

In Vitro Assessment of a Cruciate Retaining and Cruciate Sacrificing Medially Pivoting Knee Replacement

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INTRODUCTION

Advances in materials processing techniques has led to a more widespread use of crosslinked polyethylene bearing components in hip and knee replacements. Crosslinking polyethylene results in improved wear characteristics, particularly where the bearings are loaded with crossing shear vectors like in the hip. The value of highly crosslinked polyethylene in total knee arthroplasty is still unknown.¹ Improved femoral component designs may lead to kinematic patterns which facilitate unidirectional bearing shear forces, thereby precluding the need for a crosslinked material to achieve low wear rates. The objective of this study was to determine the wear rates of the new EVOLUTION™ Total Knee Replacement (TKR) system with conventional polyethylene using an in-vitro wear simulator in accordance with ISO 14243-3 and to compare these results with other knee systems.

MATERIALS AND METHODS

Knee wear testing was conducted on the EVOLUTION™ Total Knee Replacement (TKR) for 5 million cycles of simulated gait. Two tibial insert designs were tested: the EVOLUTION™ TKR - Cruciate Substituting (TKR-CS) and EVOLUTION™ TKR - Cruciate Retaining (TKR-CR). Five tibial inserts were tested in each group, with two inserts from each group used as load soak controls. All inserts were tested in a bearing couple with the Size 4 EVOLUTION™ CR/CS femoral component, manufactured from Cobalt Chrome Molybdenum alloy (ASTM F75). The EVOLUTION™ TKR Posterior Stabilized was not tested because the articular geometries of the femur and tibial insert components are identical to the TKR-CS throughout the range of motion tested, as specified in ISO 14243-3.

A simulated gait profile (triple peak Paul load profile, per ISO 14243-3) with minimum and maximum axial compressive forces of 168N and 2600N, respectively, was applied to the inserts. The range of flexion applied to the inserts was from 0° to 58°, where 0° is full extension of the knee. The range of IR rotation was -1.9° internal to 5.7° external. The range of AP translation was different between the CS and CR inserts. An abbreviated AP translation was applied to the CS inserts, with total range between 0.5mm posterior to 0.5mm anterior, which is consistent with the clinical performance of similarly congruent devices in vivo.² The full profile, applied to the CR inserts, had a range of 5.8mm posterior to 0mm anterior. Frequency of the test was set to 1Hz for completion of a single simulated gait cycle, including swing phase.

Weight measurements were made every half million cycles until one million cycles was reached, and then at every million cycles thereafter. The load soak control parts were cyclically loaded at 1Hz and weight measurements were taken at the same cyclic intervals as the wear test components. The weights of the wear test components were corrected at each time point using the weight increases observed in the load soak control components.

Wear rates for the subject EVOLUTION™ TKR designs and predicate ADVANCE® TKR designs were calculated using a linear regression of individual specimen gravimetric weight loss.³ The wear rates for the MG II and NexGen® knee systems were taken from the literature.^{4,5} Statistical analyses were conducted using SigmaStat (Systat Software Inc., San Jose, CA) with significance set to 0.05.

RESULTS

The average cumulative wear for the EVOLUTION™ CS was 10.4 ± 0.82 mg, and for the EVOLUTION™ CR was 37.64 ± 3.92 mg following five million cycles. Values include corrections for weight gained due to fluid absorption, as calculated using the load soak controls. Wear rate values with one standard deviation for the EVOLUTION™, ADVANCE® and published Zimmer MG II and NexGen® CR data are shown in Figure 1. At the end of five million cycles, the wear rates were 1.9 ± 0.2 mg/Mc and 7.1 ± 0.5 mg/Mc for the TKR-CS and TKR-CR, respectively. The EVOLUTION™ CR had a higher wear rate than the EVOLUTION™ CS (p < 0.001). No difference was found between the wear rate of the TKR-CS with conventional

UHMWPe and ADVANCE® Medial Pivot with either conventional or cross-linked UHMWPe (p = 0.077 and p = 0.243, respectively).

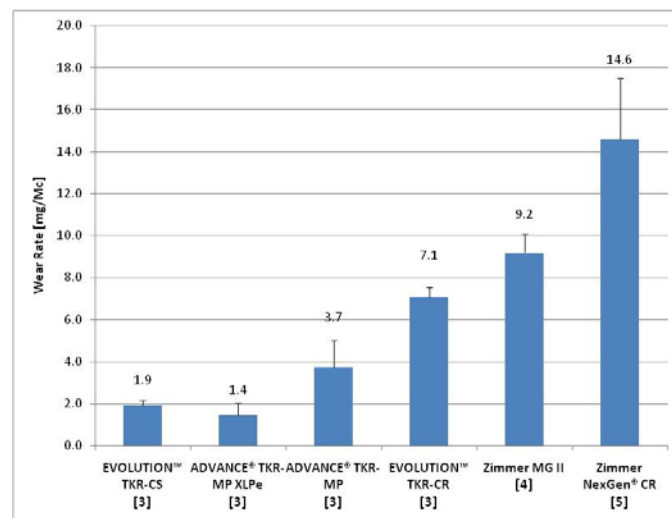


Figure 1: Wear rates for EVOLUTION™, ADVANCE® and two Zimmer® systems

CONCLUSION

The EVOLUTION™ system has three insert options: the Cruciate Retaining (CR), the Cruciate Substituting (CS), and the Posterior Stabilized (PS). Post-cam engagement for the PS insert does not begin until 75° of flexion, and it's articular geometry is identical to that of the CS insert for the first 58° of motion. Therefore, the in-vitro wear results for the EVOLUTION™ CS would be identical to those for a PS insert.

The EVOLUTION™ Cruciate Retaining insert had a lower wear than published data for two competitive knee systems when tested under similar conditions. Zimmer's Miller-Galante II (MG II) and NexGen CR were also tested according to ISO 14243-3 specifications, with the full AP displacement profile.^{4,5} The EVOLUTION™ TKR-CR had a statistically significantly lower wear rate than published data for the Zimmer Miller-Galante II TKR-CR (p = 0.024) and Zimmer NexGen® TKR-CR (p = 0.008). These knee systems were evaluated under similar conditions as the EVOLUTION™ TKR-CR, however, because these tests were conducted at other institutions not all testing variables can be accounted for. Small differences arising from the use of different knee simulators, lubricants, measurement systems, and environmental conditions cannot be evaluated and may have had an effect on the data comparison.

The wear rate for the EVOLUTION™ Total Knee Replacement with Cruciate Substituting tibial insert is equivalent to that of the ADVANCE® Medial Pivot with conventional UHMWPe and with 5 Mrad crosslinked UHMWPe. The results for the EVOLUTION™ CS illustrate how modern designs with advanced manufacturing techniques can successfully reduce the wear rate of knee replacements without sacrificing fatigue strength in exchange for low wear.

REFERENCES

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