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CLINICAL/SURGICAL

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# The iDuo Bi-compartmental Knee Replacement: Our Early Experience

Jemmett P<sup>1</sup>, Roy S<sup>1</sup>

### Abstract

We present the first UK single surgeon case series for the iDuo knee. This is a CT based custom fit monolithic bi-compartmental design that resurfaces both trochlea and condyle. Perceived benefits include maintenance of normal kinematics and preservation of bone stock on the unaffected side. The femoral component is tailored to the patient with no compromise of either the trochlea or femoral geometry.

*Method:* Patients were selected based on functional ability and physiological age who had an intact symptom free lateral compartment. Knee Society scoring (KSS) was performed pre-operatively and at regular intervals. Patients were asked whether they would undergo the same operation at the one-year mark.

**Results:** Seven patients have undergone this procedure from 2013 until present. Average age is 60 (Range 55- 82). Average pre-op KSS was 108. All patients consistently scored higher at each interval follow up with excellent results at one year (Av KSS 194). This benefit was seen past two years in all but one in those reaching this point.

*Conclusion:* Our early results suggest that the iDuo knee is a good option for those with isolated bicompartmental disease and outcome scores are comparable with those reported for the BKA. This bicompartmental design may bridge the gap between the uni-compartmental and total knee replacement. The choice between monolithic or modular designs remains in debate. We will continue to use this prosthesis for a carefully selected group of patients.

*Keywords*: knee; arthroplasty; bi-compartmental; monolithic *Level of Evidence*: AAOS Therapeutic Level IV

### Introduction

Even today, it is not uncommon for patients with isolated compartmental wear to be treated with total knee replacement. Whilst an acceptable result is obtained in many cases, it seems unnecessary to sacrifice healthy bone stock and the anterior cruciate ligament when all three compartments are not affected. There has been a resurgence in the use of uni-compartmental replacement granting a select

- 1 Dr Peter Jemmett, Dr Stuart Roy Royal Glamorgan Hospital, Cwm Taf University Health Board, United Kingdom (Direct reprint requests to Peter Jemmett)
- © 2016 Jemmett, Roy. All rights reserved.

Reconstructive Review is a peer-reviewed, open-access orthopaedic journal devoted to publishing papers in the area of reconstructive arthroplasty. Authors retain copyright and grant the journal right of first publication with the work. Reconstructive Review follows the <u>Creative Commons</u> <u>Attribution-NonCommercial CC BY-NC</u>. This license allows anyone to download works, build upon the material, and share them with others for non-commercial purposes as long as they credit the senior author, Reconstructive Review, and the Joint Implant Surgery & Research Foundation (JISRF). group of patients a better chance of returning to normal functional activity and low impact sports [1,2]. Unfortunately, medial compartmental structural cartilage damage will often progress to the patella-femoral joint [3] and given the strict criteria in most centers, UKA for these younger patients with some additional patella-femoral involvement may not be appropriate [4].

The use of bi-compartmental knee arthroplasty (BKA) to address this problem is in its infancy. Data for these is sparse and reports are mixed. Parratte et al [5] retrospectively analyzed a patient group who had undergone patella-femoral and unit-condylar arthroplasty in combination. Functional scores at a mean of 12 years were encouraging but implant survival was 54% at 17 years. Recent short term results using combinations of commonly used implants are promising [6,7,8] and yet studies exist to suggest no benefit of bi-compartmental arthroplasty over total knee replacement when considering functional outcome [9].

The Journey-Deuce bi-compartmental prosthesis (Smith & Nephew, Memphis, Tenn) was introduced in 2005. This employed a single femoral component (monolithic), which resurfaced the medial femoral condyle and trochlea groove. Unfortunately tibial plate loosening and inconsistent pain relief led to its withdrawal [10,11].

More recently, ConforMIS (Bedford, MA) has developed the iDuo monolithic partial knee replacement for bicompartmental disease affecting the medial or lateral tibio-femoral and patella-femoral joints. This system seen radiologically and graphically in Figure 1, employs single use jig instrumentation customized for each patient following pre-operative CT scanning. Again the femoral component resurfaces both the condyle and trochlea groove. The perceived benefits, as with the Journey-Deuce knee include maintenance of normal kinematics, preservation of bone stock on the unaffected side and preservation of both cruciates. Unlike the Deuce knee however, the femoral component is tailored to each patient with no compromise of either the trochlea or femoral geometry. In addition, operating room efficiency may be improved with pre-sterilized disposable instruments and a single reusable instrument tray.

This study is the first short term outcome study for the iDuo knee and aims to investigate whether we now have a viable monolithic option to bridge the gap between unicompartmental and total knee replacement (TKR).

### Method

Patients were listed for this procedure provided that they had established medial and patella-femoral compartment osteoarthritis with an intact lateral compartment. Examination and plain films in tandem were employed to make this decision. Whilst age was not used as an absolute exclusion factor we felt it important that patients should lead an active lifestyle without significant co-morbidity. Patients then underwent mapping CT scanning within 3 months of the procedure. Patient specific jigs and prostheses were manufactured accordingly. A final decision to perform bi-compartmental resurfacing rather than total replacement was made at the time of surgery with full evaluation of all compartments via a midvastus approach. All patients that were scheduled for bi-compartmental surgery were implanted with the iDuo; there were no patients who were converted at time of surgery.

All patients underwent Knee Society Scoring (KSS) on the day of surgery and at 6 weeks, 3 months, 6 months, 1 year and annually from then on where possible. This system scores the knee itself and the overall function of the patient. A Knee or function score of 80-100 can be classified as excellent, 70-79 as good, 60-69 as fair and below 60 as poor. At one year, patients were asked whether they would be prepared to undergo the same procedure again.



Figure 1: Post op and graphic images of the iDuo knee replacement



Seven patients underwent bi-compartmental knee replacement using the iDuo system between 2013 and present time. The senior author performed all procedures. Average patient age was 60 (range 49-82) three of whom were female and four male. All but one patient have passed the one year follow up period, four have passed the two year stage and one has thus far been seen as an out-patient for over three years. Only

Pt.	Age	BMI	ASA	Date of surgery	Pre-op KS	6 week KS	3 month KS	6 month KS	1year KS	2 year KS	3year KS
1	58	28.2	2	12/02/14	40	50	80	79	81	47	
2	57	23.5	1	19/11/14	48	48	90	90	97		
3	82	25.3	2	12/02/04	65	85	N/A	87	86	92	
4	57	29.3	2	03/12/14	37	85	92	85	95		95
5	61	26.9	2	30/07/14	74	80	N/A	87	98	95	
6	55	23.9	1	26/08/15	60	N/A	81	91			
7	49	26.2	1	04/12/13	75	N/A	94	N/A	97	100	

### Table 1a: Interval knee scores (KS)

Table 1b: Interval function scores (FS)

Pt.	Age	BMI	ASA	Date of surgery	Pre-op FS	6 week FS	3 month FS	6 month FS	1 year FS	2 year FS	3year FS
1	58	28.2	2	12/02/14	25	40	90	80	80	50	
2	57	23.5	1	19/11/14	50	70	90	95	100		
3	82	25.3	2	12/02/04	40	50	N/A	70	100	70	
4	57	29.3	2	03/12/14	50	60	80	70	100		100
5	61	26.9	2	30/07/14	60	60	N/A	100	100	100	
6	55	23.9	1	26/08/15	60	N/A	80	100			
7	49	26.2	1	04/12/13	70	N/A	80	N/A	100	100	



### Figure 2: Average Knee & Function Scores

one patient is retired. The remaining patients continue to work, three working in a clinical setting for the NHS. They all lead active lives, as reflected in part by body mass index (BMI) and American Society of Anesthesiologists scoring (ASA) shown in Table 1a&b.

Scoring was not completed in two patients at 6 weeks, two patients at 3 months and in one patient at 6 months. Other than these omissions, the data set is complete (Table 1a & b). The average pre-operative KSS was 108 (knee score 57/function score 51). These scores increased to reach excellent results above 80 in all cases (Table 1a/b & Figure 2). Where follow up was chronologically possible, we see that this outcome is maintained with the exception of one.

Patient 1 returned to theatre at 6 weeks for manipulation as her range of movement progression was deemed poor. She progressed well following this intervention and her scoring was excellent at 1 year. More recently she has developed increasing pain and stiffness as depicted in the Table 1 figures. Despite normal radiographs she is now under investigation for infection but as yet nothing abnormal has been found and she continues to work full time in the outpatients department.

These particular scores have lead to the 2 year dip in Figure 2. Patient 3 has noticed a decline in function during the last year but attributes this to an arthritic contralateral knee. Other than patient 1, all remaining patients would be willing to undergo the same operation again.

Interestingly, despite excellent outcomes even at 3 months, several patients subjectively felt that it took at least a year to start feeling satisfied with their recovery. Patient 4 previously underwent a unicondylar knee replacement in his contralateral knee. He feels that recovery with

this particular knee was much quicker although long-term outcome has been subjectively similar to that of his iDuo knee. Morning stiffness/aching has been noted in most patients but only lasts a few steps. Knee scores have thus persistently failed to reach 100.

### Discussion

Amongst those undergoing TKR, it has been shown that 28% have a preserved lateral tibio-femoral joint [12]. The idea to replace only two compartments is attractive but by no means new [13,5]. Despite this, progression seems slow

and evidence to support this concept is sparse. What is certain is that the arthroplasty cohort is becoming younger and has both higher functional demands and an increased chance of revision at a later date. Bone preservation and near normal joint kinematics should therefor be a priority.

The literature suggests relatively normal kinematics can be achieved by preserving both cruciates. PCL retention alone may lead to inconsistent femoral rollback [14] and paradoxical anterior translation in TKR during deep flexion [15]. In vivo bi-unicondylar knee studies have shown that their kinematics and stability are comparable with the native knee [16,17]. Wang et al [18] compared gait kinematics in BKA versus control limbs at 1 year. They showed little difference in walking performance, coronal plane mechanics and knee extensor moment. More recently this same group compared the iDuo knee with TKR patients and healthy controls. This study demonstrated that iDuo limbs possessed comparable strength, mechanics and speed to healthy controls during daily activities and that TKR limbs showed significant deficit to both healthy control subjects and iDuo limbs [19].

