3.6 Is the OXINIUM Technology a Useful Technology in Total Joint Arthroplasty?

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What is the OXINIUM Technology?

The OXINIUM technology, developed by Smith & Nephew, is designed to oxidize a wrought 97.5% zirconium – 2.5% niobium alloy by means of thermal diffusion and so create a zirconia surface about 5 μm thick [1], as shown in Figure 1 [1].

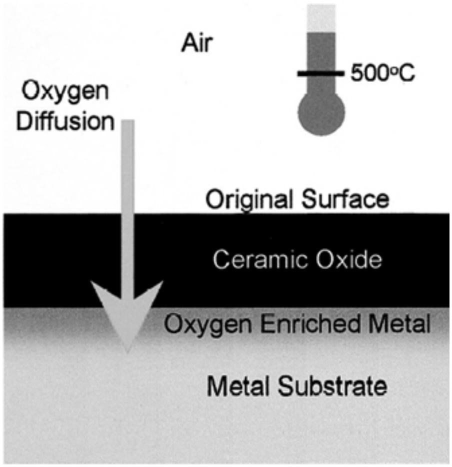

Figure 1:
The OXINIUM technology.

This zirconia layer on the zirconium-niobium alloy is not an externally applied coating, but the original metal transformed into zirconium-oxide ceramic.

According to the information published by Smith & Nephew [2] and shown in Figure 2, the nano-hardness of the zirconia layer ranges from 14 – 15 GPa. This nano-hardness is much higher than that of the untreated alloy, which is about 3 GPa. An abrupt hardness transition is evident at the interface, i.e. between the ceramic oxide and the oxygen-enriched metal. This confirms that the surface treatment of the zirconium-niobium alloy may have the same behaviour as a coating. Such an abrupt hardness transition may involve the risk of sub-surface interface cracking due to internal stresses, and could lead to the delamination of the zirconia layer.

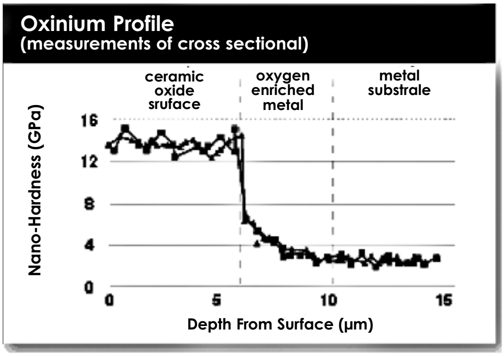

Figure 2:
Nano-hardness profile.

The information published by Smith & Nephew [3] states that all the tests performed during the development stage (abrasive wear tests, adhesive wear tests, friction tests against cartilage, oxide adhesion tests, fatigue tests, hip simulator tests, knee simulator tests, biocompatibility tests) were completed positively. The OXINIUM technology is therefore available for both total hip and knee prostheses.

This OXINIUM technology offers an advanced surface with good wear properties. These properties are definitively better than those of the underlying zirconium-niobium alloy. Hence, should the layer fail for any particular reason, the tribologic situation may lead to a large amount of metallic wear.
Such failures are well documented with TiN coatings on titanium alloys. Like the OXINIUM technology, the TiN coating has a high hardness (even higher than the one realized with the OXINIUM technology), a thickness of about 5 µm and also offers good adhesion to the metallic substrate. An example of such a failure is shown in Figure 3.

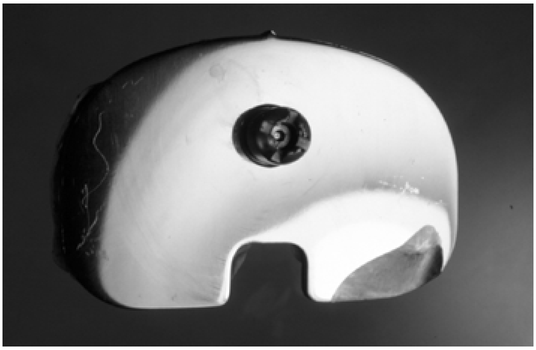

Figure 3:
Failure of a TiN coating.

The TiN coating on the tibial baseplate of this mobile bearing, total knee prosthesis, failed after an implantation time of only 7 months.

OXINIUM Technology for Total Hip Prostheses

According to Smith & Nephew [2] and also V. Good et al. [4], the OXINIUM technology offers the following advantages for total hip prostheses:

- Lower polyethylene wear rate in comparison with CoCr ball heads. Wear reduction of 98% in combination with highly cross-linked polyethylene.
- Lower production of polyethylene wear particles.
- Due to the higher hardness, the OXINIUM ball heads offer better resistance to scratches than CoCr ball heads.
- No risk of fracture with OXINIUM ball heads.

These advantages are well documented.

