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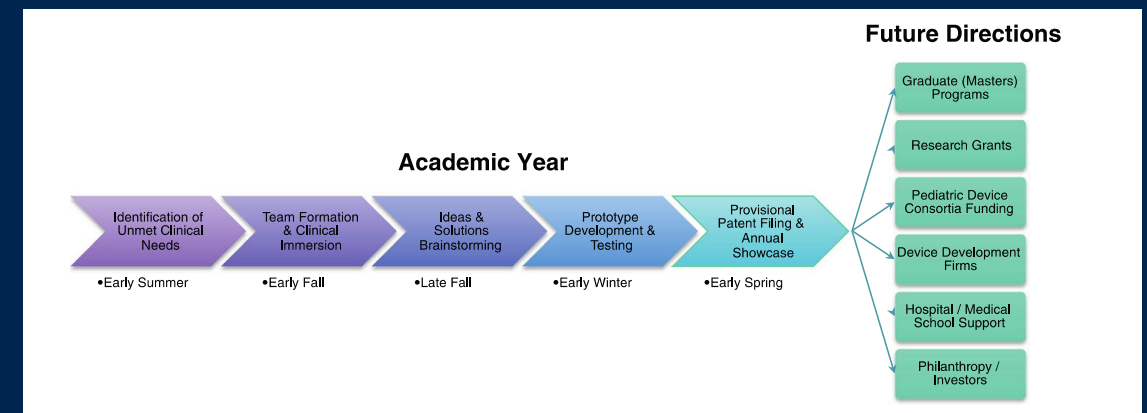
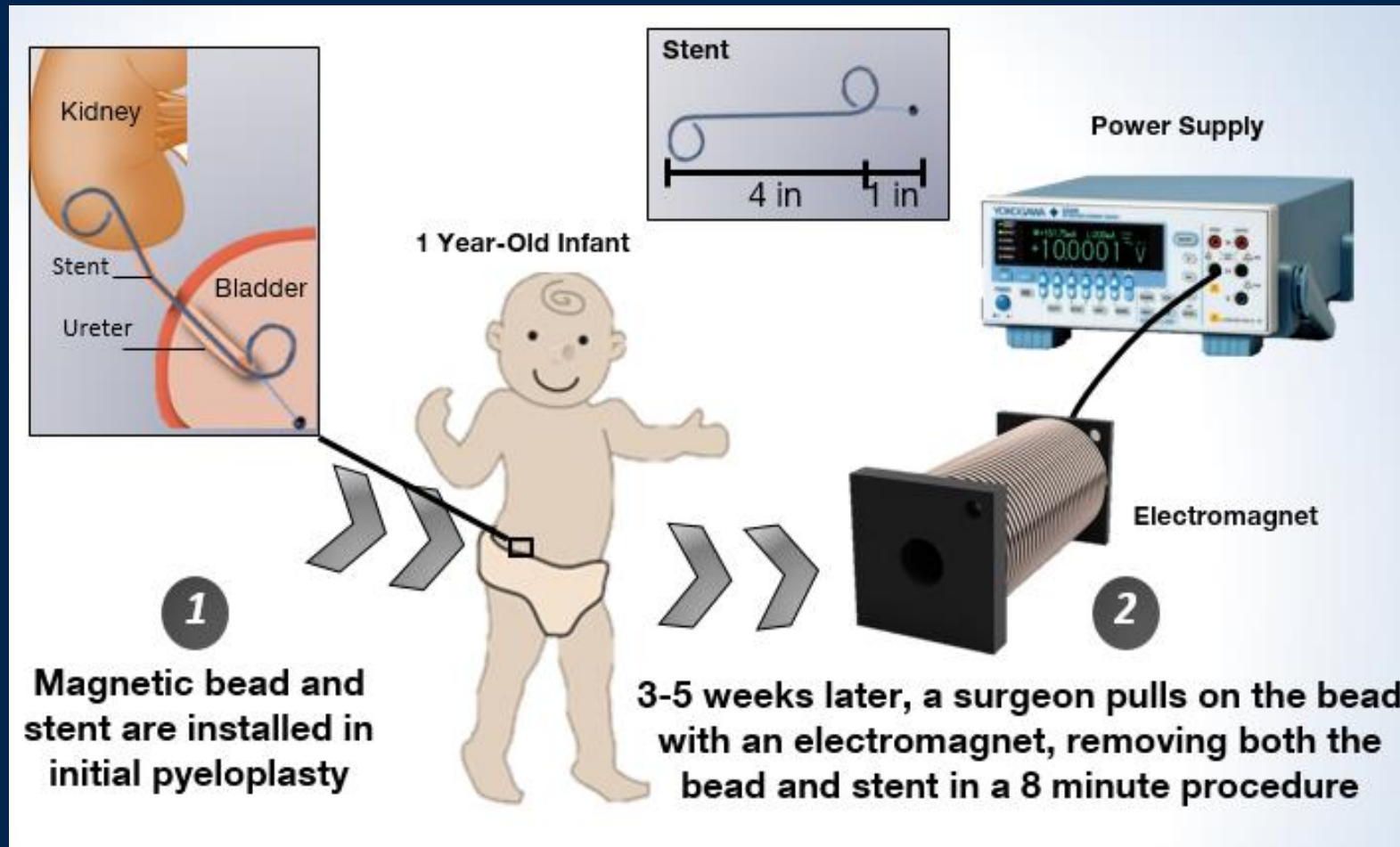
Baylor
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Quantifying the Force Needed for Ureteral Stent Removal:

