

Medical Stents Design, Applications and Current Clinical Trials

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Abstract

Stents play a crucial role in the treatment of various cardiovascular and arterial diseases, including coronary artery disease, peripheral artery disease, renal artery stenosis, and carotid artery disease. They are used to restore blood flow and prevent life-threatening complications in cases of arterial blockage or narrowing. This paper discusses the pathologies that require stent placement, the different types of commercial stents, and the evolving field of stent geometry design. It also explores the potential of biodegradable stents and the need for further research in this area.

The paper highlights the significance of stent selection based on the specific condition and patient's health, emphasizing the use of drug-eluting stents (DES) and bare metal stents (BMS) in clinical practice. It presents clinical trials evaluating the safety and efficacy of different stent types and materials, with a focus on biodegradable stents (BDS). The research suggests that BDS may offer a promising alternative by reducing the risk of long-term complications associated with stent placement.

In addition, the study emphasizes the importance of optimizing stent geometry to strike a balance between flexibility and support while minimizing issues such as foreshortening during expansion. It proposes innovative approaches, such as 3D-printed patient-specific stents and smart stents that monitor plaque accumulation and arterial conditions in real-time.

Introduction

In the US and around the world, stents have had a major role in healthcare. Annualy, Over 2 million people require stents mainly for coronary artery disease (CAD) [1]. Stents are a lower cost and a more effective way to keep a confined space in the human body from closing, or eventually collapsing. Originally introduced in 1986, they were created to prevent arterial recoil and restenosis after balloon dilation. Recently, stents were used to treat many other diseases, such as Peripheral Artery Disease (PAD), renal artery stenosis, carotid artery disease, aortic aneurysms, esophageal disorders, and coronary artery disease . As the horizons for stents increase, they become more commonly used, essentially growing the market. he average cost of placing stents ranges between \$11,000 and \$41,000 without insurance [4], stents can be a hefty charge to many, and unaffordable to others, but according to Fortune Business Insights, " The Global Coronary Stent Market Size is projected to reach USD 8.08 billion by 2027,



exhibiting a CAGR of 6.7% during the forecast period" [3]. The stents market is growing exponentially by the year, and as the market sees growth, the amount of research being done will also increase. One of the lead diseases which requires stents is thrombosis, the formation of a blood clot, leading to its class risk of diseases. It affects a wide age range, from 15-80 years old. Although its common amongst people of all age, it can be prevented by simple movements such as staying active and keeping legs and body part uncrossed allowing blood to flow smoothly. Eating well and creating healthy lifestyle habits such as avoiding junk food can help reduce the risk of thrombosis.

Pathologies that require stent placement

I. Coronary Artery Disease (CAD)

Coronary artery disease, also known as CAD, is one of the most common cardiovascular disease among humans. Common risk factors for CAD include diabetes, high blood pressure, smoking, high cholesterol levels, obesity, homocystinuria, and psychosocial stress[6]. CAD, is when there is an excess of plaque buildup on the walls of the arteries of the heart. Generally made up of cholesterol deposits, generally formed through a high cholesterol diet. When the plaque builds up, it essentially clogs the arteries, this process is medically called atherosclerosis. When a human of any age deals with deposits of cholesterol narrowing a specific artery, they may experience Chest pain or discomfort (angina) weakness, light-headedness, nausea (feeling sick to your stomach), or a cold sweat, pain or discomfort in the arms or shoulder and shortness of breath [7]. Having CAD may also lead to increased risks of heart attacks, and strokes. The most common group affected by this disease is middle-aged men and women. Although it is possible for anyone to experience CAD. Its prevalence increases after 35 years of age in both men and women. The lifetime risk of developing CAD in men and women after 40 years of age is 49% and 32%, respectively. CAD can be developed through family history as well. If someone in your family has a previous history of a heart attack or stroke-related disease, it is common for it to be passed down genetically. Some common risk factors relating to CAD, can be any of the following; hypertension (high blood pressure), hyperlipidemia, (elevated calcium levels), diabetes mellitus(increased heart rate), obesity, poor diet, as well as smoking. Smoking increases the risk of CAD by over 50%, making it the 2nd leading cause of CAD, only behind Hypertension, increased blood pressure. Although CAD is one of the most common heart diseases, it can be prevented in various ways. According to John Hopkins Medicine, quitting smoking can significantly reduce risk of CAD as well as any heart-related issue. Becoming more active, focusing on maintaining a healthy weight, and managing stress, are all ways to reduce your risk of developing CAD [7]. However, there are other external factors, such as family history, which may result in the progression of these diseases in the future, so it's important for anyone with history to get annual electrocardiograms (ECGs).

