

## Less fretting with ceramic

In his presentation at SICOT 2016 in Rome, **Steven Kurtz, Ph.D.** highlighted the results of a retrieval study using matched cohorts of metal and ceramic femoral ball heads. He pointed out that with ceramic heads there is less material loss in head/trunnion junctions than with metal heads. He also noted that CoCr heads are responsible for more than 90% of the material loss in modular tapers and concluded that "ceramic heads are a solution for reducing taper corrosion".

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## NIH on cobalt carcinogenicity

In their 14<sup>th</sup> Report on Carcinogens, the US NIH added cobalt and cobalt compounds to their list, rating that the release of cobalt ions in vivo makes them "reasonably anticipated to be a human carcinogen". The listing for cobalt includes different types of cobalt compounds that release ions into the body. The highest exposure to the metal occurs in the workplace and from failed surgical implants. <https://www.nih.gov/news-events/news-releases/seven-substances-added-14th-report-carcinogens>

## BIOLOX®delta – a game changer?

A comparative analysis of 30,617 primary total hip implants with ceramic components from the Italian RIPO registry was recently conducted by **Toni et al.** It demonstrates that BIOLOX®delta components represent a significant improvement with substantially less fractures and significantly improved survivorship. The Kaplan-Meier survivorship at 8 years was 95.9% for implants with BIOLOX®forte-BIOLOX®forte bearings and 97.4% for BIOLOX®delta-BIOLOX®delta.

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## Increased evidence: Ceramic heads recommended

The body of evidence on tribocorrosion of modular junctions in total hip arthroplasty and its subsequent effect of metal particle and ion release into the surrounding tissue was a major topic in the past two years.

**Tan et al.** confirmed the results from **Kurtz et al.** on the positive effect of ceramic femoral heads reducing tribocorrosion. The clinical effect of metal degradation products has also been demonstrated in several papers. **Lash et al.** presented ten cases with metal-on-polyethylene bearings with delayed dislocations associated with unrecognized adverse tissue reactions due to corrosion at the trunnion and pseudotumor formation. In a large retrospective case study, **McGrory et al.** showed that the soft tissue damage due to tribocorrosion advances over time. They advocate early surgical intervention and also recommend the use of ceramic femoral heads until this complication is better understood. **White et al.** found in their comparative study of metal vs. ceramic heads after 5 years elevated cobalt levels in 57% of the metal head group with 13% of the patients with adverse local tissue reaction. 7% of those patients have been revised already. CoP bearings were eventless.



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## Ceramic fracture rates significantly reduced

**Lee and Kim** used the CeramTec database to determine fracture rates for alumina (BIOLOX®forte) and mixed-ceramic (BIOLOX®delta) femoral ball heads. Between January 2000 and December 2013, over 3.2 million BIOLOX®forte and 2.78 million BIOLOX®delta heads have been sold and implanted. During that period, 672 alumina and 28 mixed-ceramic head fractures were recorded. The fracture rate was 0.02% for BIOLOX®forte and only 0.001% for the latest generation ceramic BIOLOX®delta. 80% of the fractures occurred within 48 months after implantation.

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## Reliability of Mixed Ceramic BIOLOX®delta: Fracture Rates

	 <b>BIOLOX®delta Mixed-Ceramic Heads</b>	 <b>BIOLOX®delta Mixed-Ceramic Inserts</b>
<b>Manufacturer Database*</b> 5'730'000 components	<b>0.001%</b> 44 fractures 4'080'000 heads	<b>0.021%</b> 351 fractures 1'650'000 inserts
<b>Registries and Health Authorities</b>		
Australian Joint Replacement Registry AOANJRR <sup>1</sup>	<b>0.002%</b> 1 fracture 54'741 heads	n.a
Massin et al. referring to French health authorities ANSM <sup>2</sup> 342'769 components	<b>0.001%</b> 3 fractures 230'769 heads	<b>0.025%</b> 28 fractures 112'000 inserts
Registry of Emilia Romagna (Italy) <sup>3</sup> 36'996 components	<b>0.005%</b> 1 fracture 20'960 heads	<b>0.050%</b> 8 fractures 16'036 inserts

\*CeramTec database 1/2003–12/2015: components sold  
<sup>1</sup>Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). Hip and Knee Arthroplasty Annual Report 2014. Adelaide: Australian Orthopaedic Association, 2014, p.108  
<sup>2</sup>P. Massin et al. Does Bioloxx®delta ceramic reduce the rate of component fractures in total hip replacement? Orthop Traumatol Surg Res, 2014, 100(6 Suppl): pp. 317-21  
<sup>3</sup>Report of R.I.P.O. Regional Register of Orthopaedic Prosthetic Implantology 2000-2014, pp.59-60

Joint replacement registries, health authority data and the CeramTec database show similarly low fracture rates for BIOLOX®delta components.

# Executive Summary

Issue December 2016

<b>Title</b>	<b>Tribocorrosion: Ceramic and Oxidized Zirconium vs. Cobalt-Chromium heads in Total Hip Arthroplasty</b>
<b>Authors</b>	Sok Chuen Tan, Adrian C.K. Lau, Christopher DelBalso, James L. Howard, Brent A. Lanting, Matthew G. Teeter
<b>Journal</b>	Journal of Arthroplasty; available online February, 27, 2016
<b>Level of Evidence</b>	None given. Matched cohort retrieval study
<b>Summary</b>	<p>Tan et al. compared the extent of tribocorrosion between 2 matched cohorts (mean implantation time approx. 8 years) of 52 ceramic vs. 52 CoCr femoral head trunnions and also 2 matched cohorts (implantation time approx. 3 years) of 8 OXINIUM™ vs. 8 CoCr femoral head trunnions, which were retrieved mostly for osteolysis, aseptic loosening, and infection (80%) between 1999 and 2015 at one center. The cohorts were matched according to taper design, head size, neck length, and implantation time (in that order). The ceramic heads were BIOLOX®<i>delta</i> (15), zirconia (29) and alumina (8). The ceramic cohort was significantly younger than the CoCr cohort, otherwise they were similar.</p> <p>Ceramic heads demonstrated a significantly lower median fretting and corrosion score for the base, the middle zone, and the total combined score. At the apex zone, the scores were similar to the CoCr cohort. The different taper types did not show significant differences within the ceramic cohort or the CoCr cohort for the combined fretting and corrosion scores. However, when analyzing the apex zones, fretting and corrosion scores were significantly different between taper types. The largest difference at the apex for the ceramic cohort was seen with the smallest taper (11/13) being worse.</p> <p>Implantation time was positively correlated with the combined fretting and corrosion score in the CoCr cohort but not in the ceramic cohort. Age, BMI, and gender were not found to be significantly correlated in either group.</p> <p>The analysis of the OXINIUM™ vs. CoCr cohort showed no significant differences for fretting and corrosion scores in the different zones between the 2 cohorts.</p> <p>This study demonstrates once again that ceramic heads exhibit lower fretting and corrosion scores compared with CoCr heads.</p>
<b>Study Limitations</b>	<p>No information on stem materials</p> <p>No information on stem offset</p> <p>Small number of components for the OXINIUM™ vs. CoCr cohorts</p>
<b>Key Messages</b>	<p><b>Ceramic femoral heads exhibit lower fretting and corrosion scores compared with CoCr femoral heads</b></p> <p><b>No significant differences of fretting and corrosion scores between OXINIUM™ and CoCr femoral heads</b></p>

Oxinium™ is a registered trademark of Smith and Nephew

# Executive Summary

Issue December 2016

<b>Title</b>	<b>Delayed dislocation following metal on polyethylene arthroplasty of the hip due to "silent" trunnion corrosion</b>
<b>Authors</b>	Lash,N.J.; Whitehouse,M.R.; Greidanus,N.V.; Garbuz,D.S.; Masri,B.A.; Duncan,C.P.
<b>Journal</b>	The Bone and Joint Journal VOL. 98-B, No. 2, February 2016
<b>Level of Evidence</b>	None given
<b>Summary</b>	<p>Lash et al. presented a case series of 10 THAs with metal-on-polyethylene (MoP) bearings with delayed dislocations associated with unrecognized adverse tissue reactions due to corrosion at the trunnion and pseudotumor formation. Dislocation/instability and pain was the reason for revision in all cases. Pseudotumors were found in all cases, causing expansion and laxity of the posterior capsule. All metal (CoCrMo) heads were well fixed on the titanium trunnion and had to be forcibly removed. All tapers (male or female) showed a black ring of debris and corrosion products without evidence of impingement or PE wear. Eight hips were revised with a ceramic-on-polyethylene (CoP) bearing (BIOLOX®<i>delta</i> with sleeve, one without sleeve), the remaining 2 received MoP bearings. Six patients suffered further complications. There were 3 cases of PJI, 2 recurrent dislocations in patients with great damage to the abductor muscles, and 1 recurrence of pseudotumor (with MoP).</p> <p>One of the key findings in this series was the "silent" nature of the taperosis, since there are no definitive symptoms pointing towards corrosion, which makes diagnosis difficult. If too much time passes until intervention, tissue damage can be extensive and revisions under these circumstances are associated with a high rate of complications, also when utilizing a ceramic ball head. However, for Lash et al. it is now routine practice to use a ceramic (BIOLOX®<i>delta</i>) femoral head with a titanium sleeve in patients with sensitivity to cobalt and/or chrome.</p>
<b>Study Limitations</b>	Case series with only 10 THAs
	No investigation of metal levels within the tissue during revision
<b>Key Messages</b>	<b>Late dislocation in MoP bearings can occur due to extensive tissue damage because of ALTR due to corrosion.</b>
	<b>BIOLOX®<i>delta</i> femoral heads with a sleeve can successfully be used in patients with ALTR after MoP THA.</b>

