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Article · August 2016

DOI: 10.1016/j.arth.2016.07.020

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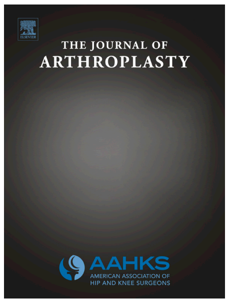
Accepted Manuscript



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PII: S0883-5403(16)30442-9

DOI: 10.1016/j.arth.2016.07.020

Reference: YARTH 55319

To appear in: *The Journal of Arthroplasty*

Received Date: 12 August 2015

Revised Date: 27 June 2016

Accepted Date: 21 July 2016

Please cite this article as: Whittaker RK, Zaghloul A, Hothi HS, Siddiqui IA, Skinner JA, Hart AJ, Clinical Cold-Welding of the Modular Total Hip Arthroplasty Prosthesis, *The Journal of Arthroplasty* (2016), doi: 10.1016/j.arth.2016.07.020.

TITLE PAGE

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Abstract

Background - A head that is 'clinically cold-welded' to a stem is one of the commonest reasons for unplanned removal of the stem. It is not clear which hip designs are at greatest risk of clinical cold-welding.

Methods – This was a case–control study of consecutively received hip implant retrievals**;** we chose the design of hip that had the greatest number of truly cold-welded heads (n=11). For our controls we chose retrieved hips of the same design but without cold-welding of the head (n=35). We compared the clinical variables between these two groups using nonparametric Mann-Whitney tests to investigate the significance of differences between the cold-welded and non-cold-welded groups.

Results - The design that most commonly caused cold-welding was a combination of a Ti stem and Ti taper: 11 out of 48 (23%) were truly cold-welded. Comparison of the clinical data showed no individual factor could be used to predict this preoperatively with none of the 4 predictors tested showing any significance: (1) time to revision ($p = 0.687$), (2) head size ($p = 0.067$), (3) patient age at primary ($p = 0.380$), (4) gender ($p = 0.054$).

Conclusion - We have shown that clinical cold-welding is most prevalent in Ti-Ti combinations of the stem and taper; approximately 25% of cases received at our centre were cold-welded. Analysis of clinical variables showed that it is not possible to predict which will be cold-welded preoperatively. Surgeons should be aware of this potential complication when revising a Ti-Ti stem/head junction.

Introduction

Modular hip replacement systems are commonly used during primary total hip replacement (THR) surgery, with approximately 70,000 modular hips implanted annually in the United Kingdom [1]. The additional interface found between the head and neck or the stem and sleeve adaptor allows for variable reconstruction of the implant. During primary surgery, this affords the surgeon greater flexibility to adjust the femoral head size, offset and leg length [2-4]. Furthermore, the ability to retain a well fixed femoral stem simplifies revision surgery as only the head in this instance would require exchange [5]. The head-neck interface however has also been shown to be subject to corrosive processes and fretting that can lead to premature implant failure [6].

When the modular hip cannot be separated during revision surgery, this is referred to as 'clinical cold-welding'. As a consequence, the inseparable implant must be removed, often requiring specialised instruments, osteotomy and a new stem with diaphyseal fixation. Alternatively, the femoral head may be sectioned to remove it from the stem trunnion however this approach has a limited margin for error. With a large at-risk population, surgeons should be aware of the possibility of a clinically cold welded head when planning revision surgery, to ensure the appropriate equipment is available for the procedure.

Several retrieval studies have reported this phenomenon in the literature [7-11] however no study has directly investigated the extent to which cold welding is prevalent within the population or the risk factors which may lead to the formation of this inseparable interface. Our aim was to investigate the factors that influence the formation of a clinical cold weld, to better understand its clinical significance and guide surgeons during revision surgery.

To achieve this, we defined the following objectives: (1) determine the effectiveness of current intraoperative equipment at separating the head from the stem, (2) determine the force required to mechanically disassemble the head from the stem in cases that could not be separated using intraoperative equipment, (3) correlate the difficulty of head-neck separation with clinical and implant factors using a control group of non- cold welded hips to ascertain if the presence of a clinical cold weld can be predicted preoperatively.

Patients and Methods

This was a retrieval study of a consecutive series of implants at our tertiary retrieval centre. Figure 1 provides a summary of the study design.

