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CLINICAL IMPORTANCE OF BIOCORROSION OF METAL IMPLANTS – EXRERIMENTATION AND MODELING

Konstantinos Kapnisis[1], Despoina Kokkinidou[1], Dehzi Wang[2], Peter Anderson[2], Brigitta Brott[2], Jack Lemons[2] and Andreas Anayiotos[1]

[1] Department of Mechanical and Materials Science and Engineering, Cyprus University of Technology, 45 Kitiou Kyprianou, 3036, Limassol, Cyprus
[2] School of Medicine, University of Alabama at Birmingham, AL, USA,
e-mail: andreas.anayiotos@cut.ac.cy

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Abstract: Medical device materials contain chemicals that pose toxicological problems if released in sufficient quantities in the body. Toxicological risk assessment and prevention by manufacturers include metal surface treatments, in vitro extraction testing and animal experiments to minimize the potential for patients to be exposed to chemicals that may possibly leach out of device materials. Stent retrieval studies by us and others [1.2.3] have shown significant corrosion and leaching of device materials into the body with significant concern by the FDA in numerous recent reports [3,4]. To investigate the peri-implant tissue response to stent biocorrosion, custom made self-expanding nitinol stents (0.7 x 3.3 mm), were implanted in the common carotid artery of male CD1 mice (Project license: CY/EXP/PR.L9/2019). Non-corroded (electropolished) and corroded (heat treated) stents were pre- and post-implantation examined using SEM and also evaluated for Ni ion release (quantified via ICP-MS) in a 60-day immersion test in PBS. Sham-stented samples were also prepared to control for any non-stent related inflammatory effects such as endothelial layer damage caused during catheter guidance. Mice were euthanized under anesthesia at 4 and 8 weeks after surgery and harvested tissue samples were perfusion fixed in situ with 4% PFA for histological analysis which included stent-tissue interaction, thrombus formation, inflammation, and the presence of neointima. A separate group of operated mice was also prepared for nickel ion quantification in peri-implant tissue (dissolved in NaOH and analyzed via ICP-MS). Right before euthanasia, whole blood samples were collected, in citrate prefilled syringes using the cardiac puncture technique, for hematological analysis. Our results indicate that stent surface condition and implantation time affect the development and extent of neointima. The hematological and histological data revealed a significant increase in inflammatory cells, thrombus formation and mature neointima in corroded stented aortas with respect to the electropolished stented aortas. Elevated metal particle contamination, prompted by corroded stents, triggers an inflammatory response. Further studies are warranted to systematically characterize this mechanism that may lead to the development of in-stent restenosis.

Selective references:

1) D. Halwani 2010; 2) DE. Halwani 2011; 3) Sullivan et al. 2017; 4) FDA Biomedical Responses to Metal Implants 2019

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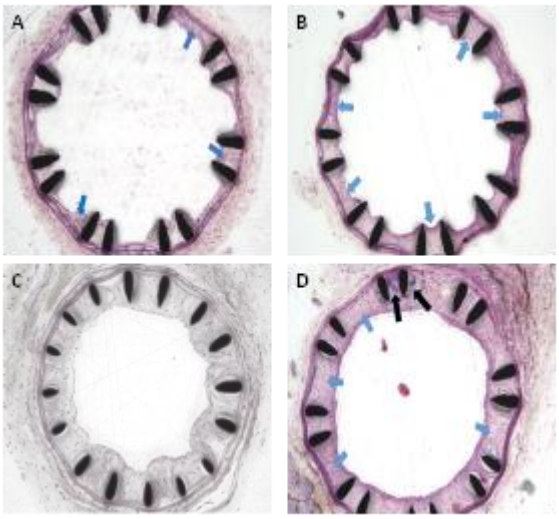

Histological evaluation of stented mice arteries. Electropolished stented artery at (A) 4 weeks and (B) 8 weeks. Corroded (heat treated) stented artery at (C) at 4 weeks and (D) 8 weeks.