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Effect of Physiological Loading on Fretting Corrosion of Zimmer® Trabecular Metal™ Coupled Tibial Cones Interacting with Tibial Baseplates

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Authors' contributions

This work was carried out in collaboration between all authors. Authors DL, TS and LK proposed the study, provided guidance and surgeon's perspective throughout the study. Authors MAD and SMH designed the study, wrote the protocol, performed the experimental study, and wrote the manuscript in consultation with authors KAR and RZ. Author GDS provided the liaison between the surgeons and the researchers. All authors read and approved the final manuscript.

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Original Research Article

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ABSTRACT

Aim: To evaluate possible micromotion between the existing design of the Zimmer® NexGen® Legacy Constrained Condylar Knee (LCCK) tibial baseplates and the Zimmer NexGen Trabecular Metal™ (TM) tibial augments, as well as with newly designed Zimmer NexGen LCCK TM coupled

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tibial cone augments.
Study Design: Fretting corrosion testing, in a simulated accelerated corrosion laboratory environment, of the TM tibial half-augment (control sample) was conducted to provide a baseline for possible micromotion and subsequent debris generation between TM augments and tibial baseplates. Identical methodology was applied to the newly designed TM coupled tibial cone augments. Samples were disassembled after load testing. Qualitative visual inspection was used to evaluate the amount of fretting and corrosion (ranked on a 0-4 scale with 0 being no observed corrosion and 4 being the most extensive/severe corrosion).
Place and Duration of Study: Zimmer, Warsaw, IN. April 4-20, 2012.
Methodology: Testing was conducted on 2-axis servo-hydraulic test machines at 10 Hz. The entire tibial component was continuously immersed in 0.9% NaCl solution while 10 million cycles (Mc) of loading was applied. The selected test loads were based on the average patient body weight (BW) for the selected implant size and elevated by a factor of 1.7. Five samples were evaluated for each test group. All samples were visually inspected without magnification and under a microscope at 17x. Ranking was performed for the extent/severity of both abrasion and corrosion for both the control and new design groups.
Results: After 10 million cycles of fretting corrosion testing, the ranking evaluation of almost no abrasion and no observable corrosion or debris is consistent with a stable fixation mechanism under aggressive loading conditions.
Conclusion: Newly designed TM coupled tibial cones will not create a new risk of potential micromotion between the TM component and the tibial baseplate in a clinical situation.

Keywords: Trabecular metal; total knee arthroplasty; revision; tibial cones.

1. INTRODUCTION

In revision total knee arthroplasty (TKA) surgery, patients often present with tibial bone defects that are both proximally located as well as cavitary in nature. In these instances, the surgeon may fill the cavitary defect and compensate for the proximal bone loss in order to properly position and stabilize the tibial components [1].

The Zimmer® NexGen® Trabecular Metal™ (TM) tibial augments (TM tibial augments or half-augments) are designed to help replace and/or augment proximal tibial bone loss. The TM tibial augments are assembled to the distal (undersurface) of the *NexGen* Legacy Constrained Condylar Knee (LCCK) tibial baseplate using tibial attachment screws and/or bone cement. The *Zimmer NexGen Trabecular Metal* tibial cone augments (TM tibial cone augments), were designed to fill major cavitary or combined cavitary and segmental bone defects. The tibial cone augments provide solutions to a variety of proximal tibial bone defects encountered clinically [2,3]. These augments enhance fixation to the damaged metaphysis and provide a stable platform for the associated *Zimmer NexGen* tibial baseplate [4,5]. Both the TM tibial cone and tibial augments (Figs. 1A-B) are intended for use where severe degeneration, trauma, or other pathology of the knee joint indicates the need for a complex total knee arthroplasty (TKA).

Fig. 1. (A) TM tibial cone augments (B) TM tibial augments/half-augments

The newly designed *Zimmer NexGen* LCCK *Trabecular Metal* Coupled Tibial Cone (TM coupled tibial cone augment) intends to combine the function of both the TM tibial augments and the TM tibial cone augments. The TM coupled tibial cone design (Fig. 2) uses the same cavitary filling geometries as the TM tibial cone augments and the mating functions of the TM tibial augments. It consists of TM implants to specifically address small to medium segmental, contained cavitary defects found during revision surgery of the proximal tibia. It provides for mechanical attachment between the TM component and the tibial baseplate to allow for modularity as well as intraoperative

assembly. The design intent is to provide and maintain stability to the tibial baseplate construct after reconstruction of the proximal tibia when subjected to high cycle normal gait activities at physiologic loads.

