Engineering solutions to ureteral stents: Material, Coating and Design

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Introduction An ideal stent would offer simple insertion and removal with no discomfort and/or migration, would have no biofilm formation or encrustation, and would also maintain patient's quality of life.

Materials and methods In this mini review we outline the engineering developments relating to stent material, design and coating.

Results There have been a wide variety of in-vitro, model based, animal based and clinical studies using a range of commercial and non-commercial stents. Ureteric stents have evolved since their first use with a wide range of stent design, material and coating available for laboratory and clinical use.

Conclusions While engineering innovations have led to the evolution of stents, more work needs to be done to address issues relating to stent encrustation and biofilm formation.

INTRODUCTION

Ureteral stents are deployed to overcome intrinsic or extrinsic causes of upper urinary tract obstruction, thus aiding the drainage of urine from kidneys to the bladder (1,2). They are often related to the treatment of kidney stone disease (KSD) and with a rising incidence and a lifetime prevalence of KSD at 14%, the use of stents is going to increase further (3). Since their first use, stents have been prone to mechanical, physico-chemical or biological failures such as encrustation and biofilm formation (5,6).
An ideal stent would offer simple insertion and removal without discomfort, would not suffer from migration upon deployment, and would resist biofilm formation or encrustations. A stent with these characteristics would not compromise a patient's quality of life (Fig 1). While a number of changes have taken place regarding size and length of a stent, in this mini review we outline engineering developments

relating to stent material, design and surface coating (Fig 2).

MATERIAL AND METHODS

To engineer an ideal ureteric stent, developments are required on three key technology areas: the constitutive material of the sent, its surface properties, and the stent architecture (Fig 2). In the following sections, we provide an overview of recent innovations in these areas.

Stent Material

There are three main classes of materials that are employed to fabricate ureteric stents: metals, polymers and bio-degradable/bio-absorbable materials (7-14) (Table 1). Polymeric stents are more favoured due to their biologically inert properties in comparison to metal stents. They typically comprise of thermoplastic, thermoset elastomers and other proprietary materials, which are mostly silicon-based (1-3). Bio-degradable/bio-absorbable stents are more recent, and have been shown to reduce the requirement for secondary procedures (i.e. stent removal). The time taken for the stent to be absorbed depends on the material type and potential surface coatings (4). Dual durometer stents consist of a material that transitions from hard proximally to soft distally, with the purpose of decreasing bladder irritation (5). Metallic stents were first introduced by Gort et al., and gained popularity due to their resistance against deformation caused by extrinsic/intrinsic strictures (6-8).

Table 1 summarises the mostly used materials for ureteral stents as well as few commercial examples (1, 2, 4, 6, 8-12).

Stent Coating

Coatings are evolutions in ureteric stents that allow decreasing friction, resulting in easier stent passage over a guidewire (13). Moreover, they can potentially help reducing formation of biofilms and encrustations (6). Coatings have also the potential for reducing inflammation caused by the release of ions from metal stents (13). Specific coatings may also be employed for drug eluting purposes (14). Notably, reduced surface adhesion and friction from coatings has been associated with increased stent lifetime and improved patient's quality of life. Table 2 summarises the stent coatings that are commonly used or have been researched (15-26).

Stent Design

Stent design, on the other hand, is one of the areas that have experienced many scientific trials and associated modifications globally (10, 27). While stent design changes have allowed the double-J structure as a default for almost all stents, its main rationale was to avoid migration of these stents once placed successfully.

Similar stent modifications have also happened with regard to the stent drainage side holes along with other novelties such as spiral stents, mesh stents, stents with variations in tail designs and the method of removal of these stents. A future research area relates to the fluidic aspects of stent drainage, which might become more important with in-vitro research data suggesting that it can govern encrustation and biofilm formation (28). Table 3 summarises various designs and provides examples of their representing stents on the market (29-37).

CONCLUSION

Stents have evolved over the last century with a wide variety of available materials, coatings and designs. An ideal stent, still, remains a panacea but potential solutions would lie in further engineering evolutions

in an era of widespread and increasing clinical use of ureteric stents.

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Attached tables:

1. Table1.docx
2. Table2.docx
3. Table3.docx

Table 1: Summary of most commonly used materials for ureteral stents to date

Innovations in material		***Key comments by manufacturer or reported in a scientific publication***	***Commercial example***
Polymeric	Silicone	Highly biocompatible when compared to other materials (1)	FLUORO-4™ (Bard Medical, USA)
	Polyurethane	High drainage performance and High epithelial erosion (1, 2)	Bardex® (Bard®, USA)
	Silitek™	High tensile strength, weak coil retention, high incident rate of edema (3)	(Medical Engineering©, Argentina)
	Percuflex™	Cost effective, efficient urine drainage and coil retention, low coil and tensile strength (4)	(Boston® Scientific, USA)
	C-Flex®	Lower surface friction allowing less particle adhesion, lower mechanical strength compared to polyurethane and PureFlex™ (4)	(Cook© Medical, USA)
	Dual Durometer	Minimises bladder irritation (5)	(Bioteq©, Taiwan)
Metal	MP35N alloy, a composite of non-magnetic nickel-cobalt-chromium-molybdenum	Metallic double pigtail stent that possesses a high tensile strength and resistance to corrosion resistance to corrosion (6)	Resonance® Metallic ureteral stent (Cook Medical, Bloomington, IN, USA)
	Nickel Titanium (Nitinol)	Soft and strong, not indicated for patients with functional stenosis or stone formation (6)	Memokath 051 ureteral stent (PNN© medical, Denmark)
	Stainless steel	Simplicity of fabrication, removal may be complex (6, 7)	Wall stent (Boston® Scientific, USA)
Biodegradable		Reduction of secondary procedures (8, 9)	Uriprene (Poly-Med Inc, USA)

