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MATERIAL FAILURE OF AN AISI 316L STAINLESS STEEL HIP PROSTHESIS

NAPAKE MATERIALA V KOLČNI PROTEZI IZ NERJAVNEGA JEKLA AISI 316L

Matjaž Godec
Institute of Metals and Technology, Lepi pot 11, 1000 Ljubljana, Slovenia
matjaz.godec@imt.si

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One of the major successes of modern surgery is the total replacement of joints by timplantation of prosthetic components by which the pain is relieved and deformity is corrected. The aseptic loosening of a prosthetic-joint component is the most common reason for joint-revision surgery. Furthermore, it is thought that wear particles are one of the major contributors to the development and perpetuation of aseptic loosening. It was ascertained that besides wear particles originated from polyethylene acetabular cup, the main reason of loosening hip prosthesis was due to the material failure. Based on stem material examination by different techniques it was found out that improper microstructure caused additional abrasion by hard particles and aseptic loosening took place.

Keywords: hip prosthesis, aseptic loosening, wear, stainless steel, polyethylene, non-metallic inclusions

Velik uspeh moderne kirurgije je med drugimi tudi popolna nadomestitev sklepov s protetičnimi nadomestki, s katerimi se omilijo bolečine in korigira deformacija. Pogosto pride do aseptičnega omajanja in potrebe po ponovni operaciji. Vzrok za to je ravno v obrabi in nastanku drobnih obrabnih delcev, ki večinoma vodijo do komplikacij in omajanja proteze. V raziskavi smo pokazali, da je poleg delcev, ki so izvirali iz polietilenske čašice bil glavni razlog omajanja ravno v napaki materiala. Na osnovi analize stebla materiala z različnimi tehnikami smo pokazali, da je neustrezna mikrostruktura povzročila dodatno abrazijo, zaradi trdih delcev in tako povzročila omajanje.

Ključne besede: kolčna, proteza, aseptično omajanje, obraba, nerjavno jeklo, polietilen, nekovinski vključki

1 INTRODUCTION

A total hip replacement is a surgical procedure whereby the diseased cartilage and bone of the hip joint is surgically replaced with artificial materials. An increasingly ageing population means that absolute numbers of people with a predilection for osteoarthritis is set to rise [1]. Hip joint replacement is usually done in people age 60 and older. It is expected that total hip replacement will increase due to population ageing.

Two types of arthroplasty are carried out nowadays with reference to mode of fixation; cemented und uncemented. Furthermore, two types of bearing surfaces have been utilised in total hip replacement. Hard-on-soft bearings have included couplings where the acetabular liner has been polyethylene (PE) and the femoral heads have been metallic, usually cobalt-chrome alloy, or ceramic. In order to assure lower abrasive wear and reduce the rate of aseptic loosening ceramic-on-ceramic or metal-on-metal bearing have been applied recently. There are three main materials used for implant stem: cobalt-chrome, stainless steel and titanium alloy. Although cobalt-chrome alloys are extensively used for manufacture of implants they have among good corrosion resistance and easily workability also some less desirable properties. One of them is high modulus of elasticity and not completely known long-term effects of metallosis arising from cobalt-chrome alloy [2,3]. Stainless steel is easy to work, has high strength and low price, however lower fatigue strength and tendency to corrosion cannot put it on the top [4–23]. One of the best is titanium alloy due to superior biocompatibility, relatively low elastic modulus and good corrosion performances [4,24–26]. However, it is softer than other metals and cannot be used for femoral heads due to wear [1].

Younger people who have a hip replaced may put extra stress on the artificial hip. That extra stress can cause it to wear out. The main cause of failure in these patients remains loosening due to osteolysis and the focus in future is going to be on extending the durability and survivorship of these components in a younger patient age group [1]. The aseptic loosening of a prosthetic-joint component is the most common reason for joint-revision surgery among all group of patient. However, there have been a few reported cases where a fracture of the stem neck has occurred, most likely due to the development of an inappropriate microstructure [27,28]. While abnormal wear at the bearing surface might give rise to excessive particle generation, the bone loss in relation to inflammation caused by these particles might in turn result in the loosening of the device and subsequent abnormal mechanical loading. In any case, wear particles are now considered to be one of the major contributors to the development and perpetuation of aseptic loosening [29]. Metal implants usually exhibit a low level of wear (40–100 times lower than ultra-highmolecular-weight-polyethylene UHMWPE), a good surface finish and excellent mechanical properties. The drawbacks of metals are the metallic, electrochemical corrosion risks (low bio-compatibility) accelerated by the ions present in the body fluids and the presence of oxygen [2,4,5].

