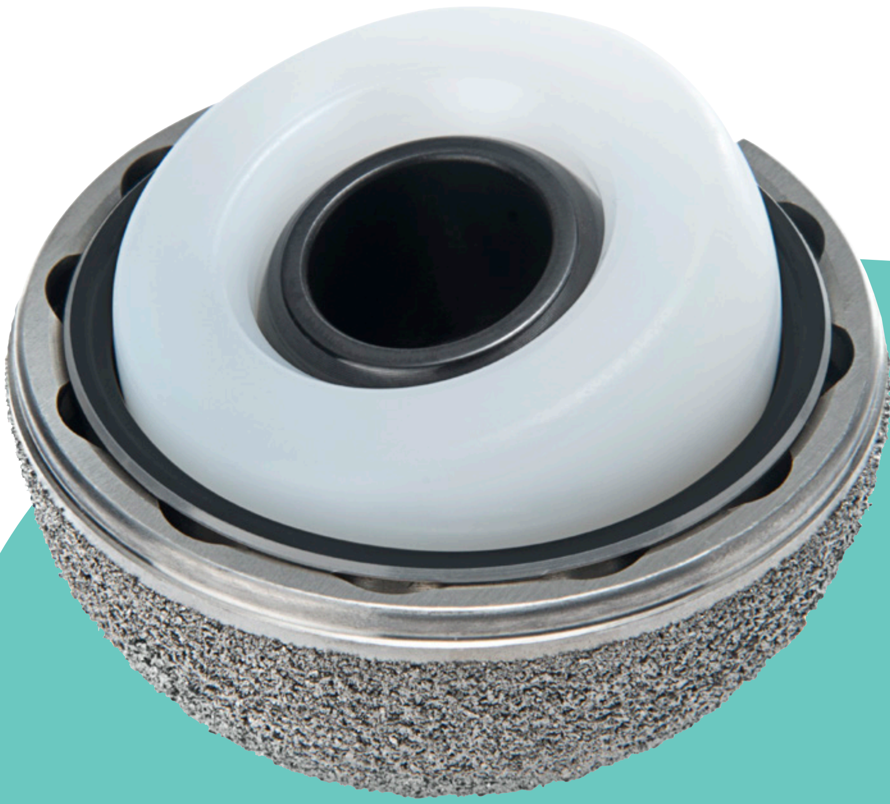
Smith+Nephew

OR3O◊

Dual Mobility with
OXINIUM◊ DH Technology

Design Rationale



An advanced option with proven technology

OR3O◊ Dual Mobility is a modular design offering the benefits of the clinically-proven OXINIUM◊ and highly cross linked polyethylene bearing along with a new proprietary bearing material, OXINIUM DH. This combination offers the benefits of dual mobility and also provides unique material and design advantages that only Smith+Nephew can deliver.[1,2]

Dual mobility – A philosophy steeped in history

Professor Gilles Bousquet of France introduced the concept of dual mobility, a monolithic shell design (Figure 1), to the market in 1974. Over the course of its four decades of use, dual mobility has gone from regional use to an accepted global bearing system with a history of strong clinical performance.[3-5]

Four components of dual mobility Construct (a) monolithic acetabular shell, **(b)** polyethylene insert, **(c)** femoral head, **(d)** femoral stem

First articulation
First articulation (A) small diameter femoral head articulates within polyethylene insert. (A)

Second articulation
Second articulation (B) stem impinges with insert causing articulation of insert within shell. (B)

