Design Rationale

smith&nephew

R3◇

Acetabular System

We would like to thank the following surgeons for their participation as part of the R3◊ Acetabular System design team:

Robert Barrack, MD
St. Louis, Missouri

Robert Bourne, MD
London Health Sciences Center
London, Ontario, Canada

Jonathan Garino, MD
University of Pennsylvania School of Medicine
Philadelphia, Pennsylvania

Wayne M. Goldstein, MD
Clinical Professor of Orthopaedics
University of Illinois at Chicago
Illinois Bone and Joint Institute
Chicago, Illinois

Richard Kyle, MD
Minneapolis, Minnesota

Stephen J. McMahon MB BS, FRACS(Orth), FA(Orth)A
Senior Lecturer Monash University
Malabar Orthopaedic Clinic
Melbourne, Australia

John L. Masonis, MD
OrthoCarolina
Hip & Knee Center
Charlotte, North Carolina

Henrik Malchau, MD
Associate Professor Harvard Medical School
Codirector The Harris Orthopaedic
Biomechanics and Biomaterials Laboratory
Massachusetts General Hospital
Boston, Massachusetts

Michael Ries, MD
University of California
San Francisco, California

Cecil Rorabeck, MD
Professor of Orthopaedic Surgery
University of Western Ontario
London, Ontario, Canada

Van Paul Stamos, MD
Illinois Bone and Joint Institute
Glenview, Illinois
Clinical Instructor of Orthopaedic Surgery
Northwestern University Medical School
Chicago, Illinois

Contents

R3volution in motion

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:

- Wide range of advanced bearing options
- Designed to achieve excellent primary stability
- Flexible instrumentation

General features

No-hole, three-hole, and multi-hole hemispherical shell offering

Polished inner surface to minimize backside wear

STIKTITE◊ Porous Coating for enhanced scratch-fit feel and initial fixation

R3◊ Liner options

XLPE
Offered in 0° and 20°,
0° and 20°+4mm lateralized,
and constrained options

Ceramic-on-ceramic
offered in BIOLOX® Delta

Biolox Delta not available in the U.S

Advanced bearing surfaces: VERILAST◊ Technology Oxidized Zirconium with XLPE

R3◊ system with VERILAST Technology is an advanced bearing option

VERILAST◊ Technology for hips from Smith & Nephew uses the exclusive bearing combination of proprietary OXINIUM◊ and highly cross-linked polyethylene, which provides proven clinical survivorship[1] and biocompatibility without sacrificing versatility or introducing the risk of ceramic-like fracture.[1,2,3]

Most importantly, VERILAST Technology provides low wear, corrosion avoidance and real-life results.[1,2,3]

Real life results

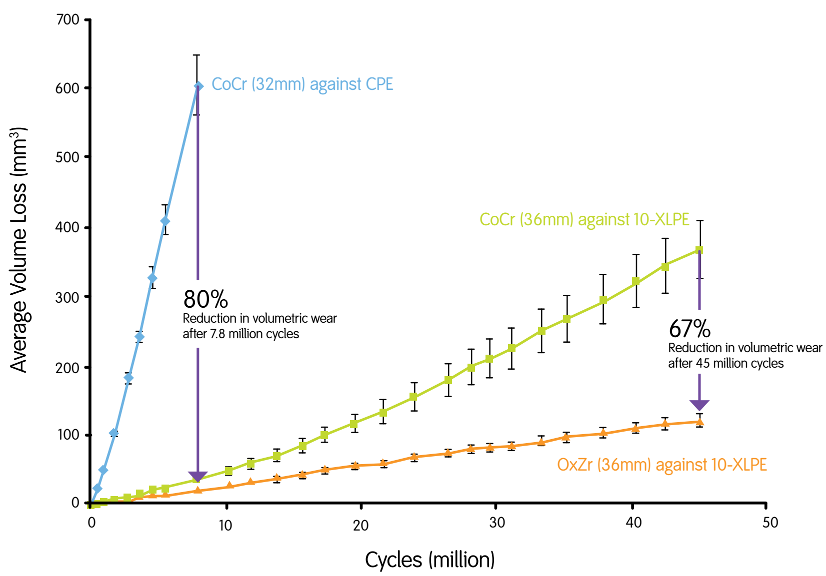
Oxidized Zirconium has a clinical history of more than 10 years. Over 500,000 components have been implanted successfully to date. Impressive clinical performance of OXINIUM heads has been reported in global registry data. In the 2016 Australian Registry, the ceramicized metal/cross-linked polyethylene category, which includes the exclusive OXINIUM alloy from Smith & Nephew, had the highest survivorship of all bearing categories at ten years: 96.8%.[1]* See the 2016 Australian Registry Results inserts to read more.

