacement was higher for the Oxford Cementless. Tibial subsidence testing revealed a more uniform pressure distribution under increasing lateralization of loading forces for Tritanium UKR.

The favorable micromotion profile of the Tritanium UKR indicates greater resistance to shear forces, possibly due to the right-angled keel [6]. Maximizing the contact area in the A/P plane,



Fig. 5. Subsidence test setup with pressure sensor locations.



Fig. 6. Indenter migration and final baseplate subsidence for both designs.

this design subjects the bone-implant interface to lower net pressure under a constant loading force. In contrast, the straight keel of the Cementless Oxford offers a limited surface area for interdigitation in the A/P plane while concentrating load across a smaller contact region. Transmission of forces that exceed the compressive strength of the surrounding bone may disrupt the bone-implant interface [23]. This is a key consideration in the context of the relatively younger, more active patients who often opt for a UKA. Based on the results of bench-top testing for micromotion testing, the Tritanium UKR may, in theory, maintain fixation for at least 8 weeks postoperatively under normal intensity ADLs outlined for a joint with instrumented TKRs which is applicable to UKRs when normalized for medial condyle only [19].

Importantly, peak micromotion of the Tritanium UKR implant was not observed to exceed 150 μ m in any plane. Prior animal studies have demonstrated that this value marks the threshold at which fibrous tissue in-growth is likely, preventing re-establishment of the bone-implant interface [4,6,24]. Cadaveric studies have found that micromotion up to 28 μ m is unlikely to result in pseudosynovium formation, whereas 40 μ m denotes the upper limit of the optimal range in humans [4,6]. Minimal micromotion is essential during the first 8 weeks postoperatively, as biologic fixation is expected to occur during this period [25].

The superior load distribution capacity of the Tritanium UKR may be a function of the advanced manufacturing techniques used in the production of the titanium porous structure when compared to the



Fig. 7. Contact pressure readings with lateralized loading.

Oxford Cementless coating technology. Additive manufacturing permits greater structural complexity than traditional "subtractive" methods, possibly resulting in a more uniform distribution of load across trabecular struts [11]. The thickness of traditional porous coatings is often inconsistent, which may also compromise load-sharing capabilities [13].

The findings of the present study are highly relevant from a clinical standpoint. Valgus subsidence of the tibial component constitutes a failure mode exclusive to cementless UKA [1]. Under the mechanism proposed by Liddle et al, peak compressive forces are generated during stair ascent. This promotes M/L micromotion of the baseplate, resulting in a relative lateralization of axial load from the femoral component [1]. Eccentric femoral loading may cause impingement of the polyethylene bearing against the lateral baseplate wall [1]. Subsequent subluxation of the bearing creates a stress riser at the lateral aspect of the baseplate [1]. Repeated loading under asymmetric, high magnitude force may eventually cause valgus subsidence of the tibial component, culminating in implant failure [1]. Our findings suggest that the superior fixation and load distribution properties of the Tritanium UKR may confer both a preventive and moderating effect on this mechanism, respectively.

This study is subject to several limitations with respect to mechanical testing and data analysis. Although Sawbones blocks are widely used to simulate the mechanical properties of bone, synthetic constructs cannot reproduce the biologic activity of in vivo bone. This may lead to relative underestimation of the fixation afforded by hydroxyapatite coating, as used in the Cementless Oxford implant [2]. Second, Sawbones blocks do not permit plastic deformation under axial compression and subsequent stabilization cycles [17]. This limits the reproducibility of press-fit insertion in the setting of trabecular collapse. Third, tibial preparation for the Oxford Cementless prosthesis allows for a 3-mm gap in the A/P plane between the tibial keel and bone [16]. This may explain the variability noted in sagittal micromotion. Finally, lateral subsidence comparison was partially based on historical data.

Conclusions

Our findings suggest that the Tritanium UKR obtains superior interface fixation due to stronger fixation relative to the Cementless Oxford in test settings, resulting in less micromotion. The results of the present study also indicate that the Tritanium UKR possesses

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Fig. 8. Micromotion measurements for both designs from all gages in 3 dimensions.

enhanced load distribution capabilities in a bench-top test setting compared to historical data published on the Cementless Oxford. Although long-term clinical studies will be required, laboratory tests show equivalent or better fixation compared to a clinically successful implant.

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