Evidence in focus

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OXINIUM◊ Oxidized Zirconium - Materials science

June 2022

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Smith+Nephew

OXINIUM Oxidized Zirconium - An Overview

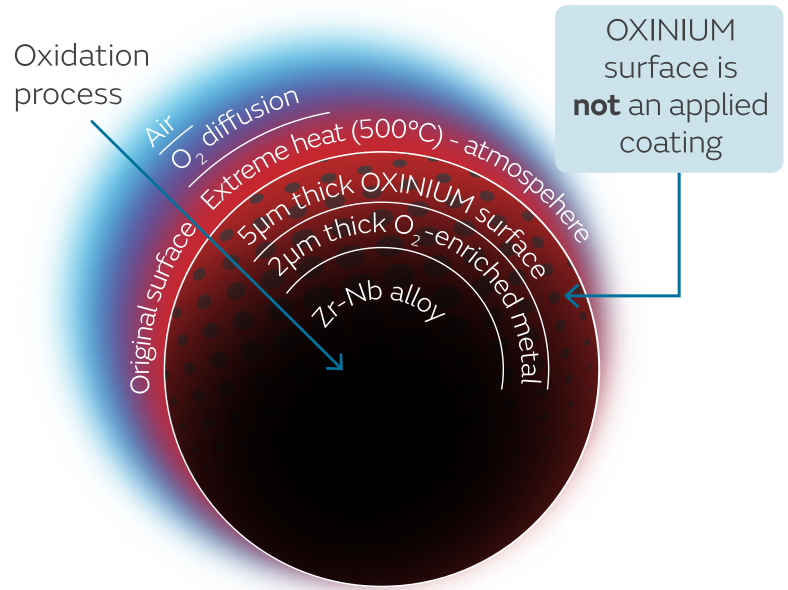
What is OXINIUM Technology?

Oxidized zirconium (**OXI**dized zirco**NIUM**) is a patented, advanced bearing material for hip and knee arthroplasty

- Alloy of 97.5% zirconium and 2.5% niobium
- Virtually no nickel, cobalt or chromium[1,2]

How is OXINIUM Technology manufactured?

The zirconium alloy core undergoes a transformation at its surface, upon heating, to form a ~5μm thick ceramicized surface[3]



Key properties of OXINIUM Technology

Wear resistance*

OXINIUM Technology demonstrates reduced polyethylene wear compared with cobalt chrome (CoCr),[4] and similar wear to ceramic at 45 million cycles[5]

Compared with CoCr, OXINIUM Technology is also:

- harder[6†] and more abrasion resistant[7†]
- more wettable[8†] and has lower friction[9†]

Strength and stability

- OXINIUM Technology behaves with the strength of a metal[10] and has been shown to withstand fracture under application of strong force[11]
- Zero recorded instances of brittle fracture in total joint arthroplasty in the published literature[12]

Biocompatibility

OXINIUM Technology (zirconium oxide and zirconium alloy) demonstrates reduced cytotoxicity and cellular inflammatory response‡ in vitro compared with CoCr and other materials[13]

Corrosion and fretting resistance

OXINIUM Technology shows lower corrosion damage compared with CoCr[14,15] and ceramic[16,17]

OXINIUM Technology combines the strength of metal with the wear resistance and biocompatibility of ceramic and corrosion resistance better than both[4–17]

*The results of in vitro wear simulation testing have not been proven to quantitatively predict clinical wear performance. †Material property refers specifically to the oxide surface of OXINIUM.
‡The results of in vitro cytokine expression analyses have not been proven to quantitatively predict clinical cytokine expression.

Key evidence

Knee Hip Material

Click on the **arrow** by the study name to view the study summary, and **click on** the **property icons** to the right to view the corresponding property summary

Study	Wear resistance	Strength and stability	Biocompatibility*	Corrosion/fretting resistance
Ezzet K, et al. 2012[18]	✓			
Good V, et al. 2003[19]	✓			
Morrison M, et al. 2015[20]	✓			
Papannagari R, et al. 2011[21]	✓			
Parikh A, et al. 2009[22]	✓			
Parikh A, et al. 2013[4]	✓			
Ries MD, et al. 2002[23]	✓			
Hobbs LW, et al. 2005[24]		✓		
Sprague J, et al. 2004[11]		✓		
Tsai S, et al. 2001[10]		✓		
Caicedo M, et al. 2014[25]			✓	
Rose SF, et al. 2012[26]			✓	
Cartner J, et al. 2017[14]				✓
Hampton C, et al. 2019[15]				✓
Pawar V, et al. 2005[27]				✓

*Particles tested in these studies were derived from diffusion-hardened OXINIUM Oxidized Zirconium material.

Further studies

11 publications

Abbreviations

References

Interactivity has been included throughout the collection of evidence to aid navigation

Menu will bring you back to this menu page

Banners at the bottom of each page will take you to previous or subsequent pages, as indicated

Key evidence is represented in **turquoise** and further evidence in **brown**

Wear resistance

Property summary:

Wear resistance

Wear resistance refers to the susceptibility of implant components to wear processes such as abrasion, scratching and fracture. Component and liner wear-related complications have a significant impact on implant longevity and are shown to be a major cause of revision and reoperation[4,19,28]

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OXINIUM Oxidized Zirconium shows reduced in vitro wear compared with CoCr, as evidenced by:[4,7,18,19,21–23,29–31*]

Lower wear rates following articulation against polyethylene liners[4,18,19,22,23,29,31]

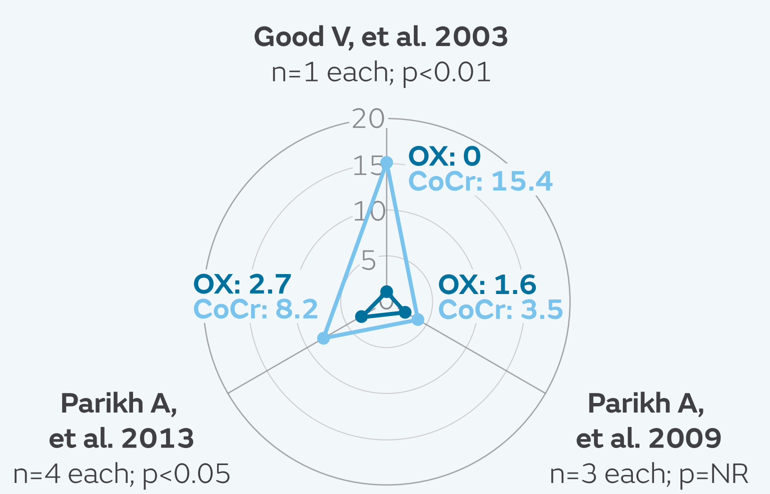


Figure 1. Wear rate (mm³/million cycles) of OXINIUM and CoCr femoral heads articulated against highly cross-linked polyethylene (XLPE) liners

- Fewer wear particles[19,23]
- Lower femoral damage scores in retrieved implants[30]
- Less scratching[7,29] and lower roughness[7,30] of retrieved implants

OXINIUM femoral heads exhibit a lower wear rate than ceramic heads in vivo:[32]

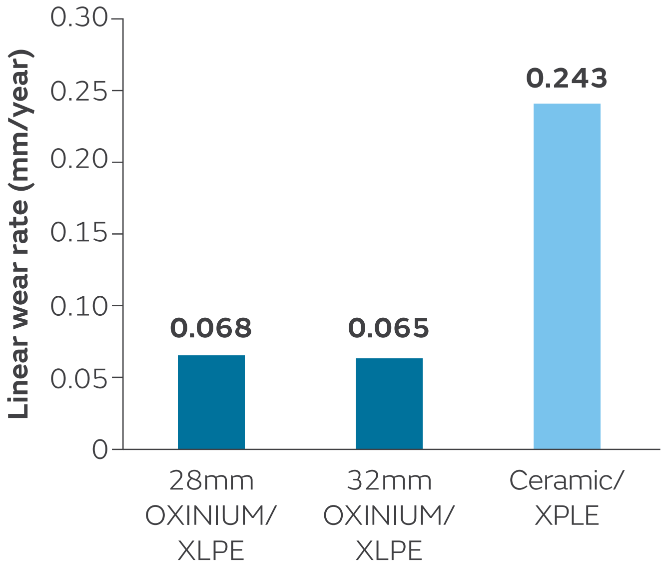


Figure 2. Linear wear rate of OXINIUM and ceramic femoral heads articulated against XLPE liners

OXINIUM Technology demonstrates superior wear resistance and reduced surface damage compared with CoCr in laboratory and retrieval studies[4,7,18,19,21–23,29–32*]

*The results of in vitro wear simulation testing have not been proven to quantitatively predict clinical wear performance.

