The Development, Quantification and Verification of a High-Fidelity Male Urethral Catheter Simulator

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Abstract

The Development, Quantification and Verification of a High-Fidelity Male Urethral Catheter Simulator

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ABSTRACT:

Urinary catheter placement is one of the most commonly performed medical procedures in the hospital setting. Many papers present issues with current training tools and educational methods that ultimately may result in injury to patients in clinical practice. Here, the skill of catheter placement is evaluated two-fold through the lens of the educational tools available for teaching the skill and the quantification of force required to perform the skill. A novel, high-fidelity, urethral catheter simulator was developed to improve upon all current commercially available simulators. The life-like appearance, realistic tactile behaviors, and quantified forces of insertion all result in a realistic simulation for urinary catheter placement education. Additionally, the force required to place a urinary catheter is characterized and the effect that lubrication volumes have on the force curve are also explored. Resulting in a trend that suggests as more lubrication is added to the male urethra, less force is required to place the catheter until a lubrication threshold is met.

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DEDICATION

This thesis is dedicated to the army of individuals who mentored, supported, and pushed me to achieve over the past 2.5 years of working on this project. It has been an absolutely wonderful experience with so many opportunities for growth as a researcher and individual.

I want to take a special moment to thank Alex T. Gong for all his specific support on this project. Alex was present day in and day out for the turbulence that was this year of data collection and design. Without the mentorship of Alex and his continued support and troubleshooting of problems, this work would not be what it is today. Alex, thank you immensely for all you have done and continue to do for not just me but all the students at CREST.

I want to specifically dedicate this work to my family as they were there to support me from Indiana day in and day out. My family has continued to support my choice to move across the US to pursue my degree in Bioengineering at the University of Washington. They helped me find the path through this work and never doubted my abilities to challenge myself and succeed in all the endeavors I took on.

On a global scale, this work is dedicated to the individuals who are learning to place catheters, already place catheters, or receive catheters for therapeutic use. Without the problems associated with urinary catheter placement this project would not exist and thus I dedicate my work to helping alleviate the pain points associated with urinary catheters and current education for learning to place catheters.

Chapter 1. INTRODUCTION

1.1 PROBLEM

Each nurse, physician's assistant and doctor must learn how to effectively place and maintain urinary catheters during their training and delivery of care. The current training regimen based on didactic materials and unrealistic simulators are insufficient for the learners to be successful during their first catheter placement attempt on a patient. It is already common for catheter placement training to include the use of a simulator; however, most of these simulators teach improper muscle memory due to their inaccurate material choice and anatomic layout. Improving the hands-on training of healthcare providers can minimize the risk of injury (i.e. urinary tract infection and urethral trauma) in the future care of all patients.

One in every four patients in the hospital will require the placement of a urinary catheter during their stay.[1] In a 2007 study, 76% of surgical interns reported feeling that their education in urethral catheter placement was lacking or nonexistent.[2] Commonly, these inexperienced hands cause injury to patients including: urethral trauma, bleeding, scarring and urinary tract infections. Another study reported 6.7 in 1000 catheter placements resulted in a traumatic injury.[3] Another academic clinical study supports the imminent need for more intensive training and improved simulation models for urethral catheter insertion education.[2]

1.2 MOTIVATION

"See one, do one, teach one" – a common mantra discussed within the world of medicine and more specifically, surgery.[4] It is commonly applied when medical students learn hand-on tasks and procedures. This mentality comes from the idea that once you have seen the skill performed you should be prepared to perform it yourself. Then, once you have mastered the skill, you are expected to teach it to someone else.

Through the years, educators in the medical field have been pushing to get away from practicing this mantra as it can lead to patient injury especially in high risk care situations.[4,5] A new method of educating students is a modification of the original mantra: "see one, simulate many, do one competently, and teach everyone."[5] Medical simulation addresses the present need for students to repeatedly practice a skill before performing it on a patient. Several urinary catheter placement simulators have been developed to date. Here, I present the work to raise the current standards for urinary catheter placement simulators through the development of a high-fidelity urinary catheter placement simulator and the collection of relevant procedural forces for verification studies.

A year of research and development during the 2018-2019 academic year resulted in two iterations of the CREST Urethral Catheter Simulator (CREST UC Sim). The initial interest shown towards the CREST UC Sim offered an opportunity to further develop and test the simulator designs during the 2019-2020 academic year. Additionally, this work employs a redesigned force measurement device to collect the forces of urinary catheter insertion across multiple mediums including human

tissue and simulated materials. The human studies are performed in unfixed human cadavers. Human cadavers are used at the present time for baseline data collection with the goal of collecting live human data in the future with IRB approval.

At present, minimal studies had been published to quantify the biomechanical properties of human urethral tissues. One study from 2009 reported an average of 5N was exerted by experienced urologists when asked to apply the normal amount of force they use to place a catheter.[6] The University of Minnesota published their own study results from urinary catheter placement in cadaveric males with an average of 5.6N.[7] Due to the few number of studies conducted to quantify the force of urinary catheter placement: a clear need to explore this topic further was presented. This work is motivated to expand upon the current knowledge of forces required to place urinary catheters, further advance urinary catheter design, enhance the realism of the CREST UC Sim, and reveal clinical implications of lubrication volumes during urinary catheter insertions.

1.3 Experimental Approach

The experimental approach extends into three arms. First, the continued research and development of improved versions of the CREST UC Sim with revised synthetic materials and new features to improve the fidelity of the simulation. Second, the modification of a force measurement tool for the purpose of procedural based quantification of urethral catheter placement studies. Third, the execution of force data collection of cadaveric and simulator studies.

1.4 Current Standards Around the Education and Common Placement of Urethral Catheters

1.4.1 *Education*

Through discussions with educators and students alike, this thesis proposes a blanket statement that all institutions and programs have their own methods of educating their students in urethral catheter placement. While methods may overlap and state similar recommendations there is no set universal standard cited by institutions. Most publications that provide recommendations for catheter placement use the phrasing: “Appropriately trained personnel should insert urinary catheters following aseptic technique.”[8,9] Each institution is responsible for determining their specific educational curricula and steps for male catheter placement.

A few national institutions have their own guidelines for this procedure. These include: the American Urological Association (AUA), Agency for Healthcare Research and Quality (AHRQ), and US Department of Health and Human Services. Creating a standardized methodology for urinary catheter placement should be explored through a review of all possible training curricula available.

1.4.2 *Catheter Lubrication Techniques – Stratified*

The techniques for urethral catheter lubrication application is diverse and depends on your local hospital/care centers guidelines. In some institutions, the policy states to apply all lubrication provided to the catheter while in the prep tray, and others have a recommendation to insert some of the lubricant directly into the urethra.[10,11] In one publication from 1991, the researcher claimed that the urethra of men and women can fully dilate with 10.6mL and 6mL of water-based lubricants respectively.[12] Common transurethral lubricant products available closely follow this determination for pre-filled syringes for males and females. An article from 2013 lists three catheter placement kits that specifically followed this guideline, another two kits included 11.8mL and 8.0mL (male and female, respectively) and one was a unisex kit with 10mL of lubricant. [13]

This guideline has not, however, translated into common clinical practice. From a variety of guidelines and standards for male and female catheter placement, the amount of lubricant to insert directly into the urethra varies. In one comprehensive study for "difficult" urethral catheterization, transurethral lubrication values included: "20-30 mL", "10-20 mL", to generic citations of "insert lubrication".[14] Another recommends the insertion of 10mL of lubricant directly to the meatus prior to insertion. [15]

According to the Agency for Healthcare Research and Quality, the US Government's Department of Health and Human Services, for male insertions the user should insert 10-15mL of lubricant directly into the urethra. [16,17]

At the University of Washington (UW), the operating room (OR) nurses must follow a specific set of guidelines that were designed to limit the potential for catheter associated urinary tract infections and urethral traumas. These guidelines specifically state to: "save about 2-3 mL of lubricant for insertion directly into the urethra."

Due to the variety of sources reporting several suggestions for the "correct" way to place a urinary catheter, finding an evidence-based consensus for standardized clinical practice is investigated. One question explored in this work is the impact of different volumes of lubrication inserted directly into the urethra and how the insertion force curve changes in response to different conditions.

Chapter 2. SIMULATION

2.1 Simulation in Urinary Catheter Placement

Simulation in medicine began to gain traction in medical education in the 1950s.[18] The first simulators available were task trainers, serving the function of training single tasks such as urethral catheter placement or intravenous needle insertion. [19] Simulation fosters learning opportunities from making mistakes and building confidence through skill repetition.[20] The use of a high-fidelity, hyper-biorealistic simulator is key to maximize the potential positive skill transfer and minimize the risk of patient injury. Providing the most realistic training experience possible

increases the potential educational value from the simulator. Learning and applying proper muscle memory for tasks such as urethral catheter placement is critical in avoiding injury to a patient.

In one study, a group of residents failed to perform proper clinical decision-making skills satisfactorily when assessing catheter type in multiple scenarios. [21] This study provides sound reasoning for the implementation of urethral catheter simulators into medical, nursing, and physicians assistance schools. By providing early and extensive hands-on education to future care providers, there is potential to reduce possible negative outcomes from urethral catheter placement.[22,23]

If a nurse learns the proper amount of force to insert a catheter in a "healthy" individual from a high-fidelity simulator, they can then apply that muscle memory into their future clinical practice. Proper muscle memory will enable a nurse to realize when their actions could lead to injury to the patient and that they need to call a urology consult for the difficult catheter placement.

2.2 Prior Commercial Art

Simulation associated with urethral catheter placement is not novel. Urethral catheter simulators have existed for a number of years. Current options available range in appearance, realism, and features. Life/Form Male Simulator (Fig 1a.) and Simulaids– Male Catheterization Trainer (Fig 1b.) are the two simulators that were accessible during this work and were evaluated to collect the forces of catheter insertion into each. The two simulators in Figure 1 are the cheapest models on the market. These models both provide the user the ability to practice catheter placement at a low cost. The NASCO Catheterization Trainer – Henri (Fig 2a.) and 3B Scientific – Transparent Male Catheter Model (Fig 2b.) are examples of the top of the line simulators available with prices ranging from $2,500-$3000. The simulators in Figure 2 claim to be life-like, modular, and include retractable foreskin. A comparison table of the included features within each of the four selected prior arts is shown in Table 1. The table is filled out based on the product information provided by the sellers.

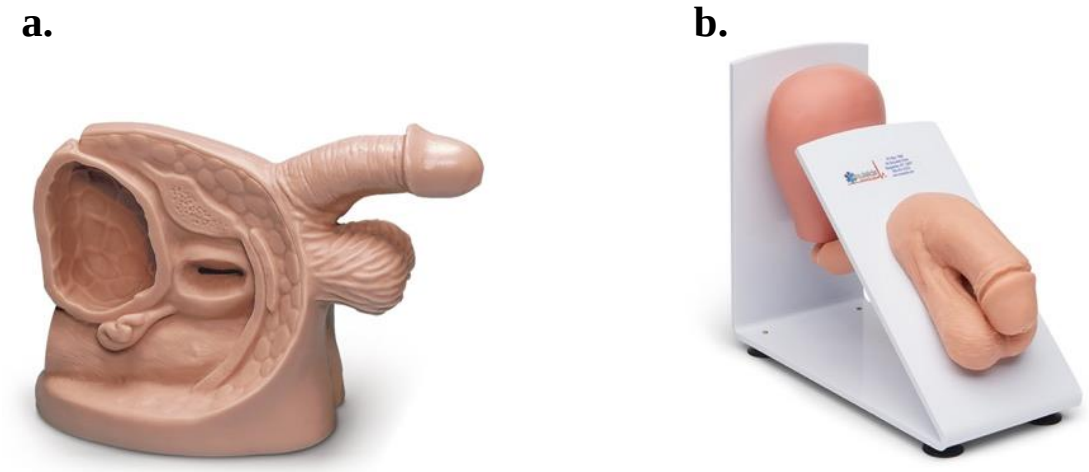


Figure 1: Commercial Simulators pt 1 a.) Life/Form Male Simulator b.) Simulaids– Male Catheterization Trainer.

a. **b.**

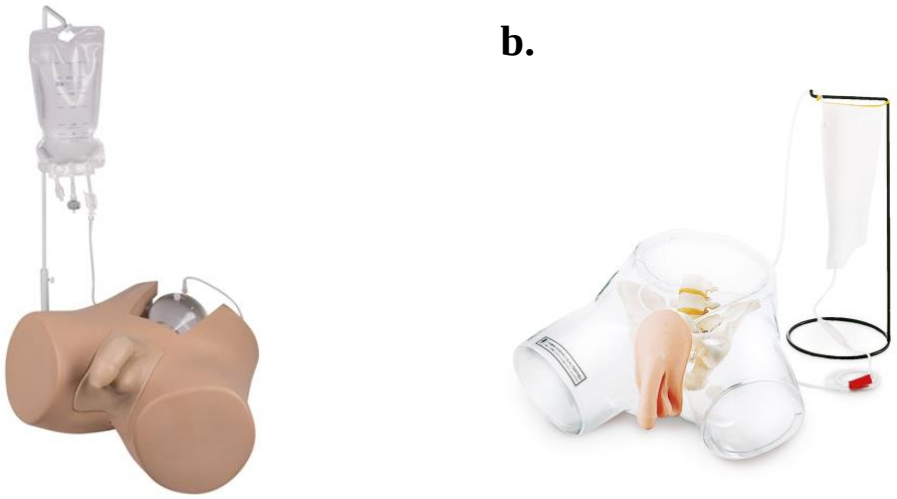


Figure 2: Commercial Simulators pt 2 a.) NASCO Catheterization Trainer – Henri b.) 3B Scientific – Transparent Male Catheter Model.

Table 1: Market comparison of commercially available urethral catheter simulators.

	 Life/Form Male	 Simulaid Male Catheter Simulator	 3B Scientific – Transparent Male Catheter Model	 Nasco – Catheterization Trainer "Henri"
Life-Like Appearance	✗	✓	✓	✓
Realistic Tactile Behavior	✗	✓	✓	✓
Modular Features	✗	✗	✓	✓
Retractable Foreskin	✗	✗	✓	✓
Research Team has access to?	✓	✓	✗	✗
	https://www.universalmedicalinc.com/life-form-male-catheter-model.html	https://www.gtsimulators.com/Male-and-Female-Catheterization-Model-p/1933.htm	https://www.a3bs.com/transparent-male-catheter-model-1017241-w43028m-m160-1,p_1057_23354.htmlaaaaaaaaaaaaa	https://www.enasco.com/p/Male-Catheterization-Trainer-%3Cq%3EHenri%3C-q%3E%2BSB53194

2.3 PREVIOUS CREST URETHRAL CATHETER SIMULATORS

2.3.1 *Version 1*

CREST UC Sim Version 1 was a pivotal point in the development of the CREST UC simulators. This was the first full construction of the male genitourinary system at CREST. The project began with Tony Chen M.D. and Yasser Noureldin M.D., whom spent time identifying the problem and need specifications for a new urethral catheter simulator. Erin Roussel and Hazel Williams began initial developments for the materials and tissues.

Initial material properties estimates were used to develop each of the tissues included within this version. The steps taken to develop Version 1 are explained in the "Development of a High-Fidelity Urethral Catheter Simulator" 2019 Capstone report.

The original base for the device it is made with a 3D printed pelvic structure and plastic supports. There was little to no effort put towards 'seaming' the skin to external penis structure which is a vast difference between it and future iterations (Fig. 3).

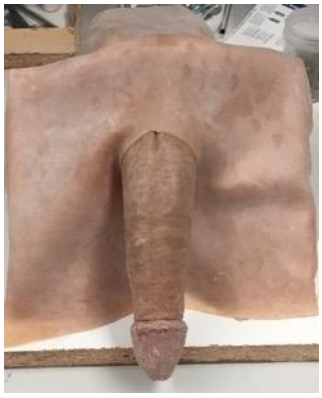


Figure 3: CREST UC Sim Version 1

2.3.2 *Version 2*

CREST UC Sim Version 2 became the first iteration that looked life-like and showed potential to be developed into a commercialized task trainer. This version, Fig. 4, improved upon the prior construction methods, included foreskin, a scrotum/testes and a fat layer. A new pelvic base was designed and implemented to support the tissue structures and limit the length of the phallus on the exterior portion of the simulator. Further material alterations and new molds were created to cater to the additional tissues added to the simulator. The addition of a fat layer provided a softer look and feel between the skin layer and the pelvic bone structure. Lastly, the design and implementation of the foreskin tissue was the biggest challenge. This material needed to be robust and pliable and allow for sliding of the tissue to simulate retractable foreskin.

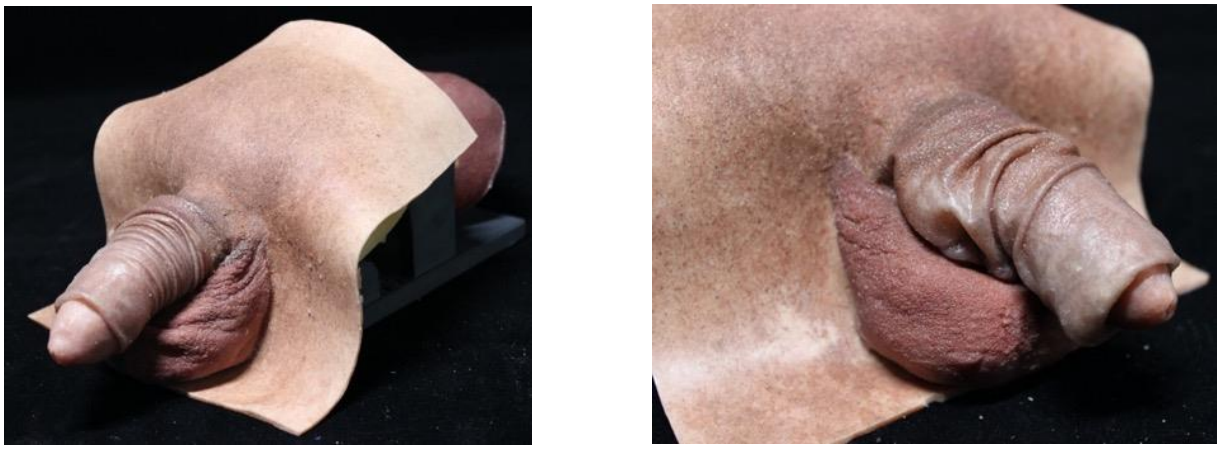


Figure 4: Version 2 of the CREST UC Sim.

2.3.3 *Included Tissue/Structure for CREST Urethral Catheter Simulator*

A list of all tissues/structures found with the CREST UC Sim after Version 2 are seen in Table 2. Version 1 does not include fat, scrotum, testicles or foreskin.

Table 2: Anatomical structures included after CREST UC V2.

Tissue/Structure
BLADDER
PROSTATE
CORPUS CAVERNOSUM
CORPUS SPONGIOSUM
PERINEAL MEMBRANE
URETHRA
GLANS
SKIN
FAT
SCROTUM
FORESKIN
PELVIC BONE
TESTICLES

2.4 CREST URETHRAL CATHETER SIMULATOR FORCE OF INSERTION STUDY

In the fall of 2018, an abstract summarizing the development and validation of the CREST UC Sim Version 2 was submitted to the American Urological Association's Annual Conference for May of 2019. The premise of the abstract included a comparison of the CREST UC Sim to the Life/Form Male Simulator (a commonly used urethral catheter simulator). An initial comparison of the force of insertion for urinary catheters was included. This study inserted a 16Fr urinary

catheter into the CREST UC Sim V2 and the Life/Form Male simulator to a depth of 1 inch. This study was limited by the tools available at the time for force collection. This initial insertion study inspired the need for a more comprehensive method by which to quantify the forces of urinary catheterization. The published abstract and poster are included in **Appendix A**.

2.5 New Developments in CREST Urethral Catheter Simulators

2.5.1 *Cross-Section Model*

To pivot from the current design of CREST UC Version 2 the next development was created to allow the user to visualize the location of the catheter along the length of the urethra. Inspiration was drawn from other simulators that show a similar cross-sectional view.

The cross-section model design is to be used as visual education aid to visualize the length and curvature of the male urethra. The length of the male urethra ranges between 15-29 cm with average of 22.3cm +/- 2.4 cm. [24] The CREST UC SIM model's urethral length is 16.2 cm. This new design aims to educate the user of the inner anatomy of the male genitourinary system and the necessity of inserting the catheter to the full length or "to the hub." If a care provider does not insert the catheter "to the hub" they run the risk of causing urethral trauma if the balloon at the top of the catheter is not contained within the bladder.

The design of a semi-translucent urethra (Fig. 5) allows the user to visualize the placement of the catheter as it enters the tip of the penis and progresses through the different anatomic urethral regions and begins to coil in the bladder. The cross-sectional model is to be used in conjunction with a full version of the simulator.

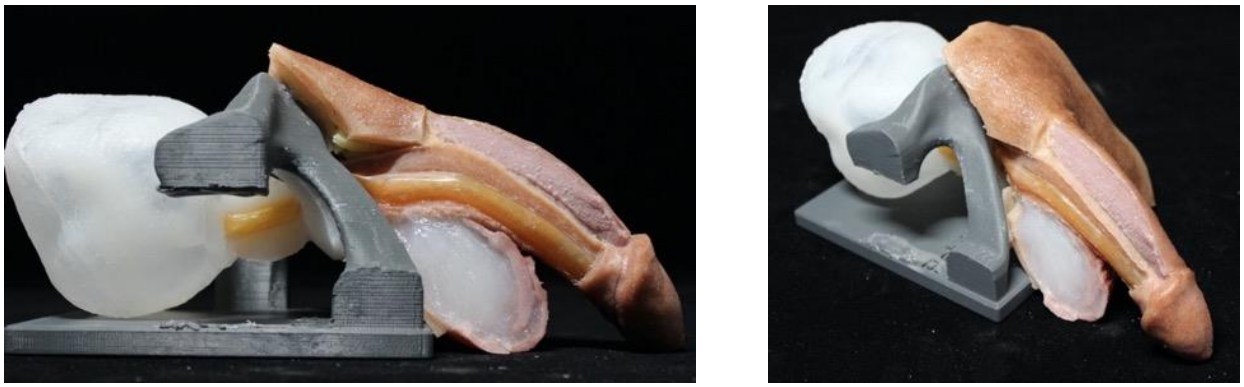


Figure 5: CREST UC Sim Cross-Section model.

2.5.2 *Version 3 with Sphincter Design*

CREST UC Version 3 (Fig.6) replicated most of the features, materials, and construction as Version 2, with the addition of a sphincter device. The importance of the sphincter mechanism is to replicate a diseased condition of the prostate called benign prostatic hyperplasia (BPH) seen

most commonly in older men. BPH is the enlargement of the prostate gland which can lead to difficulty urinating and associated issues such as urinary tract or kidney problems.[25] This diseased state simulated within the CREST UC Sim enables education at a variety of skill levels. The healthy patient state has no prostatic urethral narrowing. Whereas the diseased state is defined by varied levels of a narrowed prostatic urethra. "Difficult catheter placement" techniques can be practiced on the simulator using the modular diseased state sphincter.

The sphincter device is used to compress the prostatic urethra region using a 3mL syringe that connects onto the sphincter tubing. The device can be inflated to different levels of occlusion as shown in **Appendix D.** The modular diseased state device enables training scenarios that require the identification of a narrowed urethra. This feature is designed to teach a care provider to recognize an obstruction and identify the need for a urology consult.

The device inspiration came from the AMS 800™ Urinary Control[26] and the methodology to create this design came from a mechanical engineering thesis into sealed silicone balloons.[27] The design in this thesis was inspired from Figure 3.2 in Hudoba.[27] The primary design components that were desired in our application was the ability to latch to the opposite edge of the sphincter device.

