

Advancements in Designing a Safer Transurethral Catheter

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ABSTRACT

The purpose of this study was to investigate urethral diametric strain and threshold maximum inflation pressure for rupture during inadvertent inflation of a catheter's anchoring balloon in the urethra. We then aimed to develop and evaluate a novel safety device for preventing urethral trauma based on these parameters. Inflation of a urethral catheter's (UCs) anchoring balloon was performed in the bulbar urethra of *ex vivo* porcine models (n=21) using 16 French catheters. Urethral trauma was assessed with retrograde urethrography. Urethral rupture was correlated with internal urethral diametric strain and maximal urethral pressure threshold values (kPa). Urethral catheters were then inflated in the bulbar urethra of fresh male cadavers (n=7). The maximum urethral pressure generated with a standard syringe was determined (kPa) until resistance pressure generated by the urethra prevented further inflation of the anchoring

balloon after depressing the syringe's plunger. Retrograde urethrography demonstrated that urethral rupture consistently occurred at an internal urethral diametric strain >40% and a maximum inflation pressure >150kPa. The volume of saline infused into a misplaced anchoring balloon correlated poorly with urethral rupture due to internal urethral diameter variability. The maximum urethral threshold inflation pressure required to activate the safety prototype syringe's 'pressure valve' was 153 ± 3 kPa. In comparison, the maximum inflation pressure was significantly greater with a standard syringe compared to the activated prototype syringe (452 ± 188 kPa); $p < 0.001$. Our results demonstrate that internal urethral diametric strain and threshold maximum inflation pressures are important parameters for designing a safer transurethral catheter. The novel prototype safety syringe presented in this chapter could be considered for designing a safer transurethral catheter system than presently commercially available.

INTRODUCTION

Urethral catheterisation (UC) is a routine task performed by junior doctors and approximately 25 % of hospitalised patients are catheterised during their inpatient stay [1]. The estimated incidence of iatrogenic catheter related urethral injury is 0.3%; but this may under represent the true incidence [2-4]. Urethral injury typically occurs in men when the catheter's anchoring balloon is inadvertently inflated in the urethra [5]. Short-term complications can include pain, bleeding and acute urinary retention. Urethral rupture can lead to the long-term complication of urethral stricture disease and may require urethral reconstruction in severe cases [6]. Dobrowolski et al. [7] reported that approximately one third of urethral injuries occur from traumatic urethral catheterisation.

Insertion technique is vital to prevent urethral trauma during urethral catheterisation (UC) [8,9]. At present, education programmes are helpful for trainee and inexperienced health care professionals but are not failsafe and successful UC remains operator dependent [10,11]. The incidence of urethral trauma secondary to catheter inflation is significantly higher among juniors compared to experienced doctors (73% versus 27% $p < 0.05$) [5]. The potential for urethral trauma is highlighted by the fact that 76% of junior doctors feel apprehensive inserting a urethral despite completing an educational teaching programme [3].

Although iatrogenic complications from UC are well described, there are no studies investigating urethral strain thresholds for rupture during inadvertent inflation of a catheter's balloon in a patient's urethra [12]. The present chapter investigates the correlation between urethral distension, urethral rupture and catheter inflation pressures during urethral catheterisation in an *ex vivo* porcine model. Based on these findings we also present our design for a safer urethral catheter system and investigate its novel safety mechanism in a cadaver model.

MATERIALS AND METHODS

Overview of Porcine Urethra Experimental Design

Fresh porcine urethra's were obtained from a commercial abattoir (Ballylanders, Co. Limerick, Ireland) and maintained *ex vivo*. Ethical approval for *ex vivo* tissue study was approved by the University of Limerick's ethics approvals process. All other materials were obtained from CABER (Centre for Applied Biomedical Engineering Research, Limerick, Ireland) unless indicated. The anchoring balloons of urethral catheters were intentionally inflated in the bulbar urethra of each porcine urethra. Retrograde urethrography was subsequently performed on each traumatised urethra. The primary endpoint of the study was to determine the correlation between urethral distension and trauma/rupture (as measured by extravasation of contrast) after traumatic urethral balloon inflation. Our secondary endpoint was to determine the resistance offered by the urethral tissue during balloon expansion and how this resistance to distension translates to an increase in balloon pressure.

Preparation of porcine urethras

Porcine urethras were acquired from male porcine models, all 7 months old, immediately after euthanasia and transported to the laboratory on ice and frozen in phosphate buffer solution (PBS) at -20°C (n=21). Porcine urethras were explanted from the genitourinary tract by thorough dissection from the urinary bladder and surrounding anatomical structures. Urethral samples were further prepared by excising excess surrounding tissue but maintaining the bulbous cavernosum musculature. The proximal urethra was ligated adjacent to the bladder neck proximal to the prostate. During the experimental process each urethra was equilibrated to room temperature in PBS, maintained in an organ bath and heated to 37°C prior to testing.

Urethral catheterisation (UC) of porcine urethras

Urethral catheter inflation was performed using standard 16 French Coloplast™ urethral catheters (n=21). The catheter's anchoring balloon was inflated in the bulbar urethra with sterile saline using a syringe pump (Harvard Apparatus, MA, USA) at a rate of 30ml/min. The volume of saline instilled during inflation was increased in increments of 1ml and ranged from 1 to 10ml. Table 1 outlines the volume of saline instilled into each sample. Urethral diameter variability was mitigated by normalising the internal diametric stretch of each sample to the original diameter at the site of inflation. After inflation of the desired amount of saline into the balloon, pressure was recorded using a transducer (SensorTeknics UK). Urethral trauma was then assessed with retrograde urethrography.

