

Aesculap[®] Knee Arthroplasty

Oxinium versus AS Knee Systems



Aesculap Orthopaedics

Comparison Smith & Nephew Oxinium vs. Aesculap AS coating



Oxinium, Smith & Nephew

"OXINIUM is a truly advanced bearing material for total joint arthroplasty!"

It's not a coating – it can't be chipped away

■ Hardness 12.1 GPa

PE wear is reduced by 85 %

Oxinium has half the coefficient of friction against PE compared to CoCr

Complete Solution

Safe Solution

Reproducible Results

Superior Tribology



AS knee system, B. Braun Aesculap

Only for the femur! The other components such as tibia, stems, wedges are made of titanium.

- Titanium contains Nickel -> not a real allergy solution
- Backside wear is not negligible (30 %)¹ even for fixed platforms! This can lead to Nickel ion release!

AS is a real allergy solution for all implant components.

- Multilayer design has proven to be resistant against mechanical ablation through Rockwell and scratch testing
- Hardness 28 GPa
- Multilayer coating proven to withstand mechanical stress (bone chips and cement particles)²

Different Oxinium studies – different results for reduction rates from 42 % to 85 %. 85 % is a questionable result, read more...

The AS coating is a ceramic coating with superior wettability which leads to a lower coefficient of friction.

Read more – understand why

Smith & Nephew claims:

“OXINIUM is a truly advanced bearing material for total joint arthroplasty!”

■ Only for the femur!

The other components (tibia, stems, wedges, ...) are made out of titanium. Backside wear is not negligible even for fixed platforms!¹ McEwen et al. describe that backside wear in fixed platforms can contribute up to 30 % of the overall wear rate.

Oxinium's claim of wear reduction fails to include backside wear.

■ Oxinium does not have any nickel ion release from the femur; however, they can not ignore metal ion releases from the tibia!

Since the coefficient of friction between titanium and polyethylene is high (0.04-0.121) a relatively high amount of nickel metal ions can be released into the body (Fig. 1).

Metal ions have been shown in many studies to be present in serum after TKA.^{3, 4}

Any material placed in a biological environment undergoes corrosion. Thus, with their large metallic surfaces, TKA implants are particularly prone to corrosion with subsequent release of

metal ions into the human body which may cause local and systemic toxic effects and hypersensitivity reactions, and might even increase the risk of cancer.⁴

The prevalence of dermal sensitivity in patients with a joint replacement device, particularly those with a failed implant, is substantially higher than that in the general population.⁵

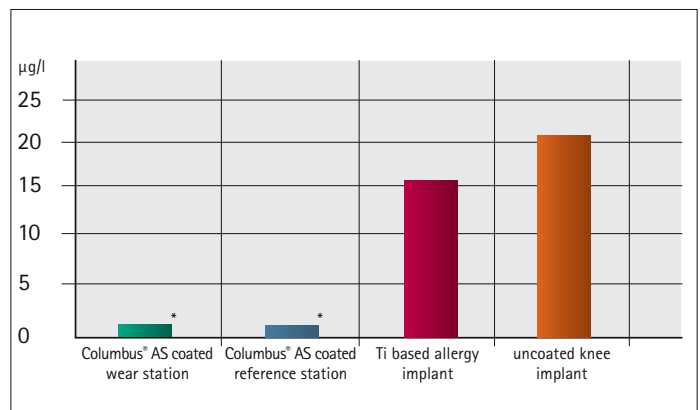


Fig. 1: Concentration of Ni ions in the lubricant of wear tests after 0.5 Mio. wear cycles.

*within the sensitivity of detection.

Metal ions can increase hypersensitivity reactions!

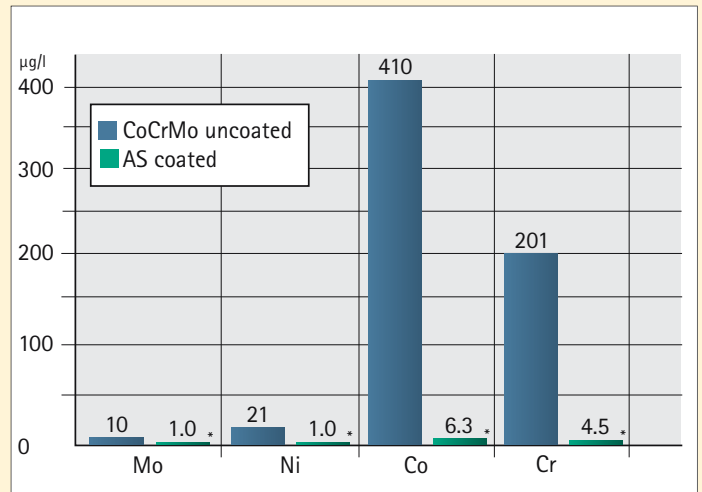


Fig. 2: Concentration of metal ions in serum after 1 million cycles.
*around threshold for detection⁶



