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Development of a novel indwelling catheter for urethral surgery

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Abstract

This study aimed to develop an indwelling catheter that can be used for urethral flushing, urethral secretion drainage, local urethral drug delivery, and urine drainage.

We designed a new indwelling catheter type that has a balloon, 4 peripheral grooves, and a C-shaped groove on its surface. In addition, there is a flushing channel, a balloon channel, and a urine drainage channel in the catheter body. However, the most critical characteristic is that the flushing channel and the 4 peripheral grooves are connected with the C-shaped groove, and the flushing liquid can reach the C-shaped groove through the flushing channel and then flow out through the peripheral grooves, while the balloon channel leads to the balloon. Generally, our design is to add 4 peripheral grooves, a C-shaped groove, and a flushing channel to the indwelling catheter that is applied clinically nowadays.

We designed a new type of indwelling catheter, which is multifunctional, and we had acquired a national patent in China. In theory, the new catheter type cannot only be used for urine drainage, bladder irrigation, but also for urethral flushing, urethral excretion drainage, and local urethral drug delivery at the same time.

This new indwelling catheter can theoretically reduce catheter-associated urinary tract infection and facilitate urethral secretion drainage or flushing out, which is especially suitable for the treatment and nursing of patients who underwent urethral operation. However, the new catheter have not been produced and tested clinically, and this is our next step.

Abbreviations: CAUTI = catheter-associated urinary tract infection, IU = internal urethrotomy, OIU = optical internal urethrotomy.

Keywords: catheter-associated urinary tract infection, indwelling catheter, urethral excretion drainage, urethral flushing, urethral operation

1. Introduction

Catheter-associated urinary tract infection (CAUTI) is a common clinically refractory disease. Previous studies have shown that the most critical risk factor for CAUTI development is prolonged use of indwelling catheter, and the formation of bacterial biofilm on the catheter surface is the key factor that causes CAUTI which is difficult to deal with.[1,2] At present, the best treatment is to remove the catheter if patients' conditions permit, but sometimes we have to delay this task. However, for congenital hypospadias, urethral stricture, and urethral injury patients, a catheter should be used to support the reconstructed urethra after urethral surgery as the reconstructed urethra requires a long healing time. The catheter can protect the reconstructed urethra from collapsing and keep the lumen of the reconstructed urethra unobstructed. In addition, patients, especially men, with indwelling catheter after urethral surgery, may always have urethral secretions, exudations, or hematocele, which are difficult to eliminate, and then accumulate between the urothelium and catheter. Moreover, in our opinion, the accumulation of urethral extravasation will constrict the reconstructed urethra, increase the risk of local infection and affect the healing of urethral anastomosis, which may causes serious complications, such as urethrostenosis, urethral diverticulum, urinary fistula, and ultimately reduce the success rate of urethral reconstruction surgery. To improve the surgical effect, we designed a specific catheter for patients who might undergo urethral operation.

2. Design

At present, 2 kinds of indwelling catheters are commonly used in clinical practice: 2-cavity and 3-cavity urethral catheters. The 2-cavity catheter has only 2 channels and 1 balloon: the urine drainage channel is used for draining urine in the bladder, and the balloon channel helps to expand the balloon to prevent the catheter from falling off. The 3-cavity catheter is equipped with another channel, which runs through the catheter and lead to the bladder lumen, in which we can irrigate the bladder. To develop a

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LL and LC contributed equally to this study.

