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The coating of the RM cup

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Introduction

The coating of the monobloc, all-polyethylene RM cup is one of the key factors that explain the clinical success of this implant. This study deals with the requirements on the RM cup regarding the surface hardness, the adhesion of the coating and the integration into the bone, as well as with the cup's properties and with some of the investigations performed.

The requirements on a cup surface include the functional goals that one aims at in a joint replacement implant, i.e. the primary and the secondary stability. This requires a close contact with the bone (i.e. a form-fit or a press-fit) and an immediate post-operative fixation as well as an osseointegration and a long-term fixation. Hence, one can devise the surface criteria such as an improved biocompatibility, an increased surface hardness and micro-roughness as well as an unchanged structural behaviour (i.e. to preserve the elasticity of the bulk implant).

One discussed two types of coating materials and used them in the RM cup [1]. These materials were the well-known standardised implant material of choice, i.e. the commercially pure titanium (TiCP according to ISO 5832-2) on the one hand, and on the other hand the hydroxyapatite (HA), a synthetic ceramic bone substitute material. TiCP is a very pure material (> 99.2 wt% of titanium) without any toxic or allergenic elements alloyed.

TiCP is corrosion resistant as well and offers a bioinertness that leads to the osseointegration through the direct contact with the bone. The powder particles used to get the coating on the RM cup have a grain size of 100–200 µm and are immediately oxidised like any titanium surface.

HA is a standardized material as well (acc. to ASTM F1185-88) and represents the long term resistant form of calcium phosphate ceramics. The granules used to coat the cup have a grain size of 125 to 250 µm. As HA is bioactive and osteoconductive, it has some advantages over the TiCP with respect to the biological response. There is not only a direct contact at the implant/bone interface, but an adherence to the bone as well, as the bone really likes to grow on a structure or a surface consisting of HA.

The design of the process of coating is such that one anchors the single particles in the cup material, the ultra-high molecular weight polyethylene (UHMW-PE). The final coating is a thin layer with a thickness of 100 to 300 µm (Fig. 1). The fact that there is no real bond between the coating particles is very important with respect to the structural stiffness or the elasticity of the cup, which remains unchanged compared to the uncoated bulk implant. Mechanically, the cup still behaves like a UHMW-PE monobloc cup independent of the selection of the TiCP or HA coating material.

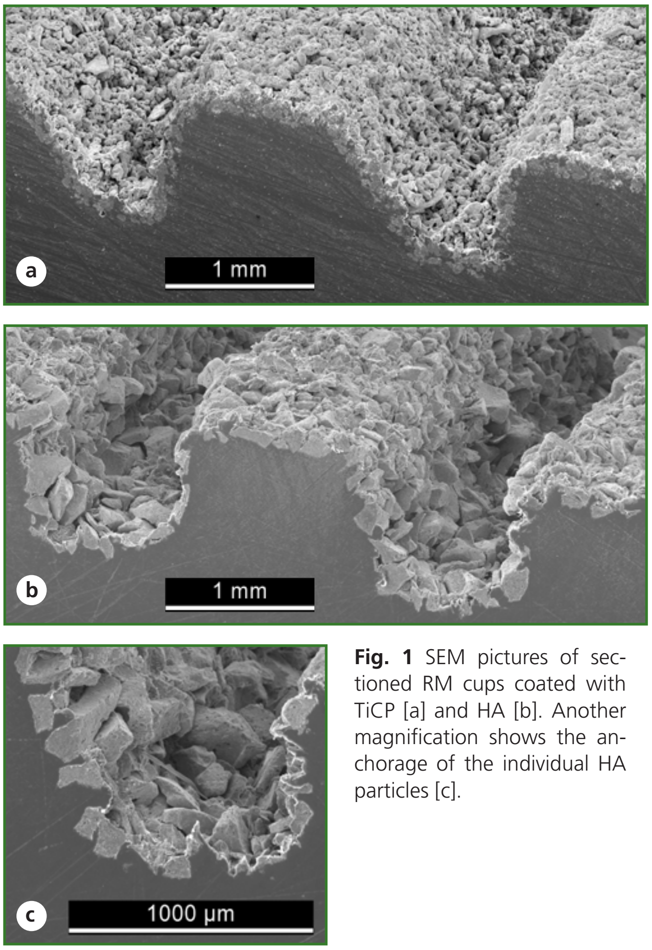

Fig. 1 SEM pictures of sectioned RM cups coated with TiCP [a] and HA [b]. Another magnification shows the anchorage of the individual HA particles [c].

To prove the functional behaviour and the efficiency of the RM cup coating quite a number of in vitro and in vivo studies took place. Some of them describing the typical features of the coating will be summarised to assess the surface hardness, the adhesion, and the push-out behaviour of implanted plugs.

