Monthly **CeraNews**

Neues aus Orthopädie und Unfallchirurgie, Ausgabe Dezember 2016

Weniger Fretting mit Keramik

Beim SICOT-Kongress 2016 stellte **Dr. Steven Kurtz** die Ergebnisse einer Explantatstudie an gematchten Kohorten von Metall- und Keramikköpfen vor. Danach gibt es mit Keramikköpfen weniger Materialverlust in der Kopf/Konus-Verbindung als mit Metallköpfen. CoCr-Köpfe seien für über 90 % des Materialverlustes bei modularen Konussen verantwortlich. Keramikköpfe „seien eine Lösung zur Verringerung der Konuskorrosion".

MEHR INFORMATION >

NIH zur Karzinogenität von Kobalt

Im 14. Karzinogen-Bericht der NIH (USA) wurden Kobalt und Kobaltverbindungen neu in die Liste aufgenommen. Die Freisetzung von Kobaltionen in vivo habe zur „begründeten Annahme der Karzinogenität für den Menschen" geführt. Der Listeneintrag für Kobalt umfasst verschiedene Kobaltverbindungen, die Ionen im Körper freisetzen. Die stärkste Exposition ist am Arbeitsplatz und bei Implantatversagen zu finden. https://www.nih.gov/news-events/news-releases/seven-substances-added-14th-report-carcinogens

BIOLOX®*delta*: ein Game Changer?

Toni et al. führten eine komparative Analyse von 30.617 primären Hüfttotalendoprothesen mit Keramikkomponenten aus dem italienischen Register RIPO durch. Sie wiesen nach, dass BIOLOX®*delta*-Komponenten mit erheblich weniger Frakturen und signifikant besseren Überlebensraten eine bedeutende Verbesserung gebracht haben. Die Überlebensrate nach Kaplan-Meier nach 8 Jahren beträgt 95,9 % für Implantate mit BIOLOX®*forte*/BIOLOX®*forte*-Gleitpaarungen und 97,4 % für BIOLOX®*delta* / BIOLOX®*delta*-Gleitpaarungen.

MEHR INFORMATION >

Herausgeber: CeramTec GmbH
CeramTec-Platz 1–9, 73207 Plochingen
Tel.: +49 7153 611-828, Tel: +49 7153 611-950
ceranews@ceramtec.de, www.biolox.de

Editorial board:
- *Hartmuth Kiefer*
- *Steven Kurtz*
- *Rocco Pitto*
- *Robert Streicher*

Zunehmende Evidenz: Empfehlung für Keramikköpfe

Die Evidenz zur Tribokorrosion in modularen Verbindungen von Hüfttotalendoprothesen und die durch sie ausgelöste Freisetzung von Metallpartikeln und Ionen waren in den vergangenen zwei Jahren ein vorherrschendes Thema. **Tan** et al. bestätigen die Ergebnisse von Kurtz et al. zur positiven Wirkung von Keramikkugelköpfen zur Reduktion von Tribokorrosion. Die klinische Wirkung von Metallzersetzungsprodukten wurde ebenfalls in mehreren Arbeiten belegt. **Lash** et al. stellen zehn Fälle mit Metall/Polyethylen-Gleitpaarung vor, bei denen es zu Spätluxation im Zusammenhang mit unbemerkter adverser Gewebereaktion aufgrund von Konuskorrosion und der Entwicklung von Pseudotumoren kam. In einer großen retrospektiven Studie zeigen **McGrory** et al., dass die Weichteilschädigung durch Tribokorrosion mit der Zeit fortschreitet. Sie plädieren für ein frühzeitiges chirurgisches Eingreifen und empfehlen den Einsatz von Keramikköpfen, bis diese Komplikation besser untersucht ist. **White** et al. stellen in ihrer Studie zum Vergleich von Metall- und Keramikköpfen nach 5 Jahren bei 57 % der Patienten in der Gruppe mit Metallkopf erhöhte Kobaltwerte fest. Von diesen trat bei 13 % eine adverse lokale Gewebereaktion auf. Bei 7 % dieser Patienten ist bereits eine Revision erfolgt. Die Ke/PE-Gleitpaarungen blieben ohne Komplikation.

MEHR INFORMATION >

Keramik-Frakturraten signifikant reduziert

Lee und **Kim** bestimmten mithilfe der CeramTec-Datenbank die Frakturraten von Kugelköpfen aus Aluminiumoxidkeramik (BIOLOX®*forte*) und Mischkeramik (BIOLOX®*delta*). Zwischen Januar 2000 und Dezember 2013 wurden über 3,2 Millionen BIOLOX®*forte*-Köpfe und 2,78 Millionen BIOLOX®*delta*-Köpfe verkauft und implantiert. Während dieser Zeit wurden 672 Frakturen von Aluminiumoxidköpfen und 28 Frakturen von Mischkeramikköpfen erfasst. Die Frakturrate betrug 0,02 % für BIOLOX®*forte* und nur 0,001 % für die Keramik der neuesten Generation, BIOLOX®*delta*. 80 % der Frakturen traten innerhalb von 48 Monaten nach Implantation auf.

MEHR INFORMATION >

Zuverlässige Mischkeramik BIOLOX®*delta:* Frakturraten

BIOLOX®*delta* Mischkeramik-Köpfe

BIOLOX®*delta* Mischkeramik-Inserts

Datenbank des Herstellers* 5.730.000 Komponenten	**0,001%** 44 Frakturen 4.080.000 Köpfe	**0,021%** 351 Frakturen 1.650.000 Inserts

Register und Gesundheitsbehörden

Australian Joint Replacement Registry AOANJRR[1]	**0,002%** 1 Fraktur 54.741 Köpfe	k.A.
Massin et al. / Französische Gesundheitsbehörden ANSM[2] 342.769 Komponenten	**0,001%** 3 Frakturen 230.769 Köpfe	**0,025%** 28 Frakturen 112.000 Inserts
Register von Emilia Romagna (Italien)[3] 36.996 Komponenten	**0,005%** 1 Fraktur 20.960 Köpfe	**0,050%** 8 Frakturen 16.036 Inserts

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

Endoprothesenregister, Daten von Gesundheitsbehörden und die CeramTec-Datenbank zeigen ähnlich niedrige Frakturraten für Komponenten aus BIOLOX®*delta*.

MT-MM 0045 1612 DE

Executive Summary

Issue December 2016

Title	**Tribocorrosion: Ceramic and Oxidized Zirconium vs. Cobalt-Chromium heads in Total Hip Arthroplasty**
Authors	Sok Chuen Tan, Adrian C.K. Lau, Christopher DelBalso, James L. Howard, Brent A. Lanting, Matthew G. Teeter
Journal	Journal of Arthroplasty; available online February, 27, 2016
Level of Evidence	None given. Matched cohort retrieval study
Summary	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®*delta* (15), zirconia (29) and alumina (8). The ceramic cohort was significantly younger than the CoCr cohort, otherwise they were similar. 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. 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. 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. This study demonstrates once again that ceramic heads exhibit lower fretting and corrosion scores compared with CoCr heads.
Study Limitations	No information on stem materials
	No information on stem offset
	Small number of components for the OXINIUM™ vs. CoCr cohorts
Key Messages	**Ceramic femoral heads exhibit lower fretting and corrosion scores compared with CoCr femoral heads**
	No significant differences of fretting and corrosion scores between OXINIUM™ and CoCr femoral heads

Oxinium™ is a registered trademark of Smith and Nephew

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Executive Summary

Issue December 2016

Title	**Delayed dislocation following metal on polyethylene arthroplasty of the hip due to "silent" trunnion corrosion**
Authors	Lash,N.J.; Whitehouse,M.R.; Greidanus,N.V.; Garbuz,D.S.; Masri,B.A.; Duncan,C.P.
Journal	The Bone and Joint Journal VOL. 98-B, No. 2, February 2016
Level of Evidence	None given
Summary	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®*delta* 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). 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®*delta*) femoral head with a titanium sleeve in patients with sensitivity to cobalt and/or chrome.
Study Limitations	Case series with only 10 THAs
	No investigation of metal levels within the tissue during revision
Key Messages	**Late dislocation in MoP bearings can occur due to extensive tissue damage because of ALTR due to corrosion.**
	BIOLOX®*delta* femoral heads with a sleeve can successfully be used in patients with ALTR after MoP THA.

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Executive Summary

Issue December 2016

Title	**A High Prevalence of Corrosion at the Head-Neck Taper with Contemporary Zimmer Non-Cemented Femoral Hip Components**
Authors	Brian J. McGrory, Johanna MacKenzie, George Babikian
Journal	The Journal of Arthroplasty 30 (2015) 1265–1268
Level of Evidence	None given
Summary	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. 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®*delta*) femoral heads.
Study Limitations	Study uses only the database of a single surgeon
	Study uses only one component manufacturer, although 5 stem types
	Inclusion criteria are random
	Authors' opinion based on findings
Key Messages	**In this study the prevalence of MACC was 1.1-1.5%, with the majority of symptomatic patients already revised.**
	All revised implants showed visible corrosion at the head-neck junction with varying degrees of soft tissue damage.
	If MACC symptoms (e.g. increasing or new pain) occur prompt surgical intervention is recommended to avoid severe soft tissue damage.
	The authors recommend the use of ceramic femoral heads with titanium stems until this problem is better understood.

