Fretting and Corrosion between a metal shell and metal liner may explain the high rate of failure of R3 modular metal on metal hips

Abstract

Background

The R3 acetabular system used with its metal liner has higher revision rates when compared to its ceramic and polyethylene liner. In June 2012 the medical and healthcare products regulatory agency issued an alert regarding the metal liner of the R3 acetabular system.

Method

6 retrieved R3 acetabular systems with metal liners underwent detailed visual analysis using macroscopic and microscopic techniques.

Results

Visual analysis discovered corrosion on the backside of the metal liners. There was a distinct border to the areas of corrosion that conformed to anti-rotation tab insertions on the inner surface of the acetabular shell, which are for the polyethylene liner. Scanning electron microscopy indicated evidence of crevice corrosion and energy dispersive X-ray analysis confirmed corrosion debris rich in titanium.

Conclusion

The high failure rate of the metal liner option of the R3 acetabular system may be attributed to corrosion on the backside of the liner which appear to result from geometry and design characteristics of the acetabular shell.

Keywords: Total hip arthroplasty, modular cup, metal liner, taper, corrosion,

INTRODUCTION

Modularity of total hip arthroplasty (THA) was developed to give more flexibility to the surgeon intraoperatively to better accommodate patient geometry as well as potentially allowing easier revision surgery in the future. Modular acetabular components have allowed the use of a metallic shell that can be coupled with different liner materials. This has permitted further choice dependent on [1]cases and functional requirement[1].

The R3 acetabular system (Smith and Nephew, Memphis, Tennessee) contains an uncemented modular hemispherical titanium shell, which was first released in Europe and Australia in 2007. For primary fixation it utilizes a porous coating with the option of three-hole shell for adjuvant screw fixation. The R3 acetabular system initially was available with three different liner options: polyethylene, metal and ceramic. The metal option for the R3 is high carbide cobalt chrome in the as-cast micro-structural condition. However the metal liner was subsequently recalled on 1st June 2012 by Smith and Nephew and on 25th June 2012 the medical and healthcare products regulatory agency (MHRA) issued a medical device alert regarding the metal liner component of the R3 acetabular system, advising to stop its use and increase surveillance of these implants.

In this study, we aim to understand the failure mechanisms of the R3 modular acetabular system with its metal liner through analysis of retrievals.

METHODS

This was a retrospective study performed at a national implant retrieval centre. We investigated all failed R3 modular acetabular systems, which consisted of a metal liner collected from July 2009 to July 2014. 6 implants, from different hospitals were collected. Pre-revision cobalt and chromium blood ion levels were collected alongside relevant patient demographic and radiographic data.

Before analysis, the implants were cleaned in a cleaning solution consisting of 10% Decon 90 and de-ionized water. The implants where then placed in an ultrasound-cleaning machine for a period of 15 minutes, then rinsed with de-ionized water, to remove loose debris and then left to dry. The components of each implant were then visually analyzed macroscopically and microscopically. A Leica M50 Stereomicroscope at x40 magnification was used to examine all areas of the acetabular shell and metal liner to identify any changes that may have occurred on their surfaces. Changes to the surface of hip implants have previously been described by Mckellop et al[2]. Evidence of corrosion and fretting were noted and their location described in relation to their proximity to its pole or equator. Severity of corrosion was not assessed due to the subjectivity of its qualitative measurement.

For further detailed analysis a scanning electron microscope (SEM, Joel, JSM 5500, Tokyo, Japan) was used to perform detailed microscopic analysis of areas of interest highlighted from the microscopic inspection, thus enabling identification of microscopic changes such as pitting and fretting scars. Energy dispersive X-ray spectroscopy (EDAX) was utilized to chemically characterize any evidence of corrosive debris.