II. Peripheral Artery Disease (PAD)



PAD is a disease similar to CAD, the difference being, PAD affects patients in the peripheral arteries, as opposed to the heart. Patients with PAD may experience a multitude of problems, such as claudication, ischemic rest pain, ischemic ulcerations, repeated hospitalizations, revascularizations, and limb loss. The survival rate for 10 years after diagnosis is 70% to 80%, remaining favorable for the patient, but some side effects of this disease can be linked to myocardial infarction, stroke, increased risk of cardiovascular death, and depression. PAD can be identified with a screening test, and some symptoms are Coldness in the lower leg or foot, especially when compared with the other side. Leg numbness or weakness. No pulse or a weak pulse in the legs or feet. Painful cramping in one or both of the hips, thighs or calf muscles after certain activities, such as walking or climbing stairs. Shiny skin on the legs [9]. PAD is also caused by excess levels of cholesterol buildup within the arteries of the limbs. Prevention methods include, no smoking, controlled levels of blood sugar, consuming low fat saturated foods, maintaining low blood pressures, and keeping a healthy weight/BMI [9].

III. Renal Artery Stenosis (RAS)

RAS is a common secondary cause of hypertension, primarily due to atherosclerosis, it is commonly seen in one of both of the arteries leading to the kidneys and can be life-threatening. It is often diagnosed non-invasively with ultrasound. Asymptomatic cases discovered incidentally usually do not need revascularization. However, symptomatic patients who require intervention typically benefit from renal artery stenting. Deciding on revascularization involves assessing the severity of the lesion and is best done by a multidisciplinary team. All RAS patients should receive guideline-directed medical therapy, which includes controlling hypertension and diabetes, using statins, and antiplatelet therapy, quitting smoking, and promoting physical activity. [10] Some risk factors to developing renal artery stenosis are, diabetes, family history of cardiovascular disease, hypertension high cholesterol and obesity,older age (men and people assigned male at birth/AMAB over 45 and women and people assigned female at birth/AFAB over 55),poor diet (high in sodium, fat and sugar). Smoking. This disease is most common among older men and women with atherosclerosis, also known as hardening of the arteries. There are no stand-out symptoms for this disease, but uncontrolled hypertension, along with family history if there is any. [11]

IV. Carotid artery disease

Carotid artery disease, also called carotid stenosis, results from narrowing or blocking of the carotid arteries, the large blood vessels that supply the brain. This condition can lead to stroke and up to one-third of all strokes are due to carotid artery disease. Treating this condition can greatly reduce the risk of stroke. Causes and risk factors for carotid artery disease include atherosclerosis. Atherosclerosis is a condition in which fatty deposits (plaque) build up in arteries, gradually reducing blood flow and causing blood clots that can lead to stroke. Risk factors include diabetes, a family history of stroke, high blood pressure, high cholesterol, older age (especially in men), smoking, alcohol or drug use, and neck trauma. In the early stages,



carotid artery disease often has no noticeable symptoms. [12] A characteristic sign is the presence of a whistling sound called a bleuet when listening to the pulse in the neck. As the disease progresses, the first sign may be a transient ischemic attack (TIA), often called a mini-stroke. Symptoms of the stroke and his TIA include blurred vision, confusion, memory loss, numbness or weakness in the body, problems with thinking, reasoning, memory, and speech. In the event of a stroke or TIA, prompt medical attention is very important to minimize long-term damage. Diagnosis includes physical examination, listening to sounds, and possibly seeing a neurologist for signs of stroke or TIA. Blood tests may be done to assess general health and risk factors such as blood sugar, cholesterol, and triglyceride levels. Imaging techniques such as the following are also used to examine blood vessels: Cerebral angiography. Mapping blood vessels in the brain. CT angiography (CTA), which uses a contrast agent and x-rays to get a detailed picture of blood vessels. MR angiography (MRA) uses a strong magnetic field to provide a clear picture of carotid artery occlusions. Carotid ultrasonography (carotid dual ultrasonography). Evaluate blood flow through the carotid artery. These tests help diagnose carotid artery disease and help determine treatment. [12]