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Executive Summary

Issue December 2016

Title	**A comparison of blood metal ions in total hip arthroplasty using metal and ceramic heads**
Authors	Peter B. White, BA, Morteza Meftah, MD, Amar S. Ranawat, MD, Chitranjan S. Ranawat, MD
Journal	J. Arthroplasty, Volume 31, Issue 6, June 2016
Level of Evidence	None given
Summary	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®*delta*) 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. 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. 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. 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. 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®*delta*) heads reduces the incidence and magnitude of cobalt and chromium ion release significantly.
Study Limitations	Detection limit for cobalt and chromium ions in serum was high.
	Results are not generalizable to other hip systems.
	Titanium ion levels were not measured.
	Age difference between the groups was > 10 years.
	Patient number was low.
	No information regarding specific patient inclusion/exclusion criteria
Key Messages	**No patient with CoP bearings had detectable cobalt or chromium level.**
	No patient with CoP bearings had any adverse reaction.
	56.7% of patients with a metal head had detectable cobalt levels in serum.
	13% of patients with MoP bearings had ALTR, 2 of them have been revised.
	Larger metal heads release larger amounts of cobalt.

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Executive Summary

Issue December 2016

Title	**Incidence of modern alumina ceramic and alumina matrix composite femoral head failures in nearly 6 million hip implants**
Authors	Gwo-Chin Lee and Raymond H. Kim
Journal	J Arthroplasty 2016 Aug 20. pii: S0883-5403(16)30510-1. doi: 10.1016/j.arth.2016.08.011
Level of Evidence	None given
Summary	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®*forte* and BIOLOX®*delta* heads as well as factors such as time in situ, head size, and taper influence on ceramic head fractures. Between January 2000 and December 2013, over 3.2 million BIOLOX®*forte* and 2.78 million BIOLOX®*delta* heads were sold and implanted worldwide. During this 14 year time interval 672 BIOLOX®*forte* and 28 BIOLOX®*delta* head fractures were reported. The fracture rate was 0.020% for BIOLOX®*forte* and 0.001% for BIOLOX®*delta*. Most of the fractures (80%) occurred within 48 months. Due to the small number of failures of BIOLOX®*delta* 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®*forte* heads (28mm) were also more likely to fracture than larger ones (≥32mm). The same trend was seen for BIOLOX®*delta* 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®*delta* heads and contamination of the stem taper was commonly found in BIOLOX®*forte* head fractures. The authors conclude that BIOLOX®*delta* femoral heads have a significantly lower fracture rate compared to BIOLOX®*forte*, larger heads (≥32mm) are less likely to fracture, dislocations and taper mismatch and contamination are associated with ceramic head fracture.
Study Limitations	Actual fracture rates might be higher due to possible underreporting of component failures to CeramTec.
	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.
	Epidemiology of BIOLOX®*delta* fractures could not be analyzed in depth due to the small number fractures.
Key Messages	**BIOLOX®*delta* femoral heads have a significantly lower fracture rate than BIOLOX®*forte* heads.**
	Smaller femoral heads (≤28mm) are more likely to fracture.
	Important factors for preventing ceramic fractures are appropriate taper design and taper fit (no taper mismatch), proper taper cleansing and impaction of the heads.

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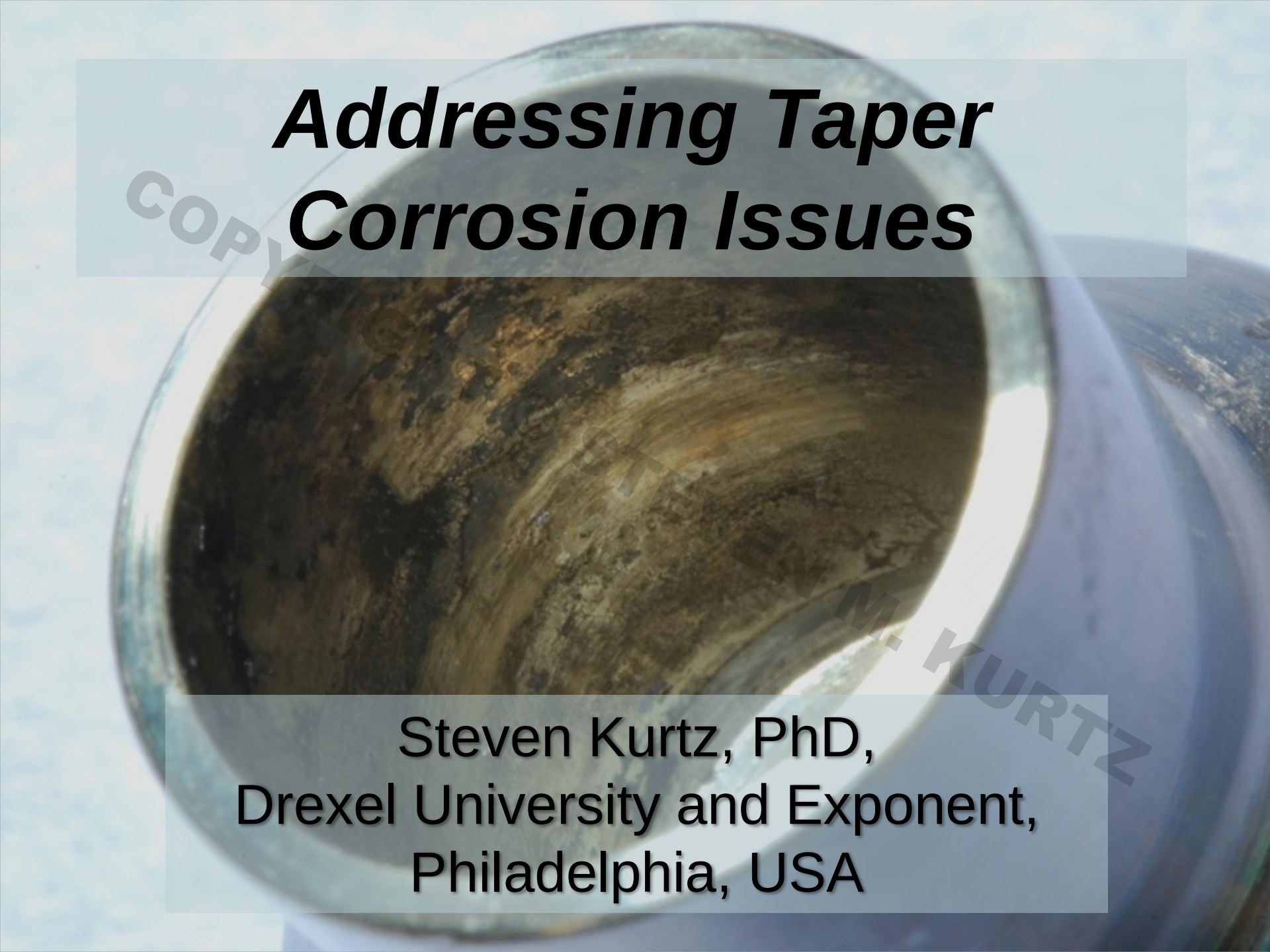
Addressing Taper Corrosion Issues



