UC Irvine

UC Irvine Previously Published Works

Title

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

Permalink https://escholarship.org/uc/item/7q28j943

Journal Journal of Endourology, O(ja)

ISSN

0892-7790

Authors

Lavasani, Seyed Amiryaghoub M Rojhani, Allen Cumpanas, Andrei Dragos <u>et al.</u>

Publication Date 2024-01-20

DOI 10.1089/end.2023.0548

Peer reviewed

JOURNAL OF ENDOUROLOGY

Journal of Endourology Manuscript Central: http://mc.manuscriptcentral.com/liebert/end

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

Journal:	Journal of Endourology
Manuscript ID	END-2023-0548-OR.R1
Manuscript Type:	Original Research
Date Submitted by the Author:	n/a
Complete List of Authors:	Lavasani, Seyed Amiryaghoub ; University of California Irvine, Urology Rojhani, Allen; University of California Irvine Department of Urology Cumpanas, Andrei; University of California Irvine, Urology Osann, Kathryn; University of California Irvine Department of Medicine, Division of Hematology/Oncology Morgan, Kalon; University of California Irvine Department of Urology Hernandez, Mariah; University of California Irvine Department of Urology McCormac, Amanda; University of California Irvine Department of Urology Piedras, Paul; University of California Irvine Department of Urology Vo, Kelvin; University of California Irvine Department of Urology Gorgen, Antonio; University of California Irvine Department of Urology Hosseini Sharifi, Seyed Hossein; University of California Irvine Department of Urology Gao, Bruce; University of California Irvine, Urology Tano, Zachary; University of California Irvine, Urology Patel, Roshan; University of California Irvine Department of Urology Clayman, Ralph; University of California Irvine, Urology
Keyword:	Ureteroscopy, Renal Stone, Urolithiasis, Simulation, Instrumentation, Uteroscopy Instrumentation
Manuscript Keywords (Search Terms):	Abbreviated injury scale, Anatomical model, Force applied, Surgical injury, Ureteroscopy, Ureteral Access Sheaths
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.

1 2		
3 4 5		
6 7		
8 9 10		
11 12		
13 14 15		
16 17		
18 19 20		
20 21 22		
23 24		
25 26 27		
28 29		
30 31 32		
33 34		
35 36		
37 38 39		
40 41		
42 43 44		
45 46		
47 48		
49 50 51		
52 53		
54 55		
50 57 58		

60

RESULTS: Participant force distributions were: \leq 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 \leq 20 ureteroscopies/month were significantly less likely to exert forces \leq 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).



1 2	
3	Abbreviations Used
4	ILAS – LIDETEDAL ACCESS SHEATH
5	N - NEWTONG
6	N = NEW IONS
7	PULS = POST-URETEROSCOPIC LESION SCALE
8	URS = URETEROSCOPY
9	TISG = TRAXER INJURY SCALE GRADE
10	CROES = CLINICAL RESEARCH OFFICE OF THE ENDOUROLOGICAL SOCIETY
11	UCI = UNIVERSITY OF CALIFORNIA, IRVINE
12	AUA = AMERICAN UROLOGICAL ASSOCIATION
13	WCET = WORLD CONGRESS OF ENDOUROLOGY AND TECHNOLOGY
14	PLR = POLYCHOTOMOLIS LOGISTIC REGRESSION
15	TER TOLITCHOTOMOOS LOGISTIC REGRESSION
10	
18	
19	
20	
21	
22	
23	
24	
25	
26	
27	
28	
29	
30 21	
37	
33	
34	
35	
36	
37	
38	
39 40	
40 41	
42	
43	
44	
45	
46	
47	
48	
49 50	
5U 51	
52	
53	
54	
55	
56	
57	
58	

• BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO



Ralph V. Clayman, MD DISTINGUISHED PROFESSOR OF UROLOGY DEPARTMENT OF UROLOGY ENDOWED CHAIR IN ENDOUROLOGY DEAN - EMERITUS UNIVERSITY OF CALIFORNIA, IRVINE 3800 CHAPMAN AVENUE, SUITE 7200 ORANGE, CA 92868 TEL: 714-456-6849 FAX: 888-378-4358 EMAIL: relayman@hs.uci.edu

Chandru P. Sundaram, MD Co-editor of *Journal of Endourology* Indiana University 140 Huguenot Street, 3rd Floor New Rochelle, NY 10801-5215

Dear Dr. Sundaram,

30 December 2023

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,

Seyed Amiryaghoub M. Lavasani Junior Research Specialist Department of Urology University of California, Irvine

Palph V. Claymon

Ralph V. Clayman, MD Distinguished Professor Endowed Chair in Endourology Department of Urology University of California. Irvine

76,700

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 $\leq 6N$ 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.000000000001719

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 <u>AND</u> 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	Low volume of URS	Intermediate volume of URS	High volume of URS
sheath size (Fr)	(<10/month)	(10-20/month)	(>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.

