Biocompatible materials for cardiovascular stents

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Abstract

One of the most common interventions performed today is intravascular stenting. A stent is a small tubular device placed into a blood vessel to hold it open. This review covers various aspects of stents from how it is placed into the vessel (e.g. the coronary artery) to the biocompatible materials used (e.g. metal). Mechanical considerations are also being discussed as well as comparison between self-expanding stents and drug eluting stents versus resorbable stents. Other latest research are also covered such as a 'smart stent monitor' based on sensors providing real-time feedback.

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1 Introduction

Biomaterials are increasingly used in numerous medical applications such as the treatment of cardiovascular diseases. These are natural or synthetic materials suitable to be introduced into living tissues and designed to interface with specific biological systems. Biomaterials' desired effects includes treatment, augmentation or replacement of biological functions. Artificial heart medical devices and joints implants are some concrete applications of that.[1, 2] Another important application where biomaterials are necessary is intravascular stenting. The Global Vascular Stent Market is indeed expected to grow significantly in the upcoming years with the increasing demand for minimally invasive surgeries, the rise of patients with cardiovascular diseases and overall the aging of the population.[3]

1.1 The variety of stents

Stents are small medical tubes inserted in the body to maintain open an obstructed hollow organ or passageway (more accurately a lumen - which is the cavity within a tube) such as a blood vessel.[4] These are woven (interlaced at right angles), knitted (interlocking loops) or braided (several parts woven together) cylindrical mesh structure made of biocompatible materials usually metals or plastics such as stainless steel, nitrol or chrome-cobalt alloy.[5] Once placed in the blood vessel, often an artery, the stents are expected to restore the flow of the fluid -in this case- blood. Traditional stents are expected to stay in place and last over the long-term. Other types of stent however may have different expected duration: dissolving or biodegradable stents.[6]

Stents have also other applications than extending obstructed blood vessels: these have also been tested for microvascular anastomosis surgery. Microvascular anastomosis is the formation of a connection between two normally distinct very small blood vessels performed under a surgical microscope. It was observed that using a dissolvable stent during this process achieved faster repair of the blood vessels and less dilation at the point of surgery.[7] In addition to these fully dissolvable stents, other stents have been designed to only allow a part of it to dissolve. An expandable stent having a dissolvable portion may have an application in arterial intersections where an aneurysm is formed (abnormal bubble of blood formed adjacent to the blood vessel where the walls had a weak spot). In this case, the stent would be expected to close the aneurysm sac, at the neck point - in the axis of the blood vessel walls. On the other side, the dissolvable portion would be in contact with an activating agent to allow the intersecting blood vessel to flow normally.[8] Dissolvable stents are also used in other lumen such as in the urinary tract[9]

Different stent types based on new materials, methods or solutions now exist. The latest innovations focus on coated, resorbable, and drug-eluting stents. The desired improvements include the release of biological active agents able to control adhesion to the lumen walls, cell differentiation, or vessel tissue development. These new stents also provide new physical–chemical properties and degradation rate. Despite the extensive progress in the research for new stents which will be discussed in this review, no ideal stent yet exists.[10]

1.2 Cardiovascular diseases and the need for Stents

As it was mentioned, stents are often used to open some obstructed lumen, especially blood vessels. Let us then look into reasons why these blood vessels may be obstructed.

The heart is the key organ which keeps blood continually circulating throughout the body. Arteries are the blood vessels which supply oxygen-rich blood to the entire organism. Arteries have much higher pressure than vein blood vessels. The arteries supplying blood to the heart are referred to as coronary arteries. Sometimes, coronary arteries become narrow due to plaque deposits or other phenomena. The plaque deposits consist of an accumulation of cells, fats, excess of cholesterol, other lipids, calcium, cellular debris and other substances. The narrowing of these vessels which is called atherosclerosis is precisely what the stents try to compensate. Atherosclerosis not only occurs in coronary arteries but in many other sites of complex blood vessel geometry: abdominal aorta, iliacs (near the abdomens), femorals (in the legs), popliteals (knees), carotids (neck), and cerebrals (brain).[11, 12] Atherosclerosis is a common disorder of the arteries and an important cause of Cardiovascular diseases (i.e. heart failure, stroke, high blood pressure and peripheral artery disease - similar to coronary artery disease but excluding the heart and the brain).[13]

The incidence of Atherosclerosis varies from 23% to 74% in various studies,[14, 15, 16, 17, 18] and it is reported to be the responsible for more than 25% of deaths on the Indian subcontinent.[18] These figures clearly demonstrate the importance in understanding, extending research and treating this condition.

