ATTUNE™ Knee System: Cruciate Retaining Fixed Bearing Insert Wear

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MULTI-FACTORIAL INFLUENCES UPON TKR WEAR & OSTEOLYSIS:

Polyethylene wear remains a significant cause for revision in total knee replacement.[1] The wear in fixed bearing total knee replacements is influenced by multiple factors. These include:

1. The proper management of sliding distance and cross-shear on the superior surface of the polyethylene insert due to translation and rotation between the femur and the tibia. This is accomplished by means of careful attention to design features related to motion and stability, which allow for higher levels of conformity in extension and more rotational freedom in deeper flexion.
2. The reduction in potential for backside wear debris due to micromotion between the polyethylene insert and the tibial tray [see LOGICLOCK™ Tibial Base].
3. A properly balanced approach to polyethylene technology [see AOX™ Polyethylene Inserts], including a thorough assessment of potential for biological reactivity.

THE ROLE OF SLIDING DISTANCE AND CROSS-SHEAR:

Wear on polyethylene surfaces has been correlated to sliding distance and the applied compressive load by Galvin et al.[2] through the following relation:

W = k x L x S

Where:
W = volume loss
k = wear factor = volume loss per unit load per unit sliding distance
L = applied load
S = sliding distance

The wear factor (k) was subsequently found by Kang et al.[3] to be strongly influenced by the level of cross-shear that the polyethylene surface is subjected to, with cross-shear inducing more than a five-fold increase in the wear factor under specific controlled laboratory conditions.

For a given applied compressive load across the tibio-femoral joint, wear is therefore primarily a function of the area of polyethylene under cross-shear and the total relative sliding distance between the femoral and polyethylene insert articulating surfaces. Andriacchi et al.[4] described the significant degree of relative sliding which can occur between the femoral and tibial articulation surfaces at heel strike during gait, and the resulting influence upon wear.

Reducing wear on the articulating surface of a fixed bearing polyethylene insert therefore is primarily a function of balancing the following factors:

1. Controlling total sliding distance by means of providing sufficient inherent implant stability to resist the shear forces that occur between the femoral component and tibial insert.
2. Reducing the level of area of polyethylene surface subjected to cross-shear through careful attention to the relative curvature between the femoral and polyethylene articulating surfaces. By increasing conformity between the femoral componenet and polyethylene insert, the femur is kept from sliding forward paradoxically in early flexion and in turn reduces the amount of total area on the polyethylene seeing cross-shear.

Recent advances in computational wear prediction at the University of Southampton were utilized during the development of the ATTUNE™ Knee tibio-femoral articulation surfaces to balance these factors with kinematic requirements.[5]

PHYSICAL WEAR TESTING OF THE ATTUNE CRUCIATE RETAINING (CR) KNEE WITH AOX POLYETHYLENE – 10MM COMPOSITE THICKNESS:

The wear of the ATTUNE Knee System CR fixed bearing knee with AOX Polyethylene was compared to the SIGMA® Knee System Curved CR fixed bearing knee with XLK Polyethylene under specific laboratory conditions using severe (high kinematics) displacement-controlled inputs for 5 million cycles (MC).[6]

The mean gravimetric wear rate of the ATTUNE Knee System was 50% less than the SIGMA Knee (3.6 ± 0.3 and 7.2 ± 1.2 mg/MC, respectively, p=0.03 utilizing unequal variance t-test). Subsequent laboratory analysis determined that the shape and size of the resulting wear debris did not differ between the two devices.

Materials

Both the ATTUNE Knee CR Fixed Bearing (FB) and the SIGMA Curved CR FB devices were of equivalent size, representing the middle of the size range (ATTUNE Knee size 5 and SIGMA Knee size 3). The ATTUNE Knee System polyethylene inserts were 6mm thick (10mm composite thickness). The SIGMA Inserts were 8mm thick (10 mm composite thickness). The ATTUNE Knee AOX Polyethylene Inserts were manufactured using antioxidant stabilized compression molded GUR 1020 UHMWPE gamma irradiated to 80 kGy in a vacuum foil pouch. The SIGMA Curved CR XLK inserts were manufactured from compression molded GUR 1020 UHMWPE that was crosslinked at 50 kGy and then remelted. The femoral components and tibial bases from both knee systems were manufactured from polished Cobalt Chromium (CoCr).

Laboratory Test Conditions

Wear was evaluated in a commercially available six-station displacement controlled knee simulator (AMTI Model KS5-6-1000, Watertown, MA). The knee components were subjected to "High Kinematics" input motions (see Table 1 below) that provide a wider range of motion than prescribed by the International Standard[7] and may better represent the range of natural knee kinematics.[8] Testing was performed at 1 Hz with the articulation fully immersed in bovine calf serum that was maintained at 37° ± 2° C via recirculation and was treated with sodium azide and EDTA to prevent bacterial growth and calcium precipitates. New serum was provided every 0.5 million cycles (MC) after the components were cleaned and the polyethylene tibial inserts were weighed on an analytical balance (0.01 mg resolution, XP205, Mettler-Toledo, Columbus, OH). Wear was determined after 5 MC of testing via linear regression using load soak compensation to account for apparent weight gain of polyethylene when subjected to compressive loading in serum.