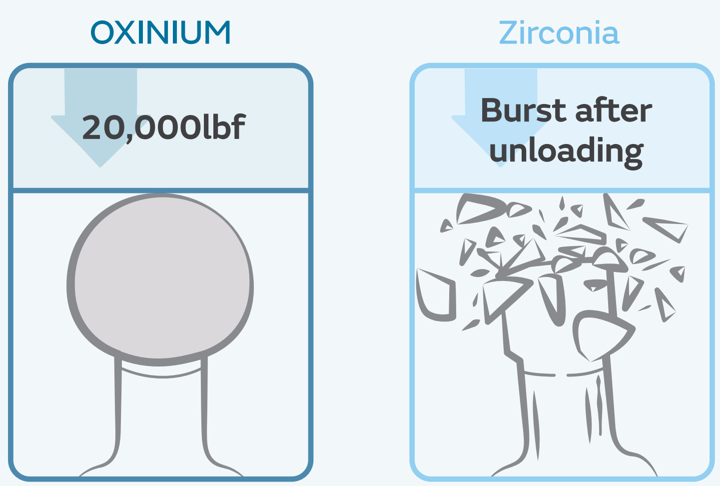
Strength & stability

Property summary:

Strength and stability

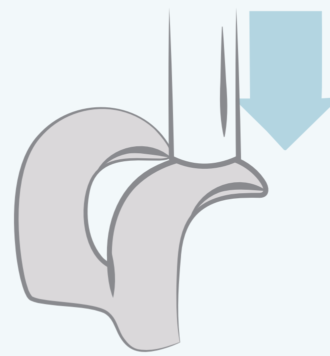
Strength refers to a material's toughness and, as a result, its ability to avoid chipping or fracture under application of force. The chemical stability of materials contributes to their susceptibility to mechanical and chemical wear during implantation

OXINIUM Oxidized Zirconium exhibits high fracture resistance in laboratory strength testing[10,11]



OXINIUM femoral heads withstood strong force without fracture, whilst zirconia heads withstood the maximum load but burst after unloading[11]

OXINIUM Technology behaves like metal under application of strong force[10]



OXINIUM knee components withstood cyclic loads estimated to be 13 times body weight without fracture[10]

Under application of substantial loads when fractures did occur, OXINIUM fractures demonstrated:[10]

- A clean break with a metal-like fracture mechanism
- No evidence of oxide delamination

The surface stability of OXINIUM Technology reduces the impact of ageing and mechanical stress compared with ceramic, including:[11]

- Less surface roughening[11]
- Reduced in vitro and in vivo phase transformation[11]

OXINIUM Technology behaves with the strength of a metal, resisting fracture under high mechanical stress in laboratory testing,[10,11] and its surface stability reduces the impact of ageing and mechanical stress versus ceramic[11]

Biocompatibility

Property summary:
Biocompatibility

Nickel (Ni), cobalt (Co) and chromium (Cr) are sensitizers in 10–15% of the general population.[33] Inflammatory responses to metal debris released by orthopaedic implants may contribute to aseptic loosening and periprosthetic osteolysis, potentially accelerating implant failure[13,25]

OXINIUM Oxidized Zirconium contains almost no Ni, Co and Cr compared with CoCr[1]

	OXINIUM	CoCr
Ni	<0.0035%	<0.5%
Co	<0.002%	59–67%
Cr	<0.02%	27–30%

OXINIUM Technology (zirconium oxide and zirconium alloy particles*) leads to improved in vitro cellular viability (ie. reduced cytotoxicity) vs CoCr in:[13,34]

- **Osteoblasts**
- **Macrophages**
- **Fibroblasts**

OXINIUM Technology (zirconium oxide and zirconium alloy particles*) induces lower inflammatory cytokine expression vs CoCr in vitro[13,34†]

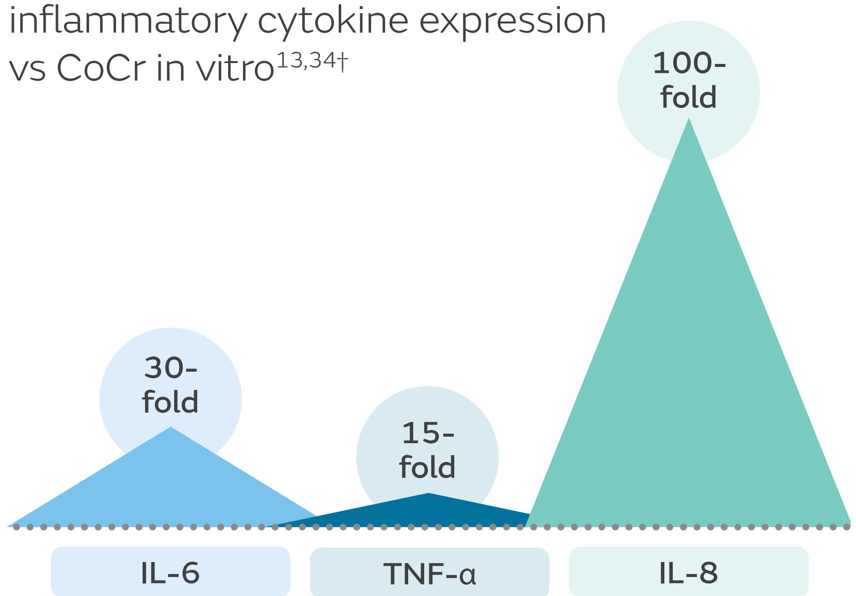


Figure. Fold-change in inflammatory cytokine expression seen with Co-alloy particles versus zirconium oxide and alloy particles in vitro*

OXINIUM Technology contains very low levels of Ni, Co and Cr,[1] and zirconium oxide and underlying zirconium particles demonstrate improved cellular viability and lower inflammatory response versus CoCr in vitro[13,25,26,34†]

*Derived from DH-OXINIUM material. †The results of in vitro cytokine expression analyses have not been proven to quantitatively predict clinical cytokine expression.

Corrosion/ fretting resistance

Property summary:

Corrosion and fretting resistance

Taper corrosion is the degradative wear of the taper junctions of modular implants and may result in the release of metal ions and construct instability. Taper corrosion is a known cause of problems with implant longevity[35,36]

OXINIUM Oxidized Zirconium shows fewer signs of corrosion damage compared with CoCr, including:[14–16,27,37]*

Lower mean Goldberg corrosion scores in retrieved hip and knee components[14,15,27,37]

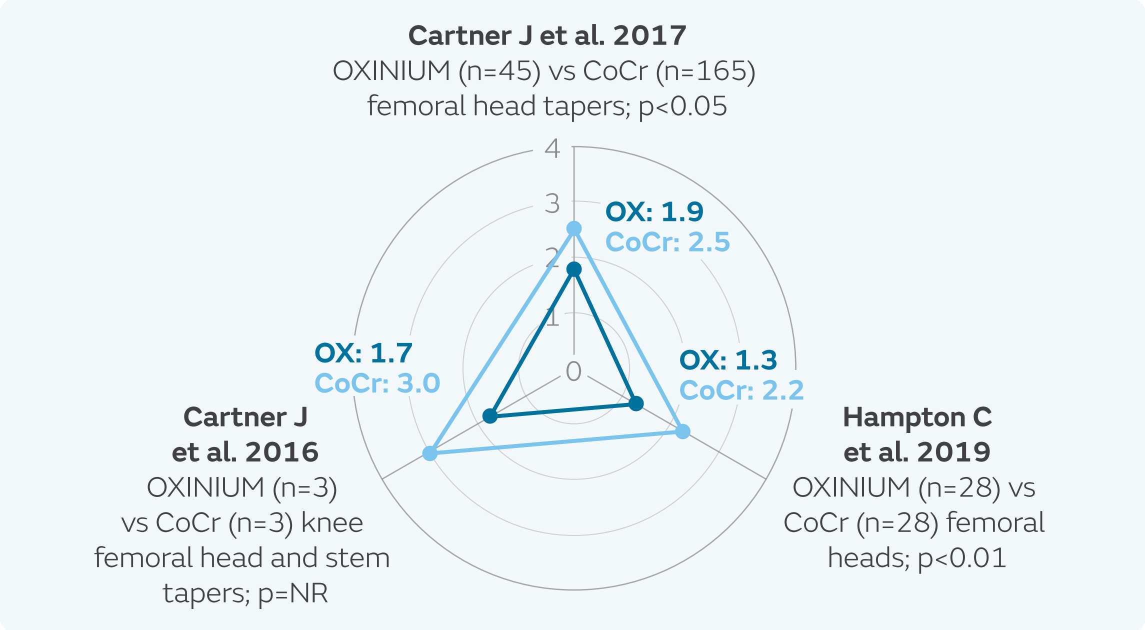


Figure 1. Mean Goldberg corrosion scores for retrieved OXINIUM and CoCr components across three studies

Reduced incidence of material loss due to MACC in worst-case retrieved femoral heads[14]

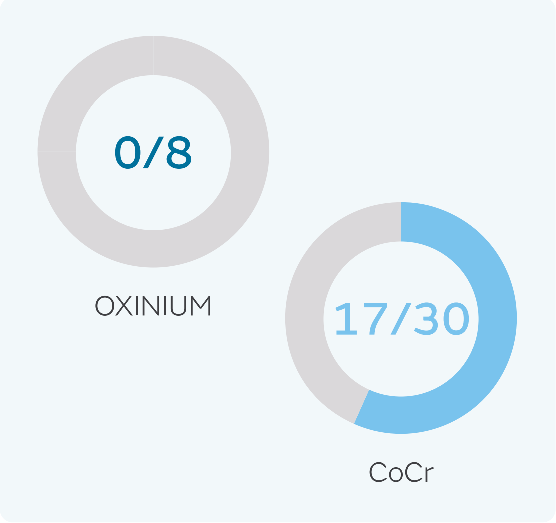


Figure 2. Proportion of retrieved OXINIUM and CoCr femoral heads with Goldberg corrosion scores >3 that exhibited material loss due to MACC

- No corrosion-induced discolouration[27,37]
- Less extensive fretting scars[27,37]
- Less metal transfer[27]
- Significantly lower metal ion concentrations on femoral heads (p<0.05)[16]

OXINIUM Technology demonstrates superior corrosion and fretting resistance compared with CoCr and other materials in laboratory and retrieval studies[14–16,27,37]*

*The results of in vitro wear simulation testing have not been proven to quantitatively predict clinical wear performance.

Wear resistance
Knee

Wear of polyethylene against oxidized zirconium femoral components: effect of aggressive kinematic conditions and malalignment in total knee arthroplasty[18]

Ezzet K, Hermida J, Steklov N, D'Lima D. *J Arthroplasty*. 2012;27:116–121.

