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ORIGINAL STUDY

Early clinical failure of the ACCIS® metal on metal hip arthroplasty system – A metal on metal hip with a difference

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The ACCIS hip system has been marketed with a unique bearing surface which the manufacturers claim to reduce wear below the level of other MoM bearings and consequently less metal ion release. The cobalt-chrome-molybdenum alloy is heat treated to reduce the number and size of block carbides and the surface is modified with titanium-niobium-nitride to create a ceramic-like surface. We present our experience with ACCIS.

148 surgical procedures were carried out in 126 patients using the ACCIS hip resurfacing (77) or large head MOM total hip replacement(71). Patients were followed up with regular clinical and radiological assessment. In addition, metal ion levels were obtained. There have been 27 revision procedures carried out for a variety of indications with a current revision rate of 18%. Seven failures could not be attributed to the prosthesis itself, still leaving a failure rate of 13.5%. The mean survival time of these is 33 months, ranging from 1 to 72 months. 13 revisions were performed for pain and revision demonstrated poor cup integration. 7 were revised because of high ion levels but this was patient choice despite remaining asymptomatic.

Whilst the testing phases indicated benefits in wear characteristics, this is not apparent in our group. We have demonstrated an unacceptably high revision rate due to unknown causes and have ceased implanting the ACCIS.

Keywords : arthroplasty ; hip ; titanium niobium ; failure ; metal on metal.

INTRODUCTION

In 2012 the ASR resurfacing arthroplasty (DePuy) was withdrawn due to unacceptably high revision rates of 13% (*4*). More recently, Professor Tim Briggs has recommended that all newly developed implants should be CE marked and fulfill essential safety and performance criteria before they are widely marketed (*3*). Pilot studies should be performed in Specialist Centers, the prostheses assessed and if acceptable only then released to the wider health service.. Existing Transparency and careful reporting via National Joint Registries is vital in identifying poorly performing implants. The British Orthopaedic Association and The Medicines and Healthcare products Regulation Agency (MHRA) have joined forces to improve safety further by introducing "Beyond Compliance", a system that achieves maximum safety whilst not just adhering to minimum regulatory requirement (*8*).

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We present our experience with the ACCIS hip arthroplasty system (ImplantCast, Germany). This implant underwent pilot study testing in Morriston Hospital, UK, Nevill Hall Hospital, UK and The Arthro Clinic, Hamburg prior to widespread release. 200 resurfacing hip prosthesis were implanted with blood ion analysis at 3, 6, 12 and 24 months. Metal ion levels were not elevated above MHRA limits in any patient (*1*). Although widely used in 'mainland' Europe the ACCIS is only used in a handful of UK centers. Despite this, no data relating to ACCIS usage has been highlighted by the UK National Joint Registry.

ACCIS is a variation of a metal-on-metal (MoM) hip arthroplasty system which differs from other systems in having a bearing modification which the manufacturers claim reduce surface wear below that of conventional MoM bearings thus reducing metal ion production and thus reducing the risk of implant failure.

The ACCIS hip system is available as a large head metal on metal MoM total hip replacement or as a resurfacing system featuring a hard on hard bearing. The components are manufactured using a high carbon cobalt-chrome-molybdenum alloy. Surface block carbides, thought to be responsible for wear in MoM prosthesis are reduced in number and size by heat treatment after which the surface is polished. This bearing features an additional surface treatment, which is thought to further improve wear characteristics of the bearing surfaces. This surface modification is applied via plasma vacuum deposition (PVD) to the Cobalt-Chrome implant creating a ceramic surface that is made of titanium-niobium nitride. This layer integrates into the underlying alloy at a depth equivalent to 1-2 atoms and creates a hard wearing surface that is resistant to corrosion.

MATERIALS & METHODS

Between 2006 and 2011 148 surgical procedures were carried out in 126 patients using either the ACCIS hip resurfacing (N = 77) or the large head MoM total hip replacement with either Ecofit (ImplantCast) or Corail stems (De Puy) (N = 71). All procedures used the ACCIS acetabular cup and so the bearing surface remained constant. There were 55 male and 71 females, mean age 58 years (Range 50-65 years). This was a single surgeon series all undertaken by the senior author RR. The surgery was carried out through the direct lateral approach to the hip. Clinical and radiographic follow-up was undertaken at 6 weeks, 3 months, 1 year and annually thereafter. In addition, metal ion levels were obtained in all but 13 within the whole study group as part of their routine follow-up at approximately one year and then annually.