# Executive Summary

Issue December 2016

<b>Title</b>	<b>A High Prevalence of Corrosion at the Head-Neck Taper with Contemporary Zimmer Non-Cemented Femoral Hip Components</b>
<b>Authors</b>	Brian J. McGrory, Johanna MacKenzie, George Babikian
<b>Journal</b>	The Journal of Arthroplasty 30 (2015) 1265–1268
<b>Level of Evidence</b>	None given
<b>Summary</b>	<p>McGrory et al. analyzed a database for a single surgeon using 5 types of non-cemented femoral stems with metal-on-polyethylene (MoP) bearings of 32 and 36mm for the prevalence of failure for mechanically assisted crevice corrosion (MACC). They included only non-septic failures due to increasing or new pain, stiffness, and/ or limping in patients with cobalt ion levels of 1.6 ng/mL or greater. At a minimum follow-up time of 2 years, they identified 15 of 1'356 patients with adverse local tissue reactions (ALTR); a prevalence of 1.1%. At time of publication of this article 12 of those patients had undergone revision and the remaining 3 are awaiting revision. All revised cases had visible corrosion at the head-neck junction with soft tissue pathology of varying degrees. Time to presentation of symptoms was 3.7 years on average, and time to revision surgery was 1.6 years on average. X-rays showed some lytic lesions for 9 of the 15 patients. Soft tissue damage, including abductor muscle loss, was greatest in the 3 patients with the longest time to treatment (37-43 months) after presentation of symptoms.</p> <p>Due to their findings the authors are concerned that once corrosion starts, soft tissue damage will follow and progress. They therefore recommend a prompt surgical intervention utilizing non-cobalt components once symptoms of MACC occur. McGrory et al. state that they cannot rule out the possible effect of genetic susceptibility or additive synergistic factors leading to adverse local tissue reactions (ALTR). However, since these clinical complications seem to be frequent, the authors express their concern regarding the general high number of THA surgeries performed worldwide and the possibly devastating and irreversible effect on soft tissue. Therefore, until the cause and prevention of MACC and ALTR is further understood, the authors recommend the use of ceramic (BIOLOX®<i>delta</i>) femoral heads.</p>
<b>Study Limitations</b>	<p>Study uses only the database of a single surgeon</p> <p>Study uses only one component manufacturer, although 5 stem types</p> <p>Inclusion criteria are random</p> <p>Authors' opinion based on findings</p>
<b>Key Messages</b>	<p><b>In this study the prevalence of MACC was 1.1-1.5%, with the majority of symptomatic patients already revised.</b></p> <p><b>All revised implants showed visible corrosion at the head-neck junction with varying degrees of soft tissue damage.</b></p> <p><b>If MACC symptoms (e.g. increasing or new pain) occur prompt surgical intervention is recommended to avoid severe soft tissue damage.</b></p> <p><b>The authors recommend the use of ceramic femoral heads with titanium stems until this problem is better understood.</b></p>

# Executive Summary

Issue December 2016

<b>Title</b>	<b>A comparison of blood metal ions in total hip arthroplasty using metal and ceramic heads</b>
<b>Authors</b>	Peter B. White, BA, Morteza Meftah, MD, Amar S. Ranawat, MD, Chitranjan S. Ranawat, MD
<b>Journal</b>	J. Arthroplasty, Volume 31, Issue 6, June 2016
<b>Level of Evidence</b>	None given
<b>Summary</b>	<p>White et al. evaluated serum cobalt, chromium, and nickel content in 60 patients implanted with the same THA type and brand (titanium alloy stem) and 32 resp. 36mm metal-on-polyethylene (MoP) or ceramic-on-polyethylene (CoP) bearing (30 hips each) at their 5-year follow up. Patients receiving a ceramic (BIOLOX®<i>delta</i>) head were significantly more than 10 years younger (mean 60.6 years) compared to those receiving a metal (CoCrMo alloy) head (mean 74.2 years). All patients also had clinical evaluations at 6 weeks, 1-, 2-, and 5-year follow up.</p> <p>56.7% of patients with a MoP bearing had detectable cobalt levels, with a mean of 2 µg/L, 20% greater 4 µg/L and 3.3% greater 7 µg/L. 17% of patients with MoP bearings had detectable chromium levels (mean 0.3 µg/L). None of the 30 patients with CoP bearings had any detectable metal ion level and no patient in either group had detectable nickel ions.</p> <p>In regard to head size, patients with 36mm metal heads had significantly higher cobalt levels compared with patients with 32mm metal heads. However, there was no difference of chromium levels in correlation to metal head size.</p> <p>No significant differences were found for most clinical evaluations between the two groups. The authors only found a slight statistical difference in the WOMAC function sub-score and total score, with patients in the CoP group scoring slightly better. No outcome scores correlated significantly with ion release. Most patients, except one in the CoP group and 3 in the MoP group, were asymptomatic. Seven patients with MoP bearings underwent further imaging for possible adverse local tissue reaction (ALTR) due to cobalt ion levels greater than 4 µg/L (6 patients) or clinical symptoms (1 patient). In 4 of those patients ALTR was identified and two of them were subsequently revised.</p> <p>The authors conclude that 36mm metal heads result in a higher cobalt level compared to 32mm metal heads and that the use of ceramic (BIOLOX®<i>delta</i>) heads reduces the incidence and magnitude of cobalt and chromium ion release significantly.</p>
<b>Study Limitations</b>	<p>Detection limit for cobalt and chromium ions in serum was high.</p> <p>Results are not generalizable to other hip systems.</p> <p>Titanium ion levels were not measured.</p> <p>Age difference between the groups was &gt; 10 years.</p> <p>Patient number was low.</p> <p>No information regarding specific patient inclusion/exclusion criteria</p>
<b>Key Messages</b>	<p><b>No patient with CoP bearings had detectable cobalt or chromium level.</b></p> <p><b>No patient with CoP bearings had any adverse reaction.</b></p> <p><b>56.7% of patients with a metal head had detectable cobalt levels in serum.</b></p> <p><b>13% of patients with MoP bearings had ALTR, 2 of them have been revised.</b></p> <p><b>Larger metal heads release larger amounts of cobalt.</b></p>

# Executive Summary

Issue December 2016

<b>Title</b>	<b>Incidence of modern alumina ceramic and alumina matrix composite femoral head failures in nearly 6 million hip implants</b>
<b>Authors</b>	Gwo-Chin Lee and Raymond H. Kim
<b>Journal</b>	J Arthroplasty 2016 Aug 20. pii: S0883-5403(16)30510-1. doi: 10.1016/j.arth.2016.08.011
<b>Level of Evidence</b>	None given
<b>Summary</b>	<p>The use of ceramic femoral heads coupled with XPE has been rising steadily in the US. In 2015, 50% of implanted femoral heads were ceramic (American Joint Replacement Registry, Annual Report 2016). Reasons for that were the expectation of decreased wear rates, use of larger heads, and concerns about trunnionosis. However, the risk of ceramic fracture still remains a concern. Therefore, the purpose of this study was to evaluate the risk of ceramic femoral head fracture through analysis of the quality control program of CeramTec. Lee and Kim aimed to determine the fracture rate of BIOLOX<sup>®</sup><i>forte</i> and BIOLOX<sup>®</sup><i>delta</i> heads as well as factors such as time in situ, head size, and taper influence on ceramic head fractures.</p> <p>Between January 2000 and December 2013, over 3.2 million BIOLOX<sup>®</sup><i>forte</i> and 2.78 million BIOLOX<sup>®</sup><i>delta</i> heads were sold and implanted worldwide. During this 14 year time interval 672 BIOLOX<sup>®</sup><i>forte</i> and 28 BIOLOX<sup>®</sup><i>delta</i> head fractures were reported. The fracture rate was 0.020% for BIOLOX<sup>®</sup><i>forte</i> and 0.001% for BIOLOX<sup>®</sup><i>delta</i>. Most of the fractures (80%) occurred within 48 months. Due to the small number of failures of BIOLOX<sup>®</sup><i>delta</i> heads, the data could not be further analyzed. Using available data for analysis, specific events such as trauma, dislocations, or component malposition were associated with fractured heads. Smaller BIOLOX<sup>®</sup><i>forte</i> heads (28mm) were also more likely to fracture than larger ones (<math>\geq 32</math>mm). The same trend was seen for BIOLOX<sup>®</sup><i>delta</i> heads, but the sample size was too small for further analysis. The 28mm head with a short neck length (S) was more likely to fracture than other neck lengths. Taper design/mismatch was the principle cause for fracture attributed to the majority of BIOLOX<sup>®</sup><i>delta</i> heads and contamination of the stem taper was commonly found in BIOLOX<sup>®</sup><i>forte</i> head fractures.</p> <p>The authors conclude that BIOLOX<sup>®</sup><i>delta</i> femoral heads have a significantly lower fracture rate compared to BIOLOX<sup>®</sup><i>forte</i>, larger heads (<math>\geq 32</math>mm) are less likely to fracture, dislocations and taper mismatch and contamination are associated with ceramic head fracture.</p>
<b>Study Limitations</b>	<p>Actual fracture rates might be higher due to possible underreporting of component failures to CeramTec.</p> <p>Implant and clinical details for the fractures were often lacking or incomplete, making it difficult to determine the exact circumstances/reasons of the component fractures.</p> <p>Epidemiology of BIOLOX<sup>®</sup><i>delta</i> fractures could not be analyzed in depth due to the small number fractures.</p>
<b>Key Messages</b>	<p><b>BIOLOX<sup>®</sup><i>delta</i> femoral heads have a significantly lower fracture rate than BIOLOX<sup>®</sup><i>forte</i> heads.</b></p> <p><b>Smaller femoral heads (<math>\leq 28</math>mm) are more likely to fracture.</b></p> <p><b>Important factors for preventing ceramic fractures are appropriate taper design and taper fit (no taper mismatch), proper taper cleansing and impaction of the heads.</b></p>



# ***Addressing Taper Corrosion Issues***

**Steven Kurtz, PhD,  
Drexel University and Exponent,  
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NIH R01 AR47904



