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Ureteral access sheath insertion forces: implications for design and training

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Abstract Ureteral access sheaths (UAS) vary in their ability to resist buckling forces. We evaluated the forces utilized during simulated placement of a UAS. A model UAS (21F OD, 9F ID) was made of polyolefin material. Mounted to the distal tip of the catheter was a spring (7/32″ × 1″ × 0.28″ wire thickness). When simulating catheter insertion, the spring was placed in contact with an Extech™ 475040 Digital Force Gauge to measure the peak compression force (Newton). Three repetitions of the task were performed by practicing urologists ($n = 8$) and urology residents ($n = 5$). Participants were instructed to "Push until you feel a level of resistance that would make you stop if you were putting in a real ureteral access sheath". Urologists applied a maximum force of 6.55 ± 0.45 N while urology residents applied a maximum force of 4.84 ± 0.64 N. There was a significant difference in the forces applied between the two groups ($P = 0.035$). No significant difference in the variance (ranges or spread) of forces applied by the urologists and residents were identified ($P = 0.11$). One-way analysis of variance demonstrated no differences in the force applied between the first, second and third attempt ($P = 0.80$). Quantifying the insertion forces used during placement of a UAS will facilitate the design of UAS and provides information critical to the design of ureteroscopic simulators. Understanding the range of forces used by experienced urologists will help establish competency parameters for professionals in training.

Keywords Ureteral access sheath · Flexible ureteroscopy · Insertion forces · Training model · Surgery simulators

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Introduction

Technological advancements have expanded the application of flexible ureteroscopy in the minimally invasive management of complex upper urinary tract abnormalities. However, ureteral access with flexible ureteroscopes remains a challenge for the urologist. For this reason, new ureteral access sheaths (UAS) were designed to facilitate the flexible ureteroscope placement and stone extraction. Ureteral access sheath leads to safe and easy ureteral entry and re-entry, decreased operative time, cost and patient discomfort and increased success rates [1]. The first UAS were described by Takayasu and Aso [2]; however, despite significant improvements, difficulties in placement and positioning in the ureter have been reported in up to 16% of patients [3].

Understanding the forces required for placement of a UAS may facilitate the design of future sheaths so as to minimize difficulties in positioning related to buckling. Defining these forces may also allow for the development of training competencies that can be incorporated into simulators and residency training. This study evaluates the forces utilized during simulated placement of a UAS, and correlates the findings with possible future clinical improvements.

Methods

A 21 Fr catheter made of polyolefin material, with a 9 Fr inner diameter was utilized for our UAS. The size and material were selected to resist buckling at up to 10 N of force, so that the catheter would not buckle before the maximum subjective force was reached. Mounted to the distal tip of the catheter was a spring (7/32″ × 1″ × 0.28″ wire thickness).

The catheter was marked to ensure that all participants held the catheter in the same position. During clinical insertion of the UAS, the sheath is commonly held approximately 5 cm from the urethral meatus as it is advanced. Therefore, the catheter was marked at 5 cm to ensure that no discrepancy would be made during the simulated insertion of the sheath.

When simulating UAS insertion, the spring was placed in contact with a Extech™ 475040 Digital Force Gauge (Fig. 1). The participants were instructed to advance the sheath onto the force gauge as if they were inserting a UAS. The tip of the force gauge engaged the tip of the sheath to stabilize it, similar to the axial stabilization that would be provided were a wire placed through the lumen of the sheath.

Eight urologists, and five urology residents were asked to apply the maximum amount of force that they would use in placing a UAS. None of the attending urologists were fellowship trained in endourology, though they had on average 9.3 ± 4.9 years of experience with UAS and performed on average 55 ureteral sheath placements per year. The urology residents tested were in their second to fourth year of urology residency training, such that they had each had a minimum of five clinical applications of the UAS (range 5–100).

The participants were told to “Push until you feel a level of resistance that would make you stop if you were putting in a real ureteral access sheath”. This instruction was reaffirmed before every new attempt, to ensure that the participants reached the maximum pressure they would normally utilize during the sheath insertion. All participants performed the task three times.

The testing was performed at ambient room temperature, similar to those conditions one would expect in the operating room. As we were testing the subjective force that an urologist would consider safe to insert a sheath, the hydrophilic coating was not activated as this would not alter that force, but only decrease the likelihood that that force would be reached.