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novel instrument that can be used for urethral support (only for patients who will undergo urethral surgery), urethral flushing, urethral excretion drainage, urine drainage, and (or) bladder irrigation, we made quite a modification of the current catheter. We equipped the current 2-cavity and 3-cavity catheters with 4 peripheral grooves, a C-shaped groove and a urine drainage channel. Consequently, we have successfully designed the new 3-cavity and 4-cavity catheters. Furthermore, we had acquired national patent in China for this invention (ZL201621439328.4). The novel catheter is composed of a balloon, 4 peripheral grooves and a C-shaped groove on their surface, a flushing channel, a balloon channel, and a urine drainage channel inside. The outlet of the urine drainage channel and the outlet of the bladder irrigation channel are at the tip of the catheter body, then is the balloon, below the balloon is the C-shaped groove and peripheral grooves. The C-shaped groove is like a circular groove but has a notch, under the notch are the bladder irrigation channel and the balloon channel, that is the notch's function is to avoid damaging the balloon channel and the bladder irrigation channel (Fig. 1). The most critical characteristic is that the flushing channel and the 4 peripheral grooves are connected with the C-shaped groove. The 4-cavity catheter has a bladder irrigation channel through its body compared with the new 3-cavity catheter. When the new 3-cavity catheter is used, if the flushing liquid is delivered through the flushing channel, the liquid will reach the C-shaped groove and then flow out through the peripheral grooves. As the liquid flowed out, urethral secretions, exudations, and hematocele will be diluted and be easily drained with flushing liquid. In addition, it can also drain the urine from the bladder and support the reconstructed urethra for patients who underwent urethral operation (Figs. 1 and 2). For the 4-cavity catheter, in addition to all the functions of the new 3-cavity catheter, it also can be used for bladder irrigation. That is, when patients are using this catheter, we can infuse buffer solution from the bladder irrigation channel to the bladder, and then, it will flow out from the urine drainage channel (Figs. 3 and 4). Because the C-shaped and peripheral grooves are on the surface of the catheter body, the wall of the urine drainage channel must be thick, reducing the lumen area of the urine drainage channel in some ways (Fig. 4). To ensure that the lumen area of the urine drainage channel is not too small being easily blocked, we can increase the number but reduce the diameter of the peripheral grooves without reducing the lumen area of the urine drainage channel, and the functionality may be the same. For patients who underwent urethral operation, urine from the bladder is usually clear and transparent, which generally does not lead to catheter blockage; hence, reduction of the lumen area of the urine drainage channel in some ways is not that influential.

3. Texture

We designed this novel kind of catheter to attain a well-drainage effect of urethral flushing, urethral excretion drainage, local urethral drug delivery, and urine drainage. We insist that silicone is the best choice for the newly developed catheter.

4. Function

For most patients with congenital urethral malformation, urethral injury, urethral stricture, and other urethral diseases, urethroplasty is the best choice of treatment. During the operation, we can place a new 3-cavity or 4-cavity catheter in the reconstructed urethra. Then, the catheter will support the reconstructed urethra and make the weak urethra easier to attach to the surrounding tissue and grow well. Besides, medicine can be delivered through the flushing channel to promote wound healing or deliver diluted iodophor or other flushing liquids to dilute urethral secretions, exudations, and hematocele for easy drainage. As a result, the risk of urethral infection will be minor, and complications will lessen. Moreover, the urine in patients' bladder will drain out through the urine drainage channel. For patients without urethral diseases but are unresponsive, suffered from bone trauma, or bedridden for a long time, using this catheter will also reduce the risk of infection. On the contrary, the 4-cavity catheter can be used for bladder irrigation after transurethral resection of patients with bladder tumor or bladder bleeding. In short, these novel catheters are suitable for patients with urethral diseases who required surgery and other patients who required indwelling catheter for a long time, especially adult male patients in theory. Since our invention have not been manufactured for the inadequate funding, we have not applied it to any patients up to now, in other words, this study did not involve patients, and it is unnecessary to get an approval of an ethics committee or institutional review board.

