Metal-on-metal total hip arthroplasty: does increasing modularity affect clinical outcome?

Kevin C Ilo, Harry S Hothi, John A Skinner and Alister J Hart

Abstract

Background: Modularity of metal-on-metal (MoM) implants has come under scrutiny due to concerns regarding additional sources of metal debris. This study is a retrieval analysis of implants from the same manufacturer with the same MoM bearing surface. The difference between the implants was presence or absence of modular junctions. Methods: This is a retrospective study of 31 retrieved implants from 31 patients who received a Conserve Wright Medical MoM hip prosthesis. The 31 implants consisted of 16 resurfacings and 15 implants with modular junctions; 4 conventional THAs and 11 modular-neck THAs.

Results: 43% of pre-revision MRI scans performed on resurfacing implants and 91% performed on the modular implants illustrated evidence of an adverse local tissue reaction. There was no difference in pre-revision blood metal ion levels or bearing surface wear between the resurfacings and modular implants. The neck-head tapers of the modular group showed low levels of material loss. However, the neck-stem tapers showed increased severity of corrosion and material loss

Conclusions: The modular implants had an increased incidence of adverse local tissue reaction. This could be related to the presence of modular junctions, particular the neck-stem junction which showed increased susceptibly to corrosion

Introduction

Modular implants were introduced to improve flexibility and restoration of individual biomechanics.[1,2] High failure rates have led to recalls of certain designs.[3] Dual-modular femoral stems such as the ABG2 and Rejuvenate (Stryker, Mahwah, NJ, USA) were recalled in July 2012 as a result of high revision rates. A PROFEMUR (Wright Medical Group Inc, Arlington, TN, USA) modular neck device; the PROFEMUR Neck Varus/Valgus cobalt chromium 8 degree, was recalled in August 2015 due to unexpected rates of fracture. Although increasing modularity did ini- tially appear attractive, higher than expected failure rates are alarming. In this study, we analysed failed implants from the same manufacturer with the same bearing sur- face. The only difference between them was the absence or presence of modular junctions. Our aim was to investigate whether implant function and survival was affected by the presence of modular junctions.

Methods

This is a retrospective study of 31 retrieved implants from 31 patients who had received a Conserve Wright Medical (Memphis, TN, USA) metal-on-metal (MoM) hip prosthe- sis. The bearing surface materials are the same for the dif- ferent designs and are manufactured from high carbon cast cobalt chrome alloy. The Conserve Wright MoM hip designs are resurfacings, conventional THAs and modular- neck THAs (Figure 1). The THA designs have a range of different femoral stem choices.

Implants were collected at a national MoM implant retrieval centre (Table 1). The patient cohort included 13 men and 18 women with an average of 67 (range 35–79) years at the index procedure. The 31 implants consisted of 16 resurfacings and 15 implants with modular junctions; 4 conventional THAs and 11 modular-neck THAs. The modular neck components provided a combination of 4/8/15 degrees of anterversion or retroversion and 6/8/15 degrees of varus or valgus (neutral = 135°).

Demographic, imaging and blood metal ions data

Patient demographics were collected (Table 2). Pre- revision whole blood cobalt and chromium ion levels and imaging data were collected. All imaging (including mag- netic resonance imaging [MRI]) were reported by an experienced musculoskeletal radiologist to evaluate any adverse local tissue reactions (ALTR).

Measurement of material loss. Volumetric wear from the bearing surfaces and head taper junction was measured. Material loss from the bearing surfaces was measured using a Zeiss Prismo (Carl Zeiss, Ltd., Rugby, UK) coordinate measuring machine utilizing a previously described proto- col.[5] Data was analysed using a previously described method, to determine volumetric wear from each bearing surface.[6]

To assess the volume of material loss from the head- neck taper junction of the conventional and modular neck THAs, a Talyrond 365 (Taylor Hobson, Leicester, UK) out-of-roundness instrument was used to measure taper surfaces using a previously described protocol.[6] The female taper of the head-neck junction was measured as its material loss is a similar magnitude to the bearing surfaces, in contrast to the male taper.

