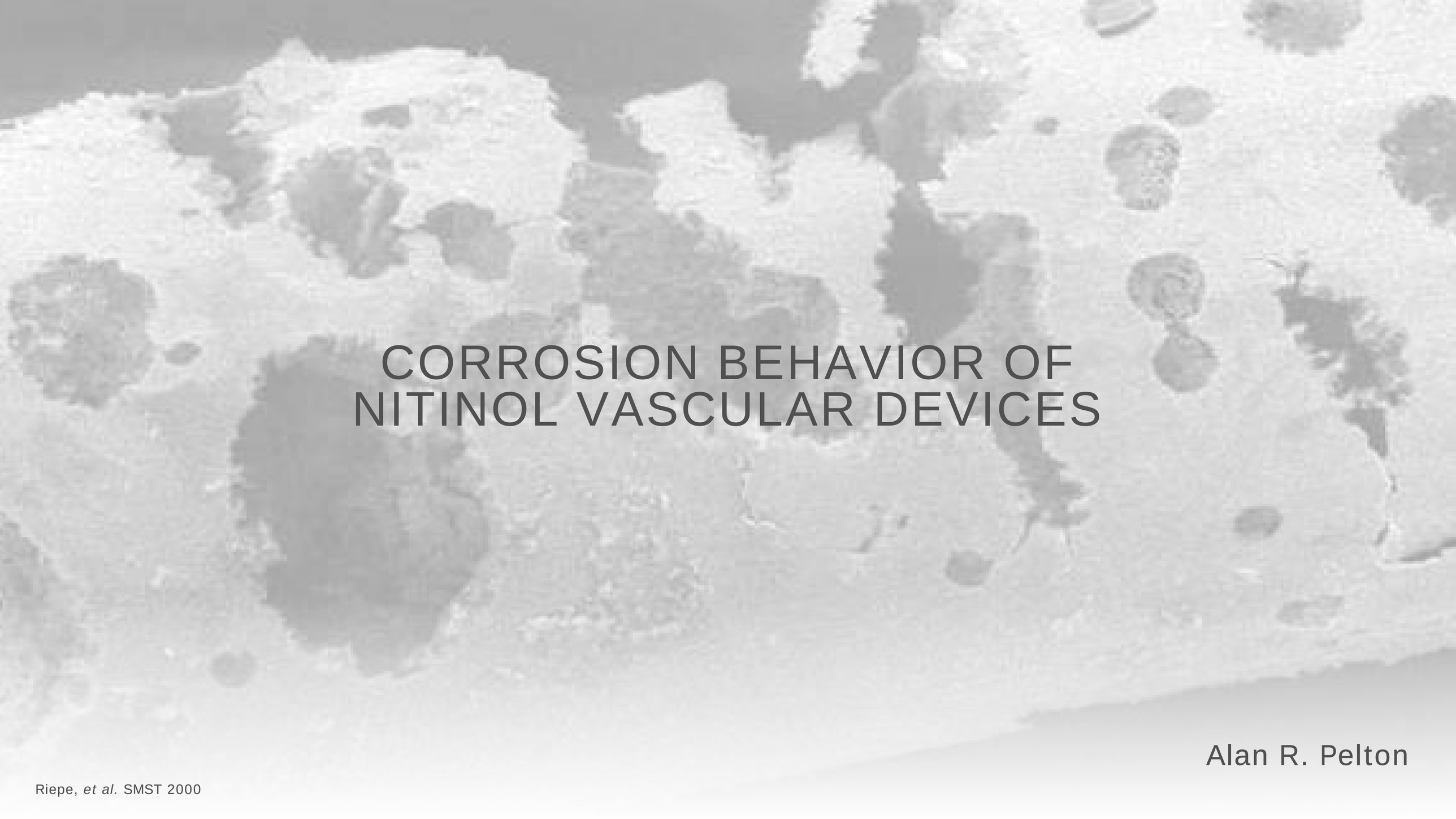