Initial evaluation of a magnetic stent removal device on benchtop and porcine models

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Stent-X Magnetic Ureteral Stent Removal Device



1st Prize – 2015 Rice Annual Showcase / Grand Prize – 2015 DMD Student Showcase

TCH Department of Surgery Seed Grant (Clayton Award)

NIDDK SBIR Phase I (1R43DK1153336-01)

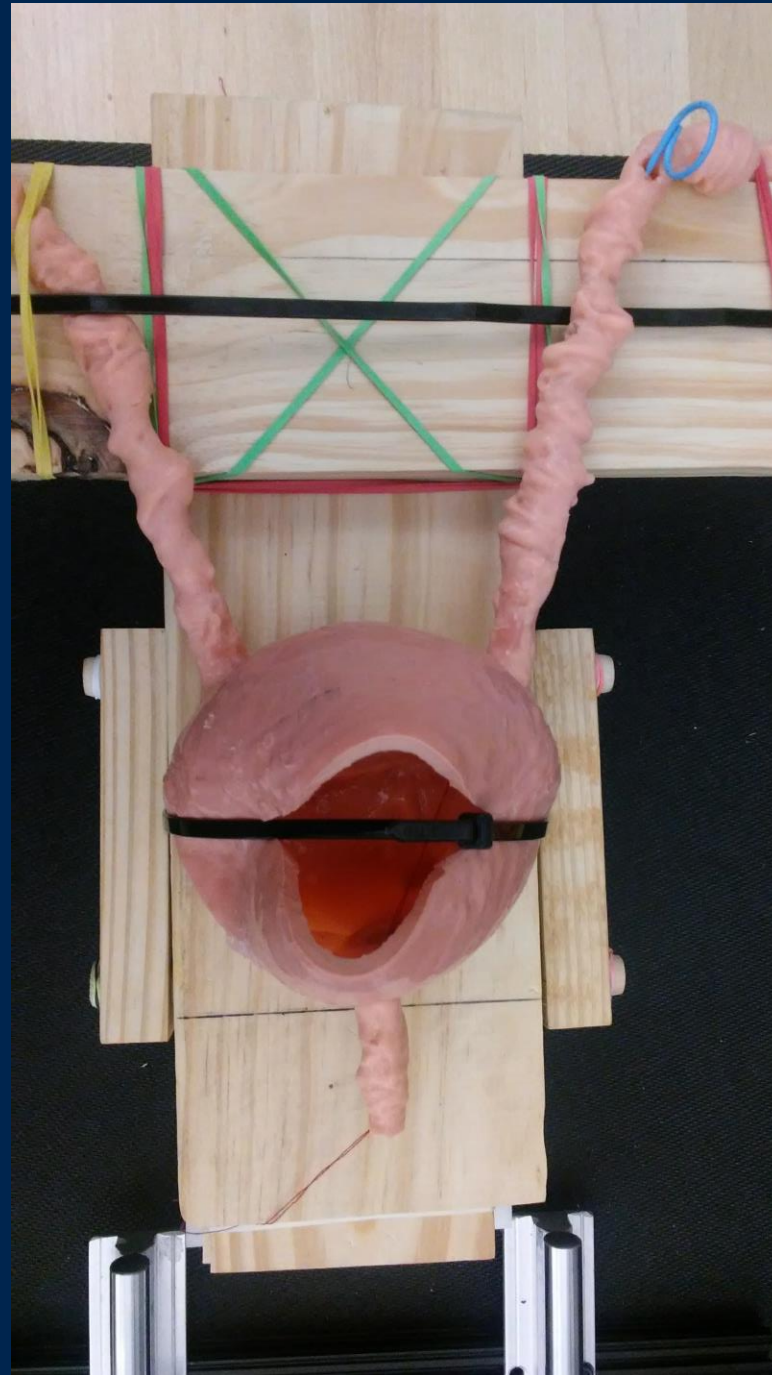
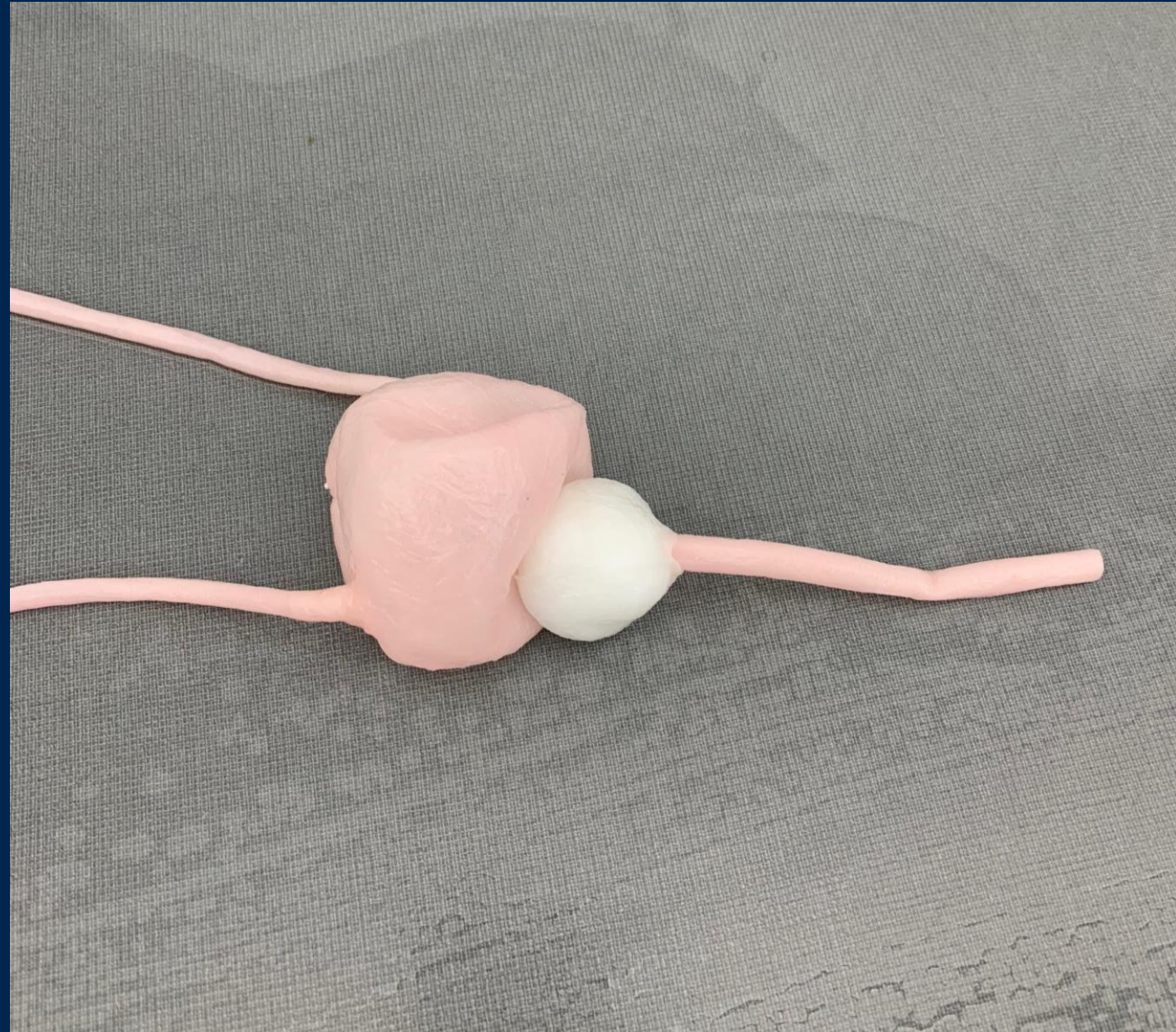
Study Objective