The Journey Deuce knee has been the only other monolithic design marketed but has now been withdrawn. Palumbo et al. converted 14% to total knee replacements at an average of 19 months for persistent pain. They found tibial base plate loosening as the cause. This could have been related to excess micro motion at the bone-cement interface [11]. Only 48% were found to have an excellent to good post - operative functional KSS. Morrison et al. revised 3 of 21 Journey-Deuce knees for persistent postoperative pain at one year and found an overall complication rate of 28.6% with BKA compared to 6.1% in their TKR cohort [20]. Tria et al. reported anterior knee pain in 26% of 40 knees and 12% needing revision after a mean follow up of 2 years [21]. All three papers reported tibial tray fractures.

Conversely, early data for the iDuo knee is more favorable. Bryant et al. reported that 91% of 34 knees at a mean follow up of 30 months had good to excellent results. Additionally, if given the choice to undergo the same operation again, 97% replied yes. Our results seem to echo this sentiment but with the benefit of prospective knee outcome scoring. Thus far we have not recorded any of the complications associated with the Deuce knee and even if when including the data of patient 1, all patients at 2 years have scores above 80. The published results of modular BKA is a little more extensive. Both Paratte et al. [5] and Heyse et al. [13] have reported long-term results with an average follow up of approximately 12 years. These papers suggest good to excellent functional and knee scores. Comparison with the iDuo knee is difficult as our cohort is small and follow up is short. This, we believe, reflects the age of the design and specific patient selection. There are currently no papers comparing modular and monolithic designs.

The question therefore, is why should the iDuo knee be any different? There are several design features, which may be key to its early success. The tibial tray is 2mm thick and thus thicker than that of the Deuce knee leading to a lower risk of fracture. There is also an additional tibial component posterior keel for increased stability. The patient specific design may have several benefits when compared with "off the shelf" incremental size designs. Koeck et al. showed that tibial cortical fit/coverage is optimized and both component alignment and balance can be reliably achieved [22]. The Koeck paper was based on the Confor-MIS iUni knee but the instrumentation, tibial tray features and design process for the implant is the same as that for the iDuo design. A patient specific femoral component not only preserves bone stock but also allows optimum geometry and alignment of both compartments. It is often difficult to gain this result with more standard designs, often achieving successful size and balance in one compartment but to the detriment of the other. Many times, we have to compromise in partial knee surgery, between fit of the implant and the alignment of the femoral and tibial interface. This can lead to edge loading on the tibial implant. The compromise is obviated with the iDuo system. By design, the fit will be specific for each patient's tibial and femoral condylar geometry and the contact area between the two will be maximized. These design features may render the iDuo knee at lower risk for loosening and pain in the future.

We mentioned earlier in this paper that it is a great shame to sacrifice healthy bone stock and the ACL when using TKR for bi-compartmental disease. Even though old age is not strict exclusion criteria for the iDuo, our patients are generally high functioning and below the age of 60. It is therefore important to discuss outcomes in those who have undergone TKR at a younger age. After all, TKR would have been a perfectly acceptable option for our cohort.

Several recent papers cover TKR performed in younger patients. Meftah et al evaluated durability and functional outcome in patients who had undergone TKR and were 60 years and younger. At mean follow up of 12.3 years, overall survivorship was 98% and KSS was 80 and above in 95% of their fixed bearing knees [23]. Long et al have published results of 45 knees with an average of 25.1 years follow up and average age of 51. The average knee score was 87.4 and functional score. 62.1. In a similar but larger cohort (108 knees), survivorship without revision for any cause was 70.1% at 30 years [24]. Kim et al have showed that the KSS in TKR were excellent at 16.8 years in a cohort with an average age of 45 years. The Kaplan-Meier survivorship for revision was 95% [25]. These results would suggest that functional outcome and survivorship is good in younger patients who undergo TKR and function rivals that of our cohort. Survivorship cannot be compared. However, one advantage of the iDuo system compared with standard TKR may be ease of revision or better function thereafter as Bone stock preservation is a key feature of the iDuo knee.

There is no doubt that the limitation of this paper is that of patient number. However, the iDuo knee is relatively new to the market and may only be appropriate for a small population. Long-term data and comparison studies are required to further evaluate this knee prosthesis with particular attention to direct comparison with TKR.

### Conclusion

Our early results suggest that the iDuo knee is a good option for those with isolated bi-compartmental disease and outcome scores are comparable with those reported for the BKA. This bicompartmental design may bridge the gap between the uni-compartmental and total knee replacement. The choice between monolithic or modular designs remains in debate. We will continue to use this prosthesis for a carefully selected group of patients.

### Disclosure

The authors declare that there is no conflict of interest regarding the publication of this paper. For full disclosures refer to last page of this journal.

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# Tissue Sparing Total Hip Arthroplasty Study Group

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**ORIGINAL ARTICLE** 

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# The History, Technical Specifications and Efficacy of Plasma Spray Coatings Applied to Joint Replacement Prostheses

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### Abstract

Thermal plasma sprayed coatings are designed to improve both the biocompatibility and durability of implantable medical devices, and include pure titanium, cobalt/chrome alloy and hydroxyapatite. Coated joint replacements have now been in continuous clinical use for thirty years and are applied to products manufactured or used in Europe, North America, South America, Africa, Asia and Australasia. Prostheses incorporating such coatings have been successfully implanted into several million of patients worldwide and to date there have been very few reports of any failure of an implant which could be attributed to problems with, or failure of, the coating. This paper summarises the early history of cementless prostheses and subsequent development, specification, validation, regulatory requirements and clinical performance of thermal plasma spray coatings provided by Accentus Medical.

*Keywords*: plasma; spray; coatings; joint; replacement; prostheses *Level of Evidence*: AAOS Therapeutic Level V

### Introduction and Background

During the development of total hip replacement, during the 1950s and 1960s, the early prostheses such as the Charnley Hip were incorporated into the bone using an acrylic cement. This was made from polymethyl methacrylate, which had originally been developed for use in the dental industry, a couple of decades before. Such a method of fixation has proved to be very successful and the technique is still in use today, especially for older, low demand patients. However, long-term follow up of patient cohorts, showed that cement was susceptible to fatigue failure in high demand patients and that the resultant cement debris led to osteolysis and death of the host bone around the implant. This phenomenon became known as cement disease

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[1], a problem that was widely researched and published in the 1980s.

There was clearly a need to eliminate cement from the artificial joints of young, active or obese patients if successful outcomes were to be achieved in these patient groups.

As a direct result of this, the 1980s saw the development of a large range of hips, knees and shoulders that were designed to be used without cement, in a press-fit fashion. Many of these designs such as the Harris Galante (Zimmer), PCA (Howmedica) and Taperloc (Biomet) incorporated porous metal coatings into the surface of the prosthesis, aimed at promoting a mechanical interlock between the bone and the prosthesis during the healing process. These surfaces were variously composed of a "spaghetti" like wire construct [2] attached to the prosthesis using a technique called diffusion bonding, sintered metal beads [3] applied by a similar method, or by a porous layer of metal powder [4] applied by a thermal plasma spray method. After some early failures due to poor mechanical design, such techniques became very popular for younger patients. The National Joint Registry of England, Wales and Northern Ireland reports that over half of total joint replacements are performed today in a cementless fashion [5,6], with good long-term outcomes. Although there are still many different types of porous metal coatings and surface modifications on the market, plasma spray coatings have become by far the most popular. Firstly, it is a very cost effective solution that is readily applicable to all designs of joint replacement. Secondly, the results are good even at long-term follow up [4,7,8,9].

In 1984, another important technology was introduced to the market. An English surgeon named Ronald Furlong introduced a cementless hip stem incorporating a surface coating of a ceramic called hydroxyapatite, which was also applied using a thermal plasma spraying technology. Hydroxyapatite is a constituent of natural bone and the coating was designed to promote the growth of new host bone around the prosthesis during the healing process.

The results of the Furlong HAC stem have been excellent [7], and many of today's world leading brands of cementless hips and knees incorporate a coating of hydroxyapatite or a bi-coating of plasma spray metal (to create a roughened surface) followed by a sequential layer of hydroxyapatite.

### Purpose of Coatings and Types Available

Plasma spay coatings on joint replacement prostheses are designed to encourage new bone formation around an implant, thereby improving fixation and long-term survivorship of the artificial joint. Many studies have shown that a well applied coating does produce the required outcome [4,7,8,9], especially in total hip and knee replacement.

Accentus Medical has developed a global reputation for the development and proprietary production of its Acusure<sup>®</sup> range of high quality plasma spray coatings aimed at meeting the requirements of its customers around the world.

The quality and validation of such coatings are governed by a series of international standards (e.g. ISO, ASTM) devised and controlled by regulatory authorities around the world, (e.g. EU Notified Bodies, FDA). These requirements are described in the following sections of this paper.

### International Standards and Regulatory Requirements

The plasma spraying of metal and hydroxyapatite coatings for orthopaedic implants is governed by a number of ISO and ASTM standards and FDA good practice guidelines. These cover the input materials specification, the control of the coating process, and the properties of the resultant coating.

### TITANIUM RAW MATERIAL & COATING

The specification and validation of the input raw materials used to produce orthopaedic implants, and to produce titanium coatings applied to orthopaedic implants, are covered by several key documents.

ISO 5832-2 "Implants for surgery – metallic materials – unalloyed titanium" and ASTM F67 "Specification for unalloyed titanium for surgical implant applications" specifically refer to the ingot or other feedstock from which orthopaedic implants are machined, and the material used to produce powder that is subsequently sprayed onto implants to produce a titanium coating. ASTM F1580 "Titanium Powders for Coating of Surgical Implants" specifies the physical and chemical characteristics of the powder for plasma spraying.

The specification and validation of titanium coatings applied to orthopaedic implants are covered by ISO 13179-1, "Implants for surgery – Plasma sprayed unalloyed titanium coatings on metallic surgical implants", and the FDA 510(k) guidelines "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopaedic Implants to Support Reconsideration of Post-market Surveillance Requirements", Issued February 2, 2000 [10].