Table 1: Volume of saline inflated into the catheter balloon within each urethra sample, the resulting maximum internal diametric strain, and maximum balloon/urethral pressure.

Volume (ml)	Maximum Internal Diametric Strain (%)	Maximum Pressure (kPa)
1 A	25.23	92.07
1 B	3.48	64.80
1 C	16.67	74.28
2 A	21.47	112.37
2 B	43.54	90.83
2 C	14.25	140.87
3 A	21.08	119.32
3 B	6.51	120.63
3 C	14.92	97.58
4 A	26.49	212.27
4 B	38.40	206.25
4 C	19.00	175.87
5 A	21.45	256.44
5 B	46.22	183.55
5 C	12.26	166.42
6 A	136.92	448.13
6 B	30.67	191.12
8 A	90.43	229.96
8 B	65.31	187.62
10 A	107.48	309.01
10 B	102.22	292.51

Retrograde urethrography to assess urethral trauma

The anchoring balloon of the misplaced urethral catheter was deflated and removed prior to retrograde urethrography. A second urethral catheter (also 16 French) was inserted into the urethral meatus and barium sulphide contrast (Rakem, UK) was instilled through the catheter's drainage channel using the syringe pump apparatus. Contrast was instilled and a valve was ligated around the urethra (at the bladder neck proximal to the prostate) to prevent extravasation of contrast from the proximal luminal end. Traumatized urethras were imaged with plane X-ray (Ziehm Vision R Fluoroscope, Ziehm Imaging GmbH, Germany) at 6 angles covering a 90° rotation. Angles were adjusted in increments of 15 degrees to accurately characterize the severity of urethral trauma at each interval. The maximum pressure within the system was recorded using a pressure transducer and the internal diametric strain was calculated by averaging the urethra's luminal diameter proximal and distal to the traumatized site and the maximum luminal diameter at the traumatized site from the images obtained from retrograde urethrography (Figure 1). Contrast

was instilled into a control sample to demonstrate that instillation of contrast medium during urethrography alone did not contribute to any urethral trauma; thus any trauma demonstrated at urethrography was solely as a result of prior balloon expansion in the urethra.

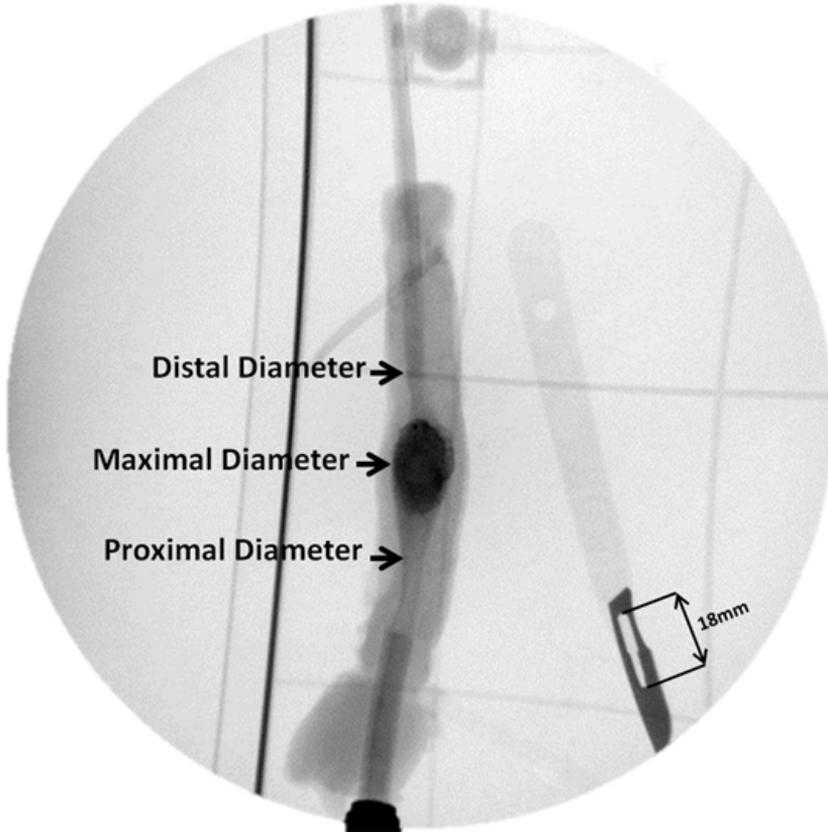


Figure 1: Retrograde urethrogram illustrating location of bulbar urethral diametrical measurements.

Internal urethral diametric strain was calculated by averaging the urethra’s luminal diameter proximal and distal to the traumatised site and the maximum luminal diameter at the traumatised site. Values for urethral diametric strain were calculated by the formula:

$$\text{Diametric Strain} = \Delta d / d$$

where d = change in diameter (Δd) divided by diameter (d)

Note: A scalpel was utilised as a known dimension to scale measurements taken from the image.

Calibrating urethral luminal diameter

The diameter of each urethral lumen was measured using Image J, a freeware image-processing programme that records accurate measurements from imported images (imagej.nih.gov/ij/).

Initially, a scale is set using a reference measurement of a known length from the imported image. In the present study a scalpel, with known measurements, was included in every radiological image and utilised as a reference (Figure 1). Proximal, distal and maximum diameters were measured as described in section 2.1.3.

