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Wear-Reduction Technology in Total Knee Arthroplasty

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Summary

Due to the increasing burden of revision in total knee arthroplasty (TKA), sustainable improvements in implant longevity may require the continued development of advanced bearing materials. The LEGION◊ Primary Knee System featuring VERILAST◊ technology is the first device to combine an OXINIUM◊ Oxidized Zirconium femoral component with a highly crosslinked ultra-high molecular weight polyethylene (UHMWPE) tibial insert to form an advanced TKA bearing. Following the review of published volumetric wear rates, this bearing coupling was found to provide the lowest observed wear of any contemporary TKA device, potentially supporting the equivalent of 30 years of normal use in vivo. This evidence supports the assertion that both tibial and femoral bearing surfaces can significantly affect TKA wear. Moreover, the use of VERILAST◊ technology may reduce long-term revision risk and support device longevity in younger, more active patients.

‡Based on in-vitro wear simulation testing, the LEGION Primary Knee System with VERILAST technology is expected to provide wear performance sufficient for 30 years of actual use under typical conditions. The results of in-vitro wear simulation testing have not been proven to quantitatively predict clinical wear performance. Also, a reduction in total polyethylene wear volume or wear rate alone may not result in an improved clinical outcome as wear particle size and morphology are also critical factors in the evaluation of the potential for wear mediated osteolysis and associated aseptic implant loosening. Particle size and morphology were not evaluated as part of the testing.

The Importance of Wear Resistance in TKA

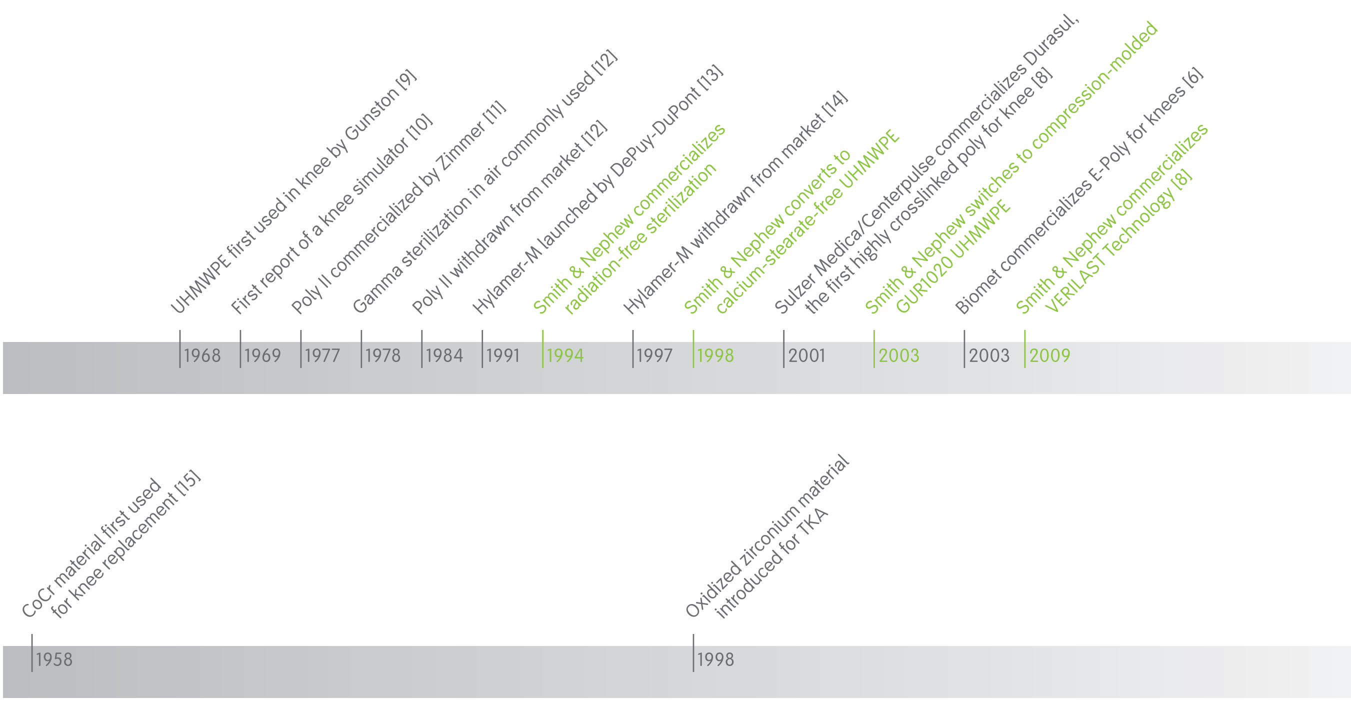
Tibial component wear, attendant osteolysis and loosening have been identified as the primary causes of long-term failure in TKA [1–3]. In 1999 alone, 22,000 TKA revision procedures occurred in the United States at an estimated cost of over $260 million [4]. In 2005, there were 38,300 revisions in the United States. This number is expected to grow to over 268,000 by 2030 [5]. In order to support optimal patient care and reduce accelerating healthcare costs, technologies must be introduced that support improved device longevity. Specifically, improved tibial and femoral bearing technologies could limit long-term revision risk in TKA, especially in relatively young and active patients.