The guidelines require a range of metallurgical analy-

sis, microstructure and mechanical properties of the coated surface:

- Metallurgical analysis of the materials
- Microstructure of the modified surface
- Mechanical properties of modified surface
- Manufacturing details

These specifications are to assess the suitability of the coating for its primary purpose, to produce a rough finish to assist with bone integration onto the orthopaedic component. The properties of the coating may differ from that of the input raw material.

ASTM and ISO standards apply to the majority of the tests including:

- ASTM F-1044 "Shear testing of calcium phosphate coatings and metallic coatings"
- ASTM F-1147 "Standard test method for tension testing of calcium phosphate and metallic coatings"
- ASTM F-1160 "Shear and bending fatigue testing of calcium phosphate and metallic medical and composite calcium phosphate/metallic coatings"
- ASTM F-1854 "Stereological evaluation of porous coatings on medical implants"
- ASTM F-1978 "Measuring abrasion resistance of metallic thermal spray coatings by using the Taber<sup>™</sup> Abraser"
- ISO 9220 "Metallic and related coatings: scanning electron microscope method for measurement of local thickness of coating by examination of cross sections".

### HYDROXYAPATITE RAW MATERIAL & COATING

The specification and validation of both the input raw materials and the hydroxyapatite coatings applied to orthopaedic implants are covered by a number of key documents, mainly BS ISO 13779-2, "Implants for Surgery – Hydroxyapatite Part 2 Coatings of hydroxyapatite" and guidelines produced by the FDA "510(k) Information Needed for hydroxyapatite Coated Orthopaedic Implants", March 10, 1995 [11].

The FDA guidance document requires the following information for validation of the hydroxyapatite coatings:

- Particle size and particle size distribution, pore volume and porosity;
- Coating thickness and tolerance as measured by scanning electron microscopy;
- Chemical analysis of the hydroxyapatite powders before and after coating, including Ca/P ratios, elemental analysis;
- Bond strength of the hydroxyapatite coating;
- Solubility products of hydroxyapatite before and after coating;

- Dissolution rate of hydroxyapatite before and after coating;
- XRD patterns of hydroxyapatite before and after coating;
- Infrared spectra of hydroxyapatite before and after coating;
- The coating tested shall be as close to final product to market as practically possible (so processed, cleaned, packaged and sterilised).

ASTM and ISO standards apply to the majority of the tests. For example:

- ISO 13779-2 "Hydroxyapatite Coatings of hydroxyapatite"
- ISO 13779-3 "Hydroxyapatite Chemical analysis and characterisation of crystallinity and phase purity"
- ISO 13779-4 "Hydroxyapatite Determination of coating adhesion strength"
- ASTM F 1044 "Shear testing of calcium phosphate coatings and metallic coatings"
- ASTM F 1147 "Tension testing of calcium phosphate and metallic coatings"
- ASTM F 1185 "Composition of hydroxyapatite for surgical implants"
- ASTM F 2024 "X-ray diffraction determination of phase content of plasma sprayed hydroxyapatite coatings"

There is some variation worldwide, sometimes in the tests themselves, others in the number of tests required for statistical validity. The authors' experience in regulatory requirements includes Europe, North America, South America, Africa, Asia and Australasia. Dr Andrew McCabe is the convenor of the ISO TC150 ceramics working group involved with hydroxyapatite coatings of medical devices.

# Coatings – Specifications, Testing and Validation

The authors have experience validating plasma sprayed titanium (chemically pure titanium, CpTi) and hydroxyapatite coatings used in the coating of orthopaedic implants.

### PROCESS AND SOFTWARE VALIDATION

The equipment and the process of applying plasma spray titanium and hydroxyapatite coatings to specific customer products requires validation by Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ) and Computer Software Qualification (CQ) methodology, as recommended e.g. by the Global Harmonisation Task Force. [12]

### **COATING DESIGN VALIDATION**

The coatings used on an orthopaedic product are subject to design validation requirements. In addition to the design criteria for the implant itself (performed by the device manufacturer), the coating vendor produces coating design validation masterfiles to support the device manufacturer's product. It should be demonstrated that the coating does not itself cause any negative effect on the final coated product, for example shear fatigue properties.

### TITANIUM COATING

Table 1 summarises the physical, mechanical and chemical testing, the international ISO and ASTM standards to which the testing is performed, the regulatory limits and the typical test results achieved with a quality titanium coating.

Table 1.	Properties	of plasma	sprayed	titanium
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Property	Standards	Requirement	Typical Value (*)
Static Tensile	ASTM F 1147, FDA Guidance [10]	>22 MPa	40 MPa
Static Shear	ASTM F 1044, FDA Guidance [10]	>20 MPa	38 MPa
Shear Fatigue	ASTM F 1160, FDA Guidance [10]	10 MPa, 10 [7] cycles	PASS
Abrasion	ASTM F 1978, FDA Guidance [10]	< 65 mg @ 100 cycles	PASS
Nitrogen		< 5 %	< 2 %
Oxygen		< 10 %	< 4 %
Hydrogen		< 0.2 %	< 0.1 %
Carbon		0.08 %	0.02 %
Iron	180 12170 1	0.50 %	0.04 %
Silicon	150 151/9-1	0.06 %	0.012 %
Chlorine		0.20 %	0.04 %
Sodium		0.50 %	0.19 %
Magnesium		0.50 %	< 0.01 %
Titanium		Balance	Balance

\* These are typical results obtained for a quality titanium coating. The data significantly exceed the minimum regulatory requirements.

In addition, thickness, porosity and density measurements are performed and reported. In these cases there are no pass/fail criteria documented in the associated standards and guidelines.

A number of OEMs, and a few independent suppliers, offer titanium and hydroxyapatite coating by 'vacuum' plasma spray (VPS). This process uses a reduced pressure of inert gas (typically 0.1 atmospheres), and claims mechanical and chemical properties substantially in excess of regulatory requirements, although at a premium price. Standard air plasma spray (APS) coatings are less dense than VPS, mainly due to less particle melting. They contain increased, but acceptable levels of oxygen, nitrogen and hydrogen due to pick up from the atmosphere and achieve coating strength in excess of the minimum regulatory requirements.

The Acusure<sup>®</sup> range uses a mixture of inert (nitrogen and argon) and reducing (hydrogen) gases within its air plasma to carefully control the structure and properties of the coating. The properties of such coatings are therefore more favourable than those generally found in the open literature for APS coatings.

A typical SEM cross section microstructure of an angular titanium coating, sprayed onto a titanium substrate (LHS white area), is shown in Figure 1a, with an SEM image of the surface topography in Figure 1b. There is the option of several alternative grades of angular titanium, providing coatings of different roughness.



Figure 1a: Cross section of a 100 micron thick Acusure angular titanium coating.



Figure 1b: The surface of an Acusure angular titanium coating.

### HYDROXYAPATITE COATING

Table 2 summarises the physical, mechanical and chemical testing, the international ISO and ASTM standards to which the testing is performed, the regulatory limits and the test results achieved with a quality hydroxyapatite coating.

In addition, thickness, porosity and density measurements, infra-red spectroscopy, and solubility and dissolution testing are performed and reported. In these cases there are no pass/fail criteria documented in the associated standards and guidelines.

The selection of hydroxyapatite raw material, and the process parameters used, result in the production of a high purity and exceptionally high crystallinity hydroxyapatite coating (80% crystallinity compared to a minimum regulatory requirement of 45%). Re-testing after five-year ageing demonstrates a very stable coating with a low level of solubility and dissolution rate.

An example of SEM cross section microstructure of a hydroxyapatite coating, sprayed directly onto a grit blast-

Table 2. Properties	s of plasma	sprayed i	hydroxyaį	oatite coating
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Property	Standards	Requirement	Typical Value (*)
Static Tensile	ASTM F 1147, FDA Guidance [11]	>15 MPa	28 MPa
Static Shear	ASTM F 1044, FDA Guidance [11]	None	>30 MPa
XRD phase analysis:-	ISO 13779-2 ASTM F 2024		
Ca/P ratio	FDA Guidanaa [11]	1.65 - 1.76	1.70
Crystallinity		45%	80 %
% HAP		> 50%	92.7%
% α-TCP		<5%	3.2 %
% β-TCP		<5%	4.1 %
% TCCP		<5%	None detected
% CaO		<5%	None detected
Trace elements:-	ISO 13779-2		
As	ASTM F	3 ppm	< 3 ppm
Cd	FDA Guidance [11]	5 ppm	< 5 ppm
Hg		5 ppm	< 5ppm
Pb		30 ppm	< 20 ppm
Total heavy metals		50 ppm	< 30 ppm

\* These are typical results obtained for a quality hydroxyapatite coating. The data significantly exceed the minimum regulatory requirements. ed titanium substrate (LHS white area), is shown in Figure 2a, with an SEM image of the surface topography in Figure 2b.



*Figure 2a: Cross section of a 130 micron thick Acusure hydroxyapatite coating.* 



Figure 2b: The surface of an Acusure hydroxyapatite coating.

It is worth noting that the titanium in Figure 1 is deliberately designed as a roughened angular coating, while the hydroxyapatite in Figure 2 is a more homogenous coating.

### **PRE-CLINICAL TESTING**

In 2002, as part of studies on the validation of plasma spray coatings, a study was commissioned [13] on the effect of coating on early implant osseointegration, using a rabbit model. The study was performed using protocols suggested by two international guidelines:

- "Evaluation of Medical Devices for Biological Hazards: Tests for Local Effects After Implantation." (ISO 10993 part 6)
- Standard Practice for Assessment of Compatibility of Biomaterials for Surgical Implants With Respect to Effect of Materials on Muscle and Bone" (ASTM F981-93)

In this model, the implants were pins of 3mm diameter manufactured from Cobalt/Chrome/Molybdenum alloy. The pins were sequentially shot blasted in order to provide a roughened surface, and coated where appropriate.

The surface coatings investigated within the study were as follows:-

- Uncoated shot blasted pins, used as a control
- Coated with a 100 micron coating of titanium powder
- Bi-coated sequentially with 100 microns of titanium powder and 100 microns of hydroxyapatite
- Bi-coated coated sequentially with 100 microns of cobalt chrome powder and 100 microns of hydroxy-apatite

At surgery, each animal received one control pin implanted trans-cortically into the proximal femur and one coated pin distally in the same femur. The animals were sacrificed at either two months or three months and then examined histologically.

