



# MP15-11: ASSESSING THE CLINICAL FORCE THRESHOLD FOR THE SAFE DEPLOYMENT OF A URETERAL ACCESS SHEATH USING A URETERAL ACCESS SHEATH FORCE SENSOR



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## INTRODUCTION

- Ureteral injury is an important clinical concern during placement of a ureteral access sheath (UAS). In a prior porcine study, using a novel force sensor developed at our institution, we identified forces of  $\leq 6$  Newtons(N) as a safe threshold for passage of an ureteral access sheath.<sup>1</sup>
- In this prospective clinical study, we sought to determine the parameters for the safe passage of an ureteral access sheath.

## METHODS

- After receiving IRB approval, 238 patients undergoing ureteroscopy or PCNL for the treatment of renal and/or proximal ureteral calculi (n = 250 renal units) were prospectively enrolled.
- The UCI Ureteral Access Sheath Force Sensor was utilized during the deployment of all UAS (Figure 1).
- A 16 Fr UAS was initially deployed; the UAS was sequentially downsized if deployment forces reached 6 N (16 Fr, 14 Fr,  $\leq 12.7$  Fr).
- At the end of each case, the surgeon determined a post-ureteroscopic lesion scale (PULS) ranging from 0 = no injury to 5 = complete ureteral disruption.

## RESULTS

**Table 1: UAS size, force, and PULS**

Successful UAS Size (Fr)	
16 Fr	145 (58.0%)
14 Fr	75 (30.0%)
$\leq 12.7$ Fr	30 (12.0%)
Mean Maximal Force for Successful UAS Deployment (N)	
16 Fr	5.47 $\pm$ 0.15
14 Fr	5.28 $\pm$ 0.22
$\leq 12.7$ Fr	4.22 $\pm$ 0.34
PULS Grade	
0	95 (38.0%)
1	96 (38.4%)
2	46 (18.4%)
3	2 (0.8%)
Not Recorded	11 (4.4%)

**Table 2: 16 Fr UAS success rate variables**

Patient characteristics	Yes (renal units)	No (renal units)	Odds Ratio	p-value
Tamsulosin*	140	110	1.024	0.926
Tadalafil*	16	234	0.417	0.093
Pre-operative Stent	182	68	2.960	<b>0.004</b>
Treated Bacteriuria	83	166	2.026	<b>0.046</b>
Antibiotics $\leq 7$ days prior to surgery	99	125	1.954	<b>0.032</b>