*Although the Ceramicised Metal/ XLPE combination has the lowest reported cumulative percent revision at 10 years, this result should be interpreted with caution. This bearing is a single company product used with a small number of femoral stem and acetabular component combinations. This may have a confounding on the outcome, making it unclear if the lower rate of revision is an effect of the bearing surface or reflects the limited combination of femoral and acetabular prostheses.

Wear performance

VERILAST Technology for total hip arthroplasty has been in-vitro tested and shown to provide superior wear performance compared to CoCr on highly crosslinked polyethelene, for up to 45 million cycles.[2] With advanced materials designed to last, VERILAST Technology is designed to help restore patients to their active lifestyles, allowing joint pain to be addressed earlier.

Cumulative volumetric wear comparison[2]



Biocompatibility
Protect against taper corrosion

There is a growing concern in the orthopaedic community about fretting and corrosion at the head neck taper junction. With its biocompatible properties, due to its use of Oxidized Zirconium,[4] VERILAST Technology has shown to reduce taper corrosion in total hip arthroplasty, which could minimize the concern of trunnionosis.[5]

A study by Pawar et al. used an acidic fretting test to compare the potential corrosive and fretting responses of OXINIUM◊ (OxZr) and cobalt chrome (CoCr) femoral heads.[3]

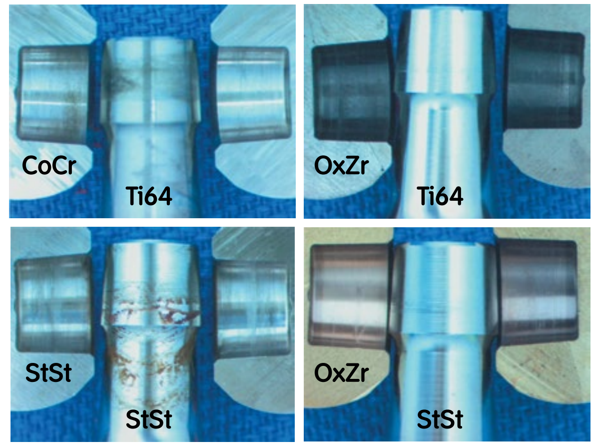


Image from Pawar et al., ASMI 2004. Oxidized zirconium femoral heads with stainless steel stems are not an approved combination.

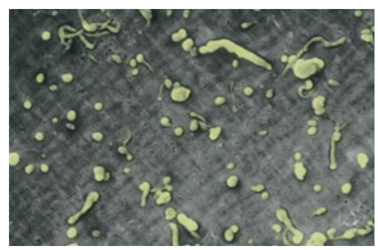
Not your average cross-linked poly

The Smith & Nephew 10 Mrad, fully annealed XLPE is proven to produce less volume of wear debris particles in all size ranges.[6,7] Less wear debris provides a reduced chance for osteolysis.

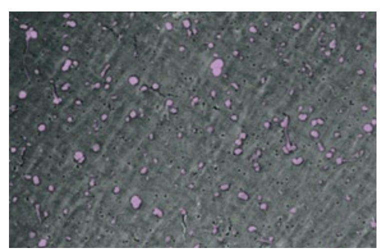
All currently marketed crosslinked poly indicates a significant improvement in the volume of wear debris, which would lead one to assume all crosslinked poly is the same. However, Smith & Nephew investigated more closely and found that not all crosslinked poly minimizes the amount of particles generated. Because the wear particles of crosslinked poly can be smaller in size than with UHMWPE, it is possible to reduce the volume but actually increase the number of particles.[6,7]