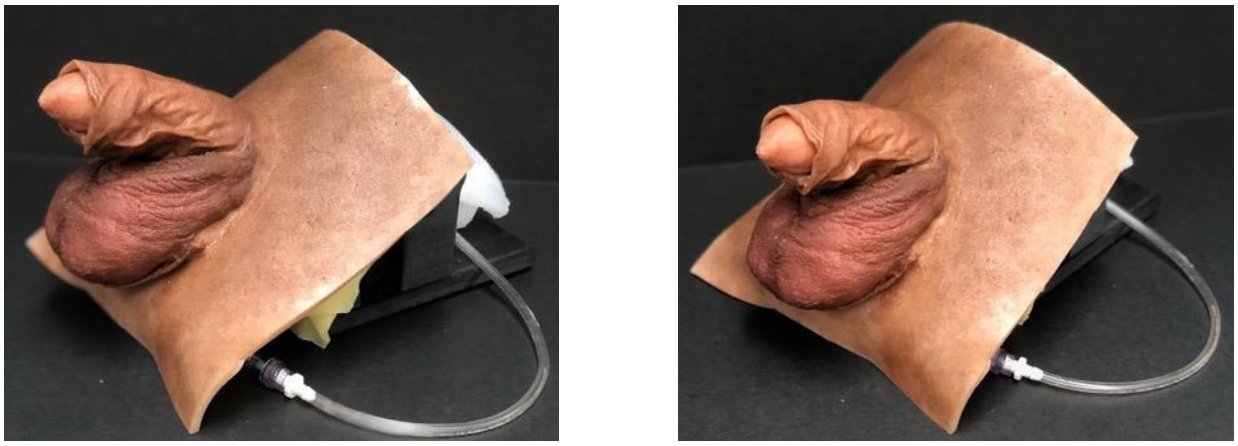


Figure 6: CREST UC Sim Version 3.

2.5.2.1 Sphincter Design + SolidWorks Parts

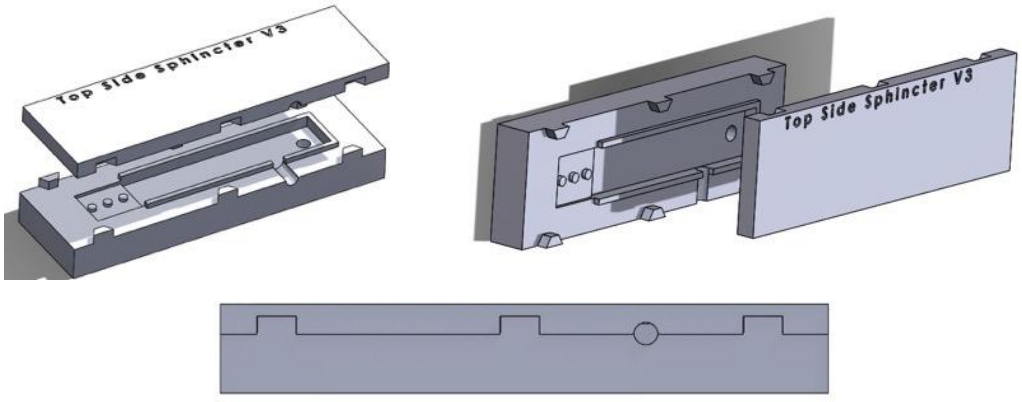


Figure 7: SolidWorks Rendering of sphincter mold design.

2.5.2.2 Sphincter Creation Methods

A 2-part sphincter mold was designed in SolidWorks (Fig. 7). This mold was printed in PLA using a Stratasys printer. The sphincter is made of Polytek – Platsil Gel-25, with an additional piece of elastic material to give a backbone to the non-expanding side of the sphincter device. The step-by-step methods to create the sphincter device are listed in Table 3. See **Appendix B** for images of steps taken when creating the sphincter.

Table 3: Methods to create sphincter device.

STEP #	METHOD DESCRIPTION
1	Mix equal parts of Platsil Gel-25 A + B
2	Pour this mixture into both sides of the mold
3	Cover all corners and parts of the inner mold, then place a piece of small silicone tubing in the vent hole for the placement of a luer insert later + cutdown elastic sheet that is placed in the bottom side of the sphincter mold
4	Let each side cure fully (wait about 30 minutes)
5	Then mix more equal parts of Platsil Gel-25 A + B which are then used to seal the pieces together
6	Apply the new mixture to the outside edges of both sides of the mold, then push the two sides together
7	Allow to cure (wait about 30 minutes)
8	Remove from mold, and look for tears or holes in the seal
8A	If there are holes, mix a small amount of Plasil Gel-25 and apply to seal the holes
9	Remove the silicone tubing piece
10	In the silicone tubing hole Insert a Male Luer Integral Ring to 20G Series Barb (1/8” / 3.2 mm ID)
11	Seal this luer in using a small amount of the Platsil Gel-25, ensuring not to get any silicone in the luer hole
12	Cut a piece of tubing (TYGON E-3603 ID:1/8in OD:3/16in) about 20cm in length
13	Attach the tubing to the luer ring side then attach a check valve luer lock component to the opposite end of the tubing
14	Using an already created synthetic urethra on a urethral core, attach the sphincter with the elastic material side out around the urethra (see **Appendix C**)
15	Mix a small batch of Platsil Gel-10 A + B to apply to the latch to permanently seal them together, then let cure
16	Once the sphincter is situated around the urethral core, it can be placed into the prostate mold to be cast within
17	Following standard silicone molding techniques, release the mold, mix the silicone for the prostate recipe, and fill the mold with the urethra piece lying properly within the mold
18	Allow the material to cure, then remove from the mold with a fully encapsulated sphincter device that is ready to be constructed into the model

2.5.2.3 Sphincter: Urethra Occlusion Study

The purpose of this study is to quantify each stage of occlusion, then assign a volume of air inserted to the % occluded. The spectrum of occlusion will be used to train for difficult catheter placement detection. The sphincter occlusion action increases the amount of force used to place the catheter as the % occluded increases. This tactile feedback aims to translate to the user that when they cannot place a catheter normally, they must call a urology consult to aid in the "difficult" catheter placement. Methods of the study are outlined in Table 4. See **Appendix D** for the images used to collect area measurements in ImageJ.

2.5.2.3.1 Methods of Study

Table 4: Methods to perform sphincter occlusion study.

STEP #	METHOD DESCRIPTION
1	Follow methods to create a working sphincter device within the prostate
2	Cut off excess parts of synthetic urethra material to visualize the prostatic urethra
3	Set up a picture taking area, using one camera to collect images at different stages
4	Using a 10mL luerlock syringe insert air into the sphincter at 0.5mL at a time until 3mL
5	Take an image at full insertion of air
6	Repeat steps 4-5 until 3mL image is taken
7	Measure % Occlusion using ImageJ software

The maximum amount of air allowed for this device design is 2mL, 71% occluded. Any higher inflation volumes lead to extremely high pressures inside the sphincter and risks failure of the device. See the results of % occluded plotted in Figure 8. Table 5 reports the numeric results in addition to the raw area values that were used to calculate the percent occluded at each volume. % Occlusion was calculated with the following equation:

$$\%\ Occlusion = 1 - \frac{Experimental\ Area\ (XmL)}{Baseline\ Area\ of\ 0mL}$$

2.5.2.3.2 Results of Study (% occluded)

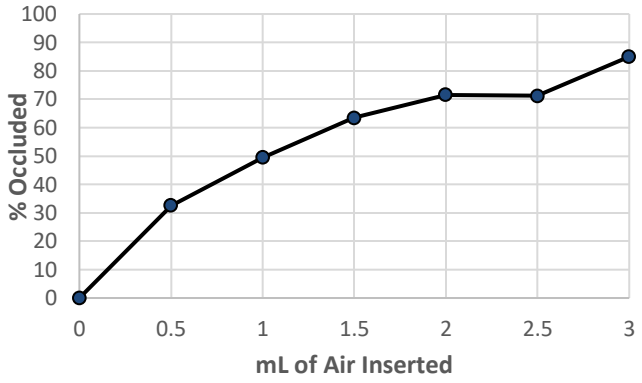


Figure 8: Results of the sphincter occlusion study.

Table 5: Numeric results from the sphincter occlusion study.

AIR INSERTED (ML)	% OCCLUSION	AREA (UNITLESS)
0	0.00	54196
0.5	32.56	36545
1	49.45	27393
1.5	63.44	19812
2	71.59	15395
2.5	71.13	15644
3	84.97	8145

2.5.3 *Version 4*

2.5.3.1 New Molds

The development of the CREST UC Sim Version 4 required a redesign of molds. This included redesigning molds for the: foreskin, testicle, urethra, combination mold for glans/spongiosum/prostate, and scrotum. The urethra and combination mold were both designed using computer-aided design software – Fusion 360. The foreskin (Fig. 9a) and testicle (Fig. 9b) molds were created in SolidWorks. Changing mold medium from silicone to 3D printed plastic offered a few benefits including a natural release agent (plastic vs. silicone), options for easy and fast mold alterations as needed, and addressed the need for manufacturability.

Additionally, the simulator base was redesigned. The new base (Fig.10) forces the tissues and structures to orient in the position of a recumbent male patient. The redesigned base improves realism, ease of attachment/construction, and simulator transport mobility.

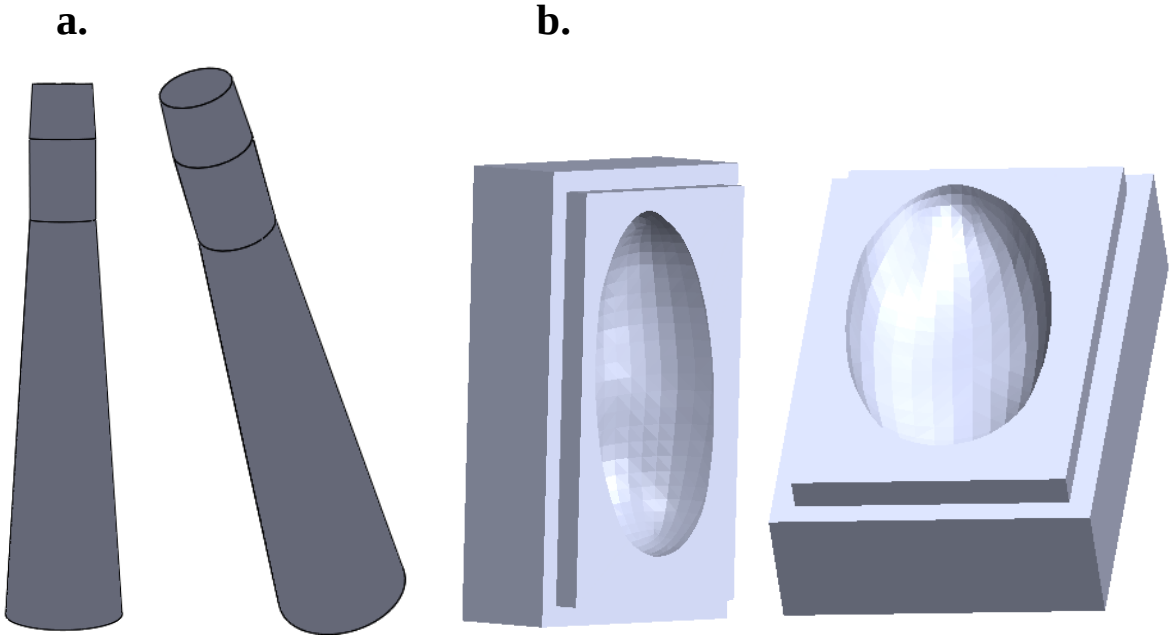


Figure 9: Examples of new molds for CREST SIM V4.

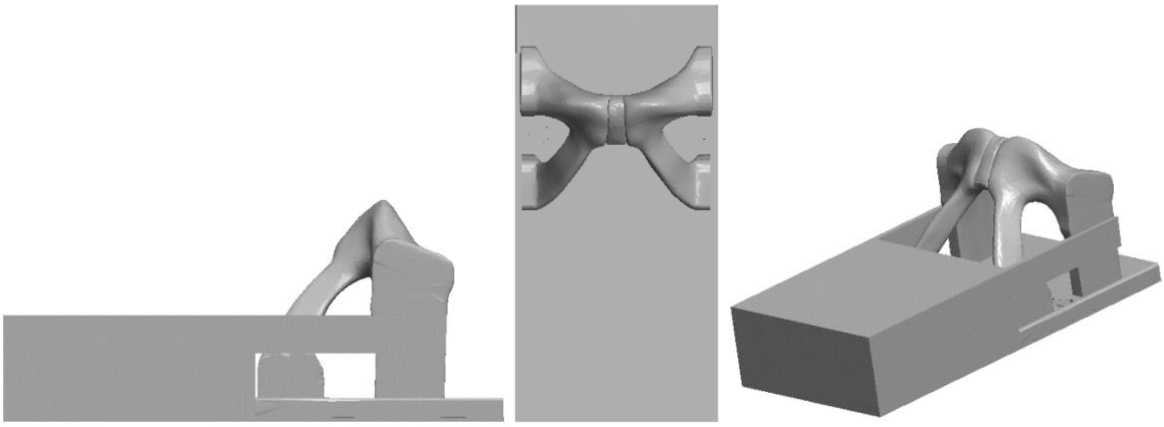


Figure 10: New pelvic base for version 4 construction.

2.5.3.2 Method Alteration

Version 4 was constructed using the newly optimized combination mold (Fig.11). This mold centers the construction around the urethra where three tissues are now created by one mold. In prior versions, each of these pieces were created and assembled separately. This revised process ensures that the urethra is one continuous lumen throughout the model from the tip of the glans to the end of the prostate into the bladder.

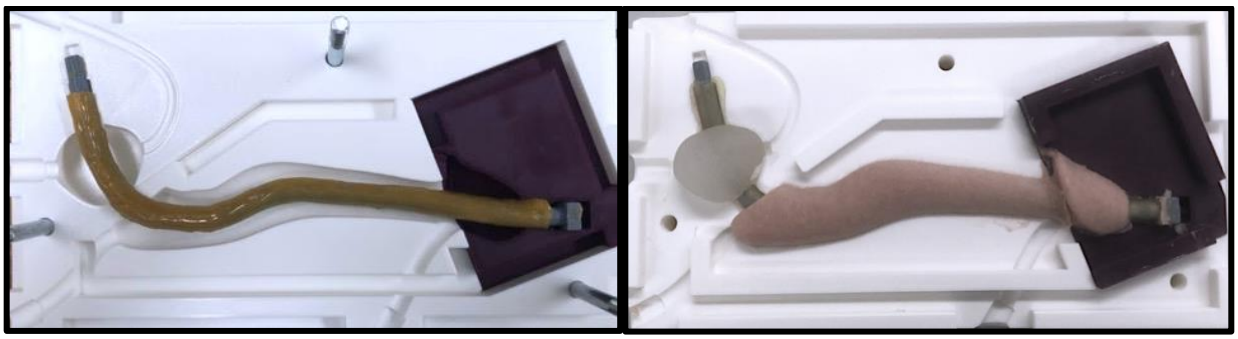


Figure 11: Urethra centered construction of the CREST UC Sim V4.

2.5.3.3 Final Construction + Notes

Version 4 is the final iteration of the CREST UC Sim. An additional external design feature added to this version was a screw-on cap to the bladder. This design change was motivated by the potential for lubrication buildup and ultimately molding in the device. CREST UC Sim V4 resulted in two model variations (Fig.12) where one is circumcised and the other is uncircumcised. Additional images of Version 4 developments are in **Appendix E.**

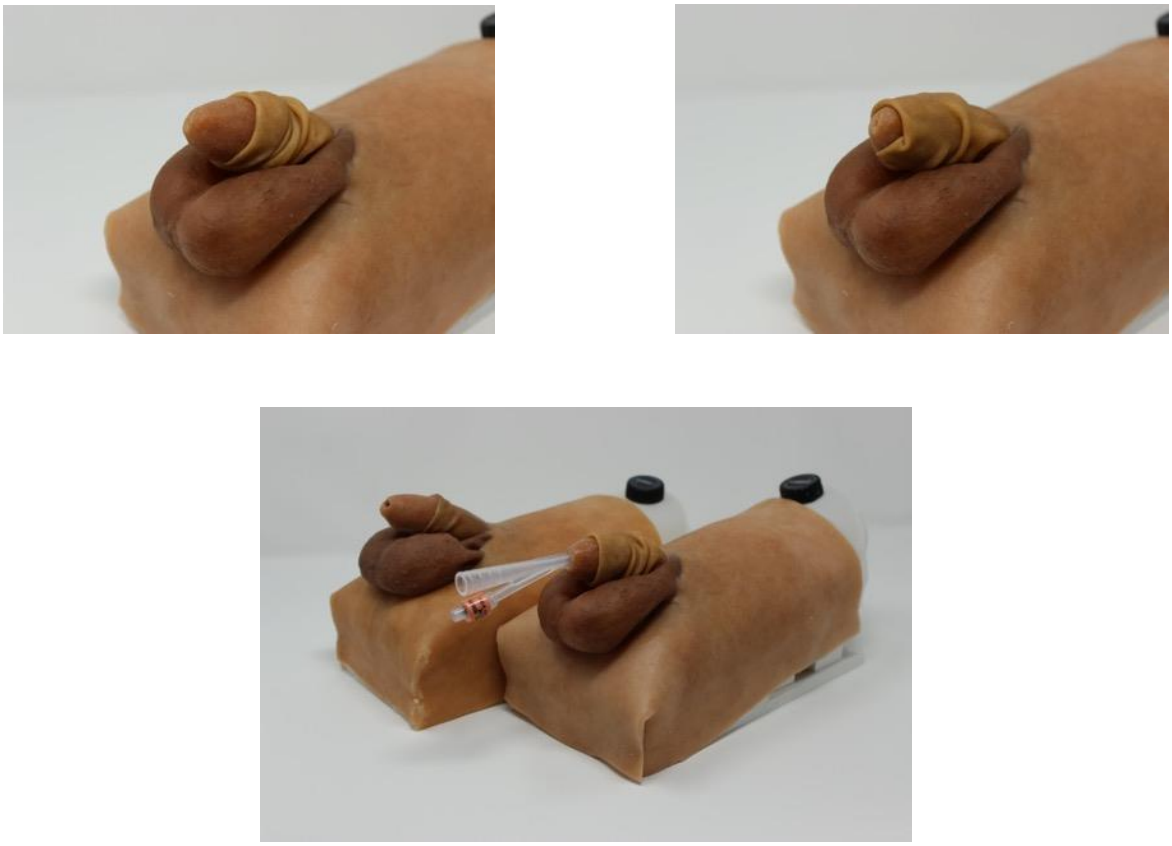


Figure 12: Images of CREST UC Sim Version 4.

2.6 USE OF CREST SIMULATOR AT UW MEDICINE NURSE ON-BOARDING

The CREST UC Sim has made an impact in the education and on-boarding of OR nurses. Over the past year, the CREST UC Sim has been used on multiple occasions to aid in the discussion around urethral catheter standards of practice and for hands-on trainings. My collaborator, Heather H. Owen MS RN CNOR, has enabled multiple opportunities for the simulator to be used and to obtain feedback from those uses. The average nurse who is going through the on-boarding process at University of Washington Medical Center (UWMC) has already placed plenty of catheters in their previous experiences. These educational moments often occur in the operating rooms of the UWMC so the user has the most realistic training possible (Fig. 13). Additional images from this collaboration are in **Appendix F**.

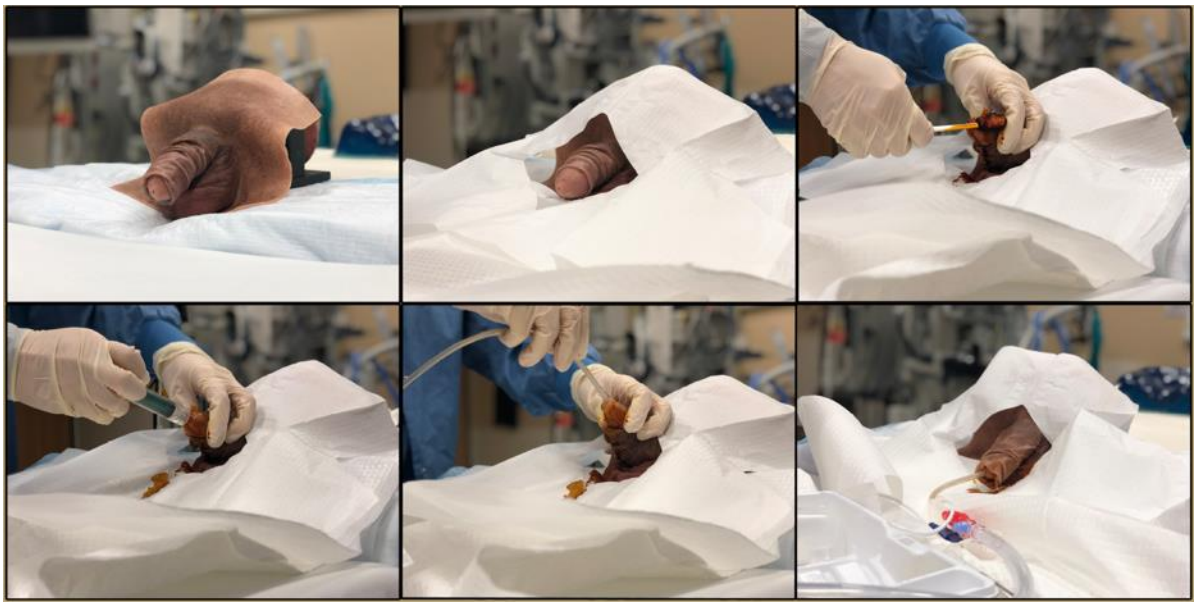


Figure 13: Spring 2019 UW OR Nurse On-Boarding session with CREST UC Sim V2.

Chapter 3. FORCE COLLECTION STUDY

Chapter 3 introduces and summarizes previous relevant research from the University of Minnesota, the goals of the *Force Measurement Instrument* redesign, the results of the *Force Measurement Instrument* verification study, a brief update on the status of the University of Minnesota's live patient study, a full explanation of the UW Cadaveric Study and the results of the UW Cadaveric Study data collection.

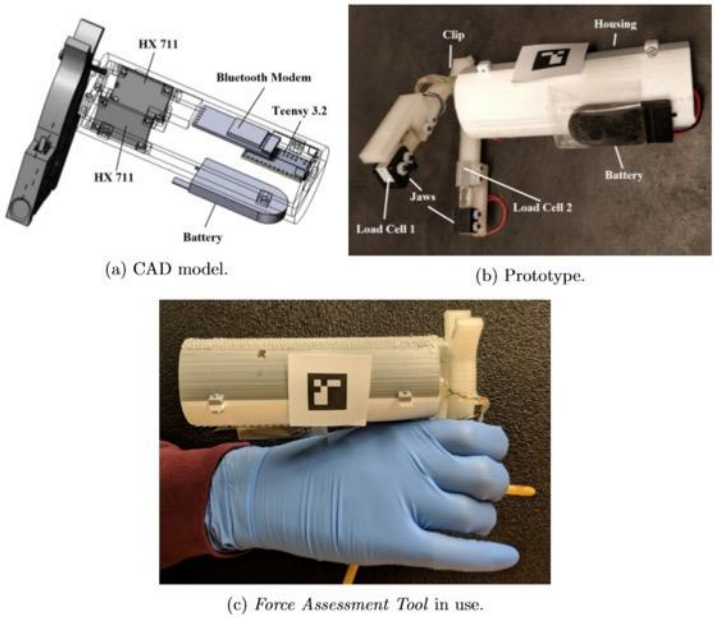
3.1 UNIVERSITY OF MINNESOTA - CADAVERIC STUDY

All data, information, and graphics produced within the 3.1 section of this thesis is work from the 2019 thesis of Catherine Ling at the University of Minnesota (UMN) in Dr. Timothy Kowalewski's laboratory. I obtained permissions directly from Miss Ling's lab to use a summation of her work to provide the background information required to understand the developments in this thesis.[7]

3.1.1 *Original Force Insertion Device*

The original design of the force assessment device (Fig. 14) was designed to balance on the user's hand(Fig. 14c). The tongs, which hold the catheter in place and house the load cells, are the main point of contact between the user and device. The user applies pressure by clamping their hand together to bring the two tongs into contact. The cylindrical processing box lays over the back of the hand where a data transmission cable leaves the rear of the housing to connect to a laptop for data collection.