Atherosclerosis is detected via electrocardiogram, ultrasound, computerized tomography (CT) scan or magnetic resonance angiography (MRA). Once the point of return is passed and prevention strategies would not work anymore, treatments become necessary. Angioplasty is the most common treatment which consists of opening up the obstructed vessel using a small flexible plastic tube or catherer with a 'balloon' at the end. The balloon is inflated which widens the vessel (Figure 1). The plastic tube is often inserted from femoral artery where a small cut allows it to be inserted. Stent implantation usually occurs at the same time.

2 Arteries and Stents Mechanics

2.1 From Arteries studies to Stents

In order to understand the mechanics of Arteries it is essential to understand their structure. Arteries like all blood vessels are made of three distinct layers also called tunicae. The first, tunica intima lines the inside walls and is very thin. It is a semipermeable membrane with various roles such as pressure regulation facilitator. When it comes to mechanical modelling, it is often neglected because of its small thickness. The second, tunica media is made of smooth muscle cells embedded in an extracellular plexus of elastin and collagen and an aqueous ground substance. The third and outermost layer is the tunica adventitia which consists of a dense network of collagen fibers with scattered fibroblasts, elastin and nerves. It appears to serve as a protective layer which prevents rupture of the vessel when an increase in pressure occurs, since fibers gradually straighten in these conditions.[3]

On the perspective of mechanical behaviors of blood vessels, many observations have been made through various research. The presence of residual stresses both in axial and circumferential directions was reported. Residual stresses appear to be related to the remodeling of the blood vessel wall which occurs when stress changes.[19] Luminal part (the innermost) is reported to be under compression while the outermost under tension which benefits to growth and remodeling of the vessels. Other characteristics include: anisotropy under load-free configuration (due to different tissue properties); incompressibility (due to the high water content); viscoelastic response of the tissues; hysteresis (dependence on history) under cyclic loads; stress relaxation after sustained deformation; pseudoelastic (behaving differently in loading and unloading). It is also observed that aged arteries are stiffer than younger arteries due to fracture of the elastic laminae (membrane) caused with fatigue in the tunica media - and due to cross linking among collagen fibers in the tunica adventitia during remodeling process.[3]

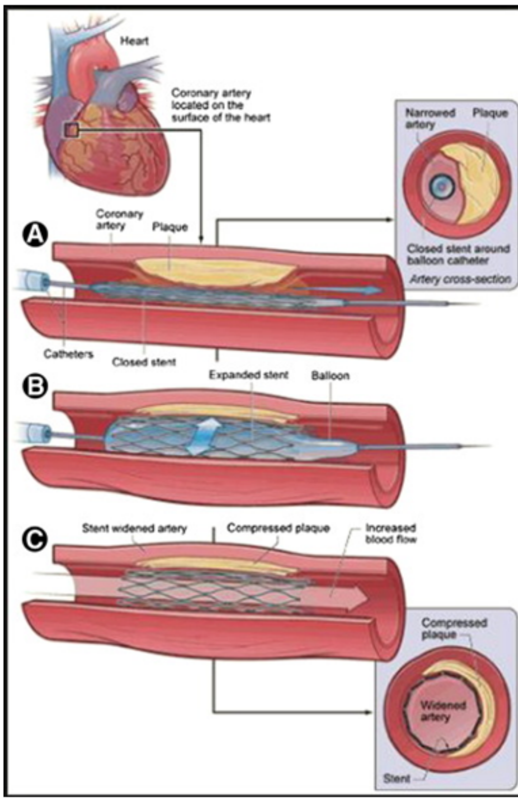

Figure 1: Process of Stent implantation with angioplasty [3]

