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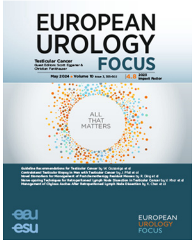

EUROPEAN UROLOGY FOCUS

Review – Infections

Innovating Indwelling Catheter Design to Counteract Urinary Tract Infection

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Abstract

Background and objective: Bacteriuria is anticipated in long-term indwelling catheter (IDC) use, and urinary tract infections (UTIs) and related issues are common. Defence mechanisms against infection are undermined by the presence of a Foley catheter, and adjustments to design could influence UTI risk.

Methods: We reviewed the various aspects of IDCs and ureteric stent designs to discuss potential impact on UTI risk.

Key findings and limitations: Design adaptations have focussed on reducing the sump of undrained urine, potential urinary tract trauma, and bacterial adherence. Experimental and computational studies on ureteral stents found an interplay between urine flow, bacterial microcolony formation, and accumulation of encrusting particles. The most critical regions for biofilm and crystal accumulation are associated with low shear stress. The full drainage system is the functioning unit, not just the IDC in isolation. This means reliably keeping the drainage system closed and considering whether a valve is preferred to a collection bag. Other developments may include one-way valves, obstacles to "bacterial swimming", and ultrasound techniques. Preventing or clearing IDC blockage can exploit access via the lumen or retaining balloon. Progress in computational fluid dynamics, energy delivery, and soft robotics may increase future options. Clinical data on the effectiveness of IDC design features are lacking, which is partly due to reliance on proxy measures and the challenges of undertaking trials.

Conclusions and clinical implications: Design changes are legitimate lines of development, but are only indirect for UTI prevention. Modifications may be advantageous, but might potentially bring problems in other ways. Education of health care professionals can improve UTIs and should be prioritised.

Patient summary: Catheters used to help bladder drainage can cause urinary infections, and improvements in design might reduce the risk. Several approaches are described in this review. However, proving that these approaches work is a challenge. Training professionals in the key aspects of catheter care is important.

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1. Introduction

Indwelling urinary catheters (IDCs) are a vital aspect of clinical care, but their use needs to be considered in view of potentially significant problems [1,2]. Short-term use (IDCs) is associated with an incidence of urinary tract infections (UTIs), which potentially persists even after catheter removal. In long-term use, bacteriuria is anticipated in the substantial majority of users. Hence, symptomatic UTIs and/or UTI-related issues, such as recurrent catheter blockages, arise in a high proportion.

The most widespread "Foley" IDC design uses a drainage channel, with eyeholes that allow entry of urine at one end, and a connector to accommodate the drainage bag or a valve at the other. A separate channel allows filling and emptying of a retaining balloon, which aims to keep the drainage holes in the bladder lumen. Variations in the product specifications accommodate differences in urethral length and external diameter [3].

The bladder's defence mechanisms against infection are undermined by the presence of a Foley catheter [4]. Conceptually, aspects of this core design may contribute to some of the UTI risk. Hence, adjustments to design and manufacturing processes could potentially exacerbate or ameliorate UTI risk. Implicitly, the presence of foreign material, breach of anatomical defences, and change in urodynamic functions all contribute to the increased UTI risk associated with IDC use.

2. Methods

Literature search was undertaken in PubMed and PubMed Central using the search terms "catheter" and "urinary tract infection", with manual search of references cited in key articles. A separate review in this special issue of *European Urology Focus* covers innovations in the materials and coatings.

3. Results

The potential improvements for reducing the UTI risk associated with IDC design are summarised in Table 1.

Table 1 – Summary of innovation concepts for reducing catheter-associated UTIs

Aim of catheter design adaptation	Examples
Reducing residual urine in the bladder	Catheter drainage holes close to the bladder base—Flume catheter [6], Optitip catheter
Reducing urinary tract trauma	1. Additional balloon to protect bladder—Duette catheter 2. Low-profile design [7] 3. "Atraumatic" catheter [9]
Reducing bacterial adherence/improving flow	1. Evaluating shear stresses [16,17] 2. Intermittent flow [18] 3. Reliable drainage systems [19] 4. Integrated valve—T-control [20] 5. Obstacles against "upstream swimming" [22] 6. Retrograde flushing [23] 7. Acoustic waves to reduce biofilm [26]
Preventing blockage	1. Local antibacterial compounds via retaining balloon [27] 2. Catheter lock solutions via lumen [29] 3. Biofilm detachment (substrate strain) [32] 4. Luminal soft robot (magnetic actuation) [33] 5. Activated surface microstructures [34,35]

UTI = urinary tract infection.

