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Investigating the Future in Ureteral Stent Biomaterials and Design: A Review

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Abstract

In today's world, urinary tract disorders such as obstructions, whatever the cause (stricture, stones), are prevalent and can be extremely dangerous and painful for individuals. One of the most important instruments in the urological sector for various clinical diseases is the ureteral stent, a minimally invasive surgical tool for relieving blockages and facilitating kidney-to-bladder drainage. This study included a thorough update on recent advancements in stent creation and issues addressed, including biofilm formation and polymers that are presently accessible for use as novel biomaterials in new ureteral stent designs. It also assessed the different biomaterials used as ureteral stents for several problems, such as encrustation, bacterial colonization, urinary tract infections, and associated clinical problems. Discussing the possible uses of biomaterials and their design in the urinary system marked the study's conclusion.

Keywords: Ureteric Stents, Ureteral Stent Encrustation, Biomaterials, Complications, Novel Technology

مراجعة لأستكشاف مستقبل المواد الحيوية و التصميم لدعامات الحالب

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الخلاصة:

في عالم اليوم، تنتشر اضطرابات المسالك البولية مثل الانسداد، أيًا كان السبب (تضيق، حصوات)، ويمكن أن تكون خطيرة للغاية ومؤلمة للأفراد. إحدى أهم الأدوات في قطاع المسالك البولية لمختلف الأمراض السريرية هي دعامة الحالب، وهي أداة جراحية طفيفة التوغل لتخفيف الانسداد وتسهيل تصريف الكلى إلى المثانة. تضمنت هذه الدراسة تحديثًا شاملاً للتطورات الحديثة في إنشاء الدعامات والقضايا التي تمت معالجتها، بما في ذلك تكوين الأغشية الحيوية والبوليمرات التي يمكن الوصول إليها حاليًا لاستخدامها كمواد حيوية جديدة في تصميمات دعامات الحالب الجديدة. كما قامت أيضًا بتقييم المواد الحيوية المختلفة المستخدمة كدعامات للحالب للعديد من المشكلات، مثل القشرة والاستعمار البكتيري والتهابات المسالك البولية والمشاكل السريرية المرتبطة بها. إن مناقشة الاستخدامات الممكنة للمواد الحيوية وتصميمها في الجهاز البولي تمثل نتيجة الدراسة.

1. Introduction

To temporarily or permanently clear the obstructed Upper Urinary System, Ureteral stents are frequently used during Urological surgeries. The basic idea is to minimize hospitalization and the detrimental effects on patients' quality of life while enabling the urine flow to circumvent internal or external obstacles [1]. Stents are offered in a range of sizes and forms to accommodate the comfort and condition of the patient [2]. To minimize clinical symptoms, the stent's length is crucial. An extended stent can result in an extended intravesical section and might cause symptoms of irritation. For a 22-cm stent, patients with a mean height of 161.9 cm make good candidates [3]. High-quality stent features include easy insertion and removal, resistance to encrustation and migration, biocompatibility, high radiopaque-ness, affordability, durability, and optimal flow characteristics. After a lengthy time of stent implantation, salts form on the inner and outer surfaces of the catheter, causing encrustation or obstruction of the lumen. When urine turns alkaline, dissolved salts that are ordinarily dissolved in acidic pee solidify.

This is the result of the microbe's effects, such as Proteus [4]. Urine's pH is raised by these bacteria, which leads to the formation of crystals [5][6].

A Stent's inability to function properly and the most common cause of stent-related infections and blockages is bacterial colonization over the stent surface [7][8]. Encrustation, on the other hand, is another complication that can influence ureteral stent indwelling and increase the risk of urinary tract infection [9]. However, stents have minimal side effects that make them difficult to use and maintain, especially if they are used as a long-term therapy option. Stents can cause irritative voiding symptoms, incontinence, hematuria, pyuria, urinary tract infections, encrustation, ureteral erosion or fistulization, malposition, and migration, among other clinical consequences. Developmental defects, physiological issues, acquired hurdles, and intrinsic or extrinsic physical obstructions are additional obstacles that these foreign devices must overcome [10].

