ROUNDUP360

Hip & Pelvis

x-ref *For other roundups in this issue that cross-reference with Hip & Pelvis see: Trauma roundup 4; Research roundups 1, 5.*

Modular femoral necks: early signs are not good!

With the ongoing scares concerning metal-on-metal arthroplasty and the potential for difficulty with elevated metal ion levels and adverse metal reactions, the focus of the orthopaedic fraternity has been turned to other non-articulating surfaces. Much concern has been raised about trunionosis and the potential for high levels of corrosive activity at the trunion interface. This has started to emerge with both implant companies and public involvement. On the one hand the marketing and market forces pressures are towards ever more 'tailored' implants with sex-specific implants and increasing modularisation (including femoral neck modularisation) in the pursuit of 'anatomical' replacement; on the other hand the rush of unproven technologies is being halted somewhat by a more conservative surgical community. The modular femoral neck has been met with particular concern in many quarters introducing yet another interface with the potential to cause metallosis. Researchers in **Wollstonecraft (Australia)** have reported a small study looking at the outcomes of a modular hip prosthesis design. They report on a small series of patients who received an ABG II dual modular hip system. Their case series reports outcomes at just under an average follow-up of four years with radiographs, MRIs, metal ion levels and, when appropriate, retrieval analysis for the prosthesis. The authors retrospectively report on 15 modular-neck hip prostheses from a single manufacturer. At a mean of 42.3 months, cobalt levels were elevated in all patients, all patients had grade 2 or 3 calcar erosion, and all patients had evidence of soft-tissue reactions on MRI. Nearly 50% of the patients had undergone revision surgery at this rather short follow-up point. Of the seven patients who underwent revision, all had evidence of adverse metal ion reactions in the explanted specimens. Soft tissue changes were present with pseudotumour formation and signs of widespread soft-tissue necrosis.[1] This is an intriguing study that once again highlights the limitations of advanced technology with limited clinical data. While this prosthesis has been recalled, it highlights the fact that registries are essential to monitor for such catastrophic failures. Moreover, as an orthopaedic community, we must continue to strive for more robust *in vitro* and *in vivo* data before new products are brought to the market.

Corrosion to blame for modular neck failures

Much like buses, reports of the outcomes of modular neck prostheses have been sporadic, then two come at once. In yet another report following hot on the heels of their colleagues in Australia, researchers in **Houston (USA)** have reported their experience with a modular neck prosthesis, highlighting the early corrosion-related failure of modular-neck stem implants. In a similar paper, the investigators aimed to establish the rate of survivorship, rates of corrosion-related complications and potential predictors of implant failure (patient and implant factors). Over a three-year period the research team implanted 123 Rejuvenate arthroplasty stems, of which 97 were modular. Following the withdrawal of this implant from the commercial marketplace, the results of this large series have been reported. Failure has been assessed, together with serum cobalt and chromium levels, and the investigators have tried to establish any potential causal relationship between implant factors (stem size, head size, head length, and femoral head-neck offset), patient factors (age, sex, and body mass index) and metal ion levels. Like many of these series in the literature, follow-up was to only just over two and a half years and the investigators were able to establish the effects of the modular neck by comparison between the two groups. They established that there were statistically significant differences in metal ion levels between the two groups, with around half of the modular neck group having raised metal ion levels whilst all of the metal ion levels in the non-modular group were normal. Factors found to be associated with failure were younger patients, larger femoral neck offsets, pain, and high serum cobalt levels which in themselves were predictive of revision surgery.[2] There was an alarmingly high failure rate in this series, with 40% survivorship at four years, and in addition, nearly 50% of the patients in the study had elevated metal ion levels. This confirms the findings of the previous (much smaller) study and leaves us wondering here at *360* how in this modern world of evidence-based medicine, implant design can gallop so far ahead of evidence without appropriate pre-market studies.

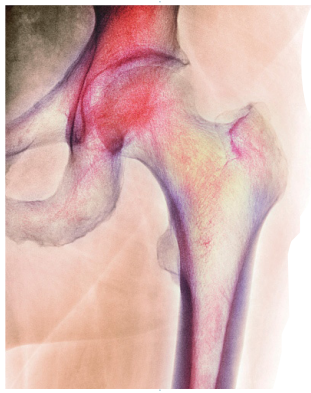
Metal-on-metal not quite a closed book

The use of metal-on-metal (MoM) total hip arthroplasty (THA) has decreased significantly over the past five years in light of poor outcomes reported by registries and investigators predominantly in Europe and Australia. Surgeons in the US and Canada were more wary of the MoM technology and in light of recent findings currently, the United States Food and Drug Administration is requesting post-market surveillance data from all manufacturers on MoM THAs. Engh et al from **Alexandria (USA)** previously reported two-year data in their prospective randomised trial of patients in three groups: 28-mm MoM THAs, 36-mm MoM THAs, and 28-mm metal-on-polyethylene (MoP) THAs. In their initial study design, 105 patients were randomly assigned to each of the three groups, and the patients themselves were blinded to their treatment group. In this five-year update of these patients the authors nicely showed that cobalt and chromium ion levels in erythrocytes, serum, and whole blood are increased

