Resorption Rate of Bioresorbable Materials for Possible Use in Self-Expanding Stents

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Introduction: Percutaneous Coronary Intervention (PCI) is the most common invasive medical procedure related to myocardial infarction (MI) prevention in which a stent is deployed. A common side effect of PCI is intimal hyperplasia induced restenosis. Intimal hyperplasia is the thickening of the blood vessel walls in response to vessel injury, as the smooth muscle cells of the media migrate and expand into the blood vessel. Restenosis occurs in 10% to 25% of patients who undergo angioplasty, with many requiring subsequent intervention. The medical complications categorized by intimal hyperplasia are linked to stent impact during its rapid expansion process inducing damage to the intima. If the expansion rate of the stent were reduced, the collagen and extracellular matrix cells would adapt and relax as the stent gradually expands the vessel walls. The current solution being explored is the use of bioresorbable materials on a Nitinol stent. The stent will be manufactured at its final diameter and then compressed to its intermediate diameter. Geometric links made of the bioresorbable material will be attached to designated sections of the stent’s framework. The stent will be further compressed for implantation, following which the links will hold the stent at its intermediate stage. As the bioresorbable material resorbs into the body in the following weeks, the nitinol stent will naturally expand until the artery has reached its full diameter. The documented testing was performed to find the best bioresorbable material.

Materials and Methods: First round testing was performed on PLA and a ceramic mixture of tricalcium phosphate and cyanoacrylate (TCP/CA). PLA and TCP/CA samples were formed onto 3mm diameter nitinol wire segments and then machined into 5mm and 6mm diameter cylinders. The samples were immersed in a flow-cell filled with Earle’s Balanced Salt Solution (EBSS) to simulate the environment of a human artery. The entire system was kept inside an incubator to maintain the EBSS at constant body temperature. The samples were measured for mass degradation periodically. A second series of tests were performed to measure the tensile strength and modulus of various polymers following degradation. Small dog-bone samples were created out of PDLA, PLA and PDLLA, which were placed in a continuously flowing EBSS. The samples were removed periodically and placed in a tensile tester to measure its modulus and tensile strength.

Results and Discussion: The mass degradation study resulted in an overall mass increase of 7mg seen in the PLA coated samples, which indicated absorption of EBSS. The TCP/CA coated samples experienced a net decrease of 6mg with visible signs of pitting occurring after 33 days. See Figure 1 for mass degradation data. The material strength degradation tests showed that the PDLA has an abrupt decrease in strength after 7 days, where it quickly became soft and elastic. The PLA and PDLLA samples did not have a significant change in strength and retained its original material properties after 2 months of testing. The data for the tensile strength of the samples can be found in Figure 2.

Conclusions: Following the two tests, PDLGA has been chosen as the ideal material candidate for the self-expanding stent. The strength of the material is maintained for a week then it is released and becomes very elastic. This will allow a stent to be inserted into the artery at its intermediate diameter, then following a week it will finish its expansion. This added period will allow the blood vessel wall to relax and reduce the risk of intimal hyperplasia and thrombosis.

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