ATHROMBOGENIC DIFFUSIE TiN SURFACE LAYERS APLICATION AND EVALUATION IN POLISH IMPLANTABLE ROTARY CONTINOUS FLOW BLOOD PUMP

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Introduction

The implantable rotary continuous flow blood pump, ReligaHeart ROT has been developed [1,2], as an implantable left ventricular assist device for patients with advanced heart failure.

The surface engineering was used to create blood pump elements surfaces structure, in order to reduce shear stress induced platelet activation on blood contacting pump elements and avoid blood clothing inside the pump. The innovative process of plasma glow discharge technology and detail appropriate surface structure and topography has been developed and confirmed first in laboratory testing [3]. The titanium nitride (TiN) surface layers proper haemolytic properties as well as athrombogenic properties (platelets activation and adhesion after contact with blood) were confirmed in vitro, under high shear stress conditions [4].

The next step of biomaterial evaluation was TiN layers application in ReligaHeart ROT device and examination of its surface structure, topography and selected biological properties (biocompatibility with blood).

Materials and Methods

The ReligaHeart ROT prototypes, with magnetically and hydro-dynamically suspended impeller, producing flow up to 10 l/min were manufactured. The athrombogenic diffusive titanium nitride $TiN+Ti_2N+\alpha Ti(N)$ layers have been applied for titanium pump's house and rotor, with roughness of Ra=80nm. The TiN surface zone was examined using TEM, SEM and AFM.

The 6 hours acute thrombogenicity test [5] on fresh animal blood was performed to validate the ReligaHeart ROT pump embolization risk (FIG. 1).

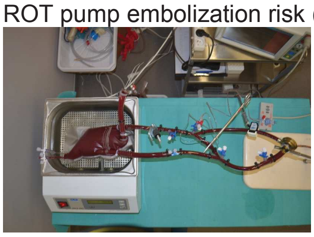

FIG. 1. The acute thrombogenicity tests.

Porcine blood, collected in slaughterhouse and anticoagulated by means of heparin in dosage of 1,5u/ml, was used. This qualitative test shows if the device made of investigated biomaterial tends to form and adhere thrombus under continuous blood flow conditions. The ReligaHeart ROT prototypes (n = 3) were examined. The circulation time was: 220, 260 and 280 min (up to reach critical ACT = 1,5*animal's ACT). The circulation parameters were: blood flow = 5lpm, afterload pressure = 100mmHg. ACT and platelet number in time during the experiment was measured. After the test the pump were disassembled and detail assessment of pump elements were performed in order to evaluate the potential thromboembolic material collected inside the pump.

Results and Discussion

The nitride layers with nanocrystalline titanium nitride (TiN) surface zone TEM, SEM and AFM examination confirmed the appropriate structure and topography on the whole blood pump elements (FIG. 2, 3).

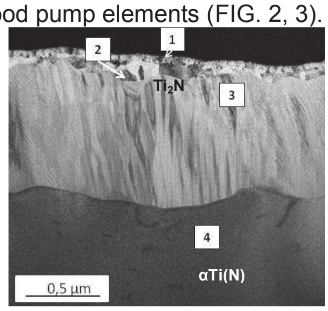

FIG. 2. Surface structure of $TiN+Ti_2N+\alpha Ti(N)$ layers on the blood pump elements.

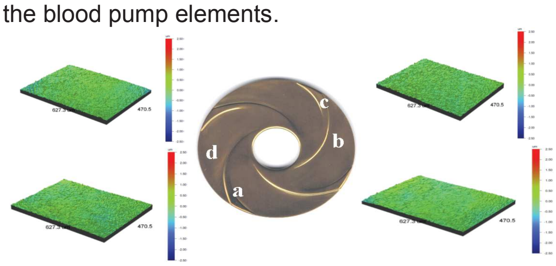

FIG. 3. Surface roughness of TiN layers on the blood pump elements.

The acute thrombogenicity test confirmed blood clotting freedom inside the pump, including impeller (FIG. 4). The micro emboli were observed at surface technological defects.

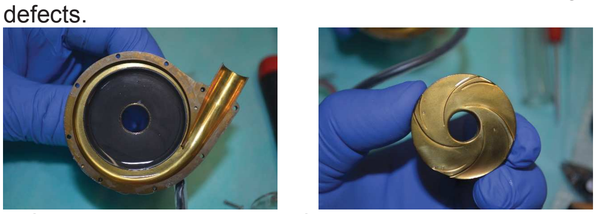

FIG. 4. The ReligaHeart ROT pump elements with the TiN diffusive surface layers after acute thrombogenicity test.

Conclusions

The ReligaHeart ROT prototypes investigations, with the applied $TiN+Ti_2N+\alpha Ti(N)$ layers, confirmed the pump and the titanium nitride layers expected surface properties, especially athrombogenic properties in the contact with blood. The further work for human device construction and manufacturing technology development will be carried out.

Acknowledgments

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