Radiopaque Nano-Porous Ta Coatings for Nitinol Medical Devices

Brent C. Bell and David A. Glocker
Isoflux Biomed

Nano-porous Ta coatings have been developed to render Nitinol medical devices fully radiopaque. These coatings are deposited atom by atom in a unique PVD process that utilizes a cylindrical cathode and operates at conditions that produce low substrate temperatures. As a result, complex 3D shapes are coated with high uniformity and the critical Nitinol mechanical properties are unchanged. Because these coatings consist of a nano-porous columnar structure they are able to withstand strains of at least 8% without delamination or cracking. X-ray and fluoroscopic imaging shows that Nitinol stents with these coatings are highly visible and reveal the entire 3D shape of the device instead of only point markers. The benefits of these coatings are easier, faster and more reliable implantation procedures, especially for difficult to visualize medical devices such as bifurcated stent-grafts. Ta is extremely biocompatible. Thirty-day and 6-month porcine studies have shown that there is no difference in stenosis, intimal thickness, injury score or inflammation score for stents with this nano-porous Ta coating compared to a bare Nitinol stent. In addition, measurement of corrosion breakdown potential show higher values for Ta on Nitinol than Nitinol alone. Aside from radiopacity, these Ta coatings, hold the potential for other highly desirable functions such as controlled drug delivery without polymers and enhanced re-endothelialization. Studies are currently underway to understand the drug loading and release kinetics as a function of a pore size and aspect ratio.