Currently there is not reliable way of determining mate- rial loss from the neck-stem taper junction as the unworn shape of the taper surfaces cannot be accurately deter- mined. To estimate the material loss of the neck-stem taper, we used the Talyrond 365 to take a series of 14 verti- cal straightness profiles along the axis of the neck-stem taper surfaces. These traces were used to estimate the max- imum linear deviation (equal to the maximum depth of material loss) on each surface.

Visual analysis

All tapers of the THAs were assessed for corrosion. For the conventional proximal taper, each male and female taper surface was inspected macroscopically with a Leica M50 light microscope (Leica Microsystems, Germany) at up to ×40 magnification. A well-published classification method was used to grade

each surface with a score of 1 (no corrosion), 2 (mild corrosion), 3 (moderate corrosion) or 4 (severe corrosion). This method has been demonstrated as being repeatable and reproducible.[7]

A visual analysis method, modified from Goldbergs' method,[8] was performed for the distal neck-stem taper. Corrosion was scored using a scale of 1 (corrosion evident on <10% of surface) to 4 (corrosion evident on >50% of surface). Fretting was not quantified due to the difficulties in the identification and quantification of fretting from pre- vious experience.[7] The explanted stems taper surfaces were also examined for evidence of surface damage. A scanning electron microscope (SEM, Joel JSM5500, Tokyo, Japan) was used to perform detailed microscopic analysis of areas of interest highlighted from the macro- scopic inspection on the neck-stem male taper surface.

Sectioned stem

A modular stem was sectioned in order to facilitate visual analysis of its female taper. Energy-dispersive x-ray spectros- copy (EDX) was performed to analyse the chemical charac- terisation of corrosive debris within the modular junction.

Results

Indications for revision are illustrated in Table 3.

Blood metal ions

Whole blood cobalt and chromium levels are illustrated in Figure 2. In the resurfacings group the median cobalt and chromium levels were 8.3 ppb and 7.4 ppb respectively. In the modular group the median cobalt and chromium levels were and 8.4 ppb and 3.4 ppb respectively and there was no statistically significant difference in cobalt (p=0.683) and chromium (p=0.440) between the resurfacings and modu- lar group. The mean ratio of Co/Cr was 1.08 in the resurfac- ing group and 1.45 in the modular group (p = 0.358).

Bearing surface wear

There was no statistically significant difference between the wear rates of the cup (p=0.86), head (p=0.103) and combined (p = 0.075).

Taper junction wear

The taper of the THA acetabular heads was measured for material loss. The modular-neck implants (median 1.164mm^3/year, range 0.16–3.94) did not have a statisti- cally significant difference in the material loss at this taper junction when compared to conventional THA (median 1.93 mm^3/year, range 0.21–3.67).

Material loss at the neck-stem taper junction

Straightness traces of the 11 male, neck-stem taper demon- strated surface damage with areas of material deposition and material loss with a maximum depth of 58.17 microns (Figure 3).

Visual analysis of taper junctions

All head-neck tapers of the modular group showed mild to moderate evidence of corrosion (mean 2, 95% confidence interval [CI], 1–2). However, the neck-stem taper showed mainly moderate to severe corrosion (mean 3; 95% CI, 2–3).

A modular neck stem was section to aid visual analysis. The trunnion showed evidence of corrosive debris present (Figure 4). Scanning electron microscope (SEM) images showed evidence of a corroded surface with corrosive debris and pitting (Figure 5).

Imaging

Pre-revision MRI scans were performed for all of the resurfacings group (*n*=16) and 11 in the modular group (*n*=15). 43% of pre-revision MRI scans performed on resurfacing implants and 91% performed on the modular implants illustrated evidence of ALTR. Radiographs were unremarkable apart from 1 modular neck implant showed extensive osteolysis of the greater trochanter.