Steven Kurtz, PhD,
Drexel University and Exponent,
Philadelphia, USA

NIH R01 AR47904

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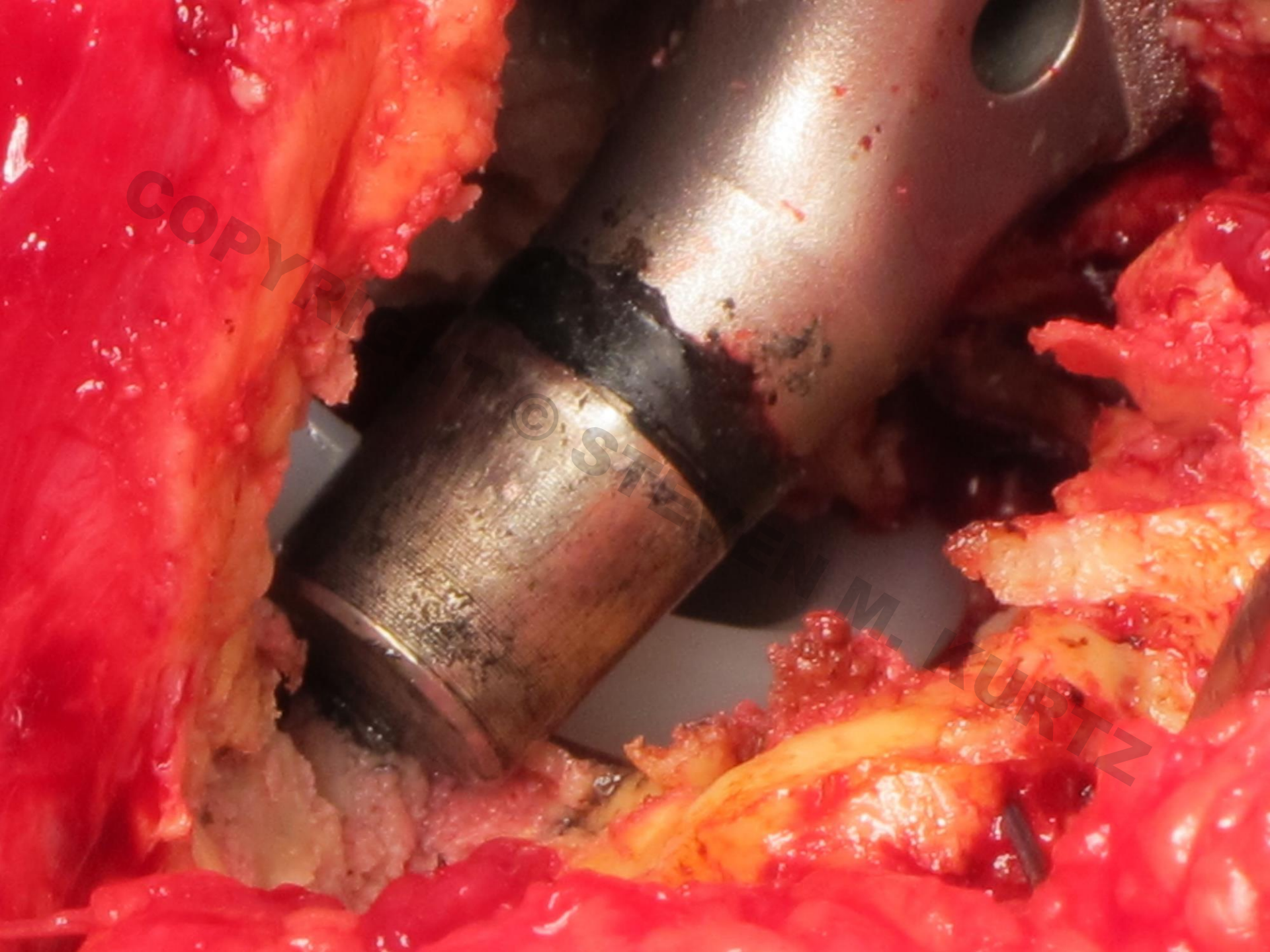
NIAMS
National Institute of Arthritis and Musculoskeletal and Skin Diseases

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?

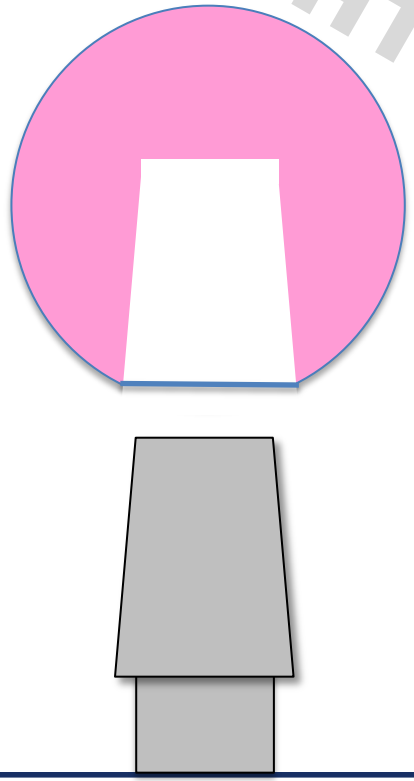


Taper Corrosion is Not New

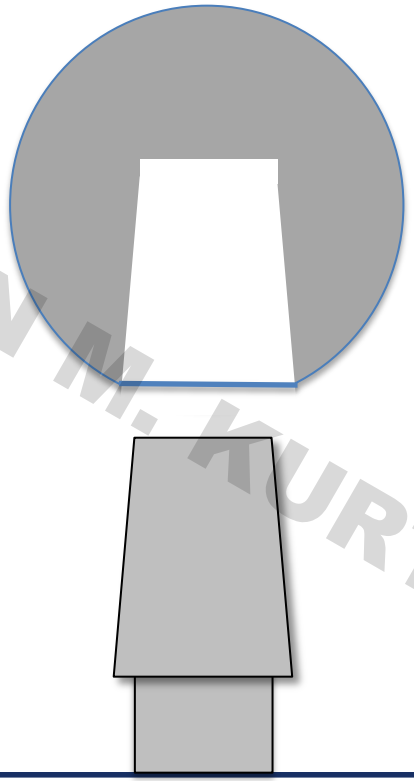
- Retrieval analyses from the late 1980's revealed corrosive attack of modular interfaces
  - Proposed mechanism: mechanically assisted crevice corrosion (Gilbert et al, 1993)
  - Complex, multifactorial problem

Are Ceramics Heads a Solution to Taper Corrosion?

Ceramic-Metal Modular Junction



Metal-Metal Modular Junction



1st Study: Taper Damage (2013)

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

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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

2nd 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

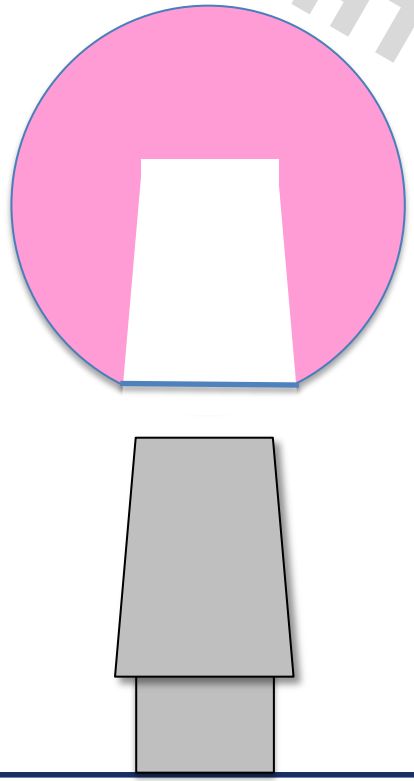
www.orthoceramics.org

2nd Study: Material Loss (2016)

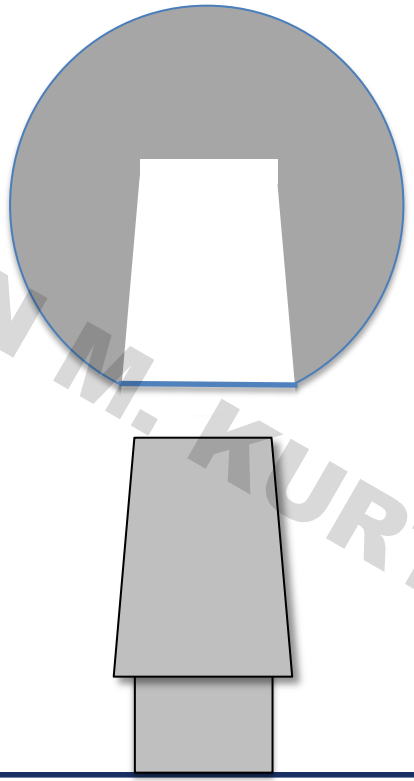
To compare taper corrosion and material loss between ceramic and CoCr head-stem tapers in retrievals using a matched cohort study design

Matched Cohort Study Design

Ceramic Head Cohort
(N = 50 pairs)