V. Aortic Aneurysms

Aortic aneurysm is a condition characterized by swelling or enlargement of the aorta, which is the main artery responsible for carrying blood from the heart to the rest of the body. This lump resembles a balloon-like structure and presents a serious health risk. Aortic aneurysms can cause two critical complications: Dissection, which occurs when the force of blood flow causes the layers of the artery wall to separate, allowing blood to flow between them. In other cases, an aneurysm can rupture, causing severe internal bleeding, known as a rupture. It should be noted that dissections and ruptures are the leading causes of death associated with aortic aneurysm. Here are some key facts about aortic aneurysms in the United States: In 2019, aortic aneurysms or aortic dissections caused 9,904 deaths. About 59% of these deaths occurred among men. Smoking is a major risk factor and accounts for about 75% of all cases of abdominal aortic aneurysm. The US Preventive Services Task Force recommends that men aged 65 to 75, with a history of smoking, obtain an ultrasound scan to scan for an abdominal aortic aneurysm, as a preventative treatment, even if they display no symptoms. When it comes to the types of aortic aneurysms, they are generally divided into two main types; Thoracic Aortic Aneurysm and abdominal aortic aneurysm. Thoracic Aortic Aneurysm involves enlargement of the aorta in the chest area. Abdominal aortic aneurysm occurs when the abdominal aorta becomes enlarged. Risk factors for aortic aneurysms include many diseases and unhealthy behaviors that can damage the heart and blood vessels. Smoking is the most important behavioral risk factor. Other risk factors include: High blood pressure Increased blood cholesterol level Atherosclerosis, which is accompanied by hardening of the arteries Certain inherited connective tissue disorders, such as Marfan syndrome and Ehlers-Danlos syndrome, can also increase the risk of aortic aneurysms. In addition, a family history of aortic aneurysm can increase the risk of developing this disease. [13]



In the comparison between directional coronary atherectomy (DCA) and balloon angioplasty, atherectomy emerges as a compelling option for the treatment of coronary artery blockages. The study's findings highlight its superiority in achieving stenosis reduction, with a remarkable 89% of patients subjected to atherectomy experiencing a reduction in plaque buildup to 50% or less, in contrast to the 80% achieved with angioplasty (p<0.001). Additionally, atherectomy exhibited another significant advantage by providing a more substantial immediate increase in the diameter of the treated vessel, with an average enlargement of 1.05 mm, as opposed to the 0.86 mm increase observed with angioplasty (p<0.001).

Directional coronary atherectomy is a highly specialized procedure aimed at alleviating coronary artery blockages caused by atherosclerotic plaque. This technique involves the meticulous removal of plaque from the narrowed coronary arteries, facilitating improved blood flow. The remarkable success of atherectomy in achieving substantial stenosis reduction to 50% or less can be attributed to its precise plaque removal mechanism. By physically extracting the obstructive plaque, atherectomy ensures a more comprehensive and immediate resolution of the stenosis. This meticulous approach not only opens up the narrowed artery but also mitigates the risk of residual plaque remnants, thus leading to a higher percentage of patients achieving the critical reduction threshold. In contrast, balloon angioplasty primarily involves dilating the plaque and vessel wall using a balloon, which may not be as effective in completely removing the plaque, potentially explaining the slightly lower success rate in achieving the 50% or less stenosis target[13].

Along with these there are also Esophageal disorders, which require stents. When the esophagus is narrowed due to a swelling or ulcer, a stent can be placed to withstand its position and prevent their collapse. All the current treatment options and when stents are sometimes necessary vs drugs or clearing out the blockage.





Figure 1: the north american stent market size (future estimation)





Commercial stents

I. First gen "Bare Metal Stents (BMS)"

Bare metal stents are composed of metal, they were mainly used to treat ilica-femoral artery stenosis, coronary artery disease, and occlusion. In 1969, Dotter began researching vascular stent structures using stainless steel to wrap the coils and conducted successful animal implantation trials. [14] The Dotter design had a nitinol-wrapped vascular stent. However, this coiled structure, characterized by a helical coil with one or more wires, it showed excellent bending flexibility but lacked radial stiffness. As a result, it could not adequately support the



vessel wall, which caused a significant elastic rebound (in up to 57% of the implanted cases)[14]. In addition, coiled stents are not suitable for the treatment of small-diameter vessels due to their larger diameter, which has limited their usefulness. The BMS was also one of the causes for vascular inflammation and later caused the risk of arteriosclerosis due to its prolonged implantation in the arteries. Although there are a few limitations to their design, they are still widely used in clinical practice as the benefits of their use outweigh the risks. [14]

