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Development of Drug Eluting Magnesium Alloy Scaffold for Coronary Arteries

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Abstract

A bioabsorbable, drug-eluting metallic scaffold is developed for coronary artery therapy. Because of its acceptable mechanical qualities and biocompatibility, magnesium (Mg) and its alloys have attracted a lot of attention as prospective biodegradable materials in the cardiovascular stent sector. However, because to their weak corrosion resistance and insufficient endothelialization, implanted Mg alloy stents can cause thrombosis, inflammation, and restenosis, which limits their clinical applicability. The majority of currently available scaffolds have bigger struts with radial strength, making them inaccessible to small coronaries. Low profile cardiovascular scaffolds with strut thicknesses of 80 - 120 µm provide sufficient radial strength and optimal flexibility for ease of deployment in arterial arteries to overcome this limitation. The scaffold adheres properly to the vessel paths. The link was designed in an "S" shape to allow unfettered growth of the scaffold during treatment.

Keywords: Bioabsorbable, drug eluting scaffold, Mg alloy, low crimp profile and coronary arteries

Introduction

Coronary arteries are the blood vessels that carry oxygen-rich blood to your heart muscle. Atherosclerosis is the cause of coronary artery disease. Plaque builds up inside your arteries, causing atherosclerosis. Scaffolds are utilized to keep the vessel lumen open and allow for regular blood flow. The balloon expanding scaffold system is utilized to treat coronary arteries in particular. The stent is a metal-studded metal scaffold, which attaches to the targeted spot of the coronary artery for a set amount of time. Magnesium is a trace metal that is needed for the human body and is processed in the body itself; therefore, a bioabsorbable magnesium scaffold has special properties. The long-term disadvantages of the permanent alloy stent are restenosis and vascular damage, as well as excessive metal leakage. There has been a significant advancement in the use of several types of permanent metallic scaffolds in the

treatment of cardiovascular diseases. Magnesium, like the drug sirolimus, has a low to no inflammatory reaction in the body, which helps to avoid metaplasia. The ideal material has suitable radial strength to resist recoil, flexibility, biocompatibility, and reduces systemic toxicities. The invention provides a balloon expandable scaffold on which a magnesium alloy scaffold is placed in order to increase flexibility. The central section of the hybrid cell design has open cells, whereas the proximal and distal regions have closed cells. During and after treatment, the small strut that defines the closed cell at both ends gives the best radial strength. The near cell design is created in such a way that it does not wander and remains stationary in its spot.

Materials and Methods

The first stage in preparing a magnesium alloy scaffold is to laser cut it to the desired size, followed by a second phase of annealing, a third step of electro polishing to remove burrs, and finally, the application of multiple layers (PLLA), which is followed by a third step of heat curing. Last but not least, the scaffold is crimped before being packaged and sealed in a tyvek pouch.

A laser cutting procedure was designed to obtain the needed and unique drug eluting absorbable Mg-Alloy scaffold. The tube is sliced in circular and horizontal patterns using a laser cut device. Preliminary studies on a flat AZ31 with 1.6 µm to obtain cutting conditions acceptable for fine mesh were used. Homogeneous heat is supplied throughout the scaffold at a constant temperature of 300 ^{o} C. X-rays were used to detect the scaffold in the human body using tantalum markers. The electro-polishing removes minute burrs, the heat zone, and micro cracks resulting in a clear surface. Spray coating can be used to apply the polymeric solution prepared from PLLA in dicholromethane. The annealing process is performed on all of the polymer-coated scaffolds by uniform heating below 100 - 110 ^{o} C. Sirolimus drug, which is well known for manufacturing of various cobalt chromium drug eluting stents, is used here also for the similar applications for inducing vascular smooth muscle proliferation and intimal hyperplasia. Drug coating and crimping is carried out in the well known and established methods. The scaffold is connected to the balloon catheter and positioned between the balloon's two radiopaque markers. The scaffold system is inserted into a protective hoop tray followed by packaging in a sterile barrier "coated 1073B Tyvek pouch". This is known as primary packaging. The scaffold is supplied with three sides sealed and one side open for the entry of the scaffold-containing hoop tray. After vacuum sealing, the Mg Alloy scaffold is stored below 20 ^{o} C temperature and is stored in a high-temperature environment. The packed scaffold has been sterilized using the ethylene oxide process, and its surface is covered in a protective layer of Mg alloy.