RESULTS

Clinical data for the retrieved R3 acetabular systems are shown in Table 1. Pre-revision magnetic resonance imaging (MRI) scans were performed for 5 implants. All showed evidence of adverse reactions ranging from fluid collections to soft tissue masses. The mean patient age was 63 (range 56-67) at time of implantation and they were retrieved after a mean of 47 months (range 28-67). All except one patient had both raised cobalt (median 9, range 5.66 – 27.7) and chromium (median 8.1, range 5.6 – 43.4) blood metal ions.

Visual analysis of each acetabular shell showed a band of debris on the inner surface, below the hard-bearing taper locking mechanism. The backside of the R3 metal liners illustrated evidence of surface damage and black debris in the same area. The areas of corrosion were clearly demarcated into a 'castle parapet' shape (figure 1). These areas of corrosion were found circumferentially at the equator of the metal liner. SEM micrographs of the backside of the liner illustrated evidence of pitting within the areas of corrosion and confirmed that the corrosive damage was clearly within the boundaries of the 'castle parapet' shape (figure 2). EDAX confirmed corrosive debris, rich in titanium (figure 3)

DISCUSSION

This study has shown a potential new mechanism of failure that affects the backside of the R3 acetabular system metal liners. Through detailed visual analysis this study has identified the presence of corrosion on the backside of the metal liner, which appears to be clearly demarcated around the equator of the metal liner. Furthermore, the corrosion observed had a pattern correlating with the inner surface of the acetabular shell. The "castle parapet' outline of the areas of corrosion conforms with the grooved areas of the acetabular shell where the polyethylene liner anti-rotation tabs insert (Figure 4). These results are important as they may help explain the high failure rates seen with the metal liner option of the R3 acetabular device and its subsequent recall.

Recall of R3 metal liners was due to their association with a higher than normal failure rate. UK national joint registry data found a revision rate of 6.3% at 4 years, compared to 2.9% revision rate for all primary THA[3]. Similar results were found in the Australian joint registry, with 2.48 revisions per 100 observation years for the R3 metal liner, compared to 0.79 for all primary THAs[4]. Unpublished implant data from the national joint registries, which is available to manufactures, reported no dominant cause of failure according to Smith and Nephew, but there has been one study which has reported a failure rate of 24% due to adverse local tissue reactions[5]. However the R3 acetabular cup used with polyethylene or ceramic liners ranks third most common acetabular component inserted in Australia[4], and Lee et al found a cumulative revision rate of 0.15% for the R3 system when used with ceramic or highly cross-linked polyethylene in 646 patients from the Australian joint registry[6].

There are a limited number of other studies that have investigated the R3 acetabular system. A radiostereometric analysis study by Grosser et al of 14 patients who had undergone implantation of the R3 modular cup found proximal migration of 0.39mm greater than the proposed safe level of 0.2mm[7]. This result put the R3 system in the 'at risk range', albeit at the lower end. Labek et al, analysed datasets from three different countries regarding the outcome of the cementless tapered SL stem[8]. This study showed that the combination with the R3 acetabular system showed a higher revision rate when compared with another more frequently used cup. However, there are no published studies investigating the cause of the increased failure rate of the R3 modular cup with a metal liner that led to its recall. In the study by Lee et al, which reported failures due to radiographic and histological confirmation of adverse local tissue reactions, there was no analysis of retrieved components. All of the patients who underwent a pre-revision MRI in this study showed evidence of adverse local tissue reactions, however we cannot conclude that this was directly caused by corrosion at the backside of the metal liner, as metal debris can occur from the bearing and other modular surfaces. However, damage to the backside of a metal liner will increase the amount of metal debris, which previous studies report that corrosion at taper junctions of THA have resulted in extensive soft tissue damage[9-15].

