The Orthopaedic Landscape Information Newsletter, Issue 3 / 2017









Taper mismatch boosts fracture risk

"Mixing and matching components can put patients at greater risk for ceramic head fracture and must be avoided at all costs." This conclusion was drawn by Gührs et al. from the Technical University in Hamburg (Germany), who analyzed the fracture resistance of ceramic heads combining head and taper components from different implant providers. The mismatch, while providing a seemingly stable taper connection, markedly reduced the mean fracture strengt.

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Ceramic fracture requires synovectomy

For the rare event of a ceramic fracture, Rambani et al. from the United Lincolnshire Hospital (UK) have searched the literature for the best revision practice. In their review they stress the importance of a complete synovectomy and thorough debridement of the affected tissues. Damaged and malpositioned components also have to be removed. Whenever possible, CoC or CoPE bearings should be used for the revision to avoid third-particle wear.

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Academia favors ceramic heads

Reconstructive surgeons involved in academic teaching in the USA use ceramic heads for 72.9% of THA cases. Nandi (University of Toledo, USA) and Austin (Rothman Institute, Philadelphia, USA) conducted a survey in 42 academic centers. Almost half of the surgeons use ceramic heads for all patients. Responding surgeons were far more concerned about taper corrosion with CoCr heads than about ceramic head fracture.

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Parvizi on PJI prevention and treatment

Registry data seem to indicate that the numbers of PJI-related revisions after THA and TKA are increasing. This was confirmed in a recent interview by Javad Parvizi from the Rothman Institute in Philadelphia. He recommends using the criteria of the Musculoskeletal Infection Society (MSIS) for diagnosis, especially to distinguish PJI from aseptic loosening.

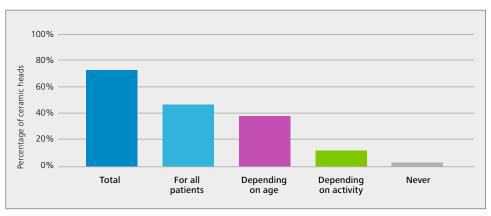
For the prevention of surgical site infection (SSI) leading to PJI, Parvizi referred to the recently updated guidelines of the WHO and the Centers of Disease Control (CDC). In the interview, he describes the prevention methods used at the Rothman Institute and points out that the use of ceramic components is associated with a reduced risk of PJI. Concerning the treatment of PJI, he states that there are no clear indications for the choice between retention, one-stage or two-stage exchange arthroplasty. Two-stage revision has to deal with the problem that available spacers do not meet current needs. These and other issues related to orthopaedic infections will be discussed in a second consensus meeting planned for READ THE INTERVIEW > July 25-27, 2018.

"Poisoning" myocardial effects of CoCr ball heads

Using CoCr femoral ball heads will lead to cobalt and chromium deposits in the myocardium, "slowly poisoning your patients". Robert Trousdale from the Mayo Clinic in Rochester (USA), reached this conclusion in a presentation at a recent VUMEDI Webinar. His study group analyzed cardiac tissue of 94 arthroplasty patients, gathered by the Mayo Autopsy Tissue Registry, from the vears 1990-2011.

Cobalt levels were significantly higher in patients with artificial joints compared to the control group without implants, rising with time after implantation. The incidence of cardiomegaly and interstitial fibrosis was approximately twice as high with an implant. Trousdale also concluded that THA with ceramic femoral heads might provide the most cost-effective option if used in all patients. He based this statement on studies matching the cost differential between metal and ceramic heads with the costs of diagnosis of metal-related effects in the case of revision arthroplasty.

Use of ceramic heads in academic centers in the USA



In US academic centers, almost three quarters of THA patients receive ceramic heads.*

*Sumon Nandi, Matthew S. Austin. Choosing a Femoral Head: A Survey Study of Academic Adult Reconstructive Surgeons J Arthroplasty; Article in press

Erratum: Handling, not trauma

In the chart "Reasons for post-operative fracture of BIOLOX® delta inserts" published in the issue 2/17 of Monthly CeraNews the two blue colors were mixed up, creating the wrong impression that most ceramic liner fractures were due to trauma. In fact, trauma accounts for only 4% of the recorded fractures and the vast majority of 82% is related SEE THE CORRECT CHART > to handling or presumed handling failure.