U.S. Department of Health  
and Human Services

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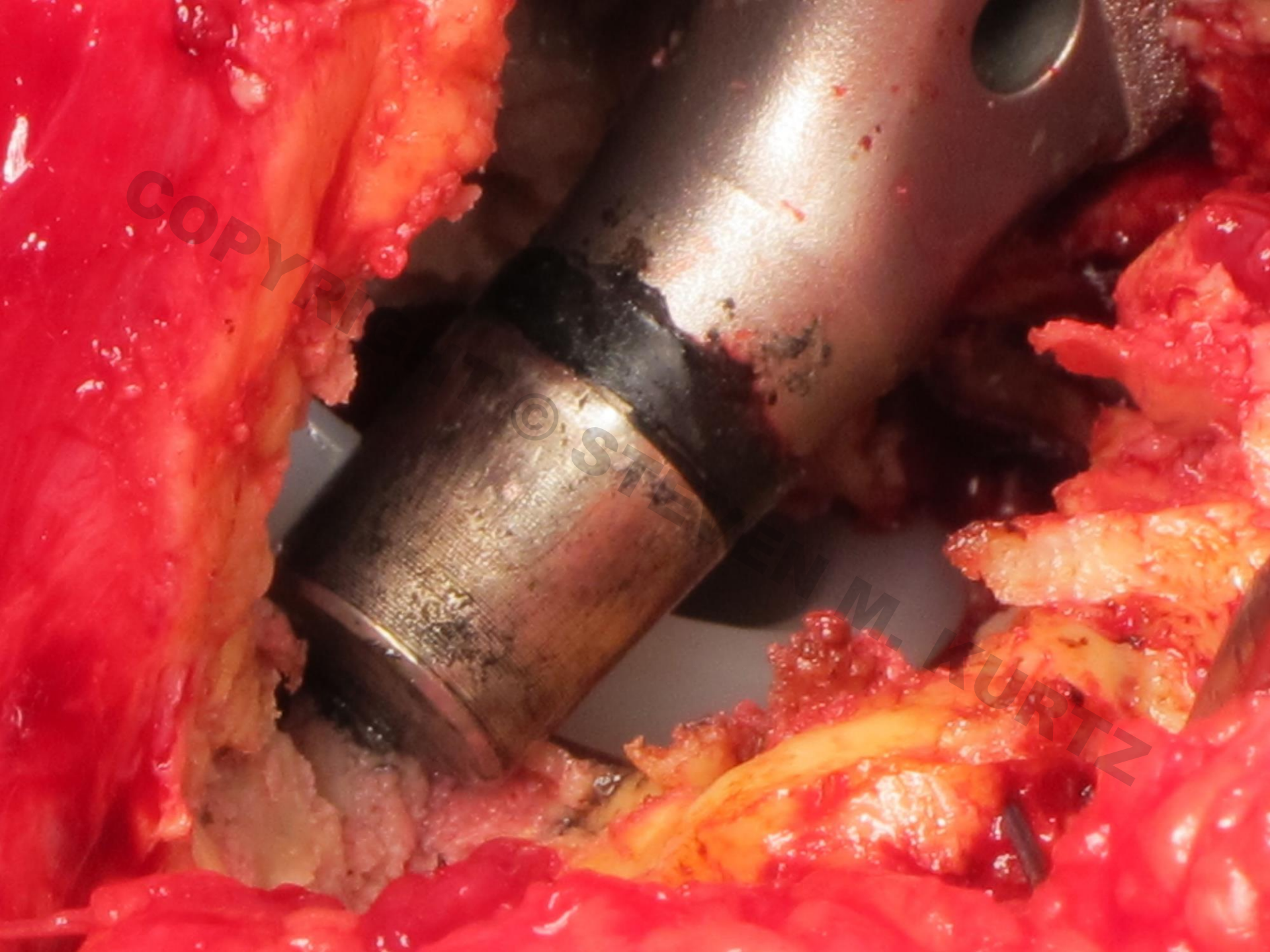
**NIAMS**

National Institute of Arthritis and  
Musculoskeletal and Skin Diseases



# Fretting and Corrosion

- Recently identified as clinically significant in MOM THA's (Langton et al, 2011)
  - Analysis initially focused on the modular head-stem interface
- Concern has expanded to M-PE bearings (Cooper et al 2012, Plummer 2016)
- Are there any solutions for taper corrosion?

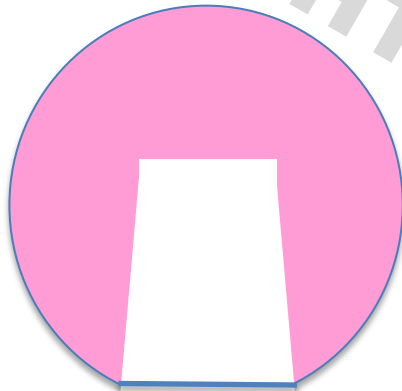


# Taper Corrosion is Not New

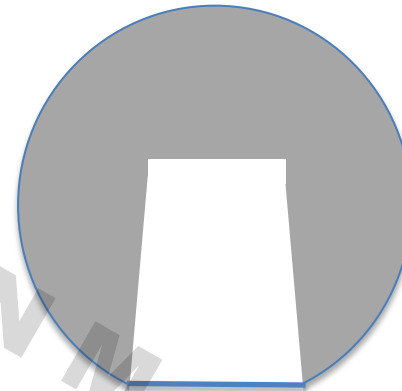
- Retrieval analyses from the late 1980's revealed corrosive attack of modular interfaces
  - Proposed mechanism: mechanically assisted crevice corrosion (Gilbert et al, 1993)
  - Complex, multifactorial problem

# Are Ceramics Heads a Solution to Taper Corrosion?

Ceramic-Metal  
Modular Junction



Metal-Metal  
Modular Junction



# 1<sup>st</sup> Study: Taper Damage (2013)

Clin Orthop Relat Res  
DOI 10.1007/s11999-013-3096-2

Clinical Orthopaedics  
and Related Research®  
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BASIC RESEARCH

## Do Ceramic Femoral Heads Reduce Taper Fretting Corrosion in Hip Arthroplasty? A Retrieval Study

Steven M. Kurtz PhD, Sevi B. Kocagöz BS, Josa A. Hanzlik MS,  
Richard J. Underwood PhD, Jeremy L. Gilbert PhD, Daniel W. MacDonald MS,  
Gwo-Chin Lee MD, Michael A. Mont MD, Matthew J. Kraay MD,  
Gregg R. Klein MD, Javad Parvizi MD, Clare M. Rimnac PhD

[www.orthoceramics.org](http://www.orthoceramics.org)

# 2<sup>nd</sup> Study: Material Loss (2016)

Clin Orthop Relat Res (2016) 474:985–994  
DOI 10.1007/s11999-015-4683-1

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BASIC RESEARCH

## Ceramic Heads Decrease Metal Release Caused by Head-taper Fretting and Corrosion

Sevi B. Kocagoz BS, Richard J. Underwood PhD, Daniel W. MacDonald MS,  
Jeremy L. Gilbert PhD, Steven M. Kurtz PhD

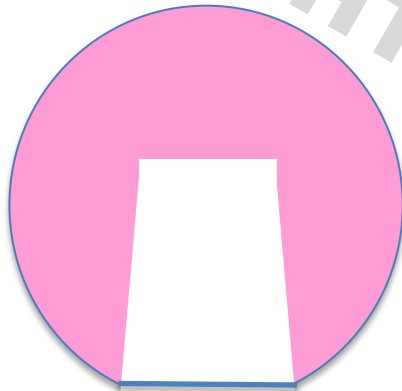
[www.orthoceramics.org](http://www.orthoceramics.org)

# 2<sup>nd</sup> Study: Material Loss (2016)

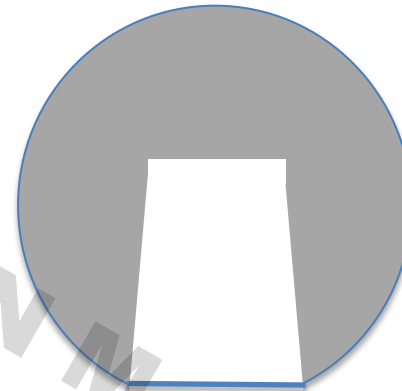
To compare taper corrosion and material loss between ceramic and CoCr head-stem tapers in retrievals using a matched cohort study design

# Matched Cohort Study Design

Ceramic Head Cohort  
(N = 50 pairs)



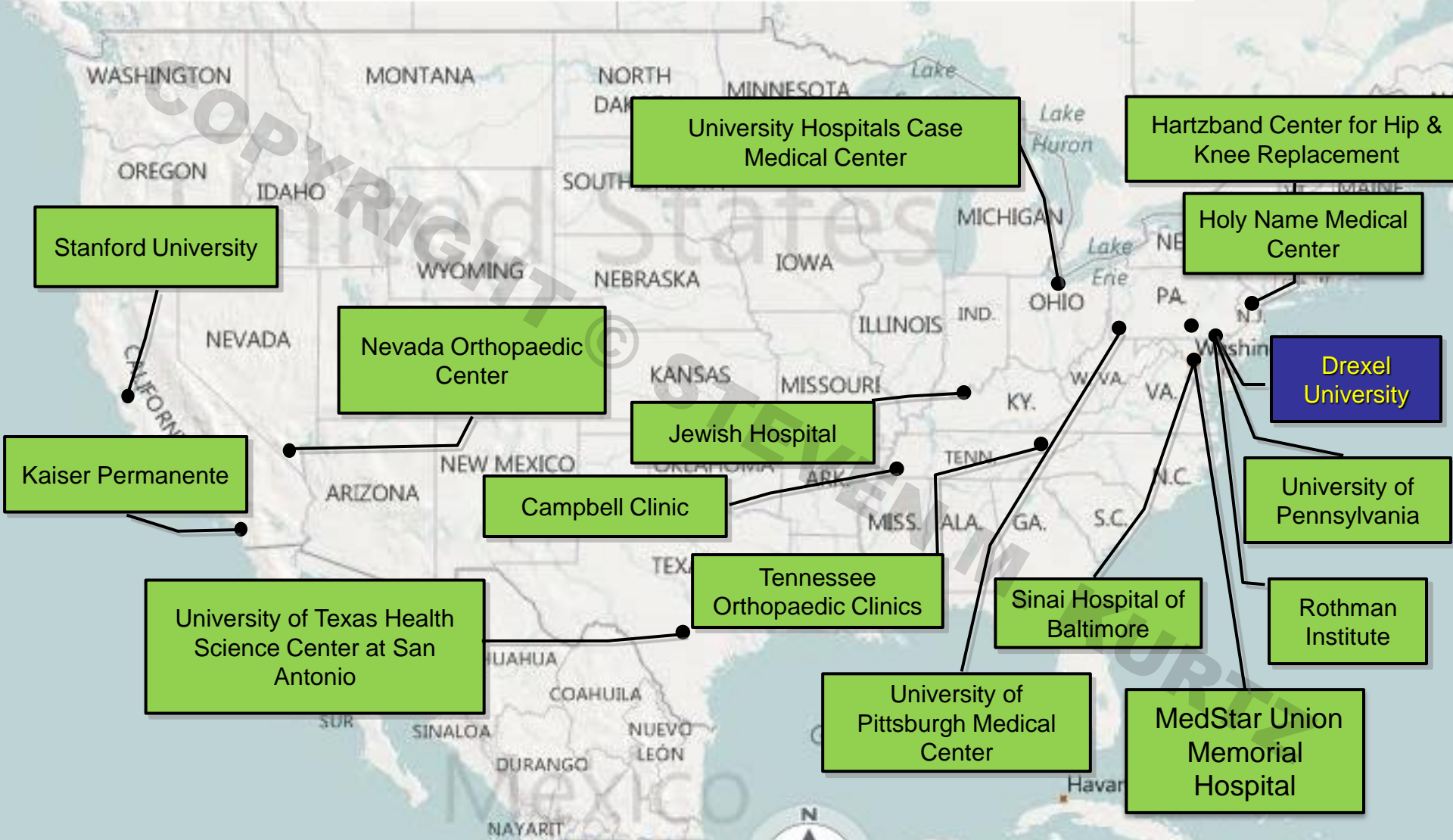
Metal Head Cohort  
(N = 50 pairs)