Summary and results of different studies

Surface hardness

In a specific test setup, one investigated the surface hardness and compared the uncoated UHMW-PE surface to the HA-coated and the TiCP coated ones. For the assessment, one pressed a 5 mm steel ball 1 mm deep into the surfaces and measured the compressive force needed to reach this predefined depth. The uncoated PE and the HA-coated surface required a force of 515 and 545 N respectively. One had to use compressive forces of 590 to 630 N when varying the TiCP grain size from 100 to 350 µm. One found as well the maximum compressive force for the TiCP grain sizes varying from 100 to 200 µm, and used these grains for the coating of the cup (Fig. 2).

The study was able to show that a thin HA or TiCP coating could increase the surface hardness compared to the uncoated UHMW-PE. This allowed the conclusion of an improved resistance against the wear by bone.

Adhesion

In another experimental study, one investigated the adhesion of an epoxy resin plug of 8 mm diameter glued onto the outer surface of the RM cup. One then compared the uncoated, HA and TiCP coated surface types with respect to the axial force necessary to tear off the glued plug. One was able to improve the adhesive strength by using a HA or a TiCP coated cup instead of the uncoated one. The adhesive strength with the HA and TiCP coating was 59% and 67% respectively of the structural tensile strength of the UHMW-PE, which was clearly higher than the 18% found with the uncoated implant.

In an in-vitro test, we used RM cups coated with HA and TiCP and implanted them in a human cadaver pelvis specimen. We then applied the load and assessed the adhesive strength of the two different coatings again [2]. As load history, we used a combination of dynamic compressive forces (min. = 0 N, max. = 1000 N) and torsional movements (min. = 0°, max. = 20°) and applied them to the cups through a femoral head at a frequency of 0.7 Hz. We investigated one million load cycles with each coating type of the cup implants (Fig. 3).

After testing, we removed the cups from the setup and made an analysis by light and scanning electron microscopy (SEM). We studied two different zones of the cup: the first one in the load axis close to the pole area of the cup where only a perpendicular loading of the coating and interface took place.

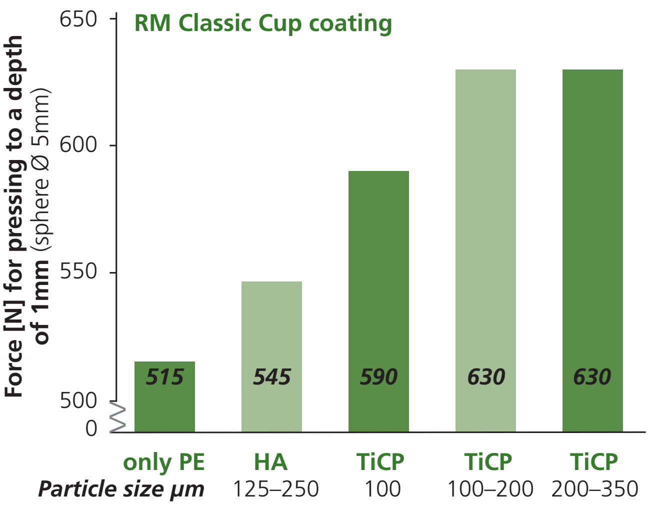

Fig. 2 Investigation of the surface hardness of PE samples, uncoated and coated with different particles.

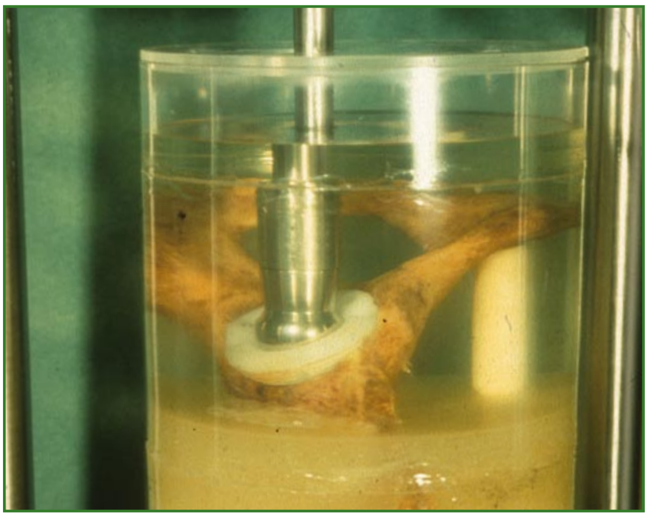

Fig. 3 Setup of the adhesion test with the coated RM cup in a pelvis specimen. The cadaver pelvis is embedded in PMMA and the whole setup is dipped into a formaldehyde solution and kept at 23°C.

The second zone was closer to the cup's rim where a combination of perpendicular and shear loading took place due to the additional rotational forces applied by the femoral head. In the zone with perpendicular loading, the particles were flattened and the TiCP particles deformed plastically as well. In the zone with the combined loading, the compaction of the particles was reduced and the intergranular spaces were filled with bony material, which was more obvious in the HA coating than in the TiCP one.

