Advanced materials for Bioresorbable stent for Real-time Health-care Monitoring
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Abstract
Purpose: Heart failure, which has a mortality rate higher than most cancers, is among the most important public health issues. Because of this, the fields of medicine and bio-medical engineering have provided a lot of attention to cardiovascular disease. In this review, we present the recent bioresorbable stent technology in aspect of advanced materials to overcome health issues.

Methodology: This study is based on reviews of Bioresorbable stent (BRS) technology from various technical resources.

Main Findings: Bioresorbable stent (BRS) shows new class of medical devices in interventional cardiology for the treatment of coronary artery disease. The concept of the BRS is to provide temporal support to the vessel during healing before being degraded and absorbed by the body, eliminating the additional surgical process.

Implications: With advances in nanofabrication, novel kinds of bioresorbable sensing/wireless component could be fabricated and integrated on the stent without failure when it expanded in the vessel. These technologies will significantly influence future diagnosis technology for future generations.

Novelty: The technology was introduced to overcome limitations of current developed drug-eluting stents, which are fabricated with metallic materials. With development of medical strategies, we could response earlier for medical issues to prevent recurrence of disease.

INTRODUCTION
A buildup of plaque inside the coronary arteries can cause the blood flow in an artery to be slowed or even reversed, which inhibits the heart muscles from getting enough blood to operate. Severe anguish and tissue death could follow from cutting off the blood supply to the arms and legs. Heart failure could come from an impaired cardiac muscle’s inability to pump properly. Among many cardiac diseases, the most common cardiovascular disease is coronary artery disease. It commonly occurs with atherosclerosis, which is a type of thickening of stiffening of the wall of arteries. This mechanical rigidity is caused from accumulation of plaque inside wall of the coronary arteries (Figure 1). Fatty compounds, cholesterol, waste materials make plaques slowly and they continue aggregate in arteries over time. From this process, the coronary artery becomes stiff and lose its elasticity, which is required for smooth flowing of blood in the vessel. A stent is a medical device that widens a narrowed area of an artery to promote blood flow; they are essential pieces of medical technology used to increase blood flow and revive the heart.

Figure 1: Schematic showing expanded stent in artery with atherosclerosis

Stents are implantable medical devices (IMD) that are commonly used in hospitals to treat atherosclerosis. Stents are circular-sectioned, tubular, implanted vascular scaffolding devices. They are made to be elastic but also maintain their shape when used in a vessel. Stents are deployed in a variety of places, including the biliary duct and coronary arteries, to unblock clogged vessels. The percutaneous coronary intervention procedure is used by the doctor to place the stent in the target artery. PCI is a procedure used to treat cardiovascular disease that uses stents. This technique involves injection and expansion process, which uses balloon angioplasty to open clogged arteries. In-stent restenosis (ISR), a phenomenon where an overgrowth of scar tissue cells occurs near or inside the stents, presented a challenge to this treatment by once more restricting blood flow. ISR appeared in 17%-41% of first-generation stents. Second-generation stents were coated with anti-proliferative medication to solve this problem. A drug-eluting stent (DES) prevents cell proliferation by gradually releasing a medication from the stent. (Martin, et.al. 2010).

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BIORESORBABLE STENT

An innovative method of treating coronary artery disease is to employ bioresorbable stents in interventional cardiology. To tackle the drawbacks of current metallic drug-eluting stents, such as late in-stent restenosis and channel permanent enclosing, bioresorbable technology was developed. The purpose of bioresorbable stent is to support the vessel temporarily before it is broken down and reabsorbed by the body, promoting vascular repair and the return of vasomotion. The efficacy of the bioresorbable stent needs to be improved even though they have several promising benefits over metallic stents, including insufficient radial strength of the bioresorbable material and a broad strut profile. Currently, there are several bioresorbable materials that are under development with some already commercially available. However, it is still challenging to make soft and fully biocompatible stent due to limitation of materials. In this section of review, we investigate the current technologies of bioresorbable stent including chemical, mechanical aspects of available materials and many approaches to improve it.

Bioresorbable metallic materials for stent application

To adjust the mechanical, electrical, and degrading properties for use in bioelectronic applications, many researchers have created bioresorbable metallic materials (Hermawan, et al. 2009). Due to their biocompatibility, Mg (Magnesium), Mg-alloy, Mo (Molybdenum), and Zn (Zinc) and their oxide form have been regarded as promising metallic materials for bioresorbable electronics. Among these, Mg-alloy metallic alloys have been used frequently for applications in bioresorbable stents (Ma, et al. 2016). Pure magnesium is not a good candidate as a structural material for stents due to its mechanical characteristics and slow rate of deterioration. For instance, pure magnesium, which is used to create stents, has a low elasticity and a high modulus (41–45 GPa), making it vulnerable to damage under stress. Because of their superior mechanical characteristics in terms of radial stiffness, biocompatibility, low cost, and low density, magnesium alloys are desirable.

Depending on the kind of stent, the mechanical properties for stent materials include expandability, plasticity, rigidity, and resistance to the elastic recoil of blood vessels (balloon-expandable or self-expandable). In addition, the stent should continue to be mechanically stable at least 4–6 months after being implanted. The mechanical characteristics of magnesium alloys are improved by hot rolling, hot extrusion, and equal-channel angular pressing in their production history. As a result, magnesium alloys become stronger, though occasionally at the expense of ductility. Additionally, alloying has the potential to improve the ductility and strength of Mg-based bioresorbable materials. The degradation of metallic bioresorbable materials occurs via the corrosion of metals, which produces metal-hydroxides, hydrogen gas, and possibly other compounds as shown in below chemical equation (Aljihmani, et al. 2019).

\[
Mg + 2H_2O \rightarrow Mg(OH)_2 + H_2 \text{ (gas)}
\]

Mg(OH)₂ is a major surface product of Mg corrosion in common biological solutions. The least amount of corrosion occurs when high-purity magnesium is exposed to air at normal temperature. Pure magnesium has drawbacks because it corrodes quickly in physiological conditions (pH 7.4–7.6) and produces hydrogen gas at rates that are too high for the host tissue to handle. Additionally, corrosion occurs quickly in acid solutions or liquids containing. Currently, alloying and surface treatment or coatings are the two most prevalent ways to increase Mg alloy biodegradation resistance.