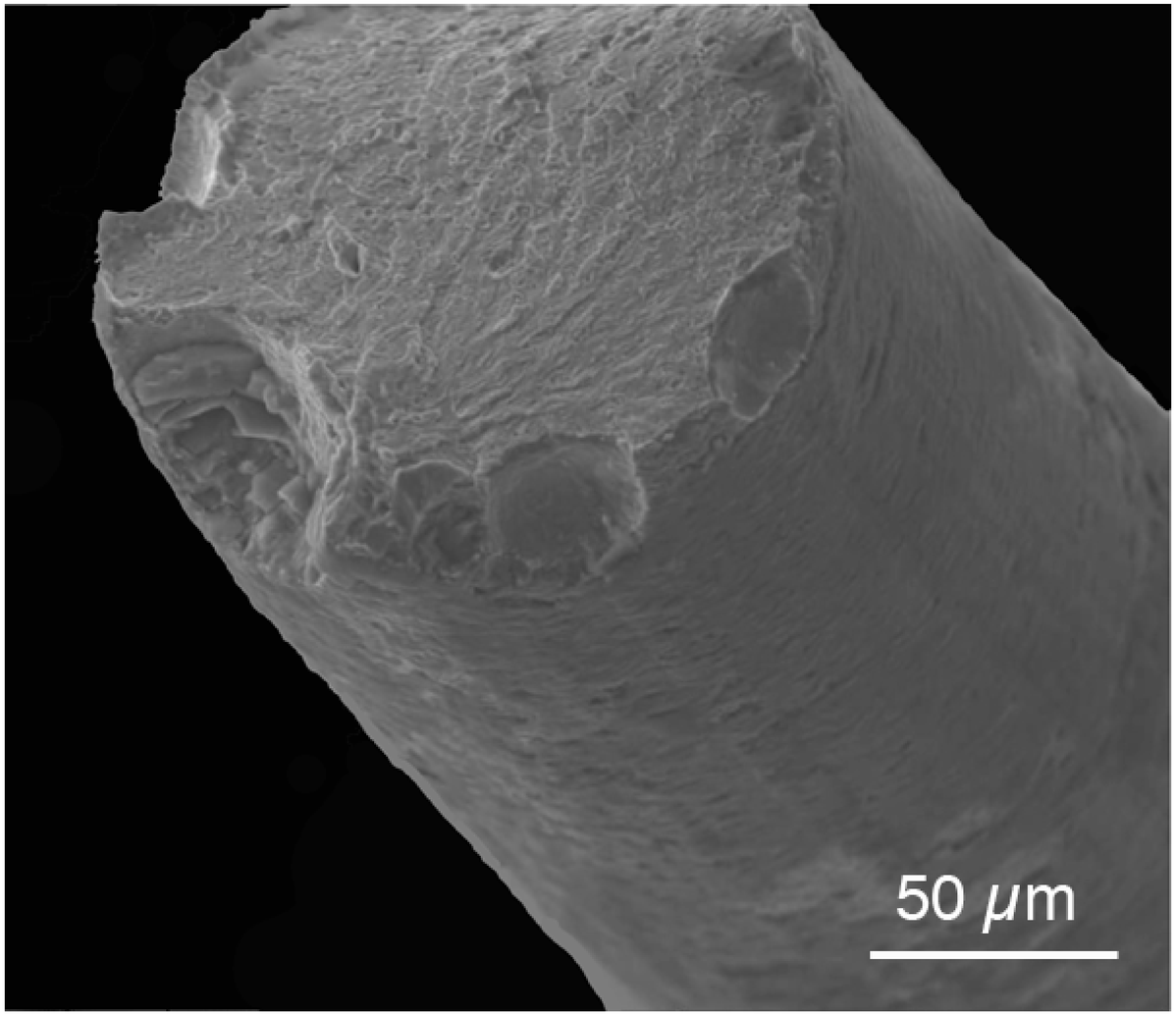


