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To cite this article: HLD Hoskin et al 2017 J. Phys.: Conf. Ser. 843 012019

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Mechanics and complications of reverse shoulder arthroplasty: morse taper failure analysis and prospective rectification

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Abstract. Since Sir John Charnley began his monumental hip arthroplasty work in 1958, clinical researchers have been incrementally improving longevity and functionality of total joint systems, although implant failure occurs on occasion. The purpose of this study is to report the fracture of the humeral tray Morse taper of a reverse total shoulder system (RTSS), which to date has not been reported with metallurgic analysis for any RTSS. There was no reported antecedent fall, motor vehicle collision, or other traumatic event prior to implant fracture in this case. Analysis was performed on the retrieved failed implant by Scanning Electron Microscopy (SEM) and Electron Dispersive Spectroscopy (EDS) in an attempt to determine the failure method, as well as to offer improvements for future implants. At the time of revision surgery all explants were retained from the left shoulder of a 61-year old male who underwent a non-complicated RTSS 4 years prior. The explants, particularly the cracked humeral tray, were processed as required for SEM and EDS. Analysis was performed on the failure sites in order to determine the chemical composition of the different parts of the implant, discover the chemical composition of the filler metal used during the electron beam welding process, and to detect any foreign elements that could suggest corrosion or other evidence of failure etiology. Gross visual inspection of all explants revealed that implant failure was a result of dissociation of the taper from the humeral tray at the weld, leaving the Morse taper embedded in the humeral stem while the tray floated freely in the patient’s shoulder. SEM further confirmed the jagged edges noted grossly at the weld fracture site, both suggesting failure due to torsional forces. EDS detected elevated levels of carbon and oxygen at the fracture site on the taper only and not on the humeral tray. In order to determine the origin of the high levels of C and O, it was considered that in titanium alloys, C and O are used as stabilizers that help raise the temperature at which titanium can be cast. Since the presence of stabilizers reduces ductility and fatigue strength, all interstitial elements are removed after casting. Considering this, the presence of C and O suggests that not all of the interstitials were removed during the manufacturing process, resulting in decreased fatigue strength. Further destructive analytical testing would verify weld quality and failure mode. RTSSs are quite successful in select patients not amenable to traditional shoulder arthroplasty options. This case report highlights how an implant may function well for several years and then suddenly fail without warning. SEM and EDS analysis suggest that residual C and O in the taper lowered the metal implant’s integrity, leading to torsional cracking at the weld junction of the humeral tray and the taper. The elevated levels of C and O measured at fracture sites on both the tray and the taper suggest poor quality filler metal
or failure to remove all interstitial elements after casting. In both cases, the results would be decreased fatigue strength and overall toughness, leading to mechanical failure. A manufacturer’s recall of all implants soon followed the reporting of this implant failure; subsequently, the metal materials were changed from Ti₆Al₄V to both titanium alloy and cobalt-chrome alloy (Co-Cr-Mo). Time will tell if the alterations were sufficient.

1. Introduction

Total joint arthroplasty has been regarded as one of the most efficacious orthopedic interventions of its time. Though inhibiting patients’ ability to participate in most high-impact activities post operation, joint replacement hip and total shoulder systems provide significant pain relief and increased mobility for patients suffering from osteoarthritis or other instances of cartilaginous degeneration [1]. Analysis of the mechanics and complications of total hip arthroplasty has led to experimentation with various materials, including titanium, cobalt-chrome, polymers, and ceramics [2]. This wide range of material options has allowed surgeons to offer patients implants specific to patients’ ages, individual lifestyles, and activity levels. A significant amount of total hip arthroplasty research focuses on optimizing implant materials to withstand pressure, loading, and friction that the acetabular joints undergo on a day to day basis [3]. As newer shoulder procedures are developed and perfected, previous research on total hip devices serves as a predicate in creating safe, effective systems. However, as the acetabular and glenohumeral joints vary in more than basic anatomy, different methods of testing are needed for total shoulder systems and RTSSs.