Fig. 2. TM tibial coupled cone augments

Modular designs introduce junctional interfaces with the potential for mechanical motion at those interfaces which may be a source of fretting corrosion debris. The metallic particles could stimulate adverse biological reactions in human body [6], as well as lead to accelerated wear at the articulation interface. *In vitro* testing, simulating *in vivo* environment, can produce fretting debris from a modular interface for comparative evaluations between designs. Therefore, an *in-vitro* fretting corrosion study was performed to evaluate the interaction and the possible micromotion between the TM coupled tibial cone augments and the tibial baseplates. It is hypothesized that the micromotion effects will be similar for the TM tibial half-augments and the currently available TM coupled tibial cone augments.

2. MATERIALS AND METHODS

Fretting corrosion testing, in a simulated accelerated corrosion laboratory environment, of the TM tibial half-augment (control sample) was conducted to provide a baseline for the possible micromotion and subsequent debris generation between the TM augments and tibial baseplates. The clinical experience of the existing TM tibial half-augments that have been in use for the last ten years have not shown any evidence of fretting corrosion debris resulting from its interaction with the tibial baseplates [2,3,5,7,8]. The same test method was then conducted using the newly designed TM coupled tibial cone augments.

The TM tibial half-augments and the TM coupled tibial cones were assembled to the tibial baseplates using recommended surgical techniques [9,10]. The TM augments were attached to the tibial baseplates using only the fixation screws. As a control, two TM coupled tibial cone augment samples were assembled and disassembled without testing and were visually evaluated to confirm that there was no surface abrasion associated with the assembly process.

A cavitary defect was artificially prepared in polyurethane foam blocks (representing a bone analogue) to mimic the loss of bone encountered during surgery. In the control test constructs, these cavities were filled with bone cement representing the current clinical practice of using TM tibial half-augments. PMMA bone cement was used to fix the distal surface of the TM augment to the foam block, which is intended to mimic the boundary conditions of bone growing into and anchoring the TM augment. For the new design, the TM coupled tibial cones were cemented within the cavity to mimic clinical bony in-growth condition.

A tibial stem extension and the articular surface were assembled to the tibial baseplate. The assembled tibial construct and the foam block were then fixed within an environmental chamber on the test machine and aligned as required relative to the femoral component. The femoral component was fixed to the crosshead of the test machine and oriented to simulate 10º of flexion relative to tibial component. The low point of the femoral condyles were then aligned with the low point of the articular surface which were inserted onto a tibial baseplate with a 7º of posterior slope. This particular orientation corresponds to the peak load during level walking gait [11].

Fig. 3 presents a model of the test setup with both TM tibial half-augments and TM coupled tibial cone augments.

2.1 Test Environment

Two primary conditions in which corrosion can occur between modular connections in a fluid environment are the following: (i) fretting mechanisms which result from the small oscillatory micromotion of the components which abrade and cause corrosion and (ii) local accelerating effects of pH changes as

restricted fluid volumes cause acidification of the solution which can accelerate the corrosion mechanisms (crevice corrosion conditions).

The test method simulated the clinical conditions by testing assembled components in Ringers saline solution under load parameters which mimic clinical conditions. The environmental test temperature maintained at 50ºC was checked and adjusted daily in order to control the temperature within ±2ºC. Normal body temperature is 37ºC; however some acceleration of the corrosion environment can be accomplished by elevating the temperature (Arrhenius effect [12]). A normal 7.0 pH (±0.5) solution was used for this testing. The solution pH was also checked and adjusted daily at a minimum, by adding small amounts of 0.5 M HCl or 1.0 M NaOH solution.

2.2 Test Samples

This study is a comparison test and consequently, any size and construct of implants could be selected as long as the two sample groups utilize similar sizes and thickness. However, the size with the largest surface area and the largest expected loading could provide a worst case condition for the test. Therefore, Size 7 *NexGen* LCCK tibial baseplates and Size G *NexGen* LCCK femoral components were chosen. Right and left implants are identical mirror geometries of each other and either can be suitable for testing. For this study, the *NexGen* LCCK 10 mm articular surfaces were used, as they are the most commonly used thickness in clinical practice. The stem extension plays a role in stabilizing the tibial component but its length has no impact on the test results of this study and therefore any size/length of stem extension may be used. In order to accommodate the amount of vertical travel in the test machines, a short (30 mm length) mid-size (15 mm) diameter *NexGen* stem extension was used. Foam blocks representing bone analog were fabricated from General Plastics FR-3725 polyurethane material, whose modulus (337 MPa) [13] is within the nominal range for cancellous tibial bone (60 to 400 MPa) [14,15]. The comparably sized Size 7 TM tibial half-augments with 5mm height (control specimens) and Size 7, 46 mm x 34 mm TM coupled tibial cone augments (new design) were selected. A total of five samples were evaluated for each test group.