- Little is known about the forces required to remove indwelling ureteral stents

Initial Objective

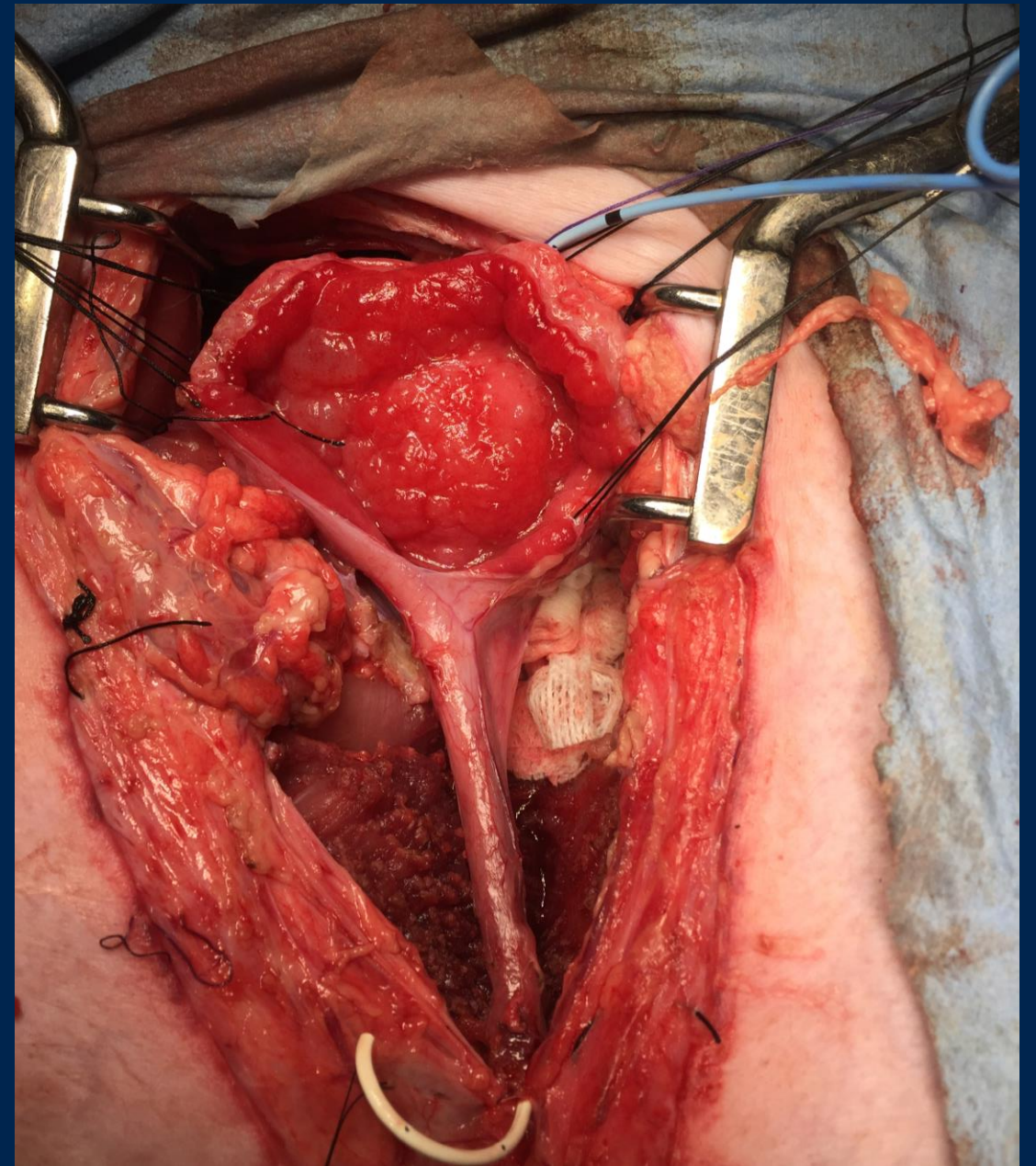
- To characterize and quantify the required forces for stent removal for testing of future prototypes

