Ti6Al4V with Anodization Type II: Biological Behavior and Biomechanical Effects

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Abstract: Industrial anodization processes have been established as standard surface treatments for titanium alloys used in traumatological applications. Although the anodization process can be described as a functional surface treatment, the corresponding effects on biological behaviour and biomechanical properties can differ significantly depending on the chosen technique. While the type-III treatment is altering the implant properties mainly in cosmetical aspects, the type-II-anodization is effectively modifying the biological and biomechanical properties relevant for traumatological situations.

Among clinically proven implant materials, Ti6Al4V with type-II-anodization treatment is showing a superior corrosion resistance which can be equated with excellent biocompatibility properties. In addition to positively influenced bony ingrowth behaviour, an increased anti-infection efficacy has been shown.

Similar benefits for the type-II-anodization treatment are also demonstrated by enhanced biomechanical properties. Compared to untreated implants, the fatigue strength is increased by 15% and the wear and friction characteristics are significantly improved.

Considering all available test data, the titanium alloy Ti6Al4V with type-II-anodization treatment provides an excellent suitability for implants used in traumatological application.

1. Introduction

The warm, humid and salty conditions inside the human body are representing a challenging environment for implant metals. In addition to this adverse chemical situation, the implants are exposed to strenuous loading conditions combined with mechanical interactions with other metallic implant components such as plates, screws, nails etc.. Despite the traditional and clinically accepted usage of stainless steel implant materials for traumatologic applications (in various qualities from 316LVM to high strength alloys like Orthinox®), titanium and its alloys have been established as the material of choice since the late 1970's [1]. The early usage of pure titanium and untreated titanium alloys has been associated with tissue discolorations [2], which raised concerns inside the orthopaedic community. Additionally, frequent problems regarding implant removal and biomechanical strength properties have been reported while using the mentioned materials in orthopaedic trauma applications [3]. Considering today's ratio between titanium and stainless steel products implanted by orthopaedic surgeons, these concerns seem to be dispelled.

Not least in combination with the traumatological usage of titanium alloys, various surface treatments have been evaluated in order to positively alter the clinical performance of the implants. Beside the anodization-type-III treatment which could be described as the industrial adaptation of the natural oxidisation process the anodization-type-II technique has been established as a commonly used treatment.

The purpose of this paper is the description of relevant aspects for implant properties like biocompatibility, osseointegration, anti-infection properties, fatigue behaviour, friction and wear characteristics. Furthermore the test results allow a direct comparison of different anodization techniques (type-II versus type-III) with untreated titanium alloys and stainless steel materials.

2. The Anodization Process

As demonstrated with other materials for implant applications, titanium and its alloys belong to the group of layer-forming materials which spontaneously create oxide layers acting as a passive barrier against corrosion[4]. Analyzing this natural oxidation process helps to understand the chemical and physical effects during anodization.

The anodization process can be described as the industrial adaptation of the natural oxidization process. During this natural process the material surface of titanium or titanium alloy materials is covered by a thin, porous layer of titanium oxide (TiO_2) which emerges from contact of the substrate with air or water and affects the corrosion resistance of the material [5].

The mentioned industrial application by controlled oxidization is processed in electrolytic (alkaline) baths. Depending on bath conditions and subsequent finishing steps, different anodization types with unique material properties and surface structures can be achieved. While the natural oxidization creates passive layers of approximately 10nm (0,00001mm), [6] the thickness of the artificially established surface can be controlled. A visible evidence of the extended thickness of the oxide layer is the appearance of interference colors. By varying the layer thickness between 60 and 200 nm, different colors of the spectrum can be applied to the implant surface (see figure 1). [7]

