Monthly **CeraNews**

The Orthopaedic Landscape Information Newsletter, Issue February 2017

### Ceramic vs. revision burden

Regarding the general revision burden, using a ceramic head is cost-effective in many cases because of the reduction of revisions of THA with ceramic heads. **Carnes et al.** focused on the factors of implant price difference in the USA and patient age. At a cost differential of US$ 325, ceramic-on-polyethylene bearings are more cost-effective than metal-on-polyethylene for patients under the age of 85. At US$ 600, cost-effectiveness is reached for patients under 65 years.

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### Economic impact of PJI in THA

In a presentation at the last ISTA Congress, **Akindolire et al.** evaluated the economic burden of PJI on Canadian healthcare. They matched primary and two-stage revision THA cases for PJI, age and BMI, recording all costs associated with each procedure. They concluded that septic revision is a significant economic burden to the healthcare system. Compared to primary THA the data show a fivefold increase in healthcare costs.

ista.online/ISTA2016-abstract-book/ISTA-2016BostonAbstracts.pdf
(Abstract #4646)

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### Consequences of tribocorrosion

Also at ISTA 2016, **McGrory** and **Hussey** gave an update about their ongoing study on the consequences of adverse local tissue reaction (ALTR) for 1'356 consecutive patients with metal-on-polyethylene THA. They found symptomatic mechanically assisted crevice corrosion (MACC) present in 2.9% of their patients. Of these, 56% have already undergone revision surgery, while the remaining 44% opted for ongoing surveillance.

ista.online/ISTA2016-abstract-book/ISTA-2016BostonAbstracts.pdf
(Abstract #4774)

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## Taper angle influence on liner positioning

The angle of the inner taper of the acetabular shell seems to have a significant influence on the placement of a ceramic liner in the cup and the dissociation force when removing it. For the study reported by **Lee et al.** three experienced high-volume arthroplasty surgeons participated in a ceramic-liner insertion test with two types of acetabular shells: 1) standard 18° taper, 2) multi-bearing option shell with 10° taper angle.
Each surgeon used three metal shells of each design and 30 ceramic liners (BIOLOX®*delta*). The metal shells were press-fit into sawbones blocks. For the push-out experiment the components were assembled manually and impacted with a 2 kN compression force. A load was applied through the hole at the apex of the shell and the maximum force to disassembly was recorded.
There was no malseating with the 18° taper, but all the participating surgeons experienced several malseated liners with the 10° taper. The dissociation force from the 10° taper (1,148.8 N) was almost three times higher than with 18° shells (389.7 N).

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## Removal of ceramic liner

For the rare event of revision of a ceramic liner, **Pitto** describes a simple procedure: "Using a metallic impactor placed along the external rim of the cup, the surgeon can hit the metal cup's rim with a robust hammer blow. The ceramic liner will dissociate from the internal metal surface. A sharp tool will be necessary to elevate the loosened ceramic liner from the cup margin". The author states that there may be a few acetabular designs that require more than one hammer blow to achieve liner dissociation.
According to the author, elasto-dynamic compressive stress waves, which are initiated by the impact on the rim of the metal shell cause the dissociation. The stress waves are reflected at physical boundaries and transformed into tensile stress waves. These, if they exceed the local stresses resulting from friction and adhesion at the taper junction, will lead to a separation at the taper interface. The author stresses the importance of choosing compatible components, because "using a wrong liner can result in a disaster. Never mix and match!"

