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Material Composition and Microstructure of Femoral Shaft Plate Implants Used at the Komfo Anokye Teaching Hospital, Kath

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ABSTRACT

Metallic materials designed for applications in surgical implants, must show a group of properties in which biocompatibility, mechanical strength, toughness and resistance to degradation by wear or corrosion are of primary importance. In order to reach these aims, orthopedic materials must fulfill certain requirements, usually specified in standards. These requirements include chemical composition, microstructure, and bending properties. In this paper, used and new implants from the different sources from which the hospital receive were studied to elucidate the causes of the failure. The chemical composition and microstructure of each material is analyzed. Comparative analysis was done between the implants that failed in vivo and the others that did not. One out of the three sources identified, failed in vivo. This could be attributed to the fact that, its chemical composition and grain size did not conform with the ASTM standards. Since coarse grains make a material withstand less force and high Carbon contents makes materials brittle.

Keywords: *femur shaft, plate implant, material composition, microstructure*

1. INTRODUCTION

A femoral shaft fracture is a severe injury that generally occurs in high-speed motor vehicle collisions and significant falls. These injuries are often one of the several major injuries experienced by patients [1].

Nowadays femoral shaft fractures in adults are usually treated operatively. With more and more of femoral shaft fractures getting operated the number of complications has proportionately increased. One such complication is implant failure. Figure 1 below shows a typical implant failure reported at KATH.

Surgery data from the orthopedic department (KATH), Kumasi- Ghana, has revealed that, there is an alarming rate of femoral shaft implant failures, and this calls for an objective assessment of the probably causes of the failure from the material structure and mechanical engineering point of view, that lead to implant failure, as it is necessary to prevent this complication in one of the major weight bearing bones of the body.

Failure of an implant is a condition that needs to be completely avoided in the human body, because of the devastating complications that it can cause. For instance, a bend in the implant may lead to aseptic inflammation [2]. Another complication is shortening of femur, and this leaves the patient with torsion on the pelvic girdle. In addition implant failure could lead to non-union, which subsequently results in delay in the healing process of the fracture.

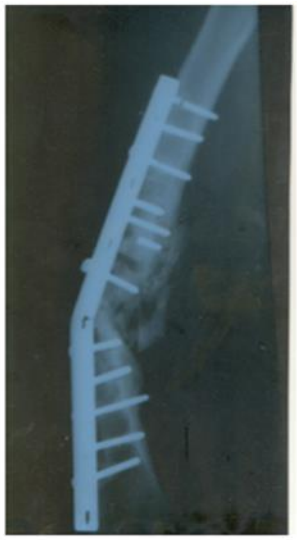

Figure 1: An X-Ray of failed Plate and Screws [Courtesy KATH]

Investigation of the causes of implant failure involves an engineer or an implant designer, a surgeon, operating-room personnel and the patient. All these people have a potential contribution to failures as well as to successes of the implant. From the standpoint of engineering, every load bearing device has points of weakness at which it will fail when the margin of safety is exceeded. It is the

designer's responsibility to provide an adequate maximum margin, and it is the responsibility of the surgeon and patient not to exceed that margin.

A lot of work has been done on the failure of femoral shaft implants in many countries, but the causes of the failure of femoral shaft implants in operative orthopeadic practice has not been reported at KATH-Ghana. In this background it was decided to study the causes of the plate implant failure of the shaft of the femur, from the points of view of material composition and grain size, to study the implant quality, so as to suggest guidelines to minimize further failures.

The objective of this work is to assess the material composition and microstructures of the femoral shaft plate implants at the KATH.

2. MATERIALS AND METHOD

2.1 Sampling of Implants

Twenty-five implants removed from 25 patients were collected over a period of four months. Out of this number three got bent and only one was completely detached due to fatigue *in vivo.* Three different companies were identified, and all the failed implants were from the same company. The number of samples selected for each company was 4, yielding a total of 12 samples in the whole study.

2.2 Microstructure Examination

The mechanical properties of metals depend on their microstructures. The internal structures determine how materials perform under a given application. The effects of most industrial processes applied to metals to control their properties can be explained by studying their microstructures. The most common method used to examine the structures of materials is the optical technique.

To reveal the structural details such as grain boundaries, phases and inclusions, the polished surface was etched. Etching is a chemical reaction in which an appropriate solution selectively attacks certain phases than others. The etchants used were 30 g of Potassium Ferricynide, $K_3Fe(CN)_6$, 30 g of Potassium hydroxide , KOH, and 150 ml of distilled water [22].

