The use of Ceramic Coatings in Orthopaedic Implants

Titanium Nitride Ceramic Articulating against Polyethylene and Cartilage

implantcast

Introduction

Joint replacement arthroplasty is considered to be one of the most successful surgical procedures.
Until recently joint replacements have only been carried out on older, less active patients. The success of these joint replacements encouraged the use of artificial joints in younger persons with a more active lifestyle (1).
Activity Levels (2, 3) and with it, the revision rates in total knee replacements is considerable higher in younger patients (4). The life expectancy of this younger patient is higher than the lifespan of the average knee or hip implant (5).
The most commonly used orthopaedic implants are of the metal-on-polyethylene type. Polyethylene wear particle induced osteolysis has been identified as the main cause of failure of total knee arthroplasty and especially the occurrence of fatigue-type wear that can destroy a tibial inlay in less than 10 years, is of major concern (6, 7, 8).

Parameters Influencing Wear in TKA

There are numerous parameters influencing the wear of polyethylene components in total knee arthroplasty : the patient's life style, the level and type of stresses on the articulating surfaces, material properties, imperfections of polyethylene components, and the coefficient of friction (9).

Improving Implant Design Geometry

In a knee implant the stress level depends on the load and the contact area between the articulating tibial and femoral components. The contact stresses in many non-mobile bearing knee designs are much higher than previously estimated and can easily exceed the yield point of UHMWPE by as much as 3 times (10).

The Mobile Bearing TKA

The introduction of the Mobile Bearing into the knee designs by Goodfellow and O'Connor and the further improvement of the meniscal bearing design by Buechel and Pappas has lead to the view that three compartmental knee implant design can contribute substantially towards the reduction of polyethylene wear (11, 12, 13, 14).

Contact Area

In the mobile knee designs, currently available, great differences can be found in the contact area between the femoral implant and the polyethylene articulating counter surface (15,16). The ACS® knee has the highest contact area at extension (where the highest load occurs) and at 60° of flexion.

Age and activity after TKA

patient Age	average steps /year
< 60 years	1.200.000
> 60 years	800.000

Fig. 1: Age and activity level

Failure rate and ages in TKA

age (years)	percentage of failures
< 65	12 %
65 - 75	10 %
> 75	4 %

Fig. 2: Age and failure rate

Life expectancy (females)

age	expected to live another
50 years	34 years
67 years	20 years

Fig. 3: Life expectancy

Fig. 4:
Fatigue wear
of polyethylene

Fig. 5: The ACS® knee implant with Mobile Bearing

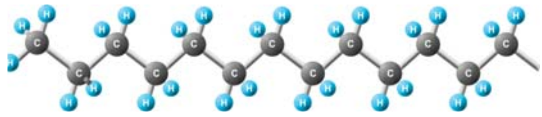

Fig. 6: Polyethylene molecule

The Polyethylene

Many attempts have been made in the past to improve the wear characteristics of polyethylene, including carbon-fiber reinforcement (PolyTwo™), polymer reprocessing like Hot Isostatic Pressing (Hylamer™). Hot Pressing (PCA™) was another attempt to improve the articular surface but was associated with early delamination. It shows clearly that the in vitro investigations may not fully predict the performance in vivo (17).

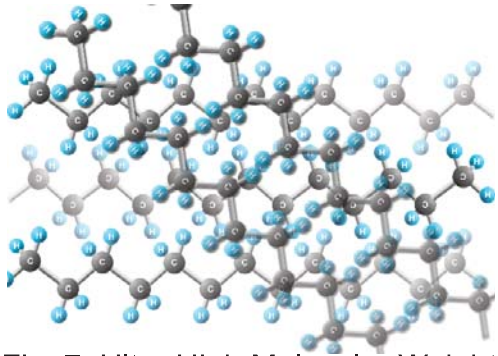

Fig. 7: Ultra High Molecular Weight Polyethylene (UHMWPE)

Cross linked Polyethylene

Laboratory simulation demonstrated that wear resistance of polyethylene improves with increased cross linking of the polymer chains, however it may also change either the amorphous or both the amorphous and crystalline regions of the resulting polymers, potentially affecting mechanical properties and fatigue characteristics. As it looks like Cross Linked PE works well in hip designs, this material for application in knee replacement is still under debate (18, 19). In the ACS® knee standard ram-extruded GUR 1000 Polyethylene (stearate free and Ethylene Oxide sterilized) is used.