 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 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 pass 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 more Reviewer 2, Comment 6: Each participant was carefully observed during passage of each ot three UAS. The model worked well throughout the entire period of testing at both the AUA WCE without any kinking of the guidewire as evidenced by the smooth passage of the new as 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 study in 200 patients with a clinically validated force sensor and determined that at greater 8N, patients were at risk of high-grade ureteral injuries (<i>Tapiero S, Kaler KS, Jiang P, et al Determining the Safety Threshold for the Passage of a Ureteral Access Sheath in Clinical Practice Using Purpose-Puil: Force Sensor. J Urol. 2021;206(2):364-372. doi:10.1097/JU.000000000001719). That being said, a limitation of the present study is th this was a simulation model, and the participants may be more inclined to apply a higher for when there is no human consequence.</i> Were participants told they exerted high levels of force? Reviewer 2, Comment 8: No. The parti	 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 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 StiffTM (Cook® Group, Bloomington, IN, USA) guidewire pass 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 more Reviewer 2, Comment 6: Each participant was carefully observed during passage of each o three UAS. The model worked well throughout the entire period of testing at both the AUA WCE without any kinking of the guidewire as evidenced by the smooth passage of the 12F 14Fr UAS in each trial. Furthermore, the guidewire and inner working components of then 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 fell 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 study in 200 patients with a clinically validated force sensor and 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 this was a simulation model, and the participants may be more inclined to apply a higher for when there is no human consequence. Were participants told they exerted high levels of force? "A preliminary survey of our UCI U		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.
 We have clarified in the Materials and Methods section. Lines 97-99: "A 0.035in. Amplatz Super StiffTM (Cook® Group, Bloomington, IN, USA) guidewire pass 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 mode Reviewer 2, Comment 6: Each participant was carefully observed during passage of each o three UAS. The model worked well throughout the entire period of testing at both the AUA WCE without any kinking of the guidewire as evidenced by the smooth passage of the 12Fr 14Fr UAS in each trial. Furthermore, the guidewire and inner working components of the n 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 conducter study in 200 patients with a clinically validated force sensor and determined that at greater 8N, patients were at risk of high-grade ureteral injuries (<i>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/JJU.000000000001719). That being said, a limitation of the present study is th this was a simulation model, and the participants may be more inclined to apply a higher fo when there is no human consequence.</i> Were participants told they exerted high levels of force? Reviewer 2, Comment 8: No. The participants were completely blinded to the measuremen the forces exerted. "A preliminary survey of ou	 We have clarified in the Materials and Methods section. Lines 97-99: "A 0.035in, Amplatz Super StiffTM (Cook® Group, Bloomington, IN, USA) guidewire pass 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 mo Reviewer 2, Comment 6: Each participant was carefully observed during passage of each o three UAS. The model worked well throughout the entire period of testing at both the AUA WCE without any kinking of the guidewire as evidenced by the smooth passage of the 12Fi 14Fr UAS in each trial. Furthermore, the guidewire and inner working components of then 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 study in 200 patients with a clinically validated force sensor and determined that at greater 8N, patients were at risk of high-grade ureteral injuries (<i>Tapiero S, Kaler KS, Jiang P, et al Determining the Safety Threshold for the Passage of a Ureteral Keess 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 th this was a simulation model, and the participants may be more inclined to apply a higher for when there is no human consequence.</i> "A preliminary survey of our UCI URS database 227 (>750 ureteroscopies) revealed that structures are rare among PULS 0, 1, and 2 patients at 0%" although noteworthy and from a trustworthy source, without	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 I The guidewire used was a 0.035 Amplatz superstiff guidewire from Cook Medical Inc.
 Lines 97-99. "A 0.035in. Amplatz Super StiffTM (Cook® Group, Bloomington, IN, USA) guidewire pass 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 mode Reviewer 2, Comment 6: Each participant was carefully observed during passage of each o three UAS. The model worked well throughout the entire period of testing at both the AUA WCE without any kinking of the guidewire as evidenced by the smooth passage of the 12F1 14Fr UAS in each trial. Furthermore, the guidewire and inner working components of the n 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 study in 200 patients with a clinically validated force sensor and determined that at greater 8N, patients were at risk of high-grade ureteral injuries (<i>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;20(62):642-372. doi:10.1097/JU.000000000001719). That being said, a limitation of the present study is th this was a simulation model, and the participants were completely blinded to the measuremen the forces exerted.</i> "A preliminary survey of our UC1 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 corpropag	 "A 0.035in. Amplatz Super StiffTM (Cook& Group, Bloomington, IN, USA) guidewire pase 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 more Reviewer 2, Comment 6: Each participant was carefully observed during passage of each o three UAS. The model worked well throughout the entire period of testing at both the AUA WCE without any kinking of the guidewire as evidenced by the smooth passage of the 12Fr 14Fr UAS in each trial. Furthermore, the guidewire and inner working components of the n 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 study in 200 patients with a clinically validated force sensor and determining that at greater 8N, patients were at risk of high-grade ureteral injuries (<i>Tagiero 5, Kaler KS, Jiang P, et al</i> 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.000000000001719). That being said, a limitation of the present study is th this was a simulation model, and the participants may be more inclined to apply a higher fo when there is no human consequence. Were participants told they exerted high levels of force? "A preliminary survey of our UCI URS database 227 (>750 ureteroscopies) revealed that structworthy source, without some form a peer reviewed reference even abstract form this cor propagated into future articles		We have clarified in the Materials and Methods section.
 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 more Reviewer 2, Comment 6: Each participant was carefully observed during passage of each of three UAS. The model worked well throughout the entire period of testing at both the AUA WCE without any kinking of the guidewire as evidenced by the smooth passage of the 12Fr 14Fr UAS in each trial. Furthermore, the guidewire and inner working components of the n 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 study in 200 patients with a clinically validated force sensor and determined that at greater 8N, patients were at risk of high-grade ureteral injuries (<i>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 the this was a simulation model, and the participants may be more inclined to apply a higher force sexerted.</i> Were participants told they exerted high levels of force? Reviewer 2, Comment 8: No. The participants were completely blinded to the measuremen 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 corpro	 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 me Reviewer 2, Comment 6: Each participant was carefully observed during passage of each o three UAS. The model worked well throughout the entire period of testing at both the AUA WCE without any kinking of the guidewire as evidenced by the smooth passage of the 12Fr 14Fr UAS in each trial. Furthermore, the guidewire and inner working components of the n 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 study in 200 patients with a clinically validated force sensor and determined that at greater 8N, patients were at risk of high-grade ureteral injuries (<i>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 th this was a simulation model, and the participants may be more inclined to apply a higher for when there is no human consequence.</i> Were participants told they exerted high levels of force? "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 furstworthy source, without some form a peer reviewed reference even abstract form this cor propagated into future articles without proper referencing. I respectfully feel it is important a		"A 0.035in. Amplatz Super Stiff [™] (Cook® Group, Bloomington, IN, USA) guidewire passe per urethra was anchored to the model's posterior wall."
 What ensured the wires didn't bend after 30 passes of a UAS etc to ensure integrity of the more Reviewer 2, Comment 6: Each participant was carefully observed during passage of each of three UAS. The model worked well throughout the entire period of testing at both the AUA WCE without any kinking of the guidewire as evidenced by the smooth passage of the 12F1 14Fr UAS in each trial. Furthermore, the guidewire and inner working components of the n 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 study in 200 patients with a clinically validated force sensor and determined that at greater 8N, patients were at risk of high-grade ureteral injuries (<i>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.000000000001719). That being said, a limitation of the present study is this was a simulation model, and the participants may be more inclined to apply a higher for when there is no human consequence.</i> Were participants told they exerted high levels of force? Reviewer 2, Comment 8: No. The participants were completely blinded to the measuremen 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 con propagated into future articles without proper referencing. I respectfully feel it is important 	 What ensured the wires didn't bend after 30 passes of a UAS etc to ensure integrity of the me. Reviewer 2, Comment 6: Each participant was carefully observed during passage of each of three UAS. The model worked well throughout the entire period of testing at both the AUA WCE without any kinking of the guidewire as evidenced by the smooth passage of the 12F1 14Fr UAS in each trial. Furthermore, the guidewire and inner working components of the n 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 study in 200 patients with a clinically validated force sensor and determined that at greater 8N, patients were at risk of high-grade ureteral injuries (<i>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.000000000001719). That being said, a limitation of the present study is ft this was a simulation model, and the participants may be more inclined to apply a higher for when there is no human consequence.</i> Were participants told they exerted high levels of force? "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 corpopagated into future articles without proper referencing. I respectfully feel it is important adhere to standard of "reference-able" facts for the journal, even if just abstract. Would it be possible that this would be an abstrac		Lines 117-118: "They received instructions to place three Cook Medical Inc. Flexor® UAS (12Fr, 14Fr, 16Fr) sequentially"
 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 study in 200 patients with a clinically validated force sensor and determined that at greater 8N, patients were at risk of high-grade ureteral injuries (<i>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 th this was a simulation model, and the participants may be more inclined to apply a higher fo when there is no human consequence.</i> Were participants told they exerted high levels of force? Reviewer 2, Comment 8: No. The participants were completely blinded to the measurement 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 con propagated into future articles without proper referencing. I respectfully feel it is important. 	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 study in 200 patients with a clinically validated force sensor and determined that at greater 8N, patients were at risk of high-grade ureteral injuries (<i>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 th this was a simulation model, and the participants may be more inclined to apply a higher for 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 measuremen 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 furustworthy source, without some form a peer reviewed reference even abstract form this cor propagated into future articles without proper referencing. I respectfully feel it is important 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?</i>	What (ensured the wires didn't bend after 30 passes of a UAS etc to ensure integrity of the more Reviewer 2, Comment 6: Each participant was carefully observed during passage of each of three UAS. The model worked well throughout the entire period of testing at both the AUA WCE without any kinking of the guidewire as evidenced by the smooth passage of the 12Fr 14Fr UAS in each trial. Furthermore, the guidewire and inner working components of the m was inspected at regular intervals to ensure that there were no kinks or degradation.
 Were participants told they exerted high levels of force? Reviewer 2, Comment 8: No. The participants were completely blinded to the measurement 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 coupropagated into future articles without proper referencing. I respectfully feel it is important adhere to standard of "reference-able" facts for the journal even if just abstract. Would it be 	 Were participants told they exerted high levels of force? Reviewer 2, Comment 8: No. The participants were completely blinded to the measuremen 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 compropagated into future articles without proper referencing. I respectfully feel it is important 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? 	The pa higher freque	aper does raise the question whether in the real-world human ureters can take slightly forces that experienced urologists felt safe using, in that you figure they do this so ntly and are not injuring ureters at high rates (hopefully). Reviewer 2, Comment 7: We agree with the reviewer's comment. We previously conducted study in 200 patients with a clinically validated force sensor and determined that at greater the 8N, patients were at risk of high-grade ureteral injuries (<i>Tapiero S, Kaler KS, Jiang P, et al.</i> <i>Determining the Safety Threshold for the Passage of a Ureteral Access Sheath in Clinical</i> <i>Practice Using a Purpose-Built Force Sensor. J Urol.</i> 2021;206(2):364-372. <i>doi:10.1097/JU.000000000001719</i>). 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 for when there is no human consequence.
"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 con propagated into future articles without proper referencing. I respectfully feel it is important adhere to standard of "reference-able" facts for the journal even if just abstract. Would it be	"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 cou propagated into future articles without proper referencing. I respectfully feel it is important 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? Mary Ann Liebert, Inc.,140 Huguenot Street, New Rochelle, NY 10801	Were	Darticipants told they exerted high levels of force? Reviewer 2, Comment 8: No. The participants were completely blinded to the measurement the forces exerted.
possible that this would be an abstract before publication?	Mary Ann Liebert, Inc.,140 Huguenot Street, New Rochelle, NY 10801	Were J "A prestrictu trustw propag adhere possib	when there is no numan consequence. participants told they exerted high levels of force? Reviewer 2, Comment 8: No. The participants were completely blinded to the measurement the forces exerted. eliminary survey of our UCI URS database 227 (>750 ureteroscopies) revealed that res are rare among PULS 0, 1, and 2 patients at 0%" although noteworthy and from orthy source, without some form a peer reviewed reference even abstract form this c gated into future articles without proper referencing. I respectfully feel it is important to standard of "reference-able" facts for the journal, even if just abstract. Would it le 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..."

<text> 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 \leq 4N) or too much force i.e., 45% exerting forces \geq 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 \leq 4N) or too much force (i.e., 32% exerting forces \geq 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.000000000003269.02.

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.

I dy te, J pass as . Ag it would n. er than 4N, there. At might safely accep. gher renal pelvic pressure.

1 2			
3	1	Surgical Force: Initial Stu	dy and Clinical Implications
4	2	in the Assessment of Ureter	al Agooss Shooth Induced Injury
5	2	In the Assessment of Oreter	al Access Sheath Induced Injuly
6	5	Saved Amiryaghouh M. Lavasania*	slavasan@bs.uci.edu
7		Allen Deihenia	slavasali@lis.uci.cuu
8 0		Andrei D. Cumponogi	anemojnani@ginan.com
9 10		Andrei D. Cumpanas"	
11		Katnryn Osann ^o	Kosann@ns.uci.edu
12		Kalon L. Morgan ^a	kalonmorgan@gmail.com
13		Marian C. Hernandez ^a	mariahch@hs.uci.edu
14		Amanda McCormac ^a	amccorma@hs.uci.edu
15		Paul Piedras ^a	ppiedras@hs.uci.edu
16		Kelvin Vo ^a	kkelvinvo@gmail.com
17		Antonio R. H. Gorgen ^a	antoniogorgen@gmail.com
18		Seyed Hossein H. Sharifi ^a	shh.sharifi@gmail.com
19 20		Bruce M. Gao ^a	bruceg1@hs.uci.edu
20 21		Zachary E. Tano ^a	ztano@hs.uci.edu
27		Roshan M. Patel ^a	roshanmp@hs.uci.edu
23		Jaime Landman ^a	landmanj@hs.uci.edu
24		Ralph V. Clayman ^a	rclayman@hs.uci.edu
25	4		
26	5	^a Department of Urology, University	v of California. Irvine. Orange. CA. USA
27	6	^b Department of Medicine. Division of Hemat	tology/Oncology. University of California Irvine –
28	7	Irvine	e. CA. USA
29	8		
30 31	9	Corresponding Author:	
32	10	Ralph V. Clayman	
33	10	Distinguished Professor of Urology	
34	11	University of California Irvino	
35	12	Department of Urology	
36	15	2800 W. Charmon Ave. Swite 7200	
37	14	Store w. Chapman Ave. Suite 7200	
38	15	Orange, CA 92868	
39	16	Tel: /14-456-640/	
40 41	17	Fax: 888-378-4358	
41	18	Email: <u>rclayman(a)hs.uci.edu</u>	
43	19		
44	20	Manuscript Keywords: Abbreviated injury s	scale, Anatomical model, Force applied, Surgical
45	21	injury, Ureteroscopy, Ureteral Access Sheaths	
46	22		
47	23	Word Count of Abstract: 233 words (max 300)
48	24	Word Count of Text: 2,495 words (max 2500)	
49 50	25		
50 51			
52			
53			
54			
55			
56			
57			
58			
59 60		Mary Ann Liebert, Inc.,140 Hugi	uenot Street, New Rochelle, NY 10801
00		, , , , , , , , , , , , , , , , , , , ,	

26 <u>ABSTRACT</u>:

27 PURPOSE: Ureteral access sheaths (UAS) pose the risk of severe ureteral injury. Our prior
28 studies revealed forces ≤6 Newtons (N) prevent ureteral injury. Accordingly, we sought to define
29 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: $\leq 4N$ (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 $\leq 4N$ (*p*=0.017 and *p*=0.041). Of those surpassing 6N and 8N, 15% and 18% respectively were high-volume ureteroscopists.