Excised femora each containing one implant plug and one control were placed whole into 70% ethanol. After 48 hours fixation the femora were divided, using a band saw, into proximal and distal sections each containing one implant plug, ensuring that there was at least 2mm of bone around each plug. After suitable labelling, the samples were dehydrated through a series of graded alcohols, defatted in acetone, returned to 100% alcohol prior to infiltration with methyl methacrylate. Samples were polymerised with fresh methyl methacrylate at 55°C.

The blocks were trimmed using a diamond band saw to expose the implant in a transverse section of the bone. Two 300 micron slices were prepared with the band saw. These slices were then attached to glass slides using hot quartz wax and a compression jig. These sections were then ground to an optical thickness using 30 micron grade aluminium oxide in ethane diol (10% w/v) as an abrasive. Sections were finally stained with Toluidine Blue and mounted with a cover glass and DPX mounting medium.

Specimens were examined visually using transmission bright filed light microscopy using x20 and x40 objectives. To verify the findings of these examinations, quantitative histomorphometry was then performed at the implant bone interfaces. This was performed utilising OsteoMeasure<sup>™</sup> software to quantify osteoid surface, osteoid volume and eroded surface.

Representative examples of the visual findings are shown in Figures 3 and 4.



Figure 3: Interface of bone and metal implant (M) with a bi-coating of titanium and hydroxyapatite (HA). Actively forming bone (B) with osteoid seams is clearly visible both at and near the bone implant interface. The bone was stained with Toluidine Blue and was observed with a x20 objective, three months after implantation.



Figure 4: Bone surfaces in the vicinity of the control uncoated metal implant (M) showing very little osteoid. Instead the bone surface is irregular, in some places appearing to have been recently eroded (ES). The bone (B) was stained with Toluidine Blue and viewed with a x20 objective 3 months after insertion of the implant.

The results of the quantitative histomorphometry are shown in Table 3.

Although the number of animals in the study was relatively small, the main reported findings of the study can be summarised as follows:

- The metal coatings or sequential coatings of metal plus hydroxyapatite significantly improved osseoin-tegration and new bone growth compared to uncoated controls.
- There was a suggestion that sequential coatings of metal followed by hydroxyapatite promoted a more rapid normalisation of bone growth at the implant interface than plasma sprayed metal only coatings. This may be important as it would theoretically shorten healing times and allow earlier weight bearing for patients following surgery.

	Osteoid volume %	Osteoid Surface %
Uncoated 3 months		
Mean	0.444	8.443
Std Error	0.161	1.948
N	3	3
Coated 2 months		
Mean	0.748	11.278
Std Error	0.220	2.771
N	3	3
Coated 3 months		
Mean	2.347*#	21.919*#
Std Error	0.397	1.022
N	3	3

Table 3. 1	Summarv	of C	Duantitative	Histomor	vhometi	ric Analysis	
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\*Significantly different from uncoated implant at 3 months P < 0.05#Significantly different from coated implant at two months P < 0.05

### Clinical Use of Thermal Plasma Sprayed Coatings

Over 16 years of clinical use, with over 200,000 implanted devices, there have been no reports of any implant failure which could be attributed to problems related to Accentus Medical's Acusure<sup>®</sup> coating or adverse bone / tissue reaction. The development of good quality coating processes has resolved challenges from cleaning, entrapment of grit media, oil or polishing compounds. The coatings have been used in primary and revision hip and knee prostheses, shoulder and elbow replacements, tumour replacement implants and pedicle screws. The coatings have been applied to implants manufactured by many different customers and implantations have taken place successfully in every continent of the world.

To illustrate the efficacy of hydroxyapatite coating in a clinical setting, Figure 5 displays Scanning Electron Microscopy of a cross section of a coated device showing formation of viable living bone at the device surface.

The presence of viable new bone, even in such difficult cases as limb salvage surgery, provides good evidence of the biocompatibility and efficacy of thermal plasma sprayed hydroxyapatite coatings.



Figure 5: Scanning electron microscope image showing detail of new viable bone formation into a hydroxyapatite coated implant collar manufactured from cobalt chrome alloy. (Image of custom prosthesis explanted from a patient undergoing complex limb salvage surgery).

### Summary

This paper summarises the early history of cementless prostheses and subsequent development, specification, validation, regulatory requirements and clinical performance of thermal plasma spray coatings provided by Accentus Medical. The growth in their use is confirmed by the National Joint Registry of England, Wales and Northern Ireland, which reports that over half of total joint replacements are currently cementless, with good long-term outcomes. Globally, there have been several million implantations of devices incorporating such coatings, with very few reports of issues related to any aspect of the coating itself. Cementless prostheses, with Accentus Medical's Acusure® plasma spray coatings, have good long-term outcomes with over 200,000 implanted devices over a sixteen year history. Many products incorporating this technology have received PMA or 510(K) approvals for the USA market and many have also been awarded an (A) rating by the Orthopaedic Data Evaluation Panel (ODEP) [15]. Thermal plasma spray coatings are a tried and tested technology that have brought benefits to millions of patients around the world for the last thirty years.

### Disclosure

The authors declare that there is no conflict of interest regarding the publication of this paper. For full disclosures refer to last page of this journal.

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15. Orthopaedic Data Evaluation Panel - <u>www.ODEP.org.uk</u>.



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CASE STUDY

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# Patient-specific Component Alignment in Total Hip Arthroplasty

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### Abstract

Appropriate component alignment is critical for improving stability, maximising bearing performance and restoring native anatomy after Total Hip Arthroplasty (THA). Due to the large variation in patient kinematics between functional activities, current technologies lack definition of what constitutes correct target alignment. Analysis of a large series of symptomatic THA patients confirms that apparently wellorientated components on standard radiographs can still fail due to functional component malalignment. Evidently, previously defined "safe zones" are not appropriate for all patients as they do not consider the dynamic behaviour of the hip joint.

The Optimized Positioning System<sup>TM</sup> (OPS<sup>TM</sup>) comprises preoperative planning based on a patient-specific dynamic analysis, and patient-specific instrumentation for delivery of the target component alignment. This paper presents the application of OPS<sup>TM</sup> in three case studies.

*Keywords*: total hip, arthroplasty, implant positioning *Level of Evidence*: AAOS Therapeutic Level IV

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### Introduction

Appropriate component alignment is critical for improving stability, maximising the performance of the bearing and restoring native anatomy after Total Hip Arthroplasty (THA). Femoral and acetabular component malalignment are key contributors to the leading causes of THA revision [1]. If appropriate component alignment can be achieved in all patients, the THA revision burden would be significantly reduced.

The limited precision with which a defined target alignment can be achieved intraoperatively, without assistive technologies, has been widely published [2-4]. Computer assisted surgery, and more recently robotics, were introduced to improve precision, but with slow uptake from the orthopaedic community. The limited acceptance of assistive technologies is likely due to the poor definition of what constitutes the correct target alignment for an individual. Contemporary literature has questioned the appropriateness of the most commonly accepted guidelines for implant alignment, with more failures observed when adhering to historical recommendations, than when not [5].

Edge-loading, accelerated wear, impingement and dislocation are leading contributors to THA revision. All occur during functional activities when the position of the pelvis and femur are different from that seen on standard radiographs or on the operating table [6-11]. Hip kinematics are specific to each individual and change the functional alignment of the components [10]. Consequently, component alignment should be planned individually, using

dynamic information, if we want to optimise to reduce failure.

The Optimized Positioning System<sup>TM</sup> (OPS<sup>TM</sup>) is a commercially-available medical device for patient-specific preoperative planning, intraoperative delivery and postoperative analysis in Total Hip Arthroplasty (Optimized Ortho, Sydney, Australia) [12]. The system comprises a preoperative planning and analysis component, along with patientspecific instrumentation for intraoperative delivery. The planning uses standard medical imaging to assess each patient's alignment, bone morphology and kinematics, and analyses the bearing contact mechanics and impingement using a rigid body dynamic simulation of functional activities. To date, over 3,000 patients have received OPS<sup>™</sup> preoperative planning in Australia and Europe. This paper presents the application of OPS<sup>™</sup> in three case studies.

### Methods

**Functional imaging:** In the weeks preceding the operation each patient receives three lateral functional radiographs; standing, flexed seated and step-up (raising the contralateral leg), Fig 1. On each of the functional images, pelvic tilt, sacral slope and lumbar lordotic angles are measured. The measured angles are used to define the positions of the bones at the limits of hip flexion and extension. In addition, bony geometry for each patient is captured in a low-dose Computed Tomography (CT) scan and three-dimensional coordinates of soft tissue and bony landmarks are virtually identified.

**Implant positioning:** Using the manufacturer's 3D implant geometries, femoral stem and acetabular shell templating is performed by a qualified engineer, Fig 2. The implants are virtually positioned within the patient's femur and acetabulum to restore native anatomy and to achieve optimal metaphyseal loading. The surgeon can feed into the preoperative plan any patient-specific clinical observations or requirements, such as preoperative leg length discrepancies measured at clinical review.



*Figure 1. The functional pelvic tilt, sacral slope and lumbar lordotic angles are measured from three lateral functional radiographs: standing, flexed seated and step-up.* 



Figure 2. Femoral stem and acetabular shell templating.

**Dynamic simulation:** The segmented bone models and planned component alignment are inputs to a rigid body dynamics simulation of flexion and extension activities, driven by the kinematic inputs from the functional radiographs. The simulation calculates the magnitude and direction of the hip joint reaction force throughout the two activities and determines the path of the contact patch



Figure 3. The hip joint reaction force is calculated during a simulation of hip flexion (middle) and hip extension (right) activities.

 $[\underline{13},\underline{14}]$  as it traces across the articulating surface, Fig 3. These contact patch paths are presented in a polar plot that represents the bearing surface in two dimensions viewed

Supine Pelvic Tilt is 10.0°.



Figure 4. Polar plots illustrating the flexion (blue trace) and extension (red trace) contact patch path for nine different cup orientations.

perpendicular to the face of the cup. The polar plots are generated for nine different cup orientations, defined in angles of radiographic inclination and anteversion [15], Fig 4. The nine plots demonstrate the effect of cup orientation on contact mechanics across a patient-specific zone, to assist the surgeon in determining an optimal cup orientation for the patient.