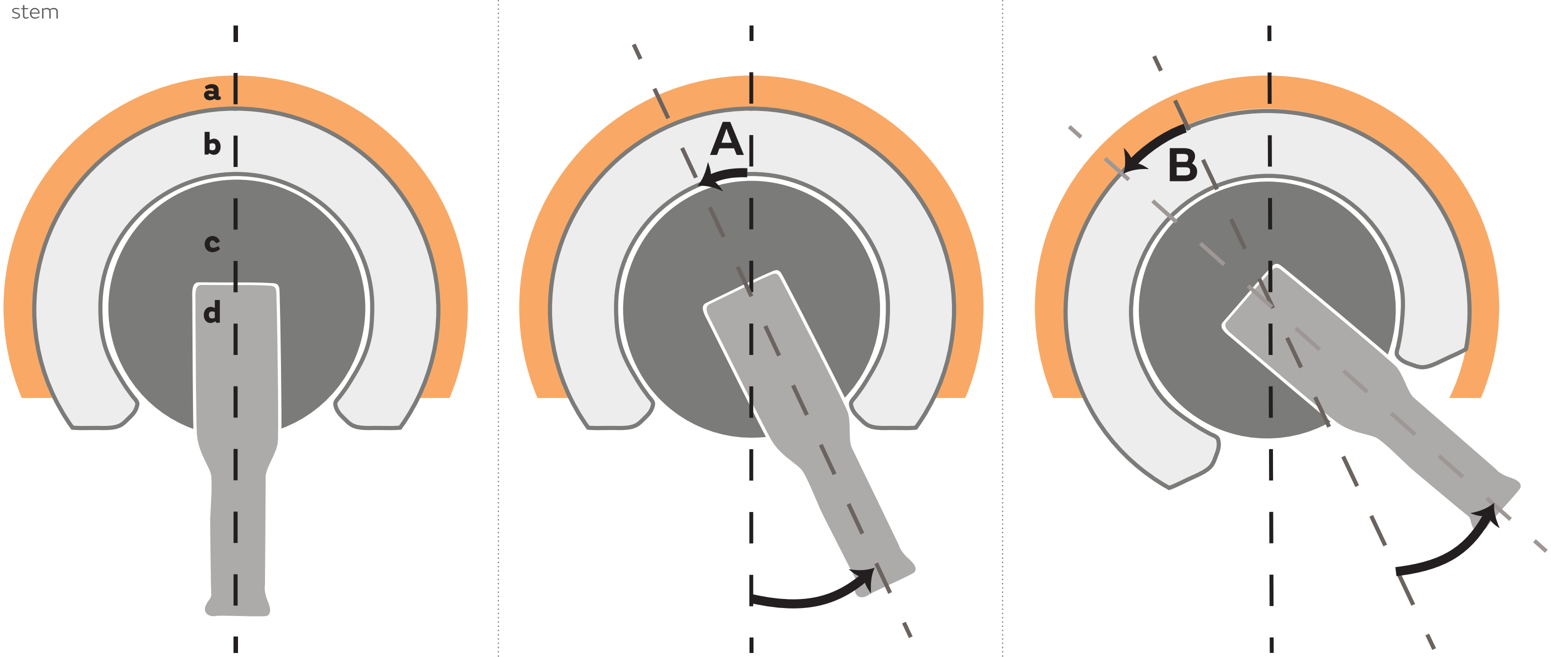


Figure 1: Design of dual mobility construct

Introduction of a modular design

A modular dual mobility concept was introduced to the market to address specific drawbacks of the monolithic shell design. The first being a desire for screw holes within the shell for additional fixation. The second being a rigid inserter to aid orientation control upon initial assembly into the acetabulum.[6]

Modern dual mobility constructs have been shown to reduce dislocation and revision resulting from dislocation for both primary and revision hip arthroplasty.[5,9] However, loss of the articulation between the inner femoral head (Intraprosthetic Dissociation or IPD), increased metal ions, and intra-operative issues continue to be areas of potential improvement for a promising technology.[8-13]

A next generation dual mobility design

Smith+Nephew desired to bring an advanced dual mobility option that incorporated learning from the history of dual mobility, clinically successful technologies, and incorporated OXINIUM◊ DH technology. OXINIUM DH was developed for use as an advanced bearing material in total hip arthroplasty between 2006 and 2020. Rigorous testing included two clinical studies and more than ninety individual pre-clinical tests that has yielded more than twenty peer-reviewed abstracts and journal articles. The end result is a device that is designed to increase stability, incorporate design elements that have a proven clinical history, and simplify the surgical experience.[3,4,13]

Designed with stability in mind

The central principle of dual mobility is stability. Every component in the OR3O◊ construct is designed to address this key need and minimize the risks associated with dual mobility-specific issues, such as intraprosthetic dissociation (IPD).

Eccentricity - Self-centering polyethylene alignment

Utilized successfully in bipolar applications for decades, the OR3O Dual Mobility construct utilizes an eccentric polyethylene design. This design medializes the polyethylene insert to the face of the shell while lateralizing the liner (Figure 2). Research has shown that an eccentric design creates a self-centering mechanism for the poly insert where it can realign itself into an anti-varus position reducing stress on the retentive rim (Figure 3).[13]

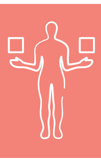
System design

Self-centering or eccentric designs have shown in the literature to:

- Reduce the risk of IPD[13,14]
- Achieve higher resistance to torque against dislocation[14]

If the motion of a dual mobility insert is limited by friction or soft tissue overgrowth, the effect of eccentricity is reduced, and the risk of impingement and poor wear can be increased.[13-15]

The ceramic surface of OXINIUM◊ DH is hydrophilic and reduces friction at the outer articulation as compared to Cobalt-Chromium (CoCrMo).[16] This will play a part in allowing the eccentric liner to operate as intended.