PJI: Trends and Strategies

An Interview with Javad Parvizi, MD

Dr. Parvizi, periprosthetic joint infection (PJI) is the most feared and most expensive complication of implant surgery. Is it on the rise?

This is a difficult question to answer because the incidence of PJI is inevitably extrapolated from various national registry databases, which have a tendency to underestimate the incidence. In addition, a large part of the published literature does not delineate between the incidence of acute vs chronic PJI. Furthermore, none of these studies discusses the criteria that were used to establish the diagnosis of PJI. It is therefore nearly impossible to calculate the "true" incidence of PJI. Nevertheless, the published registry data seems to suggest that PJI is on the rise. (see table 1 and 2)

Table 1: Infection rates after arthroplasty

Country	After THA	After TKA
Denmark ¹	0.86% (1 year postop.)	
	1.03% (5 years postop.)	
Finland ²	0.92%	1.41%
New Zealand ³	1.1%	
USA ⁴	2.18%	2.18%

Table 2: Increasing incidence of PJI in the USA4

Procedure	2001	2009
THA	1.99%	2.18%
TKA	2.05%	2.18%

Kurtz et al. sampled the NIS database and showed an increase in PJI for both THA and TKA from 2001 to 2009. This study also projected the nationwide hospital costs of treating PJI to be US\$ 785 million in 2010. It is expected to have amounted to US\$ 1 billion by 2014 and to reach US\$ 1.62 billion by 2020.4

Diagnosis of PJI is cumbersome. How do you differentiate it from allergies or aseptic loosening?

The diagnosis of PJI can at times be very challenging as it can masquerade in a multitude of clinical presentations. The workup begins with a thorough history to clearly delineate the timeline of the patient's symptoms as well as a comprehensive physical exam and radiographs of the hip or knee to rule out other non-infectious etiologies. In terms of distinguishing between aseptic loosening vs PJI, we have found the MSIS criteria to be very reliable in most situations. The laboratory investigation will begin by obtaining ESR and CRP levels and this is usually followed by an aspiration of the affected joint with either one or both of these labs elevated. The synovial fluid will be tested for cell count, differential, and culture. In addition to the "classic" laboratory tests that are routinely used, we recently have been utilizing additional serum and synovial biomarkers such as leukocyte esterase, D-dimer, α-defensin, and next-generation sequencing (NGS). The goal of these additional biomarkers is not only to increase the accuracy of diagnosis PJI, but also to identify the causative microorganisms, which at times can be quite elusive.

With this armamentarium of tests, we generally feel comfortable distinguishing between PJI and aseptic loosening, however, making the diagnosis of a true metal allergy is still hotly debated among arthroplasty surgeons. The difficulty is that there isn't a specific test to confirm the diagnosis of a metal allergy. For instance, skin patch testing for "metal allergy" can be positive in up to 20% of the general population. A recent study from Denmark concluded that patients with metal allergy prior to implantation did not appear to have a higher prevalence of complications or revision surgery compared to patients who had a negative skin patch test (Munch et al., Acta Orthop, 86(3), 2015). At this point, the diagnosis of a "true" metal hypersensitivity reaction remains a diagnosis of exclusion.

I am very excited about an emerging molecular technique that may be able to help us with the diagnosis of PJI in the future. With the dramatic decline in the cost of genomic sequencing, next-generation sequencing (NGS) has arrived in the clinical scene. We have exciting data showing that NGS is capable of identifying the infecting organism in over 90% of culture negative PJI. I really believe this is a quantum leap for us in orthopaedics.

What are hot topics in PJI prevention? What is the protocol at the Rothman Institute (RI) to prevent infection?

The world health organization (WHO) just published their recommendations for prevention of surgical site infection (SSI). The Centers for Disease Control and Pre-



Javad Parvizi, MD, Vice Chairman of Research and Director of Joint Research, Rothman Institute, Philadelphia, USA

^{1.} Gundtoft et al., Acta Orthop, 86(3), 2015

^{2.} Huotari et al.. Acta Orthop. 86(3), 2015

^{3.} Following THA, Zhu et al., Acta Orthop. 87(4), 2016

vention (CDC) was occupied over the last three years in renewing their SSI prevention guidelines also. The CDC guidelines will be published shortly, if not published already. The guidelines have visited many of the strategies that are important in prevention of SSI. The CDC guidelines will visit the issue of perioperative antibiotics, normothermia, strict glucose control and so on with very useful guidance on many issues. The CDC and the WHO guidelines, however, remain silent on many other issues that we know predispose our patients to SSI and PJI. For example, the influence of smoking, alcohol consumption, obesity and other factors are not explored in these guidelines as there is lack of evidence related to these issues.