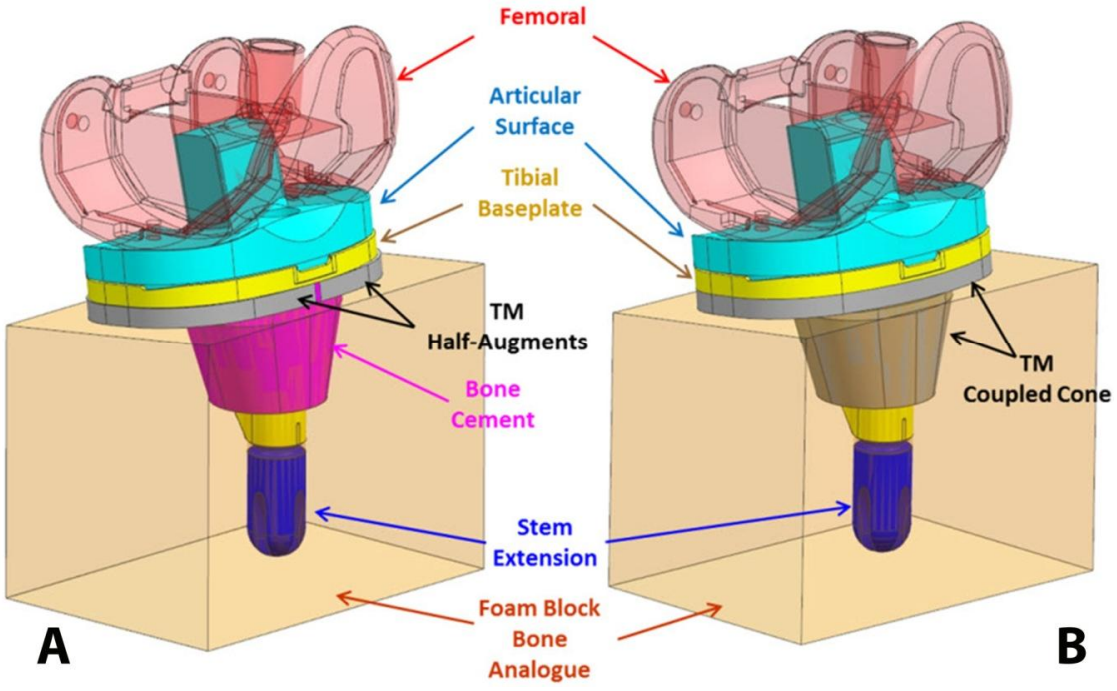

Fig. 3. Schematic of test setup (A) TM tibial half-augments. (B) TM coupled tibial cone augments

2.3 Loading

In situ corrosion is a function of both the micromotion environment and time. Loads applied to the joint are dominated by walking loads, but also include more aggressive loading events such as stair climbing, rising from sitting, and other activities, but at much lower frequencies. For fretting corrosion testing, the best lab/clinical correlation for hip implants was found with loads which were 1.7 x those of typical, average walking loads for the implant [16]. It was rationalized that this 70% load elevation corrects for the shorter test time and the simplification of loading to a single load profile compared to in-vivo corrosion. Therefore, the current test series selected test loads based on those derived for the average patient body weight (BW) for the selected implant size and elevated them by a factor of 1.7.

The load profiles used in this test were derived from the data measured in situ by Kutzner et al. [11]. The test machines used for this study are capable of applying load in two control directions. The primary loading condition for this test includes the joint reaction load and the anterior-posterior (A/P) shear load. Since remaining force and moment loads are small in magnitude, the loading profile selected for this test using two prominent loading components was accepted as a reasonable simulation of implant forces within the knee during normal walking and deemed sufficient for the purposes of this evaluation. Table 1 presents the knee loading data as a percentage of body weight (BW) derived for this test during normal walking (Table 1 – Load) and then elevated by a factor of 1.7 (Table 1 – Test Load) for the testing. The test loads were applied using a patient body weight of 222 lbs. (100 kg), derived from knee registry of 37,641 total knee replacement components implanted between February 1995 and October 2010 [17].

2.4 Testing

All testing was conducted on 2-axis servo-hydraulic test machines at no more than 10 Hz as corrosion mechanisms are time dependent and frequencies above this threshold may not permit sufficient time for passivation/corrosion mechanisms to occur. The entire tibial component was continuously immersed in in 0.9% NaCl solution while 10 million cycles (Mc) of loading was applied through the femoral component. Considering that an average hip or knee implant patient walks approximately 0.9 Mc per year, the selection of loading cycles for this test represents a 10-year span on an average [18]. While a lower number of cycles could have been used for this comparative test, 10 Mc was selected to produce detectable corrosion over a span that is clinically relevant.