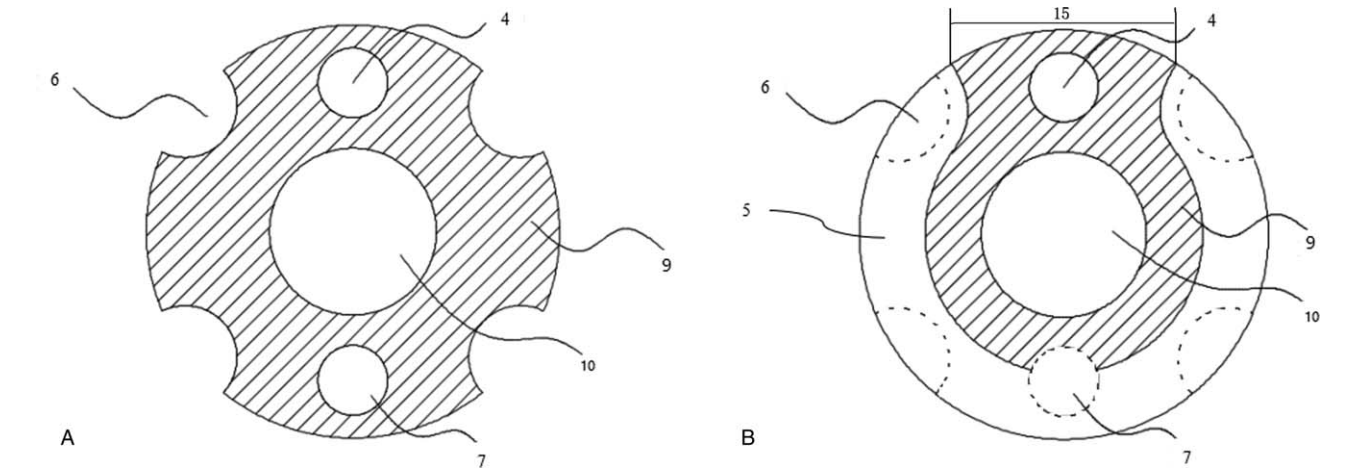

Figure 1. Cross-section of the new 3-cavity catheter. (A) Cross-section of the body of the catheter (non-C-shaped groove). (B) Cross-section of the C-shaped groove. 4. Balloon channel. 5. C-shaped groove. 6. Peripheral grooves. 7. Flushing channel. 9. Body of the catheter. 10. Urine drainage channel. 15. Notch.