Stent fractures and breakage are examples of late complications. The latter impedes additional stent implantation and complicates the removal procedure. When choosing a material for a stent, the mechanical qualities of the polymers are crucial. More work needs to be done to properly address these problems since they have a significant impact on the therapeutic outcome, the patient's quality of life, and the expenses incurred by healthcare providers [11] [12] [13] [14].

It has been proposed that differences in the biomaterial's surface characteristics, such as hydrophobicity, charge, and roughness, maybe the reason why some biomaterials are less likely than others to promote bacterial encrustation and adherence. Microscopic defects on the biomaterial surface facilitate bacterial adherence and encrustation because they act as nucleation sites for crystal formation and subsequent bacterial colonization [15].

2. Materials for Ureteral Stents

a) Metals and Polymers materials for Ureteral Stent

Biocompatible materials come in two primary categories [16] [17] that are typically used in Ureteral stents: Metals and Polymers. Due to their familiarity and simplicity of use, silicone or plastic Ureteral stents are the most widely utilized Ureteral stents. despite their benefits, conventional ureteral stents have shown very high rates of failure when used to treat chronic ureteral obstruction, particularly when retroperitoneal metastases or advanced pelvic cancer are present [18] [19]. Nevertheless, the stent's direct contact with urine and frequent use in clinics can lead to infection and encrustation, which can result in significant morbidity.

One form of the stent includes "pigtail" spirals to keep it in place [20] and the NiTi stent, which unavoidably stays in the body, has reduced infection and encrustation through simpler endothelialization. Meanwhile, urinary tract infections and catheter encrustation continue to occur following long-term stent insertion, regardless of the type of stent—Double-J or NiTi—and require immediate attention. [21] [22]. The first-generation polymer utilized in stents is silicone, which is considered the gold standard; nonetheless, the high frictional coefficient renders these stents unsuitable. Polyethylene eventually took the place of silicone, but its instability in the urine environment can cause early fractures. Polyurethane is a third-generation polymer that is still unquestionably exceptional [23].

Tecoflex, an aliphatic polymer, has a high radiopacity and is mixed with barium sulfate. Because Tecoflex, a thermoset polyurethane, softens as the body warms it after stenting, it is utilized in stents. This makes it possible for it to be stiff during implantation but more flexible following insertion for improved patient comfort [24].

Alphatic Polyurethane based on polytetramethylene glycol is called hydrothane. The hydrophilicity of the polymers is increased by the inclusion of the glycol subunits. Hydrothane can be processed without aromatic groups when utilized for stents. Because there are fewer aromatic groups present, there are fewer dispersion forces (Van der Waals forces) between the polymer and the proteins in urine, which promotes biological inertness [25] [26].
Furthermore, Chronoflex was created to be a more resilient PU, and research has revealed that it cracks less easily under environmental stress than other Polyurethane [27]. Because of its increased hydrophobicity, this polymer may create a stable conditioning layer that inhibits encrustation [28] and this polymer is an additional thermosetting polymer that is a patented olefinic block copolymer. Compared to Polyurethane, Percuflex has superior physical qualities and softens the body. Encrustation is comparable to regular Polyurethane, though. These stents are not employed in strictures caused by extrinsic blockage because of the softening effect as they are easily squeezed. [29]. It yields squalene, a polyurethane mixture with polyethylene oxide. It swells when submerged in water, growing in size while not losing strength. To facilitate implanting and improve patient comfort, squalene is tougher in dry environments and quickly softens when hydrated [30].
Polyurethane is the main constituent in Sof-flex, a patented polymer. It is widely utilized in ureteral stents. Because water is held to its surface by its hydrophilic qualities, it has an extremely low coefficient of friction. Research has revealed that there is less biofilm growth but more calcium carbonate encrustation [31]. To replace Silicone, a unique polyester copolymer called Silitek was developed. To withstand compression, it is robust and has a high radial stiffness. Its encrustation profile is identical to silicone, according to studies. Its coil retention strength is comparatively weak, which could increase the likelihood of migration [32]. The polymer known as C-flex is composed of block copolymers of styrene, ethylene-butylene, and styrene. It has been employed in stents for clinical purposes and possesses thermoplastic qualities. Although it is not as strong as other stent types, it is sufficient for most stenting procedures [33].