The corrosion on the backside of the retrieved metal liners in this study appears to have a clear pattern. Micrographs highlighted that there was a clear border as to which areas where corroded. These areas are exactly matched to corresponding areas on the inner surface of the shell illustrating that the geometry of the R3 acetabular shell does not fully conform to the metal liner. The R3 polyethylene liner is different to the ceramic and metal liners as it has anti-rotational tabs to prevent torque and allow a lock fit with the grooves on the acetabular shell. The insertions for the polyethylene tabs are visible on the inner surface of the R3 acetabular shell (figure 4). The metal liner does not have anti-rotation tabs therefore having intermittent areas of contact between the shell and liner at its equator. Where there is close contact between two different metals there is potential for corrosion. The acetabular shell is constructed from titanium, whereas the liner is constructed from a cobalt chromium alloy. The mixing of different metals permits galvanic corrosion and studies have shown that there is increased damage at taper junctions in mixed alloy implants[16-20]. When a metal liner is used in the R3 acetabular system, due to the anti-rotational tabs insertions on the equator of the shell it can permit joint fluid and debris to infiltrate the crevices between the liner and shell. This can cause an exacerbation of corrosion at this taper junction.

When a metal liner is used in the R3 acetabular system there are areas between the grooves on the shell and the backside of the liner that are in close contact. This area of close contact between the dissimilar metals can create a crevice and a subsequent galvanic environment. SEM imaging showed evidence of pitting within areas of corrosion, which is suggestive of crevice corrosion. Differences in tolerances and also micromotion can exacerbate the potential for corrosion in this area. The presence of screw holes and decreased conformity between the liner and shell interface can permit fluid and debris into crevices. Previous studies have shown that fluid within a crevice can cause ion exchange and prevent a friction fit, increasing corrosion[21, 22].

Due to the small number of retrievals in this study, we cannot conclude that backside corrosion occurs with all the metal liners of the R3 acetabular system. However, the clear corrosive patterning found during this retrieval study appears to be linked to the implant design and metallurgy. All R3 acetabular shells accommodate for the polyethylene inserts with the anti-rotational tabs. As all retrievals showed the same pattern of liner damage, this suggests that the metal liner may not be a suitable option for the R3 acetabular system. This problem ideally should have been discovered during in-vitro testing. The results of this study suggest that through increasing implant adjustability, the R3 acetabular system long-term success could be compromised, as the shell may not be suited for its metal liner. Although larger studies are needed to confirm our results, we suggest that a testing standard for modular cups should be developed to reduce potential future issues like this occurring.

Backside corrosion can potentially arise with any acetabular system that contains a liner with metal on its backside. Therefore acetabular systems with metal backed ceramic liners and modular dual mobility components may also be susceptible to this issue, in the long term. Further research is required to understand the significance of the backside liner corrosion. However, as an extra source of metal debris, close monitoring for evidence of metallosis and adverse tissue reactions is essential as advised by the MHRA for all MOM implants. Further information is required as to whether all acetabular systems with metal backed liners, regardless of bearing surface should be monitored.

Limitations

This study has analyzed a small number of retrieved R3 components; therefore the results may not be representative all R3 components with a metal liner. Also, we do not know if the corrosion at the backside of the metal liner was a direct cause of failure, however this is an undesirable outcome. Further analysis is required to investigate the significance of corrosion of the backside of the metal liner and whether any patients or surgical factors contributed to its failure.

Conclusion

This study has shown that the issue regarding the R3 acetabular system and its metal liner is due to the geometry of the inner surface of the shell. Whilst allowing for anti-rotational tabs of the polyethylene liner, this appears to permit corrosion between the metal liner and shell, leading to corrosive damage of the backside of the liner. The modular design of the R3 acetabular system is not suited for the metal liner and future designs of modular acetabular systems should take these findings into account.