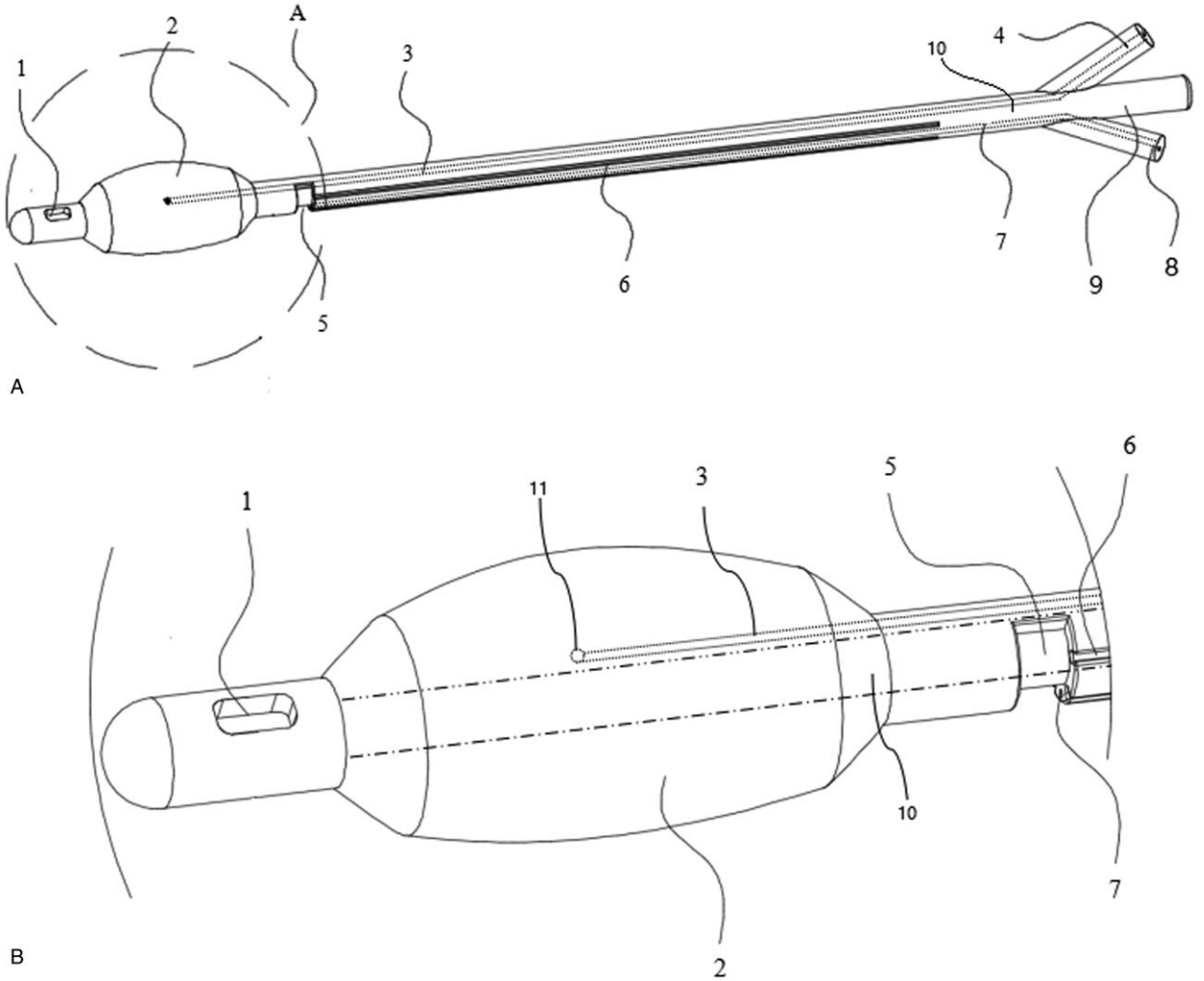

Figure 2. The model of the new 3-cavity catheter. (A) Overall structure. (B) Amplification of (A). 1. Outlet of the urine drainage channel. 2. Balloon. 3–4. Balloon channel. 5. C-shaped groove. 6. Peripheral grooves. 7–8. Flushing channel. 9. Body of the catheter. 10. Urine drainage channel. 11. Outlet of the balloon.

5. Discussions

In recent years, with the development and wide use of endoscopic technology, increasingly more patients suffer from urethral injury and stricture after endoscopic surgery.[3] Besides, along with the development of vehicle and construction industry, the number of urethral injury patients continuously increase, which results in the increased incidence of traumatic urethral stricture.[4,5] Moreover, the number of patients with urethral stricture secondary to radiotherapy cannot be ignored.[6–8] A study[9] showed that radiotherapy is an effective treatment for pelvic malignancies; however, during the radiographic treatment of advanced rectal cancer, prostate cancer, bladder cancer, etc., radiation will also damage the urinary trophic blood vessels, weaken the function of fibroblasts, and limit collagen synthesis, which lead to urethritis and urethral stricture. In addition to acquired urethral diseases, congenital malformations of the urethra have a high incidence. For example, the rate of hypospadias is 1 in 300 men. However, urethroplasty is a well-recognized surgery for the treatment of urethral diseases.[10,11] Recent studies[12] found that the complication rate of urethroplasty for hypospadias is up to 53%, including urinary fistula (29.1%), urethral stricture (24.6%), and urethral diverticulum 9%. At present, the occurrence of complications after urethroplasty is believed to be associated with local infection and scar formation. This is compatible with another study[13] which reported that urethral strictures are more likely secondary to local urethral fibrosis due to the infection or inflammation of the reconstructed urethra. The above results suggest that effective control of postoperative infection after urethral reconstruction may significantly improve the effect of urethroplasty.

However, beyond that, urethral dilatation, optical internal urethrotomy (OIU), and urethral stenting are always performed for urethral stricture after surgery for hypospadias and traumatic urethral stricture. A study[14] had shown that OIU with intralesional injection of the mixture solution of triamcinolone, mitomycin C, and hyaluronidase is a great treatment method for anterior urethral strictures. In addition, urethral submucosal injection of triamcinolone at the urethrotomy site significantly reduced stricture recurrence after internal urethrotomy (IU).[15] Conversely, managing bulbar urethral strictures, especially those who are poor candidates for urethroplasty with high-dose corticosteroid injection at the time of cold-knife direct vision internal urethrotomy can significantly delay anatomical and symptomatic recurrence.[16] In addition, a double-blind, randomized, placebo-controlled study[17] had shown that patients