Polyethylene and Wear Performance

The History of UHMWPE

UHMWPE was first utilized in TKA in 1968, setting a standard for knee replacement that continues today (Figure 1) [6]. More than 40 years later, every TKA in the world still utilizes a UHMWPE tibial bearing. However, polyethylene wear remains a primary cause of long-term failure [3]. During normal articulation, millions of microscopic polyethylene wear particles are released into the tissues surrounding the knee joint. These particles can cause a cascade of biological responses leading to osteolysis, aseptic loosening, and eventual revision [7]. In order to address these risks many attempts have been made to improve polyethylene wear performance, including the unsuccessful introductions of Poly II in 1977 and Hylamer in 1991. In

Figure 1: TKA Milestone Timelines



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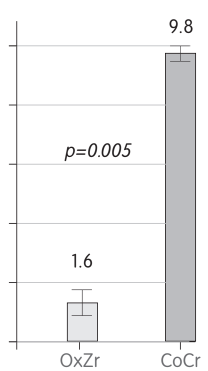
contrast, crosslinked polyethylene has been used since 2001 and has been shown to be highly successful clinically [8].

The Development of Crosslinked UHMWPE

It is well established that the wear resistance of UHMWPE quickly improves with increased irradiation dose. However, this gain in wear resistance is attained at the expense of mechanical properties. If greater wear resistance is desired, the UHMWPE can be exposed to a higher radiation dose, but the mechanical properties will be further decreased. This balance is particularly important in TKA, where contact stresses are higher than in total hip arthroplasty (THA). Based on material and device testing, a highly cross-linked UHMWPE with a radiation dose of 7.5 Mrad (75 kGy) appears to result in an optimal balance between wear performance and mechanical properties for TKA [16].

Figure 2: Comparison of wear grades (scratching, pitting, delaminations, striations) by visual score for OxZr and CoCr bearing surfaces.



Femoral component	
OxZr	1.6±1.3
CoCr	9.8±0.5
p	*0.005*

The total average score was significantly lower for the OxZr components (1.6±1.3 vs. 9.8±0.5, p=0.005) [26].

OXINIUM◊ Oxidized Zirconium in TKA

Cobalt chrome (CoCr) alloy has served as the standard material for femoral components in TKA for more than 40 years (Figure 1). However, the surfaces of retrieved CoCr femoral components have been shown to exhibit roughening that can significantly increase polyethylene wear [17–19]. This evidence suggests that a femoral bearing surface with improved wear performance could improve implant longevity.

In contrast to the UHMWPE milestones shown in Figure 1, the introduction of OXINIUM◊ (Smith & Nephew, Inc., Memphis, TN, USA) Oxidized Zirconium femoral components in 1998 was the first major TKA bearing advancement on the femoral side in 40 years. This material was developed to combine the observed wear benefits of ceramics with the toughness of metals. The resulting bearing surface is resistant to in-vivo roughening, is less abrasive than CoCr, and has enhanced biocompatibility, without any risk of catastrophic fracture [20–25]. Retrieval studies have shown that Oxidized Zirconium femoral components exhibit minimal scratching. A matched pair analysis performed at The Hospital for Special Surgery showed that in vivo femoral scratching was 12 times greater in the CoCr components compared to Oxidized Zirconium (Figure 2) [25, 26].