II. Drug covered stents "Drug Eluting Stent"

To address the problem of In-Stent Restenosis (ISR), researchers have developed a second-generation stent known as the drug-eluting stent (DES). DES are built on a bare metal stent body and they are coated with biocompatible materials and antiproliferative drugs. This innovation led to significant advances in clinical applications. Currently, DESs use drugs such as rapamycin, paclitaxel, and everolimus and are made of materials such as stainless steel, cobalt-chromium alloy, NiTi shape memory alloy, and polymers such as PLLA, PDLLA, PCL, PGA, and their copolymers. [14]

The addition of polymers changes the properties of these stents, affecting aspects such as biocompatibility and biomechanics. In a comprehensive review of DES, emphasizing different coating materials. Their review also discusses the evolution of stent materials over time. In 2002, Cordis Corporations launched Cypher DES, which showed impressive results. Compared to conventional bare metal stents, the Cypher stent reduced target lesion revascularization (TLR) by approximately 80% and target vessel revascularization (TVR) by approximately 70% or nine months after implantation. In addition, there were no significant differences in mortality or myocardial infarction (MI). However, ISR still occurred at 5-10% of cases. [14]

DESs effectively prevent neointimal hyperplasia, reduce the early inflammatory response after stent implantation and significantly reduce vascular restenosis, TLR and TVR. However, the most commonly used DESs have permanent metal substrates. Even after the medicinal coating is released, these metal substrates remain in the body indefinitely, which can lead to vascular inflammation and the risk of recurrent atherosclerosis in the long term. In addition, DESs face the challenges of slow drug degradation and carrier release.

III. Biodegradable stents (BDS)

Biodegradable stents are an alternative to permanent stents, they bioedegrade over time and are beneficial to the general area and degrade once their job is completed. "Once drug-eluting stents (DES) are deployed, they encounter the same issues as bare-metal stents (BMS). Addressing these problems requires stents that provide initial support to blood vessels and then gradually dissolve as the diseased vessels return to their normal state, thereby avoiding long-term stent presence in the body. Biodegradable stents (BDS), representing a third-generation stent technology, are constructed from materials that can naturally degrade and are compatible with the body's tissues [14]. BDSs effectively dilate blood vessels immediately upon implantation and subsequently degrade within the body. The resulting breakdown products can be metabolized or absorbed without impacting vascular function. The concept of bioabsorbable stents was pioneered by Stack in 1988, with additional studies conducted by Stack and Chapman in 1991, including animal experiments involving implantation. They observed good vascular permeability, an absence of inflammation, and minimal thrombosis during the early stages of implantation. BDSs primarily utilize degradable polymers such as polylactic acid (PLA), poly-L-lactic acid (PLLA), polycaprolactone (PCL), and racemic polylactic acid (PDLLA), as well as degradable alloys like magnesium, zinc, and iron alloys. In 1998, Yamawaki et al. presented the first practical application of biodegradable stents in animal studies using a poly-L-lactic acid (PLLA) stent. A subsequent study focused on degradable polymers by Tamai et al., who conducted the first human trials in 2000 using an Igaki-Tamai-PLLA biodegradable stent."[14]

Atherectomy vs. Angioplasty

Atherectomy is a medical procedure used to treat coronary artery disease (CAD) and peripheral artery disease (PAD) by removing atherosclerotic plaque that has accumulated in the arteries. Atherosclerosis is a condition in which fatty deposits, cholesterol, calcium and other substances accumulate in the walls of the arteries, causing them to narrow and weaken. This narrowing can restrict blood flow, causing various cardiovascular problems. During an atherectomy procedure, a special catheter tipped with a cutting or ablating device is inserted into the affected artery through a small incision or through the blood vessels under the guidance of fluoroscopy (live X-ray imaging) or other imaging techniques. The catheter is carefully moved to the place of plaque formation.[15]

Similarly, angioplasty is a medical procedure used to treat narrowed or blocked blood vessels, usually arteries, in various parts of the body. The most common form of angioplasty is coronary angioplasty, which is used to treat blockages in the coronary arteries that supply blood to the heart muscle. However, angioplasty can also be performed on other arteries throughout the body, such as the legs, neck or kidneys[15].