In the present study an AISI 316L stainless steel total hip prosthesis with unusual microstructure regarding the presence of non-metallic inclusions was investigated in order to find eventual connections with aseptic loosening and material microstructure.

2 EXPERIMENTAL DETAILS

A 63 years old male patient underwent total hip arthroplasty revision surgery due to aseptic loosening of both the femoral and acetabular components. The prosthesis was 106 months in use before exchange due to severe pain caused by loosening of stem. The femoral component was AISI 316L stainless steel stem (0.03 wt% C, 16–18 wt% Cr, 10–14 wt% Ni, 2–3 wt% Mo) and UHMWPE acetabular cup cemented with polymethylmethacrylate (PMMA). The hip prosthesis was immediately cleaned, using only distilled water, after surgical removal. The specimens for the surface examination were cut from the hip stem and the polyethylene cup and cleaned in ethanol in an ultrasonic bath. The metal specimen for the microstructural examination was metallographically prepared by a standard procedure using 3 and 1 µm diamond polishing paste, and then etched by glyceregia to reveal the grain boundaries. The specimens for electron backscatter diffraction (EBSD) analyses were, after polishing, given an additional polish with colloidal silica oxide for 3 min and cleaned in ultrasonic bath. Furthermore, ion etching was performed in PECS 682 Gatan using 2,5 kV beam energy in rotation mode at 50° gracing angle. The specimens were analyzed using a light microscope Microphot FXA (Nikon) and with a FE-SEM JEOL JSM 6500F field-emission scanning electron microscope with attached EDX (an INCA X-SIGHT LN2 type detector, INCA ENERGY 450 software and an HKL Nordlys II EBSD camera using Channel5 software). For the EDX analysis, a 15 kV accelerating voltage and a probe current of 0.8 nA were used. The EBSD was performed at a 20 kV accelerating voltage and 2.7 nA probe current. The polyethylene specimen was covered with a 4 nm AuPd conductive layer for a subsequent SEM examination.

3 RESULTS AND DISCUSSION

After stainless steel (AISI 316L) total hip prosthesis had been surgical replaced, it was microscopically and spectroscopically examined. Polyethylene acetabular cup as well as stainless steel stem were studied together with the cement binder in order to find out the cause of its loosening (**Figure 1**). Bone cement (PMMA) is an excellent type of fixation for the hip prostheses, especially for elderly, relatively inactive patients who are usually also suffering from osteoporosis. During patient movement the wear between the polyethylene acetabular cup and the metallic head caused formation of very fine, irregularly shaped and elongated particles not longer than 1 µm. Furthermore, tribological activity of the acetabular cup and the metallic head caused tearing of larger particles from the inner acetabular cup wall. It is supposed that in overload situations adhesion caused conditions that part of the acetabular cup can be pulled out. As a result, the polished surface of the inner wall of the polyethylene acetabular cup with 300 µm deep cavities randomly distributed was formed (**Figure 2**) and consecutively looseness the hip joint.