A wide range of products is available in AS version for e.motion and Columbus.

Studies

- Clinical evidence: Prof. Thomas (Dermatological Hospital at the LMU Munich) has examined the effectiveness of the AS coating in patients with diagnosed nickel and cobalt hypersensitivity. The patients did not exhibit any reactions to the coated test samples whereas they showed clear reactions to the uncoated alloy samples.^{7,8}
- Laboratory measurements proved: AS coating does not release any metal ions -> All ion releases are around threshold for detection (Fig. 2).^{2,6,9}

**No metal ion release with AS implants.
All components are coated!**

Read more – understand why

Smith & Nephew claims:

It's not a coating – it can't be chipped away

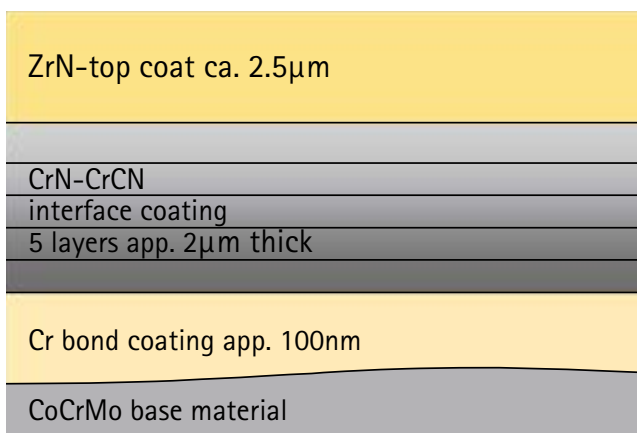
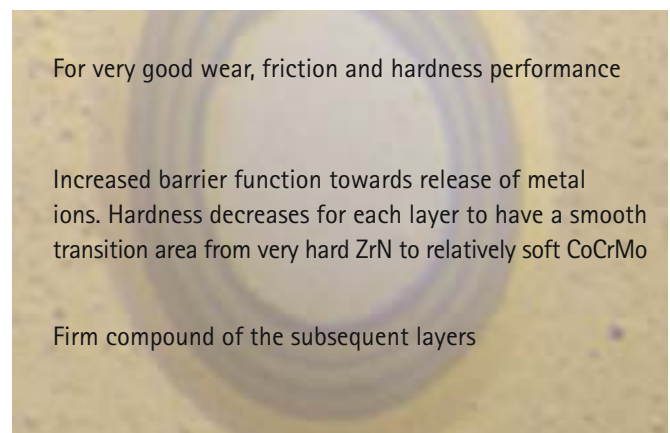


Fig. 3: Composition of the AS coating architecture.

- The multilayer design of the AS coating is mechanically consistent against ablation. AS implants have been successfully implanted since 2006, since then there has been no revision reported because of mechanical ablation problems (Fig. 3).

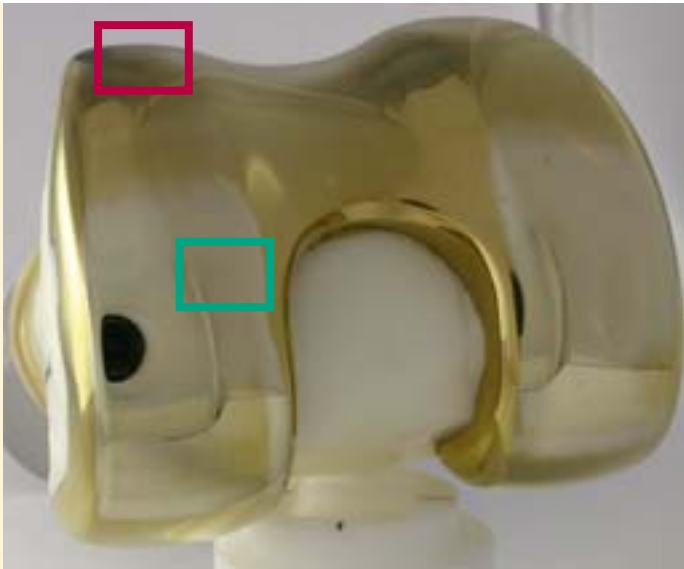
Problems with Monolayer PVD coatings have been reported in literature.^{10, 11} Compared to the monolayer coating, the multilayer AS coating has a strong proven improvement of mechanical ablation.²