This study was limited by the maximum number of load cycles applied to the pelvis sample given by its elasticity and its strength. Yet, the important finding was that the particles of the coating remained in place and did not detach from the UHMW-PE cup. What is more, we did not find particles in the collecting basin or in the acetabulum after the tests.

We then concluded that the adhesive strength of the HA or TiCP coating was at least as strong as that of the bone structure.

In vivo push out strength

We finally made an in-vivo investigation with the aim to assess the mechanical and histological aspects of uncoated and coated UHMW-PE plugs implanted transcortically into the femurs of white New Zealand rabbits for 6, 9, and 12 weeks [3].

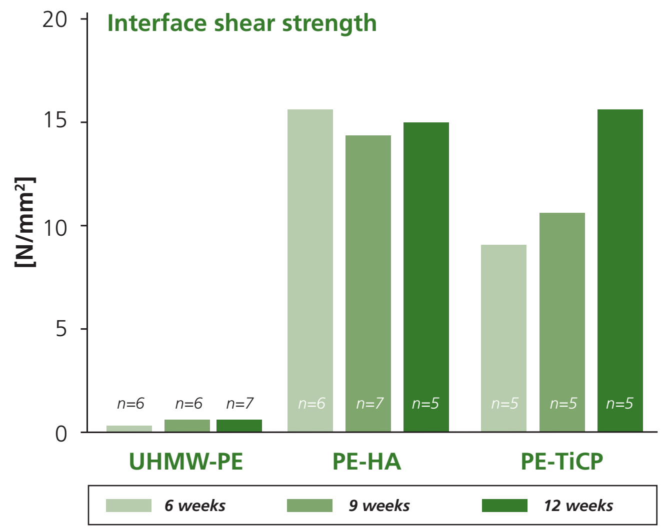

Fig. 4 Mean interface shear strength of uncoated (PE) and coated (PE-HA, PE-TiCP) UHMW-PE plugs based on push-out tests after implantation for 6, 9 and 12 weeks into the femur of rabbits.

In a push-out test, we analysed uncoated cylindrical plugs (3 x 12 mm diameter) and plugs coated with HA granules or TiCP particles to determine the shear strength at the interface. Beside the strength values at the interface, the study should yield the locations of interface failure and allow an examination of the tissue reaction.

The coated implants always had a significantly better interface strength (up to a factor of 20) than the uncoated plugs. The HA coated plugs reached their final shear strength after a shorter period of implantation (at 6 weeks) than the TiCP coated plugs, but both yielded the same strength after 12 weeks (Fig. 4). The microscopic analysis suggested that the failure at the interface initially took place between the coating and the bone in the crossover zone from the existing cortical bone to the newly formed bone wedge.

The histology revealed a stable bony integration of all the plug types. We were unable to explain the increase in interface shear strength of the coated versus the uncoated implants by histological findings. Hence, the main cause has to be in the different surface structures of the coatings.

Discussion

Based on the clinical outcome of 460 implanted HA coated RM cups, Morscher et al. [4] reported on the problem of the detachment of the HA particles.

In six revisions after 9 to 14 years, they found a loosening of the cup in four cases and an osteolysis of the proximal femur in three cases. They attributed the reason for the revision to the single HA particles they found in the articulation and to the traces of scratches on the metal balls found upon inspection of the explants.

Aside from the coating technology used, one may argue that the known brittleness of the ceramics or the ceramic coatings represents a clearly higher risk for detachment of the HA particles than the TiCP ones. Furthermore, one could relate the detachment of the particles as well to the migration of the cup, which a screw fixation in the immediate postoperative phase could potentially minimise. This risk of an increased particle detachment in the HA versus the TiCP coating is opposed by an increased acceleration with respect to the bony integration.

Ochsner [5] performed a histological investigation of an explanted RM cup after a revision of a 45-year-old patient due to ankylosis. He found quite a lot of bone attached to the outer surface of the cup. Histological sections showed that the bone really grew into the circular grooves of the cup. He found as well a direct bone apposition at the edge between the pole and the pegs. This example of bone integration in a TiCP coated RM cup clearly demonstrates the functioning of this specific type of surface coating.

Conclusion

The non-cemented anchorage of the RM cup is based on the superposition of the macro- and microstructures with their increased surface roughness and hardness due to the coating of the UHMW-PE. Single titanium or HA particles are anchored in the PE surface with no bond to each other. The structural stiffness and elasticity of the PE cup remains more similar to the characteristics of bone than a cup made from any other implant material available. The RM cups therefore are able to adapt to the microdeformation of the pelvis which leads to an optimal osseointegration and load transfer between implant and bone. A number of studies proved that the adhesion of the coating is sufficient and that the TiCP or HA coating shows an improved biocompatibility leading to a direct contact with the bone. A survival rate for the RM Classic cup of 94.4% after 20 years [6,7] is the best proof for this philosophy.

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