The spatial tracking data collection was performed by using computer vision to track QR images in 3D space. Their study employed the use of a GoPro camera to collect a recording of their insertion. Ling used the video to extract the distance between the tool and the user's other hand (also had a QR code) which quantified the length of the catheter that was placed during each push.



(a) CAD model. (b) Prototype.

(c) *Force Assessment Tool* in use.

Figure 14: Figure 2.1 from Ling's 2019 Master's thesis.

3.1.2 *UMN - Pilot Study*

3.1.2.1 Methods

The UMN study used a 16Fr Lubri-Sil catheter for all donors (except one who required the use of a coude tipped catheter). The catheter was dipped into 5mL of PDI Lubricating Jelly. A video of the insertion was collected with a GoPro camera. The medical professional held the Force Assessment Tool and inserted the catheter into the cadaveric donor while the data from the unidirectional loadcells was collected.

3.1.2.2 Analyzed Data

The donors (n=5) were aged 29, 31, 72, 76, and 92. Any known relevant medical history was collected. The number of days postmortem was noted for each donor. The data was analyzed to quantify the insertion forces, depths, and speed profiles. A single push segmentation that characterized the force in a non-prostatic and prostatic region of the urethra were used to compare across donors.

3.1.2.3 Take-Aways

The work performed at UMN paved the direction and motivations for the re-design and goals of the UW Cadaveric study. The overall takeaway from Ling's work is a baseline force curve to define the standard force applied in specific anatomic regions of the male urethra. Ling claimed a clear difference in the average force between non-prostate and prostate pushes. More specifically, Ling derived that the major player in the force collected was less due from friction and primarily caused by pushing tissues apart. This novel research proved that the forces of catheter insertion need to be better defined with further studies in both cadaveric and live patient collections.

Another piece of Ling's thesis explored the force of insertion of two commercially available simulators. These simulators were both compared to the cadaveric data and concluded that they required much larger force to place the catheter in the models than in the cadaveric donor. Ling additionally claimed that the simulators did not have natural variation in the force required to place the catheter as seen in cadaveric studies from non-prostate to prostate pushes. The simulators also required the inserter to increase the number of pushes to fully place the catheter, meaning that the simulators required shorter insertion pushes due to buckling effects encountered.

3.2 Redesign of Force Measurement Insertion Instrument

Section 3.2 explains the transition from the original UMN Force Assessment Tool to the UW designed *Force Measurement Instrument*.

3.2.1 *Goals of Redesign*

After transferring the files of the original insertion instrument from University of Minnesota to the University of Washington, our two groups worked together to determine a basic outline of goals to achieve for the redesign of the *Force Measurement Instrument* (formerly titled the Force Assessment Tool) (see Table 6).

Table 6: outlines the goals the UW redesign of the *Force Measurement Instrument* was to accomplish.

#	**Goal Description**
1	Decrease the length of the tongs to fit within the palm of the researcher
2	Remove the cylindrical hull → create alternative housing for circuits
3	Improve the ergonomics of the device
4	Lower the distance between the user's fingers and where the catheter is held
5	Thread wires from the load cells to inside the tongs (limit potential for shock or other issues)
6	Make device look less intimidating for future use with live patients
7	Alter location/depth measurement methodology from GoPro to trakSTAR Sensor

3.2.2 *Bill of Materials for Force Measurement Instrument*

For ease of replication, the *Force Measurement Instrument's* bill of materials is listed in Table 7. One highly convenient feature of this device is the low-cost materials required to construct the device.

Table 7: Bill of materials for the *Force Measurement Instrument*

Part #	Quantity	Part Name
1	2	Phidgets Micro Loadcell 780g – CZL616C
2	1	Teensy USB Board, Version 3.2
3	2	SparkFun Load Cell Amplifier
4	1	180° Left-Handed Torsional Spring – 9287K271 (McMaster)
5	1	Nylon Hex Nut (M3-0.5) – 93800A400 (McMaster)
6	8	Nylon Slotted Flat Head Screw (M3-0.5) – 92929A250 (McMaster)
7	8	Steel Slotted Flat Head Screw (M3-0.5, 6 mm Long) - 90274A116 (McMaster)
8	3	Nylon Pan Head Slotted Screw (M3-0.5) – 95836A535 (McMaster)
9	1	4 Conductor 32 AWG Cable – T1244-30-ND

3.2.3 *SolidWorks Parts and Assemblies*

The redesigned components of the *Force Measurement Instrument* used in the UW Cadaveric Study are shown below (Fig. 15 and 16). Two versions were designed, one with (Fig.16) and one without a trakSTAR sensor (Fig.15a). Note the red circle highlights the flat face and V-shape used to hold the catheter in place during studies(Fig.15a). This type of closure enables a tight grasp on the catheter to avoid slipping and ensures a perpendicular orientation between the catheter and the load cells to minimize error during data collection. A calibration stand was designed in SolidWorks to fit and support the *Force Measurement Instrument* (Fig.17). The calibration stand holds the device horizontal during the calibration process before each study. Additional images of the *Force Measurement Instrument* are in **Appendix G**.

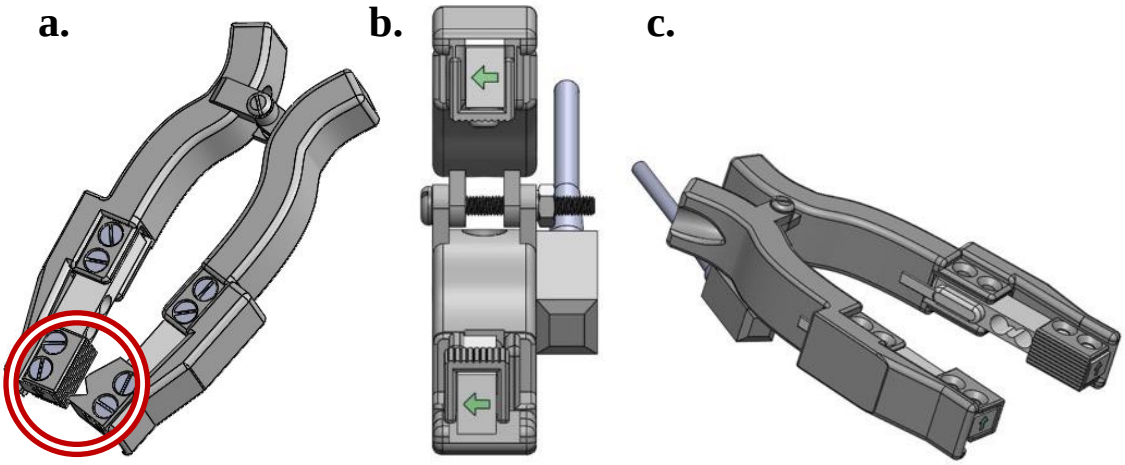


Figure 15: *Force Measurement Instrument* revisions.

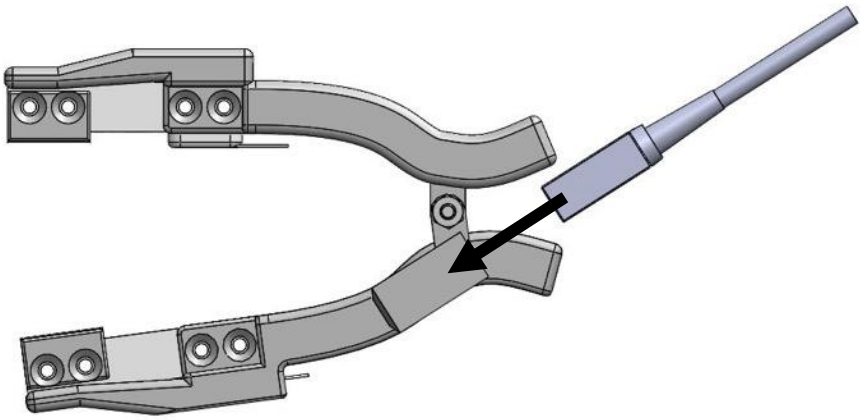


Figure 16: Full body view of the *Force Measurement Instrument* + trakSTAR Sensor.

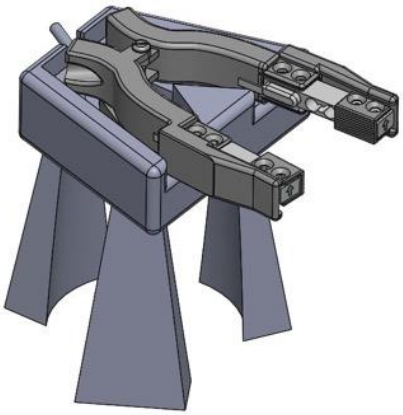


Figure 17: *Force Measurement Instrument* + Calibration Stand

3.2.4 *Data Processing Box (DPB), Circuits & Alteration of Connection*

The data processing box (DPB) is the redesigned housing for the circuitry included in the *Force Measurement Instrument*. The DPB was designed in SolidWorks and includes a lid that can hinge open and close (Fig.18). The semi-circle opening is used as a port to plug in the micro-USB to the Teensy 3.2 board. The vertical slit opening is used for the placement and removal of the circuit system into the DPB. The clip-like appendage on the box is used to secure the box to the research physician's belt or scrub waist band. The circuit design (Fig. 19) for the *Force Measurement* Instrument is compact enabling the design and fit into a small housing unit (Fig. 20).

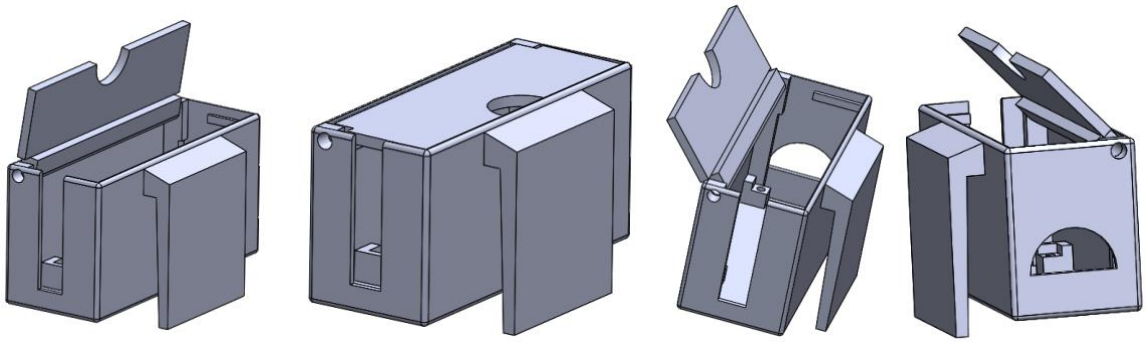


Figure 18: Data Processing Box Renderings

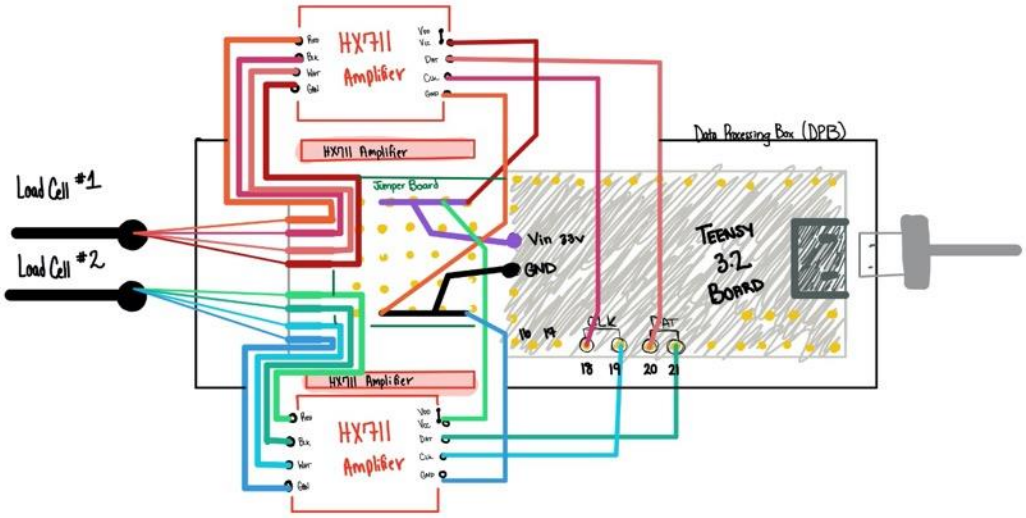


Figure 19: *Force Measurement Instrument* - Circuit Diagram Schematic.

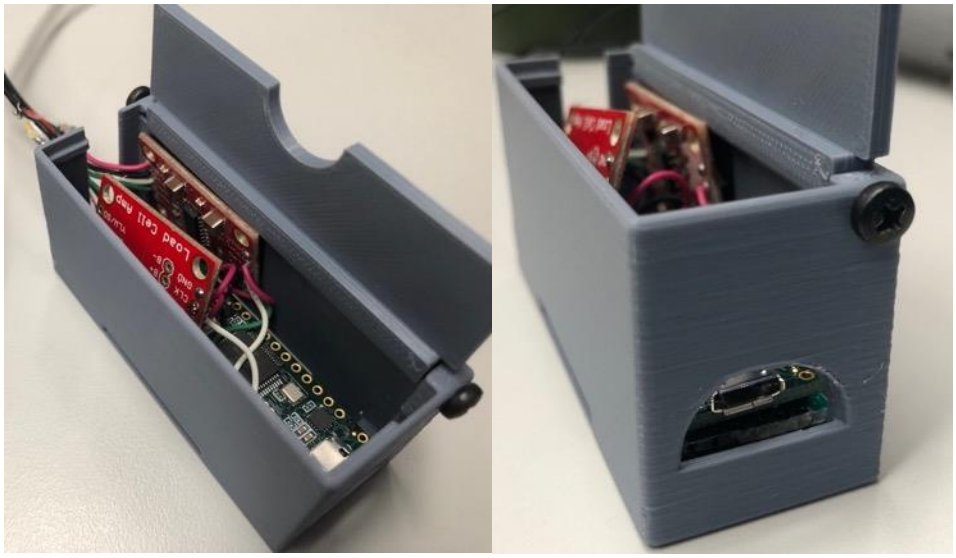


Figure 20: Circuit assembly secured inside the DPB.

3.2.5 *Notes on Construction of the Force Measurement Instrument*

Sparkfun HX711 amplifiers require a solder bridge between VCC and VDD on the output side of the amplifier. A stock Sparkfun HX711 amplifier's acquisition rate is limited to 10 bits per second(bps) due to a preconnected bridge on the physical circuit. The rate of acquisition can be increased to 80 bps when this bridge is physically broken on the backside of the amplifier chip. For the UW and UMN studies, the *Force Measurement Instrument* requires this higher rate of acquisition. The Nylon flat head screws (92929A250) are used to attach the 3D printed load cell shields to the load cells. The metal flat head screws (90274A116) are used to secure the load cell to the 3D printed tong structures. To improve the fit of these M3 screws, a small amount of parafilm is wrapped around the screws before the final placement into the tongs.

3.2.6 *Calibration of Phidget Load Cells*

An Arduino script with the installation of the HX711 library is required to calibrate the load cells. The HX711 library comes with a calibration sketch to easily dial in the calibration factor that is used in the data acquisition sketch. Each load cell must be calibrated separately and before each test or study using the *Force Measurement Instrument*. The methods to calibrate each load cell are summarized in Table 8. Once each calibration factor is determined, they must be written down to be passed to the separate data acquisition sketch. The weights used in the calibration protocol are altered to include a paperclip hook (Fig. 21a). The paperclip hook was attached to each weight to enable the larger weights to hang down from the load cell with minimal surface area required. Table 9 lists the combined weight of the paper clip attached weights.

Table 8: Protocol to calibrate the load cells of the *Force Measurement Instrument*.

Step #	Method Description
1	Open Arduino Calibration Sketch (**Appendix H**)
2	Plug in the circuit to the computer and select the proper Port and board
3	Place and Secure the Force Measurement Instrument to the Calibration Stand (Fig.21b)
4	Upload the sketch, take note of which load cell is active
5	Open the serial window (ctrl + shift + M), check data is being collected
6	Place known weight on load cell
7	Using the command bar to enter **z**(+1000) or **a**(-1000) to alter the calibration factor to fluctuate the read towards the known weight used
8	Repeat this step with each of the weights
9	Once done adjusting the calibration factor, write it down to use in the data acquisition script
10	Repeat to calibrate the other load cell

a.

b.

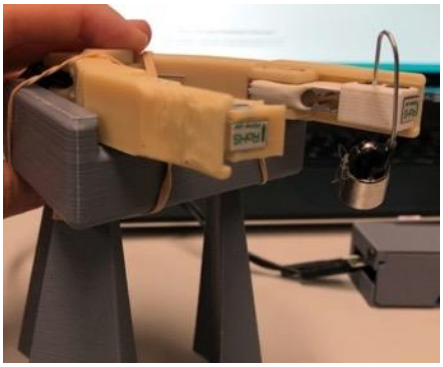


Figure 21: Calibrating the Load Cells: a. Weights + b. Example Calibration Setup.

Table 9: Combined weight of the calibration weights and paper clip.

INITIAL WEIGHT	NEW WEIGHT
10g	10.649g
20g	20.702g
50g	50.698g

3.2.7 *How it is used?*

The *Force Measurement Instrument* is used to collect data by utilizing two, single-axis load cells (Phidgets Micro Loadcell 780g) in the tong extensions to hold the catheter during the insertion(Fig.22a+b). Each additional push requires the user to re-grip the catheter as it is inserted further into the urethra. The load cells only collect force data in the direction the catheter is being inserted(Fig.22c). The two loadcell force readouts are summed to make resultant total force of insertion for each push.

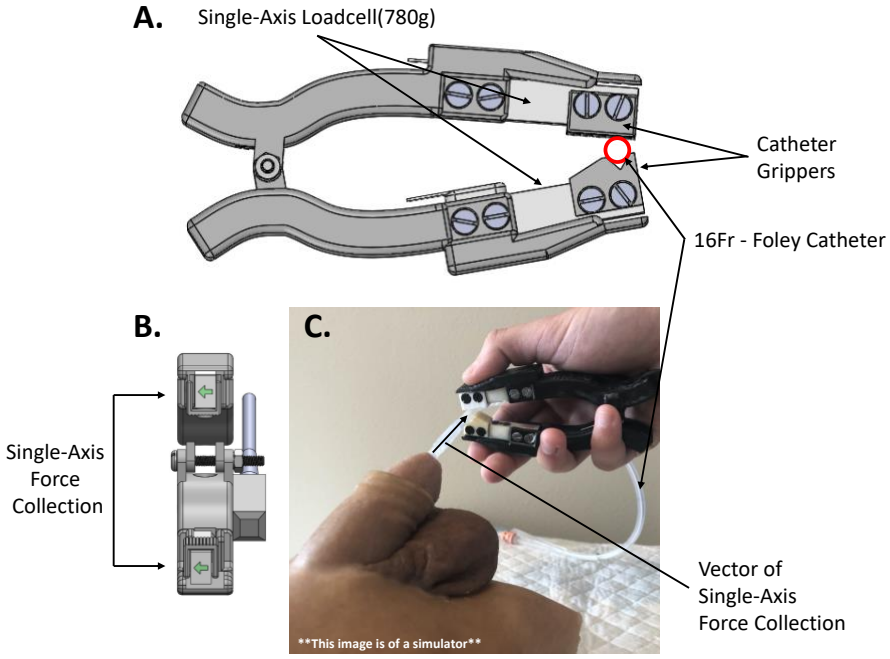


Figure 22: *Force Measurement Instrument:* highlighted functionality + how force is collected.

3.2.8 *Integration of Ascension – trakSTAR: 6DOF Spatial Tracking*

UMN used computer vision to track the depth of the catheter being placed. For future studies that will involve live humans, both research teams will be using the Ascension - trakSTAR 6 degree of freedom magnetic tracking system. This device enables tracking of up to four sensors on one processing system simultaneously. The trakSTAR technology introduces a magnetic field (Fig.23) to the area of motion, the user can track the insertion tool with a high precision and collection rate. Previous methods using video were limited by low frame rate and thus lost data precision. The future live patient studies at UW and UMN will be using the: Model 800 sensor(8mm) and the Mid-Range Transmitter (MRT).

Some limitations do come with the use of the Ascension trakSTAR system. Although there is a high data acquisition rate and precision, there has proven to be difficulty when extracting location data and syncing it with the force data collected simultaneously. In a preliminary verification study, the manual data analysis using an audio file to determine start and end of each push created significant error when compared to the measured distance values. A 16Fr Bard catheter was used to calculate the error between the two methods of distance collection. Location data from the trakSTAR was collected in addition to physical markings on the catheter from a sharpie after each insertion push. The measured (directly from the marked catheter) and calculated distances (using trakSTAR data + MATLAB) from the study are reported in Table 10. The third column calculated the percent error between the two measurements. Images of the marked catheter and measurements at each push can be seen in **Appendix I**.

A high rate of error was noted for the first insertion push. Thus, further methods to minimize this error need to be investigated before employing this technology in live patient studies. For this reason, the UW Cadaveric Study will utilize alternative methods of catheter depth measurement. The two methods are described in depth in Section 3.6.4.

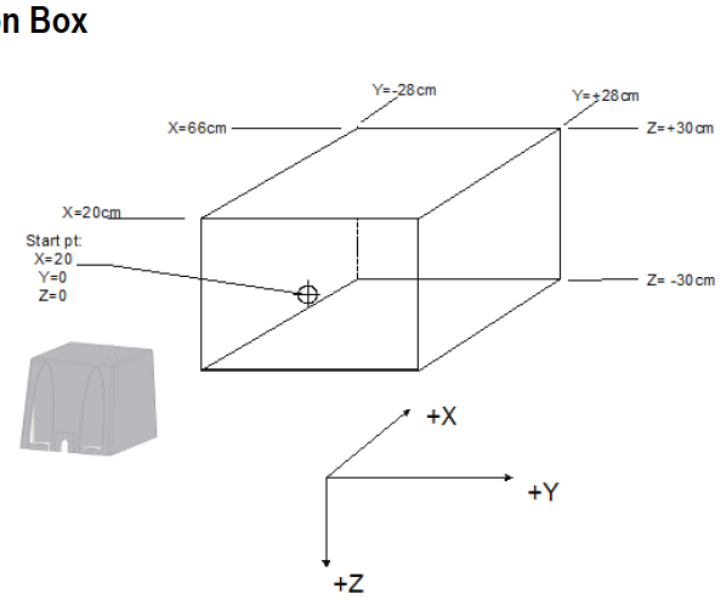


Figure 23: Ascension trakSTAR User Handbook pg28. [28]

Table 10: Results of trakSTAR verification study.

Push #	Measured Distance (mm)	Calculated Distance (mm)	% Error
1	73.98	52.462	29.09%
2	37.21	39.068	4.99%
3	40.92	37.50	8.35%

3.2.9 *Accuracy Testing of New Force Measurement Instrument*

To estimate the amount of error expected from the selected load cells due to gravity or other motion related factors, two tests were run for 15 seconds each. The load cells were calibrated and zeroed in a flat neutral state on the calibration stand before being tested under both conditions. The plotted 15 second trials for condition 1 (Fig. 24) and condition 2 (Fig. 25) are included below. The max and min peaks are outlined using red and black markers, respectively. Table 11 reports the results of the error spread from both condition trials.

These two tests concluded that there is some error due to gravity and other locomotive factors when the *Force Measurement Instrument* is moved around in random circles and inverted. This error must be taken into consideration when evaluating the accuracy of force measurements collected during future studies using the *Force Measurement Instrument*.