When comparing directed coronary angioplasty (DCA) and balloon angioplasty, atherectomy appears as a convincing alternative in the treatment of coronary occlusion. Study results highlight its superiority in reducing stenosis: a remarkable 89 percent of patients who underwent atherectomy had plaque accumulation reduced to 50 percent or less, compared to 80 percent who received angioplasty. In addition, atherectomy showed another important advantage, significantly increasing the immediate diameter of the treated vessel with a mean dilation of 1.05 mm compared to an increase of 0.86 mm observed with angioplasty (pandlt; 0.001). Guided coronary atherectomy is a highly specialized procedure designed to relieve coronary blockages caused by atherosclerotic plaque [15]. This technique involves carefully removing plaque from narrowed coronary arteries to facilitate blood flow. The remarkable success of atherectomy in significantly reducing stenosis to 50% or less can be explained by its precise plaque removal mechanism. By physically removing the stenotic plaque, atherectomy provides more complete and immediate healing of the stenosis. This careful approach not only



opens the narrowed artery, but also reduces the risk of residual plaque, resulting in a higher percentage of patients reaching the critical reduction threshold. In contrast, balloon angioplasty primarily involves expanding the plaque and vessel wall with a balloon, which may not be as effective at completely removing the plaque, which may explain the slightly lower success rate in achieving the goal of 50% or less stenosis. Although atherosclerosis seems like the most optimal procedure for plaque build up, atherectomy led to a higher rate of early complications, increased cost, and no apparent clinical benefit after six months of follow-up, making angioplasty more ideal in terms of effectiveness [15].

Selected clinical trials

Table 1

Clinical trial	Main findings
NCT01612767 BIOHELIX-I Bare Metal Stent Study (BIOHELIX-I)	The 9-month TVF rate of the PKE stent was comparable to other BMS and is a viable option for treating CAD. The low observed rate of ischemia-driven TVR supports the safety and efficacy of the novel BMS design [16].
NCT00217269 The ENDEAVOR IV Clinical Trial: A Trial of a Coronary Stent System in Coronary Artery Lesions (ENDEAVOR IV)	After 2 years of follow-up, ZES demonstrated efficacy and cost-effectiveness comparable to PES, with fewer MIs and a trend toward less VLST. (The ENDEAVOR IV Clinical Trial: A Trial of a Coronary Stent System in Coronary Artery Lesions; NCT00217269) [17]
NCT00217269	Over 5 years, there was no increased risk of death, myocardial infarction, or stent thrombosis, and there was a benefit of prevention of repeat revascularization procedures in ZES compared with BMS. (The ENDEAVOR Pharmacokinetic ([PK)]



The ENDEAVOR Pharmacokinetic (PK) Registry: The Medtronic Endeavor Drug Eluting Coronary Stent System (ENDEAVOR PK)

Registry: The Medtronic Endeavor Drug Eluting Coronary Stent System [ENDEAVOR PK]; NCT00314275) (The **ENDEAVOR II Clinical Trial: The Medtronic** Endeavor Drug Eluting Coronary Stent System in Coronary Artery Lesions [ENDEAVOR II]; NCT00614848) (The Medtronic Endeavor III Drug Eluting Coronary Stent System Clinical Trial [ENDEAVOR III]; NCT00217256) (The ENDEAVOR IV Clinical Trial: A Trial of a Coronary Stent System in Coronary Artery Lesions[ENDEAVORIV]; NCT00217269)[18].

NCT00140101	After 9 months, the ZoMaxx stent showed less neointimal inhibition than the Taxus
Safety and Efficacy of the ZoMaxx™	stent, as shown by higher in-stent late loss
Drug-Eluting Stent System in Coronary	and restenosis by qualitative coronary
Arteries (ZoMaxx™ II)	angiography.[19].

NCT00307047

SPIRIT IV Clinical Trial: Clinical Evaluation of the XIENCE V® Everolimus Eluting Coronary Stent System

In the SPIRIT IV randomized trial, EES compared with PES provided similar clinical outcomes in diabetic patients and superior clinical outcomes in nondiabetic patients at 1 year. (SPIRIT IV Clinical Trial: Clinical Evaluation of the XIENCE V Everolimus Eluting Coronary Stent System in the Treatment of Subjects With de Novo Native Coronary Artery Lesions; NCT00307047)[20].