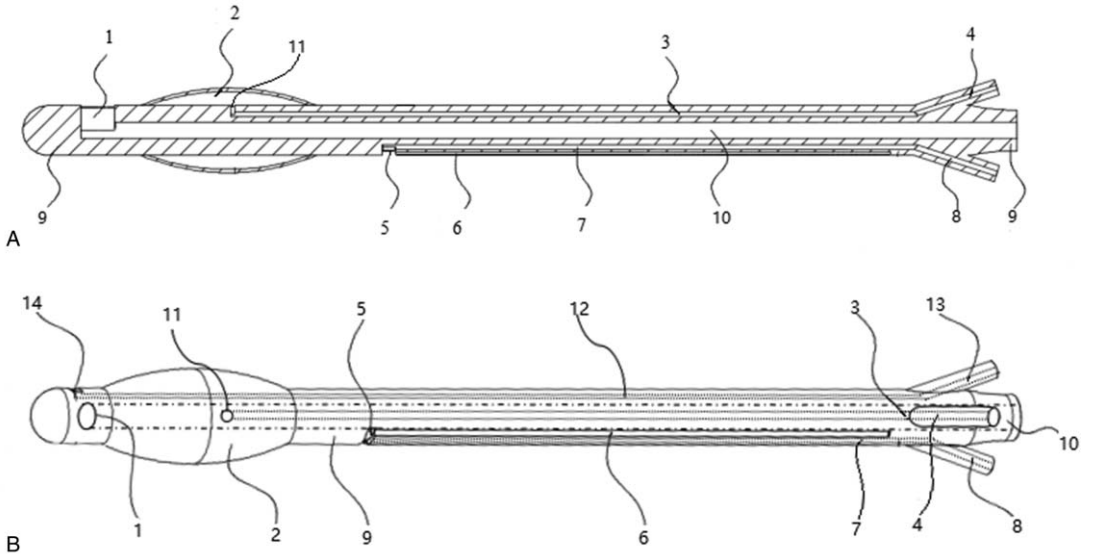

Figure 3. (A) Longitudinal section of the new 3-cavity catheter. (B) Four-cavity catheter model. 1. Outlet of urine drainage channel. 2. Balloon. 3–4. Balloon channel. 5. C-shaped groove. 6. Peripheral grooves. 7–8. Flushing channel. 9. Body of the catheter. 10. Urine drainage channel. 11. Outlet of the balloon. 12–13. Bladder irrigation channel. 14. Outlet of the bladder irrigation channel.

with urethral stricture received triamcinolone acetonide injection after IU may delay the recurrence of urethral stricture. However, a systematic review of the literature[18] revealed that local steroids with IU appeared to delay the time to stricture recurrence, but may not affect the rate of stricture recurrence following IU. In brief, further effective studies are required.

CAUTI as a refractory disease often occur in patients with long-term indwelling catheters. Previous studies[1,2] have shown that the formation of bacterial biofilm is the key factor that causes disease. However, in our view of patients with indwelling catheter, the gap between the urethral epithelium and the catheter surface is too small to allow drainage of urethral secretions. Especially, the adult male patients usually have urethral secretions, which always increase the risk of CAUTI. To address CAUTI, many scientists had hammered at developing new catheters with anti-infective function, but none of the achieve-