Wear Performance of CoCr and OXINIUM TKA Bearings

With a CoCr bearing, the only way to significantly improve wear performance is by increasing the irradiation dose of the polyethylene. However, as previously described, this improved wear performance must be balanced against unfavorable changes in mechanical properties. OXINIUM femoral components effectively alter the dynamic between irradiation dose, wear resistance and mechanical properties. Compared to CoCr, OXINIUM results in less UHMWPE wear at any given irradiation dose, without any sacrifice in mechanical properties

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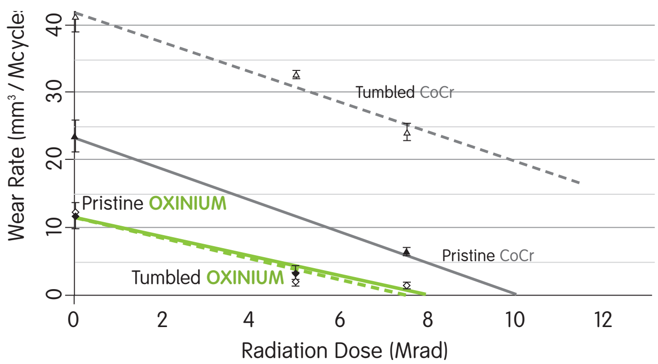
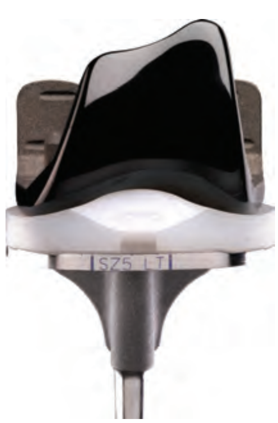
Figure 3: Plot of the mean wear rates



Plot of the mean wear rates (± standard deviations) in a knee simulator for UHMWPE crosslinked to various doses against either CoCr or OXINIUM femoral components in pristine (solid symbols and lines) and tumbled (open symbols and dashed lines) conditions.

Figure 4: LEGION◊ Primary Knee System



LEGION◊ Primary Knee System featuring VERILAST◊ technology (Smith & Nephew, Inc., Memphis, TN USA).

(Figure 3). For example, the wear rate of OXINIUM against a 7.5 Mrad crosslinked UHMWPE is approximately equivalent to that of CoCr against a 10 Mrad crosslinked UHMWPE with pristine, new components.

Utilizing an OXINIUM femoral component instead of CoCr provides a reduction in wear equivalent to an additional 3 Mrad irradiation dose. In the end, mechanical properties are improved because about 25% less radiation exposure is necessary to achieve the same wear resistance.

The previously described testing conditions represent an ideal situation with pristine, new components, featuring highly polished surfaces. However, the presence of third-body debris such as bone cement, bone chips, or debris shed from ingrowth surfaces can significantly diminish the gains in wear resistance provided by crosslinked UHMWPE [27]. Using an in-vitro tumbling protocol designed to simulate roughening from third-body debris [28], the polyethylene wear against tumbled OXINIUM components was compared to the wear produced by tumbled CoCr femoral components. Results indicated that the abrasion resistance of OXINIUM appears to prevent scratching by third-body debris, enabling improved wear resistance (Figure 3).

Muratoglu et al [29] examined the wear of conventional UHMWPE and highly crosslinked polyethylene on new and retrieved CoCr femoral components. Their data indicated that femoral scratching increases wear in both crosslinked and conventional polyethelene. The increase was over 800% for the crosslinked polyethylene, but only 266% for conventional UHMWPE [29]. Based on this data, the scratch-resistant properties of OXINIUM appear to be especially important in maintaining the wear resistance of crosslinked polyethylene.

Wear Performance of VERILAST◊

The LEGION◊ Primary Knee System featuring VERILAST◊ technology (Smith & Nephew, Inc., Memphis, TN USA; Figure 4) is the first TKA device to combine the advanced wear properties of 7.5 Mrad highly crosslinked ultra-high molecular weight polyethylene (XLPE) tibial inserts with the superior abrasion resis-

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tance of OXINIUM femoral components. This advanced bearing couple could provide improved implant longevity in TKA.

