

TANTALUM BASED MATERIALS FOR IMPLANTS AND PROSTHESES APPLICATIONS

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Abstract: *The performance of biomaterials in biological systems is of critical importance for the development of biomedical implants and tissue engineering. Using a coating (thin film) as the interface between the bulk material and the biologic environment is one of the solutions which can potentially lead to better bioresponse, improved mechanical characteristics and lower overall cost, compared to the same material as the coating, but used in bulk form. In this paper, an overview on tantalum based biomaterials will be presented, both in bulk and coating form, with emphasis on the advantages or drawbacks reported for the particular type of material.*

Key words: *tantalum, biomaterials, bioresponse.*

1. Introduction

A biomaterial is a material used in medical devices intended to interact with biological systems in order to evaluate, treat, augment or replace any tissue, organ or function of the body [39], with as little as possible negative effects to the tissue with which they come in contact. Currently there are numerous biomaterials that are successfully used in the human body, ranging from metallic materials, to ceramics, and synthetic and natural polymers [23].

Metallic materials have been used in medical applications, mainly in orthopaedics, cardiovascular applications or dentistry, for several decades. The key characteristics that allow using metallic materials for these types of applications are: their resistance to body fluid effects, great tensile strength, flexibility and high corrosion resistance, among others [15].

Certain features are desired from the material, depending on the type of tissue (cells) with which there will be contact and location of the implant. For example, if the biomedical device is intended to be a blood-contacting device (catheter, graft and stent), blood compatibility of the biomaterials (haemocompatibility) is crucial. If the material will be used for orthopaedics applications, and depending on the location (in direct contact with bone tissue), osseointegration is the key parameter. For both types of applications, the host response and its severity are strictly related to the surface properties of the biomaterial [15].

Generally speaking, the mechanical properties of metals and their alloys surpass those of other classes of biomaterials. However, there are still some drawbacks when using metallic materials as implants. One of these disadvantages is

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the fact that they are usually inherently bioinert. This phenomenon is, on one hand, beneficial, because there will most likely be no inflammatory response, and on the other hand, disadvantageous, because the material surface tends to be overgrown by fibrous tissue, especially for orthopaedics implants. This leads to loosening of the implant, which may induce pain and discomfort in the patient [29].

One of the most successful metallic materials, at least in terms of bioperformance, is tantalum. Tantalum usage in the biomedical field dates back to the 1940s, when Burke successfully performed several pure tantalum implantations, i.e., skin, subcutaneous and tendon sutures, as well as several plates [45], [7]. Tantalum has the ability to spontaneously form a compact passive oxide layer that strongly adheres to it. This oxide layer has the capacity to facilitate bone in-growth under *in vivo* conditions via the development of bone-like apatite that promotes hard- and soft-tissue adhesion [18]. Furthermore, Ta is a hard, ductile, highly chemically resistant material with good apposition to human bone [12]. Depending on the required application, tantalum based implants can be available in bulk form (usually porous) and in coating form, generally as tantalum oxides. Porous metals have the ability to allow for bone ingrowth [35]. The relatively high cost of manufacturing and the inability to produce modular implants have limited the acceptance of tantalum, in spite of its excellent *in vitro* and *in vivo* biocompatibility [3]. One of the main reasons for the relative success of tantalum based implants is the fact that the biocompatibility of tantalum is higher in bulk form and significantly higher in powder form than titanium [19]. Furthermore, it has been reported that in different animal models, tantalum demonstrates no remarkable inflammatory

response, regardless of the implantation positions, types of tissues and the forms (shapes) of implants [20], [21].

In this paper, some information regarding the manufacture technologies, mechanical characteristics and bio-performance features regarding tantalum based biomaterials will be presented.

2. Case Reports

Orthopaedic implants are hard tissue substitutes for impaired human bones in case of trauma, diseases, and aging. Metallic materials are used due to their inertness and structural functions. They are generally preferred over other types of materials (such as polymers or ceramics). If the implants are subjected to static, dynamic or cyclic loads that require a combination of strength and ductility, metallic materials are generally required. Orthopaedic implants are considered to be the largest use of metals in the body [10]. These types of implants can have the following functions and/or geometries: wires, screws, fracture-fixation plates, and total joint prostheses (artificial joints) for hips, knees, shoulders, elbows etc. The latter variations consist of metallic parts and other types of materials, for example polymers (polyethylene - PE, ultra high molecular weight polyethylene - UHMWPE etc.) The requirements for metals in orthopaedics application are their ability to bear significant loads, withstand fatigue loading and undergo plastic deformation prior to failure [30].

