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Efficacy of Bioresorbable Vascular Scaffolds as a new Prototype in Case of Coronary Artery Disease: A Review Article

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Abstract
Bioresorbable scaffolds (BRS) represent a recent approach in coronary artery stenting technology. In contrast to the metallic stents, they provide transient scaffolding, thereby safeguarding early vessel patency and acute gains at the site of the pre-procedural minimal lumen area. Subsequently, a process of decomposition occurs, that results in the complete absorption of the scaffold, allowing the vessel to maintain its integrity and physiological function. It also minimizes the risk of late complications, allowing the vessel to maintain its integrity and physiological function. This unique ability has attracted much interest and at present several BRS are available. Fully bioresorbable coronary scaffolds function transiently to prevent acute recoil, but it has the potential to inhibit neointima proliferation by eluting drugs. The aim of this review is to describe the advances in the field of the bio-absorbable polymer stent. An overview of the ongoing clinical trials to examine the effectiveness of BRS in the clinical setting has also been evaluated. In order to reduce the rate of clinical events, improvements in the device, as well as implantation procedure, long-term follow-up data is necessary to provide further efficacy and safety.
Keywords: coronary artery disease, bioresorbable vascular scaffold, vascular restoration therapy, restenosis of coronary arteries, absorbable implants.

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Introduction

PCI is a life-saving intervention for treatment of coronary artery disease. Gruntzig invented Percutaneous Transluminal Coronary Angioplasty (PTCA) to treat coronary artery disease in 1977. Bio-Absorbable Stents are now beginning to be the focus of attention and hotspot [1-3]. Plain balloon angioplasty, bare metal stents, first and second generation drug-eluting stents, bio-resorbable and bioabsorbable scaffolds have offered a great advance diachronically against coronary artery disease and have enriched our medical armamentarium. At present, there are two kinds of stents in a clinical practice: Multi-polymer absorbable stent and absorbable metallic stent [4- 5]. The former manufacturing process is relatively mature, while the latter is not widely used in the clinical practice because of its degradation rate and inflammatory reaction. Today huge scaffolds are available in different composition (e.g. metallic alloy or polymer), strengths and weaknesses. Some of these are under development, some undergoing preclinical trial and others have already been implanted in a human. The biodegradable stents combine bioresorbable-bioabsorbable stent technology that has been designed to reduce or even to abolish late/very late stent thrombotic risk. This advanced technology allows positive remodeling, enables restoration normal vasomotor tone while simultaneously reducing the trigger for persistent inflammation and facilitating further interventions by percutaneous or surgical means. With bioresorbable technology, all stent components (drug, polymer, or scaffold) are absorbed, and none are left behind, while with bioabsorbable stents only the drug and the polymer are absorbed and leave behind a bare metal scaffold[6]. Therefore, understanding the mechanisms, the causes and the manners of prevention of dangerous stent thrombosis by developing new stent scaffolds is of paramount importance in clinical practice. In this review article, we have summarized the research progresses in the treatment of coronary artery disease with multi-polymer biodegradable stents.

1. Advances in clinical research of bio-absorbable Polymer stents

The prototype of bio-Absorbable Stent is a poly-scaffold made of macromolecular polymers, which

can provide the necessary support for the vessels in the short term, and then degrade gradually, thereby avoiding the complications caused by the long-term retention of metallic stents. Nowadays, the multi-polymer absorbable stents which have been carried out in clinical research worldwide include Iga-ki-Tamai stent, Abbott BVS Stent, REVA Stent, ReZolve Stent, Desolve stent, XINSORB stent, ART18Z sten, etc. Till now, only Abbott's bioabsorbable stent (Abbott BVS stent) and Elixir Company's Desolve stent has been awarded the European Community Quality Certification Safety Mark (CE).

1.1. Igaki- Tamai Stent Igaki-Tamai

R & D of Japan Igaki Medical Company is the first biodegradable scaffold for the human body to be fully degraded. Stents consist of a high molecular weight of the left-spin polylactic acid, which is designed for Z-shaped spiral and does not contain an anti-endometrial proliferative drug. The stent can be fully absorbed in 18-24months. FIM trials selected in 15 cases with Igaki-Tamai stent in 25 patients.