We have proven the stability of the coating in different mechanical tests such as Rockwell test (VDI 3198) and scratch (Reve-Test) test (see brochure no. O36802 The Premium Knee System).^{2, 12}

In a mechanical stress test with the addition of cortical bone chips and bone cement particles after 1.0 million cycles no damage (scratch, nicks, etc.) could be detected on the condyle surfaces (Fig. 4).^{9, 12}

Multilayer coating is resistant against mechanical ablation!



Outside the area of articulation



Inside the area of articulation

Fig. 4: No scratches after 5 mio cycles + 1.0 mio cycles with cortical bone chips and cement particles

■ One reason for this highly resistant surface is the hardness of the material. Hardness of the AS coating is more than doubled compared to Oxinium! The hardness of the AS coating is 28 GPa compared to Oxinium 12.1 GPa and CoCr 5.4 GPa (Fig. 5).

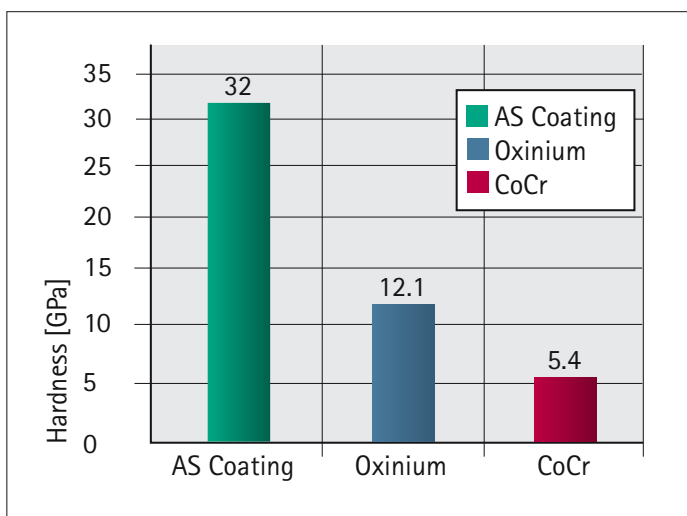


Fig. 5: Hardness of common implant materials.^{13, 14}

No scratches even under abrasive conditions!^{9, 12}

Read more – understand why

Smith & Nephew claims:

PE wear is reduced by 85 %

There are several studies available addressing the wear reduction of oxidized zirconium femur components¹⁵⁻¹⁸. Depending on the source the results differ tremendously from reduction rates of 42 % to up to 85 %. There are even more differences for the wear rates itself (0.69 mm³/Mc to 12.4 mm³/Mc), mostly due to varying test set up and conditions such as implant design.

The results from Spector et al.¹⁶ for the Oxinium wear rate are very low (0.69 mm³/Mc) compared to results from a comparison study (Triathlon vs Genesis Oxinium II: 12.1 mm³/Mc).¹⁹ Although one was PS and the other was CR, the difference between the two studies seem to be quite high.

One reason for the extreme low wear rate for Spector et al. could be the bovine concentration of the serum. Standard is 20 %, Spector et al. used 50 %. The higher the bovine serum concentration is the lower wear rates are. This also explains the low wear rate results for CoCrMo (0.69 mm³/Mc) implants in this study. Comparison values in literature for CoCrMo are between 6 and 12 mm³/Mc.

For all other studies (Table 1) the wear rate for Oxinium is between 11.6 mm³/Mc and 12.4 mm³/Mc which is even higher than wear rates for Columbus CR (8.8 mm³/Mc) uncoated.

In all wear rate tests for the AS coating we have reproducible reduction of wear of around 60 % (Table 2).

