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Current Frontiers in Ureteral Stent Development

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Abstract

This article describes the early history of stents, their current state, and future directions. We analyzed the PubMed, EMBASE, Web of Science, and Cochrane Library databases up to December 2021 to find recent information about future stent developments. Today, ureteral stents are widely used in urology for the treatment of upper urinary tract obstruction. However, the polymeric materials from which stents are made are prone to bacterial colonization, the development of urinary tract infections and salt encrustation. In addition, stents, after performing their function, require additional interventions to remove them. The new generation of stents will have improved properties, antibacterial activity, and biodegradability in the body.

Keywords: Urinary tract drainage; Ureteral Stent; Upper Urinary Tract Obstruction; Metallic Stents; Magnesium Alloy; Zinc Alloy

Introduction

Background

In the 1850s, Dr. Charles Thomas Stent invented the first device for taking impressions of teeth, and this device was named a stent [1,2]. Thereafter, the term "stenting" was used to describe a surgical procedure or operative intervention, which was eventually used in other systems and anatomical organs, such as the urinary tract, as a supportive device to facilitate the flow of urine [2,3]. In urology, terms such as a tube, catheter, and splint were used until the mid-20th century. Stenting was first introduced to urology in the 1970s when Goodwin suggested using the word "stent" in his manuscript "Splint, stent, stint" [4]. After that, ureteral stents began to be widely used in operations on the urinary tract [2-4].

But, when more widely ureteral stents began to be used in patients, urologists began to note their shortcomings associated with patient discomfort in the form of dysuria, sexual dysfunction, the formation of encrusted stones in the lumen with a violation of its main intended function, infections and the formation of a biofilm, against which even long-term antibiotic therapy becomes ineffective.

The Purpose

To review and analyze the literature data of recent years devoted to the work on the creation of a new generation of stents.

Materials

We analyzed the PubMed, EMBASE, Web of Science, and Cochrane Library databases up to December 2021.

Results

Silicone and polyurethane became materials of choice in the early stages of stent development because they could reduce the encrustation of urinary salts on the surface of a foreign body [1]. More recently, modern double-J stents (JJ) developed by Finney RP and Hepperlen T have become widely used in the urinary tract [5].

In the development of obstructive uropathy, ureteral obstruction is usually caused by an external or internal compression [6,7]. The main goal of treating ureteral obstruction is to ensure urinary patency, optimize kidney function, and relieve symptoms of anxiety due to irrigative symptoms [7,8]. Traditional methods of treating urological diseases include open, endourological operations and minimally invasive techniques, while ureteral stenting becomes the preferred method of treatment at a certain stage of the development of the disease [6,9,10]. A ureteral stent is an implant for draining the upper urinary tract and facilitating ureteral patency for urine in case of obstruction [7,10]. Polymers are the most widely used conventional materials for ureteral stents, especially double-J stents, which are preferred for short-term treatment. However, frequent replacement of the stent is necessary to prevent various complications, including salt encrustations, peri-infections, recurrent stenosis, and even tumor growth [11,12].

The ideal material for the manufacture of ureteral stents should be completely biodegradable *in vivo*. Biodegradable materials, also known as bioresorbable materials, can be gradually degraded in the human body without causing cytotoxicity [13,14]. Several studies have reported the use of biodegradable polymer ureteral stents. For example, Soria, et al. reported a biodegradable ureteral stent based on a polymer consisting of Glycomer 631 (Biosyn) and polyglycolic acid. The ultimate strength of this polymer stent was 57 MPa [12]. Barros, et al. Developed a self-degradable ureteral stent in a biological environment (biodegradable, bioresorbable) based on drug-eluting gelatin for ureteral stenting in the treatment of upper urinary tract carcinoma, and the mechanical properties of this stent were lower than those of commonly used polymeric materials [15]. Unlike biodegradable polymer-based ureteral stents, metal biodegradable stents have received considerable attention from scientists recently because the mechanical properties of metals are inherently better than those of polymers and are more effective in dilating the urinary tract. The use of biodegradable metals in urology is an innovative concept first reported by Lock, et al. [16].

Compared with polymer-based materials for ureteral implants, metal materials have higher inherent antibacterial activity and better mechanical properties of urine conductivity [17]. Since polymeric materials for ureteral stents are susceptible to bacterial infection, modern polymeric stents are designed to be placed in the urinary tract for a short period [18]. Frequent replacement is necessary to prevent various complications, including salt encrustation, peri-infection, and recurrent stenosis [12]. Thus, metal ureteral stents are being developed to reduce replacement frequency, maintain better lumen patency, and prevent complications [12,19]. In recent years, metal ureteral stents have been increasingly used as first-line therapy or when traditional approaches have failed. The analysis showed that several metal ureteral stents, including Memokath™, Resonance™, Uventa™, etc., have passed clinical trials [12]. Unlike polymer stents, metal stents have higher mechanical properties and longer service life. However, infections and bacteriuria due to biofilm formation cannot be avoided over a long period of stent placement [20,21].