46 CONCLUSIONS: Despite years of practice or volume of monthly ureteroscopic cases
47 performed, most urologists failed to pass 16Fr access sheaths within the ideal range of 4N-6N
48 (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 undefined¹. 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 formation⁸⁻¹⁴. 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
occurred⁹. 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 postoperative ureteral stricture formation¹⁸.

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 swine¹⁹. Subsequent clinical studies revealed a deployment force of $\leq 6N$ 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 8N²⁰. 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.

89 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).

Journal of Endourology

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 StiffTM (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 (\mathbb{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

2		
3 4	118	three Cook Medical Inc. Flexor® UAS (12Fr, 14Fr, 16Fr) sequentially while verbalizing their
5 6	119	decisions and indicating when they would cease UAS passage. Access sheaths were denoted with
7 8	120	colored lines to approximate the distance from the obturator's tip to what would be the "distal
9 10 11	121	ureter", "mid-ureter", and "ureteropelvic junction" in the model. Participants remained unaware
12 13	122	that applied force was being measured.
14 15	123	
16 17 19	124	Following UAS passage, participants completed a demographic and practice-based survey
19 20	125	including age, employment type, years of practice and training, fellowship, monthly URS
21 22	126	volume, UAS usage, and most commonly used size of UAS, if applicable.
23 24 25	127	
23 26 27	128	Statistical Analysis:
28 29	129	Participants were divided based on the maximum force recorded during UAS placement, based
30 31 32	130	upon thresholds of 4N, 6N, and $8N^{19,20}$. A descriptive analysis using either a two-group <i>t</i> -test or
32 33 34	131	Chi-square test was performed to identify differences between the groups when passing a 16Fr
35 36	132	UAS. A polychotomous logistic regression (PLR) model served to determine participant
37 38	133	characteristics associated with exceeding the 6N (or 8N) threshold or remaining below 4N
39 40 41	134	compared to reference levels of 4N-6N and 4N-8N with a 16Fr UAS. Odds ratios and 95%
42 43	135	confidence intervals were calculated.
44 45	136	
46 47 48	137	RESULTS
40 49 50	138	Among 121 participants (74 AUA and 47 WCET), there were 106 (88%) males and 15 (12%)
51 52	139	females (Table 1). There were 27 residents and fellows, 55 faculty urologists, and 39 urologists
53 54 55 56	140	listed as "other" (e.g., military, community, or private practice physicians). Sixty-seven
57 58 59 60		Mary Ann Liebert, Inc.,140 Huguenot Street, New Rochelle, NY 10801

Journal of Endourology

1		,
2 3	141	participants (55%) had fellowship training in endourology (49/121) or oncology (18/121).
4 5 6	142	Regarding monthly URS volume, 9/121 (7%) reported 0 URS, 45/121 (37%) reported 1-10 URS,
7 8	143	36/121 (30%) reported 11-20 URS, and 31/121 (26%) reported >20 URS/month. UAS placement
9 10 11	144	was routinely done by 88/121 (73%) participants. Among these 88 participants, a 10Fr, 12Fr,
12 13	145	14Fr, and 16Fr UAS was employed in their own clinical practice 17%, 65%, 31%, and 3% of the
14 15 16	146	time, respectively.
10 17 18	147	
19 20	148	Forces ≤4 versus >4:
21 22 22	149	Among the participants, 86 (71%) exceeded 4N with a 16Fr UAS, with 73% of the respondents
23 24 25	150	routinely using a UAS. In contrast, 35 participants (29%) remained below 4N, with 71%
26 27	151	routinely using a UAS. Participants exerting >4N had significantly more monthly URS volume
28 29	152	(p=0.012). No significant differences were found in years of practice, age, sex, type of
30 31 22	153	employment, endourology fellowship training, or UAS deployment (Table 1).
32 33 34	154	
35 36	155	Forces ≤6 versus >6:
37 38	156	Among the participants, 55 (45%) exceeded 6N with a 16Fr UAS, with 71% routinely using a
39 40 41	157	UAS. Conversely, 66 participants (55%) remained below 6N, with 74% routinely using a UAS.
42 43	158	Participants exerting >6N were significantly older (mean age 45.7 years vs. 40.4 years, $p=0.023$),
44 45	159	had significantly more years of practice (13.5 years vs. 8.0 years, $p=0.008$), and had performed
46 47 48	160	significantly less URS/month ($p=0.026$). No significant differences were found in sex, type of
49 50	161	employment, endourology fellowship training, or UAS deployment (Table 1).
51 52	162	
53 54	163	Forces ≤8 versus >8:
55 56		
57 58		
59 60		Mary Ann Liebert, Inc.,140 Huguenot Street, New Rochelle, NY 10801

2 3 4	164	Among the participants, 39 (32%) exceeded 8N with a 16Fr UAS with 72% routinely using a
5 6	165	UAS. Conversely, 82 participants (68%) remained below 8N, with 73% routinely using a UAS.
7 8 0	166	Participants exerting >8N were significantly older (46.7 years vs. 40.9 years, $p=0.018$) and had
9 10 11	167	significantly more years of practice (14.2 years vs. 8.8 years, $p=0.014$). No significant
12 13	168	differences were found in the number of URS/month, sex, type of employment, endourology
14 15	169	fellowship training, or use of a UAS (Table 1).
16 17 18	170	
19 20	171	In the univariate logistic regression analysis, older age, more years of practice, and lower number
21 22	172	of URS/month were associated with higher forces; however, while older age was associated with
23 24 25	173	higher force, this variable was excluded from the multivariate model due to its multicollinearity
26 27	174	with years of practice.
28 29	175	
30 31 32	176	In the first PLR model, more years of practice was significantly associated with using higher
33 34	177	forces >6N relative to the 4N-6N reference level (OR 1.049, 95% CI 1.004-1.096, <i>p</i> =0.032;
35 36	178	Table 2A). This parameter was not significantly associated with use of forces <4N compared to
37 38 30	179	the 4N-6N reference level (OR=1.004, p =0.893). In terms of URS/month, both the 1-10 and 11-
40 41	180	20 subgroups were associated with <i>higher</i> likelihood of forces >6N; however, ORs were not
42 43	181	statistically significant ($p=0.137$ and $p=0.432$ respectively). Both subgroups were associated with
44 45 46	182	lower likelihood of force <4N relative to the reference level; similarly, this was non-significant
40 47 48	183	(<i>p</i> =0.1 and <i>p</i> =0.25 respectively; Table 2 Model 1).
49 50	184	
51 52	185	Results for the second PLR model using forces of 4N-8N as a reference were similar to the
53 54 55 56 57	186	previous model. More years of practice was significantly associated with generating forces >8N
59 60		Mary Ann Liebert, Inc.,140 Huguenot Street, New Rochelle, NY 10801

2		
3 4	187	relative to the 4N-8N reference level (OR 1.04, 95% CI 1.001-1.081, <i>p</i> =0.045; Table 2 Model 2).
5 6	188	Conversely, years of practice was not significantly associated with generating forces <4N
7 8	189	compared to forces between 4-8N (OR=0.991, p=0.698).
9 10 11	190	
12 13	191	There was a significant negative association between the number of URS/month and force <4N
14 15	192	relative to 4N-8N. In reference to performing >20 URS/month, performing \leq 20 URS/month was
16 17 18	193	associated with significantly lower likelihood of using forces <4N (1-10 URS: OR 0.231, 95%
19 20	194	CI 0.069-0.771, <i>p</i> =0.017; 11-20 URS: OR 0.3, 95% CI 0.095-0.95, <i>p</i> =0.041).
21 22	195	
23 24	196	DISCUSSION
25 26 27	197	The risk of urothelial splitting during UAS passage is concerning given publications by highly
28 29	198	experienced ureteroscopists citing a high-grade injury rate (i.e., a ureteral wall tear) of 13-26%
30 31 22	199	when passing only a 14Fr UAS ^{9,16,17} . This problem has a) dissuaded physicians from using a
33 34	200	UAS (about one-quarter of our study population) and b) caused those who use a UAS to opt for a
35 36	201	smaller, less efficient sheath (i.e. \leq 12Fr for 82% of the participants) ²¹ .
37 38	202	
39 40 41	203	Prior to our study, Monga et al. evaluated insertion forces using a 21Fr catheter-based UAS
42 43	204	prototype and a digital force sensor in a non-anatomic bench-top setting ²² . Among 13
44 45	205	participants (8 urologists and 5 residents), there was a difference in maximum force between
46 47 48	206	trained urologists and residents (6.55N vs. 4.84N, $p=0.035$). Subsequently, we sought to expand
49 50	207	on the initial study by Monga et al. by determining the forces commonly applied during the
51 52	208	passage of commercially available 12Fr, 14Fr, and 16Fr UASs among a large group of urologists
53 54 55 56	209	and urology residents using an anatomically accurate genitourinary model. We then related the
57 58 59		Mary Ann Liebert, Inc. 140 Huguenot Street, New Rochelle, NY 10801
00		, , , ,

