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Using biomaterials to treat myocardial infarction

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Abstract. Myocardial infarction (MI) as a risky disease, raises the awareness of the public. It results in insufficient oxygen supply due to cardiovascular blockage and ultimately leads to extensive cell necrosis. Hence, biomaterial-based therapy, angioplasty, and cardiac patches are exposed for the two stages of MI and indicate a promising direction for future MI treatment. This paper focuses on the biomaterials applicable to them one by one, including (1) The crucial function of angioplasty in treating MI; the discussion of its efficacy, mechanics, and results; analysis of clinical studies, material improvements, procedural advancements, and both the effectiveness and limitations of angioplasty. (2) The application of cardiac patches for post-MI treatment; synthetic or natural patches with different structures; review and highlight how these patches promote tissue repair and functional recovery; and the advantages and disadvantages of each patch.

Keywords: biomaterial, myocardial infarction, angioplasty, cardiac patch.

1. Introduction

Myocardial infarction (MI) is the major contributor to human death [1-4], also known as a 'heart attack'. MI refers to the sudden and severe interruption of blood supply to a part of the myocardium. Having a piece of dysfunctional myocardium is a life-threatening problem. According to a recent statistical report on the global prevalence of MI, 2,982,6717 people under 60 years old were analyzed and 3.8% of them were diagnosed as having MI. In the group with an age over 60, 9.5% of 5.071.185 individuals are MI patients [2]. Although the incidence rate is declining annually, the complications and sequelae brought by MI also can not be underestimated. Therefore, in recent decades, the field of medical science has witnessed remarkable advancements, and the utilization of biomaterials stands out as a promising avenue for treating complex cardiovascular conditions. Despite treating post-MI, the precaution for pre-MI is also meaningful. Angioplasty and cardiac patches are two of the most effective and well-known methods. This paper reviews the biomaterials used in angioplasty and cardiac patches from past research, offering potential therapeutic approaches for both the early and late stages of MI. The thesis elaborates on various biomaterials and highlights their applicability and effectiveness from different perspectives.

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2. Angioplasty for Pre-Myocardial Infarction Treatment

The pre-myocardial infarction period is between the period when atherosclerosis first appears in a coronary artery to the instance when the artery is entirely blocked [1]. Angioplasty is a technology that was first described by Charles Dotter in 1964, while it remains today a practical approach to treating narrowed arteries due to atherosclerosis and is minimally invasive [5].

2.1. Angioplasty for atherosclerosis

The pre-myocardial infarction period is between the period when atherosclerosis first appears in a coronary artery to the instance when the artery is entirely blocked. While heart attacks are characterized by acute disease [1], blocking blood flow to the heart is a process that requires different times, depending on the individual patient, to the extent that the coronary artery is completely blocked.

2.2. Mechanism

Although angioplasty is a medical procedure that has existed for decades, the fundamental logic behind its function has not changed in most parts. In angioplasty, a catheter is inserted into a blocked or narrowed blood vessel and then guided to the blocked site using X-ray tracking. Contrast dye is injected into the artery during this process so that the artery and the heart can be highlighted on an X-ray [6,7]. Afterward, the first catheter will be replaced by another catheter with a deflating balloon covered with a stent. When the balloon reaches the blocked area, it expands, pushing the plaque toward the arterial wall and causing the artery and stent to expand. After expansion, the balloon and catheter will be removed, leaving only the stent to maintain the artery. Ideally, it can continuously improve blood flow [5]. This is the basic procedure of angioplasty with stent and balloon, and it does not vary when changing the insertion position. The insertion usually happens in the patient's arm, wrist, or groin [8]. Drug-eluting stents (DES) and bare metal stents (BMS) are currently the two most common types of stents, with the main difference being that DES has multiple layers of drugs/polymers that can reduce the risk of restenosis, thrombosis, and other complications [9].

2.3. Structure and Design

Various research and experiments have been performed to understand how the difference in the design and structure of stents affects the patients' body reactions, and this passage focuses on the effect of the size of stents, the thickness of the strut, and the size of blood vessels on complications [8,10]. Stents were placed in small coronary vessels where a slight change in stent design would significantly change the outcome of the operation. Elezi et al. provided data on the restenosis rates for vessels that were under 2.8 mm and vessels that were between 2.8 and 3.2 mm, as well as vessels over 3.2 mm., with a result of 38.6%, 28.4%, and 20.4% [11], demonstrating a clear pattern of decrease in restenosis rate as the vessels are getting wider. Lau et al. used different-sized stents and resulted similarly: as the stent size increased, which increases the size of the vessel, the rate of restenosis decreased [11]. Considering that metal stents can expand and enlarge the vessel's radius, the stent size is essential for controlling the restenosis rate. In addition, the thickness of stent struts has been shown to impact stent performance. More radiopacity, more radial force, and better vascular support are all provided by thicker struts, but this means a more significant force acted on the arterial wall, causing a greater risk of vessel wall injury such as intimal hyperplasia [12], which brings a higher risk of restenosis [11].