3.1. *Microbiological impact in IDC users*

To constitute a UTI, there need to be specific systemic and microbiological features, including the presence of symptoms, an inflammatory response, and a single organism cultured in sufficient numbers. Where there is a factor such as the presence of an IDC, it is referred to as a "complicated UTI". Urine specimens typically find bacteriuria once people have had an IDC in place beyond a few days, but this is usually not considered clinically significant, and guidelines do not support antibiotic treatment to prevent catheter-associated UTIs in patients with a long-term indwelling catheter [5]. More direct evaluation of the catheter surface reveals extensive bacterial presence, with a range of organisms giving rise to a biofilm. If antibiotics are given, the urine sample may no longer show growth temporarily, but the biofilm will persist. Bacteria in the biofilm can cause problems by their physical extent and also release enzymes that can alter the nearby environment; in the case of urine, this can lead to precipitation of salts out of solution. The physical and chemical effects in the locality of the catheter lumen or drainage holes can lead to a blockage, precipitating a medical emergency. The use of antibiotics could influence the nature of the bacteria present and provide a selection pressure in favour of more pathogenic organisms.

Against the microbiological pathogenicity, the patient has defences, including immunity, and specific molecules in the urine. For most patients, the relatively low incidence of UTIs probably reflects the ability of the host to kill organisms away from the location of the IDC. However, the IDC itself is a protected environment enabling bacterial persistence. Furthermore, many patient groups have less effective defences, as a result of impaired immunity or immunosenescence.

Thus, UTIs in IDC users are an endpoint following a complex interplay of factors. Adaptations of IDC design are appropriate measures given the problems patients experience with each UTI. However, such adaptations influence just one step in the chain of factors and so are only indirect when it comes to UTI prevention. In particular, measures to reduce catheter blockages are important because of the seriousness of a blockage event in terms of symptoms, emergency care needs, and cost. However, this IDC microenvironment complication is not indicative for a systemic UTI risk, so reduced blockage events can be considered only an indirect proxy measure of improvement in UTIs.

3.2. *IDC adaptation to reduce residual urine*

In the Foley design, the drainage holes are above the retaining balloon, such that balloon inflation places the holes away from the bladder base. Physical separation of drainage holes from bladder base could allow a persistent reservoir of urine to remain undrained. The stagnation of the urine in this "sump" might be a risk factor for bacterial replication, which may predispose to UTIs. This concept is hard to test in vivo, but an in vitro model, using artificial urine seeded

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with uropathogenic *Proteus mirabilis* in glass incubation chambers, found that a reduction of the urine sump volume appeared to influence the time to blockage [6].

Based on the apparent desirability to reduce the sumping risk factor, the Flume catheter has the drainage holes at the same level as the contact point between the bladder base and the retaining balloon (Fig. 1), and hence should effectively avoid any sump effect. Human tests of a prototype of this catheter have taken place for the first time [6]. The catheter is too early in the innovation pathway to report on whether there is an actual reduction of UTI risk in general clinical use. The Optitip catheter (Linc Medical, Leicester, UK) has two drainage eyes (Fig. 2): one below the balloon and one in a reduced profile tip (see the next section on measures to reduce IDC trauma). As yet, there is no available evidence on the reduction of UTIs or other catheter-associated harms.

3.3. *Measures to reduce IDC-related trauma of the urinary tract*

Several aspects of catheter use place the urinary tract at risk of direct trauma. Given that anatomical integrity is important, damage (where present) is a cause for concern by providing a potential focus for persistence of infecting organisms and enabling deeper penetration of UTIs to increase the risk of systemic consequences. However, whether the trauma risks truly predispose to UTIs is hard to confirm. Furthermore, there is little information on the proportion of people genuinely affected by these issues; hence, the solutions may not be generalisable.