Overview of Cadaveric Urethra Experimental Design

Transurethral catheters were inflated in the bulbar urethra of 7 fresh male cadavers (age: 21-90 years) at the Royal College of Surgeons in Ireland (RCSI). Ethical approval for cadaver testing was approved by the RCSI's ethics approvals process. Maximum urethral pressure testing with a standard catheter syringe was determined by measuring pressure values (kPa) until opposing resistance pressure generated by the urethra prevented further inflation of the anchoring balloon after depressing the syringe's plunger. A novel 'prototype syringe' with a safety valve was developed to prevent over inflation of the catheter's anchoring balloon in the urethra during the catheterisation process (Figure 2A). During prototype syringe testing, the plunger of the syringe was depressed filling the catheter balloon until sterile water decanted through an activated safety pressure valve. A transducer (General Electric, UK) recorded the pressure reached during each test. A syringe pump (Harvard Apparatus, US) was used to examine the effect of constant flow rate balloon inflation within cadaveric urethras. Figure 2B illustrates the experimental set up.

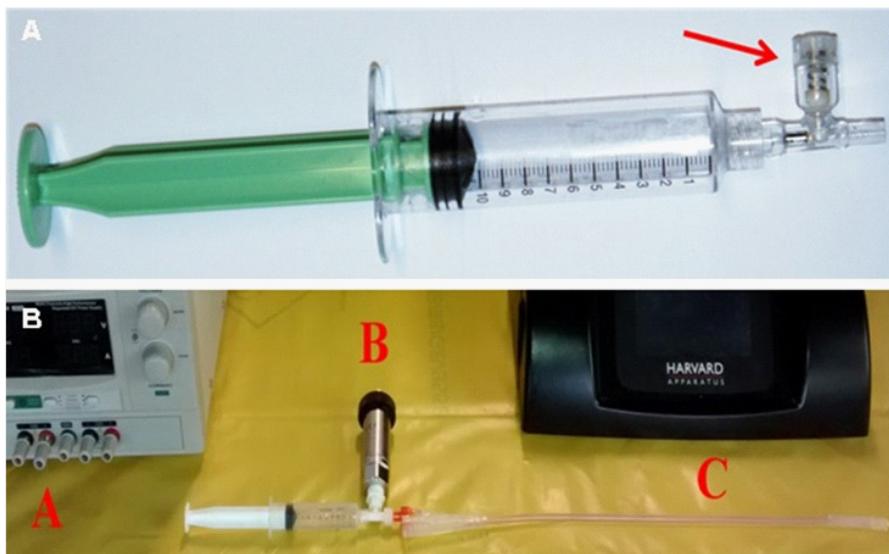


Figure 2: **A:** Prototype syringe used to determine urethral resistance pressure. The safety valve (arrow) is activated at a threshold resistance pressure allowing fluid to vent out of the activated valve. **B:** Experimental set-up comprised of a power supply (A), standard syringe; catheter and pressure transducer system (B) and syringe pump (C). During the testing process, the plunger of the prototype syringe was depressed by each doctor until the saline within the syringe decanted through an activated pressure valve that was connected to a pressure transducer.

Prototype Testing

Three different brands of 16 French silicone transurethral catheters were lubricated and inserted into the bulbar urethra of 7 cadavers by 2 different urology trainees using a standard urethral catheterisation insertion technique. Position within the bulbar urethra was confirmed by palpation. Ten millilitres of sterile water was used to attempt to fill the catheter's anchoring balloon in the urethra. Three units of 'Brand 1' were inserted into 3 cadavers, 2 units of 'Brand 2' were inserted into 2 cadavers and 2 units of 'Brand 3' were inserted into the remaining 2 cadavers. Each urethral catheter was inflated three times by both urology trainees using the prototype syringe. During syringe testing, the plunger of the prototype was depressed by each doctor until water within the syringe decanted through an activated safety pressure valve (switching pressure: 150 kPa) connected to a pressure transducer (Figure 3B) (General Electric, UK). The resistance pressure and volume of sterile water administered into the anchoring balloon were recorded at this point. The testing process was repeated until each trainee had performed 3 urethral catheter inflations to ensure that the safety valve reliably activated during each inflation and to ensure that the brand of catheter did not inhibit the activation process.

