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Method for treatment medical devices made from nickel - titanium (NiTi) alloys

Junkar I., Benčina M., Zaplotnik R., Kovač J., Mozetič M.
Department of Surface Engineering and Optoelectronics, Jožef Stefan Institute,
Jamova 39, SI-1000 Ljubljana, Slovenia

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Abstract: The present invention improves the surface modification of NiTi alloys used for instance in medical devices through treatment with hydrogen particles in a suitable gaseous discharge and with oxygen atoms. The technique according to the present invention provides the formation of biocompatible solely titanium oxide layer thus preventing nickel to be present in the top surface layer. Furthermore this enables nanostructuring of the surface which depends on the treatment conditions. Devices made from NiTi alloys treated with the method according to the present invention have improved biocompatibility; platelets do not readily attach and activate on such surfaces and the thrombus formation rate is reduced in comparison with extensively used untreated NiTi alloys.

Results

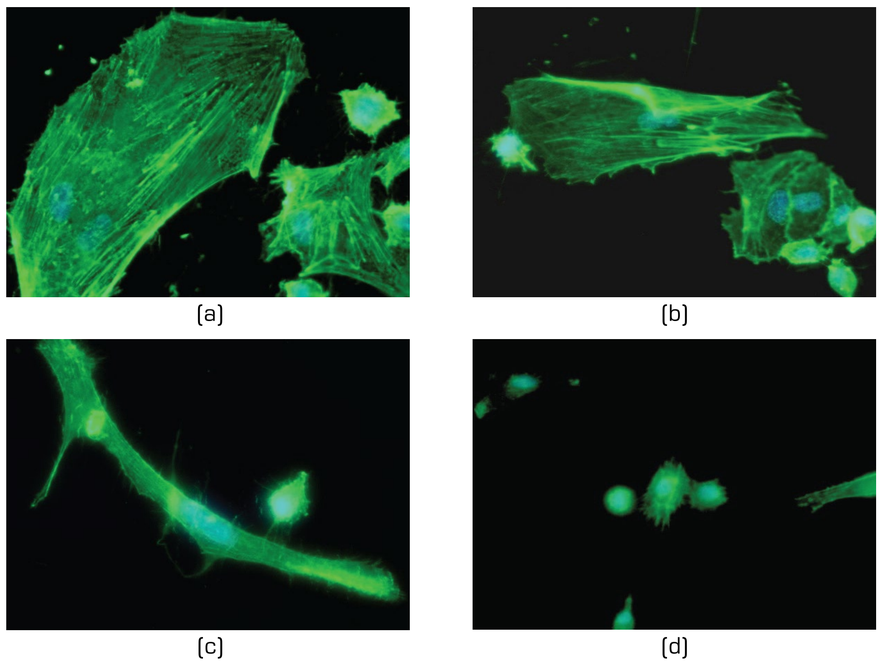


Fig. 2: Fluorescence microscopy images of human coronary artery endothelial cells (HCAEC) on the surface of (a) NiTi foil and (b) NiTi foil treated with plasma and human coronary artery smooth muscle cells (HCASMC) on the surface of (a) NiTi foil and (b) NiTi foil treated with plasma. F-actin is shown in green (Fluorescein Phalloidin) and nuclei are shown in blue (4',6-diamidino-2-phenylindole - DAPI) [4,5].

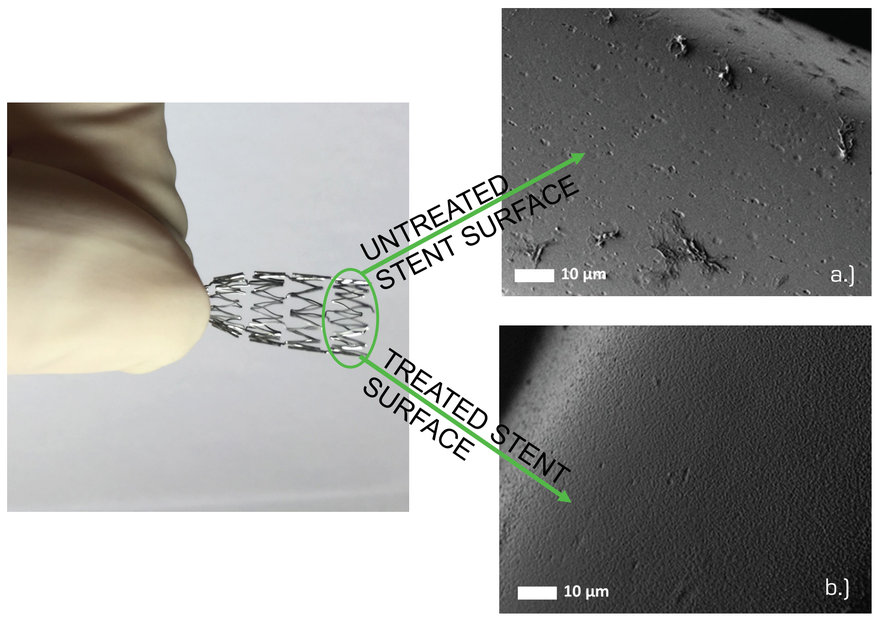
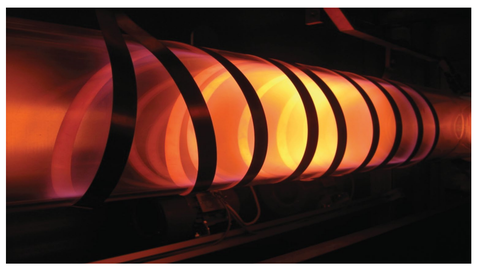


Fig. 3: SEM analysis of stent after incubation with whole blood: (a) untreated NiTi stent and (b) NiTi stent treated by the method of invention.

