A Novel Rapid Polymer Cardiovascular Stent Fabrication System

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Abstract

Cardiovascular disease (CVD) is the most prevalent health conditions in the United States. It is estimated that approximately 80 million American adults (one in three) have cardiovascular disease. Many of them will require angioplasty stent procedures to save their lives. It was estimated that cardio vascular stent market in the year of 2008 was $1.8 billions in America. The world wide market was estimated as $7 billions with an annual growth rate of about 7%. Although all the cardiovascular stents approved by FDA are all metallic, there are many issues associated with them, such as stent thrombosis, not compatible with modern imaging technologies such as magnetic resonance imaging (MRI) and multi slice computerized tomography (MSCT), which eventually will become the default noninvasive imaging modality for the coronary anatomy.

In contrast, bioabsorbable stents, once they are bioabsorbed, leave behind only the healed natural vessel, allowing restoration of vasoreactivity with the potential of vessel remodeling. Late stent thrombosis is unlikely since the stent is gone, and prolonged anti-platelet therapy is not necessary in this instance. It is now generally believed that a stent should be gone once the vessel is healed. Therefore, many major cardiovascular device companies, such as Abbott Vascular, Boston Scientific and J&J all heavily invested in the development of these 3rd generation bioabsorbable stents.

Commonly used stent fabrication process is a two step process in which a polymer tube has to be fabricated first. Then the stents will be cutting from the tube in a laser cutting machine which is originally developed for metal stent fabrication. This two step process is time consuming and not efficient in using bioabsorbable polymers. 3D Biotek has developed an innovative rapid stent fabrication (RSF) technology for fabrication of bioabsorbable polymer stents. With this novel biodegradable stent fabrication system, Polymer stents with various patterns can be directly fabricated from using polymer pellets/powders. A wide range of bioabsorbable polymers, such as polycaprolactone (PCL), poly(lactide-co-glycolide) (PLA), and polyglycolide (PGA) can be used for fabrication of bioabsorbable polymer stents in a very efficient way. It also opens a new way for fabrication of drug loaded bioabsorbable stents. Therefore, using this technology will accelerate the stent product development process and reduce the R&D cost. 3D Biotek is currently working on the commercialization of this innovative technology.

Rapid Stent Fabrication Technology

Based on 3D Biotek's 3D Precision Microfabrication Technology, we further developed RSF Technology which can be used to fabricate bioabsorbable porous tubular scaffolds from PCL, PLGA, and PGA polymers, which have extensive applications, including the cardiovascular field. Figure 1 shows an intricately engineered, tubular PCL scaffold. Also possible with this technology are biodegradable periphery vascular (ID 8 mm) (Fig. 2A-B) and balloon expandable coronary stents (ID 4 mm) (Fig. 2C)

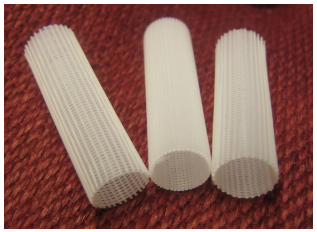

Figure 1. Bioabsorbable Porous Tubular Scaffolds (PCL)

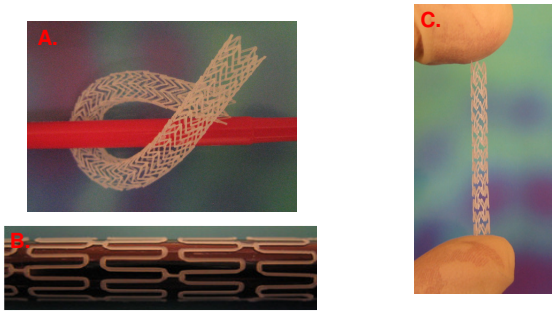

Figure 2. Bioabsorbable Scaffolds

The results above demonstrate that Rapid Stent Fabrication Technology is a revolutionary method for fabrication of polymeric tubular porous scaffolds, specifically for cardiovascular fields such as stent, which has a huge market. Furthermore, 3D Biotek believes that the use of this technology will reduce overall stent development costs and accelerate the stent development process.

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