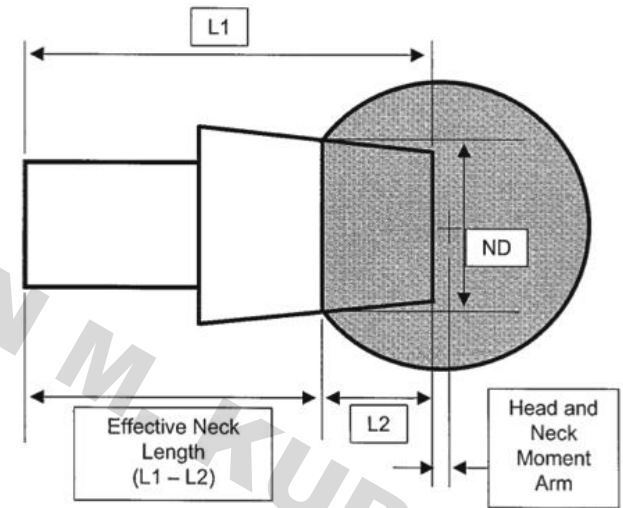
# Drexel University Implant Repository Clinical Partners

- 15 Participating Clinical Centers



# Cohort Matching Criteria

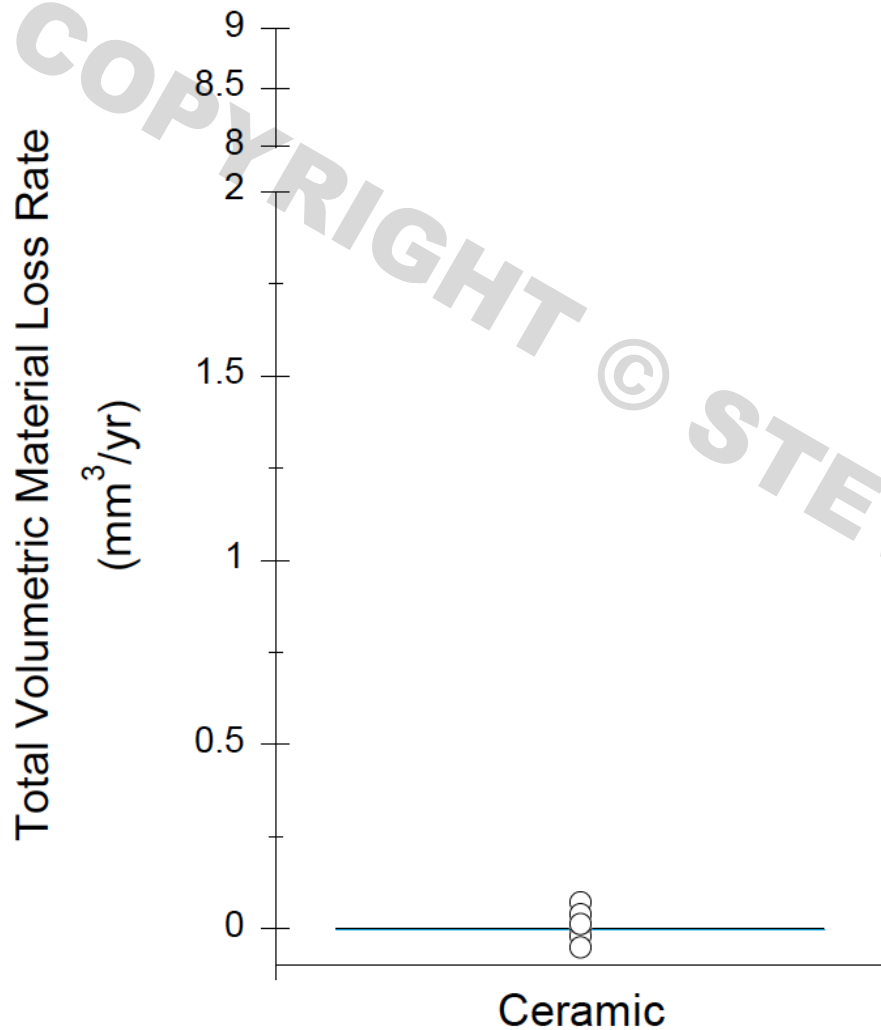
- 1) Implantation time (most important)
- 2) Stem flexural rigidity
- 3) Lateral offset
- 4) Head size



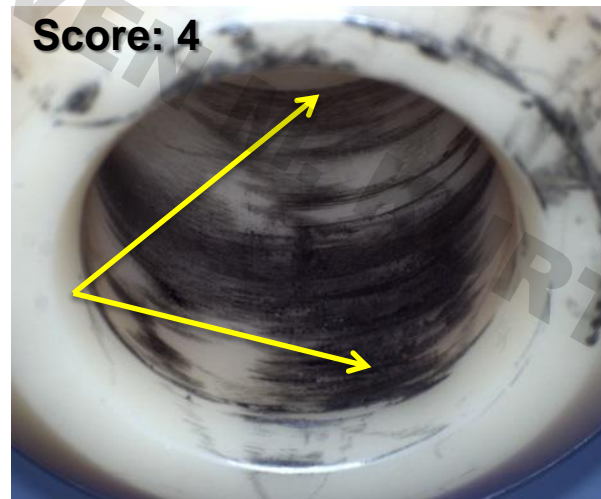
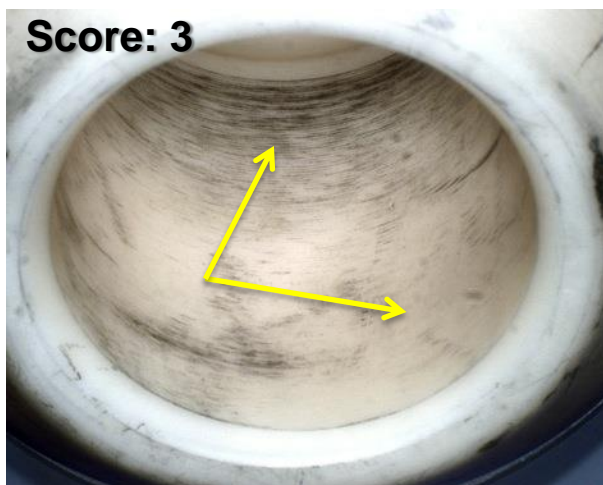
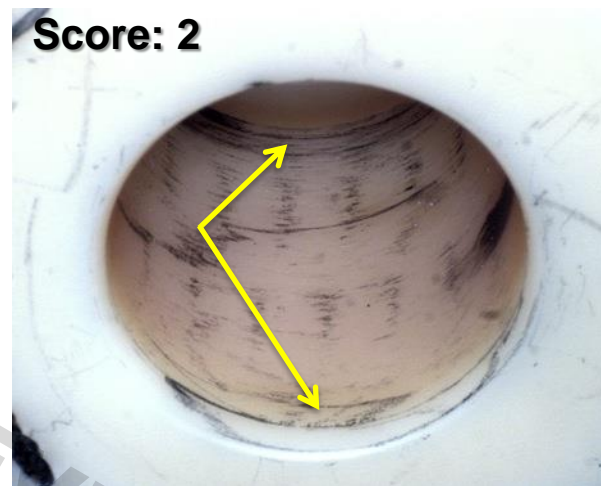
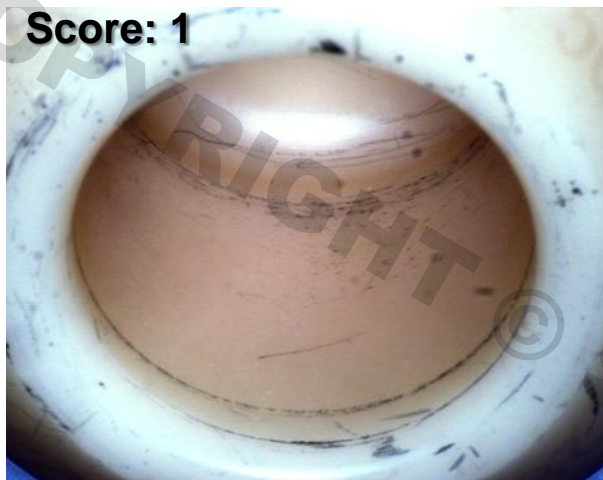
- Goldberg et al., CORR, 2002
- Higgs et al., AAHKS, 2012