Figure 1: Hip prosthesis together with acetabular cup and residues of cement after being surgery removed

Slika 1: Kolčna proteza z acetabularno čašico in ostanki cementa po operaciji

Accurate stainless stem surface examination showed that original rough surface, caused by sand-blasting as a last step in manufacturing process of the stem, in some areas transformed into smooth surface with some rough islands residues. During this process the metallic particles and ions accumulate in the body tissues and fluids. Debonding between the cement and implant might reduce the life-time of the implant fixation. Small

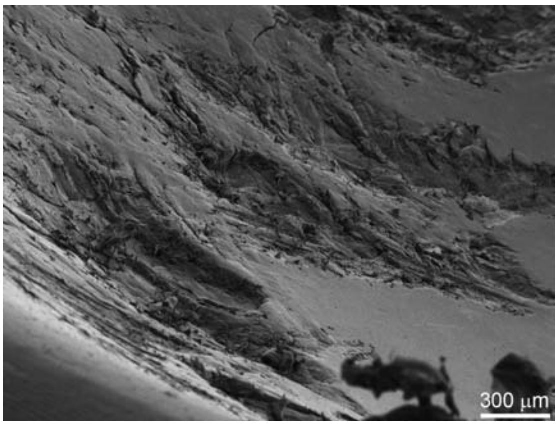

Figure 2: Surface modification of the polyethylene acetabular cup's inner wall with deep cavities, SE image

Slika 2:. Sprememba površine polietilenske čašice z globokimi jamicami, SE slika

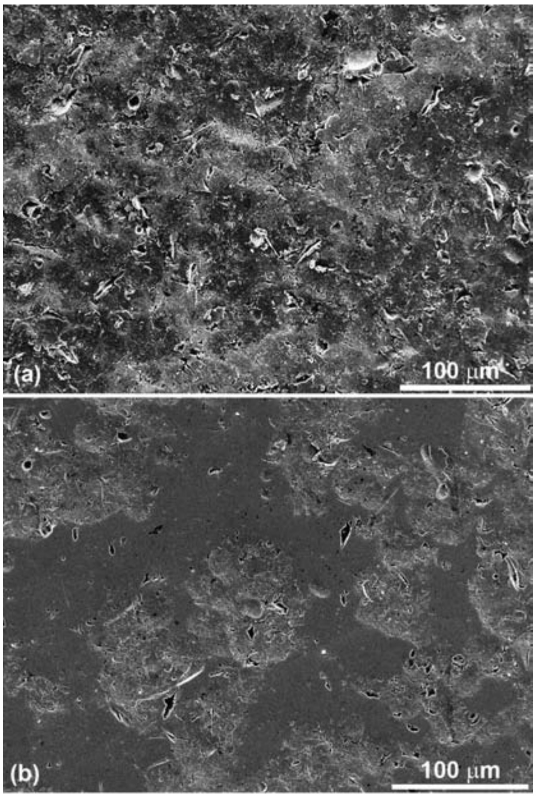

Figure 3: (a) Original sand blasted surface, SE image; (b) surface modification due to wear process, SE image

Slika 3: (a) Originalna površina po peskanju, SE slika; (b) sprememba površine zaradi obrabe, SE slika

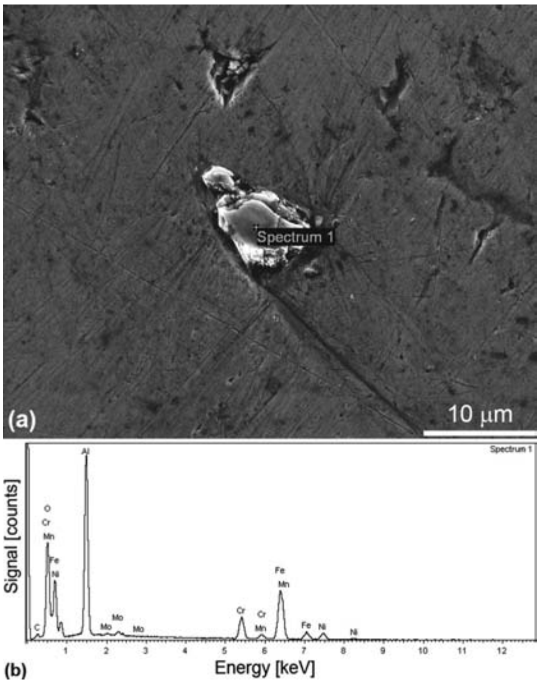

Figure 4: (*a*) SE image of alumina particle due to residue of surface sand blasting with marked spot of the EDX analysis; (*b*) EDX spot analysis of an alumina particle