Stent geometry

The design of stents has changed dramatically over time, in attempts to improve their effectiveness and reduce the associated complications. Specific studies and experiments that shed light on key design parameters and their impact on stent performance have heavily influenced this evolution.

Early stent designs, such as the "Palmaz-Schatz Coronary Stent", revolutionized interventional cardiology while also highlighting the need for further advancement. Researchers conducted numerous studies to investigate various materials and geometries in order to address



the problem of restenosis. For example, the BENESTENT trial in 1995 provided compelling evidence of the benefits of stenting, demonstrating that the slotted tube construction of the Palmaz-Schatz stent significantly improved clinical efficacy. This pivotal study laid the groundwork for further investigation.

Flexibility was critical in stent placement and "conformity" to natural vessel. The effect of cell structures, connector types, and stent dimensions on stent flexibility has been studied. In the mid-1990s, the introduction of laser micromachining and photochemical etching marked a watershed moment, allowing stent designers to create intricate geometries that offered both flexibility and strength. Studies on laser-machined stents and their clinical outcomes have confirmed their efficacy.

The selection of materials has been the subject of research. With their distinct properties, stainless steel and Nitinol have been the leading contenders. Studies comparing these materials' mechanical properties, biocompatibility, and long-term performance have influenced design decisions. Nitinol has gained prominence in self-expanding stent designs, dominating non-vascular markets due to its ability to withstand dynamic forces and recover from deformations due to its superelasticity.

Experiments with bridge connection strategies have also influenced stent design evolution. Peak-to-peak, peak-to-valley, and midstrut connections have been studied in order to optimize stent scaffolding while minimizing foreshortening during expansion. These experiments paved the way for a variety of bridge connection options that meet specific clinical needs.

To discuss stent geometry, a stent's cell structure has a significant impact on its flexibility. Stents are classified into two types: open cell structures and closed cell structures. Open cell structures are more flexible in general because they allow for some independence between adjacent struts or rings. This adaptability is required for maneuvering through complex blood vessels and ensuring proper placement within the body. However, open cell structures may have some disadvantages, such as the struts of the stent lifting up or spreading apart when subjected to tight bends, which is known as "fish scaling" or "cell separation." Closed cell structures, on the other hand, have their inflection points connected, which can improve support and radial strength but can also cause cracking. To some extent, flexibility is restricted. Researchers have conducted studies to examine the trade-offs between open and closed cell designs, which has aided in the refinement of stent geometry for specific clinical applications.

Furthermore, the type of connector elements used in a stent's geometry has a significant impact on its flexibility and strength. These connectors are in charge of connecting adjacent rings or struts within the stent. Flex connectors, which look like the letters "S," "N," or "V," add flexibility to the stent by allowing some movement between the rings. While they improve maneuverability, they also compromise support and radial strength because the presence of flex connectors necessitates larger cell sizes and less interconnection between struts. This balance of flexibility and strength is critical in stent design research. As investigators aim to optimize connector types and dimensions to meet specific clinical needs.



The placement of bridge connections within the geometry of a stent can also affect its performance. The manner in which struts are connected, such as peak-to-peak, peak-to-valley, or midstrut connections, influences how the stent expands. Peak-to-peak connections, for example, tend to separate adjacent expanding rings as the strut angles increase during expansion, potentially resulting in foreshortening. Valley-to-valley connections, on the other hand, tend to push adjacent rings apart, causing the stent to elongate during expansion [21].

Discussion

Stents are primarily used in conditions where there is a significant risk of arterial blockage or narrowing, such as coronary artery disease (CAD), peripheral artery disease (PAD), and renal artery stenosis. These conditions necessitate stents because the blockage can lead to life-threatening complications like heart attacks and strokes. Stents effectively restore blood flow, making them essential in these cases. On the other hand, stents may not be needed in conditions like carotid artery disease, where the arteries leading to the brain are blocked or narrowed. While carotid artery stents can be used, they are often considered when other treatments have failed or when there is a high risk of stroke. The decision to use stents in such cases depends on a careful assessment of the individual's risk factors, overall health, and the extent of blockage. So, the need for stents varies depending on the specific condition and its severity.