$$\text{Flexural Rigidity} = E \cdot I = E \cdot \frac{\rho \cdot (ND)^4}{64}$$

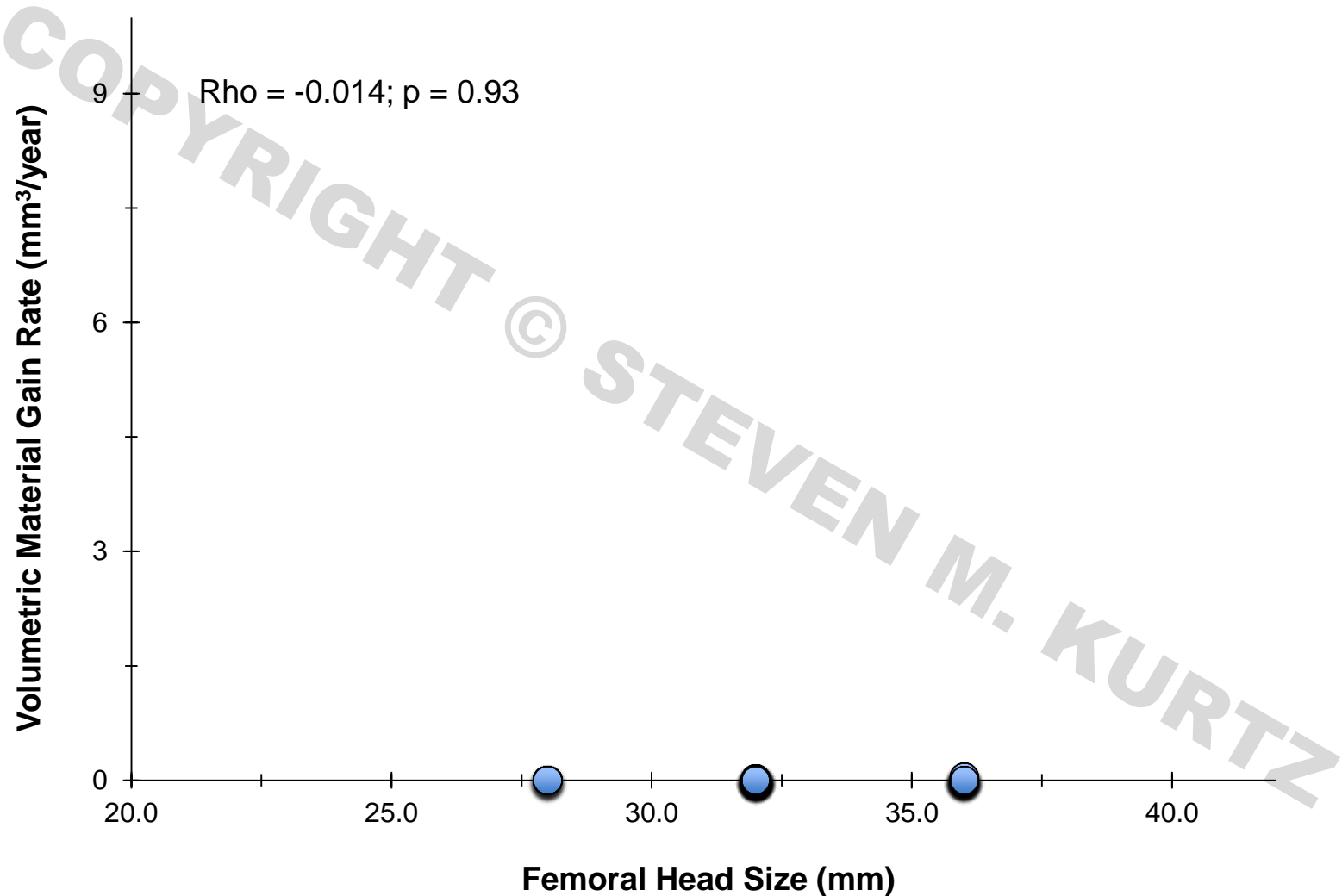
# Total Material Loss Rate



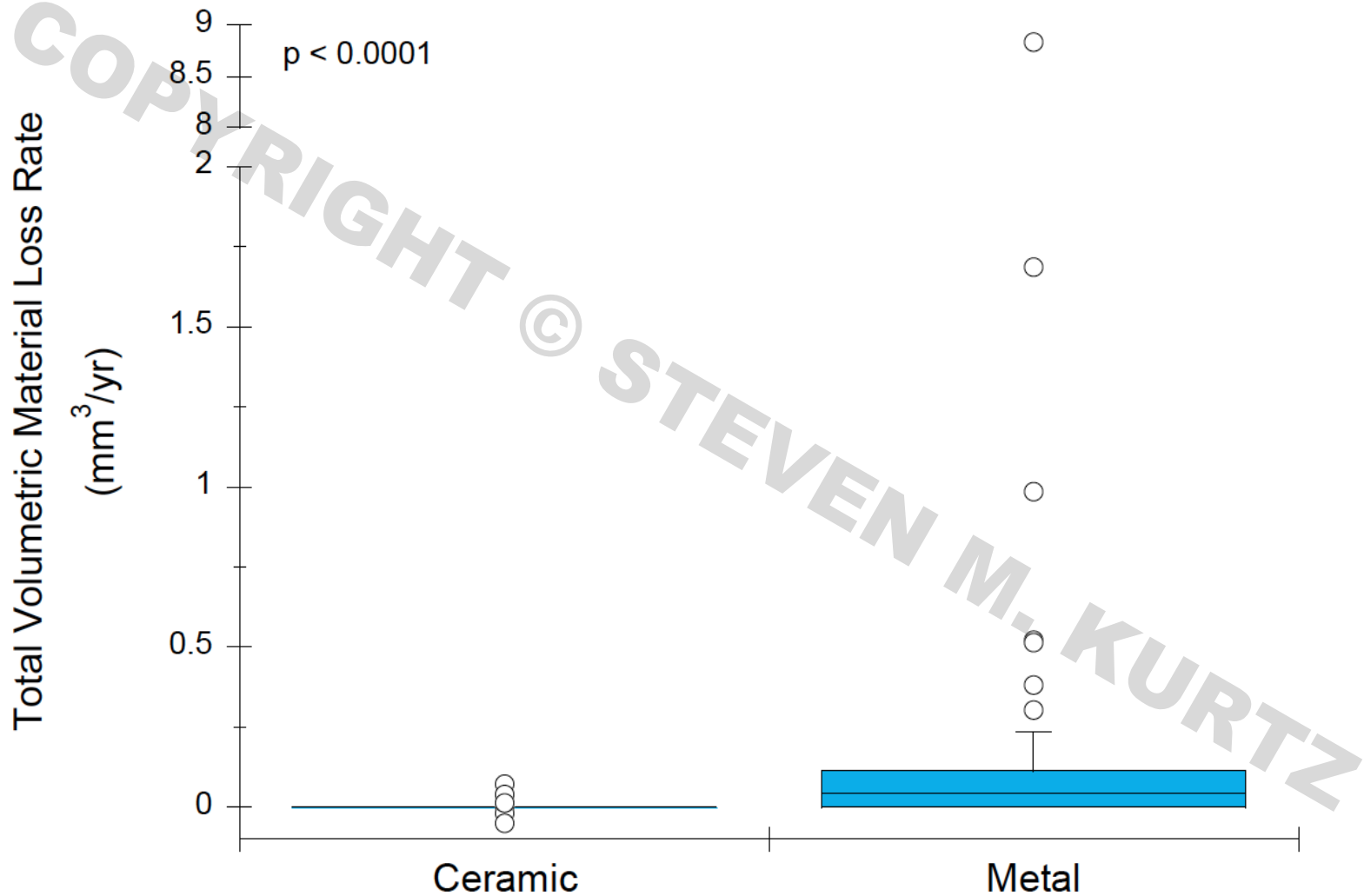
# Head Taper (Ceramic)



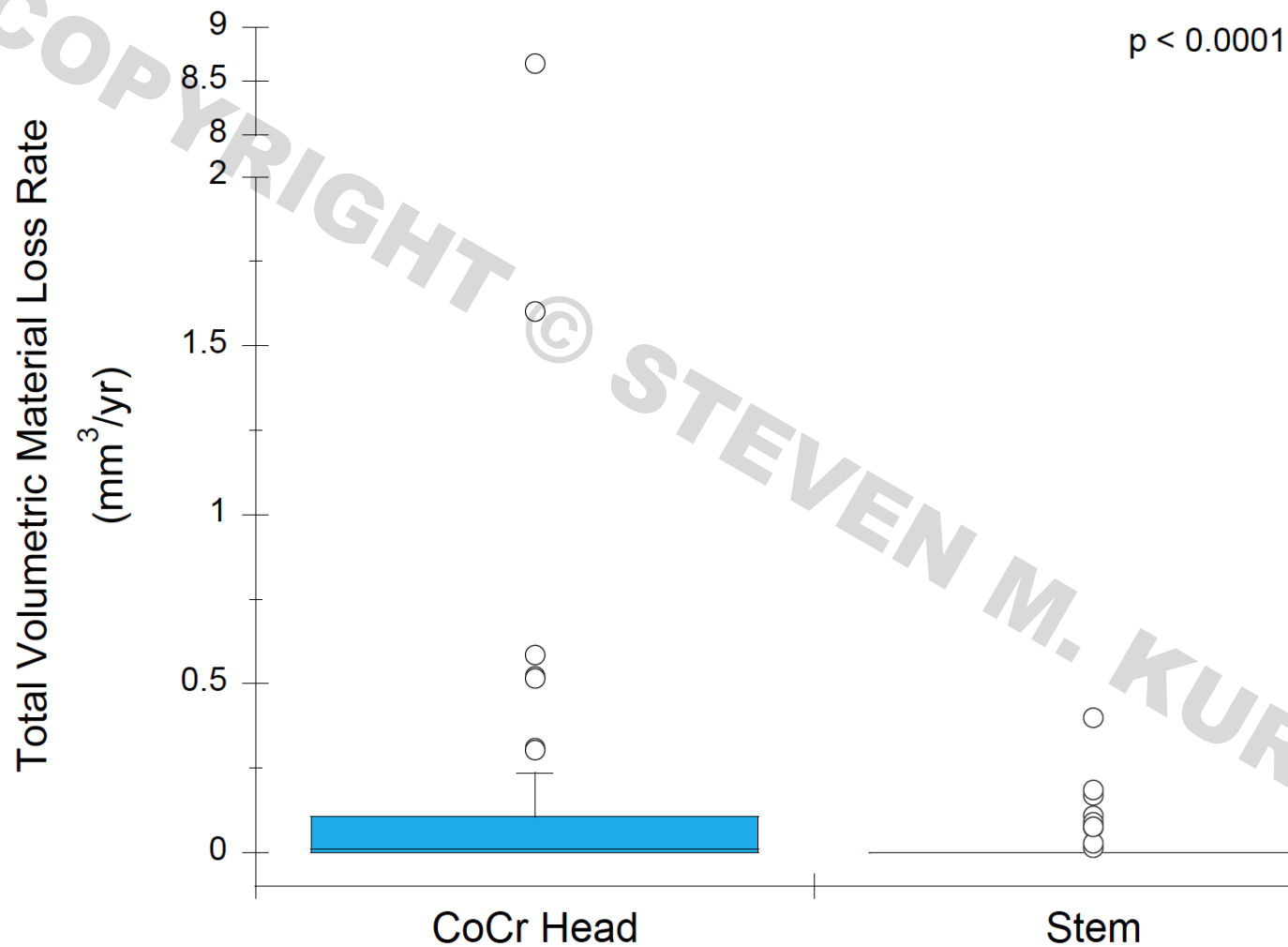
# Head Size (Ceramic Cohort Heads)