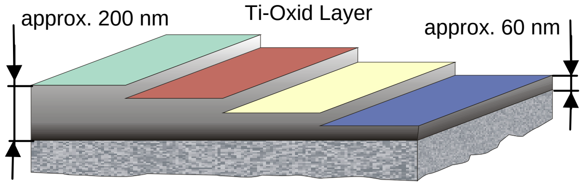

Figure 1: Anodization Type III; influence of layer thickness

Although this kind of surface treatment is also used for traumatological implants, it has to be considered that this coloring process effect is restricted to the surface only without any substantial influence on the implant performance. Furthermore the implant surface remains sensitive to mechanical impairments like chipping, peeling and discoloration.
In contrast to the mentioned process, the anodization-type-II treatment does not provide any visible cosmetical effects. By altering the electrolytic bath conditions and the applied voltage, a controlled spark discharge leads to a temperature increase and a partial melting of the surface which allows the anodic film to become an interstitial part of the titanium (see figure 2). [8]

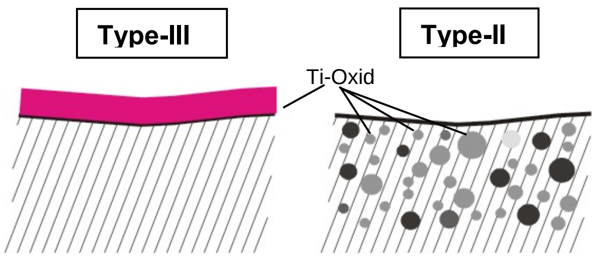

Figure 2: Differences in surface structure Type III vs. Type II

During this process oxygen and oxides are becoming an integral part of the material and they are forming a so-called conversion layer with a thickness of 2000 …10000nm [8, 9].
Due to the fact that the anodic film becomes an interstitial part of the metal substrate, an obvious benefit can be found in a reduced risk for chipping or peeling of the implant surface.

3. Biological Behavior

For the assessment of the biological behavior and the potential interactions between the human body environment and the implant surface, the biocompatibility, the evaluation of bony ingrowth potential and the anti-infection efficacy are the chosen fields of interest.

3.1. Biocompatibility

For the assessment of the biological response caused by the implant material, no single indicator or test is available to determine the biocompatibility. The definition of biocompatibility is established in international standards and does not only pertain to toxicity but rather to all adverse effects of a material on surrounding tissue. Steinemann [10/11] posted a general correlation between biocompatibility, toxicity and corrosion resistance of the elements (see figure 3).

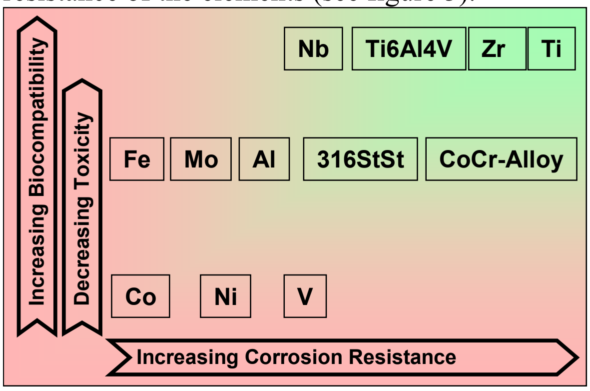

Figure 3: Biocompatibility and corrosion resistance acc. to Steinemann (schematic) [11]

Laboratory tests by conducting electrochemical measurements have shown that the corrosion resistance of anodized-type-II surfaces is up to 44% higher compared to untreated material [8]. In combination with the results of Steinemann, an excellent biocompatibility can be equated.

3.2. Osseointegration / Bony Ingrowth

The tendency for in-vivo osseointegration and bony ingrowth is a general concern for trauma implants due to the expected complications (e.g. secondary fractures) during implant removal. Ideally an implant surface suitable for trauma-

tological application should suppress the attachment of osteoblastic cells.
A general accepted supposition for cell adherence is protein adsorption at the implant surface. Following this approach one potential solution for an effective reduction of bony ingrowth could be a decrease in protein adsorption in the process of interaction between blood and implant surface directly after the surgical intervention.
To assess the potential for the above mentioned risks the protein adsorption rate is used to determine the influences. Figure 4 is presenting a reduction in protein adsorption by 19% [12] which can be achieved by utilizing the anodization-type-II treatment in comparison to untreated titanium alloy. Considering this results a decreased risk of bony ingrowth and associated concerns can be expected.
The corresponding data for type-III-anodization is not available.

