Ti6Al7Nb ALLOY SURFACE IMPROVEMENT FOR IMPLANTABLE BLOOD PUMPS APPLICATIONS

MAŁGORZATA GONSIOR[1]*, MICHAŁ TARNOWSKI[2], KAROLINA JANICZAK[1], BARBARA ZAWIDLAK-WĘGRZYŃSKA[1], TADEUSZ WIERZCHOŃ[2], MACIEJ GAWLIKOWSKI[1], ROMAN KUSTOSZ[1]

[1] PROFESSOR ZBIGNIEW RELIGA FOUNDATION OF CARDIAC SURGERY DEVELOPMENT, POLAND
[2] WARSAW UNIVERSITY OF TECHNOLOGY, POLAND
*E-MAIL: GOSIAG@FRK.PL

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Introduction

Despite the significant advances in continuous flow heart assist devices technology, these pumps have been associated with important adverse events, including pump thrombosis, stroke, bleeding, and device-related infection, and have caused unanticipated alterations in human biology that are related in part to shear stresses of the pump or reduced pulsatility [1,2]. Construction of implantable blood pump is a huge challenge in the aspect of long-term contact with blood under high shear stress conditions.

In the clinical version of Polish implantable rotary blood pump (FIG. 1) ReligaHeart ROT (RH ROT) [3] the polymer parts has been replaced with ceramic composite, ZrO_2-Y_2O_3, with high hardness, to improve device wear resistance. Additionally, modification of the well-known glow discharge assisted nitriding process called active screen plasma nitriding has been used for enhancing the properties of titanium pump parts, made from Ti6Al7Nb alloy through production of TiN+Ti_2N+αTi(N) diffusive surface layers in order to increase corrosion and wear resistance as well as device's biocompatibility.

FIG. 1. ReligaHeart ROT implantable blood pump clinical version prototype.

Materials and Methods

The athrombogenic diffusive nitrided surface layers TiN+Ti_2N+αTi(N)- type have been produced on Ti6Al7Nb titanium alloy surface, with roughness of Ra=80nm, using plasma nitriding process with active screen.

The microstructure and surface topography of the TiN – outer zone of nitrided layer were examined using TEM, SEM and AFM. HV0.05 Vickers microhardness measurements were carried out. Corrosion resistance, including impedance and potentiodynamic methods, as well as wear resistance (PN-83/H-04302 and ASTM G99-05 standards), of TiN layers were studied.

First investigation of TiN biocompatibility properties were performed according to PN EN ISO 10993 standard requirements. Biomaterials were sterilized with ETO, as the final device RH ROT sterilisation method (EOGas 4, H.W.Andersen Products Ltd.). Haemolysis assessment was performed on diluted human blood (HGB 10g/L) in direct contact. Biomaterial was incubated with blood in temperature of 37°C for 3h. After incubation free haemoglobin level was assessed and haemolytic index was calculated. Cytotoxicity examination was carried out on fibroblasts L929 incubated for 24h in Medium 199 supplemented by 10%FCS. Live and necrotic cells were marked by FDA and PI, respectively. Biodegradation tests were carried out for 30 and 60 days in SBF. The degradation medium was investigated by ICP analysis. Biomaterial surface morphology was investigated by SEM. Thrombogenicity assessment was carried out in static as well as in dynamic conditions. Static thrombogenesis evaluation was performed by biomaterial incubation in platelet rich plasma, temperature of 37ºC for 1h, washing and fixation with formaldehyde. Presence of adhered blood elements on biomaterials surface was investigated with SEM utilisation. Evaluation of thrombogenic properties in dynamic conditions was performed utilizing Impact-R analyser and fresh human blood, by generating physiological blood flow above the investigated surface. Platelets activation and platelet-leukocyte aggregates formation were determined utilizing flow cytometry. Analysis of adhered cells to the biomaterial surface with active receptors (CD62P, CD45) was performed utilizing fluorescent microscopy.

Results and Discussion

TiN+Ti_2N+αTi(N) layers produced on Ti6Al7Nb using glow discharge nitriding process with active screen improve titanium alloy surfaces hardness (FIG. 2), wear (FIG. 3) and corrosion resistance, allow to confirm the homogeneity of surface layer on the whole biomaterial samples area.

The first results of biological evaluations have confirmed that TiN+Ti_2N+αTi(N) layers produced on Ti6Al7Nb titanium alloy surface are non- haemolytic and non-cytotoxic with additionally high resistant for biodegradation and are characterized by good athrombogenic properties.

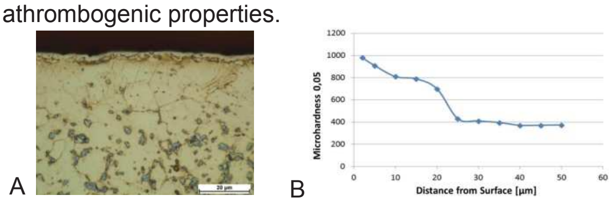

FIG. 2. Microstructure (A) and microhardness profile (B) of TiN+Ti_2N+αTi(N) layers produced on Ti6Al7Nb alloy.

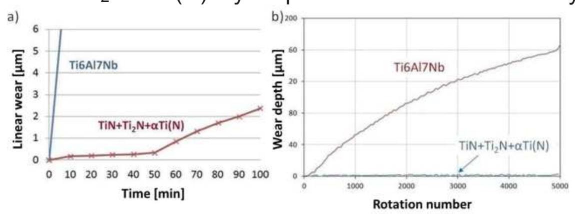

FIG. 3. Wear resistance of TiN+Ti_2N+αTi(N) layers and initial state Ti6Al7Nb alloy.

Conclusions

The TiN+Ti_2N+αTi(N) nitrided layers, with nano-crystalline TiN outer zone, produced on Ti6Al7Nb titanium alloy using active screen plasma nitriding process will improve ReligaHeart ROT parts hardness, wear and corrosion resistance, also in contact with zirconia parts during blood pump working. TiN layers have necessary biological properties; however complex biocompatibility has to be evaluated in order for biomaterial application in finale medical device for human use.

Acknowledgments

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