CORROSION BEHAVIOR OF NITINOL VASCULAR DEVICES

Alan R. Pelton

Riepe, *et al.* SMST 2000

Corrosion and Biocompatibility Depend on Surface Processing



Jetty, *et al.* J Vasc Surg 2013

FDA Stent Guidance Document 2015

Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems

This guidance provides updates for the following topics:

- Pitting corrosion potential;
- Galvanic corrosion;
- Surface characterization; and
- Nickel ion release.

Designation: F2129 – 17

Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices[1]

Designation: F3044 – 14

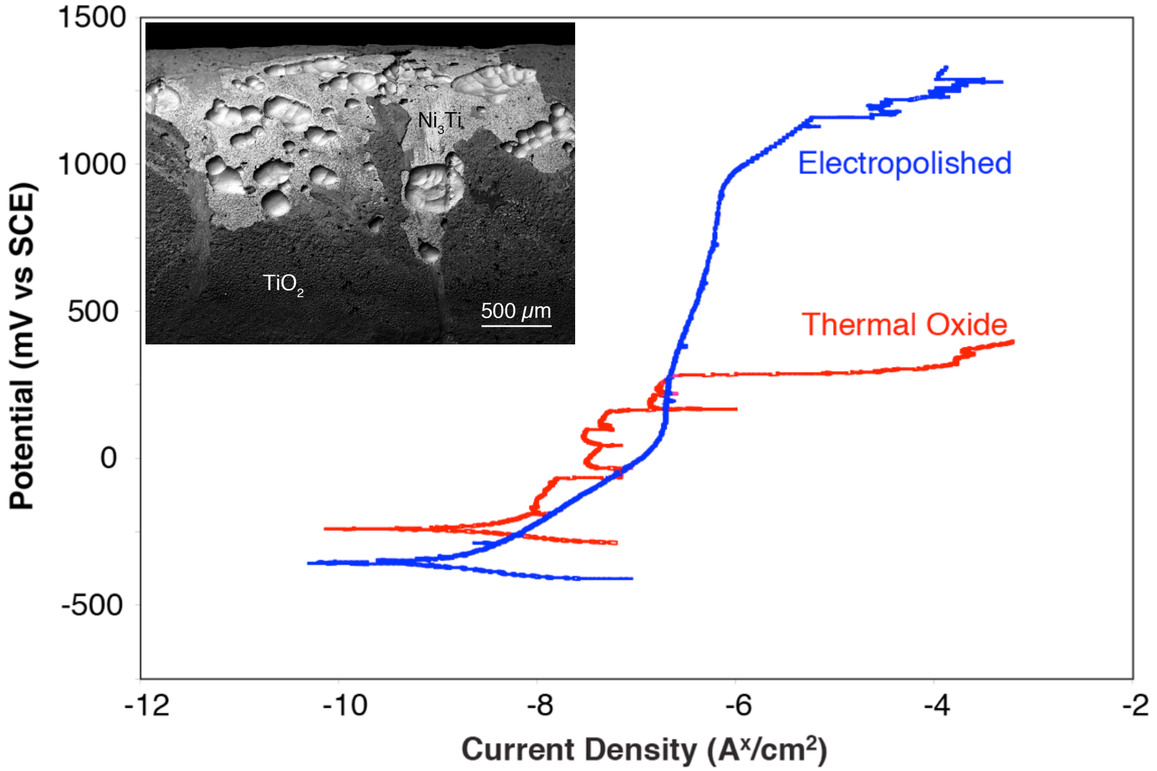
Test Method for Standard Test Method for Evaluating the Potential for Galvanic Corrosion for Medical Implants[1]

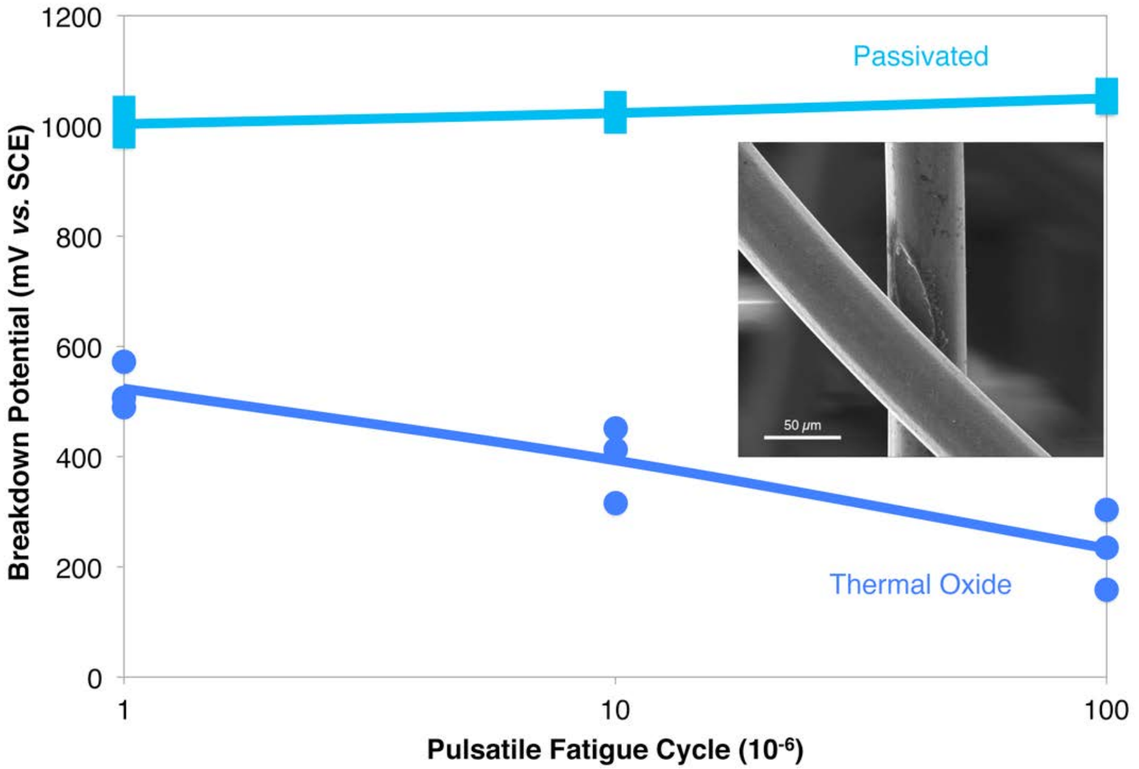
American National Standard ANSI/AAMI/ISO 10993-15:2000