Slika 4: (a) SE slika aluminijevega oksida, ki je ostal na površini po peskanju, z označenim mestom EDX analize, (b) EDX točkovna analiza aluminijevega oksida

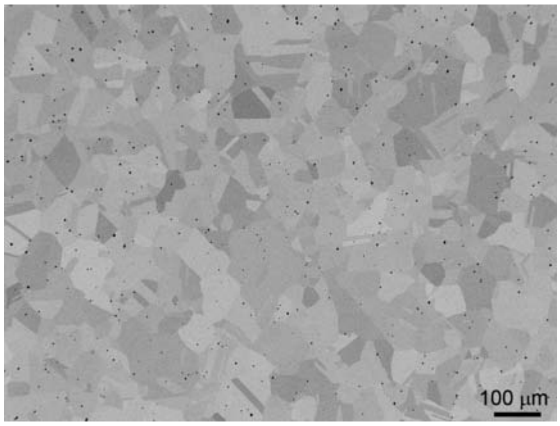

Figure 5: Microstructure of stem specimen showing plenty of Al_2O_3 non-metallic inclusions, BE image

Slika 5: Mikrostruktura vzorca stebla, ki prikazuje veliko Al_2O_3 nekovinskih vključkov, BE slika

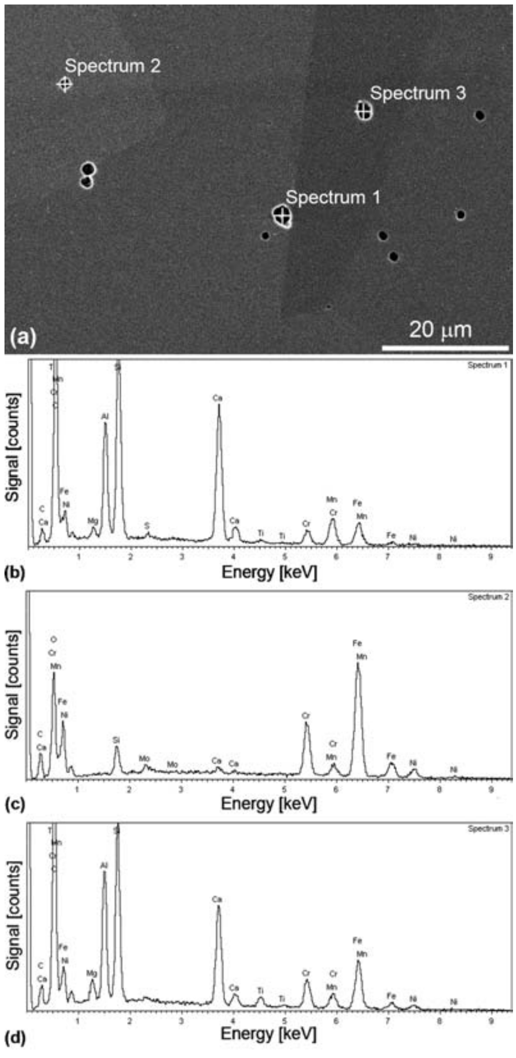

Figure 6: EDX spot analysis, (a) SE image of stem specimen with marked spots of EDX analysis, (b), (c) and (d) EDX spot analysis of non-metallic inclusions

Slika 6: EDX točkovna analiza stebla, (a) SE slika stebla z označenimi mesti EDX analize, (b), (c) in (d) EDX točkovne analize nekovinskih vključkov

