Ceramic Surface Engineered Metal-on-Metal Hips system for Total Hip Arthroplasty and Resurfacing Hip Arthroplasty

The design rationale, pre-clinical testing and interim report on 2-7 years of clinical results

By Karel J Hamelynck MD PhD and Ron G. Woering

The ACCIS® system for total hip arthroplasty (THA) and resurfacing hip arthroplasty (RHA) consists of metal components for the reconstruction of the acetabulum and metal femoral head components for conventional THA and RHA. The ACCIS® metal components are made of a chrome-cobalt-molybdenum alloy, but are different from other metal-on-metal prostheses. The surfaces of the metal components are engineered with the ceramic Titanium-Niobium-Nitride (TiNbN) in order to minimize metal particulate wear, to prevent corrosion and to prevent metal ion release.

Introduction
In the recent past metal-on-metal hip arthroplasty has attracted the renewed interest of the orthopedic world, when polyethylene wear and subsequent osteolysis were recognized as important causes of failure of hip implants (1-3) and excellent long term results of some original metal-on-metal prostheses without any obvious wear and without osteolysis were demonstrated (4). New prostheses were designed with a metal-on-metal articulation and 28 mm femoral heads (5). An old dream of “surface replacement” in the hip became a reality when metal was used for material, resulting in minimal bone resection of the acetabular and femoral side (6). The larger diameter of the femoral head provided the hip joint with improved stability and increased range of motion (7-9). As a result of the early success of surface replacement hip arthroplasty total hip systems were also designed with large femoral heads.

Metal particles
So far the good story. Soon after the introduction of new metal-on-metal hip prostheses serious concerns about the presence of metal degradation products in or near the hip joint or disseminated into the body were expressed in the literature (10). It became clear that metal-on-metal articulations, despite the fact that the volumetric wear is less, may generate more wear particles (3,4). Metal wear particles, much smaller than polyethylene particles can be ingested by histiocytes and macrophages and may become biologically active (11,12). Tumour-like proliferations of soft tissues around the hip were described (22-25). High blood levels of chrome and cobalt were found in patients with metal-on-metal prostheses and changes in red and white blood cells have been reported (24,26-43). High metal ion levels are important, knowing the fact that chrome and cobalt may cause cancer and may be mutagenic although investigations are not conclusive about the relation with orthopedic implants (43,44).

Fixation of all metal acetabular components
Lack of fixation of the acetabular component was a frequent complication of the original metal-on-metal hip prostheses and is a remaining problem today. The problem was then caused by a variety of reasons: insufficient surgery, impingement by the femoral neck, deformation of the sometimes very thin cup and high frictional torques caused by insufficient clearance between the femoral and acetabular component especially at the equator. Today with improved manufacturing capabilities clearances can be made small enough to allow fluid film or mixed lubrication at the dome of the articulation and wide enough to prevent equatorial impingement. Current mechanical loosening is probably caused by insufficient primary fixation. Most cup designs are spherical. These spherical cups run the considerable risk of being pushed out of the acetabulum due to forces around the whole cup after impaction, called “the rebound effect”. Press fit fixation by equatorial over-sizing as seen in cups with a three radial design is enhanced by compression forces only and is probably more reliable.

Metal ion release
Metal bearings corrode at a rate determined by their surface area and cause a release of metal ions. When wear particles are being formed, the total surface area of metal is increased considerably. These ions may attach to proteins and cause allergic reactions (1,19-21). Hypersensitivity reactions of surrounding tissues were described (22-25). High blood levels of chrome and cobalt were found in patients with metal-on-metal prostheses and changes in red and white blood cells have been reported (24,26-43). High metal ion levels are important, knowing the fact that chrome and cobalt may cause cancer and may be mutagenic although investigations are not conclusive about the relation with orthopedic implants (43,44).

Conclusion
Despite the fact that metal surfaces of prosthetic components for total hip replacement demonstrate less wear than surfaces of polyethylene, there is sufficient reason to try and reduce wear of metal components further, because a relatively high amount of submicron size metal particles is generated, that may become biologically active and may jeopardize the success of the implant. A treatment to prevent corrosion of the metal surfaces is also needed in order to inhibit the formation of free metallic ions, which will be disseminated into the body with unknown effects. The mere presence of un-physiologically high serum levels of cobalt and chromium in the blood of patients after metal-on-metal hip arthroplasty remains a matter of concern. The question is “Can we take the risk of using metal-on-metal prostheses knowing that increase of metal ion levels is a fact?”
The ACCIS® prosthesis system
The ACCIS® hip prosthesis system for conventional total hip arthroplasty and surface replacement arthroplasty is especially designed to overcome the possible disadvantages of metal-on-metal articulations.