Experimental: The NiTi surfaces and stents made from NiTi alloy were subjected to highly reactive plasma in order to improve biocompatibility



- Prevent adhesion and activation of platelets
- Improve proliferation of endothelial cells
- Reduce proliferation of smooth muscle cells

Fig. 1: Highly reactive plasma chamber used for treatment of NiTi alloy.

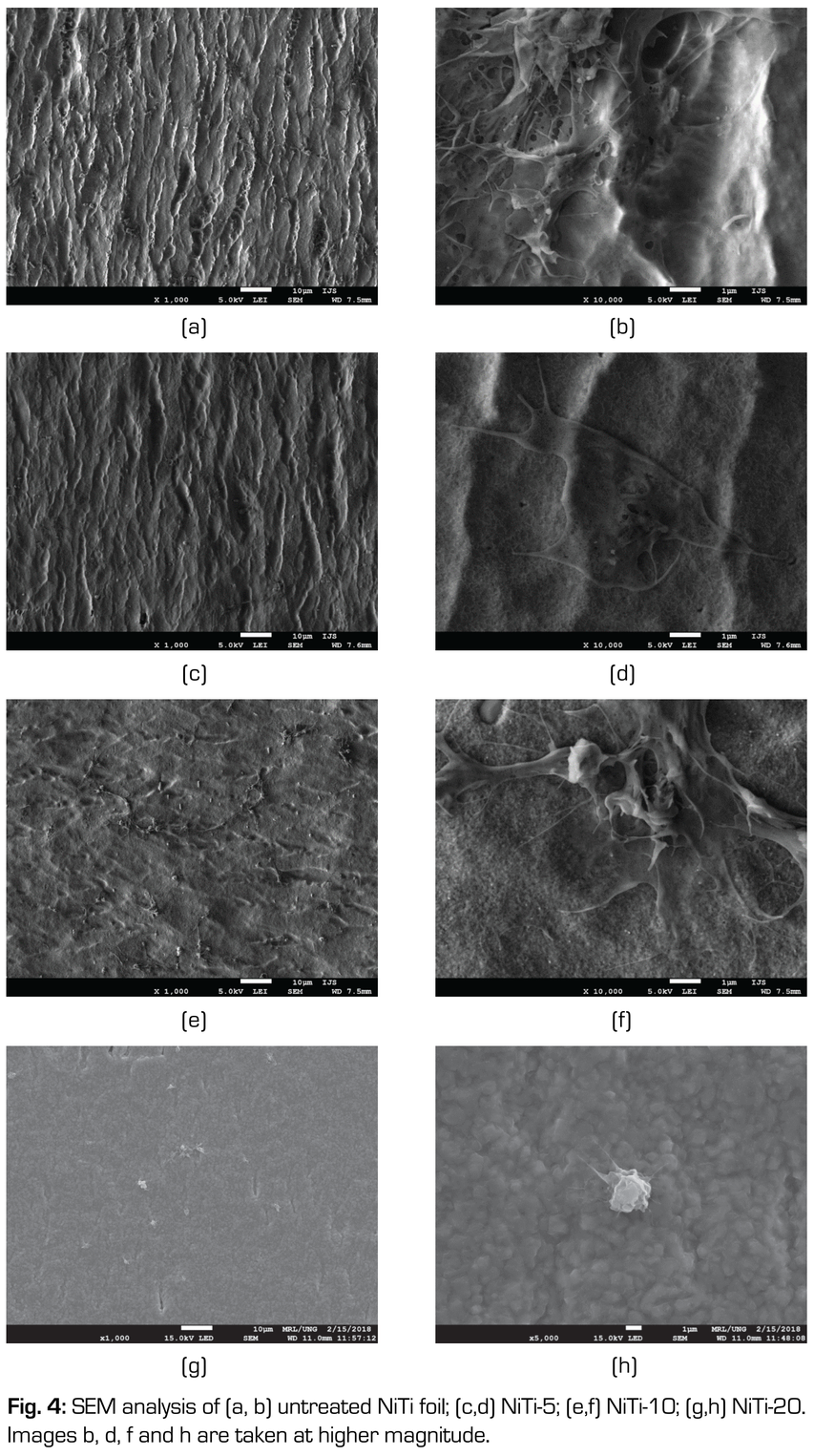


Fig. 4: SEM analysis of (a, b) untreated NiTi foil; (c,d) NiTi-5; (e,f) NiTi-10; (g,h) NiTi-20. Images b, d, f and h are taken at higher magnitude.

Conclusions: The implantation of currently available stents often induces inflammation responses that could lead to stent thrombosis, which still represents a major concern in clinical practice. This condition is closely related to topology and chemical composition of implantable surfaces. Treatment of stent materials with H_2/O_2 non-thermal plasma could therefore represent a new generation of medical devices that would prevent clotting, thrombosis and restenosis, which are still the major limitations of stent technology. Importantly, within the H_2/O_2 plasma treatment there may lay an essential role as it can optimize surface properties for various applications. Appropriate tuning of surface morphology and chemical composition allows for reduced adhesion and activation of platelets and reduces the risk of thrombosis. The current results prove that NiTi treated with H_2/O_2 plasma is a viable and outstanding technological development, potentially enhancing the outcome of patients treated by percutaneous coronary intervention that can radically change further stenting practices.

CONTACT DETAILS
Tomaž Lutman
Center for Technology Transfer and Innovation,
Jožef Stefan Institute,
Jamova cesta 39, SI-1000 Ljubljana
http://tehnologije.ijs.si
Phone: +386 1 477 3801
tomaz.lutman@ijs.si

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