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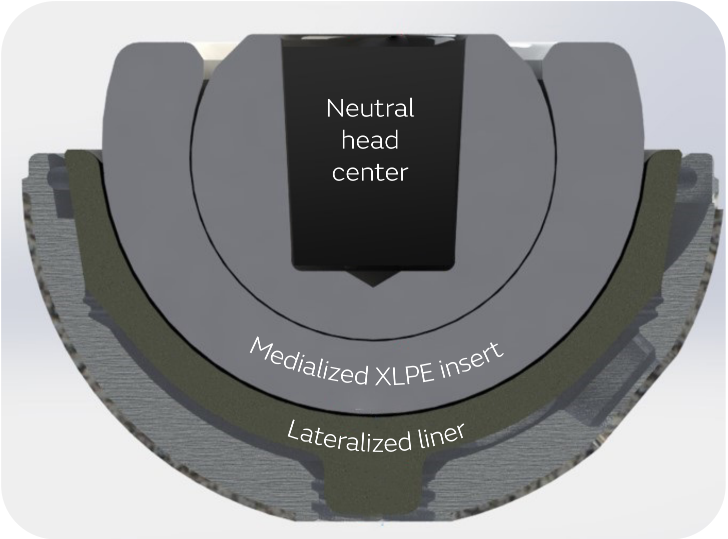


Figure 2: Eccentric dual mobility design

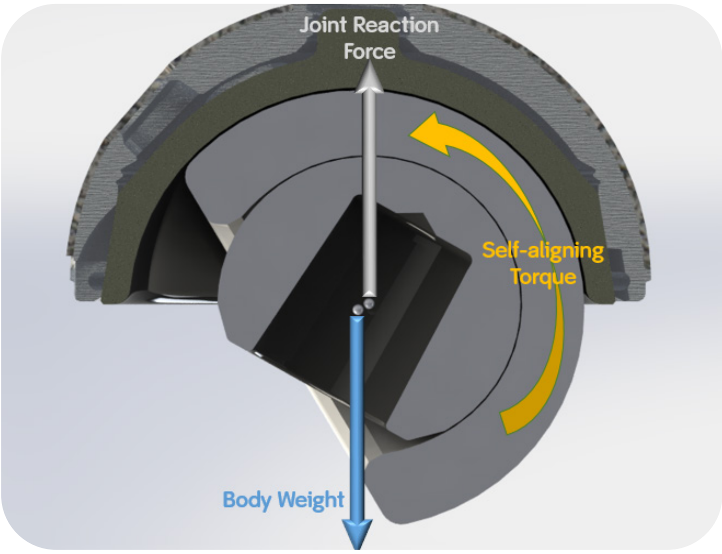


Figure 3: Eccentric design in motion

Dual mobility – Stability

In vitro studies suggest that stability of a reconstructed hip joint is influenced by both the range of motion to impingement and the subsequent translation of the femoral bearing from the acetabular cup.[14,17] The balance sought by the OR3O◊ design delays component impingement while considering the resulting translational jump distance, or distance that the center of the femoral component can travel before risking dislocation.

Range of motion

Impingement-free range of motion determines how far the femoral component can articulate before contact occurs between the femoral neck and soft tissue or implant. The femoral stem then becomes a lever to force the femoral head out of the acetabular cup. As shown in (Figures 4 and 5), the OR3O design improves range of motion in both combined flexion/extension as well as internal/external rotation.

Flexion/Extension

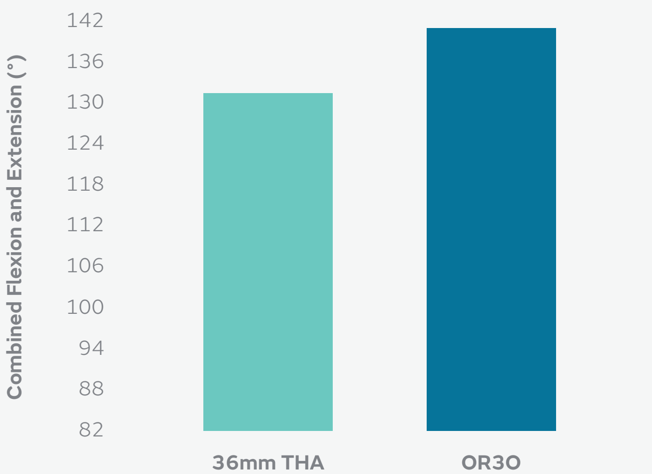


Figure 4: Flexion/Extension of OR3O compared to a conventional 36mm THA[18]