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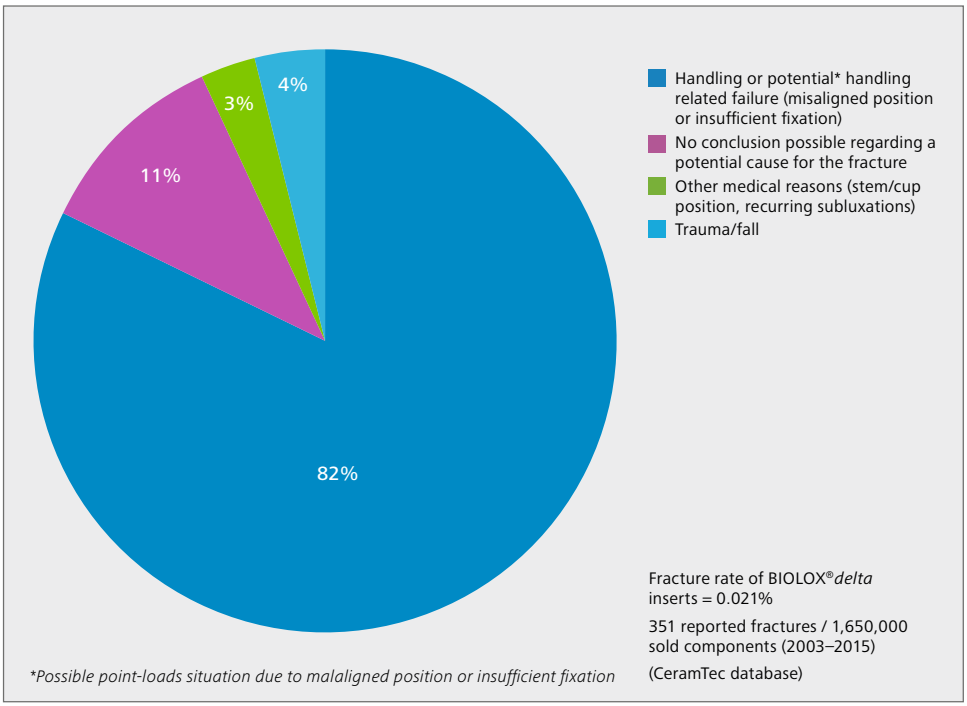
## Reasons for post-operative fracture of BIOLOX®*delta* inserts




MT-00016-1702-EN-01

# Executive Summary

Issue February 2017

| | |
|---|---|
| **Title** | **Effect of inner taper angle of the acetabular metal shell on the malseating and dissociation force of ceramic liners.** |
| **Authors** | Young-Kyun Lee, Ki-Chul Kim, Woo-Lam Jo, Yong-Chan Ha, Javad Parvizi, Kyung-Hoi Koo |
| **Journal** | J Arthroplasty. 2016 Nov 10. pii: S0883-5403(16)30770-7. doi: 10.1016/j.arth.2016.11.002. [Epub ahead of print]. |
| **Level of Evidence** | None given. |
| **Summary** | The common taper angle of acetabular shells for ceramic liners is 18°, however, for acetabular shells with multibearing options (metal, polyethylene, ceramic) the taper angle is lower. **Lee et al.** compared the disassociation force, as well as the incidence of malseating ceramic liners, in two different 52 mm acetabular shell designs, which of which included a different taper angle.<br>Insertion and push-out tests were performed in a laboratory setting on two types of acetabular shells with either 18° (Exceed ABT, Biomet) or 10° (Pinnacle, DePuy) taper. Three experienced high volume arthroplasty surgeons participated in the insertion tests. Each used 3 metal shells and 30 ceramic liners (BIOLOX®*delta*) of each design. Metal shells were press-fit into Sawbones blocks. For the push-out experiment the components were assembled manually and impacted with a 2 kN compression force. A load was applied through the hole at the apex of the shell and the maximum force to disassembly was recorded.<br>No malseating of metal shells with an 18° taper was observed. Conversely all 3 surgeons had several malseated liners with the 10° taper (8, 6 and 8/30, respectively). The dissociation force from 10° compared to 18° shells was almost 3 times higher (1,148.8±46.7 N and 389.7±108.3 N, respectively).<br>The authors caution about malseating of ceramic liners , which may negatively affect the outcome of an all ceramic bearing. |
| **Study Limitations** | Only one design per group, shell angle was confounded by other design changes, such as shell thickness, surface roughness; and design may play a role. |
| | Factors such as taper length or roughness were not included. |
| | Only one size of metal shell was tested. |
| | Experimental set-up with Sawbones, study was not blinded or randomized. |
| | Relationship between shell deformation and malseating was not evaluated. |
| **Key Messages** | **The risk of malseating a ceramic liner is significantly higher for metal shells with a 10° taper compared to metal shells with a 18° taper.** |
| | **Surgeons should be always be cautious about malseating of ceramic liner. There may be design factors, such as taper angle, that may complicate effective seating of the liner.** |
| | **The dissociation force (push-out) of ceramic liners in metal shells with a 10° taper was almost 3-times higher than in shells with an 18° taper.** |
| **Commentary** | This is the first study to suggest that the risk of malseating of ceramic liners may be shell design dependent, and that taper angle may be an important design variable. This is a concern regarding the function and fracture risk of ceramic liners, if not correctly placed by the surgeon. Unexperienced surgeon should perform specific lab training and use appropriate insertion tools. |

