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Surgical Force: Initial Study and Clinical Implications in the Assessment of Ureteral Access Sheath Induced Injury

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Surgical Force: Initial Study and Clinical Implications in the Assessment of Ureteral Access Sheath Induced Injury

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Abstract:	PURPOSE: Ureteral access sheaths (UAS) pose the risk of severe ureteral injury. Our prior studies revealed forces ≤6 Newtons (N) prevent ureteral injury. Accordingly, we sought to define the force urologists and residents-in-training typically use when placing a UAS. MATERIALS & METHODS: Among urologists and urology residents attending two annual urological conferences in 2022, 121 individuals were recruited for the study. Participants inserted 12Fr, 14Fr, and 16Fr ureteral access sheaths into a male genitourinary model containing a concealed force sensor; they also provided demographic information. Analysis was completed using t-tests and Chi-square tests to identify group differences when passing a 16Fr sheath UAS. Participant traits associated with surpassing or remaining below a minimal force threshold were also explored via polychotomous logistic regression.

RESULTS: Participant force distributions were: ≤4N (29%), >6N (45%), and >8N (32%). More years of practice were significantly associated with exerting >6N relative to forces between 4-6N; results for >8N relative to 4N-8N were similar. Compared to high-volume ureteroscopists (those performing >20 ureteroscopies/month), physicians performing ≤20 ureteroscopies/month were significantly less likely to exert forces ≤4N (p=0.017 and p=0.041). Of those surpassing 6N and 8N, 15% and 18% respectively were high-volume ureteroscopists.

CONCLUSIONS: Despite years of practice or volume of monthly ureteroscopic cases performed, most urologists failed to pass 16Fr access sheaths within the ideal range of 4N-6N (74% of participants) or within a predefined safe range of 4N-8N (61% of participants).

Abbreviations Used

UAS = URETERAL ACCESS SHEATH
N = NEWTONS
PULS = POST-URETEROSCOPIC LESION SCALE
URS = URETEROSCOPY
TISG = TRAXER INJURY SCALE GRADE
CROES = CLINICAL RESEARCH OFFICE OF THE ENDOUROLOGICAL SOCIETY
UCI = UNIVERSITY OF CALIFORNIA, IRVINE
AUA = AMERICAN UROLOGICAL ASSOCIATION
WCET = WORLD CONGRESS OF ENDOUROLOGY AND TECHNOLOGY
PLR = POLYCHOTOMOUS LOGISTIC REGRESSION

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30 December 2023

Dear Dr. Sundaram,

We would like to express our sincere gratitude to the reviewers for their valuable comments and suggestions on our manuscript entitled "*Surgical Force: Initial Study and Clinical Implications in the Assessment of Ureteral Access Sheath Induced Injury*". We appreciate the time and effort invested in evaluating our work. We greatly appreciate the opportunity to enhance the quality of our manuscript and hope that it is now suitable for publication in the Journal of Endourology.

Thank you for your time and consideration.

Sincerely,

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Reviewer: 1

Comments to the Author
An experimental study examining forces produced by passage of ureteral access sheaths. The paper provides new knowledge in this area and is part of the progression along the pathway to development of a commercial force sensing ureteral access sheath.

Do they have any theories as to why the more experienced and busier ureteroscopists seemed more likely to exert higher {and according to their previous papers even "dangerous"} forces. It seems a bit counterintuitive to surgical judgement and experience that this would be the case. Perhaps the experienced just get more cavalier over time and the lees experienced are more tentative -- but it seems like a strange phenomenon.

Reviewer 1, Comment 1: Thank you for your insightful comment about URS experience and exerted forces. For the purposes of this investigation, we define URS "experience" among our participants as URS/month volume, as it is difficult to truly define overall experience (e.g., years of practice, volume of procedures, age, and specialty specific responsibilities). Overall, it is possible, as the reviewer suggests, that experienced practitioners may have developed a sense of confidence that leads to the application of greater force. Conversely, less experienced ureteroscopists may exercise more caution and thus apply less force as they are more tentative and possibly more conscious of the potential for harm. We elected to not include any comments to this effect in the manuscript given the absence of any supportive data.

We've also gone through the manuscript and changed the word "experienced" to better reflect what we mean.

Its not the main thrust of the current paper but looking forward they might want to comment that their suggested "safe" forces apply to a normal ureter under normal circumstances. What I mean by this is that there will likely be a wider range of what may or not be safe. Reimplanted ureters, diversions, transplants, prior radiation, adjacent pelvic surgery eg hysterectomy, previous stenting might all affect ureteral compliance and thus the safe vs not safe forces.

Reviewer 1, Comment 2: This is an excellent point. There are certainly factors that would affect the safety and efficacy of ureteral instrumentation. For example, in our earlier work (Tapiero et al. 2021) we compared patients with prior ureteroscopic surgery and found that ureteral stents and tamsulosin led to a higher incidence of successful atraumatic 16Fr UAS insertion. Overall, the surgical thresholds referenced in our study apply to a normal ureter under normal circumstances. Reimplanted ureters, ureters involved with a diversion, transplant ureters, or ureters that had been previously irradiated were not included in the prior study.

We have now clarified that these force thresholds are based on normal ureters under normal circumstances in the manuscript in the Introduction section.

Lines 81-83:

"Subsequent clinical studies revealed a deployment force of ≤6N resulted in no PULS 3 lesions among 200 patients (210 anatomically normal ureters without prior radiation, reimplantation, reconstruction, or transplantation), despite successful passage of a 16Fr UAS in 61% of patients."

Tapiero S, Kaler KS, Jiang P, et al. Determining the Safety Threshold for the Passage of a Ureteral Access Sheath in Clinical Practice Using a Purpose-Built Force Sensor. J Urol. 2021;206(2):364-372. doi:10.1097/JU.0000000000001719

Reviewer: 2

Comments to the Author

Overall interesting paper regarding the use of ureteral access sheath and the bench model for assessing force. The manuscript is well written with no major concerns.

My main question is to distinguish or beak down participants by regular UAS use and not, i.e. the most experienced quartile/quintiles (highest volume surgeons and highest percentage of UAS users) vs middle group vs novice.

Reviewer 2, Comment 1: We appreciate the reviewer's comment and have further assessed as a group those individuals who had the highest % usage of UAS *AND* were also in the >20 procedures/month group. Upon analyzing the cohort of participants employing ureteral access sheaths (UAS) into their regular clinical practice and stratifying them based on their caseload of flexible ureteroscopies performed per month, we found that high volume surgeons (>20 URS/month) tended to apply less force than low volume surgeons (<10 and 10-20 URS/month) with a 16Fr UAS. An analysis done for those who reported not using the UAS was found to be statistically inconclusive.

Average calibrated maximum force (95% confidence intervals) for the cohort of participant who reported using UAS as stratified by the caseload per month.

Ureteral access sheath size (Fr)	Low volume of URS (<10/month)	Intermediate volume of URS (10-20/month)	High volume of URS (>20/month)
16 Fr	8.37 (6.53 – 10.21)	6.84 (5.01 – 8.67)	5.81 (3.88 – 7.74)

Further, it would be useful to know what size of UAS they commonly deploy. Like are the novice and no UAS participants more cautious then the high volume 12 or 14F UAS users as revealed in their survey?

Reviewer 2, Comment 2: When filling out the survey, if participants indicated that they did in fact use a UAS, they were further instructed to select the most common UAS they use. Among these participants, the most common UAS types were 12Fr and 14Fr. The no UAS participants would not come into play here as they are NOT using a UAS.

This is discussed in the Results section Lines 144-146 "Among these 88 participants, a 10Fr, 12Fr, 14Fr, and 16Fr UAS was employed in their own clinical practice 17%, 65%, 31%, and 3% of the time, respectively."

URS/month	10Fr	12Fr	14Fr	16Fr
<10	6	32	12	1
10-20	8	25	15	1
>20	4	20	11	2

Further, participants passed different sized UAS (12, 14, 16) what was the result of size differences (supposedly a smaller UAS would results on less shear forces the majority of the time in a set sized outer tube, i.e. controlling for a set size of a ureter a larger UAS will results in more sheath forces.

Reviewer 2, Comment 3: The reviewer's comment is well taken. The model was created such that the 12Fr and 14Fr size access sheath would pass with less than 6N of force; only for the

16Fr UAS was there narrowing such that it would not pass regardless of the force applied. This was done in order to determine the maximum amount of force that each participant would feel comfortable exerting prior to abandoning passage.

Did a 12F UAS have the same percentage of >8N passes vs. 16F UAS?

Reviewer 2, Comment 4: No, as the model was designed such that neither the 12Fr nor 14Fr UAS would require more than **6N** to pass.

What brand of UAS was used and what type of wire?

Reviewer 2, Comment 5: The UAS used in the study were all obtained from Cook Medical Inc. The guidewire used was a 0.035 Amplatz superstiff guidewire from Cook Medical Inc.

We have clarified in the Materials and Methods section.
Lines 97-99:
"A 0.035in. Amplatz Super Stiff™ (Cook® Group, Bloomington, IN, USA) guidewire passed per urethra was anchored to the model's posterior wall."

Lines 117-118: "They received instructions to place three Cook Medical Inc. Flexor® UAS (12Fr, 14Fr, 16Fr) sequentially…"

What ensured the wires didn't bend after 30 passes of a UAS etc to ensure integrity of the model?

Reviewer 2, Comment 6: Each participant was carefully observed during passage of each of the three UAS. The model worked well throughout the entire period of testing at both the AUA and WCE without any kinking of the guidewire as evidenced by the smooth passage of the 12Fr and 14Fr UAS in each trial. Furthermore, the guidewire and inner working components of the model was inspected at regular intervals to ensure that there were no kinks or degradation.

The paper does raise the question whether in the real-world human ureters can take slightly higher forces that experienced urologists felt safe using, in that you figure they do this so frequently and are not injuring ureters at high rates (hopefully).

Reviewer 2, Comment 7: We agree with the reviewer's comment. We previously conducted a study in 200 patients with a clinically validated force sensor and determined that at greater than 8N, patients were at risk of high-grade ureteral injuries (*Tapiero S, Kaler KS, Jiang P, et al. Determining the Safety Threshold for the Passage of a Ureteral Access Sheath in Clinical Practice Using a Purpose-Built Force Sensor. J Urol. 2021;206(2):364-372. doi:10.1097/JU.0000000000001719*). That being said, a limitation of the present study is that this was a simulation model, and the participants may be more inclined to apply a higher force when there is no human consequence.

Were participants told they exerted high levels of force?

Reviewer 2, Comment 8: No. The participants were completely blinded to the measurement of the forces exerted.

"A preliminary survey of our UCI URS database 227 (>750 ureteroscopies) revealed that strictures are rare among PULS 0, 1, and 2 patients at 0%" although noteworthy and from a trustworthy source, without some form a peer reviewed reference even abstract form this could be propagated into future articles without proper referencing. I respectfully feel it is important to adhere to standard of "reference-able" facts for the journal, even if just abstract. Would it be possible that this would be an abstract before publication?