3.2.9.1 Condition 1 – Open Tongs moving Up and Down (in plane of calibration)

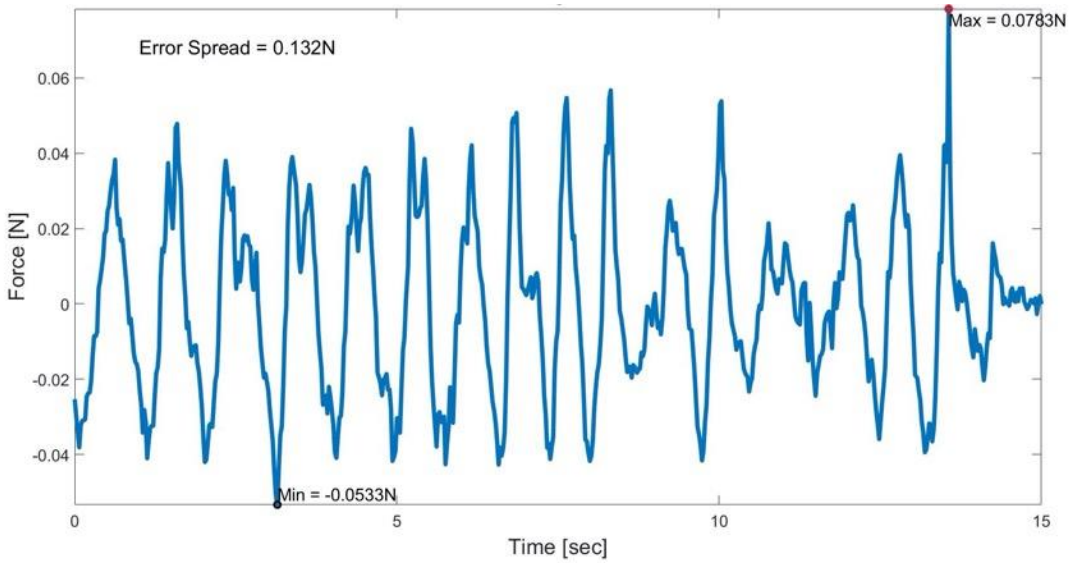


Figure 24: 15 seconds of force data acquisition under Condition 1.

3.2.9.2 Condition 2 – Open Tongs moving in 360° (out of plane of calibration)

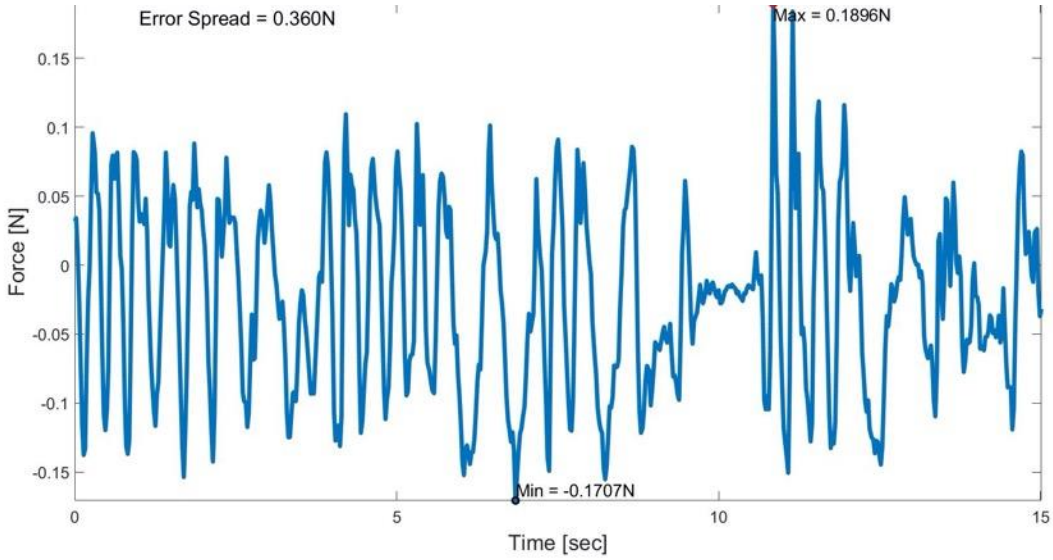


Figure 25: 15 seconds of force data acquisition under Condition 2.

Table 11: Error spread for each condition over a 15 second data acquisition period.

	Condition #1	**Condition #2**
Error Spread	0.132N	0.360N

3.3 Force Measurement Instrument Verification Study

3.3.1 *Study Set-Up*

To verify that the redesigned *Force Measurement Instrument* is consistent with the UMN's Force Assessment Tool design a study was performed to compare the force collected on the two devices. The study consisted of testing the Life/Form Male simulator and an analog tube (ID – 6.25mm OD – 9.5mm) "urethra" to compare the tools force collection to one another. The same researcher (myself) performed all of the insertions. The catheter used was a pre-marked (Fig.26) 14Fr BardEx IC coude tip. The catheter was pre-measured with the intention of ensuring the same data would be compared over multiple trials at the same locations. Pre-conditions for the Life/Form Male simulator included 1 mL of lubrication into the urethra before each trial. The analog tube was preconditioned with 3-5mL of lubricant run through the tube, then an additional 1 mL of lubricant was added before each trial. See **Appendix J** for analog tube study set up images.

The study set up included using the same catheter (cleaning with water in-between trials) to catheterize the device used. The Life/Form Male Simulator was tested with an N = 3. The analog tube was tested with an N = 5. Each device was used the same way to insert the catheter and followed the 12 pre-marked depth pattern during data collection. Each trial was audio recorded to be used for processing the data.

The alteration in the study format (number of trials) between the Life/Form Male and the analog tube was due to the Life/Form Male's data being much more sporadic and randomized upon visualization. This finding triggered the decision to find an alternative "urethra" medium to test. The design and material of the Life/Form male gave rise to these results seen below in Figure 26.

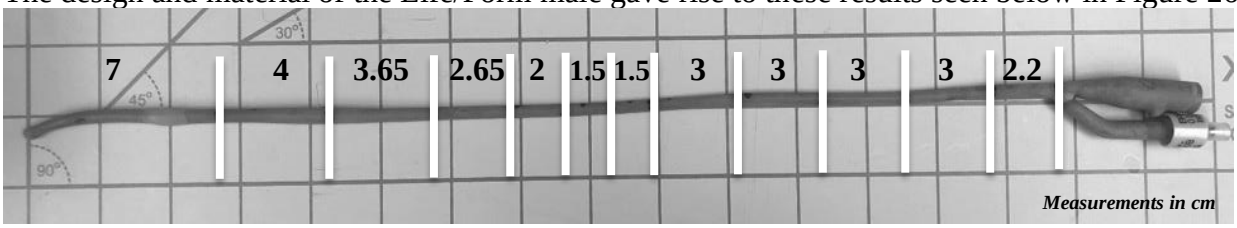


Figure 26: Pre-marked catheter for *Force Measurement Instrument* verification study.

3.3.2 *Results*

The force incurred at each depth was used to compare the two instruments in both urethra mediums. Processed raw data is included in **Appendix K.** The process of identifying which force data is relevant is performed by listening back to the voice recording taken during the study. MATLAB was used to identify which peak will be used as the max force value of that insertion depth.

The max force at each push was identified in each trial. Overlain bicolored boxplots were produced for the Life/Form Male Simulator (Fig. 27) and analog tube study (Fig. 28). Both Figures include the same x-axis which is the depth measurement for each increment marked. The y-axis is the amount of force used to insert the catheter at that depth. The Life/Form Male simulator force results range from 0.5 N to 9 N, whereas the analog tube force results range from 0.5 N to 3.5 N.

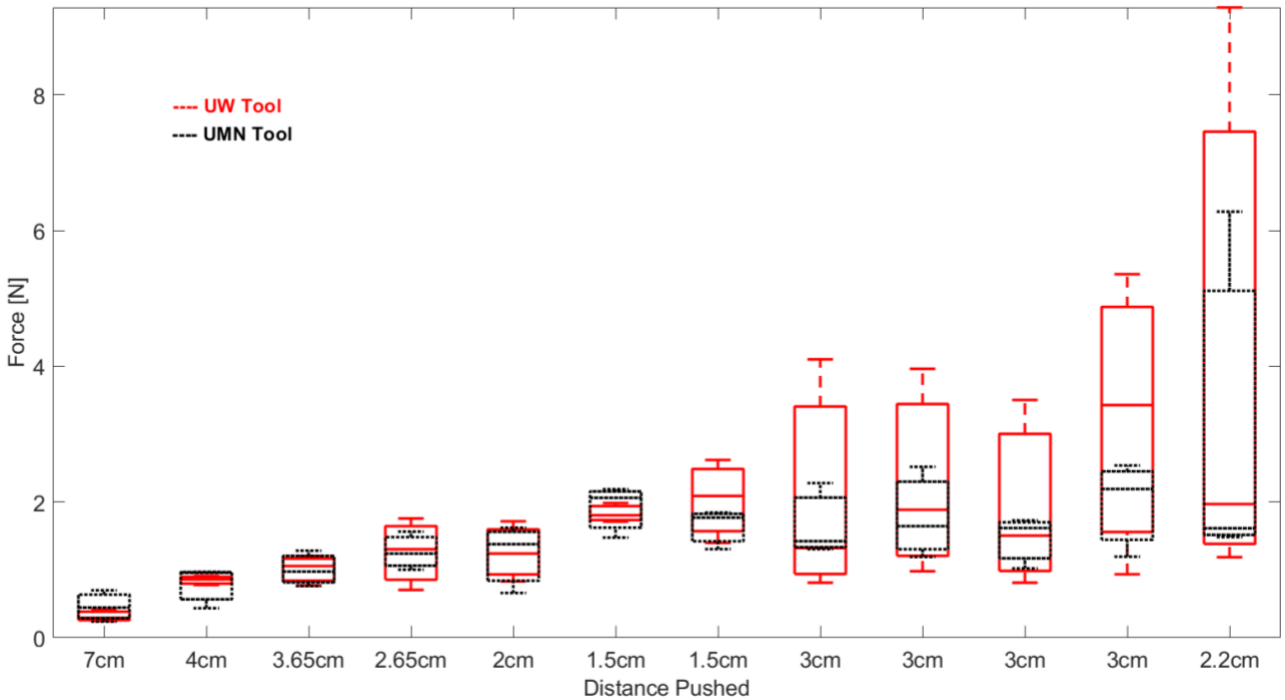


Figure 27: Catheter insertion force data from Life/Form Male Simulator.

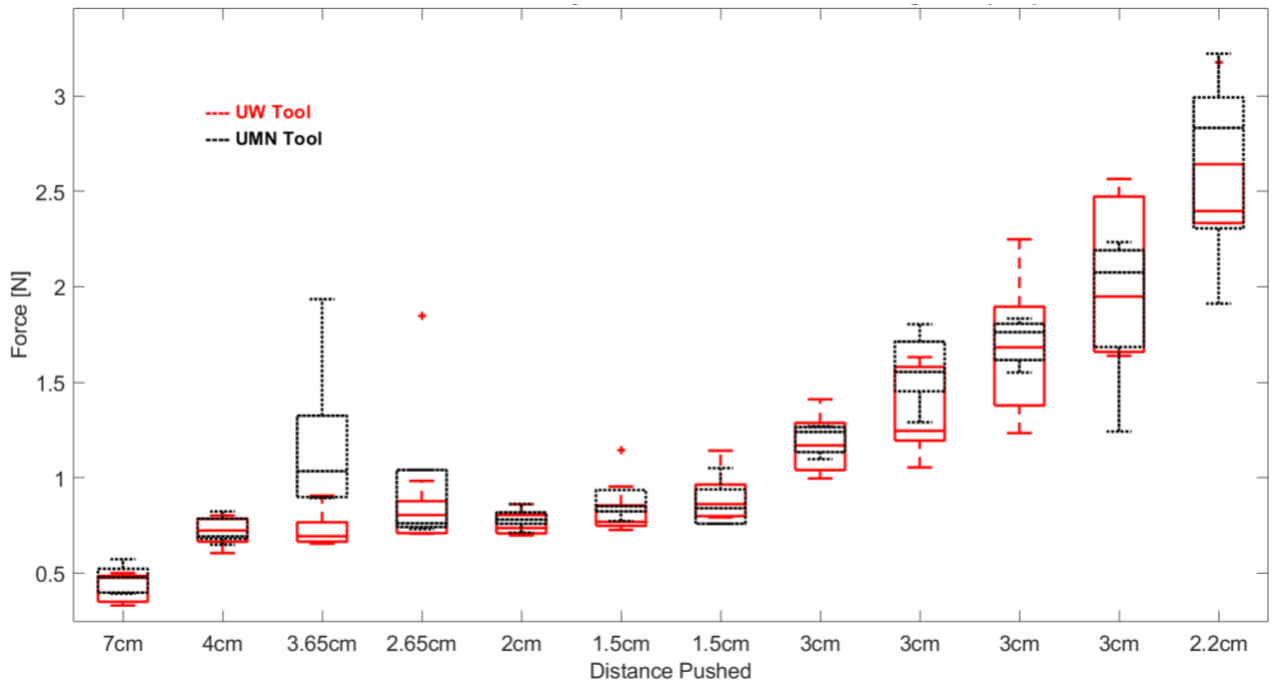


Figure 28: Catheter insertion force data from analog tube using.

3.3.3 *Statistics*

For the statistical comparison of the two devices, a two-sample t-test was performed to compare the average force of insertion per push between the two instruments. The results of this two-sample t-test are shown in Table 12. Additionally, results of a percent error calculation are listed in Table 13.

Null Hypothesis: The *UW Force Measurement Instrument* redesign yields equivalent mean force data results in the same experimental setup as original UMN Force Measurement Instrument.

3.3.4 *Discussion*

Statistical analysis was not performed on the Life/Form Male study due to the spread of resultant forces from the study which led to a follow-up verification study using the analog tube.

The two-sample T-test resulted in a failure to reject the null hypothesis at a 95% confidence level for all depths in the study. The most significant differences were noted between the 3rd, 4th and 9th distances in Table 13. The percent error ranges from 16% to 61%. This range of error was attributed to normal human user error. Most insertions from this study yield low % error and these significant errors moving forward. Thus, these results suggest that there is no significant difference between the two designs of the insertion instrument. The UW Cadaveric Study will use the re-designed *Force Measurement Instrument* for the human cadaveric and future live patient studies at the University of Washington.

Table 12: Results of Force Measurement Verification Study - two-sample t-test analog tube.

Distance [cm]	Null Hypothesis	P-Value	Confidence Interval 1	Confidence Interval 2	T-Stats	Degree of Freedom
7	0	0.4250	-0.0716	0.1537	0.8406	4
4	0	0.8865	-0.1020	0.1159	0.1473	4
3.65	0	0.0549	-0.0121	0.9090	2.2455	4
2.65	0	0.4915	-0.3569	0.6816	0.7210	4
2	0	0.4815	-0.0600	0.1165	0.7382	4
1.5	0	0.2715	-0.0854	0.2646	1.1811	4
1.5	0	0.6585	-0.2315	0.1547	-0.4589	4
3	0	0.7392	-0.1586	0.2144	0.3447	4
3	0	0.1508	-0.0996	0.5406	1.5886	4
3	0	0.8195	-0.3740	0.4592	0.2358	4
3	0	0.6117	-0.7503	0.4707	-0.5281	4
2.2	0	0.6701	-0.5167	0.7619	0.4422	4

Table 13: Results of Force Measurement Verification Study - percent error test.

Distance [cm]	UW Mean Force (N)	UMN Mean Force (N)	% Error
7	0.429	0.470	**9.576**
4	0.719	0.726	**0.968**
3.65	0.729	1.177	**61.559**
2.65	0.809	0.972	**20.059**
2	0.758	0.787	**3.723**
1.5	0.805	0.895	**11.130**
1.5	0.900	0.862	**4.267**
3	1.175	1.203	**2.372**
3	1.347	1.567	**16.367**
3	1.674	1.716	**2.545**
3	2.052	1.912	**6.813**
2.2	2.541	2.664	**4.823**

3.4 University of Minnesota – IRB Live Human Study

The University of Minnesota recently received IRB approval for a live human insertion studies using their Force Assessment Tool. They received a recommendation that they should redesign the tool to look less intimidating to patients. The redesigned *Force Measurement Instrument* with the inclusion of the trakSTAR sensor fitted tongs was sent to UMN on 12/13/19. They will be using the trakSTAR for depth of insertion tracking. They are not allowed to use the original computer vision method as this is a violation of privacy to the study subjects. The SolidWorks renderings of the trakSTAR sensor fitted tongs is in **Appendix G.**

3.5 UW Cadaver Study

Below, the University of Washington's Cadaveric Study is discussed. This section includes the assumptions made, explanations of the catheter marking methods, study protocols for male/female donors, data analysis methods, results, and limitations of the study.

3.5.1 *Assumptions for UW Cadaver Study*

The human UW cadaveric catheter force insertion study has its limitations. Although the donors are all unfixed and attended to as soon after death as possible, uncertainty remains regarding differences in tissue characteristics that may influence the forces collected during this study. Table 14 lists the assumptions made when collecting data in the UW Cadaveric Study.

Table 14: Assumptions for UW Cadaveric Study catheter force insertion study.

#	Assumption Description
1	For male studies, the prostatic urethra is 4.5 cm [29]
2	For female studies, the full length of the urethra is 4 cm[30]
3	During male studies we will fully insert the catheter to the hub (inserted full length of the catheter) + expect to see urine return to confirm placement in the bladder
4	During female studies we will only place the catheter to 8 cm using a pre-marked catheter
5	The research physician is always inserting the catheter with the catheter perpendicular to the Force Measurement Instrument to ensure all the force is being collected by the two load cells
6	When the catheter buckles the force read by the load cells is inaccurate and a shorter distance will be gripped to continue pushing forward. There may be two summations of a push that make up a specific distance after the first insertion for males.

The results of a literature review for the published lengths of the male urethra and the anatomic parts that comprise it are listed in Table 15. When analyzing the male insertion data, the data will be binned into three anatomic segments: anterior (comprised of: penile, bulbar, and membranous), prostatic, and bladder neck (Fig 29). The binning methods are described in the UW Cadaver Study

data analysis section 3.5.7. 4.5 cm was used as the prostatic length to aid with data separation into anatomic regions and to better represent the length of an elderly male prostate.

Table 15: Literature review of male urethra lengths.

Anatomic Segment of Male Urethra	Literature Values (cm)	Reference Values (cm)
Penile + Bulbar	10-15 cm[30]	-
Membranous	1 cm[30] 2 cm [33] 1-1.5 cm [34]	2 cm
Prostatic	4.53-3.53cm [29] 3-4 cm [30,32] 3 cm [35] 2.5 cm [36] 2.4 cm [37]	4.5 cm [29]
Total Urethra Length	22.3 +/- 2.4 cm [24] 15-20 cm [30] 20 cm [32,35] 15-25 cm [36] 17.55 +/- 1.42 cm[38] 17.5 – 20 cm [39]	22.3 cm [24]

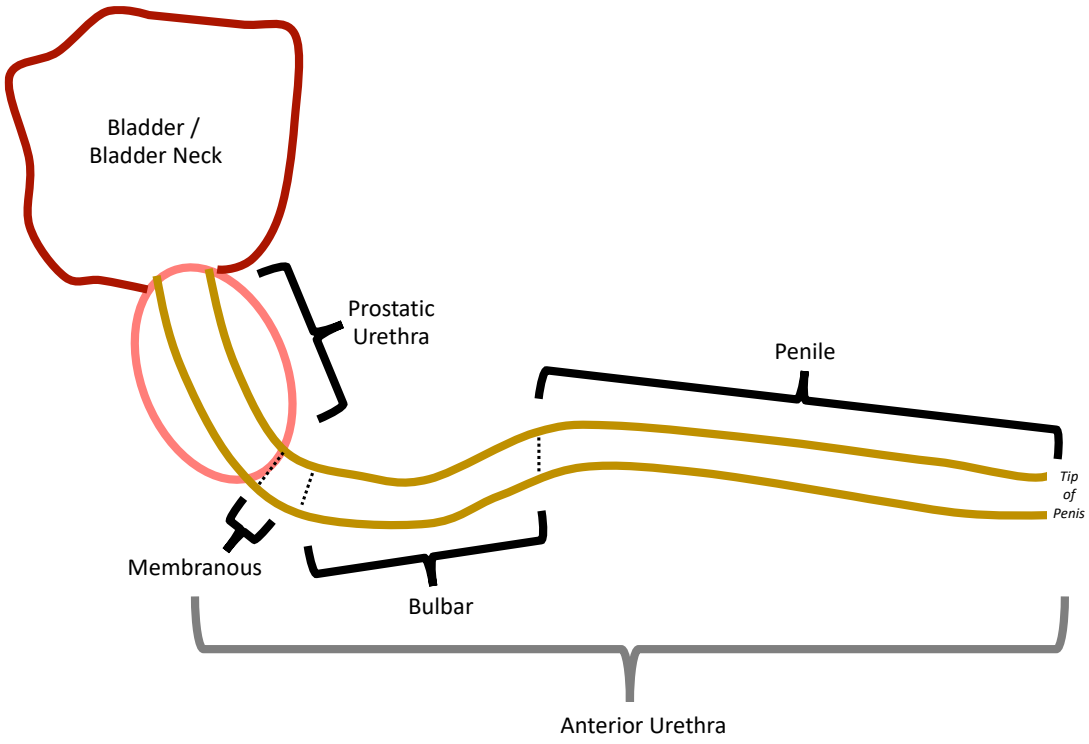


Figure 29: Male urethra anatomic segmentation into anterior urethra, prostatic urethra, and bladder neck regions.

3.5.2 *UW Willed Body*

Cadaveric data collection would have not been possible without the help and collaboration with UW Willed Body program. Dr. John Clark, Jason Sturm, and Mark Hendricksen were key resources during the active months of the cadaveric study.

The mission and purpose at the UW Willed Body program:

> The University of Washington's Willed Body Program is a whole-body donation program for donors from Washington State. The gift of your body to the UW School of Medicine is an invaluable contribution to the education of future healthcare providers, enabling them to study and understand the complexity of the human body in a way that is not possible by any other means.
>
> In addition to helping students in the health professions master complex anatomy, your donation will allow medical researchers to develop and maximize important tools to help patients. The University of Washington is one of the foremost medical research institutions in the world, conducting studies that will not only further develop the body of knowledge within the field of medicine, but eventually alleviate human suffering.
>
> We are deeply grateful for your consideration of this extraordinary gift. Donating your body is a significant decision, and we understand there are complex questions that arise when considering it. We have prepared a letter that answers many of the questions potential donors have asked us over the years, and also includes legal and medical reasons that a donation may be declined. In order to fully benefit from the exceptional gift you are providing, it is important that you, your family and the University of Washington have a mutual understanding and agreement about the donor process. This letter is prepared in the spirit of promoting this understanding. [40]

3.5.3 *Measure-as-you-go vs Premeasured Catheter Study*

The results from the preliminary distance verification study (section 3.2.8) suggest that the trakSTAR system introduced an unfavorable amount of error. An evaluation was performed to determine how to effectively measure the distance of catheter placed with minimal error in the UW Cadaveric Study. Two options were tested and analyzed to find the most appropriate method for the study. The first option was a measure/mark-as-you-go method and the other was to use a premeasured/marked catheter.

One concern considered when deciding between the two methods for distance tracking was the introduction of an unnatural insertion. The premeasured method introduces unnatural stops and starts during insertion which may collect misleading data. Thus, the male insertion protocol will use the measure/mark-as-you-go method. The measure/mark-as-you-go method uses the first insertion attempt into each male donor as the set depth insertion pattern for all following insertion attempts on that donor. Each push is marked using a sharpie until the catheter hub is reached. This method introduces reproducibility between lubrication conditions in a single donor as the catheter

will travel the same depth at each push. For females, their urethra is significantly shorter than males. Thus, the premeasured method is adequate for female data collection and will allow for comparison across all female donors.

