9ο Κοινό Κύπρο-Ελλαδικό Καρδιολογικό Συνέδριο
26, 27 Μαρτίου 2011, Λεμεσός, Κύπρος

ΠΕΡΙΛΗΨΗ
(Επιθυμητός τρόπος παρουσίασης: ΠΡΟΦΟΡΙΚΗ)

BIOCORROSION AND BIOMECHANICAL ANALYSIS OF EXPLANT DEVICES

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Introduction: Preliminary studies have revealed that stents undergo corrosion in vivo, with significant release of metallic ions into surrounding tissues. It is believed that high concentrations of metal ions from 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 surface corrosion with the explanted stents.

Materials and Methods: Accelerated biomechanical studies were performed on Stainless Steel (SS), Nickel Titanium (NiTi) and Cobalt-Chromium (CoCr) stents using Bose®ElectroForce®9110 Stent/Graft mechanical testing instrument. The tested stents underwent surface evaluation by Scanning Electron Microscope (SEM) to identify locations of pitting, fretting and cracking phenomena due to interfacial conditions.

Results: Wear features were observed on mechanically tested stents, in single and overlapping cases, in both straight and curved modes. Surface alterations predominantly due to fretting had occurred in the overlapping cases where we observed localized fret features in the areas where there is significant crossing of the wire from both stents. Crevices and fractures were observed in the presence of geometric curvature.

Discussion and conclusion: Wear features from cadaver specimens were similar to the surface alterations from some of the mechanical studies. The key finding was that mechanical factors such as arterial curvature combined with stent overlapping enhanced surface alterations, increased the corroded regions and the degree of corrosion in comparison to the single stent-straight artery configuration. 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.