Review Article

Innovation and new technology in ureteral stents

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Abstract
Ureteral stent insertion is a procedure performed extensively by all urologists. Nevertheless, stent-related symptoms and stent encrustation are still common complications pushing the innovation and development of novel ureteral stents. Developments are focussing on three significant aspects: material, design, and removal technique. Various materials including silicone, polymers, and metals are frequently utilized, with or without an additional coating. The use of biodegradable materials is looking promising but these is a lack of proven clinical trials in association with this in humans. The new designs focus on the reduction of stent-related symptoms through the modification of the bladder end. The new stent removal techniques with extraction strings or novel magnetic end may exclude subsequent cystoscopic procedures. Finally, utilization of a ureteral stent tracker application helps in reminding both physicians and patients to remove the stent at the appropriate time.

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Introduction

Ureteral stent insertion is one of the most commonly performed endourological procedures. Its indication includes ureteral obstruction, the promotion of healing of ureteral anastomosis, and placement following stone management.[1] Even though its benefits are well-established, there are some drawbacks associated with its use. Stent-related symptoms, stent encrustation, and urinary tract infection significantly impact on patient quality of life, leading to the need to explore the development of a new ideal ureteral stent with optimal effectiveness but minimal side effects.

History of the Ureteral Stent

The endoscopic technique of ureter cannulation was initiated by Brown J in 1893. Using the Brenner-Leiter cystoscope with a working channel, he cannulated both ureters to enable the separate drainage and collection of urine.[2] For the earliest experiments with ureteral stent development, polythene tubes were used in an animal study but the results were not promising. The successful breakthrough came in 1952 when Tulloch S inserted a polythene tube into the right ureter and a T-tube into the left ureter of a patient with bilateral ureteral injury after a hysterectomy.[3] In 1967, Zimskind PD was the

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first to report a cystoscopic insertion of a silicone ureteral stent in 13 patients. In 1976, Gibbons et al. redesigned the ureteral stent by adding wings and flanges to prevent stent migration. They also added a radiopaque tip to enable the checking of the position of the stent under fluoroscopy (Figure 1).[5] Finally, in 1978, Finney et al. published their work describing the original double J stent design (Figure 2). Construction of both ends into a J-shape coil prevents stent migra-tion without compromising the overall shape and diameter.[6] However, this original stent design was not suitable for some specific situations for example extrinsic malignant ureteral obstruction. However, in 1992, Wallstent, a self-expandable metallic stent, was developed to overcome this issue.[7] The double J design has been a milestone in the development of the modern ureteral stent but even so innovation and technology are constantly being incorporated to improve the stent function, along with utilization of various synthetic polymers and metallic materials.

Ideal Stent

According to Finney RP,[6] the ideal ureteral stent should have the following properties:

1. A primary composition of silicone due to its softness, flexibility, and resistance to encrustation properties
2. Radio-opaque
3. Uniformed diameter without barb or flanges
4. Easy insertion from either antegrade or retrograde approach
5. Prevention of migration
6. Reusable ability by autoclaving

Although some of these ideal properties are invalid nowadays, they still may be summarized into three aspects: stent materials, stent design, and stent removal, on which this review aims to focus.

Stent-related Symptoms

Unrelated to any medical indications, the use of the ureteral stent inevitably leads to stent-related symptoms (SRS). Researchers have raised several hypotheses to explain the etiology of SRS. They include: 1) irritation of the bladder mucosa by the stent's distal end; 2) stent migration during daily activities; and 3) urine reflux into the kidney resulting in increased intrarenal pressure.[8] To evaluate SRS objectively, Joshi et al. have proposed the Ureteral Stent Symptom Questionnaire (USSQ) which consists of six aspects: urinary symptoms, body pain, general health, work performance, sexual matters, and additional problems.[9] A later study on SRS revealed that stent placement affected patient daily life in 80% of cases, increased analgesic usage in 70% due to pain in the flank, suprapubic, or penis, and caused sexual dysfunction in 32% of patients.[10] Another study from the same group reported that 80% of patients with a ureteral stent had at least one lower urinary tract symptom according to the International Prostate Symptom Score (IPSS).[11]