2.4. Stents for angioplasty

Due to the limited number of instruments used in balloon angioplasty, there are not many factors that can be improved on the stent itself. However, some aspects of angioplasty have been modified in the past few decades, and the core of the modification has always been the stent. Currently, two types of stents are applied in clinical practice: bare metal stents and drug-eluting stents. While the DES has made significant improvements compared to BMS, it still does not prevent neo-atherosclerosis, leading to the development of bioresorbable stents (BRS) [9,12,13].

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2.4.1. Bare Metal Stents. The choice of material for stents comes with many, but it all surrounds different types of metals. Metallic scaffolds, an early innovation in the field, have played a central role in revolutionizing coronary artery treatment, especially in angioplasty. BMS can be further classified into different types, including wire mesh stents, tubular stents, and multicellular stents. Even though the self-expanding wire mesh stent called Wallstent was the first stent to be injected in humans, its inability to prevent elastic recoil and tissue prolapse limited the spread of the stent with balloon angioplasty [11,14]. The Palmaz-Schatz stent, the first tubular BMS that was used industrially, was put into use in 1986 to preserve the lumen's stability and prevent elastic rebound. It was the stent model that demonstrated the effectiveness of coronary stent implantation over traditional balloon angioplasty [11,15]. The Palmaz-Schatz stents were applied to the experiment to test their success rate, complication rate, and restenosis rate. The two hundred and forty-seven patients (192 men and 55 women) were given aspirin, dipyridamole, and a calcium channel blocker for 24 to 48 hours before and three months after stenting. As a result, the stent delivery was successful in 94% of the patients, with 16.5% of the successful patients encountering complications after coronary stenting, and angiographic restenosis for 20% of patients who only injected one stent and 50% for patients who injected between two to six stents [15]. As the first version of BMS used in angioplasty, the Palmaz-Schatz stents already demonstrated its capability and potential but also revealed the high probability of finding restenosis and thrombosis.
The material for the metal stents should have the following characteristics: elasticity, X-ray visibility, rigidity, biocompatibility, and corrosion resistance [12]. The stents need to achieve their functions while being safe for injection. This is also why polymers, ceramics, and other materials are not used for stent material. They cannot achieve all these requirements in a human body environment. The most common material is 316L stainless steel because of its resistance to corrosion and heat, strength, biocompatibility, and nonferromagnetic. While strong enough, stainless steel also shows elongation. This makes it easier to create stents, maintain morphology to withstand blood vessels' elastic recoil, and be elastic enough for balloon expansion [11,12]. However, while stainless-steel is not very visible on fluoroscopy, studies have also shown that there is a chance for inflammatory responses due to the existence of eluted nickel, molybdenum, and chromium from the stainless-steel surface [12,16,17]. Other common alloys used, such as Ni-Ti alloy, tantalum, and Co-Cr alloys, each have advantages and disadvantages [11].

2.4.2. Drug-eluting Stents. As an improvement from BMS, DES is developed to reduce in-stent restenosis and thrombosis. A metallic stent platform, a polymer covering, and an antiproliferative agent make up drug-eluting stents [13,18]. The sirolimus-eluting stent and paclitaxel-eluting stent were the first generation of DES. After being put into clinical practice, DES showed significant improvement from BMS regarding in-stent late loss, in-stent restenosis, and target lesion revascularization. However, for patients who received DES for more than one year, there was a greater chance of late stent thrombosis, and delayed in-stent restenosis was observed [13]. The second-generation DES improved all three components of the first-generation. Stents were changed from stainless steel to alloys with better performance, such as cobalt-chromium. The polymers were made more biocompatible, and different types of more functional drugs, including zotarolimus, phosphorylcholine [12], and everolimus [19]. Everolimus-eluting stents are one example of a newer generation of DESs demonstrated to lower long-term thrombosis and MI risk [13].

