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Case Report

Metallosis following a dual coat porous hydroxyapatite shoulder hemiarthroplasty

Humza Khan^{*}, Mark Hurworth, Alan Kop

Royal Perth Hospital, Western Australia, Australia

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ABSTRACT

We report a case of metallosis following a shoulder hemiarthroplasty with a humeral component resurfacing shoulder replacement.

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1. Introduction

Metallosis in arthroplasty has become a topic of increasing relevance with the need for revision procedures particularly seen in hip and knee arthroplasty.^{1,2} Metallosis is the infiltration of periprosthetic tissue by metal debris and the subsequent localised inflammatory response with macrophages and giant cells leading to granulation tissue.^{3,4} There has been little evidence of shoulder arthroplasty failure due to metallosis in the literature. A case report of metallosis in a total shoulder arthroplasty in an uncemented Nottingham shoulder was reported 2007⁵; however humeral component resurfacing shoulder hemiarthroplasty metallosis has not previously been described. We describe a case of metallosis in a DePuy Global Hemi Cap shoulder hemiarthroplasty with a DuoFix surface that was revised due to metallosis failure in a similar manner to the recently recalled DePuy Low Contact Stress DuoFix rotating knee prosthesis.²

2. Case report

An 84-year-old woman presented after 5 years with right shoulder pain following the implantation of a DePuy Global Cap Resurfacing shoulder hemiarthroplasty for osteoarthritis. The patient has a background of generalised osteoarthritis with multiple large joint replacements including bilateral hips, knees and a left total shoulder replacement. The primary procedure was performed in 2006 to alleviate an intermittently painful and stiff right shoulder which she suffered with over the preceding five years. The DePuy Global Hemi Cap resurfacing shoulder used was manufactured from a cobalt chromium molybdenum (cobalt chrome) alloy with a porous coated bead in growth surface that is further treated with plasma sprayed hydroxyapatite (trade name “DuoFix”⁶).

Her post-operative recovery was satisfactory with physiotherapy reporting gradual improvements in range of

^{*} Corresponding author.

E-mail address: Humza.Khan@health.wa.gov.au (H. Khan).

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movement achieving ninety degrees active shoulder flexion and abduction. She continued to experience minor strength deficits and anterior shoulder pain associated with reaching and lifting, for which she was given ongoing strength exercises. Overall the patient reported that she was functionally better than before the procedure.

After five years she was referred for further opinion and management of her right shoulder pain. She reported discomfort and reduced range of movement. Radiographs, a CT scan and blood tests were performed to further investigate the shoulder. These tests revealed superior subluxation of the humeral component with respect to the glenoid and a normal white cell count [Fig. 1].

Revision to a reverse shoulder arthroplasty was carried out in 2013 using the DePuy DELTA Xtend shoulder system. The primary intra-operative finding was tissue staining consistent with significant metallosis. There was surrounding inflammatory and granulomatous tissue. The prosthesis was still fixed. The remainder of the procedure was conducted without complication. The retrieved implant was sent for analysis to the Biomaterial Laboratory at Royal Perth Hospital following standard retrieval protocols.

Evaluation of the device incorporated the following; qualitative macro analysis of the component in terms of degradation mechanisms and metal loading of the intra-operative tissue biopsy sample. Inductively Coupled Plasma – Atomic Emission Spectroscopy⁷ was undertaken to determine the metal ion levels, specifically chromium, cobalt, titanium, vanadium and aluminium, as per the standard RPH protocol in the biopsied tissue.

Fig. 2 – DuoFix Shoulder Multidirectional scratching.

Macro analysis using a Leica MZ6 stereomicroscope revealed good bony ingrowth with geometrically diverse spicules of bone; however also noted was metallic stained tissue peripherally. Minor remnant HA coating was observed. The bearing surface showed fine scratching and scouring over most of the surface with a small unworn region towards the edge of the device as shown in Fig. 2.

Assessment of the intra-operative tissue biopsy revealed 835 ppm of cobalt, and 926 ppm of Chromium, which is

Fig. 1 – X-ray progression.

considered highly elevated compared to normal levels associated with arthroplasty of <0.146 ppm chromium and 0.049 ppm cobalt.⁸ The levels of titanium (0.35 ppm, normal 0.2 ppm)⁹ and aluminium (<3 ppm, normal 1–3 ppm)¹⁰ were not considered of clinical significance.