To minimize SRS, innovation of ideal stent and medical treatment by either alpha-1 blockers or antimuscarinic agents have been explored.[12] The American Urological Association and Endourological Society Guidelines 2016 recommended alpha-1 blockers and antimuscarinic agents for reducing SRS.[13] According to a randomized controlled study, a daily dosage of 0.4 mg tamsulosin significantly reduced IPSS irritative and obstructive symptom scores.[14] A meta-analysis by Chen et al. reported that tamsulosin significantly decreased Urinary Symptoms (p = 0.0001) and Body Pain (p = 0.0002) USSQ

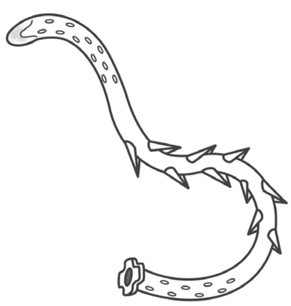

Figure 1. Gibbons ureteral stent by Gibbons RP (Illustration by Pea Poppan, MD)

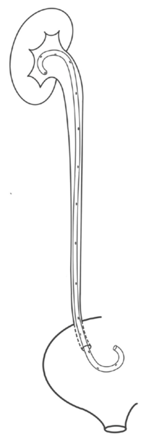

Figure 2. The original double J stent by Finney RP (Illustration by Pea Poppan, MD)

subscores.[15] Another meta-analysis by Wang et al. demonstrated that solifenacin significantly reduced the total USSQ score in comparison to controls (p = 0.005).[16] Moreover, a combination of alpha-1 blocker and antimuscarinic agent could improve an outcome.[17] Recently, more studies have shown that mirabegron and pregabalin may be effective in treating SRS.[18,19]

As a foreign body, the ureteral stent interacts with local tissue and induces inflammation. Bacteria may colonize on the ureteral stent and produce a biofilm, which precipitates stent encrustation.[20,21] Kawahara et al. demonstrated that the degree of encrustation was associated with indwelling time. Indwelling of a stent for less than 6 weeks, 6 to 12 weeks, and more than 12 weeks had encrustation rates of 26.8%, 56.9%, and 75.9%, respectively.[22] Stent encrustation may be associated with difficulty of stent removal. Sometimes, a more advanced endourological technique is necessary, which results in patient morbidities such as pain, ureteral injury, or even urosepsis.

1. Stent Material

The original double J stent designed by Finney RP was made from silicone, which is flexible and has a low order of tissue response. However, silicone has a high frictional coefficient, thus creating difficulty in stent insertion.[6] Later, several materials were explored, including polyethylene, polyurethane, metal, and co-polymers.[23] The development of effective stent materials is still an ongoing process. By integrating different polymers into one stent, better properties are created, and now there are a large variety of polymeric stents available on the market (Table 1).

Additional coatings play an important role in improving the properties of ureteral stents. Hydrogel, a hydrophilic polymer, becomes more slippery when in contact with water. Coating a ureteral stent with hydrogel helps pass a stent through the narrow path of the urinary tract. Coating a stent with ketorolac may reduce pain after stent insertion[24] and coating with antibiotic or metal compounds may reduce bacterial colonization (Table 2).[25,26]

Table 1. Advantages and disadvantages of different polymeric ureteral stent materials

Stent material	Advantages	Disadvantages
Silicone	• Biocompatibility • Encrustation resistance	• High frictional coefficient
Polyurethane	• Good urinary drainage	• High tissue reaction
Ethylene-Vinyl acetate (PercuflexTM, Boston Scientific, Marlborough, MA, United States)	• Coil retention to prevent stent migration • Large internal diameter • Softer at body temperature	• Easy compression
Ethylene/Butylene-Styrene copolymer with added polysiloxane (C-Flex®, Cook Medical, Bloomington, IN, United States)	• Low frictional coefficient • Resistance to biofilm formation and encrustation	
Polyester (Silitek®, Surgitek, Medical Engineering Corporation, Racine, WI, United States)	• Softer bladder end of the stent	• High bacteria adhesion

Table 2. Ureteral stent coatings and their properties

Coating	Properties
Hydrogel	Hydrophilic properties facilitating stent insertion and preventing biofilm formation
Ketorolac	Reduction of pain after stent insertion[24]
Heparin	Prevention of biofilm formation and stent encrustation[27]
Diamond-like carbon	Prevention of biofilm formation and stent encrustation[28]
Silver	Reduction of bacterial colonization[29]
Triclosan	Reduction of bacterial colonization[25]

