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Study on the biocompatibility and wear of stainless steel 316L and UHMWPE materials

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ABSTRACT – The objective of this work are to study biocompatibility and wear of stainless steel AISI 316L (SS316L) and ultra-high molecular weight polyethylene (UHMWPE) materials. For the biocompatibility, the materials were installed in Rabbit's tissues. Then, after three weeks the tissue reactions were examined. Statistical test was performed using analysis of variance (ANOVA). To obtain the wear phenomena, a wear test of the materials using the hip joint simulator was performed. Results showed that the Rabbit tissues reactions around the implant materials are positive. In addition, wear occurred only in the UHWPE material.

1. INTRODUCTION

In general, the presence of implant in a human body may cause certain reactions in muscle tissue and bone. In addition, wear debris of implant is also contributed. The biomaterial implanted into the body must meet the function of the body system without causing adverse reactions to one another or must be biocompatible [1, 2]. Furthermore, the implant material must have stable physical and mechanical properties, and the implant should be relatively easy to fabricate, reproduce, and meet the technical and biological requirements [3]. Implants and prostheses from SS316L and UHMWPE materials for domestic orthopedic purposes in Indonesia are developed and manufactured by several companies. However, the biocompatibility and wear analysis of these materials has not been reported yet.

The objective of this research is to study the biocompatibility and wear of the SS316L and UHMWPE materials. The installments of these materials in tissues of rabbits were performed. To obtain the wear phenomena, wear test of the SS316L and UHMWPE materials using a hip joint simulator was performed.

2. MATERIALS AND METHOD

2.1 *Materials*

The implants used in this study are the SS316L and UHMWPE materials obtained from Indonesia market domestic. For the biocompatibility, the SS316L geometry sample was calculated using the length ratio of the 8-hole broad plate implant with a length typically for Indonesian people femur [4]. A similar approach was applied to the UHMWPE implant. The material properties of these materials are given in Table 1. For the wear test, the 28mm diameter femoral head and the 8mm thickness acetabular liner were used.

Table 1 The mechanical properties of the SS316L and UHMWPE materials.

Materials	Yield stress	Hardness		Flexural strength
		Macro	Micro	
SS316L	356.14 MPa	64.5 HRA	197 VHN	-
UHMWPE	25.25 MPa	8.8 VHN	-	18.71 ± 0.63 MPa

2.2 *Biocompatibility of SS316L and UHMWPE*

Number of sample was determined using "Meads resource equation" [5]. Based on the sample calculation, the number of the rabbit is selected to be 11 rabbits, where the rabbits have 1 Kg average weight. The SS316L and UHMWPE samples were implanted in the right femur of the rabbit, one implant sample per rabbit. After the end of the test period of eight weeks, the rabbits were euthanized with a lethal dose of ketamine IM injection of 200 mg/kg [6]. After that, the muscle and bone tissue of the rabbit were cut into samples for further macroscopic and microscopic histological analyzes. For the SS316 material, the tissue reaction test is performed using score system, where for the soft tissue reaction score based on Erdmann et al. [7], while the bone tissue reaction score based on Huehnerschulte et al. [8]. For the UHMWPE material, the tissue reaction capsule is determined using Mirra score [9]. The tissue reaction score of the cartilage is determined using the score by the International Cartilage Research Society (ICRS) [10]. To obtain the average score for the SS316L and UHMWPE materials, ANOVA test using SPSS software was performed [11].

2.3 *Wear of SS316L and UHMWPE*

To measure wear in the SS316L and UHMWPE materials, a wear test using hip joint simulator was performed. Wear was measured by the weight of the femoral head and acetabular liner after running for certain cycle. Tests were designed for several cycles.

3. RESULTS AND DISCUSSION

3.1 *Biocompatibility of SS316L and UHMWPE*

SS316L. Figure 1a shows the macroscopic results of the SS316L implant sample. There is no difference between the muscle and bone tissues adhered to the implant sample compared to the reference tissues. Based on the ANOVA data, muscle and bone tissue reactions to SS316L material shows no significant difference compared to control group.

UHMWPE. Similar results were also found for the UHMWPE implant samples, see Figure 1b. Almost all the samples show no significant reaction between the UHMWPE implant with the bone and the muscle tissues. Based on the ANOVA data, the UHMWPE material has the same biological compatibility with control group.

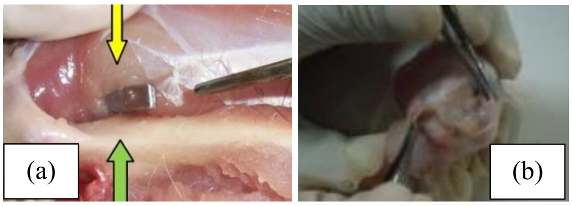

Figure 1 Macroscopic appearances of the muscle and bone in the area where, (a) the SS316L and (b) the UHMWPE sample is implanted.

3.2 *Wear of SS316L and UHMWPE*

Figure 2 shows the wear volume on the acetabular liner surface (ALS) as a function of cycles. As can be seen in this figure wear is increasing as the number of cycle increases. There is no wear in the femoral head.

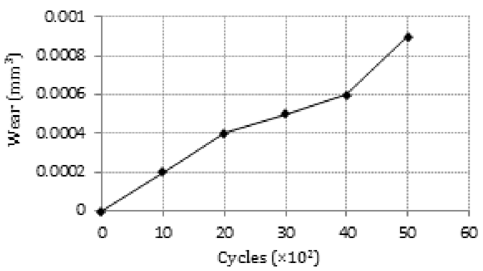

Figure 2 Wear volume on the ALS as a function of cycles.

4. CONCLUSIONS

Study on the biocompatibility and wear of the SS316L and UHMWPE materials have been performed. For the biocompatibility, analyzes were conducted macroscopically and microscopically. The hypothesis is performed to the average score (mean) of each group using ANOVA. Results show that the SS316L and UHMWPE materials did not significantly trigger the muscle and bone tissues reactions. It was concluded that the SS316L and UHMWPE materials are biocompatible and the applications of these materials for implants seems conceivable. Based on the wear test analysis, it shows that wear occurs only in the acetabular liner made from the UHMWPE, whereas in the SS316L there is no wear observed.

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