**Preoperative report:** The preoperative plan, including results from the dynamic analysis and implant templating, is presented to the surgeon for approval in the weeks prior to surgery. The system determines a preliminary target orientation based on a series of preferences defined by the surgeon. These parameters take into consideration the surgeon's accepted ranges for acetabular inclination and anteversion, the surgical approach, acetabular shell coverage, acceptable boundaries from the anterior and posterior edges of the bearing, as well as any expected changes in pelvic kinematics postoperatively. The surgeon has the opportunity to change the templated implants and target orientation prior to finalising the plan.

**Patient-specific guide design:** Two patient-specific guides are designed to deliver the preoperative plan in surgery. The acetabular guide is designed to fit within the patient's acetabulum and guide the planned cup orientation, Fig 5a. The femoral guide is designed to fit on the available surface of the femoral head and neck and guide the planned femoral osteotomy, Fig 5b. Once the guide designs have



*Figure 5. a) the acetabular guide delivers the target cup orientation; b) the femoral guide controls the femoral neck osteotomy.* 

been accepted by the surgeon, both guides and corresponding bone models are 3D printed from medical grade Nylon and sterilised for use in surgery.

Intra-operative delivery: The OPS<sup>™</sup> guides can be used with any surgical approach. After the surgeon performs their routine exposure, the femoral guide is positioned on the femoral head-neck junction, and secured in place with a spring-loaded pin. The osteotomy is made along the open capture feature on the femoral guide. The acetabular guide is then seated within the acetabulum after the fat pad and any soft tissue remnants in the acetabular fossa are excised. The in vivo position can be checked against the markings on the sterile bone model. A laser handle connects to the axis of the guide and projects the target orientation onto the operating room ceiling or wall. A second laser mounted to the pelvis is orientated to converge with the projection on the ceiling or wall, and secured to mark the target orientation relative to the pelvis. Any intraoperative movement of the pelvis will therefore not affect the target orientation, which is not dependent on a particular position in the operative theatre. Reaming is completed per the surgeon's routine technique, to the preoperatively planned depth. Final cup orientation is guided by a laser on the end of the impactor handle. The handle is orientated so the laser aligns with the projection of the pelvic reference laser. Cup orientation is also confirmed by referencing anatomical features such as osteophytes around the acetabulum to the rim of the cup, using the markings on the sterile bone model. The placement of the patient-specific guide and planned cup in the acetabulum can also be visualised in three-dimensional models on a tablet during the operation.

All patients provided consent that they were happy to be involved in the case series review.

### Results

### Case Study 1

79 year old male requiring right side THA, Fig 6. Patient also had an arthritic left side. CT analysis showed equal pre-op leg length. The femoral neck osteotomy was planned 13mm above the lesser trochanter to provide 0mm of lengthening on the right side. 3D planning recommended a 125° Metafix stem (Corin Group, Cirencester, UK) with a +4mm head and the cup positioned 2mm off the true acetabular floor. Planned stem anteversion was 21° to preserve the AP position of the native femoral head.



Figure 6. Preoperative and postoperative radiographs.

Dynamic analysis showed the patient had minimal pelvic movement between functional positions, with no risk of edge-loading. Consequently, due to the low risk profile of the patient's pelvic kinematics, the surgeon chose a standard cup orientation of 40°/20° (inclination/anteversion). Large osteophytes could be visualised in the OPS<sup>™</sup> report which was used intraoperatively as a guide for what needed to be removed, Fig 7.

The procedure was performed through a posterolateral approach.



Figure 7. Threedimensional model from the OPS<sup>™</sup> report illustrating the templated acetabular cup and surrounding osteophytes.

### Case Study 2

52 year old female requiring right side THA. CT analysis showed a 6mm leg length discrepancy (LLD), with the right side shorter. The femoral neck osteotomy was planned 15mm above the lesser trochanter to provide 6mm of lengthening on the right side, Fig 8. 3D planning recommended a lateralised TriFit stem (Corin Group, Cirencester, UK) with the cup positioned 2mm off the true acetabular floor. This alignment restored global hip offset. Planned stem anteversion was 18° to preserve the AP position of the native femoral head.

Dynamic analysis showed the patient had a significant anterior pelvic tilt  $(32^\circ)$  in the flexed seated position, Fig 1. This represented a 25° anterior rotation from standing, and highlighted the risk of posterior edge-loading and instability in flexion. There was minimal sagittal pelvic rotation from supine to standing. There were no signs of degenerative disease of the lumbar spine. The surgeon would generally favour a ceramic-on-ceramic bearing in this younger patient. However, given recent literature showing an increased risk of squeaking in patients with large anterior pelvic tilts in flexion [11], the surgeon chose to

discuss bearing choice with the patient in more detail. In consultation with the patient, the decision was made to use a ceramic-on-ceramic bearing. with a target orientation of 34°/27° (inclination/anteversion). The amount of uncovered posterosuperior shell could be visualised in the OPS<sup>™</sup> report, Fig 9.



Figure 9. Three-dimensional model from the  $OPS^{TM}$  report illustrating the templated acetabular cup position and orientation in relation to the surrounding anatomy.

The procedure was performed through a posterolateral approach.

### Case Study 3

51 year old male with contralateral THA required right side replacement. CT analysis showed a 3mm LLD, with the right side shorter. The femoral neck osteotomy was planned 20mm above the lesser trochanter to provide 3mm of lengthening on the right side, Fig 2. 3D planning recommended a lateralised TriFit stem (Corin Group, Cirencester, UK) with the cup positioned 2mm off the true acetabular floor. This alignment restored global hip offset. Planned stem anteversion was 21° to preserve the AP position of the native femoral head.

Dynamic analysis showed significant changes in pelvic tilt during functional activities. The pelvis rotated 15° posteriorly from the supine to the standing position, leaving the patient with a 19° posterior pelvic tilt in extension. In the flexed seated position the pelvic tilt was 5°, a 24° anterior rotation from the standing position. There were no



*Figure 8. Left: Templated implants from OPS<sup>TM</sup> report; Right: postoperative radiograph.* 

signs of degenerative disease of the lumbar spine. With the patient potentially at risk of functional cup malorientation in both flexion and extension, a dual mobility bearing was considered most appropriate by the operating surgeon, with a target orientation of  $42^{\circ}/13^{\circ}$  (inclination/anteversion).

The procedure was performed through a direct anterior approach.

### Discussion

Total hip arthroplasty is a successful operation, providing pain free function for patients with debilitating osteoarthritis. Fortunately, the procedure is relatively forgiving of component malalignment, and this has concealed the poor levels of precision achievable without assistive technologies [2-4,16-21]. Despite the generally high rates of patient satisfaction, failures still occur. It is important to address these failure mechanisms through responsible innovation, in both preoperative planning, as well as intraoperative delivery, to continue to improve outcomes and reduce revision rates in THA.

This paper provides an introduction to the OPS<sup>™</sup> dynamic planning and delivery system for THA. Using standard medical imaging, OPS<sup>™</sup> determines optimal component sizing and alignment for each patient. The defined targets are then achieved intraoperatively using 3D patientspecific guides. The OPS<sup>™</sup> technology emphasises the importance of component alignment as well as functional analysis of patients.

The position of the pelvis in the sagittal plane changes significantly between functional activities [10]. The extent of change is specific to each patient. Often components



Figure 10. Supine and functional radiographs of a patient experiencing recurrent anterior dislocations.

will appear well oriented on standard views, but become malorientated during more functionally-relevant postures. Lembeck et al. showed that for every 10° of pelvic rotation in the sagittal plane, the anteversion of the acetabular component will change by around 7° [22]. Posterior pelvic rotation will increase the functional anteversion and inclination of the acetabular cup. This mechanism is protective in flexion, but problematic in extension. Conversely, an anterior pelvic rotation will decrease the functional orientation of the acetabular component. This is beneficial in extension, but can lead to posterior instability in flexion. It is not possible to predict these functional pelvic tilts from a standard AP radiograph.

Understanding the clinical relevance of functional component malalignment in the symptomatic THA was the catalyst for the development of the OPS<sup>™</sup> preoperative planning system. Analyses of hundreds of symptomatic THA patients confirmed that apparently well-orientated components on standard pelvic radiographs can still fail due to impingement, dislocation, squeaking and runaway wear [23]. Fig 10 shows an example of a patient with recurrent anterior dislocation. Computer-assisted surgery was used to implant the acetabular component at an orientation of 42°/25° through a posterolateral approach. The supine radiograph looks unremarkable. However when standing, the patient's pelvis rotated posteriorly by 23°, leading to a functional cup orientation in extension of 54°/42° and anterior subluxation. Retrospective OPS<sup>™</sup> analysis determined a more appropriate target orientation, given the patient's kinematics, would have been 34°/9°. This orientation would have reduced the risk of anterior subluxation in extension, whilst maintaining a safe boundary at the posterior edge in flexion.

The precision of the acetabular patient-specific guides has been confirmed in clinical practice. In a consecutive series of 100 OPS<sup>™</sup> THAs, Spencer-Gardner et al. showed mean absolute deviations from the planned cup inclination and anteversion of 3.9° and 3.6° respectively. 91% of cups were within 10° of both the planned inclination and anteversion [24]. These results are comparable with published data on the precision of computer-assisted THA surgery [16-19], summarised in Table 1. Importantly, the OPS<sup>™</sup> system defines a patient-specific target derived from functional, dynamic analysis, and does not require any registration to define the intraoperative reference frame.

Recreation of the femoral head centre in THA is important for maintaining leg length and offset, as well as improving muscle function and tissue tension. The femoral neck osteotomy can influence the size and alignment of the femoral component in THA, which in turn can affect the position of the prosthetic head centre. Dimitriou et al dem-

Table 1: Summary of published precision of the acetabular cup
orientation for computer-assisted surgeries as compared with the
OPS <sup>™</sup> system.

