WEAR ADVANTAGE OF A NOVEL ROTATING BEARING KNEE – AN IN-VITRO STUDY

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OBJECTIVE
A novel Rotating Bearing Knee (RBK) is characterized by a unique distal bearing, shaped like a “wave,” which is intended to reduce the risk of peg wear by shielding the tibial insert central peg from loading (see Figure 1). The purpose of this study was to evaluate the wear of peg wear by shielding the tibial insert central peg from loading (see distal bearing, shaped like a “wave,” which is intended to reduce the risk of low wear (based on macroscopic microscopic visual examination). This is different from traditional flat on flat rotating bearing knee design and is a direct benefit of the wave concept, as the shear loads are constrained by the internal curvature of the wave shape rather than the central peg. As a result, this concept promotes the reduction of wear caused by contact between the central peg and tibial tray bore in prostheses associated with a flat tibial tray (when tested on a knee simulator).

DISCUSSION
In addition to the low wear rate, low kinematic variation in response to the simulated cycle between the three novel RBK stations was observed. Because the surface contact between the tibial insert and the tibial tray is controlled (i.e. along the “deepest” portion of the wave), the torque required to initiate rotation at the lower bearing is predictable. A visual analysis of the novel RBK tibial inserts demonstrated that all exhibited identical contact patterns on the second bearing after test (see Figure 3).

Finally, the amount of central peg and tibial tray bore wear was minimal as evidenced by microscopic visual examination (see Figure 4). This is unusual for rotating bearing knee designs with flat second bearings, which under anterior-posterior force application typically demonstrate large wear patterns along the anterior face of the central peg.

MATERIALS AND METHOD
The general procedure was based on ISO 14243-1, with the exception of the fluid test medium formulation. Rather than diluting the serum to 25% as indicated by ISO 14243-1, the protein concentration used for all Endolab tests has been set at 30 g/l. A final protein content of 30 g/l is regularly used for simulator tests. According to a first wear test, three novel Optetrak® RBK™ (Exactech, Inc.; Gainesville, FL.) components were used. According to a second wear test, two Optetrak® PS fixed bearing knees were used, which provided a solid comparison between the novel RBK and its fixed bearing version. Finally, the laboratory performing this study (Endolab, Rosenheim, Germany) shared individual wear rates for all the rotating bearing knee systems they have tested (n=16) using the same protocol that exhibited more than one degree of axial rotation between the femoral and tibial components (n=9). For confidentiality reasons, the laboratory did not share the trademark for these systems.

RESULTS
After correcting for fluid test medium absorption, the net wear rate averaged 2.11 ± 0.47 milligram per million cycles (mg/Mc) (range 1.69 to 2.92 mg/Mc) and 3.00 ± 0.47 mg/Mc (range 2.67 to 3.33 mg/Mc) for the novel RBK and its fixed bearing version, respectively. No significant difference between these two tests (P > 0.05) could be found using Student’s t-Test.

The mean wear rate reported by the laboratory for the historical rotating bearing knee systems that exhibited more than one degree of axial rotation between the femoral and tibial components was 6.65 mg/Mc (range 2.42 to 16.7 mg/Mc), which was higher than the novel RBK.

Figure 1: “Wave-shaped” distal bearing of the novel Optetrak RBK

Figure 2: Graph showing the weight changes of the novel RBK, its fixed bearing knee version and historical rotating bearing knees. The error bars indicate the minimum and the maximum.

Figure 3: Major contact area (tibial side) after five million cycles is similar for all test specimens. Novel Optetrak RBK tibial insert #1 (left) to #3 (right).

Figure 4: Wear on the anterior face of the central peg is macroscopically invisible (Figure 4A). A microscope was required to detect lightly polished contact regions with residual machine marks at the completion of the wear test (Figure 4B).

CONCLUSION
Results of this wear test demonstrate that the novel RBK tibial insert test specimens are associated with the lowest wear rate for a rotating bearing knee design measured at Endolab (with normal kinematics during the wear test in response to load control). The mean wear rate (i.e. 2.11 mg per million cycles) is at least as good as the results from its fixed bearing version specimens (i.e. 3.00 mg per million cycles), which were considered the “gold standard” for their excellent clinical outcomes and low wear. In addition to the low wear results; these tests validate the theoretical advantages of the wave feature based on microscopic visual inspection. This is different from traditional flat on flat rotating bearing knee design and is a direct benefit of the wave concept, as the shear loads are constrained by the internal curvature of the wave shape rather than the central peg. As a result, this concept promotes the reduction of wear caused by contact between the central peg and tibial tray bore in prostheses associated with a flat tibial tray (when tested on a knee simulator).

NOTE
Optetrak® RBK™ is not available for sale in the United States.

REFERENCES
2. Cotrell JM; Townsend E; Lipman J and Wright, TM. Total knee design changes affect wear performance. Presented at ORS 2006.