3. Cardiac Patches for Post-Myocardial Infarction Treatment

3.1.1. Although angioplasty does progress in reducing the risk of hemorrhage, it still does not eliminate the underlying problem of MI. If the plaque expands and compresses the stents, the hemorrhage occurs for an instant as the blood vessels burst, and the patient is life threatening. Fortunately, the possibility of survival still exists - in some cases, the direct cause of death is complications and dysfunctional tissue rather than cardiac hemorrhage. Therefore, many therapies have emerged to treat these consequences, and one of them, heart patches, seems to have immeasurable prospects. Each of them comprises three symbolic examples with their unique properties.

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3.2. Natural Biomaterials in Cardiac Patches

3.2.1. Fibrin. Fibrinogen serves as the precursor to fibrin, a crucial protein in the coagulation process. Fibrinogenesis involves a series of intricate steps. When a blood vessel's endothelium is compromised, platelets are summoned to create a platelet plug. These platelets carry receptors for thrombin on their surfaces. These receptors bind with circulating thrombin molecules, catalyzing the conversion of soluble fibrinogen within the serum into fibrin at the injury site [20]. A technology has been developed to design fibrin patches with physical properties that interact well with the body. This process involves quickly blending the solution of fibrinogen and the thrombin and curing in a pre-placed mold in a short period to form a patch on the infarcted area [21]. Notably, this methodology has demonstrated success in delivering mesenchymal stem cells and human embryonic stem cell-derived vascular cells (hESC-VCs), to animal subjects in clinical experiments [22].

Fibrin has been extensively used as a biopolymer scaffold for cardiac patches in tissue engineering, taking advantage of its unique biological and physical characteristics [20,23]. It is a viscoelastic polymer [20], and its extraordinary extensibility, elasticity, and strain stiffening have been demonstrated and quantified at the level of individual fibrin fibers [24]. Initial findings show that uncross-linked fibrin fibers can extend significantly, increasing in length by 3.2 to 3.7 times, while cross-linked fibers demonstrate even more impressive behavior, stretching to 4.3 to 5 times their original length, with exceptional cases reaching 6 times [25]. The fibers recover their shape after stretching, with uncross-linked ones returning to their initial form after elongating up to 2.2 times their length and cross-linked fibers maintaining integrity at 2.8 times. When multiple fibers form networks, their collective expansion is limited to 2 to 3 times the original size [25]. Using fibrin as a potential scaffold presents several disadvantages that cannot be ignored. These include gel shrinkage, rapid degradation before the optimal development of tissue-engineered structures, and limited mechanical stiffness [26]. To tackle gel shrinkage, a practical solution is to add poly-L-lysine to the gel during culturing, which effectively counteracts the undesirable shrinkage effect [27]. When using fibrin as a scaffold, adding fibrin degradation inhibitors can prevent rapid breakdown of the structure [28]. For improved mechanical stiffness in certain tissue engineering applications, an advisable method is to combine fibrin hydrogels with compatible scaffold materials. This approach creates structures with the desired mechanical strength and resilience [26].

3.2.2. GelMA. GelMA, an engineered gelatin-based biomaterial, finds widespread application in regenerative medicine [29-31]. It is a bioactive and resorbable substance, boasting crucial attributes such as biocompatibility, enzymatic cleavage, cell adhesion, and customizable mechanical properties [29,31]. The prior study unveiled an innovative one-pot synthesis approach for GelMA, showcasing precise control over key characteristics such as degrees of substitution (DS), secondary structure, and other properties [29]. This method it permits the production of GelMA with a desired degree of substitution while maintaining remarkable stability. Remarkably, producing GelMA with higher degrees of substitution retains a slower degradation rate, thus bolstering cell viability [29].GelMA, a widely used biomaterial, encounters a shared limitation: its low viscosity leads to inadequate structure resolution during printing. At times, it's even entirely non-printable at lower concentrations, particularly when utilizing common extrusion-based bioprinters [32,33]. Addressing this issue, low-viscosity GelMA bioinks intended for inkjet bioprinting necessitate swift crosslinking mechanisms [33].

3.2.3. Collagen. Collagen is the preeminent natural substance for fabricating cardiac patches, predominantly found within the cardiac extracellular matrix (ECM). It has been widely used as a biomaterial in various medical fields [34]. Collagen has low antigenicity and chemotaxis, providing a favorable environment similar to natural tissue for cell growth and development [35]. In this case, by harnessing the capacity of paracrine signaling and force transmission, collagen-based scaffold patches exhibit promising potential in therapeutic applications aimed at myocardial infarction (MI). The inherent

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qualities of collagen scaffolds empower them to contribute effectively to treating these cardiac conditions [21,35].

