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Test and Application Prospect of Tracheal Stent *in Vitro* and *in Vivo*

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Abstract: The development and improvement of tracheal stents, as an effective treatment for respiratory diseases such as tracheal stenosis and tracheal collapse, has been a hot topic in the field of medical engineering. *In vitro* testing and animal experiments are key steps in evaluating the performance and safety of tracheal stents. This paper reviews the *in vitro* testing methods, animal experimental models, current research status, and future directions of tracheal stents, aiming to provide research directions for the development and *in vitro* and *in vivo* testing of tracheal stents.

Keywords: Tracheal stent; *In vitro* testing; Animal experimental model

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1. Introduction

Tracheal stenosis and tracheal fistula are serious respiratory diseases that seriously affect the quality of life and survival rate of patients. Tracheal stents, as an effective treatment method, have become a common approach for treating these diseases by providing mechanical support, restoring airway patency, and improving respiratory function. However, the safety, effectiveness, and long-term stability of tracheal stents are key factors determining the success of their clinical application.

In order to ensure that tracheal stents can achieve the expected therapeutic effects in practical applications while minimizing potential side effects on patients, strict *in vitro* testing and animal experiments must be conducted to validate them. *In vitro* testing can evaluate the mechanical properties, biocompatibility, and degradability of stents, while animal experiments can simulate the human environment to assess the clinical efficacy and safety of stents.

In recent years, with the interdisciplinary integration of biomaterials science, biomedical engineering, and computer science, significant progress has been made in the research of tracheal stents. The development of new biocompatible materials, optimization of stent design, improvement of *in vitro* testing methods, and innovation of animal experimental models have all provided new ideas and methods for the research of tracheal stents. The *in vitro* testing methods, animal experimental models, and research status of tracheal stents was reviewed in this article, which aim to provide research directions for the development and *in vivo* and *in vitro* testing of tracheal stents.

2. In vitro testing of tracheal stents

In vitro testing is the preliminary stage of tracheal stent research, aimed at evaluating the performance and safety of the stent before practical application. The following are some commonly used *in vitro* testing methods.

2.1. Mechanical performance testing

The primary performance requirement for tracheal stents is to have sufficient radial support force to open the airway and ensure smooth gas flow. Radial compression testing can determine the radial compressive strength of the stent.

Zeng Jun et al. used the LLY-06D human biological pipeline compressibility tester to test the radial support force of tracheal stents. The radial compression test of the stent is used to determine its radial compressive strength [1]. The stent must be able to exert sufficient radial force to ensure that it stays in the narrow trachea while adapting to tracheal contraction. Secondly, tracheal stents need to undergo tensile strength and fracture strain testing. Currently, there is no specialized instrument or evaluation standard for measuring the displacement resistance of tracheal stents. Yang Xinyue et al. used a multifunctional tensile tester, silicone hose, and thin wire to build a simple pull-out force testing device to measure the displacement resistance of tracheal stents, providing a new method for measuring the tensile strength of tracheal stents [2]. Again, the good anti migration and anti-fatigue properties of tracheal stents under forced vibration are important indicators to ensure long-term treatment effectiveness. Qu Shengqian simulated the effect of tracheal stents under cyclic stress loads of respiratory movement and radial displacement loads of tracheal circulation under random stimulation during service, and observed the fatigue damage of tracheal stents under two working conditions [3].

The research results showed that the better the support performance of tracheal stents under the same deformation, the worse their anti-fatigue performance. The above research provides valuable experience for the mechanical performance testing of tracheal stents, and in the future, standardized and systematic testing instruments and evaluation indicators should be established for the support force testing, tensile strength, and fatigue resistance of tracheal stents.