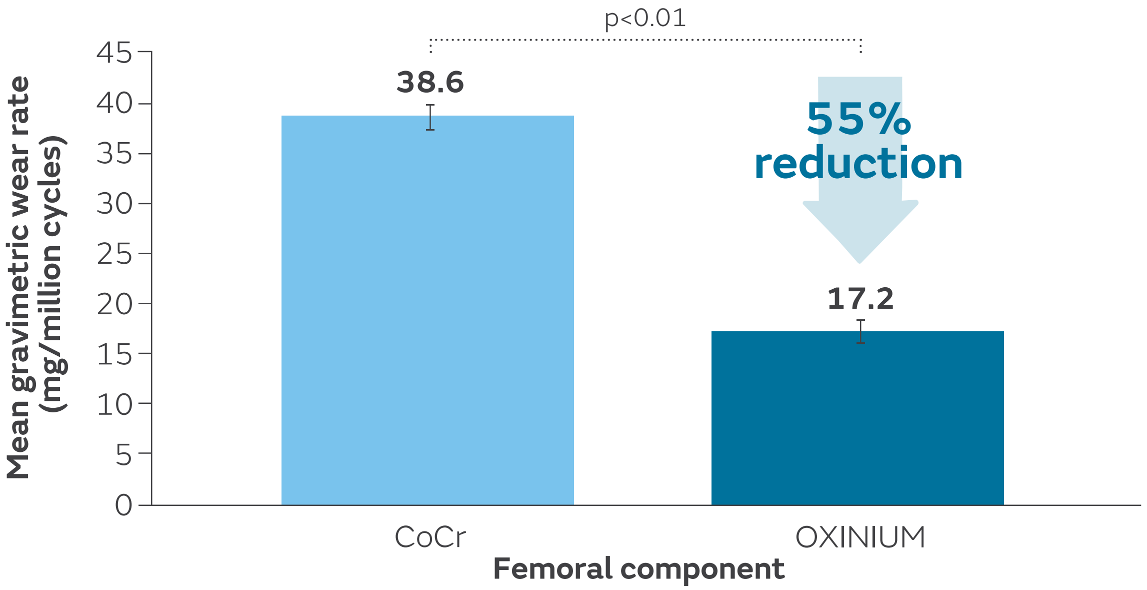
Objective

Determine whether OXINIUM Oxidized Zirconium femoral components can reduce polyethylene wear under conditions of varus malalignment (75:25 mediolateral distribution of vertical tibial load) and excessive tibiofemoral rotations (20° tibial axial rotation) in vitro

Results

The mean±SD gravimetric conventional polyethylene (CPE) wear rate was 55% lower with OXINIUM versus CoCr components (17.2±1.2 vs 38.6±1.3mg/million cycles, respectively; $p<0.001$; Figure)

Volumetric CPE wear rate was also significantly lower with OXINIUM versus CoCr components ($p<0.001$)



Values reported in the original material have been rounded to 1 d.p. in the present summary.

Figure. Mean gravimetric CPE wear rate with CoCr and OXINIUM femoral components

Conclusion

OXINIUM femoral components substantially reduced CPE wear compared with CoCr under simulated conditions of athletically active patients with modestly malaligned TKA prostheses

Link to published paper

Wear resistance
Hip

Reduced wear with oxidized zirconium femoral heads[19]

Good V, Ries M, Barrack RL, Widding K, Hunter G, Heuer D. *J Bone Joint Surg Am.* 2003;85-A Suppl 4:105–110.

Objective

Evaluate the in vitro wear characteristics of CPE and 10-XLPE liners articulating against OXINIUM Oxidized Zirconium femoral heads under both smooth and clinically relevant, roughened conditions using a hip simulator

Results

Wear rate for CPE liners was significantly lower when articulated against OXINIUM heads than CoCr heads under all test conditions ($p<0.01$; Figure)

Wear rate for 10-XLPE liners was undetectable when articulated against smooth or rough OXINIUM heads, but wear was detected with rough CoCr heads (Figure)

Compared with CoCr heads, smooth and rough OXINIUM heads generated fewer polyethylene particles per cycle against CPE (-30%; $p=0.01$ and -45%; $p<0.01$, respectively), and fewer polyethylene particles per cycle against 10-XLPE (-27%; $p=0.03$ and 63%; $p=0.03$, respectively)

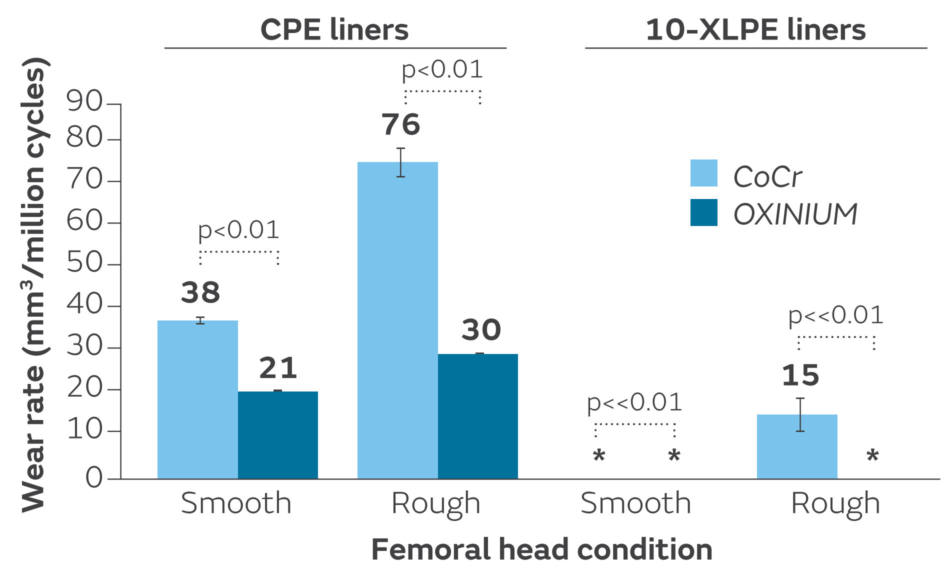


Figure. Wear rate of CPE and 10-XLPE liners against CoCr and OXINIUM femoral heads under smooth and roughened conditions

*Wear undetectable.

Conclusion

OXINIUM heads produced significantly less wear and fewer polyethylene particles than CoCr heads when articulated against CPE and XLPE liners, under both smooth and clinically relevant, roughened conditions

Link to published paper

Wear resistance
Knee

Design of an advanced bearing system for total knee arthroplasty[20]

Morrison M, Jani S, Parikh A. *Lubricants.* 2015;3:475–492.

Objective

Evaluate the in vitro wear performance of 5-XLPE and 7.5-XLPE tibial inserts coupled with OXINIUM Oxidized Zirconium and CoCr femoral components under pristine and rough conditions using a knee simulator

Results

Mean±SD wear rates of 5-XLPE and 7.5-XLPE tibial inserts articulating against pristine OXINIUM components were lower (72 and 79%, respectively; p≤0.001) than with pristine CoCr components (Figure)

Mean±SD wear rates of 5-XLPE and 7.5-XLPE tibial inserts articulating against rough OXINIUM components were also lower (80 and 83%, respectively; p≤0.003) than with pristine CoCr components (Figure)

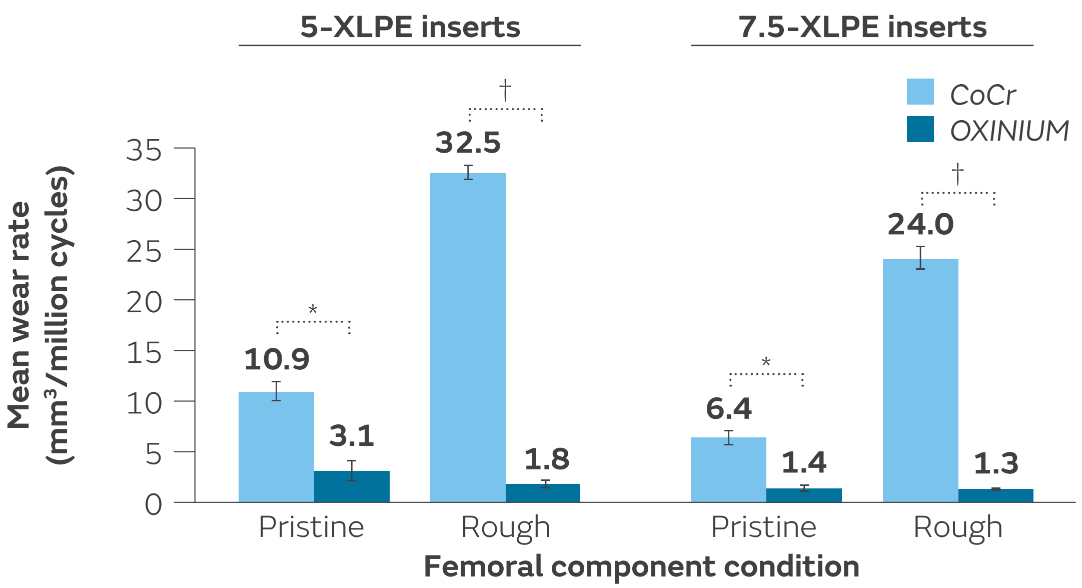


Figure. Wear rate of 5-XLPE and 7.5-XLPE tibial inserts against OXINIUM and CoCr femoral components

*†Denotes statistical difference of p≤0.001 and p≤0.003, respectively.

Conclusion

OXINIUM femoral components coupled with 5-XLPE and 7.5-XLPE tibial inserts demonstrated superior wear resistance versus CoCr components under both pristine and rough conditions

Link to published paper

Wear resistance
Knee

Long-term wear performance of an advanced bearing technology for TKA[21]

Papannagari R, Hines G, Sprague J, Morrison M. Poster presented at: Orthopaedic Research Society Annual Meeting; 2011; Long Beach, CA.

Objective

Evaluate the long-term in vitro polyethylene wear performance of OXINIUM Oxidized Zirconium femoral components (LEGION◊ Cruciate Retaining [CR] TKA) coupled with 7.5-XLPE tibial inserts and CoCr femoral components (LEGION◊ CR TKA) coupled with CPE tibial inserts using a knee simulator

Results

Compared with CoCr/CPE couples after 5 million cycles (120.4±12.0mm^3), the mean±SD volumetric wear of OXINIUM/7.5-XLPE couples was 98% lower after 5 million cycles (2.7±1.5mm^3; $p<0.01$) and 81% lower after 45 million cycles (22.8±7.2mm^3; $p<0.01$; Figure)

OXINIUM femoral component roughness did not change during wear testing ($p>0.05$) and there was no measurable loss of oxide surface

Values reported in the original material have been rounded to 1 d.p. in the present summary.