In clinical settings, drug-eluting stents (DES) and bare metal stents (BMS) are the most commonly used types of stents. Drug-eluting stents are widely employed in coronary interventions due to their ability to release drugs that inhibit the growth of scar tissue, reducing the risk of restenosis. Bare metal stents are still used, particularly in cases where the patient may need shorter-term support, or if there is a contradiction to drug-eluting stents. The choice between these two types depends on factors like the patient's health, the location of the stenosis, and the risk of restenosis. In addition to these two stents, there has been another study assessing the use of biodegradable stents in place of the BMS stents and the DES stents, although it has not yet been cleared to be used in a clinical setting, various trials are being conducted in hopes of generating a new type of stent.

DES, drug eluting stents, are currently being tested in clinical trials, there are various types of drugs eluing the stent that are being tested. In the Zotarolimus clinical trial, the use of the zotarolimus drug stents were being tested, and it was deemed a successful drug, there was not an increased risk of death or any other known complication. This drug-eluting stent could be used in a clinical setting Another stent being tried clinically currently is th BDS stent. It serves the purpose of degrading into the body after treatment is complete. It alleviates the risk of long-term issues with the placement of stents.t also eliminates the risk of tissue build up forming on the stent. At the conclusion of these studies, BDS stents could be used in clinical settings, and may serve as an improvement over previous treatments.

In the future, I believe that more funding should be spent on studying and developing biodegradable stents. Althought their use may introduce risk, the BDS serves a greater



potential. It works to eliminate the risk of stent collapse over time, and reduce the risk of blood clots and other plaque build up ontop of the stent. Along with benefits, the BDS stent also paves the way for other long-term dieases. DES stents, are also viable sources of treatment, but when compared to the primary BMS stents, there is not much differentiation in efficacy. According to the Pooled Analysis of Zotarolimus-Eluting Stents clinical trial, over a 5-year period, ZES - the DES stent, did not demonstrate an increased risk of death, myocardial infarction, or stent thrombosis when compared to BMS. According to this study, we can conclude that the DES stent doesn't add any extra risk to the patient health, but it also doesn't prove to have a noticeable difference in comparison to the BMS. Therefor, instead of pooling more money into researching DES, I think there should be more research done on the BDS stent, they allow for a higher ceiling with more potential and they could be a huge advancement in the treatment of diseases requiring stents. According to another clinical trial, ZoMaxx vs. Taxus Express2, the tests resulted in Taxus stent at 9 months, having higher in-stent late loss and restenosis rates. This supports an added risk when comparend to BMS. After looking at the facts, it is safe to conclude that BDS stents have the most scop to research, they provide solutions to problems both the DES and BMS face and are a huge improvement and advancement in technology which will better treatment in the future.

Improving the design of stents is critical to enhance their safety and efficacy in clinical settings. Optimizing stent geometry by investigating open-cell versus closed-cell structures, connector types, and bridge connections can strike a balance between flexibility and support while minimizing issues like foreshortening during expansion is key while trying to advance delivery systems at heter technology and imaging guidancecan enhance stent placement accuracy and safety. Furthermore, Building on these aforementioned strategies about in the stent design portion of the paper - the V,N and S flex connectors work extremely well but the stent design can be further improved. By exploring the use of 3D printers and after taking a patient-specific scan of the artery requiring treatment. Once we have acess to the 3D printed stent, the risk of loosening over time or collapsing is reduced significantly. Although the cost maybe increased to the additional steps, it helps ensure the fitment of the stent increasing efficacy while treating the patient. If we design the stent in a way where the plague accumulatd melts away, doesn't stick to the stent, we can help reduce the increased risk of retnossis and thrombosis. In order to reduce the plaque build up over time, we can thin out the stent as a whole, leaving more space for the blood to travel. Over the next couple of decades, as technology advances, if feasible, the introduction to smart stents that monitor the thickness and the level of accumulation on the stent will drastically help improve stents as a whole. The smart stent would occupy a similar design, but instead constantly monitor the functions inside the artery, it will give alerts on a device and could help determine when a doctors appointment to intervene is needed.

Conclusion



There is a growing market for stents. Stent design has evolved significantly over the last two decades. They are used to treat a wide spectrum of pathologies such as CAD and aortic aneurysms. Emerging stent technologies such as DES have shown promising results. More work is needed to evaluate their efficacy and maximize their clinical effectiveness.