2.2. Biocompatibility testing

In tissue engineering trachea, the ideal tracheal stent should have good biocompatibility, biodegradability, sufficient mechanical strength, biological flexibility, and three-dimensional porous structure, which is conducive to cell adhesion. The biocompatibility testing of tracheal stent is an important link to ensure its safe use in the human body. The ISO 18562 series of standards provide a detailed evaluation framework and testing methods for the biocompatibility testing of tracheal stents by evaluating their compatibility with biological tissues through contact with cells or tissues, including cytotoxicity testing, tissue compatibility testing, and immune response testing, to ensure that the stent material does not cause excessive immune reactions or tissue damage. Li Yahua designed a biocompatible drug-eluting tracheal stent in a mouse model with laryngeal and tracheal stenosis [4].

The study found that the 70% poly (L-lactide) and 30% poly (caprolactone) constructs had the best biomechanical strength and biocompatibility, and could elute drugs and provide drug delivery systems for various immunomodulators. Scholars have found that materials such as polylactic acid and polycaprolactone have good biocompatibility and degradability. In the future, *in vivo* and *ex vivo* animal experiments should be conducted to evaluate the biocompatibility of different materials, and standardized qualitative and quantitative biocompatibility evaluation indicators should be continuously explored and established.

2.3. Degradation testing

The appropriate degradation time for biodegradable stents has guiding significance for the clinical use of absorbable stents. If the degradation time of the stent is shorter than the tissue repair time, the stent will lose its support and slip due to degradation, which can easily cause further damage to the wound; If the degradation time is too long, the duration of the stent's presence in the body will be prolonged, which may not only cause discomfort to the patient, but also increase the risk of inflammation and infection [1]. Chen Shaosen et al. evaluated the degradation rate and degradation products of degradable tracheal stents, which can help predict the lifespan of the stent *in vivo* and the potential impact of degradation products on the body [5]. By monitoring the degradation process of the stent in a simulated *in vivo* environment, the design and material selection of the stent can be optimized. At present, the degradation methods of degradable stents are divided into non enzymatic hydrolysis and enzymatic degradation. Different degradation rates of degradable tracheal stents can be developed for different degradation methods to cope with airway lesions of different degrees of stenosis, providing reference for the refined development of degradable tracheal stents.

3. Animal experimental model of tracheal stent

Animal experiments are a direct method for evaluating the safety and effectiveness of tracheal stents. Choosing the appropriate animal model is crucial for the success of the experiment. Here are some commonly used animal models.

3.1. Rabbit model

The rabbit trachea is relatively long and suitable for evaluating the long-term stability and biocompatibility of the stent. The rabbit model has advantages in evaluating the long-term effectiveness and tissue response of scaffolds. Compared to rats and pigs, the rabbit model has a moderate cost and is suitable for medium scale experiments. The rabbit model was used for long-term stability testing and tissue response evaluation to assess the ability of the stent to maintain its shape and function *in vivo* for a long time. The long-term effects of stent implantation on surrounding tissues, such as granulation tissue formation and inflammatory response, were observed. Liu Geng tested the degradation and biocompatibility of magnesium alloy tracheal stents in New Zealand white rabbits under the conditions of mechanical performance testing and *in vitro* testing [6]. The stent was implanted using balloon dilation, and the dilation rate was 85.78%, which was close to the rebound rate of the radial compression test *in vitro*, indicating good dilation of the magnesium alloy tracheal stent. And mild inflammatory damage was found in the early stage of implantation, which gradually recovered, indicating that the tissue compatibility of magnesium alloy tracheal stent is good. The above animal experiments provide reference for compatibility testing and fatigue resistance testing of tracheal stents.

3.2. Pig model

The anatomical structure and physiological characteristics of pig trachea are closest to those of humans, making it an ideal model for simulating the complexity of human trachea and evaluating the clinical effectiveness of stents. Compared to rats and rabbits, the cost of pig models is higher, and they provide experimental results that resemble to humans. The pig model is used for clinical efficacy evaluation and complex case simulation of tracheal stents. By implanting and evaluating the function of tracheal stents in the pig model, the application effect of stents in humans is predicted. Junhyoung Ha et al. conducted a 28 days spiral tracheal stent implantation experiment in a 20 kg Yorkshire pig. The study found that the animals had good tolerance to the spiral stent and did not observe coughing and respiratory distress. Weekly and retrograde bronchoscopy and chest X-ray examinations proved that the spiral tracheal stent was safe, providing reference for the development of tracheal stents and animal experiments.

