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The new generation Ti6Al4V artificial heart valve with nanocrystalline diamond coating on the ring and with Derlin disc after long-term mechanical fatigue examination

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Abstract

An artificial heart valve ring made of titanium alloy Ti6Al4V was coated with nanocrystalline diamond (NCD) with the use of RF PACVD technique. Then the heart valve with NCD coating and Derlin disc was tested by means of a long-term mechanical fatigue examination in a home-designed apparatus manufactured at the Technical University of Lodz (Poland).

Before and after the mechanical fatigue experiments, the surface of the valve ring was examined by Scanning Electron Microscopy (SEM) and by Raman Spectroscopy. The investigations verified the good quality of the coating covering all the surfaces, even in the most critical points where plasma didn't penetrate well during the coating deposition. Moreover, the comparison of studies before and after mechanical fatigue experiments show that the surface after the experiments is in good condition, still tight, and the range of the NCD layer thickness is the same as before the operation. The Raman spectra indicate that the NCD coating still covers all the surface of the ring (even in the places of the disc–ring interaction during relative motion of the disc).

Keywords: Nanocrystalline diamond; Surface characterisation; Heart valves; Biomaterials

1. Introduction

The man-designed and man-made “spare parts” for the human organism are made of materials, called biomaterials, which are able to function in intimate contact with the living tissue, with minimal adverse reaction or rejection by the body. Generally, an implant has to replace the destroyed natural organ and to function continuously in a proper way restoring the normal life of the man. The biomaterial from which an implant is made of has to fulfil four groups of requirements [1,2]:

- biocompatibility, which means the ability of the human body to endure the implants without destruction of the tissue,
- chemical stability, which means that the material is not degraded by environmental agents such as alcohol, sterilants, etc.,
- biostability, meaning resistance of the material to degradation resulting from biological interactions with the body,
- very good and proper mechanical characteristics according to particular applications of the implant.

There is a necessity to improve the biomaterials currently used for implant manufacturing and develop the technologies connected with the implant manufacturing. Among possible improvements there are different kinds of carbon coatings (among them diamond-like carbon) deposited on the surface of implants. They increase the implant biocompatibility, haemocompatibility and serve the role of barrier against corrosion [3–5].

The term diamond-like carbon (DLC) films refers to a wide range of materials with properties depending on the nature of carbon bonding (sp^2/sp^3 ratios), hydrogen content, inclusion of dopants, etc. It is necessary to know and understand their biocompatibility as well as their mechanical and other surface properties for specific applications. Some research teams focus on the carbon coatings, especially DLC in cardiac applications, including artificial heart valves [3–15]. DLC coated heart valves and stents are already commercially available or at the stage of

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development: the Cardio Carbon Company offers DLC coated titanium implants (“Angelini Laminaflo” mechanical heart valve and “Angelini Valvuloplasty” ring); Sorin Biomedica produces heart valves and stents coated with Carbofilm™; the company PHYTIS sells DLC coated stents [3]. Also another kind of carbon coatings, called nanocrystalline diamond thin films, can be used for biomedical implant purposes [16]. A very interesting research on ultra-low temperature nano-diamond coatings is carried out by Hasegawa et al. [17]. They can coat different substrates at room temperature conditions (stage of development). It will enable coating materials with the low melting point, so it will open the door to new possible applications in medicine (for instance as coating for artificial heart elements).

At the Technical University of Lodz the Mitura team invented the radio frequency plasma activated chemical vapour deposition (RF PACVD) method enabling coating different substrates with carbon films such as diamond-like carbon (DLC) and more recently nanocrystalline diamond (NCD) [1,2,6–10,18–21]. NCD coatings manufactured by the Mitura team have found many applications, especially in medicine. They can be used as coatings for implants, for instance orthopaedic implants and for artificial heart valves [1,6,7,10], and can be coated on different materials, such as medical steel AISI316L, titanium and its alloys such as Ti6Al4V [1,6,20].