Internal/External rotation

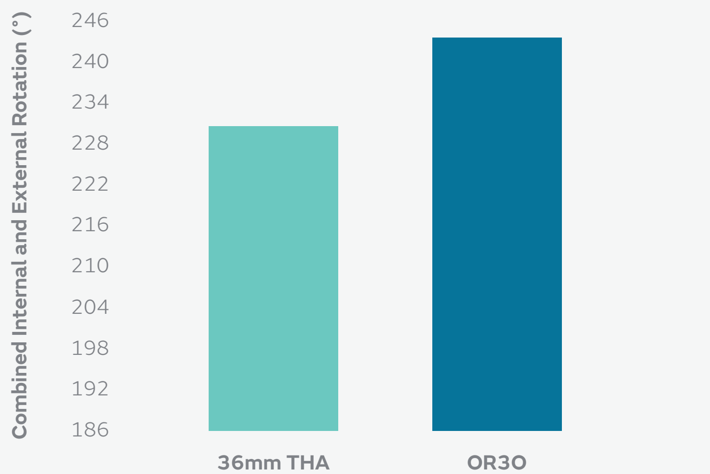


Figure 5: Internal/External Rotation of OR3O compared to a conventional 36mm THA[18]

Jump distance

Assuming a cup position of 45° of inclination and 15° of anteversion, the OR3O bearing showed a 13% increase in the distance required for the femoral construct to dislocate laterally as compared to a like-sized 36mm conventional THA (Figure 6).[18]

Jump distance

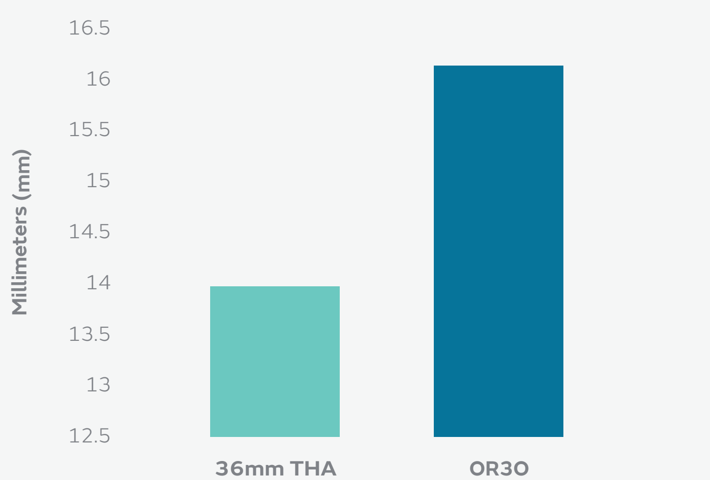


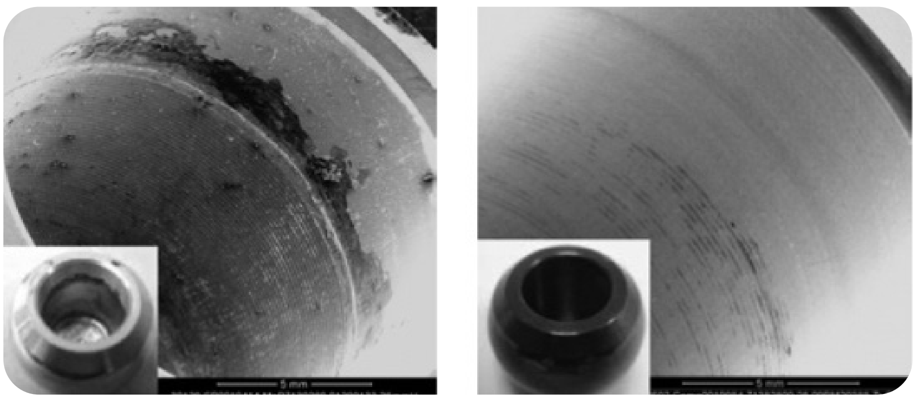
Figure 6: Jump distance comparison of OR30 to conventional 36mm THA

Designed with safety in mind – Corrosion avoidance

OXINIUM◊ Technology has shown to reduce taper corrosion in total hip arthroplasty (THA), minimizing the concern of trunnionosis.[19]

An article published in the HSS Journal showed that in a 22-year retrieval database, OXINIUM femoral heads were associated with decreased corrosion damage compared to CoCrMo femoral heads (Figure 7).[20]

Another separate article published in the British Bone and Joint Journal highlighted that OXINIUM femoral heads had significantly lower mean fretting and corrosion scores compared to CoCrMo femoral heads, concluding that OXINIUM femoral heads were effective at reducing taper corrosion.[21]



OXINIUM femoral heads are associated with decreased corrosion damage compared to CoCrMo femoral heads.

Figure 7: SEM image of worst case CoCrMo taper (at left) and worst case OXINIUM (at right).

OXINIUM/OXINIUM DH - Impact of zirconium-alloy devices on periprosthetic tissues

Smith+Nephew has extensively studied the biological effects of zirconium-based alloys to support the use of the OXINIUM DH technology as an acetabular bearing.