Figure 3. Resonance® metallic stent (Cook Medical, Bloomington, IN, United States)

Metal is another material used for the construction of a ureteral stent. Compared to other materials, metallic ureteral stents are more rigid and durable, thus more preferable in the setting of malignant ureteral obstruction.[7] Chow et al. compared the Resonance® metallic stent (Cook Medical, Bloomington, IN, United States) (Figure 3) to polymeric stents in 42 patients with malignant ureteral obstruction. They found there was a longer functional duration at 4 months in the Resonance® stent.[30] Another study compared the UVENTA metallic stent (Instrumed Surgical, Mississauga, ON, Canada) with the polymeric stent. The metallic stent demonstrated a better patency and a lower technical failure (Table 3)[31].

Table 3. Advantages and disadvantages of various metallic ureteral stents

Metallic stent	Material	Advantages and disadvantages
Resonance® (Cook Medical, Bloomington, IN, United States)	Cobalt-chromium-nickel-molybdenum alloy (MP35N)	• Resistance to external compression[32] • Longer functional duration in cases of malignant ureteral obstruction[33] • Urine flow either through or around the stent • Lower cost compared to changing polymeric stent every 3 months[34]
UVENTA (Instrumed Surgical, Mississauga, ON, Canada)	Expanded polytetrafluoroethylene (PTFE) between two Niti-D stents (nitinol wire)	• Prevention of stent migration by Niti-D wire • Prevention of urothelial tissue ingrowth by PTFE layer • Fewer side effects due to the segmental stent design • Ability to be left in place for up to two years[31] • Ureteroenteric fistula and ureteroarterial fistula have been reported[35]
Allium URS (Allium Medical, Israel)	Super-Elastic nickel-titanium alloy (Nitinol) covered with co-polymer	• Larger diameter • Prevention of tissue ingrowth and encrustation by the co-polymer layer[36] • Facilitation of stent removal by the intra-vesical anchor
EGIS Urexel (S&G Biotech, Gyeonggi-do, Korea)	Silicone covered metallic stent	• Prevention of urothelial tissue ingrowth by the silicone layer[37]
MemokathTM 051 (Pnn Medical, Kvistgaard, Denmark)	Thermo-expandable nickle-titanium alloy spiral stent	• Themo-expandable capability • Higher stent migration rate compared to UVENTA[38]

Biodegradable ureteral stent (BUS)

The biodegradable ureteral stent (BUS) is a promising development in exploring an ideal stent since it does not necessitate another appointment for stent removal. Thus, BUS theoretically reduced the treatment time burden for all patients, saves medical expense, and avoids the painful experience of stent removal. Initial research demonstrated that gelatin, alginate, and gellan gum BUSs degraded at between 14 and 60 days in artificial urine.[39] In 2014, Zhang et al. invented a BUS made from polyglycolic acid and polyglycolic acid/ polylactic acid coated with barium sulfate. They compared this BUS to polyurethane stents in 24 beagles and found no difference in inflammatory reaction. The BUS lost its mass by 44.8% at one week, 70.8% at two weeks, 99.1% at three weeks, and 100% at four weeks.[40] Chew et al. developed multiple generations of BUS from uriprene, which dissolved completely within 4 to 10 weeks.[41,42] Publications regarding BUS investigations in humans are still unavailable; however, one multi-center clinical trial began in December 2020.[43] It is envisioned that BUSs will be available in the foreseeable future for all patients, with clarified properties of stable degradable time and minimal tissue reaction.

In addition, a BUS integrated with supercritical CO_2 impregnation has been tested. This technology allows us to impregnate the material used to construct the BUS with chemotherapeutic agents such as paclitaxel, epirubicin, doxorubicin, and gemcitabine. Initial experiments in artificial urine showed a 50% release of the chemotherapeutic agent in the first 4 hours, a rate which stabilized until completion at 72 hours. The release level of the chemotherapeutic agent could inhibit the cell growth of T24 cells, a representative cancer cell line.[44] Implementation of 3D printing for constructing BUS is also under investigation. This method permits us to customize the most suitable stent for each individual in terms of anatomy.[45,46]