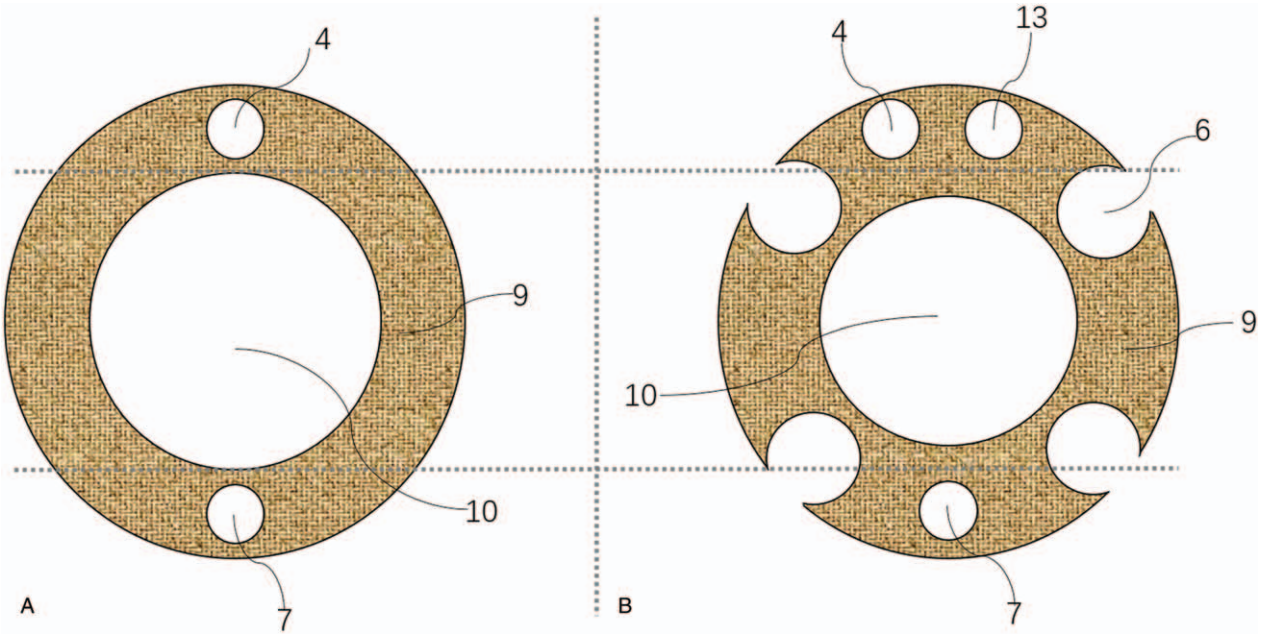

Figure 4. (A) Cross-section of the common 3-cavity catheter. (B) Cross-section of the 4-cavity catheter. As the dotted line shows, the lumen areas of the new 3-cavity and 4-cavity catheters are less than the current catheters. 4. Balloon channel. 6. Peripheral grooves. 7. Flushing channel. 9. Body of the catheter. 10. Urine drainage channel. 13. Bladder irrigation channel.

ments have been applied in clinical practice. In patients with urethral disease who underwent surgery, accumulation of urethral secretions, exudations, and hematocele may also compress the incision and result abnormal healing of the incision, which influences the effectiveness of the operation.

To solve the above-mentioned problem and increase the therapeutic effectiveness of urethral diseases, we made some modifications to the current catheter and then successfully designed the new 3-cavity and 4-cavity catheters, which can satisfy the needs of urethral flushing (buffer solution or medicament), urethral excretion drainage, urine drainage, and (or) bladder irrigation at the same time. In theory, through our newly designed catheters, we can deliver the flushing liquid, for example, the diluted iodophor to the urethra to dilute the urethral secretions, exudations, and hematocele for easy drainage; consequently, the surgical incision may heal well. Furthermore, the drug solution (mitomycin C, hyaluronidase, steroids, etc.) can be easily delivered to the operative region after urethroplasty, OIU, etc., to promote wound healing, reduce local urethra infection, delay the time to recurrence, and improve the success rate of operation. However, with the C-shaped and peripheral grooves are designed on the wall of this new catheter the lumen area of the urine drainage channel is smaller than the usual catheter. In some ways, it is not that influential and we have the solution as previously mentioned. Besides, this new 3-cavity and 4-cavity catheters have not been manufactured because of inadequate funding. We certainly hope that the novel catheter could be produced and applied for clinical trials to verify its function, but the most attractive is to apply it clinically and benefit the patients.

Author contributions

Lilong Liu, Lili Chen contributed equally to this work. Lilong Liu, Lili Chen, Yinghao Chao contributed to the literature search, study design and manuscript writing. Lilong Liu, Ning Zhao, Changfei Yuan contributed to the implementation of this study. Min Chen contributed to the review and revise of the manuscript.

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