Beyond the mechanics of arteries mentioned, there are a number of deformations these vessels undergo when subjected to mechanical forces - be it from internal blood flow, contiguous tissue tethering or implanted devices such as stents. Musculoskeletal motions are also widely studied through magnetic resonance angiography imaging to show how these strongly impact arterial deformations: twisting, shortening and bending angles are observed. These deformations are more significant in older patients due to loss of arterial elasticity. In addition to in vivo observations many biomechanical models on twisting, kinking or tortuosity deformations using finite elements methods are used to theoretically predict parameters such as critical loads. Similarly, 3D-model algorithms showed that fracture mechanism on the stent may occur in situations of compression or movement of the blood vessels in supine and fetal positions (of the patient) where maximum hip and knee flexion happen.[20, 21] Many others papers report on modeling algorithms among which the study of physical forces on stented and non-stented femoropopliteal arteries (commonly subject to Atherosclerosis) in patients with peripheral arterial disease based on different leg positions.[22, 23] All these findings provide an essential ground to understand the mechanical behaviors of stents and thus the requirements when designing them.

2.2 Mechanical considerations for Stent design

Mechanical behaviour of balloon-expandable stents (also called expanding stents) have been studied by Dumoulin et al.[24] The metallic P308 Palmaz stent with diamond-shaped cells (once expanded) and made of stainless-steel was tested through several models. One important challenge to deal with when designing these stents is the recoil phenomena.[25] Stent recoil refers to the percentage by which the diameter of the stent decreases between its expanded diameter (from the angioplasty) to its relaxed diameter (either following angioplasty or over the long-term).[26] That is an aspect where stent design firms often focus on with additional connectors on the more proximal end of the stent for more axial strength; or with wider peaks which focus strain to reduce recoil as well as other connector (to the lumen walls) design innovation.[27] Pattern of cells and thickness appeared to also provide less recoil and foreshortening and better flexibility.[28] From Dumoulin et al.'s models it was highlighted that not only expansion and intrinsic recoil is correlated with the stent shape but also its mechanical properties and the external stresses in that location - which leads to most stents being designed 10 to 15 percent larger than the targeted blood vessel. Their crushing modelling showed that buckling is a critical issue in stent design. Comparison between coated stents (with self-adhesive foil to facilitate embedding to lumen walls) and bare stents showed no change in stiffness. Palmaz stents have the advantage of high radial strength which is recommended for highly resistant plaque obstructions (severe Atherosclerosis) - but its plastic nature makes it less suitable for pulsating or compressing blood vessel sites, with higher permanent collapse risks. Alternatively, these locations would require purely elastic stents allowing reversible deformations and thus avoiding collapse.[24]

3 Influence of biocompatible materials on stent performances

Let us extend on the advantages between balloon-expandable stents which Palmaz belongs to and other types of stents, as well as comparing the various biocompatible materials used.

Before recoil even becomes a challenge, the ease of deploying the stent is essential as well as its resistance to dislodgement. For metallic stent such as the Palmaz, it requires a higher yield point value or lower modulus of elasticity. Stainless steel which is widely used achieves moderately well for yield point and radial force. However the modulus of elasticity (200 GPa) is not low, which can only be compensated with design shapes. Another metal used, Nitinol (Nickel titanium alloy) is more complex in that regards. The nickel-to-titanium ratio and the high-temperature heat treatment influences the thermal memory and the temperature at which the crystalline structure changes - which consequently changes the material flexibility and malleability. Ideally, high flexibility and malleability are desired when the stent is inserted in the implantation system (tube) at room temperature. Then, low flexibilitity with high rigidity (achieved with austenite crystalline structure) is desired when the stent is released in the blood vessel at around 30 degrees Celsius. These key temperature points therefore play a major role in stent performances for the nitinol material, unlike stainless steel. Dyet et al. demonstrate two distinct groups of metallic stents in terms of mechanical properties: those affected by their construction and those directly affected by the metal properties. Overall they consider high radial strength, high radio-opacity, elasticity, flexibility, good trackability as being the ideal properties of a stent ; although none of the stents they tested or researched on (in 2000) met these criteria. The necessity of assessment of metal fatigue is also stated, since several incidents of stents breaking up occurred when submitted to repeated flexing.[29] Since 2000, many other biocompatible materials appeared and were widely tested.