Reviewer 2, Comment 9: We appreciate the reviewer's sage comment. This information has been submitted in abstract form for consideration for presentation at the 2024 AUA in San Antonio. **(Ureteral Strictures Following Ureteroscopic Ureteral Wall Injury: A Previously Unidentified Concern**
Andrei D. Cumpanas, Seyed Amiryaghoub Lavasani, Jake C. Tsai, Brandon Camp, Seyedamirvala Saadat, Bruce M. Gao, Zachary E. Tano, Pengbo Jiang, Roshan M. Patel, Jaime Landman, Ralph V. Clayman)

We have clarified in the Discussion section Lines 229-233 and added a reference: "A preliminary retrospective survey of our UCI URS database…"

Overall great idea in the manuscript and clearly demonstrates the need for an objective measurement during UAS deployment for patient safety and surgeon comfort. The objective doesn't need to be more people using larger UAS per se, but bringing the 25% non-users on board even at a small size if rates of sepsis, intra-renal pressures are lower, and potential for higher stone free rates without increased rates of ureteric injury and more importantly strictures.

Reviewer 2, Comment 10: We are 100% in agreement with the reviewer's comments.

Reviewer: 3

Comments to the Author

The authors have asked conference attendees to insert a 16Fr UAS with a force meter and detected that many surgeons applied too much force above the safe zone. Lower volume surgeons were more likely to exert higher insertion forces. The majority of urologists (74%) go above the ideal range of 4-6N and the safe range (<8N) and usually push too hard.

Reviewer 3, Comment 1: We apologize for any misunderstanding. In respect to the 4-6N range, a majority (i.e. 74%) of participating urologists either applied too little force (i.e., 29% exerting forces ≤4N) or too much force i.e., 45% exerting forces ≥6N).

Similarly for the 4-8N range, the majority (i.e. 61%) of urologists are either applying too little force (i.e., 29% exerting forces ≤4N) or too much force (i.e., 32% exerting forces ≥8N).

In the discussion, there is mention that the authors are able to insert a 16Fr UAS in 58% of their patients without PULS 3 lesion and note that only 3% of their subjects use a 16Fr UAS.

In the authors other 42% where they could not insert a 16Fr, did they go to a smaller sheath or no sheath?

Reviewer 3, Comment 2: We would downsize. When the 16Fr would not pass at 6N, we would remove the UAS and then take the 14Fr obturator out of the 16Fr sheath and see if that would pass at 6N. If it did, we would pass a 14Fr UAS; if the 14Fr obturator did not pass, we would try to pass a 12Fr UAS. At our institution, we use an additional safety Terumo glidewire outside the UAS when the UAS is 12Fr in order to maximize the lumen of the UAS. If the 12Fr UAS did not pass at 6N, we would place a 6Fr indwelling ureteral stent and terminate the procedure with the plan being to come back in another 1-3 weeks to do the procedure knowing that the ureter should then be 3-4Fr larger.

I feel like there is an agenda to insert a 16Fr UAS only as there is no other talk of the other sizes (Which, even in their admittance, are more common). It feels as if it's "16Fr or bust".

Reviewer 3, Comment 3: We apologize for giving this impression. While we prefer a 16Fr UAS, if it does not go at 6N, then we begin to downsize (vide supra). The goal is to pass the largest UAS that the patient's ureter will accept at 6N given the work by Tracey and associates showing a more efficient procedure with the larger UAS.

For the model, could you please comment on how similar it is to human anatomy. Are there any differences or does it completely simulate the male anatomy?

Reviewer 3, Comment 4: Externally, the model is "very similar" to the human anatomy (i.e. draped male genitalia with a wire exiting from the urethral meatus, similar to the appearance of an actual clinical case). Internally, the model mimics the human anatomy by containing the urethra, bladder, and ureteric orifice leading to a simulated ureter. Most importantly the simulation demonstrates high biomechanical fidelity by eliciting realistic motor movements that would be used by a surgeon during UAS insertion.

Do the zip ties installed along the length provide normal resistance or are they designed to provide the feeling of a very tight ureter? I am asking just to put into context how hard someone would push in a human otherwise.

Reviewer 3, Comment 5: The model is designed such that the 12Fr and 14Fr access sheaths pass at < 6N of force. Resistance was encountered only with attempted passage of the 16Fr UAS as the model was created such that regardless of the amount of force exerted, the 16Fr UAS would not pass. As such, what was obtained was the maximum amount of force a participant would feel comfortable in applying to pass a UAS.

We have clarified this in the Materials and Methods section.
Lines 99-103:
"A separate "receiver tube" (22/26Fr) with a UAS hub at its distal end was positioned in-line with the introduction tube (Figure 2). Sequential narrowing was achieved through zip ties along the tube's length, creating a proximal gradual constriction. This design aimed to allow smooth passage of a 12Fr and 14Fr UAS while precluding passage of a 16Fr UAS thereby revealing the maximum force an individual would exert in passing a UAS prior to electing to stop."

It is interesting the title reports only on the 16Fr UAS when only 3% of the urologists enrolled use that size UAS. You say that you put the 12, 14, and 16Fr UASs through their paces but then only report on 16Fr UAS. I know the authors prefer to use this but as a reader, I would like to know about the other size sheaths as well too as these are more clinically relevant.

Reviewer 3, Comment 6: Thank you for your insightful comment. You are correct in saying that the model was designed to resist the passage of only a 16Fr UAS but not a 12Fr or 14Fr UAS. Overall, we believe the key to this study is deciphering when a urologist feels like they are applying too much force to a UAS. The determination of this key threshold is assessed by the participant's feeling of when they are pushing too hard that they would feel uncomfortable. With how our model is designed, this key threshold is determined during insertion of a 16 Fr UAS given that a 12Fr and 14Fr UAS will always insert without major resistance in our model. If anything, with the 16Fr UAS being resisted, this may increase the fidelity of our simulator and improve relevance given that most urologists appear hesitant to use a larger 16Fr UAS like you mentioned. To be sure, the model could have been adjusted to not accept a 14Fr UAS or even a 12Fr UAS as this was the most commonly used size among our participants. To do this, it would have required a different model – the reviewer's comment is well taken and indeed it would be interesting in a future study to have the model such that a 14Fr UAS would not pass.

what were the pressures for the other UASs? why just report on 16Fr which most urologists don't use anyway? Without this data, I feel like this is not relevant to the majority of the surgical population. There is a definite push that highlighted by the statement "we also believe that the potential exists for safe deployment of UAS larger(!!) than 16Fr". and go up to 18Fr or larger.

Reviewer 3, Comment 7: Again we could have done the same study using a 14Fr UAS in which the model was constructed such that only the 12Fr would pass easily, but the 14Fr UAS would not pass at all due to narrowing of the receiver tube. Again, the stated purpose of the study was to define the maximum force a participant would be willing to exert in attempting to pass a UAS. We believe that the maximum force a participant felt safe to apply in passing a 16Fr UAS, when that UAS met resistance to its passage, would likely be similar/identical to the force that same individual would apply when attempting to pass a 12Fr or 14Fr UAS, when resistance to its passage was encountered.
Given the ability to monitor the force applied while passing a UAS provides the user with a comfort level knowing that by staying below 8N, tearing of the ureter should not occur. As such, in some cases, it is clear to us, based on our work in sizing the human ureter, that upwards of 15% of patients undergoing a ureteroscopic or PCNL procedure would indeed be able to accept an 18Fr or larger UAS if it were available.

McCormac A, Vu MC, Afyouni AS, et al. Clinical measurement of maximum safe ureteral distensibility using a novel force sensor. J Urol 2023;209 (Supplement 4):e468; doi: doi:10.1097/JU.0000000000003269.02.

While this is a well done study in terms of the equipment, i find that either the hypothesis or bias towards 16Fr UASs do not make this applicable to most urologists. It would be nice to see the data on all the other UAS sizes.

Reviewer 3, Comment 8: Thank you for your comment. Again, there are no data from this study with regard to the force to pass a 12Fr or 14Fr UAS as the study was designed such that both would pass with little or no resistance in every case. The model could be reconstructed next time to stop a 14Fr or 12Fr UAS. However, we also feel that resistance at a 16Fr UAS may increase the fidelity of the simulation for our participants given the general hesitance by urologists to place larger instruments up the ureter, as the reviewer implies. Overall, the size of the UAS being passed is not the focus of the study. The main key outcome of interest is defining the force at which a urologist encountering resistance to passage of a UAS would cease and desist. In this manner, we were able to determine the maximum force a given participant would exert in trying to pass a UAS. Indeed, we felt it important that the 12Fr and 14Fr UAS pass easily in order to familiarize the participant with the model and gain confidence in using it. Overall, 32% of participants exceeded 8N which would lead to possibly tearing the ureter; we believe this would occur regardless of the size UAS they were trying to pass as this merely defined how much force they were willing to exert on a UAS before deciding it would not pass. Also of interest is that 29% of participants would not apply a force greater than 4N, thereby invariably undersizing the ureter and passing a UAS smaller than the patient might safely accept thereby compromising the efficiency of the procedure and also risking higher renal pelvic pressures during the procedure.

Surgical Force: Initial Study and Clinical Implications in the Assessment of Ureteral Access Sheath Induced Injury

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ABSTRACT:

PURPOSE: Ureteral access sheaths (UAS) pose the risk of severe ureteral injury. Our prior studies revealed forces ≤6 Newtons (N) prevent ureteral injury. Accordingly, we sought to define the force urologists and residents-in-training typically use when placing a UAS.

MATERIALS & METHODS: Among urologists and urology residents attending two annual urological conferences in 2022, 121 individuals were recruited for the study. Participants inserted 12Fr, 14Fr, and 16Fr ureteral access sheaths into a male genitourinary model containing a concealed force sensor; they also provided demographic information. Analysis was completed using *t*-tests and Chi-square tests to identify group differences when passing a 16Fr sheath UAS. Participant traits associated with surpassing or remaining below a minimal force threshold were also explored via polychotomous logistic regression.

RESULTS: Participant force distributions were: ≤4N (29%), >6N (45%), and >8N (32%). More years of practice were significantly associated with exerting >6N relative to forces between 4-6N; results for >8N relative to 4N-8N were similar. Compared to high-volume ureteroscopists (those performing >20 ureteroscopies/month), physicians performing ≤20 ureteroscopies/month were significantly less likely to exert forces ≤4N (*p*=0.017 and *p*=0.041). Of those surpassing 6N and 8N, 15% and 18% respectively were high-volume ureteroscopists.

CONCLUSIONS: Despite years of practice or volume of monthly ureteroscopic cases performed, most urologists failed to pass 16Fr access sheaths within the ideal range of 4N-6N (74% of participants) or within a predefined safe range of 4N-8N (61% of participants).

INTRODUCTION

Historically, various catheters, guidewires, and endoscopes have been used without knowing the tolerance of the tissues comprising the lumen through which they were being passed; in all cases, patients rely upon the surgeon's skill and deftness of touch to prevent injury. Despite technological advances, surgical tools have not been designed to detect excessive force applied to structures; indeed, for most tissues, the threshold force at which injury occurs is undefined[1]. To date, there have been no studies coupling documented in-vivo tissue injury-causing forces with the actual clinical forces being applied by physicians performing procedures. In this manuscript, we define the relationship between known forces associated with ureteral injury during ureteral access sheath (UAS) passage with the force urologists and urologists-in-training may apply during UAS placement.

