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VERILAST◊ Technology
An advanced bearing system for TKA

Introduction

Long-term success of total knee arthroplasty (TKA) is a multi-factorial issue. Implant design and materials selection play an important role in the wear-related performance of TKA. It is widely recognized that excessive wear of UHMWPE tibial inserts can result in mechanical implant instability and, in some instances, catastrophic wear. However, the more harmful effect occurs with time in vivo when UHMWPE tibial inserts, which wear at a steady rate, annually release billions of sub-micron particles into the host biological environment. The ultimate effect of this wear is osteolysis and attendant implant loosening, which is a major reason for revision surgery at middle to long-term follow-up.

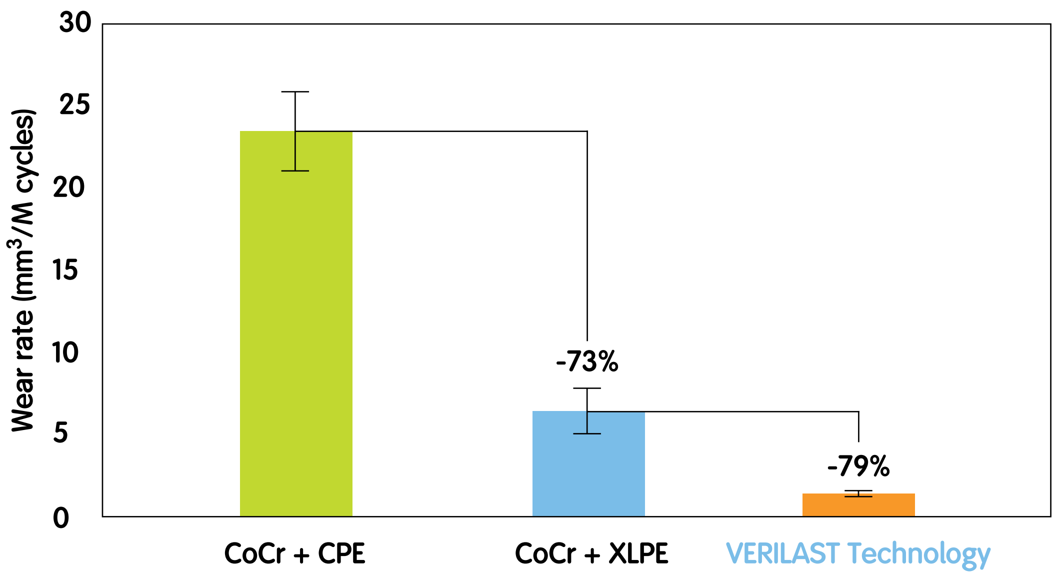


Figure 1: Knee simulator wear rates of virgin UHMWPE (CPE) and 7.5 Mrad XLPE against pristine CoCr and OXINIUM Oxidized Zirconium.

Wear of UHMWPE tibial inserts is a system-wide issue, i.e., it is influenced by the TKA system, which includes the UHMWPE tibial (and patellar) bearing surfaces and the metallic femoral component. Therefore, it stands to reason that the ideal solution to wear in TKA will include improvements to both the UHMWPE bearing materials and the metallic counter-bearing materials. This paper describes wear performance of the VERILAST Technology which features cross-linked UHMWPE (XLPE) tibial inserts mated to OXINIUM◊ Oxidized Zirconium femoral components.

Cross-linked UHMWPE

Cross-linked UHMWPE exhibits improved wear properties compared to virgin UHMWPE. However, crosslinking also affects mechanical and fatigue properties of UHMWPE. Wear and material properties of UHMWPE are influenced by the choice of powder resin (GUR 1050 or GUR 1020), the consolidation method (ram extrusion or compression molding), the crosslink irradiation dose, and finally the post-irradiation thermal treatment (re-melt or sub-melt anneal)[1]. All of these factors need to be balanced for a particular bearing application. For instance, the choices that are ideal for total hip replacement (THA) are not necessarily optimal for TKA.