The reverse shoulder design incorporates a socket where the head of the humerus is normally located and a ball where the glenoid is normally situated; by switching the components of a normal shoulder, greater stability is added. The configuration allows the deltoid to elevate the shoulder in place of the rotator cuff muscles, helping patients to overcome shoulder pseudo-paralysis and carry out basic shoulder functions on a daily basis [4]. Although both total shoulder and RTSSs are generally successful, cases of both non-mechanical and mechanical failure have been reported. Previously recorded issues include glenoid component disengagement (Fig. 1), loosening of humeral stem/metaphysis resulting in interfragmentary strain (Fig. 2), and Morse taper dissociation (Fig. 3). In nearly all cases, the failures were not reportedly caused by single incidents [5].
Examples of mechanical failure bring into question the integrity of the metal. In one case, a patient had a RTSS implanted for about 3 years before developing pain and "clunking" noises. Radiographs revealed glenosphere disengagement as well as detachment of the humeral tray from the stem (Fig. 4) [5]. The taper dissociated from the humeral tray at the weld, leaving the taper embedded in the humeral stem while the tray floated freely in the patient’s shoulder (Fig. 5). Note jagged edges at the fracture site, which suggest failure due to torsional forces (Fig. 6).

![Fig. 4 Post-operative film of completed, fully functional reverse total shoulder system (Ref. 11).](image1)

![Fig. 5 Radiographic findings reveal disengaged glenoid component and dissociation of the humeral tray (Ref. 11).](image2)

![Fig. 6 Separated tray (still attached to polyethylene cup) and taper removed from patient. Note jagged edges of fracture site (Ref. 11).](image3)

FDA testing requirements for total hip and total shoulder procedures differ mostly in that the shoulder is not usually subjected to the greater axial loading and torsional forces the hip experiences on a daily basis [6]. Testing processes consider glenohumeral joint flexibility, reduced loading, and greater range of motion (higher tendency for instability and/or dislocation) than the acetabular joint [7]. RTSSs are newer and not as thoroughly researched as total hip procedures; revisions to FDA testing and requirements for RTSS implants are needed. Fatigue strength, biocompatibility, and other requirements must be verified as adequate for the new RTSSs, as there is considerable difference in forces on the shoulder and hip. The recent development of RTSS as a surgical intervention has been coupled with greater incidence of morbidity in these new systems, as is common in the early phases of the innovation of any new technique. Failure of the original RTSS system has guided research to refine and implement improvements to the designs, materials, instrumentation systems, and the procedures themselves.

Author EF offers a similar case that prompted this review and eventually became the foundation for this case report. In part, he summarized, “A 61-year-old male was evaluated 4 years following a non-complicated left RTSS. The patient was doing well until the sudden onset of pain, “heaviness” and limited motion after light lifting, coming in approximately 3 weeks after the onset of symptoms. Physical exam revealed no obvious deformity. Motion was limited to 90 degrees flexion, 75 degrees abduction and 45 degrees external rotation passively with pain. No evident open wounds, swelling, ecchymosis or erythema. Radiographic evaluation revealed a separation of the humeral tray at the trunnion with retention of the reverse Morse taper humeral component within the stem. Despite aggressive efforts to remove the taper, it remained within the humeral stem.” EF also noted no antecedent trauma prior to the catastrophic RTSS failure. Fig. 7 displays the radiograph of the separated humeral tray/taper component. Also pictured is the stem/taper and tray once removed from the patient; note how the edges of the fracture site are relatively smooth compared to those viewed in the former example (Fig. 8).
2. Materials & Methods

At the time of revision surgery all explants were retained from the left shoulder of a 61-year-old male who underwent a non-complicated RTSS 4 years prior. The explants were processed as required for SEM and EDS. Analysis was performed on the failure sites in order to determine the chemical composition of the different parts of the implant, discover the chemical composition of the filler metal used during the electron beam welding process, and to detect any foreign elements that could suggest corrosion or other evidence of the cause of failure.