3.5.4 *Protocol/Methods – Males*

The methods of the UW Cadaver Study were modified from those of the UMN study. An additional research question is addressed regarding lubrication effects. This study required the research physician to insert the catheter into the male donor 10 separate times whilst following the same depth insertion pattern defined by the measure-as-you-go catheter marking method. The two studies performed are motivated by evaluating the effects of adding lubricant step-wise(Study A) or all at once(Study B).

3.5.4.1 Study A

Here, Study A is defined by 5 insertion attempts where 2mL of lubricant is inserted directly into the urethra from a premeasured 12mL slip tip syringe before each insertion trial. This procedure follows an assumption that lubrication added directly into the urethra is additive in consecutive trials. Thus, by trial 5, there is a total 10mL of lubricant added to the urethra (in 2mL increments). This study was designed to evaluate the trends in the force curve as more lubricant was introduced to the urethra.

3.5.4.1 Study B

Study B immediately follows the completion of Study A on the same male donor. Study B is defined by the assumption that lubrication is not additive. It is assumed that only the amount of lubrication added right before the insertion plays a major effect on the force curve collected. Exact volumes of 2, 4, 6, 8, and 10 mL of lubricant are added directly into the urethra over five trials, respectively. Study B looks to discern whether the lubricant added in Study A plays a major role in the forces collected in Study B. Additionally, Study B will be used as a baseline for comparison to Study A and analyzed to define an average force curve for male catheter insertion.

3.5.4.2 Protocol Male

The full outlined protocol can be read in **Appendix L.** Using a standard OR BARD 16Fr Uncoated Silicone Foley Catheter (PID: 165816), Study A is performed by conducting five trials of catheter insertions with increasing amounts of lubrication inserted into the urethra by 2mL until 10mL is reached. The five conditions are: 2mL, 2mL, 2mL, 2mL, and 2mL. This study assumes that each condition will be additive, thus by the conclusion of Study A Trial 5, a total of 10mL will have been inserted. Study B is then performed by conducting five trials of insertions with increasing amounts of lubrication inserted into the urethra with the five quantities of 2mL, 4mL, 6mL, 8mL, and 10mL(summing to a final total of 30mL of lubricant added during Study B).

The *Force Measurement Instrument* is used to collect the force data. The number of regrips is counted and a voice recording during each study is collected. Catheter depth data is collected using the measure-as-you-go method. The same catheter is used throughout the insertion trials for each specific donor. During the final insertion trial of Study B, the catheter balloon is filled, and the

catheter is pulled taut to the bladder neck. A sharpie mark is then made where the tip of the penis touches the most distal portion of catheter. This mark is denoted as the urethral length and is a critical data point for calculating the donor's urethral length. At the conclusion of the study, the catheter is bagged and measured in the CREST lab space before being disposed of as biohazard waste. The depth measurements are used during data analysis to accurately bin the anatomic segments(anterior/prostatic/bladder).

3.5.4.3 Notes Regarding Limitations of Studies and Methods Chosen

Some limitations of this data included using three different researchers to perform the insertion studies, the variability in the insertion methods between individuals, and failure to refill the bladder with "urine" after each insertion.

The choice to include three researchers to perform the studies was due to availability of some of the researchers. Two researchers included were practicing urologist that were not always available when the research team had access to new donors. This forced Alyssa to become involved in the data collection process as the insertion researcher. Prior to this, Alyssa was properly trained and educated using the CREST Urethral Catheter Simulator ensure her technique would be as close to the same as that of the others in the study. An additional limitation to using three insertion researchers is the variability in methodology when inserting the catheter. While all insertion researchers were instructed to avoid any contact with the tip of the penis, this did not always occur and tried to be noted when it did occur. For example, Donor 2 was noted to have come in contact with the insertion researchers hands.

Lastly, we used the indication of urine return through the catheter as a measure of a successful catheter placement into the bladder. The research team did not continue to "refill" the bladder with saline for subsequent trials thus cannot confirm that the following insertions yielded placement into the bladder and may have resulted in a false passage (a tear in the urethra).

3.5.5 *Protocol/Methods - Females*

The full outlined protocol can be read in the **Appendix M.** Using a standard OR BARD 16Fr Uncoated Silicone Foley Catheter (PID: 165816). One lubrication condition is used. The research physician will dip the tip of the catheter into about 5mL of lubricant prior to an initial insertion attempt. The *Force Measurement Instrument* will be used to collect the force data. The number of regrips is counted and a voice recording during the study is collected. Catheter depth data is collected using a premeasured catheter of 8cm total. The premeasured catheter (Fig. 30) is measured out to 140 mm total over three pushes 50 mm, 50 mm, 40 mm.

NOTE: Due to time constraints/COVID-19 the female data collection for catheter placement did not occur, thus we use Appendix M as a protocol guideline for future studies that include female donors.

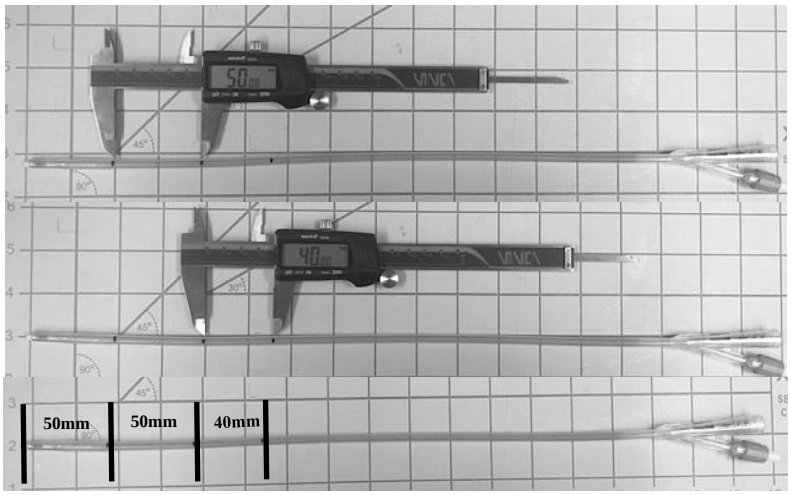


Figure 30: Pre-measured catheter standard to be used on all female donors.

3.5.6 *Hypothesis*

Catheter Force Placement (Males) Question: This is a repeat exploratory study to evaluate the forces of catheter placement into cadaveric donors. This study will look to replicate or show variation from the previously published UMN cadaveric study. The major differences between the two studies include the time between when the donor died, when the test was performed, the number of insertion trials performed on any one donor, and the stratified lubrication conditions.

Lubrication Hypothesis: If you increase the amount of lubrication inside the male urethra, then forces of catheter placement will decrease with each addition.

3.5.7 *Data Analysis Methods*

The UW Cadaveric study used their own MATLAB processing scripts for data analysis. The general data processing schematic is proposed in Figure 31. Each donor's data was separated into a Donor + Trial specific Analysis Sheet. Using the voice recording for each donor the correct peaks are identified for each of the respective pushes. The peak force is selected using the MATLAB figure window and is recorded for each push. The raw data sheets (Fig. 32) were printed to pick force peaks to represent each push. MATLAB uses the selected data from both studies and plots them separately (Fig. 33). This method was employed to identify the force required to overcome the frictional force required to move the catheter further in the urethra. This is confirmed by the sharp drop in force following each peaks. Two additional plots combine the data from both studies to one plot (Fig. 34a) and the averages of the two studies plotted together (Fig. 34b). An example of the standard depth recording table used during data analysis is shown in Table 17. This table includes the catheter depth inserted per push. The running total column is included to understand where the catheter tip is located in the urethra anatomy for each push. Lastly, the calculated urethral length value is a result of the anterior and prostatic push depths summed together and subtracted by the tip to balloon data point. Two final plots were created that show the force boxplots at the

three identified anatomic regions (Fig. 35). The anatomic splitting methods are thoroughly discussed using Donor 2 data as an example in Table 16.

Table 16: Methods to complete anatomic splitting process.

Step #	Description
1	Identify the push # where the "urethra length" measurement (**line 9a-Table 17**) was taken from the donor collection worksheet.
2	Sum the measured catheter measurements (**column a -Table 17**) up to and including the push number identified in step 1.
3	Add "urethra length" measurement (**line 9a-Table 16**) to the result of step 2.
4	Subtract the "balloon measurement" **(line 10a -Table 17)** from the result of step 3.
5	The resulting value is the measured urethral length of the donor (**line 9b-Table 17**)
6	An assumption was made to use a prostatic length of 4.5cm for anatomic region splitting.
7	Depth thresholds are created to split the # of measured pushes into anatomic regions. Subtract the prostatic length (4.5cm) from the measured urethral length of the donor (**line 9b-Table 17**).
8	The result of step 7 is the upper bound of penile urethra segment in length. The penile urethra pushes were assigned using the pushes depth that ranged from 0mm to the depth result of step 7. (Note: none of the pushes collected were partially binned into two anatomic regions, assume all regions are being binned correctly using this method)
9	The prostatic region pushes were binned using the pushes immediately following the anterior region. (**Note:** each prostatic urethra is assumed to be two pushes)
10	Finally, the bladder neck pushes are assumed to be any of the insertion pushes beyond the prostatic urethra to the final push when the catheter is hubbed.

****Note:** See the anatomic binning results for the example Donor 2 data in **column B - Table 17** in *italics***

Table 17: Donor Analysis Sheet: Measured Catheter Lengths for Donor 2.

Insertion #	Measured **[a]**	Running Total(mm) // *Anatomic Region Binned* **[b]**		
1	73.04	73.04	*anterior*	**[1]**
2	32.91	105.95	*anterior*	**[2]**
3	70.22	176.17	*anterior*	**[3]**
4	43.99	220.16	*prostatic*	**[4]**
Urethral Length Mark after ==> 5	34	254.16	*prostatic*	**[5]**
6	46.7	300.86	*bladder*	**[6]**
7	26.79	327.65	*bladder*	**[7]**
8	20.06	347.71	Total Catheter Placed /// *bladder*	**[8]**
Urethra Length (measured)	34	247.6 Calculated	24.7 cm long urethra tip to bladder	**[9]**
Measurement from tip to end balloon	40.56			**[10]**

3.5.7.1 Data Processing Schematic

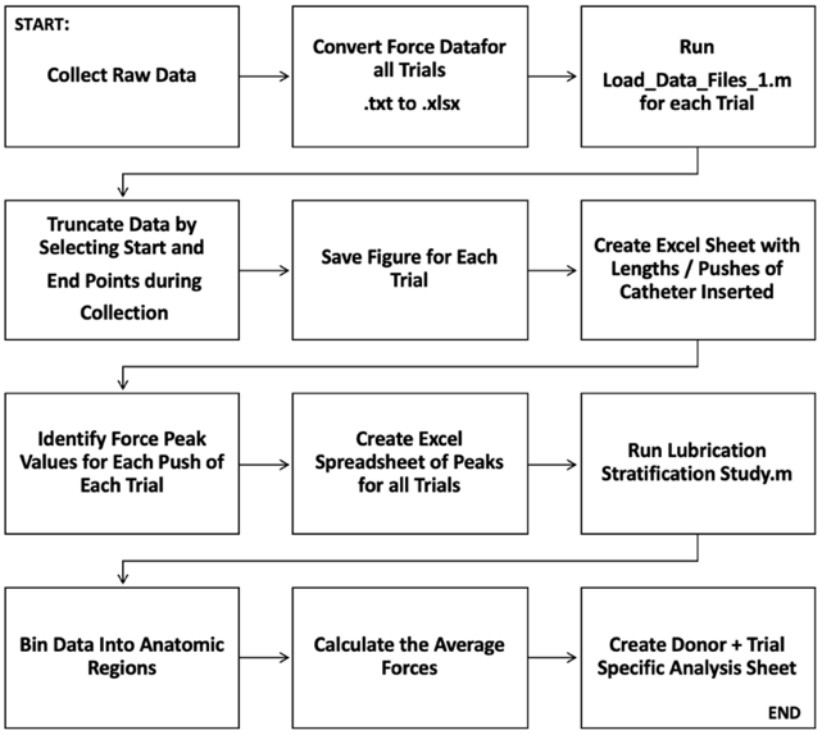


Figure 31: UW Cadaveric Study Data Analysis workflow schematic.

3.5.7.2 Example Donor + Trial Specific Analysis Sheet

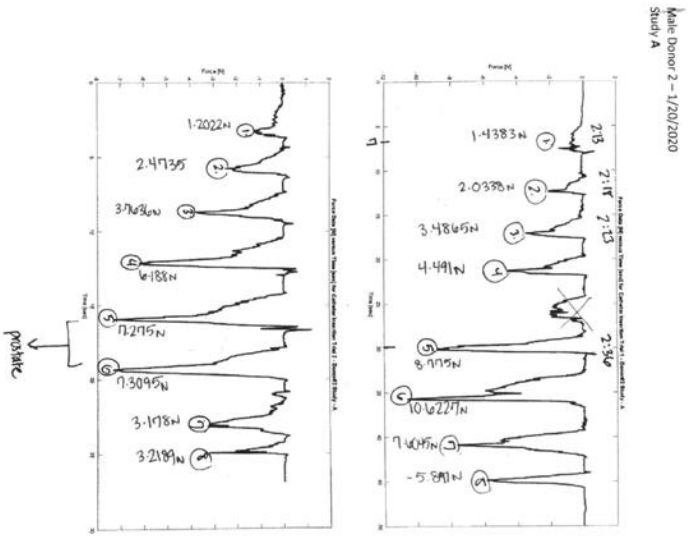


Figure 32: Donor Analysis Sheet: Page 1 – for Donor 2.

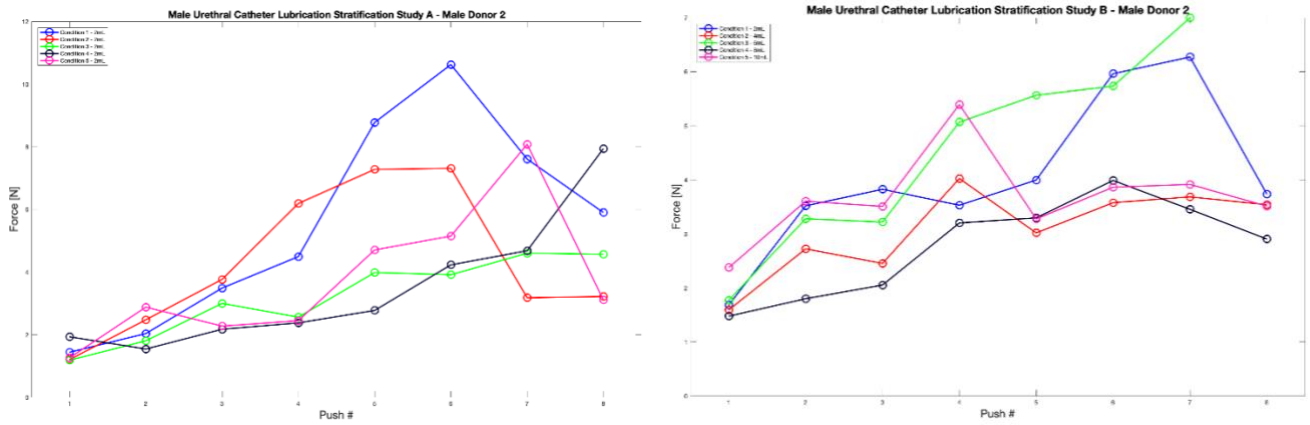


Figure 33: Donor Analysis Sheet: Page 2 – for Donor 2.

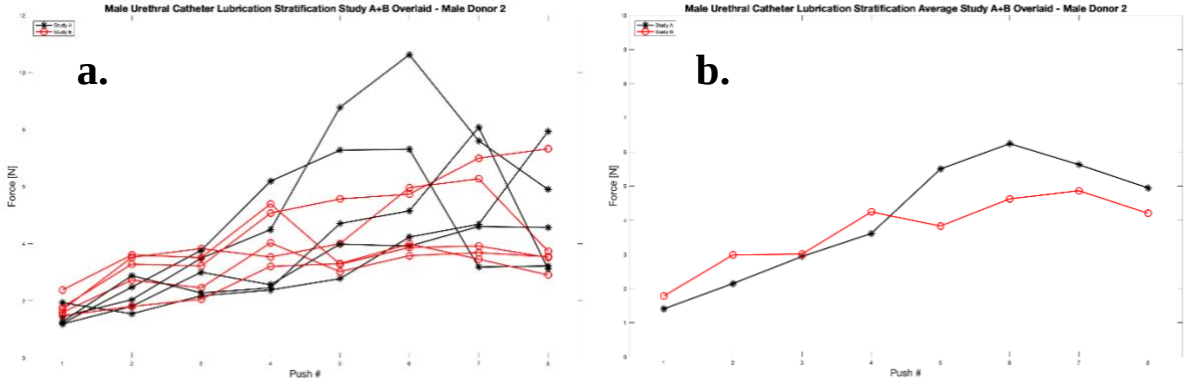


Figure 34: Donor Analysis Sheet: Page 3 – for Donor 2.

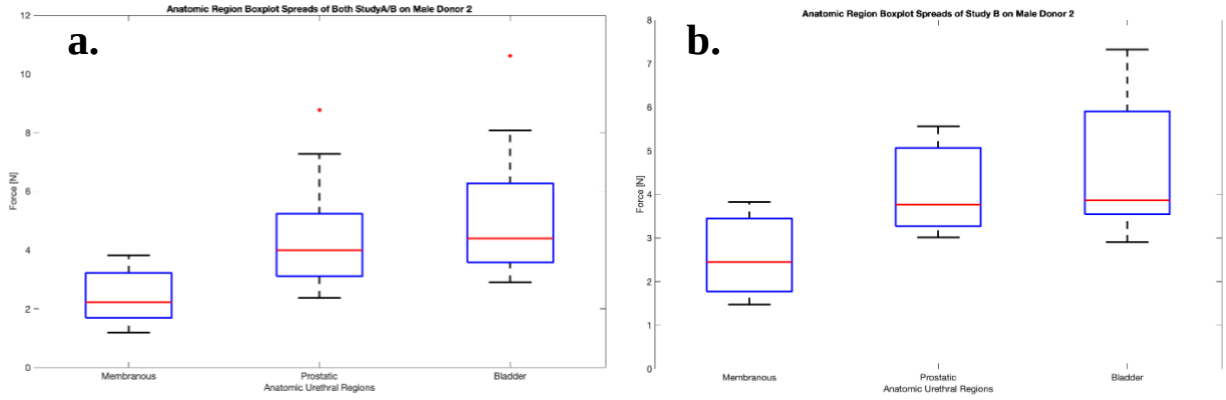


Figure 35: Donor Analysis Sheet: Page 4 – for Donor 2.

3.5.8 *Donor Collection Worksheet*

For ease and streamlined data collection, a standardized Donor Collection Worksheet is used for study. This document is in **Appendix N.** The document aids in analyzing data, organizing various donors, and collecting donor specific information.

3.5.9 *Donor Demographics*

Table 18 outlines the demographics for each donor included/excluded from the UW Cadaveric Study. The fields included: age, number of days postmortem, and a section for the calculated urethral length. Each donor listed below in Table 18 has their own data analysis section in **Appendix O.** This includes the data processing plots for each donor and initial analysis performed before combining the data together in addition to each of the Donor Collection Worksheets.

3.5.9.1 Male Donors

Table 18: UW Cadaveric Study Demographic Table.

Donor #	Age	# of Days Postmortem*	Urethral Length(cm)	Included in Study?
2	72	2	24.7	✓
3	96	2	16.2	✓
4	86	2	17.5	✓
5	89	1	16.8	
6	96	1	17.9	✓
7	71	1	-	
8	71	1	-	
9	79	1	16.4	✓
10	88	2	22.6	✓
Averages	83	1.4	18.9	

*Days between when the donor was declared deceased and when the test was performed

NOTE: Donor 1 is not included here as the Force Measurement Instrument changed between Donor 1 and Donor 2

3.5.10 *Inclusion/Exclusion Criteria for Analysis*

Due to the nature of the study and limited information regarding each donor, 4 of the 10 donors were excluded from the lubrication study results. Donors 7 and 8 were excluded due to the failure to properly insert the catheter successfully into the bladder and reaching the catheter hub. Proper measurements for urethral length were not collected and we thus could not include these donors for the lubrication stratification study results. Donor 1 was excluded because of an alteration in the *Force Measurement Instrument* that occurred after the data had been collected. Donor 5 was

excluded due to deviation from protocol. See Table 18 for indication of included donors in the lubrication stratification study.

3.5.11 *Limitations of the UW Cadaver Study*

The UW Cadaver study results were limited by a few factors. First, the population included in the study were all elderly. This does not allow for a clear connection to a younger male anatomy or behaviors. Second, due to the requirement of keeping the bodies from decaying prior to embalming, the donors were not at physiological temperatures when tested. Finally, a small sample size may misrepresent the true force curve seen in a larger group of male donors.