Metallic implants are also widely used in oral and maxillofacial surgery and cardiovascular surgery. As far as cardiovascular implants are concerned, the treatment of coronary and peripheral artery disease using metallic stents has been one of the most revolutionary and most rapidly adopted medical interventions of our time [25]. The purpose of a cardiovascular stent

is to repair an obstruction which occurs inside a blood vessel, thus reinstating the normal blood flow. The requirements for this type of device are the following: the plasticity of the material should be adequate in order for the stent to remain at the necessary size when deployed; if self-expanding stents are used, the material should be sufficiently elastic so it can be compressed and then expanded and retain sufficient radial hoop strength to prevent vessel recoil or closure once in place [32]. The majority of current coronary and peripheral stents are made from either stainless steel, cobalt-chromium alloys, or from nickel-titanium materials (nitinol) [26]. However, the major drawback for these types of materials is observed when subjecting the patient to magnetic resonance imaging (MRI), because most of these materials are paramagnetic or ferromagnetic. This means that several effects can be observed: the most serious of these include the risk of stent movement and heating, due to the magnetic field applied by the MRI equipment; furthermore, the presence of artefacts on the MRI image can limit the clinical interpretation of the data.

Hereinafter, a few representative examples for tantalum based orthopaedic and cardiovascular implants will be presented, with emphasis on the manufacture techniques, and the advantages or disadvantages compared to other materials for particular applications.

2.1. Tantalum Based Materials Used in Orthopaedic Applications

Tantalum is a biocompatible metal with excellent strength and anticorrosion properties even in an acidic medium. The anticorrosion properties of tantalum are due to the stable, native, Ta_2O_5 protective film formed on the surface [34]. However, certain negative characteristics limit the

widely spread use of this material, at least in bulk form. Firstly, its large elastic modulus of over 186 GPa and density of 16.6 g/cm^3 make direct clinical application difficult [31]. These features, in particular the high elastic modulus, when applied to orthopaedics implants, are detrimental, mainly due to the significant difference when compared to those of natural cortical (12-18 GPa) and cancellous bone (0.1-0.5 GPa) [20]. Secondly, the manufacture of bulk tantalum implants is somewhat difficult, mainly due to the fact that this metal is refractory, which means that it can be melted only at a very high temperature ($3017 \text{ }^\circ\text{C}$) [3].

Consequently, for better osseointegration and adequate mechanical characteristics, porous tantalum based implants have been recently developed. One example of such porous structure is presented in Figure 1.

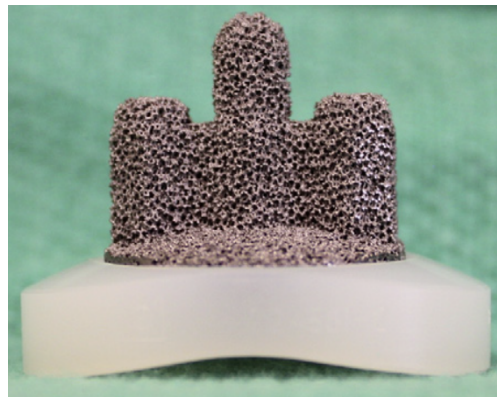


Fig. 1. *Tantalum based porous implant used for total shoulder arthroplasty* [6]

In this particular case, the implant is one of the components used for total shoulder arthroplasty. One can notice the porous tantalum structure in the upper region of the image, which due to its porosity, allows for proper osseointegration. In the lower region of the image, one can observe the polyethylene PE friction cup. The implant presented in the image is the 46 mm PT-backed (PT - porous tantalum) glenoid

prosthesis, produced by Zimmer Inc., Warsaw, IN, USA. Apart from the fact that the shape and size of the porous structure has a significant role on the osseointegration, using a porous structure has also the effect of lowering the elastic modulus and weight of the implant [5]. The manufacture of these types of porous structures has been done mainly using two techniques: chemical vapour infiltration and deposition [13], and powder metallurgy [41]. In the chemical vapour infiltration method, tantalum is chemically vaporized, infiltrated, and deposited on the surface of a low-density carbon skeleton. The powder metallurgy technology consists in submerging polyurethane sponges in tantalum slurry, followed with a thermal treatment at 1950 °C for 2 h. Tantalum foams have been also reported to be produced using sodium chloride as space-holders. Briefly, tantalum powder is mixed with sodium chloride particles, placed in a furnace at 1800 °C, under protective atmosphere (to avoid oxidation), followed by rinsing with water, to remove the salt particles [44]. Furthermore, the manufacture of net-shape porous tantalum structures with varying porosity using Laser Engineered Net Shaping (LENS) [3] and Selective Laser Melting (SLM) was also recently reported [35]. For these types of porous tantalum structures, several beneficial characteristics have been reported: relatively high resistance to cyclic loading and substantial bone ingrowth after 12 weeks [35]; increased volume of tissue ingrowth due to high porosity (75%-85%), comparable elastic modulus to trabecular bone (2.5-3.9 MPa) to reduce stress shielding, and favourable frictional characteristics to reduce micromotion [11]; radiographic signs of osseointegration and no migration or loosening of components [24]; propensity for bony ingrowth [36]; decreasing osteolysis and mechanical loosening [37].

All things considered, there have been also reported a few disadvantages for these types of structures: tantalum particulates could be observed, originated from the surgical removal of the implant or from implant wear, during implant revision procedures. Furthermore there was noticed a difficulty to remove the implant during revision, as they could remain skeletally attached [28]. Tantalum implants may also reduce the effect of Doxorubicin (DOX) in bone cancer treatment where both the Ta implant and DOX administration are required [9].