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 procedure²¹. 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 scores¹⁸. A preliminary retrospective survey of our UCI URS database (>750 ureteroscopies) revealed that strictures are rare among PULS 0, 1, and 2

Journal of Endourology

1		
2 3	232	patients at 0%, 0.4% (1/253), and 0.93% (1/108) respectively, while PULS 3 patients
4 5 6	233	experienced a disconcerting high stricture rate: 10.5% (2/19 patients) ²³ .
7 8 9	234	
10 11	235	Conversely, insufficient force during sheath insertion is related to smaller UAS placement, which
12 13	236	can hinder the procedure. To explore this further, we analyzed physicians exerting forces below
14 15	237	4N. There was a direct significant difference in URS/month between those exerting ≤4N versus
16 17 18	238	>4N (Table 1).
19 20	239	
21 22	240	During clinical practice, when the force of UAS passage can be objectively monitored, the
23 24 25	241	outcome is far different. To date, armed with the UAS force sensor, our clinical work has
25 26 27	242	enabled us to routinely place a 16Fr UAS (58% of our patients) without incurring any PULS 3
28 29	243	lesions ²⁴ . This sharply contrasts with the current survey group, where only 3% of the participants
30 31	244	routinely used a 16Fr UAS; this finding mirrors a global survey of 216 endourologists, where
32 33 34	245	just 2.73% commonly employed a 16Fr UAS ²⁵ . Of note, the 13-26% injury rate reported in the
35 36	246	literature all occurred during passage of a smaller 14Fr UAS.
37 38	247	
39 40 41	248	Our findings are the first to couple the surgical force associated with ureteral injury during UAS
42 43	249	placement with an investigation of forces exerted by urologists. We contend that a reliable and
44 45	250	practical method to measure UAS deployment force is critical ^{22,24,26} . The <i>sine qua non</i> is for the
46 47 48	251	urologist to stay within the Goldilocks range-knowing when force levels have not yet surpassed
48 49 50	252	4N, exceeded 6N, or in a worst-case scenario, reached 8N. Our current investigational UCI UAS
51 52	253	force sensor, while expensive and cumbersome, is being developed into a commercial product
53 54	254	for widespread use. This device, when used in tandem with UASs, would alert urologists to force
55 56 57		
58 59		
60		Mary Ann Liebert, Inc.,140 Huguenot Street, New Rochelle, NY 10801

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 ≥ 18 Fr²⁴. 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.

1 ว		
2	272	
4	272	ACKNOWLEDGEMENIS
5	273	We extend our sincere appreciation to all the physicians who kindly dedicated their time during
6	2/4	their conference day to participate in our research.
7	275	
8	276	AUTHORS' CONTRIBUTIONS:
9	277	The authors confirm their roles and contributions to the article as outlined: Study conception and
10	278	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.,
11	279	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.,
12	280	M.C.H., A.M., P.P., K.V. Formal Analysis: S.A.M.L., K.O. Manuscript preparation and review:
14	281	all authors. Critical manuscript revision: S.A.M.L., R.M.P., J.L., R.V.C. Each author conducted a
15	282	review of the results and granted their approval for article submission.
16	283	
17	284	AUTHOR DISCLOSURE STATEMENT
18	285	No competing financial interests currently exist.
19	286	
20	287	FUNDING INFORMATION
21	288	All funds were provided by the Curiosity and Innovation Laboratory in the Department of
22	280	Urology at the University of California Irvine
23 24	20)	orology at the oniversity of camorina, itvine.
25	270	
26		
27		
28		
29		
30		
31		
32		
27 27		
35		
36		
37		
38		
39		
40		
41		
42		
43 11		
44 45		
46		
47		
48		
49		
50		
51		
52 53		
54		
55		
56		
57		
58		

1			14
2			
3	201		REFERENCES
4	291		Colohmodi AK Khan DZ Mulanaz CD at al Tool tique formas in gurgarry A gustamatic
5	292	1.	review. Ann Med Surg 2021:65:102268: doi: 10.1016/j.amsu.2021.102268.
0	294	2	Wong VK Aminolteiari K Almutairi K et al Controversies associated with ureteral access
/ 0	205		sheath placement during ureteroscopy. Investig Clin Urol 2020:61(5):455_463: doi:
0	206		10.4111/inv. 20200279
10	290	2	10.4111/100.20200276.
11	297	3.	Bustos NH, Yaghoubian A, Mozafarpour S, et al. History of the Development of Guidewires,
12	298		Access Sheaths, Baskets, and Ureteral Stents. In: History of Technologic Advancements in
13	299		Urology. (Patel SR, Moran ME, Nakada SY, Eds.) Springer International Publishing; 2018;
14	300		pp. 79–85.
15	301	4.	Bozzini G, Bevilacqua L, Besana U, et al. Ureteral access sheath-related injuries vs. post-
16	302		operative infections. Is sheath insertion always needed? A prospective randomized study to
17	303		understand the lights and shadows of this practice. Actas Urol Esp 2021:S0210-
18	304		4806(21)00125-X: doi: 10.1016/i.acuro 2020.11.010
19	305	5	Kourambas I Byrne RR Preminger GM Does a ureteral access sheath facilitate
20	206	5.	uratorosoopy? LUrol 2001-165(2):780, 702
21	207	6	Auga DK Distroyy DK Lalles CD, et al. Urstaral access shooth provides protection accingt
22	200	0.	Auge DK, Flettow FK, Lanas CD, et al. Official access sheath provides protection against
23	308		elevated renal pressures during routine nexible dreferoscopic stone manipulation. J Endouroi
24	309	-	2004;18(1):33–36; doi: 10.1089/08927/904322836631.
25	310	7.	L'esperance JO, Ekeruo WO, Scales CD, et al. Effect of ureteral access sheath on stone-free
20	311		rates in patients undergoing ureteroscopic management of renal calculi. Urology
28	312		2005;66(2):252–255; doi: 10.1016/j.urology.2005.03.019.
29	313	8.	Huang J, Zhao Z, AlSmadi JK, et al. Use of the ureteral access sheath during ureteroscopy: A
30	314		systematic review and meta-analysis. PLOS ONE 2018;13(2):e0193600; doi:
31	315		10.1371/journal.pone.0193600.
32	316	9.	Traxer O, Thomas A. Prospective evaluation and classification of ureteral wall injuries
33	317		resulting from insertion of a ureteral access sheath during retrograde intrarenal surgery. J
34	318		Urol 2013;189(2):580–584; doi: 10.1016/j.juro.2012.08.197.
35	319	10.	Lildal SK, Nørregaard R, Andreassen KH, et al. Ureteral access sheath influence on the
30 27	320		ureteral wall evaluated by cyclooxygenase-2 and tumor necrosis factor- α in a porcine model.
27 28	321		L Endourol 2017:31(3):307–313: doi: 10.1089/end 2016.0773
39	322	11	Özsov M Kyriazis I Vrettos T et al Histological changes caused by the prolonged
40	323	11.	nlacement of ureteral access sheaths: An experimental study in porcine model. Urolithiasis
41	323		$2018 \cdot 46(A) \cdot 397 - 40A \cdot doi: 10.1007/s00240-017-1007-9$
42	324	12	Lallas CD Auga BK Rai GV et al Laser Donnler flowmatric determination of urateral
43	225	12.	blood flow after ursteral access shorth placement. J Endoursel 2002:16(2):522-500: doi:
44	520 227		10 1080/080277002220012288
45	327	10	10.1089/0892//902320913288.
46	328	13.	Delvecchio FC, Auge BK, Brizuela KM, et al. Assessment of stricture formation with the
4/	329		ureteral access sheath. Urology 2003;61(3):518–522; discussion 522; doi: 10.1016/s0090-
48 40	330		4295(02)02433-0.
49 50	331	14.	Abrahams HM, Stoller ML. The argument against the routine use of ureteral access sheaths.
51	332		Urol Clin North Am 2004;31(1):83–87; doi: 10.1016/S0094-0143(03)00085-5.
52	333	15.	Schoenthaler M, Wilhelm K, Kuehhas FE, et al. Postureteroscopic lesion scale: a new
53	334		management modified organ injury scaleevaluation in 435 ureteroscopic patients. J
54	335		Endourol 2012;26(11):1425–1430; doi: 10.1089/end.2012.0227.
55			
56			
57			
58			
59 60			Mary Ann Liebert, Inc., 140 Huguenot Street, New Rochelle, NY 10801
00			