- A cohort of 19 OXINIUM DH liners with the same acetabular taper design as OR3O◊ have been implanted for seven years with no revisions. Two-year cobalt, chromium, titanium, and nickel levels in whole-blood, and functional assessment provided similar outcomes as compared to OXINIUM/XLPE controls.[22]
- Wear debris from OXINIUM, OXINIUM DH, Zr-2.5Nb implants eluted minimal ions in an animal study.[24]
- An *in vitro* test to measure toxicity and inflammation showed OXINIUM wear and corrosion product produced less cytotoxicity and cell death in periprosthetic tissue than CoCrMo particles.[23]
- A Murine air pouch study showed similar cellular response between Zr-2.5Nb wear debris and saline controls. CoCrMo exhibited a greater cellular response.[25]
- An study published in the Journal of Biomedical Material Research stated that "Submicron Zr-based particles induced less toxicity and inflammatory responses when compared with larger CoCrMo-Alloy and Ti-alloy particles."[26] Typically, sub-micron particles are presumed to be more reactive.
- A laboratory study assessing the effect of metal ions and particles on lymphocytes from healthy volunteers showed that "more chemically stable materials like oxidized Zr-alloy can result in lower rates of *in vitro* lymphocyte hypersensitivity compared to traditional implant materials like Co-alloy and Ti-alloy."[27]

OR3O◊ Dual Mobility uses clinically proven design elements

Smith+Nephew uses the exclusive bearing combination of proprietary OXINIUM◊ and highly cross-linked polyethylene (XLPE). It has been used globally in total hip arthroplasty for over a decade and has a number of differentiating characteristics.

Wear performance

OXINIUM with XLPE for total hip arthroplasty has been laboratory tested and shown to provide superior wear performance compared to CoCrMo on highly-cross linked polyethelene, for up to 45 million cycles (Figure 8).[28] Another study showed that a 54mm OR3O XLPE insert had comparable wear to a 36mm OXINIUM/XLPE bearing at 5 million cycles.[29]