The Smith & Nephew crosslinked polyethylene significantly reduces the number of particles generated. The gravimetric wear rate of R3 XLPE is not measurable in a hip simulator, but the number of particles generated is reduced by 80% compared to traditional CoCr on conventional poly bearing.[8]

High magnification images of captured particles



Standard unirradiated polyethylene



5 Mrad irradiated crosslinked poly, showing an increase in the number of particles in conjunction with a decrease in average size

10 Mrad irradiated R3◊ XLPE showing a reduction in total number of particles

Advanced bearing surfaces: ceramic-on-ceramic

R3◊ ceramic-on-ceramic bearing couple

Ceramic-on-ceramic bearing surfaces have been used worldwide in total hip replacement for more than 30 years. Renewed interest in ceramics as an alternate bearing surface has been driven by the following:

- New technology
- Improved manufacturing processes and standards
- New designs

This translates into improvements in the following:

- Mechanical and physical properties
- Wear characteristics
- Optimized biocompatibility
- Reliability expected by today's more active patients

Neck impingement
The flush-seating liners of the R3 ceramic acetabular system in combination with Smith & Nephew femoral stem neck geometry:

- Designed to increase the range of motion and consequently, may reduce the likelihood of impingement.[9]
- Mitigates the risks of metal transfer and increased friction imposed by designs with a raised rim.[10]

The R3 system's ceramic design is an assembled combination of:

- A ceramic component made from orthopaedic industry standard material, BIOLOX® Delta
- A precision-machined support ring made of a Titanium alloy (Ti-6Al-4V) that is commonly used in orthopaedic implants.

Titanium support ring for added strength
The unique feature about R3 ceramic liners is that they come with a titanium support ring around the periphery of the liner. The support ring and ceramic liner are precisely assembled utilizing a cold pressing process. This process is used so that the material properties of the ceramic and titanium are not altered.

The supporting ring is designed to protect against chipping the ceramic liner.

Stability: head/shell ratios

Optimized head/shell ratios

Use of larger diameter femoral heads has been clinically reported to decrease the probability of dislocation in patients.[11-14]

- Large heads provide better potential ROM of the joint.[11-13]
- Large heads may reduce the incidence of neck impingement with soft tissue or the edge of the shell[14]

Stability: head/shell ratios *continued*

With the R3° Acetabular System, surgeons have the option of using larger head sizes in smaller acetabular shells:

	XLPE						Ceramic	
Cups	**22**	**28**	**32**	**36**	**40**	**44**	**32**	**36**
40	●							
42	●							
44	●							
46		●						
48		●	●				○	
50		●	●				○	
52		●	●	●				○
54		●	●	●				○
56		●	●	●	●			○
58		●	●	●	●			○
60		●	●	●	●	●		○
62			●	●	●	●		○
64				●	●	●		○
66				●	●	●		○
68				●	●	●		○
70				●	●	●		
72				●	●	●		
74				●	●	●		
76				●	●	●		
78				●	●	●		
80				●	●	●		

