Optimised protection against allergic reactions and wear through the use of durable ceramic coatings
Avoiding inflammation and endoprosthctic loosening

**Background**

Joint replacement implants, particularly knee and hip prostheses, are subjected to a high degree of load and wear-inducing movement that results in the release of abrasive particles. Wear and also the release of metal ions is caused by contact stress between the implant’s polyethylene bearing surfaces and the metallic components. Wear debris and metal ions have been shown to be the main cause of inflammation, premature loosening and allergic reactions associated with joint replacement implants.

In comparison to other joint prostheses, knee replacement implants, which are mainly manufactured from cobalt/chromium/molybdenum-based alloys, are required, for technical reasons to consist of up to 1 percent nickel traces. They also have a far larger bearing surface area than other joint prostheses. This can result in the continuous release of allergenic metal ions (nickel, chrome or cobalt) into the tissue surrounding the implant. Hence, the risk of post-implantation adverse tissue reactions is particularly high in patients that are prone to allergy. Additionally one of the main development goals of modern manufacturing technologies, for new orthopaedic implants, is to improve their surfaces with a view to avoiding allergic reactions and wear debris caused by the articulating components.

**Technologies**

A fully biocompatible titanium nitride (TiN) or titanium niobium nitride (TiNbN) ceramic surface coating on metallic implant components ensure a minimizing wear on implant as well as a reduction of ion release. So the coatings are to counteract allergic reactions and inflammations. These ceramic coatings have been employed successfully in the U.S. since the early 1980s, and their use has been steadily increasing in Europe since the early 1990s.

The ceramic coating technique utilises a technology known as physical vapour deposition, which involves coating the implant during the vapour phase in a high-vacuum chamber to which nitrogen is added. The outstanding reproducibility of this computer controlled process produces coatings of consistently high quality. In this manufacturing process, the coating is securely anchored in several atomic layers of the implant surface.
Broad range of applications

Orthopaedic implants are not the only area where an outstanding surface wear resistance is a key quality parameter. The benefits of durable ceramic coatings are increasingly being applied in the development and manufacture of surgical instruments such as rotary dental instruments.

Diamond-like carbon coatings are (in addition to the use of TiN and TiNbN) an additional service that DOT offers in this segment for durable coatings.

Properties

Ti(Nb)N coatings modify surface properties only and have no effect on the substrate properties or biomechanical functionality of the implant.

<table>
<thead>
<tr>
<th>Coating thickness</th>
<th>Approximately 4 μm Coating thickness is measured using a process known as calotte grinding test, on test pieces that are coated with each implant batch.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hardness</td>
<td>Ca. 2400 HV (0.1 N) Hardness is measured using a micro-hardness test. The hardness of CoCrMo alloys is only 650 HV (0.1N).</td>
</tr>
<tr>
<td>Adhesive strength</td>
<td>Adhesive strength 1-2 Adhesive strength is tested in accordance with VDI guideline 3824 using the Rockwell HRC test. In addition, a thorn bending test is carried out using a Scratch test plate. These tests have demonstrated that the coating has outstanding adhesive properties.</td>
</tr>
<tr>
<td>Roughness</td>
<td>Ra &lt;0.05 μm Roughness determined with the profile method acc. to DIN EN ISO 4287. These roughness values are in compliance with the DIN EN ISO 21534.</td>
</tr>
<tr>
<td>Tribology and wear resistance</td>
<td>Low friction coefficient in contact with UHMWPE; ion release is suppressed upon exposure to frictional fretting. A significantly higher degree of surface scratch resistance.</td>
</tr>
<tr>
<td>Biocompatibility and corrosion resistance</td>
<td>The biocompatibility of Ti(Nb)N has been demonstrated in numerous published studies.</td>
</tr>
</tbody>
</table>

Advantages at a glance

- Outstanding biocompatibility
- Reduction of ion release
- Hardness superior to cobalt–chrome–molybdenum-based alloys
- Higher wettability with synovial fluids
- Low Friction articulation
- Long-term chemical stability

Bonding strength of Ti(Nb)N coatings in bending tests

Ti(Nb)N coating wear resistance as shown by pin-on-disc test compared to bone cement

1. Titanium alloy wear resistance as shown by pin-on-disc test compared to bone cement
2. Ti(Nb)N wear resistance as shown by pin-on-disc test compared to bone cement
Clinical results

Since 1995, DOT has coated more than 500,000 joint replacement implants with Ti(Nb)N for German and international OEM’s. To date, not one failure relating to the coating has been reported. Studies have shown that Ti(Nb)N coatings provide better polyethylene wear resistance and a more effective friction coefficient reduction than cobalt/chromium/molybdenum-based alloy coatings. Medium term clinical trial results confirm the durability of Ti(Nb)N coatings.

Bibliography

10. IMA Dresden, Prüfbericht-Nr.: C 34/8 vom 20.5.1999
14. IMA Dresden, Prüfbericht- Nr.: C 106/0 vom 27.4.2001