Since its advent in 1974, UAS use has been controversial. While it enhances endoscopic visibility, improves stone removal efficiency, reduces intrarenal pressure, and eases repeated entry of the flexible ureteroscope[2–7], there are concerns over the frequency of ureteral injury and possible post-operative ureteral stricture formation[8–14]. In this regard, two scales assessing ureteral injury following ureteroscopy (URS) have been proposed: the Post-Ureteroscopic Lesion Scale (PULS: grades 0-5) and the Traxer Injury Scale Grade (TISG: grades 0-4)[9,15].

When considering injury grades ≥2 (i.e. a tear in the ureteral wall of varying depth and extent), Traxer et al. found that in 13% of cases in which a 14Fr UAS was deployed, a grade ≥2 injury occurred[9]. This was further corroborated in several other publications employing only a 14Fr UAS; Monga et al. reported urothelial disruption in 23-26% of cases (TISG ≥2) and

Schoenthaler et al. reported a 24% injury rate (PULS ≥2)[9,15–17]. Despite this high level of acute urothelial disruption, the Clinical Research Office of the Endourological Society (CROES) found that cases with and without UAS deployment generally had an equally low, 1% rate of post-operative ureteral stricture formation[18].

In conjunction with the Samueli School of Engineering at the University of California, Irvine (UCI), we developed a UAS force sensor for continuous intraoperative measurement, in hundredths of a Newton (N), of the force applied during UAS deployment. Previously, forces <4.84N routinely demonstrated no ureteral damage, while forces >8.1N often resulted in a PULS score ≥3 in swine[19]. Subsequent clinical studies revealed a deployment force of ≤6N resulted in no PULS 3 lesions among 200 patients (210 anatomically normal ureters without prior radiation, reimplantation, reconstruction, or transplantation), despite successful passage of a 16Fr UAS in 61% of patients. Only two PULS 3 scores were reported, both with forces exceeding 8N[20]. This investigation prompted further scrutinization of forces applied during UAS placement in the context of ureteral injury. Herein, we explore UAS force exerted by over 100 urologists and residents-in-training on a male genitourinary model.

MATERIALS AND METHODS

In this study, we utilized a male genitourinary model outfitted with an internal force-sensing mechanism (Pasco® Scientific PASport™; PS-2104, PASCO Scientific, Roseville, CA, USA) and connective tubing; only the external genitalia and UASs were visible to participants (Figure 1).

Following removal of the ureter and kidney from the model, an “introduction tube” (22Fr lumen, 26Fr outer diameter) was inserted through the silicone urethra and bladder, terminating where the ureterovesical junction would have been. A 0.035in. Amplatz Super Stiff™ (Cook® Group, Bloomington, IN, USA) guidewire passed per urethra was anchored to the model's posterior wall. A separate "receiver tube" (22/26Fr) with a UAS hub at its distal end was positioned in-line with the introduction tube (Figure 2). Sequential narrowing was achieved through zip ties along the tube's length, creating a proximal gradual constriction. This design aimed to allow smooth passage of a 12Fr and 14Fr UAS while precluding passage of a 16Fr UAS thereby revealing the maximum force an individual would exert in passing a UAS prior to electing to stop. The Pasco® force sensor was mounted underneath the bladder and connected to the UAS hub on the receiver tube (Figure 3). The sensor registered the force applied to the receiver tube during UAS insertion with a 0.03N sensitivity.

SPARKvue® software was used to record and analyze the Pasco® force sensor readings. The sensor underwent calibration with the UCI UAS force sensor prior to both the 2022 American Urological Association (AUA) and World Congress of Endourology and Technology (WCET) meetings. Linear regression performed via scatter plot data reconciled the internal Pasco® values with the external UCI UAS force sensor values. The best fit lines revealed a reliable, consistent relationship between the Pasco® and UCI UAS force sensors (R^2 value ≥0.9) (Figure 4).

Urologists and residents-in-training were recruited during the 2022 AUA and WCET annual meetings. Participants were made aware that the study’s primary emphasis was to evaluate their decision-making process with respect to UAS placement. They received instructions to place three Cook Medical Inc. Flexor® UAS (12Fr, 14Fr, 16Fr) sequentially while verbalizing their decisions and indicating when they would cease UAS passage. Access sheaths were denoted with colored lines to approximate the distance from the obturator's tip to what would be the "distal ureter", "mid-ureter", and "ureteropelvic junction" in the model. Participants remained unaware that applied force was being measured.

Following UAS passage, participants completed a demographic and practice-based survey including age, employment type, years of practice and training, fellowship, monthly URS volume, UAS usage, and most commonly used size of UAS, if applicable.

Statistical Analysis:

Participants were divided based on the maximum force recorded during UAS placement, based upon thresholds of 4N, 6N, and 8N[19,20]. A descriptive analysis using either a two-group *t*-test or Chi-square test was performed to identify differences between the groups when passing a 16Fr UAS. A polychotomous logistic regression (PLR) model served to determine participant characteristics associated with exceeding the 6N (or 8N) threshold or remaining below 4N compared to reference levels of 4N-6N and 4N-8N with a 16Fr UAS. Odds ratios and 95% confidence intervals were calculated.

RESULTS

Among 121 participants (74 AUA and 47 WCET), there were 106 (88%) males and 15 (12%) females (Table 1). There were 27 residents and fellows, 55 faculty urologists, and 39 urologists listed as "other" (e.g., military, community, or private practice physicians). Sixty-seven participants (55%) had fellowship training in endourology (49/121) or oncology (18/121). Regarding monthly URS volume, 9/121 (7%) reported 0 URS, 45/121 (37%) reported 1-10 URS, 36/121 (30%) reported 11-20 URS, and 31/121 (26%) reported >20 URS/month. UAS placement was routinely done by 88/121 (73%) participants. Among these 88 participants, a 10Fr, 12Fr, 14Fr, and 16Fr UAS was employed in their own clinical practice 17%, 65%, 31%, and 3% of the time, respectively.

Forces ≤4 versus >4:

Among the participants, 86 (71%) exceeded 4N with a 16Fr UAS, with 73% of the respondents routinely using a UAS. In contrast, 35 participants (29%) remained below 4N, with 71% routinely using a UAS. Participants exerting >4N had significantly more monthly URS volume (p=0.012). No significant differences were found in years of practice, age, sex, type of employment, endourology fellowship training, or UAS deployment (Table 1).

Forces ≤6 versus >6:

Among the participants, 55 (45%) exceeded 6N with a 16Fr UAS, with 71% routinely using a UAS. Conversely, 66 participants (55%) remained below 6N, with 74% routinely using a UAS. Participants exerting >6N were significantly older (mean age 45.7 years vs. 40.4 years, p=0.023), had significantly more years of practice (13.5 years vs. 8.0 years, p=0.008), and had performed significantly less URS/month (p=0.026). No significant differences were found in sex, type of employment, endourology fellowship training, or UAS deployment (Table 1).

Forces ≤8 versus >8:

Among the participants, 39 (32%) exceeded 8N with a 16Fr UAS with 72% routinely using a UAS. Conversely, 82 participants (68%) remained below 8N, with 73% routinely using a UAS. Participants exerting >8N were significantly older (46.7 years vs. 40.9 years, p=0.018) and had significantly more years of practice (14.2 years vs. 8.8 years, p=0.014). No significant differences were found in the number of URS/month, sex, type of employment, endourology fellowship training, or use of a UAS (Table 1).

In the univariate logistic regression analysis, older age, more years of practice, and lower number of URS/month were associated with higher forces; however, while older age was associated with higher force, this variable was excluded from the multivariate model due to its multicollinearity with years of practice.

In the first PLR model, more years of practice was significantly associated with using higher forces >6N relative to the 4N-6N reference level (OR 1.049, 95% CI 1.004-1.096, p=0.032; Table 2A). This parameter was not significantly associated with use of forces <4N compared to the 4N-6N reference level (OR=1.004, p=0.893). In terms of URS/month, both the 1-10 and 11-20 subgroups were associated with *higher* likelihood of forces >6N; however, ORs were not statistically significant (p=0.137 and p=0.432 respectively). Both subgroups were associated with l*ower* likelihood of force <4N relative to the reference level; similarly, this was non-significant (p=0.1 and p=0.25 respectively; Table 2 Model 1).

Results for the second PLR model using forces of 4N-8N as a reference were similar to the previous model. More years of practice was significantly associated with generating forces >8N relative to the 4N-8N reference level (OR 1.04, 95% CI 1.001-1.081, p=0.045; Table 2 Model 2). Conversely, years of practice was not significantly associated with generating forces <4N compared to forces between 4-8N (OR=0.991, p=0.698).

There was a significant negative association between the number of URS/month and force <4N relative to 4N-8N. In reference to performing >20 URS/month, performing ≤20 URS/month was associated with significantly lower likelihood of using forces <4N (1-10 URS: OR 0.231, 95% CI 0.069-0.771, p=0.017; 11-20 URS: OR 0.3, 95% CI 0.095-0.95, p=0.041).

DISCUSSION

The risk of urothelial splitting during UAS passage is concerning given publications by highly experienced ureteroscopists citing a high-grade injury rate (i.e., a ureteral wall tear) of 13-26% when passing only a 14Fr UAS[9,16,17]. This problem has a) dissuaded physicians from using a UAS (about one-quarter of our study population) and b) caused those who use a UAS to opt for a smaller, less efficient sheath (i.e. ≤12Fr for 82% of the participants)[21].

Prior to our study, Monga et al. evaluated insertion forces using a 21Fr catheter-based UAS prototype and a digital force sensor in a non-anatomic bench-top setting[22]. Among 13 participants (8 urologists and 5 residents), there was a difference in maximum force between trained urologists and residents (6.55N vs. 4.84N, p=0.035). Subsequently, we sought to expand on the initial study by Monga et al. by determining the forces commonly applied during the passage of commercially available 12Fr, 14Fr, and 16Fr UASs among a large group of urologists and urology residents using an anatomically accurate genitourinary model. We then related the forces exerted by the participants to the known safe force thresholds for UAS passage based on our earlier porcine and clinical studies.

Our study revealed that the majority of urologists miss both the "sweet range" of 4-6N (74%) as well as the "safe range" of 4-8N (61%); they either push too hard, risking ureteral injury, or push too gently, thus placing a smaller UAS and diminishing the efficiency of the URS procedure[21]. In essence, this is a *Goldilocks* conundrum; there currently is no instrument available for urologists to indicate when the applied UAS force is *"just right,"* neither *too soft* nor *too hard*.

An applied safe force of 6N versus a potentially injurious force of 8N differs by less than a half-pound. Our results revealed that 32% of physicians exceeded 8N, posing a risk of high-grade injury. Indeed, even among participants with a high-volume of URS cases (i.e., >20 URS/month), 15% and 18% exceeded forces of 6N and 8N, respectively. Clearly, even in the hands of high-volume ureteroscopists, differentiating between a safe UAS placement force of 6N (i.e., 1.35lbf) and a potentially injurious force of 8N (i.e., 1.80lbf) is too subtle for most surgeons to discern.

Furthermore, we are concerned that the significance of higher grade PULS scores may not be fully appreciated. The CROES database indicated UAS passage does not increase ureteral stricture risk versus ureteroscopy without UAS passage, however UAS patients were not subcategorized based on PULS or TISG scores[18]. A preliminary retrospective survey of our UCI URS database (>750 ureteroscopies) revealed that strictures are rare among PULS 0, 1, and 2 patients at 0%, 0.4% (1/253), and 0.93% (1/108) respectively, while PULS 3 patients experienced a disconcerting high stricture rate: 10.5% (2/19 patients)[23].