2		
3	336	16. Loftus CJ, Ganesan V, Traxer O, et al. Ureteral wall injury with ureteral access sheaths: A
4	337	randomized prospective trial. J Endourol 2020:34(9):932–936: doi: 10.1089/end.2018.0603.
5	338	17 Fulla J. Prasanchaimontri P. Rizk A. et al. Ureteral diameter as predictor of ureteral injury
6 7	339	during ureteral access sheath placement IUrol 2021.205(1):159–164. doi:
/ 8	340	10 1097/II J 0000000001299
9	341	18 Traver O Wendt-Nordahl G Sodha H et al Differences in renal stone treatment and
10	347	outcomes for patients treated either with or without the support of a ureteral access sheath:
11	343	The Clinical Research Office of the Endourological Society Ureteroscopy Global Study
12	344	World LUrol 2015:33(12):2137_2144: doi: 10.1007/s00345-015-1582-8
13	3/15	10 Kaler KS Lama DI Safullah S et al Ureteral access sheath deployment: How much force
14	346	is too much? Initial studies with a novel ureteral access sheath force sensor in the porcine
15 16	340	ureter I Endourol 2010:32(0):712, 718: doi: 10.1080/end.2010.0211
17	247	20 Taniara S. Kalar K.S. Jiang P. et al. Determining the safety threshold for the passage of a
18	240	20. Tapleto S, Kalet KS, Jiang T, et al. Determining the safety the should for the passage of a uratoral access shouth in aligned practice using a purpose built force songer. [Ural
19	250	2021.206(2).264 272. doi: 10.1007/11.000000000001710
20	550 251	2021,200(2).504-572,001.10.1097/JU.0000000000001719.
21	252	21. Tracy CR, Ghareed GM, Paul CJ, et al. Increasing the size of ureteral access sheath during
22	332 252	World LUrol 2019:26(6):071 078: doi: 10.1007/c00245.018.2204.7
23	222 254	Wolld J Ulol 2018, 50(0). 9/1-9/8, doi: 10.100//S00545-018-2204-2.
24 25	255	for design and training. Ural Des 2007:25(2):107, 100; doi: doi:10.1007/s00240.007.0086.4
26	333 256	101 design and training. Utor Res 2007, 55(2).107–109, doi: doi:10.1007/s00240-007-0080-4.
27	250	25. Cumpanas AD, Lavasam SAW, Isai JC, et al. Oreteral strictures following ureteroscopic
28	22/ 250	a previously undentified concern. J Otol 2024, Adstract submitted for
29	220 250	24 MaCarman A. Vy, MC, A fyouri AS, at al. Clinical manufacture of manimum cofe unstand
30	260	24. MicCollinac A, Vu MC, Alyouni AS, et al. Clinical measurement of maximum safe ureteral distancibility using a nexual forma gangar. LUral 2022;200 (Supplement 4):44(8): dai:
31 22	261	distensionity using a novel force sensor. J $O(012025,209)$ (Supplement 4).e468, doi:
33	262	001.10.1097/JU.00000000000000209.02.
34	262 262	during urateresseenv for nonbrolithingis: a survey among endourologists worldwide DMC
35	264	Ural 2010:10:59: dai: 10.1186/a12804.010.0480 x
36	265	0101 2019,19.30, doi: 10.1100/S12094-019-0409-X.
37	266	20. Lindai SK, Andreassen KH, Christiansen FE, et al. Filannacological relaxation of the ureter when using urstered access shooths during urstererenegoency. A rendemized fossibility study
38	267	in a paraina model. A dy Urol 2016;2016;2064649; doi: 10.1155/2016/2064649
39 40	269	III a porcine model. Adv 0101 2010,2010.8004048, doi: 10.1133/2010/8004048.
41	308	
42		
43		
44		
45		
46 47		
47		
49		
50		
51		
52		
53 51		
55		
56		
57		
58		
59		

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

	Group 1: Forces ≤4N	Group 2: Forces >4N	P *	Group 3: Forces ≤6N	Group 4: Forces >6N	P *	Group 5: Forces ≤8N	Group 6: Forces >8N	Р*
	(n = 35)	(n = 86)		(n = 66)	(n = 55)		(n = 82)	(n = 39)	
Mean vears of	8.3	11.5	0.167	8.0	13.5	0.008	8.8	14.2	0.014
practice (SD)	(10.3)	(11.7)		(11.4)	(13.7)		(12.0)	(12.2)	
Mean age (SD)	41.1	43.5	0.365	40.4	45.7	0.023	40.9	46.7	0.018
	(11.5)	(13.1)		(9.4)	(12.4)		(10.6)	(13.5)	
Number of			0.012			0.026			0.154
ureteroscopies (%)									
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 De	eviation						Z	
372 *p-values of	0.05 significan	ce were calcula	ted using Pe	earson's Chi-squ	are test except	for the diffe	erence in mean y	years of practice	;
and age (two	-group <i>t</i> -test)								
5/4									

375	Table 2. The polychotomous logistic regression comparing the nonideal force ranges to the ideal
376	force ranges.
377	

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

		95% Confid	95% Confidence Interval		
	Odds Ratio	Lower	Higher	Р	
<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	

27 378

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

		95% Confid	ence Interval	
	Odds Ratio	Lower	Higher	Р
<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





Figure 1. Urinary tract model with built-in Pasco® Scientific PASport[™] force sensor.

A) Participant view of model. B) Aerial view of interior components.

Mary Ann Liebert, Inc., 140 Huguenot Street, New Rochelle, NY 10801







FIGURE LEGENDS

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

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

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 were used to calibrate the internally mounted force sensor to the handheld University of California, Irvine (UCI) ureteral access sheath force sensor previously used to determine the 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 (R² = 0.9869) for the pre-American Urological Association (AUA) test.
- -Figure 4.B) Linear regression yielded a relationship of y = 1.2084x - 0.8906 (R² = 0.9209)
 - for the pre-World Congress of Endourology and Technology (WCET) test.

f y = 1.395. f test. p of y = 1.2084x - v. Technology (WCET) tes.

1 2			
3	1	Surgical Force: Initial Stu	dy and Clinical Implications
4	2	in the Assessment of Ureter	al Access Sheath Induced Injury
5	3		
7		Seyed Amiryaghoub M. Lavasani ^a *	slavasan@hs.uci.edu
8		Allen Rojhani ^a	allenrojhani@gmail.com
9		Andrei D. Cumpanas ^a	acumpana@hs.uci.edu
10		Kathryn Osann ^b	kosann@hs uci edu
11		Kalon L. Morgan ^a	kalonmorgan@gmail.com
12		Mariah C. Hernandez ^a	mariahch@hs.uci.edu
13		Amanda McCormac ^a	amccorma@hs.uci.edu
14		Paul Piedras ^a	nniedras@hs.uci.edu
15 16		Kelvin Voa	kkelvinvo@gmail.com
10		Antonio P. H. Gorgona	antoniogorgon@gmail.com
18		Saved Hessein H. Sherifi	antoniogoigen(@ginan.com
19	1	Dress M. Cara	
20		Bruce M. Gao"	oruceg1@ns.uci.edu
21		Zachary E. Tano ^a	ztano@ns.uci.edu
22		Roshan M. Patel ^a	roshanmp@hs.uci.edu
23		Jaime Landman ^a	landmanj@hs.uci.edu
24		Ralph V. Clayman ^a	rclayman@hs.uc1.edu
25	4		
20 27	5	^a Department of Urology, University	of California, Irvine, Orange, CA, USA
27	6	^b Department of Medicine, Division of Hemat	ology/Oncology, University of California Irvine –
29	7	Irvine	e, CA, USA
30	8		
31	9	Corresponding Author:	
32	10	Ralph V. Clayman	
33	11	Distinguished Professor of Urology	
34	12	University of California, Irvine	
35	13	Department of Urology	
30 27	14	3800 W. Chapman Ave. Suite 7200	
38	15	Orange, CA 92868	
39	16	Tel [.] 714-456-6407	
40	17	Fax: 888-378-4358	
41	18	Email: rclayman@hs.uci.edu	
42	19	Email: <u>rotayman@ib.doi.odd</u>	
43	20	Manuscript Keywords: Abbreviated injury s	cale Anatomical model Force applied Surgical
44	20	injury Ureteroscony Ureteral Access Sheaths	eure, Finatonnear model, Force appried, Surgicar
45 46	$\frac{21}{22}$	injury, orecroscopy, orecertar recess sheatins	
40 17	22	Word Count of Abstract: 233 words (max 300)	
48	23	Word Count of Text: 2 483405 words (max 300	(00)
49	24	word Count of Text. $2,433495$ words (max 25	
50	23		
51			
52			
53			
54			
22 56			
50			
58			
59			
60		Mary Ann Liebert, Inc.,140 Hugu	ienot Street, New Rochelle, NY 10801

26 <u>ABSTRACT</u>:

27 PURPOSE: Ureteral access sheaths (UAS) pose the risk of severe ureteral injury. Our prior
28 studies revealed forces ≤6 Newtons (N) prevent ureteral injury. Accordingly, we sought to define
29 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: $\leq 4N$ (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 $\leq 4N$ (*p*=0.017 and *p*=0.041). Of those surpassing 6N and 8N, 15% and 18% respectively were high-volume ureteroscopists.

46 CONCLUSIONS: Despite years of practice or volume of monthly ureteroscopic cases
47 performed, most urologists failed to pass 16Fr access sheaths within the ideal range of 4N-6N
48 (74% of participants) or within a predefined safe range of 4N-8N (61% of participants).

49	INTRODUCTION
50	Historically, various catheters, guidewires, and endoscopes have been used without knowing the
51	tolerance of the tissues comprising the lumen through which they were being passed; in all cases,
52	patients must rely upon the surgeon's skill and deftness of touch to prevent injury. Despite
53	technological advances, surgical tools have not been designed to detect excessive force applied
54	to a structure structures; indeed, for most tissues, the threshold force at which injury occurs is
55	undefined ¹ . To date, there have been no studies coupling documented in-vivo tissue injury-
56	causing forces with the actual clinical forces being applied by the physician physicians
57	performing the procedure procedures. In this manuscript, we define the relationship between
58	known forces associated with ureteral injury during ureteral access sheath (UAS) passage with
59	the force urologists and urologists-in-training may apply during UAS placement.
60	
61	Since its advent in 1974, use of UAS has been controversial. While it enhances endoscopic
62	visibility, improves stone removal efficiency, reduces intrarenal pressure, and eases repeated
63	entry of the flexible ureteroscope ^{2–7} , there are concerns over the frequency of ureteral injury and
64	possible post-operative ureteral stricture formation ⁸⁻¹⁴ . In this regard, two scales assessing
65	ureteral injury following ureteroscopy (URS) have been proposed: the Post-Ureteroscopic Lesion
66	Scale (PULS: grades 0-5) and the Traxer Injury Scale Grade (TISG: grades 0-4) ^{9,15} .
67	
68	When considering injury grades ≥ 2 (i.e. a tear in the ureteral wall of varying depth and extent),
69	Traxer et al. found that in 13% of cases in which a 14Fr UAS was deployed, a grade ≥ 2 injury
70	occurred ⁹ . This was further corroborated in several other publications employing only a 14Fr
71	UAS; Monga et al. reported urothelial disruption in 23-26% of cases (TISG \geq 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 formation¹⁸.