Demographics (Table 1)

Between 2007-2015, a total of 600 metal-on-metal (MOM) failed total hip replacement (THR) prostheses were received at our centre. These consisted of 440 THR bearing couples that were received without a femoral stem and 180 bearing couples with a femoral stem. Of the 180 received with a femoral stem, 27 had the femoral head retained on the femoral stem such that the implant appeared to be clinically cold-welded (CCW).

The 27 bearings that appeared to be CCW consisted of Biomet M2a-Magnum (Warsaw, Indiana) paired with a Taperloc or Bi-Metric femoral stem (n=13), Pinnacle (DePuy, Warsaw, Indiana) paired with a Corail (n=2), ASR (DePuy, Warsaw, Indiana) paired with a Corail (n=4) Mitch Exeter (Kalamazoo, Michigan, United States) (n=2).

The Biomet M2a-Mangnum are such that the stems (Taperloc and Bi-Metric) and the taper sleeve are both Ti with CoCr bearings; all other head-stem junctions had a cobalt-chromium-titanium (CoCr-Ti) or cobalt-chromium-stainless steel (CoCr-SS) material combination with either monoblock CoCr head or a CoCr head with a CoCr taper sleeve (Table 2).

These implants were retrieved from 13 male and 14 female patients with a median age of 58 years (48-78) and a median time to revision of 53 months (25-131). The median head size of the implants was 46mm (28-58).

Disassembly Test: Head-neck separator

We obtained 5 commercially available femoral head-neck separators that are commonly used at our institution intraoperatively to attempt disassembly of the head-neck junction; these were manufactured by JRI, Stryker, Biomet and Smith & Nephew. Each implant that we suspected as being clinically cold welded was individually secured to a laboratory bench with a clamp. Disassembly of the head from the stem was then attempted by two experienced orthopaedic surgeons using the 5 head-neck separators; both surgeons were informed to limit the force applied to the separators to that which they would expect to apply intraoperatively. In this study we considered an implant to be truly clinically cold welded if the head-neck junction could not be separated by any of the 5 devices. The JRI head-neck separator is shown in figure 2.

Disassembly Test: Mechanical testing system

For this test we used the Ti-Ti pairing of the Biomet M2a-Magnum with the Biomet Type 1 Taper; this combination was discovered to have the highest prevalence of cold welding from our head-neck separator tests. We then selected a single implant at random that was found to be clinically inseparable and performed a mechanical disassembly test using a Proline (Zwick Roell) testing machine To secure the implant for the test, we clamped the femoral head to the base of the machine and fixed the shaft of the stem to the opposing end of the machine using polymethylmethacrylate (PMMA) bone cement. A controlled tensile test at a speed of 1mm/min was performed to determine the force at which disassembly would occur; the test was to be ended if separation of head and stem occurred or if the limit of the testing device (5000 Newtons) was reached.

Corrosion Surface Assessment

We obtained informed consent to section a cold-welded Biomet M2a-Magnum/Taperloc hip along the Ti sleeve adapter in order to reveal the engaged surfaces of the taper and trunnion. A single examiner experienced in retrieval analysis used macroscopic and light microscopy to determine the severity of corrosion of both engaging surfaces using the scoring system (scale 1 to 4) developed by Goldberg and colleagues [12]. Using the same criteria, we also corrosion scored the head and trunnion of the implants that were successfully disengaged by the head-neck separators.

Selection of Control Group

To ascertain if any factor could be used to determine if cold welding had taken place pre-operatively we chose the design of hip that had the greatest number of truly cold welded heads (Biomet M2a-Magnum, n=11). We then chose retrieved hips of the same design that had not cold welded (n=35). We used a non-parametric Mann-Whitney tests to investigate the significance of differences between the cold welded and non cold welded groups in relation to (1) time to revision, (2) head size, (3) patient age at primary surgery, and (4) gender.

Results

Of the 600 failed THRs received at our centre, 4.50% were received with the femoral head retained on the femoral stem such that the implant appeared to be clinically cold-welded.

Disassembly Test: Head-neck separator

We found that the head could be separated from the stem using the head-neck separators in 11 cases (Table 3); this revealed that 16 implants received at our centre were truly clinically cold-welded. These were the M2a-Magnum/Type 1 Taper (n=11), ASR XL/Corail (n=2), Cormet/Zweymuller (n=2) and Mitch/Exeter (n=1) (Table 4).