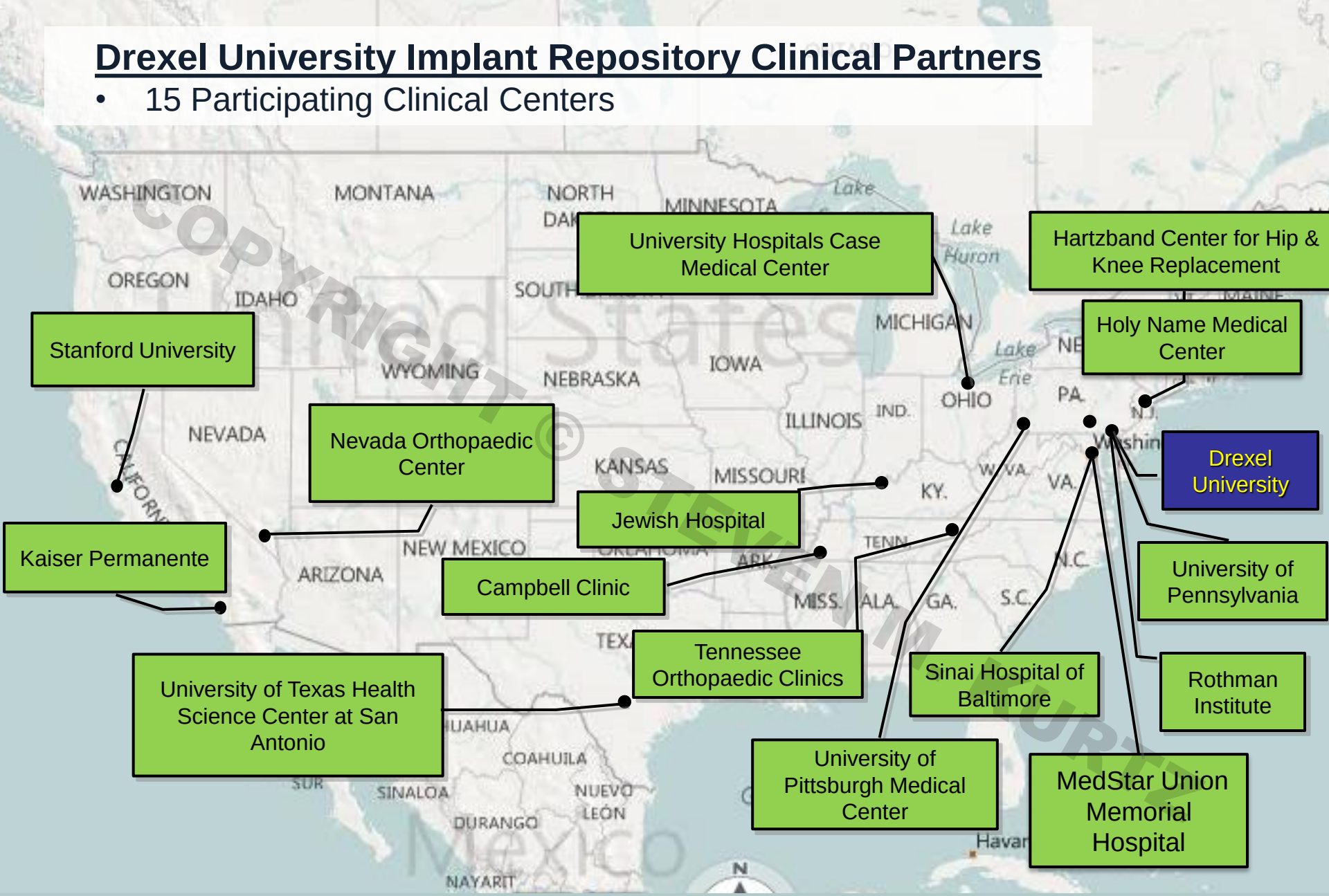


Metal Head Cohort
(N = 50 pairs)



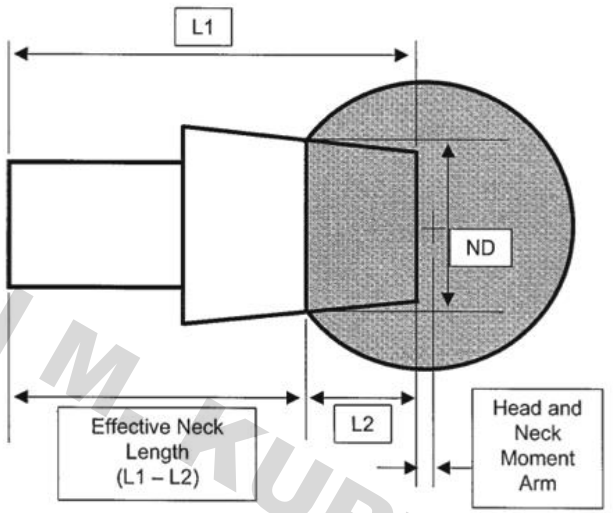
Drexel University Implant Repository Clinical Partners

- 15 Participating Clinical Centers



Cohort Matching Criteria

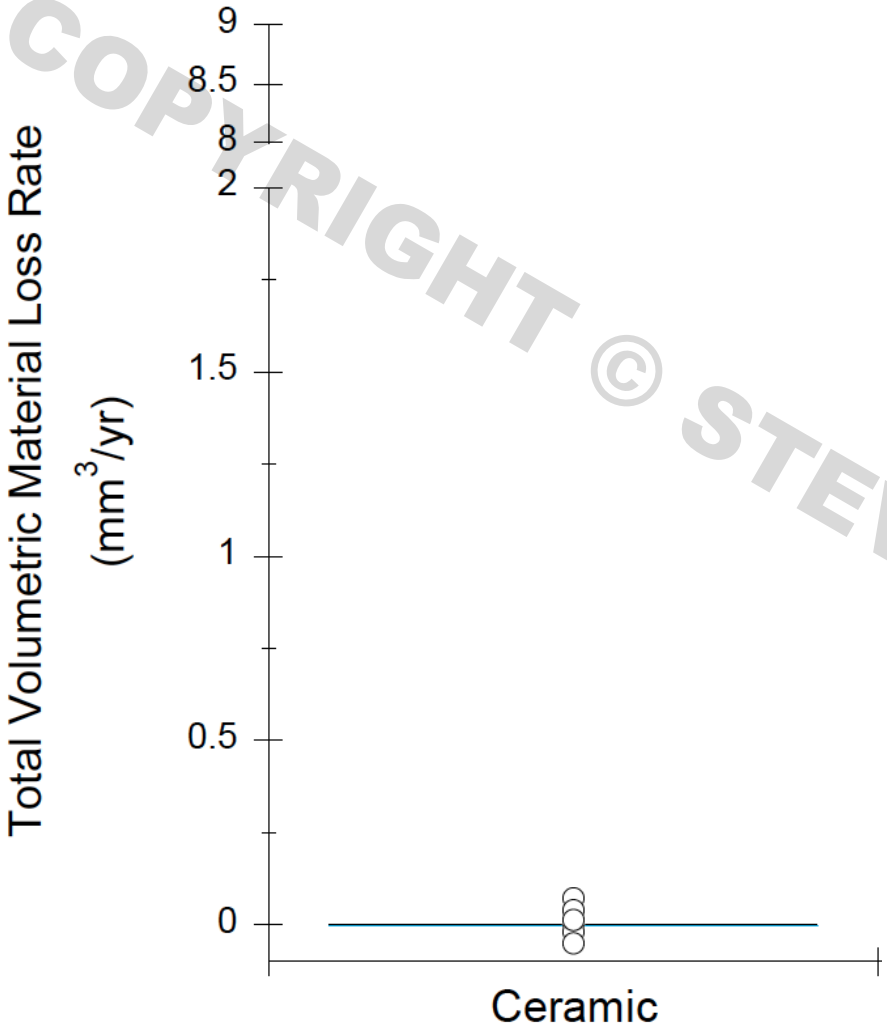
1) Implantation time (most important)
2) Stem flexural rigidity
3) Lateral offset
4) Head size



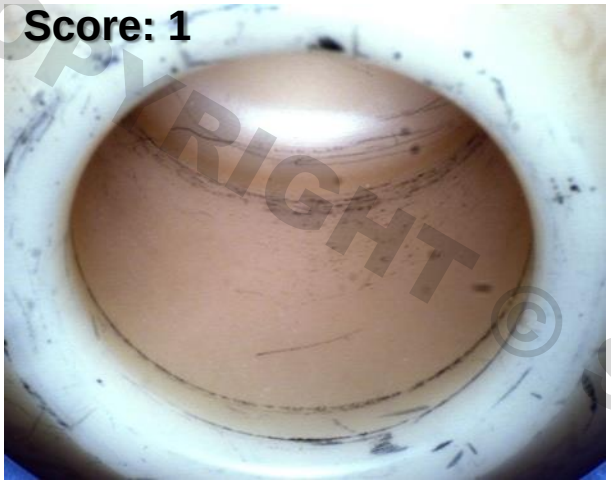
- Goldberg et al., CORR, 2002
- Higgs et al., AAHKS, 2012

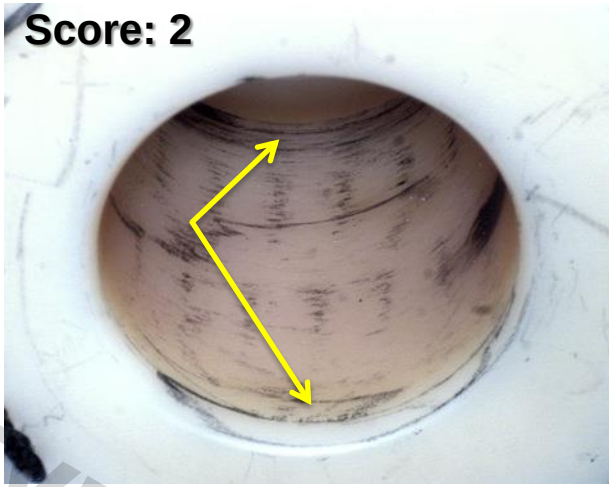
$$Flexural Rigidity = E' I = E' \frac{p' (ND)^4}{64}$$