Manufacturing of the ACCIS® components
The ACCIS® prosthetic components are manufactured from hi-carbon cobalt-chrome-molybdenum alloy according to the ISO standard 5832-4. The components are casted, cooled and then undergo a heat treatment. During the heat treatment block-carbides, which are found at the metal surfaces of the components and may cause abrasive wear in metal-on-metal prostheses, are reduced in number and size. After heat treatment the surfaces are polished. The next step in manufacturing is a very important one: surface micro finish. After this treatment the components are completely smooth, any remaining asperities are at nanometer level. At this point the surfaces of the ACCIS® prosthesis undergo another treatment: surface engineering using the ceramic Titanium-Niobium-Nitride. The TiNbN is integrated into the metal surfaces by physical vapor deposition (PVD). The value of PVD technology lies in its ability to modify the surface properties of a device without changing the underlying material properties and biomechanical functionality. In addition to enhanced wear resistance, PVD coatings reduce friction, are compatible with sterilization processes and improve corrosion resistance.

Acetabular components for THA and RHA:
The acetabular cup has a tri-radial outside geometry (fig. 2). The main sphere (b) is purely spherical. At the pole (a) there is a small area which is relatively flat (has a smaller radial diameter). Near the equator (c) the cup is incrementally widened 1.6 – 2.1 mm. This equatorial oversizing provides excellent press fit fixation provided the cup is well surrounded by pelvic bone. There will be line-to-line contact between the large middle sphere of the cup providing excellent circumstances for secondary bone in-growth.

Preventing rebound:
The press fit fixation by equatorial over-sizing is different from the fixation principle of over-sizing with spherical cups. While spherical cups run the considerable risk of being pushed out of the acetabulum due to the forces around the whole cup, called the rebound effect (46), fixation of cups with equatorial over -sizing is enhanced by compression forces only (figure 3). Two fins are added near the equator of the ACCIS® acetabular components to support rotational stability (arrow in figure 2 ). The cup coverage angle is incrementing from 9.31mm, for the small size acetabular component 42mm (which is seldom used), till 16.24mm, for the larger component with the cup size 64 mm.

The outside of the cup is coated with a plasma spray of pure Titanium (cpTi) according to the ISO standard 5832-2. The pore diameter is 75-350 micron, the coating thickness 300 +/- 50 micron and the roughness RA is 50 micron.

The solidity of the fixation is specified as Rh = 45 MPa, while a minimal strength of 22 MPa is required according to the “FDA-Guidance for the industry”. The metal surface of the inner side of the acetabular component is engineered with the ceramic TiNbN by PVD.
Cementless and cemented
It is the aim to use the non-cemented cup in most THA’s and RHA’s. However, a cemented cup is available for less than optimal bone conditions (picture 4).

Fig. 4 ACCIS®Cemented Acetabular Component

The clearance between acetabular and femoral head components is approximately 100 microns in all sizes.

The femoral component for RHA
The purely spherical femoral head component is designed for cemented fixation. The inside of the femoral head component has a 1 mm clearance at the top of the head. There is some clearance around the head incrementing from a proximal 0.1 mm tight fit towards distal 0.9 – 1.4 mm clearance to give space to an adequate cement mantle. Radially placed cement pockets at the proximal part of the femoral head (figure 5) provide room for additional cement, which contributes to the quality of the fixation with cement.

Fig. 5 ACCIS®Cemented Femoral Component

The small central stem does not contribute to the fixation (no cement should enter the prepared canal), but serves as a positioner for the head component. The articulating side of the head component is engineered with the ceramic TiNbN by PVD.

Femoral components for THA
ACCIS® femoral heads for total hip replacement are available in sizes 38 to 58 mm in 2 mm increments; the neck length of the femur may be adjusted with cone adaptors in three sizes: short (-4 mm), standard (0 mm) and large (+4 mm); the cone adaptor is made of a Titanium alloy and has standard a 12/14 mm cone. (figure 6)

Fig. 6 ACCIS®Large head and cone adaptor for THA

Component sizes

<table>
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<tr>
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Fig. 7 ACCIS®component sizes
How does the ceramic work?