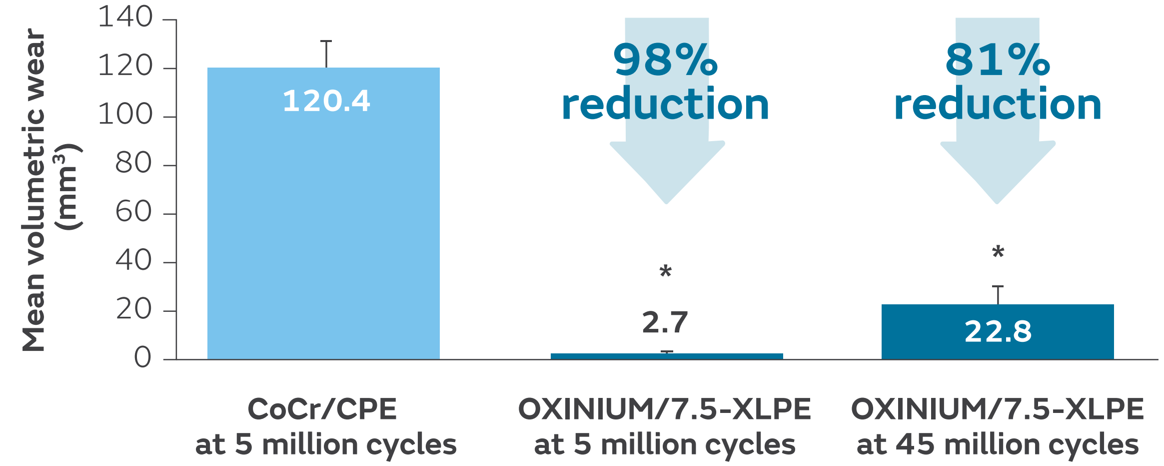


Figure. Mean volumetric wear of CoCr/CPE and OXINIUM/7.5-XLPE couples

*Denotes statistical difference ($p<0.01$) versus CoCr/CPE.

Conclusion

OXINIUM femoral components coupled with 7.5-XLPE tibial inserts demonstrated superior long-term wear resistance compared with CoCr heads and CPE inserts. OXINIUM components were in excellent condition following 45 million cycles of lab testing

Link to published poster

Wear resistance

Hip

Wear of conventional and highly crosslinked polyethylene liners during simulated fast walking/jogging[22]

Parikh A, Hill P, Hines G, Pawar V. Poster presented at: Orthopaedic Research Society Annual Meeting; 2009; Las Vegas; NV.

Objective

Determine if OXINIUM Oxidized Zirconium femoral heads provide an advantage over CoCr femoral heads during simulated fast walking/jogging in vitro

Results

The mean±SD wear rate of 10-XLPE liners was significantly lower when articulated against 36mm OXINIUM versus CoCr heads (1.6±0.2 and 3.5±0.2mm^3/million cycles, respectively; $p<0.01$)

The cumulative wear of 10-XLPE liners was lower with 36mm OXINIUM versus CoCr heads when tested under fast walking/jogging conditions (Figure)

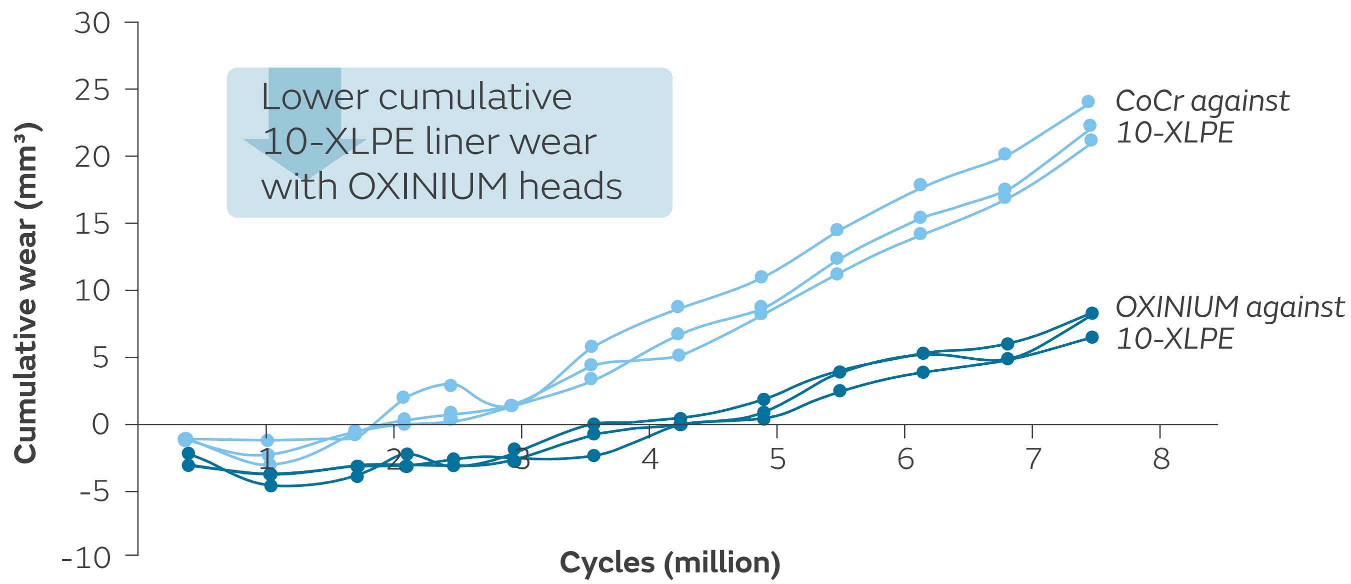


Figure. Cumulative wear of 10-XLPE liners articulated against 36mm OXINIUM and CoCr heads

Conclusion

OXINIUM femoral heads demonstrated superior wear resistance to CoCr femoral heads during simulated moderate physical activity

Wear resistance

Hip

Long-term simulator wear performance of an advanced bearing technology for THA[4]

Parikh A, Hill P, Pawar V, Sprague J. Poster presented at: Orthopaedic Research Society Annual Meeting; 2013; San Antonio, TX.

Objective

Assess the long-term in vitro polyethylene wear performance of OXINIUM Oxidized Zirconium femoral heads coupled with 10-XLPE liners using a hip simulator

Results

Mean volumetric liner wear after 45 million cycles with OXINIUM femoral heads and 10-XLPE was 67% lower than with CoCr and 10-XLPE ($p<0.05$; Figure), and 80% lower than with CoCr and CPE after 7.8 million cycles ($p<0.05$)*

No significant loss in OXINIUM femoral head surface thickness was observed over 45 million cycles

*Approximately 7.8 and 45 million cycles of testing were completed for CPE and 10-XLPE liners, respectively.

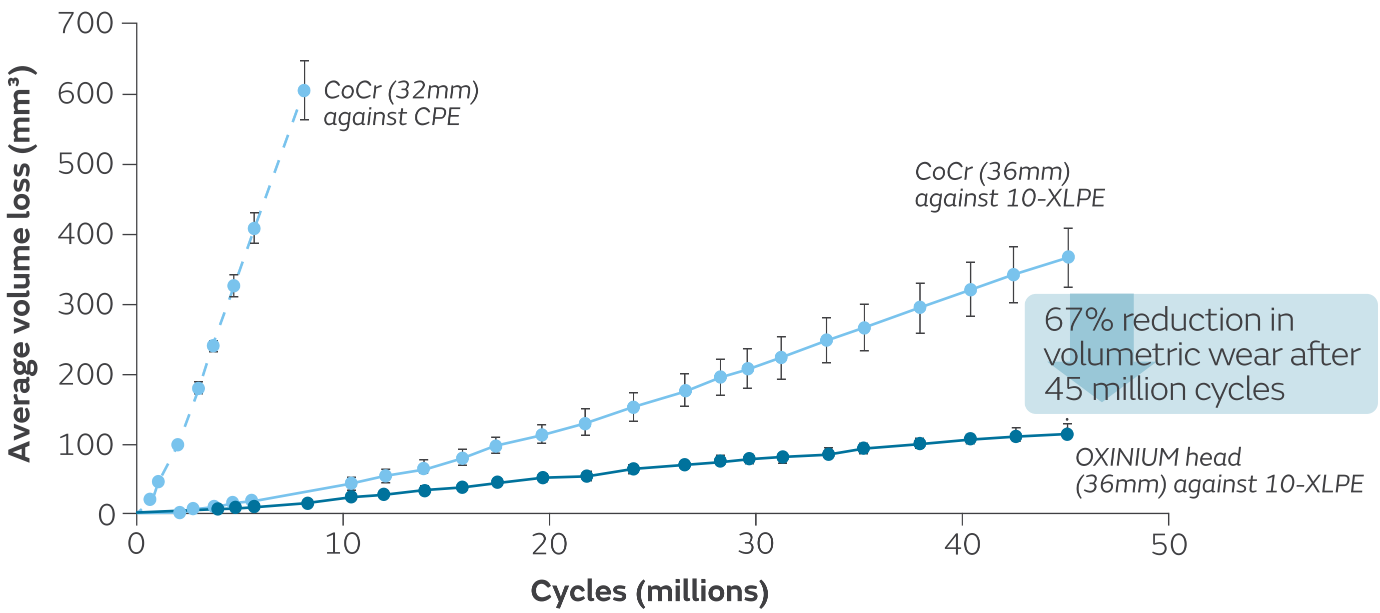


Figure. Mean volumetric liner wear with CoCr and OXINIUM femoral heads

Conclusion

OXINIUM femoral heads combined with 10-XLPE liners demonstrated superior long-term wear resistance versus CoCr femoral heads coupled with either 10-XLPE or CPE liners in hip simulator testing

Link to published poster

Wear resistance

Knee

Polyethylene wear performance of oxidized zirconium and cobalt-chromium knee components under abrasive conditions[23]

Ries MD, Salehi A, Widding K, Hunter G. *J Bone Joint Surg*. 2002;84-A (S2):129–135.