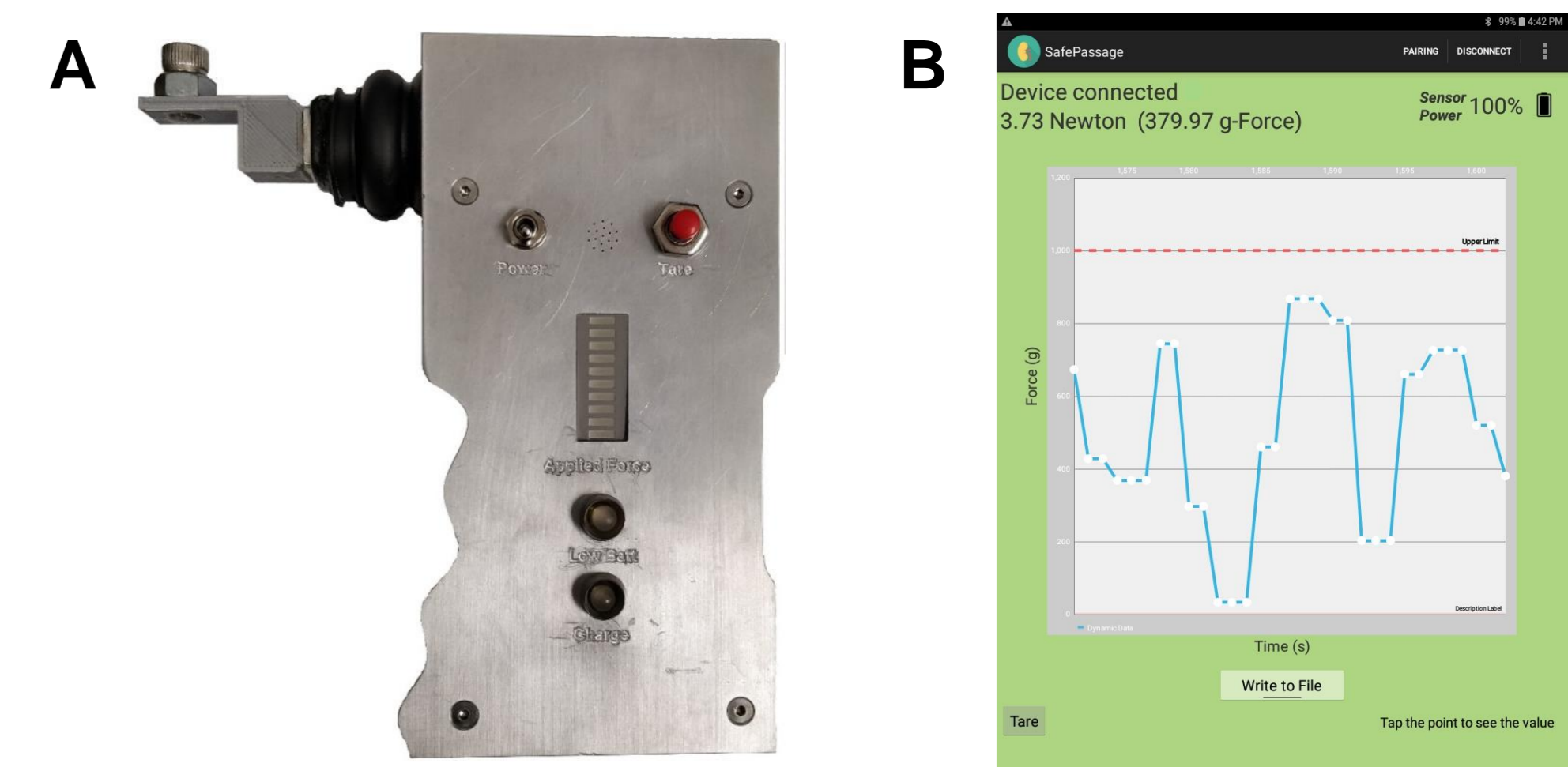
**Table 1 Final UAS size, force measurements and ureteral injury data:**

- All UAS sizes were deployed with an average force of  $< 6$  N and the largest (16 Fr) UAS was deployed 58% of the time with a mean force of 5.47 N.
- The highest PULS grade was 3 (= splitting of the urothelium) in 2 cases; in both instances the applied force exceeded 8 N.

**Table 2 16Fr UAS success rate variables:**

- A univariate\* and multivariate analysis of patient characteristics associated with a successful deployment of a 16 Fr UAS was performed.
- Pre-operative stents, history of treated bacteriuria within 60 days prior to the procedure, and pre-operative antibiotics received at least 7 days prior to surgery were found to be independent factors for successful deployment of a 16 Fr UAS.

## RESULTS



**Figure 1. A)** The UCI Ureteral Access Sheath Force Sensor, continuously measures force within 1/100<sup>th</sup> of a Newton. **B)** Sample force output reading from the ureteral access sheath force sensor.

## CONCLUSIONS

- Among 250 ureters, UAS insertion force  $\leq 6$  N precluded  $\geq$  PULS grade 3 ureteral injury.
- A 16 Fr UAS was safely passed in 58% of ureters.
- Pre-operative stenting, a history of treated bacteriuria, and pre-operative antibiotics were independent predictors of atraumatic deployment of a 16 Fr UAS.