in both MoM groups when compared with MoP patients. Moreover, cobalt in serum and erythrocytes had a significant increase from two to five years in the 36-mm MoM group, but not in the other groups. Of the 105 patients, the authors only report a single revision for adverse metal reaction (in the 36-mm group).[3] From a metal ion standpoint, the 36-mm MoM group underperformed the 28-mm MoM group, which did worse than the 28-mm MoP group. From a governance point of view, it is quite clear that surgeons with MoM patients in their practice must closely monitor them, as indicated by this study. Our interest here at *360* has been piqued by the observation that the 36-mm heads have a higher metal ion release rate (which continues to rise) when compared with the 28-mm heads. An interesting observation. In theory at least, the 36-mm heads should be capable of thick film lubrication where the 28-mm heads should not. This observation theoretically lends weight to concerns about metal ion release from the trunion as a larger head would exert higher forces on the trunion which should lead to higher rates of fretting corrosion.

No excess failures in fixation of displaced femoral neck fractures x-ref

■ In light of the threatened tidal wave of elderly hip fractures starting to emerge across the developed world, studies comparing outcomes of similar treatment modalities are becoming more and more valuable help to guide decision making for healthcare providers and policy makers alike. Displaced femoral neck fracture treatment in the elderly is a balancing act, with the most optimal treatment method taking into account both the surgical and medical risks. Surgeons in **Linköping (Sweden)** have published a paper at 15 years follow-up of their initial recruitment to a randomised controlled trial comparing internal fixation with total hip replacement for displaced femoral neck fractures. The study cohort of 143 patients was originally recruited over a four-year period between 1994 and 1998, and were randomised to either screw fixation (n = 78) or cemented a THR (n = 68). As expected, the failure rate was 55% after internal fixation, compared with 5% after THR. Failure of internal fixation was defined as early redisplacement, non-union, symptomatic segmental collapse, or deep infection. Failure in the arthroplasty group was defined as two or more dislocations, implant loosening, deep infection, or a periprosthetic fracture. More interestingly, the authors divided patients into those who were lucid or with mental impairment. When looking at those with mental impairment, the failure rate was 16% in both groups.[4] Given the inherent higher morbidity associated with total joint replacement surgery in patients with mental impairment, we are slightly bemused as to why this was not an initial exclusion criteria for this study. However, we are heartened to find that there was no difference in failure rate for internal fixation, suggesting that for patients with mental impairment, reduction and fixation may be as good as any other option.



Noise no problem in hip replacement

■ It seems the decision making in selecting a surface bearing for young high-activity patients continues to be a tricky one. With concerns over the potential for failure with metal-on-metal and the revision implications of metal-on-polyethylene bearings when used in young patients, many surgeons have been reaching for ceramic-on-ceramic, only to be disappointed (sometimes like their patients) with the incidence of ceramic 'squeak'. Despite these concerns, there is little data to suggest whether this is indeed likely to be signaling a future related problem. Researchers in **Oxford (UK)** in what we are sure will become a key study in this area, set out to establish the incidence of noise generation arising from the large-diameter Delta Motion ceramic total hip bearing. Their study population consisted of 208 consecutive DeltaMotion THRs which were examined at a mean follow-up of just under two years. Outcomes were assessed using a clinical and radiological review as well as clinical outcome measures. In addition, noise levels were measured and the investigators attempted to ascribe the incidence of noise to a number of potential risk factors including range of movement, laxity, PROMs, activity levels and component orientations. Interestingly, there were only 143 silent hips (69%). Of the remainder, 11% generated other noises (e.g. clunking), 8% had unreproducible squeaking and 13% reproducible squeaking. More importantly, the authors examined the noise production against range of movement, ligamentous laxity, patient-reported outcome scores, activity level, and orientation of the acetabular component. Hips with reproducible squeaking had a greater mean range of movement and mean ligament laxity, smaller median head sizes, and decreased mean acetabular component inclination and anteversion angle.[5] Despite the high incidence of squeaking, it did not affect the long-term outcomes of the joint replacements in this study, either in terms of patient satisfaction or rate of failure. Paying attention to the identified risk factors in this study is ideal to reduce the rate of persistent squeaking, but it does appear that patient and clinicians alike can be re-assured that a squeak is in fact a harmless squeak.