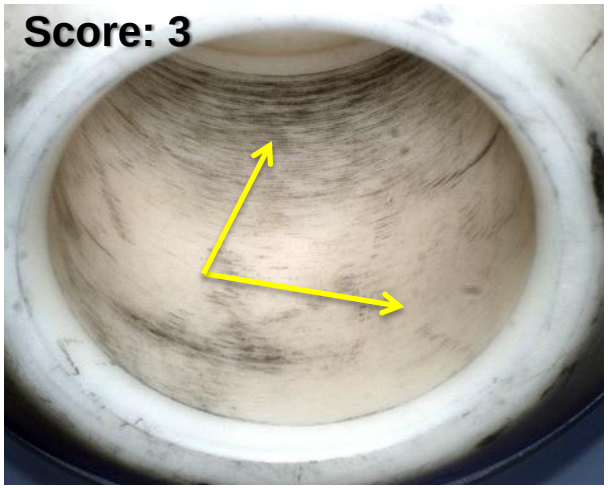
Total Material Loss Rate

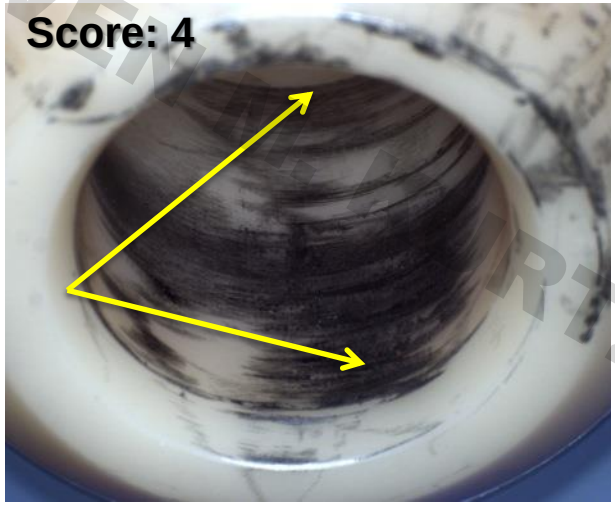


Head Taper (Ceramic)