3.5.12 *Results*

Two plots report the compiled data collected for all included male donors in Study A (Fig. 36) and Study B (Fig. 37). These plots distinguish different donors by marker shape (i.e. circle for Donor 2) and stratify the trial attempt by color (Trial 1 – is Pink, Trial 2 – Forest Green, Trial 3 – Blue, Trial 4 – Light Green, and Trial 5 – Purple). The x-axis represents the running total depth inserted. A boxplot used to separate the average forces per anatomic region is included in **Appendix P.**

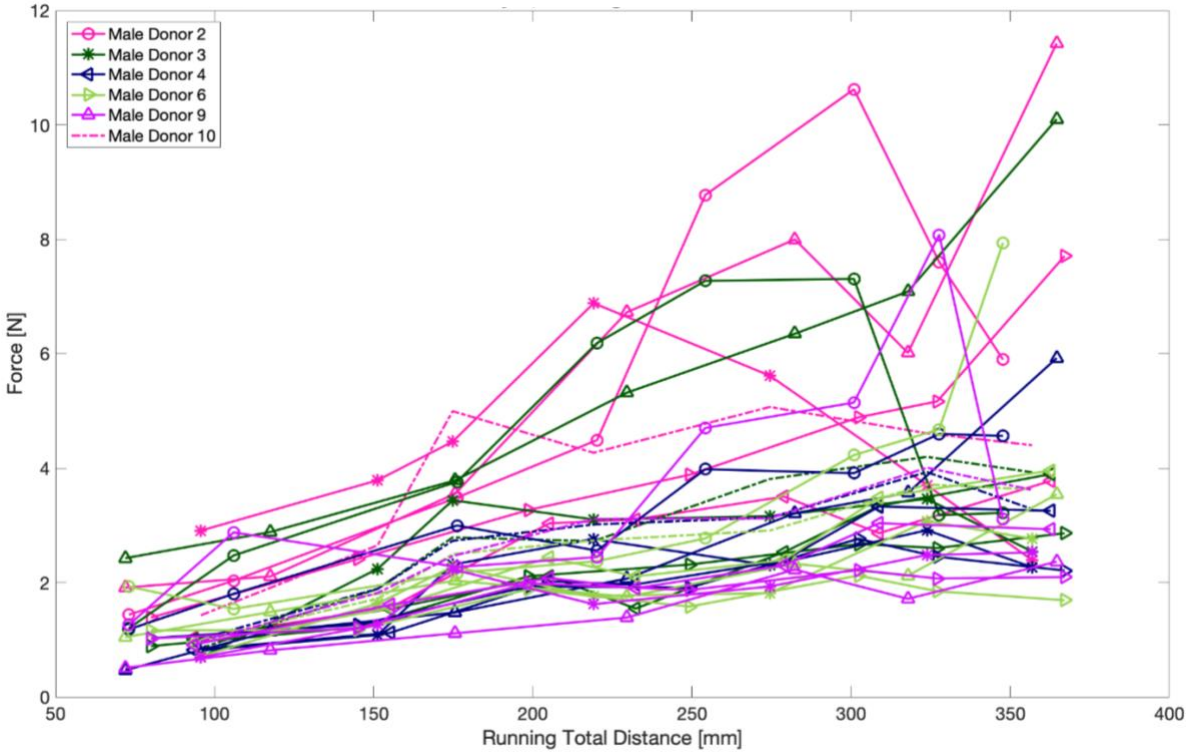


Figure 36: UW Cadaver Study – Lubrication Stratification Plot: Study A

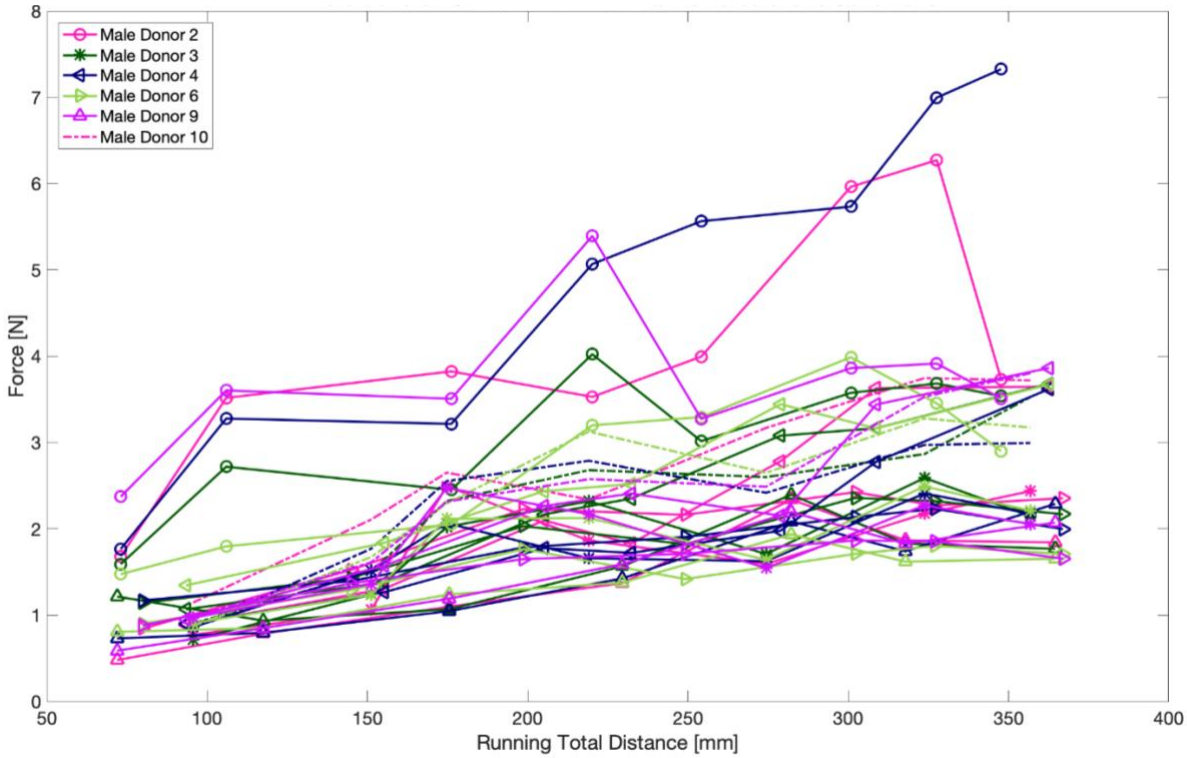


Figure 37: UW Cadaver Study – Lubrication Stratification Plot: Study B

3.5.12.1 Study A – Assumption: Lubrication is Additive

The raw data results of Study A were sub-plotted for each of the 6 donors (Fig. 38). The y-axis was standardized to 11N (except for Donor 9) to enable ease of comparisons between donors. These plots suggested a large variation in force results in-between all donors. Specifically, Donor 2 data revealed large variation in force readouts over the five conditions in Study A whereas, Donor 4 revealed a consistent force trend between lubrication conditions. The remaining Donors (Donor 3, 6, 9, and 10) presented a stratified force result between the different lubrication conditions.

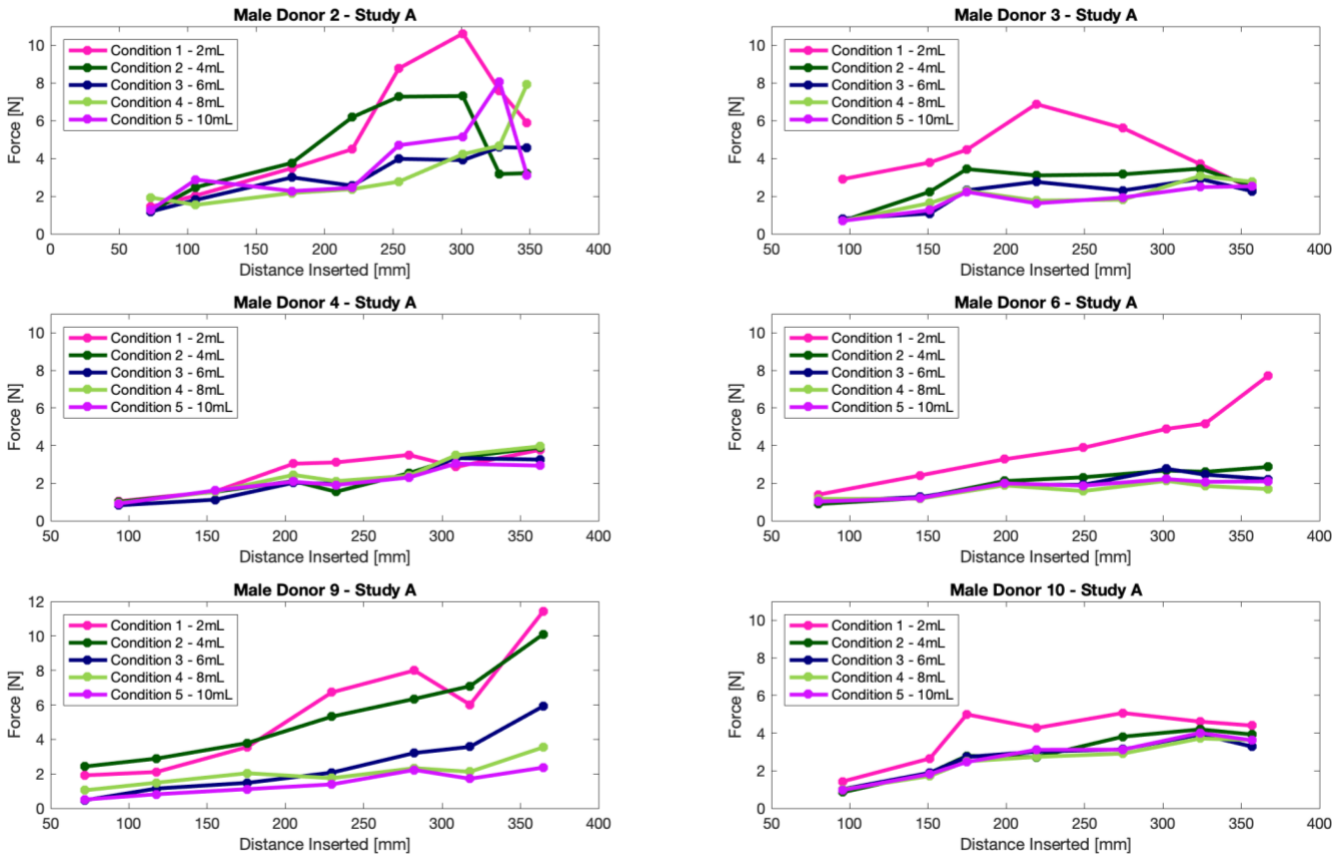


Figure 38: UW Cadaver Study – Lubrication Stratification – Separated by Donor: Study A.

3.5.12.2 Study B – Assumption: Lubrication is NOT Additive

The raw data results of Study B were sub-plotted for each of the 6 donors (Fig. 39). The y-axis was standardized to 5N (except for Donor 2) to enable comparisons between donors. Visually, the general trend across donors suggests minimal variation between lubrication conditions in Study B.

The average force curve for each donor using the Study B data was plotted in Figure 40. This plot was created to define the baseline force curve for each donor using the data collected during Study B. Each donor was plotted using a different color and named in the legend. There was a clear separation between Donor 2 average force curves and the remaining donors.

A linear model was fit to the average insertion curves of all donors and plotted in black in Figure 41. This model was created based on the proposed average force of insertion curves vs catheter depth inserted (N=6). The slope and y-intercept of this linear model are defined in Table 19. This linear model suggests a positive slope that correlates to requiring more force to push the catheter deeper into the urethra.

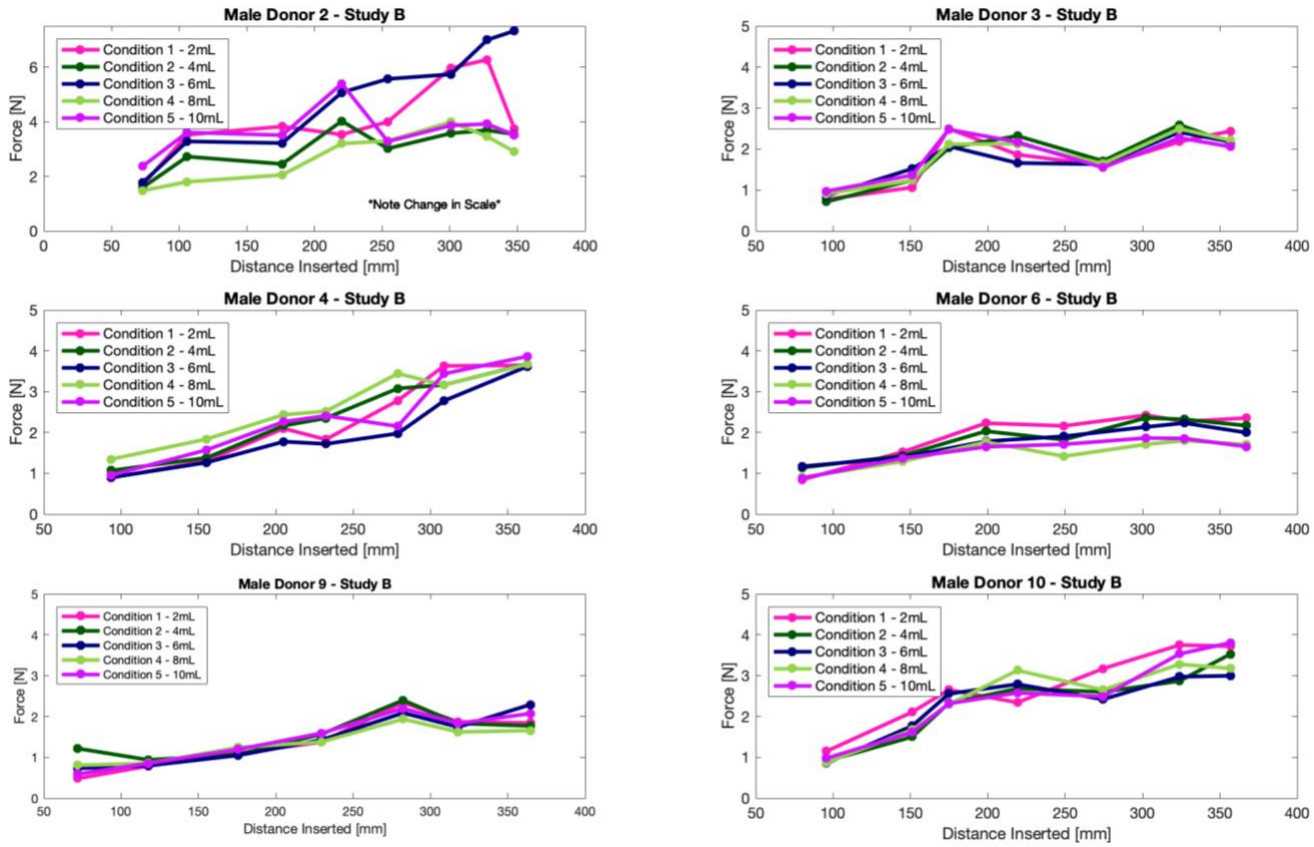


Figure 39: UW Cadaver Study – Lubrication Stratification – Separated by Donor: Study B

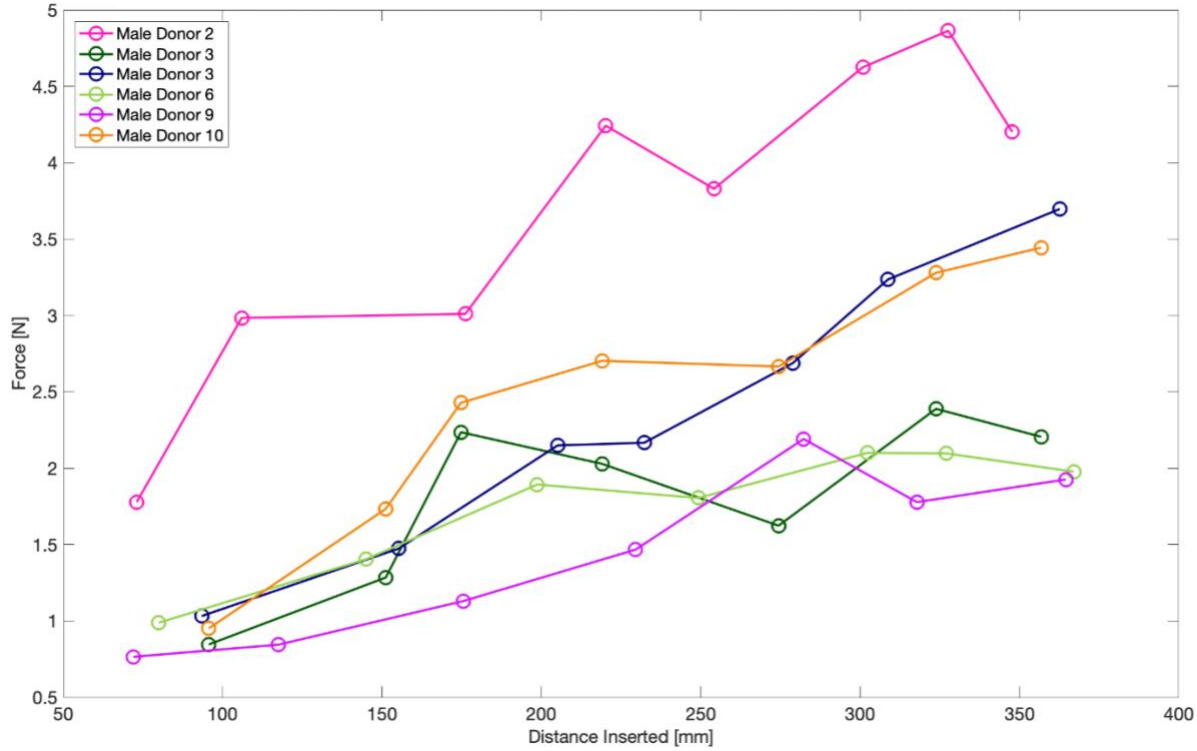


Figure 40: Study B Average force of insertion curves stratified by donor.

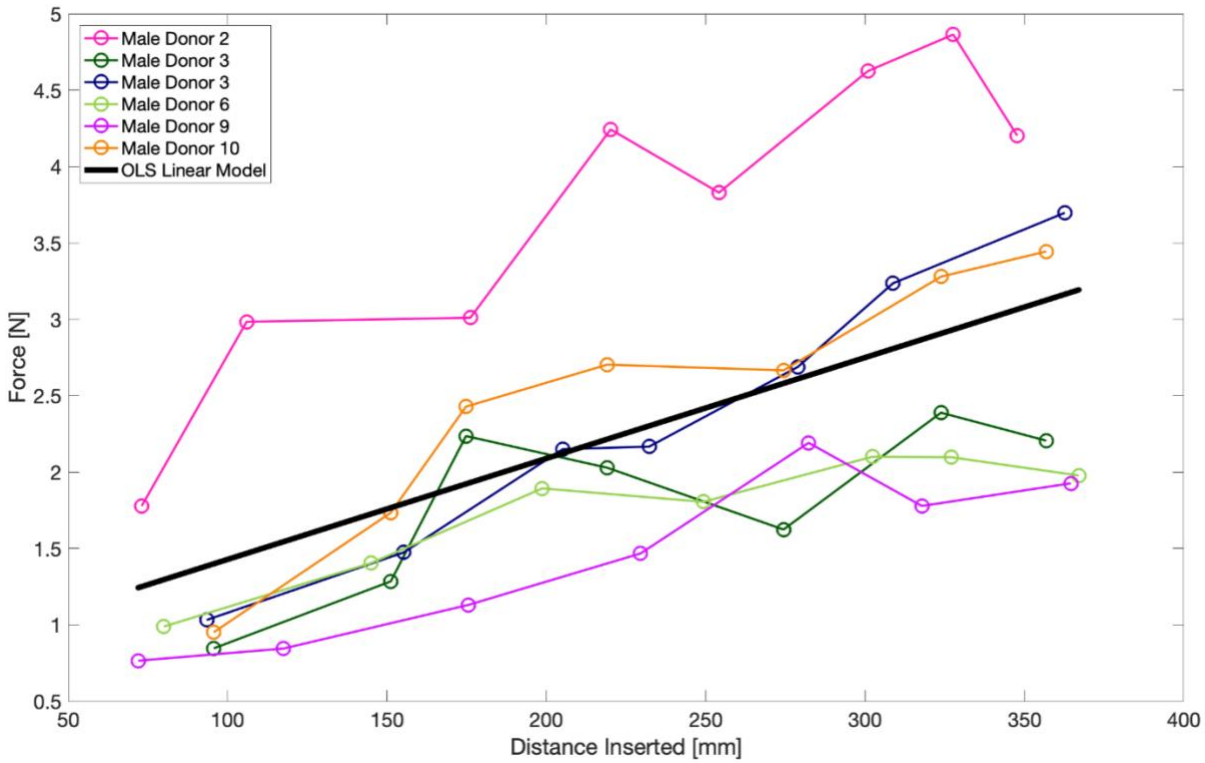


Figure 41: Fitted linear model of Study B Average Force of Insertion Curve.

Table 19: Study B Average Force of Insertion Curve Linear Model Fit Parameters

Linear Model Characteristics	Value	p-value
Intercept	0.76711	2.75E-05
Slope	0.0066	5.46E-17
R^2	0.2778	-
F-Stat	83.3	5.46E-17
Equation: Y = 0.767 + 0.0066X		

Chapter 4. DATA ANALYSIS RESULTS

4.1 LUBRICATION STRATIFICATION STUDY ANALYSIS

4.1.1 *All Male Donor Compared to Hyper-Lubrication Condition*

Study A was analyzed to look at the effects of lubrication on the forces of insertion. Trial 2 of Study B was used as the control or the hyper-lubricated condition for data analysis. The results of Study A were compared to the hyper-lubricated condition (black line) in Figure 42. This plot displayed a clear separation between the lubrication conditions, particularly when the hyper-lubricated condition is compared to Trial 1 data across all donors.

I consulted with practicing urologists to discern the practicality of the hyper-lubrication condition. These individuals shared that it is not uncommon when placing "difficult" urinary catheters to insert upwards of 10mL of lubricant directly into the urethra. The urologists also shared the process by which a standard catheter placement becomes a "difficult" placement. Once a nurse fails to place the catheter after one or two attempts, they call to the urology service to obtain a urology consult in attempt to place the urinary catheter.

The motivation behind the analysis of Study A was to observe how much the force decreases with the step-wise addition of 2mL of lubrication over 5 insertion trials. Ultimately, the goal was to determine at what point the force difference between the hyper-lubricated and each trial condition is no longer significantly different.

4.1.2 *All Male Donor Separated by Anatomic Region*

Study A data was further analyzed using the anatomic splitting methods (see section 3.5.7 or Table 16) to define the forces within each anatomic region (penile, prostatic, and bladder/bladder neck). Each donor's Study A data was binned into anatomic regions and the forces averaged per lubrication condition. These binned regions were separated by lubrication condition and plotted in Figure 43. Previously, the x-axis was the depth inserted, but each donor did not follow the same depth of insertion pattern. By binning the data into anatomic regions, there is now a common unit by which direct force comparison can be performed between donors. Figure 43 suggests similar findings to Figure 42 regarding a distinct separation between the various lubrication conditions.

The binned anatomic regions enabled donor-specific (Fig. 44) and average all donor (Fig. 45) lubrication condition vs force comparisons. All anatomic regions were signified by a color code in the legend and the three binned points were stacked vertically to indicate similar lubrication condition groupings. Across the six donors, the force of insertion decreases as more lubricant is added (Fig. 44).

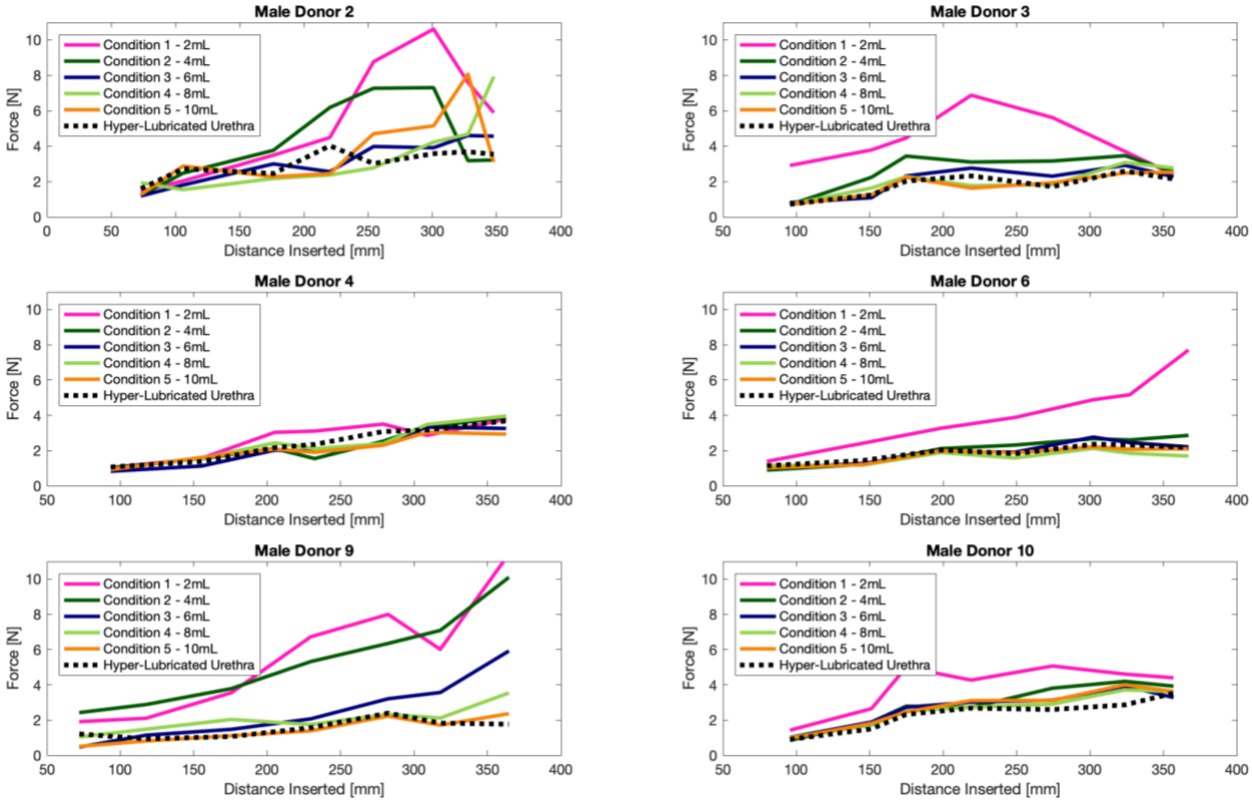


Figure 42: UW Cadaveric Study A – Lubrication Stratification + Hyper-Lubricated Condition.