Lazarus 3D Benchtop Model



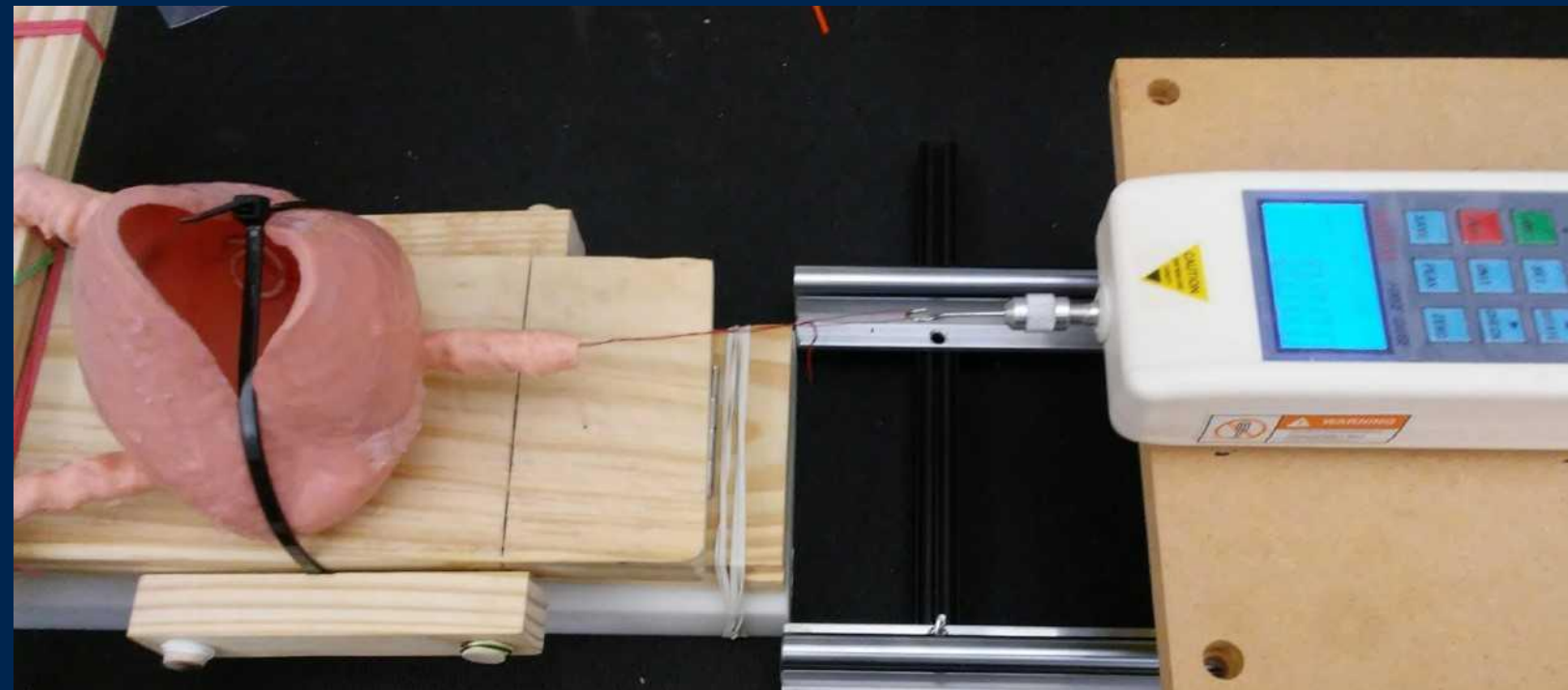
Modified Porcine Model

- Midline suprapubic incision
- Distal ureter transected for antegrade stent placement
- Urethra dissected distally from the bladder
- Urethral transection close to the urogenital sinus
- Urethra sutured to the inferior portion of the skin incision
 - cutaneous urethrostomy