Resorbable stent also called biodegradable stent which are manufactured from a material capable of dissolving or being absorbed in the organism, are becoming increasingly popular since these avoid many risks and long-term issues - permanent stents bring. A zinc-copper biodegradable metal stent developed by Zhou et al. in 2019 achieved less intrinsic elastic recoil than standard stainless steel stents; better trackability (less push force when passing through curved vessels thus reducing mechanical stimulation on them). Their stent also facilitates the recovery of vascular pulsatility (difference between blood systolic and diastolic velocities).[30] Choubey et al. performed Finite element analysis to compare predicted Von-Mises Tress, recoil, Fracture point, Ultimate Tensile strength and factor of safety for seven stent materials: Stainless Steel 316L, Cobalt Chromium L-605 Stent, biodegradable Stent (PCL), Nitinol Stent (Austenite), Elgiloy Stent, Tantalum Stent, Cobalt Chromium. Biodegradable stents made of polycaprolactone (PCL) polymer had the most significant recoil making it less ideal than the other materials. Its Ultimate Tensile strength was also the lowest. Tantalum (a transition metal) achieved poor performances too. Overall Cobalt Chromium L-605 and Nitinol (with good corrosion resistance) have the best balance and make better material for stent.[31] Other research support the use of cobalt-chromium stent.[32] Biodegradable stints remain at the center of innovation, in addition to zinc-copper or PCL, some use Fe–Mn alloys. [33]

Drug eluting stents are another important segment of research, improving standard or coated stents. Stent coatings can control biocompatibility, degradation rate, protein adsorption, and adequate formation of endothelial tissue. These are parameters making stents perfom better. Coating materials are either organic polymers, biological components or inorganic coatings (e.g. nitrides). Drug eluting stents aim to reduce the overproduction of tissue in the stent site which would cause obstruction again. Antiproliferative substances 'drugs' are therefore used such as paclitaxel or limus.[10]

4 Perspectives of improvement

In 2020, researchers from ETH Zurich developed a high-level precision, biocompatible and 3D-printable micro-robot which delivers drug in the organism through the blood vessels. They are now investigating the use of such micro-robots for implementation of surgical tools especially stents.[34] The same university also introduced a new technology based on '4-D printing' which allows stents to be up to forty times smaller than existing ones.[35]

To alert potential recoil, pressure monitors placed on the stent - at both ends - have been developed which informs the patient or doctor when there is a drop in blood pressure across the stent. The information is transmitted wirelessly to a reader placed on the body close to the stent site. These inexpensive small scale technologies aim to better monitor the evolution of the stents over time.[36, 37, 38]

When it comes to the blood vessel conditions (such as atherosclerosis) in the coronary artery, several research show opposing findings, conclusions and recommendations between stenting or bypass surgery. Some research demonstrate that coronary artery bypass surgery may be the best treatment option for the majority of patients having more than one blocked heart artery instead of placing stents. This highlights the need for further research and improvement of stents which may allow patients to avoid open heart surgery while obtaining the same treatment performance.[39]

The motivations of innovation is often to overcome the current limitations of stents, such as restenosis (the recurrence of narrowing of a blood vessel, sometimes from recoil), or inflammation and thrombosis (formation of blood clot) at the stent site. Other characteristics are also often desired such as biodegradability and some mechanical parameters based on the targeted blood vessel. Finding the ideal design and material doesn't suffice, when biocompatibility remains the most important constraint when designing a stent. Promising stent solutions are currently in development, the numerous stent patents filled in recent years can testify this.[10] Clinical trials and market approval requests from companies have also been rising.[35]

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