Conventional ureteral stents have a constant and inevitable susceptibility to biofilm formation on the surface of the material, which is reported to be the first step in the peri-implant infection process [10,22,23]. According to a study by Beysens M, Tailly TO bacterial biofilm formation was detected in 24% of cases in the first 4 weeks after surgery and in more than 70% after 6 weeks [10]. In addition, studies have also reported diabetes mellitus and chronic renal failure associated with peri-implant infections. Routine antibiotic treatment is not effective in preventing these complications. For example, Akay, et al. Reported long-term antibiotic treatment throughout the entire period of the stent in the urinary tract, with no significant remission of infections observed [20,23]. Stenting duration is the most important risk parameter for the biofilm formation [24].

Junlin Lu, et al. Conducted a meta-analysis of a database of various sources up to December 2018 of studies comparing sexual function before and after endourological procedures with a JJ stent in 485 sexually active men and women and concluded that a ureteral stent after endourological procedures may be a decisive factor causing temporary sexual dysfunction in the postoperative period in both men and women [25].

It should also be noted that after performing their function in the body, ureteral stents are removed using cystoscopy procedures, in some centers under local, and even under general anesthesia [26]. However, the procedure for removing a ureteral stent often causes physical discomfort and creates an additional economic burden for both patients and the healthcare system. In addition, repeated exposure to anesthesia for the human body is undesirable [27-29]. Therefore, research work is actively carried out aimed at studying alternative devices for stenting that can effectively drain urine and at the same time exclude secondary

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operations to remove the stent [27,30]. Thus, biodegradable stents are of increasing research interest due to their natural advantage of a permanently degrading surface that is immune to biofilm formation [31-33].

A study of the degradability and antibacterial activity of pure magnesium, Mg-Y alloys, and AZ31 alloy in artificial urine demonstrated for the first time the potential use of biodegradable magnesium alloys for urological applications [16,30]. To date, there are very few studies on the use of biodegradable metal ureteral stents. In 2017 Zhang, et al. Demonstrated that pure magnesium, Mg-6Zn alloy (w/w), and ZK60 alloy had no significant adverse effects on the ureters of rats and had no significant toxicity to their liver and kidneys [34]. A more recent study by Champagne, et al. showed a slower in vitro corrosion rate of pure zinc and zinc alloys (Zn-0.5mass%Mg, Zn-1mass%Mg, and Zn-0.5mass%Al) than pure magnesium and Mg-Zn-Mn alloy [30]. However, given that the average clinical residence time of ureteral stents is 8 to 12 weeks, depending on the goal pursued, magnesium alloys have shown the closest degradation period to clinical needs [11,35]. It turns out that iron and zinc, two widely studied biodegradable metals, generally have a much longer degradation period than magnesium and its alloys, according to Bowen, et al. and Hernandez-Escobar, et al. [36,37]. Another advantage of magnesium alloys was their antibacterial activity when used as materials for implantation into the ureters [38,39].

Lock JY, et al. Found a significant reduction in bacterial proliferation during the degradation of magnesium alloys in artificial urine [16], and similar phenomena were also reported by Zhang, et al. [40]. Thus, the apparent antibacterial activity makes magnesium alloy a very suitable candidate as a biodegradable material for implantation in the ureters.

Thus, compared to other potential biodegradable metallic materials such as iron and zinc, magnesium has proven to be the best candidate for ureteral stents due to its suitable corrosion rate and antimicrobial activity against a wide range of bacteria and yeasts, which are more common in clinically significant cases of urinary tract infections.

Tie D, et al. Developed a series of Mg-Ag alloys as biodegradable and antibacterial materials [32], as well as biodegradable Mg-Sr alloys for bone fracture fixation [40]. Tian Q, et al. Also investigated the cytotoxicity of Mg-4Zn-1Sr (wt %, ZJ41) against human urothelial cells and their degradation *in vitro* [41].

Tie D, et al. Fabricated a ureteral stent based on the ZJ41 alloy, described its microstructure and electrochemical properties, evaluated *in vitro* cytotoxicity, and studied biodegradability, histocompatibility, and *in vivo* biocompatibility in a large animal model [42]. Thus, the possibility of using the ZJ41 alloy for urological implants and clinical applications was determined. This was the first *in vivo* study in a large animal model to assess the feasibility of fabricating magnesium alloy ureteral stents. To mimic stent implantation in the human body, the scientists chose the wild boar variety *Guangxi Bama Minipig* as an ideal animal model for this *in vivo* study [43]. The researchers chose stainless steel as the control material because other ureteral implant materials, which are polymers, are designed for shorter insertion times. In this study, a unique semi-solid reshaping process was used to fabricate Mg alloy ureteral stents [44]. The reforming process can result in finer non-dendritic microstructures and significant differences in mechanical strength between primary solid phases and secondary phases [45]. As a result, the microstructure and mechanical properties of reformed magnesium alloys are better compared to magnesium alloys solidified in traditional metallurgical processing [46]. This study provided important results for demonstrating ZJ41 magnesium alloy as a potential alternative for the production of biodegradable ureteral stents.