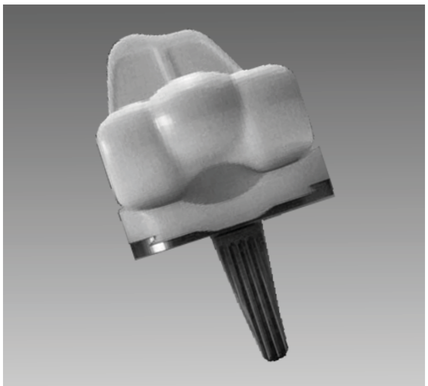

Fig. 8: Monolithic ceramic femoral component

Metal Substrate

In the hip, damage or scratching of the metal counterface has been shown to accelerate polyethylene wear and similar data have been found in knees. In the hip the use of ceramic femoral heads (Alumina™, Zirconia™) is recommended which are more damage- and scratch resistant and show extreme lower long term wear rates (20).

Monolithic Ceramic components, investigated mainly in Japan, have not shown to reproduce the same clinical longivety as the Cobalt Chromium implants (21).

Oxidized Zirconium implants show excellent wear characteristics against polyethylene, but at this time require the use of bone cement for fixation (22, 23).

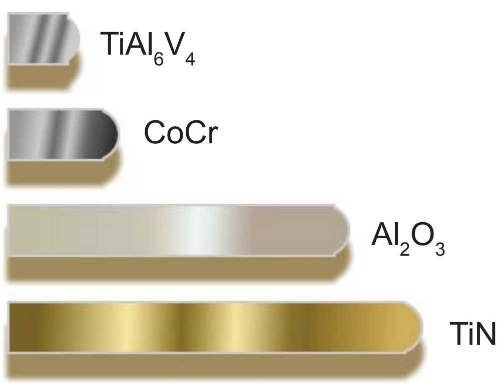

Fig. 9: Relative hardnesses in Vickers of orthopaedic implant materials

Ceramic Coatings to reduce wear, corrosion and to increase scratch resistance

- increased hardness of the articulating surface (Fig. 9)
- increased scratch resistance
- lower friction coefficient
- improved wettability
- reduced wear of the counterface
- higher corrosion resistance
- decreased metal ion release
- enhanced bone ingrowth capacity
- increase fatigue strength
- increased biocompatibility

Titanium Nitride Coating

In the late 70 and 80's of the last century, some of the Cobalt Chromium implants had a small Nickel content to add to strength of the implant. Nickel is the primary cause for metal sensitivity, although some patients have shown to be hypersensitive to other metals such as Cobalt and Chromium.

Since the end of the 1990's TiN (Titanium Nitride coatings) have been successfully applied to shield the body from metal ions that could cause allergic reactions (24, 25).

Fig. 10: Lymphadenitis in a patient with Ni-hypersensitivity after TKA

Less Wear from Carbides

During the casting of orthopaedic components the carbon content of the alloy will form carbides, junctions between metal and carbon. Where these much harder particles protrude the surface they may harm the articulating counterface. By covering these carbides with a harder ceramic this wear will be reduced (26, 27).

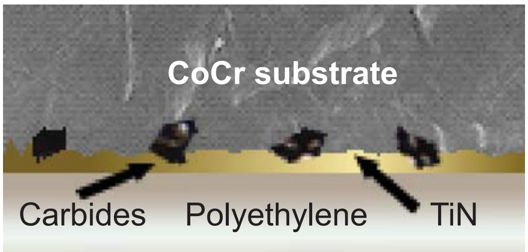

Fig. 11: TiN covering carbides

Higher resistance to scratch formation

Wear simulator tests are usually done with implants that come right from production. However it is known that particles in the body such as bone chips and bone cement particles can lead to increased abrasive wear (26). Ceramic coated implants have a higher resistance against scratching (28, 29).