Discussion

MoM bearing surface for THA improves wear properties in comparison to metal-on-polyethylene. Although this is desirable for hip prostheses, there are concerns regarding metal debris release.[9,10] Metal debris produced from bear- ing surfaces has a large surface area and is small in size, the small particle size leads to large number of particles for a given wear volume compared to metal-on-polyethyl- ene bearings.[11] For resurfacings, metal debris release is from the bearing surface, whereas conventional and mod- ular neck THA have taper junctions which are additional sources of metal ion release. Modular-neck THA permits optimisation of hip biomechanics but taper junction cor- rosion results in further biologically active metal debris.[12] This cohort showed no statistically significant difference in wear rates between resurfacings and modular implants. The majority of the retrievals had shown levels of wear within expected limits. There were a small number of resurfacings which exhibited large amounts of volumetric wear from the head and the cup components. These implants illustrated a wear pattern equivalent to edge loading, which affects resurfacings more due to retention of the neck which can lead to impingement-type edge loading.[13] Edge-loading occurs in a mal-positioned pros- thesis, It has been shown that other factors such as stem subsidence and tissue laxity could facilitate edge loading and lead to implant failure.[14] Nonetheless, there is signifi- cant importance in implant design and insertion in its opti- mum position.[14]

Corrosion at taper junctions is reported to be a cause failure of hip implants.[10,15] Hip resurfacing implants are exempt as they do not contain a taper junction. In this study, the modular group consisted of conventional and modular-neck THAs. The head-neck male tapers were measured for material loss and this was relatively low, visual analysis of this junction also did not indicate severe corrosion. Measuring material loss from the neck-stem junction of dual-modular implants is challenging. Linear measurements of the male taper of the neck-stem junction illustrated that this surface can undergo severe damage and material loss. Mechanical *in vitro* studies of modular-neck implants show that at the neck-stem taper junction there is potential for micromotion resulting in fretting and corro- sion.[16] We used visual corrosion scores to assess the changes at this taper junction. Matthies et al.[6] showed that scoring systems for corrosion and fretting are correlated with material loss, although this was for the neck-head taper. In this study, the stem-neck taper junctions exhibited a greater severity of corrosion than the head-neck taper junction. Nearly all stem-neck taper junctions of the mod- ular-neck THA illustrated moderate to severe corrosion.

Corrosion is an inevitable complication of implant design and metallurgy. Mixed alloy couples at modular junctions contribute to greater corrosion as the 2 alloys have different properties. The titanium alloy of the stem is softer and its oxide layer is more susceptible to fracture than the cobalt chromium alloy, therefore when coupled the corrosion and fretting resistance may be effected. However, conventional THA tapers and the modular neck- stem taper are both mixed alloy couples, yet the modular neck stem tapers exhibited greater corrosion. Mechanically- assisted crevice corrosion explains how mechanical load- ing can cause fretting, fracture of passive oxide films, repassivation and crevice corrosion.[17] The increased corro- sion at the neck-stem junction is likely due to many fac- tors. Greater micromotion at the neck-stem taper junction has been shown with modular-neck hip prosthesis, likely caused by a 20-fold larger lever arm between load applica- tion and taper engagement.[18] Also, tolerances of the neck- stem junction can lead to a gap between the taper surfaces.[19] This gap can facilitate micromotion and promote crevice corrosion. The mixing of metals at the neck-stem junction can hypothetically promote galvanic corrosion. This is concerning as metal debris from taper junctions may have a greater clinical impact than that from bearing surfaces.[15]

In this study, 1 modular-neck stem component was sec- tioned to better visualise the stem trunnion. Severe damage secondary to corrosion was evident. A hypothetical benefit of modular implants is a well-fixed stem can potentially be left *in situ* during revision surgery. However, with dual modular prosthesis the question arises whether a well- fixed stem should still be explanted as the neck-stem taper is susceptible to damage secondary corrosion.