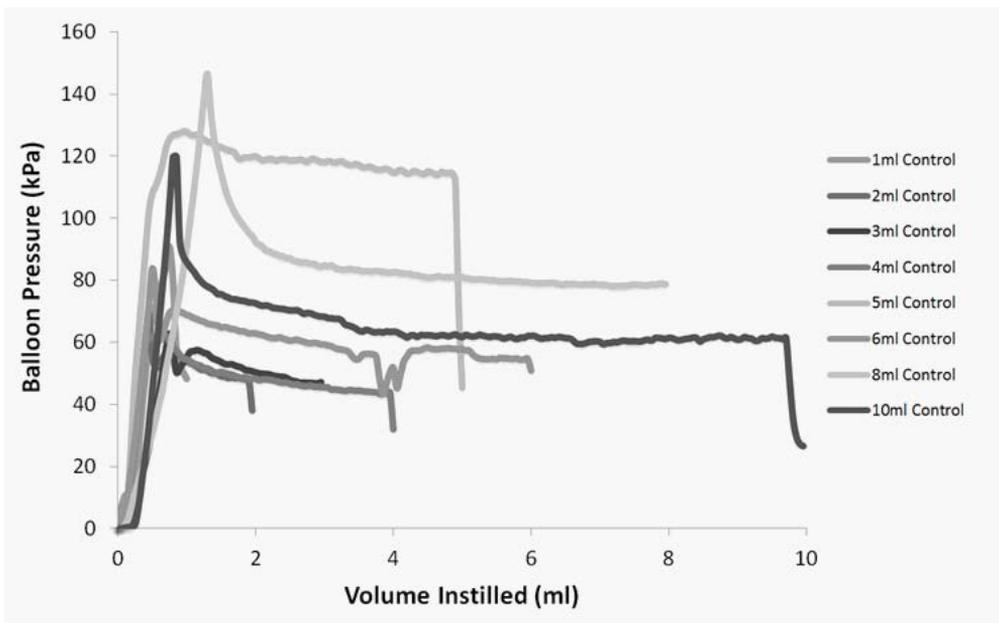


Figure 3: Pressure volume relationships for anchoring balloons of urethral catheters inflated at atmospheric pressure and not inserted into the animal model: i.e. pressure would approximate to the pressure achieved when the catheter balloon is inflated in the urinary bladder (n=10).

Each anchoring balloon is inflated with a graduated volume of saline. The maximum pressure required for inflation ranged from 70-150kPa. The pressure relationships differed for each

catheter due to the volume of fluid instilled but overall there is a unimodal pressure increase followed by a stable sustained pressure pattern. As the anchoring balloon distends the pressure decreases and the balloon material offers less resistance to expansion.

Maximum pressure testing

Following prototype testing, each urethral catheter was inflated one additional time using a standard commercial syringe. The plunger of the standard syringe was depressed until resistance pressure generated by the cadaver urethra prevented further inflation. The pressure (kPa) at this point was recorded as the maximum inflation pressure.

Constant Flow Rate Testing

A 'flow-resistance' technique was designed for the prototype syringe in an effort to control the inflation profile of the catheter and to eliminate the potential for user variability during the inflation process. A urethral catheter was inserted into the bulbar urethra of one cadaver and the anchoring balloon was inflated at a constant flow rate of 30ml/min, initially using the prototype syringe. The inflation process was repeated using a standard syringe and inflation pressure profiles between both syringes were compared.

Statistical analysis

Statistical analysis was performed using Student's t-tests with unequal variances for pairwise comparisons between groups. Differences were considered significant at $p < 0.05$ (SPSS 16.0 for Windows).

RESULTS

Traumatic Catheterisation to Porcine Urethras

Baseline inflation pressures

Pressure volume curves for inflating the catheter's anchoring balloon at atmospheric pressures at a constant flow rate were measured (Figure 3, $n=10$). These curves serve as controls to compare with anchoring balloons inflated in porcine urethras: they approximate to the pressure volume behaviour of the catheter's anchoring balloon within the urinary bladder. Widespread variations in the anchoring balloons' material properties were noted in response to increasing volumes during the inflation process (range: 60-130kPa after instilling 1ml of saline). Initially, a large increase in pressure was required to commence the distension process for the catheter's anchoring balloon. After this initial distension pressure was achieved, the pressure relationships differed for each catheter due to the volume of fluid instilled but overall there is a unimodal pressure increase followed by a stable sustained pressure pattern. As the anchoring balloon distends the pressure decreases and the balloon material offers less resistance to expansion.

Mitigating urethral diameter variability

The variable internal luminal diameter between porcine urethras was also measured (Figure 4). In sample A (red line), instillation of approximately 3ml of saline was required before contact occurred between porcine urethral tissue and the catheter's anchoring balloon. However, only approximately 1ml of saline was required in sample B (green line). Consequently, urethral rupture occurred after infusing approximately 6ml of saline for sample A compared to approximately 5ml in sample B. Variations in internal urethral diameter prevented a reliable correlation between the volume of infused fluid that is required for urethral rupture. Table 1 correlates the volume of infused fluid with urethral diametric strain values obtained from retrograde urethrography and the maximum recorded inflation pressure. Again, the volume of fluid infused correlated poorly with internal diametric strain due to urethral diameter variability. For example, infusing 6ml of saline into the anchoring balloon resulted in 136.92% strain in one urethra compared to 30.67% strain in another sample at an identical volume. However, correlating urethral trauma with internal urethral diametric strain mitigated internal urethral diameter variability and produced results representative of the degree of urethral trauma required to cause rupture (Figure 5).

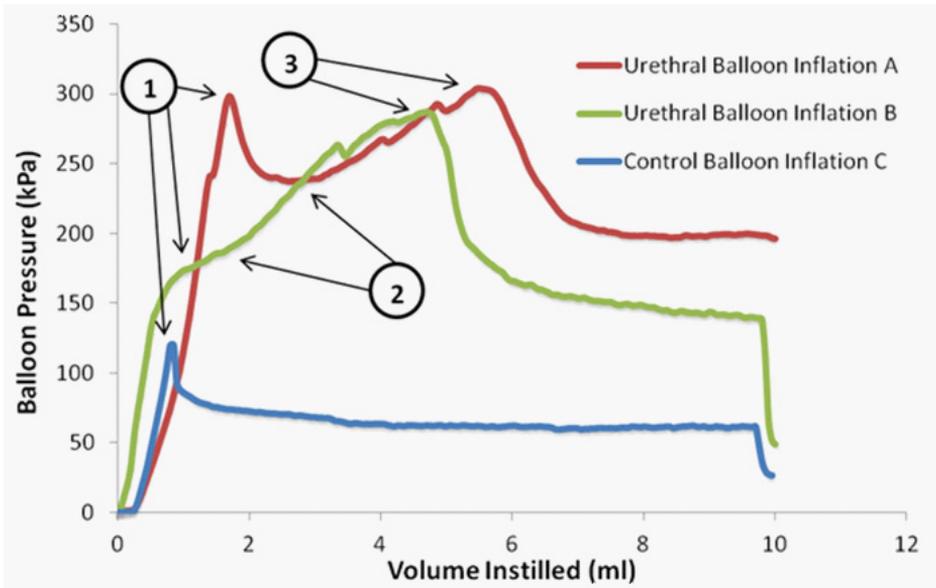


Figure 4: The pressure volume profiles for inflating the anchoring balloon in the porcine urethra (n=2 [A+B]) compared to a control inflation at atmospheric pressure (C) (Volume=10ml).