Literature Reference	Mean Absolute Inclination Deviation ± SD (Range)	Mean Absolute Anteversion Deviation ± SD (Range)
Kalteis 2006	<b>3.6°</b> (1° to 12°)	<b>4.2°</b> (0° to 10°)
Lass 2014	<b>3.0°</b> ± 2.5° (0 to 10°)	<b>5.5°</b> ± 3.6° (0° to 14°)
Hohmann 2011	<b>3.4°</b> ± 2.2° (0.2° to 6.8°)	<b>5.5°</b> ± 4.0° (0.2° to 14.7°)
Gurgel 2014	<b>3.0°</b> ± 1.8° (0.3° to 6.2°)	<b>5.5°</b> ± 3.8° (0.5° to 12.3°)
Spencer-Gardner 2016	<b>3.9°</b> ± 2.9° (0.0° to 13.6°)	<b>3.6°</b> ± 3.2° (0.0° to 12.9°)

onstrated that the level and angle of the femoral neck osteotomy affects the varus/valgus alignment and anteversion of the stem, respectively [25].

Two-dimensional radiographs are conventionally used to template implant sizes and plan the femoral neck osteotomy. Often, the scale of the radiographs and the rotational alignment of the proximal femur misrepresent the patient's anatomy. The OPS<sup>™</sup> preoperative planning determines the optimal position of the components to restore native anatomy and to achieve optimal metaphyseal loading based on three-dimensional reconstruction of the anatomy from CT. The target osteotomy is defined from the planned stem position, and delivered intraoperatively with a 3D printed guide.

In a series of 33 cases performed by two surgeons at a single institution, the OPS<sup>TM</sup> femoral guides reproduced the planned osteotomy level within 1mm in 85% of the cases [26]. Accurately achieving the optimal osteotomy will assist in attaining the desired post-operative leg length.

Hip kinematics are highly variable between individuals and between different functional activities. These dynamic changes have a significant effect on the functional alignment of the prosthetic components. Previously defined "safe zones" are not appropriate for all patients as they do not consider this dynamic behaviour of the hip joint. Further, templating from two-dimensional radiographs does not provide the surgeon with information about the three-dimensional position of the femoral head and proximal femoral anatomy. The OPS<sup>™</sup> preoperative planning and delivery system is an innovative new technology that provides a dynamic simulation and personalised implant alignment, from standard medical imaging.

### Disclosure

One or more of the authors have disclosed information that may present potential for conflict of interest with this work. For full disclosures refer to last page of this journal.

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**CASE REPORT** 

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# Prosthetic Fracture of a Cemented Exeter Femoral Stem

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### Abstract

We present a single case of fracture of an Exeter femoral prosthesis at the neck, occurring after a fall from standing height, in a lean 70yr lady at 6 years post implantation. The fracture propagated from the insertion dimple on the superior aspect of the prosthesis shoulder. Materials analysis suggested variance in composition of the alloy, particularly with grain size heterogeneity. Whilst Exeter femoral prosthesis fracture is extremely rare, when it does occur the literature suggests it is often in the context of excessive mechanical stresses (obesity, high offset, falls). However, this case may represent a failure of materials rather than mechanical stresses alone.

*Keywords*: hip arthroplasty, prosthesis failure, stem fracture, hip prosthesis, revision total hip replacement *Level of Evidence*: AAOS Therapeutic Level IV

### Introduction

The Exeter<sup>TM</sup> Universal hip stem (Stryker Inc., Newbury, UK) is a commonly used and well-performing prosthesis in hip arthroplasty. The Australian Orthopaedic Association National Joint Replacement Registry has recorded its use in 91, 601 procedures, which includes 71,849 total hip replacements and 19,752 hip hemiarthroplasties (unipolar, bipolar and trauma stem types), of both the older Exeter type and modern Exeter V40 type. [1] The overall revision rate for all stem types is low, at 0.61 revisions/100 observed years.

The Exeter stem is a highly polished, double tapered, stainless steel stem, designed for use with acrylic bone cement. The modern or Universal Exeter stem was introduced in 1988 with the addition of more sizes and offset options while preserving the original shape and design. [2]

The Exeter stem is reported to have excellent long term survival results, and failure due to stem fracture is an extremely rare occurrence. [3,4]

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### **Case Report**

Our patient is a healthy and lean (71kg) 70 year old female, who underwent routine right hip arthroplasty in 2009 for osteoarthritis, via posterior approach. A cemented, flanged polyethylene cup (Contemporary Acetabulum, Stryker Inc.) was inserted with a cemented, size 0 Stryker Exeter V40 stem with 44mm offset, and a metal (CoCr) 28mm +0 head. Our patient had an unremarkable post-operative recovery and her hip arthroplasty had been functioning well with no complications.



Fig 1: Prosthetic fracture of a polished, tapered, collarless femoral stem; a cemented polyethylene cup has been used.

In June 2015, she had a fall from standing height causing a painful right hip. Radiographic examination showed a femoral prosthetic fracture at the base of the neck of the femoral component (Fig 1).

After discussion and appropriate consent, we performed cement-in-cement revision surgery to exchange the broken femoral stem using a new Exeter femoral component. Intra-operatively, the implant appeared well-fixed without signs of loosening or infection. Positioning of the cup and stem and were appropriate, with an intact satisfactory cement mantle, although the shoulder of the stem was proud of the level of femoral osteotomy by 10mm.

The stem fracture had initiated from the insertion guide 'dimple', at the point of its maximum diameter, and propagated transversely (Fig 2). The proximal neck fragment and taper well were engaged with the femoral head, and in turn were located in the acetabular component. The acetabular component had an intact rim with no signs of neck impingement and no evidence of eccentric wear of the cup.

The patient underwent revision of the femoral stem uti-



Fig 2: The prosthetic stem fracture propagated inferiorly from its origin at the insertion "dimple".

lizing the previous posterior approach and a cement-in-cement revision technique. The stem was removed without damaging the cement mantle, and a smaller stem of the same design (Exeter 44mm No.00) designed for the use in cement-in-cement revisions was used. The cement cavity was cleaned and thoroughly dried, and the new stem installed using cement within the existing mantle with a hollow centraliser (Fig 3). The surgical procedure proceeded successfully and the patient made an uneventful recovery. She was allowed to mobilise full weight bearing on day one and received rehabilitation with physiotherapy prior to discharge 6 days after surgery. Our patient received routine post-operative follow up and reported good function with Oxford Hip Score 37, 12-months after her revision surgery.



Fig 3: Successful cement-in-cement technique using smaller sized stem.

### Results

Retrieval analysis of the fractured Exeter components was performed. Macroscopically, "beach marks" were seen across the fractured surface, a sign of chronic material fatigue (Fig 4). Evidence of corrosion was detected



Fig 4: Concentric "beach marks" seen at the fracture plane, an indication of material fatigue; they represent successive arrests or decreases in the rate of fatigue crack growth due changes in material loading over time. This pattern indicates rapid progression from the initiation site, and slower progression where the beach marks are seen.

along the medial edge and posterior surface of the stem, with minor corrosion in the trunion and no evidence of corrosion on the neck. The stem exhibited heterogeneity of microstructure; specifically, there was a high proportion of large grains near the prosthesis surface, which can be observed when an alloy has re-crystallized after heat-treatment, whereas the rest of the stem was fine-grain austenite (Fig. 5). This variance in composition has been noted in previous prosthesis retrieval analysis [5] which showed that coarse grain size, and grain heterogeneity, were consistent with lower fatigue and yield strengths.



Fig 5: Variability in grain microstructure between surface region (right side) and central portion (left side) of prosthesis seen on this high power view.

Chemical analysis of the stem composition was undertaken with SpectroMaxx Optical Emission Spectroscopy (OES) to verify composition; there were minor, non-significant aberrations in manganese and nitrogen, but no evidence of abnormalities to account for fracture (Table 1). More significant was variability of microhardness with distinct hardness difference according to grain size. The average hardness of large grains was 292 Hv, while average hardness of small grains was 362 Hv.

Element	Composition %	Composition limits (ISO 5832-9)
Carbon	0.05	0.08 max
Silicon	0.25	0.75 max
Manganese	4.32	2 - 4.25
Nickel	9.3	9 - 11
Chromium	21.7	19.5 - 22
Molybdenum	2.2	2 - 3
Niobium	0.28	.25 - 0.8
Sulphur	0.003	0.01
Phosphorus	0.02	0.025 max
Copper	0.07	0.25 max
Nitrogen	0.56	0.25 - 0.5
Iron	balance	balance

Table 1: Chemical analysis

Chemical composition of the femoral stem compared to composition limits outlined in ISO 5832-9, showing only manganese and nitrogen to be slightly outside specified norms.

SEM of the fracture surface revealed dimple rupture, cracking, beach marks and some areas showing fatigue striations, common to a fatigue failure. Apart from the insertion guide hole, no other obvious stress risers were detected near the crack initiation zone. The fracture initiated at the anterosuperior edge of the stem in close proximity to the stem insertion guide hole. Lack of proximal bone or cement support at this region can result in increased bending forces.

### Discussion

The Exeter<sup>TM</sup> stem is a polished and double-tapered collarless stainless steel stem with a "V40" Morse taper and a hollow distal centraliser which allows subsidence for compressive loading throughout the cement mantle. There is a "dimple" on the superior aspect of the shoulder to allow the introducer pin to secure the stem during insertion, a potential stress riser which was relevant in this case.

The evolution of the Exeter stem is relevant as much of the previous literature reviewed older stem generations that are no longer used. The polished, double-tapered collarless Exeter stem originated in 1970, manufactured from stainless steel alloy (EN58J); at the time, British manufacturing standards required that stems made of this alloy be polished. It was designed for a posterior approach, and the rationale for the double taper was to improve cement compression during insertion. The stem had good results, but due to reports of fracture at the neck, the material was changed to 316L stainless steel in 1976; at the same time, the surface finish was altered to a matte type. In 1983, nitrogen was added to create an alloy that was stronger and more corrosion resistant; this was classed as a "high-nitrogen stainless steel" (HNSS) and marketed as Orthinox<sup>TM</sup>. The finish was ultimately reverted to the polished type in 1986 due to inferior results.

The Exeter is a superior prosthesis with a long history and excellent long term results in all major registries [6]. Specifically, the Contemporary/Exeter stem combination has a 10yr revision rate of ranging from 3.2-6.0% depending on acetabular component choice. [1] Prosthesis fracture rates are extremely low in modern type HNSS stems with polished, tapered morphology.