RESULTS

Of the 148 primary procedures, 27 joints, (24 patients, 15 female and 9 male) have undergone revision at a mean of 33 months (range 1-72 months) after the index surgery (see Fig. 1 & 2). Revision procedures were carried out for a variety of indications within 3 months (Table I). Of 27 revised cases, 16 were resurfacing type procedures and 11 large head total hip replacements although this paper makes no attempt to consider these as separate groups but rather as one group sharing the same bearing surface and acetabular component. The revision rate in this series is currently 18%.

Serum ion levels were measured in 21 of the 27 revised cases (Fig. 3). Seven of these were revised purely for high metal ion levels above MHRA guidelines (Cobalt > 119 nmols/L or 7 ppb and chromium > 134.5 nmols/L) but were asymptomatic. These patients were revised at a mean of 56 months post index procedure (range 41-72 months), two of whom had levels greater than 3000 nmols/L. This group of seven were advised that high levels alone without persistent elevation were not a direct indication for surgery but requested revision never the less. In the non failure group

Table I

Reason for revision	Number of Cases
Acetabular Capsize	3
Stem subsidence	2
Groin pain & well fixed acetabular cup	2
Groin pain & poorly fixed acetabular cup	11
Femoral component loosening	2
High metal ions	7

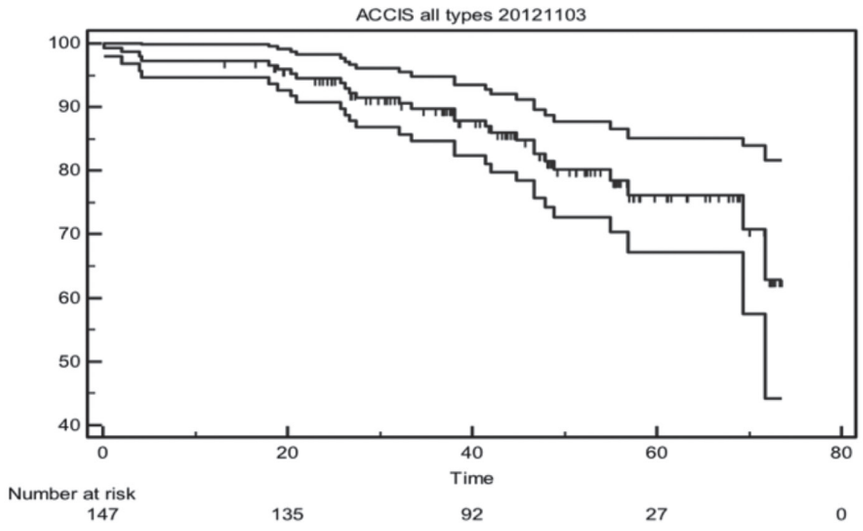

Fig. 1. — Kaplan-Meier survival curve of all cases

(121 joints), 7 patients have not had post operative ion levels checked. Of those that have had blood ion measurements, only 3 had consistently elevated levels above 1000 nmols/L but no further increase and remain asymptomatic . Unfortunately metal artifact reduction sequence MRI (MARS/MRI) scanning is not available to the trust.

Thirteen were revised for groin pain and eleven of these were found to have poor acetabular component integration. Within these two groups complaining of groin pain, two had pain with high ion levels but a seemingly well-integrated cup at revision. The remaining eleven patients with pain had poor cup integration, five of which had elevated ion levels, the remaining six had ion levels within defined acceptable limits. All those with poor cup integration had no clinical evidence of metallosis at the time of revision.

In three patients the acetabular cup completely capsized within the first few post operative days indicating a failure to achieve stable implantation. Immediate post operative films were not obtained in this group for comparison. Two resurfacing patients developed loosening of the femoral component and a further two had stem subsidence. Whilst this group of 7 are included in our failure group, we cannot attribute their demise to the prosthesis itself. With exclusion of these patients the failure rate is 13.5%

Five patients underwent bilateral resurfacing. Three of them underwent bilateral revision procedures due to high metal ion levels. Bilateral resurfacings were responsible for some of the highest ion recordings (> 3000 nmol/L). Of the remaining two, one had a unilateral revision for pain and the other underwent revision for high ion levels which resulted in a substantial lowering of ion levels and retention of the contralateral ACCIS prosthesis.