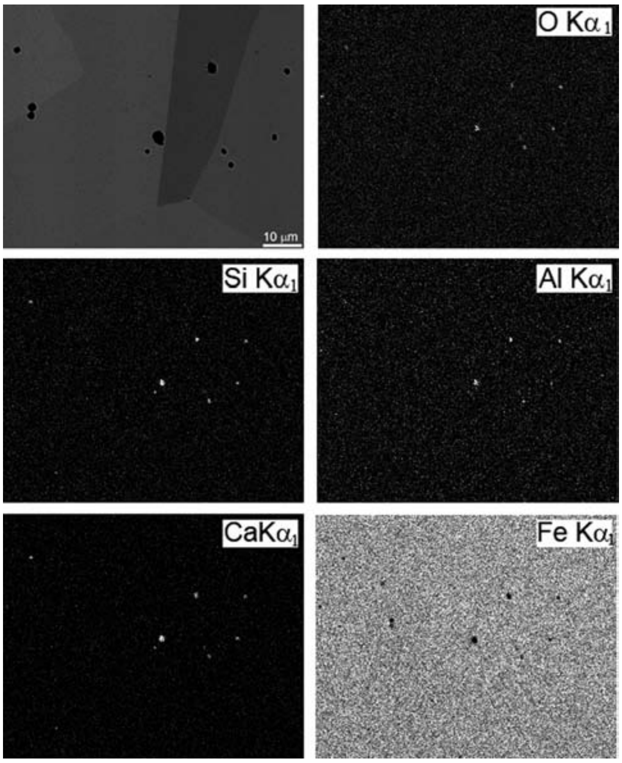

Figure 7: EDX mapping, (a) BE image of stem specimen with corresponding EDX images of (b) O Kα_1, (c) Si Kα_1 (d) Al Kα_1, Ca Kα_1 and Fe Kα_1

Slika 7: EDX ploskovna analiza, (a) BE slika vzorca stebla s pripadajočimi EDX slikami (b) O Kα_1, (c) Si Kα_1 (d) Al Kα_1, Ca Kα_1 in Fe Kα_1

cement fractures are thought to play a significant role in the initiation of the cement failure [1]. The prevailing stress between the stem and the cement is mostly caused by shear, whereas compressive-stress occurs in acetabulum, especially among active patients. The wear particles from the cement, the metal and the polyethylene (PE) are claimed to play a major role in the aseptic loosening. Osteolysis without any signs of infection is

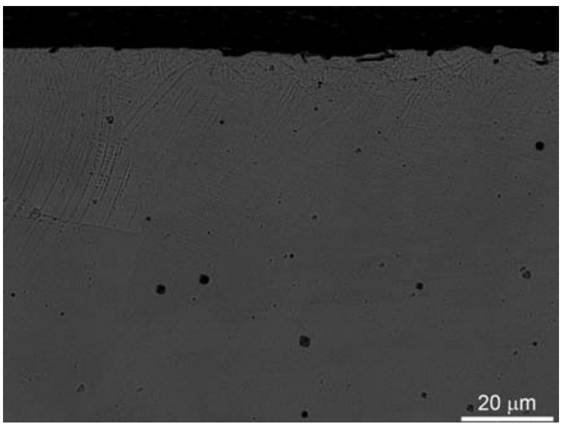

Figure 8: BE image of hip stem microstructure close to the surface with the slip lines due to surface deformation by sand-blasting

Slika 8: BE slika mikrostrukture stebla blizu površine z drsnimi črtami, zaradi deformacije povzročene s peskanjem

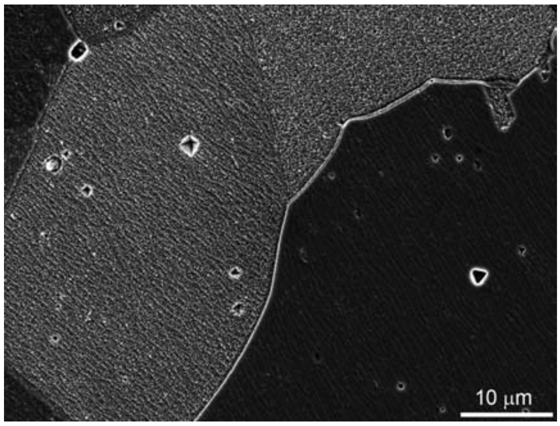

Figure 9: SE image of stem microstructure consist of austenite grains. Grain boundaries are free of any carbides and other phases. Etched by glyceregia

Slika 9: SE slika avstenitne mikrostrukture stebla. Na mejah ni karbidov in ostalih faz. Jedkano z zlatotopko

mostly related to release of PMMA debris in the tissues by micro-motion which initiates the cement failure. As a consequence a foreign-body reaction occurs and initiates osteolysis and finally leads to loosening. Once metallic particles are formed by wear, the new particles will be generated by friction and apart from causing a mild foreign-body reaction, such a metals debris can be involved in the process of aseptic loosening mostly due to cytoxine release from macrophages.