Out of total 50 patients studied, no elasticity retraction was seen after 24hrs of stenting. No MACE and stent thrombosis was seen after 30days. Stent placement in 3-month follow-up showed that the stent continued to expand and the stent was no longer further expanded after three months, and there was no significant change in the cross-sectional area of the lumen. Only one patient with 6-month follow-up were required to target lesion revascularization, without stent thrombosis and MACE occurred. Nishio et al. [7] placed the Igaki-Tamai stent (84 pieces) in 50 patients, a total of 63 coronary artery lesions were studied; the follow-up of the first three years of Intravascular ultrasound showed that stents disappeared completely. 4-years clinical follow-up showed a mortality rate of 2.0%, stent thrombus incidence 2.0%, Target lesion revascularization 18. 0%, the incidence of Q-wave acute myocardial infarction 2.0%. Among total only nine patients needed to do PCI again, no patients needed to carry out coronary artery bypass grafting. Only 2 cases of thrombus formation occurred within ten days follow-up; 1 case due to intraoperative heparin not being adequately administered occurred on the 5th day after stent, another 1 case as very late stent thrombosis [8-9], but appeared in the Igaki-Tamai stent proximal to the rapamycin drug elution stent.

Although the results of the trials were encouraging, further research on the stent was halted. The reason is that stent expansion requires heating. Even a short period of moderate heat (65- 75 degree Celsius lasts for few seconds) can still lead to vascular wall necrosis, increase platelet adhesion probability, and thus increase the risk of thrombosis, and the prolonged dilation caused by prolonged stent dilation can cause vascular wall injuries. The stent is currently approved for peripheral vascular disease treatment only in Europe. The new generation of Igaki-Tamai stents overcomes these shortcomings, and the stent expansion does not need to be heated, a preclinical assessment is currently underway in Germany.

1.2 Abbott BVS Stent

Abbott BVS Stent is the only drug-eluting bioabsorbable stent that has been carried out on a large scale clinical trial and has been CE certified. The stent has a high molecular weight left poly-lactic acid as the scaffold platform; the left spin poly-lactose coated its surface, rapamycin derivatives as anti-proliferation drugs, stent expansion through the balloon; and its operational flexibility similar to metal drug-eluting stent. The bracket is not visible under the X-ray, so it is conveniently positioned at the end of the bracket with two platinum markers. First-generation Abbott BVS stent (I) Version 0.1 degree is 150 μ m, the cross-section is facing line length 1. 4 mm. A plurality of reverse loops and small beams are connected. Stents must be kept in-20 ℃ environment to avoid the natural aging of the polymer.

1.2.1 The Absorb Cohort Test

It is the world's first clinical trial to evaluate the safety and viability of a fully biologically absorbable drug stent in the treatment of coronary artery disease. The study was selected in 30 cases with stable, unstable and asymptomatic myocardial ischemia implantation in the Abbott BVS stent. All of the patients with single coronary artery lesions, the results showed that the success rate of 100%. The incidence of thrombosis postoperatively 30 days showed 1 case of stent thrombosis or MACE, and postoperatively six months without stent thrombosis are followed; MACE incidence rate was only 3. 3% (1 case of non-Q-wave myocardial infarction). The incidence of MACE was consistent with the results of 6 months to one year of the follow-up without stent thrombosis. The 2-year follow-up including unintentional death, ischemic-driven target lesion revascularization and stent thrombosis, only one patient with non-Q-wave myocardial infarction

showed no statistically significant difference. At this time, the stent placement of the blood vessels has recovered normal relaxation activities, and optical coherent tomography display; 34. 5% of the stent beams are not visible. 4-year clinical follow-up showed that only 1 patient with ischemic-driven MACE had (non-Q-wave myocardial infarction) unintentional death. 5-year follow-up of ischemia-induced MACE was 3. 4% similar to 1 year rate without stent thrombosis, 2 cases of non-cardiac death, 18 patients underwent multislice coronary angiography and found that all the stents were intact. ABSORB cohort trials showed that stent wrinkling could be one of the major causes of high rates of late lumen loss, and this discovery promotes Abbott's further improvement of stents[10]. The second generation with same poly-polymer is still used in the version I, but the stent can be kept intact for 6 months by improving the process. At the same time, the new technology allows the stent to carry more medicines, more uniform beam layout to give the stent better support. The second generation of bio-absorbable Stent (I) was verified by ABSORB cohort B test [11,12]. The effect of version I in 101 Cases (102 lesions) were placed in the bio-absorbable stent (I). Stent version I of the patient divided into B1(45 cases) and B2(56 cases) groups; in which both the group patients underwent vascular imaging follow-up at 6 months, 1, 2 and 3 years after operation. The incidence of MACE was 9 in 101 patients; 3 cases of non-Q-wave myocardial infarction and 6 cases of ischemia-induced lesions in the target of revascularization with two years of follow-up [13-15].