Initially, a large pressure increase occurred in all 3 samples as the balloon distension process commenced (1). The pressure volume relationships then varied for each sample. In the control sample, pressure decreased after the initial distension pressure of 120kPa. In sample A, an initial peak pressure of 300kPa was required to overcome the balloon's material properties before

pressure decreased. Pressure then decreased to 250kPa as 2ml of saline was instilled. After this instillation the pressure increased as the balloon contacted the urethral lumen and provided resistance to balloon expansion (2). Urethral resistance pressure continued to increase to 300kPa as continuous inflation to 6ml occurred. Thereafter, inflation pressure decreased acutely indicating urethral rupture (3).

In sample B, the balloon's material properties were overcome at 160kPa (1) and the rate of change of pressure with volume (i.e. slope of the line) changed indicating that the balloon had contacted the urethral lumen (2). Again, the maximum inflation pressure increased to 280kPa as continuous instillation occurred. The resistance pressure dropped after 5ml was instilled indicating urethral rupture (3).

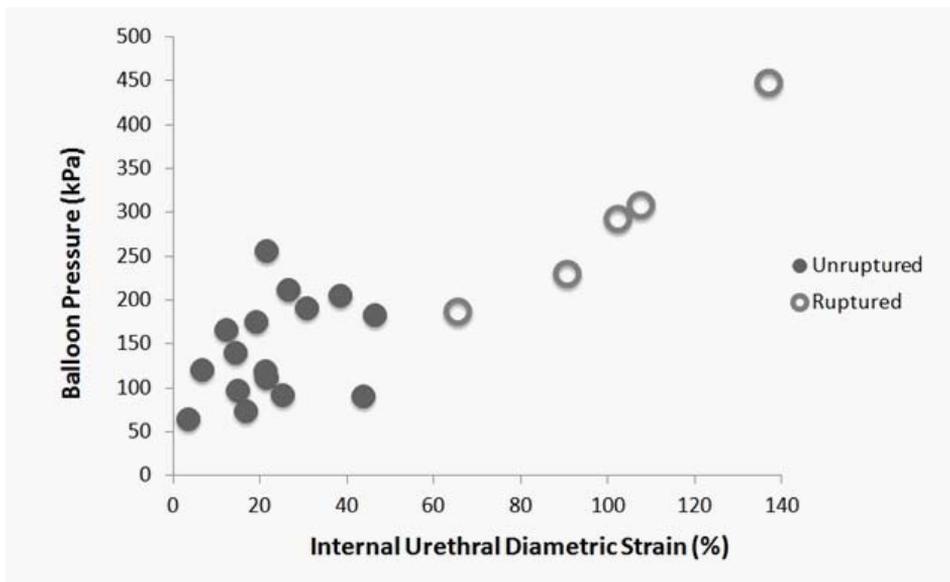


Figure 5: Relationship between maximum catheter balloon/ urethral pressure values and internal diametric strain recorded for each urethral sample tested (n=21).

The light grey markers indicate ruptured urethral samples and the dark grey markers indicate unruptured samples. The figure clearly demonstrates a safety cut-off of 40% internal urethral diametric strain and/or a maximum balloon pressure cut-off of 150kPa prior to urethral rupture.

Internal diametric strain and urethral rupture

The internal diametric strain induced on each urethral specimen due to the inflation process was investigated (Figure 5). Urethral rupture consistently occurred at an internal diametric strain >40%. The maximum pressure recorded within the transurethral catheter's anchoring balloon during the inflation procedure is also represented. Findings demonstrated no evidence of urethral trauma below an inflation pressure of 150kPa. The lowest recorded maximum inflation pressure required for urethral rupture was 187kPa.

Traumatic Catheterisation to Cadaveric Urethras

Maximum pressure testing with standard syringe

Maximum pressure profiles within the 7 cadaveric urethras using a standard inflation syringe are shown (Figure 6). The maximum inflation pressure was 545.09 ± 203.28 kPa for doctor 1 and 472.21 ± 260.71 kPa for doctor 2. There was no statistical difference between operators, $p=0.57$. The maximum inflation pressure was significantly greater with a standard syringe compared to the prototype syringe that activated its safety valve at the urethra's threshold resistance pressure (504.6 ± 255.74 kPa versus 153 ± 3 kPa respectively, $p<0.001$). A comparative assessment of maximum inflation pressures for a standard syringe in each cadaveric urethra is demonstrated in Table 2. The average volume of sterile water infused with a standard syringe was 3 ± 0.76 ml and 2.35 ± 0.38 for doctor 1 and 2 respectively ($p=0.65$). The average volume of sterile water infused was 2.68 ± 0.57 ml with a standard syringe. Activation of the prototype syringe's safety valve occurred at 1.32 ± 0.47 ml indicating urethral resistance at these volumes. The difference in volume infused into both syringe types was statistically significant ($p=0.0004$).

