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Research Progress of Biological Scaffold Materials in Pelvic Organ Prolapse

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Abstract

Pelvic organ prolapse (POP) is a common condition that affects women's quality of life. Traditional surgical and non-surgical treatments face challenges such as limited efficacy, high reoperation rates, and numerous complications, making it difficult to meet clinical demands. In recent years, the rapid development of tissue engineering technology has provided new directions for POP treatment. Among these, biomaterial scaffolds have become a research hotspot in this field due to their unique potential in supporting pelvic floor tissue regeneration and repairing pelvic floor support structures. This article reviews the core characteristics that ideal biomaterial scaffolds for POP repair should possess. On this basis, it categorizes and provides an in-depth discussion of the main scaffold materials currently applied in clinical practice and research, including natural biomaterials, synthetic polymer materials, and natural-synthetic composite materials. It is worth noting that, at present, the vast majority of novel scaffold materials are still in the preclinical research or early clinical trial stages, while in clinical practice, non-degradable synthetic meshes such as polypropylene (PP) remain the predominant option. This article aims to provide a reference for future research and clinical translation in this field.

Keywords

Biological Scaffold, Pelvic Organ Prolapse, Biomaterial

1. Introduction

POP is a common clinical problem in gynecology. Its main pathogenesis lies in the weakening or damage of the pelvic floor support structures (including muscles, fascia, and other tissues). The disease manifests as the displacement of pelvic organs from their normal anatomical position, with downward migration into the vagina or protrusion outside the vagina. Common symptoms include a sensation

of pelvic heaviness, soreness and distension in the lumbosacral region, as well as urination or defecation disorders. These clinical symptoms not only interfere with patients' daily activities but also significantly affect their overall quality of life and emotional state [1] [2]. With the increasing aging population, the economic burden of POP at both societal and individual levels continues to grow. A national multi-center cross-sectional clinical study showed that symptomatic POP accounts for 9.6% of adult women [3]. For moderate to severe POP, surgery is the main treatment modality, and mesh implantation is often required to enhance support; however, this procedure may be associated with complications such as mesh exposure and erosion [4]. In recent years, due to serious complications related to PP mesh, several countries have implemented regulatory restrictions on its use [5], highlighting the urgency of developing safer novel biomaterial scaffolds. Meanwhile, tissue engineering technology has shown broad application prospects in the field of POP treatment, with novel tissue-engineered biological meshes receiving considerable attention. However, in the field of pelvic floor reconstruction, tissue engineering approaches still face multiple challenges, including the selection of ideal biomaterials, identification of suitable seed cells and inducing factors, and rational design of scaffold structures. This article aims to review the research progress of biomaterial scaffolds in the treatment of pelvic organ prolapse, covering scaffold materials from synthetic materials widely used in clinical practice to novel composite materials in the preclinical research stage, in order to provide a reference for the further development of this field.

2. Ideal Biomaterial Scaffolds

Biological scaffolds are one of the key fundamental elements of tissue engineering. They not only provide the necessary three-dimensional spatial structure for cell proliferation and tissue regeneration, but the inherent properties of the material itself also directly affect the biocompatibility post-implantation, mechanical support effectiveness, and subsequent repair and functional reconstruction of damaged tissues.

Ideal scaffold materials should possess the following characteristics [6] [7]: 1) Good biocompatibility: They should provide a favorable environment for the growth, adhesion, proliferation, and differentiation of seed cells. Their interaction with tissue fluids and cells can be evaluated through *in vitro* experiments to ensure they do not cause changes in physical properties, electrolyte imbalances, or abnormal biochemical activities, while minimizing [foreign body reaction (FBR)] [8]. They should also be non-cytotoxic, non-carcinogenic, and non-teratogenic. 2) Biodegradability: The degradation rate of the scaffold must be coordinated with the tissue regeneration process. Degrading too quickly can lead to insufficient mechanical support, affecting repair outcomes; degrading too slowly may hinder tissue regeneration and cause complications. 3) Appropriate mechanical properties: The scaffold needs sufficient and stable mechanical strength to provide effective *in vivo* support. Scaffolds used for POP repair typically need to meet specific