Beach marks and fatigue striations noted on the fracture surface in our case indicate a fatigue mode of failure. Variation in microstructure, as well as hardness, suggest alloy segregation. Large grains near the surface are most likely a form of secondary recrystallization as a result of heat treatment. These are significant factors that can predispose the stem to failure. Unfortunately this is not an isolated case and we have observed grain size and hardness variation on five previous Exeter stem fractures. [5] Only the manganese and nitrogen concentration slightly exceeded the compositional limits outlined in ISO 5832-9. These are only minor non-conformances and would not be expected to have any influence in stem failure. Other clinical factors that may have contributed to failure include: patient fall, medium to high activity level and femoral canal morphology.

There are very few reports in the literature of femoral prosthetic fractures at the neck or trunion, and most of these date back to use of out-dated designs and materials. In 1995, Rokkum reported on a series of 3 stem fractures in a cohort of 27 Exeter hips that were followed over 10 years [2] but this was an analysis of older style stems manufactured between 1983 and 1985. More recently, Yates et al reported on two prosthetic neck fractures, both in obese patients (BMI 33 and 49) who were very active, and with high-offset (44mm) stems [7]. They made particular note of the variability in grain size seen with one of those two stems after metallurgical analysis, and hypothesized that the combination of high loads and material aberrations may contribute to neck fracture.

Swarts et al (2007) examined 6 fractured femoral stems, which occurred within a 3 year period (2002-5), four of which were Exeter stems; all were of modern design with HNSS components [5]. The fractured stems were all examined by stereomicroscopy and scanning electron microscopy, and their chemical composition determined. Three of the fractures occurred at stem and only one occurred at the superior aspect of neck, although it was not at the insertion guide hole as in our case. None had chemical composition anomalies. Swarts hypothesized that an abundance of coarse grains near the surface in the stems that fractured (an abnormality in the manufacture process) was detrimental to controlling micro-fracture propagation and hence shortened the fatigue life; they suggested further microstructural optimization as part of the manufacture process.

Yates (2008) reported on 5 Exeter prosthesis fractures, two of which were fractures of the neck [7]. They proposed a distinction in the cause of fractures of the prosthetic neck (which they associated with mechanical overload) and stem fractures (associated with fatigue fracture and grain size anomalies). The neck fractures were again not associated with the insertion guide hole. Akinola (2009) then reported on a single case of Exeter prosthetic neck fracture in a 121kg male who had a fall from standing height [8]. In agreement with the suggestion of Yates, the failure was attributed to mechanical overload, and the authors suggested a recommended maximum weight be considered for the Exeter prosthesis. O'Neil (2011) et al reported on a single Exeter prosthetic neck fracture that had propagated from the insertion guide hole, just as in our case [9]. This stem however was a cement-in-cement type, which is narrower in design. The failure occurred at 5 years post implantation in a patient with a BMI of 27.8.

Davies (2013) reported on four fractures of modern design V40TM Exeter stems, all of which occurred within the body [10]. All four of the patients were classed as obese. Three of the patients were noted to have "low" neck cuts, with proud shoulders, although the authors noted that the technique guide specifically refers to the neck resection as unimportant.

Hamlin et al (2014) reported on a single case of Exeter prosthesis fracture at the trunion-neck junction, in an obese (141kg), elderly male patient who sustained a fall from standing height [11]. He was also noted to have a relatively under-sized stem. Analysis of the stem concluded the fracture had initiated from the lateral side of the trunion-neck junction, and was due to fatigue. They proposed that consideration be given to the situation of highly overweight patients given the increased stresses they subject a standard prosthesis to, and highlighted that the problem may become increasingly frequent given the trend in rising BMI globally.

Reito et al (2015) reported on three fractured Exeter prostheses, all of which occurred more proximally along the neck, and near to the trunnion [12]. All patients were overweight (BMI>25, weights of 84kg, 92kg and 120kg), with higher offset stems (No. 44), 36mm heads and "plussize" heads (+5mm, +8mm and +10mm offsets). They reviewed their series of 2,521 Exeter femoral stems to calculate a prosthesis fracture rate of 0.1% overall. They hypothesized that the combination of obese patients, high offset stems and large heads (with extended offsets) may be increasing lever arm forces significantly, and may warrant investigation.

In our case we believe the factors implicated in the Exeter stem fracture include:

- Poor proximal support (loosening)
- Canal morphology (champagne-glass femurs)
- · Poor microstructural homogeneity
- Surface corrosion

### Conclusion

The Exeter femoral stem has a long history with reliable results. There are few reports in the literature of failure at the prosthetic neck, and these rare cases are associated with increased mechanical strain: falls, increased body weight, increased offset, and increased femoral head size. The failure of the Exeter prosthesis in our case is likely a result of a combination of factors including poor microstructural homogeneity, high patient activity level, poor proximal support and a mechanical fall. Our case is unique in that the patient had few of the typical risk factors; whilst she did have a No. 44 stem, she was not overweight, and had a smaller prosthetic head (28mm) without increased offset. Her materials analysis may indicate that some degree of manufacture variance may have contributed to her prosthesis fracture. Future cases of prosthetic neck failure should undergo material analysis.

### Disclosure

The authors declare that there are no conflict of interest regarding the publication of this paper. For full disclosures refer to last page of this journal.

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**CASE REPORT** 

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# Prosthetic Hip Loosening Due to Brucellar Infection: Case Report and Literature Review

Tebourbi A<sup>1</sup>, Hadhri K<sup>2</sup>, Salah M<sup>2</sup>, Bouzidi R<sup>1</sup>, Kooli M<sup>2</sup>

### Abstract

*Context:* Brucellosis is actually considered to be the commonest zoonotic infection worldwide; conversely prosthetic infection due to brucella is extremely rare. Although diagnostic is easily achieved, management of such situations is extremely challenging.

*Aims:* To report the case of prosthetic hip loosening due to brucellar infection, discuss management manners and to summarize data about 19 cases reported in the literature.

*Methods:* We report the case of a 73-year-old woman with brucellar prosthetic hip loosening treated with 2-stage exchange of the prosthesis and prolonged double antibiotherapy

**Results:** At two years follow up the patient is pain free with total functional recovery and no clinical and radiographic signs of prosthetic loosening

**Conclusions:** Brucella should be evocated as a cause of total joint arthroplasty infection especially in patients from endemic regions and with occupational exposure. Antibiotic treatment alone can be followed if there are no signs of implant loosening. Tow stage revision should be considered in other cases

Keywords: total hip arthroplasty; prosthetic joint infection; Brucellosis Level of Evidence: AAOS Therapeutic Level IV

### Introduction

Brucellosis is now considered to be the commonest zoonotic infection worldwide with more than 500.000 new cases annually [1,2]. According to the World Organization for Animal Health, North Africa has been traditionally considered endemic. Brucellosis affects several types of animals, including cows, sheep, goats, deer, pigs and dogs. Six species of gram-negative bacteria belonging to the genus Brucella are responsible for infection: B. melitensis, B. abortus, B. suis, B. canis, B. ovis, and B. neotomae. Only the first four are able to infect humans by ingestion of con-

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Osteoarticular infection is the most common complication and has been described with rates of 10% - 85% in patients infected by brucella [3,4]. It affects the large joints, especially the sacro-iliac joint. Spondylitis, bursitis, tenosynovitis and osteomyelitis have been also described [5-11].

Conversely prosthetic infection due to brucella is extremely rare. In the literature there are 19 cases of total joint arthroplasty infected by Brucella involving only 9 hips.

In the present report we describe a case of prosthetic hip loosening due to this infection and review the literature.

### **Case Report**

73-year-old woman presented to our hospital in March 2002 with two years history of hip pain. After radiographic examination, the patient was diagnosed with osteoarthritis of the hip. The peripheral white blood cell (WBC) count was 5500cells/mm3, the erythrocytes sedimentation rate (ESR) was 50mm/h, and the C-reactive protein (CRP) level was 4, 8mg/l.

She underwent cemented Charnley total hip arthroplasty through a posterior approach. Culture of specimen from the synovium obtained during surgery was negative and microscopic examination showed degenerative changes.

The hip was pain free and annual postoperative radiographs were satisfactory until the 10th year.

On February 2012 the patient was hospitalized for L2-L3 and T6-T7 brucellar spondylitis with discovertebral needle biopsy showing brucellar granuloma, positive Rose bengal test and 1/640 brucella serum antibody titer . She received standard chemotherapy with oral Doxyciline and Rifampicine.

In February 2014 the patient presented complaining of hip pain that had been present for the previous 8 months. There were no external signs of infection and no previous episod of fever. Radiographic examination showed evident signs of prosthetic loosening [Figure 1]. The inflammatory biomarkers included blood leukocytes count (8700cells/ mm3) and C- reactive protein level (7,6 ng/l). A revision total hip arthroplasty (THA) was planned because of suspected asceptic loosening.

During the surgical procedure, purulent white fluid poured out of the joint with abundant necrotic tissue and marked loosening of the prosthesis.

At this stage revision total hip arthroplasty was abandoned and we proceed to resection arthroplasty through a



Fig. 1: Twelve year control x-ray demonstrating bipolar loosening of a total Charnley prosthesis of the left hip.



Fig. 2: Postoperative control x-ray after femorortomy and prosthesis extraction.

large femorotomy [Figure 2] Several bacteriologic culture specimen and materials for pathologic examination were taken.

Empirical antibiotic treatment with Rifampicine 600mg and Ofloxacine400 was started.

The bacteriological culture were negative but serum antibody titer for Brucella was 1/320 and microscopic ex-



Fig. 3: Radiographic examination at two year follow up.

amination showed a brucellian granuloma. The antibiotic chemotherapy was maintained for 3 months, Ofloxacine wasn't changed because a history of digestive disagreement during the previous uses of Doxcycilline

A second stage of THA reimplantation was performed at the end of the antibiotic treatment period. At two years follow up the patient is pain free with total functional recovery and no clinical and radiographic signs of prosthetic loosening [Figure 3].

### Discussion

Infection is considered to be the most devastating of prosthesis-related complication, leading to prolonged hospitalization, repeated surgical intervention. The incidence of prosthetic joint infection (PJI) is 1-2.5% for primary hip or knee replacements and 2.1 - 5.8% for revision surgeries [12-14].