Cumulative volumetric wear comparison

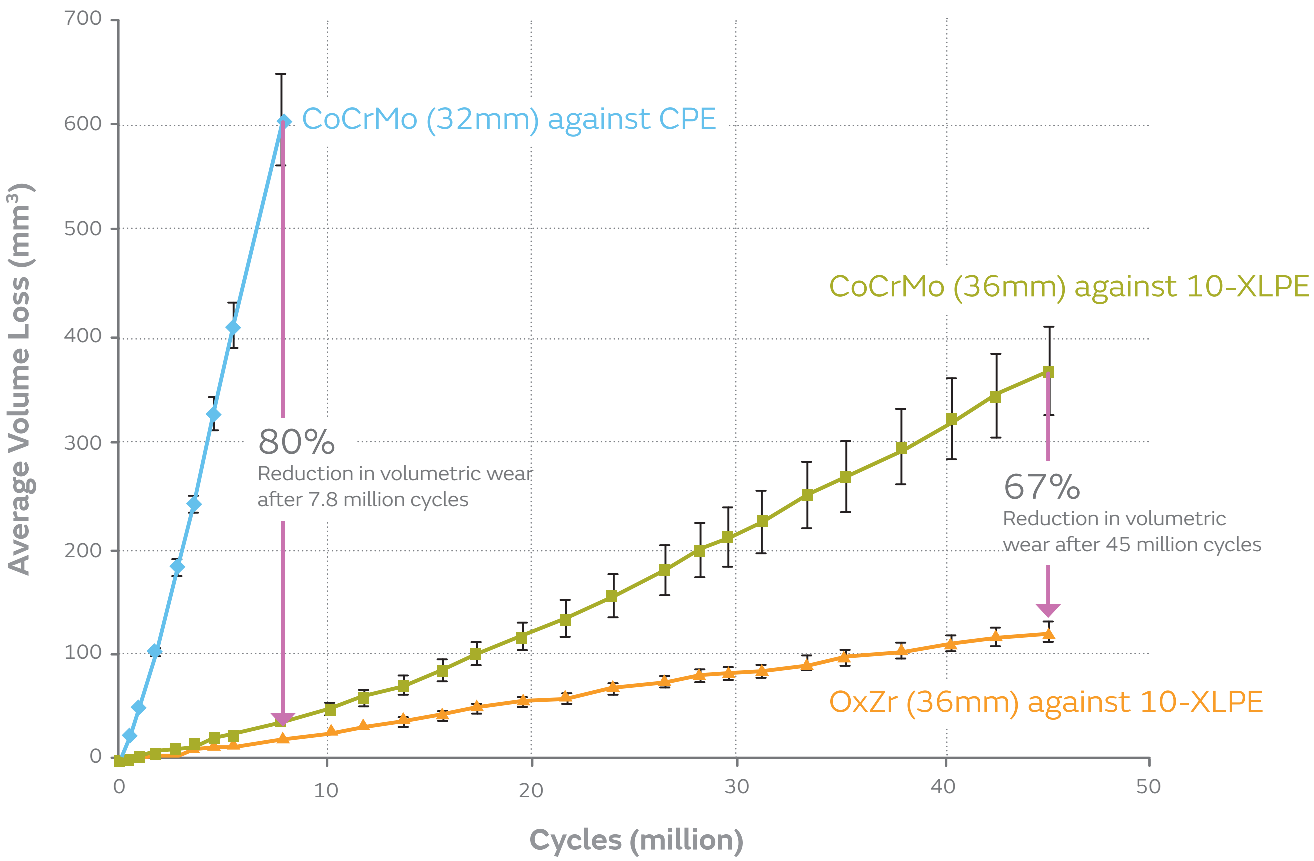


Figure 8: Cumulative volumetric wear comparison of CoC/CPE (blue), CoCrMo/ XLPE (green), and OxZr (orange). Error bars graphically represent standard deviation in gravimetric measures of volume loss across all samples.

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

Wettability and friction - Reducing wear potential in the joint

OXINIUM◊ is a more wettable surface than CoCrMo, improving lubrication. A surface drop test showed that OXINIUM was 30% more wettable than CoCrMo (Figure 9). OXINIUM alloy has also shown to reduce friction and polyethylene (Figure 10).[16]

Wettability test results Oxidized Zirconium (OxZr) vs CoCrMo

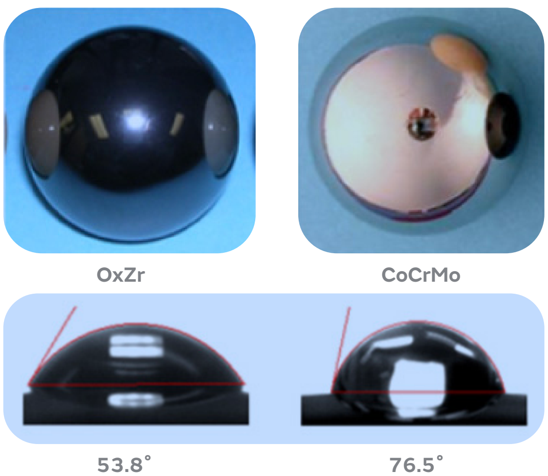


Figure 9: OxZr surface was more wettable than CoCrMo.

Friction test results Cobalt Chrome vs. OXINIUM Oxidized Zirconium

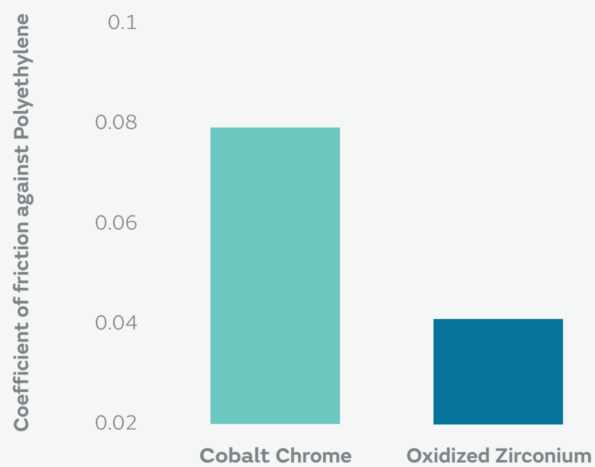


Figure 10: Oxidized Zirconium demonstrated a lower coefficient of friction against polyethylene compared to Cobalt Chrome.

Registries around the world have highlighted the best in class performance of OXINIUM.

Australian Registry[31]

2019 Australian Orthopaedic Association National Joint Replacement Registry

- 95% at 15 years
- 29% lower risk of revision compared to CoCr from 3+ months

Dutch Registry[32]

Dutch Arthroplasty Register

- 96.5% at 9 year with conventional polyethylene (PE) and highly cross linked polyethylene (HXLPE)
- 17% lower risk of revision compared to Metal/HXLPE
- 6% lower risk of revision compared to Ceramic/HXLPE

Italian Registry[33]

Register of Orthopaedic Prosthetic Implants

- 98.2% at 10 years

OXINIUM◊ DH – A next-generation advanced bearing material for hip arthroplasty

The OR3O◊ Dual Mobility System is the first Smith+Nephew system to use the latest advanced bearing technology, OXINIUM DH. Built on the long history of our patented OXINIUM alloy, OXINIUM DH retains all of the benefits of our legacy material but is truly a hip-specific OXINIUM solution.