quantitative parameters. The scaffold should possess adequate tensile strength to withstand changes in intra-abdominal and pelvic pressure. Some studies report that electrospun scaffolds can achieve tensile strengths of 3.5 - 15.4 MPa [9], with burst strength maintained at approximately 35N [10], and an elastic modulus similar to native vaginal tissue to avoid stress shielding. Pelvic floor reconstruction surgery aims to restore pelvic floor anatomical structure and mechanical function. The implanted mesh should support fragile tissues, promote cell migration, and assist in reconstructing fascial tissue, while avoiding excessive tension. The material should have appropriate tensile strength to withstand pelvic floor pressure, along with considerations for elasticity, suturability, and tailorability. 4) Rational structural design: The scaffold's porosity, weight, morphology, and composition all influence cell behavior and tissue formation. Scaffolds require suitable porosity to facilitate cell migration and collagen ingrowth, typically requiring > 65% [9]. Its weight depends on material density and pore structure, which should be optimized in design and processing. 5) Synergy with cytokines: The scaffold should be able to combine well with cytokines to help maintain cell phenotype. Additionally, characteristics such as anti-infection, ease of sterilization, stable performance, long shelf life, and metabolizability are beneficial features for ideal scaffolds.

3. Classification and Characteristics of Scaffold Materials

Currently, scaffold materials used for POP repair can be classified into three categories: natural materials, synthetic materials, and composite materials. They exhibit significant differences in biocompatibility, mechanical properties, degradation behavior, host immune response elicited, and stage of clinical translation.

3.1. Natural Materials

Natural material scaffolds originate from biological tissues or their extracts, mainly including natural polymer polymers and decellularized matrices. Natural polymer polymers can be further divided into two subcategories: 1) Protein-based biomaterials: Common examples include collagen, gelatin, silk fibroin, fibronectin, and keratin. 2) Polysaccharide-based biomaterials: Mainly including hyaluronic acid, alginate, chitosan, cellulose, and chondroitin sulfate.

Collagen is the main structural protein in connective tissue. Due to its wide availability, low antigenicity, good biodegradability, and excellent biocompatibility, it is widely used as a tissue engineering scaffold. Some studies suggest that the occurrence of POP is related to damage to collagen structure and composition in tissues [11]. However, collagen itself has issues such as excessively rapid biodegradation, weak mechanical properties, and poor film-forming ability, thus its use alone for pelvic floor reconstruction is relatively limited. Chitosan [12] possesses good biocompatibility, promotes wound healing, and has antibacterial and bacteriostatic properties, helping to reduce the risk of infection and mesh exposure after implantation; however, its toughness is poor, making its mechanical support as a pelvic floor repair material insufficient. Decellularized extracellular matrix

(dECM) scaffolds refer to extracellular matrix scaffolds obtained by removing cells from tissues or organs through decellularization techniques. They retain ultrastructure similar to native tissue, have low immunogenicity, and are rich in various growth factors, capable of transmitting physical, chemical, and biological signals, thereby promoting cell adhesion, proliferation, migration, differentiation, and angiogenesis, which is conducive to tissue regeneration [13]. Based on source, dECM can be classified into xenografts (e.g., porcine, bovine origin) and allografts (human origin). Xenogeneic dECM (e.g., porcine dermis, bovine pericardium) is widely sourced, lower in cost, and relatively common, but residual α-Gal antigens or DNA fragments may activate Toll-like receptor (TLR) pathways, inducing a Th1-type immune response, leading to chronic inflammation or graft contraction [14]-[16]. Zhu Keying *et al.* [17] found that allogeneic dECM has lower immunogenicity, and its ECM components are closer to recipient tissues, but its application is limited by donor scarcity and potential viral transmission risks. Other studies have shown that xenogeneic dECM implantation often induces M1 macrophage polarization, releasing pro-inflammatory factors like TNF-α and IL-6, whereas optimizing the decellularization process can promote M2 macrophage polarization, secreting factors like IL-10 and TGF-β, creating a microenvironment conducive to tissue repair [18] [19]. Furthermore, research by Liu Xiu *et al.* [20] indicates that placenta-derived dECM contains immunomodulatory factors such as HLA-G, which can inhibit NK cell activity, thereby reducing rejection reactions.