4. Application and research status of tracheal stents

4.1. Clinical application of tracheal stent

Tracheal stents play an important role in the treatment of diseases such as tracheal stenosis and bronchial fistula. With the advancement of biomaterials science and minimally invasive surgical techniques, tracheal stents are gradually developing towards better biocompatibility, degradability, and personalized customization. Modern stent design focuses more on reducing tissue stimulation and promoting endometrial growth, while utilizing 3D printing technology to achieve precise matching of complex airway shapes, improving treatment effectiveness and patient comfort.

4.2. Material innovation of tracheal stent

Nickel titanium memory alloy is widely used in the manufacturing of tracheal stents due to its shape memory effect and super-elasticity. This material can restore its original shape *in vivo* and provide stable support. Domestic tracheal stents are mostly made of nickel titanium memory alloy as raw material, which has advantages such as safety, reliability, and strong biocompatibility. The application of biodegradable materials such as polylactic acid and polycaprolactone in tracheal stents is becoming increasingly widespread. These materials not only have good mechanical properties, but also gradually degrade in the body, reducing the occurrence of long-term complications [7].

The application of natural polymer materials such as chitosan and alginate in tracheal stents has also made progress. These materials have good biocompatibility and biodegradability, but further improvement of their mechanical properties is needed. The application of artificially synthesized materials such as polylactic acid hydroxyacetic acid copolymers in tracheal stents is also constantly developing. These materials have easy to regulate properties and good biocompatibility. The polylactic acid hydroxyacetic acid copolymer stent has good mechanical properties and biocompatibility, and has a good implantation effect on the tracheal wall.

4.3. Design optimization of tracheal stent

Through computer-aided design and 3D printing technology, personalized and optimized stent design can be achieved, which can better adapt to the anatomical structures and needs of different patients, improve treatment effectiveness and patient comfort. The covered tracheal stent uses biocompatible materials such as silicone and polyurethane, with a design focus on reducing irritation, preventing excessive tissue growth, and providing stable support. It also integrates drug release function to promote healing or inhibit inflammatory reactions [8]. Future tracheal stent designs are more inclined towards personalized customized products, which can be optimized for specific conditions and improved and innovated on the basis of traditional tracheal stents.

4.4. Functional evaluation of tracheal stent

Evaluating the correct position and stability of the stent without displacement through imaging examinations (X-rays, CT scans) can help to more accurately understand the actual manifestation of the stent *in vivo*. The functional evaluation of tracheal stents includes improvement of patient symptoms, restoration of airway patency, and enhancement of quality of life. By using the European Cancer Collaboration Scale to evaluate the functional status of patients before and after tracheal and bronchial stent implantation, it can be found that there is a significant improvement in postoperative symptoms. The degree of airway opening after stent implantation is evaluated to determine whether it effectively alleviates airway stenosis and improves the patient's respiratory function. Pulmonary function testing can evaluate the improvement of respiratory function after stent implantation, ensuring the effectiveness and safety of the stent.