We noted that the JRI model head-neck separator removed the head most frequently when the four others had failed. This model successfully separated 10 of the 11 that we managed to disengage.

We noted that the Ti-Ti M2a-Magnum/Type 1 Taper had the highest prevalence of clinically cold welding of the implants that we received at our centre. This implant design was used for our mechanical disassembly test.

Disassembly Test: Mechanical testing system

Figure 3 represents the stress-strain graph produced from our disassembly test. We found that the M2a-Magnum/Taperloc Ti-Ti taper junction could not be separated even after reaching the maximum separation force of 5000 Newtons of the testing system.

Corrosion Surface Assessment

Examination of the engaged surfaces following sectioning of the taper adapter revealed evidence of severe corrosion on both the head taper and stem trunnion; these were graded as 4 according to Goldberg's classification system. The length of engagement of the two surfaces was measured as 18mm.

Figure 4 shows in detail the Ti corrosion of the M2A-Magnum sleeve and stem trunnion. The original surface of both the taper sleeve and the trunnion have corroded to deviate from the 'as manufactured' profile.

All heads and trunnions that could be disengaged with the head-neck separator showed evidence of mild to severe corrosion. The heads had a median corrosion score of 4 (2-4) and the trunnions had a median corrosion score of 3 (2-4).

Comparison of cases and controls

The design that most commonly caused cold welding was a combination of a Ti stem and Ti taper: 11 out of 48 Ti-Ti interfaces received at the retrieval centre between 2007-2015 (23%) were truly cold welded after use of 5 head/stem separators. Comparison of the clinical data from the cold welded group to the non cold-welded group with Ti-Ti interfaces showed no individual factor could be used to predict this preoperatively as none of the 4 predictors tested showed any significance (1) time to revision ($p = 0.687$), (2) head size ($p = 0.067$), (3) patient age at primary ($p = 0.380$), (4) gender ($p = 0.054$) (*Table 5)*.

Discussion

We have presented evidence of clinical cold welding of retrieved THRs received at our centre in which the femoral head was inseparable from the femoral stem intraoperatively. We report a prevalence of 4.5% at our centre.

There is little clinical or retrieval evidence to indicate the scale of the problem of cold welding of the head and stem. Mokka et al. reported 2 cases in which a Biomet M2a-Magnum head could not be detached from its corresponding stem (Ti-Ti junction); this was attributed to extensive corrosion at the engaging interface [11]. Furthermore, two Australian studies found 22% and 27% of cases were clinically cold welded. The figure we reported is likely to underestimate the true population prevalence due to inherent collection bias however we used a broad inclusion criteria to minimise this effect.

A number of studies have reported evidence of CCW of the titanium modular neck and stem [7-9] in which all the retrieved components showed signs of severe fretting-corrosion. Kop et al. demonstrated that severe corrosion can occur at the modular junctions of THRs regardless of the material of stem and taper, however noted that cold welding only occurred in titanium based junctions [9].

We attempted disassembly of the components in our laboratory to ascertain the number of truly inseparable implants using all current intraoperative equipment. After the use of the 5 commercially available head-neck separators, we discovered that 16 implants could still not be separated. Therefore, of the implants that appeared clinically cold welded at retrieval, approximately 40% were able to be separated using the correct equipment. We found the JRI separator was superior as this model was able to successfully remove the head when the 4 others had failed.

The most frequent cold-welded design was that of the Biomet M2a-Magnum head and Type 1 Taper stems; this was the only design with a Ti-Ti taper junction. Further testing of this implant design using our mechanical disassembly machine was also unable to separate the head from the stem, despite reaching a maximum separation force. Clinical cold-welding is therefore most prevalent in Ti-Ti combinations of this stem and taper in our study, with approximately 25% of cases cold-welded.

A Ti-Ti junction is an indicator that a clinical cold-weld maybe present at revision surgery. The mechanism that facilitates the Ti-Ti junctions becoming cold welded appears to be caused by the corrosion of the Ti causing the material in the junction to decrease in density and therefore increase in volume preventing it from becoming disengaged due to an increase in the sheer force needed to overcome the friction as shown in figure 4. A reason this may not be seen in CoCr-Ti head-stem combinations is that the corrosive processes that take place with these material combinations includes galvanic corrosion, with the CoCr head corroding preferentially to the Ti stem due to the more stable oxide film on the Ti when paired with CoCr. This mechanism has been shown in a number of retrieval studies and is exemplified by the imprinting of the Ti stems machined groves on the head taper [6, 13-17].

