

Cobalt toxicity can be fatal

Though very rare, cobalt toxicity is a severe and potentially fatal complication in THA. In a literature review, **Zywiell et al.** identified 18 cases, most of which reported systemic toxic reactions at cobalt levels above 100µg/L. Eight cases, one of which was fatal, were related to the use of metal-on-polyethylene (MoP) bearings in revision THA after the fracture of a ceramic component. The other ten cases were judged as possibly malfunctioning metal-on-metal (MoM) bearings. In all cases treated, cobalt levels in the serum decreased after revision. The authors recommended using cobalt-free materials such as titanium and ceramic for revision.

[READ MORE >](#)

More ceramic heads in USA

In the USA, the use of ceramic femoral heads for THA has grown steadily according to registry data from the **AJRR** of the years 2012–2015. Ceramic heads are favourable for their friction and wear characteristics, and especially address concerns regarding trunnionosis and corrosion with metal heads, which probably has contributed to this growth. Ceramic heads are chosen more often for younger than for older patients, but there is also growth in the latter group.

When antioxidant or “enhanced” polyethylene acetabular liners are chosen, the combination with a ceramic head is favored in the majority of cases. Conventional polyethylene liners are typically chosen together with metal heads. Femoral head size has remained relatively constant between 2012 and 2015, with 36mm heads used in more than 50% of the procedures performed.

[READ MORE >](#)

Published by CeramTec GmbH
CeramTec-Platz 1–9,
73207 Plochingen, Germany
Tel.: +49 7153 611-828, Fax: +49 7153 611-950
ceranews@ceramtec.de, www.bioloX.com

Editorial board:
• Hartmuth Kiefer
• Steven Kurtz
• Rocco Pitto
• Robert Streicher

Concept and Editing:
Florence Petkow
Director Marketing Services
f.petkow@ceramtec.de

Registries look at cancer, PJI and fracture

Cancer, PJI and periprosthetic fracture were the main subjects discussed at the **Sixth International Congress of Arthroplasty Registries (ISAR)** held May 20-22, 2017, in San Francisco, USA. According to the Australian registry, the overall incidence of cancer for THA patients was 6% higher than the population average. The authors did not find a significant difference in all-site cancer rates between metal-on-metal (MoM) and other bearings. Nevertheless, the incidence of Hodgkin’s Lymphoma was 117% higher with MoM.

PJI remains one of the most frequent reasons for failure in THA worldwide, according to the authors of an international registry collaboration study. **The British National Joint Registry (NJR)** shows an increased risk of revision for PJI in males, smokers and patients with high BMI, diabetes, rheumatoid arthritis, chronic pulmonary disease or liver disease. The authors also identified an influence of dementia, fractured neck of femur, previous history of infection and lateral surgical approach. There was no evidence of association with the presence of a consultant (none, assisting, operating), grade of operating surgeon (consultant, other) and place of surgery (England, Wales). Ceramic bearings showed a protective effect against PJI.

[READ THE ISAR SUMMARY >](#)