The wear debris was analyzed at 1, 3, and 5 million cycles via Low Angle Laser Light Scattering (LALLS) and Scanning Electron Microscopy (SEM).

	ISO 14243-3[7]	High Kinematics[9]
Peak Axial Force	2.6 Kn (584 lbf)	2.6 Kn (584 lbf)
Flexion/Extension Angle	0-58°	0-58°
Internal/External Rotation	-2° to +6°	-5° to +5°
A/P Displacement	5mm	10mm
Interval Duration	0.5 MC	0.5 MC
Cycle Frequency	1 Hz	1 Hz
M/L load distribution	4.8mm medial offset	
Serum Concentration	25%	

Table 1. Testing conditions and kinematic ranges

Results

The mean gravimetric wear rate of the ATTUNE Knee System was 3.6 ± 0.3 mg/MC and was statistically different ($p=0.03$) from the SIGMA System, which wore at 7.1 ± 1.2 mg/MC (see Figure 1).

The ATTUNE System AOX Polyethylene mean particle diameter (LALLS volume analysis), aspect ratio (SEM), roundness (SEM), and perimeter (SEM) measured 118.8µm, 2.10, 0.56, and 3.56µm while SIGMA XLK measured 64.4µm, 2.06, 0.56, and 3.17µm respectively. No significant differences between the AOX Polyethylene and XLK Polyethylene debris samples were found.[10]

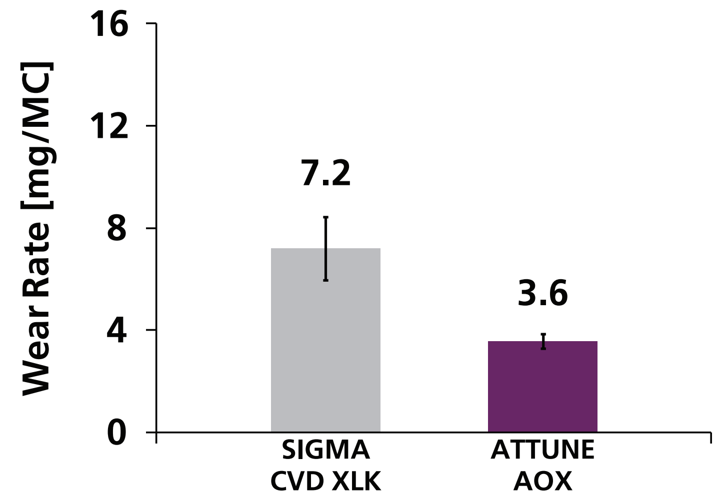

Figure 1 – Comparative Wear Rates for 10mm Total Construct Thickness.[10]

PHYSICAL WEAR TESTING OF THE ATTUNE KNEE SYSTEM CR WITH AOX POLYETHYLENE – THINNEST COMPOSITE THICKNESS:

To assess the long term wear resistance of the thinnest fixed bearing polyethylene insert, ATTUNE Knee CR AOX fixed bearing (5mm thick polyethylene, 9mm overall) and SIGMA Curved CR XLK fixed bearing XLK constructs (6mm thick polyethylene, 8mm overall) were tested for 10 MC. The same method previously described, including the severe (high kinematics) displacement-controlled inputs, was utilized.

The mean gravimetric wear rate of the ATTUNE Knee System was statistically equivalent to that of SIGMA Knee (5.4 ± 0.5 and 5.7 ± .7 mg/MC, respectively, $p=0.57$).[10]

CONCLUSIONS

When testing 10mm thick overall constructs, the ATTUNE Knee CR fixed bearing with AOX Polyethylene (6mm thick polyethylene) wore significantly less than the SIGMA Curved CR fixed bearing total knee system with XLK Polyethylene (8mm thick polyethylene) under a severe, high kinematics, displacement controlled wear test. This demonstrates that when using ATTUNE System polyethylene inserts which are 6mm thick or greater, the wear is reduced relative to SIGMA Knee with a similar overall construct thickness.

When testing the thinnest available constructs (ATTUNE Knee 5mm polyethylene, 9mm overall, versus SIGMA 6mm polyethylene, 8mm overall) the wear between the two groups was not significantly different. The reason for this was due to the smallest SIGMA Polyethylene being 1mm thicker than the smallest ATTUNE Knee polyethylene. However, this data still demonstrates that, although the thinnest ATTUNE System polyethylene insert is 1mm thinner than the thinnest SIGMA Polyethylene insert, there is no detrimental effect upon wear.

In both tests, with equal and unequal composite thicknesses, the shape and size of the resulting wear debris particles did not differ between the two designs.

The end result of these tests demonstrated that ATTUNE Knee AOX Polyethylene is as good or better than SIGMA XLK Polyethylene in reducing wear in a fixed bearing cruciate retaining construct.

(Please note that in vitro knee wear simulator tests are for comparison purposes only under specific laboratory conditions and have not been shown to quantitatively predict clinical wear performance.)

References

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