Collagen (COL) is a pivotal fibrous protein constituting over a third of the body's total protein content. It permeates various body systems with connective tissue, making it a fundamental component [36]. Collagen type I (COL1), a fibrillar protein, significantly contributes to the interstitial membrane's structure, and it's widely recognized as the most prevalent form. This COL type is a crucial structural element in numerous tissues, found throughout various connective tissue structures. Another vital form, collagen type III (COL3), boasts a unique molecular arrangement. Its elongated protein chain imparts tensile stiffness and biomechanical attributes to tissues. This distinct feature defines specific properties within the ECM when this collagen type takes precedence [37].

A study has shown that a special acellular scaffold composed of COL1 with specific physical and mechanical properties can effectively improve MI and restore myocardial function to some extent. Utilizing Echocardiography, the study meticulously monitored and documented the condition of the mice. After 4 weeks, the researchers observed that compared to the control group, the treatment effect of mice with MI without patch implantation was significantly lower than those with patch implantation [38]. Collagen's mechanical strength is inherently restricted, attributed to its susceptibility to rapid and uncontrolled biodegradation [39]. To address this challenge and enhance the biodegradability of collagen-based scaffolds, integrating thermal or chemical cross-link treatments emerges as a viable solution. These treatments not only extend the biomaterial's durability but also bolster its mechanical capabilities, presenting a promising strategy to overcome collagen's limitations [40,41].

3.3. Synthetic Biomaterials in Cardiac Patches

3.3.1. Polyester based scaffold. Polyglycerol sebacate (PGS) was manufactured to be an elastomer through the polycondensation reaction of polyglycerol and sebacic acid by Wang et al. in 2002 [42]. It is one of the most widely explored scaffold materials due to its advantages of low cost, considerable biocompatibility, good thermal resistance, high elasticity, and mechanical support. In 2008, Chen and colleagues completed an investigation on Young's Modulus of PGS under 110-130°C. The results met all the mechanical requirements of the materials for the cardiac patch [43]. This inherent elastic property allows PGS to mimic the myocardium's mechanical dynamic system.

It has been found that Ravichandran et al. examined the efficacy of a PGS scaffold that served as a biomimetic support in restoring infarcted myocardium. They applied bone marrow-derived mesenchymal stem cells to the PGS and fibrinogen-based scaffold, and transplanted this complex into the LV of a porcine infarction model. They found this cardiac patch enhanced the function of LV. In addition, the cardiac marker proteins were present in the experiment, indicating this scaffold was applicable for the differentiation and proliferation of the bone marrow-derived mesenchymal stem cells into cardiac cells [44].

Polycaprolactone (PCL) has features like good mechanical strength and degradability, rapid availability, nontoxicity, and low-budget for the design of cardiac patches [45]. PCL-based scaffold was exemplified in the work undertaken by Liu et al. in 2016. The team postulated that incorporating high concentrations of elastin and collagen, which were cardiac natural protein (NP) with hybrid PCL electrospun nanofibrous sheets, could play the same role as the biomimetic cardiac patch. 80% NP/PCL sheet with or without bone-marrow c-kit (+) cells were appraised by applying to a MI mice model. Significant diminution of the infarcted area and renewal of cardiac function was demonstrated compared with the sham operation group, the untreated MI group, the pure PCL group, and the NP-only group after 4 weeks of transplantation. The effectiveness of the NP/PCL sheet was substantiated by the enhancement of cellular proliferation, elasticity, and attachment. The addition of NP concentration could advance Young's Modulus and tensile strength compared to the pure PCL group [46].

Polypropylene-co-ε-caprolactone (PLCL) is an elastic, degradable, and mechanically strong material. It can cooperate with biocompatible materials to make a tissue engineering available scaffold. By way of illustration, Sugiura et al. display the expression of increased myocardial-specific proteins in the

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infarcted site after 16 weeks of the PLCL-based scaffold transplantation to prove PLCL is a feasible material for cardiac patches. In this experiment, the biodegradable scaffold was made by 50:50 PLCL and polyglycolic acid (PGA), and cultured human-induced pluripotent-stem-cell-derived cardiomyocytes (hiPSCs-CMs) were planted upon the scaffold [45].