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 \geq 3 in swine¹⁹. Subsequent clinical studies revealed a deployment force of \leq 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 8N²⁰. 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. 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 47. 1000 Scale (PULS: grades 0-5) and the Traxer Injury Scale Grade (TISG: grades 0-4)^{9,15}.

94	When considering injury grades ≥ 2 (i.e. a tear in the ureteral wall of varying depth and extent),
95	<u>Traxer et al. found that in 13% of cases in which a 14Fr UAS was deployed, a grade ≥ 2 injury</u>
96	occurred ⁹ . This was further corroborated in several other publications employing only a 14Fr
97	<u>UAS; Monga et al. reported urothelial disruption in 23-26% of cases (TISG \geq2) and</u>
98	Schoenthaler et al. reported a 24% injury rate (PULS ≥ 2) ^{9,15–17} . Despite this high level of acute
99	urothelial disruption, the Clinical Research Office of the Endourological Society (CROES) found
00	that cases with and without UAS deployment generally had an equally low, 1% rate of post-
)1	operative ureteral stricture formation ¹⁸ .
)2	
)3	In conjunction with the Samueli School of Engineering at the University of California, Irvine
)4	(UCI), we developed a UAS force sensor for continuous intraoperative measurement, in
)5	hundredths of a Newton (N), of the force applied during UAS deployment. Previously, forces
)6	<4.84N routinely demonstrated no ureteral damage, while forces >8.1N often resulted in a PULS
)7	<u>score \geq3 in swine¹⁹. Subsequent clinical studies revealed a deployment force of \leq6N resulted in</u>
)8	no PULS 3 lesions among 200 patients (210 anatomically normal ureters without prior radiation,
)9	reimplantation, reconstruction, or transplantation), despite successful passage of a 16Fr UAS in
0	61% of patients. Only two PULS 3 scores were reported, both with forces exceeding 8N ²⁰ . This
1	investigation prompted further scrutinization of forces applied during UAS placement in the
2	context of ureteral injury. Herein, we explore UAS force exerted by over 100 urologists and
3	residents-in-training on a male genitourinary model.
4	
5	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 distal end, was positioned in-line with the introduction tube (Figure 2). ZipSequential 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

Journal of Endourology

3 4	139	with the external UCI UAS force sensor values. The best fit lines revealed a reliable, consistent
5 6	140	relationship between the Pasco [®] and the UCI UAS force sensors (R^2 value ≥ 0.9) (Figure
7 8	141	4).
9 10 11	142	
12 13	143	Urologists and residents-in-training were recruited during the 2022 AUA and WCET annual
14 15 16	144	meetings. Participants were made aware that the study's primary emphasis of the study was to
16 17 18	145	evaluate their decision-making process with respect to UAS placement. They received
19 20	146	instructions to place three Cook Medical Inc. Flexor® UAS (12Fr, 14Fr, 16Fr) sequentially
21 22	147	while verbalizing their decisions and indicating when they would cease UAS passage. Access
23 24 25	148	sheaths were denoted with colored lines to approximate the distance from the obturator's tip to
26 27	149	what would be the "distal ureter", "mid-ureter", and "ureteropelvic junction" in the model.
28 29	150	Participants remained unaware that applied force was being measured.
30 31	151	
32 33 34	152	Following UAS passage, participants completed a demographic and practice-based survey
35 36	153	including age, employment type, years of practice and training, fellowship, monthly URS
37 38	154	volume, UAS usage, and most commonly used size of UAS, if applicable.
39 40 41	155	
42 43	156	Statistical Analysis:
44 45	157	Participants were divided based on the maximum force recorded during UAS placement, based
46 47 48	158	upon thresholds of 4N, 6N, and 8N ^{19,20} . A descriptive analysis using either a two-group <i>t</i> -test or
48 49 50	159	Chi-square test was performed to identify differences between the groups when passing a 16Fr
51 52	160	UAS. A polychotomous logistic regression (PLR) model served to determine participant
53 54	161	characteristics associated with exceeding the 6N (or 8N) threshold or remaining below 4N
55 56 57		
58		

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 experiencevolume, 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. 0. 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

Journal of Endourology

2 3 4	184	experience volume ($p=0.012$). No significant differences were found in years of practice, age,
4 5 6	185	sex, type of employment, endourology fellowship training, or UAS deployment (Table 1).
7 8	186	
9 10 11	187	Forces ≤6 versus >6:
12 13	188	Among the participants, 55 (45%) exceeded 6N with a 16Fr UAS, with 71% routinely using a
14 15	189	UAS. Conversely, 66 participants (55%) remained below 6N, with 74% routinely using a UAS.
16 17 18	190	Participants exerting >6N were significantly older (mean age 45.7 years vs. 40.4 years, $p=0.023$),
19 20	191	had significantly more years of practice (13.5 years vs. 8.0 years, $p=0.008$), and had performed
21 22	192	significantly less URS/month ($p=0.026$). No significant differences were found in sex, type of
23 24 25	193	employment, endourology fellowship training, or UAS deployment (Table 1).
26 27	194	
28 29	195	Forces ≤8 versus >8:
30 31 32	196	Among the participants, 39 (32%) exceeded 8N with a 16Fr UAS with 72% routinely using a
33 34	197	UAS. Conversely, 82 participants (68%) remained below 8N, with 73% routinely using a UAS.
35 36	198	Participants exerting >8N were significantly older (46.7 years vs. 40.9 years, $p=0.018$) and had
37 38 30	199	significantly more years of practice (14.2 years vs. 8.8 years, $p=0.014$). No significant
40 41	200	differences were found in the number of URS/month, sex, type of employment, endourology
42 43	201	fellowship training, or use of a UAS (Table 1).
44 45 46	202	
40 47 48	203	In the univariate logistic regression analysis, older age, more years of practice, and lower number
49 50	204	of URS/month were associated with higher forces; however, while older age was associated with
51 52	205	higher force, this variable was excluded from the multivariate model due to its multicollinearity
55 55	206	with years of practice.
56 57		
58 59 60		Mary Ann Liebert, Inc.,140 Huguenot Street, New Rochelle, NY 10801

2 3	207	
4	207	
6	208	In the first PLR model, more years of practice was significantly associated with using higher
7 8 9	209	forces >6N relative to the 4N-6N reference level (OR 1.049, 95% CI 1.004-1.096, <i>p</i> =0.032;
10 11	210	Table 2A). This parameter was not significantly associated with use of forces <4N compared to
12 13	211	the 4N-6N reference level (OR=1.004, p =0.893). In terms of URS/month, both the 1-10 and 11-
14 15 16	212	20 subgroups were associated with <i>higher</i> likelihood of forces >6N; however, ORs were not
17 18	213	statistically significant ($p=0.137$ and $p=0.432$ respectively). Both subgroups were associated with
19 20	214	<i>lower</i> likelihood of force <4N relative to the reference level; similarly, this was non-significant
21 22 22	215	(p=0.1 and p=0.25 respectively; Table 2 Model 1).
23 24 25	216	
26 27	217	Results for the second PLR model using forces of 4N-8N as a reference were similar to the
28 29 20	218	previous model. More years of practice was significantly associated with generating forces >8N
30 31 32	219	relative to the 4N-8N reference level (OR 1.04, 95% CI 1.001-1.081, <i>p</i> =0.045; Table 2 Model 2).
33 34	220	Conversely, years of practice was not significantly associated with generating forces <4N
35 36 27	221	compared to forces between 4-8N (OR=0.991, p=0.698).
37 38 39	222	
40 41	223	There was a significant negative association between the number of URS/month and force <4N
42 43	224	relative to 4N-8N. In reference to performing >20 URS/month, performing \leq 20 URS/month was
44 45 46	225	associated with significantly lower likelihood of using forces <4N (1-10 URS: OR 0.231, 95%
40 47 48	226	CI 0.069-0.771, <i>p</i> =0.017; 11-20 URS: OR 0.3, 95% CI 0.095-0.95, <i>p</i> =0.041).
49 50	227	
51 52 53 54 55 56 57 58	228	DISCUSSION
59 60		Mary Ann Liebert, Inc.,140 Huguenot Street, New Rochelle, NY 10801

59

60

Journal of Endourology

229	The risk of urothelial splitting during UAS passage is concerning given publications by highly
230	experienced ureteroscopists citing a high-grade injury rate (i.e., a ureteral wall tear) of 13-26%
231	when passing only a 14Fr UAS ^{9,16,17} . This problem has a) dissuaded physicians from using a
232	UAS (about one-quarter of our study population) and b) caused those who use a UAS to opt for a
233	smaller, less efficient sheath (i.e. ≤12Fr for 82% of the participants) ^{219,16,17} . This problem has a)
234	dissuaded physicians from using a UAS (about one-quarter of our study population) and b)
235	caused those who use a UAS to opt for a smaller, less efficient sheath (i.e. ≤ 12 Fr for 82% of the
236	participants) ²¹ .
237	
238	Prior to our study, Monga et al. evaluated insertion forces using a 21Fr catheter-based UAS
239	prototype and a digital force sensor in a non-anatomic bench-top setting ²²
240	Prior to our study, Monga et al. evaluated insertion forces using a 21Fr catheter-based UAS
241	prototype and a digital force sensor in a non-anatomic bench-top setting ²² . Among 13
242	participants (8 urologists and 5 residents), there was a difference in maximum force between
243	trained urologists and residents (6.55N vs. 4.84N, $p=0.035$). Subsequently, we sought to expand
244	on the initial study by Monga et al. by determining the forces commonly applied during the
245	passage of commercially available 12Fr, 14Fr, and 16Fr UASs among a large group of urologists
246	and urology residents using an anatomically accurate genitourinary model. We then related the
247	forces exerted by the participants to the known safe force thresholds for UAS passage based on
248	our earlier porcine and clinical studies.
249	
250	Our study revealed that the majority of urologists miss both the "sweet range" of 4-6N (74%) as
251	well as the "safe range" of 4-8N (61%); they either push too hard and risk, risking ureteral
	229 230 231 232 233 234 235 236 237 238 239 240 241 242 243 244 245 244 245 246 247 248 249 250 251

injury, or push too gently-and, thus placeplacing a smaller UAS therebyand diminishing the
efficiency of the URS procedure²¹²¹. 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*.