Objective

Evaluate the in vitro polyethylene wear performance of OXINIUM Oxidized Zirconium and CoCr femoral components in vitro under abrasive conditions (produced through tumbling)

Results

The aggregate±SD wear rate of UHMWPE inserts was 89% lower with OXINIUM versus CoCr components following abrasion (5.3±0.6 vs 46.1±4.7mm^3/million cycles, respectively; $p<0.01$)

OXINIUM components produced 44% fewer submicrometre UHMWPE particles than CoCr ($p=0.02$)

Condyle roughness scores were lower for OXINIUM than CoCr components, suggesting that the former was roughened less by tumbling

Values reported in the original material have been rounded to 1 d.p. in the present summary.

Conclusion

OXINIUM femoral components demonstrate superior resistance to roughening versus CoCr components, which may have contributed to a reduction in wear under abrasive conditions

Link to published paper

Strength & stability

Material

Oxidation microstructures and interfaces in the oxidized zirconium knee[24]

Hobbs LW, Rosen VB, Mangin SP, et al. *Int J Appl Ceram Technol.* 2005;2:221–246.

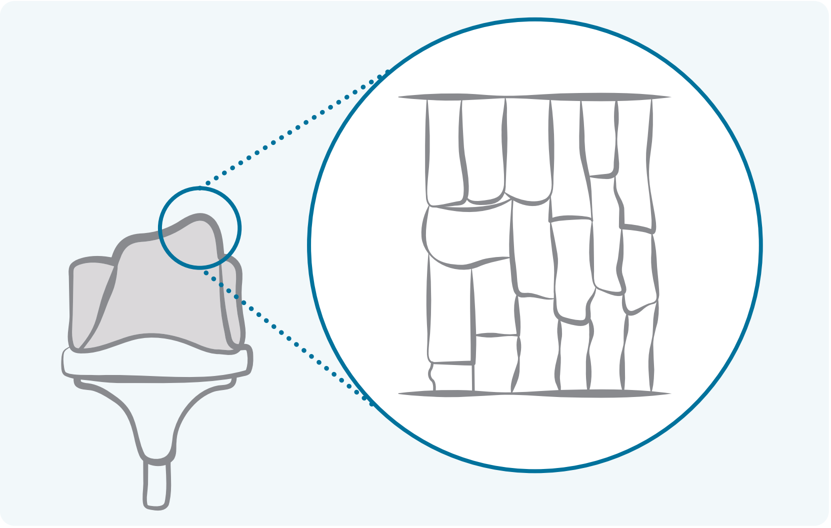
Objective

Characterise the microstructural basis for the surface durability and strong adherence of the oxide layer of OXINIUM Oxidized Zirconium Technology

Results

'Grains' of zirconium oxide arranged in columns were observed at the surface of the oxide layer and may contribute to its surface durability (Figure)

A lack of pores at the oxide-alloy interface and regions of alloy material anchoring the two layers were observed, potentially contributing to the strong oxide-alloy interface adhesion of the OXINIUM oxide layer



- Resistance to lateral crack propagation
- Maintenance of surface smoothness
- Resists extensive spallation

Figure. Columnar arrangement of OXINIUM oxide layer and features that may confer its surface durability

Conclusion

Microstructural features observed in the oxide and alloy layers, as well as at the oxide-alloy interface, may contribute positively to the wear resistance, low friction and strong adhesion of the OXINIUM oxide layer when used in orthopaedic applications

Link to published paper

Strength & stability

Hip

Mechanical behaviour of zirconia, alumina, and oxidized zirconium modular heads[11]

Sprague J, Salehi A, Tsai S, Pawar V, Thomas R, Hunter G. In: Brown S, Clarke IC, Gustafson A, eds. International Society for Technology in Arthroplasty. Birmingham, AL; 2004.

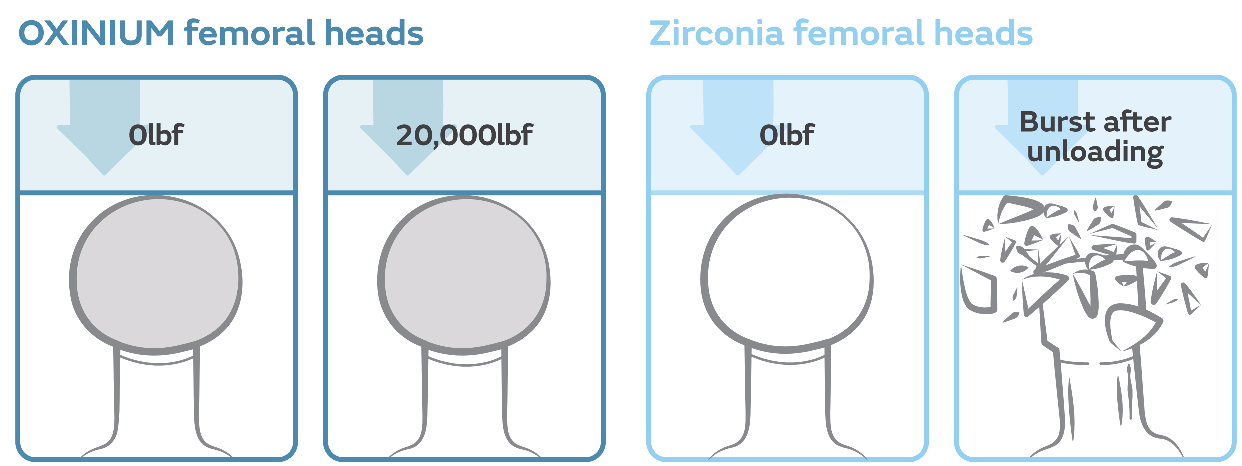
Objective

Compare the in vitro strength and stability of OXINIUM Oxidized Zirconium and ceramic (alumina and zirconia) femoral heads before and after autoclaving that simulated 80 years of in vivo ageing

Results

Pre- (n=3) and post-autoclaved (n=3) OXINIUM femoral heads did not fracture and displayed virtually no signs of damage at 20,000lbs of force during crush testing. By contrast, pre- (n=3) and post-autoclaved (n=2/3) zirconia heads withstood the maximum load but all burst after unloading (Figure), and alumina heads (n=6) all fractured during testing

OXINIUM heads were largely unaffected by autoclaving, whereas zirconia heads displayed phase transformation, surface roughening and microcracks



Conclusion

OXINIUM femoral heads did not display brittle fracture during crush testing and exhibited greater stability after autoclaving compared with ceramic heads

Strength & stability
Knee

Mechanical testing and finite element analysis of oxidized zirconium femoral components[10]

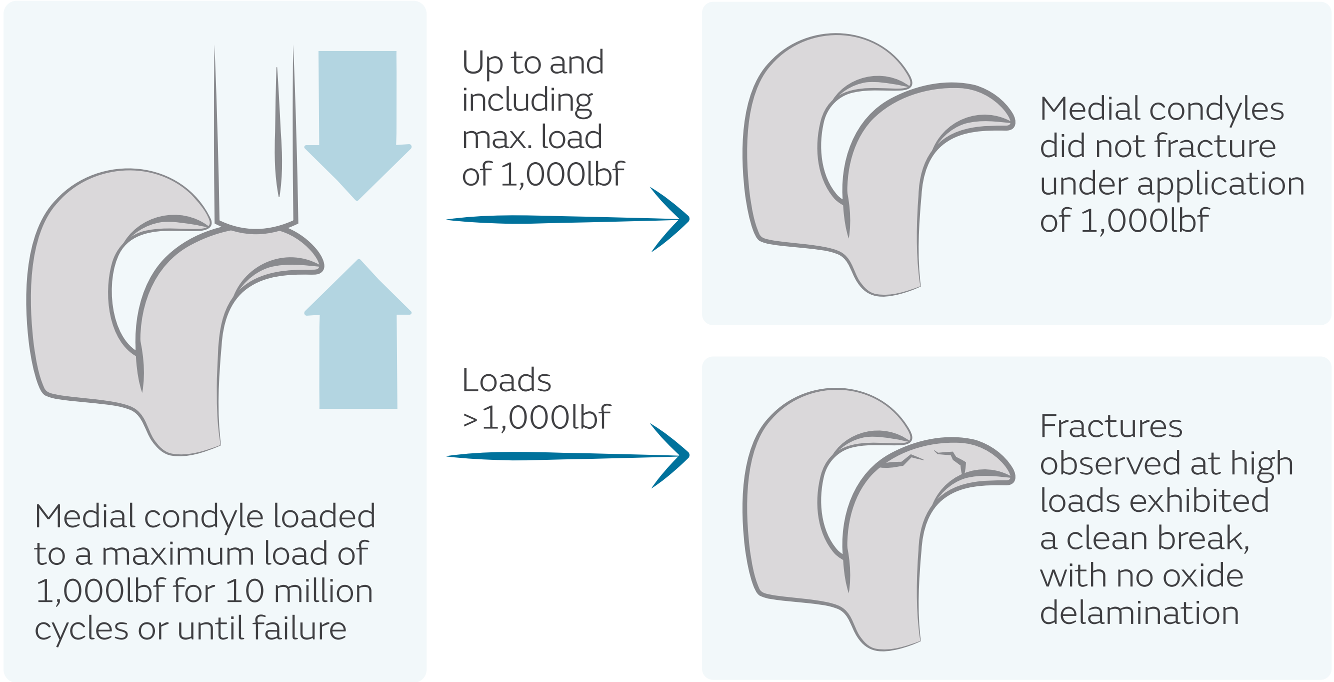
Tsai S, Sprague J, Hunter G, Thomas R, Salehi A. *Trans Soc Biomaterials*. 2001;24:163.