Despite improved results for wear rates, Göbel et al found a statistically significant higher rate of radiolucent lines in zones 1 and 4 at the tibia site in the zirconium group.²⁰

Reproducible results for wear rates.

Literature	Products	wear rate CoCrMo [mm ³ /Mc]*	wear rate Oxinium [mm ³ /Mc]	Reduction in %
Ezzet et al. ¹⁵	Profix	20.0	11.6	42 %
Tsukamoto et al. ¹⁷	Profix	28.5	12.4	56 %
Triathlon vs Genesis ¹⁹	Genesis II PS Oxinium	NA	12.1	-
Spector et al. ¹⁶	Genesis II CR	4.68	0.69	85 %

Table 1

Source	Products	wear rate CoCrMo [mm ³ /Mc]*	wear rate AS coating [mm ³ /Mc]	Reduction in %
Grupp + Schwiesau ²¹	Columbus CR	8.8	3.7	58 %
Grupp + Schwiesau ²² / Affatato et al. ²³ (unicondylar system)	univation M	3.7	1.4	62 %

Table 2

* 1 mg/Mc is equal to 1 mm³/Mc; 0.945 mg/mm³ (density)

Read more – understand why

Smith & Nephew claims:

Oxinium has half the coefficient of friction against PE compared to CoCr

This is the case for all ceramic surfaces. Oxinium does not have any advantages over other ceramic surfaces such as TiN or ZrN (AS) coatings.

The coefficient of friction decreases with a high wettability of the surface, which is excellent for the AS coating. Together with the very hard surface characteristics it leads to very low wear rates as biomechanical testing showed (Fig. 6).²¹⁻²⁵

Due to the low coefficient of friction the AS coating has reduced abrasive wear and reduced adhesive wear.

