Study on Degradation of Ureteral Stent Coated with Polycaprolactone Lactide

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Abstract. Ureteral stent has become a necessary consumptive device in the urinary system in the routine clinical practice. However, indwelled stent can cause complications such as hematuria, stone formation, and bladder irritation, et al. In recent years, the use of coating has become an important research direction to modify the surface of the stent and to reduce complications. In this paper, polycaprolactide lactide copolymer was used as coating material, uniformly coated the polymer on ureteral stent surface using solution impregnation method, so as to prepare ureteral stent with a certain coating thickness, and study the degradation behavior of coating in urine.

1. Introduction

With the aging of the population and the development of minimally invasive surgery ureteral stent tube has become a clinical and nursing in the urinary system in the routine necessary consumptive equipment \cite{1}. The treatment of ureteral injury with double J catheter stent is the most common in clinical practice, and it has an exact effect in maintaining urine drainage and protecting renal function. However, the use of double catheter will be accompanied by some complications, such as discomfort after catheterization, stent displacement, Urinary tract infection, bladder obliteration, ureteral reflux and so on, affect the patient's disease treatment effect and quality of life \cite{2}. In this study, biodegradable composite anti-hyperplasia drugs were used to construct a new biodegradable ureteral drug-loading scaffold material, and the degradation characteristics, drug release characteristics and histocompatibility of this material were evaluated, providing basic support for the construction of ureteral scaffolds with reliable degradation time and controllable drug release \cite{3}.

2. Characteristics of Biodegradable Ureteral Stent

2.1. Materials Used Before.

Non-degradable stents, such as stainless steel, cobalt-chromium alloy, nickel-titanium alloy and platinum, will be permanently retained in the body after implantation, increasing the risk of late thrombosis, vascular restenosis and other adverse events \cite{4}. Ideal vascular stents should be degraded, absorbed or excreted by the body after vascular repair to restore vascular elasticity with less side effects on the body \cite{5}.
2.2. Characteristics of Degradable Materials.

Biodegradable stent materials have become a research hotspot. Degradable stent materials mainly include polymer, magnesium alloy, ferroalloy and zinc alloy [6]. The degradation behavior of polymer materials is related to molecular weight, monomer type, collateral group, etc., and the degradation time can be regulated, but there are problems such as insufficient supporting capacity, thicker scaffold wall and poor vascular adherence [7]. At present, the degradable metal support materials are mainly magnesium alloy, ferroalloy and zinc alloy. The biodegradation rate of magnesium alloy is too fast, the degradation is not uniform, the mechanical properties are lost too early, and the degradation process is accompanied by gas generation and local environmental PH value increase [8]. The degradation rate of fe-based alloys is too slow, which increases the risk of adverse events. However, the research on zinc alloys is still in its infancy [9]. In this paper, the studies on the biodegradation of polymer, magnesium alloy, ferroalloy and zinc alloy vascular stent materials and the related factors were reviewed, providing reference for the research and development of biomaterials and related products.

2.3. Biodegradable Ureteral Stent

It has been reported in the literature that other biodegradable materials, such as p-dioxycyclohexanone, fibroin, etc. can also be used as biodegradable scaffold materials. Xuhuijun et al. [9] studied the degradable endovascular stent made of polyp-dioxanone (PDO). The degradation process is hydrolysis, and the scaffold may eventually decompose into CO2 and H2O and be discharged from the body. The PDO in 37 °C, PH = 7.2 of the phosphate buffer solution (PBS) degradation test showed that the degradation process was conducted from the outside in, gradually obvious defects in four weeks before the longitudinal, 8 weeks began to appear on the surface of the obvious lateral spot mark, 12 weeks surface has appeared more obvious longitudinal crack, crack on the surface of the 16 weeks corrosion is serious, transverse and longitudinal cracking in different degree, fault occurs [10]. (Table 1.) During the degradation process, the degradation rate in the first 10 weeks was relatively gentle, and the mass loss was less than 5%. Then the degradation rate increases and the mass loss increases.

| Sample | PLLGA (g) | PCL (g) | Weight ratio | Sample | PLLGA (g) | PTMC (g) | Weight ratio |
|--------|-----------|--------|--------------|--------|-----------|----------|--------------|
| S_{c-0} | 1.003     | 0      | 10:0         | S_{T-0} | 1.003     | 0        | 10:0         |
| S_{c-0.1} | 0.900 | 0.091 | 9:1          | S_{T-0.1} | 0.900 | 0.091 | 9:1          |
| S_{c-0.2} | 0.795 | 0.203 | 8:2          | S_{T-0.2} | 0.795 | 0.203 | 8:2          |
| S_{c-0.3} | 0.695 | 0.298 | 7:3          | S_{T-0.3} | 0.695 | 0.298 | 7:3          |
| S_{c-0.4} | 0.504 | 0.498 | 5:5          | S_{T-0.4} | 0.504 | 0.498 | 5:5          |

3. Advance of Degradable Ureteral Stent

3.1. Vivo Experimentation of Degradable Ureteral Stent

Angan et al. studied the degradation behavior of AZ31 magnesium alloy scaffolds implanted in rabbits [11]. The results showed that the degradation rate of different parts of the magnesium alloy two weeks after implantation was > in bone marrow muscle and > in bone cortex. Constant scour of the body fluid in the bone marrow cavity will accelerate its degradation. The muscle and bone cortex are encased by tissue, which slows down the degradation rate of the material [12]. After 5 weeks of implantation, the rabbit was covered with a layer of degradation products, which had rough surface, loose structure, low strength and irregular crack shape. It was even more pronounced after 20 weeks.
At 30d, 60d, 90d and 120d after stent implantation, the XRD analysis and the vascular histological observation of the stent implantation segment were carried out. It cost 60d for scaffold deformation, part of the scaffold fracture, loss of support. After 90 days, only a small number of support rods remained, and most of the supports were degraded. There was no residual strut in the 120d blood vessel, and the scaffold had been completely degraded [13].

3.2. Development of Degradable Ureteral Stent

It is an inevitable trend to develop safe and effective intravascular biodegradable materials. At present, there are polymer scaffolds, magnesium alloys, ferroalloys and zinc alloys, and there will be new biodegradable materials in the future [14]. Of the above materials in endovascular degradation behavior and influence factors of research and metabolic product of local blood vessels and the effect of human body after the study also is just the beginning, need to further to reveal a lot of in vivo and in vitro data, to develop a new generation of intravascular biodegradable stents, meet the needs of human health and medical development [15].

4. Conclusion

To sum up, using polycaprolactide lactide copolymer as coating material, the polymer was uniformly coated on ureteral stent surface by solution impregnation method, so as to prepare coated ureteral stent with a certain thickness, and the degradation behavior of coating was studied in artificial urine. Polycaprolactone lactide copolymer has good biocompatibility, degradability, mechanical properties and drug-carrying property. As a coating material, it can improve the surface properties of the scaffold and can also be used as a drug carrier to treat urinary system diseases.

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