IN-VITRO BIOMECHANICAL STUDIES OF ENDOVASCULAR DEVICES

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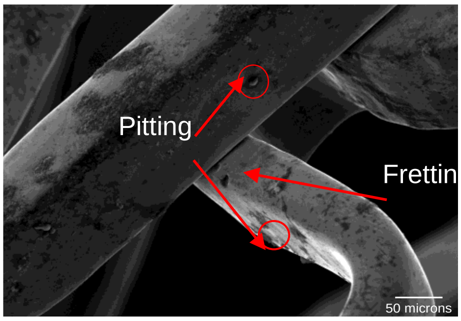
Introduction: Preliminary studies have revealed that stainless steel (SS) and nickel titanium (NiTi) stents undergo corrosion in vivo, with significant release of metallic ions into surrounding tissues. It is believed that high concentrations of metal ions from both SS and NiTi stents are toxic to vascular smooth muscle cells and stimulate both inflammatory and fibrotic reactions leading to neointimal formation and a predisposition to device failure. To separate the mechanical effects from the local environmental effects on the stent surface, in-vitro mechanical studies were performed on various combinations of stents under low and high curvature and in overlapping positions to compare the results of fretting, pitting and gouging with the explanted stents.

Methods: Accelerated biomechanical studies were performed on SS, NiTi and Cobalt-Chromium (CoCr) stents using Bose®ElectroForce®9110 Stent/Graft Test (Bose Corporation, Bethel, WA) mechanical testing instrument. The stents were deployed in latex tubing mock arteries and the system was exposed to flow of saline representative of coronary flow under physiologic wall motion 5-10% and was programmed to perform several million of cycles to simulate several years of operation. The tested stents underwent surface evaluation by Scanning Electron Microscope (SEM) and optical microscope Keyence to identify locations of pitting, fretting and cracking phenomena due to interfacial conditions.

Results: Wear features were observed on the stents surface in both straight and low curvature modes especially in the overlapping cases where we observed localized fret features in the areas where there is significant crossing of the wire from both stents. Fracture was also observed in addition to fretting features on both the NiTi and CoCr stents placed in a curved latex tube at 40% overlap under 104 million cycles. Fracture surfaces show a fatigue mechanism.



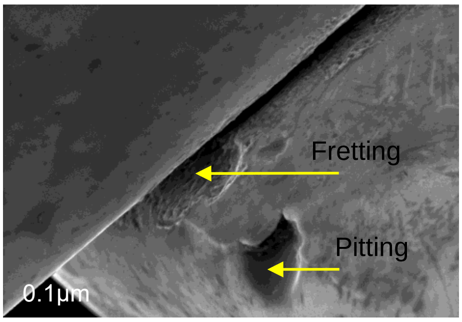


Figure 1: SEM images of mechanically tested overlapping SS stents (BiOLISYS lab, CUT). Wear features were found at the wire crossings. The mechanically tested stents were deployed in a low radius of curvature latex tube with 66% overlapping and undergone testing for 28 days at 50Hz which corresponds to approximately 120 million cycles or an equivalent of 3 years of duration in the body.

Discussion and conclusion: Fretting features from cadaver specimens were similar to the fretting features from some of the mechanical studies. High curvature and stent overlapping favored surface alterations increased the corroded regions and the degree of corrosion in comparison to the single stent-straight artery configuration. Mechanical factors such as arterial curvature combined with stent overlapping may enhance surface alterations and stent corrosion. The effect of metal corrosion on the arterial wall, the vascular responses and possible cause-effect relationships for biological reactions leading to restenosis are unknown and need further investigation.