The peak compression force (Newton units) applied by the study participant was measured using the Digital Force Gauge. Statistical comparison of forces between the groups was performed using the *T* test, with a P value <0.05 defining significance. Comparison of variance in force between the two groups was performed using the O’Brien test of homogeneity of variance. Variance in force between attempts was evaluated using the one-way analysis of variance.

Results

Urologists applied a maximum force of 6.55 ± 0.45 N while urology residents applied a maximum force of 4.84 ± 0.64 N (Fig. 2). There was a significant difference in the forces applied between the two groups ($P = 0.035$).

The sheath did not buckle during any of the simulated insertions. No significant differences in the variance (ranges or spread) of forces applied by the urologists and residents were identified ($P = 0.11$). One-way analysis of variance demonstrated no differences in the force applied between the first, second and third attempt ($P = 0.80$).

Discussion

Cannulation of the ureteral orifice with a flexible ureteroscope poses a challenge; even when backloaded over a guide wire on occasion the scope will buckle. The UAS overcomes these difficulties, allowing repeated ureteroscope

Fig. 1 Simulation of ureteral access sheath insertion

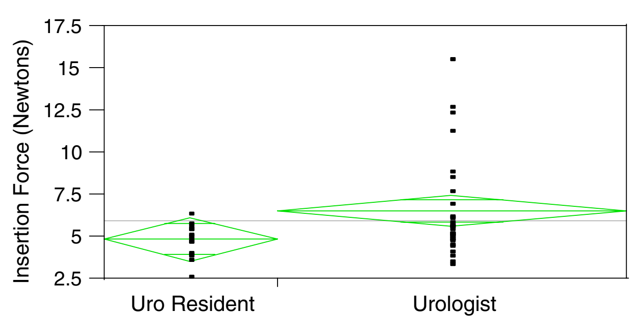

Fig. 2 Insertion forces (Newtons) for urology residents and urology faculty

introduction, decreasing operative time and costs, optimizing success and minimizing morbidity [4]. In addition, the use of UAS may decrease the frequency of ureteroscope damage [5].

To be most effective at minimizing intrarenal pressures, it has been recommended to position the sheath as close as possible to the target stone, and for intrarenal calculi, positioning at the ureteropelvic junction has been advocated [6]. However, a common criticism has been the inability to place the sheath adequately into the ureter, jeopardizing the procedure by increasing the risks of ureteral injuries and/or sheath buckling. Abrahams et al. [7] reported that, despite new UAS with lubricous coating, the risk of ureteral damage prevailed over the benefits it provided. They explained that the placement of UAS applies a substantial shear force to the ureter and also gives the surgeon a false sense of security.

It has been proposed that advancing the UAS inside the ureter is dependent on the coefficient of friction of the sheath surface and the axial force that results in the buckling of the sheath at the ureteral orifice [8]. It means that, to insert a UAS properly, the surgeon has to apply a gentle pressure not higher than the axial resistance of the sheath, otherwise it buckles. At the same time, the force has to be enough to smoothly progress up the ureter, but not enough to cause ureteral injury.

Therefore, the ability to appreciate the upper limits of force applied during UAS placement is the cornerstone of a safe and effective procedure, and is currently acquired by trial and error. To date, there is no training model that reproduces with efficiency the amount of force utilized during endourological procedures, despite newly developed endourological simulators [9].

This study evaluated the forces utilized during simulated placement of a UAS. We demonstrated a significant difference in the total force applied by urologists, (higher forces applied) than by urology residents, suggesting different levels of surgical competency. The amount of force utilized to insert a ureteral sheath was measured with accuracy by the model, and was reproducible for each individual tested. This information might open the door that separates empirically acquired knowledge from standardized training competencies.

The ranges of force applied (4–6 N) correlate with the forces we have previously determined were sufficient to result in ureteral perforation (4.7–7.6 N) [10]. Commercially available UAS buckle at a range of 3–6 N, thereby providing some inherent safety to the user [8].

Incorporation of forces responsible for ureteral avulsion or ureteric perforation into training models may help decrease the risk of iatrogenic injury in the future. It may be possible to envision other "smart" medical devices, such as urologic guide wires, that buckle or send a signal to the surgeon as the maximum insertion force is approached.

Conclusions

Experienced endourologists exert significantly higher forces during UAS insertion than trainees. The model utilized in this study to evaluate the forces exerted could be utilized to facilitate training in the future.

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