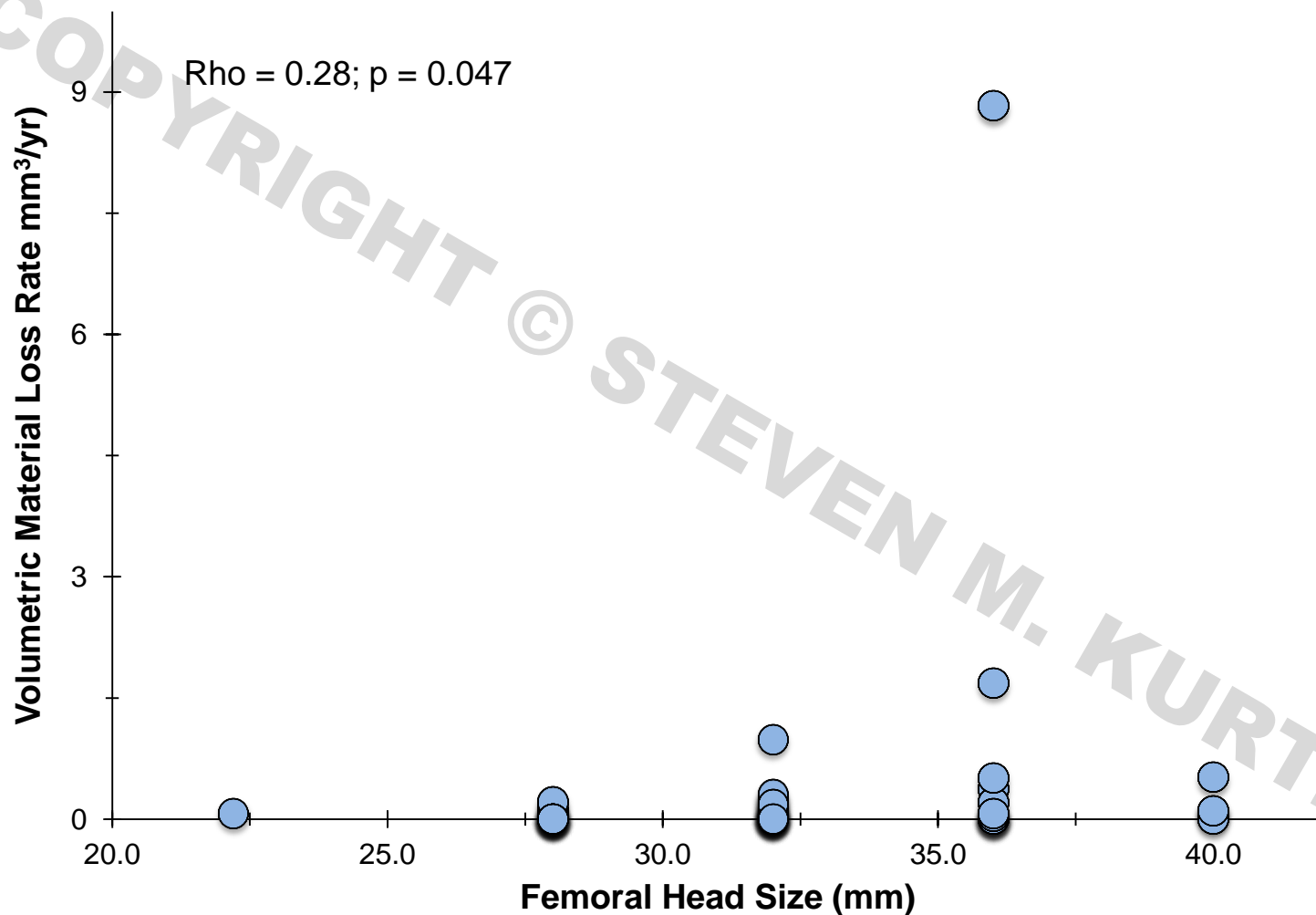
# Total Material Loss Rate



# Material Loss (Metal Cohort)

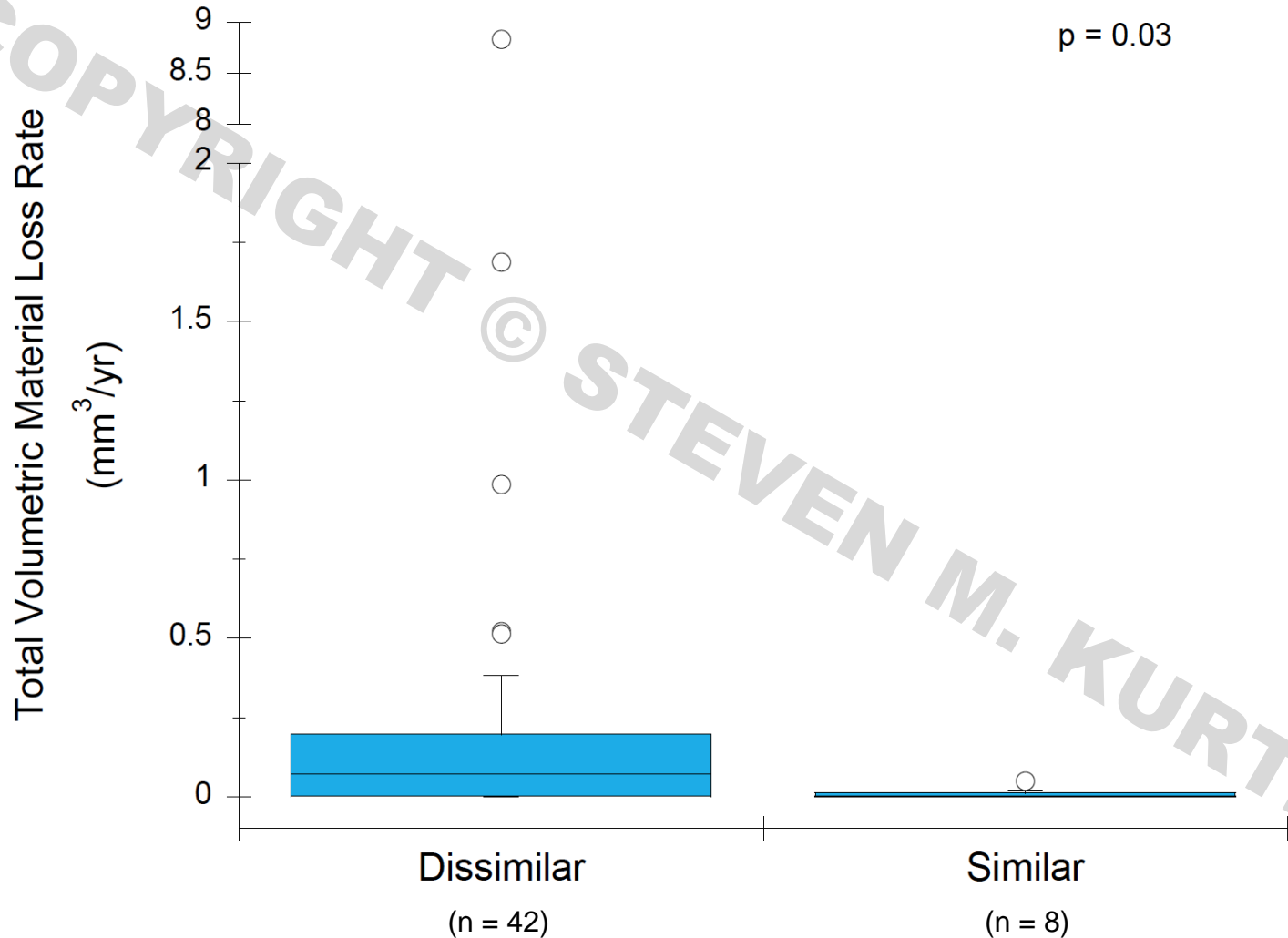


# Head Size (Metal Cohort)





# Alloy Combination (Metal Cohort)



# The Bearing Makes A Difference!

- Total material loss is less in ceramic head modular junctions than in metal head junctions
  - Ceramic head size ( $\leq 36$  mm) not associated with material loss
- CoCr heads generate  $>90\%$  of the material loss in modular tapers
- Ceramic heads are a solution for reducing taper corrosion

# Fretting and Corrosion Damage in Taper Adapter Sleeves: A Retrieval Study

2016 SICOT: Thursday Morning Hip Free Papers



# Taper Adapter Sleeves

- How to replace CoCr femoral head during revision for ALTR and taper corrosion?
- Revise using CoCr or Ceramic head?
- What to do when the taper is damaged?

1655

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## Corrosion at the Head-Neck Taper as a Cause for Adverse Local Tissue Reactions After Total Hip Arthroplasty

H. John Cooper, MD, Craig J. Della Valle, MD, Richard A. Berger, MD, Matthew Tetreault, BA, Wayne G. Paprosky, MD, Scott M. Sporer, MD, and Joshua J. Jacobs, MD

Investigation performed at the Department of Orthopaedic Surgery, Rush University Medical Center, Chicago, Illinois

**Background:** Corrosion at the modular head-neck junction of the femoral component in total hip arthroplasty has been identified as a potential concern, although symptomatic adverse local tissue reactions secondary to corrosion have rarely been described.

**Methods:** We retrospectively reviewed the records of three different manufacturers, who underwent revision

**Results:** All patients presented with pain or swelling. Serum cobalt levels were elevated prior to the revision at the femoral head-neck junction; the two patients had abductor musculature. Pathology specimens were treated with debridement and a femoral head and sleeve in eight cases. The mean Harris hip score in 13.0 months after the revision surgery ( $p = 0.01$ ). In 6 months following revision, decreased to a mean of 13.0 months with moderate hip abductor muscle in second revision arthroplasty.

**Conclusions:** Adverse local tissue reactions can occur at the modular femoral head-neck taper, as seen in patients with a metal-on-metal bearing. Elevated cobalt levels with respect to chromium levels, can

**Level of Evidence:** Diagnostic Level III. See Instr

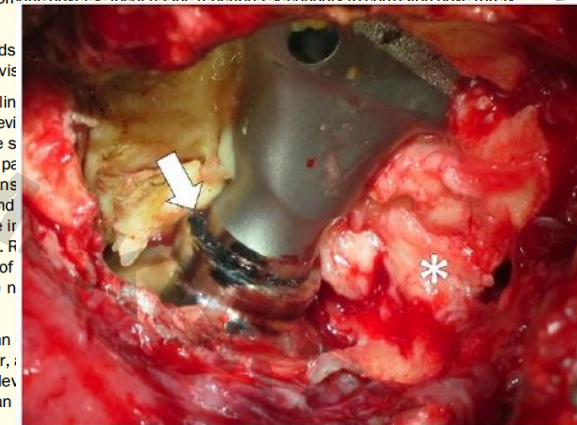


Fig. 2  
Intraoperative photograph demonstrating corrosion (arrow) at the modular head-neck taper between the femoral component and a collared (+10.5-mm) head. The pseudocapsule is markedly hypertrophic and avascular (asterisk), which is typical of this adverse local tissue reaction.

# Research Questions

1. What is the prevalence mechanically assisted crevice corrosion in **retrieved** taper adapters used in THA?
2. What implant and patient factors influence the fretting corrosion behavior of titanium taper sleeves?

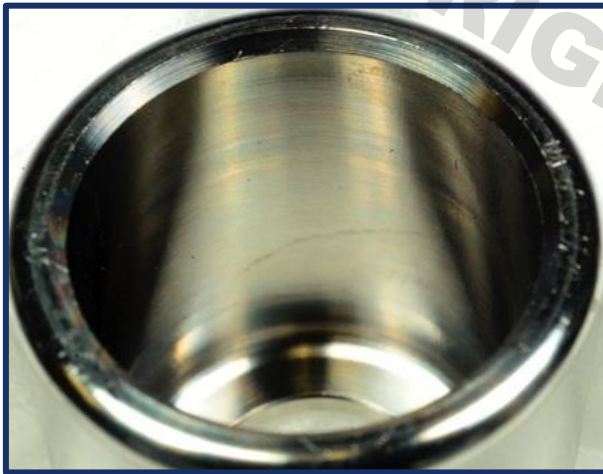


# Patient Demographics

- In vivo  $0.7 \pm 0.9$  years
  - Range: 0 – 3.2 years
- 49% Female (18/37)
- Age:  $58 \pm 9$  years
- UCLA Activity Score = 5
- 53% (19/37) were implanted in primary surgery.