One of the methods of modifying the overall characteristics of implants is to use different materials in tandem, each of their respective advantages improving the final product. Considering that the surface of the implant is the only region in direct contact with the biological medium, one could deposit a biocompatible coating on a material that has adequate mechanical characteristics, but lacks in bio-performance. Several reports can be found in the literature, related to the effects of tantalum based coatings (mostly oxides), deposited on different kinds of substrates. The manufacture of these coatings can be achieved using: magnetron sputtering [8], [27], [33], [42], pulse metal vacuum arc source deposition [17], thermal treatment in molten salts [1], plasma immersion ion implantation deposition [44], polymer-assisted deposition [40], and Laser Engineered Net Shaping (LENS) [2]. Some of the results concerning tantalum based coatings that can be found in the literature are: dense and adhesive tantalum coatings deposited on the NiTi alloy improve its corrosion resistance [43]; the same improved corrosion resistance is noticed when deposited on Ti substrates, and improved cellular responses (e.g., adhesion, proliferation and differentiation), are also noticed [40]; increase in hardness compared to the untreated (CoCrMo) alloys (used for

total hip and knee replacement), followed by improved wear resistance [1]; good results have been obtained for tantalum coated Co-Cr alloys, in terms of the attachment, proliferation and differentiation of pre-osteoblasts (MC3T3-E1) [27]; good antimicrobial performance against *S. aureus* and *A. actinomycetemcomitans* for Ta₂O₅ films [8]; enhanced cell attachment and proliferation on the Ta surface as a consequence of its high wettability and surface energy [2]; antithrombotic performance [42]; and better adherence, growth, shape and proliferation of endothelial cells on tantalum and tantalum oxide films when compared to 316L stainless steel [17].

2.2. Tantalum Based Materials Used in Cardiovascular Applications

As far as cardiovascular devices are concerned, tantalum was used since the early days of stent development in both coronary and peripheral stent applications. These types of stents were helical wound wire and knitted wire structures, respectively. One of the factors which have led to its use as a stent material is its radio-opacity. Furthermore it was thought that the inert nature of tantalum oxide surfaces would lead to improved vascular compatibility and in particular reduced thrombogenicity. Wire coiled and woven structures were eventually replaced by slotted tube/laser-cut designs [25]. Corrosion properties are paramount, when discussing of metallic stents. The formation of a surface metal oxide-film retards corrosion. For some metals, including tantalum, this passivation is highly effective [4]. Currently, metallic stents are manufactured from nickel - titanium alloys and stainless steel with relatively high contents of nickel and chromium. The latter element increases both the mechanical properties (hardness,

strength) and its corrosion resistance [4]. Apart from bulk tantalum stents, several other materials have been developed, which benefit from the desired characteristics of tantalum, while in the same time displaying overall better properties. For example, a device comprised of a thin layer of tantalum sandwiched between two layers of 316L stainless steel exhibits sufficient strength (due to the stainless steel layers) and radio-opacity (due to the tantalum layer) to allow significantly lower strut thicknesses. Thinner stent struts have been reported to cause lower restenosis rates [25]. On one hand 316L stainless steel occasionally reveals biotoxicity [14]. On the other hand bulk tantalum has good radio-opacity, but also has less radial force and is broken more easily [16]. This means that this combination of materials should benefit from the advantages of both materials. One of the earliest reports on bulk tantalum stents showcased the advantage of being easily seen with fluoroscopic imaging in contrast to the relatively poor visibility of stainless steel devices, while in the same time showing an ease of implantation and no evidence of causing an excessive proliferative healing response, which could lead to stenosis [38]. The good radio-opacity of tantalum has also been exploited when proposing new biomedical alloys, such as the one reported in Ref. [26]. In this particular case, the surface of the Nb-28Ta-3.5W-1.3Zr alloy is covered by niobium oxide, and to a smaller extent with some tantalum oxide, both appearing naturally. Furthermore, this alloy may be similar to stainless steel for supporting cell growth, while the main advantage is its reduced magnetic susceptibility, making it suitable for MRI imaging. Nickel - Titanium (NiTi) alloys are already used with significant success in both hard and soft tissue biomedical applications that include orthodontic wire guides, braces,

self-expandable vascular stents, and others. The biocompatibility of these types of alloys is due to the formation of a protective TiO₂ passivation layer. However, if there are defects in the oxide layer, the undesirable release of Ni²⁺ ions can occur. McNamara et al. [22] have reported the deposition of tantalum oxide coatings on Ni-Ti substrates, by reactive magnetron sputtering. The films formed on the alloy surface were composed of TaO, and to some extent of TaO₂. The biocompatibility was reported to be high, making this coating to be an important candidate for biomedical applications.

3. Conclusions

Tantalum-based materials, in bulk and coating form, have been used successfully as materials for implants and prostheses applications. There is room for improvement of these types of materials, considering the fact that some problems are still reported. Their bioperformance properties can be influenced by the fabrication method, while the possibility to tailor the desired characteristics (porosity, surface roughness etc.) represents an advantage. Several drawbacks of certain materials can be overcome if one would use combinations of materials, each with its beneficial properties.

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