In the absence of clear guidelines related to these issues we have implemented many protocols at the Rothman Institute that allow us to minimize the risk of SSI as much as possible. The most important protocols include asking our patients to shower or cleanse the entire body with chlorhexidine wipes two days prior to surgery, having a strict glycemia control (HbA1C<8% and fasting glucose under 200), avoiding revision surgery in the malnourished, administering first generation and weight-based dose of cephalosporins, administration of tranaxemic acid, irrigation of the incision with dilute betadine, the use of aspirin as venous thromboembolism prophylaxis in our patients, and the application of silver impregnated occlusive dressing on the incisions. All of the protocols have been developed based on studies conducted at the RI or other academic centers. In the absence of evidence, we have attempted to start studies addressing these issues. For example, we have a randomized study underway that examines the role of heavy smoking in the incidence of SSI.

Registry studies show differences in the prevalence of infection for different materials. Did you make similar observations?

We have been interested in the role of bearing surface on the incidence of PJI and SSI. Based on a preliminary analysis that was conducted at the Rothman Institute a few years ago we noted that the incidence of PJI was markedly higher in patients with metal-on-metal (MoM) bearing surface, something that is also reflected in the Medicare database. An interesting observation from that initial analysis also revealed that the use of ceramic heads and/or liners was associated with a lower incidence of PJI. Our initial impression was that because of the use of ceramic in younger patients, the findings may have reflected the demographic differences. A follow-up multivariate analysis appeared to demonstrate that the bearing surface, independent of the demographics, appeared to influence the incidence of PJI. There have been numerous studies and further presentations that mirror our findings. Ceramics for some reason appear to have a lower incidence of PJI. Although numerous speculative explanations for this observation can be provided, further research into this issue is warranted to unravel the mechanism by which ceramics may impart a lower incidence of PJI.

How do you treat patients affected by PJI?

The management of PJI continues to evolve. There are no clear indications to when irrigation and debridement with retention of the prosthesis (otherwise known as DAIR) is of any value. The indications and the technique for DAIR are continuing to evolve. There has been more utilization of one-stage exchange arthroplasty for the management of acute and chronic PJI in the US. There are in fact two world-wide randomized, prospective studies that are attempting to identify the indications and the outcome of one-stage compared to two-stage exchange arthroplasty. What has become clear is that the success of any surgical intervention for the management of PJI depends largely on the effectiveness of the surgical procedure to remove the bioburden and also on the immune status of the host. The resistance profile of the infecting organism also plays some role in influencing the success of surgical intervention. Moving into the future, I believe we will be focusing more on immune system enhancing strategies, much like the current oncological approach, and less on administration of antibiotics. The future will be very different for patients with PJI. There are also novel products and antibiotics in development that may allow us to shorten the period of antibiotic treatment of these patients.

Do available spacers address the current needs?

There are major issues with the current spacers. The spacers are either prefabricated and need to be purchased or the surgeons need to use the molds and fabricate the spacers in the OR. Some surgeons use sterilized explanted components or even new components that are loosely cemented into bone. There are issues with all the available spacers. They are either costly, contain inadequate amounts of antibiotics (if prefabricated), lack the appropriate length and offset (leading to dislocations), are cumbersome to fabricate, cannot be used in patients without collateral ligaments or large bone loss and so on. There is a desperate need to introduce spacers that can address these problems and can be used in most circumstances.

Are you planning a second consensus meeting?