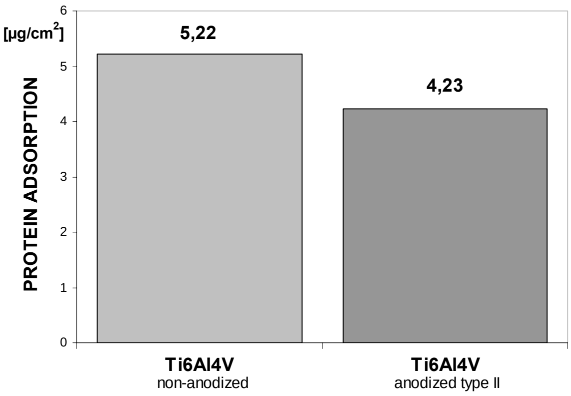

Figure 4: Protein Adsorption, determined in immersion tests [12]

3.3 Anti-Infection Behaviour

Although a comprehensive explanation of the implant site infection process does not exist, an influence of material properties on the infection rate is generally accepted[13.] The implant surface has been described as a field of competition between bacteria and healthy tissue cells to colonize the surface like „a race for the implant surface“ [14]. The outcome of this competition is influenced chemically (by the composition of the material) and physically (by the mechanical and / or electronical structure). The anti-infection efficacy of an implant surface can be quantified by calculateing the anti-infection score relative to polished stainless steel surfaces [15.]

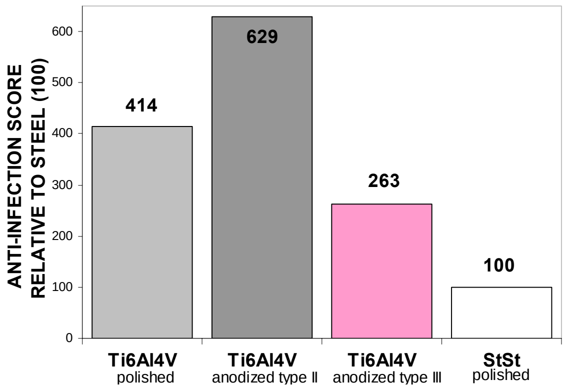

Figure 5: Anti-Infection Score relative to stainless steel control group

The data in figure 5 demonstrates the superior anti-infection efficacy of titanium alloys vs. stainless steel in general. Furthermore the results are also proving the positive influence of anodization-type-II.

4. Biomechanical Properties

The anodization process causes an essential influence of the material properties for traumatological applications. The different effects have been qualified and quantified in various test series and have led to the results described below.

4.1. Fatigue Strength

Due to the dynamic loading in a traumatological fracture situation the implants are essentially endangered by fatigue failure. To verify effects of the anodization-type-II process concerning the fatigue behavior of the implants, various dynamic laboratory test were performed. One of these series has demonstrated an increase in fatigue strength of 15% compared to untreated material (see figure 6)[16] . Results of other comparative tests report increase in fatigue strength as a result of the anodization process between 0 and 15% [17/18/19/20]. In contrast, anodization type III is reported to decrease fatigue strength by 15% compared to non-anodized control [18].

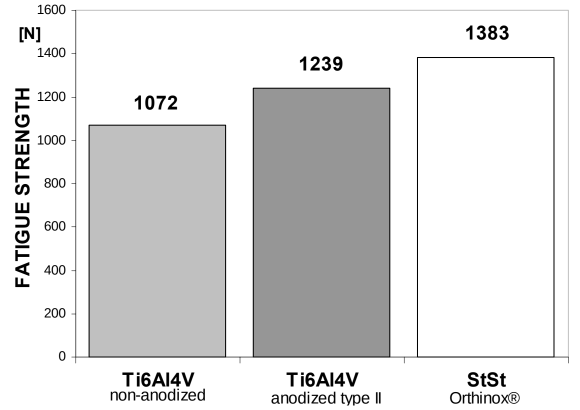

Figure 6: Fatigue Strength; determined for drilled nail shafts in bending tests [22]

4.2. Wear and Friction Characteristics

From clinical and laboratory experiences, untreated titanium components are showing excessive friction and wear when sliding on a surface of equal kind. The following results are demonstrating the positive effects of the anodization-type-II process.