We correlated the difficulty of head-neck separation with clinical and implant factors using a control group of non cold-welded hips to ascertain if cold-welding could be predicted preoperatively. Analysis of these clinical variables showed that it is currently not possible to predict which implants will be cold welded preoperatively using these factors alone with an example of this shown in figure 5, however, we were unable to assess the power needed so the lack of a relationship may be due to the numbers used in the study. A larger data set may show one of these variables to be significant in the future.

Surgeons should be aware of the potential risk of a cold welded implant prior to revision surgery. The presence of a cold weld can significantly increase operation time and may increase patient morbidity as often, a more complicated procedure is required. With all the correct equipment available, at least one hour of operation time is added for the trochanteric osteotomy with cables +/- plating and the use of a more complicated femoral stem [18]. If the equipment is unavailable then the procedure can take multiple extra hours or the surgery must be abandoned, as has happened in our experience. This, furthermore, may increase the length of in-patient stay or recovery time and the risk of future complications in patients [19]

In our study, although surgeons were instructed to apply a force no greater than that used during surgery while testing the head neck separates, we acknowledge that our investigation may not fully simulate the intraoperative environment. Furthermore, a large multicentre analysis of cold welding is required to reveal whether patient factors can be used to predict the formation of a cold-weld. It was only possible to section one implant and we can therefore only have extrapolated that all similar inseparable implants have undergone a similar processes of corrosion.

Our study was the first to directly investigate prevalence and risk factors of clinical cold-welding within the population. Clinical cold welding was found in 4.5% of retrieval implants. Using the appropriate equipment, we found that cold welding was truly present in 2.7% of cases at our UK retrieval centre. The potential risk of a cold weld at revision surgery can be established using the implant design, interface materials and this problem can be partially solved with the use of appropriate equipment. The Biomet/Type 1 Taper design and the Ti-Ti interface material showed the greatest number of true clinical cold-welds and these were most likely as a result of corrosion at this interface. Currently, no patient or surgical factors can be used to predict clinical cold-welding. We found the JRI model separator to be superior at separating apparently cold welded implants. To minimise the risk to the patient and manage resources appropriately, we encourage surgeons to consider these factors when planning revision surgery.

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Acknowledgements

We are grateful for the support of Gwynneth Lloyd, and Elizabeth Ellis for their coordination of the retrieval centre. Two authors received funding from the British Orthopaedic Association through an industry consortium of nine manufacturers: DePuy International Ltd (Leeds, UK), Zimmer GmbH (Winterthur, Switzerland), Smith & Nephew UK Ltd (Warwick, UK), Biomet UK Ltd (Bridgend, South Wales, UK), JRI Ltd (London, UK), Finsbury Orthopaedics Ltd (Leatherhead, UK), Corin Group PLC (Cirencester, UK), Mathys Orthopaedics Ltd (Alton, UK), and Stryker UK Ltd (Newbury, UK).

Table 1 – Demographic, Metal Ion Concentrations, Reason for Revision and Implant Information

	Number	Medians	Range
Gender (male:female) Age at primary surgery (years) Time to revision (months) Femoral head diameter (mm) Whole blood cobalt (ppb) Whole blood chromium (ppb)			12:15 50-78 25-131 28-58 0.60-97.53 0.71-60.53
Bearing design Biomet Magnum **Stem Design** Biomet – Taperloc Biomet – Bi-Metric	 13 11 2		
Bearing design ASR **Stem Design** Corial	 4 4		
Bearing design Pinnacle **Stem Design** Corial S-ROM	 2 1 1		
Bearing design Cormet **Stem Design** Zweymuller	 5 5		
Bearing design Mitch **Stem Design** Exeter	 2 2		
Bearing design Metasul **Stem Design** Sulzer Allo Pro	 1 1		
Reason for Revision Unexplained Pain Aseptic Loosening (Femoral) Aseptic Loosening (Acetabular) Fracture Osteolysis Gluteal Atrophy	 12 10 1 2 1 1		