Utilizing the same proprietary manufacturing processes, OXINIUM and OXINIUM DH implants undergo a surface transformation from Zr-2.5Nb alloy to a phase-stable, monoclinic zirconia bearing surface. However, the OXINIUM DH diffusion process drives the depth of hardening from ~7microns to ~25microns, a 3-4 times increase over traditional OXINIUM.[34] This results in damage resistance similar to that of CoCrMo alloys.[16,35]

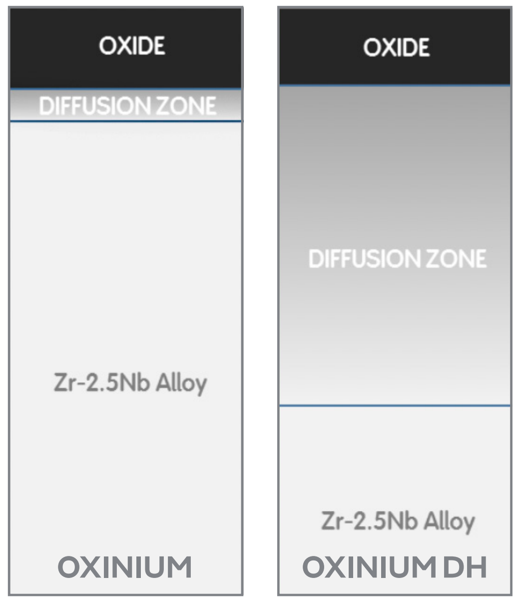


Figure 11: OXINIUM and OXINIUM DH composition

OXINIUM DH - Damage resistance

OXINIUM DH has demonstrated better or comparable damage resistance to CoCrMo in both abrasion and dislocation damage studies.

Abrasion damage resistance: Material removal

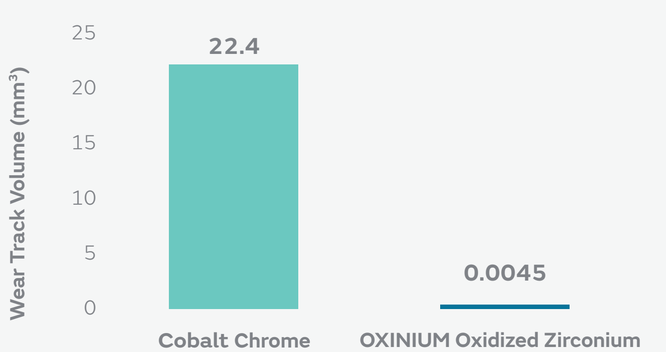


Figure 12: In a pin on disc test, OXINIUM alloy demonstrated significantly increased abrasion resistance than CoCrMo ($p<0.01$).[36]

Dislocation damage resistance: Surface profile traces

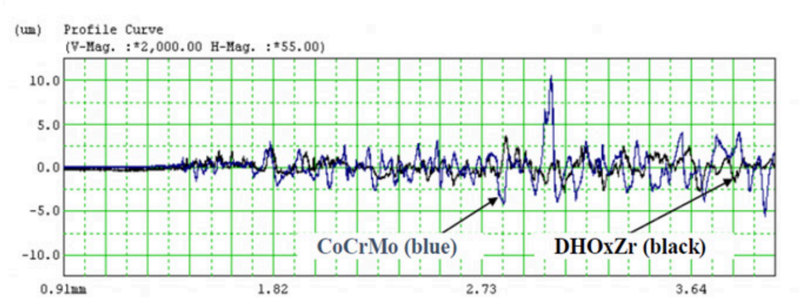


Figure 13: Representative surface profile traces within wear track on disks from 20 cycles of 300lb load. OXINIUM DH (DHOxZr) and CoCrMo show comparable damage resistance.[35]

Designed with simplicity in mind

Efficiency is an important part of any surgery. OR3O◊ Dual Mobility is designed with features that assist in simplifying the dual mobility procedure, whether it is through ease of insertion, removal, or acetabular cup selection.

