MatOrtho

Technical Stop-Press

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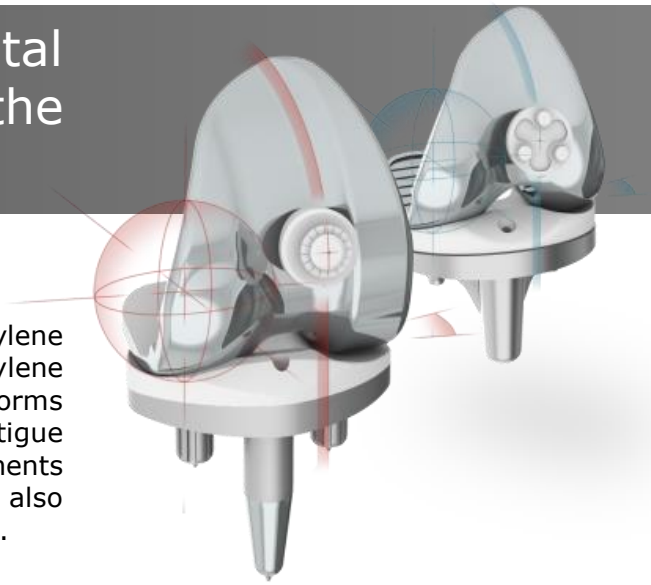
Cross-linked Polyethylene and Total Knee Replacements: What is the Future for MRK™ and SAIPH®?



XLPE in Total Hip Replacement

To date cross-linking of ultra-high molecular weight polyethylene is generally accepted to reduce wear rates of metal-polyethylene hip articulations, despite there being a number of different forms of crosslinking and that it is clear some can compromise fatigue strength[1]. This may limit the longevity of some hip components and the use of highly cross-linked polyethylene (XLPE) also represents increased costs to both hospitals and manufacturer.

Is XLPE better for Total Knee Replacement?

The use of XLPE for Total Knee Replacement (TKR) components is growing despite a lack of clear evidence that it provides a long-term benefit.

The 2017 annual report of the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) reports that comparing XLPE with non-XLPE revision rates shows a clear benefit for XLPE. From 163,042 XLPE bearings and 370,987 non-XLPE bearings reported to the AOANJRR, the overall 10-year cumulative rate of revision for XLPE bearings is lower (3.7% vs. 5.7%, respectively)[2]. However the report also points out that of the 16 knee combinations analysed in the comparison only 3 demonstrated lower revision rates, the remaining 13 showed no difference.

The AOANJRR classes XLPE as polyethylene that has been irradiated by a high dose (≥50 kGy) gamma or electron beam radiation[2]. Conventional ultra-high molecular weight polyethylene (UHMWPE or non-XLPE) is manufactured and sterilised by a number of different methods. With a broad variety of production techniques, the real benefits of one method over another remain unknown. Of the brands that perform better with XLPE, which are mostly variants of the Genesis II, the difference in revision rate between non-XLPE and XLPE is <0.5% in over half of those reported[2]. The data also shows that the Triathlon cruciate retaining (CR) and Scorpio posterior stabilised (PS) knees perform worse with XLPE variants and there is no discernible improvement for the Nexgen CR knees.

Designed for low wear

Medial ball-and-socket knees have a much larger contact area than other bearings, which is maintained throughout flexion[3]. Testing has confirmed this relates to low contact pressure throughout flexion (up to 120°)[4]. With a high level of conformity, the bearing design guides the path of motion, unlike unconstrained designs and those that retain the PCL, which have multidirectional wear paths and associated increase in wear. A medial ball-and-socket knee might incorrectly be likened to a hip replacement because of the ball-and-socket arrangement on the medial compartment. However, unlike hips and other knee types, it has very little or no multidirectional motion. The Evolution Knee, a medial pivot type of knee design (Microport Orthopedics Inc.), has demonstrated this with very low wear rates compared to different types of knee design with non-XLPE and against 70% of XLPE bearings tested[5].

The performance of the MatOrtho® Medial Rotation Knee™ (MRK™) and SAIPH® Knee are continually monitored and reviewed in line with other devices. There is no evidence that the rate of revision for loosening or polyethylene wear is higher than expected when compared to other total knee

replacements. Indeed, longer term National Joint Registry (NJR) data for the MRK™ (which has been in use for 23 years) reports no difference in polyethylene wear and a significantly *lower* rate of revision for tibial component loosening when compared to all TKR designs (p=0.009; 11,122 knees, max. 14.0 years, mean 4.6 years)[6] – the AOANJRR identified loosening as the principal reason for the difference in revision rates between XLPE and non-XLPE.

Degradation and oxidisation of polyethylene

The issue of polyethylene degradation through oxidisation was resolved for standard polyethylene in the late 1990s with modification to the sterilisation and packaging process. However, the additional processing of UHMWPE (non-XLPE) to create XLPE has reintroduced the problem. The subsequent development of anti-oxidant versions of XLPE is still relatively new; most have less than 10 years of clinical evidence[2]. Therefore the long term benefits in terms of reduced wear and loosening (as a result of osteolysis) in knee replacement with XLPE constructs remains to be seen. The medium-term advantages are also not universally demonstrated.

Proven longevity

The MatOrtho® MRK™ medially stabilised design shows exceptional longevity and outcomes with well-proven and well-manufactured UHMWPE[2,6,7]. To date, there have been no revisions associated with loosening or wear of any component of the newer MatOrtho® SAIPH® medially stabilised knee (from a cohort of 668 knees: max. 7.6 years, mean 2.0 years)[8]. To introduce a new material to a device that out-performs many of its competitors presents a risk that cannot be taken without conclusive evidence. Increased brittleness of the polyethylene due to cross linking is likely affect the locking mechanism of all tibia designs but to what extent is unknown.

Responsible development

Worse performance with XLPE as shown by the Triathlon cruciate retaining (CR) and Scorpio posterior stabilised (PS) may be due to increased brittleness of PS type designs and, if so, not directly a wear phenomenon; however it is an important observation in the face design principles, which should be to not make for worse outcomes. Hence extreme care must be taken in evaluating every aspect of a blanket, statistically-based step that may indicate some improvement.

To introduce XLPE polyethylene for the MRK™ or SAIPH® knees based upon the Australian data and general enthusiasm it has drawn is not a safe logical step. MatOrtho® will further investigate the potential of XLPE to have a benefit for its ball-and-socket knee designs and have planned a series of *in vitro* wear tests starting in early 2018. We will report on the comparative wear rates of our standard non-XLPE and XLPE variants for the MatOrtho® medial ball-and-socket knees. It will however be difficult to draw any completely certain conclusions from such testing as it is not possible to fully simulate patients' activities or for the time periods in which any difference might show.

Information provided by MatOrtho® research and development department. Please feel free to contact me if you have any queries on this Technical Stop-Press.

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