Analysed stainless steel stem indicated some of the surface areas not affected by wear while some parts of stem underwent significant changes due to wear process. **Figure 3 (a)** shows original sand blasted surface and **Figure 3(b)** demonstrated the surface which was

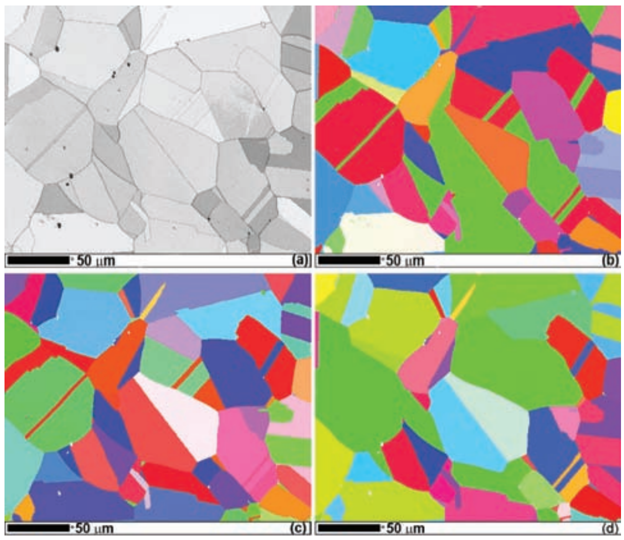

Figure 10: EBSD mapping (a) band contrast image (b) inverse pole figure in X direction, (c) inverse pole figure in Y direction, (c) inverse pole figure in Z direction

Slika 10: EBSD ploskovna analiza (a) slika kvalitete uklona (b) inverzna polova figura v X smeri, (c)) inverzna polova figura v Y smeri, (c) inverzna polova figura v Z smeri exposed to wear process. Rougher surface had plenty of small mechanically produced pits visible at a higher magnification. There were also plenty of Al_2O_3 particles embedded in the material most likely due to sand blasting procedure in order to make the surface rougher and easier for bone tissue to grow into. Al_2O_3 particles were detected by EDX in the stem surface (**Figure 4**).

Stainless steel stem microstructure across whole inner and outer part of implant had plenty of non-metallic inclusions (**Figure 5**). The inclusions were analysed by EDX. The inclusions were combinations of Al_2O_3, SiO_2 and CaO particles and were consequences of problems during steel making. The presence of non-metallic oxide inclusions is a major cause of incompatibility between the attainable and desirable level of cleanliness in many grades of commercial steel. Generally, inclusions degrade the mechanical properties of the steel and thereby reduce the ductility of the cast metal and increase the risk for mechanical and/or corrosion failure of the final product. The number of these inclusions was too large for the AISI 316L steel grade particularly in an orthopaedic application. Oxide inclusions originate from two sources: (a) residual products resulting from intentionally added alloying elements to deoxidize the molten steel after oxygen treatment (endogenous or micro inclusions); (b) products resulting from reactions between the melt and atmosphere, slag, or refractory (exogenous or macro inclusions) [30]. Alumina inclusions occur as deoxidation products in the aluminum-based desoxidation of steel. Most grades of steel are treated with calcium using Ca-Si alloy is certain amount of silicon is permitted in steel. During calcium treatment, the alumina and silica inclusions are converted to molten calcium aluminates and silicate which are globular in shape because of the surface tension effect. The change in inclusion composition and shape is known as the inclusion morphology control. However, such high amount of that type of inclusions is an evidence of wrong desoxidation process. The size of inclusions was from less than 1 μm and up to 5 μm. **Figures 6** and **7** show EDX spot analyses and mapping of such inclusions, respectively. There were some pure Al_2O_3 as well as pure SiO_2, but most of them were combination of both with additional CaO content. During conventional metallographic sample preparation due to water presence a part of calcium inclusions might be lost. If calcium inclusions are of high interest of study the ion etching (cross-section polisher) or some similar techniques shall be used.