Conversely, insufficient force during sheath insertion is related to smaller UAS placement, which can hinder the procedure. To explore this further, we analyzed physicians exerting forces below 4N. There was a direct significant difference in URS/month between those exerting ≤4N versus >4N (Table 1).

During clinical practice, when the force of UAS passage can be objectively monitored, the outcome is far different. To date, armed with the UAS force sensor, our clinical work has enabled us to routinely place a 16Fr UAS (58% of our patients) without incurring any PULS 3 lesions[24]. This sharply contrasts with the current survey group, where only 3% of the participants routinely used a 16Fr UAS; this finding mirrors a global survey of 216 endourologists, where just 2.73% commonly employed a 16Fr UAS[25]. Of note, the 13-26% injury rate reported in the literature all occurred during passage of a smaller 14Fr UAS.

Our findings are the first to couple the surgical force associated with ureteral injury during UAS placement with an investigation of forces exerted by urologists. We contend that a reliable and practical method to measure UAS deployment force is critical[22,24,26]. The *sine qua non* is for the urologist to stay within the *Goldilocks* range–knowing when force levels have not yet surpassed 4N, exceeded 6N, or in a worst-case scenario, reached 8N. Our current investigational UCI UAS force sensor, while expensive and cumbersome, is being developed into a commercial product for widespread use. This device, when used in tandem with UASs, would alert urologists to force levels of 4N, 6N, or, in the most concerning case, 8N, allowing them to prevent under-sizing at 4N and avoid the risks of ureteral injury at 6N or 8N. We also believe that the potential exists for safe deployment of UAS larger than 16Fr. Indeed, a recent UCI clinical study revealed that at the 6N threshold, 15% of human ureters could safely accept a urethral dilator ≥18Fr[24].

Limitations of this study include its bench-top nature and conference setting. The absences of lubricant and the model's inability to duplicate the three distinct areas of narrowing in the human ureter are also noted. Our survey was limited as participants' location of practice (state/country) and an evaluation of the face validity of the model was not obtained. Lastly, participants' awareness of prior UCI publications on UAS force measurement might have influenced how they proceeded to pass each UAS.

CONCLUSIONS

Overall, 29% of participating urologists and urology residents-in-training exerted ≤4N and 45% exceeded a clinically defined safety threshold of 6N when placing a 16Fr UAS. Moreover, 32% of the participants exceeded 8N, a level of force associated with high-grade ureteral injury.

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AUTHORS' CONTRIBUTIONS:

The authors confirm their roles and contributions to the article as outlined: Study conception and methodology: S.A.M.L., K.L.M., R.V.C. Data collection: S.A.M.L., A.R., A.D.C., K.L.M., M.C.H., A.M., P.P., K.V., A.R.H.G., S.H.H.S. Data curation: S.A.M.L., A.R., A.D.C., K.L.M., M.C.H., A.M., P.P., K.V. Formal Analysis: S.A.M.L., K.O. Manuscript preparation and review: all authors. Critical manuscript revision: S.A.M.L., R.M.P., J.L., R.V.C. Each author conducted a review of the results and granted their approval for article submission.

AUTHOR DISCLOSURE STATEMENT

No competing financial interests currently exist.

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Table 1. Univariate analysis of participant characteristics and relationship to force exerted during insertion of a 16Fr ureteral access sheath.

	Group 1: Forces ≤4N (n = 35)	**Group 2: Forces >4N (n = 86)**	***P****	**Group 3: Forces ≤6N (n = 66)**	**Group 4: Forces >6N (n = 55)**	***P****	**Group 5: Forces ≤8N (n = 82)**	**Group 6: Forces >8N (n = 39)**	***P****
Mean years of practice (SD)	8.3 (10.3)	11.5 (11.7)	0.167	8.0 (11.4)	13.5 (13.7)	***0.008***	8.8 (12.0)	14.2 (12.2)	***0.014***
Mean age (SD)	41.1 (11.5)	43.5 (13.1)	0.365	40.4 (9.4)	45.7 (12.4)	***0.023***	40.9 (10.6)	46.7 (13.5)	***0.018***
Number of ureteroscopies (%)			***0.012***			***0.026***			0.154
0 per month	4 (11%)	5 (06%)		6 (09%)	3 (05%)		6 (08%)	3 (08%)	
1-10 per month	7 (20%)	38 (44%)		18 (27%)	27 (49%)		25 (30%)	20 (51%)	
11-20 per month	9 (26%)	27 (31%)		19 (29%)	17 (31%)		27 (33%)	9 (23%)	
>20 per month	15 (43%)	16 (19%)		23 (35%)	8 (15%)		24 (29%)	7 (18%)	
Sex (%)			0.688			0.920			0.382
Male	30 (86%)	76 (88%)		58 (88%)	48 (87%)		70 (85%)	36 (92%)	
Female	5 (14%)	10 (12%)		8 (12%)	7 (13%)		12 (15%)	3 (08%)	
Employment (%)			0.706			0.585			0.207
Resident/fellow	8 (23%)	19 (22%)		17 (26%)	10 (18%)		22 (27%)	5 (13%)	
Faculty	14 (40%)	41 (48%)		28 (42%)	27 (49%)		36 (44%)	19 (49%)	
Other	13 (37%)	26 (30%)		21 (32%)	18 (33%)		24 (29%)	15 (38%)	
Fellowship (%)			0.628			0.117			0.541
None	10 (29%)	29 (34%)		17 (26%)	22 (40%)		25 (30%)	14 (36%)	
Endourology	18 (51%)	31 (36%)		32 (48%)	17 (31%)		36 (44%)	13 (33%)	
Other	7 (20%)	26 (30%)		17 (26%)	16 (29%)		21 (26%)	12 (31%)	
Sheath Use (%)			0.838			0.682			0.874
Yes	25 (71%)	63 (73%)		49 (74%)	39 (71%)		60 (73%)	28 (72%)	
No	10 (29%)	23 (27%)		17 (26%)	16 (29%)		22 (27%)	11 (28%)	

N = Newton; SD = Standard Deviation

**p*-values of 0.05 significance were calculated using Pearson's Chi-square test except for the difference in mean years of practice and age (two-group *t*-test)

Table 2. The polychotomous logistic regression comparing the nonideal force ranges to the ideal force ranges.

Model 1: Applied force outside of 4-6N reference range.

		95% Confidence Interval		
	Odds Ratio	**Lower**	**Higher**	***P***
<4N vs 4N-6N				
Years of practice	1.004	0.954	1.056	0.893
Ureteroscopies per month				
0 vs >20	1.073	0.16	7.2	0.942
1-10 vs >20	0.341	0.095	1.227	0.1
11-20 vs >20	0.481	0.139	1.672	0.25
>6N vs 4N-6N				
Years of practice	1.049	1.004	1.096	***0.032***
Ureteroscopies per month				
0 vs >20	1.384	0.167	11.473	0.763
1-10 vs >20	2.536	0.745	8.64	0.137
11-20 vs >20	1.668	0.465	5.979	0.432

Model 2: Applied force outside of 4-8N reference range.

		95% Confidence Interval		
	Odds Ratio	**Lower**	**Higher**	***P***
<4N vs 4N-8N				
Years of practice	0.991	0.947	1.037	0.698
Ureteroscopies per month				
0 vs >20	1.184	0.179	7.844	0.861
1-10 vs >20	0.231	0.069	0.771	***0.017***
11-20 vs >20	0.3	0.095	0.95	***0.041***
>8N vs 4N-8N				
Years of practice	1.04	1.001	1.081	***0.045***
Ureteroscopies per month				
0 vs >20	1.769	0.216	14.465	0.595
1-10 vs >20	1.43	0.435	4.699	0.555
11-20 vs >20	0.597	0.164	2.174	0.434

N = Newton

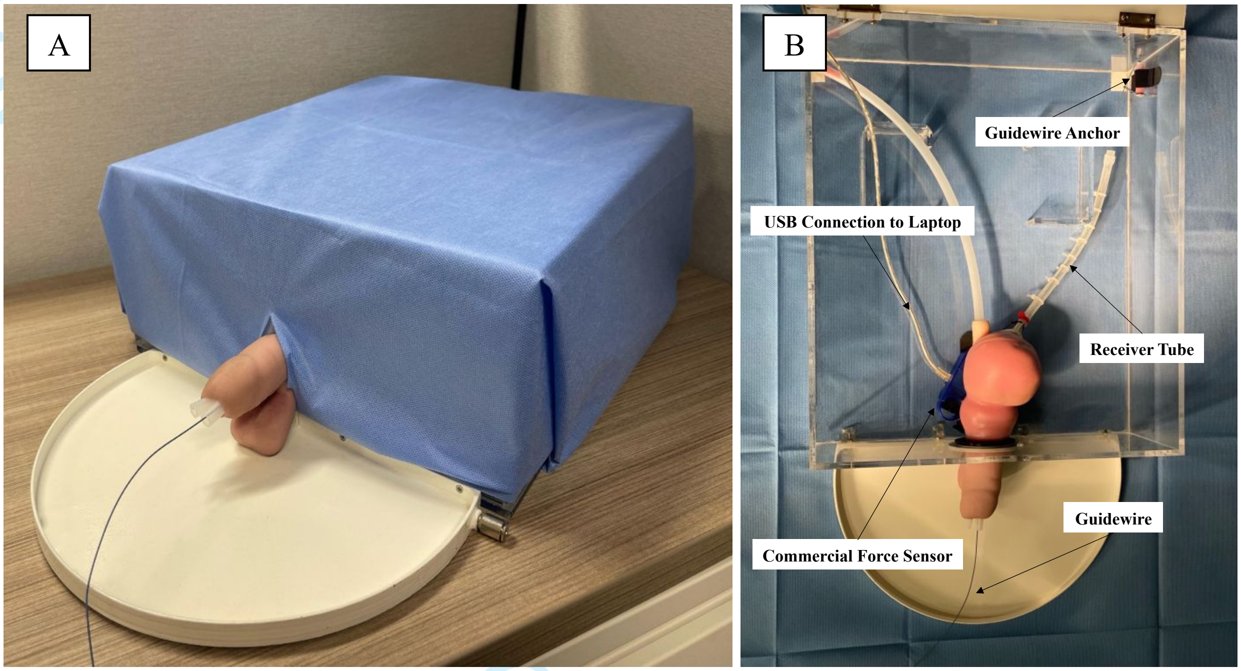


Figure 1. Urinary tract model with built-in Pasco® Scientific PASport™ force sensor. **A)** Participant view of model. **B)** Aerial view of interior components.