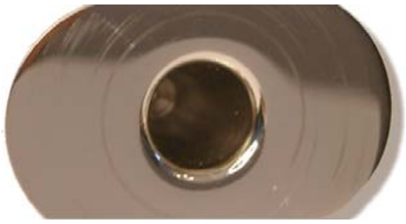

Fig. 12: Scratched non-coated CoCrMo tibial component

Less deeper Scratches

The height of the lip of a scratch is directly related to the amount of abrasive wear. TiN coated implant have a lower scratch lip (30).

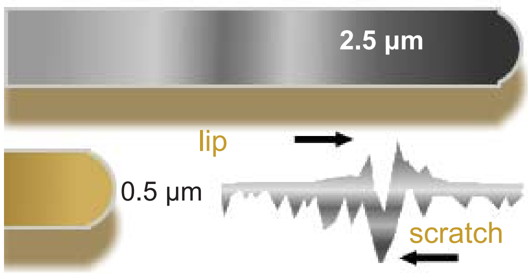

Fig. 13: Height of lip of scratches

Less wear from scratched components

When a wear simulator test is performed with explanted components it shows the reduction of abrasive wear in TiN coated implants (27).

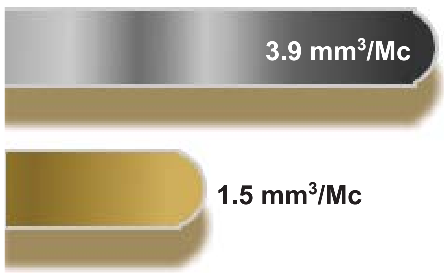

Fig. 14: Wear rates of scratched components in mm^3/Mc

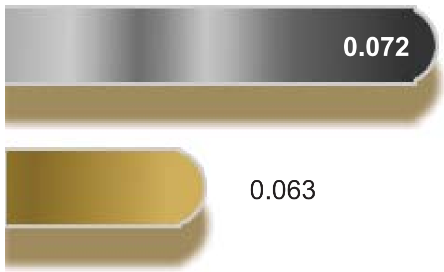

Fig. 15: Coefficent of friction

Lower Coefficient of Friction

Wear damage to the articulating surfaces is associated with the frictional forces at the interface. The coefficient of friction depends on the material and the surface finish of the articulating surfaces and the lubricating regimen (31).


Fig. 16: Wettability of non coated and coated femoral components

Better Wettability

When placing a droplet of de-ionised water on the surface of an implant, the contact angles can be measured. TiN shows to be more hydrophilic than non coated CrCoMo. A better wettability will increase the lubrication, decreasing the coefficient of friction and this will help to reduce the wear (29, 31).

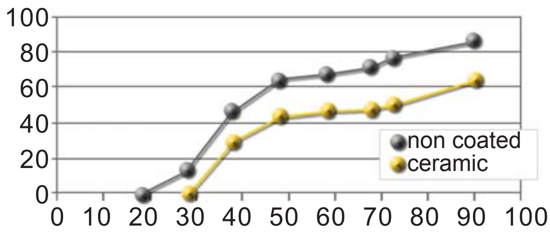

Fig. 17: Relation between surface tension (in mN/m) and wettability angle

Lower Surface Tension:

DOT Rostock established the relation between wettability angle and surface tension of non-coated and TiN coated implants (32).

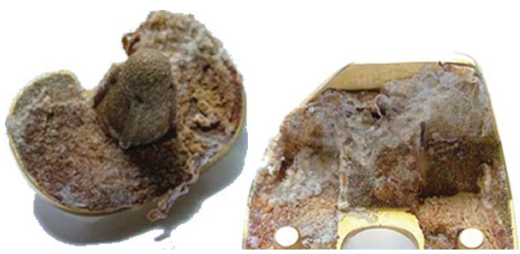
Fig. 18: Bone ingrowth in TiN coated CoCrMo knee replacement components

Better and faster bone ingrowth.