Objective

Evaluate the in vitro strength of OXINIUM Oxidized Zirconium femoral components (GENESIS◊ II TKA) during cyclic fatigue testing

Results

The medial condyle of OXINIUM knee femoral components (n=24) withstood a maximum fatigue load of 1,000lbf (equivalent to 6.67 times body weight) for 10 million cycles without fracture, and both medial condyles were estimated to be able to withstand the equivalent of 13 times body weight



Conclusion

Medial condyles of OXINIUM knee femoral components behaved like metal under application of strong force, and at higher loads fractured with a metal-like mechanism

Biocompatibility

Material

Oxidized Zr-alloy particles induce a lower incidence of in vitro lymphocyte metal-sensitivity responses compared to cobalt and titanium implant alloys[25]

Caicedo M, Pawar V, Hallab NJ. Poster presented at: Orthopaedic Research Society Annual Meeting; 2014; New Orleans, LA.

Objective

Compare the in vitro immune hypersensitivity response to OXINIUM Technology (zirconium oxide, zirconium alloy particles* and ziconium ions) with that of Co-alloy, Ti-alloy and bone cement particles using peripheral blood mononuclear cells from healthy volunteers (n=50)

Results

Zirconium ions did not induce a significant increase in the proliferation of cultured cells (quantified using the stimulation index†) in any of the subjects tested, with effectively 0% incidence of zirconium reactivity

The incidence of metal hypersensitivity (at a stimulation index of >4, indicating moderate reactivity) was substantially lower for zirconium oxide and zirconium alloy particles (0%) versus Ti-alloy (5%) and bone cement (5%; Figure)

†The stimulation index measures reactivity to different particles, with results that range from 0–2 (non-reactive), 2–4 (mildly reactive), 4–8 (reactive) and >8 (highly reactive).

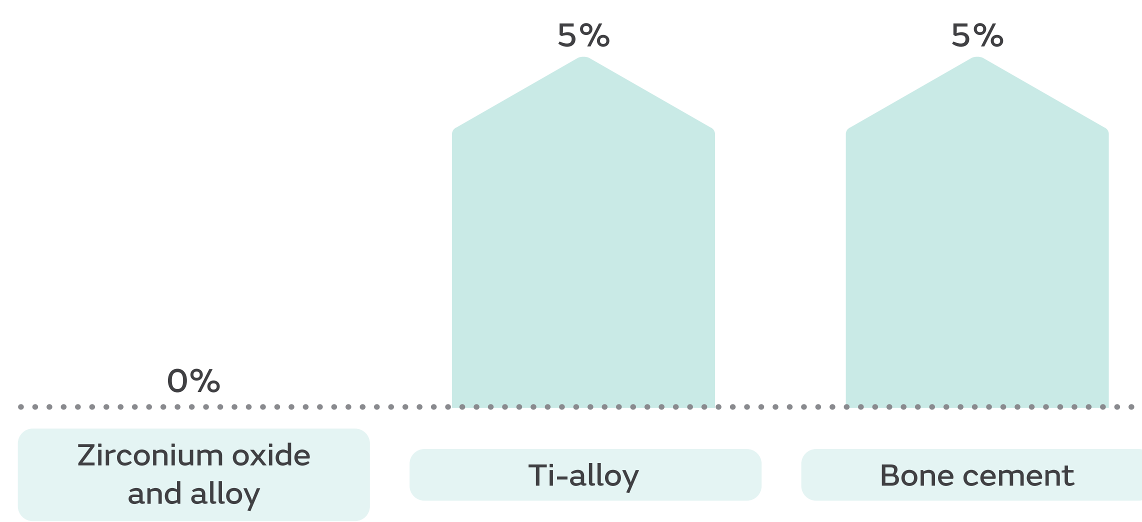


Figure. Incidence of hypersensitivity at a stimulation index >4 for zirconium oxide and alloy particles, Ti-alloy and bone cement particles

Conclusion

Zirconium oxide and zirconium alloy particles resulted in lower rates of in vitro lymphocyte hypersensitivity compared with Ti-alloy and bone cement

Link to published poster

*Derived from DH-OXINIUM material.

Biocompatibility

Material

The effect of diffusion hardened oxidized zirconium wear debris on cell viability and inflammation – an in vitro study[26]

Rose SF, Weaver CL, Fenwick SA, Horner A, Pawar VD. *J Biomed Mater Res Part B.* 2012;100B:1359–1368.

Objective

Evaluate the in vitro biocompatibility of wear debris generated by OXINIUM Technology (zirconium oxide and zirconium alloy particles*) compared with Ti, Co and CoCr

Results

Zirconium oxide and zirconium alloy particles did not induce significant increases in TNF release above the media control at most doses at 4 or 8 hours (except 1mg at 4 hours), in contrast to Ti, Co and CoCr, which dose-dependently stimulated TNF release at all timepoints (Table)

Wear debris generated by zirconium oxide and zirconium alloy particles demonstrated lower cytotoxicity than Co and CoCr in both osteoblast- and fibroblast-like cells

	4hr		8hr		24hr	
	0.1mg	1mg	0.1mg	1mg	0.1mg	1mg
Co	✓	✓	✓	✓	✓	✓
CoCr	✓	✓	✓	✓	✓	✓
Ti		✓	✓	✓	✓	✓
Zirconium oxide and alloy particles		✓			✓	✓

Table. Doses (mg) at which a significant increase in TNF release above the media control was observed following exposure to wear debris particles (tested doses were 0.001mg, 0.01mg, 0.1mg and 1mg)

Conclusion

Wear debris generated by zirconium oxide and zirconium alloy particles was less cytotoxic and elicited a reduced inflammatory response versus Co and CoCr†

Link to published paper

*Derived from DH-OXINIUM material. †The results of in vitro cytokine expression analyses have not been proven to quantitatively predict clinical cytokine expression.

Corrosion/ fretting resistance

Hip

Characterization of femoral head taper corrosion features using a 22-year retrieval database[14]

Cartner J, Aldinger P, Li C, Collins D. *HSS Journal*. 2017;13:35–42.

Objective

Compare taper corrosion severity and extent of material loss in retrieved CoCr and OXINIUM Oxidized Zirconium femoral heads

Results

CoCr femoral heads (n=165) exhibited higher average corrosion scores* compared with OXINIUM heads (n=45; 2.5±1.0 vs 1.9±0.7; $p<0.05$; Figure)

Of femoral heads with a corrosion score ≥3, measurable material loss due to MACC was found on 17/30 CoCr heads, and was not observed on any of the OXINIUM heads (0/8)

*Corrosion was assessed using the semi-quantitative Goldberg scoring system. Scores of 1 (none), 2 (mild), 3 (moderate) or 4 (severe) were assigned to taper surfaces depending on the level of discolouration, fretting and corrosion evidence according to Goldberg et al.[38]

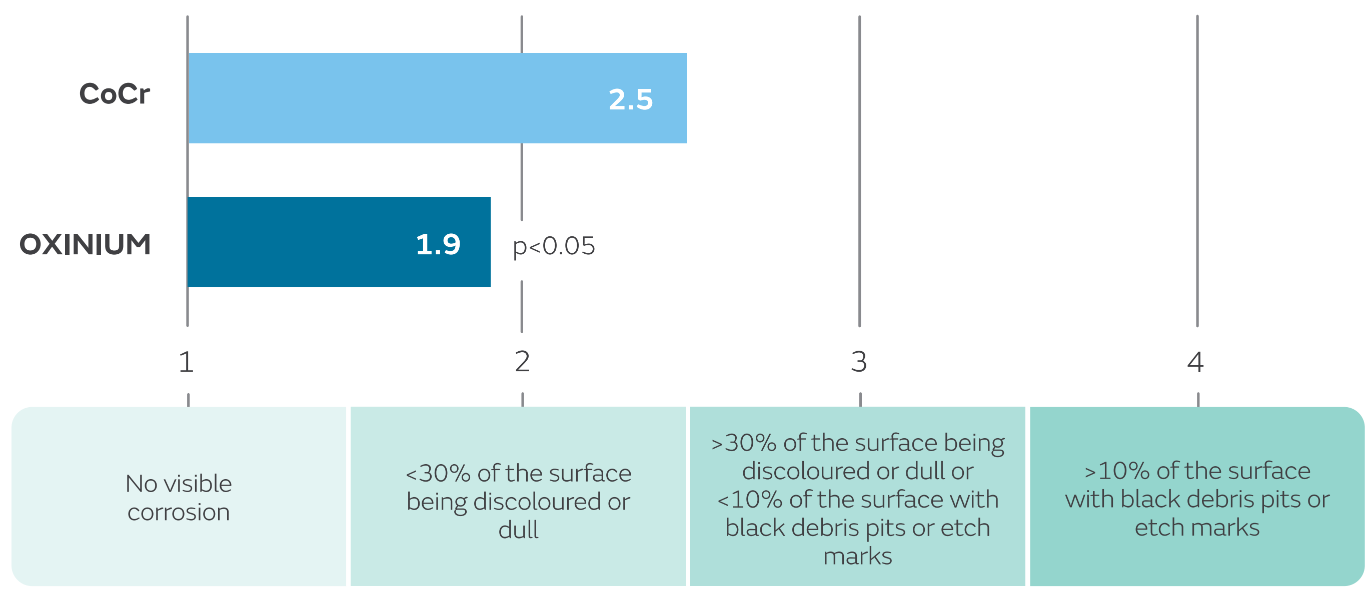


Figure. Mean corrosion score of retrieved CoCr and OXINIUM femoral heads

Conclusion

OXINIUM femoral heads were associated with less corrosion damage than CoCr heads, with lower corrosion scores and no evidence of material loss due to MACC

Link to published paper

Corrosion/ fretting resistance

Hip

Do oxidized zirconium heads decrease tribocorrosion in total hip arthroplasty?[15]

Hampton C, Weitzler L, Baral E, Wright TM, Bostrom MPG. *Bone Joint J*. 2019;101-B:386–389.

Objective

Evaluate female taper fretting and corrosion (tribocorrosion) in retrieved OXINIUM Oxidized Zirconium femoral heads and matched* CoCr heads (n=28 for both)

Results

OXINIUM femoral heads showed significantly lower mean [range] corrosion (1.3 [1–2.8] vs 2.2 [1–4]; p<0.01) and fretting scores† (1.3 [1–2] vs 1.5 [1–2.3]; p=0.02) compared with CoCr heads (Figure)

Fretting or corrosion was observed in 29% (8/28) of OXINIUM femoral heads, compared with 96% (27/28) of CoCr heads

Values reported in the original material have been rounded to 1 d.p. in the present summary. *Retrieved OXINIUM and CoCr femoral heads were matched according to length of implantation within ±5 months and patient BMI within ±3kg/m^2. †Corrosion and fretting was assessed using a modified Goldberg scoring system,[38] with scores of 1–4 assigned to each femoral head according to the criteria presented in the Figure.