Head size ranged from 42-50 mm (Av – 44.7) in the failure group and 38-54 mm (Av – 47.5) in the non failure group. Cup abduction angle was measured in 23 of 27 revisions with a mean of 50.6° (range 37°-75°). This was performed on our PACS system using AP pelvis radiographs. In all patients with a cup inclination greater than 50° a significantly elevated metal ion level was noted. Conversely, five patients with angles between 42 and 47 degrees also had significantly elevated ion levels and so no clear correlation was found between cup angle and metal ion levels. All explanted heads showed loss of the gold coloured ceramic coating superficially and equally on the corresponding region of the cup.

No patient reported any symptoms of soft tissue destruction such as dislocation. At the time of revision no evidence of metallosis was documented in the operative notes. This was based on visual assessment and in the literature defined as aseptic

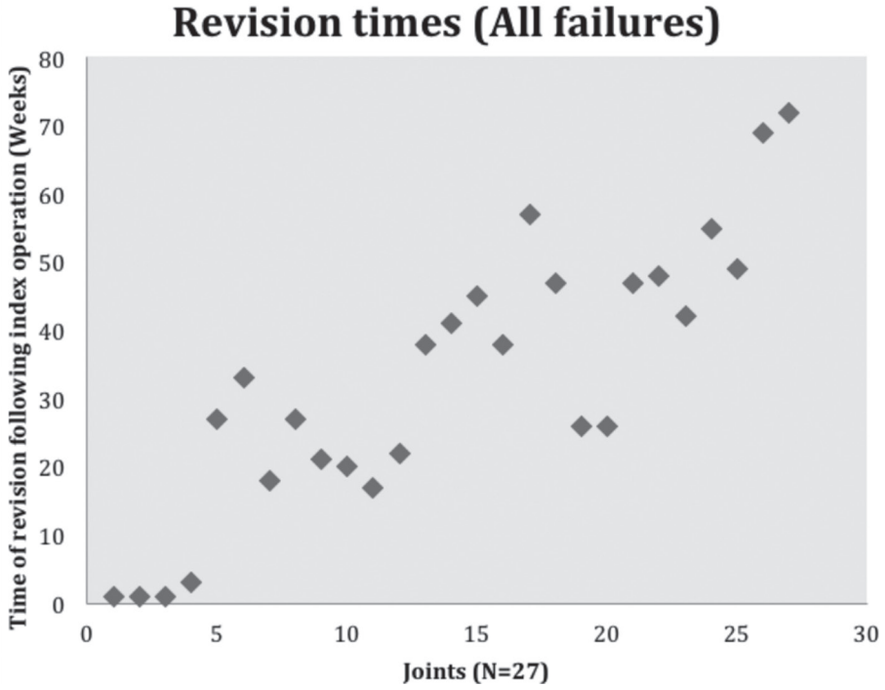

Fig. 2. — Revision times of all failures

fibrosis, local necrosis or loosening of a device secondary to metallic corrosion and release of metallic wear debris (*6,9*). Infection was excluded in all revisions using both pre-operative blood tests (including CRP and ESR) and intra-operative culture samples. In no patient was local pseudotumour formation discovered and documented intra-operatively. Histological testing was not performed.

DISCUSSION

The ACCIS hip replacement system demonstrates an unacceptably high early failure rate. Studies have compared the tribolgical properties of titanium niobium (Ti-Nb) ceramic coated bearings with other recognized surface materials and shown it to be superior in terms of wear (*11*). The coating is very hard, having similar properties to diamond-like coatings. In laboratory-based studies, running-in phase, TiNbN-coated prostheses showed a 6-10 fold reduction of wear compared to MoM articulations with 32 mm femoral head components (*5*). More recently work has shown that Ti–Nb alloys have a high corrosion resistance suggesting that they should be promising materials for biomedical implants (*15*).

Despite these clear advantageous tribological properties and acknowledging the learning curve for a new design, there is a high revision rate amongst our patient population, many of whom have been noted to have abnormally high ion levels. This contrasts with only 3 of the 121 non failure group. The interpretation of metal ion levels is not entirely straight forward and this retrospective study containing many variables does not give us the capacity to make firm conclusions, particularly as we have no histology, tribological evaluation or MARS/MRI.