This lady received a Titanium Nitride coated knee implant, but unfortunately she fell during shopping at 3 months post-operatively. As she tore both collateral ligaments the implant had to be revised for a type with more intrinsic stability. Notice the abundant bone ingrowth on both components (pictures courtesy of Mr D. Woodnutt, consulting orthopaedic surgeon Morriston Hospital Swansea UK).

Fig. 19: Chromium ion release

Less Ion Release

All implants corrode at a rate determined by their surface area and cause a release of metal ions, In this graph, derived from a test done at the University of Würzburg, Germany it shows that the passive Chromium ion release (without articulation) is reduced to less that 10% at 10 days in NaCl solution (35).

Quality Assurance

The application of the Titanium Nitride Ceramic coating is a Physical Vapour Deposition(*). The name PVD stands for a wide range of applications each with its own physical characteristics. In order for the coating of an implant to be able to function long term it is crucial that the PVD process is reliable, reproducable and has proven itself in clinical application. Especially the adhesive strength of the coating onto the substrate is of vital importance. Various in-process and batch quality checks are performed.

Fig. 20: TiN coated components

Rockwel test

A diamond cone penetrates the coating layer with defined force. This will deform both the coating and the substrate. Optimal coating will show no delamination (picture left). Insufficient adherence of the coating will result in delamination as seen on the right (31,34).

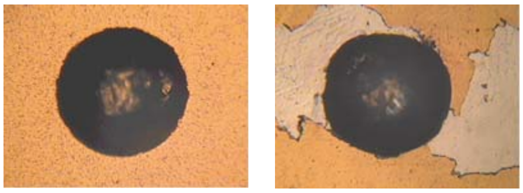

Fig. 21: Two PVD coated implants with different adhesive strengths

Bending test

A metalstrip is included in each batch of implants to be coated. To check the adhesive strength of the coating the strip is bend up to 180°. Uniform crack network is seen without delamination (34).

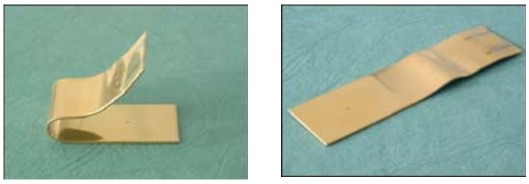

Fig. 22: Bending test to prove adhesive strengths

Technical Data of TiN

Coating Thickness: 4.5 +/- 1.5 µm
Hardness of TiN: 23000 (+/- 2000 MPa)
Hardness of CrCoMo: 5000 MPa
Adhesion Strength: HF 1-4
Surface Roughness: Ra < 0.03 µm

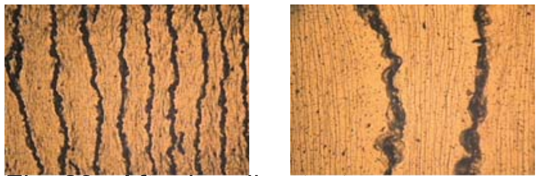

Fig. 23: After bending test
magnification 100x magnification 400x

Pin-on-Disk test

As the main cause for scratches of implant components may be the presences of bone cement particles, a disk of PMMA bone cement is used against a TiN coated metal disk. No delamination is seen, not even at a load of 500 MPa, which is 50 times higher than the normal, vivo pressure in the knee, being less than 10MPa (26, 31, 34).

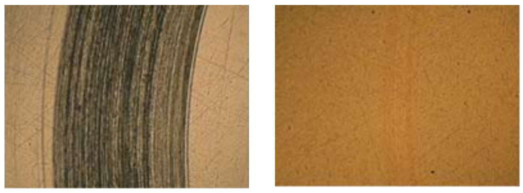

Fig. 24: Pin-on-Disk test of PMMA on TiN coated substrate.