Table 2. Summary of most commonly used coatings for ureteral stents to date

Innovations in material	***Key comments by manufacturer or reported in a scientific publication***	***Commercial example or method of reported study***
Heparin (a blood thinner)	Prevention of biofilm and encrustation (1)	In-vivo human patient
Polyvinylpyrrolidone (PVP)	Provides a non-adhesive surface due to its lubricant properties and water-solubility (2)	In-vitro study
Antibiotic	Bacterial uropathogens growth prevention, antimicrobial properties, drug elution (3)	In-vivo study on rat model
Carbon (diamond-like)	Decreasing biofilm formation and encrustation (4)	In-vivo study human patient
Hyaluronic acid	Prevention of growth and nucleation of salts, decreasing protein surface assimilation (5)	In-vitro study on rat model
Triclosan	Uropathogens and bacterial growth prevention, FDA concern on the potential for causing bacterial resistance (6)	In-vivo studies e.g. Triumph™ (Boston® Scientific, USA)
Silver	In comparison to silver stents, silver-coated stents appear to perform better in preventing biofilm formation; however, prolonged usage of these coatings can potentially cause argyria (7)	In-vitro study "plant infection model"
Gendine	Biofilm and ureteric infection prevention (7)	In-vivo study on rabbit
Chitosan	Biofilm prevention, especially a derivation with polymethylmethacrylate (PMMA) (8, 9)	In-vitro study
Salicylic acid	Salicylic acid release, due to the hydrolysation of the salicyl acrylate polymer coating in aqueous environment, prevents biofilm formation (10, 11)	In-vitro study
Hydrogel	High water solubility properties provide a thin layer of water that potentially prevents the creation of conditioning film and biofilm. However, there are variable results regarding the level of effectiveness of this coating (12)	In-vitro (in human urine) study

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Table 3: Summary of most commonly used designs for ureteral stents to date

Innovations in design	**Key comments by manufacturer or reported in a scientific publication**	***Commercial example or method of* reported *study***
Double-J	Decreasing migration of stent both proximally and distally. This design is employed in most of the ureteral stents currently on the market (1)	In-vivo human patient
Double-J 3D	Believed to provide a better proximal and distal retention	Silicon Figure Four (SFF) (Bard®, USA)
Loop	Believed to provide a 69% volume reduction in the amount of material inside bladder, and better patient comfort	Polaris™ Loop ureteral stent (Boston® Scientific, USA)
Mesh	Less frequency of upper urinary tract inflammation, but more difficult to place compared to standard unmeshed ureteral stents (2)	In-vivo study on pig model
Expandable	This design is believed to provide a higher intra-luminal flow, and ease of insertion and retrieval	Allium® Ureteral Stent (Allium Medical Solutions®, Israel)
Magnetic-tip	Allowing more effective retrieval due to the presence of magnetic material (stainless steel bead) at the distal end of the stent	Magnetic Black-Star (Urovision, Germany)
String	The extraction string is designed to be attached to the stent to facilitate removal (3)	In-vivo human patient study
Coil-Reinforced	It allows efficient drainage because of the larger lumen, it reduces kinking and buckling, and has high compressive resistance (4)	Silhouette® stent (Applied Medical, USA)
Basket	Its ability to widen laterally upon an activation force improves passageway for small stones and stopping bigger stones' migration through ureter	Ureteral Stone Sweeper® (Fossa® Medical, USA)
Spiral Cut	This type includes having the standard solid lumen of the ureteral stent at the distal and proximal region and spiral cut lumen through the rest of the stent. The stent is claimed to result in fewer upper tract symptoms (5)	In-vivo pig model study

Linearly Expandable	A design in which the stent has got spiral wire spring sandwiched between inner and outer lining of the stent wall to maintain urine flow in the presence of an obstruction (6)	In-vitro study
Helical	Side holes that emerge from the main body of the stent, direct the flow into the lumen thanks to the hole projecting out of the stent lumen and therefore potentially better drainage of the urine and passage of small stones (7)	In-silico study
Grooved	Specifically designed for patients treated with lithotripsy, enabling stone fragments to travel efficiently along the ureter (8, 9)	Towers Peripheral Ureteral Stent (Cook® Medical, USA)

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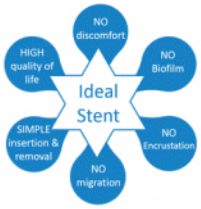
ATTACHED FIGURES



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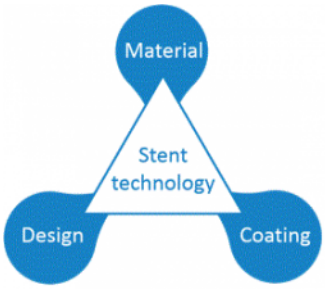

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