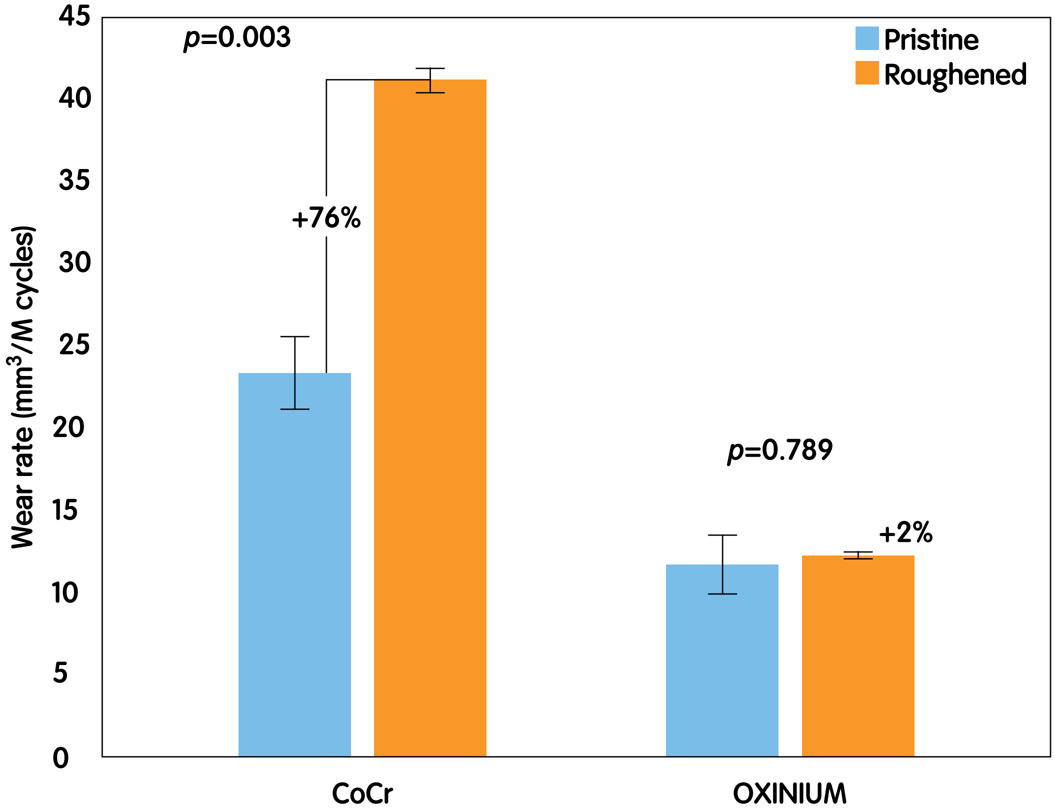


Figure 2: Knee simulator wear rates of virgin UHMWPE (CPE) against pristine and roughened CoCr and OXINIUM Oxidized Zirconium.

The Smith & Nephew XLPE for TKA is manufactured from compression-molded GUR 1020, gamma-irradiated to a dose of 7.5 Mrad, and subsequently re-melted. It has the following attributes:

- Passes all component level static and fatigue strength requirements[2].
- Free radical concentration (FRC) is not detectable by state-of-the-art electron spin resonance techniques[2].
- Resistant to oxidative degradation[2].
- Resistant to delamination under worst-case testing regimen[2].
- Provides up to 73% reduction in wear compared to unirradiated conventional UHMWPE (CPE), as shown in Figure 1, when tested against pristine CoCr femoral components[3].
- When compared to CoCr/XLPE, VERILAST◊ Technology provides up to a 79% additional reduction in wear (Figure 1).

OXINIUM Oxidized Zirconium

OXINIUM Oxidized Zirconium metallic femoral components feature a bearing surface that is transformed to ceramic, which is twice as hard as CoCr[4]. OXINIUM Oxidized Zirconium therefore has toughness and ductility of metals and wear properties of ceramics. The surface ceramic has lower frictional forces than CoCr against UHMWPE. Hence, OXINIUM Oxidized Zirconium reduces the wear rate of CPE and XLPE compared to CoCr[3, 5], as shown in Figure 1. Furthermore, it is well known that CoCr femoral components undergo microabrasive scratching in vivo, from the action of third body debris such as cement fragments, inorganic portions of bone, and other metal debris in the joint[6, 7]. The wear rate of UHMWPE tibial inserts increase under these microabrasive conditions[8]. The harder surface of OXINIUM Oxidized Zirconium is more resistant than CoCr to microabrasive scratching[5]. Therefore OXINIUM Oxidized Zirconium maintains the improved wear behavior even under such microabrasive conditions[3], as shown in Figure 2 for CPE. An additional benefit of OXINIUM Oxidized Zirconium is that it does not contain any measurable nickel and is therefore a good choice for nickel-sensitive patients. Approximately 200,000 OXINIUM Oxidized Zirconium knee femoral components have been implanted since 1997.