2.3 Determination of Material Composition

A clean flat, electrically conductive sample was placed on the source after the sample has been weighed on a microbalance. The sample was sputtered under predetermined conditions while sequential spectrograms are recorded. The resulting spectra were interpreted by digitally measuring the percent light transmission of selected emission lines and comparing this to the transmission of standards. These data were then computer-reduced to give a tabulation of the elemental concentration as a function of depth.

3. RESULTS AND DISCUSSIONS

3.1 Chemical Composition

The implants from the various companies revealed some sort of consistency in their chemical composition. All tested implants had more than 59% iron, about 10% nickel and more than 23% chromium with other 12 trace elements. It can be inferred from the chemical composition tables that all the companies produce high corrosion resistance austenitic stainless steels. The failed implants had higher carbon content, up to about 0.1%, whereas the others have about 0.03% of carbon.

Table 1: Chemical compositions of Plate implants, from each of the three sources

ANALYSTICAL RESULTS OF CHEMICAL COMPOSITION BY PERCENTAGE WEIGHT						
SERIAL NUMBER						
	A		B		C	
Elements	Average	Standard deviation	Average	Standard deviation	Average	Standard deviation
Fe	61.27	0.10132	61.427	0.1178	59.555	0.2608
C	0.0315	0.00129	0.1225	0.0170	0.0302	0.0005
Si	0.6725	0.08261	0.5525	0.0125	0.4675	0.0263
Mn	1.0382	0.01588	0.77	0.0938	1.345	0.0984
P	0.0227	0.01857	0.01	0	0.012	0.001414
S	0.0212	0.00499	0.0375	0.0089	0.0755	0.0086
Cr	22.867	0.11295	22.975	0.05	23.992	0.222317
Mo	1.2875	0.04573	1.1075	0.1241	1.16	0.0648
Ni	10.28	0.14877	10.65	0.1194	10.737	0.0478
Al	0.0117	0.00236	0.0145	0.0051	0.011	0.0008
Cu	0.302	0.00216	0.31	0.1009	0.3615	0.0012
V	0.0122	0.00170	0.0202	0.0038	0.0117	0.0015
Ti	0.0285	0.00506	0.031	0.0043	0.0265	0.0026
W	2.1575	0.11672	2.0152	0.2556	2.2125	0.0125
B	0.0034	0.00045	0.0030	0.0000	0.003	0.0000

Total	100.00	0.00612	100.04	0.0537	100.0	0.0009

3.2 Microstructures of Specimen

The microstructures of the plate implants are shown in Figure 2, 3 and 4. The figures show that the grains from all sources were austenitic. However, the microstructure of implants from source B recorded coarse grains, which means that, under the same load, this implant is more likely to fail than the others.

The average grain sizes were determined in accordance with the American Society for Testing and Materials (ASTM). The average grain size was measured for samples A and P as 19.23 μm corresponding to grain size number 5.2, which is in accordance to the ISO 5832-1 standard requirements. However, the average grain size measured for samples H, was 32.258 μm corresponding to grain size number 3.5