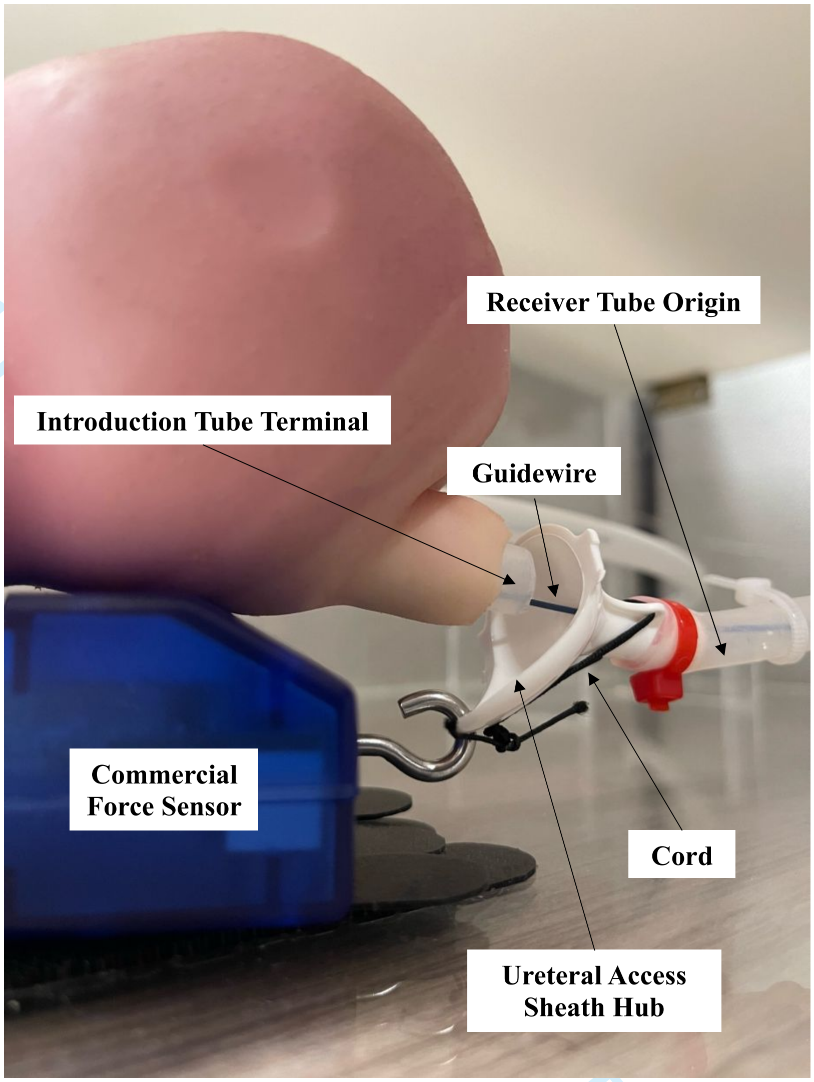
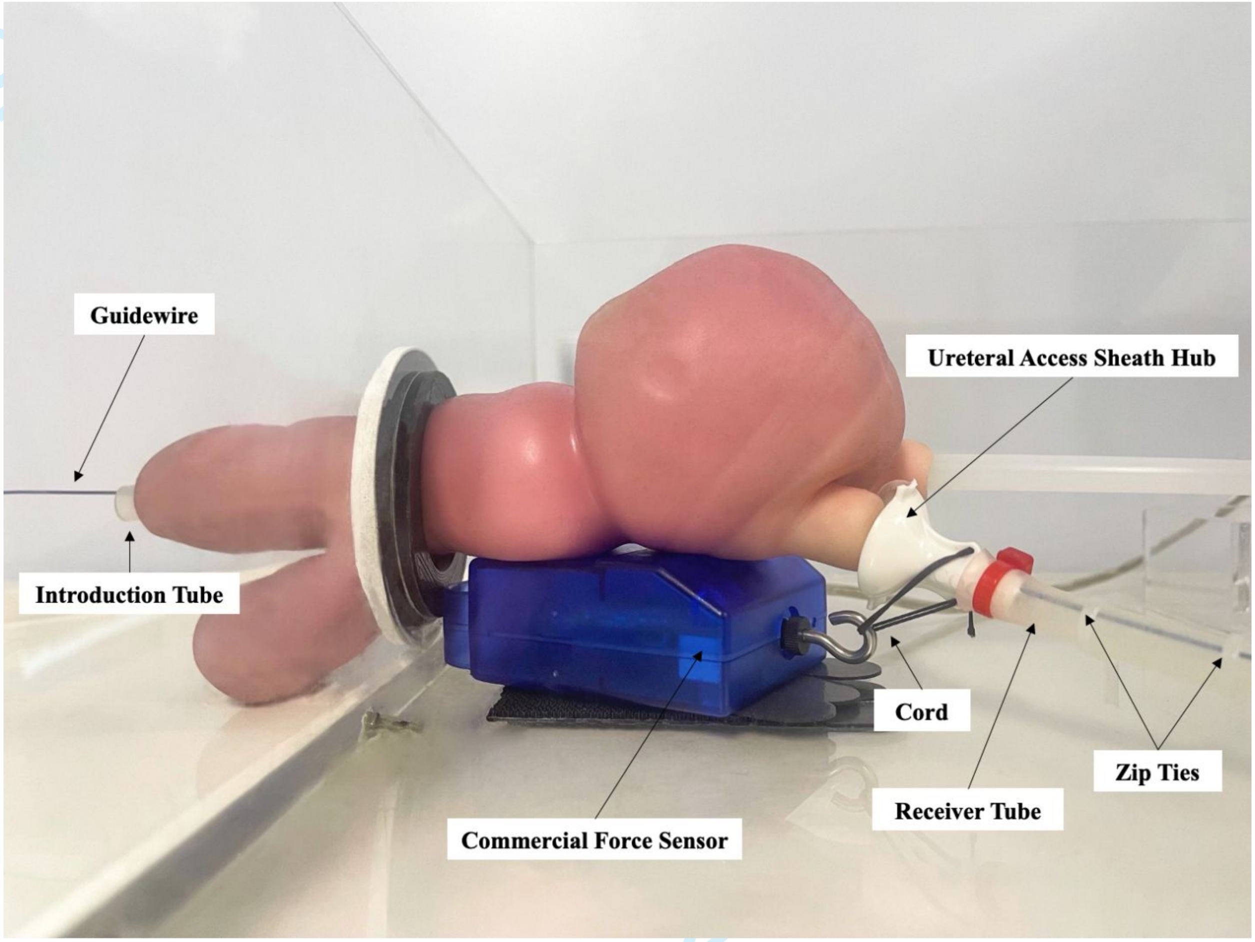


Figure 2. Enlarged view of the gap between the introduction tube and receiver tube.



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390 **Figure 3.** Detailed presentation of the male genitourinary force sensor model components.
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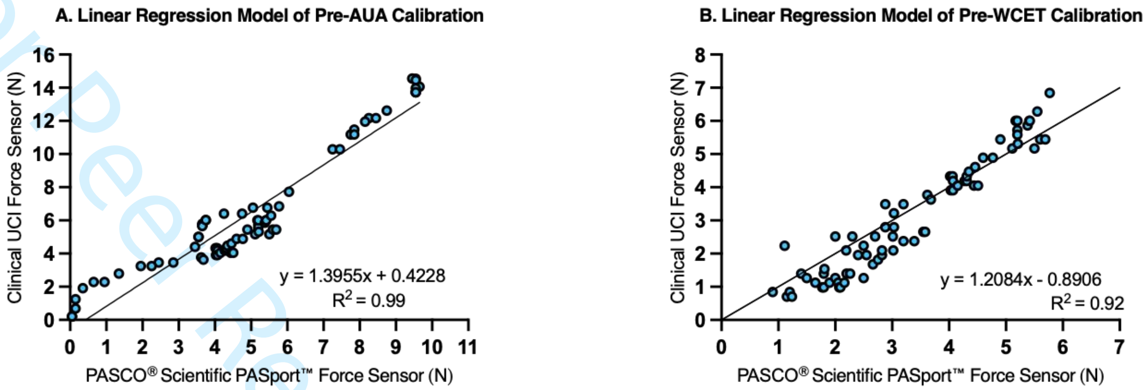

Figure 4. Linear regression model comparing the force data for both the handheld force sensor (y-axis) and the internally mounted force sensor (x-axis) plotted. These measurements calibrated the internally mounted force sensor to the handheld University of California, Irvine (UCI) ureteral access sheath force sensor, which had previously been used to determine force values for ureteral injury in both porcine and human ureters.

-Figure 4.A) Linear regression yielded a relationship of $y = 1.3955x + 0.4228$ ($R^2 = 0.9869$) for the pre-American Urological Association (AUA) test.

-Figure 4.B) Linear regression yielded a relationship of $y = 1.2084x - 0.8906$ ($R^2 = 0.9209$) for the pre-World Congress of Endourology and Technology (WCET) test.

FIGURE LEGENDS

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Surgical Force: Initial Study and Clinical Implications in the Assessment of Ureteral Access Sheath Induced Injury

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ABSTRACT:

PURPOSE: Ureteral access sheaths (UAS) pose the risk of severe ureteral injury. Our prior studies revealed forces ≤6 Newtons (N) prevent ureteral injury. Accordingly, we sought to define the force urologists and residents-in-training typically use when placing a UAS.

MATERIALS & METHODS: Among urologists and urology residents attending two annual urological conferences in 2022, 121 individuals were recruited for the study. Participants inserted 12Fr, 14Fr, and 16Fr ureteral access sheaths into a male genitourinary model containing a concealed force sensor; they also provided demographic information. Analysis was completed using *t*-tests and Chi-square tests to identify group differences when passing a 16Fr sheath UAS. Participant traits associated with surpassing or remaining below a minimal force threshold were also explored via polychotomous logistic regression.

RESULTS: Participant force distributions were: ≤4N (29%), >6N (45%), and >8N (32%). More years of practice were significantly associated with exerting >6N relative to forces between 4-6N; results for >8N relative to 4N-8N were similar. Compared to high-volume ureteroscopists (those performing >20 ureteroscopies/month), physicians performing ≤20 ureteroscopies/month were significantly less likely to exert forces ≤4N (p=0.017 and p=0.041). Of those surpassing 6N and 8N, 15% and 18% respectively were high-volume ureteroscopists.

CONCLUSIONS: Despite years of practice or volume of monthly ureteroscopic cases performed, most urologists failed to pass 16Fr access sheaths within the ideal range of 4N-6N (74% of participants) or within a predefined safe range of 4N-8N (61% of participants).

INTRODUCTION

Historically, various catheters, guidewires, and endoscopes have been used without knowing the tolerance of the tissues comprising the lumen through which they were being passed; in all cases, patients ~~must~~ rely upon the surgeon's skill and deftness of touch to prevent injury. Despite technological advances, surgical tools have not been designed to detect excessive force applied to ~~a structure~~structures; indeed, for most tissues, the threshold force at which injury occurs is undefined[1]. To date, there have been no studies coupling documented in-vivo tissue injury-causing forces with the actual clinical forces being applied by ~~the physician~~physicians performing ~~the procedure~~procedures. In this manuscript, we define the relationship between known forces associated with ureteral injury during ureteral access sheath (UAS) passage with the force urologists and urologists-in-training may apply during UAS placement.