The majority of infections (65%) are caused by aerobic gram-positive cocci, most commonly Staphylococcus aureus, coagulase negative staphylococci and enterococci. Aerobic gram-negative bacilli, anaerobes and mycobacterial infection are far less frequent [15]. PJI due to Brucella is an extremely rare condition, and only 19 cases have been reported in the literature [16-28]. The demographic characteristics of the 19 cases and our patient are summarized in Table 1 [Table 1]. Among these patients, there were 12 men with a mean age of 59 years. Most patients had occupationnal exposure to brucella history of unpastorised milk products consumption and lived in areas where brucellosis

is endemic. The Hip was involved in 10 patients. Knees were involved in 8 patients with two bilateral cases. Systemic symptoms of brucellosis as fever, headache, weakness, sweetness, profuse sweating, splenomegalia, adenopathy are non specific and were present in only four cases. Local symptoms as night pain, swelling, local inflammation, sinus tract formation and restriction of the joint movement were present in nearly all cases. Radiographic signs of loosening were found in nine cases. The rate of isolation of brucella in patients with osteoarticular brucellosis oscillates between 33% and 77% [3]. In the reviewed cases culture of synovial fluid sample or tissue sample recovered brucella in 17 cases (85%). In one case the germe was isolated from a sinus tract discharge [28] and from blood samples in two cases [18,23]. Laboratory culture of brucella is often unsuccessful because of the slow-growing nature of these microorganisms and the requirement for special media and high Co2 tension. So the culture period should be made longer than usual and clinicians should notify the laboratory staff if there is a suspicion of brucellosis [29]. Negative joint culture result does not rule out osteoarticular brucellosis and the diagnosis can be made through the detection of specific antibodies in serum. In active brucellosis, high titers of IgM antibodies can be detected by standard agglutination and Rose Bengal tests, which are followed by an increase of IgG and IgA antibodies in chronic stage of the disease [30]. In our review 18 patients (90%) had positive titers of specific antibodies ( >=80) . Generally joint prothesis can become infected through three different routes: Implantation, hematogenic infection, and reactivation of latent infection [31]. In Brucellar PJI most of the authors support the hematogenous route [24]. Previous spinal brucellosis in our patient supports this septic pathogenesis of the articular involvement. Because of the rare occurrence of PJI caused by Brucella, there is no consensus on its management. The most accepted course is antibiotic treatment with removal or retention of prosthetic components [23]. A variety of drugs have activity against brucella, however the results of in vitro susceptibility tests do not always predict clinical efficacy [32]. The intracellular localization of brucella is believed to offer some protection against antimicrobials, and drugs with good penetration into cells are thought necessary for cure. Monotherapy for brucellosis has generally been considered inadequate due to unacceptably high relapse rate. Of the 20 cases that we reviewed, 14 were treated with double antibiotic therapy  $[\underline{16}, \underline{18}, \underline{20}, \underline{23}, \underline{25}, \underline{28}]$ , the most used association was Doxycylline and Rifampicine (8 cases) this association offers the advantage of an all-oral treatment and was recommended by the World Health Organization (WHO) in 1986 [33] and by Consensus "Loannina Recommendations" for

	Year	Age / sex	Implant	Exposure	Symptoms	Radiology	Surgical treatment	Antibiotic treatment	Recurrence	Follow up
Jones et al (16)	1983	54 /M	THA	Professional	Systemic	No Loosening	Surgical debridement	Doxycycline 6w/ Streptomycine6w	No	3у
Agarwall et al (17)	1991	24/f	02 TKA	No	local	No Loosening	NO	Rifampicine 19m/ cotrimoxazole19m	NO	19m
Malizos et al (18)	1997	74 /M	02TKA	Professional	Systemic	No Loosening	NO	Streptomycine 3w/ Doxycycline 5m	yes	2у
Orti et al (19)	1997	60 /M	TKA	Professional	local	No Loosening	NO	Doxycycline 6w Rifampicine 6w Streptomycine 3w	NO	8m
Ortega et al (20)	2002	63/M	THA	Professional	local	Prosthetic loosening	2 stage replacement	Streptomycine 3w Doxycycline 3m	NO	6m
Weil et al (21)	2003	38/M	THA	Unpastorised milk consumption	local	Prosthetic loosening	2 stage replacement	Doxycycline 12w Rifampicine12w	NO	1y
Weil et al (21)	2003	61/M	TKA	Unpastorised milk consumption	local	Prosthetic loosening	2 stage replacement	Doxycycline 12w Rifampicine 12w	NO	1y
Weil et al (21)	2003	67/M	ТКА	Unpastorised milk consumption	Systemic	Prosthetic loosening	2 stage replacement	Doxycycline 12w Rifampicine12w	NO	1y
Kasim et al (22)	2004	54/F	THA	No	local	Prosthetic loosening	1 Stage replacement	Vibramycin 5m Rifampicine5m	NO	4y
Cairo et al (23)	2006	50/M	THA	Professional	local	NR	NO	Doxycycline 26m Streptomycine 2w	NO	5у
Cairo et al (23)	2006	21/M	THA	Professional	local	NR	1 Stage replacement	Doxycylline 6m Rifampicine 6m Streptomycine 10d	NO	Зу
Tena et al (24)	2007	56/M	THA	Professional	local	Prosthetic loosening	2 Stage replacement	Doxycylline 2m Rifampicine 2m Streptomycine 2w	NO	4y
Ruiz-Iban (26)	2006	66/F	THA	Contact with Cattle	local	Prosthetic loosening	2 Stage replacement	Doxycylline 6w Rifampicine 6w	NO	5,5y
Ruiz-Iban (26)	2006	71/M	THA	Professional	local	No Loosening	Surgical debridement	Doxycylline 6m Rifampicine 6m Strptomycine 1m	NO	5y
Tassinari et al (25)	2008	68/M	TKA	NR	Systemic	No Loosening	NO	Doxycylline 8w Rifampicine 6w	NO	1y
Wunschel et al (28)	2011	64/F	TKA	NR	Local	Prosthetic loosening	1 Stage replacement	Doxycylline 8w Rifampicine 6w	NO	NR
Erdogan et al (27)	2010	63/F	TKA	Unpastorised milk consumption	local	No Loosening	NO	Doxycylline 4m Rifampicine 4m	NO	Зу
Our Case	2014	73/F	THA	Unpastorised milk consumption	Local	Prosthetic loosening	2 Stage replacement	Rifampicine 6m Ciprofloxacine 6m	No	6m

*Table1: Summuary of the reported cases in the literature* 

M= Male, F= Female ; TKA= Total Knee arthroplasty, THA= Total Hip arthroplasty ; y= years, m= Months, w= Weeks,

the Treatment of Human Brucellosis in 2006 [34]. The most used antibiotics are Doxycyclline in 15 cases, Rifampicine in 14 cases, Streptomycine in 8 cases, Vibramicyne in 1 case, cotrimoxasole in 1 case and ciprofloxacine in 1 case. In our patient, because of the digestive disagreement, we used flouroquinolone which is considered as an acceptable alternative to doxycycline [34]. The total duration of antibiotic therapy necessary for eradication of the infection is unknown. In the review antibiotic treatment lasted from 6 weeks to a maximum of 26 months. Six Weeks is the duration recommended by the WHO and the Loannina Consensus. In six cases out of twenty the infection resolved with the sole use of the antibiotic therapy without having to resort to surgical revision [17,18,19,23,25,27] in this patient there was no radiographic evidence of implant loosening. A single stage prosthetic revision was done in 3 cases but only because the infection had not been suspected from the beginning [22,23,28]. In 7 cases a two stages revision was done, this procedure is believed to be the treatment of choice for loosened total joint arthroplasty infected with brucella. In brucellosis, even with effective drug treatment, relapses occur in 5-10% of patients, usually in the early post-treatment period [34], in our review the infection was recurrent in only one patient out of twenty [<u>18</u>].

### Conclusions

Brucella should be evocated as a cause of total joint arthroplasty infection especially in patients from endemic regions and with occupational exposure. Antibiotic treatment alone can be followed if there are no signs of implant loosening. Tow stage revision should be considered in other cases.

### Disclosure

The authors declare that there is no conflict of interest regarding the publication of this paper. For full disclosures refer to last page of this journal.

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	Therapeutic Studies – Investigating the results of treatment	Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic Studies – Investigating a diagnostic test	Economic and Decision Analyses – Developing an economic or decision model					
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Level II	<ul> <li>Lesser quality RCT (e.g. &lt; 80% follow- up, no blinding, or improper randomization)</li> <li>Prospective<sup>4</sup> comparative study<sup>5</sup></li> <li>Systematic review<sup>2</sup> of Level II studies or Level 1 studies with inconsistent results</li> </ul>	<ul> <li>Retrospective<sup>6</sup> study</li> <li>Untreated controls from an RCT</li> <li>Lesser quality prospective study (e.g. patients enrolled at different points in their disease or &lt;80% follow-up.)</li> <li>Systematic review<sup>2</sup> of Level II studies</li> </ul>	<ul> <li>Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)</li> <li>Systematic review<sup>2</sup> of Level II studies</li> </ul>	<ul> <li>Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses</li> <li>Systematic review<sup>2</sup> of Level II studies</li> </ul>					
Level III	<ul> <li>Case control study<sup>7</sup></li> <li>Retrospective<sup>6</sup> comparative study<sup>5</sup></li> <li>Systematic review<sup>2</sup> of Level III studies</li> </ul>	• Case control study <sup>7</sup>	<ul> <li>Study of non- consecutive patients; without consistently applied reference "gold" standard</li> <li>Systematic review<sup>2</sup> of Level III studies</li> </ul>	<ul> <li>Analyses based on limited alternatives and costs; and poor estimates</li> <li>Systematic review<sup>2</sup> of Level III studies</li> </ul>					
Level IV	Case Series <sup>8</sup>	Case series	<ul><li>Case-control study</li><li>Poor reference standard</li></ul>	• Analyses with no sensitivity analyses					
Level V	Expert Opinion	Expert Opinion	Expert Opinion	Expert Opinion					

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Article 2, page 19. McCabe [1]; Pickford [1]; Shawcross [1]

Article 3, page 27. Pierrepont [2]; Stambouzou [3]; Miles [2]; O'Connor [2]; Ellis [1]; Molnar [1]; Baré [2]; Solomon [2]; McMahon [2]; Shimmin [2]; Li [1]; Walter [2]; Marel [2]

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