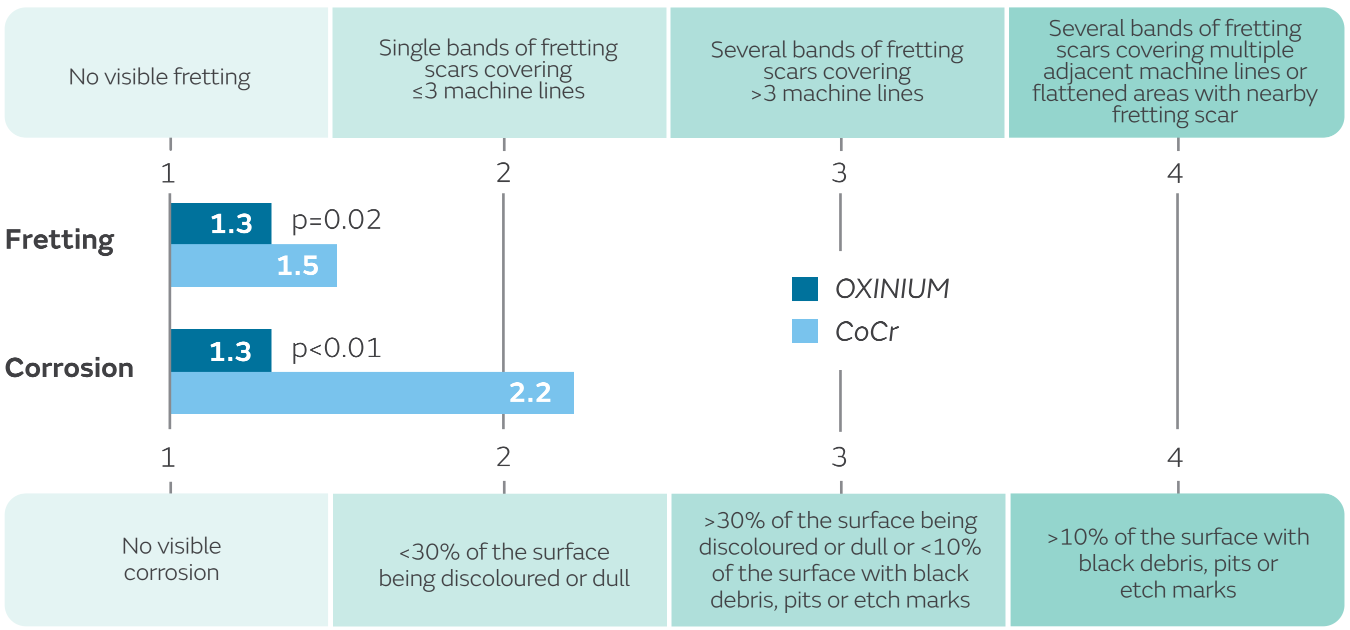


Figure. Mean fretting and corrosion scores of retrieved CoCr and OXINIUM femoral heads

Conclusion

Retrieved OXINIUM femoral heads displayed reduced taper fretting and corrosion compared with matched CoCr heads

Link to published paper

Corrosion/ fretting resistance

Hip

Acidic fretting tests of oxidized Zr-2.5Nb, CoCr and SS femoral heads[27]

Pawar V, Jones B, Sprague J, Salehi A, Hunter G. In: Medical Device Materials II: Proceedings of the Materials and Processes for Medical Devices Conference. Helmus M, Medlin D, eds. ASMI; 2005;403–408.

Objective

Evaluate the relative resistance of OXINIUM Oxidized Zirconium, CoCr and stainless steel (SS) femoral heads combined with Ti or SS stem trunnions to fretting corrosion damage following in vitro cyclic fatigue testing under extreme, supra-clinical conditions of elevated temperature and acidity

Results

Femoral head tapers and trunnions of OXINIUM-Ti/-SS combinations showed the lowest level of chemical attack with no discolouration and fewer signs of damage when compared with other head-trunnion combinations

Couple	Femoral head	Trunnion
CoCr-Ti	Cr-rich deposits and Ti transfer	Co-, Cr- and Mo-rich deposits
OXINIUM-Ti	Few areas of damage to the OXINIUM material and minimal Ti transfer	Fretting scars and weak Zr signal, no chemical etching or pitting
SS-SS	Extensive chemical activity, iron oxide and Cr-rich deposits	Iron oxide deposits
OXINIUM-SS	Few areas of damage to the OXINIUM material and small iron rich areas	Fretting scars, no chemical etching or pitting

Table. Observations on the taper of the femoral head and trunnion from several bearing combinations based on SEM/spectrometry analysis

Conclusion

OXINIUM-Ti/SS femoral-head trunnion combinations demonstrated the lowest levels of corrosion compared with the CoCr-Ti and SS-SS combinations

Wear resistance

Further studies

Wear resistance

Study	Design / n=	Key findings
Bourne RB, Barrack R, Rorabeck CH, Salehi A, Good V. **Arthroplasty options for the young patient**. *Clin Orthop Relat Res*. 2005;441:159–167.[29] Available at: Clinical Orthopaedics and Related Research	In vitro hip simulator testing of femoral heads damaged by simulated dislocation and undamaged heads; analysis of retrieved implants Implant tested: hip Six damaged OXINIUM Oxidized Zirconium heads (articulated against CPE liners, n=3; articulated against XLPE liners, n=3); four retrieved femoral heads (CoCr, n=2; OXINIUM, n=2)	• Hip simulator testing showed equivalent mean±SD wear rates for damaged OXINIUM heads and undamaged CoCr heads that were articulated against conventional UHMWPE liners (37.4±0.7 vs 38.5±0.7mm^3/million cycles, respectively; p=0.46)* – When articulated against XLPE liners, damaged OXINIUM heads demonstrated a low mean±SD wear rate of 2.4±0.3mm^3/million cycles* • Retrieval analysis revealed scratching of both types of metal femoral heads with in vivo use, though CoCr femoral heads showed more severe scratching compared with OXINIUM heads
Carli AV, Patel AR, Cross MB et al. **Long-term performance of oxidized zirconium on conventional and highly cross-linked polyethylene in total hip arthroplasty**. *J Int Soc Orthop Surg Traum*. 2020;6.[39] Available at: SICOT-J	Single-centre, longitudinal, retrospective study; in vivo radiographic assessment of polyethylene wear rates and osteolysis Implant tested: hip 168 patients who underwent THA with OXINIUM Oxidized Zirconium femoral heads (UHMWPE liners, n=80; XLPE liners, n=88)	• When compared with OXINIUM/UHMWPE couples (average follow-up: 10.5±1.2 years), OXINIUM/XLPE couples (average follow-up: 10.3±1.0 years) were associated with:* – A significantly lower mean±SD annual wear rate (0.05±0.03 vs 0.21±0.12mm/year, respectively; p<0.001) – A significantly lower incidence of acetabular osteolysis (0 vs 21.2%, respectively; p<0.001) and femoral osteolysis (0 vs 46.3%, respectively; p<0.001) • No OXINIUM/XLPE patients underwent revision THA, compared with six patients (7.5%) who received OXINIUM/UHMWPE

*Values reported in the original material have been rounded to 1 d.p.

Further studies

Wear resistance

Study	Design / n=	Key findings
Karidakis GK, Karachalios T. **Oxidized zirconium head on crosslinked polyethylene liner in total hip arthroplasty: A 7- to 12-year in vivo comparative wear study**. *Clin Orthop Relat Res*. 2015;473:3836–3845.[32] Available at: Clinical Orthopaedics and Related Research	Single-centre, prospective, randomised trial; in vivo assessment of polyethylene wear Implant tested: hip 85 patients who underwent THA with different femoral head/liner combinations and completed 10 years of follow up (28mm ceramic/CPE, n=20; 28mm ceramic/XLPE, n=21; 28mm OXINIUM Oxidized Zirconium, n=23; 32mm OXINIUM/XLPE, n=22)	• At 10 years follow-up, compared with both 28mm ceramic groups, the 28mm OXINIUM/XLPE group showed: – Lower mean±SD volumetric wear (28mm OXINIUM/XLPE: 35.6±6.4; ceramic/CPE: 89.5±13.1; ceramic/XLPE: 162.5±25.3mm^3) – Lower mean±SD volumetric wear rates (OXINIUM/XLPE: 21.5±5.4; ceramic/CPE: 38.0±8.0; ceramic/XLPE: 48.0±10.1mm^3/year • Compared with both 28mm ceramic groups, the 32mm OXINIUM/XLPE group showed: – Lower mean±SD volumetric wear (OXINIUM/XLPE: 35.4±5.0; ceramic/CPE: 89.5±13.1; ceramic/XLPE: 162.5±25.3mm^3) – Lower mean±SD volumetric wear rates (OXINIUM/XLPE: 21.0±6.4; ceramic/CPE: 38.0±8.0; ceramic/XLPE: 48.0±10.1mm^3/year)
Heyse TJ, Elpers ME, Nawabi DH, Wright TM, Haas SB. **Oxidized zirconium versus cobalt-chromium in TKA: profilometry of retrieved femoral components**. *Clin Orthop Relat Res*. 2014;472:277–283.[7] Available at: Clinical Orthopaedics and Related Research	Analysis of retrieved implants Implant tested: knee OXINIUM Oxidized Zirconium femoral components, n=10; matched CoCr femoral components, n=10	• CoCr femoral components showed more scratching than matched OXINIUM components on visual assessment • The average surface roughness for retrieved CoCr components was 83% greater than that of the retrieved OXINIUM components, with CoCr showing significantly higher surface roughness than OXINIUM across all four surface roughness parameters (all $p \leq 0.036$) • CoCr bearing surfaces showed 39% greater maximum peak-to-peak height roughness and 33% greater 10-point height roughness, when compared with OXINIUM components • The increase in surface roughness between retrieved and pristine OXINIUM implants was less than the increase between retrieved and pristine CoCr implants (20 vs 267%, respectively)