3.3.2. Polyurethane based scaffold. Polyurethane (PU) is formed from the reaction of di-isocyanates with polyols in the presence of a catalyst. It is one of the most versatile polymeric materials in the field of biomedical engineering, which possesses all the qualities that satisfy the requirements for the materials of cardiac patches. Hashizume et al. addressed polyester-urethane urea (PEUU) in investigating the capacity of biodegradable, elastomeric patch graft onto a 2-week post-MI porcine model. Echocardiography measured the end-diastolic area (EDA) and fractional area change (%FAC) after 4 and 8 weeks of the sham surgery and PEUU patch implantation. The data demonstrated that PEUU has a higher percentage of FAC and lower EDA but thicker infarcted ventricular wall than the sham group, which indicates better remodeling [47]. The degradation of PU will affect the functional benefit of an applied patch. The change in its physical and chemical properties depends on the type of PU present in the polymer chain. This can be seen in the evaluation of PEUU, polyester-carbonate-urethane urea (PECUU), and polycarbonate-urethane urea (PCUU) patches for a rat postinfarction model. Each patch was placed on the LV lesion and compared with the control group. PECUU performed remarkably in the functional and histological assessment, including Masson's trichrome staining, EDA and %FAC by echocardiography, Neovascularization, MRI analysis, Neovascularization, Immunohistochemistry for macrophages and αSMA, and area of the infarcted site [48].

3.3.3. Polyacid based substrates. Polylactic acid-glycolic acid (PLGA) is a widely used block copolymer, which emerges biocompatibility, controlled biodegradability, easy customizability, nontoxicity, high porosity, and mechanical strength for scaffold construction [45]. The cardiac patch involves a porous 50:50 PLGA and poly-L-lactide (PLLA) scaffold with cultured human embryonic stem cell-derived cardiomyocytes (hESC-CMs) alone or cooperated with endothelial cells and embryonic fibroblasts on it. Lesman et al. transplanted the multicellular construct or hESC-SMs scaffold onto the LV of immunocompromised rats when the continuous synchronized beating was observed in the patch. 2 weeks after the engraftment, mature implants merged with rats' vascular network to assist the vascularization in impressive progress.

4. Conclusion

In conclusion, the application of stent with balloon angioplasty emerges as a promising therapeutic approach in the management of pre-MI periods. A successful angioplasty performs remarkably in preventing irreversible damage to the cardiac muscle. In essence, while BMS provides mechanical support to keep arteries open, DES offers the additional benefit of drug delivery to minimize the risk of restenosis, making them a preferred choice in many cases of coronary artery disease intervention. However, neo-atherosclerosis remains a challenge for both BMS and DES.

Furthermore, recent studies of adopting natural and synthetic cardiac patches in post-MI treatment reveal an encouraging prospect. The natural biomaterials share similarities of acclimatizing to organisms' inner environment and easily be accepted by body cells. Representativies for cardiac scaffold are fibrin, collagen, and GelMA. Fibrin offers excellent extensibility and elasticity, making it resistant to deformation after stretching. GelMA has controllable degradation during production, resulting in reduced patch degradation and improved cell activity. Collagen is less likely to cause cell rejection and promotes cell recovery due to its low chemotaxis. Synthetic biomaterials, mainly including polyester, polyurethane, and polyacid substrates, show progress in stress attenuation and controllability of degradation rate. Under the category of polyester, PGS has high elasticity and can withstand the stress from the heartbeats for the renovation of cardiac function; PCL is innocuous, used for revitalizing cardiomyocytes; PLCL owns the common features of synthetic materials, elevates the number of myocardial-specific proteins in the infarcted site. PU, as a multifunctional biomaterial, and PLGA as a

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polyacid, can make remarkable results in enhancing neovascularization and reconstructing cardiac function.

In general, natural scaffolds are prone to failure with the stress exerted by heartbeat due to weak viscosity and poor mechanical properties. Their exceptional biodegradability gives them a fast degradation rate, which sometimes cannot sustain the cells until the end of the therapy. The implantations of those synthetic patches that lack elasticity are hard to adapt to the mechanical strength of natural myocardium and tend to shift from the infarcted site. As foreign substances to the organisms, synthetic patch grafts tend to trigger immune rejection and induce lesion inflammation.

Overall, after years of innovation and improvement, mature vascular stents have become a reliable and effective treatment method for early-stage MI. They have great potential and strength both in the past and future. While most cardiac patch applications are in animals, many of them have shown significant efficacy in curing. Cardiac patches are strongly believed to be a promising primary treatment for post-MI.

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