Femoral heads

● CoCr and OXINIUM°

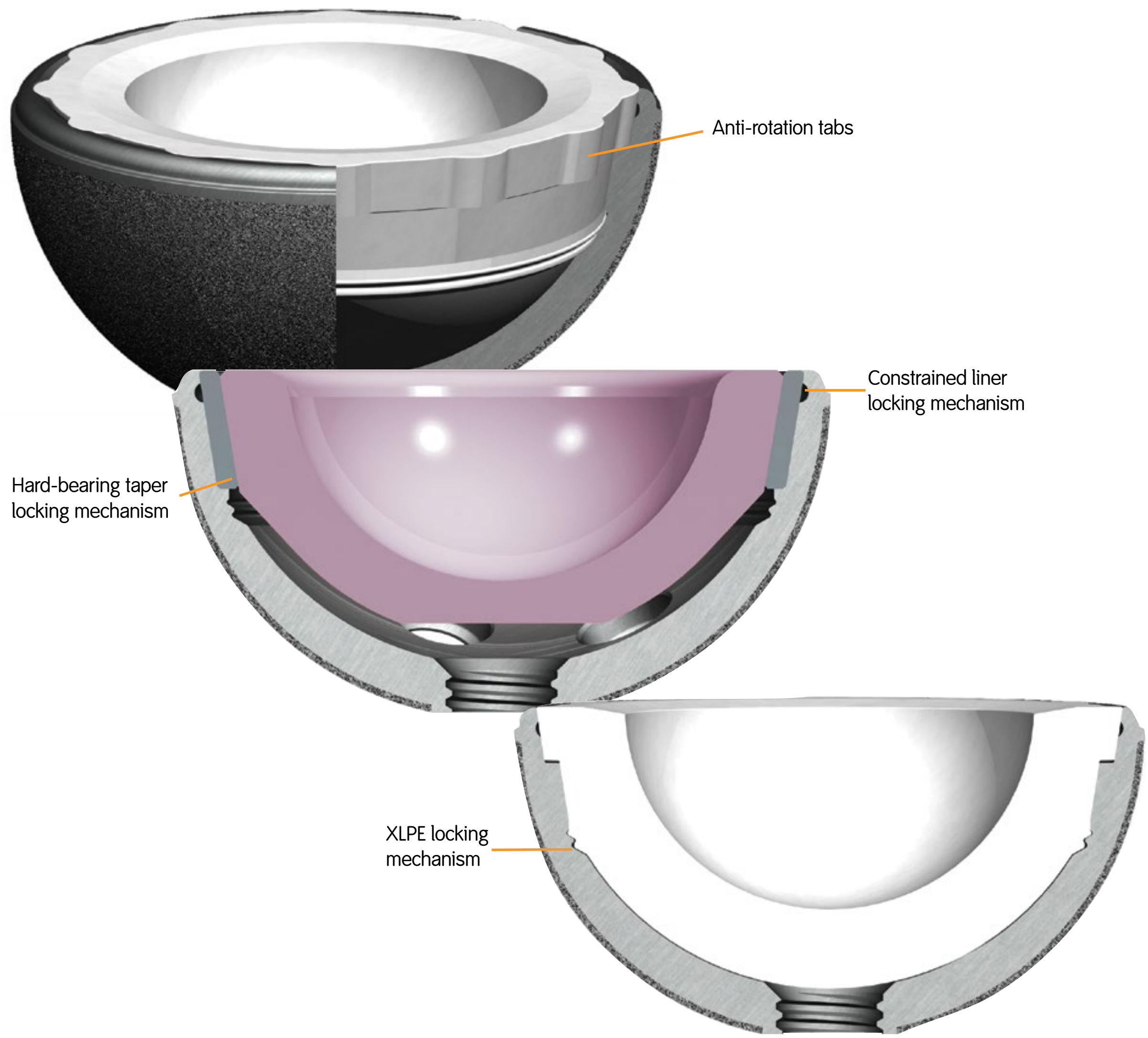
○ Ceramic

Stability: locking mechanism

R3◊ locking mechanism for secure liner stability

R3 locking mechanism design features:

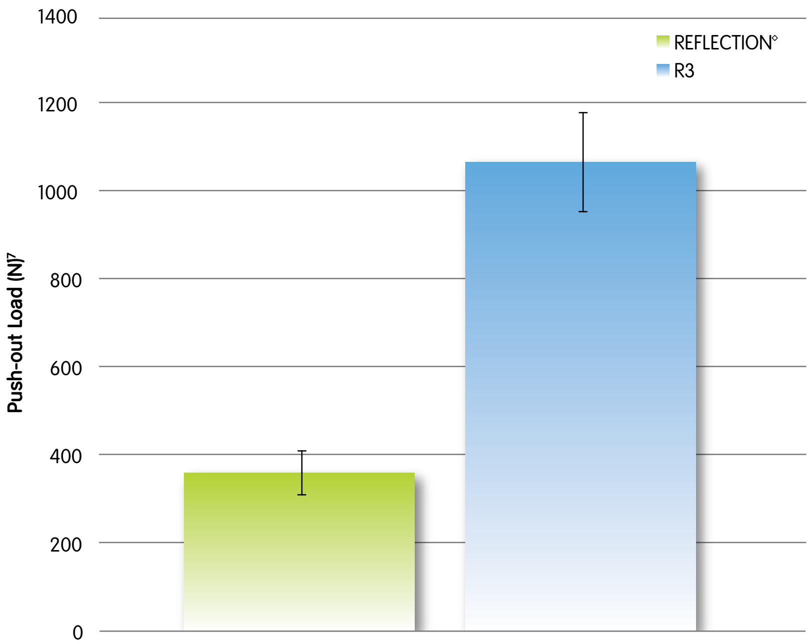
- Locking taper that supports ceramic liners
- Double-channel lock design is intended to provide axial stability for poly liners
- 12 large anti-rotational tabs on the poly liner intended to provide rotational stability