The surface modification of the metal components serves two objectives: the minimization of wear and the prevention of corrosion.

1. The minimization of wear

To understand the effect on wear of a TiNbN coating it is important to know how M-on-M prostheses wear. Most wear in metal-on-metal articulations occurs in the first few millions of cycles of weight bearing. During this running-in phase surface asperities are worn flat. These asperities on metal surfaces are formed by block carbides.

Block carbides are molecules formed from metal atoms and carbon; a typical structure is M7C3. They are formed during the cooling phase of the metal component and are particularly common at the surface. The molecules are relatively large: 20 – 30 microns. Their presence in the alloy makes the alloy less homogeneous and weaker, but they are more wear resistant. The presence of block carbides in the metal alloy thus imparts both advantages and disadvantages.

The block carbides are much harder than their housing alloy, and may cause abrasive wear on the opposing prosthetic surface. Asperities may also break free from the surface and cause three-body abrasive wear.

To minimize the disadvantages it is possible to reduce the number and size of the carbides present. Heat treating the component after the cooling process leads to the presence of fewer carbides, with remaining molecules reduced in size to 5 – 10 microns. This process leads to retention of block carbide advantages, while reducing disadvantages.

A ceramic coating is helpful to further reduce the disadvantages of block-carbides. Ceramics have the advantage of being extremely hard. The titanium-niobium-nitride coating is very wear resistant, capable of slicing asperities off as small particles; this prevents the breaking away of carbides and the initial high wear of metal-on-metal articulations is to a large extent reduced. After the running in phase the opposing surfaces are completely flat and show minimal wear.

2. prevention of corrosion

Coating of implants with Titanium niobium nitride may also prevent metal ion release by “isolating” the components. There is no contact with the synovial fluids that are contributing to corrosion. As a result no metal ions are produced. In vitro studies support this belief.

Pre-clinical testing and results

Pre-clinical testing of the ACCIS® prosthesis consisted of several tests of the fixation of the ceramic to the components, wear tests, corrosion tests, biological testing of the ceramic TiNbN, and several tests of the fixation of the acetabular component.

1. fixation of the coating

During the application of the TiNbN ceramic by PVD the ceramic is integrated into the surface. To test the fixation of the coating several tests were performed:

- pin-on-disc test: the test revealed no dislodging nor scratching of the coating.
- bending test: no delamination of the coating did occur
- Rockwell test: no delamination of the coating did occur

2. wear tests

Wear evaluations using hip simulators were performed by independent investigators at the Institut für Materialforschung und Anwendungstechnik, IMA in Dresden, Germany, and at the Atomic Energy Authority in Harwell, UK. ACCIS® ceramic coated MoM hip implants with femoral head components of 42 and 46 mm were compared to prostheses with bearing surfaces of metal-on-polyethylene, ceramic-on-polyethylene and metal-on-metal.

These studies resulted in the following conclusions:

- the wear of the TiNbN-coated ACCIS® prostheses was limited to the running in phase: partial removal of the ceramic coating occurred during the initial 1-2 million cycles after which removal was negligible.
- during the running-in phase TiNbN-coated prostheses showed a 6-10 fold reduction of wear compared to M-on-M articulations with 32 mm femoral head components.
- the ceramic layer was intact after 5 million cycles.
- hip simulator tests comparing ACCIS® ceramic coated and ACCIS® non-ceramic coated components confirmed the beneficial effect of the ceramic coating.
- shed particles were shown to be of sub-micron size: < 0.1µ
3. corrosion testing
At the University of Würzburg the release of chromium ions was measured by placing a ceramic coated CoCrMo prosthetic component and a non-ceramic coated CoCrMo prosthetic component in a boiling saline solution for 240 hours. A 90% reduction of chrome ion release with the TiNbN coated component was demonstrated (55). The TiNbN coating provides a great amount of protection against corrosion.