The artificial heart valve is one of the most responsible “spare parts” that is implanted into the human body. Extremely high reliability and fatigue strength are demanded due to very difficult operation conditions and risk of the death of the patient if a break of operation or malfunction occurs. Almost all closing elements of mechanical artificial heart valves are made of pyrolitic carbon. However, different materials are used for valve rings. Owing to its physical and mechanical properties, such as low density, high strength and fatigue resistance, as well as resistance to corrosion, especially in physiological fluids, titanium or Ti6Al4V titanium alloy seemed to be very promising for heart valve rings of high reliability. Unfortunately, more and more cases of allergy to titanium and its alloys are reported each year all over the world [6]. Due to this fact heart valve rings made of such materials have to be modified to create at their surfaces the barrier between the material and cells, tissues, blood and other human organism fluids.

2. Experimental details

2.1. Heart valve operation conditions

The direction of the blood flow is controlled by four heart valves. Considering the flow parameters of each valve in the heart it can be stated that the highest pressure difference and velocity during cardiac contraction characterise the aortic position of the valve. Due to the extremely high risk of a patient’s death an artificial heart valve has to fulfil very strict biocompatibility and failure strength standards. In order to improve the properties of the newly designed tilting disc valve, its ring made of titanium or Ti6Al4V titanium alloy was coated with an NCD layer with the use of RF PACVD technique (see Fig. 1) [6,23,24].

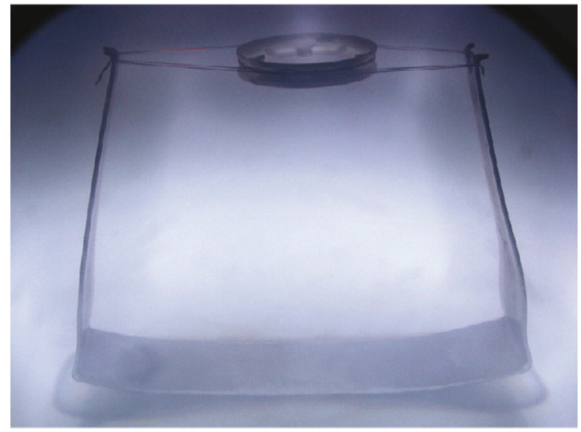

Fig. 1. Artificial heart valve ring made of Ti6Al4V during deposition of an NCD layer [6].

The NCD layer deposited on metals is characterised by very good mechanical properties and improves the biocompatibility and haemocompatibility of the substrate [1,2,6,7,10,18,21]. It also exhibits high level of resistance to bacterial colonization [19]. Compared to DLC, NCD coatings prove to have a very good adhesion. In the early articles it was mentioned that DLC peeled out of the implant surface [16, 22] ruled out its application in medicine. The adhesion of DLC films to metallic substrates is usually improved by the use of intermediate layers such as silicon, chromium and tantalum [25]. The very good properties of NCD for biomedical applications result from its structure [1,10,18], a few micrometers thick coating consists of the diamond crystals the size of which is calculated in nanometers (nanocrystalline diamond). Crystalline graphite as the allotropic form of carbon fills the spaces between grains of diamond and creates the continuity and relative flexibility of the layer. The interface layer obtained from metal carbides (in this case titanium carbides) increases the coating adhesion [10].

The modification of the heart valve ring material would assure better comfort of living to the patient with the implant, especially preventing thrombus formation (possibly patient will not need coagulants). The question is: How long will this thin layer represent excellent properties knowing that the disc of the artificial heart valve operates in a cycle of 0.8 s (as the average value of the time of this period) for years? In each cycle relatively low loads are exerted but the number of cycles is huge, which results in a continuous friction between the disc and the nanocrystalline diamond layer of the titanium heart valve ring [9].

The modified surface has to be checked and verified after the simulated long time of the valve operation. Long-term mechanical experiments may be shortened by increasing the number of cycles performed in a time interval and by operation in conditions similar to the ones in the human body, which causes faster fatigue of valve elements.

2.2. Set-up for the long-term mechanical fatigue examination of the heart valve

All vessels in the human body are elastic. In case of stiff vessels even short pump stoppage causes almost an immediate