TiN diffusive layers applied as athrombogenic surface for cardiac implants: heart valves, rotary blood pumps
Diffusive layers developed in so called glow discharge plasma potential:

nitriding layer

\[ \text{TiN+Ti}_2\text{N+\alphaTi(N)} \]

oxynatriding layer

\[ \text{TiO}_2+\text{TiN+Ti}_2\text{N+\alphaTi(N)} \]
TiN+Ti₂N+αTi(N)
TiO₂+TiN+Ti₂N+αTi(N)

✓ High adhesion to the surface (diffusive character)
✓ High biocompatibility with fibroblasts, osteoblasts and blood
✓ High surface hardness and wear resistance

minimization of thrombogenicity risk during long term utilization and providing durability of cardiac implants (heart valves, rotary blood pumps etc.)
TiN + Ti₂N + αTi(N)

Process parameters:
T = 700°C
T = 680°C, t = 4 hours
p = 2.5 mbar
p = 3 mbar

1st phase: nitriding
2nd phase: oxidation

TiO₂ + TiN + Ti₂N + αTi(N)

1200HV₀.₀₅
415HV₀.₀₅

880HV₀.₀₅

2μm
TiN+Ti$_2$N+αTi(N)

GDOS chemical analysis

Chemical elements concentration [% mass.]

Distance [µm]
Ti6Al4V

TiN+Ti2N+αTi(N)

Ra: 161.91 nm
Rq: 213.50 nm
TiN + Ti₂N + αTi(N)

TiO₂ + TiN + Ti₂N + αTi(N)
TiN+Ti$_2$N+$\alpha$Ti(N)
TiO$_2$+TiN+Ti$_2$N+$\alpha$Ti(N)

**Homogenous surface structure and topography**

**Possibility of surface topography control during the process**

**High hardness**

**Very good wear resistance**

**High corrosion resistance**

[18] Borowski T., Sowińska A., Ossowski M., Czarnowska E., Wierzchoń T. Engineering of Biomaterials, Rytro (2009);
[19] Ossowski M., Borowski T., Wierzchoń T. Inżynieria Materiałowa, v. 30, nr 5, pp. 294-297 (2009);
[20] Brojanowska A., Kamiński J., Ossowski M., Wierzchoń TOchrona przed korozją, nr 4-5, pp. 135-139 (2008);
PLATELET ADHESION
PLATELET ACTIVATION
PLATELET AGGREGATION

Static contact with blood - 2 hours of incubation

P selectine, GPIIb/IIIa receptor

TiN+Ti₂N+αTi(N)

TiO₂+TiN+Ti₂N+αTi(N)
Dynamic contact with blood – shear stress model

Impact-R
Dynamic contact with blood shear stress model

Number of platelets staying in the blood after shear stress conditions [%]

Number of activated platelets [%] (GPIIb/IIIa receptor)

Number of platelets staying in the blood after shear stress conditions [%]

Original Polish Tilting Disc Valve


Valve house: Ti6Al4V with TiN+Ti2N+αTi(N) / TiO2+TiN+Ti2N+αTi(N) layers

Valve disc: PEEK OPTIMA polymer
Polish extracorporeal ventricular heart assist device POLCAS

First implantation: 1995
Clinical trials: 1995 - 2000
Clinical utilization: 2000 - 2013

TOTAL IMPLANTS:
323 patients
The longest assistance toward heart transplantation: BiVAD=12; LVAD=13 months, SCCS Zabrze: 2009 - 2010
The longest heart assistance toward heart regeneration; 
LVAD = 23 months; SCCS Zabrze, 2011 -2013
New Polish extracorporeal heart support system

Technological Department – ReligaHeart EXT production
ReligaHeart EXT VAD

- Volume 70 ml and optimized blood chamber construction
- New membrane system with lower profile
- New generation innovative biocompatible PU with modified surface structure (DSM Biomedical USA).
- New tilting disc valves type Moll
- Special cannulas protection system
- Modern technological process of pump elements manufacturing
- Automatized pump assembling process
Valves used in POLCAS system

Sorin

Medtronic Hall

Valves used in ReligaHeart EXT system

Moll
Tilting disc Moll Valves with surface engineering

- Inlet valve: size 20 mm
- Outlet valve: size 24 mm
- Ring: Titanium TiN coated
- Disc: PEEK Optima Carbon coated
ReligaHeart EXT - Preclinical laboratory examinations