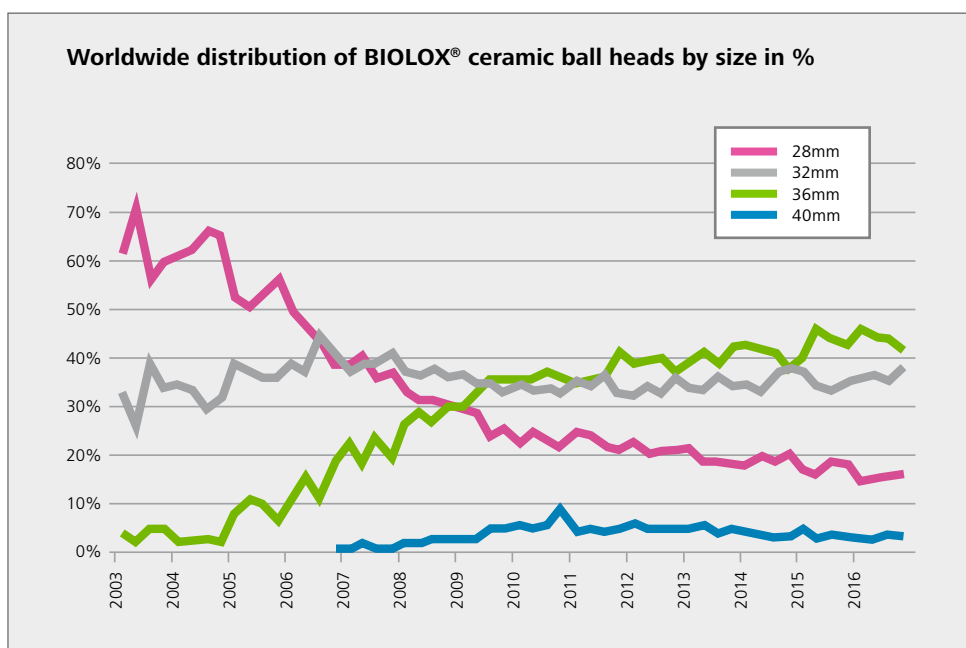
CoC results with patients under 30

In patients under 30 at the time of primary implantation, CoC bearings have a revision rate of 1.1% at 11.5 years compared to 7.9% at 7.3 years for hard-on-soft bearings. This is one of the results of a systematic review by **Walker et al.** The authors identified 14 articles from peer-reviewed journals published between 1981 and 2013. When only uncemented THA were assessed, CoC revision rate was only 0.78% at 12.2 years while the overall revision rate was 1.3% at 9.9 years. In this comparison, there was also a significant difference in the rate of radiographic loosening: 0.2% with CoC and 12.2% with hard-on-soft bearings.

The results suggest that CoC bearings outperform hard-on-soft couples in terms of improved HHS, revision rate and loosening. However, the differences in bearing surfaces are confounded by differences in fixation and the use of historical polyethylene varieties obsolete today in the hard-on-soft group. Thus, no conclusions about modern bearing materials can be drawn from this study.

[READ MORE >](#)

36mm bearing diameter ranking on top



Source: CeramTec, based on CeramTec sales data. BIOLOX®delta and BIOLOX®forte ball heads and inserts, BIOLOX®OPTION, are registered by CeramTec’s customers. They are not registered / available in all countries.

CONGRESS REPORT

Issue 05 / 2017



Sixth International Congress of Arthroplasty Registries (ISAR)

May 20th-22nd, 2017, San Francisco, USA

The Annual Meeting was attended by 150 arthroplasty registry specialists from Academia, Health Authorities and Industry from 14 countries. The meeting gave them the opportunity to discuss about registry datasets, the refinement of statistical methods, international coordination and collaboration. The latter includes the harmonization of registries to provide a single international registry which should allow fast identification of worse than normal performing implants and the establishment of a single benchmarking system for prostheses.

In the scientific studies presented, the most important topics were cancer risk analysis, periprosthetic joint infection (PJI), obesity and dislocation.

Cancer

Both the Norwegian and the Australian (AOA NJRR) arthroplasty registries linked their data with the national cancer registries to quantify the risk of cancer after total hip replacement (THR) surgery.

The Australian registry compared 127'245 patients who underwent a THR procedure for osteoarthritis between September 1st, 1999 and December 21st, 2009 to the general Australian population. They found that the overall incidence of cancer was a significant 6% higher for THR patients. The authors did not find a significant difference in all-site cancer rates between metal-on-metal (MoM) and other bearings. Nevertheless, the incidence of Hodgkins Lymphoma was 117% higher with MoM. A limitation of the study was caused by the incompleteness of the cancer registry.

The Norwegian Arthroplasty Register evaluated the risk for cancer related to THR fixation. Cancer beyond 10 years after surgery was the primary outcome measurement. The patients (41'402; age: < 75 years, osteoarthritis) in the arthroplasty registry during 1987 and 2009 were linked with the national cancer registry. The analysis was adjusted for age, gender and THR surgery for cemented, uncemented and hybrid fixations. It showed that the cancer risk for THR patients with uncemented fixation increased by 28% compared with cemented prostheses after 10 years follow-up. Hybrid prostheses did not significantly increase the risk for cancer in comparison with cemented THR.

PJI

A series of talks dedicated to PJI confirmed a general increase of the infection burden, higher revision costs for PJI, higher risk of mortality after PJI and an influence of the bearing material.

An international registry collaboration of six registries confirmed the increase in infection burden, defined as the number of TJA revisions performed for PJI divided by all revision and primary THR over the period of 2000-2015. PJI remains one of the most frequent reasons for failure in THR worldwide according to the authors.

Daniel Berry from the Mayo Clinic showed the hospital cost associated with two-stage management of PJI to be up to 2.5-fold higher than aseptic revision procedures. For the study, the hospital and components costs of patients who underwent two-stage joint reconstruction for PJI of the hip and the knee (212 and 305, respectively) over a 7 year-time period were compared with those of revision for aseptic loosening. The mean overall hospital cost per THR for a two-stage treatment was US\$ 55'530, which was significantly higher than the mean overall cost for a revision for aseptic loosening of US\$ 21'925. An average two-stage total knee replacement (TKR) revision for PJI costs US\$ 54'300, thus significantly more than the US\$ 23'640 revision for aseptic loosening TKR.