~~Since its advent in 1974, use of UAS has been controversial. While it enhances endoscopic visibility, improves stone removal efficiency, reduces intrarenal pressure, and eases repeated entry of the flexible ureteroscope[2–7], there are concerns over the frequency of ureteral injury and possible post-operative ureteral stricture formation[8–14]. In this regard, two scales assessing ureteral injury following ureteroscopy (URS) have been proposed: the Post-Ureteroscopic Lesion Scale (PULS: grades 0-5) and the Traxer Injury Scale Grade (TISG: grades 0-4)[9,15].~~

~~When considering injury grades ≥2 (i.e. a tear in the ureteral wall of varying depth and extent), Traxer et al. found that in 13% of cases in which a 14Fr UAS was deployed, a grade ≥2 injury occurred[9]. This was further corroborated in several other publications employing only a 14Fr UAS; Monga et al. reported urothelial disruption in 23-26% of cases (TISG ≥2) and~~

Schoenthaler et al. reported a 24% injury rate (PULS ≥2)[9,15–17]. Despite this high level of acute urothelial disruption, the Clinical Research Office of the Endourological Society (CROES) found that in general, cases with and without UAS deployment had an equally low, 1% rate of post-operative ureteral stricture formation[18].

In conjunction with the Samueli School of Engineering at the University of California, Irvine (UCI), we developed a UAS force sensor for continuous intraoperative measurement, in hundredths of a Newton (N), of the force applied during UAS deployment. Previously, forces <4.84N routinely demonstrated no ureteral damage, while forces >8.1N often resulted in a PULS score ≥3 in swine[19]. Subsequent clinical studies revealed a deployment force of ≤6N resulted in no PULS 3 lesions among 200 patients (210 ureters), despite successful passage of a 16Fr UAS in 61% of patients. Only two PULS 3 scores were reported, both with forces exceeding 8N[20]. This investigation prompted us to further examine the forces exerted during UAS placement in the context of ureteral injury. Herein, we explore the UAS force applied by over 100 urologists and residents-in-training while passing a UAS on a male genitourinary model.

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MATERIALS AND METHODS

In this study, we utilized a male genitourinary model outfitted with an internal force-sensing mechanism (Pasco® Scientific PASport™; PS-2104, PASCO Scientific, Roseville, CA, USA) and connective tubing; only the external genitalia and UASs were visible to ~~the~~ participants (Figure 1).

Following removal of the ureter and kidney from the model, an “introduction tube” (22Fr lumen, 26Fr outer diameter) was inserted through the silicone urethra and bladder, terminating ~~at what would have been~~where the ureterovesical junction~~.~~ would have been. A 0.035in. Amplatz Super Stiff™ (Cook® Group, Bloomington, IN, USA) guidewire passed per urethra was anchored to the model's posterior wall. A separate ~~“~~"receiver tube~~”~~" (22/26Fr~~), featuring~~) with a UAS hub at ~~the tube’s~~its distal end~~,~~ was positioned in-line with the introduction tube (Figure 2). ~~Zip~~Sequential narrowing was achieved through zip ties ~~installed~~ along the tube's length~~ of the tube provided sequential narrowing, resulting in~~, creating a proximal gradual constriction. This design aimed to allow smooth passage of a 12Fr and 14Fr UAS while precluding passage of a 16Fr UAS thereby revealing the maximum force an individual would exert in passing a UAS prior to electing to stop. The Pasco® force sensor was mounted underneath the bladder and connected to the UAS hub on the receiver tube (Figure 3). The sensor registered the force applied to the receiver tube during UAS insertion with a 0.03N sensitivity.

SPARKvue® software was used to record and analyze the Pasco® force sensor readings. The sensor underwent calibration with the UCI UAS force sensor prior to both the 2022 American Urological Association (AUA) and World Congress of Endourology and Technology (WCET) meetings. Linear regression performed via scatter plot data reconciled the internal Pasco® values with the external UCI UAS force sensor values. The best fit lines revealed a reliable, consistent relationship between the Pasco® and the UCI UAS force sensorsensors (R^2 value ≥0.9) (Figure 4).

Urologists and residents-in-training were recruited during the 2022 AUA and WCET annual meetings. Participants were made aware that the study's primary emphasis of the study was to evaluate their decision-making process with respect to UAS placement. They received instructions to place three Cook Medical Inc. Flexor® UAS (12Fr, 14Fr, 16Fr) sequentially while verbalizing their decisions and indicating when they would cease UAS passage. Access sheaths were denoted with colored lines to approximate the distance from the obturator's tip to what would be the "distal ureter", "mid-ureter", and "ureteropelvic junction" in the model. Participants remained unaware that applied force was being measured.

Following UAS passage, participants completed a demographic and practice-based survey including age, employment type, years of practice and training, fellowship, monthly URS volume, UAS usage, and most commonly used size of UAS, if applicable.

Statistical Analysis:

Participants were divided based on the maximum force recorded during UAS placement, based upon thresholds of 4N, 6N, and 8N[19,20]. A descriptive analysis using either a two-group *t*-test or Chi-square test was performed to identify differences between the groups when passing a 16Fr UAS. A polychotomous logistic regression (PLR) model served to determine participant characteristics associated with exceeding the 6N (or 8N) threshold or remaining below 4N

~~compared to the reference levels of 4N-6N and 4N-8N with a 16Fr UAS.~~[19,20]. A descriptive analysis using either a two-group *t*-test or Chi-square test was performed to identify differences between the groups when passing a 16Fr UAS. A polychotomous logistic regression (PLR) model served to determine participant characteristics associated with exceeding the 6N (or 8N) threshold or remaining below 4N compared to reference levels of 4N-6N and 4N-8N with a 16Fr UAS. Odds ratios and 95% confidence intervals were calculated.

RESULTS

Among 121 participants (74 AUA and 47 WCET), there were 106 (88%) males and 15 (12%) females (Table 1). There were 27 residents and fellows, 55 faculty urologists, and 39 urologists listed as "other" (e.g., military, community, or private practice physicians). Sixty-seven participants (55%) had fellowship training in endourology (49/121) or oncology (18/121). Regarding monthly URS ~~experience~~volume, 9/121 (7%) reported 0 URS, 45/121 (37%) reported 1-10 URS, 36/121 (30%) reported 11-20 URS, and 31/121 (26%) reported >20 URS/month. UAS placement was routinely done by 88/121 (73%) participants. Among these 88 participants, a 10Fr, 12Fr, 14Fr, and 16Fr UAS was employed in their own clinical practice 17%, 65%, 31%, and 3% of the time, respectively.

Forces ≤4 versus >4:

Among the participants, 86 (71%) exceeded 4N with a 16Fr UAS, with 73% of the respondents routinely using a UAS. In contrast, 35 participants (29%) remained below 4N, with 71% routinely using a UAS. Participants exerting >4N had significantly more monthly URS

~~experience~~volume (*p*=0.012). No significant differences were found in years of practice, age, sex, type of employment, endourology fellowship training, or UAS deployment (Table 1).

Forces ≤6 versus >6:

Among the participants, 55 (45%) exceeded 6N with a 16Fr UAS, with 71% routinely using a UAS. Conversely, 66 participants (55%) remained below 6N, with 74% routinely using a UAS. Participants exerting >6N were significantly older (mean age 45.7 years vs. 40.4 years, *p*=0.023), had significantly more years of practice (13.5 years vs. 8.0 years, *p*=0.008), and had performed significantly less URS/month (*p*=0.026). No significant differences were found in sex, type of employment, endourology fellowship training, or UAS deployment (Table 1).

Forces ≤8 versus >8:

Among the participants, 39 (32%) exceeded 8N with a 16Fr UAS with 72% routinely using a UAS. Conversely, 82 participants (68%) remained below 8N, with 73% routinely using a UAS. Participants exerting >8N were significantly older (46.7 years vs. 40.9 years, *p*=0.018) and had significantly more years of practice (14.2 years vs. 8.8 years, *p*=0.014). No significant differences were found in the number of URS/month, sex, type of employment, endourology fellowship training, or use of a UAS (Table 1).

In the univariate logistic regression analysis, older age, more years of practice, and lower number of URS/month were associated with higher forces; however, while older age was associated with higher force, this variable was excluded from the multivariate model due to its multicollinearity with years of practice.

In the first PLR model, more years of practice was significantly associated with using higher forces >6N relative to the 4N-6N reference level (OR 1.049, 95% CI 1.004-1.096, *p*=0.032; Table 2A). This parameter was not significantly associated with use of forces <4N compared to the 4N-6N reference level (OR=1.004, *p*=0.893). In terms of URS/month, both the 1-10 and 11-20 subgroups were associated with *higher* likelihood of forces >6N; however, ORs were not statistically significant (*p*=0.137 and *p*=0.432 respectively). Both subgroups were associated with l*ower* likelihood of force <4N relative to the reference level; similarly, this was non-significant (*p*=0.1 and *p*=0.25 respectively; Table 2 Model 1).

Results for the second PLR model using forces of 4N-8N as a reference were similar to the previous model. More years of practice was significantly associated with generating forces >8N relative to the 4N-8N reference level (OR 1.04, 95% CI 1.001-1.081, *p*=0.045; Table 2 Model 2). Conversely, years of practice was not significantly associated with generating forces <4N compared to forces between 4-8N (OR=0.991, *p*=0.698).

There was a significant negative association between the number of URS/month and force <4N relative to 4N-8N. In reference to performing >20 URS/month, performing ≤20 URS/month was associated with significantly lower likelihood of using forces <4N (1-10 URS: OR 0.231, 95% CI 0.069-0.771, *p*=0.017; 11-20 URS: OR 0.3, 95% CI 0.095-0.95, *p*=0.041).

DISCUSSION

The risk of urothelial splitting during UAS passage is concerning given publications by highly experienced ureteroscopists citing a high-grade injury rate (i.e., a ureteral wall tear) of 13-26% when passing only a 14Fr UAS[9,16,17]~~. This problem has a) dissuaded physicians from using a UAS (about one-quarter of our study population) and b) caused those who use a UAS to opt for a smaller, less efficient sheath (i.e. ≤12Fr for 82% of the participants)~~~~[21]~~[9,16,17]. This problem has a) dissuaded physicians from using a UAS (about one-quarter of our study population) and b) caused those who use a UAS to opt for a smaller, less efficient sheath (i.e. ≤12Fr for 82% of the participants)[21].

~~Prior to our study, Monga et al. evaluated insertion forces using a 21Fr catheter-based UAS prototype and a digital force sensor in a non-anatomic bench-top setting[22]~~

Prior to our study, Monga et al. evaluated insertion forces using a 21Fr catheter-based UAS prototype and a digital force sensor in a non-anatomic bench-top setting[22]. Among 13 participants (8 urologists and 5 residents), there was a difference in maximum force between trained urologists and residents (6.55N vs. 4.84N, p=0.035). Subsequently, we sought to expand on the initial study by Monga et al. by determining the forces commonly applied during the passage of commercially available 12Fr, 14Fr, and 16Fr UASs among a large group of urologists and urology residents using an anatomically accurate genitourinary model. We then related the forces exerted by the participants to the known safe force thresholds for UAS passage based on our earlier porcine and clinical studies.

Our study revealed that the majority of urologists miss both the “sweet range” of 4-6N (74%) as well as the “safe range” of 4-8N (61%); they either push too hard~~ and risk~~, risking ureteral injury, or push too gently~~ and~~, thus ~~place~~placing a smaller UAS ~~thereby~~and diminishing the efficiency of the URS procedure~~[21]~~[21]. In essence, this is a *Goldilocks* conundrum; there currently is no instrument available for urologists to indicate when the applied UAS force is *"just right,"* neither *too soft* nor *too hard*.