Upon completion of each test, the tibial baseplate and TM components were carefully handled to avoid any damage. Both components were removed from the foam block bone analogue and all the remaining bone cement was dissolved from the components using an acetone soak. The TM augment components were carefully disassembled from the tibial baseplates. Then the tibial baseplate and TM augment mating surfaces of each test sample were visually inspected via naked eye as well as under magnification to document the component conditions.

2.5 Measurement of Fretting Corrosion

A qualitative visual inspection, similar to the approach used by Hood et al. [19] was used to evaluate the amount of fretting and corrosion. Each sample surface was inspected and ranked on a 0-4 scale with 0 being no observed corrosion and 4 being the most extensive/severe corrosion. Ranking was evaluated for both extent/severity of abrasion and the extent/ severity of corrosion. The same scale system was used for both the control and new design groups. Additionally, four different engineers conducted the inspection exercise independently for all the samples. All the samples were visually inspected without magnification as well as under a microscope at 17x.

3. RESULTS AND DISCUSSION

Minor abrasion, which consisted of slight scratching of the surface in local areas visible only under magnification, was observed on samples from both the half augment and coupled tibial cone test groups indicating that the fixation mechanism was stable and retained the components without allowing significant micromotion, even under the aggressive loading conditions.

The ranking results were averaged by sample groups and are included in Table 2. The ranking evaluation is consistent with almost no abrasion and no observable corrosion or debris.

Table 1. Knee level walking load data

Load type	Load [8] (% x BW) min/max	Test load (1.7 x Load)	
		(% x BW) min/max	Lbs. min/max
Joint load	26 / 261	44 / 444	98/986
A/P shear load	-26 / 25	-44 / 43	-98/96

Table 2. Fretting corrosion ranking results

	Augment		Distal Tibia	
	Abrasion	Corrosion	Abrasion	Corrosion
TM Half augment	0.45	0	0.435	0
TM coupled tibial cone	0.1	0	0.35	0

Fig. 4 shows the distal surface of tibial baseplates before and after the tests. Please note that the two post-test pictures (Figs. 4B and 4C) have black colored taper plug assembled in the taper portion of the keel. Additionally, the two control samples were disassembled and examined using the same methodology. Those samples exhibited no abrasion damage from the assembly/ disassembly process.

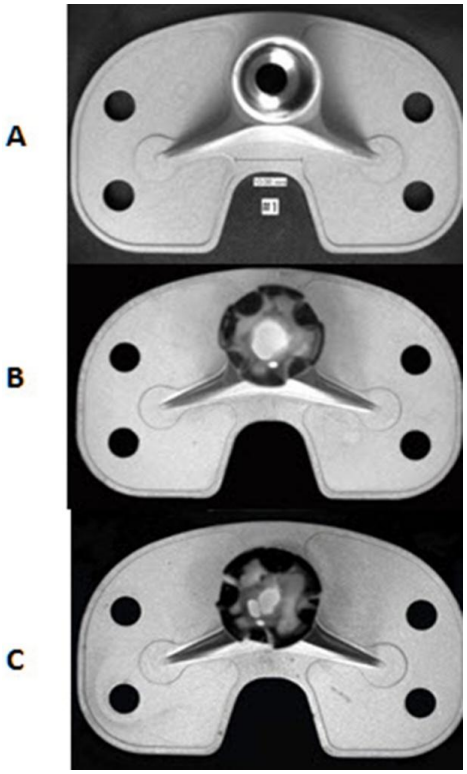

Fig. 4. Tibial baseplate distal surface (A) Pre-test (B) Post-test using TM tibial half-augments (C) Post-test using TM coupled tibial cone augments

4. CONCLUSION

After 10 million cycles of fretting corrosion testing, no abrasion visible to the naked eye and no observed corrosion or fretting corrosion debris from micromotion between the tibial baseplates and the TM tibial half-augments or the TM coupled tibial cones was observed. These results are consistent with the clinical experience of the existing TM tibial half-augments that have been in use for the last ten years [2,3,5,7,8]. Therefore, the newly designed TM coupled tibial cones will not create a new risk of potential micromotion between the TM component and the tibial baseplate in a clinical situation.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

MD, SH, KR, GS, and RZ are employees of Zimmer, Inc. DL, TS, and LK are developing surgeons who participated in this study conducted by Zimmer, Inc".

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