4. biological testing
Biocompatibility testing was performed at the LPT Laboratory of Pharmacology and Toxicology, Prof.Dr.med F. Leuschner, in Hamburg Germany in order to investigate possible biological reactions to TiNbN when implanted into the body.
- implantation test according to the USP XXII following the LPT protocol 7362/92. Result: No difference in tissue reaction was found between Titanium-Niobium-Nitride ceramic implanted in rabbits and negative control material. The effect observed was limited to a non-specific tissue reaction (56).
- examination for cytotoxic properties of plates made of CoCrMo coated with TiNbN in a cell culture test according to USP 28 and EN 30993-5. Result: no signs of cytotoxicity were revealed, while the positive control revealed severe cytotoxicity (57).

5. tests for the fixation of the cup
The primary fixation of the tri-radial design of the ACCIS® acetabular component for cementless press-fit application and the fixation of the spherical ACCIS® component for cemented fixation were tested at the Technical University Hamburg-Harburg (Prof. Dr.habil. M.M. Morlock). To determine the ideal external configuration pull-out, cantilever and rotational stability tests were performed and various types of surface geometries for the acetabulum components were compared. The triple-radius design with equatorial over-sizing and two equatorial fins gave optimal primary stability and became the definitive design (58).
The pure Titanium plasma sprayed outer surface was selected, because of its excellent contribution to primary fixation and proven bone in-growth capacity. The acetabular components do not deform during implantation. The impaction of cups into the pelvis of a calf was tested at the Technical University Hamburg-Harburg. Result: the deformation of the cup, which may result from impaction of the ACCIS® acetabular component, is neglectable, no decrease in function of the MoM articulation has to be expected; the strength of the cup is adequate (59)

Clinical results of the ACCIS® prosthesis
In this paragraph special attention is given to those aspects of the ACCIS® prosthetic, that are specific for its design. More common aspects like clinical function and hip scores are being published in the literature. This paragraph is focussed on (1) fixation of the cup, (2) the absence of metal wear and (3) the absence of any increase of metal ions in the blood of patients after THA and SRHA with the ACCIS® prosthesis.

1. fixation of the cup
The first clinical trial was performed at the Slotervaart Ziekenhuis, Amsterdam, the Netherlands (Karel J. Hamelynck MD PhD and Paul Winia MD). From March 2000 till September 2002, 80 ACCIS® total hip replacements were performed using a prototype spherical ACCIS® cup with a casted porous coating and three fins at the dome to enhance rotational stability. This type of fixation demonstrated to be insufficient. The primary fixation of this cup appeared to be inadequate for two reasons. The adequate seating of the spherical slightly over-sized cup may have been hindered by the so-called rebound effect (46 and figure 3). Forces around the cup are pushing the cup out of the acetabulum leaving a gap between the acetabular bone and the component. The fins at the dome of the cup may have contributed to the rebound effect. When primary fixation is inadequate, secondary fixation may not occur. The results caused a design change. The fins were abandoned and hydroxyapatite was added to improve the secondary fixation.(prototype 2)

A second clinical trial was performed at the Morriston Hospital, Swansea, Wales (UK), David J Woodnutt, MD FRCS, FRCS (Orth). Between April 2003 and December 2003 sixty THA’s were performed using prototype 2 ACCIS® spherical cementless acetabular component. The results of this trial revealed again the negative influence of the rebound effect on primary fixation, which is typical for the spherical cup design. For that reason the shape of the cup was changed from purely spherical to tri-radial with a small flattened part at the dome and a peripheral widening at of 1.7 - 2.0 mm at the equator. The fixation of this tri-radial cup design during testing demonstrated a press-fit fixation that was clearly superior to the fixation of spherical designs. The best results were achieved when two fins were added at the equator (58). The tri-radial shape became the definite shape of the ACCIS® cementless acetabular pressfit cup.

The third clinical trial was again performed at the Morriston Hospital, Swansea, Wales (UK). Starting from April 2005 a great number of total hip replacements and surface replacement arthroplasties has been performed using the definite press-fit tri-radial acetabular component. To date no problems with the fixation of the cup have been encountered.
From 2006 more RHA trials using the ACCIS® prosthesis with the definite acetabular component have been performed. No problems with fixation of the cup have been reported except for the occasional early fixation problem due to surgical error. Surgeons needs to follow the precise surgical technique: the equatorial press fit fixation of the cup functions best, when the cup is completely surrounded with acetabular bone.
2. the absence of wear

The metal surfaces of the ACCIS prosthesis are engineered with the ceramic Titanium-Niobium-Nitride (TiNbN). TiNbN is integrated into the metal surfaces by physical vapor deposition to minimize wear.