A "run in period" needs to be taken into account. The significantly elevated ion levels were found at greater than 40 months post surgery, a time when the run in period should be complete but this is assuming that the ACCIS behaves like other MoM articulations. Bowsher *et al* (*2*) suggest that there may be alternatives to the run in phase. The elevated levels in this study may just reflect a variant in wear

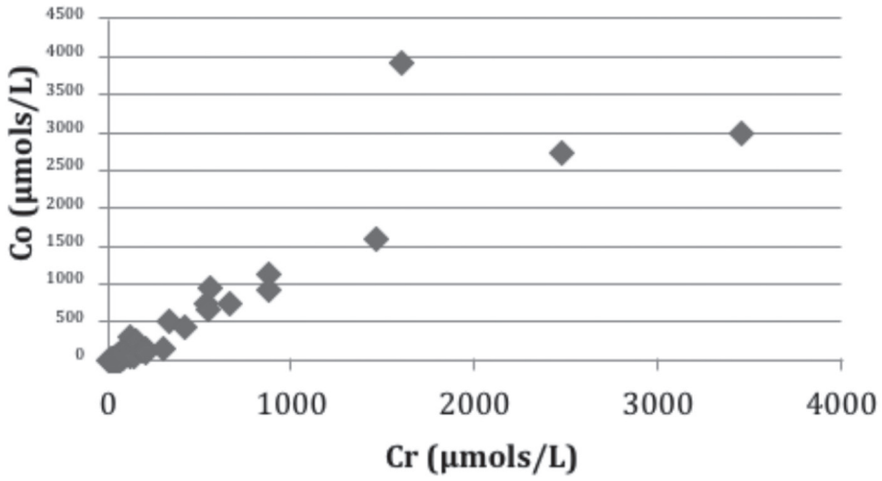

Fig. 3. — Graph showing all cobalt & chromium levels in the failure group

pattern and so further in vitro studies are required. There is fairly consistent opinion that higher levels suggest an increased wear rate (*7*) and can discriminate between poorly functioning and well functioning hip replacements but the exact levels for clinical use remain unclear (*10,13*). If a bedded in state is indeed reached at two years we could suggest that the ACCIS bearing fails to convey any additional benefit against wear. Conversely this study would suggest that it fails to evoke the spectrum of local tissue reactions found with other MoM articulations. Without imaging and histology of all patients, including those who are asymptomatic but may have pseudotumour, we cannot draw any conclusions. Those revised for high ion levels alone were done so at the patients' request and despite the evidence above, we cannot be sure that these hips would have failed had they not been revised. Regular blood evaluation showed their levels to be in ascent however. Excluding this group would of course reduce the failure rate further to 8.8%.

Cup inclination and head size are influential mechanical variables and whilst mentioned in our results, this paper cannot consider these variables as individual factors of failure.

The majority of our revisions were performed because of pain. At the time of revision the acetabular components in 11 of these patients did not appear to have solidly integrated and were relatively easy to remove. The post-operative films of those with poorly integrated acetabular components demonstrated no evidence of cup malpositioning. In other studies the most common problem reported in those reacting adversely to metal debris is also pain. The reaction to the debris causes cup loosening, discovered at revision (*12*).

Whilst 7 of our cases did have elevated metal ion levels at the time of revision, more than half of our series did not and there was no evidence of metallosis. This may suggest that the ACCIS behaves differently to other systems and there may be factors other than an adverse reaction to the bearing surface that could be responsible for its failure.

With this in mind, cup failure due to lack of primary fixation was noted during the design and initial trial of the implant. The original design was spherical and so failure was thought to be caused by the rebound effect (*17*). As a result the cup was produced using a tri-radial design coupled with two equatorial fins. In the spherical design, forces act on the entire back surface of the cup thus pushing it out of the acetabulum. In the modified design there are only equatorial compression forces which hold the cup in position and a ream to fit method is applied. Studies demonstrated further stability optimization by adding two equatorial fins (*16*). Other than this

specific design feature, the cup has a titanium plasma spray surface similar to other cups on the market. Whilst the data is not as long term as fiber mesh screw supplemented cups, survivorship for this on growth surface is 99% at 8-10 year follow up (*14*). This surface preparation therefore rivals other fixation options.