Methods - Force Measurements

- HF-10 digital force gauge by M&A Instruments
 - Quantified force required to remove different stents
- External magnets versus catheter tip magnets
 - Quantified magnetic force
 - Measured success with various magnetic beads

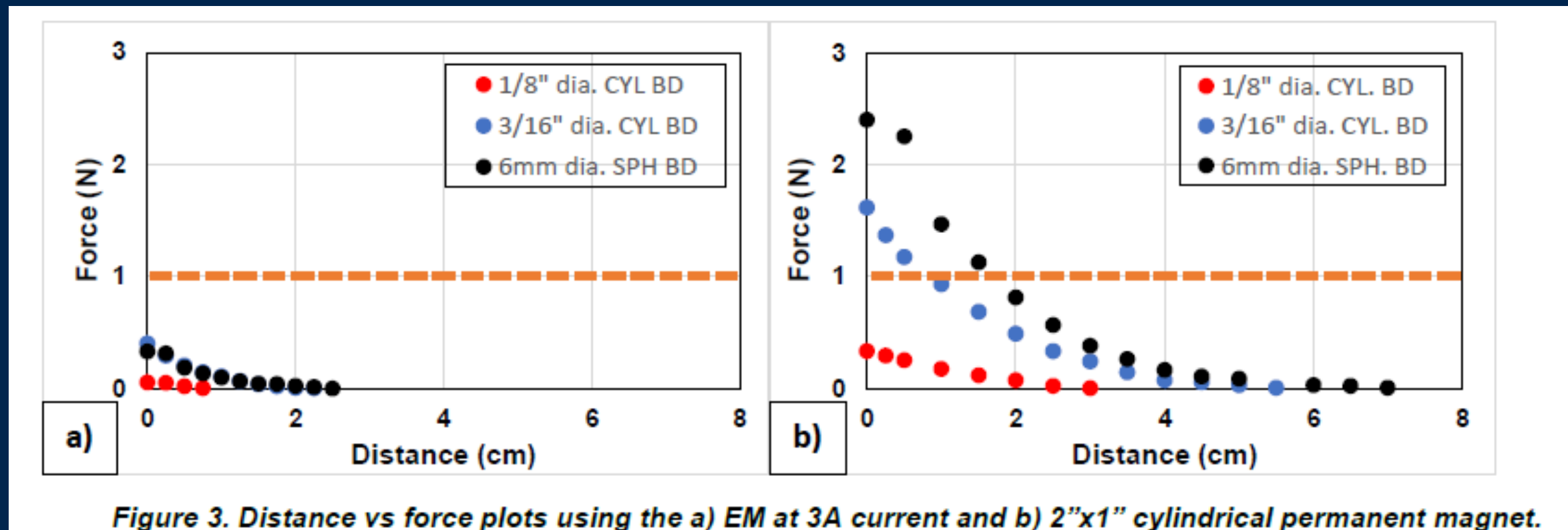


Results – Force Measurements

Table 1: Force to remove ureteral stent on benchtop and porcine model			
Bead type/Stent size	BENCHTOP - Max Retrieval Force in N		PIG - Max Retrieval Force in N
	Bladder	Ureter	Ureter
5Fr x 14cm double-J Stent	0.793 ± 0.216	4.734 ± 0.620	0.841 ± 0.586
5Fr x 14cm double-J Stent with 3.2x3.2mm cylindrical, hollow bead	0.993 ± 0.137	4.055 ± 0.564	0.784 ± 0.363
5Fr x 14cm double-J Stent with 4.8x4.8mm cylindrical, hollow bead	1.685 ± 0.154	3.920 ± 0.624	
3.2x3.2mm cylindrical, hollow bead	0.198 ± 0.044		0.939 ± 0.269
4.8x4.8mm cylindrical, hollow bead	1.893 ± 0.186		
5Fr x 14cm equivalent straight stent	0.293 ± 0.148	4.284 ± 0.584	0.211 ± 0.046
Stent unfurling only		0.793 ± 0.216	