Table (1): The Metals and polymer materials for Ureteral Stents with a few key aspects of each.

No.	Materials	Advantages	Disadvantages
1	Silicone	Smooth, flexible, less irritation, Better performance against encrustation compared to polyurethane.	Easy to slip the ureter out High friction coefficient, impossible for implantation [34].
2	Polyethylene	High flexibility, low water absorption, and good chemical stability. Polyurethane has better drainage efficiency	Easily becomes brittle, prone to breaking. Unstable in the urinary environment, early fracture [35].

		compared to silicone.	
3	Polyurethane	Hard and soft, with good elasticity.	Cause ulcers, the mucosa is easily damaged, encrustation formation, bacteria and protein adhesion, and less indwelling time [36].
4	Titanium	More than 80% of individuals get improvement in benign prostatic hyperplasia.	High cost [37].
5	Nitinol	A titanium and nickel blend that improves stent insertion and removal by softening below 10 °C and hardening as the temperature rises, temperature memory, ureter adaptability, and simplicity in implantation and extraction.	High cost and difficult preparation[38].
6	Stainless steel	Resistant to erosion, long-lasting use, is acknowledged as an operational tool for tumor-associated hydronephrosis and does not have any significant insertion adverse effects.	High cost [39].
7	Tecoflex	Softens significantly in a matter of minutes, making insertion easier.	Severe calcium oxalate monohydrate, protein, and uric acid encrustation [40].
8	Hydrophane	Demonstrates a quick rate of water absorption, good mechanical property retention when hydrated, and elastomeric characteristics even in the absence of moisture.	The complement system may become activated if the hydrophilic moieties are reoriented, making them an unsuitable substrate for cell attachment [41] [42].
9	ChronoFlex	Promotes the cell cycle, growth, and adhesion of fibroblasts.	Maintains hydrophobic proteins, which promotes the development of a steady conditioning layer [43] [44].
10	Percuflex	This material's stents have improved physical qualities, are smooth and soft, and offer long-term internal support.	Not recommended in the event of a malignant extrinsic blockage since a tiny force could cause the expensive stents to compress [45].
11	Sof-Flex	Offers a surface with minimal friction.	Extremely prone to calcium carbonate and oxalate encrustation [46].
12	Aquavene	Increased ability to withstand encrustation and intraluminal obstruction.	No clinical data have been released [47].
13	C-Flex	Extremely resilient to compressive stress from the outside a thermoplast polymer belonging to the silicone family. In comparison to Percuflex and polyurethane, its surface friction was reduced.	Effective alone in an environment devoid of proteins [48].
14	Silitek	Increased resilience against external compression.	Increased adherence of bacteria [49].

b) Biodegradable Polymers for Ureteral Stent

The biodegradable polymers are most interesting due to their resistance to encrustation and the elimination of a stent removal procedure [50]. For Ureteric stents, biodegradable materials such as polylactic acid (PLA), polyglycolide (PGA), polycaprolactone (PCL), and their copolymers are frequently utilized. Depending on the size of the devices and the surrounding environment, PLA degrades extremely slowly and takes over 24 months to completely break down and be absorbed. Because ureteral healing takes only 6–8 weeks, it is not good for Ureteric stents. Ureteral blockage and scratching will result from incomplete degradation and fragmentation after the stent's role is achieved. It was shown that the pace at which individual polymers degrade can be increased by approximately 8–10 times through the copolymerization of glycolide (GA) into lactide (LA). It can mediate and regulate the rate and duration of degradation by varying the proportions of the monomers [51].

Table (2): Examples of the Biodegradable Polymers for the Ureteral Stents that have been studied within this scope

No.	Materials	Advantages	Disadvantages
1	Polycaprolactone (PCL)	High strength and good biocompatibility.	Obstacles in mechanical qualities and deterioration rate control[52].

2	Polyglycolide (PGA)	Good water absorption.	PGA degrades quickly into fragments of uneven size, mechanically insufficient, and brittle [53].
3	Polylactide (PLA)	Good mechanical properties and highly tensile.	PLA degrades slowly during implantation [54].