(*) DOT GmbH
Charles Darwin Ring 1A
D 18059 Rostock
Germany

ACS® Mobile Bearing Knee Prosthesis is available in cemented and cementless design and the cemented semi constrained ACS® SC version

ACS® Femoral components for cementless fixation with or without HA/TCP

ACS® Cemented Tibia with shaft extension

ACS® SC semi constrained femoral component and detail of the mechanism

28 and 32 mm heads for Hip Implants articulating against polyethylene

Capica® Shoulder Surface Replacement

A selection of implants available with TiN Coating

Virtually any orthopaedic implant articulating against polyethylene may benefit from the application of a ceramic surface coating.

Advanced Ceramic Coated Implant System

A special application of ceramic coating on orthopaedic implants is the ACCIS® coating in which a Ceramic Coated surface articulates against a Ceramic Coated Surface. It is available for Total Hip and Resurfacing Hip arthroplasty. A dedicated brochure is available.

Agilon® shoulder and Mutars® humerus replacement

Literature

(1) Source: The Swedish Joint Replacement Register: http://www.jru.orthop.gu.se/
(2) Assessing activity in joint replacement patients: Zahri CA et al. J Arthroplasty, 1998,13, 890-95
(3) Activity level and wear in total knee arthroplasty: Carlos J. Lavernia MD, Rafael J. Sierra MD, David S. Hungerford MD and Kenneth Krackow MD The Journal of Arthroplasty Volume 16, Issue 4, June 2001, Pages 446-453
(4) Source: Robertsson Lund Sweden 2001 Thesis: http://www.sos.se/mars/kva012/robertssonthesis.pdf
(5) Source: National Centre for Health Statistics: http://www.cdc.gov/nchs/data/hus/tables/2003/03hus027.pdf
(6) Catastrophic Wear of Tibial Polyethylene Inserts: D.J. Kilgus, J.R. Moreland, G.A.M. Finnerman, T.T. Funahashi, and J.S. Tipton, CORR 1991, 273: 223.
(7) Catastrophic Osteolysis in Total Knee Replacement: A Report of 17 Cases,"E.J. Robinson, B.D. Mulliken, R.B. Bourne, C.H. Roraback, and C. Alvarex, " CORR, 1995, 321:98.
(8) Why Are Total Knee Arthroplasties Failing Today?: Peter F. Sharkey, MD; William J. Hozack, MD; Richard H. Rothman, MD, PhD; Shani Shastri, MD; Sidney M. Jacoby, BA CORR november 2002 pag 7-14
(9) Factors Affecting Polyethylene Wear in Total Knee Arthroplasty: Markus S. Kuster MD, PD, PhD; Gwidon W. Stachowiak, PhD Klinik für Orthopädische Chirurgie, Kantonsspital, CH 9007 St Gallen, Switzerland
(10) Analysis of the Failure of 122 Polyethylene Inserts from Uncemented Tibial Knee Components: J.P. Collier, M.B. Mayor, J.L. McNamara, V.A. Surprenant, and R.E. Jensen, CORR, 199, 273: 232.
(11) The Mechanics of the Knee and Prosthesis Design: Goodfellow, J.W., O'Connor, J.J, JBJS. Vol. 60-B, No.3, August 1978, p.358-369
(12) The Oxford medial unicompartmental arthroplasty, a ten year survival study: D.W., O'Connor, J.J., Goodfellow, J.W.,:, Murray, JBJS Vol 80-B, No.6., November 1998, p.983-989
(13) The New Jersey Low-Contact-Stress Knee Replacement System: Buechel, F.F. and Pappas, M.J. Archives of Orthopaedic and Traumatic Surgery, No. 105, 1986, pp. 197-204
(14) Mobile-Bearing Knee Replacement: clinical Results A Review of the Literature: John J. Callaghan, MD CORR 200Q NO.392, pp. 221–225
(15) Mobile-bearing Total Knee Arthroplasty Design Factors in Minimizing Wear: Douglas A. Dennis, and Richard D. Komistek CORR 2006 Number 452, pp. 70–77