3.2. Synthetic Biomaterials

Currently, synthetic materials dominate as scaffold materials for POP repair, mainly divided into non-degradable and degradable categories. Non-degradable materials are represented by PP; degradable materials include Polylactic Acid (PLA), Polyglycolic Acid (PGA), Poly lactic-co-glycolic acid (PLGA), Polycaprolactone (PCL), and Polyurethane (PU).

PP mesh possesses good thermal stability and excellent mechanical properties, with a slow degradation rate, making it suitable for long-term implantation applications. It is currently the most widely used POP repair material in clinical practice. However, its clinical application is associated with significant complication risks. Therriault *et al.* [21] showed that the complication rate after PP mesh implantation exceeds 10%. The core mechanism lies in the host's immune response to the foreign material, mainly characterized by the dominance of M1 pro-inflammatory macrophages, forming a pro-inflammatory signaling microenvironment that affects tissue healing. A long-term implantation study in a sheep model demonstrated that PP mesh undergoes oxidative degradation over time *in vivo*, manifesting as surface microcrack formation and oxidative product deposition. These changes may exacerbate local inflammatory reactions and increase the risk of mesh fracture [22]. Additionally, morphometric analysis of the vaginal mucosa suggests that PP material may have potential destructive effects on the local tissue

microenvironment [23]. Despite issues such as late-stage erosion, exposure, and chronic pain associated with PP mesh, research on improving its prognosis through composite with other substances remains a current focus. Among degradable materials, PLA scaffolds can mimic natural fascial structure, possessing good cell infiltration, pro-angiogenic ability, and the capacity to induce M2 macrophage responses [24], helping maintain cell phenotype, promote metabolic activity, proliferation, and matrix and collagen deposition. However, PLA degrades slowly *in vivo*, and the acidity of its degradation products (lactic acid) and the material's high crystallinity can easily induce inflammatory reactions. PLGA exhibits good biocompatibility, controllable biodegradability, lower inflammatory response, and good film-forming properties. Its metabolites are non-toxic, have low immunogenicity, and it easily composites with other materials, but its mechanical strength is often limited. PCL is a semi-crystalline polyester characterized by good thermal stability, suitable mechanical properties, and a slow degradation rate. Its strength is comparable to native tissue, and it is easy to process and surface modify. Coimbra *et al.* [25] showed that surface-modified electrospun PCL patches possess good biomechanical properties and did not cause significant inflammatory reactions *in vivo*; however, the PCL molecular chain lacks active groups like carboxyl, making the material surface relatively hydrophobic, which limits cell adhesion and proliferation to some extent.

PU serves as a physical carrier for pelvic floor implantation, maintaining its own strength and excellent elasticity, and can withstand certain pressure. PU can be customized according to the required elasticity and degradability. Shafaat *et al.*'s research confirmed that Z3 electrospun PU scaffolds with appropriate strength and elasticity have the potential to promote angiogenesis, showing application prospects for supporting pelvic floor structures [26]. Furthermore, Callewaert *et al.* [27] compared electrospun PU mesh and PP mesh in a sheep model, finding that both integrated well, with PU inducing a milder inflammatory response.

3.3. Novel Composite Materials

The pelvic floor repair environment is dynamic and complex, and single materials often struggle to fully meet its requirements. Consequently, researchers have developed composite material scaffolds by combining natural and synthetic materials, aiming to integrate the advantages of both: retaining the bioactivity of natural components (such as promoting cell proliferation and tissue regeneration) while achieving controllability in mechanical stability, degradation rate, and macroscopic structure from synthetic materials. The mechanism of action is primarily reflected in: the biological signals provided by natural components enhance cell adhesion and proliferation, while the synthetic skeleton ensures sufficient mechanical support during the initial stage of tissue regeneration; simultaneously, the composite strategy allows for fine control of the overall degradation rate by adjusting the component ratio, better matching the formation process of new tis-

sue.

Wolf *et al.* [28] coated porcine dermis-derived extracellular matrix hydrogel onto the surface of polypropylene mesh. *In vivo* implantation in rats showed that compared to uncoated PP mesh, this hydrogel coating significantly alleviated foreign body reaction, oxidative stress, and cell apoptosis, indicating that modifying PP mesh through a composite strategy may enhance its clinical applicability for POP repair. Stangel-Wójcikiewicz *et al.* [29] conducted a comparative study in a sheep model, showing that chitosan material implantation induced a milder inflammatory response and resulted in better vaginal tissue healing compared to PP mesh implantation. However, the application of such composite materials still faces challenges in practice, such as sometimes low compatibility between materials, often requiring the addition of active components like cytokines to optimize function. Additionally, whether the degradation products of the material have adverse effects on surrounding tissues requires careful evaluation.