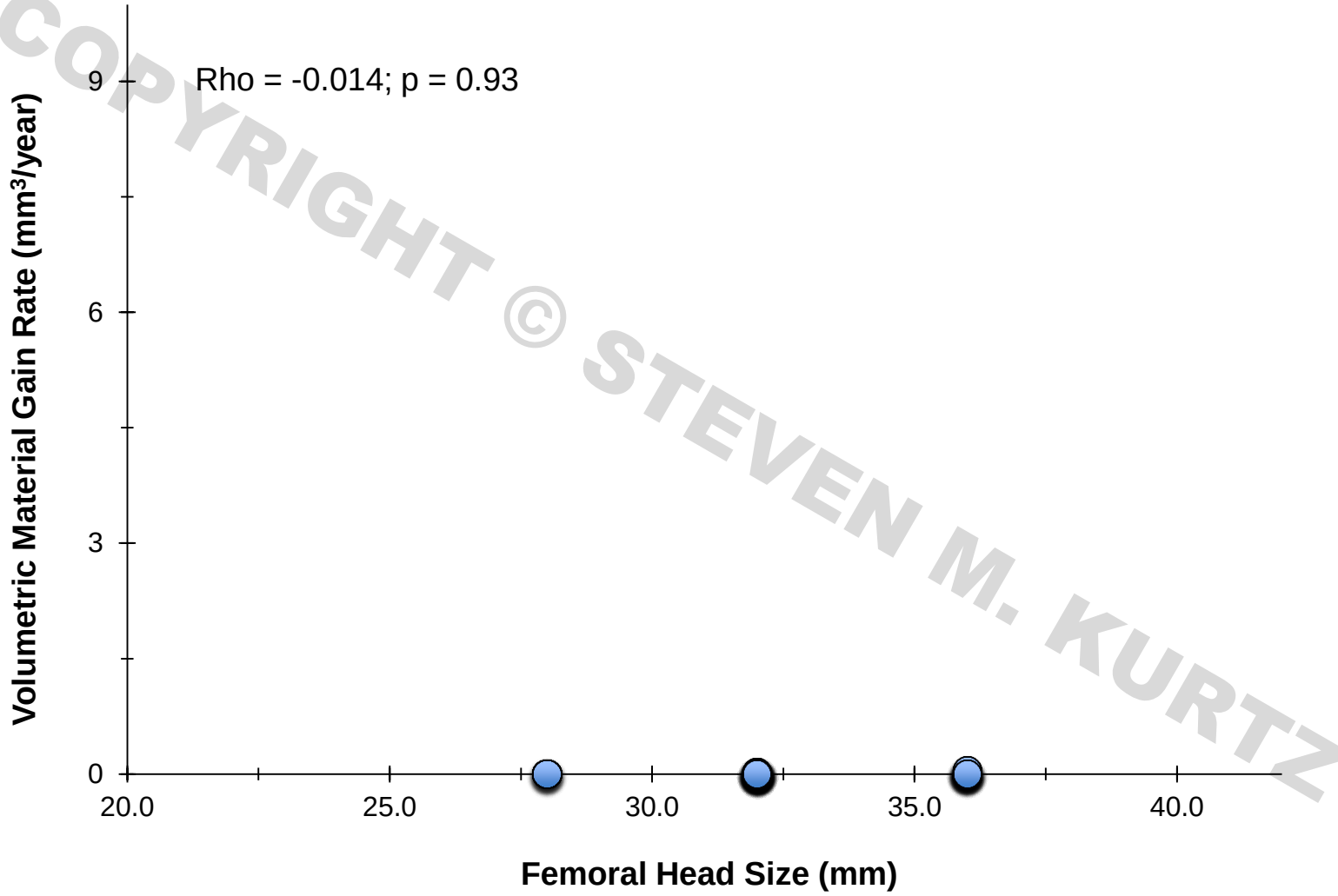




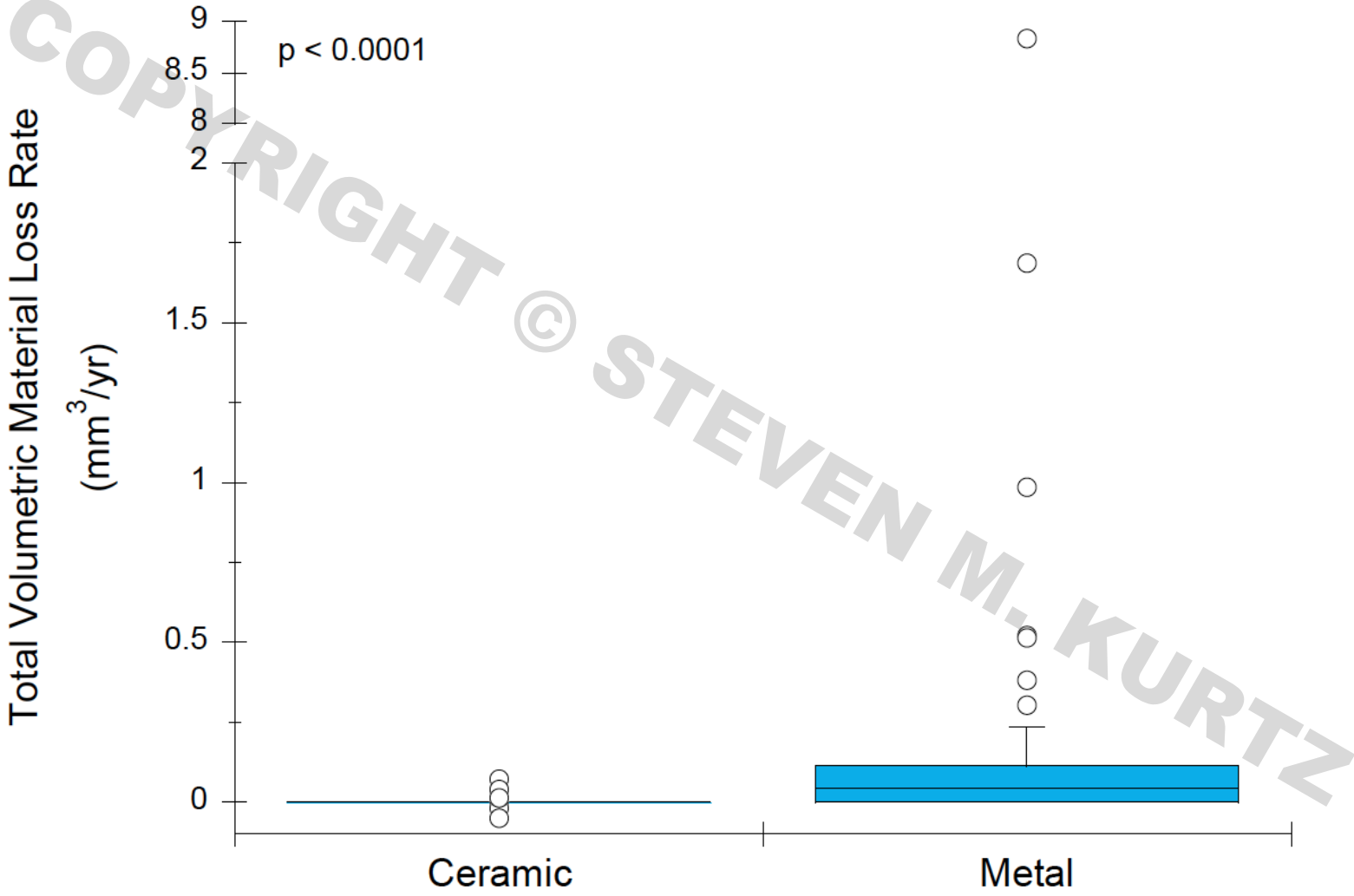




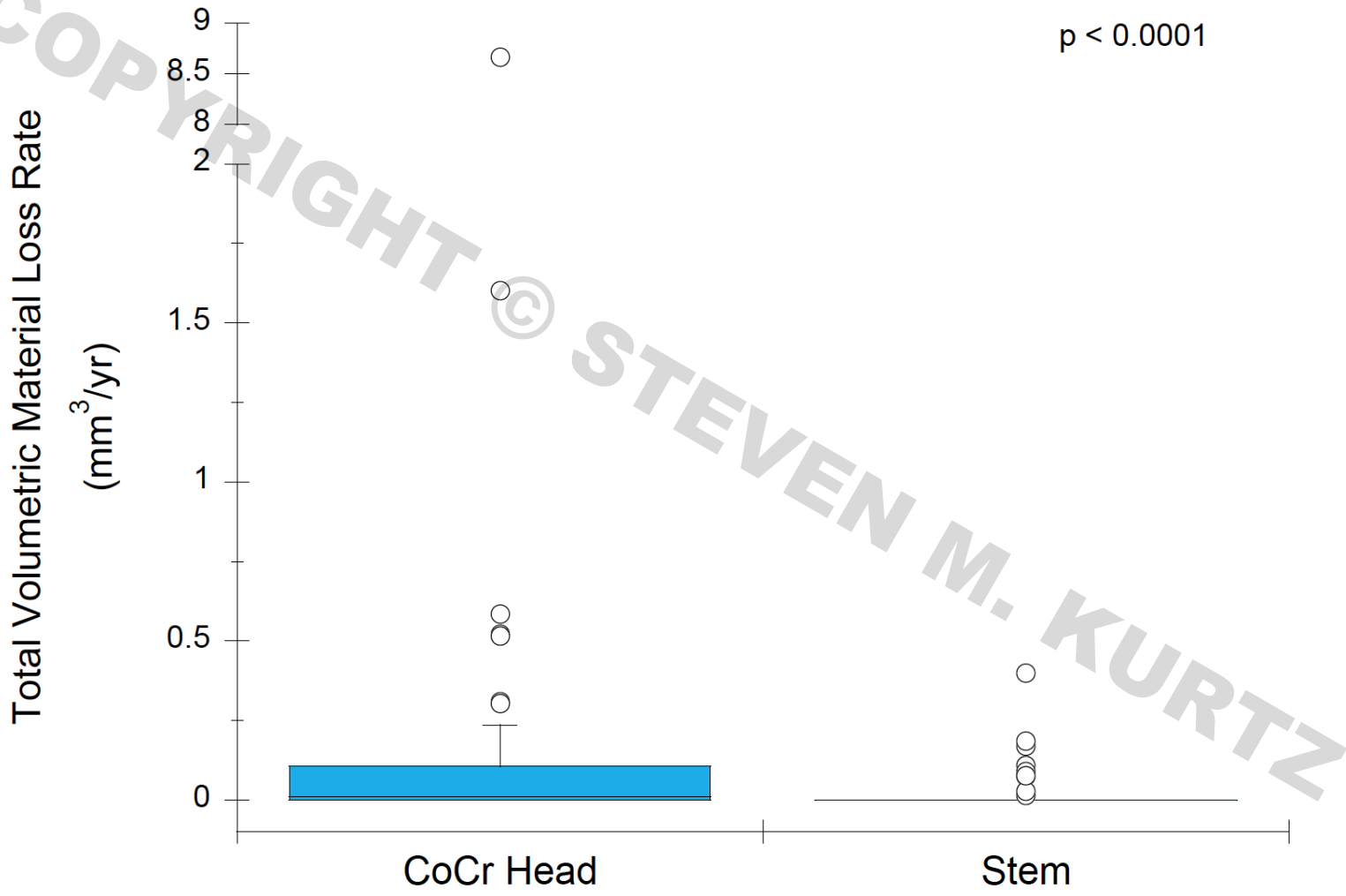
Head Size (Ceramic Cohort Heads)