3.Design of Ureteral Stents

The design of Ureteral stents has undergone many scientific approaches and a series of extensive modifications. The development of novel stent designs has recently focused on stent architectures that could reduce tissue irritation and urinary reflux. Recent developments in stent design are highlighted in the section that follows. An overview of them is also given in Table (3) [55] [56].

a) Spiral Ureteral Stents

This design had a metal wire within the stent to maintain it into a spiral shape and was believed to improve urine drainage in case of extrinsic blockage by providing a stable and durable opening of the ureteric lumen. In 2000, Stoller et al. employed the spiral design to evaluate urine flow in an in vitro model. Results from this study demonstrated increased flow in the model using a spiral stent as opposed to the traditional design [57] [58].

b) Horn-shaped Ureteral Stents

The horn-shaped stent was designed with L-polylactic acid and is mainly used for obstructions of the ureteropelvic junction. The unique structure of the stent makes it difficult to slide out of the ureter tract, and patients have an uncomfortable feeling after the operation, which indicates that the stent has good biocompatibility and tolerance. Figure 1 is a horn-shaped stent, which is shaped like a long trumpet and has good anchoring performance in the ureter [59] [60].

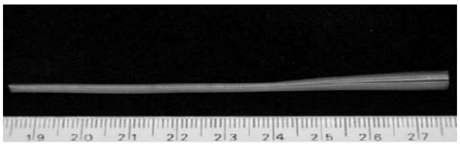

Figure (1): Horn-shaped stent

c) Dual-durometer Ureteral Stents

Dual-durometer stents have a similar architecture to that of tail stents. The main difference is in the mechanical properties of the stent body, which transitions from harder at the proximal end (kidney) to softer at the distal end (bladder). This design was introduced to decrease irritation due to its soft composite tail, therefore increasing the tolerability of the stent [61].

d) **Grooved Ureteral Stents**

Grooved stents, having external grooves along the stent lumen, were introduced by Finney in 1981.

This design was developed specifically as a post-lithotripsy treatment option, to improve the stone clearance by introducing multiple pathways for urine drainage [62] [63].

e) Magnetic Ureteral Stents

The magnetic stent is a new type of stent tube described by Taylor and McDougall, with stainless steel columns that can be attached to the distal end of the stent with a magnet catheter, and the stent is removed without the guidance of cystoscopy or ureteroscopy.

During the implantation and removal process, the stent is magnetically suctioned.

The stent tube is placed according to the urinary tract direction, which reduces the use of extra equipment and improves the safety and accuracy of the stent placement.

In the future, the effects of this kind of stent need to be evaluated by a large number of clinical experiments. Figure 2 shows a magnetic ureteral stent [64].

f) Expandable Ureteral Stents

Is a self-expanding metal-based ureteral stent, composed of nickel and titanium. The stent is thermo-expandable, deploying in warm saline and shrinking in cool saline, which allows the stent to be implanted and extracted easily [65].

Figure (2): Magnetic Ureteral stent

g) Double J Ureteral Stents

Double-J' refers to the most common type of stent design that was initially introduced by Finney in 1978. The term 'Double-J' refers to the 'J' shape of each end of the stent, which is designed to anchor the stent and prevent its displacement. Since then, different biomedical companies have fabricated stents that have different architectures with the main aim of decreasing the impact of encrustation and infection, as well as improving urine drainage and lessening the impact on patients' quality of life [61] [66] [67].

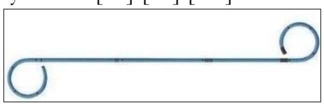

Figure (3): Double J Ureteral Stent

Table (3): Advantages and disadvantages of the different designs of Ureteral stents.