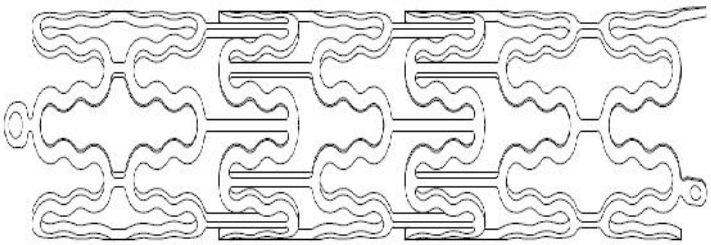

Fig. 1 Open and close cell

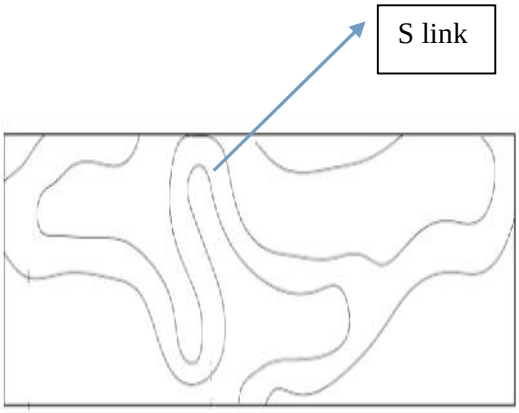

Fig. 2 S - links of scaffold

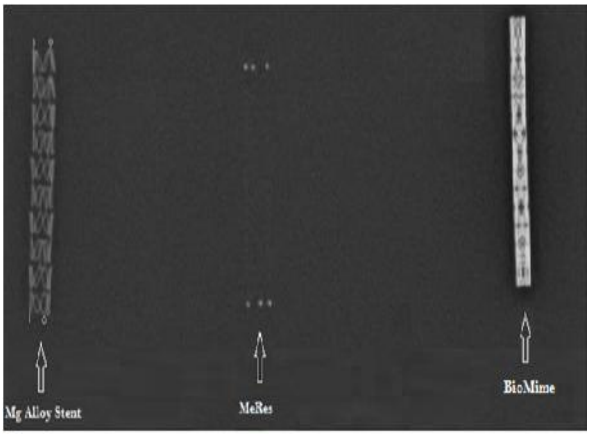

Fig. 3 Compare radiopacity of different material

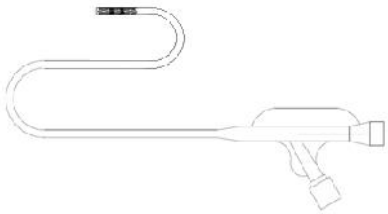

Fig. 4 Bioresorbable magnesium scaffold crimped over delivery catheter

Results and Discussion

The new design of a bioabsorbable magnesium alloy scaffold allows it to cling to the targeted vessel without inflicting suffering. The scaffold flexibility is ensured by the new hybrid cell design, which has open cells in the middle and closed cells in the proximal and distal regions. Despite the low profile of the struts, they have considerable radial strength. It is kept low-profile in this current design in order to facilitate deployment. The thickness of a low profile strut is approximately 80 m. The scaffold is flexible; however, it has a low radial strength of less than 20 N. Furthermore, more than two thin layers of PLLA polymer were coated, resulting in a further increase in radial strength of 20 to 30 N but a reduction in scaffold flexibility. The small strut at both ends of the closed cell provides high radial strength during and after the treatment. The closed cell is constructed in such a way that it does not wobble and remains in place without dislodging. The radial strength of the design was found to be in the 20 to 30 N range, with high flexibility and simplicity of deployment. In addition, bilayer polymers extended the period of degradation by two years. Similarly, the long strut maintains optimum radial strength to the scaffold not only at both ends, but also in the middle. The peak to peak open cell design, combined with the

long strut, provides two key mechanical properties to the scaffold in a single design: radial strength and high pliability to the blood artery, lowering the chance of injury to the patient.

The idea provides a balloon expandable scaffold to promote flexibility without compromising radial strength. The magnesium alloy scaffold is crimped after being put to the balloon. The balloons are blown in such a way that they retain the crimp profile while simultaneously acting as a safety barrier and preventing migration of the scaffold as it is being transported from the patient to the target site. The in-house developed dislodgement test, ASMT F2391 and ISO25539-1 & 2, corroborated this. This newly designed scaffold's test value was discovered to be between 3 and 7 N.

As the scaffold was covered with drug solution, it was crimped with a multi-stage crimping technique over an Rx PTCA balloon catheter. As indicated in the table, a steady dwell speed of 10 seconds from stage 1 to 3 indicates that the balloon is slowly inflating. The steady expansion is deflated with a reduction in diameter in step 4. Pressure is increased in stage 5 to allow the balloon markers to be changed. In stages 5 to 7, the lowering in pressure causes the scaffold to crimp. The pressure implication ended at stage 8, and the balloon was deflated. Type "F" scaffolds are crimped according to the delivery size scheme, as shown in the table. The pressure should not exceed 85 PSI.

Type	Stage	Dia/Force	Speed	Dwell (Sec)	Interval	Balloon State	Dwell (Sec)
D	1st	2.75mm	0.99	10	N	Amb	0
D	2nd	1.80mm	0.99	10	N	Amb	0
D	3rd	1.50mm	0.99	10	N	Amb	0
D	4th	1.30mm	0.03	10	N	Amb	0
D	5th	1.10mm	0.03	10	Y	Amb	0
D	6th	0.90mm	0.99	20	N	Amb	0
D	7th	0.80mm	0.99	20	N	Amb	0
F	8th	25.0lb	1.0lb/s	100	N	Amb	0

Conclusion

For the therapy of coronary arteries, a drug-eluting metallic scaffold is employed. Mg Alloy scaffolds have outstanding radial strength, biocompatibility, elasticity, and biodegradability, making them suitable for coronary usage. According to the findings of the present invention, a low-profile cardiovascular scaffold with suitable radial strength and flexibility allows for easy deployment in arterial vessels. Lower strut thickness of 80 to 120 m provides excellent tractability into the tortuous architecture of coronary arteries while having no influence on radial strength. The scaffold is utilized to keep the patency of the wound.

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