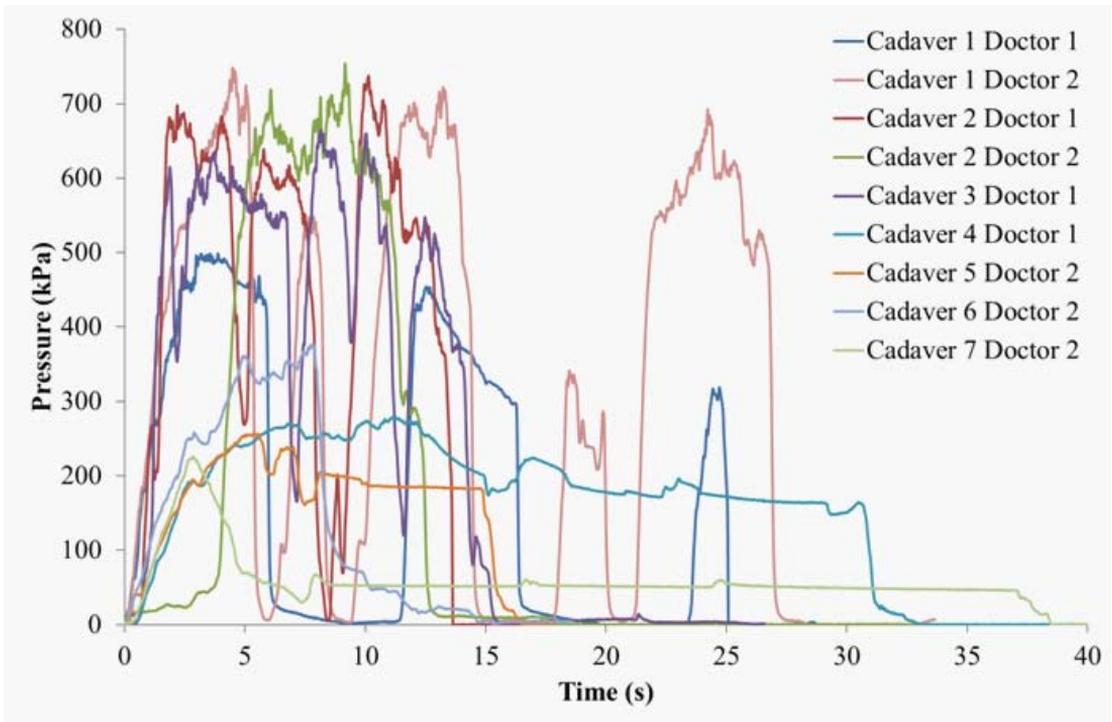


Figure 6: Pressure profiles during inflation of each catheter within the bulbar urethra of cadavers using a standard syringe by 2 doctors (n=7). There was no significant interoperator variance ($p=0.57$). The maximum inflation pressure achieved was 737 kPa (range: 279- 737 kPa).

Table 2: Maximum inflation pressures for a standard syringe and prototype syringe in each cadaveric urethra.

Cadaver	Maximum Pressure (kPa) Standard Syringe	Maximum Pressure (kPa) Prototype Syringe
	1	498.8
2	737.34	159.39
3	664.74	150.40
4	279.47	153.99
5	552.34	152.64
6	589.07	152.61
7	493.88	151.48
Mean	545.09	153.13

Maximum urethral pressure testing was measured (kPa) until resistance pressure generated by the urethra prevented further inflation of the anchoring balloon after depressing the syringe's plunger.

Pressure profiles with prototype safety valve syringe

The pressure profiles during the urethral catheter inflation process in the cadaveric urethra using a prototype safety syringe are illustrated (Figure 7: A-G). The average maximum 'threshold' inflation pressure (before sterile water decanted through the safety pressure valve) was 153.13 ± 2.99 kPa for doctor 1 and 153.91 ± 2.81 kPa for doctor 2. There was no statistical difference between the 2 doctors ($p=0.9$). Mean volume of water infused required to activate the safety valve was 1.35 ± 0.44 ml and 1.29 ± 0.46 ml for doctor 1 and 2 respectively. Again there was no statistical difference between the operators ($p=0.8$).