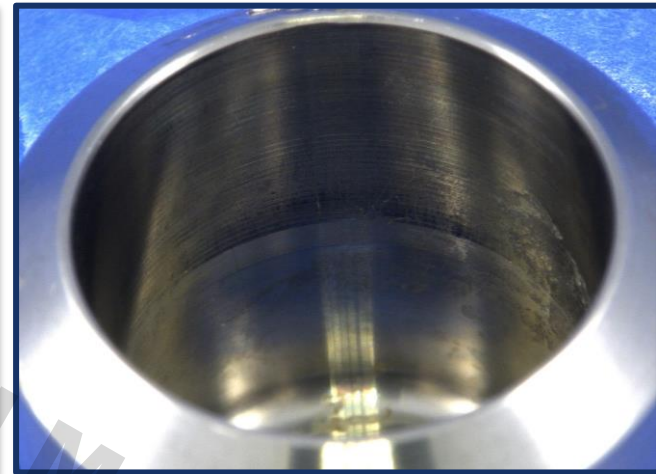
# Exemplar Fretting Corrosion Scores



1

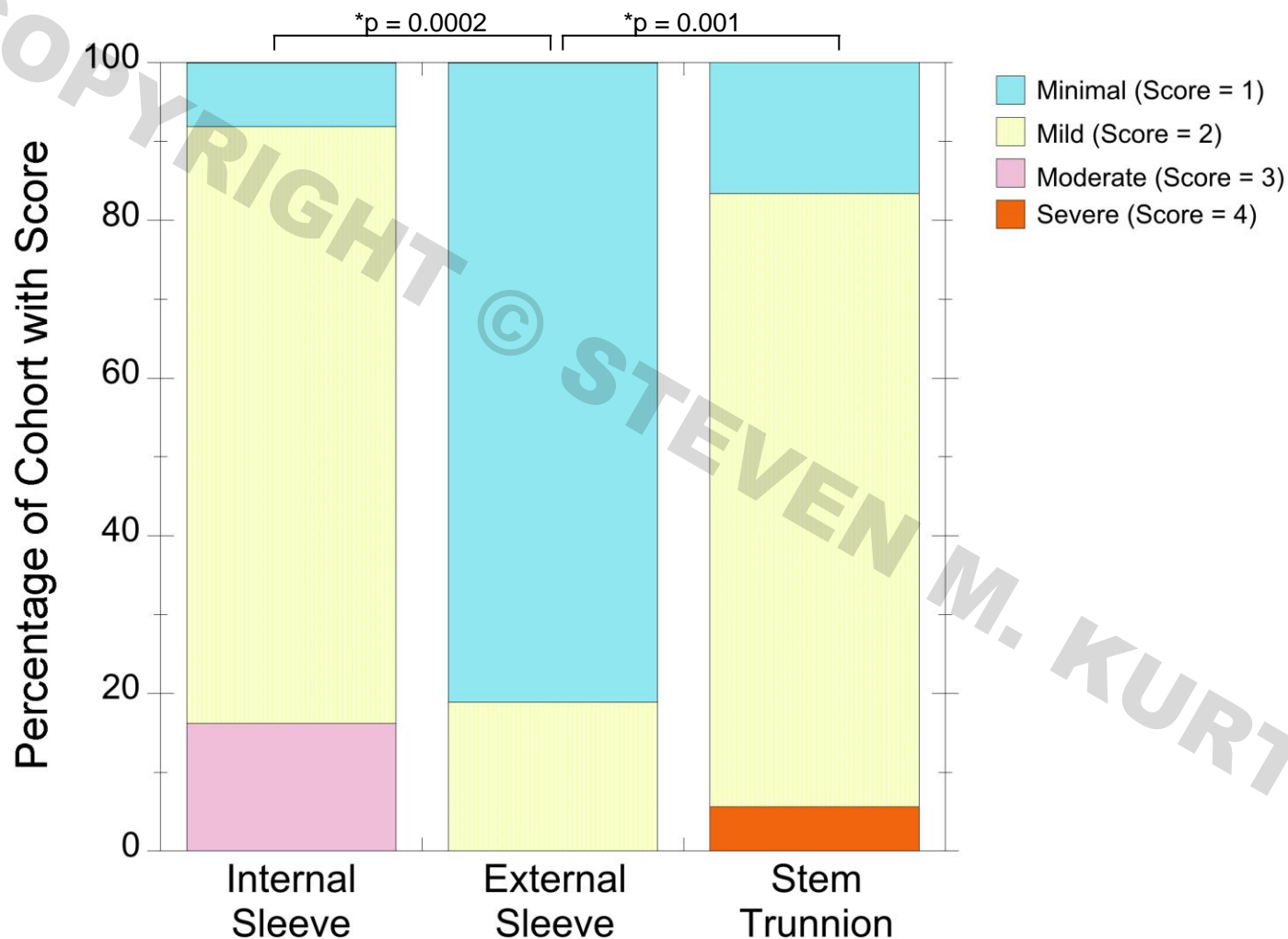


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# Fretting Corrosion Scores





# Discussion

- Limited revision options when faced with revision surgery involving a corroded, damaged taper:
  - Ceramic head + Ti sleeve
  - CoCr head
  - Revise stem
- Sleeves are Ti alloy
  - Ti corrosion products are considered to be less cytotoxic than Co and Cr

# Thank You!



## Welcome to the Medical Ceramics Encyclopedia

Our goals are to provide an online reference and education about the peer-reviewed literature for ceramic biomaterials used in total joint replacements and to stimulate hypothesis-driven research in applications of ceramic biomaterials. The focus of the site is to summarize the clinical performance of medical grade ceramic and ceramic implants.

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## Evaluation of the performance of BIOLOX<sup>®</sup>*delta* vs BIOLOX<sup>®</sup>*forte* components in total primary hip arthroplasty: Data from the RIPO Register

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### Abstract

Data of 30,617 primary uncemented total hip arthroplasty implants with at least one ceramic component produced by CeramTec have been extracted from the RIPO Registry and analyzed. The endpoint of analysis was revision of any component. Implants with pre-assembled ceramic inserts, double mobility systems, ceramic sandwich inserts as well as implants revised because of exchangeable neck breakage, were excluded from the study to avoid bias.

Survivorship analysis according to Kaplan-Meier at 8 years follow-up showed that 95.9% of the implants with BIOLOX<sup>®</sup>*forte*-BIOLOX<sup>®</sup>*forte* bearings have survived, while the figure was 97.4% for implants with BIOLOX<sup>®</sup>*delta*-BIOLOX<sup>®</sup>*delta* bearings at the same follow-up. BIOLOX<sup>®</sup>*forte* head fracture occurred in 0.55% of all cases and the same incidence was observed for damage or fracture of BIOLOX<sup>®</sup>*forte* inserts, both at 14 years follow-up. For BIOLOX<sup>®</sup>*delta* only one case of head fracture was observed (0.008%) as well as less complications for BIOLOX<sup>®</sup>*delta* liners (i.e. 0.05%), although at a shorter follow-up of 8 years.

It can be concluded that the ceramic composite material BIOLOX<sup>®</sup>*delta* represents a significant improvement in terms of fracture and survivorship when compared to the previous ceramic generation BIOLOX<sup>®</sup>*forte*.

### Introduction

The Registry for Orthopaedic Prosthetic Implants (RIPO) was established in the Italian region of Emilia-Romagna on January 1, 2000. The registry collects data on primary hip replacements and revision surgeries performed in public and private hospitals of the region. Surgeons provide data in specific register forms, which are completed before the patients are discharged. The registry capture rate is nearly 98%. The principal outcome measured is time to revision surgery, defined as removal or exchange of at least one component.

The present study compares the survival of BIOLOX<sup>®</sup>*delta* with BIOLOX<sup>®</sup>*forte* components, considering possible confounding factors.

### Study population

Patients implanted with Total Hip Arthroplasty (THA) in the Emilia-Romagna Region in the period from 01/01/2000 to 12/31/2013 are included. Only patients living in the region are analyzed to avoid any bias from possible loss to follow-up of non-resident pa-

tients. The extraction from the database was made on 04/18/2015.

The total number of implants recorded was 36,849 excluding all THA bearings with metal articulation components. To reduce the amount of other confounders, cemented, hybrid THA, metal backed components with pre-assembled ceramic inserts, double mobility cups and ceramic sandwich inserts were excluded. Additionally, to avoid possible bias, revisions of the prostheses due to modular neck fracture were also excluded and only ceramic components produced by CeramTec GmbH (Plochingen, Germany) were taken into account for the present study. Consequently the final number of THA analyzed in this study is 30,617 cases. Table I gives the number of implants per bearing type for the years 2000 to 2013. In the 14 year period more than 20,000 ceramic-on-ceramic bearings have been implanted in the Region of Emilia Romagna, the majority being BIOLOX<sup>®</sup>*delta*-BIOLOX<sup>®</sup>*delta* (Delta-Delta). Clearly the preferences and trends can be seen with phasing out BIOLOX<sup>®</sup>*forte* (Forte) and conventional polyethylene (Poly) over the years.

Year	Forte–Forte	Forte–Delta	Forte–Poly	Forte–XL Poly	Delta–Delta	Delta–Forte	Delta–Poly	Delta–XL Poly	Total
2000	244	–	270	7	–	–	–	–	521
2001	471	–	548	31	–	–	–	–	1,050
2002	594	–	620	53	–	–	–	–	1,267
2003	646	4	671	42	–	–	–	–	1,363
2004	775	27	697	66	2	–	–	1	1,568
2005	993	107	562	74	18	1	–	2	1,757
2006	1,162	141	489	55	46	11	–	19	1,923
2007	1,056	288	356	136	256	28	22	9	2,151
2008	341	288	219	183	1,213	72	104	79	2,499
2009	231	166	158	137	1,701	65	137	322	2,917
2010	43	68	49	102	2,263	110	154	498	3,287
2011	18	19	20	36	2,426	49	156	564	3,288
2012	4	16	10	12	2,610	11	103	740	3,506
2013	1	9	5	3	2,592	6	81	823	3,520
<b>Total</b>	<b>6,579</b>	<b>1,133</b>	<b>4,674</b>	<b>937</b>	<b>13,127</b>	<b>353</b>	<b>757</b>	<b>3,057</b>	<b>30,617</b>

**Forte** – BIOLOX®forte  
**Delta** – BIOLOX®delta  
**Poly** – conventional polyethylene  
**XL Poly** – highly cross-linked polyethylene

Table I: Total number of THA by year of surgery

### Descriptive statistics of patients

The total number of patients studied is 27,325, with 30,617 THA in a 14-year period. The demographics of the patient population is summarized in Table II.