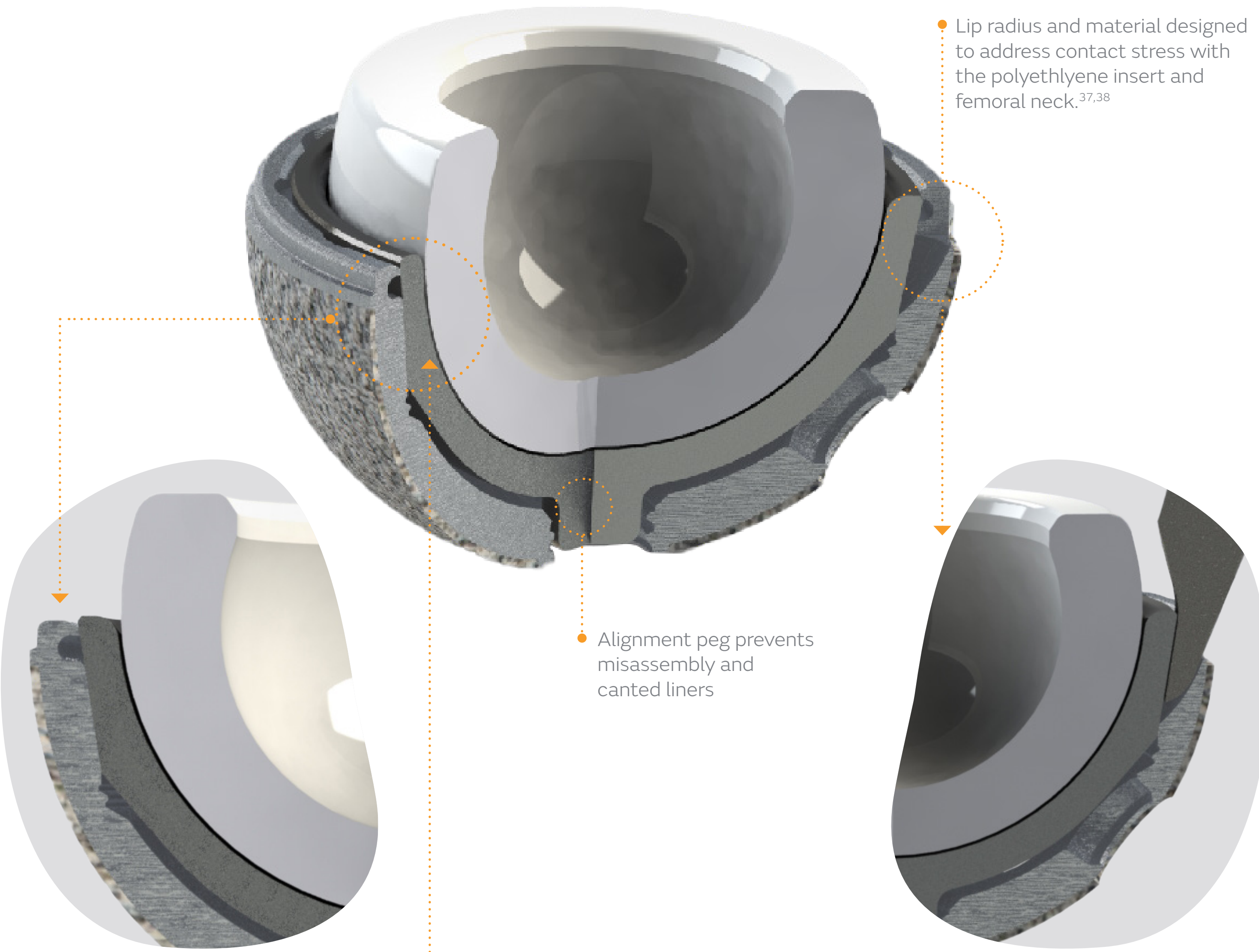


Figure 16: OR3O design features

Proven locking taper design

The 18° locking taper of the OR3O◊ liners utilizes the same locking mechanism as the clinically-successful R3◊ ceramic liners which have been on the market since 2007.[40,41]

Literature has shown that an 18˚ taper is easier to insert into a multi-bearing acetabular cup than a more acute taper angle and is correlated with less malseating.[42] Coupled with the alignment peg, the OR3O liner is designed to prevent off-axis liner insertion.

Post-fatigue push out

All metallic or ceramic acetabular liners are subjected to fatigue loading during the normal course of development. The lower modulus of the OXINIUM◊ DH acetabular liners is beneficial in this regard because it better matches the modulus of the titanium R3 and REDAPT◊ modular acetabular shells than CoCrMo.[43-45]

Ease of liner removal

The R3 and REDAPT Modular cup systems incorporate a liner removal feature and instrument that provides up to a 43:1 mechanical advantage. If implemented correctly, every pound applied to the handle will apply thirty pounds to disrupt the locking taper of the OR3O liner.[46]

OR3O◊ Dual Mobility - From primary to revision

Intended for use with both the R3 Acetabular system and REDAPT◊ Modular Cup, the OR3O Dual Mobility construct can address patient needs across the care continuum.

The OR3O Dual Mobility construct can address patient needs across the care continuum

R3◊ Acetabular System

Launched over ten years ago and with over one million acetabular cup implants sold, the R3 Acetabular System provides surgeons the perfect combination of clinical heritage with modern day design. The R3 Acetabular System combined with the Smith+Nephew portfolio of hip stems provides an advanced hip replacement system with:

- 10A* ODEP rating[47]
- Wide range of advanced bearing options
- An advanced porous coating designed to achieve excellent primary stability[48]
- Flexible instrumentation

REDAPT◊ Acetabular System

Our pioneering approach to the design of our products is vividly displayed through the REDAPT Acetabular System. A number of features set the system apart including:

- CONCELOC◊ Advanced Porous Titanium: An additive, or 3D-manufactured, Ti-6Al-4V advanced bearing surface with up to 80% porosity[49]
- Designed for an optimized screw hole pattern
- Variable angle locking screws that create a more stable construct than one using non-locked screws[50]
- Designed to have a high-friction surface from topographically-mapped "bumps" on all bone-interfacing surfaces

Notes

Notes

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