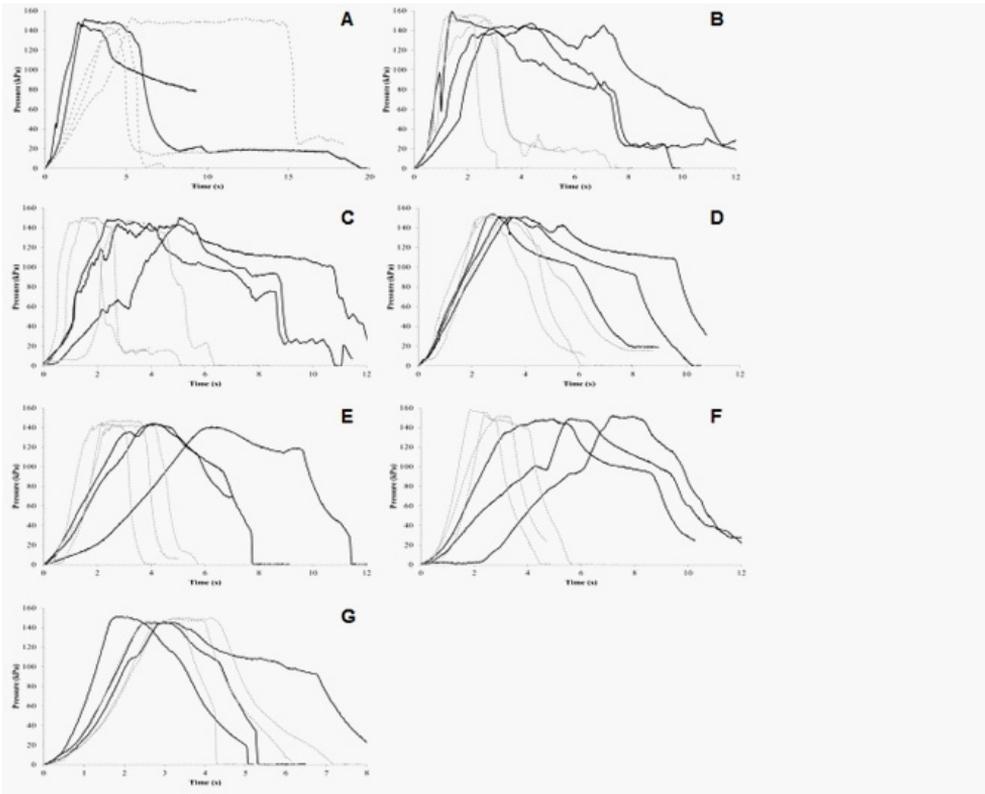


Figure 7: Pressure profiles during inflation of each catheter within the bulbar urethra of 7 cadavers (A-G) using the prototype syringe. The black lines denote the inflations performed by Doctor 1 and the grey dashed lines denote the inflations performed by Doctor 2. There was no significant difference in the volume of infused water for activating the safety valve between both doctors ($p=0.8$). The maximum inflation pressure achieved was 159 kPa (range: 150-159 kPa).

All urethras behaved identically regardless of the operator. As the inflation process commenced there was a universal (acute or gradual) rise in pressure which was operator dependent. The threshold/ maximum inflation pressure was not operator dependent and remained constant for each inflation. Once the maximum pressure was reached the pressure decreased as each operator discontinued the inflation process.

Pressure profile at constant flow rate

The pressure profile of a catheter balloon inflated in the urethra of a fresh cadaver using a syringe pump at a constant flow rate of 30 ml/min is shown (Figure 8). The testing was performed with a prototype safety syringe (grey line) and standard syringe (black line). Activation of the prototype's safety threshold pressure valve occurred at 150kPa. In contrast, the standard syringe achieved an inflation pressure of 450kPa before the experimental protocol was discontinued. This pressure difference was statistically significant ($p<0.001$).

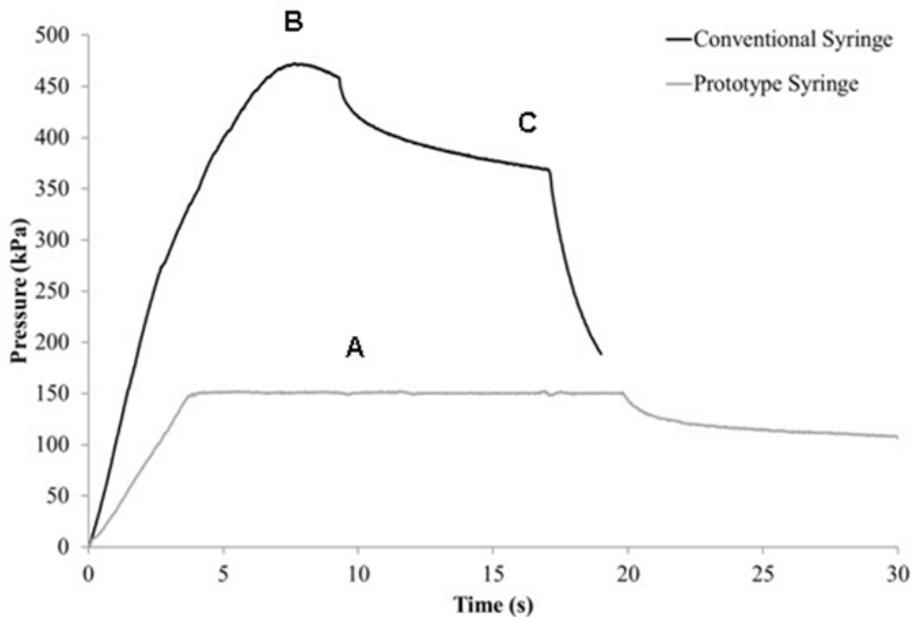


Figure 8: Pressure profiles of a catheter inflated in a cadaveric urethra using a ‘flow-resistance’ technique with a syringe pump at an infusion rate of 30 ml/min. Testing was performed with a standard syringe (black line) and prototype syringe (grey line). The grey line clearly shows the safety of the novel prototype safety syringe as the maximum inflation pressure was limited to a safe plateau pressure of 150 kPa up to 20 seconds (when the inflation process had been completed [A]). In contrast, a flow resistance approach with a standard syringe achieved an inflation pressure of 450 kPa (B). The inflation pressure decreased at approximately 8 seconds indicating that the urethra’s threshold pressure had been breached and pressure continued to decrease until the inflation process was discontinued at approximately 16 seconds (C).

DISCUSSION

Millions of UCs are inserted annually on a global basis and urethral injuries caused by inadvertent inflation of the anchoring balloon in the urethra represent a potentially preventable source of iatrogenic injury in hospitalised patients [6]. The incidence of iatrogenic urethral trauma during UC is approximately 4% but may be under-reported due to inadequate documentation and auditing among healthcare professionals managing this patient cohort [6]. Iatrogenic complications associated with UC have decreased in recent years due to training programmes provided by senior healthcare professionals [11]. Medical students and junior doctors are supervised when performing UC and a sufficient amount of catheterisations may be required before complete independence is gained [13]. Moreover, the anchoring balloon is still inadvertently inflated in the urethra in approximately 3% of hospitalised inpatients with resultant urethral trauma [5]. In

the present chapter we investigated the strain threshold for urethral rupture for a transurethral catheter. Our primary findings are that urethral rupture occurs at an internal urethral diametric strain $>40\%$ and/or a maximum inflation pressure $>150\text{kPa}$.