Any difference between the bearing groups was tested with the Chi-square or ANOVA test depending on the distribution of data. A significant difference between

the groups in pathology distribution (Chi-Square Test,  $p < 0.05$ ) and BMI distribution (Chi-Square Test,  $p < 0.05$ ) was found. The mean age at surgery was different, too (ANOVA,  $p = 0.001$ ). As expected older patients received more often a bearing with a Poly component compared to all-ceramic solutions.

Head–liner	Forte–Forte	Forte–Delta	Forte–Poly	Forte–XL Poly	Delta–Delta	Delta–Forte	Delta–Poly	Delta–XL Poly
<b>N.</b>	6,579	1,133	4,674	937	13,127	353	757	3,057
<b>Mean age (range)</b>	63.2 (17–93)	63.5 (25–90)	69.1 (23–94)	66.8 (23–91)	66.0 (13–95)	65.1 (30–89)	71.4 (31–90)	71.8 (22–94)
<b>% Female</b>	59.9	71.0	63.3	63.1	57.9	51.3	70.7	58.9
<b>BMI mean (% obese)</b>	26.7 (14.6%)	26.7 (14.1%)	26.5 (12.0%)	27.3 (16.8%)	27.4 (16.4%)	27.1 (19.8%)	26.5 (13.2%)	27.3 (17.6%)
<b>% Coxarthrosis</b>	66.4	54.1	71.6	70.1	71.9	69.1	72.9	72.4

Table II: Patient demographics

### Descriptive statistics of the implants

While the 28 mm is the most frequently used bearing diameter for Forte-Forte the usage shifted to 32 and 36 mm with Delta-Delta, shown in Table III. The same

trend can be observed for Delta-XL Poly bearings. The diameters of implant bearings with Poly is generally smaller; the majority being 28 mm.

Diameter of the head (mm)	Forte–Forte	Forte–Delta	Forte–Poly	Forte–XL Poly	Delta–Delta	Delta–Forte	Delta–Poly	Delta–XL Poly
<b>28</b>	3,537 (53.8%)	7 (0.6%)	4,246 (90.8%)	477 (50.9%)	164 (1.2%)	206 (58.4%)	554 (73.2%)	474 (15.5%)
<b>32</b>	1,974 (30.0%)	411 (36.3%)	422 (9.0%)	268 (28.6%)	4,212 (32.1%)	57 (16.1%)	189 (25.0%)	971 (31.8%)
<b>36</b>	1,068 (16.2%)	715 (63.1%)	6 (0.1%)	192 (20.5%)	7,273 (55.4%)	90 (25.5%)	12 (1.6%)	1,542 (50.4%)
<b>≥40</b>	–	–	–	–	1,478 (11.3%)	–	2 (0.3%)	70 (2.3%)

Table III: Implant bearings used (number; percentage of diameter)

### Survivorship analysis

The unadjusted survival curves for each bearing combination, calculated according to the Kaplan-Meier method, are presented in Fig. 1 and Table IV. The analysis has been conducted for cementless THA only; end point is prosthesis failure, defined as the revision of any prosthetic component. Eight years follow-up was reached for all bearing

(i.e. periprosthetic fractures). As different cups and stems were used, this effect also needs to be considered.

In the case of Delta, component fracture is only a rare reason for revision (see Table V). The fracture rate of components made from CeramTec's 3<sup>rd</sup> generation monolithic alumina (i.e. 36 out of 6,579: 0.55%) is two

Head-liner	Number of implants	Number of revisions	(%) surviving at 8 years	Confidence interval at 95%	
<b>Forte-Forte</b>	<b>6,579</b>	<b>267</b>	<b>95.9</b>	<b>95.4</b>	<b>96.4</b>
<b>Forte-Delta</b>	<b>1,133</b>	<b>30</b>	<b>97.2</b>	<b>96.2</b>	<b>98.2</b>
<b>Forte-Poly</b>	<b>4,674</b>	<b>218</b>	<b>95.8</b>	<b>95.2</b>	<b>96.4</b>
<b>Forte-XL Poly</b>	<b>937</b>	<b>29</b>	<b>96.2</b>	<b>94.7</b>	<b>97.7</b>
<b>Delta-Delta</b>	<b>13,127</b>	<b>195</b>	<b>97.4</b>	<b>96.8</b>	<b>98.0</b>
<b>Delta-Forte</b>	<b>353</b>	<b>6</b>	<b>98.3</b>	<b>96.9</b>	<b>99.6</b>
<b>Delta-Poly*</b>	<b>757</b>	<b>17</b>	<b>96.0</b>	<b>93.0</b>	<b>99.1</b>
<b>Delta-XL Poly*</b>	<b>3,057</b>	<b>72</b>	<b>96.0</b>	<b>94.8</b>	<b>97.2</b>

Table IV: Survivorship of primary THA by bearing combination (\*survival at 6 years)

couples. At this point, the Cox multivariate analysis shows that Delta-Delta has a significantly lower hazard ratio compared to Forte-Forte (HR=1.36; p=0.002). Consequently, Delta-Delta reduces the risk of revision compared to Forte-Forte. The performance of Delta-Forte articulations has to be interpreted with caution, because of the low number of procedures.

Table V shows the rate of revision according to the cause of revision together with the percentage distribution of the causes of failure. Data are limited to the two most frequently used bearings, which is Forte-Forte and Delta-Delta.

It must be pointed out that all causes for revision are considered, even if not related to ceramic components

orders of magnitude higher than that of the 4<sup>th</sup> generation composite ceramic Delta (i.e. 1 out of 13,127: 0.008%) for ball heads, however, at a shorter follow-up (8 years) for Delta. Delta inserts have a tenfold decrease of fractures when compared to the monolithic alumina.

The lower dislocation rate found for Delta-Delta is probably due to the larger head sizes used with the composite material. It is worth mentioning that a larger diameter could be taken advantage of because of the better mechanical properties of the composite ceramic. They consequently allow the usage of thinner ceramic inserts, permitting larger ball heads, which was not possible with alumina inserts.

Cause of revision	Bearing	Forte-Forte			Delta-Delta		
	Number	6,579			13,127		
	Nr.	%	% of failures	Nr.	%	% of failures	
<b>Periprosthetic bone fracture</b>	54	0.82	20.2	28	0.21	14.4	
<b>Recurrent prosthesis dislocation</b>	46	0.70	17.2	40	0.30	20.5	
<b>Aseptic loosening of the stem</b>	36	0.55	13.5	41	0.31	21.0	
<b>Breakage/damage of the insert</b>	36	0.55	13.5	6	0.05	3.1	
<b>Breakage of the head</b>	36	0.55	13.5	1	0.008	0.5	
<b>Aseptic loosening of the cup</b>	8	0.12	3.0	13	0.10	6.7	
<b>Global aseptic loosening</b>	8	0.12	3.0	1	0.008	0.5	
<b>Pain without loosening</b>	7	0.11	2.6	11	0.08	5.6	
<b>Septic loosening</b>	7	0.11	2.6	16	0.12	8.2	
<b>Primary instability</b>	5	0.08	1.9	15	0.11	7.7	
<b>Heterotopic bone</b>	4	0.06	1.5	6	0.05	3.1	
<b>Breakage of the stem</b>	1	0.02	0.4	1	0.008	0.5	
<b>Other</b>	5	0.08	1.9	4	0.03	2.1	
<b>Unknown</b>	14	0.21	5.2	12	0.09	6.2	
<b>Total</b>	<b>267</b>	<b>4.1</b>	<b>100</b>	<b>195</b>	<b>1.5</b>	<b>100</b>	

Table V: Reasons for failure of CoC bearings

**Forte** – BIOLOX<sup>®</sup>forte  
**Delta** – BIOLOX<sup>®</sup>delta  
**Poly** – conventional polyethylene  
**XL Poly** – highly cross-linked polyethylene

## Conclusion

A detailed analysis of 30,617 THA cases with at least one ceramic component from CeramTec documented by the Emilia-Romagna Region arthroplasty Registry over a period of 14 years shows a major improvement in fracture rate and cumulative percentage of revisions for implants with BIOLOX<sup>®</sup>delta ceramic composite bearings compared to the previous generation BIOLOX<sup>®</sup>forte. The 4<sup>th</sup> generation BIOLOX<sup>®</sup>delta ceramic in a hard-on-hard configuration demonstrated to have the best survivorship of all bearings included in the study. Component fracture of this composite ceramic is an extremely rare complication today.

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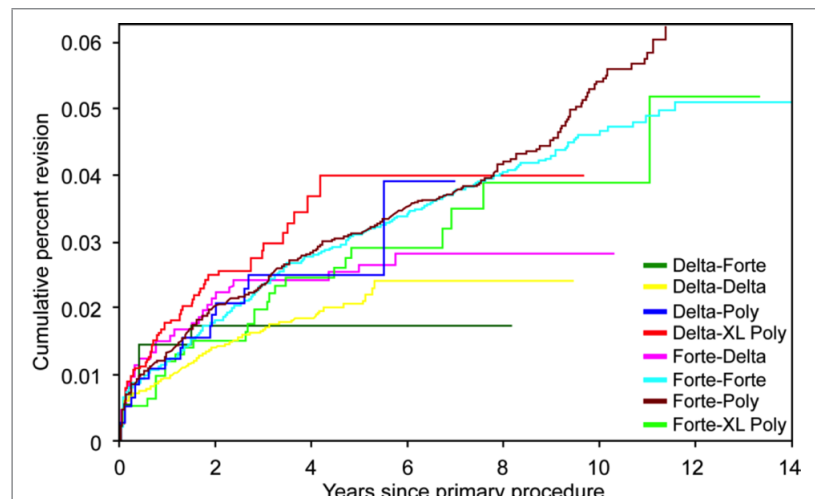


Figure 1: Cumulative percent revision of primary Total Conventional Hip Replacement according to coupling



**Aldo Toni** is Head of the Special Orthopedic-Trauma Pathology Department and responsible for prosthetic surgery and revision of hip and knee implants ward. He is also responsible for the Medical Technology Lab at the Istituto Ortopedico Rizzoli. His main surgical activity is related to hip prosthetic surgery, both primary and complex revision. Since 1990, he has been first surgeon in 3,000 primary THA and 1,200 revisions. In the vast majority of the cases ceramic components have been implanted.