Biological evaluation of medical devices—Part 15: Identification and quantification of degradation products from metals and alloys

Anodic Polarization Corrosion Resistance: Passivated and Thermal Oxide Surface

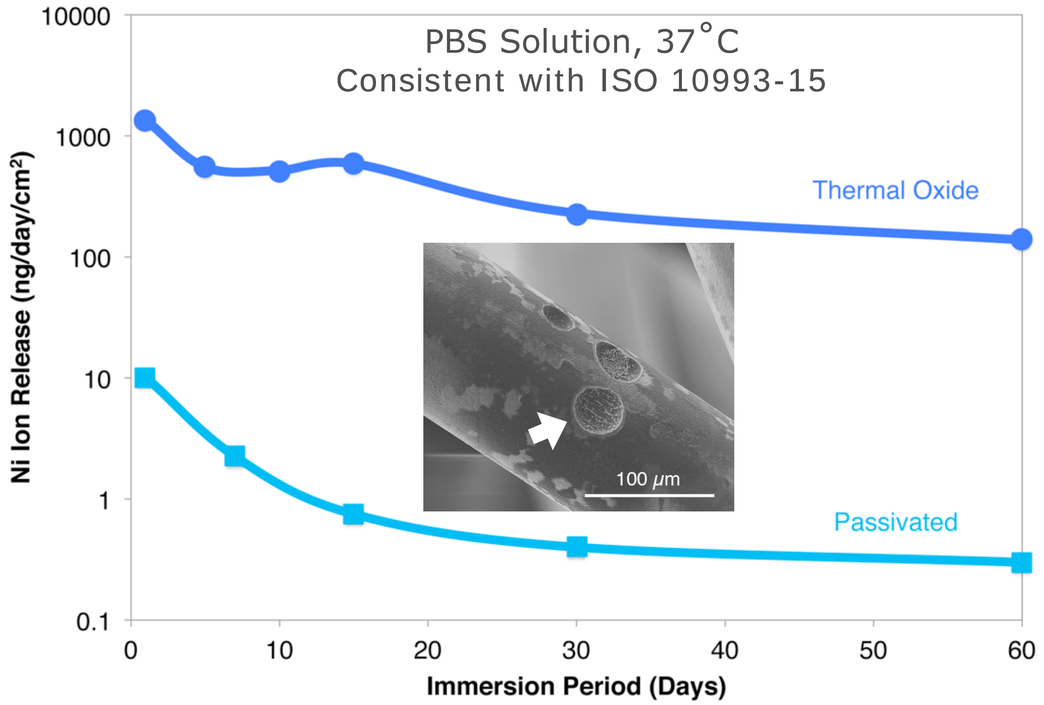