Analysis of the failed implant began with separation of the Morse taper from the humeral stem; the taper was so firmly inserted that the insertion site at the superior end of the stem had to be cut out with a Dremel handheld rotary tool (Fig. 9). During the procedure to fix the failed RTSS, surgeons aggressively attempted to remove the dissociated taper from the stem using pliers or a similar device. The removal attempts badly damaged the surface of the trunnion at the tray/taper connection, making taper analysis more difficult than that performed on the tray (Fig. 10).

SEM imaging was executed on both the fracture site along the rim of the humeral tray and the trunnion of the taper, as shown in Figs. 11-16. Electron Dispersion Spectroscopy (EDS) was performed on the failure sites in order to determine the chemical composition of the implant, discover the composition of the filler metal used during the electron beam welding process, and to detect any foreign elements that could suggest corrosion or other evidence of the cause of failure [8]. EDS of the inner rim of the humeral tray revealed unusually high levels of C and O. EDS was also performed on both compromised and uncompromised sections of the trunnion of the Morse taper (Fig. 18). EDS was executed on the smooth shaft, uncompromised fracture site, and a compromised area, which provided chemical composition data of three separate areas for comparison. Slightly elevated but insignificant levels of C and O were detected at the fracture site on the taper, and significant levels were detected on the humeral tray.
3. Results
Gross visual inspection of all explants revealed that implant failure was a result of Morse taper dissociation from the humeral tray at the weld. SEM further confirmed the likelihood of torsional failure due to the presence of jagged edges at the fracture site. EDS detected elevated levels of C and O at the edge transition of the humeral tray and not on the taper. Fig. 17 (area 3) indicates the presence of various elements, transitioning from the planar area of the tray to the inner rim. Comparison of the presence of elements on the planar area of the tray, the edge of the inner rim, and on the inner rim itself enabled determination of failure method. The presence of other trace elements (Na, P, Si, Cl, etc.) was assumed to be due to handling during testing.
EDS was performed on both compromised and uncompromised sections of the trunnion of the Morse taper (Fig. 18). EDS was executed on the smooth shaft, uncompromised fracture site, and a compromised area. Insignificant levels of C and O were detected at the fracture site on the taper, and lack of foreign elements suggests that either no filler metal was used to weld the two pieces together, or that the filler metal is also composed of Ti₆Al₄V.

4. Discussion
Fatigue testing for acetabular and glenohumeral joints is designed for each joint based on primary function. The contact between the acetabulum and femoral head is much broader and closer than the contact between the glenoid and the humeral head; in the shoulder, this implies greater range of motion but decreased stability [9]. In order to determine the respective joint loads and muscle forces during active motion, one study applied five advanced biomechanical techniques to obtain clinically relevant data regarding joint loading. Techniques included in vivo instrumented implants to capture joint forces and movements, load sensors to assess external forces such as ground reaction forces, and synchronized...
data of joint loads, external loads, and skeletal motion as applied to a musculoskeletal computer model for the calculation of muscle forces and muscle activation patterns, among other testing methods. In the hip, peak loading reaches 270% of body weight during walking and 520% during running. Climbing stairs induces similar peak forces with an 80% increase in rotational movements. Glenohumeral contact forces range up to only 130% of body weight when performing daily activities, although concentration of forces varies as the center of gravity is altered [3]. Activities inducing forces of 150% of body weight or more such as doing a handstand are not typically executed by patients who have undergone total shoulder arthroplasty [10]. Successful total joint arthroplasty in the shoulder must be preceded by careful consideration of dependency on ligaments and thorough biomechanical analysis of joint constraints and motion; incorrect placement or poor balancing can result in undue joint loading and wear, as well as instability [9].