4.2.1. Wear Characteristics

Titanium components are known for their excessive wear in articulating conditions (metal-to-metal wear). This is affected by the abrasion of the hard surface oxides, which do not show sufficient adhesion to the base material. The abrasion process is followed by material micro welding and a permanent re-oxidization [9/21].

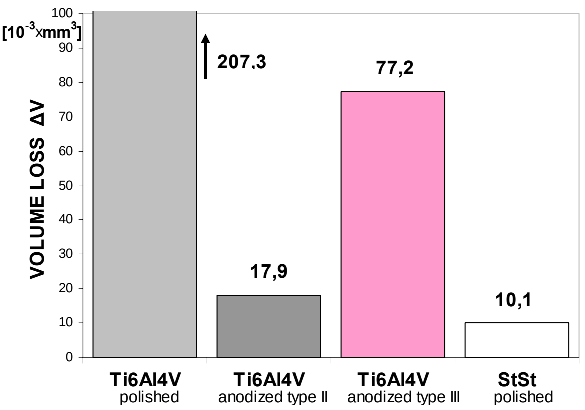

Figure 7: Volume Loss ΔV; determined by dynamic cylinder-on-cylinder test [22]

As displayed in figure 7 [22], the volume loss in articulating conditions can be significantly reduced by applying a anodization-type-II treatment to the implant surface.

4.2.2. Friction Characteristics

Articulating surfaces require appropriate sliding characteristics in order to guarantee proper function of the implant. Considering for example the Gamma®-Nail, the unhindered movement between nail and lag screw is essential for the outcome of the osteosynthesis.[23] Tests utilizing a hip screw in nail model were carried out to determine the influence of the anodisation process on the friction behavior.[24] The coefficient of friction (μ) represents the characteristic value for sliding resistance. The higher this coefficient the higher the sliding resistance will be.

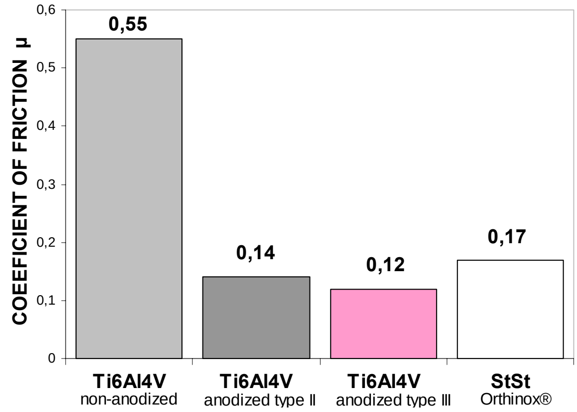

Figure 8: Coefficient of Friction μ [24/25]

The results displayed in figure 8 are proving that the coefficient of friction can be reduced to a level comparable to polished stainless steel by applying the anodization-type-II treatment.

5. Summary

The titanium alloy Ti6Al4V represents a generally accepted material for osteosynthesis in traumatological situations. It combines an excellent biocompatibility with outstanding biomechanical performance. This can even be improved by applying the electrolytic anodization-type-II process. While the anodization-type-III treatment is associated with a colorization effect the type-II-anodization renounces any cosmetical alteration for the benefit of improved biomechanical implant properties.

The established conversion layer, integral part of the base material, leads to improvements of several essential aspects of the implant performance. Besides an increase in fatigue strength of 15%, the corrosion resistance and therefore the biocompatibility is influenced positively. The improvements in terms of wear and friction characteristics are also enhancing the suitability for traumatological applications. Positive effects of the anodization-type-II treatment can also be observed in anti-infection efficacy compared to other clinically accepted surfaces.

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