VERILAST◊ Technology
As discussed, wear is a system-wide issue in TKA and involves both UHMWPE tibial inserts and metallic femoral components. Therefore, sustainable improvements in wear of TKA should include improvements to both sides of the wear couple, namely UHMWPE tibial inserts, and metallic counterbearing femoral components.

VERILAST Technology marries two independent wear reducing technologies, namely OXINIUM◊ Oxidized Zirconium femoral components and cross-linked UHMWPE tibial inserts. It is the only system-wide solution to wear in TKA. The wear performance of VERILAST Technology is shown in Figure 3. This graph shows that, under micro-abrasive conditions, OXINIUM Oxidized Zirconium or XLPE independently provide improved wear rates compared to CoCr and CPE, respectively. Furthermore when OXINIUM Oxidized Zirconium and XLPE are combined in the VERILAST Technology, sustainable wear reductions up to 97% are achieved[3].

Currently, other orthopaedic technologies** only offer wear reductions on the tibial components, by crosslinking the UHMWPE inserts. However, the wear rates of cross-linked UHMWPEs increase when CoCr femoral components get scratched. In Figure 4, the wear rates of VERILAST under pristine and roughened conditions are compared to cross-linked doses of UHMWPE currently on the market for TKA. VERILAST provides up to a 96% lower wear rate than competitive cross-linked UHMWPE materials.