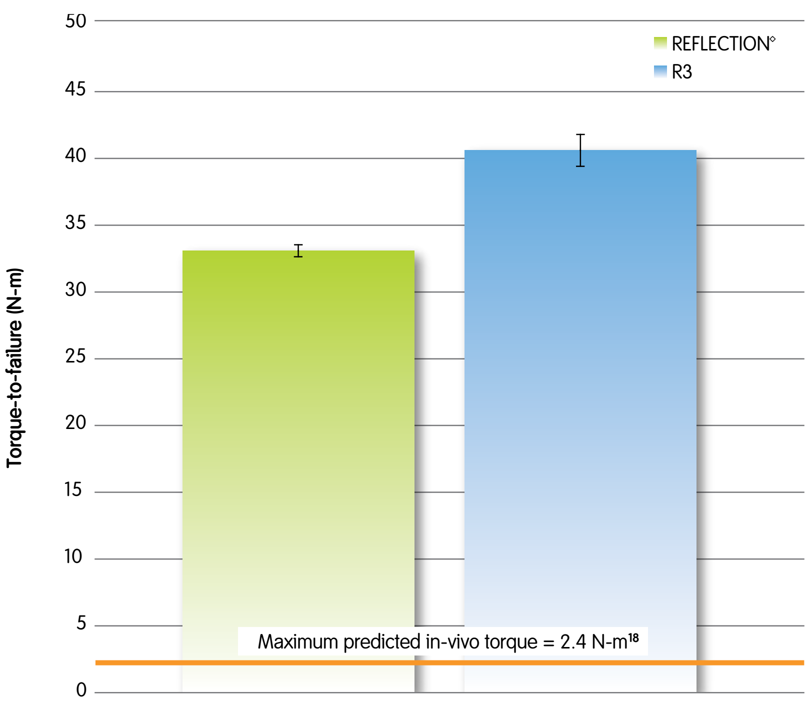


Intraoperative adjustments to the liner position may be performed with true confidence. Independent researchers confirm that in some competitive locking designs, the liner can be significantly damaged by extraction, which prohibits liner repositioning.[15] Laboratory tests of the R3 locking mechanism have shown it withstands consecutive insertions of the same liner without damaging its locking integrity.[16]

Stability: locking mechanism *continued*

Push-out and torque-to-failure tests of the R3◊ locking mechanism demonstrate that it offers the benefit of a secure and stable liner. The R3 lock can withstand over 1112N of push-out force in any of its liner options and over 40 N-m of torque.





Stability: STIKTITE◊ Porous Coating

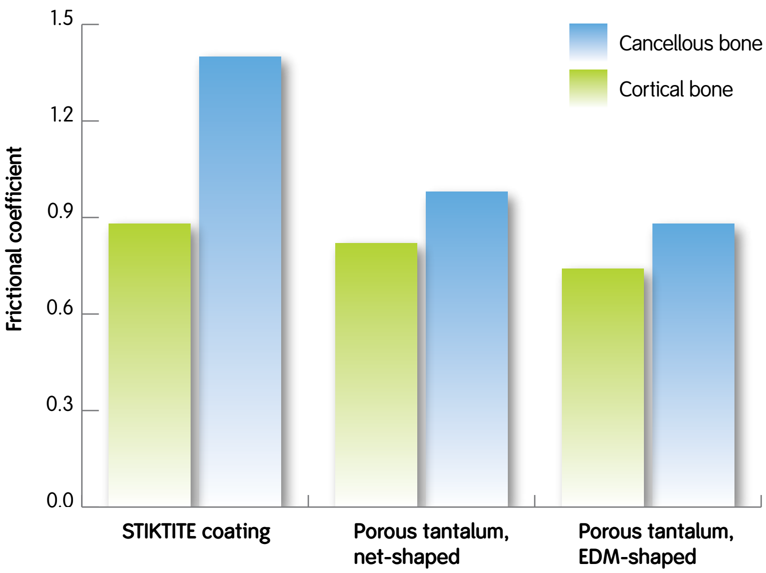
Enhanced stability and fixation with STIKTITE Porous Coating