Chromium and cobalt alloys are popular for use in MoM prosthesis, excellent wear properties make it attractive for use in bearing surfaces. However, the clinical relevance of this debris is not fully understood. There are results show- ing that the elevated blood metal ion levels leads to a greater chance of an adverse outcome and that cobalt is the more clinically relevant metal responsible for adverse tissue reactions.[20] Also, exposure to high levels of these elements can lead to osteolysis, carcinogenic, teratogenic and aller- genic responses.[21,22] Therefore, blood metal ion levels have been used to monitor MoM hip implants. In this cohort of retrievals, there was no statistically significant difference in blood metal ion levels between the resurfacing and modular groups, even though the modular groups had taper junc- tions which is additional source of metal ion release. There are reports that Co/Cr ratio might be a tool for detecting taper corrosion as it is speculated that there is a greater release of cobalt compared to chromium at taper junc- tions.[23] In a study by Laaksonen et al.,[24] they found a Co/Cr ratio of 1.4 was highly sensitive to ALTR and indepen- dently predictive of ALTR presence. In this study, the mean Co/Cr ratio for the modular group was 1.45 (resurfac- ings = 1.08). Pre-revision MRI scans showed that there was evidence of an ALTR in 43% of the resurfacing group and 91% of the modular group. Metal debris stimulates a host inflammatory response mainly due to macrophage activa- tion.[25] A study by Xia et al.[26] showed that tissues from patients with dual modular implants have a higher amount of lymphocytes and tissue destruction when compared to conventional THA and resurfacings. The amplified inflam- matory response to taper debris may explain the increased presence of ALTR within the modular group of retrievals.

In this study, there was 1 modular-neck implant which radiographs illustrated worsening osteolysis of the greater trochanter that occurred over a period of time. The retrieved implant showed wear of the bearing surface wear and the neck-head taper within expected limits, however visually the stem-neck taper had moderate cor- rosive damage. There are reports of ALTR reactions caused solely by metal debris from taper junctions, in the presence of a non-metal articulating surface.[27] For MoM implants, it is difficult to ascertain whether such reactions can be attributed to metal debris solely from taper junc- tions, bearing surfaces or from all sources. ALTR are not always associated with high wear volumes.[28] Both cobalt and chromium are known to be cytotoxic and can initiate an immune response.[29] This can result in periprosthetic osteolysis but some studies have shown cobalt and chro- mium to be mutagenic and genotoxic.[30] It is beneficial to minimise the volume of wear debris, but patient-related factors need to be further understood. The combination of macrophage-induced necrosis and T-lymphocyte medi- ated hypersensitivity reactions may explain differences in thresholds of toxicity, sensitivity and response to metal debris amongst individuals.[30] This may explain why there are many well-functioning hip implants with MoM bear- ing surfaces and modular junctions. Further research is required to understand the clinical significance of mod- ular junctions and patient related factors which may increase susceptibility to metal debris.

Limitations

This study discussed findings from a small cohort of retrieved Conserve hip implants and, therefore, does not represent all of those implanted. We are not able to com- ment on the failure rate of the Conserve hip compared to other manufacturers and designs. Also, the number of retrievals is not enough to draw significant conclusions regarding the performance of this implant.