5. Development trends and application prospects of tracheal stents

5.1. Development of new materials

The material selection of tracheal stent is the key to its design and application. The ideal tracheal stent material should have good biocompatibility, strong mechanical properties, and biodegradability. Polymer materials such as polycaprolactone, poly (L-lactide caprolactone), polypropylene, polylactic acid, etc. are widely used in tracheal stents. These materials have different mechanical strength, porosity, and biodegradation characteristics. The development of 3D printing technology makes it possible to construct personalized tissue-engineered tracheas. Simultaneously utilizing 3D printing technology to achieve precise matching of complex airway shapes has improved treatment efficacy and patient comfort. The application of biodegradable materials such as polylactic acid and polycaprolactone in tracheal stents not only has good mechanical properties, but also gradually degrades in the body, reducing long-term complications [9]. Bioactive materials include collagen, hyaluronic acid, alginate, etc. Their common feature is that they are highly similar to the composition and microstructure of the extracellular matrix of the body. The advantages of such materials are low immunogenicity, good tissue compatibility, and less likely to cause host immune reactions, making them widely applicable. The materials for future tracheal stents tend to be organic polymer materials such as polylactic acid and polycaprolactone, which can meet the performance requirements of biodegradability and 3D printing technology, and help develop personalized and functional tracheal stent products.

5.2. Personalization and intelligence

Future tracheal stent technology will focus more on intelligence and functionality. In recent years, 3D printing technology has played an important role in the personalized manufacturing of tracheal stents. Through 3D printing technology, the shape and size of the stent can be customized according to the specific situation of the patient, improving the fit and treatment effect, and better adapting to the anatomical structure and needs of different patients. This includes stents that can automatically adjust their shape according to changes in tracheal pressure.

The integration of implantable sensors can monitor airway pressure, inflammatory response, etc. in real time, providing treatment feedback for doctors. The intelligent drug release system can automatically adjust the drug release amount according to changes in the condition, achieving precise treatment [10]. The development of future tracheal stents tends towards intelligent and personalized development. The design and production of tracheal stents can be customized for various types of airway diseases, providing development ideas for tracheal stent research and development enterprises.

5.3. Application prospects of tracheal stent

Tracheal stents play an important role in the treatment of diseases such as tracheal stenosis and bronchial fistula. Tracheal stent implantation is suitable for various malignant and benign diseases, with the most common indications including minimizing external pressure from tumors or lymph node enlargement, maintaining tracheal patency in cases of tracheal obstruction after tumor resection under bronchoscopy, and treating screened patients with benign tracheal diseases. Tracheal stents are also used to seal fistulas between the respiratory and digestive tracts. When surgical correction is contraindicated, stents are used to treat tracheoesophageal fistula or broncho-esophageal fistula. Simultaneous stent implantation in the trachea and esophagus is superior to single stent implantation in either channel. Tracheal stents can prevent tumors from extending into the trachea, aid in the healing and management of tracheal fistulas, and support the tracheal wall to prevent collapse or external compression. It can be seen that tracheal stents have a wide range of clinical applications and can meet the treatment needs of different airway diseases.

6. Summary and prospect

As an effective means of treating respiratory diseases such as tracheal stenosis and collapse, the development and improvement of tracheal stents have always been a hot topic in the field of medical engineering. *In vitro* testing and animal experiments are important steps in evaluating the safety and effectiveness of tracheal stents. By simulating physiological environments and mechanical loads, *in vitro* testing can evaluate the mechanical properties of tracheal stents, such as strength, elasticity, and durability. Biocompatibility testing ensures the compatibility of scaffold materials with human cells and tissues, while degradability testing is particularly important for biodegradable scaffolds. Animal models provide key data for the functional evaluation and safety research of tracheal stents. The selection of different animal models based on their anatomical and physiological similarities with the human trachea can help predict the performance of stents in the human body.

Future research will continue to explore new biocompatible materials to improve the safety and biodegradability of tracheal stents and reduce long-term complications. By combining advanced technologies such as 3D printing, intelligent sensing, and biodegradable materials, tracheal stents will develop towards personalization and intelligence, better adapting to the physiological needs of patients. Through continuous technological innovation and in-depth research, tracheal stents are expected to provide more effective and safer treatment options for more patients in the future, improve their quality of life, and promote the development of the entire medical engineering field.

Disclosure statement

The authors declare no conflict of interest.

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