Wear resistance

Further studies

Wear resistance

Study	Design / n=	Key findings
Morrison ML, Jani S, Parikh A. **Development of an advanced bearing couple for total knee arthroplasty**. Poster presented at: Orthopaedic Research Society Annual Meeting; 2011; Long Beach, CA.[31] Available at: Orthopaedic Research Society	In vitro knee simulation of in vivo scratching and wear against different UHMWPE materials Implant tested: knee OXINIUM Oxidized Zirconium femoral components, n=3; CoCr femoral components, n=3	• OXINIUM femoral components showed lower surface roughness compared with CoCr components following tumbling ($p<0.001$) • When articulated against UHMPWE liners, pristine OXINIUM components showed a significantly lower wear rate than pristine CoCr components ($p\leq0.001$) • OXINIUM femoral components did not show any significant changes in wear rates ($p\geq0.181$) following tumbling against any UHMWPE liner, in contrast to CoCr components, which showed significantly increased wear rates following tumbling ($p\leq0.003$)
Anderson FL, Koch CN, Elpers ME, Wright TM, Haas SB, Heyse TJ. **Oxidized zirconium versus cobalt alloy bearing surfaces in total knee arthroplasty**. *Bone Joint J.* 2017;99-B:793–798.[28] Available at: The Bone & Joint Journal	Analysis of retrieved implants Implant tested: knee Tibial inserts that had been articulated against OXINIUM Oxidized Zirconium femoral components, n=20; matched inserts that had been articulated against CoCr, n=20	• Compared with retrieved inserts that had been articulated against CoCr components, retrieved inserts articulated against OXINIUM components demonstrated: – A significantly lower overall mean±SD volume loss from the UHMWPE bearing surface (122±87 vs 170±96mm^3; p=0.03) – A smaller mean±SD loss of volume in the medial (72±67 vs 92±60mm^3) and lateral (49±36 vs 79±61mm^3) compartments (p=n.s.)

Wear resistance

Further studies

Wear resistance

Study	Design / n=	Key findings
Brandt JM, Guenther L, O'Brien S, Vecherya A, Turgeon TR, Bohm ER. **Performance assessment of femoral knee components made from cobalt–chromium alloy and oxidized zirconium**. *Knee*. 2013;20:388–396.[30] Available at: Knee	Analysis of retrieved implants Implant tested: knee OXINIUM Oxidized Zirconium femoral components, n=26; matched CoCr knee femoral components, n=26	• Retrieved CoCr components had a femoral damage score (FDS) 1.8 times greater than retrieved OXINIUM components • No significant difference was observed between any surface parameters measured on the condyles of the new, never implanted OXINIUM components and the retrieved OXINIUM components ($p \geq 0.201$) • The surface roughness of retrieved CoCr femoral components was found to be significantly higher than that of retrieved OXINIUM femoral components across three parameters ($p \leq 0.031$)

Biocompatibility

Further studies

Biocompatibility

Study	Design / n=	Key findings
Dalal A, Pawar V, McAllister K, Weaver C, Hallab NJ. **Orthopedic implant cobalt-alloy particles produce greater toxicity and inflammatory cytokines than titanium alloy and zirconium alloy-based particles in vitro, in human osteoblasts, fibroblasts, and macrophages**. *J Biomed Mater Res Part A.* 2012;100A:2147–2158.[13] Available at: Journal of Biomedical Materials Research	In vitro cytotoxicity and inflammatory reactivity testing in human peri-implant cells Implant tested: material only OXINIUM Technology (zirconium oxide and zirconium alloy particles*); particles derived from CoCr-alloy and Ti-alloy	• Zirconium oxide and zirconium alloy particles led to improved viability of osteoblasts, fibroblasts and macrophages at 48hrs compared with CoCr-alloy particles • Osteoblast and fibroblast cell proliferation was inhibited significantly less with zirconium oxide and zirconium alloy particles versus CoCr-alloy particles ($p<0.05$) • Inflammatory cytokine expression was lower following exposure to zirconium oxide and zirconium alloy particles, compared with CoCr- and Ti-alloy particles:† – Significantly lower levels of IL-6 and TNF-α in osteoblasts ($p<0.05$) – Significantly lower levels of IL-8 in macrophages ($p<0.05$)
Hallab NJ, McAllister H, Jacobs JJ, Pawar V. **Zirconium-alloy and zirconium-oxide particles produce less toxicity and inflammatory cytokines than cobalt-alloy and titanium-alloy particles in vitro, in human osteoblasts, fibroblasts and macrophages**. Poster presented at: Orthopaedic Research Society Annual Meeting; 2012; San Francisco, CA.[34] Available at: Orthopaedic Research Society	In vitro cytotoxicity and inflammatory reactivity testing in human peri-implant cells Implant tested: material only OXINIUM Technology (zirconium oxide and zirconium alloy particles*); Co-alloy and Ti-alloy particles	• Zirconium oxide, and zirconium alloy and zirconium oxide mix, particles led to improved viability of osteoblasts, fibroblasts and macrophages compared with Co-alloy particles • Inflammatory cytokine expression (IL-6 and TNF-α in all cells and IL-8 in macrophages) was significantly lower following exposure to zirconium oxide and zirconium alloy particles, compared with Co- and Ti-alloy particles†

*Derived from DH-OXINIUM material. †The results of in vitro cytokine expression analyses have not been proven to quantitatively predict clinical cytokine expression.

Corrosion/ fretting resistance

Further studies

Corrosion and fretting resistance

Study	Design / n=	Key findings
Aldinger P, Williams T, Woodard E. **Accelerated fretting corrosion testing of zirconia toughened alumina composite ceramic and a new composition of ceramicised metal femoral heads**. Poster presented at: Orthopaedic Research Society Annual Meeting; 2017; San Diego, CA.[16] Available at: Orthopaedic Research Society	In vitro accelerated fretting corrosion testing Implant tested: hip Biolox® Delta* (ZTA) femoral heads, n=3; CoCr femoral heads, n=6; diffusion-hardened OXINIUM Oxidized Zirconium (DH-OXINIUM) femoral heads, n=6	• Signs of metal transfer on the femoral heads and fretting on the stem tapers of ZTA couples were observed upon visual examination • DH-OXINIUM total metal ion concentration was significantly lower compared with ZTA and CoCr heads ($p<0.05$) • The average wear depth for DH-OXINIUM heads was significantly lower than that of CoCr heads, over 10 million cycles ($p<0.05$)
Cartner J, Aldinger P, Newman M. **Characterization of tapers in TKA revisions from a 16-year retrieval database**. Poster presented at: Orthopaedic Research Society Annual Meeting; 2016; Orlando, FL.[37] Available at: Orthopaedic Research Society	Analysis of retrieved implants Implant tested: knee 70 tapers from 27 retrieved TKAs (Ti6Al4V stems/couplers, n=35; TiAl4V tibial baseplates, n=21; Ti6Al4V femoral stems, n=7; CoCr femoral components, n=3; OXINIUM Oxidized Zirconium femoral components, n=3; CoCr tibial baseplate, n=1)	• OXINIUM tapers did not show any significant discoloration, wear scars, fretting or corrosion precipitates on their surface, while CoCr and titanium tapers exhibited all of these features, upon SEM analysis • Compared with retrieved tapers comprised of CoCr/Ti6Al4V material combinations, OXINIUM/Ti6Al4V couples showed significantly fewer corrosion artifacts upon microscopic analysis and scoring ($p<0.05$)

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Abbreviations

AL	Alabama
ASMI	American Society for Metals International
BMI	Body mass index
CA	California
Co	Cobalt
CoCr	Cobalt chrome
CPE	Conventional polyethylene
CPM	Counts per minute
Cr	Chromium
d.p.	Decimal place
DH-OXINIUM	Diffusion-hardened OXINIUM
EtOH	Ethanol
FDS	Femoral damage score
FL	Florida
IL-6	Interleukin-6
IL-8	Interleukin-8
kg	Kilogram
kGy	kilo-Gray (unit of radiation)
LA	Louisiana
lbf	Pound-force
MACC	Mechanically assisted crevice corrosion
mg	Milligram
mm	Millimetre
MN	Minnesota
Mo	Molybdenum
Mrad	Megarad (unit of radiation)
Nb	Niobium
Ni	Nickel

Abbreviations

NR	Not reported
n.s.	Not significant
NV	Nevada
OxZr	Oxidized Zirconium
PE	Polyethylene
SD	Standard deviation
SEM	Scanning electron microscopy
SS	Stainless steel
THA	Total hip arthroplasty
Ti	Titanium
TiAlV/ TiAl4V/ Ti6Al4V	Titanium-aluminium-vanadium alloy
TKA	Total knee arthroplasty
TNF	Tumour necrosis factor
TNF-α	Tumour necrosis factor alpha
TX	Texas
UHMWPE	Ultra-high molecular weight polyethylene
5-XLPE/ 7.5-XLPE/ 10-XLPE*	Highly crosslinked polyethylene
Zr	Zirconium
Zr-2.5Nb	Zirconium-niobium alloy
ZrO_2	Zirconium oxide
ZTA	Zirconia toughened alumina
µm	Micrometre

The results of in vitro wear simulation testing have not been proven to quantitatively predict clinical wear performance. The results of in vitro cytokine expression analyses have not been proven to quantitatively predict clinical cytokine expression.

*XLPE is classified as ultra-high molecular weight polyethylene that has been irradiated by high dose (>50kGy) gamma or electron beam radiation. The 5-XLPE, 7.5-XLPE and 10-XLPE acetabular liners described within this collection are manufactured using 5 (50kGy), 7.5 (75kGy) and 10 (100kGy) Mrad doses of gamma radiation, respectively.

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