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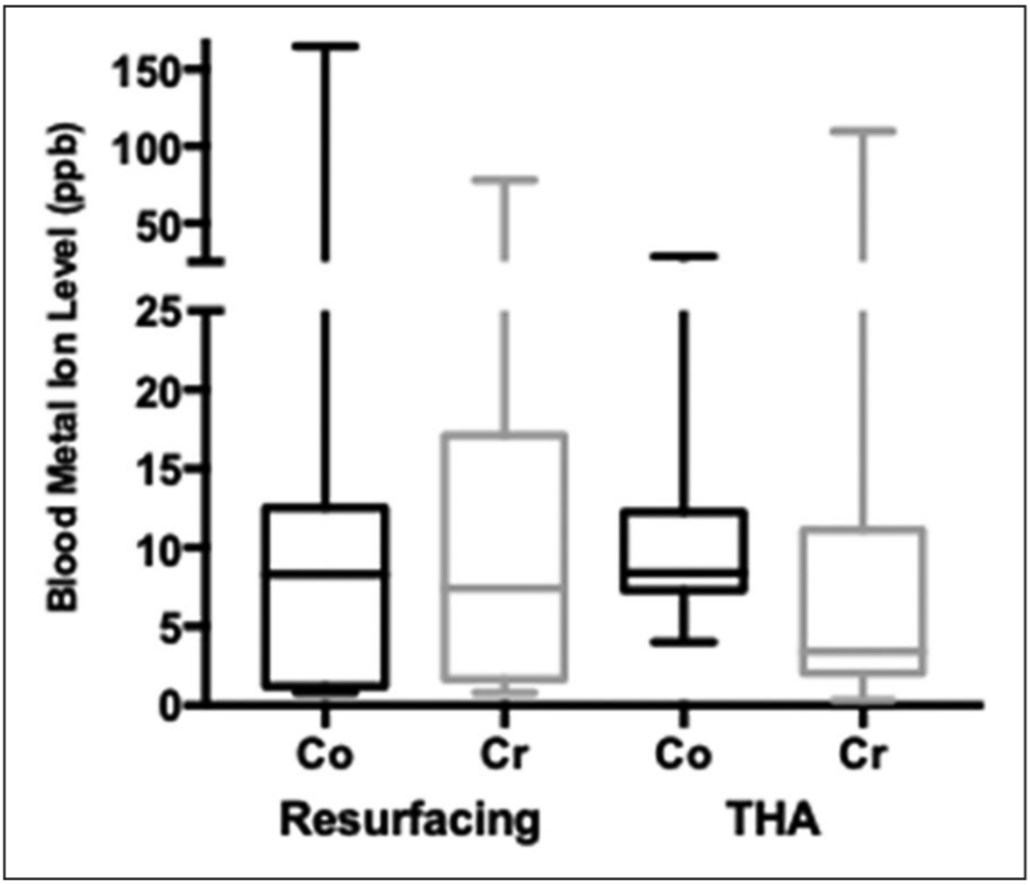
Figure 1



Blood Metal Ion Level (ppb)
150
100
50
25
20
15
10
5
0
Co
Cr
Co
Cr
Resurfacing
THA