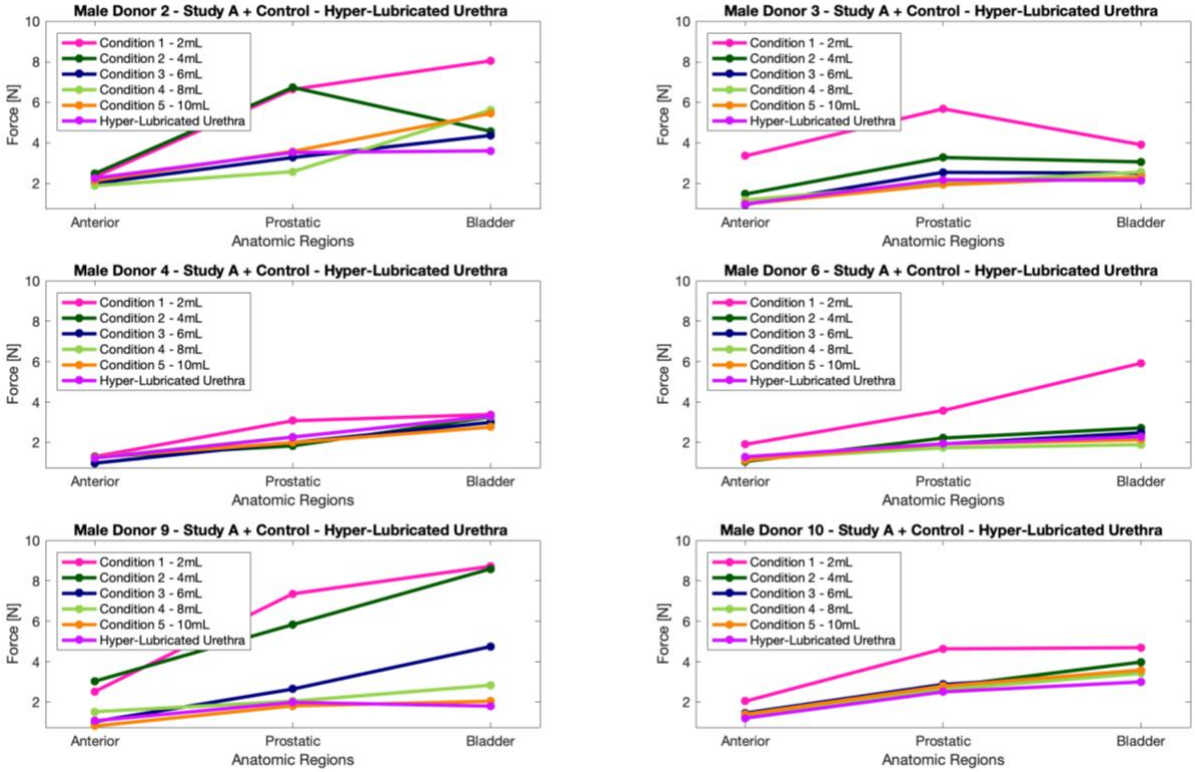


Figure 43: UW Cadaveric Study A – Anatomic Region Split over Lubrication Stratification + Hyper-Lubricated Condition.

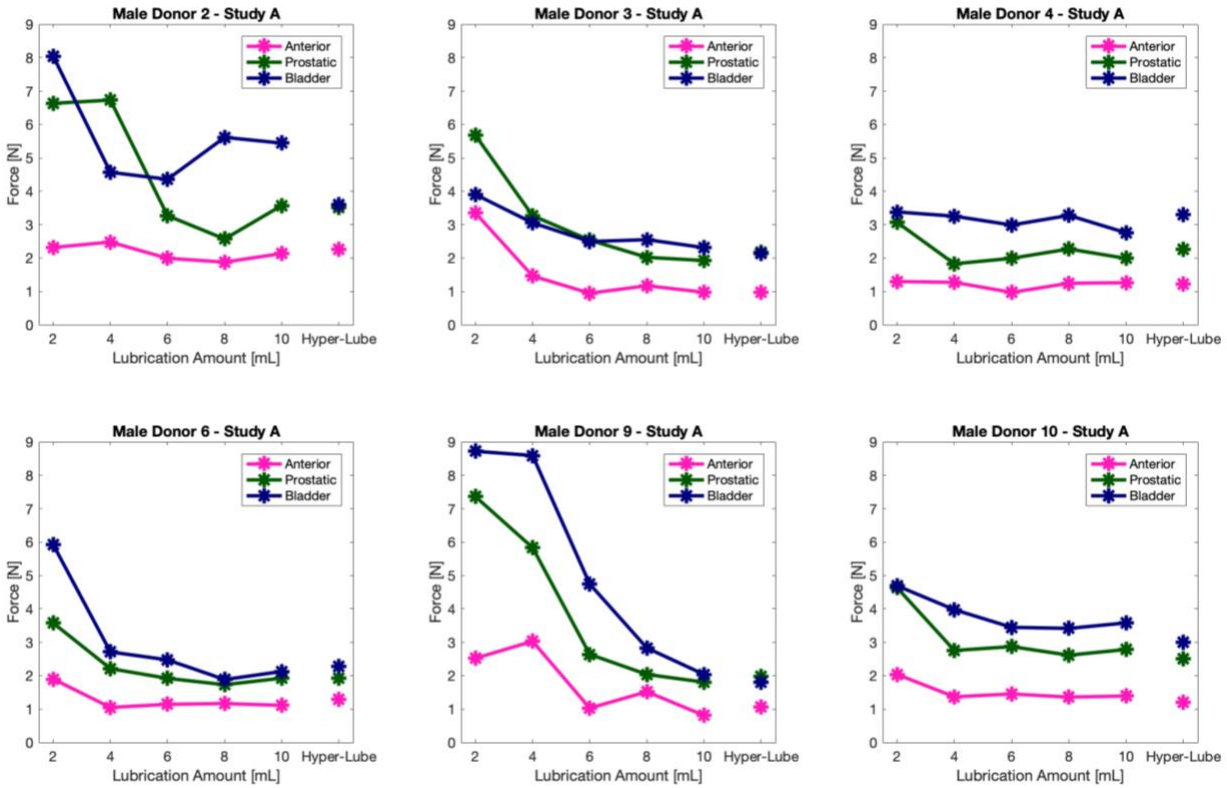


Figure 44: UW Cadaveric Study A Force vs Lubrication Amount – Stratified by Anatomic Region + Hyper-Lubricated Condition.

4.1.3 *Proposed Force Curve per Anatomic Region vs Lubrication Condition*

The individual donor plots were combined to create an averaged force of insertion curve for each anatomic region over the 5 lubrication conditions (Fig. 45). This plot suggested the force collected in the 2mL lubrication condition is greater than all other lubrication conditions.

Table 20 reports the numeric binned force data and the results of a two-sample t-test for each lubrication condition tested against the hyper-lubricated condition. Each lubrication condition was averaged across the six donors for each of the three anatomical regions. Each average was compared to the hyper-lubricated condition. Only groups within the same anatomic regions were compared to one another. The results suggest the only group significantly different from the hyper-lubricated condition was all anatomic regions within Condition 1 – 2mL.

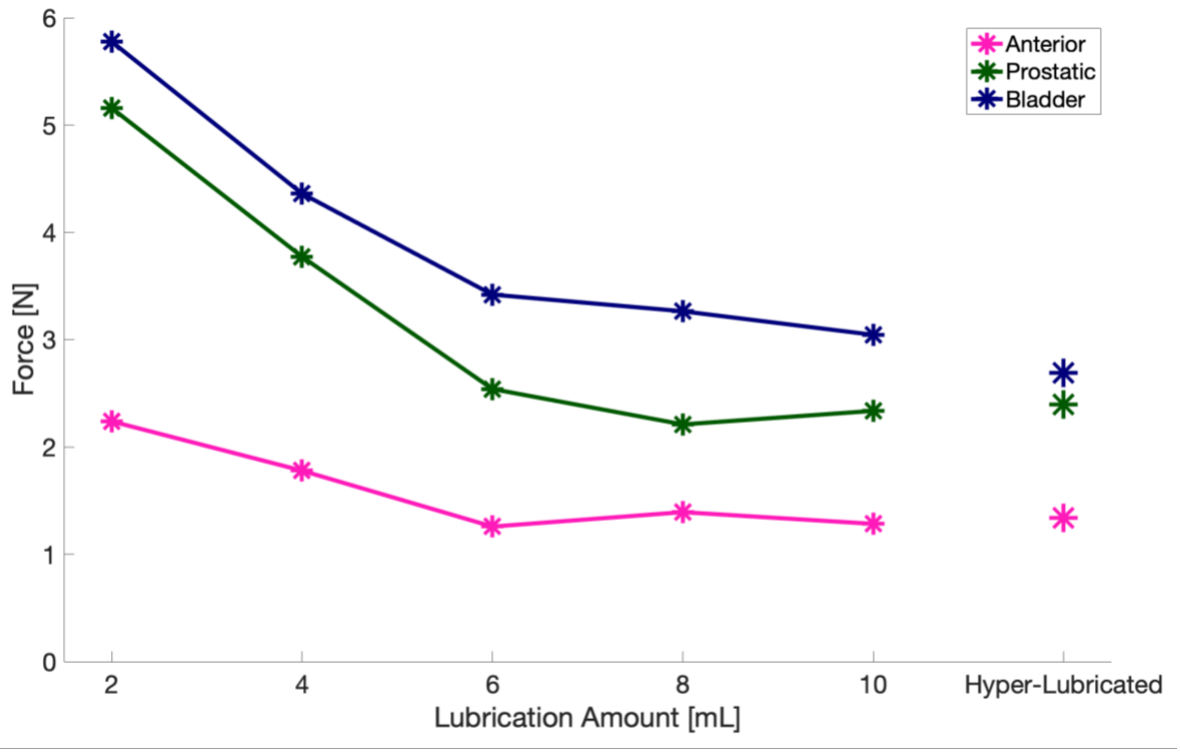


Figure 45: UW Cadaveric Study A All Donor (N=6) Results of Force vs Lubrication Condition

Table 20: Lubrication Stratification Study Analyzed Data + Statistical Results

Lubrication Condition:	Donor # 2	3	4	6	9	10	Average Force [N]	P-Value
2mL	*Average Force [N]*							
Anterior	2.32	3.35	1.30	1.90	2.52	2.04	2.24	0.024
Prostatic	6.63	5.67	3.07	3.58	7.36	4.63	5.16	0.004
Bladder Neck	8.04	3.90	3.38	5.92	8.72	4.69	5.78	0.009
4mL								
Anterior	2.48	1.46	1.27	1.05	3.03	1.37	1.78	0.264
Prostatic	6.73	3.27	1.83	2.21	5.84	2.76	3.77	0.140
Bladder Neck	4.57	3.05	3.26	2.71	8.59	3.98	4.36	0.105
6mL								
Anterior	1.99	0.95	0.97	1.15	1.03	1.46	1.26	0.760
Prostatic	3.27	2.54	1.99	1.92	2.64	2.87	2.54	0.658
Bladder Neck	4.36	2.50	2.99	2.48	4.75	3.45	3.42	0.165
8mL								
Anterior	1.88	1.17	1.25	1.17	1.52	1.36	1.39	0.806
Prostatic	2.57	2.02	2.27	1.73	2.04	2.62	2.21	0.523
Bladder Neck	5.62	2.55	3.28	1.89	2.83	3.42	3.26	0.359
10mL								
Anterior	2.14	0.98	1.26	1.11	0.81	1.40	1.28	0.846
Prostatic	3.57	1.93	1.99	1.93	1.81	2.79	2.34	0.880
Bladder Neck	5.44	2.31	2.76	2.13	2.04	3.58	3.04	0.572
Hyper-Lubricated								
Anterior	2.25	0.98	1.22	1.29	1.07	1.20	1.34	
Prostatic	3.52	2.17	2.26	1.93	1.98	2.50	2.39	
Bladder Neck	3.60	2.15	3.31	2.28	1.80	3.00	2.69	

4.1.4 *Linear Model for the Lubrication Stratification Force Curve*

Two linear models were fit to the data in Figure 44. Fit 1 (Fig. 46) excluded the hyper-lubrication condition, whereas Fit 2 (Fig. 47) included the hyper-lubrication condition. The slope and y-intercept (with their respective p-values) for the two fits for each anatomic region are listed in Table 21. The adjusted R^2 were included as a measure of statistical fitness.

Limited by a small sample size, the two linear models yield ill-fitting curves. In Fit 1, the lines of the prostatic and bladder neck regions cross the x-axis (0N) at 14-16mL of lubricant which would never be observed in clinical practice. This result suggested that the inclusion of the hyper-lubricated condition, in Fit 2, is a better model to follow.

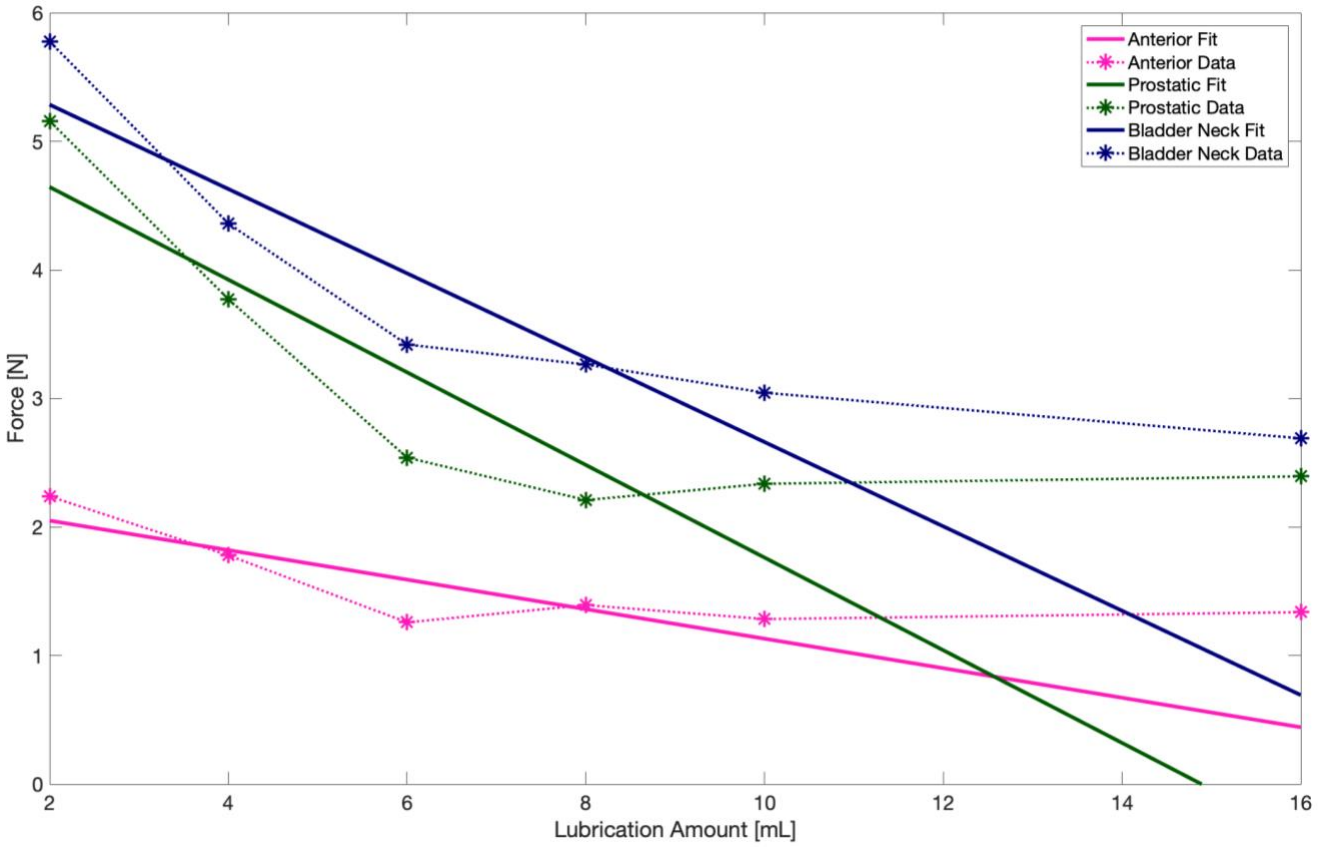


Figure 46: Lubrication Stratification Study : Fit 1.

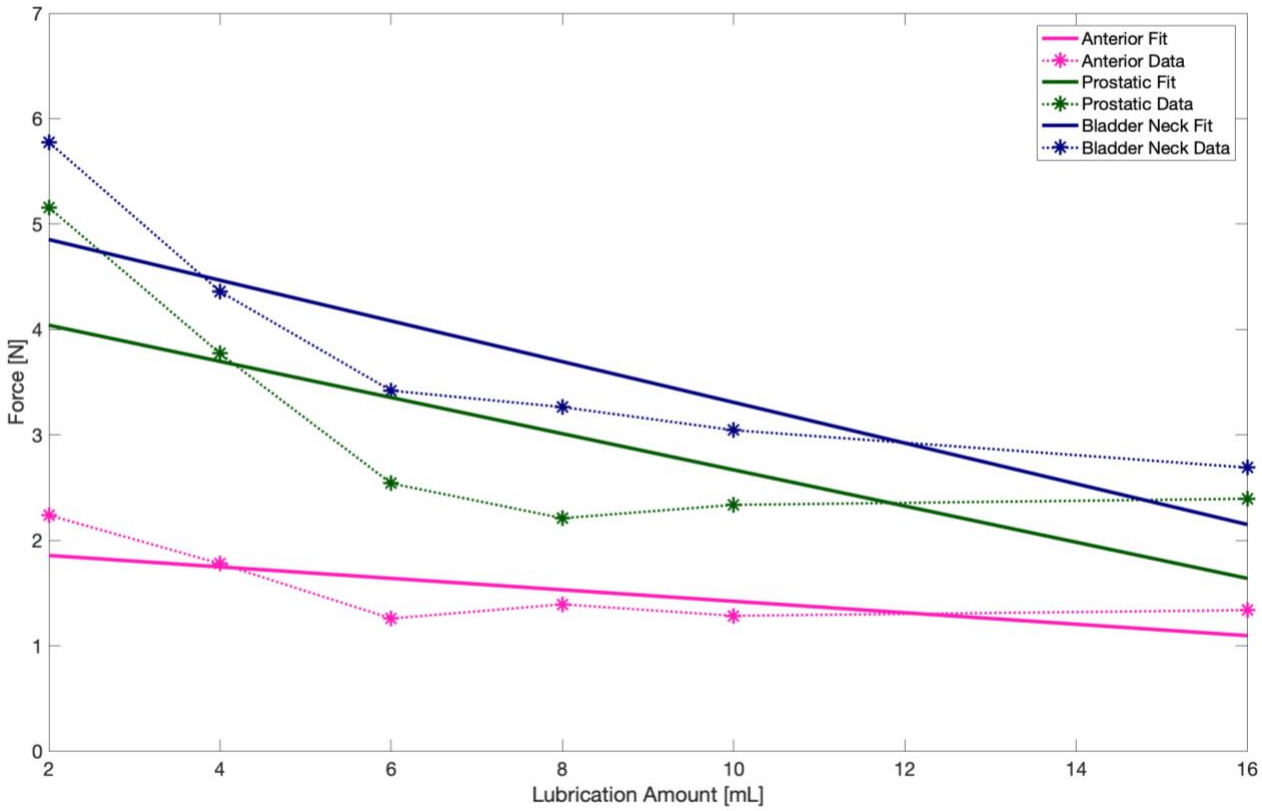


Figure 47: Lubrication Stratification Study : Fit 2.

Table 21: Linear Model Fits 1 and 2 Characteristic of Lubrication Stratification Study A

Linear Model Characteristic	Intercept	p-value	Slope	p-value
Fit 1- w/o Hyper-Lubrication Condition				
anterior	2.28	2.91E-10	-0.115	3.61E-03
prostate	5.37	1.63E-10	-0.360	1.63E-04
bladder	5.94	2.74E-09	-0.328	4.06E-03
Fit 2- w/ Hyper-Lubrication Condition				
anterior	1.96	3.48E-12	-0.054	1.43E-02
prostate	4.38	1.06E-11	-0.172	1.33E-03
bladder	5.24	6.15E-12	-0.193	1.91E-03

4.1.5 *Anatomic Region Force Differences Test*

The results of the anatomic region force comparison test are listed in Table 22. This maintains the general clinical consensus that the deeper the catheter is placed in the urethra the higher the forces associated with each push in that region will be. A statistical test was performed to look for significant differences between the anterior, prostatic, and bladder neck regions. Across all lubrication conditions, the null hypothesis for the anterior urethra vs prostatic urethra and anterior vs bladder neck can be rejected. For the prostatic urethra vs bladder neck, a significant difference was not detected, and the null hypothesis could not be rejected. These results lean towards confirming the initial assumption that there are higher forces encountered as the catheter is inserted

further in the male urethra. This change in force is likely due to the natural curvature within the male urethra and the distinct curvature in the urethra noted at the prostate region.

Table 22: Anatomic Region Force Comparison Study Results.

Lubrication Condition:	P-Value
2mL	
Anterior vs Prostatic	0.0029*
Prostatic vs Bladder Neck	0.5977
Anterior vs Bladder Neck	0.0037*
4mL	
Anterior vs Prostatic	0.0484*
Prostatic vs Bladder Neck	0.6387
Anterior vs Bladder Neck	0.0213*
6mL	
Anterior vs Prostatic	0.0007*
Prostatic vs Bladder Neck	0.0754
Anterior vs Bladder Neck	0.0005*
8mL	
Anterior vs Prostatic	0.0011*
Prostatic vs Bladder Neck	0.0792
Anterior vs Bladder Neck	0.0056*
10mL	
Anterior vs Prostatic	0.0121*
Prostatic vs Bladder Neck	0.2686
Anterior vs Bladder Neck	0.011*

* Reject Null Hypothesis at 95% Confidence

4.2 Using Study B to Propose a General Force Curve for Male Urethral Catheterization

One identified gap in knowledge in current published literature was the "average" male urethral catheterization force curve. Study B offers a preliminary estimate for the "average" male urethral catheterization force curve into deceased male donors. Study B initially followed an assumption that lubrication was not additive. This maintained that the force curve was dependent not on how much lubricant had been added up to that point but rather how much lubrication is added just before the insertion attempt. The results of Study A, debunked this assumption for Study B. A new assumption for Study B was created: lubrication is additive up to a point, then a hyper-lubricated state is reached in which the amount of lubricant added has no effect on the catheter insertion forces. All Study B data will be assumed to be hyper-lubricated.

Each donor's Study B binned anatomic region force data separated by lubrication condition is sub-plotted in Figure 48. Donor 2 presented unexpected force readings in the bladder region (this could

be due to procedural error during collection), whereas all other donors result in consistent force curves in Study B. The individual donor plots were combined to create an averaged force of insertion curve for each anatomic region over the 5 lubrication conditions in Study B (Fig. 49). A linear regression was applied to the data to discern if the slope for each anatomic region was significantly different from 0. The linear regression models were plotted with the averaged data points in Figure 50. Table 23 lists the characteristics of these linear regression fits. The three models fail to yield a significant F-statistic which signifies if the slope is significantly different from 0. These results suggest that the differing conditions of lubricant added in Study B do not result in significantly different forces between conditions. Thus, the assumption that all trials in Study B are hyper-lubricated is maintained and can be further analyzed to define an average force curve.

A boxplot reporting the span of forces collected at each anatomic region across all donors in Study B was included in Figure 51. Table 24 proposes the average minimum force required to place a male urinary catheter in a hyper-lubricated urethra at each of the identified anatomic regions. These values result from the average force of insertion over the six donors collated at each anatomic region. This data is offered as a baseline force profile for the quantification of the procedure of male urethral catheter placement using a BARD 16 Fr Uncoated Silicone Foley Catheter (PID:165816).