1.2.2 Absorb II Test

It is a prospective, randomized controlled study of the world's first comparative Abbott bio-absorbable stent and metal drug-eluting stent (Xienceprime, Abbott R & D) in the treatment of coronary artery disease efficacy and safety research, selected 501 patients for 3-year follow-up. The study found that the incidence rate of MACE was 7 in the 1-year ABSORB stent. 3%, 3-year MACE incidence rate was 10%, target lesion failure rate was 4. 8%, there was no statistically significant difference between the metal drugs eluting stent. But 1 year of postoperative analysis showed that the incidence of angina pectoris in ABSORB group was significantly decreased compared with the drug-eluting stent group. In addition, in the subgroup of 45 patients, the most advanced imaging techniques were used, the results of measurements in the 1th and 3rd years showed that vascular systolic and diastolic function improved, and total lumen gained increased by 7. 2%. 3-year follow-up data supported ABSORB stents better long-term efficacy than metallic stents.

1.2.3 ABSORB Japan Research

It is a forward-looking multi-centric trial, which incorporates 400 patients with 38 Japanese centers, comparing the safety and efficacy of ABSORB Stents with metallic drug-eluting stents. The main endpoint was a 12-month target lesion failure rate. The study showed that the main endpoint incidence rate of the bio-Absorbable Stent Group was 4.2%, metal bracket Group was 3. 8%, the non-inferior validity of bio-absorbable Stent was confirmed [16]. The secondary endpoint was 13 months in contrast, with the loss of the late lumen in the segment; two groups were not statistically significant, confirming the non-inferior validity of the bio-absorbable stent. Clinical safety and efficacy were similar in 12 months.

1.2.4 ABSORB China study

It was selected for patients with coronary heart disease, receiving Abbott bio-absorbable Stent therapy. ABSORB China is the world's first clinical study on the end of the primary study of the loss of tube cavity in the late stage of coronary artery angiography in a 1-year follow-up. The study was selected in 24 centers in China, 480 PCI patients, 11 randomly assigned to accept Bio-absorbable Stents (241 cases) or metal drug-eluting stent (239 cases). In the follow-up one years, the terminal segment of the main terminal was lost in the biological Absorbable Stent Group 0. 19 ± 0. 38 mm (200 cases), metal drug-eluting stent Group 0.13 ± 0. 38 mm (195 cases), the bio-absorbable stent reached the end of non-inferior validity. Also, two groups of patients with a follow-up of 1-year target lesion rate of similar, bio-absorbable Stent Group and metal drug-eluting stent Group was 3. 4%, 4. 2%. Two groups of definite/probable stent thrombosis rates are similar. The results showed that ABSORB was not inferior to the metal drug-eluting stent in the late stage of coronary artery lesion in the primary endpoint of 1 years, and the clinical safety and efficacy of 1 year were comparable two groups [17-25].

1.2.5 Absorb Stemi Trofi test

For the first time using optical coherent fault the effect of the bio-absorbable stent and metallic stent in patients with acute ST-segment elevation myocardial infarction was evaluated by layer imaging (9). The study included eight medical centers in 191 patients

with acute ST-elevation myocardial infarction in PCI, randomly assigned to bio-Absorbable Stent Group (95 cases) and Metal Stent Group (96 cases). The main endpoint was six months with stent coverage scoring and vascular restenosis. The results showed that the stent covering score of the bio-absorbable stent was not inferior to metal stent group. The clinical endpoint was the compound endpoint of cardiac death, target vascular myocardial infarction or clinically driven target lesion, and the bio-absorbable Stent Group and Metal Stent Group were 1. 1% and 0, no statistical difference; the biological absorbable Stent Group has 1 case confirmed the occurrence of Subacute stent thrombosis. In addition to the ongoing follow-up of ABSORB cohort A and B trials, there are current studies on ABSORB Physiology, ABSORB Ⅲ, ABSORB Ⅳ ABSORBEXT END, etc.

1.2.6 Absorb Extend

The trials were conducted globally in non-randomized, single-group trials, to be selected in 100 centers of 800 patients with single or double vascular lesions, assessing the efficacy and safety of the Abbott Bioabsorbable stent. Clinical follow-up was performed in 1, 2 and three years after the operation also a 30days, six months, and angiography follow-up and an optical coherence tomography was performed in 2 years. The results of 1-year follow-up showed that the incidence of ischemic MACE and the failure rate of target lesion caused by ischemia were 4. 3% and 4. 9% respectively. Clear/probable stent thrombosis rate was 0. 8%. ABSORB EXTEND test results demonstrated that the incidence of thrombus in MACE and stent was lower in Abbott bio-absorbable stent [26].