In the Foley design, the balloon may push the pointed tip into the bladder wall, whilst suction effects may draw the urothelium into the drainage holes. The first problem can be addressed with a “low-profile” design, which effectively removes the tip, giving direct access to the lumen from the proximal catheter end. Preliminary data on very short-term use have been published [7]. The Poiesis Duette dual-balloon Foley design aims to reduce both risks through the inclusion of an additional balloon, along with the retaining balloon, placed at the tip of the catheter. This shields both the tip (hence reducing trauma to the urothelium) and the drainage holes of the standard Foley design. Likewise, the Flume catheter tip is shielded once the balloon is inflated.

Additional trauma risks with IDCs include the following:

1. Avulsion with the balloon inflated: The US Food and Drug Administration regulatory authorisation of urinary catheters stipulates high force resistance to reduce the risk of avulsion. However, as a result, if sufficient longitudinal force is applied to avulse the catheter with the balloon inflated (as can happen if a patient stands up when their catheter is tethered), the balloon will transmit a substantial radial force onto the urethra as it comes out [8]. This force is lower with the Flume design [8]. Another design in very early stage development, an “atraumatic urinary catheter”, showed that injury is less common following forceful extraction when compared with a conventional Foley in a rabbit model [9].
2. Cuffing: The retaining balloon may be inflated for up to 3 mo for some patients. This prolonged duration means that the balloon material may not return fully to its original unstretched state, resulting in a cuff of material protruding around the catheter shaft, which can cause urethral trauma when the catheter is removed [10]. This is a well-recognised issue, which should be within the remit of design improvements.
3. Patulous urethra and traumatic hypospadias: These indicate tissue breakdown, resulting from chronic physical and inflammatory factors. This is quite an extreme consequence of IDC use, and improvement is highly desirable for many reasons, over and above the risk of UTIs.
4. False passages: Catheter placement requires the device to follow the course of the urethral lumen as it is advanced. In male patients, this relies on the catheter following the natural anatomical curvatures and any additional distortions resulting from scarring or hyperplasia. Unfortunately, the tip may abut against the urethral wall whilst being introduced, and the longitudinal force may then breach the urethral epithelium. An adaptation introducing slight angulation of the catheter tip can allow an experienced practitioner to reduce the risk of a false passage, since rotation of the tip can facilitate negotiation of these obstacles.

Fig. 1 – Balloon designs of the standard Foley catheter (left) and the Flume catheter (right).

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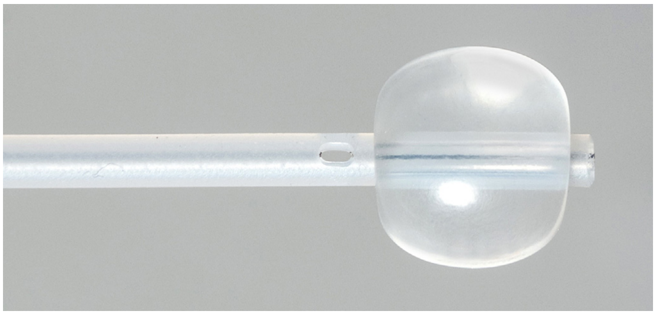

Fig. 2 – The Optitip catheter, with a hole below the balloon (visible in the photograph) and another hole above the balloon at the end of the tube (not visible).

3.4. IDC adaptations to reduce bacterial adherence and improve flow

Adherence of bacteria is a key step in infection; once adherent, the bacteria can proliferate, form biofilm, and change the microenvironment, and thereby lead to a blockage. Design issues can have implications for adherence. For example, increased surface area in contact with urine may be a risk factor. This extends to the manufacturing process in producing the final product. For example, the process of making the drainage eyeholes needs to result in a smooth surface, since rough surfaces predispose to bacterial adhesion [11]. Punching the holes with a metal stamp potentially leads to a rougher surface than a laser-cut hole, with demonstrable implication for bacterial adhesion in vitro. This is especially problematic, given that the drainage holes are key for IDC function.

Experimental and computational studies on ureteral stents found an interplay between urine flow, bacterial microcolony formation, and accumulation of encrusting particles, such as urine crystals. Side holes in stents are often the triggering sites for these processes, due to flow stagnation and the formation of laminar vortices. These slow vortices can become entrapment sites for small particles, such as bacteria and crystals, thereby promoting adhesion and growth on the surface [12]. The most critical regions, in terms of biofilm and crystal accumulation, are generally associated with low shear stresses [13–15]. Using computational fluid dynamics simulations, new stent designs have been proposed to maximise shear stresses [16,17], which may reduce bacterial attachment and encrustation [17]. These findings highlight the key role played by urine flow, which should be considered when designing new IDCs.