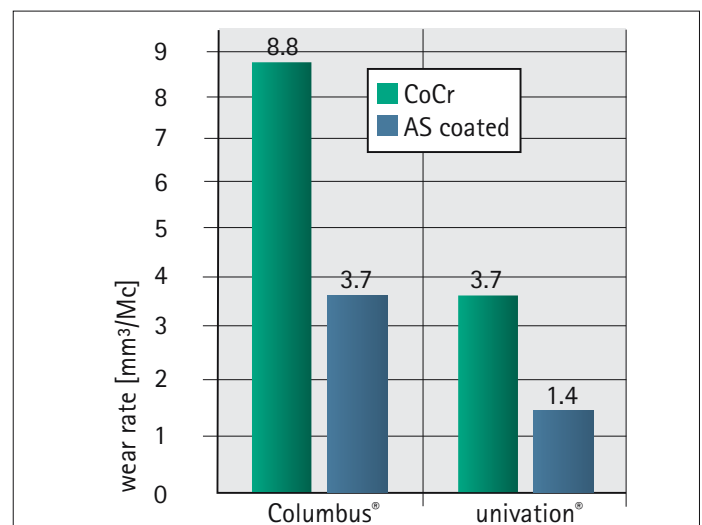


Fig. 6: Wear rates for Columbus and univation.²¹⁻²⁵



Columbus



univation

References

- 1) McEwen HM, Barnett PI, Bell CJ, Farrar R, Auger DD, Stone MH, Fisher J. The Influence of design, materials and kinematics on the in vitro wear of total knee replacements. *J Biomech.* 2005 Feb;38(2):357-65.
- 2) Thull R, Gradingner R. Allergy Solution for orthopaedic knee implants; *Biomaterialien* 2007;8(2):109-10.
- 3) Summer B, Fink U, Zeller R, Rueff F, Maier S, Roeder G, Thomas P. Patch test reactivity to a cobalt-chromium-molybdenum alloy and stainless steel in metal-allergic patients in correlation to the metal ion release. *Contact Dermatitis.* 2007 Jul;57(1):35-9.
- 4) Luetzner J, Krummenauer F, Lengel AM, Ziegler J, Witzleb WC. Serum metal ion exposure after total knee arthroplasty. *Clin Orthop Relat Res.* 2007 Aug;461:136-42.
- 5) Hallab N, Merritt K, Jacobs JJ. Metal sensitivity in patients with orthopaedic implants. *J Bone Joint Surg Am.* 2001 Mar;83-A(3):428-36.
- 6) Reich J, Hovy L, Lindenmaier HL, Zeller R, Schwiesau J, Thomas P, Grupp TM. Preclinical evaluation of coated knee implants for allergic patients. *Orthopade.* 2010 May;39(5):495-502.
- 7) Thomas P. [Allergic reactions to implant materials]. *Orthopade* 2003 Jan;32(1):60-4.
- 8) Thomas P. Einfluss einer Oberflächenbeschichtung auf die Nickel-, Chrom- und Kobaltfreisetzung aus Legierungsmetallen: Evaluierung über Eluatanalyse sowie über Hauttestreaktion und Reaktivität peripherer humaner Blutzellen. Internal test report 2008.
- 9) Grupp TM, Stulberg SD, Hovy L. Biotribology in total knee arthroplasty – influence of tibio-femoral congruency, bearing type and a new zirconium nitride coating on in vitro wear generation. 39^o Congresso Nazionale Ortopedici e Traumatologi Ospedalieri d'Italia. Monastier-Treviso, Italy 2008.
- 10) Raimondi MT, Pietrabissa R. The in-vivo wear performance of prosthetic femoral heads with titanium nitride coating. *Biomaterials.* 2000 May;21(9):907-13.
- 11) Harman MK, Banks SA, Hodge WA. Wear analysis of a retrieved hip implant with titanium nitride coating. *J Arthroplasty.* 1997 Dec;12(8):938-45.
- 12) B. Braun Aesculap brochure O36802 The Premium Knee System.
- 13) www.medthin.com (access date 2010-09-16)
- 14) Long M, Riester L, Hunter G. Nano-hardness measurements of oxidized Zr-2.5Nb and various orthopaedic materials. *Trans Soc Biomaterials.* 1998;21:528.
- 15) Ezzet KA, Hermida JC, Colwell CW Jr, D'Lima DD. Oxidized zirconium femoral components reduce polyethylene wear in a knee wear simulator. *Clin Orthop Relat Res.* 2004 Nov;428:120-4.
- 16) Spector BM, Ries MD, Bourne RB, Sauer WS, Long M, Hunter G. Wear performance of ultra-high molecular weight polyethylene on oxidized zirconium total knee femoral components. *J Bone Joint Surg Am.* 2001;83-A Suppl 2 Pt 2:80-6.
- 17) Tsukamoto R, Chen S, Asano T, Ogino M, Shoji H, Nakamura T, Clarke IC. Improved wear performance with crosslinked UHMWPE and zirconia implants in knee simulation. *Acta Orthop.* 2006 Jun;77(3):505-11.
- 18) White SE, Whiteside LA, McCarthy DS, Anthony M, Poggie RA. Simulated knee wear with cobalt chromium and oxidized zirconium knee femoral components. *Clin Orthop Relat Res.* 1994 Dec;(309):176-84.
- 19) Stryker Orthopaedics, Triathlon PS Knee System vs S&N Genesis II Oxinium PS System. *Knee Simulator Wear Results.*
- 20) Göbel F, Ulbricht S, Hein W, Bernstein A. Radiological mid-term results of total knee arthroplasty with femoral components of different materials. *Z Orthop Unfall.* 2008 Mar-Apr;146(2):194-9.
- 21) Grupp T, M Schwiesau J. Determination of the wear behaviour of the AS Columbus CR Knee System with ZrN coating. T075, 2008 May.
- 22) Grupp T, M Schwiesau T. Determination of the wear behaviour of the univication mobile knee system T018, 2007 Mar.
- 23) Affatato S, Spinelli M, Lopomo N, Grupp TM, Marcacci M, Toni A. Can the method of fixation influence the wear behaviour of ZrN coated unicompartmental mobile knee prostheses? *Clin Biomech (Bristol, Avon).* 2010 Oct 7. [Epub ahead of print]
- 24) Spinelli M, Grupp TM, Lopomo N, Marcacci M, Affatato S. Influence on wear behaviour of the unicompartmental knee prosthesis under different femur fixation. *Biomaterialien* 2010;11(S1):81.
- 25) Grupp TM, Affatato S, Jansson V, Müller P, Schwiesau J, Fritz B, Blömer W. Biotribology of a mobile unicompartmental knee bearing design, 18th European Orthopaedic Research Society Meeting, Davos, Switzerland 2010.