- failure of cup fixation in patients of the first trial at the Slotervaart Ziekenhuis Amsterdam, the Netherlands, gave the opportunity of examining the capsule and soft tissue from behind the cup in 15 patients: examination of the biopsies demonstrated the complete absence of any adverse reactions to metal particles: no signs of hyper-sensitivity, necrosis, pseudotumour formation and no signs of inflammation (figure 9).

- during the third clinical trial at the Morriston Hospital, Swansea, UK, no problems originating from the TiNbN ceramic coating have occurred.

- all components revised for whatever reason, have been studied extensively by implantcast GmbH, the manufacturer of the prosthesis. No errors of manufacturing could be detected. The TiNbN coating remained intact and present around the full femoral head and inside of the acetabular component with the exception of a very small area at the dome of the cup in some cases, demonstrating the effect of running in.

comment:

Some wear does occur during the running in phase of any metal-on-metal prosthesis. Fluid-film lubrication cannot be achieved in all prostheses. In most prostheses there will be initial contact at the dome due to the diametrical clearance between head and cup. With the ACCIS prosthesis this running in wear is limited to the running-in period. However the presence of the coating around the whole femoral head and the almost complete inside of the cup guarantees that corrosion cannot occur.

3. the absence of any increase of metal ions in the blood

The metal surfaces of the ACCIS prosthesis are engineered with the ceramic Titanium-Niobium-Nitride (TiNbN). TiNbN is integrated into the metal surfaces by physical vapor deposition to minimize wear and to prevent corrosion as well.

Blood tests of metal ion levels of 30 patients from the second trial at the Moriston Hospital, Swansea, UK, 2-5 years after THA with the ACCIS acetabular and femoral head components with femoral heads of 42 and 46 mm or more demonstrated, that none of the patients had metal ion levels, that were elevated 2-5 years after ACCIS THA (figure 10).

The metal ion levels were equal to the average metal ion levels in controls without a prosthesis shown by a dotted line in figure 10 (60,61). Patients with a titanium femoral stem had no increase of metal ions at all, while patients with a cobalt-chromium-molybdenum femoral stem had some increase of chromium ions.

The metal ion concentration of patient with an Accis THA median Chromium: 3.61 (0.25-8.5) and median Cobalt: 1.3 (0.25-2.2) (60) show significant lower levels of metal ions than levels published in other studies such as by Langton (62): median Cr: 3.42 (1.5-69.8), median Co: 1.99 (0.4-271) and by De Smet (63): median Cr 13.2 (0.4-93) and median Co 5.8 (1-94) And this despite the fact that most of the THA patients had CoCrMo femoral stems (60)!

A clinical multi-centre follow-up study on 200 ACCIS® Resurfacing implants (Morriston Hospital, Swansea, UK: David J Woodnutt, MD, FRCS, FRCS (Orth); Neville Hall Hospital, Abergavenny, UK: Robin Rice, MD,BMBS,FRCS; Arthro Clinic Hamburg: Genio Bongaerts, MD) is performed. Blood samples of 60 patients are analysed before, immediately after surgery and at intervals of 3, 6, 12 and 24 monts after surgery.

The results of this ongoing study are shown in figure 11. None of the patients at any moment after operation has shown any significant increase of cobalt and chrome ions in the blood and none of the blood ion levels has been above the normal limits for metal ions in the blood as described in the Hand book for environmental medicine (61).
The conclusion is justified that corrosion of the articular surfaces of the metal components of the ACCIS® prosthesis by the process of surface engineering of the surfaces with the ceramic TiN6N, is completely inhibited. Early clinical results were presented at various meetings (60,64-66). The above mentioned study will be finished in the 4th quarter of 2009 and subsequently published.

conclusions:
The components of the ACCIS® system for THA and RHA incorporate important advantages over other metal-on-metal hip prostheses with large femoral heads:

(1) The primary fixation of the acetabular component is very reliable due to the tri-radial design, equatorial press fit and TPS coating.

(2) Ceramic engineering of the articular surfaces of the metal components causes a minimization of metal wear.

(3) Corrosion of the metal surfaces is prevented and reduced to the minimum.

There is no need to fear for increased levels of metal ions in the blood and the unknown consequences of this increase.

October 4th 2009

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