ASTM F2129, PBS, 37°C

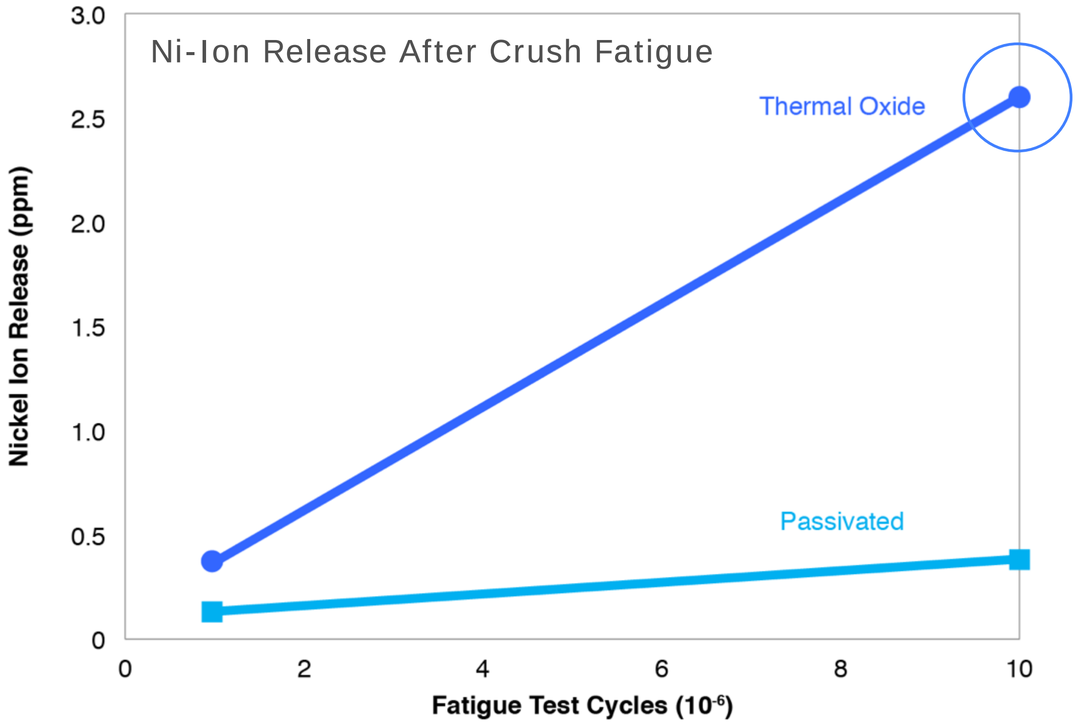




Pelton and Blaich SurFACTS in Biomaterials 2017

Thermal Oxide: Greater Ni-ion Release From Devices





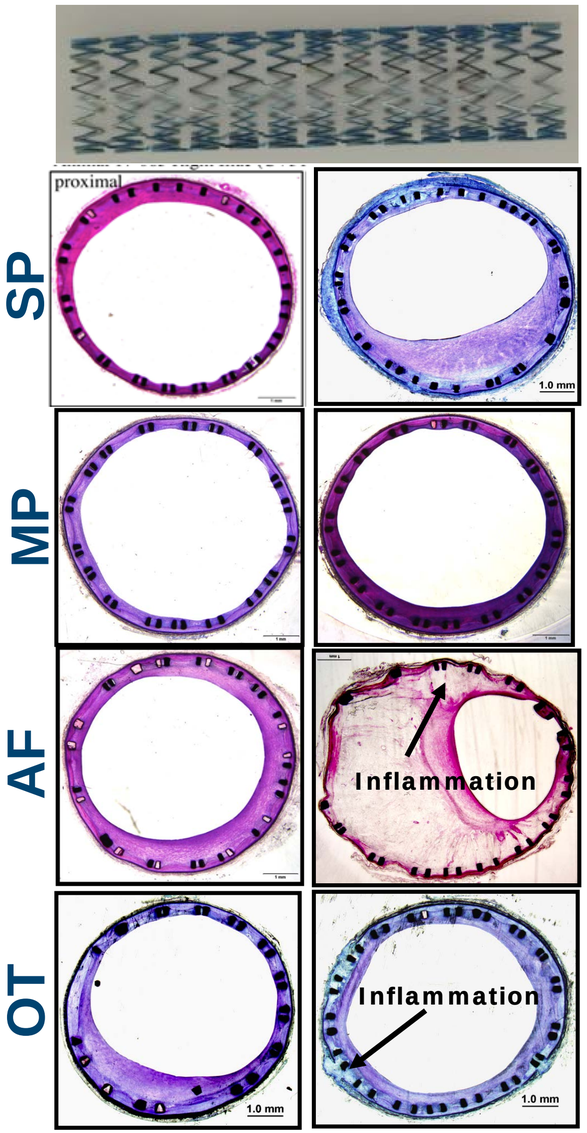
Pelton and Blaich SurFACTS in Biomaterials 2017

