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2025,Volume 10, Issue 2
Advances in Precision Medicine
Online ISSN: 2424-9106
Print ISSN: 2424-8592

Research and Development and Clinical Application of Drug-controlled Release Esophageal Stents Based on 3D Printing Technology

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Abstract: 3D printing technology is greatly revolutionizing the R&D model of medical devices. Therefore, this paper conducts a comprehensive review of the application progress of 3D printing technology in the field of drug-controlled release esophageal stents, focusing on aspects such as material selection, structural design, drug loading strategies, and clinical application effects. After reviewing the current literature, it is found that 3D printing technology can achieve personalized customization of esophageal stents, manufacturing of complex structures, and precise drug-controlled release, providing a brand-new idea for solving problems such as displacement and restenosis faced by traditional esophageal stents. At present, 3D-printed drug-controlled release esophageal stents have shown good application prospects in the treatment of diseases such as radiation esophagitis and esophageal cancer. However, it is still necessary to further optimize the material properties and conduct long-term safety evaluations.

Keywords: 3D printing; Esophageal stent; Controlled release of drugs; Personalized medical care; Organizational engineering

Online publication: June 28, 2025

1. Introduction

Esophageal cancer, esophageal stenosis, and other esophageal diseases have always been very difficult problems to overcome in clinical practice. The metal stents used in the past often had displacement and tissue hyperplasia. However, the emergence of drug-eluting stents has brought hope to these problems [1]. 3D printing technology has the advantage of high precision and can also be customized according to the specific conditions of patients, opening up a brand-new path for the research and development of new drug-controlled release esophageal stents.

2. The advantages of 3D printing technology in the manufacturing of medical devices

2.1. Personalized customization

One of the significant advantages of 3D printing technology lies in its powerful personalized customization capability. In clinical practice, doctors can rely on patients' medical imaging data, such as CT and MRI, to convert them into three-dimensional models that conform to the individual's anatomical structure. This modeling method, based on real data, can achieve the "tailor-made" manufacturing of esophageal stents, providing patients with the treatment plan that best suits their physiological characteristics [2]. For patients with esophageal lesions in special locations and irregular shapes, the significance of this personalized customization is particularly significant. For instance, in practical clinical applications, some patients' esophageal lesion sites have unique curvatures or varying degrees of stenosis. With the aid of 3D printing technology, stents can be precisely manufactured according to the specific dimensions and shapes of the patient's esophagus. These stents can fit the esophagus more closely, effectively enhancing the therapeutic effect.

2.2. Complex structure manufacturing capability

Traditional manufacturing methods have some limitations when dealing with complex internal structures and fine pores. However, 3D printing technology can easily address these challenges. By meticulously designing the shape and size of pores through 3D printing technology, not only can tissue growth be promoted, but also precise control of drug release can be achieved. Research findings [3–5] show that stents with helical structures have significantly better anti-migration performance than non-helical stents. This is mainly because the helical structure can form a more stable support in the esophagus, greatly reducing the risk of stent displacement caused by factors such as swallowing actions. In addition, the stents with hierarchical pore structures manufactured by 3D printing have large pores that are conducive to tissue penetration and enhance the stability of the stent's binding to esophageal tissues, while small pores can be used to precisely control the drug release path and rate. The manufacturing capacity of this complex structure provides new possibilities for the performance improvement of esophageal stents.

2.3. Precise drug loading

Achieving precise distribution and controlled release of drugs is another important application of 3D printing technology in the manufacturing of esophageal stents. 3D printing, through various technical means such as material blending and micro-nano structure construction, can precisely distribute drugs within scaffolds and precisely regulate the drug release rate [6–8]. Specifically, researchers can control the drug release rate by ingeniously adjusting the porosity and internal structure of the scaffold. For example, drug storage microcavities with specific sizes and distributions are constructed inside the stent, and the high-precision characteristics of 3D printing are utilized to precisely fill the drugs into these microcavities. After the stent is implanted in the human body, the drug can be slowly released at a pre-designed rate through the contact interface between the microcavity and the surrounding tissues, achieving continuous and effective treatment of the lesion site.