Heterotopic ossification after hip arthroscopy: are NSAIDs the answer?

■ As hip arthroscopy continues to emerge as an accepted treatment modality, characterisation of complications and outcomes continues, as does the evaluation of strategies to optimise both. While not often a seriously limiting problem, heterotopic ossification is relatively common after hip arthroscopy, with up to a quarter of patients reported to suffer from the problem. Researchers in **Salt Lake City (USA)** report their experience with a change of practice to using prophylactic NSAIDs and the impact this had on their incidence of heterotopic ossification (HO). They report on a comparative cohort study (Level III evidence) straddling the introduction of NSAID prophylaxis in their practice. The authors were able to report 357 consecutive cases (117 without NSAIDs and 240 with) who had undergone hip arthroscopy over a three-year period. The authors report the outcomes of 288 patients and their headline result was a dramatic drop in the incidence of HO from 25% (n = 23/92) to 5% (n = 11/96) after the introduction of naproxen prescription giving an odds ratio of 13.6 (95% CI 2.44 to 75.5). Identified risk factors included not only the omission of administration of NSAIDs, but also surgery type (highest incidence was seen with FAI resection for mixed type disease where both acetabuloplasty and osteochondroplasty are performed).[6] The authors report a dramatic reduction in the rate of HO but do not report the usual gamut of complications with NSAID therapy including renal impairment and GI symptoms, and there is certainly a balancing act required here with gastric protection if NSAIDs are to be prescribed.

Thrombotic and bleeding events surprisingly low in total joint replacement

■ With so much focus based on large (often commercially funded) studies aimed at establishing the relative risks of one treatment *versus*

another in reduction of thromboembolism risk, there has been a lack of focus on the topic behind the debate surrounding fatal bleeding and thromboembolic events. Researchers in **Aarhus (Denmark)** have carried out a laudable study to examine the risk of thrombotic and major bleeding events on a large scale. After all, if we don't understand the scale of the problem it is difficult to understand the benefit of the treatments. They included patients undergoing total hip and knee replacement treated with thromboprophylaxis, using national surveys. Their study included a whopping 83 756 primary procedures carried out over a 15-year period and focused on a number of end points across the 90-day post-operative period including venous thromboembolism (VTE), myocardial infarction (MI), stroke, death and major bleeding. The annual risk of VTE varied across the study period between 0.9% and 1.6%, and that of bleeding between 0.4% and 0.8%.[7] The overall risk of VTE and bleeding was unchanged over the 15-year period of the study. While approximately 3% of patients experienced VTE, MI, stroke or bleeding in the study, these risks did not decline during the 15-year study period, but the risk of dying fell substantially despite no change in these event rates.

The elephant in the room: complications and surgical volume

■ It is well known that low volume surgeons run the risk of higher complication rates. Just how much volume is enough to lower complication rates is difficult to quantify, but the effect of surgical volumes on peri-operative outcomes is well recognised (and allowed for with statistical techniques such as the funnel plot) but it is difficult to establish exactly where the threshold for 'safety' lies. Health economists in **Tokyo (Japan)** have taken another look at the problem of surgical competence and volume using the end point of peri-operative complications rather than the more commonly used end point of 'revision'. Using discharge data from 8321 patients from Japan, all of whom underwent THA, the research team explored the relationship between complications and surgical volume using multivariate logistic regression models. Correction was made for patient demographics including age, sex, and Charlson comorbidity index, while hospitals were categorised according to the volume of THA procedures performed every six months. In line with almost every other published report on post-operative complications, the most common complications following THR in this series were dislocation (1.41%) and infection (1.24%). The researchers established that patients who underwent THA in hospitals with the highest surgical volume had lower risk of dislocation and infection (odds ratio 0.32 and 0.12, respectively).[8] Despite the accumulating data that complication rates and outcomes such as revision are surgeon- and unit volume-dependent, there continues across all regulated healthcare economies to be no regulation on a minimum safe surgical volume. We wonder here at *360* with the ongoing publication of articles like this, how long it can (or should) be before healthcare regulators act on the growing volume of information supporting the desirability of high volume specialist surgeons.

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