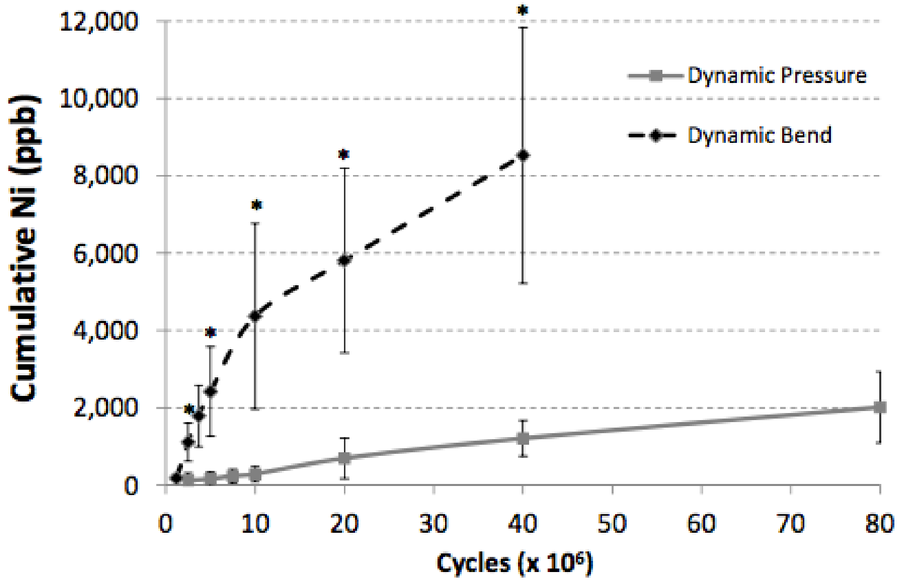
Acute **Ni** intoxication in dialyzed patients Ni ~ 3 ppm (Webster, *et al*. 1980)

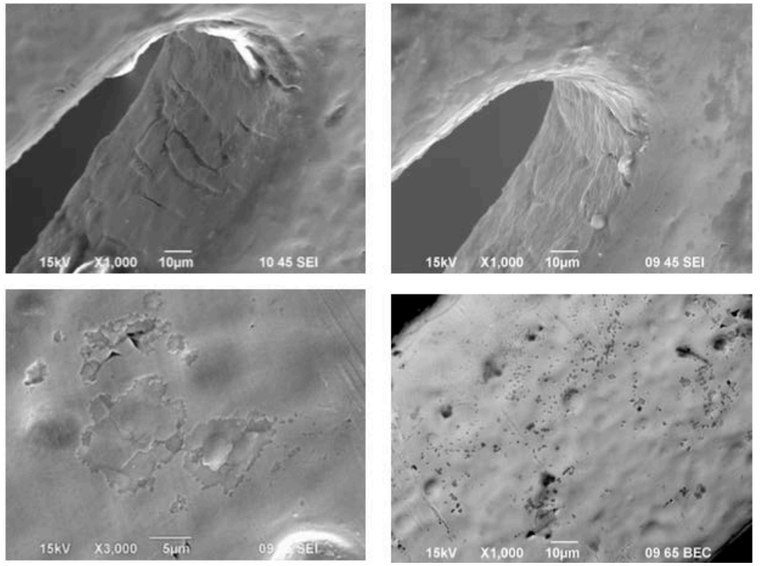
Ni cytotox response at > 6 ppm (Messer, *et al.* 2005); 9 ppm (Shih, *et al.* 2000)