2.4. Rapid manufacturing

3D printing technology does not require complex molds in the manufacturing process, significantly shortening the

cycle from design to product formation. In emergency situations, the advantage of this rapid manufacturing is very obvious. Take the severe complications caused by acute esophageal perforation as an example. Traditional manufacturing methods may take several days or even weeks to make molds and produce stents, while 3D printing technology can complete the entire process from model design to stent manufacturing within a few hours. This efficient manufacturing method can win precious treatment time for patients [9].

3. Material selection for 3D printed esophageal stents

3.1. Degradable polymer materials

Polylactic acid (PLA) has excellent biodegradability and biocompatibility. It can be gradually degraded into lactic acid in the body and eventually excreted. Polyurethane (TPU) also has outstanding flexibility and durability. Studies have shown [10] that the PLA/TPU composite support not only maintains good mechanical properties but also exhibits excellent self-expansion characteristics. After this composite stent is implanted into the esophagus, it can adaptively adjust its shape along with the physiological peristalsis and dilation of the esophagus, thereby reducing the stimulation and damage to the esophageal tissue. Moreover, its degradation characteristics also avoid problems such as foreign body reactions that may be caused by long-term retention in the body.

Polyurethane (PU), especially chronosil, is renowned for its outstanding biochemical stability, mechanical properties and wear resistance. Chronosil, through hot melt extrusion (HME) technology, can uniformly disperse drugs such as 5-fluorouracil (5-FU) in the polymer matrix. The selection of this material ensures the mechanical strength and durability of the stent, and allows for the continuous release of drugs in the stent, playing an important role in the treatment of esophageal cancer [11].

3.2. Bioactive materials

Decellularized extracellular matrix (dECM) hydrogels have received extensive attention due to their excellent biological activities and histocompatibility. Among them, the dECM hydrogel derived from the esophagus has a significant promoting effect on the repair of esophageal tissues. It was found through research [12] that the dECM hydrogel with a concentration of 3% has the best rheological properties and degradation characteristics. This hydrogel can create a microenvironment similar to the natural extracellular matrix for esophageal tissue repair, promote cell adhesion, proliferation and differentiation, and accelerate the healing process of esophageal injury sites.

3.3. Composite materials

The application of composite materials can integrate the advantages of different materials. For example, polydopamine (PDA) modification can significantly enhance the hydrophilicity and cell affinity of the materials. The addition of layered double hydroxides (LDHs) can enhance the mechanical properties of the scaffold and achieve ion-controlled release simultaneously. After combining multiple materials, the scaffold can not only meet the requirements of biocompatibility and biological activity, but also has sufficient mechanical strength to support the esophagus. In addition, the ion-controlled-release function can be utilized to further regulate the local microenvironment and enhance the therapeutic effect.

4. Design and optimization of drug controlled-release system

4.1. Structural design

The structural design of the scaffold plays a key role in drug release kinetics. Adjusting porosity and constructing internal channels can effectively regulate the drug release rate. Generally speaking, the higher the porosity of the scaffold, the faster the drug release, but it is not a simple linear relationship [13]. Special structures, such as helical structures, can not only enhance the anti-migration ability of the stent but also serve as drug storage sites. In the helical structure of the stent, a certain amount of drugs can be stored in the helical gaps. Over time, the drugs are gradually released from the gaps to achieve a continuous therapeutic effect [14–16]. In addition, the scaffold design of the hierarchical pore structure has also attracted much attention. The large pore area can achieve rapid initial release of the drug and quickly reach the therapeutic concentration. The small pore area maintains the slow and continuous release of the drug, keeping the drug at an effective concentration for a relatively long time. This design fully considers the phased needs of drug treatment and is of great significance in clinical applications.