Stem microstructure consist of pure austenite phase. No other phases as delta ferrite, sigma phase and chi phase were observed and detected in the microstructure even though the specimens were etched or colloidal silica polished and observed by EBSD. Only in the very surface region in cross-section mode it was possible to observe slip lines caused by sand-blasting deformation (**Figure 8**). If deformation is enough high the deformation martensite will take place. Such a microstructure is usually not desirable.

In some cases the formation of stress-induced martensite might lead to micro-crack formation, which, especially in combination with intercrystalline corrosion, leads to material fracture in overload situations [31]. Due to the low carbon content in the examined steel, the possibilities of intercrystalline corrosion are negligible in contrast to the stainless steels with a higher carbon content, where $Cr_{23}C_6$ carbides along the grain boundaries are formed. **Figure 9** shows grain boundary between two of austenite grains. The grain boundary was free of any carbide. EBSD was performed in order to find out any possible presence of other unwanted phases in stainless steel grades. However, the technique was primarily developed for texture analyses, but nowadays it is used for phase analyses, misorientation measurements as well as strain and stress detection [32–38]. **Figure 10** shows results of EBSD measurements. Band contrast (BC) image sometimes referred as pattern quality image and can tell us a lot of microstructure details mostly impossible revealed by chemical etching because of EBSD being a very surface sensitive techniques. Band contrast image of analysed sample (**Figure 10 (a)**) very precisely revealed all of those non-metallic inclusions based on aluminium, silicon and calcium oxides[39]. Unfortunately, it was almost impossible to obtain sufficiently good Kikuchi pattern for indexing it. Therefore, in EBSD map the only iron FCC crystal lattice was considered. All three inverse pole figure (IPF) images in X, Y and Z direction were performed. Analysed steel had no texture and had equiaxed austenite grains. Because of forging of stem part and further annealing it is expected to have such microstructure.

4 CONCLUSIONS

Shortly after total hip surgical replacement septic loosening might occur due to several reasons. If this is not about to happen the patient has good chances to undergo recovery successfully. However, after several years usually due to the process of adhesive and abrasive wear as well as to wear polishing, polyethylene and metallic debris occurs in between polyethylene acetabular cup and metallic ball as well as in between stainless steel stem and cement bond in the case of cemented prostheses. Based on the investigation performed on an AISI 316L stainless steel hip prosthesis it was found that in the present case wear polishing and adhesive wear played an important role. Acetabular cup areas exposed to adhesive wear had rough regions where larger pieces were pulled out while wear polishing of the polyethylene acetabular cup caused a very smooth, glossy-like appearance of the surface. Wear polishing of the femoral stem was observed to occur unevenly over the stem surface. Certain areas were higher exposed to wear and are seemed to be more curved part. The wear polishing of the surface caused a loss of material from the surface of the implant, the formation of metallic particles and the possibility of metal-ion formation. The AISI 316L stainless steel microstructure is austenitic with typical twin grain boundaries but with no other usually unwanted phases. Also no carbides at grain boundaries were found. But an unusually large number of aluminium-silicon-calcium based non-metallic inclusions were detected. Such high amount of that type of inclusions is an evidence of wrong desoxidation process during steel production. However, the number of these inclusions is too large for the AISI 316L steel grade especially in an orthopaedic application. Furthermore, Al_2O_3 particles due to sand-blasting were found in the surface. The long-term wear polishing strengthened by hard Al_2O_3 particles in the surface and as such might digs out hard non-metallic inclusions as well and thus complementing the wear-polishing mechanism with abrasive wear. Usually the loosening of the components is triggered by the micromotion of cemented components which causes the abrasion of the implant's surface, producing metal-wear debris and a proliferative soft-tissue reaction. Based on case study investigation it is no doubt that such a bad quality stainless steel by huge amount of hard non-metallic inclusions accelerating the loosening process much faster due to potentially toxic and human body irritating debris formed during wear.

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