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Figures

Figure 1: Photographs of 6 retrieved metal liners used in the R3 acetabular system illustrating a distinctive pattern of corrosion on the backside of the liners

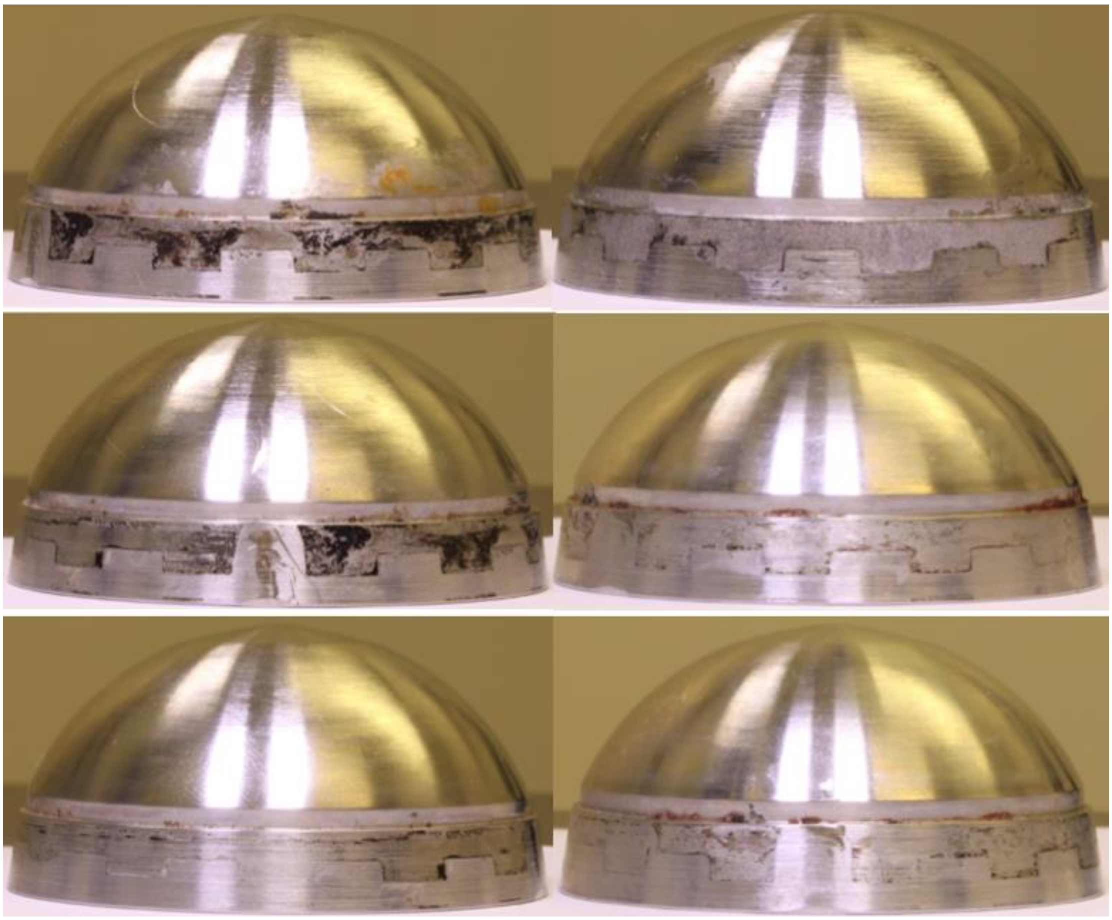

Figure 2: [A] Scanning electron microscopy image [x70] illustrating extensive pitting in areas of corrosion on the backside of the metal liner. [B] Scanning electron microscopy image [x70] illustrating a clear demarcation between the corroded [right of image] and non-corroded areas [left of image].