Results – Magnetic Force Requirements

- Based on the measurements, a goal force of 1 N would be required to definitively remove the stent
- For the external magnet design, this force needed to be present at a distance of 4-5 cm, correlating to urethral length



Design Change → Magnetic Tip Catheter

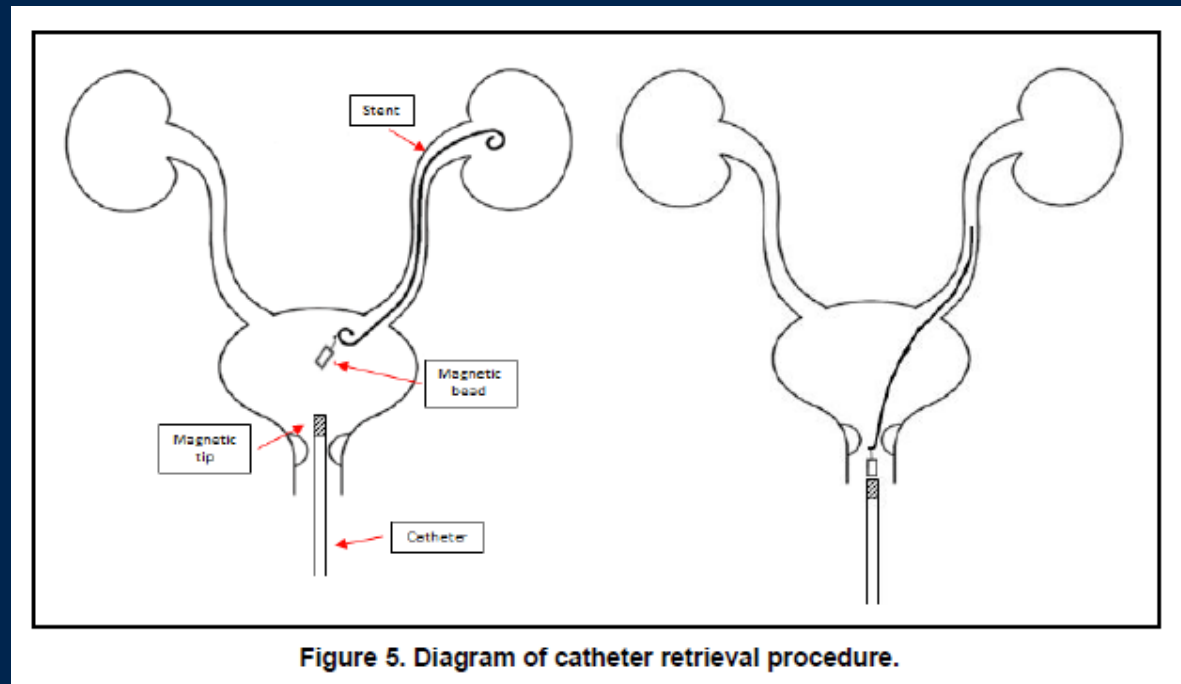


Table 4. Results of animal testing using catheter-based retrieval device.

Catheter Variant	Stent variant				
	3 Fr 8 cm	3 Fr 12 cm	5 Fr 12 cm	5 Fr 12 cm	5 Fr 14 cm
	1.6x6.5 mm	1.6x3.2 mm	1.6x3.2 mm	1.6x3.2 mm (saline filled)	3.2x3.2 mm
C1 (6 Fr, 1.5x6.5 mm)	0%		14%	100%	100%
C2 (8 Fr, 2.5x6.5 mm)	29%		0%	100%	
C2- (6 Fr, 2.5x13 mm)	80%		100%		
C3 (10 Fr, 3.1x13 mm)			100%		
C3- (8 Fr, 3.1x13 mm)		100%	100%		

- Filled bladder appears to reduce friction and allow for easier passage
 - Allows for better results with smaller magnet

Conclusions

- The ureteral stent removal force is $< 1\text{N}$ on the porcine model
- However, external magnets could not generate sufficient force due to the inverse square relationship with urethral length
- Alternatively, the catheter tip magnet model appears to overcome the limitation of distance
- Further studies are needed to define the optimal combination of catheter tip magnet size and stent magnetic bead size

Acknowledgements

1. TCH Department of Surgery Cooley Innovation Award
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