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MT-00075-1702-EN-01

# Executive Summary

Issue February 2017

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| **Title** | **Pearls: How to remove a ceramic liner from a well-fixed acetabular component** |
| **Authors** | Rocco P. Pitto MD, PhD, FRACS |
| **Journal** | Clin Orthop Relat Res (2016) 474:25–26 / DOI 10.1007/s11999-015-4617-y |
| **Level of Evidence** | None. Expert opinion. |
| **Summary** | In the rare event that revision of a ceramic liner is necessary, dissociation of the liner from the metal cup can be difficult. In order to avoid unnecessary removal of the liner with the cup, Pitto describes a simple procedure. Quote: "Using a metallic impactor placed along the external rim of the cup, the surgeon can hit the metal cup rim with a robust hammer blow. The ceramic liner will dissociate from the internal metal surface. A sharp tool will be necessary to elevate the loosened ceramic liner from the cup margin". The author states that there may be a few acetabular designs that require more than one hammer blow to achieve liner dissociation.<br>According to the author the explanation of this technique are elasto-dynamic compressive stress waves, which are initiated by the impact on the rim of the metal shell. These stress waves are reflected at physical boundaries and transformed into tensile stress waves. These, if they exceed the local stresses resulting from friction and adhesion at the taper junction, will lead to a separation of the taper interface.<br>The author stresses the importance of choosing compatible components, because a wrong liner can result in a disaster. Never mix and match! |
| **Study Limitations** | Expert opinion |
| | Personal experience |
| **Key Messages** | **To remove a fixed ceramic liner, impact the external rim of the cup with a metallic impactor.** |
| | **Replace removed liner with a compatible component.** |
| **Commentary** | This expert opinion can be of help for surgeons facing the situation to remove a well seated ceramic liner. However, they need to be cautious about possible damages inflicted on the metal shell. If its taper is damaged using a ceramic insert as replacement is not recommended. |
| **Personal Comment (Kiefer)** | **Instead of using a sharp instrument to remove the loosened liner you can use a syringe with saline and flush the liner out.** |