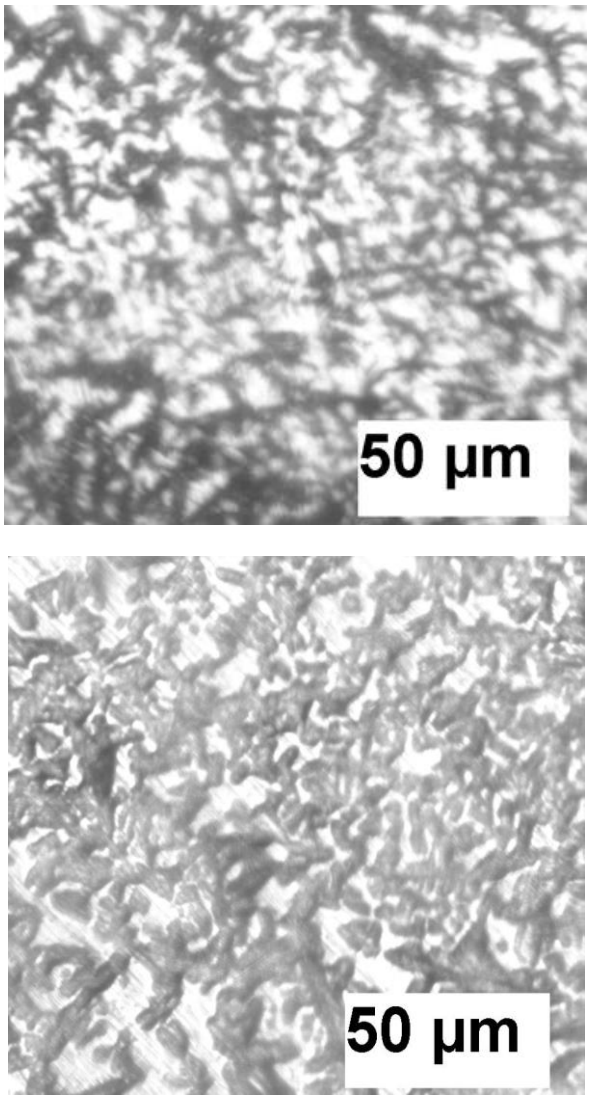

Figure 2: Microstructure of samples from source C

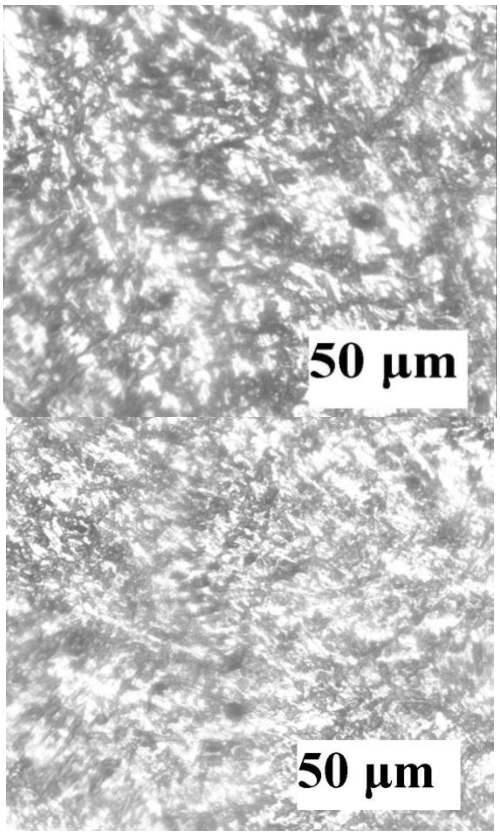

Figure 3: Microstructure of samples from source A

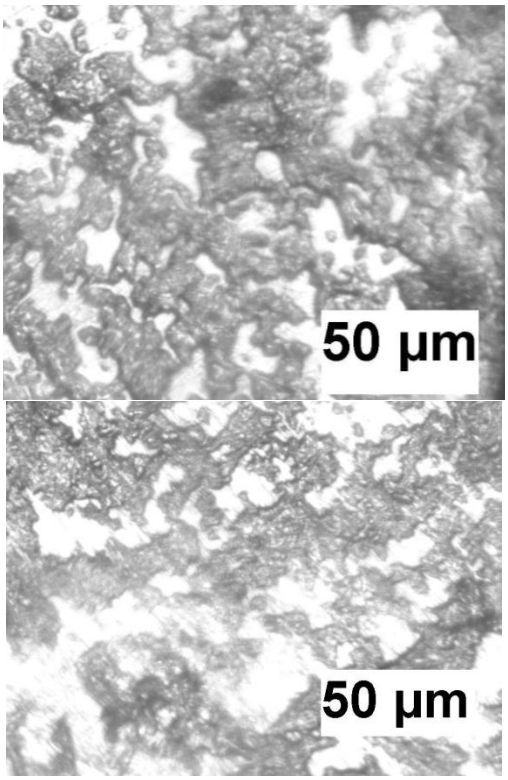

Figure 4: Microstructure of samples from source B

4. CONCLUSIONS AND RECOMMENDATIONS

This study attempted to assess the material composition and microstructures of the plate implants, received from the various sources at the KATH, in the treatment of femur shaft fractures.

Based on our findings it was confirmed that, all the identified sources produce austenitic stainless steel. And that, the austenitic stainless steel plate, is a good implant material provided it possesses a number of applicable standard, including, 0.03% carbon, 16-26% chromium, and 7-12% nickel as reported in ASTM standards [22]. The recommended grain size of this type of steel is, ASTM No. 5 or finer. One out of the three sources identified, failed *in vivo.* And this could be attributed to the fact that, its chemical composition and grain size did not in conformity with the above stated standards.

The recommendations are as follows;

Based on the results and main findings of the study we recommend that, Material test should be done on any consignment of implants received, at any given point in time, at the hospital before usage. To avoid using low quality implants, which could cause devastating effects to patients.

Also, the hospital should stop using plate implants from source B, until it is proven that their implants meets the standard requirements.

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