At a macroscopic level, a lot of credence is given to a supposed “flushing effect” generated by urine throughput. However, this is probably marginally beneficial and impractical for many individuals. Alternatively, intermittent flow (using a valve to enable reservoir filling, with sporadic opening for emptying) increases the time for catheters to block with crystalline biofilm in vitro [18]. Hence, the full drainage system has to be evaluated as a functioning unit, not just the IDC in isolation. Other important considerations include a priority to maintain a closed drainage system. Accordingly, it is important to ensure that any connectors between the IDC and a valve or drainage bag are reliable and minimise the risk of disconnection, with associated breach of the closed system. Care of the tubing is needed to reduce the chance of it getting kinked or squashed, and hence blocked [3]. The drainage bag should not be elevated, in case gravity or siphoning leads to a retrograde flow of urine. These apparently simple processes may be important factors for potential individual risks of catheter-associated UTIs. The Accuryn SmartFoley and Monitoring System (Potrero Medical, Hayward, CA, USA) aims to reduce standing urine in the drainage system with an active drain line clearance and three one-way valves to eliminate urinary backflow and airlocks. Introduction of this system was reported to reduce catheter-associated UTIs in a burns unit [19]. T-Control is a silicone Foley catheter incorporating an integrated valve with three different positions—“open”, “closed”, and “insertion”. Trial protocols for this have been proposed [20,21].

A geometric design using triangular obstacles against bacterial “upstream swimming”, optimised by an artificial intelligence model, has also been proposed to reduce retrograde spread along the catheter lumen [22]. However, this needs detailed evaluation to identify whether the approach might be disadvantageous in terms of biofilm adherence.

Retrograde flushing with saline or washouts could in theory displace bacteria, or exert an antibacterial effect. Indeed, a randomised trial of 60 comatose patients found that daily bladder irrigation using saline was associated with a reduced risk of UTIs [23]. However, a Cochrane analysis did not find adequate evidence to support catheter washouts on a wide range of indications [24].

Low-frequency surface acoustic waves have demonstrated the ability to interfere with the early stages of microbial biofilm formation, resulting in a significant reduction of biofilm in catheters [25]. Additionally, these waves have been found to enhance the susceptibility of certain bacteria to antibiotic treatments [26]. Uroshield (NanoVibronix, Elmsford, NY, USA) is a small device designed to be attached to the tubing of an IDC, transmitting low-frequency acoustic waves along both the inner and the outer surface of the catheter.

3.5. Preventing or clearing blockages

Catheter designs could incorporate measures to facilitate the use of techniques to counteract blockages. The drainage balloon appears to provide a means for introducing antibacterial compounds, with the benefit of proximity to the drainage holes in most designs. Triclosan in this location reduces the *P. mirabilis* biofilm in an in vitro setting [27]. For individual users, this can improve blockages, but an

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attempt to run a clinical trial, with UTI rates as an outcome measure, did not reach the planned endpoint [28]. Another approach is to place the antibacterial substance into the catheter lumen, described as "catheter lock solution", and triclosan/cranberry appears to prevent all tested strains from adhering onto the catheter surface in vitro (though filled via the eye hole, whereas clinical use would necessitate retrograde filling) [29]. However, although certain antimicrobial substances/coatings can decrease bacterial attachment on urinary stents and catheters, their effectiveness may be undermined by the formation of crystal deposits that form soon after placement, providing a surface for bacteria to adhere over the antimicrobial layer [30,31].

Alternatively, physical methods can be applied. For example, *P. mirabilis* crystalline biofilms detach from silicone elastomer substrates upon application of strain to the substrate, and increasing the strain rate increases biofilm detachment [32]. Potentially, methods could be developed to achieve surface strain selectively in a catheter lumen [32]. Another concept has been proposed to clean biofilm from the lumen of a urethral catheter with a soft robot, actuated by a magnetic field [33]. Such a method would need to ensure that displaced biofilm was drained outwards only and that retrieval of the robot could be ensured (otherwise a retained robot would be the cause of a blockage).