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MT-00076-1702-EN-01

# Executive Summary

Issue February 2017

| | |
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| **Title** | **Cost Analysis of Ceramic Heads in Primary Total Hip Arthroplasty** |
| **Authors** | Keith J. Carnes, Susan M. Odum, Jennifer L. Troyer, Thomas K. Fehring |
| **Journal** | J Bone Joint Surg Am. 2016;98:1794-800. http://dx.doi.org/10.2106/JBJS.15.00831 |
| **Level of Evidence** | Level III |
| **Summary** | Carnes et al used a Markov decision model to compare the cost-effectiveness of ceramic (C) with metal (M, CoCr) femoral heads for bearings with Polyethylene (P) liners. In order to determine cost-effectiveness patient-level hospitalization costs were obtained from the Premier Research Database. Included in the study were primary THA patients, with bearing types identified by ICD9 codes, in patients older than 45 years (20,398 of 54,662 THAs). Three price scenarios for CoP and MoP articulations were calculated: (1) $325 cost differential, (2) $1,003, and (3) $600; CoP bearings were always assumed to be more expensive.<br>Based on information from the HealthEast Joint Replacement Registry the 20-year cumulative revision rate of MoP bearings was estimated to be 14.5 revisions per 100 THAs, corresponding to an incremental annual revision rate of 0.724 per 100 THAs. According to data from the National Joint Registry for England, Wales and North Ireland) the revision rate of THAs with CoP bearings is 25-35% less than for MoP bearings. The authors used the midpoint (30%) to calculate the incremental annual revision rate of CoP bearings to be 0.507 per 100 THAs.<br>The number of revisions that need to be avoided with CoP bearings in order to be more cost effective strongly depends on the age of the patients as well as the cost differential between ceramic and metal femoral heads. E.g. at a cost differential of $1,003 for a ceramic femoral head, 4.5 revisions per 20 years and 100 THAs have to be avoided for a 50 year old patient, while it is 10.5 for a 80 year old patient. The Markov model indicates that CoP bearings at a cost differential of $325 are cost effective for all patients under 85 years, but not for any patient age group at a cost differential of $ 1,003.<br>The authors conclude that the results presented in their study can be used to guide the decision making of major stakeholders (including patients, surgeons, hospitals, and device manufacturers) regarding the choice of the bearing surface implanted. At a low cost differential CoP bearings are cost-effective for patients < 85 years of age. |
| **Study Limitations** | Results only applicable for the US market. |
| | Based only on implant cost and revision rates; important cost effectiveness metrics like QALY or QoL have not been included. |
| | The choice to use cost and revision only to characterize performance may lead to an overstatement of the required revision rates for CoP bearings to be cost-effective. |
| | Information on revision rate was only available at 9 and 17 years. |
| | Type of ceramic and PE are not specified and may have an effect on cost as well as revision rates |
| **Key Messages** | **When CoP bearings are more expensive than MoP bearings, at a cost differential of $325, CoP bearings were cost effective for all patients under the age of 85y.** |
| | **At a cost differential of $1,003 CoP bearings were not cost effective for any patient age group.** |
| | **At a cost differential of $600 CoP bearings were cost effective for patients under the age of 64y.** |
| **Commentary** | This is another study investigating cost effectiveness of CoP bearings in comparison to MoP bearings in the US. In contrast to Wyles et al 2016, who looked at treatment cost for metal work-ups (Monthly CeraNews January 2017) and revisions in patients with ALTR issues, Carnes et al investigate general revisions only, however, with a much more elaborate statistical method.<br>Generally, there is a clear trend within all health care systems towards more cost-consciousness and therefore the necessity to better understand the cost-effectiveness of an implant system.<br>Further research is needed to clarify the relationship between effectiveness and costs of articulating bearings in THR. |

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# CONGRESS REPORT

Issue February 2017

**29th Annual Congress International Society for Technology in Arthroplasty (ISTA)**
October 5th-8th, 2016 Boston MA, USA

ISTA's 29th Annual Congress attracted over *700 surgeons, researchers and industry members* from 26 countries. A total of *729 presentations* covered all aspects of arthroplasty in: *31 podium sessions*, *38 e-posters* with short talk sessions, and *147 static e-posters*. The main topics were Total Hip and Knee Arthroplasty. However other joints like shoulder, elbow and ankle joint were addressed as well. Additionally two specific sessions dealt with Economics and Innovation.