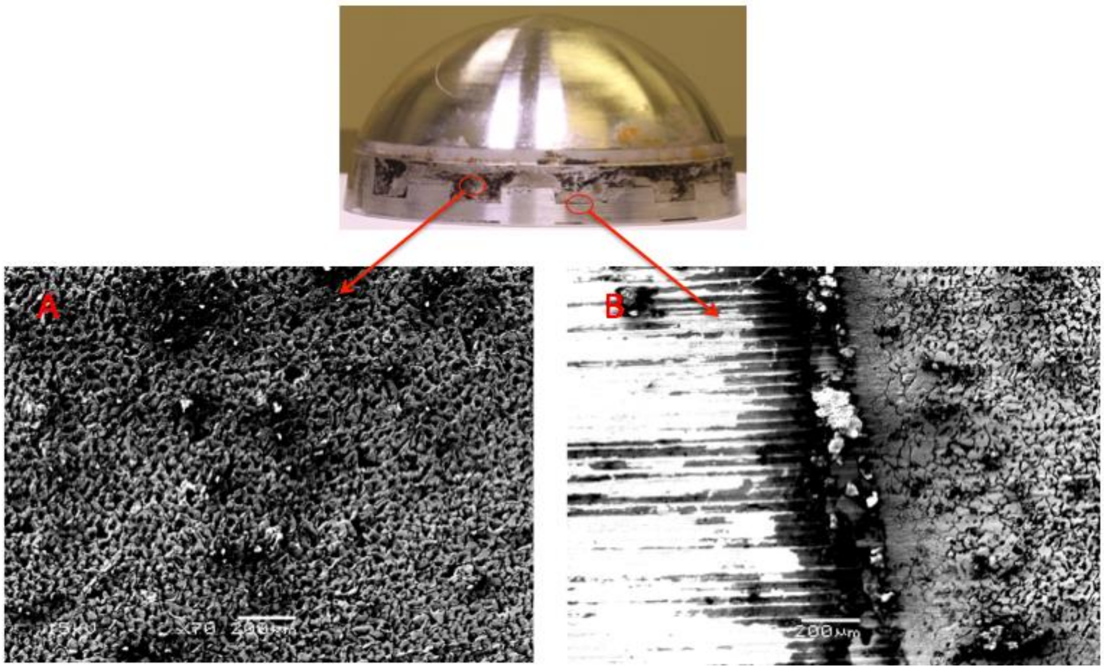

Figure 3: Energy dispersive X-ray spectroscopy of corrosive debris on the backside of the metal liner showing titanium rich deposits

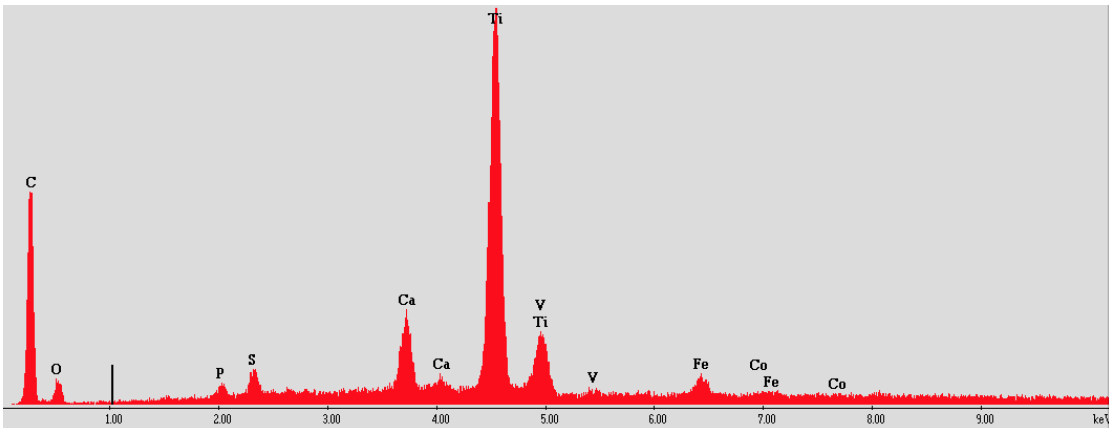

Figure 4: Photograph [100mm lens] of the R3 acetabular shell highlighting the insert for the polyethylene liner anti-rotation tabs [arrows]