Furthermore, dynamic, activatable microstructures on the walls of stents and catheters have been introduced to increase wall shear stresses "on demand", effectively cleaning surfaces from biofilms and crystals through two different approaches. The first approach employs magnetically actuated microstructures (ie, pillar-like structures [34]) that prevent biofilm formation through periodic vibration. This vibration locally increases fluid velocity, thereby increasing wall shear stress. However, the effectiveness of this method is limited by the challenge of inducing high-frequency vibrations magnetically (above 100 Hz), which restricts the range of achievable velocities and wall shear stresses. To overcome these limitations, the second approach uses ultrasound-activated cilia operating at frequencies above 20 kHz [35]. When activated by ultrasound, these cilia vibrate, producing acoustic streaming with high fluid velocities, resulting in significant wall shear stress. Initial microfluidic results indicate that these microstructures can effectively clean typical urinary crystals and biofilms off surfaces, suggesting a potential for transcutaneous cleaning using ultrasound.

3.6. *Demonstrating reduced UTIs*

The lack of clinical data on the effectiveness of these IDC design features is, in part, due to the challenges of undertaking trials. Users of long-term IDCs often have complex needs, and many are reliant on carers for the day-to-day management of their device. The provision of associated health services is usually spread over multiple providers (eg, community nursing for planned IDC changes, general practice for prescription, and acute care for unplanned management). Additionally, the length of intervention period needed to support the identification in a meaningful change in the incidence of UTIs and other outcomes is likely to be at least 6 mo. These factors mean that trial recruitment and data collection are resource intensive and burdensome, with a risk of high levels of participant withdrawal. Whilst large-scale trials with short-term hospitalised IDC users have provided useful insights into UTIs and other outcomes, definitive trials of community-based long-term IDC users are limited.

4. Discussion

IDC use is a well-recognised risk factor for the development of UTIs. Any measure to reduce infections is a welcome tool, given the nature of the symptoms and the potential consequences—particularly in patients with extensive comorbidity. However, many factors make it hard and expensive to research and confirm a reduction in infections. Understandably, many researchers focus on proxy measures, such as reduction in blockages. Achieving reduced blockages is highly desirable in itself, but affirming that this truly translates into a reduction in UTIs is likely to be an oversimplification; proxy measures are simply that. A catheter blockage is a local infection and not a systemic one, predisposed by the microenvironment. The presence of bacteriuria is inevitable and may well not lead to systemic infection, particularly in people whose immune systems are fully functioning. Measures to reduce trauma or the presence of a residual "sump" are indirect factors, which may be applicable to only a subgroup of IDC users. Furthermore, modifications may be advantageous in one way, but potentially might bring problems in other ways. Hence, there is very little convincing evidence to demonstrate that these innovations genuinely deliver a reduction in UTI risk.

For these reasons, it is essential to develop reliable in vitro and computational testing [36] platforms that can compare the performance of various catheter solutions in terms of urine drainage, blockages, and other factors accurately and reproducibly. These platforms should be designed to model precisely the geometrical, tissue and fluid mechanical, biological, and chemical properties of the lower urinary tract. More representative in vitro models are needed to back up these findings, ideally aspiring to maintain tissue models [37,38].

A large focus now needs to prioritise the contribution of best practice in catheter-associated UTI prevention strategies [39]. Attention to fundamentals, such as training of health care professionals overseeing IDCs, is known to improve outcomes [40]. Quality improvement interventions can achieve large declines in UTI rates; net costs to hospitals vary, but on average are not significantly different from zero over 3 yr [41]. Hence, it is clear that education of health care professionals can have a significant influence, and this should be prioritised in current practice. This will ensure that the whole drainage system, and not only the catheter component of it, is considered.

Ultimately, the potential of microorganisms to adapt and thrive in the urinary tract must not be underestimated, and it appears inevitable that UTIs will continue to be a persisting challenge for the foreseeable future [42].

5. Conclusions

Design innovations attempting UTI prevention may focus on a range of measures. Nonetheless, modifications need to ensure that other problems do not emerge, and their

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real-life influence on UTI rates needs to be demonstrated rather than assumed. Education of health care professionals can improve UTI risk for catheter users and should be prioritised.

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Study concept and design: Drake, Fader.
Acquisition of data: Drake, Clavica, Murphy.
Analysis and interpretation of data: Drake, Clavica.
Drafting of the manuscript: Drake.
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