In recent years, 3D printing technology has brought new breakthroughs in the preparation of tissue engineering scaffolds. This technology allows precise control over the macroscopic structure and microscopic pores of scaffolds, enabling ordered distribution of seed cells in three-dimensional space. A review has systematically summarized the research progress on the application of 3D bioprinting in the pelvic floor field [30]. Paul *et al.* [31] utilized 3D bioprinting technology, using melt electrospun fibers as a supporting framework and printing endometrial mesenchymal stem cells (eMSCs) encapsulated in an aloe-alginate hydrogel. The results showed that compared to 3D printed mesh alone, this cellularized scaffold significantly reduced foreign body reaction and degradation-related adverse responses, recruited more host macrophages, and promoted scaffold-host tissue integration. Wu *et al.* [32] used a composite material of PCL and silk fibroin as bioink to prepare composite mesh via 3D printing that exhibited excellent mechanical properties, good biocompatibility, controllable degradation, and the ability to promote ligament and muscle fiber repair. Chen *et al.* [33] combined solution-extrusion 3D printing with coaxial electrospinning technology to develop a biodegradable pelvic floor prolapse repair pad. This repair pad utilized a PCL mesh as a scaffold, surface-coated with a PLGA nanofiber layer loaded with multiple active ingredients (lidocaine, estradiol, metronidazole, and connective tissue growth factor), structurally mimicking the characteristics of the natural connective tissue extracellular matrix. Recent studies further indicate [34] that combining computational modeling with 3D printing for degradable meshes holds promise for achieving personalized and safer surgical treatment of POP.

4. Comparative Analysis of Different Scaffold Materials

Summarizing the characteristics of the materials mentioned above: Natural materials (such as collagen, dECM) generally possess excellent biocompatibility and pro-regenerative capacity, inducing favorable M2 macrophage polarization. How-

ever, their mechanical strength is often insufficient, and degradation rates are difficult to precisely control. Currently, except for some decellularized matrix products, most are in the preclinical research stage. Synthetic materials, especially non-degradable PP mesh, offer excellent mechanical properties and have long been the most widely used choice in pelvic floor reconstruction surgery. However, the chronic foreign body reaction, fibrosis, and M1 macrophage polarization they induce can lead to severe long-term complications. Degradable synthetic materials (such as PLA, PCL) have tunable mechanical properties, but the acidic environment from their degradation products may exacerbate inflammation. Composite materials, by leveraging complementary advantages, show the best potential, achieving a balance between mechanical support, bioactivity, and immunomodulation. However, their design and preparation processes are complex, and most are currently in preclinical or early clinical trial stages.

5. Conclusion

The treatment of POP is a persistent challenge in clinical gynecology. Although traditional surgical procedures are widely used, they are often associated with mesh-related complications. The development of tissue engineering technology, particularly biomaterial scaffolds, offers new approaches for reconstructing pelvic floor structure and function. An ideal scaffold must balance biocompatibility, controllable degradability, appropriate mechanical properties, and tissue regeneration-promoting capacity. Current research focuses on three main material categories: natural materials offer good bioactivity but often lack sufficient mechanical properties; synthetic materials allow controlled mechanics but face issues like inflammatory degradation products and biological inertness. PP mesh is currently the most widely used synthetic material in clinical practice. However, with increasing awareness of its complications, some countries and regions have implemented regulatory restrictions on its use. Composite materials, by combining the advantages of both and utilizing advanced manufacturing technologies like 3D printing to achieve structural biomimicry, load active factors and cells, demonstrate immense potential for precisely modulating the repair microenvironment. Future directions should focus on: developing smart materials capable of dynamically responding to microenvironmental changes and immunomodulatory scaffolds that regulate host immune responses; utilizing biomanufacturing techniques to achieve personalized customization based on patient imaging data; deepening research on the interaction mechanisms between scaffolds and the host immune microenvironment; and conducting rigorous long-term preclinical and clinical evaluations to facilitate the clinical translation of safe and effective novel pelvic floor repair materials.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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