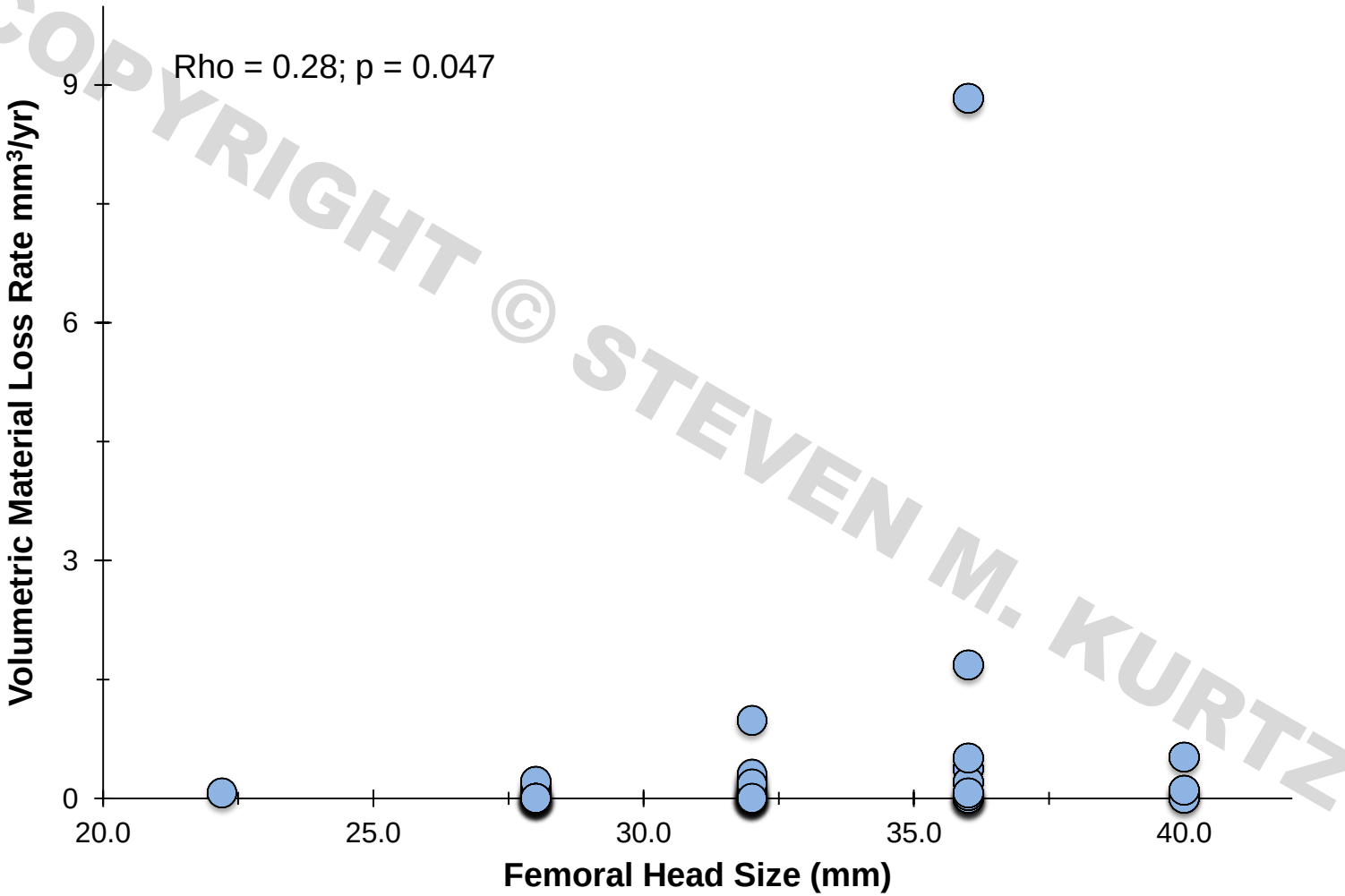
Total Material Loss Rate



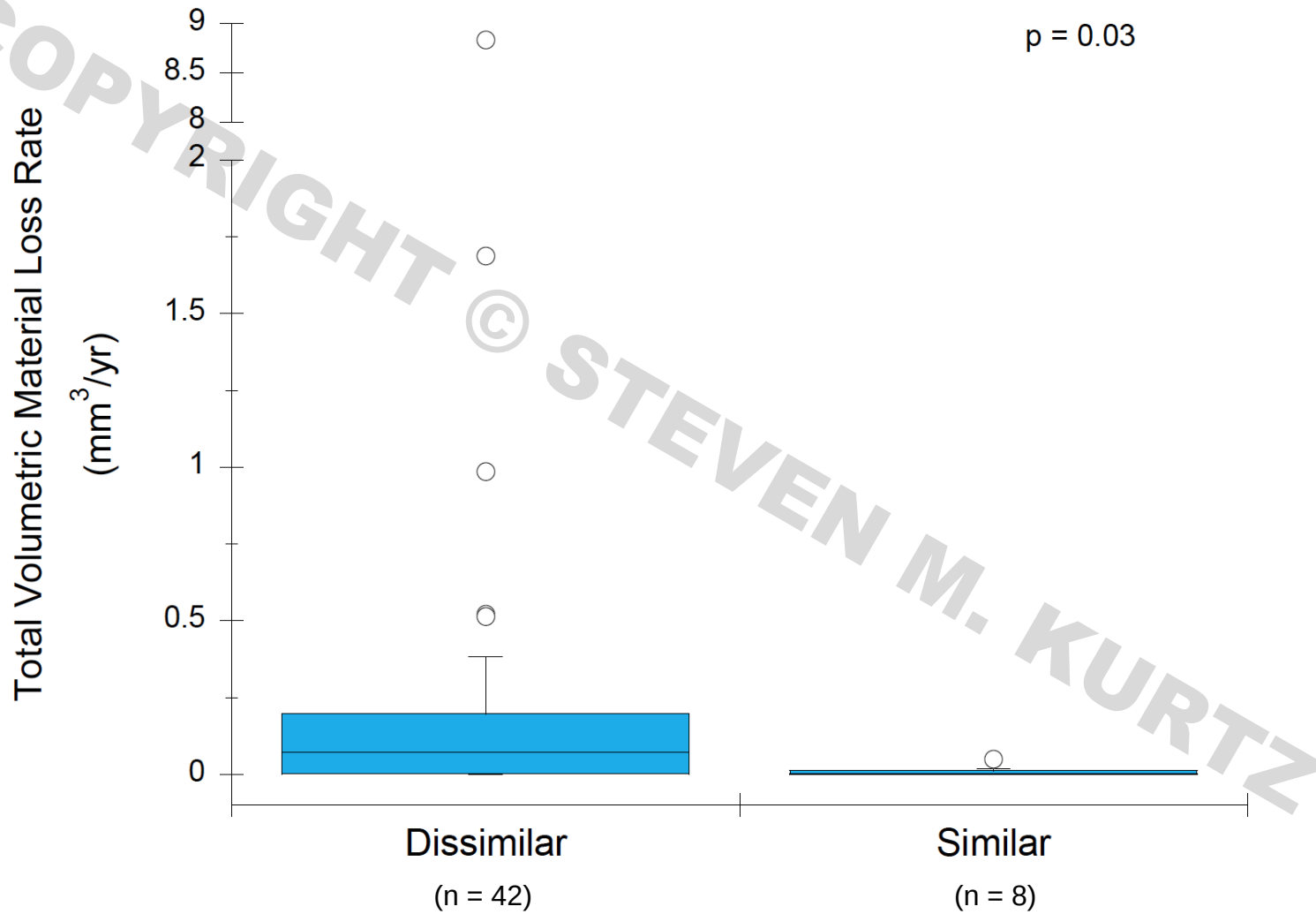
Material Loss (Metal Cohort)



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 (≤ 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

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MacDonald DW, Chen A, Lee GC, Klein GR, Cates H, Mont MA, Rimnac CM, and Kurtz SM

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?

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
three different manufacturers, who underwent revis

Results: All patients presented with pain or swellin
Serum cobalt levels were elevated prior to the revi
chromium levels. Surgical findings included large s
sion at the femoral head-neck junction; the two pa
abductor musculature. Pathology specimens cons
treated with debridement and a femoral head and
sleeve in eight cases. The mean Harris hip score ir
13.0 months after the revision surgery ($p = 0.01$). R
months following revision, decreased to a mean of
One patient with moderate hip abductor muscle n
second revision arthroplasty.

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

Level of Evidence: Diagnostic Level III. See Instru

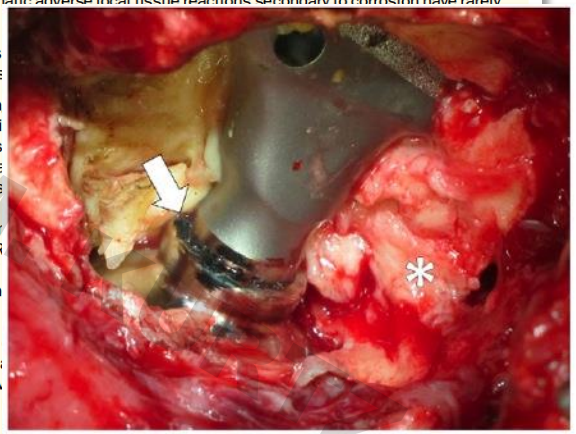


Fig. 2

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.

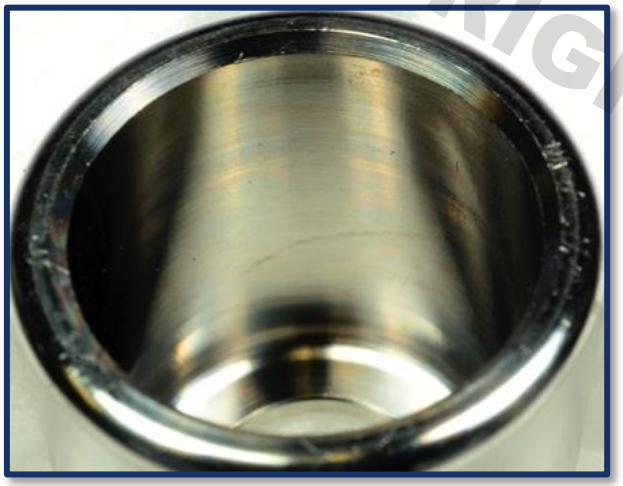
Research Questions

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

Exemplar Fretting Corrosion Scores



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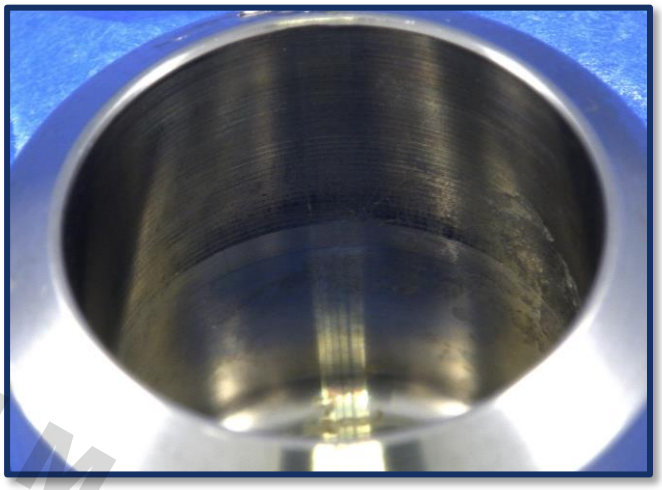