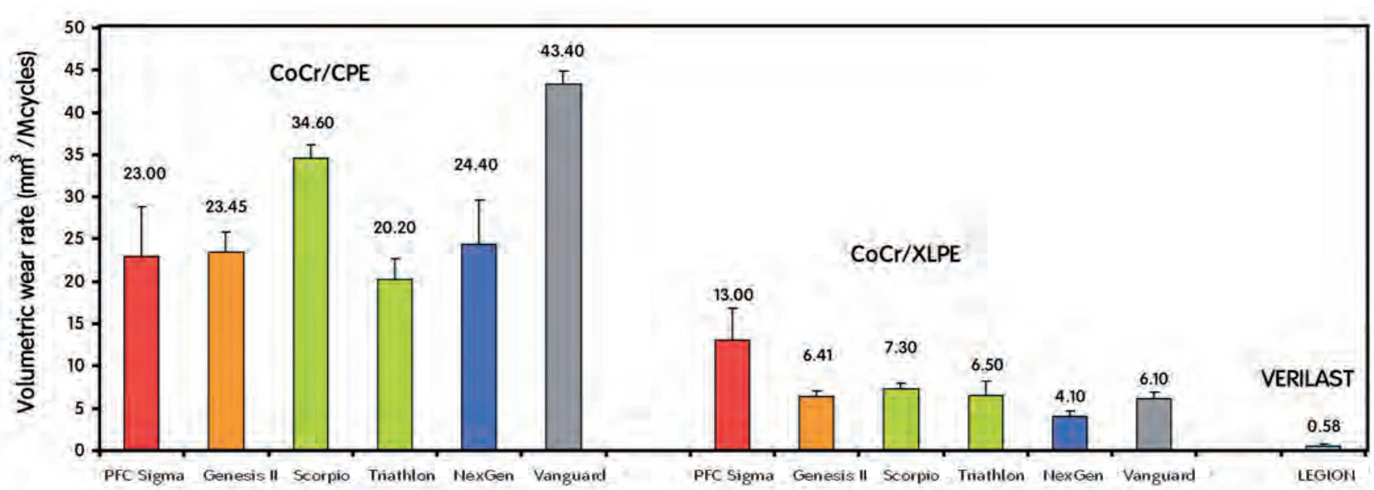
In order to evaluate bearing performance, wear rates from independent, published studies were compared to wear results for VERILAST (Figure 5). Volumetric wear rates for CoCr and conventional UHMWPE (CoCr/CPE) range from 20–43 mm3/Mcycles. The wear rates for CoCr and crosslinked UHMWPE (CoCr/XLPE) is significantly less, ranging from 4–13 mm3/Mcycles. In contrast, a wear rate of 0.58 mm3/Mcycles was observed for VERILAST in the 45 Mcycles test.

These results are especially impressive considering the testing protocols that were utilized. The VERILAST bearing was tested with the kinematically aggressive Leeds protocol [35]. Moreover, the bearing was tested for 45 Mcycles. Simulator tests reported in the literature are typically conducted for only 5 to 20 Mcycles [30–43].

Some specific examples of reported wear cycles include the following:

– Crosslinked polyethylene (Prolong) using NexGen CR (Zimmer, Warsaw, IN) TKR – 20 Mcycles (Popoola et al [39]).

Figure 5: Comparison of mean volumetric wear rates



Mean volumetric wear rates (+/- std. dev.) of CoCr against conventional polyethylene (CPE), CoCr against crosslinked polyethylene (XLPE) and OXINIUM against XLPE (VERILAST) [30-36].

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– Crosslinked polyethylene (Durasul) using Natural Knee II (Zimmer, Warsaw, IN) TKR – 10 Mcycles (Muratoglu et al [40]).
– Insall-Burstein I (Zimmer, Warsaw, IN) and Kinematic (Howmedica, Rutherford, NJ) TKR – up to 11 million cycles (Walker et al [41]).
– Insall-Burstein II (Zimmer, Warsaw, IN) TKR – approx. 11 million cycles (Beaule et al [42])
– JOURNEY (Smith & Nephew, Memphis, TN) TKR – up to 10 million cycles (Ries et al [43])

Conclusion

The amount of volumetric wear observed per million cycles of testing suggests that the LEGION primary knee coupled with VERILAST bearing technology may remain viable in vivo for the equivalent of 30 years of normal use. Moreover, when tested under relatively extreme simulation conditions, this system demonstrated the lowest wear rate of any contemporary TKA device.

These wear results may be particularly relevant for younger patient populations. While the longevity of contemporary TKA implants has remained relatively unchanged, the typical patient has not. Initially, TKA was primarily performed in patients over the age of 65. However, today an ever increasing number of patients are having surgery in their 40's and 50's [44, 45]. An estimated device longevity of approximately 15 years may be sufficient for older populations, but the increased demands of younger patient groups require an additional 5–15 years of in-vivo use prior to revision TKA. This demographic shift suggests that advanced bearing technologies should be adopted to resolve an inevitable increase in long-term revision TKA rates.

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