CONGRESS REPORT

Issue 05 / 2017



The Danish Registry presented a study recently published in CORR, in which the authors examined if revision of early PJI following primary THA was associated with an increased risk of mortality. The primary THR dataset of the Danish Hip Arthroplasty Register from 2005 to 2014 was linked to the National Registry of Patients and the Civil Registration System. A total of 68'504 primary THR were linked, of which 445 underwent revision for PJI and 1'350 had aseptic revision. The remaining 66'709 were not revised. The relative mortality risk (adjusted for age, sex and Charlson Comorbidity Index Score) for THR with revision for PJI was 2.18 compared to the non-revised patients. It was 1.87 when adjusted for age, sex and Charlson Comorbidity Index Score, duration of surgery and the number of secondary THR revisions for PJI compared with THR revised for aseptic revisions. If the THR was revised for enterococci-infection the mortality risk was 2.89 times higher than for those induced by other bacteria. In conclusion, revision for PJI within one year following primary THR increased the mortality risk.

The British National Joint Registry (NJR) dataset was analysed by **Lenguerrand et al.** to identify the patient, perioperative and healthcare system risk factors for PJI following primary THR. 85% of primary procedures from 2003 to 2013 were linked to the Hospital Episode Statistics for England and Wales. The study showed an increased risk of revision for PJI in males, patients with high BMI, diabetes, rheumatoid arthritis, chronic pulmonary disease, smoking and liver disease. The authors also identified an influence of dementia, fractured neck of femur, previous history of infection and lateral surgical approach. There was no evidence of association with the presence of a consultant (none, assisting, operating), grade of operating surgeon (consultant, other) and place of surgery (England, Wales). Ceramic bearings showed a protective effect against PJI.

Svensson et al. of the Swedish Hip Arthroplasty Registry analyzed their data specifically for infection and found no difference in the risk of re-revision between one- and two-stage revisions. Nevertheless, the authors concluded that prospective randomized studies are needed to validate these findings. **Bloemheugel et al.** of the Dutch Arthroplasty Registry presented their analysis on the beneficial effect of dual mobility cup THR in terms of decreased risk for dislocation in comparison with conventional cups. But they pointed to the increased risk of infection. The cumulative incidence of revision was 40% higher in comparison to conventional cups.

Periprosthetic fracture

Several registries have noticed an increased risk of periprosthetic fracture. In the discussion, there was a consensus that the effect might be related to the difficulty of positioning a cementless stem (**Dale et al.**, Norwegian Arthroplasty registry). Additionally, the risk for revision for aseptic loosening and lysis decreased due to the usage of Ceramic bearings as shown by **Steiger et al.**, AOA NJRR. Consequently, the relative risk for periprosthetic fracture has increased. According to **Steiger et al.**, in case of first revision for periprosthetic fracture the most common reason for a second revision was infection, followed by loosening, lysis, prosthesis dislocation and re-fracture.