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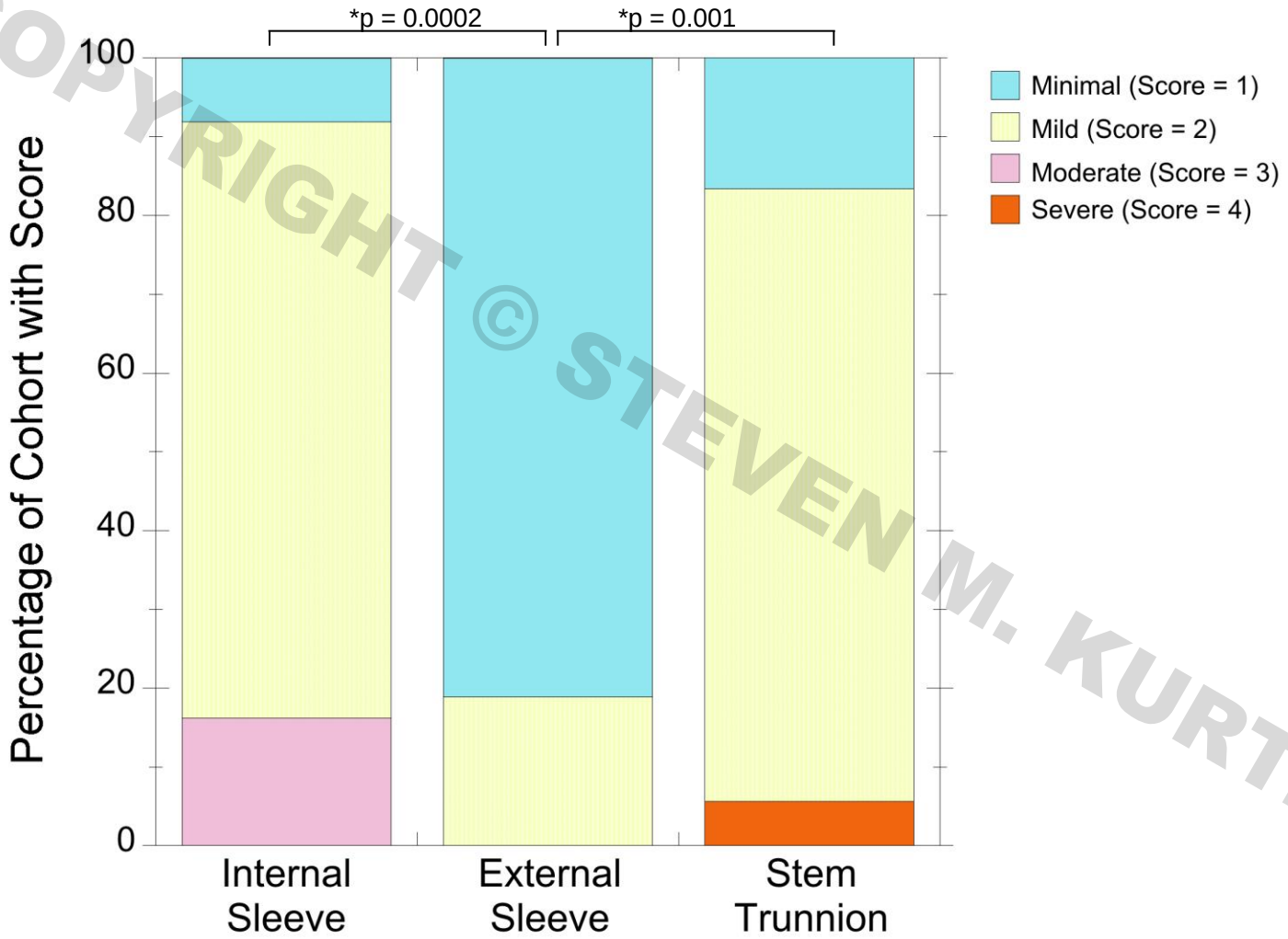
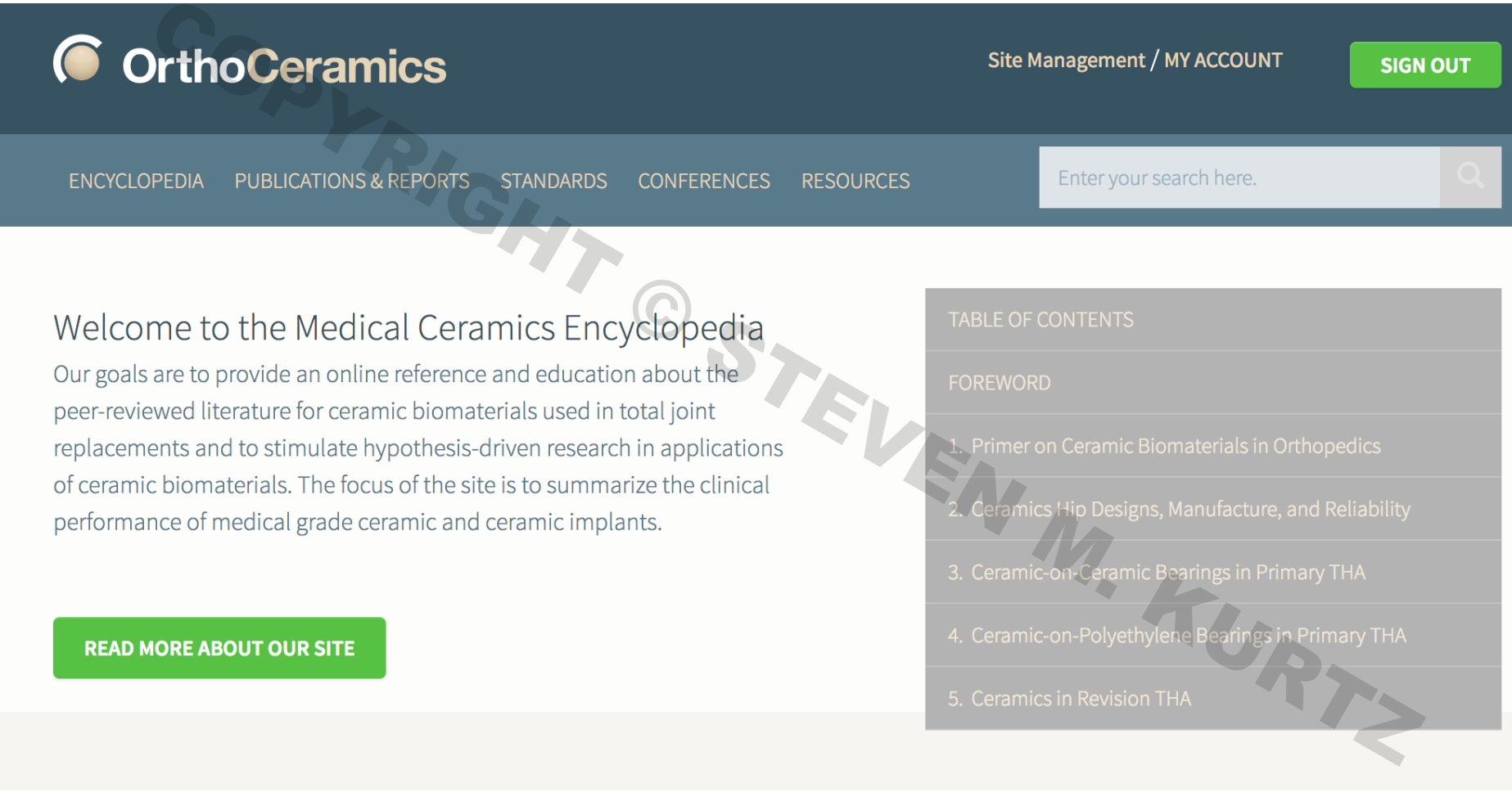
Fretting Corrosion Scores



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!



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

Aldo Toni, Barbara Bordini, Cristina Ancarani, Susanna Stea

RIPO Register c/o Medical Technology Laboratory, Istituto Ortopedico Rizzoli,
Via di Barbiano 1/10, 40136 Bologna (Italy)

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®*forte*-BIOLOX®*forte* bearings have survived, while the figure was 97.4% for implants with BIOLOX®*delta*-BIOLOX®*delta* bearings at the same follow-up. BIOLOX®*forte* head fracture occurred in 0.55% of all cases and the same incidence was observed for damage or fracture of BIOLOX®*forte* inserts, both at 14 years follow-up. For BIOLOX®*delta* only one case of head fracture was observed (0.008%) as well as less complications for BIOLOX®*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®*delta* represents a significant improvement in terms of fracture and survivorship when compared to the previous ceramic generation BIOLOX®*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®*delta* with BIOLOX®*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 patients. 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®*delta*-BIOLOX®*delta* (Delta-Delta). Clearly the preferences and trends can be seen with phasing out BIOLOX®*forte* (Forte) and conventional polyethylene (Poly) over the years.

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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**
Total	**6,579**	**1,133**	**4,674**	**937**	**13,127**	**353**	**757**	**3,057**	**30,617**

Table I: Total number of THA by year of surgery

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

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
N.	6,579	1,133	4,674	937	13,127	353	757	3,057
Mean age (range)	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)
% Female	59.9	71.0	63.3	63.1	57.9	51.3	70.7	58.9
BMI mean (% obese)	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%)
% Coxarthrosis	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.

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Diameter of the head (mm)	Forte–Forte	Forte–Delta	Forte–Poly	Forte–XL Poly	Delta–Delta	Delta–Forte	Delta–Poly	Delta–XL Poly
28	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%)
32	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%)
36	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%)
≥40	–	–	–	–	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 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 (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 3rd generation monolithic alumina (i.e. 36 out of 6,579: 0.55%) is two orders of magnitude higher than that of the 4th 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.

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

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

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

Table V: Reasons for failure of CoC bearings

Forte – BIOLOX®*forte*
Delta – BIOLOX®*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®*delta* ceramic composite bearings compared to the previous generation BIOLOX®*forte*. The 4th generation BIOLOX®*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.

Contact details:
Susanna Stea
Susanna.stea@ior.it
+39 51 6366861

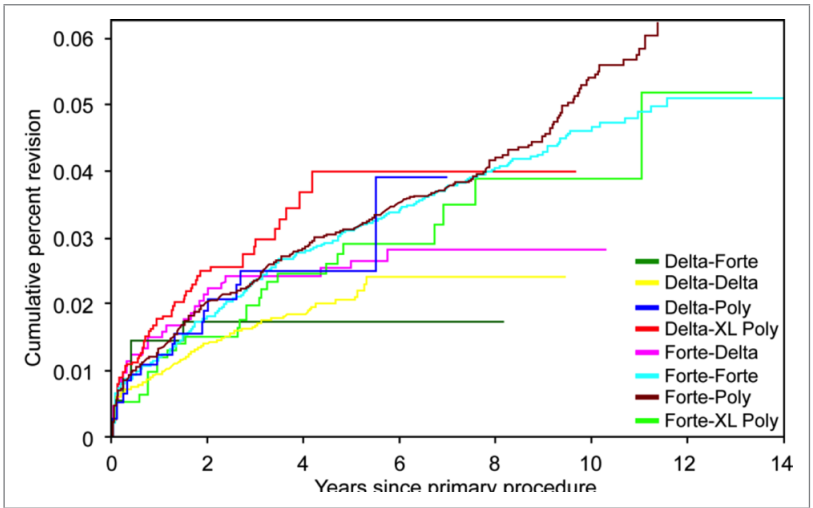

Figure 1: Cumulative percent revision of primary Total Conventional Hip Replacement according to coupling

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.

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