Bioresorbable polymeric materials for stent application

Biodegradable polymers are divided into natural and synthetic biodegradable polymeric materials. The degradation rate of natural biodegradable polymers such as cellulose and glycogen is slower, which might be optimal for bio-implantable devices, however extraction of these materials is too difficult due to high cost of process. In contrast, synthetic polymers are easier to tune their structure and dissolution time by changing their chemical structures. Due to this characteristic, synthetic polymers can be modified to desired properties.

Biodegradable includes the meaning of being biocompatible. Being biocompatible means polymers must chemically (i.e., non-toxic, hydrophilic) and mechanically (i.e., being flexible to stretch when expanded) be compatible with its surroundings like our internal body.

Two key mechanisms including hydrolysis and oxidation are used by human bodies to break down synthetic biodegradable polymeric polymers. Most polymers degrade primarily through hydrolysis, such as polyesters, polycaprolactone (PCL), polycarbonates, polyvinyl alcohol (PVA), and polyactic acid (PLA) (Leja, et al. 2009). In hydrolysis-based degradation, water promotes the cleavage of ester bonds in the polymer chain, breaking polymers into a small number of oligomers or monomers that may be visibly absorbed in the body fluid. For instance, lactic acid and 6-hydroxyhexanoic acid are two examples of small molecules produced during the decomposition of PLA and PCL. After degradation process, small molecules like carbon dioxide and water may finally be expelled from the body and go outside.

Biodegradable polymers perform two crucial roles in the stent: encapsulation, and chamber for storage of nanoparticle-based agent. Bio-implantable devices are exposed to bodily fluids like blood, which might induce electrical malfunctions of sensors. To protect the device from fluids, protective encapsulation layer is adopted on the surface of bioresorbable sensor, devices. Moreover, catalytic reactive oxygen species scavenging, and hyperthermia-based drug release can be used as advanced therapies in stent technology. During this process, the polymer-based materials are used as chamber to capture the nanomaterials, which is released to blood.

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Transient biomedical devices integrated on stent

Implantable electronic devices can communicate with the human body, retrieve useful data in real time, and use electrical stimulation to activate the associated tissue activities. Biodegradable electronic devices offer a stable functioning in a specified time before completely degrading within the body, in contrast to most traditional bio-implantable electronics that stay functional and intact in the body for an infinite amount of time. The idea of a transient device has significant benefits for immediately controlling diagnostic or therapeutic functions, enabling the monitoring of short-term biological responses, such as for the healing of wounds and the prevention of infections, while avoiding negative effects related to the long-term implantation of bio-implantable devices. Furthermore, removing the gadget requires further surgical operations without this characteristic.

We require sophisticated bio-implantable sensor and wireless electronic components to build such a system. Many advancements in biodegradable electronic devices have been made that could be integrated with stents for biomedical applications. These advancements include implantable pH and pressure sensors for detecting the rheological characteristics of blood flow in the vessel, impedance sensors to detect the growth of cells close to the endothelium, wireless antenna for data and power transmission (Park, et al., 2018), and memory to memorize data that the doctor might miss. The creation of flexible thin film biodegradable electronic components and their incorporation into stents was recommended by earlier investigations.

For instance, researchers describe materials, device architectures, integration techniques, and in vivo tests of implantable, multifunctional silicon sensors in rats. All the constituent materials for these sensors naturally resorb through hydrolysis and/or metabolic action, eliminating the need for extraction (Son, et al., 2015). All of the sensors are made of thin film and are capable of detecting internal body flow rate, temperature, and PH, which are also essential elements in biodegradable electronics stents. An antenna for power and data transmission, flow and temperature sensors, memory storage devices, anti-inflammatory nanoparticles, and drug-loaded core/shell nanospheres that are activated by an external optical stimulus are all integrated into the multifunctional stent, according to another research team.

The whole stent operation process as follow: The flow sensor measures blood flow, and this information is stored in the embedded memory module for pattern analysis and diagnosis throughout Catalytic reactive oxygen species scavenging and hyperthermia-based drug release can be used as advanced therapies.

CONCLUSION

In this assessment, we consider the state-of-art stent technology. The need for multi-functional biodegradable stents, which are mostly made of biocompatible and biodegradable material, is first discussed. To address the promising biodegradable materials, we divided the categories as two: biodegradable metallic materials and biodegradable polymeric materials. Metal is a vital component of a stent because it supports the structure of stent and provides electrical functions.

Most of the sensors included on biodegradable stents were created using biodegradable metals like Mg, Zn, and Mo. To give all the components of a stent mechanical flexibility, biodegradable polymer is another essential component. Additionally, unlike metal, it might be utilized as an encapsulating layer to stop current leakage from wireless/sensor components, which could lead to malfunction. The biodegradable polymeric components are primarily responsible for the lifetime of biodegradable stent. We review the sensor/wireless devices for multi-functions, which could be integrated on biodegradable stent. Such devices offer great potential for real-time and ongoing monitoring of variables like blood flow and endothelial stress. Furthermore, the monitoring carried out with smart stents may aid in preventing some clinical side effects of traditional stents, such as stent thrombosis and in-stent restenosis.

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REFERENCE