In titanium alloys, carbon and oxygen are used as stabilizers that help raise the temperature at which titanium can be cast. Since the presence of stabilizers reduces ductility and fatigue strength, the interstitial elements are removed after casting [11]. Considering this, the presence of C and O could suggest that not all of the interstitials were removed during the manufacturing process, resulting in decreased fatigue strength. The presence of C and O might also be attributed to various bodily deposits. The lack of significant traces of foreign elements suggests either no filler metal was used or a Ti_6Al_4V filler metal. According to the American Filler Metals Company, a titanium alloy surgical implant should be Grade 23 Ti_6Al_4V with a filler metal of equal composition and grade. Grade 23 titanium alloy has lower levels of Al, C, O, and other interstitial elements to improve toughness, fabricability, and weldability [11]. Additional destructive metallurgical examination is required to evaluate the nature and location of residual C, O, and other metal processing aids. To eliminate residual biological deposits, a combination of solvent cleaning and high temperatureashing procedures could be undertaken.

In the summer of 2011, the FDA posted a recall notice for three sizes of the Biomet standard RTSS humeral tray with locking ring, due to possible faulty locking ring mechanism on the humeral trays [12]. The 510(k) summary report submitted several months later, dated January 11, 2012, acknowledged product improvement as the reason for the submission [6]. The materials composing the humeral tray were changed from Ti_6Al_4V to both titanium alloy and cobalt-chrome-molybdenum alloy (Co-Cr-Mo). Using the Vicker's hardness values for measurement, CoCrMo has a higher hardness value than Ti6Al4V; conclusively, CoCrMo is more fracture resistant than Ti_6Al_4V due to its greater interfacial adhesion strength and stronger surface oxide [13]. CoCrMo is less biocompatible than titanium alloy but much stronger [9], but in view of the elderly age of most patients in which the new system is utilized, negative effects such as metallosis would most likely take more time than the patient's remaining lifespan to set in. Taking into consideration the health and well-being of the patient, the sacrifice of some biocompatibility for the sake of producing stronger implants was a decision that positively influenced total shoulder and RTSS development.

5. Conclusions
RTSSs have reportedly been quite successful in select patients not amenable to traditional shoulder arthroplasty options. This case report highlights how an implant may function well for several years and then suddenly fail without warning. New information guides both development and improvement of total shoulder and RTSSs and surgical techniques. The total hip is barely 125 years old; technological advancements since then have led to better-engineered implants, extended life due to reduced wear properties, and better personalization of anatomical replacements to sustain normal joint movement.

Based on the results gathered from SEM and EDS analysis, it is likely that several factors contributed to the mechanical failure of the implant. The striations observed on the uncompromised areas of the taper (Figs. 13, 14, 15, 18) are an indication of brittle-like failure, most likely caused by fatigue. The combination of rotational and toggle-like forces acting on the weld site produced wave movements [14]. This wave-like motion would have occurred any time the patient engaged in activities requiring flexion, abduction, and/or external rotation, and constant cyclic loading over the course of nearly four years ultimately resulted in failure of the implant. Once enough brittle-like failure had occurred over time,
the trunnion of the taper pulled away from the humeral tray, fully separating the pieces by means of ductile rupture (Fig. 19) [15].

![Fig. 19 SEM imaging of Morse taper failure site indicates brittle-like failure resulting from fatigue as the initiation of the failure (outlined in blue). Ductile rupture occurred when enough brittle damage had been done, and the taper could no longer handle the cyclic loading (green).]

Despite the cyclic loading and forces placed on the shoulder during everyday activities, the main issue surrounding the failure of this implant is the poor design of the system. The entire system is undersized considering the actions the shoulder is expected to be able to carry out; the short length of the Morse taper, thinness of the humeral tray, weaker metal system, and small surface area of the weld site between the taper and tray all pose probable causes of failure. Fortunately, the design flaws of this particular system were quickly recognized, and engineers took action to recall the titanium alloy implants, recasting the pieces using stronger materials. Time will tell if the alterations were sufficient.

6. References