Ni release rate in blood should not exceed 35 µg/day (Sunderman, 1983)

in vitro and Six-Month Animal Investigation







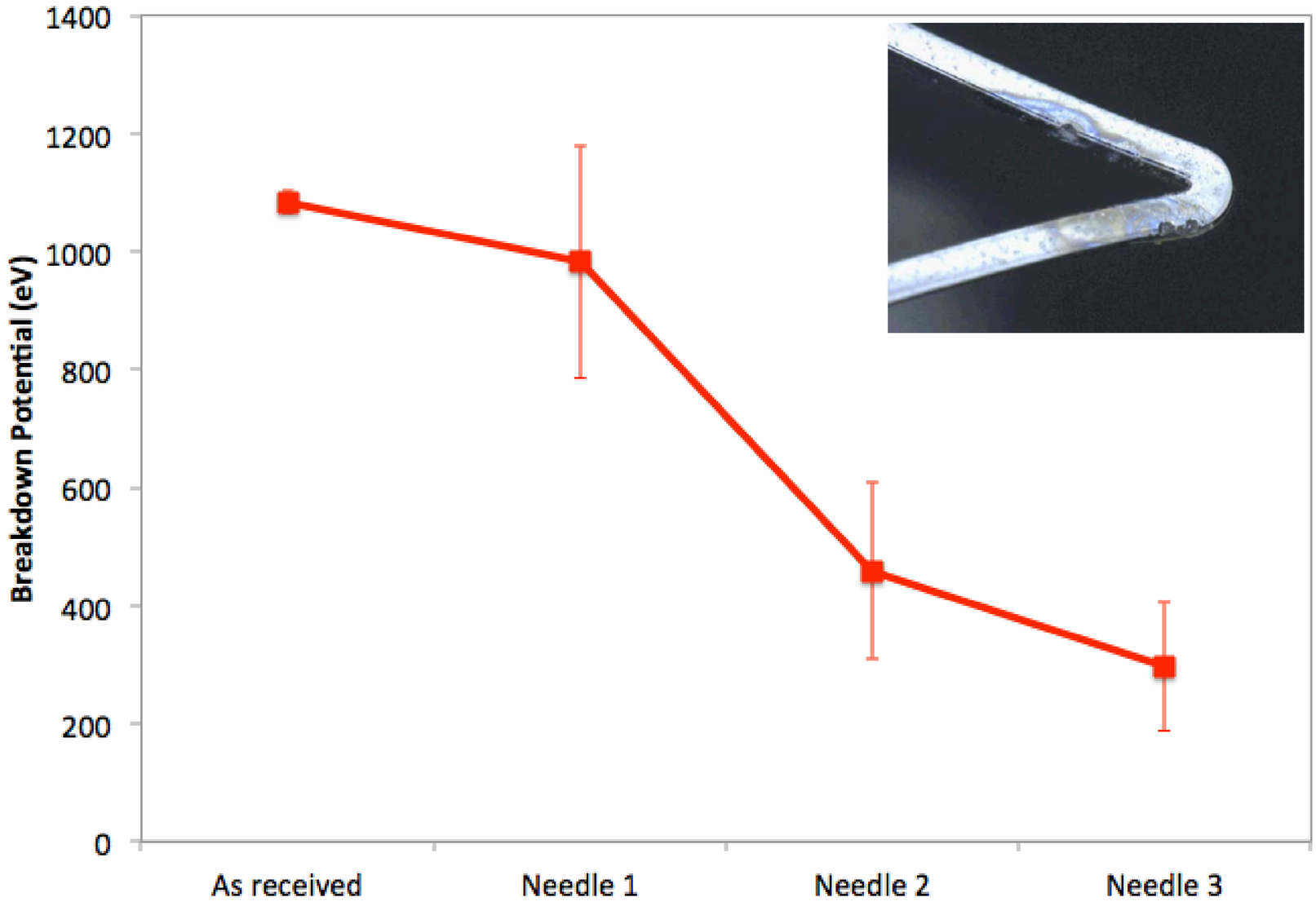
Ni release is not correlated to pitting potentials from ASTM F2129

Nagaraja *et al.*, SMST 2017

Stacey J.L. Sullivan[1]
Daniel Madamba[2]
Shiril Sivan[1]
Katie Miyashiro[2]
Maureen L. Dreher[1]
Christine Trépanier[2]
Srinidhi Nagaraja[1]

Sullivan *et al.*, Acta Biomaterialia https://doi.org/10.1016/j.actbio.2017.08.029

Needle Selection for Graft Suturing Affects Corrosion



Corrosion and Biocompatibility of Nitinol

Imperative to remove Ni + Ni_3Ti + TiO_2 after thermal processing

Create Ni-free amorphous Ti-O surface for passivation

2015 FDA Guidelines *necessary but not sufficient* to predict chronic corrosion behavior

Recommend dynamic corrosion and Ni-ion release testing for vascular devices


Thank You!