- 35 millions membrane work cycles = 340 days of 70 bpm stable work
- 10,5 millions RH EXT device workcycles = over 100 days of 70 bpm stable work
- Increasing both: static (+5%) and dynamic (+23%) stroke volume
- No deformations nor damages of PU pump elements, neither the valves
ReligaHeart EXT - Preclinical animal study

- 7 animals
- Up to 30 days investigations
- Warfarin, Aspirin clinical protocol treatment
ReligaHeart EXT system usage during over 1500 hours of exploitation confirmed the proper safety of the system.
Development of pediatric pulsatile VAD – ReligaHeart PED
TiN+Ti₂N+αTi(N) / TiO₂+TiN+Ti₂N+αTi(N) application

ReligaHeart ROT
Polish left ventricle implantable rotary pump

- low profile impeller, suspended in the middle of pump house, with symmetric gap between pump house and impeller, of 0,15 mm nominal distance each side;
- the jointly acting static magnetic and hydrodynamic forces are used for impeller suspension, while rotating with speed varied from 2000 to 5000 rpm.
• Centrifugal LVAD
• Contactless suspended rotor
• BLCD double motor
• Battery powered
• Remote control
• Long distance communication
Shear stress in hydraulic bearings area numerically determined for impeller rotation speed of 3000 rpm

The numerically determined wall shear stress produced on the hydraulic bearing blade elements surface (bearing inlet, bearing lifting surface, bridging surface) showed the shear stress values varied from 0.00 to 0.048 kPa. The shear stress exceeding 0.2 kPa level occurred only on small area of bearing bridging surface.
The physical model for blood rotating with different rotational velocity over a biomaterial surface

Disk to chamber bottom distance: 0,05 - 0,30mm
Disk rotation speed: 500 - 5000 rpm.
Controlled blood flow: 1 - 15 ml/min.

The shear stress exposed thrombocytes activity was determined.
Platelet activation was investigated using flow cytometry.

The biomaterial surface after blood contact was evaluated using fluorescent and confocal microscopy.
Free haemoglobin level reported in blood after single exposure to high shear stress, produced experimentally by different TiN modified titanium Grade2 surfaces

- ref1, ref2 – Titanium Grade 2 reference samples, roughness 0,08µm;
- A008A1 – TiN layer (created at cathode potential) with Ra=0,08µm;
- A016A2 – TiN layer (created at cathode potential) with Ra=0,16µm;
- A008A2 - TiN layer (created at plasma potential) with Ra=0,08µm;
- A016A1 – TiN layer (created at plasma potential) with Ra=0,16µm;
- A063A - TiN layer (created at plasma potential) with Ra=0,63µm
Platelets aggregation level reported in blood after single exposure to high shear stress, produced experimentally by different TiN modified titanium Grade2 surfaces

- ref1, ref2 – Titanium Grade 2 reference samples, roughness 0.08µm;
- A008A1 – TiN layer (created at cathode potential) with Ra=0.08µm;
- A016A2 – TiN layer (created at cathode potential) with Ra=0.16µm;
- A008A2 - TiN layer (created at plasma potential) with Ra=0.08µm;
- A016A1 – TiN layer (created at plasma potential) with Ra=0.16µm;
- A063A - TiN layer (created at plasma potential) with Ra=0.63µm
The thrombogenicity and hemolytic examinations results analysis demonstrated that diffusive TiN+Ti$_2$N+αTi(N) layer produced on titanium surface does not cause erythrocytes damage and platelets adhesion in the dynamic high shear stress conditions.
The developed glow discharge process at plasma potential has allowed to produce diffusive TiN micro-layer on titanium, with controlled surface topography in micro and nano-scale level. The several microns thick diffusive TiN layers were produced on the different rotary blood pump elements: rotors and blood pump house. The roughness of TiN layers showed homogeneity on whole modified surface, despite the complex blood pump element’s shape.
Conclusions

Results obtained promise good properties of new developed TiN+Ti$_2$N+αTi(N) layers for application in blood contacting elements of heart valves and particularly rotary blood pumps, where blood velocity and shear stresses are very high and increase the risk of thrombosis.
Future steps

The validation of the obtained results will be performed in further laboratory and biological experimental investigations of the ReligaHeart ROT prototype equipped with developed impeller suspension system, with rotor and pump house blood contact surfaces modified of TiN layers, created by glow discharge at plasma potential.

- In vitro long term work tests
- In vitro acute thrombogenicity tests with the fresh animal blood
- In vivo trials
Thank you for your attention