The first consensus meeting on PJI was held in 2013 and attracted over 400 participants from 52 countries. Over 200 questions or issues were discussed during that meeting and the document produced at that time has been translated into 18 languages. Over 150 societies sent representatives to that meeting. The document is hailed as the "bible" of PJI at the moment. We are planning to hold the next consensus meeting July 25 – 27, 2018. The next consensus meeting will be different on many accounts. First, we plan to include all orthopaedic subspecialties. The issues related to man-

agement of infections in spine, shoulder and elbow, trauma, foot and ankle, sports, and oncology will be discussed. Because of the broader scope there will be over 700 delegates from 155 countries attending the next meeting. Second, and similar to the first consensus meeting, every article published on the subject of orthopaedic infections will be reviewed and evaluated. The recommendations or answers to various questions will then be graded based on the level of evidence. Fi-

nally, we plan to include only experts with published or established expertise in orthopaedic infections. It is anticipated that all issues related to orthopaedic infections will be discussed. We have already begun the work, the delegates have all been identified. The initial round of questions that will be covered and discussed in the meeting has been determined. I am personally excited about the next consensus meeting and look forward to the document that will be created.

Executive Summary

Issue 3-2017

Title	Stem taper mismatch has a critical effect on ceramic head fracture risk in modular hip arthroplasty	
Authors	J. Gührs , M. Körner, M. Bechstedt, A. Krull, M. M. Morlock	
Journal	Clinical Biomechanics 41 (2017) 106–110	
Level of Evidence	None applicable. Laboratory study.	
Summary	Mixing and matching of modular neck/ceramic heads from different manufacturers can lead to an increased risk of head fracture. Gührs et al. from Hamburg investigated component mismatch, using non compatible components from two implant providers, which seemed to provide a stable fixation during assembly. They hypothesized that the fracture resistance of ceramic femoral heads is reduced due to the taper angle mismatch. The angular mismatch between the stem tapers and alumina ceramic femoral heads was 1.69°, which is approx. 17 times larger than the commonly tolerated taper angle difference from one manufacturer. The tapers were assembled and pre-loaded with 2kN (axial). Axial loading tests to fracture were performed according to ISO 7206-10 with a constant displacement rate of 0.04mm/s. The fracture load for the mismatched ceramic femoral heads was 23.68kN, which is almost only 50% of the minimum fracture load of 46kN recommended by the FDA for ceramic heads. The fracture load was still higher than hip joint forces during stumbling; however, axial loading does not pose a worst case scenario in-vivo. Also, in contrary to correctly matched components the contact pattern (circular metal transfer on the inner taper of the ceramic head) was much smaller and concentrated at the proximal end of the taper. The authors conclude that modular component mismatch should be avoided to prevent patients from the higher risk of ceramic fracture. Only component combinations approved by the same manufacturer should be used.	
Study Limitations	Different mismatch parameters were not evaluated separately.	
	Only angular mismatch was evaluated.	
	Tests were performed with alumina ceramic only.	
Key Messages	Only use component combinations from the same manufacturer.	
	Quote: "Mixing and matching components can put patients at greater risk for ceramic head fracture and must be avoided at all costs".	
	Mismatch still can provide a subjectively stable taper connection. However, it may still reduce the fracture resistance of ceramic components.	
Commentary	This study adds scientific evidence to not mix and match modular head-taper components from different implant providers. An important finding was that even if this taper connection seems stable after assembly it can still decrease the fracture resistance of alumina heads substantially.	