However, similar results may be obtained by using other technologies:

- Even higher wear rate reductions have been measured by different laboratories using conventional CoCr ball heads and highly cross-linked polyethylenes [5]. These spectacular wear reductions, which are due to the extreme wear resistance of the newly developed highly cross-linked polyethylenes, are hardly influenced by the OXINIUM technology.
- A recent review of the literature by Dumbleton et al. [6] has shown that osteolysis is rarely observed when the polyethylene wear rate is less than 0.1 mm/y. The authors suggest that a practical wear-rate threshold of 0.05 mm/y would eliminate osteolysis. Since such wear rates were measured in-vitro with highly cross-linked polyethylenes, this review implies that highly cross-linked polyethylenes would eliminate osteolysis. In such a case, the lower production of wear particles observed in-vitro with the OXINIUM ball heads has no clinical relevance.
- Plain ceramic ball heads (alumina heads, zirconia heads and zirconia-toughened alumina heads) have a comparable or an even higher hardness than the OXINIUM ball heads. Furthermore, they offer the same or even better resistance against scratches than OXINIUM ball heads.
- Being a metallic ball head with a zirconia layer on its surface, the OXINIUM ball head cannot fracture like an alumina or zirconia head. A similar fracture resistance has also been observed with newly developed and tougher ceramic materials (for example, zirconia-toughened alumina) and has not resulted in any in-vivo fracture to date [7].

OXINIUM Technology for Total Knee Prostheses

According to M. Spector et al. [1], Smith & Nephew [2] and M. Ries et al. [8], the OXINIUM technology offers the following advantages for total knee prostheses:

- Lower polyethylene wear rate in comparison with a CoCr femoral component - wear reduction of 85%.
- Lower polyethylene wear rate in comparison with a CoCr femoral component in the abraded condition – eight-fold wear reduction.
- Lower production of polyethylene wear particles.

These advantages are well documented.

These better wear properties of OXINIUM femoral components are certainly interesting, but do not solve one of the major tribologic problems of total knee prostheses, namely the delamination of the polyethylene insert [9]. This is attributable to the synergical effects that result from the mechanical overloading of the polyethylene (contact stresses in excess of 20 MPa) and an in-vivo oxidation of the polyethylene. The following strategies will have to be implemented to reduce the incidence of delamination:

- Better congruency will have to be designed between the articulating surfaces. This will increase the areas of contact and lower the stress sustained by the polyethylene. Modern knee designs (fixed bearing or mobile bearing total knee prostheses) are an efficient way of improving the matching of the articulating surfaces.
- A highly cross-linked polyethylene without free radicals is the best available method [5] for minimizing the in-vivo oxidation of the polyethylene.

When these two strategies are combined, the probability of delamination is kept very low and independent of the material used to manufacture the femoral component (OXINIUM technology or conventional CoCr alloy).

Furthermore, the abrasive/adhesive polyethylene wear rate observed in-vitro in total knee prostheses is much lower than that observed in-vitro in total hip prostheses. For example, the following wear rates were published in the OXINIUM studies:

- CoCr femoral component [8] for knee: 4.7 ± 2.3 $mm^3/10^6$ cycles
- CoCr femoral component [4] for hip: 38 ± 0.6 $mm^3/10^6$ cycles

The observed wear rate for total knee prostheses is eight times less than that observed by hip prostheses and such a low wear rate could be below the threshold level for osteolysis.

Discussion

The OXINIUM technology is an elegant technology for adding a zirconia layer to a zirconium-niobium alloy.

Being a hard layer on a soft metallic substrate, the interface between the ceramic oxide and the oxygen-enriched metal has to be carefully manufactured to avoid any risk of delamination. Furthermore, should the layer fail, the tribologic situation may lead to a large amount of metallic wear, which has been the case with TiN coatings.

There are alternative-bearing systems with similar or better wear properties for total hip prostheses. Most of these systems have been clinically approved and do not entail the risks induced by any new technology.

The OXINIUM technology does not help to solve the main tribologic problem that has to be met with total knee prostheses – the delamination of the polyethylene insert.

Being a new technology, the OXINIUM was tested extensively in-vitro (abrasive wear tests, adhesive wear tests, friction tests against cartilage, oxide adhesion tests, fatigue tests, hip simulator tests, knee simulator tests, biocompatibility tests) prior to its market launch. As these tests provided positive results, the OXINIUM technology was made progressively available to the orthopaedic community. For a new technology like the OXINIUM, it is extremely difficult to estimate all the tests to be conducted and to determine the severity of these tests. And even with a comprehensive test program, it is not possible to obtain the 100% confidence that the in-vivo behaviour will match up with the in-vitro results. For instance, the interface of OXINIUM uncemented components with the bone substrate is extremely difficult to investigate in-vitro.

Smith & Nephew may have experienced such difficulties with the OXINIUM technology, because the sale of two uncemented OXINIUM femoral components (GENESIS II and PROFIX) was stopped in September 2003. According to the available information, about 1% of these uncemented femoral OXINIUM components became loose. Unfortunately, Smith & Nephew has not released any further information on this matter.

Conclusions

The OXINIUM technology is a sophisticated technology for covering a zirconium-niobium alloy with a thin zirconia layer. Due to its higher hardness, this technology helps to lower the amount of adhesive/abrasive polyethylene wear observed on total joint prostheses.

Like any new technology released in the field of orthopaedics, the technology has to be monitored carefully before its propagation on a large scale. Since some of the unexplained problems seem to have been caused by two types of OXINIUM femoral component, I would not recommend the use of this OXINIUM technology before a clear explanation of these events is forthcoming. Furthermore, alternative solutions with greater clinical experience than the OXINIUM technology are available for reducing the adhesive/abrasive polyethylene wear rate observed in total hip and knee arthroplasties.

References

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