2. Stent Design

Design of the ureteral stent plays an important role in SRSs. The bladder end of the stent may irritate the bladder mucosa causing irritative symptoms and local tissue reaction.[8] In addition the larger diameter of the stent may intensify SRSs.[47] Lee et al. compared three ureteral stents with different firmness levels; Endo-Sof® Radiance® (rigid polyurethane with hydrophilic coating, Cook Medical, Bloomington, IN, United States), PolarisTM Loop (thermal polyurethane with hydrophilic coating; Boston Scientific, Marlborough, MA, United States), and PolarisTM Ultra (firm Percuflex plus in the renal pelvis, soft Percuflex in the bladder, Boston Scientific, Marlborough, MA, United States). International Prostate Symptom Score and Visual Analogue Pain Scale (VAS) were statistically significant lower in the PolarisTM Ultra group in comparison to the other two groups (p = 0.016 and < 0.001, respectively).[48]

Apart from the conventional J-shape of the bladder end, several new designs have been implemented. The loop-tailed ureteral stent (PolarisTM Loop) replaces the J-end with a smaller loop-tail made from a softer material (Figure 4). Lingeman et al. compared this loop-tail stent to other stents with the original double-J design. They found no difference in the total USSQ scores four days after insertion. Side effects were lower in the loop-tailed stent group but did not reach statistical significance.[49] Yoshida et al. modified the insertion technique of the loop-tailed stent by completely advancing it into the ureter and leaving only a string down into the bladder. When comparing this so-called complete intra-ureteral stent placement (CIU-SP) technique to conventional stent placement, the authors found significantly lower VAS scores at postoperative day 3 and 14 (4.85 versus 9.78, p = 0.003, and 3.15 versus 6.20, p = 0.014, respectively). In addition, the total analgesic use was also lower in the CIU-SP group (19.23 mg versus 88.54 mg, p < 0.001).[50] Finally, Vogt et al. customized their own stent by cutting the bladder end perpendicularly and replacing with a silicone end piece. They found significantly better Urinary Symptoms USSQ subscores at 15 days after insertion compared to the baseline (23.0 ± 7.0 versus 34.4 ± 3.6, p = 0.0004). Good urine drainage without dislodgement or calcification was observed during a 6-month period.[51]

Another promising stent design is the suture stent, created by cutting the bladder end perpendicularly and tying the edge with a polypropylene suture. The suture serves as a string in the bladder to facilitate stent removal. The later commercialized versions are known as JFil® and MiniJFil®

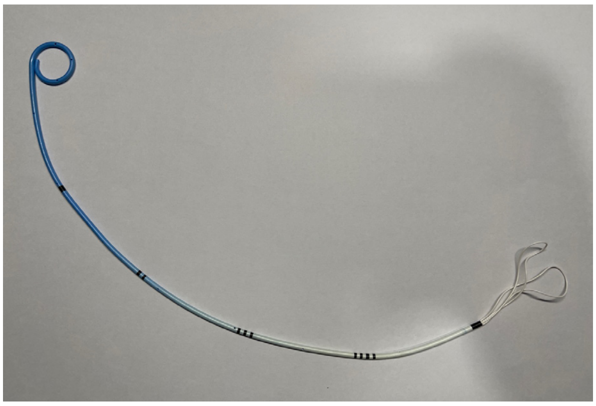

Figure 4. Polaris™ Loop loop-tailed ureteral stent (Boston Scientific, Marlborough, MA, United States)

(Rocamed, Signes, France) (Figure 5). Vogt et al. compared the suture stent to conventional stents and found a reduction in Urinary Symptoms (23.6 ± 5.4 versus 35.2 ± 7.5, $p < 0.001$) and less Body Pain (4.9 ± 3.1 versus 11.0 ± 3.9, $p < 0.001$) USSQ subscores. In addition, the ureteral diameter was found to be enlarged at one month after suture stent insertion, which may, in turn, facilitate ureteral access sheath insertion and stone clearance.[52] A later clinical study in 2016 demonstrated that inserting a MiniJFil® stent a few weeks before extracorporeal shock wave lithotripsy resulted in a stone clearance rate as high as 96.4%.[53]

3. Stent Removal

Modification of the stent removal technique may reduce treatment time, medical expense, and patient discomfort resulting from the removal procedure. Stents with an extraction string and magnetic ureteral stents are the available alternatives.