**Main topics:**
For Total Hip Arthroplasty the sessions focused on:
- o Surgical techniques and technologies for improved implant positioning
- o Material aspect addressing modular junctions and wear
- o Clinical aspects and related complications
- o Metal on Metal issues and benefits

**Abstracts:** are available at http://ista.online/ISTA2016-abstract-book/ or from the Bone & Joint Journal, February 2017; Volume 99-B, Issue SUPP 3 at http://www.bjjprocs.boneandjoint.org.uk/content/by/volume/99-B

**Highlights THA:**
**Articulation / bearings**
- **Ceramic**: Due to the issues with metal (CoCr) heads and the information about their carcinogenicity (MCN 1_2017) ceramic was back into the spotlight. The *fracture rate* of a large number of BIOLOX®*delta* components was presented to be extremely low. *Ageing* has been investigated (**Esposito, Parkes**) and, despite some phase transformation, showed no effect on strength and surface roughness of this mixed ceramic. Several long-term studies with ceramic-on-ceramic (CoC) articulation in young patients demonstrated the excellent survivorship and functional outcome of this bearing combination (e.g. **Lim, Murphy, Baek** – 15 years, **Garcia-Rey** - 17 years, **Sedel** - 30 years). *Noise* with CoC was also a topic of several presentations. It is complex and still poorly understood. Although a disturbing phenomenon, almost no revisions due to squeaking were reported. Clicking is especially prominent in the Asian population and with 28 mm heads (**Baek**).
- **Polyethylene**: XLPE data up to 15 years shows that osteolysis is becoming apparent, although consistently to a much lesser extent than for CoPE (e.g. **Baek, Garcia-Rey, MacLean**). Despite the overall positive results most researchers are waiting for the outcomes of the 2nd decade of usage.

**Tribocorrosion (MACC)**
- MACC (Mechanically assisted crevice corrosion) and adverse local tissue reaction (ALTR) remain still the hottest topics in THA and have been observed in 70% of all retrievals (**Noble, Kurtz**). The biological effect of metal wear particles and ions was also topic of several presentations (e.g. **Paulus**, **Barlow, Van der Straeten** - TKA, **Reiner** - TSA). Evidence is increasing that it leads to ca. 2% revisions (**McGrory, Urish**), levering it into the top failure reasons for THA. As this issue is increasing with time (**Lange, Kurtz**) a further aggravation of these numbers is expected. The causes of MACC are still under investigation (Teeter) and laboratory experiments are executed to find the potential mechanisms (**Gilbert, Bitter, Mueller, Noble**). The main factors seem to be seating strength of modular connections and neck offset (**Gilbert, Noble**), while taper morphology seems to be not significant (**Noble, Kurtz**). The benefit of using ceramic heads for reducing this issue has been confirmed by several presentations (e.g. **Kurtz, Meftha**).

**Health Economics / PJI**
- Several presentations and a whole session were dedicated to the question of the value of advanced technologies. Consensus is that any new technology or method must demonstrate its efficacy by clinical evidence to address a clinical need and also its financial effectiveness. The revision burden is increasing and the outcomes, especially after PJI, are much worse, the sequelae must also be taken into consideration and mathematical modelling of the cost. Revision for infected THA is a significant economic burden to the healthcare system with a significant 5-fold increase in healthcare cost when compared to primary THA (**Akindolire**).

**Innovation presentations**
- Therapeutic UHMWPE as a bearing surface against PJI (**Muratoğlu**)
- New CoC TKA implant (**Sedel**)
- All-Polymer TKA implant (**Cowie)**
- Ceramic Hip Resurfacing and Hip Resurfacing Revision (**Khan**)
- Positioning devices for the cup (e.g. **Murphy**)
- Biomarkers for Painful Knee Arthroplasty
- TiO2 Nanotubes and Antimicrobial Silver (**Justin**)
- Polycarbonate Urethanes vs. an articular cartilage counterface (**Kanca**)
- Ceramic on Phospholipid Polymer Surface for THA (**Weisenburger**)
- Ceramic vs. CoCrMo-Alloy in the Articulation With Living Cartilage (**Wimmer**)

By Robert M. Streicher

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