The ZJ41 alloy used for this study is named according to the American Society for Testing and Materials (ASTM) guidelines. Alloy ZJ41 has a nominal composition of 4.00 wt% Zn and 1.00 wt% Sr in an Mg matrix. Pure zinc (99.99 wt%, Zhuye Group, Zhuzhou, China) and Mg-10Sr alloy (wt%) (Norsk Hydro A.S., Oslo, Norway) were mixed with pure Mg (99.999 wt%; Luxfer, Manchester, UK) and melted by the nominal composition at a temperature of 720.0 °C. Using the developed vibrating device, semi-solid slurry was prepared using a rheological pulping system. The melting point was about 685.0 °C and was in the semi-solid temperature range for this alloy. The prepared alloy was transferred to a continuous re-extrusion machine to produce alloy wire with a diameter of 1.0 mm [44]. The stent was then fabricated from the alloy wire using a manual winder.

The researchers compared the effectiveness of the developed biodegradable magnesium alloy ureteral stent with stainless steel in a porcine ureter model for 14 weeks. The scientists concluded that the period of degradation of magnesium alloy stents fully corresponded to the expected residence time of clinical ureteral stents and did not cause either post-interventional inflammation or pathological changes in the urinary system. Compared to a commonly used ureteral stent material such as stainless steel, the alloy showed similar biocompatibility but with significantly higher antibacterial activity. The results confirmed the feasibility of using magnesium alloys to manufacture biodegradable ureteral stents and expanded the knowledge about how the urinary tract responds to increased concentrations of metal ions and pH [44]. Tie D, et al. Based on the results of

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the effect of the Mg-4Zn-1Sr alloy (mass fraction, ZJ41) on urine quality, evaluated the possibility of using a new Mg-4Zn-0.5Sr alloy (wt %, ZJ40) for the manufacture of ureteral stents in porcine models. From this experimental study, it was concluded that due to volume reduction and antibacterial activity, ZJ40 alloy had no significant effect on urine output and urination (93.6±9.7 ml and 10.7±1.2 times) compared to the control group (99.1±8.2 ml and 10.2±1.0 times) after 14 weeks of implantation. Inhibition of peri-implant infection virtually prevented potential damage to the ureteral wall. *In vivo* results demonstrated good biocompatibility as well as antibacterial activity of the ZJ40 alloys [47].

By Tie D, et al. Mg-1.0Sr-0.5Ag alloy (wt.%) was fabricated using semi-solid extrusion method [48]. The processing scheme and mechanism of which were refined in the publications of other authors [44,49]. The alloy was named as JQ alloy according to the ASTM standard, in which J means strontium and Q means silver [50]. Three animals stented with pure magnesium (Mg) implants were taken as the control group and three other animals' stented with JQ implants as the main test group. To comprehensively examine the potential toxicity of stent degradation to the urinary system, tissue sections of the renal tubules, renal pelvis, ureter, and bladder were collected and stained with hematoxylin/eosin for histological evaluation after 12 weeks of implant placement by biomicroscopy. Bladder urodynamics was assessed in both experimental groups in automatic urodynamic analyzer using the method of conscious unobtrusive cystometry. Bacteriuria was studied by agar diffusion methods and expressed in CFU (colony-forming units) per milliliter of urine. The cellular morphology of transitional epithelial cells after implantation was observed using a transmission electron microscope.

The researchers concluded that the biodegradable Mg-Sr-Ag alloy showed significant potential as an antibacterial biodegradable ureteral stent. According to the authors, during recurring, the matrix, as well as $Mg_{17}Sr_2$ and Mg_4Ag particles were completely spheroidized and crushed. Mg (OH) 2, MgO, CaC_2O_4, $SrCl_2$, and AgCl were detected in the decomposition layer by XPS analysis. The tensile strength increased from 105.9 MPa in pure magnesium to 223.7 MPa in JQ alloy. *In vitro* testing confirmed the acceptable cytotoxicity of the alloy, and blood tests for four important biochemical parameters showed its excellent histocompatibility. Cystometry results showed a less negative effect of JQ alloy on bladder function than pure magnesium, due to the higher antibacterial activity caused by the release of silver ions. Due to this antibacterial activity, significantly fewer bacteria were observed in the urine [48]. Additional benefits of the alloy reflected a reduction in other complications such as ureteral stones caused by unnecessary residence time. These discoveries make the antibacterial biodegradable metal materials represented by JQ alloy especially noteworthy candidates for ureteral implants.

Conclusions

An analysis of the literature data showed that to date, the ideal material for the manufacture of ureteral stents has not been determined. Widely used polymeric ureteral stents do not prevent the formation of a bacterial biofilm on their surface, are prone to encrustation with urine salts during a long stay, and also require additional interventions to replace or remove them.

Nowadays ureteral stents are being developed based on alloys of various metals, which have antibacterial activity and biodegradability in the natural environment of the body. Potential candidates that have shown the best results in experimental applications have been various magnesium alloys. However, further randomized, prospective, and multicenter studies using several animal models are needed to select the optimal composition of the alloy and its application in clinical settings.

We think that the biodegradable stents made of magnesium alloys, which will be created in the future, with all the indicated positive properties, will not cancel other catheters that are widely used today. But urologists will have a choice and an opportunity in each case to use the necessary stent to achieve the desired therapeutic effect for a particular patient.

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