Iatrogenic urethral injury from a misplaced catheter is associated with considerable morbidity with incidences of urinary tract infection (UTI), cystitis, and septicaemia after traumatic UC being 12.72%, 3.45%, and 1.90% respectively [14]. These iatrogenic complications are associated with considerable costs, financial penalties and longer inpatient stays as demonstrated by Chavez et al. [14] where the costs of treating UTIs, cystitis and septicaemia post traumatic UC were \$11,052, \$484, and \$48,935 respectively on an annual basis [14]. Furthermore, corrective surgical procedures for managing traumatic UC ranged from \$8,000 to \$17,000 per patient [14]. Fenton et al. [4] demonstrated that traumatic urethral catheterisation is responsible for approximately 30% of urethral strictures that are referred to urologists. High incidences of procedural associated complications and their mounting costs highlight a potential opportunity among researchers for designing a safety mechanism that optimises the UC process.

A safer urethral catheter would be of particular benefit to junior doctors and community healthcare professionals. Manalo et al. [13] assessed the knowledge of 225 medical interns and identified significant deficits in the knowledge of correctly performing catheterisation, identifying urethral injury and the short-term and long-term risks associated with urethral injury. The authors emphasise the importance of developing a safer process for patients that are being catheterised by inexperienced healthcare professionals. To this end it is important to understand the correlation between urethral trauma and distension of urethral tissue as such knowledge can be used to develop technologies to eliminate inadvertent inflation of the balloon in the urethra.

Our most notable finding is that urethral rupture occurs at an internal diametric strain $>40\%$ (i.e. misplaced anchoring balloon inflation will cause urethral rupture when the internal urethral diameter is increased $>40\%$ of its original diameter). Diametric strain measures the change in luminal diameter due to expansion of the anchoring balloon. It is calculated as the change in diameter divided by the original diameter and is consequently expressed as a percentage (%). In addition to this strain threshold, we have also demonstrated that an anchoring balloon inflation pressure $<150\text{kPa}$ reliably prevents urethral rupture as rupture only occurred at pressures exceeding 150kPa .

The present chapter also demonstrates that the urethra's threshold resistance pressure is at least 3 times lower than the maximum inflation pressure that can be achieved when inflating the catheter's anchoring balloon with a standard syringe using a constant flow rate technique. It is notable that an inflation pressure $>700\text{ kPa}$ can be generated during the balloon inflation process with a standard syringe. This finding highlights the potential danger inherent with current catheter design such that this pressure can be generated but remain unknown by an inexperienced operator. Designing a safer UC with lower maximal threshold inflation pressures

could therefore significantly decrease the potential for iatrogenic urethral trauma during the catheterisation process. There are a number of additional findings demonstrated herein. We have shown that the maximum inflation pressure generated by inflating the anchoring balloon of a standard urethral catheter within the bulbar urethra is at least 3 times greater than the maximal inflation threshold pressures (i.e. >150kPa) for urethral trauma. We have also demonstrated that user variability during the balloon inflation process can be mitigated by utilising a flow-resistance inflation technique. Regulating the inflation rate eliminates operator variability and permits sufficient time for the safety valve to activate if the anchoring balloon has been misplaced. Finally, we have demonstrated the reliability of the safety-pressure valve as it activated once a predefined threshold pressure was breached in each cadaver model for both operators and for every brand of catheter assessed.

The necessity for a modified safely designed UC has been explored. Wu et al. [15] compared anchoring balloon pressures between the urethra and bladder in cadaver models. Filling the anchoring balloon within the urethra causes at least a 2-fold increase in pressure compared to filling the balloon within the urinary bladder. The authors suggest differences in balloon pressures between the urethra and bladder in conjunction with the amount of force (N) required to remove the anchoring balloon from the bladder should be investigated for designing a safer urethral catheter [15]. That promising data was limited in that the pressure threshold after inflating the balloon in the urethra was not investigated. Which was investigated in the current study where we determined an excess of 150kPa is sufficient to precipitate urethral trauma during the inflation process. The addition of a controlled flow rate in this present study generated a more steady inflation profile as evident from the initial slope of the graph in Figure 8. An increase in the duration to peak pressure will permit time for the pressure valve to activate if the threshold pressure generated within the urethra is breached.

A potential limitation to our study is that fresh cadaveric urethra pressure profiles may not be truly representative of *in vivo* situations due to loss of elasticity/ 'stiffening' effects of rigor-mortis. However, our study demonstrates a significant trend in 'fold-differences' between urethral threshold pressures with a prototype syringe and maximum inflation pressures with a standard catheter syringe that are likely to remain constant *in vivo*.

CONCLUSION

Inadvertent inflation of a urinary catheter's anchoring balloon in the urethra is a cause of morbidity in clinical practice. The findings presented herein have a number of implications that may be relevant for clinical practice. Significant variations in user variability demonstrate the potential for urethral injury during UC as clinicians can easily breach a urethral threshold rupture pressure of 150kPa. A novel safety syringe with a predetermined flow-rate and lower threshold inflation pressure could be considered for designing a safer transurethral catheter system than presently commercially available.

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