Utilizing STIKTITE coating on the R3◊ Acetabular Shells allows for a true scratch-fit feel during the shell seating and a clinically proven in-growth surface for long-term implant success.[19]

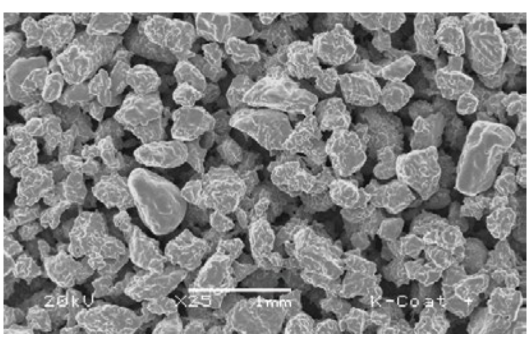
Stability: STIKTITE◊ Porous Coating *continued*

STIKTITE Porous Coating demonstrated a higher coefficient of friction compared to porous tantalum when tested by the same method.[20] The mean coefficient of friction for STIKTITE coating was higher than that of porous tantalum against both cancellous and cortical bone. These results indicate that STIKTITE coating should have superior friction, scratch-fit feel and initial fixation stability as compared to porous tantalum.

Frictional coefficients of bone ingrowth structures against cancellous and cortical bone.[20*]



STIKTITE's increased roughness and 61% porosity provide greater coefficient of friction against cancellous bone than competitive porous coatings. Improved initial stability is a prerequisite to boney ingrowth and long term stability.[21,22] The average pore size of STIKTITE coating (200 μm) is within the 100– to 500–μm range for optimal bone ingrowth.[23]



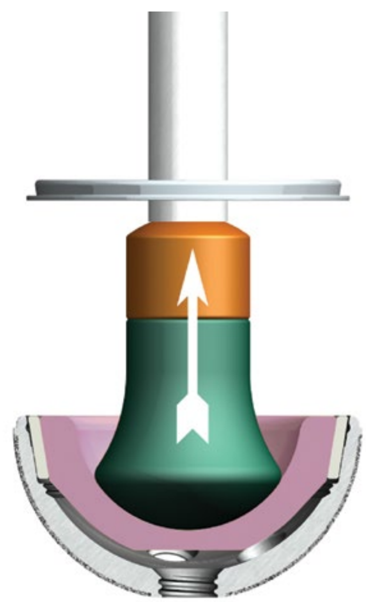
*The results of in-vitro simulation testing have not been proven to predict clinical performance.

Streamlined instrumentation improves surgical efficiency

This seemingly simple technique is a very effective way of precisely placing the ceramic liner inside the shell without the issue of improper seating due to misalignment as seen in other competitive systems.[24-25] Cocking of a ceramic liner, in particular, during impaction can lead to a fracture of the liner.

Preassembled alignment ring on all ceramic liners.

Alignment ring allows for easy placement of the ceramic liner in the shell. The liner impactor can then be inserted through an opening in the alignment ring and the liner can be seated with an impaction force.



Upon impaction the ring will disengage and remain on the liner impactor for later disposal.

The ceramic liner is now properly seated in the shell.

References

1 Australian Orthopaedic Association National Joint Replacement Registry Annual report. Adelaide: AOA; 2015.

2 Parikh, P. Hill, V. Pawar and J. Sprague, “Long-term simulator wear performance of an advanced bearing technology for THA,”Orthop Res Soc, San Antonio, TX, Jan 26-29, 2013, 1028.

3 Pawar V, Jones B, Sprague J, Salehi A, Hunter G. Acidic Fretting Tests of Oxidized Zr-2.5Nb, CoCr, and SS Femoral Heads, ASMI, 2004.

4 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. Annual meeting of the Orthopaedic Research Society (ORS) San Francisco, CA. 097, 2012.