 $\frac{2}{3}$ 256

An applied safe force of 6N versus a potentially injurious force of 8N differs by less than a halfpound. 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 experienceURS 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 score¹⁸. 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 scores¹⁸. A preliminary retrospective survey of our UCI URS database (>750 ureteroscopies) revealed that strictures are

י ר	
2	
3	
4	
5	
6	
7	
א	
0	
9	
10	
11	
12	
13	
14	
15	
16	
17	
17	
10	
19	
20	
21	
22	
23	
24	
25	
ע∠ ב	
20	
27	
28	
29	
30	
31	
32	
22	
ככ ∧ כ	
34 2-	
35	
36	
37	
38	
39	
40	
л Л 1	
41	
42	
43	
44	
45	
46	
47	
48	
10	
49	
50	
51	
52	
53	
54	
55	
56	
20	
5/	
58	
59	
60	

282

275 rare among PULS 0, 1, and 2 patients at 0%, 0.4% (1/253), and 0.93% (1/108) respectively,
276 while PULS 3 patients experienced a disconcerting high stricture rate: 10.5% (2/19 patients)²³.
277

278 Conversely, insufficient force during sheath insertion is related to smaller UAS placement, which 279 can hinder the procedure. To explore this further, we analyzed physicians exerting forces below 280 4N. There was a direct significant difference in URS/month between those exerting \leq 4N versus 281 >4N (Table 1).

283 During clinical practice, when the force of UAS passage can be objectively monitored, the 284 outcome is far different. To date, armed with the UAS force sensor, our clinical work has 285 enabled us to routinely place a 16Fr UAS (58% of our patients) without incurring any PULS 3 286 lesions²³. 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 287 just 2.73% commonly employed a 16Fr UAS²⁴.²⁴. This sharply contrasts with the current survey 288 289 group, where only 3% of the participants routinely used a 16Fr UAS; this finding mirrors a 290 global survey of 216 endourologists, where just 2.73% commonly employed a 16Fr UAS²⁵. Of note, the 13-26% injury rate reported in the literature all occurred during passage of a smaller 291 292 14Fr UAS.

293

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

2	
2	
3	
4	
5	
6	
7	
/	
8	
9	
10	
11	
12	
12	
13	
14	
15	
16	
17	
10	
10	
19	
20	
21	
22	
22	
2-J 2-≬	
24	
25	
26	
27	
28	
20	
29	
30	
31	
32	
33	
34	
25	
22	
36	
37	
38	
39	
40	
/1	
1 T	
42	
43	
44	
45	
46	
<u>4</u> 7	
77 10	
4ð	
49	
50	
51	
52	
53	
51	
54 55	
55	
56	
57	
58	
59	
60	

298 vet surpassed 4N, exceeded 6N, or in a worst-case scenario, reached 8N. Our current 299 investigational UCI UAS force sensor is expensive, cumbersome, and overly precise for 300 widespread dissemination. Accordingly, we are in the process of developing a commercial 301 product to be used in tandem with the UAS during its passage; the device would alert the 302 urologist when 4N, 6N, or in the most concerning case, 8N force levels are exerted. We believe 303 that having this information would prevent UAS under-sizing at 4N, while warning of impending 304 ureteral injury risk should 6N be exceeded or 8N be reached. We also believe that the potential 305 exists for safe deployment of UAS larger than 16Fr. Indeed, a recent ureteral-sizing clinical 306 study completed at UCI revealed that at the 6N threshold, 15% of human ureters could safely 307 accept a urethral dilator ≥ 18 Fr²³. 308 Limitations of this study include its bench-top nature and conference setting. The absence 309 310 Our findings are the first to couple the surgical force associated with ureteral injury during UAS 311 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 312 313 urologist to stay within the Goldilocks range-knowing when force levels have not yet surpassed 314 4N, exceeded 6N, or in a worst-case scenario, reached 8N. Our current investigational UCI UAS 315 force sensor, while expensive and cumbersome, is being developed into a commercial product 316 for widespread use. This device, when used in tandem with UASs, would alert urologists to force 317 levels of 4N, 6N, or, in the most concerning case, 8N, allowing them to prevent under-sizing at 318 4N and avoid the risks of ureteral injury at 6N or 8N. We also believe that the potential exists for 319 safe deployment of UAS larger than 16Fr. Indeed, a recent UCI clinical study revealed that at the 320 6N threshold, 15% of human ureters could safely accept a urethral dilator ≥ 18 Fr²⁴.

, pla.

1 2 3	bai	
4 5	321	
6 7	322	Limitations of this study include its bench-top nature and conference setting. The absences of
8 9	323	lubricant and the model's inability to duplicate the three distinct areas of narrowing in the human
10 11	324	ureter, are also noted. Our survey was limited as participants' location of practice (state/country)
12 13	325	and an evaluation of the face validity of the model was not obtained. Lastly, participants'
14 15	326	awareness of prior UCI publications on UAS force measurement might have influenced how
16 17 18	327	they proceeded to pass each UAS.
19 20	328	
21 22	329	CONCLUSIONS
23 24 25	330	Overall, 29% of participating urologists and urology residents-in-training exerted ≤4N and 45%
26 27	331	exceeded a clinically defined safety threshold of 6N when placing a 16Fr UAS. Moreover, 32%
28 29	332	of the participants exceeded 8N, a level of force associated with PULS 3high-grade ureteral
30 31 32	333	injury.
33 34	334	
35 36		
37 38		
39 40 41		
42 43		
44 45		
46 47		
48		
49 50		
51 52		
53		
54 55		
56		
57 58		
59 60		Mary Ann Liebert, Inc., 140 Huguenot Street, New Rochelle, NY 10801
00		, , , , , , , , , , , , , , , , , , , ,

ACKNOWLEDGEMENTS

We extend our sincere appreciation to all the physicians who kindly dedicated their time during their conference day to participate in our research. **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. <text> **AUTHOR DISCLOSURE STATEMENT** No competing financial interests currently exist. **FUNDING INFORMATION** All funds were provided by the Curiosity and Innovation Laboratory in the Department of Urology at the University of California, Irvine.

1			17
2			
3	354		REFERENCES
4	355	1	1 Golahmadi AK Khan DZ Mylonas GP et al Tool-tissue forces in surgery: A systematic
5	256	1.	review Ann Mod Surg 2021:65:102268: doi: 10.1016/j.amgu 2021.102268
6	550 b=7	2	$\frac{1}{2} = \frac{1}{2} = \frac{1}$
7	321	∠.	2. wong VK, Aminoitejari K, Almutairi K, et al. Controversies associated with ureteral
8	358		access sheath placement during ureteroscopy. Investig Clin Urol 2020;61(5):455–463; doi:
9	359		10.4111/icu.20200278.
10	360	3.	<u>3.</u> Bustos NH, Yaghoubian A, Mozafarpour S, et al. History of the Development of
11	361		Guidewires, Access Sheaths, Baskets, and Ureteral Stents. In: History of Technologic
12	362		Advancements in Urology. (Patel SR, Moran ME, Nakada SY, Eds.) Springer International
13	363		Publishing: 2018: pp. 79–85.
14	364	4	4 Bozzini G Bevilacoua L Besana U et al Ureteral access sheath-related injuries vs. post-
16	365		operative infections. Is sheath insertion always needed? A prospective randomized study to
17	366		understand the lights and shadows of this practice. Actas Ural Esp 2021:S0210
18	267		4806(21)00125 V. doji 10 1016/j course 2020 11 010
19	$\frac{507}{600}$	5	4600(21)00125-A, 001. 10.1010/j.acu10.2020.11.010.
20	508	Э.	5. Kourambas J, Byrne KR, Preminger GM. Does a ureteral access sheath facilitate
21	369	-	ureteroscopy? J Urol 2001;165(3):789–793.
22	370	6.	<u>6.</u> Auge BK, Pietrow PK, Lallas CD, et al. Ureteral access sheath provides protection
23	371		against elevated renal pressures during routine flexible ureteroscopic stone manipulation. J
24	372		Endourol 2004;18(1):33–36; doi: 10.1089/089277904322836631.
25	373	7.	7. L'esperance JO, Ekeruo WO, Scales CD, et al. Effect of ureteral access sheath on stone-
26	374		free rates in patients undergoing ureteroscopic management of renal calculi. Urology
2/	375		2005;66(2):252–255; doi: 10.1016/j.urology.2005.03.019.
28	376	8.	8. Huang J, Zhao Z, AlSmadi JK, et al. Use of the ureteral access sheath during
30	377		ureteroscopy: A systematic review and meta-analysis. PLOS ONE 2018;13(2):e0193600;
31	378		doi: 10.1371/iournal.pone.0193600.
32	379	9	9 Traxer O Thomas A Prospective evaluation and classification of ureteral wall injuries
33	380	2.	resulting from insertion of a ureteral access sheath during retrograde intrarenal surgery. I
34	381		Urol 2013:189(2):580_584: doi: 10.1016/j.juro.2012.08.197
35	282	10	10 Lildal SK Narragaard P. Andraassan KH at al. Urataral access sheath influence on the
36	292	10.	<u>IV.</u> Endar SK, Nonegard K, Andreassen KH, et al. Oreieran access sheath influence on the
37	202		L En devine 1 2017;21(2):207, 212; doi: 10.1080/and 2016.0772
38	384 bos	1.1	J = 10000001 2017, 51(5):507 - 515, doi: 10.1089/end.2010.0775.
39	385	++.	1. Ozsoy M, Kyriazis I, Vrettos I, et al. Histological changes caused by the prolonged
40 41	386		placement of ureteral access sheaths: An experimental study in porcine model. Urolithiasis
41 42	387		2018;46(4):397–404; doi: 10.1007/s00240-017-1007-9.
42	388	12.	<u>12.</u> Lallas CD, Auge BK, Raj GV, et al. Laser Doppler flowmetric determination of ureteral
44	389		blood flow after ureteral access sheath placement. J Endourol 2002;16(8):583–590; doi:
45	390		10.1089/089277902320913288.
46	391	13 .	<u>13.</u> Delvecchio FC, Auge BK, Brizuela RM, et al. Assessment of stricture formation with the
47	392		ureteral access sheath. Urology 2003;61(3):518–522; discussion 522; doi: 10.1016/s0090-
48	393		4295(02)02433-0.
49	394	14.	14. Abrahams HM, Stoller ML. The argument against the routine use of ureteral access
50	395		sheaths. Urol Clin North Am 2004:31(1):83–87: doi: 10.1016/S0094-0143(03)00085-5
51	396	15	15 Schoenthaler M Wilhelm K Kuehhas FE et al Postureterosconic lesion scale: a new
52	397		management modified organ injury scaleevaluation in 435 ureterosconic nations. I
55 51	308		Endourol 2012.26(11):1425_1430: doi: 10.1080/and 2012.0227
54	570		Lindouror 2012,20(11).1723 1730, doi: 10.1007/ciid.2012.0227.
56			
57			
58			
59			
60			Mary Ann Liebert, Inc.,140 Huguenot Street, New Rochelle, NY 10801

