PROGRESS IN DRUG-ELUTING BIORESORBABLE STENT TECHNOLOGY

Robert Eberhart[1,2], Shi-Horng Su[2], Trè Welch[2], Pankaj Satasiya[2], Sushma Gampa[2], Anup Dasnurkar[2], Brett Thomes[2] and Richard Timmons[3].

Departments of Surgery[1], Bioengineering[2] and Chemistry and Biochemistry[3] University of Texas Southwestern Medical Center at Dallas[1], and University of Texas at Arlington[2,3]

We developed a bioresorbable stent, deployable by standard techniques, that allows strong vascular wall support plus drug delivery. The helical coil design is based on the limaçon of Pascal and is fabricated with 100 µm poly-(L-lactic acid) fibers (PLLA). The 1.5 mm diameter furled stent expands, at 2 to 6 atm (depending on design), to a 3.0 mm helix. Buckling resistance is 140-210 KPa, depending upon fiber ply and coil spacing. Stent strength comes from torsional set of the fibers as the internal coils expand: thermal annealing is unnecessary. Preliminary results of 28-day implants in pig coronary arteries have been promising. Anti-inflammatory agents (curcumin, paclitaxel) have been loaded into PLLA fibers by melt extrusion. A tradeoff exists between fiber strength and drug capacity. Curcumin loading at 10 wt% reduces individual fiber strength but does not induce stent collapse. Uniform curcumin elution from PLLA fibers continues for > 1 month. Eluted curcumin retains significant bioactivity as measured by reductions in pre-activated neutrophil and macrophage adhesion to curcuminated PLLA fibers, and residual activity ($p \leq 0.05$ in all cases). Inflammation was observed near drug-free PLLA stent fibers in early implant studies. This has been reduced by improving both polymer purity and fabrication quality. We are awaiting implantation of curcuminated PLLA stents to assess potential improvements in the inflammatory response. Multiple-ply fiber designs, and supercritical CO_2 foamed polymer coatings permit polymer blends and multiple drug loadings to be used in advanced designs. Foams can be coated with a nanoporous film to control drug elution rate.

Key words: bioresorbable stent, curcumin, PLLA