Table 2 – Implant Design and Material Combinations

Bearing Design	Head Material	Taper Sleeve Y/N	Taper Sleeve Material	Stem Material	Number
Biomet M2a-Magnum	CoCr	Y	Ti	Ti	13
ASR	CoCr	Y	CoCr	Ti	4
Pinnacle	CoCr	N	N/A	Ti	2
Cormet	CoCr	N	N/A	Ti	5
Mitch	CoCr	N	N/A	SS	2
Metasul	CoCr	N	N/A	SS	1

Table 3 – Demographic, Metal Ion Concentrations, Reason for Revision and Implant Information for Components that were Successfully Separated after Disassembly Test

	Number	Medians	Range
Gender (male:female)			7:4
Age at primary surgery (years)		55	50-73
Time to revision (months)		49.5	25-96
Femoral head diameter (mm)		44	28-56
Whole blood cobalt (ppb)		6.9	0.60-20.41
Whole blood chromium (ppb)		3.38	1.20-60.53
Bearing design			
Biomet M2A-Magnum	2		
Stem Design			
Biomet – Taperloc	2		
Bearing design			
ASR	2		
Stem Design			
Corial	2		
Bearing design			
Cormet	3		
Stem Design			
Zweymuller	3		
Bearing design			
Pinnacle	2		
Stem Design			
Corial	1		
S-ROM	1		
Bearing design			
Mitch	1		
Stem Design			
Exeter	1		
Bearing design			
Metasul	1		
Stem Design			
Sulzer Allo Pro	1		
Reason for Revision			
Aseptic Loosening (Femoral)	8		
Fracture	1		
Unexplained Pain	1		
Gluteal Atrophy	1		

Table 4 – Demographic, Metal Ion Concentrations, Reason for Revision and Implant Information for Components that were CCW after Disassembly Test

	Number	Medians	Range
Gender (male:female)			5:11
Age at primary surgery (years)		62.5	51-78
Time to revision (months)		62	29-131
Femoral head diameter (mm)		46	42-58
Whole blood cobalt (ppb)		7	1.07-97.53
Whole blood chromium (ppb)		10.19	0.71-31.46
Bearing design			
Biomet Magnum	11		
Stem Design			
Biomet – Taperloc	9		
Biomet – Bi-Metric	2		
Bearing design			
ASR	2		
Stem Design			
Corial	2		
Bearing design			
Cormet	2		
Stem Design			
Zweymuller	2		
Bearing design			
Mitch	1		
Stem Design			
Exeter	1		
Reason for Revision			
Unexplained Pain	11		
Aseptic Loosening (Femoral)	2		
Aseptic Loosening (Acetabular)	1		
Calcar Lysis	1		
Osteolysis	1		

Table 5 – Demographic, Metal Ion Concentrations, Reason for Revision and Implant Information for the group of retrieved implants that arrived with femoral head still attached to stem

Cold-Welded	Yes	No	p-value
Taper Type	Type 1	Type 1	-
Head Taper Material	Ti	Ti	-
Stem Trunnion Material	Ti	Ti	-
Gender (Male : Female)	3:8	12:23	p = 0.054
Head Size (mm)	48 (44-58)	46 (36-58)	p = 0.067
Age at Primary Surgery (years)	64.5 (50-78)	59 (40-82)	p = 0.380
Time to Revision (months)	53.5 (28-95)	49 (12-149)	p = 0.687
Whole Blood Cobalt (ppb)	8.16 (0.6-97.53)	4.23 (0.6-212.4)	-
Whole Blood Chromium (ppb)	8.26 (0.71-31.46)	3.76 (0.71-96.7)	-
Reason for Revision			
Unexplained Pain	8	22	
Femoral Loosening	1	2	
Acetabular Loosening	1	4	
Osteolysis	1	1	
Impingement	0	3	
ARMD	0	2	
Acetabular Fracture	0	1	