Figure 2

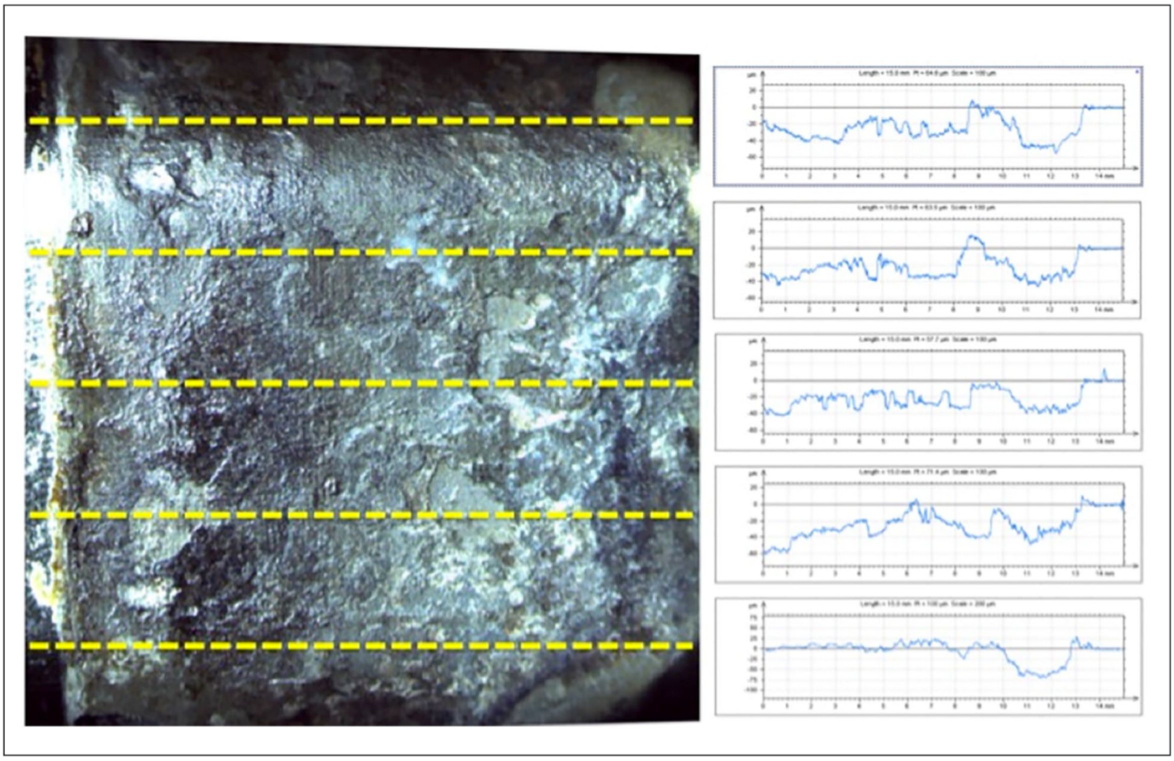


Figure 3

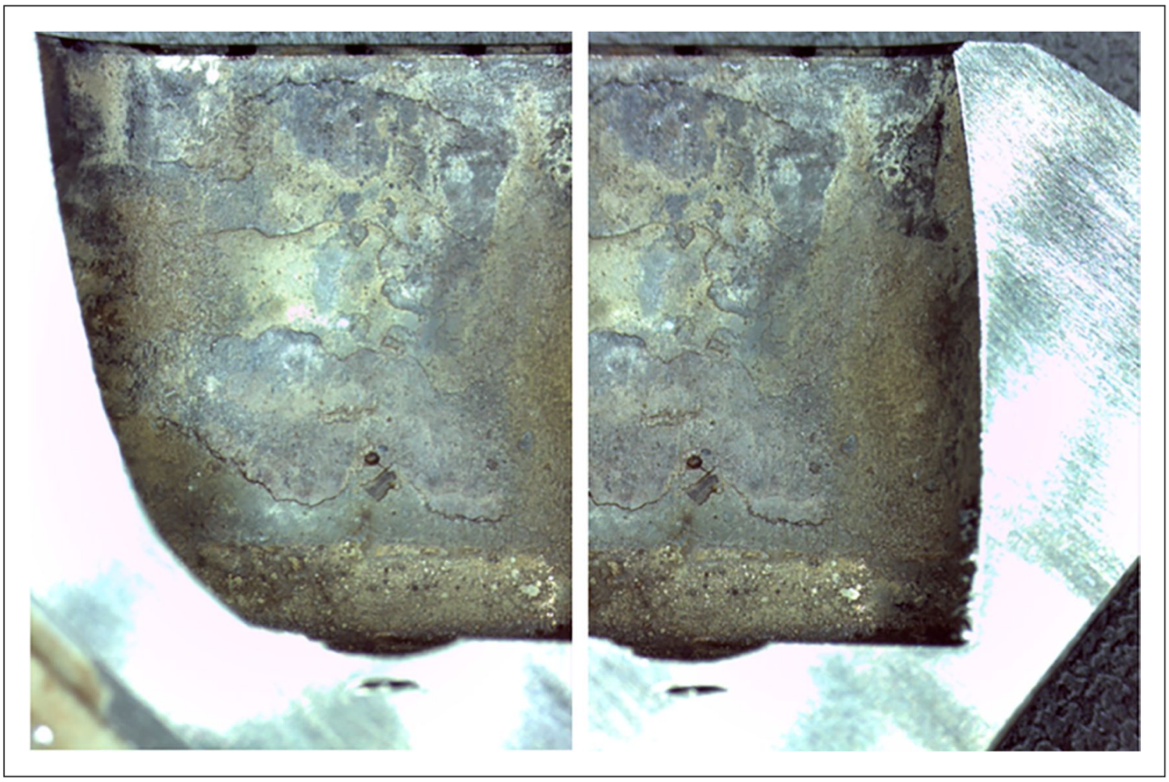