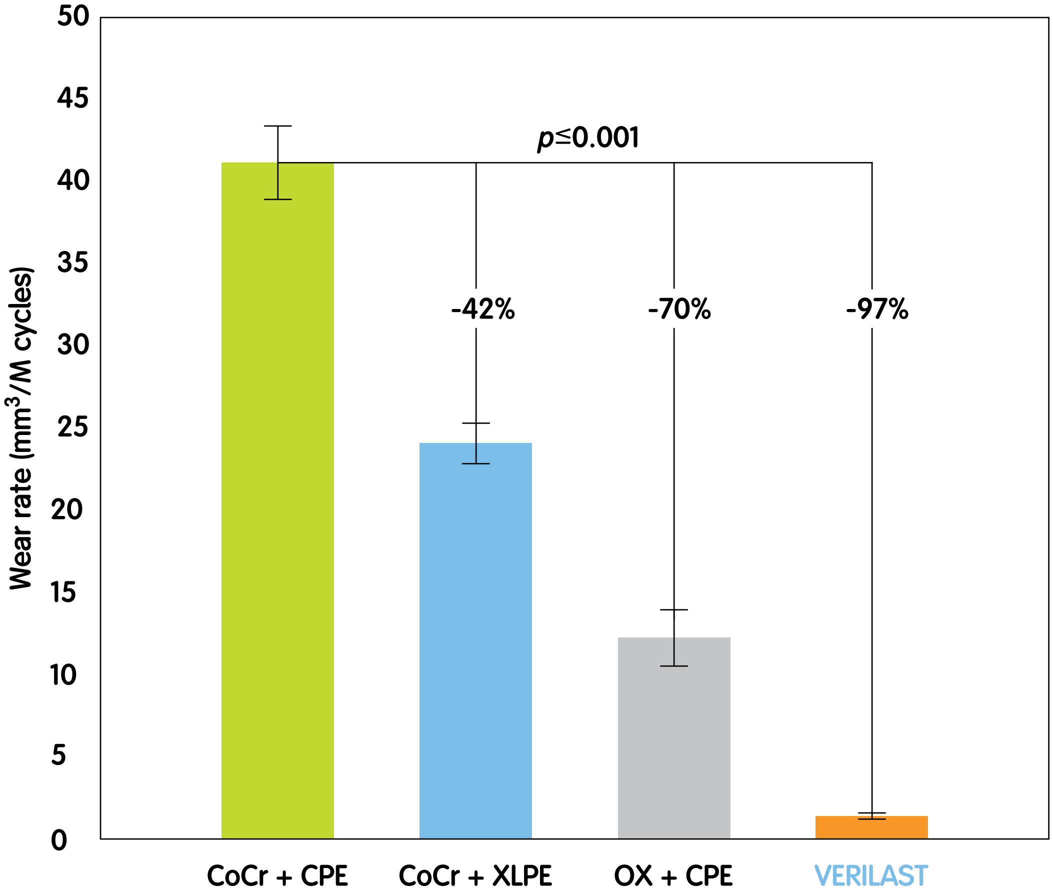
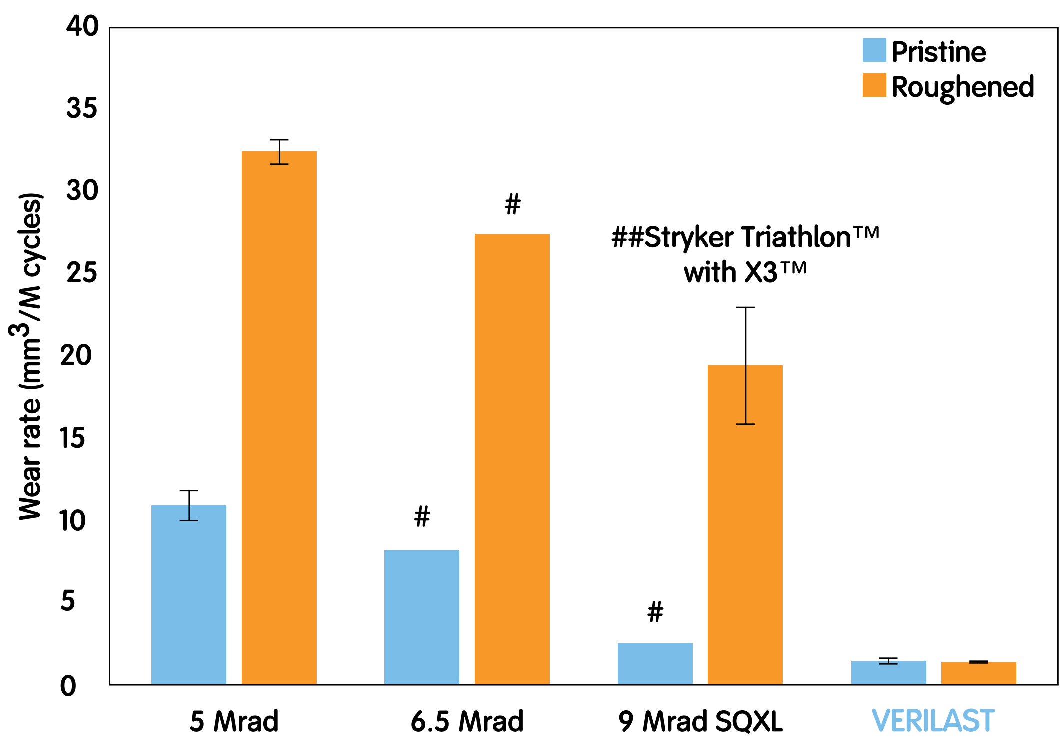


Figure 3: Microabrasive knee simulator wear rates of VERILAST◊ (OXINIUM Oxidized Zirconium on 7.5 Mrad XLPE) compared to other combinations of CoCr, OXINIUM◊ Oxidized Zirconium, CPE and 7.5 Mrad XLPE.



Estimated wear rate based on correlation between wear rate and radiation dose (r^2>0.96)[2]

Figure 4: VERILAST Technology reduces wear by 94%-96% vs. other XLPE technolgies.[3]

In summary, by coupling the microabrasive scratch resistance of OXINIUM Oxidized Zirconium, with a highly cross-linked UHMWPE engineered specifically for knees, VERILAST* maintains superior wear reduction over all other bearing couples currently available for TKA.

**Currently marketed cross-linked UHMWPE for TKA are:
Depuy XLK™, 5 Mrad re-melted
Zimmer Prolong™, 6.5 Mrad re-melted
Stryker X3™, 9 Mrad total in 3 x 3 Mrad doses, sub-melt annealed after each irradiation step

References

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