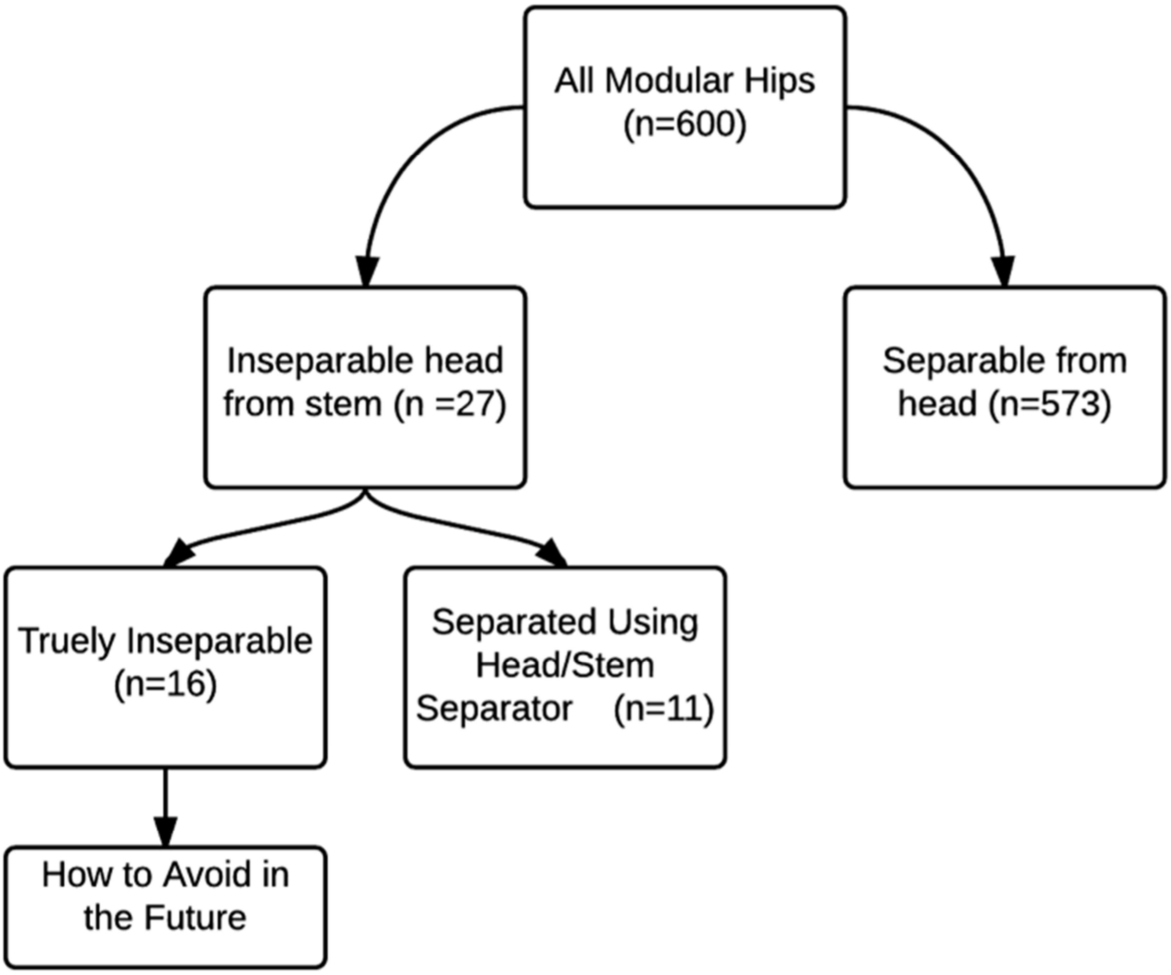
Figure 1: Study design

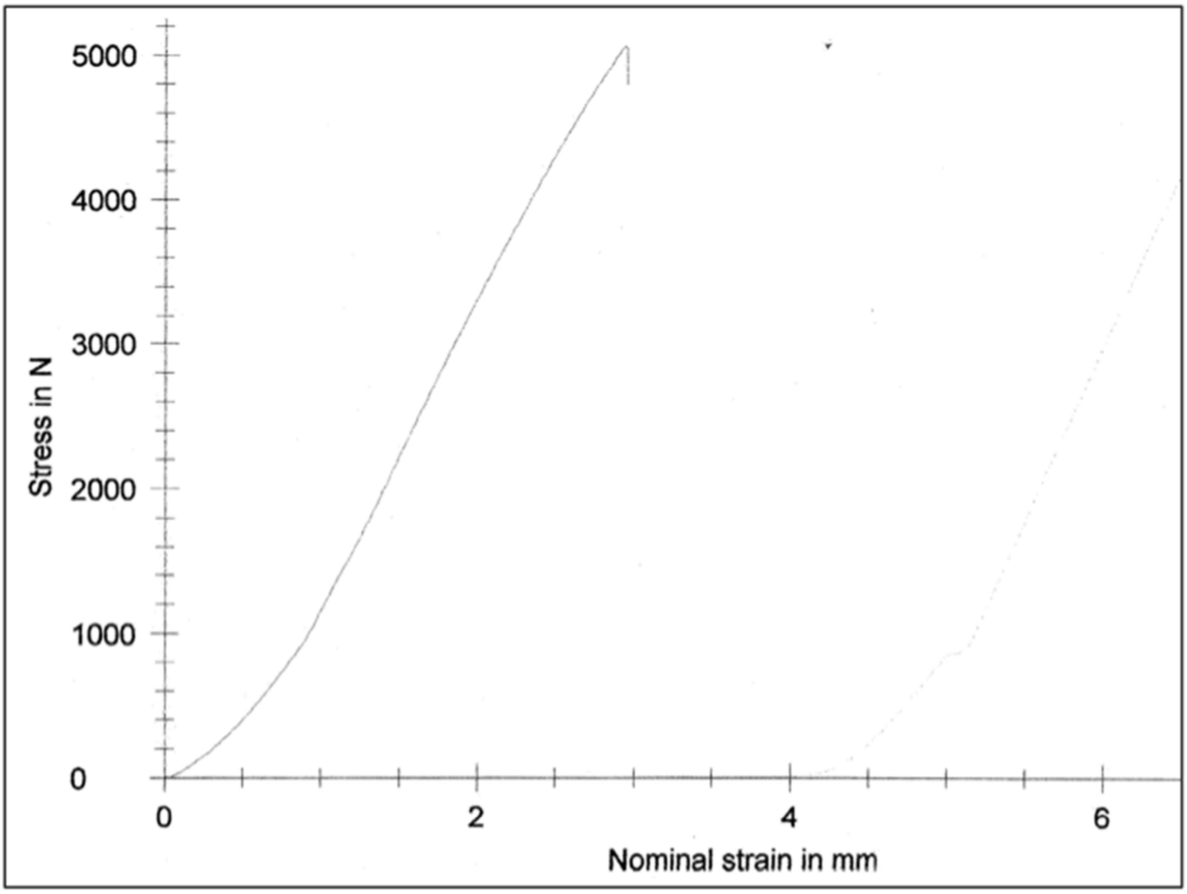
Figure 2: Image of the JRI head/neck separator

Figure 3: Graph showing the stress/strain during the mechanical disassembly test

Figure 4: (a) Photograph showing sectioned Biomet M2a-Magnum titanium taper sleeve with trunnion still engaged after CCW with red box highlighting the corrosion at the interface (b) microscopic image (x30) showing the corrosion products in the interface

Figure 5: (a) Pre-revision plain radiograph showed a well-fixed stem, (b) the retrieved implant (Ti stem trunnion and Ti taper sleeve) were inseparable / "truly clinically cold-welded" after use of 5 types of head-neck separators, (c) Ti stem trunnion and Ti taper sleeve junction, (d) evidence of corrosion at this junction, (e) sectioned cold welded head showing corrosive debris on the taper and trunnion


All Modular Hips (n=600)
Inseparable head from stem (n =27)
Separable from head (n=573)
Truely Inseparable (n=16)
Separated Using Head/Stem Separator (n=11)
How to Avoid in the Future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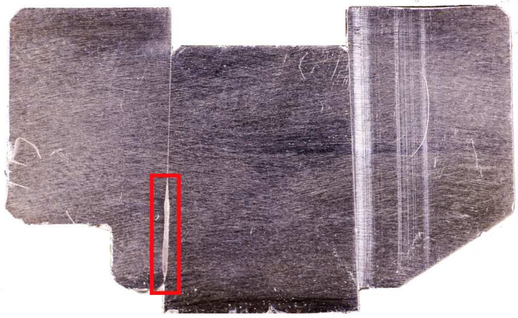