By Alessandro Alan Porporati

Executive Summary

Issue 5 / 2017

Title	Functional outcomes of total hip arthroplasty in patients aged 30 years or less: a systematic review and meta-analysis.
Authors	R.P. Walker, M. Gee, F. Wong, Z. Shah, M. George, M.J.K. Banks, A. Ajuied <i>Department of Orthopaedics, Guy's and St Thomas' NHS Foundation Trust and Department of Orthopaedics and Trauma, King's College Hospital, London, UK</i>
Journal	Hip Int 2016; 26 (5): 424-431
Level of Evidence	Review and meta-analysis of level IV studies.
Summary	<p>Walker et al performed a systematic review of outcomes in total hip arthroplasty (THA) in patients < 30 years old. They identified 14 articles from peer-reviewed journals published between 1981 and 2013. Primary outcome measure was the Harris Hip Score (HHS); secondary measures were implant survivorship, effect of fixation (cemented/ uncemented stem) and bearing surface (hard-soft/CoC).</p> <p>In total 743 THAs were included in the analysis with a mean follow up of 8.4 years. Mean patient age was 22.7 years (range 13-30y). Hard-on-soft (metal or ceramic femoral heads) bearings were used in 461 cases and ceramic-on-ceramic (CoC) bearings in 282 cases. In 457 cases uncemented THA was used with a mean follow up of 9.9 years. All studies showed similar significant improvement in HHS with a mean difference of 43 points for hard-on-soft bearings and 45.8 points for CoC bearings, statistically not significant. Overall 155 complications were reported, including revisions (5%) and radiographic loosening (5.4%). Further complications were heterotopic ossification (4.3%), dislocation (1.9%), substantial PE wear (2.1%), infection (0.8%), periprosthetic fracture (0.5%), sciatic nerve injury (0.5%), squeaking (1%), ceramic fracture (0.5%), vascular injury (0.2%), and pulmonary embolism (0.2%).</p> <p>When the bearings of all fixation cohorts were analysed separately, CoC bearings had a revision rate of 1.1% at 11.5 years compared to 7.9% for hard-on-soft bearings at 7.3 years. When only uncemented THAs were assessed the overall revision rate was 1.3% at 9.9 years with a radiographic loosening of 0.2%. For cementless THA the revision rate with CoC bearings was only 0.78% at 12.2 years. In the hard-on-soft group the revision rate was 1.2% at 7.2 years and radiographic loosening was 12.2%.</p> <p>The authors summarize that the combined revision rate of 5% in this very young patient group is comparable with the results in older patient groups. However, only a large randomized controlled trial comparing cemented/ uncemented mode of fixation with CoC vs. hard-on-soft bearings will be able to determine any significant difference.</p>
Study Limitations	<p>Level of evidence low for all included studies (Level IV).</p> <p>No differentiation between ceramic- and metal-on-Polyethylene bearings.</p> <p>Type of PE not assessed, some early studies included historical gamma-air.</p> <p>No information on head size and its influence.</p>
Key Messages	<p>Revision rate in these very young patients was 5% at 8.4 years, comparable with results of older age groups.</p> <p>The results appear to suggest that CoC bearings outperform hard-on-soft couples in terms of improvement in the HHS, revision rate and loosening. However, the differences in bearing surfaces are confounded by differences in fixation and historical (obsolete) polyethylene in the hard-on-soft group. Thus, no conclusions about modern bearing materials can be drawn from Walker's study.</p>
Commentary	This literature analysis shows an excellent performance of uncemented THA with CoC bearings in very young patients.

Executive Summary

Issue 5 / 2017

Title	Systemic cobalt toxicity from total hip arthroplasty. Review of a rare condition part 2: Measurement, risk factors, and step-wise approach to treatment.
Authors	M.G. Zywiol, J.J. Cherian, S. Banerjee, A.C. Cheung, F. Wong, J. Butany, C. Gilbert, C. Overgaard, K. Syed, J. J. Jacobs, M. A. Mont <i>Rubin Institute for Advanced Orthopedics, Baltimore, USA</i>
Journal	Bone & Joint Journal 2016; 98-B(1): 14-20
Level of Evidence	Level IV: unsystematic review of case series.
Summary	<p>Zywiol et al reviewed the literature to examine the use of Co-alloys in THA and methods of measuring circulating cobalt levels to define a level, which is considered pathological, as well as review the pathophysiology, risk factors and treatment of cobalt toxicity. They identified 18 published cases in THA. Most of these cases reported systemic toxic reactions at cobalt levels greater than 100µg/L.</p> <p>Cobalt ion levels can be measured from whole blood, serum or erythrocytes. However, the values cannot be used interchangeably. Different units are used for cobalt levels, which are easily convertible: 1ppb = 1µg/L = 1ng/ml; which is approx. 16.97nmol/L. The natural level of Co in serum is believed to be about 0.1 ppb. The authors were not able to define a pathological Co ion level since it is highly likely that the systemic risks from Co ion release is complicated by patient-specific factors that increase or decrease susceptibility.</p> <p>From the eighteen cases of systemic Co toxicity described with elevated Co levels and multisystem effects, eight were related to the use of metal-on-polyethylene (MoP) bearings in revision THA for ceramic component fracture, one even fatal. The other ten cases were judged to be potentially malfunctioning MoM bearings. In all cases serum Co levels decreased after revision. Based on their review the authors state that drawing conclusions about the relationship between elevated Co levels and systemic symptoms is limited.</p>
Study Limitations	Aggregation of case reports related to Co levels; not systematic.
	Results cannot be generalized.
	Small number of patients with extremely rare circumstances.
Key Messages	Eight published cases of Co toxicity after ceramic fracture and revision to MoP bearings, including one death.
	In case of revision Co free components such as Ti and ceramic are recommended.
	Early intervention (removal of Co components) may prevent further complications.
	Early awareness of the variety of symptoms of cobalt toxicity needs to be increased.
Commentary	The case reports extracted from the literature were insufficient to determine a cause and effect between Co levels and the patient's reported symptoms. Although the paper is only a summary of case reports, it shows the risk of using CoCr femoral heads in revisions for ceramic fracture.