At the time of the prosthesis white paper publication (August 2009), no cup failures had been reported. Overall it is difficult to come to any conclusion as to why the ACCIS cup is not gaining good fixation in some patients with the absence of metallosis. The ACCIS hip continues to be used in Europe.

CONCLUSION

The failure rate in this population is high but the cause is uncertain. This coated prosthesis does not seem to protect against metal ion release but also does not behave as other MOM devices in terms of failure and soft tissue destruction. The results highlighted provide sufficient evidence to be of concern and we have ceased implanting the ACCIS at our institution.

REFERENCES

1. **Bongaerts G , Woodnutt DJ, Rice R , Hamelynck KJ.** Ceramic surface engineering of the articulating surfaces effectively minimizes wear and corrosion of metal-on-metal hip prostheses. *EFORT*, 2010.
2. **Bowsher J, Clarke I, Williams P, Donaldson T.** What is normal wear pattern for metal-on-metal hip bearings ? *J Biomedical Mater Res*. 2009 ; 91 : 297-308.
3. **Briggs TWR.** Getting it right first time – Improving the quality of orthopaedic care within the National Health Service in England. September 2012.
4. **British Orthopaedic Association** : *Withdrawal of DePuy ASR Resurfacing and XL metal on metal bearings – Information for and Advice to Surgeons*.
5. **Comparative wear analysis of metal on metal, metal on polyethylene and ceramic coated on ceramic coated hip implants.** Atomic Energy Authority Plc, Didcot, Oxfordshire, UK.
6. **De Haan R, Campbell PA, Su EP, De Smet KA.** Revision of metal on metal resurfacung arthroplasty of the hip : the influence of malpositioning of the components. *J Bone Joint Surg* 2008 ; 90-B : 1158-63.
7. **De Smet K, De Haan R, Calistri C.** Metal ion measurment as a diagnostic tool to identify problems with metal on metal hip resurfacing. *J Bone and Joint Surg* 2008 ; 90 : 202-208.
8. **Dias J.** Project 'Beyond Compliance' – for the safer introduction of Orthopaedic Implants – Statement by the BOA President.
9. **Doorn PF, Mirra JM, Campbell PA, Amstutz HC.** Tissue reaction to metal on metal total hip prostheses. *Clin Orthop* 1996 ; 329 (suppl) : 187-205.
10. **Hart AJ, Sabah SA, Bandi AS.** Sensitvity and specificity of blood cobalt and chromium metal ions for predicting failure of metal on metal hip replacement. *J Bone and Joint Surg Br* 2011 ; 10 : 1308-1313.
11. **Hennig FF, Von Kroge H, Repenning D.** A comparative study of the characteristics of femoral hip prosthesis heads – study and results ceramic-coated hip joint heads of titanium. *Biomed Tech* 1992 ; 37 : 200-4.
12. **Langdon DJ, Joyce TJ, Jameson SS.** Adverse reation to metal debris following hip resurfacing : The influence of component type, orientation and volumetric wear. *J Bone and Joint Surg Br* 2011 ; 93 : 164-171.
13. **Langton DJ, Sidaginmale RP, Joyce TJ, Natu S, Blain P, Jefferson RD, Rushton S, Nargol AV.** The clinical implications of elevated blood metal ion concentrations in asymptomatic patients with MoM hip resurfacings : a cohort study. *BMJ open* 2013 ; 12 : 3.
14. **Reina R, Rodriguez JA, Rasquinha VJ.** Fixation and osteolysis in plasma sprayed hemisperical cups with htbrid total hip replacement : 5-11 year results. *Annual AAOS meeting*. Washington DC, 2005.
15. **Rossalbino F, Maccio D,Scavino G, Saccone A.** In vitro corrosion behaviour of Ti-Nb-Sn shape memory alloys in Ringer's physiological solution**.** *J Mater Sci Mater Med* 2012 ; 23 : 865-71.
16. **Sellenschloh K, Morlock MM.** Comparative study of the primary stability of various acetabular cup designs. Technical University of Hamburg, Germany, 2002 on file.
17. **Spiers IR, Morlock MM, Pfeiderer M, Schneider E, Hille E.** The influence of friction an interference on the seating of a hemispherical press-fit cup : A finite element investigation. *J Biomech* 1999 ; 32 : 1183-1189.