The Bioengineering report concluded that the wear on the bearing surface was similar to that observed for the recalled Duofix LCS knee devices [Fig. 3].

3. Discussion

Metallosis in a shoulder hemiarthroplasty to our knowledge has not previously been described in the literature. This case posed the question as to whether the metallosis resulted from a similar failure mechanism to that observed for the DePuy LCS DuoFix Knee arthroplasty.

Metallosis has been described as fragments of metallic material infiltrating periprosthetic structures that may be surrounded by foreign body giant cells, increased inflammatory reaction and granulation tissue.^{3,4} Commonly intra-operatively this process is observed as gross metallic staining of the localised tissue, the extent of which is dependent on the degree of metallic wear debris.

In recent years this type of failure has become increasingly concerning and most commonly associated with metal-on-metal total hip arthroplasty and in modular neck THR devices.^{3,11–13} Of more relevance to the present case was the recent recall of the DePuy rotating platform cementless total knee replacement due to metallosis related failures.²

In 2009 a worldwide recall of the LCS DuoFix knees took place after early failure was noted with metallosis and scratching of the prosthesis.² The mechanism of failure was believed to be related to the porous coating plasma sprayed hydroxyapatite undersurface of the femoral components. DuoFix technology is the combination of porous coating, which is a beaded structure designed to provide mechanical interlocking,¹⁴ with hydroxyapatite (HA) plasma spray coating. This HA coating provides a 35 micron application to the beads preventing occlusion of the pores⁶ and is designed to enhance osteo-integration [Fig. 4⁶: DuoFix coating].

Fig. 3 – LCS knee scratching.

Analysis of failed Duofix devices found particles of alumina ceramic embedded in the polyethylene of the liners. The explanation for this is that alumina is used to roughen the surface of the beaded coating prior to the application of hydroxyapatite to allow component adherence. It was suggested that these particles may have broken down and were not adequately removed in the cleaning process prior to HA application. Thus the alumina particles were likely shed into the joint on implantation, embedding into the relatively soft ultra-high molecular weight polyethylene bearing subsequently causing severe scratching, generalised wear and metallosis.²

This draws attention to the actual process of manufacturing implants with regard to optimum preparation and processing of the bony integration surface. Spherical metal beads are commonly placed onto the surface of a device to produce a minimum density and maximum porosity coating. These can then be blasted with a solid medium to roughen the surface allowing for better adherence of the hydroxyapatite coating.¹⁵ Alumina, being of high hardness is one of the mediums used in this process called grit blasting.^{16,17} Surface preparation is the most critical step in a plasma spraying operation¹⁶ such as that used in the application of HA.

Importantly, the implant surface may be contaminated with fragments of the grit blast particles or breakdown residue.^{15–17} It becomes crucial to remove this particulate debris prior to use to prevent adverse events such as “particulate disease” whereby macrophages ingest particles and elicit an immune response resulting in metallosis.^{1–5,13,15} The grit residue cleaning process generally involves air blasting followed by ultrasonic cleaning or flushing with a biocompatible liquid medium to remove blasting residue.^{15,16} Albeit, due to propriety process the exact method used by the company is unknown. The recent recall of the LCS DuoFix knee prosthesis however highlights the importance of process quality control [see Fig. 5].

We hypothesise an additional complication of grit blasting a beaded surface is related to geometry. Both the present device and the LCS femoral component have concave geometry and very fine (250 µm) beads. The geometry and bead size would make removal of grit blast media inherently difficult from a concave surface. In contrast, the HA Duofix coating on the planar tibial trays has never been implicated in failure, which is supported by our observations of fifty three retrieved Duofix tibial trays when coupled with a non Duofix femoral component. We propose that there remains some residue on these concave surfaces that is able to infiltrate soft tissue on implantation that results in scratching and the metallosis and abrasive wear noted in our shoulder hemiarthroplasty in a similar way to the LCS DuoFix femoral component knee failure.