1		10
2		
3	200	16 16 Loftus CL Canasan V. Travar O. at al. Urataral wall injury with urataral accase shooths:
4	400	10. Lottus CJ, Ganesan V, Haxel O, et al. Official wan injury with different access shears.
5	400	A randomized prospective that. J Endouroi $2020,34(9).932-936$, doi:
6	401	10.1089/end.2018.0603.
7	402	17. <u>17. Fulla J, Prasanchaimontri P, Rizk A, et al. Ureteral diameter as predictor of ureteral</u>
8	403	injury during ureteral access sheath placement. J Urol 2021;205(1):159–164; doi:
9	404	10.1097/JU.00000000001299.
10	405	18 Traxer O Wendt-Nordahl G Sodha H et al Differences in renal stone treatment and
11	406	outcomes for patients treated either with or without the support of a ureteral access sheath:
12	407	The Clinical Descarch Office of the Endourological Society Ursteressony Clobal Study
13	407	The Chinical Research Office of the Endourological Society Officeroscopy Global Study.
14	408	World J Urol 2015;33(12):2137–2144; doi: 10.1007/s00345-015-1582-8.
15	409	<u>19.</u> <u>19.</u> Kaler KS, Lama DJ, Safiullah S, et al. Ureteral access sheath deployment: How much
16	410	force is too much? Initial studies with a novel ureteral access sheath force sensor in the
17	411	porcine ureter. J Endourol 2019;33(9):712–718; doi: 10.1089/end.2019.0211.
18	412	20. 20. Tapiero S, Kaler KS, Jiang P, et al. Determining the safety threshold for the passage of a
19	413	ureteral access sheath in clinical practice using a purpose-built force sensor J Urol
20	414	2021·206(2)·364–372· doi: 10.1097/IU.00000000001719
21	415	21 21 Treas CP. Charach CM. Paul CL at al Increasing the size of urateral access shorth
22	416	<u>21.</u> <u>21.</u> maty CK, Ohareeo OW, Faul CJ, et al. increasing the size of theteral access sheath during notice and introgenal approximation of the size
23	410	during retrograde intrarenal surgery improves surgical efficiency without increasing
24	417	complications. World J Urol 2018;36(6): $9/1-9/8$; doi: 10.100//s00345-018-2204-z.
25	418	22. <u>22.</u> Pedro RN, Weiland D, Reardon S, et al. Ureteral access sheath insertion forces:
26	419	implications for design and training. Urol Res 2007;35(2):107–109; doi:
27	420	doi:10.1007/s00240-007-0086-4.
28	421	23. Cumpanas AD, Lavasani SAM, Tsai JC, et al. Ureteral strictures following ureteroscopic
29	422	ureteral wall injury: a previously unidentified concern. J Urol 2024: Abstract submitted for
30	423	consideration at AUA 2024
22	123	$\frac{1}{22} 24 \text{ MeCorman A Vu MC} A \text{ fround AS} at all Clinical manufactors of maximum safe}$
32	424	23. 24 . Moconnac A, Vu MC, Aryouni AS, et al. Chine al measurement of maximum sate
34	425	ureteral distensibility using a novel force sensor. J Urol 2023;209 (Supplement 4):e468; doi:
35	426	doi:10.1097/JU.0000000003269.02.
36	427	24. <u>25.</u> Zilberman DE, Lazarovich A, Winkler H, et al. Practice patterns of ureteral access sheath
37	428	during ureteroscopy for nephrolithiasis: a survey among endourologists worldwide. BMC
38	429	Urol 2019;19:58; doi: 10.1186/s12894-019-0489-x.
39	430	25, 26, Lildal SK, Andreassen KH, Christiansen FE, et al. Pharmacological relaxation of the
40	431	ureter when using ureteral access sheaths during ureterorenoscopy. A randomized feasibility
41	/32	study in a porcine model. A dy Urol 2016:2016:8064648: doi: 10.1155/2016/8064648
42	422	study in a potenie model. Nav 0101 2010,2010.0004048, dol. 10.1135/2010/0004048.
43	433	
44		
45		
46		
47		
48		
49		
50		
51		
52		
55 ۲		
54 55		
56		
57		
58		
59		
60		Mary Ann Liebert, Inc.,140 Huguenot Street, New Rochelle, NY 10801

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)	Р*	Group 3: Forces ≤6N (n = 66)	Group 4: Forces >6N (n = 55)	Р*	Group 5: Forces ≤8N (n = 82)	Group 6: Forces >8N (n = 39)	-
Moon voors of	8 2	11.5	0 167	8.0	12.5	0 000	00	14.2	0
practice (SD)	(10.3)	(11.7)	0.107	(11.4)	(13.7)	0.000	(12.0)	(12.2)	U.
Mean age (SD)	41.1	43.5	0.365	40.4	45.7	0.023	40.9	46.7	0.
	(11.5)	(13.1)		(9.4)	(12.4)		(10.6)	(13.5)	
Number of			0.012			0.026			0
ureteroscopies (%)									
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
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
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
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
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.

		95% Confid	ence Interval	
	Odds Ratio	Lower	Higher	Р
<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	Р	
<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	







Figure 1. Urinary tract model with built-in Pasco® Scientific PASport[™] force sensor.

A) Participant view of model. B) Aerial view of interior components.

Mary Ann Liebert, Inc., 140 Huguenot Street, New Rochelle, NY 10801

Journal of Endourology







3	469	FIGURE LEGENDS
4	470	
5	471	Table 1. Univariate analysis of participant characteristics and relationship to force exerted
0 7	172	during insertion of a 16Fr ureteral access sheath
8	472	during insertion of a for r dictoral access sheadi.
9	4/3	
10	474	Table 2. The polychotomous logistic regression comparing the nonideal force ranges to the ideal
11	475	force ranges.
12	476	
13	477	Figure 1. Urinary tract model with built-in Pasco® Scientific PASport [™] force sensor.
14	478	A) Participant view of model. B) Aerial view of interior components.
15	479	
16	480	Figure 2. Enlarged view of the gap between the introduction tube and receiver tube.
17 18	481	
19	482	Figure 3. Detailed presentation of the male genitourinary force sensor model components.
20	483	
21	484	Figure 4. Linear regression model comparing the force data for both the handheld force sensor (y-
22	485	axis) and the internally mounted force sensor (x-axis) plotted. These measurements were used to
23	486	calibrate the internally mounted force sensor to the handheld University of California, Irvine (UCI)
24	487	ureteral access sheath force sensor previously used to determine the force values for ureteral injury
25	488	in both porcine and human ureters.
26 27	489	-Figure 4.A) Linear regression yielded a relationship of $y = 1.3955x + 0.4228$ (R ² = 0.9869)
27	490	for the pre-American Urological Association (AUA) test
20	491	-Figure 4 B) Linear regression yielded a relationship of $y = 1.2084x - 0.8906$ (R ² = 0.9209)
30	492	for the pre-World Congress of Endourology and Technology (WCET) test
31	493	for the pre-world congress of Endourorogy and recimiciogy (well') test.
32	195	
33		
34		
35		
37		
38		
39		
40		
41		
42		
43		
44 45		
46		
47		
48		
49		
50		
51		
52 52		
55 54		
55		
56		
57		
58		
59 60		Mary Ann Liebert, Inc. 140 Huguenot Street, New Rochelle, NY 10801
00		mary man closely ment to magnetic street, new noticity of tool

ί y = 1.2 mology (W