Executive Summary

Issue 3-2017

Title	Revision Total Hip Arthroplasty for fractured ceramic bearings: a review of best practices for revision cases	
Authors	R. Rambani, D.M. Kepecs, T.J. Mäkinen, O.A. Safir, A.E. Gross, P.R. Kuzyk; United Lincolnshire Hospital UK & University of Toronto, Canada	
Journal	The Journal of Arthroplasty (2017), doi: 10.1016/j.arth.2016.12.050. Article in press.	
Level of Evidence	Not applicable (review).	
Summary	Rambani et al. searched the available literature for the terms ceramic, fracture, total hip arthroplasty and revision and selected based on evidence level, bias and quality 199 articles out of 228 for their review. Alumina ceramic heads fractured after trauma but also during daily activities; most fractures occurred with 28mm diameter short necks. Ceramic liners had a different fracture mechanism compared to the femoral heads. Malalignment of the acetabular component and/or liner malpositioning were identified as the 2 risk factors for ceramic liner fracture. Only a very small number of fractures has been reported if alumina matrix composite heads were used. Patients with fractured femoral heads usually present with impaired hip function, possible crunching noise and pain in the groin area. If the diagnosis of ceramic component fracture is confirmed revision should be performed urgently. According to the authors it is the key decision whether to retain or replace well-fixed implant components. This decision should be made taking into account all available factors, e.g. mechanism of fracture, component position, state of the metal components, etc. In any case a complete synovectomy should be performed to remove as many ceramic fragments as possible. If there is damage to the locking mechanism, general significant damage to the metal shell or if the component position is unacceptable, it should be revised. If the stem taper is significantly damaged it should also be revised. The use of a ceramic component with a titanium sleeve (BIOLOX®OPTION) should be reserved to cases with only moderate damage of the trunnion. Regarding the right choice of bearing surface for revision after ceramic component fracture there is no consensus in the literature, though bearings with metal heads have been shown to be associated with poorer results and even death. Ceramic-on-ceramic and ceramic-on-polyethylene bearings seem to reduce the risk of third body wear as the most recent publications have shown, with no evidence of superior	
Study Limitations	Review article, summary of current knowledge.	
	Several outdated articles using old technology included.	
	No differentiation between various generations of ceramics.	
Key Messages	Revision THA for a fractured ceramic component is challenging and a complete synovectomy is mandatory.	
	Extremely low number of head fractures with alumina matrix composite to date.	
	Femoral and acetabular metal components should be removed if they are damaged or mal-positioned.	
	Whenever possible bearings with ceramic components should be used.	



Executive Summary

Issue 3-2017

Title	Choosing a Femoral Head: A Survey Study of Academic Adult Reconstructive Surgeons
Authors	S. Nandi, M.S. Austin; University of Toledo, Ohio & Rothman Institute, Philadelphia, USA
Journal	The Journal of Arthroplasty 2017; in press, http://dx.doi.org/10.1016/j.arth.2016.12.009. Online Dec 2016
Level of Evidence	Not applicable.
Summary	Nandi and Austin investigated the attitude of academic orthopaedic surgeons towards the use of ceramic and CoCr femoral heads for THA using a simple 16-question survey which they sent to 274 faculties at 42 US adult reconstruction fellowship programs. The response rate was 42.2%. The responding surgeons use ceramic heads 72.9% of the time and 47% use ceramic heads for all their patients. 38% use ceramic heads dependent on age, and 12% dependent on activity level. 3% of respondents do not use ceramic heads at all. If a CoCr head is chosen, costs (45%), limitations in neck length options (33%) and concern with potential ceramic fracture (11%) are the main reasons. 4% of the academic surgeons think that there is no benefit in using ceramic heads. Cost difference between ceramic and CoCr heads varies between none (22%) and up to \$1'000 (9%), 18% of surgeons did not know the cost difference. If it is below \$300 surgeons would preferably use ceramics heads. Surgeons have personally observed corrosion at the head-neck tapers with CoCr or ceramic heads on polyethylene in 94% and 9.5%, respectively. For revision THA due to corrosion 96% would use a ceramic femoral head and in case the stem is left in situ 91% would use a ceramic head with a titanium sleeve. 81% expect the possibility of corrosion at any time if a CoCr head is used on any stem taper and 72.4% are concerned about it. Nevertheless, only 46% of the respondents think that a ceramic head should be the standard of care. There is still a concern for ceramic fracture (16%) and 6% of the responding surgeons have already seen a fracture of a BIOLOX® delta ceramic head. The long-term wear of CoCr and ceramic heads on cross-linked PE was not thought to be different (53% yes, 46% no). The authors conclude that the respondent surgeons are guided by evidence which indicates that taper corrosion and fracture is rare with ceramic heads. However, implant selection is strongly influenced by cost and personal experience.
Study Limitations	Survey in USA only. Response rate only 42%.
	Not clear if survey responses are an accurate reflection of actual surgeons practice.
	Similar questions received different answers.
	Choices for survey answers may not have addressed all possible practices.
	Answers were not collected anonymously.
Key Messages	Almost half of the responding surgeons survey use ceramic heads and think that ceramic femoral heads should be standard of care.
	The most common reason for not using ceramic heads in all patients was costs followed by limited neck length options.
	Most surgeons were concerned about taper corrosion and have actually seen it.
	Concerns about ceramic fracture still exist.
	About half the respondents think that long-term wear performance is not significantly different between ceramic and CoCr heads on cross-linked PE.