4.2. Drug loading strategy

Drug loading strategies directly affect the distribution and release characteristics of drugs in stents. Currently, the main methods include direct mixing, hierarchical loading, and microsphere encapsulation. Light-curing 3D printing technologies such as DLP (Digital Light Processing) can precisely control the position of drugs in stents and achieve fixed-point loading of drugs [17,18]. The PET-RAFT polymerization technology generates a more uniform drug distribution network through a unique polymerization process, enhancing the uniformity of drug loading. The direct mixing strategy is relatively simple to operate. The drug is directly mixed with the stent material to evenly disperse the drug inside the stent. However, this method has certain difficulties in the precise control of drug release. The hierarchical loading strategy loads different types or doses of drugs hierarchically at different parts of the stent based on the time requirements for drug release, achieving phased drug release and better meeting the dynamic needs of clinical treatment. The microsphere encapsulation strategy involves encapsulating the drug in microspheres and then evenly distributing the microspheres within the scaffold. The degradation of the microspheres is utilized to control drug release, making the controlled release of the drug more precise. This not only enhances the therapeutic effect of the drug but also reduces its side effects.

4.3. Research on controlled-release mechanism

Scaffolds based on the RAFT (Reversible addition - Chain Break transfer) mechanism demonstrate unique advantages in drug release. Compared with traditional photolymerization scaffolds, the drug release curve of RAFT scaffolds is more stable and has a lower standard deviation, as it can be more precisely controlled during the polymer synthesis process. The stent structure based on the RAFT mechanism is more stable and the drug release is more uniform, providing a reliable drug release guarantee for clinical treatment. Important progress has also been made in the research of drug loading with dECM hydrogels. dECM hydrogels can form a protective microenvironment and prolong the action time of drugs. The three-dimensional network structure of hydrogels hinders the rapid diffusion of drugs while providing a relatively stable storage environment for drugs, reducing the contact between drugs and the external environment, lowering the risk of drug degradation, and effectively prolonging the effective action time of

drugs [19].

5. Progress in clinical application research

5.1. Treatment of radiation esophagitis

For the treatment of radiation esophagitis, 3D-printed stents loaded with EdECM hydrogel have achieved remarkable results in rat model experiments. This stent effectively alleviated the inflammatory response and promoted tissue repair. This is mainly attributed to its unique design. The exterior of the bracket is equipped with an open groove. This structure not only protects the hydrogel, making it less likely to be eroded by esophageal peristalsis and food, but also ensures that the hydrogel can fully contact the esophageal tissue. Radiation esophagitis is usually caused by radioactive damage to the esophageal tissue and can lead to inflammation, ulcers, and other lesions. The biological activity of EdECM hydrogel is good, and it can effectively promote the repair and regeneration of damaged esophageal tissues. Based on this distance, 3D-printed stents bring hope to patients with radiation esophagitis, with the potential to improve their symptoms and enhance their quality of life.

5.2. For patients with esophageal cancer

For patients with esophageal cancer, 3D-printed flexible polymer stents offer an effective palliative treatment option. Taking the PLA/TPU composite stent as an example, it has excellent self-expanding performance and can effectively alleviate the swallowing difficulties of patients. The advantage of this kind of stent also lies in that it can be customized according to the individual anatomical structure of the patient. Patients with esophageal cancer often experience esophageal stenosis due to tumor growth, which seriously affects the swallowing function. The 3D-printed flexible polymer scaffold, precisely due to its self-expanding property, automatically opens up the narrow part of the esophagus after being implanted, restoring the patency of the esophagus. Of course, personalized customization also enables the stent to be more precisely adapted to the specific conditions, such as the location, size and shape of each patient’s esophageal tumor, significantly improving the treatment effect and making patients feel more comfortable.

6. Conclusion

The emergence of 3D printing technology has completely overturned the research and development process of drug-controlled release esophageal stents. With this technology, researchers can precisely control the microstructure of the stents, meticulously plan the distribution of drugs, and tailor exclusive treatment plans for each patient. At present, in the treatment of difficult diseases such as radiation esophagitis and esophageal cancer, 3D-printed drug-controlled release esophageal stents have emerged and demonstrated clinical application value. With the deep integration of materials science, manufacturing technology and the biomedical field, this innovative technology is expected to unlock more solutions to clinical problems and bring better treatment effects to patients with esophageal diseases. However, to turn this vision into reality, researchers, clinicians, and related enterprises, among other forces, must join hands and work together to overcome the numerous challenges currently faced in technology, materials, and clinical applications, and promote the continuous optimization and improvement of this technology step by step.

Disclosure statement

The author declares no conflict of interest.

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