An applied safe force of 6N versus a potentially injurious force of 8N differs by less than a half-pound. Our results revealed that 32% of physicians exceeded 8N, posing a risk of high-grade injury. Indeed, even among participants with a high-volume of ~~UAS experience~~URS cases (i.e., >20 URS/month), 15% and 18% exceeded forces of 6N and 8N, respectively. Clearly, even in the ~~most experienced~~ hands of high-volume ureteroscopists, differentiating between a safe UAS placement force of 6N (i.e., 1.35lbf) and a potentially injurious force of 8N (i.e., 1.80lbf) is too subtle for most surgeons to discern.

Furthermore, we are concerned that the significance of higher grade PULS scores may not be fully appreciated. ~~The CROES database indicated UAS passage does not increase ureteral stricture risk versus ureteroscopy without UAS passage, however UAS patients were not subcategorized based on PULS or TISG score[18]. A preliminary survey of our UCI URS database (>750 ureteroscopies) revealed that strictures are rare among PULS 0, 1, and 2 patients at 0%, 0.4% (1/253), and 0.93% (1/108) respectively, while PULS 3 patients experienced a disconcerting high stricture rate: 10.5% (2/19 patients).~~ The CROES database indicated UAS passage does not increase ureteral stricture risk versus ureteroscopy without UAS passage, however UAS patients were not subcategorized based on PULS or TISG scores[18]. A preliminary retrospective survey of our UCI URS database (>750 ureteroscopies) revealed that strictures are rare among PULS 0, 1, and 2 patients at 0%, 0.4% (1/253), and 0.93% (1/108) respectively, while PULS 3 patients experienced a disconcerting high stricture rate: 10.5% (2/19 patients)[23].

Conversely, insufficient force during sheath insertion is related to smaller UAS placement, which can hinder the procedure. To explore this further, we analyzed physicians exerting forces below 4N. There was a direct significant difference in URS/month between those exerting ≤4N versus >4N (Table 1).

During clinical practice, when the force of UAS passage can be objectively monitored, the outcome is far different. To date, armed with the UAS force sensor, our clinical work has enabled us to routinely place a 16Fr UAS (58% of our patients) without incurring any PULS 3 lesions~~[23]. This sharply contrasts with the current survey group, where only 3% of the participants routinely used a 16Fr UAS; this finding mirrors a global survey of 216 endourologists, where just 2.73% commonly employed a 16Fr UAS[24].~~[24]. This sharply contrasts with the current survey group, where only 3% of the participants routinely used a 16Fr UAS; this finding mirrors a global survey of 216 endourologists, where just 2.73% commonly employed a 16Fr UAS[25]. Of note, the 13-26% injury rate reported in the literature all occurred during passage of a smaller 14Fr UAS.

~~Our findings are the first to couple the surgical force associated with ureteral injury during UAS placement with an investigation of forces exerted by urologists. We contend that a reliable and practical method to measure UAS deployment force is critical[22,23,25]. The *sine qua non* is for the urologist to stay within the *Goldilocks* range, specifically, to know when force levels have not~~

~~yet surpassed 4N, exceeded 6N, or in a worst-case scenario, reached 8N. Our current investigational UCI UAS force sensor is expensive, cumbersome, and overly precise for widespread dissemination. Accordingly, we are in the process of developing a commercial product to be used in tandem with the UAS during its passage; the device would alert the urologist when 4N, 6N, or in the most concerning case, 8N force levels are exerted. We believe that having this information would prevent UAS under-sizing at 4N, while warning of impending ureteral injury risk should 6N be exceeded or 8N be reached. We also believe that the potential exists for safe deployment of UAS larger than 16Fr. Indeed, a recent ureteral-sizing clinical study completed at UCI revealed that at the 6N threshold, 15% of human ureters could safely accept a urethral dilator ≥18Fr[23].~~

~~Limitations of this study include its bench-top nature and conference setting. The absence~~

Our findings are the first to couple the surgical force associated with ureteral injury during UAS placement with an investigation of forces exerted by urologists. We contend that a reliable and practical method to measure UAS deployment force is critical[22,24,26]. The *sine qua non* is for the urologist to stay within the *Goldilocks* range–knowing when force levels have not yet surpassed 4N, exceeded 6N, or in a worst-case scenario, reached 8N. Our current investigational UCI UAS force sensor, while expensive and cumbersome, is being developed into a commercial product for widespread use. This device, when used in tandem with UASs, would alert urologists to force levels of 4N, 6N, or, in the most concerning case, 8N, allowing them to prevent under-sizing at 4N and avoid the risks of ureteral injury at 6N or 8N. We also believe that the potential exists for safe deployment of UAS larger than 16Fr. Indeed, a recent UCI clinical study revealed that at the 6N threshold, 15% of human ureters could safely accept a urethral dilator ≥18Fr[24].

Limitations of this study include its bench-top nature and conference setting. The absences of lubricant and the model's inability to duplicate the three distinct areas of narrowing in the human ureter~~,~~ are also noted. Our survey was limited as participants' location of practice (state/country) and an evaluation of the face validity of the model was not obtained. Lastly, participants' awareness of prior UCI publications on UAS force measurement might have influenced how they proceeded to pass each UAS.

CONCLUSIONS

Overall, 29% of participating urologists and urology residents-in-training exerted ≤4N and 45% exceeded a clinically defined safety threshold of 6N when placing a 16Fr UAS. Moreover, 32% of the participants exceeded 8N, a level of force associated with ~~PULS 3~~high-grade ureteral injury.

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The authors confirm their roles and contributions to the article as outlined: Study conception and methodology: S.A.M.L., K.L.M., R.V.C. Data collection: S.A.M.L., A.R., A.D.C., K.L.M., M.C.H., A.M., P.P., K.V., A.R.H.G., S.H.H.S. Data curation: S.A.M.L., A.R., A.D.C., K.L.M., M.C.H., A.M., P.P., K.V. Formal Analysis: S.A.M.L., K.O. Manuscript preparation and review: all authors. Critical manuscript revision: S.A.M.L., R.M.P., J.L., R.V.C. Each author conducted a review of the results and granted their approval for article submission.

AUTHOR DISCLOSURE STATEMENT

No competing financial interests currently exist.

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Table 1. Univariate analysis of participant characteristics and relationship to force exerted during insertion of a 16Fr ureteral access sheath.

	Group 1: Forces ≤4N (n = 35)	**Group 2: Forces >4N (n = 86)**	***P****	**Group 3: Forces ≤6N (n = 66)**	**Group 4: Forces >6N (n = 55)**	***P****	**Group 5: Forces ≤8N (n = 82)**	**Group 6: Forces >8N (n = 39)**	***P****
Mean years of practice (SD)	8.3 (10.3)	11.5 (11.7)	0.167	8.0 (11.4)	13.5 (13.7)	***0.008***	8.8 (12.0)	14.2 (12.2)	***0.014***
Mean age (SD)	41.1 (11.5)	43.5 (13.1)	0.365	40.4 (9.4)	45.7 (12.4)	***0.023***	40.9 (10.6)	46.7 (13.5)	***0.018***
Number of ureteroscopies (%)			***0.012***			***0.026***			0.154
0 per month	4 (11%)	5 (06%)		6 (09%)	3 (05%)		6 (08%)	3 (08%)	
1-10 per month	7 (20%)	38 (44%)		18 (27%)	27 (49%)		25 (30%)	20 (51%)	
11-20 per month	9 (26%)	27 (31%)		19 (29%)	17 (31%)		27 (33%)	9 (23%)	
>20 per month	15 (43%)	16 (19%)		23 (35%)	8 (15%)		24 (29%)	7 (18%)	
Sex (%)			0.688			0.920			0.382
Male	30 (86%)	76 (88%)		58 (88%)	48 (87%)		70 (85%)	36 (92%)	
Female	5 (14%)	10 (12%)		8 (12%)	7 (13%)		12 (15%)	3 (08%)	
Employment (%)			0.706			0.585			0.207
Resident/fellow	8 (23%)	19 (22%)		17 (26%)	10 (18%)		22 (27%)	5 (13%)	
Faculty	14 (40%)	41 (48%)		28 (42%)	27 (49%)		36 (44%)	19 (49%)	
Other	13 (37%)	26 (30%)		21 (32%)	18 (33%)		24 (29%)	15 (38%)	
Fellowship (%)			0.628			0.117			0.541
None	10 (29%)	29 (34%)		17 (26%)	22 (40%)		25 (30%)	14 (36%)	
Endourology	18 (51%)	31 (36%)		32 (48%)	17 (31%)		36 (44%)	13 (33%)	
Other	7 (20%)	26 (30%)		17 (26%)	16 (29%)		21 (26%)	12 (31%)	
Sheath Use (%)			0.838			0.682			0.874
Yes	25 (71%)	63 (73%)		49 (74%)	39 (71%)		60 (73%)	28 (72%)	
No	10 (29%)	23 (27%)		17 (26%)	16 (29%)		22 (27%)	11 (28%)	

N = Newton; SD = Standard Deviation

*p-values of 0.05 significance were calculated using Pearson's Chi-square test except for the difference in mean years of practice and age (two-group t-test)

Table 2. The polychotomous logistic regression comparing the nonideal force ranges to the ideal force ranges.

Model 1: Applied force outside of 4-6N reference range.

	Odds Ratio	95% Confidence Interval Lower	Higher	*P*
<4N vs 4N-6N				
Years of practice	1.004	0.954	1.056	0.893
Ureteroscopies per month				
0 vs >20	1.073	0.16	7.2	0.942
1-10 vs >20	0.341	0.095	1.227	0.1
11-20 vs >20	0.481	0.139	1.672	0.25
>6N vs 4N-6N				
Years of practice	1.049	1.004	1.096	***0.032***
Ureteroscopies per month				
0 vs >20	1.384	0.167	11.473	0.763
1-10 vs >20	2.536	0.745	8.64	0.137
11-20 vs >20	1.668	0.465	5.979	0.432

Model 2: Applied force outside of 4-8N reference range.