1.3 DEsolve STENT

Desolve stent by the rotary poly-Lactic acid platform for the stent, the surface has two new anti-proliferative drugs (Novolimus and Myoli-mus), its radial support is similar to the Elixir metal bare stent, the stent is completely degraded 2-3 years, is another currently obtained CE certified bio-absorbable stent. The FIM test of Desolve Stent was selected in 16 patients with single coronary artery lesion were with lesion length <10 mm, evaluation of Desolve stent efficacy and safety was done [27]. The results showed that on 30days post operation follow-up two patients underwent emergency coronary artery bypass grafting for 1 case had spiral dissection, and 1 patients underwent target lesion revascularization during 30-180d follow-up time. The quantitative analysis of coronary angiography showed that the lumen was lost in the late 6 months after operation 0.19 ± 0.19 mm, and no late retraction or stent collapse. Intravascular ultrasound observation confirmed the inhibition of intimal hyperplasia, only 7.2% area blockage rate. 10 patients underwent optical coherent tomography, and showed 6 months after 98. 68% of the stent beams have been fully covered by the inner membrane. On 6-month follow-up only 1 patient due to stent stenosis increased need to reconstruct again, while stent patency. The study showed that the vascular wall of Desolve stent had good mechanical support and low acute retraction rate. On this basis, DesolveNX study was selected in 120 patients with single primary coronary artery lesions, the end of 6 months' stent was lost in the late stage, evaluating the efficacy and safety of Desolve stent. DesolveNX Ⅱ Study on evaluation of stents in patients with larger sample sizes.

1.4 Xinsorb Stent

XINSORB stent is the first self-developed fully absorbable stent in China. Chinese Ge Junbo Academician began the basic research of bio-absorbable stents in 2007, and formally passed the XINSORB support clinical trial of Huaan Biotechnology in 2013. A study on the XINSORB stent in China was made at the European Conference on Interventional heart disease in 2013 and 2015 respectively. The XINSORB stent was treated with an 18-month follow-up healing of a single or B1 coronary artery lesions; intravascular intimal hyperplasia can be suppressed six months after stent placement. The optical coherence tomography and intravascular ultrasound examination confirmed that the endothelial healed well and no apparent scaffold structure remodeling.

2. Advantages and limitations of Bio-absorbable Stents

Bio-absorbable scaffold materials can be absorbed gradually in vivo, there will be no residual in removal of the metal stent to avoid the potential adverse reactions caused by long-term retention in vivo, It can restore blood vessels to a more natural state, eliminating chronic vascular stimulation and inflammation of the source, It will not imprison the sides of the blood vessels, repeated PCI in the same lesion site, compatible with MRI examination, shortening the treatment of double-linked antiplatelet therapy. It improves the patient's long-term clinical results, improve the quality of life. Previous studies have shown that vascular reactivity decreases after

drug-eluting stent implantation, leading to persistent vascular endothelial dysfunction and atherosclerosis progression. Optical coherent tomography detection reveals that the lesion of the angiogenesis stent implantation is similar to a thin fiber cap, suggesting that it contributes to the formation of stable endothelial cells [28-29].

The bio-absorbable Stent is a new revolutionary technique, even known as the fourth revolutionary progress in the history of interventional cardiology [30-35]. However, the bio-absorbable stent still has some limitations: ***(1)*** The strength is inferior to the metal stent; compared with cobalt-chromium alloy or stainless steel; polymer mechanical properties are also inherently inadequate, and its elastic modulus is 100 times lower than metal. AbbottBVS1.0 in a clinical study showed more serious elastic retraction which resulted in a significant loss of the late lumen. ***(2)*** The local inflammatory response is stronger; the degradation of lactic acid can stimulate local blood vessels to cause inflammatory reactions, whereas inflammatory reactions have been proven to be related to restenosis and thrombosis in the stent. (3) The application of the bifurcation lesion is limited: because the ABSORB bio-absorbable stent it is different from the traditional metallic stent [36-40], it is impossible to squeeze stent CRUSH surgery or culottes (CULOTTE) as a metal drug-eluting stent. Once the absorbable stent is placed in the back of the blood flow affected, the expansion stent lateral holes will inevitably lead to stent deformation and cannot be like metal stent through the balloon to the aid expansion repair, limiting the absorption of the stent in the use of bifurcation lesions. (4) The stent is difficult to locate in operation: In the multi-polymer stent currently used, the visibility is poor, and there is a need to add X-ray marker to indicate the position of the stent in the vessel, it also increased the difficulty of locating stent at follow-up. (5) The biodegradation rate is slow and can still cause restenosis: The main advantage of the bio-absorbable stent is the total degradation, it is best to be completely degraded after placing in 6 months, the current DEsolve stent degradation time is one year, Abbott Bioabsorbable stent for 2-3 years. Slow degradation will trigger vascular inflammation and restenosis [41-45].

3. Prospect and application of bio-absorbable Polymer stent

In the long run, bio-absorbable polymer scaffolds should be superior to other stents, but there are many limitations and problems. In short, the bio-absorbable polymer stent should further improve its performance to prove its efficacy and safety, the value of absorbable stents in PCI of coronary heart disease can be proved only by accumulating more clinical research data, bring another revolution for PCI heart disease.

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