5. Cartner et al ORS 2014

6 Scott M, Morrison, Mishra SR, Jani S. A method to quantify wear particle volume using atomic force microscopy. ORS Transaction. 2002:27:132.

7 Ries MD, Scott ML. Relationship between gravimetric wear and particle generation in hip simulators: conventional versus crosslinked polyethylene. Scientific exhibit at American Academy of Orthopaedic Surgeons; Feb 27-March4, 2001; San Francisco, CA.

8 Good V, Widding K, Heuer D, Hunter G. Reduced wear using the ceramic surface on oxidized zirconium heads. InL Lazennec JY, Dietrich M, eds. Bioceramics in Joint Arthroplasty. Darmstadt, Germany; Steinkopff; 2004:93-98.

9 Elkins JM, O’Brien MK, Stroud NJ, Pedersen DR, Callaghan JJ, Brown TD. Hard-on-Hard Total Hip Impingement Causes Extreme Contact Stress Concentrations. Clin Orthop Relat Res (2011) 469:454–463; 16 October 2010.

10 Knahr K. Total Hip Arthroplasty, Tribological Considerations and Clinical Consequences. Orthopaedic Hospital Vienna-Speising, Vienna, Austria, 2013.

11 Berry DJ, von Knoch M, Schleck CD, Harmesen WS. Effect of femoral head diameter and operative approach on risk of dislocation after primary total hip arthroplasty. J Bone Joint Surg AM. 2005 Nov;87(11):2456-2463.

12 Barrack RL, Butler RA, Laster DR, Andrews P. Stem design and dislocation after revision total hip arthroplasty: clinical results and computer modeling. J Arthroplasty. 2001 Dec;16(8 Suppl 1):8–12.

13 Barrack RL. Dislocation after total hip arthroplasty: implant design and orientation. J Am Acad Orthop Surg. 2003 Mar-Apr;11(2):89–99.

14 Barrack RL, Lavernia C, Ries M, Thornberry R, Tozakoglou E. Virtual reality computer animation of the effect of component position and design on stability after total hip arthroplasty. Orthop Clin North Am. 2001 Oct;32(4):569–577, vii.

15 Tradonsky S, Postak P, Frimson A, Greenwald A. Performance characteristics of two piece acetabular cups. Cleveland, OH: The Orthopaedic Research Laboratory, Mt. Sinai Medical Center. 1992.

16 Data on file.

17 Data on file.

18 FDA guidance document for testing acetabular cup prosthesis. US Food and Drug Administration. May 1995.

19 Bourne R. Randomized controlled trial to compare acetabular component fixation of two porous ingrowth surfaces using RSA analysis. London, Ontario, Canada: London Health Science Center. 2007. Internal report on file at Smith & Nephew, Memphis, TN.

20 Heiner AD, Brown TD. Frictional coefficients of a new bon ingrowth structure. Poster no. 1623 presented at: Orthopaedic Research Society Annual Meeting; Feb 11-14, 2007; San Diego, CA.

21 Naudie D et al. A randomized trial comparing acetabular component fixation of two porous ingrowth surfaces using RSA. The Journal of Arthroplasty 28 Suppl. 1 (2013) 48-52.

22 Gilmour et al, 8th WBC, 2611, 2008.

23 Kienapfel H, Sprey C, Wilke A, and Griss. Implant fixation by bone in-growth. J Arthroplasty, 14(3):355-68, 1999. This citation is part of SMF Design Rationale 00561 V2 3/14

24 Padgett DE, Miller AN, Du EP, Bostrom MPG, Nestor BJ. Ceramic liner malseating in total hip arthroplasty. Poster P097 at American Academy of Orthopaedic Surgeons; Feb 14-18, 2007; San Diego, CA.

25 Langdon AJ, Pickard RJ, Hobbs CM, Clarke HJ, Dalton DJ, Grover ML. Incomplete seating of the liner with the Trident acetabular system: a cause for concern? J Bone Joint Surg Br. 2007 Mar;89(3):291-295.

Smith & Nephew, Inc.
7135 Goodlett Farms Parkway
Cordova, TN 38016
USA

www.smith-nephew.com

Telephone: 1-901-396-2121
Information: 1-800-821-5700
Orders and Inquiries: 1-800-238-7538