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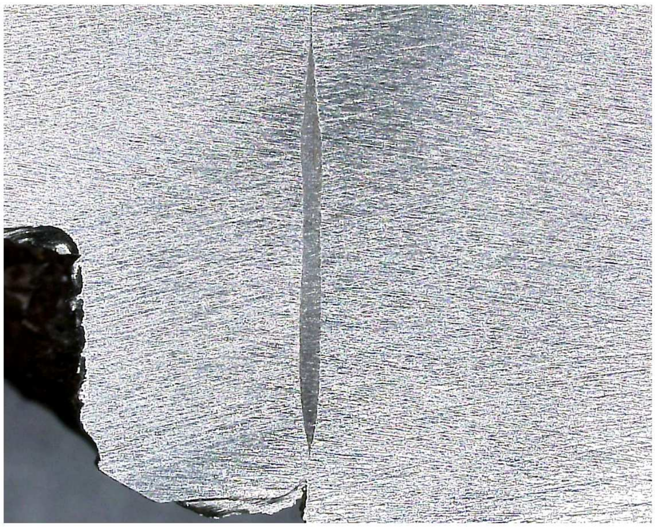

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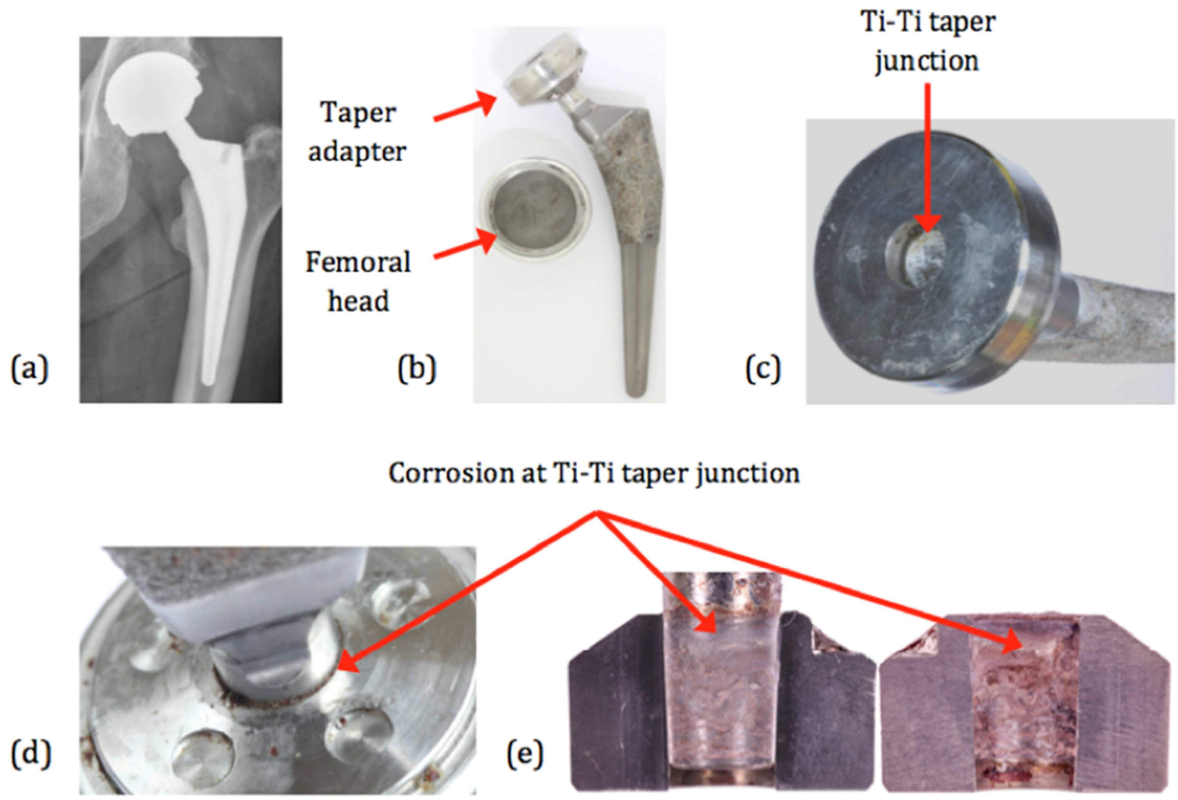

Taper
adapter
Femoral
head
Ti-Ti taper
junction
(a)
(b)
(c)
Corrosion at Ti-Ti taper junction
(d)
(e)