	Odds Ratio	95% Confidence Interval Lower	Higher	*P*
<4N vs 4N-8N				
Years of practice	0.991	0.947	1.037	0.698
Ureteroscopies per month				
0 vs >20	1.184	0.179	7.844	0.861
1-10 vs >20	0.231	0.069	0.771	***0.017***
11-20 vs >20	0.3	0.095	0.95	***0.041***
>8N vs 4N-8N				
Years of practice	1.04	1.001	1.081	***0.045***
Ureteroscopies per month				
0 vs >20	1.769	0.216	14.465	0.595
1-10 vs >20	1.43	0.435	4.699	0.555
11-20 vs >20	0.597	0.164	2.174	0.434

N = Newton

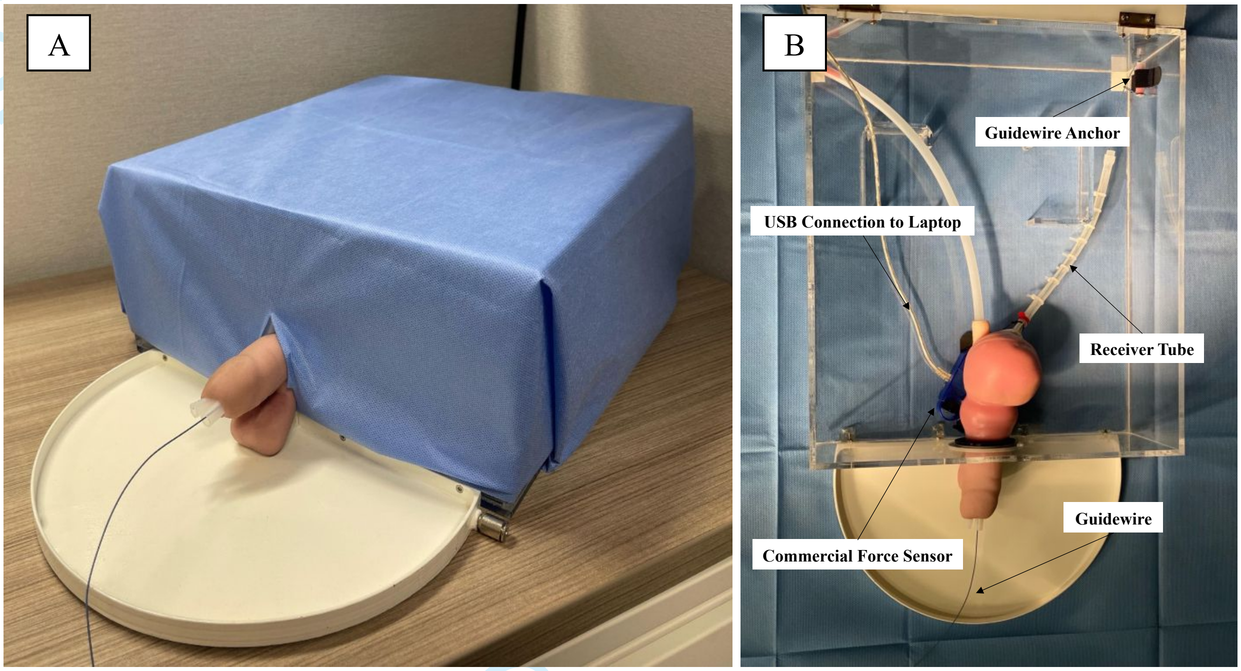

Figure 1. Urinary tract model with built-in Pasco® Scientific PASport™ force sensor. **A)** Participant view of model. **B)** Aerial view of interior components.

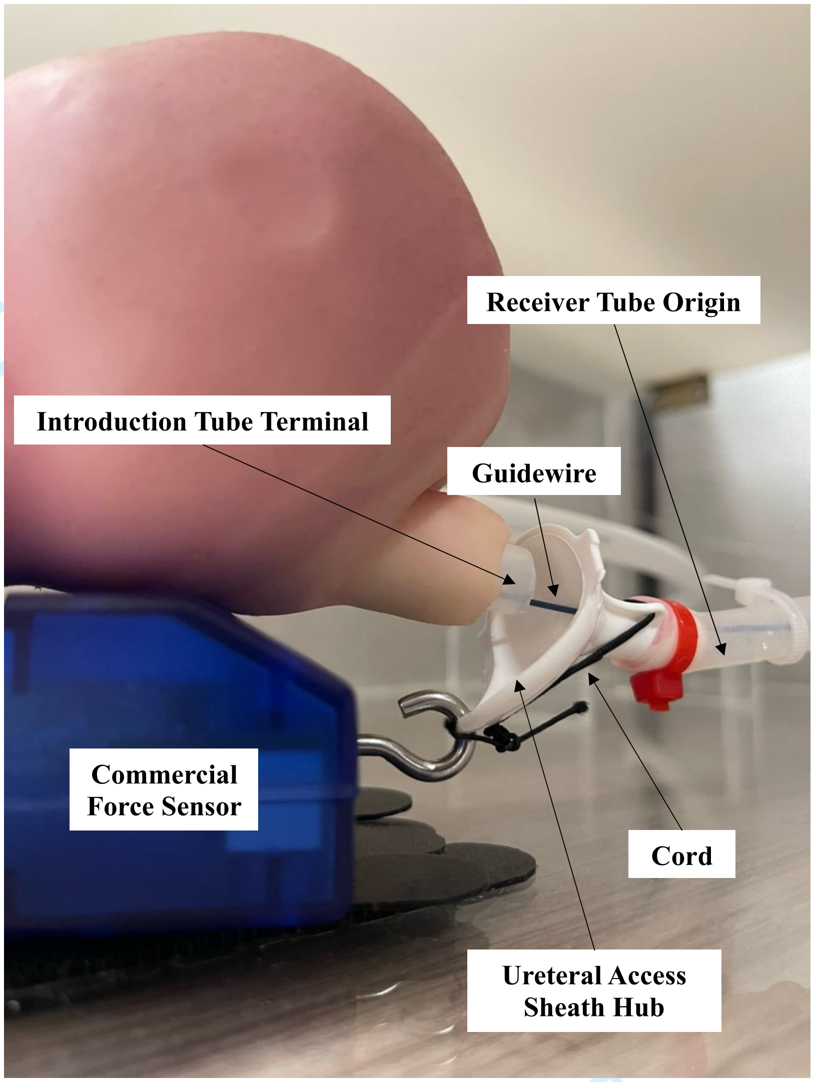

Figure 2. Enlarged view of the gap between the introduction tube and receiver tube.

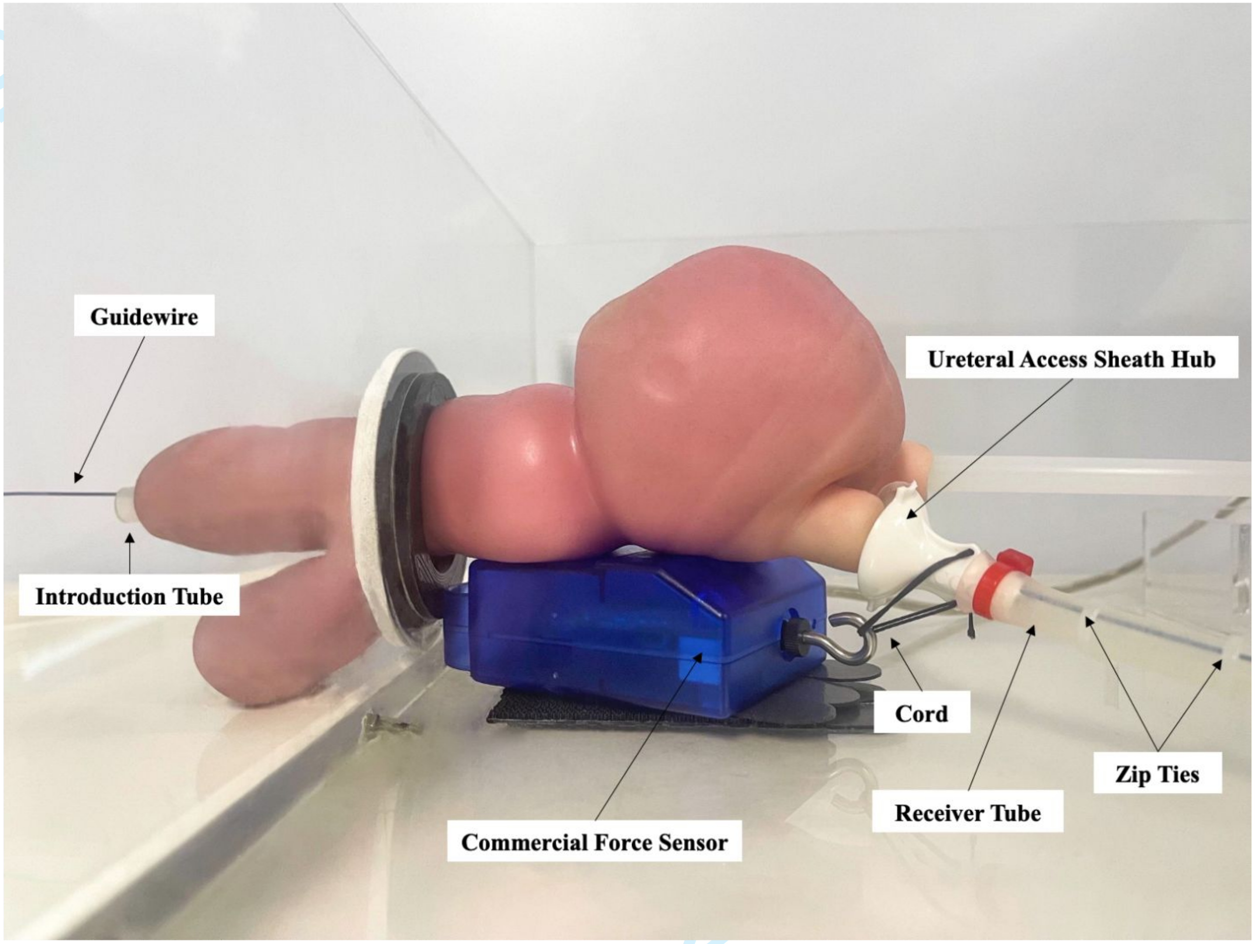

Figure 3. Detailed presentation of the male genitourinary force sensor model components.

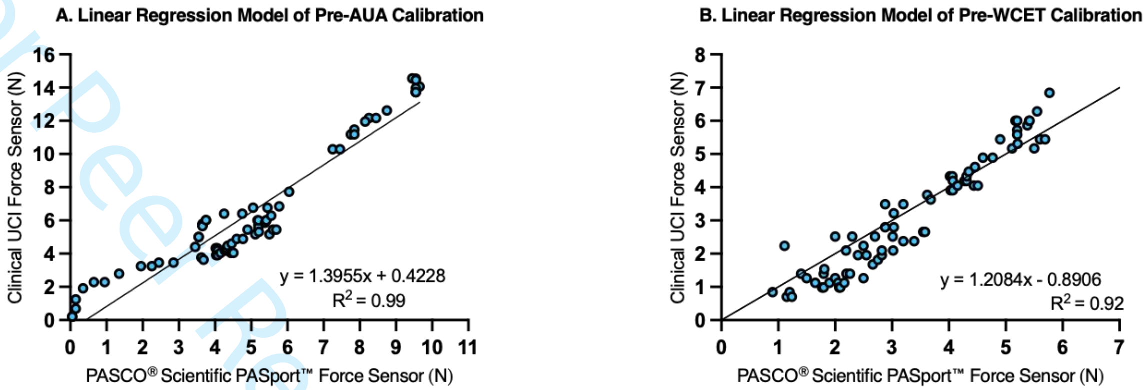

Figure 4. Linear regression model comparing the force data for both the handheld force sensor (y-axis) and the internally mounted force sensor (x-axis) plotted. These measurements calibrated the internally mounted force sensor to the handheld University of California, Irvine (UCI) ureteral access sheath force sensor, which had previously been used to determine force values for ureteral injury in both porcine and human ureters.

-Figure 4.A) Linear regression yielded a relationship of y = 1.3955x + 0.4228 (R^2 = 0.9869) for the pre-American Urological Association (AUA) test.

-Figure 4.B) Linear regression yielded a relationship of y = 1.2084x - 0.8906 (R^2 = 0.9209) for the pre-World Congress of Endourology and Technology (WCET) test.

FIGURE LEGENDS

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