Safety and efficacy of a mobile unicondylar knee implant design concerning wear

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INTRODUCTION: In the last years, the number of unicondylar knee replacement (UKR) surgeries, in which only one of the compartments affected by osteoarthritis (OA) is replaced, has increased. It is a less invasive surgery as compared to total knee replacements (TKR), allowing faster recovery of the patient by preserving more of the host bone. An UKR is comprised of three parts: a metallic femoral component that articulates against a tibial insert of ultra-high molecular weight polyethylene (UHMWPE), which, in turn, may be fixed or mobile relatively to a metallic tibial baseplate. As in all joint replacements, the wear of the UHMWPE is a critical factor to the safety and efficacy of the UKR, limiting its long-term use due to debris generation. Therefore, wear evaluation of new UKR designs in pre-clinical stage is crucial to demonstrate that the implant will be beneficial to the patient. The wear of a UKR design can be assessed by the use of machines that simulate the biomechanics of the knee operating under physiological environment, by applying loads and motions representative of the human gait to the UKR components. This work presents the wear performance evaluation of a mobile UKR design, in which a tibial insert made of non-crosslinked UHMWPE articulates against a single radius femoral component of cobalt chromium alloy through its concave bearing surface, and against a flat tibial baseplate, also of cobalt chromium alloy, through its opposite bottom surface.

METHODS: The selected UKR specimens were representative of the worst-case scenario for wear, comprised by a large size (#7) and a small 3.6 mm thickness of the UHMWPE tibial insert, and absence of constraints for translation movement of the tibial insert. Three specimens were wear tested and one active control specimen was used to correct the mass gain of the UHMWPE by fluid sorption. The human gait was replicated in a simulator machine (AMTI Knee ADL). The contact force (Fz), the angular motions of flexion/extension (FE) and internal/external rotation (IR/OR), as well as the anterior/posterior (AP) displacement, were applied in the wear specimens following ISO 14243-3. The specimens were mounted with both medial and lateral coupling to keep the motions stable during the test. The reference position, or the angular and linear alignment of the tibial insert in respect to the femoral component, was set as described in ISO 14243-3. Bovine calf serum with (20 ± 2) g/L protein concentration was used as lubricant. The wear rate of the medial and lateral tibial inserts was determined as the slope of the cumulative mass loss as a function of the number of cycles performed in the test, as described in ISO 14243-2. Two million test cycles were performed. Photographical images were used to observe the location of the wear scar in the specimens. Using optical microscope (Carl Zeiss, Axio Scope.A1), the main wear mechanisms in the worn surfaces were identified after the end of the test.

RESULTS SECTION: With respect to the worn area of the tibial inserts, polishing was located mostly in the bottom surface, close to the edges (red arrows in Figure 1a), and, in the top surface, abrasion and adhesion were the main wear modes, identified through optical microscopy (Figure 1b). Some original machining marks were also observed, particularly where no mechanical contact occurred during the wear test (Figure 1b). The femoral component showed a slight scratched surface, mainly aligned in the flexion/extension direction (Figure 1c, red arrows), indicative of abrasion mechanism. The tibial inserts presented a linear wear up to 2 million cycles, with a wear rate of (3.87 ± 0.50) and (3.59 ± 2.10) mg/10^6 cycles for the medial and lateral tibial inserts, respectively.

DISCUSSION: The wear in the bottom surface of the UHMWPE tibial insert was mainly seen in the center at its lateral edges; this was associated to the axial force applied along the anterior posterior sliding distance of 5 mm that was selected so as to follow ISO 14243-3. The wear mechanisms of adhesion and abrasion seen in the tested UKR design are the mostly expected ones in joint implant tests. The wear rates were close to the values reported in the literature (Kretzer et al., 2011).

SIGNIFICANCE/CLINICAL RELEVANCE: Considering that both the wear rate and wear mechanisms found it the tested UKR design were in agreement with the findings reported in the literature, it was demonstrated that the pre-clinical wear test was useful to conclude the implant complies with safety and efficacy requirements.

REFERENCES
ISO 14243-2, Implants for surgery — Wear of total knee-joint prostheses — Part 2: Methods of measurement
ISO 14243-3, Implants for surgery — Wear of total knee-joint prostheses — Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test
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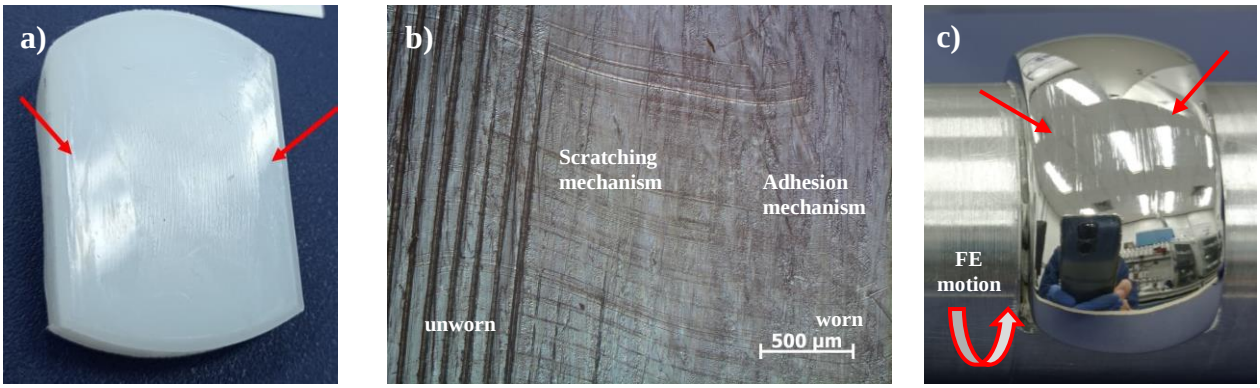

Figure 1 –a) Bottom and b) top surface of the tibial insert, and c) Visualization of scratching in the femoral component.