Figure 4

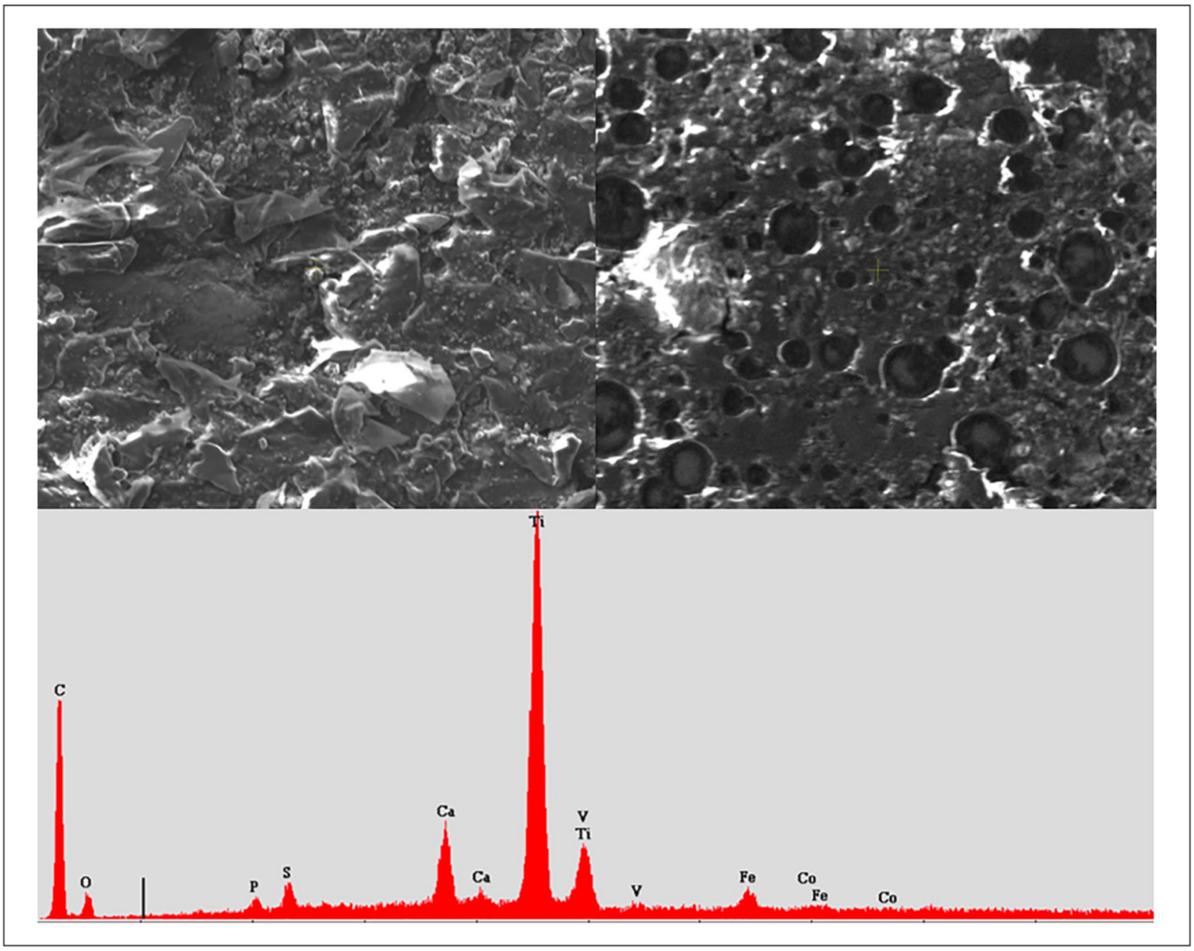


Figure 5