No.	Stent design	Advantages	Disadvantages
1	Spiral stents	Has good mechanical properties, lumen, fewer lower ureter symptoms Providing a stable and durable lumen.	Loses efficacy easily
2	Horn-shaped stents	Good anchoring properties and less bladder irritation.	Short indwelling time in the patients' ureters

3	Dual-durometer stents	Provides less bladder irritation compared to conventional stents and better stability in the kidney.	Complicated manufacturing process
4	Grooved stents	Providing multiple pathways for urine drainage.	Complicated manufacturing process
5	Magnetic stents	Provides an improvement toward stent removal and avoiding the use of cystoscopy.	Hard to manufacture
6	Expandable stents	Providing a wider pathway for urine compared to conventional stents, ease of implantation and valve, and mechanism to prevent reflux.	Prone to transformation in its radial direction.
7	Double J stents	Decreases the migration both in the proximal and distal ends.	Bladder irritation.

4. Discussion

The materials of the Ureteral stent have a tremendous impact on the performance and mechanical properties of ureteral stents. The material of the stent has been experienced by artificial non-degradable polymers, metals, and degradable materials. Artificial polymers were first used in the manufacture of urinary stents, mainly polyethylene, silicone rubber, and polyurethane.

Stents made of these materials need to be replaced regularly, and sometimes a stent implanted in the patient that prolonged positioning in the ureter may cause re-obstruction, infection, or even severe complications. One study found that the accumulation of Urinary salts caused by Silicon was severe and that stent tubes made of the material were too smooth and soft, so they were slowly abandoned. Metal stents have also been widely used in recent years. Nickel-titanium alloys and Stainless Steel are commonly used metals. Metal stents have good mechanical properties and are often used in cases of malignant obstruction and invalidation in conventional treatment.

However, in recent years, the Metal stents easily migrate in the ureter, and the long-term effect is not ideal, so their use has gradually decreased. The use of degradable materials for manufacturing stents is of great significance because it eliminates the trouble of forgetting the stents in the Ureter and avoiding a secondary removal of them.

The design of the Ureteral stent, starting from the first generation of double pigtail stents, has been slowly evolving into other types of stents in clinical applications, including coated stents, drug-eluting stents, magnetic stents, self-expanding stents, spiral stents, and dual durometer stents. The design principle of the stent is to reduce displacement and decrease bladder irritation.

The length and diameter of the and so on, have also plagued patients and designers in recent years. At present, research on ureteral stents mainly focuses on the optimization of material and the stent configuration design. Ureteral stents will likely respond to more indications and resist various complications in the future. The Magnetic stent allows for more efficient implantation and the removal of the stent without a cystoscope. Self-expanding stents have a high ratio of inside to outside diameter, and they have a high intraluminal flow. The Spiral stent is not prone to be displaced in the body and has good anchoring properties. It is reported that this stent can reduce the occurrence of upper urinary tract symptoms. The dual-durometer stent is placed in the kidney as a hard material, while the material placed in the bladder is softer to reduce irritation to the bladder triangle and reduce patient discomfort.

Future Ureteral stents should be designed with better anchoring properties and low potential migration in mind. The shape of Ureteral stents should be by the anatomical structure of the Kidney-Ureter-bladder, which avoids bladder irritation. The material used to make Ureteral stents should have a suitable hardness, one which provides good mechanical and tensile strength. Stents with different degradation cycles will also appear on the market to accommodate different demands. The use of eluting stents and coated stents reduces stent-related complications such as infection, encrustation formation, biofilm formation, and stone re-formation. The combination of eluting drugs and degradable properties, coupled with good anchoring features, are the future trends of ureteral stents, and they will bring more convenience and comfort to patients.

5.Conclusion

The illustrated studies discover the Various advancements in the design and composition of biomaterial for Ureteral stents are reviewed in this paper and summarized in the Tables. Each of these advancements attempts to target particular reasons why stents fail, namely encrustation, fracture, and biofilm growth.

The creation of the ideal stent would be possible by combining the best materials and designs.

Additionally, the dynamics of urine flow are important in controlling encrustation and biofilm growth in stents, and they were also taken into in the creation of the materials that were utilized to design the stent.

Although there isn't a perfect stent that never has problems or fails, research has shown that polymer biomaterials can resist bacteria and have strong mechanical qualities that allow them to stay in the patient's body for the right amount of time. This review also summarized the technological obstacles that must be solved to create a better stent.

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