(16) The influence of Mobile Bearing Knee Geometry in the Wear of UHMWPE Tibial Inserts: A.Seth Greenwald et al: Three publications available at: http://orl-inc.com/knee_publications
(17) Failure of the Porous-Coated Anatomic Prosthesis in Total Knee Arthroplasty Due to Severe Polyethylene Wear: A. Tsao, L. Mintz, C.R. McRae, S.D. Stulberg, and T. Wright, JBJS, 1993, Vol. 75-A, No. 1: 19.
(18) New Polys for Old, Contribution or Caveat: A.Seth Greenwald et.al: Available at http://orl-inc.com/aaos_publications/2002/NewPolys.pdf
(19) Alternative Bearing Surfaces: The Good, The Bad, and the Ugly: A.Seth Greenwald JBJS Am. 2001;83-A Suppl 2 Pt 2:68-72
(20) The influence of cratches to metallic counterfaces on the wear of ultra-high molecular weight polyethylene: J. Fisher, P. Firkins, E.A. Reeves, J.L. Hailey, and G.H. Isaac, Proc. Instn. Mech. Engrs., 209 (H4), 1995, pp. 263-264.
(21) The Bisurface Total Knee Replacement: A Unique Design for Flexion Four-to-Nine-Year Follow-up Study: Masao Akagi, M.D., Takashi Nakamura, M.D., Yoshitaka Matsusue, M.D., Toyoji Ueo, M.D., Kohichi Nishijyo, M.D. and Eijiro Ohnishi, M.D. JBJS 82:1626 (2000)
(22) Oxinium: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=498618
(23) An Oxidized Zr Ceramic Surfaced Femoral Component for Total Knee Arthroplasty: Richard S. Laskin, MD CORR Number 416, pp. 191–196 B
(24) Biocompatibility of wear-resistant coatings in orthopaedic surgery in vitro testing with human fibroblast cell cultures: J. J. A. M. Van Raay1, P. M. Rozing1, C. A. Van Blitterswijk2, R. M. Van Haastert2 and H. K. Koerten3 Journal of Materials Science: Materials in Medicine Volume 6, Number 2 / February, 1995
(25) The Influence of PVD Coatings on the Ion Release of Chromium Cobalt Alloys: DOT Gmbh and Nodrum GmbH 2006 .(on File)
(26) The Influence of TiN coating on the Wear Characteristics of TiAlVa against PMMA in a Pin-on-Disk Test: Bauman A (in German on File)
(27) Tribology of a TiN Coated Total Knee Implant against PE in a Knee Simulator: Dr. rer. nat. Kremling IMA Dresden GmbH (On File)
(28) Scratches on condyles in normal functioning total knee arthroplasty: M. Levesque, B.J. Livingston, W.M. Jones, and M. Spector, Trans. 44th Ann. Mtg. Orthop. Res. Soc., Orthopaedic Research Society, Chicago, IL, 1998, p.247
(29) Biologic and Tribologic Considerations of Alternative Bearing Surfaces: Pat Campbell, PhD, Fu-Wen Shen, PhD, and Harry McKellop, PhD CORR • Number 418, January 2004 98-111
(30) Kratzspuren auf Femurkomponent durch Arthroskopie Studie am Leichenknie mit CrCo und TiN implantaten: Witt M, Schröder L, Plath J Orthopaedisch universitätsklinik D 18055 Rostock (on file)
(31) Titanium Nitride Coatings for Orthopaedic Implants: DOT GmbH 2005 (On File)
(32) Characterizing and Optimizing the Allergy-Reducing PVD Coating in Medcial Applications: Retzlaff M. Thesis (in German on File)
(33) The Influence of Surface Treatment on the Surface Roughness of PVD Coatings: Bauman A . (In German on File)
(34) The Adherence Strength of TiN PVD Coatings on Orthopaedic Implant Alloys: Bauman A (in German on File)
(35) Metal Ion Release from Non-Coated and Ceramic Coated Femoral Knee Components: Boil test 240 h in NaCl-solution nach FMZ PhysWerk VA 97350, University Würzburg (D) (On File)

implantcast

implantcast GmbH
Lüneburger Schanze 26
D-21614 Buxtehude
Germany
phone: +49 4161 744-0
fax: +49 4161 744-200
e-mail: info@implantcast.de
internet: www.implantcast.de

CE 0123

Your local distributor:

TINCOOVE-051108