While this is only a single case of metallosis and clinical failure of an implant, the possible mechanism of failure is interesting in the context of the DuoFix coating and scratched surfaces of the implant. Even so, failure of shoulder arthroplasty due to metallosis has limited mention in the literature. A case report of a total shoulder arthroplasty failure due to metallosis was described in 2007.⁵ This Nottingham total shoulder prosthesis consisted of a plasma sprayed titanium

Fig. 4 – DuoFix coating.

humeral stem to encourage osteo-integration. On retrieval the humeral head showed abrasive wear and the stem coating had started to delaminate. Not only were cobalt and chromium particles found on the articular surface but titanium particles from the plasma sprayed stem were also found in the polyethylene surface producing abrasive wear.

Similar cases of metallosis related failure in total shoulder arthroplasty have been reported in the *Journal of British Elbow and Shoulder Society*.^{18,19} One such case involved a bipolar bearing shoulder replacement with ultra-high molecular weight polyethylene.¹⁹ It reported extensive tissue metallosis without wear of the bipolar articulation, consisting of titanium suspected to originate from areas of the debonded humeral stem porous titanium coating. Another case described such severe metallosis that there was cutaneous pigmentation associated with metallosis eight years after a reverse total shoulder replacement.¹⁸

Fig. 5 – Grit Blast flow diagram.

In 2010 an article published in the *Journal of Shoulder and Elbow Surgery* commented on the outcomes of a new soft metal backed glenoid component designed to facilitate bone fixation using a highly porous titanium back coating.²⁰ This was a retrospective review of 22 cases with total shoulder arthroplasty. It was found that the majority of cases showed good clinical and radiological outcome; however, there were three implant failures that were considered unacceptable. Each of these failures demonstrated metallosis on removal. It was suggested that there was a weakness in the connection between the polyethylene and the soft metal backing, however the reason for failures were not clear.

As such, metallosis related failure in shoulder prostheses has been described in only a few cases, and seems to be linked to porous coating osteo-integration interfaces and in total shoulder replacement arthroplasties only.

Our case draws attention to a potentially different origin for metallosis failure not previously seen in shoulder arthroplasty surgery. On retrieval and analysis of the component we found good bony ingrowth to beaded surfaces with geometrically diverse spicules of bone; however, also noted was metallic stained tissue on the outer edge and circumference of the under surface of the device. Additionally there was fine scratching noted over most of the bearing surface with a small region of unworn area towards the edge of the bearing. Intra-operative tissue samples showed elevated levels of cobalt and chromium consistent with metallosis and similar to other reported metallosis cases, most notably metal-on-metal THR devices. Given the clinically noted metallosis and the fact that the component was uncemented therefore eliminating the potential of third body cement debris, the question was asked whether this DuoFix implant had suffered a similar failure mechanism to those described in literature for the LCS DuoFix knees [see Fig. 6: this is the retrieved prosthesis from the patient in the case report].

Our findings of microscopic scratching together with clinically stained tissue indicate a wear problem. The appearance of a typical shoulder hemiarthroplasty bearing after 5 years is not reported in the literature for comparison however the scratch pattern is similar to that seen in the LCS DuoFix knees. Elevated levels of aluminium were found in the LCS knee failure cases while our aluminium levels were not considered clinically significant. However the scratch pattern is

Fig. 6 – Retrieval prosthesis.

suggestive of particulate debris that is not accounted for by any other source in this case. The cause for clinical failure was examined prior to surgery and progressive wear of the glenoid was believed to be responsible. At the time of surgery the metallosis was evident in the tissue and histology was consistent with this finding. While general conclusions cannot be drawn from a single case, we can certainly ask the question as to whether one can transpose the success of one technology on a particular prosthesis to another.²¹

4. Conclusion

The clinical picture, nature of the scratching wear and in light of an uncemented device it is suggestive that the mechanism of failure was related to the surface coating. While Duofix coatings have demonstrated good integration in the flat tibial components in knee replacements their function in concave surfaces is somewhat less predictable. Metallosis in our shoulder hemiarthroplasty similarly relates to the coating on the under-surface of a concave prosthesis. We present the possibility that the concave geometry of the prosthesis hinders the complete removal of grit blast residue thereby facilitating metallosis.

Conflicts of interest

All authors have none to declare.

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