Among these developments, Drug-Eluting Stents (DES) have gathered significant attention due to their encouraging outcomes. These innovative stents, bearing a coating of "drugs", have demonstrated considerable potential in enhancing clinical outcomes. Preliminary investigations have shown promising results in reducing complications and facilitating the recovery of patients.

The aim of stent technology in medicen remains characterized by its ongoing evolution. Researchers, remain determinein their commitment to the enhancement of stent technologies. The objective is to refine these medical devices, making them moreefficacious and benifical to patients.

References

[1] "When Do You Need a Heart Stent? - Harvard Health." Accessed October 20, 2023.

[2] "A Brief History of Coronary Artery Stents | Revista Española de Cardiología." Accessed October 20, 2023.

[3] "Coronary Stent Market Size, Share, Growth & Industry Report, 2030." Accessed October 20, 2023.

[4] "Pathophysiology of Thrombotic Thrombocytopenic Purpura | Blood | American Society of Hematology." Accessed October 20, 2023.

[5] "Cost of a Heart Stent - 2023 Healthcare Costs - CostHelper." Accessed October 21, 2023.

[6] "Journal of Cellular Physiology | Cell Biology Journal | Wiley Online Library." Accessed October 20, 2023.

[7] "Coronary Artery Disease | Cdc.Gov." Accessed October 20, 2023.



[8] Brown, Jonathan C., Thomas E. Gerhardt, and Edward Kwon. "Risk Factors for Coronary Artery Disease." In *StatPearls*. Treasure Island (FL): StatPearls Publishing, 2023.

[9] Mayo Clinic. "Peripheral Artery Disease (PAD) - Symptoms and Causes." Accessed October 20, 2023.

[10] "Renal Artery Stenosis - ScienceDirect." Accessed October 20, 2023.

[11] "Renal-Artery Stenosis - PMC." Accessed October 20, 2023.

[12] "Carotid Artery Disease: Symptoms and Causes | Penn Medicine." Accessed October 20, 2023.

[13] "Aortic Aneurysm | Cdc.Gov." Accessed October 20, 2023.

[14] "Micromachines | Free Full-Text | Structural Design of Vascular Stents: A Review." Accessed October 20, 2023.

[15] "A Comparison of Directional Atherectomy with Coronary Angioplasty in Patients with Coronary Artery Disease | NEJM." Accessed October 20, 2023.

[16] "Nine-month Results of the BIOHELIX-I Clinical Trial Study: Evaluation of the PRO-Kinetic Energy Cobalt Chromium Bare-metal Stent System - Michael - 2018 -Catheterization and Cardiovascular Interventions - Wiley Online Library." Accessed October 20, 2023.

[17] Leon, Martin B., David E. Kandzari, Eric L. Eisenstein, Kevin J. Anstrom, Laura Mauri, Donald E. Cutlip, Eugenia Nikolsky, et al. "Late Safety, Efficacy, and Cost-Effectiveness of a Zotarolimus-Eluting Stent Compared With a Paclitaxel-Eluting



Stent in Patients With De Novo Coronary Lesions." *JACC: Cardiovascular Interventions* 2, no. 12 (December 2009): 1208–18.

[18] "Long-Term Clinical Outcomes With Zotarolimus-Eluting Versus Bare-Metal Coronary Stents | JACC: Cardiovascular Interventions." Accessed October 20, 2023.

[19] "A Randomized, Controlled, Multicenter Trial to Evaluate the Safety and Efficacy of Zotarolimus- Versus Paclitaxel-Eluting Stents in De Novo Occlusive Lesions in Coronary Arteries: The ZoMaxx I Trial | JACC: Cardiovascular Interventions." Accessed October 20, 2023.

[20] "Outcomes in Diabetic and Nondiabetic Patients Treated With Everolimusor Paclitaxel-Eluting Stents: Results From the SPIRIT IV Clinical Trial (Clinical Evaluation of the XIENCE V Everolimus Eluting Coronary Stent System) | Journal of the American College of Cardiology." Accessed October 20, 2023.

[21] Pelton, Alan, and Tom Duerig. "SMST-2003: Proceedings of the International Conference on Shape Memory and Superelastic Technologies," n.d.

[22] "Cardiovascular Stents: Overview, Evolution, and next Generation | Progress in Biomaterials." Accessed October 21, 2023.