1. Stents with an extraction string (Figure 6) have a string attached to the bladder end.[54] The string continues to pass out through the urethra meatus for approximately 10 cm and is secured to the surrounding skin to prevent inward migration into the urethra. A systematic review by Sun et al. revealed a lower VAS following the removal of the stent with the extraction string in comparison to the traditional cystoscopic method (mean difference -0.14, $p < 0.00001$). However, the extraction string group encountered a higher incidence of stent dislodgement.[55] This finding showed a strong correlation with another study which also found that dislodgement may occur four times more frequently in females.[56]

2. Magnetic ureteral stent (Magnetic Black-Star, UROTECH GmbH Germany) is a polyurethane stent equipped with a magnet attached to the bladder end. Stent removal requires blind insertion of a Tiemann catheter with a magnetic tip via the urethra into the bladder. After the two magnets connect, the removal then carefully procedes. Rassweiler et al. carried out a study comparing the magnetic ureteral stent to the conventional stent and found a statistically lower VAS during removal (3 versus 4, $p = 0.019$). The subsequent cost analysis also showed a lower stent removal cost of 100 euro per case for the magnetic ureteral stent.[57]

Forgotten ureteral stent

Sometimes patients fail to present for stent removal. The longer the ureteral stent is left inside, the more potentially complicated the removal of the stent. The degree of stent encrustation is directly related to the indwelling time. When severe encrustation occurs, there is the potential for other complications to increase, such as ureteral obstruction, renal failure, urinary tract infection, and stent removal difficulty. Additional procedures, including extracorporeal shockwave lithotripsy, ureteroscopy, or percutaneous nephrolithotomy, may be necessary in such cases. In particular cases, stent fragmentation occurs, thus making stent removal more complicated.[58]

Notification via e-mail or text message is usually employed with limited success. Recently, a reminder through a smartphone-based tracking application has been a new approach. Ulker

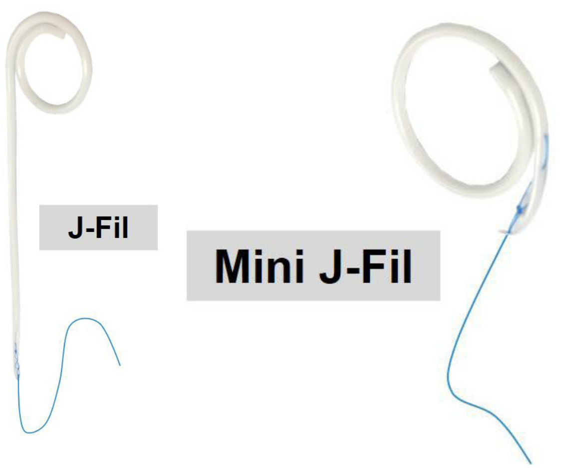

Figure 5. JFil® and MiniJFil® suture stents (Rocamed, Signes, France)

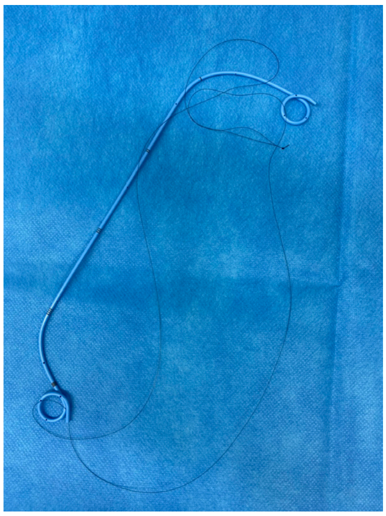

Figure 6. Stent with extraction string

et al. prospectively compared the Ureteral Stent Tracker application (Boston Scientific, Marlborough, MA, United States) to appointment cards. The application resulted in significantly shorter mean overdue times (2.5 ± 0.9 days versus 16.3 ± 5.0 days, p = 0.001) and helped track the stent patients more effectively.[59]

Conclusion

Ureteral stent insertion is fundamental for all urologists. The procedural skills and the knowledge of the equipment are crucial for the best treatment outcomes. The development of new ureteral stents continues enthusiastically, especially in the field of biodegradable ureteral stents. The predictability of degradation and the reliability of the manipulation of the stent are crucial factors in the breakthrough of new forms of this device. Integration of nanotechnology for stent coating and impregnation is another promising way to improve stent properties. Finally, 3-D stent printing, combined with computed tomography, may assist in the creation of a personalized stent for each patient.

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