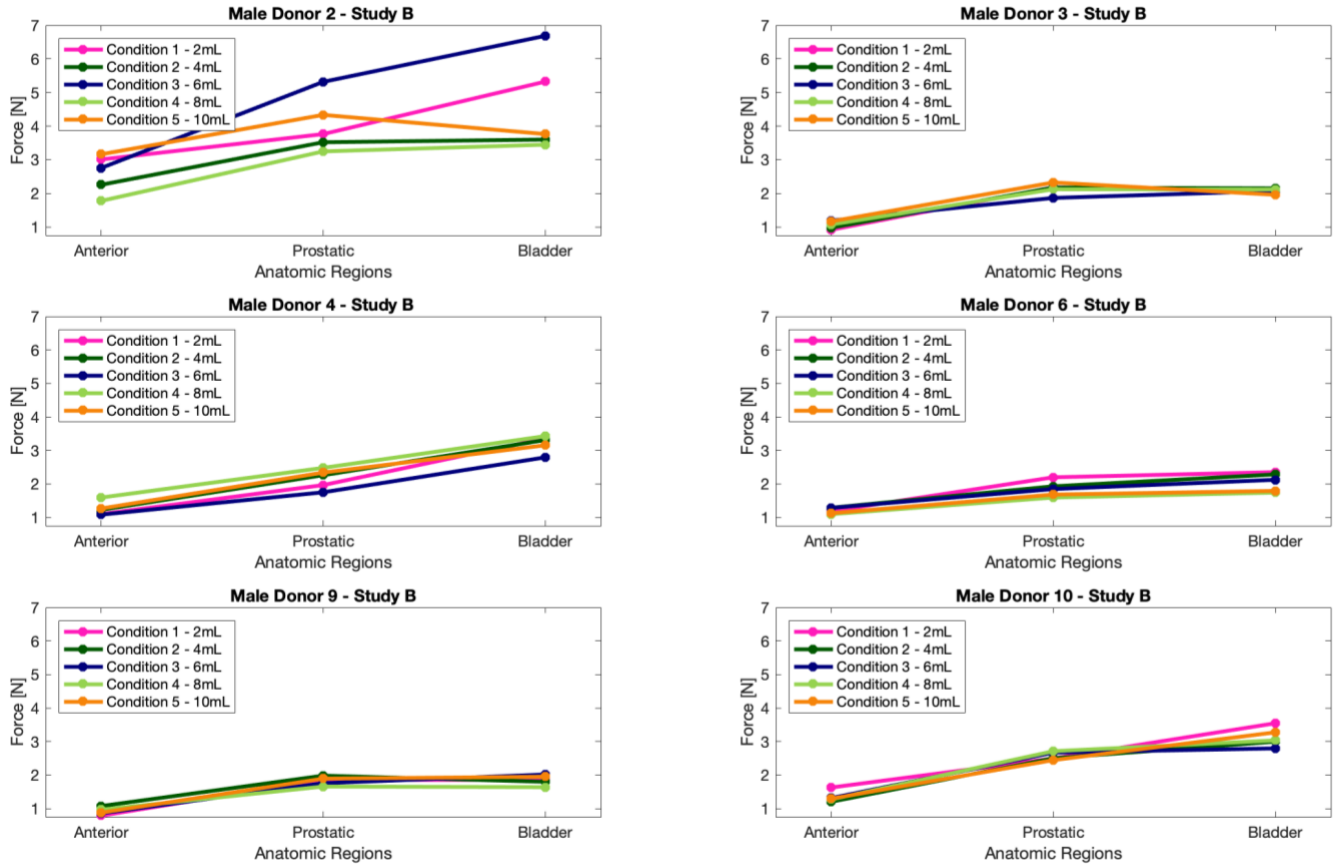


Figure 48: UW Cadaveric Study B– Anatomic Region Split with Lubrication Stratification

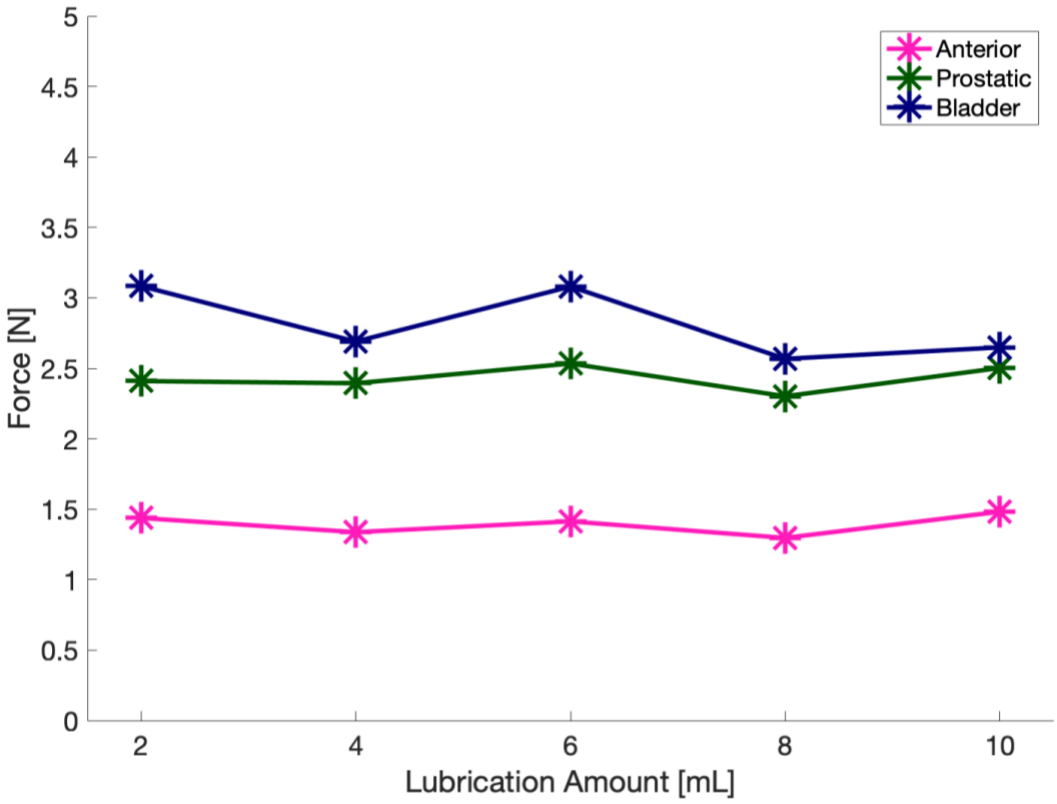


Figure 49: UW Cadaveric Study B All Donor (N=6) Results of Force vs Lubrication Condition

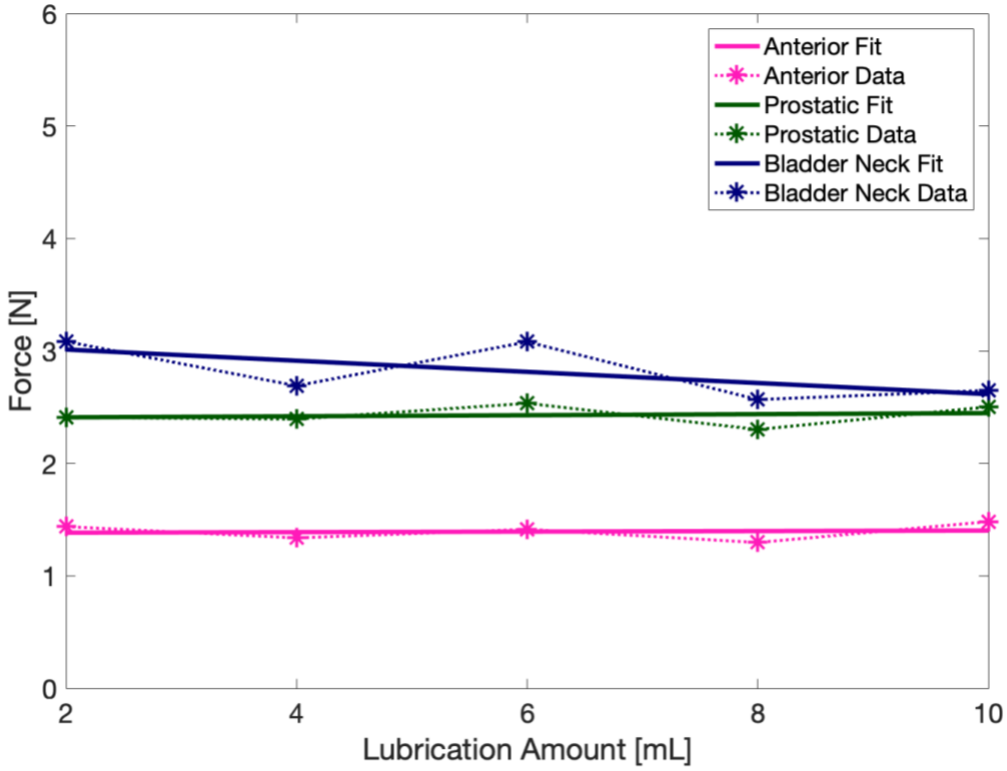


Figure 50: UW Cadaveric Study B – Lubrication Stratification Linear Models

Table 23: Linear Model Fit Characteristics of Lubrication Stratification Study B

Linear Model Characteristics	Intercept	p-value	Slope	p-value	F-Stat
anterior	1.38	1.77E-05	0.0024	0.95317	0.953
prostate	2.4	4.75E-07	0.0047	0.93341	0.933
bladder neck	3.11	4.98E-07	-0.0496	0.49842	0.49842

Table 24: UW Cadaveric Study B – Anatomic Region Averages + Standard Deviations

	Study B Average Force [N]
Anterior	1.39 +/- 0.61
Prostatic	2.43 +/- 0.85
Bladder Neck	2.81 +/- 1.11

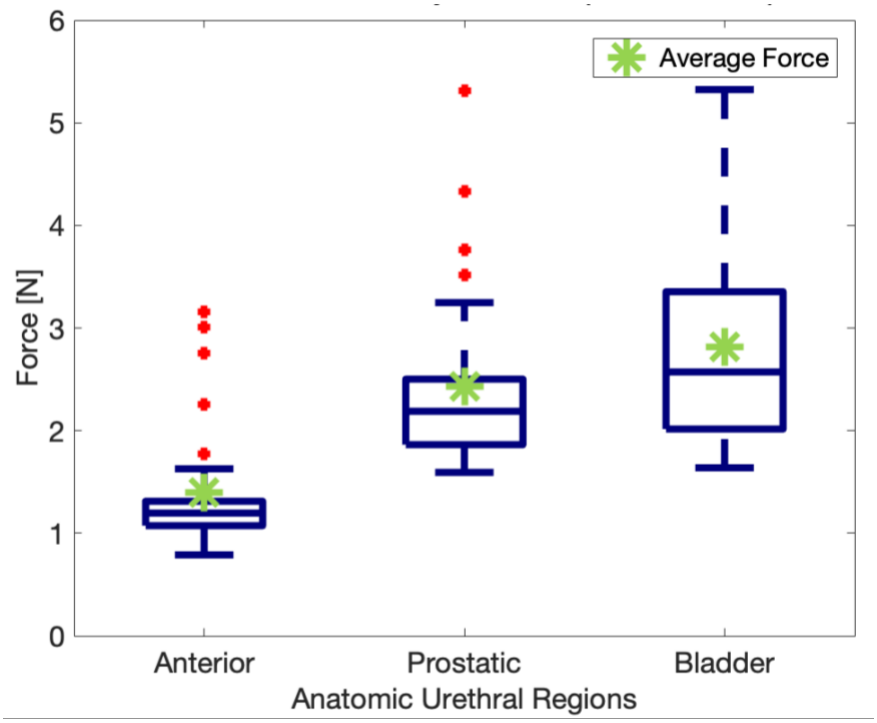


Figure 51: UW Cadaveric Study B – Anatomic Region Boxplots

4.3 CREST Urethral Catheter Simulator Force Verification Tests

4.3.1 *CREST Urethral Catheter Simulator Insertion Data*

The CREST Urethral Catheter Simulator Version 4 was tested following the same protocols defined for Study A and Study B in the cadaveric donors. One catheter was used and marked after each insertion during Trial 1, then each of those insertion depths was repeated over the two studies. Figure 52 depicts the average curve from the data collection from the CREST Sim V4. Additional

plots for the CREST Sim V4 are included in **Appendix Q.** The measurements for each push in the CREST Sim V4 studies with an image of the marked catheter used are included in **Appendix R.**

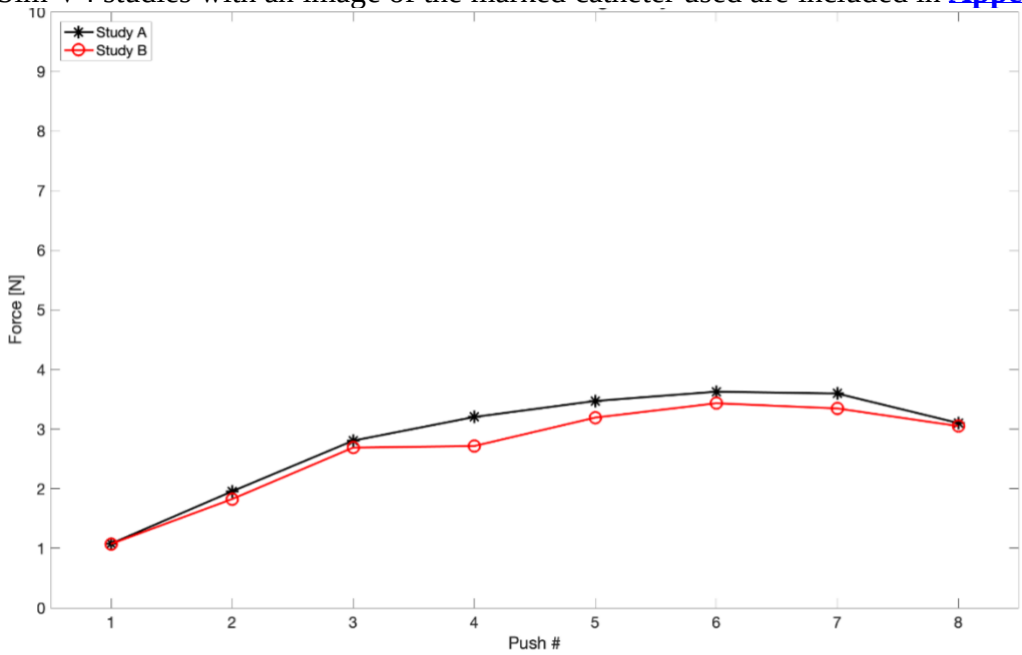


Figure 52: CREST UC Sim V4 Comparison Study – Average Force of Insertion Curve

4.3.2 *CREST Sim Anatomic Regions v Overall Cadaver Anatomic Data*

The CREST Sim data was processed using the same methods as the cadaveric donors and was split into the anatomic regions to compare to the cadaveric donor studies. Overlain boxplots of the CREST Sim V4 and Study A+B UW Cadaver Study force data was included in Figure 53. The purple boxplots represent the CREST Sim V4 and the grey is the Cadaveric study. A two-sample t-test was performed between the CREST Sim V4 and UW Cadaveric Study data at each anatomic region. The results of these tests are in Table 25. This comparison resulted in a significant (pval=0.0369) result for the penile urethra region. Following the standard 95% significance level, this group would yield a significant difference. If the significance level were changed to 99% this would not yield a significant result. Thus, minding the level at which the significance level is altered easily changes the significance of the result. The CREST Sim is noted to have slightly higher forces at each of the anatomic regions when compared to the cadaveric donors. Additionally, the CREST Sim does follow the same gradual increase in force as the Cadaveric study reported. Overall, the results suggest the CREST UC Sim V4 yields similar forces to the UW Cadaveric Study results.

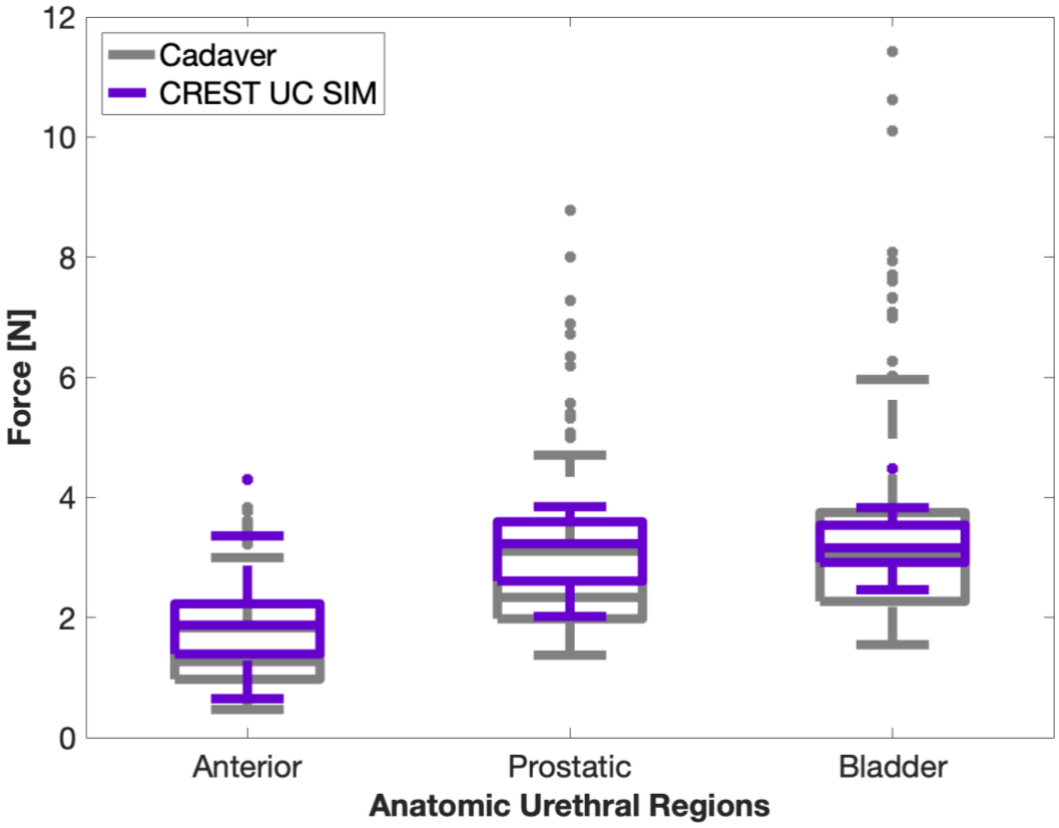


Figure 53: CREST UC Sim V4 Comparison Study – Overlaid Boxplots with UW Cadaveric Study.

Table 25: CREST UC Sim V4 Comparison Study – Statistical Results

2-Sample T-Test to Compare CREST UC SIM to Cadaveric Study (N=6)			
Anatomic Region	**CREST UC SIM**	**Cadaveric**	**P-Value**
Anterior	1.90N	1.54N	0.0396*
Prostatic	3.12N	2.82N	0.3653
Bladder Neck	3.22N	3.38N	0.6327

4.4 Force Collection of Commercially Available Simulators

4.4.1 *Motivation*

Current simulators on the market are quite diverse in price, material choice, and anatomic layout. The CREST UC Sim is in direct competition to those currently available, thus a study to compare the experience and force of insertion is performed here.

4.4.2 *Which Simulators Were Chosen?*

Due to the costs associated with several different urethral catheter simulators the options to test for this comparison were limited. CREST owns the Life/Form Male simulator, and the UWMC

Simulation Center – WISH, owns and allowed us to borrow the Simulaid – Male Catheterization Model. Images of the two commercial simulators were presented in Figure 1. The full list of simulators included in this comparison study is in Table 26.

Table 26: Simulator Comparison Study – Simulators Used.

SIMULATOR #	COMMERCIAL NAME
1	Life/Form Male Catheter Model
2	Male Catheterization Model Mounted on a Training Stand
3	CREST Urethral Catheter Simulator – V4

4.4.3 *Methods*

This simulator study methods are not the same as the cadaveric study methods. Following the same lubrication stratification as the cadaveric study leads to insertion issues in the simulators used in this study. Each simulator was prepared by cleaning out the urethral passage with warm tap water. An assumption was made that all the simulators reach a hyper-lubricated state after an initial pre-lubrication step. The pre-lubrication step includes inserting 3mL of lubricant and running a catheter all the way through the device to emulate a moist urethra in a human. The insertion protocol follows 5 trials with 1mL of lubrication inserted directly into the urethra of each simulator before the beginning of each insertion. Limiting each insertion's lubrication amount to 1mL enables consistent insertion attempts while each simulator is hyper-lubricated. The *Force Measurement Instrument* was implemented in this study to maintain consistency with prior insertion studies.

4.4.4 *Results*

The raw data from each of the simulator studies were plotted in Figure 54. This data is separated by the trial number. The average force of insertion for each simulator is plotted in Figure 55, with the results of the UW Cadaver Study B plotted in black. The average force of insertion per push for the three simulators and the UW Cadaver Study B anatomic region force ranges is listed in Table 27. Table 28 presents the average force of insertion per anatomic region for the three simulators. Three plots that compare the spread of each simulator's data and average force curve to the averages of the UW Cadaveric Study B data are in **Appendix S.**

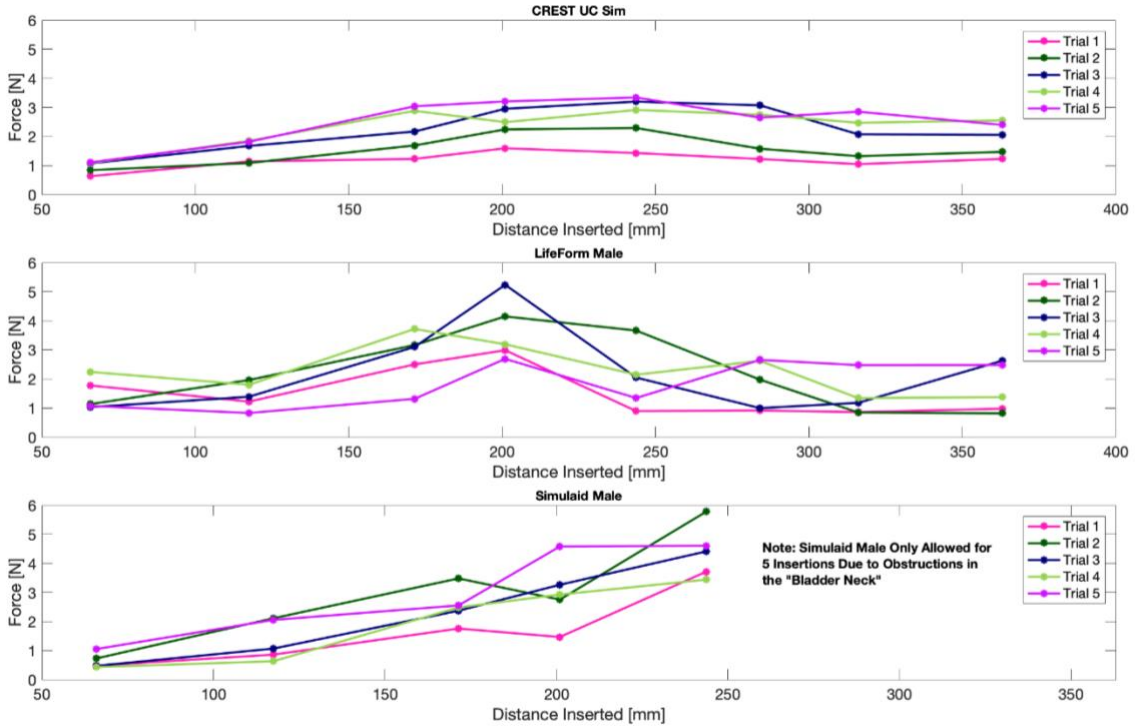


Figure 54: Simulator Comparison Study – Raw Data for 3 Commercial Simulators.

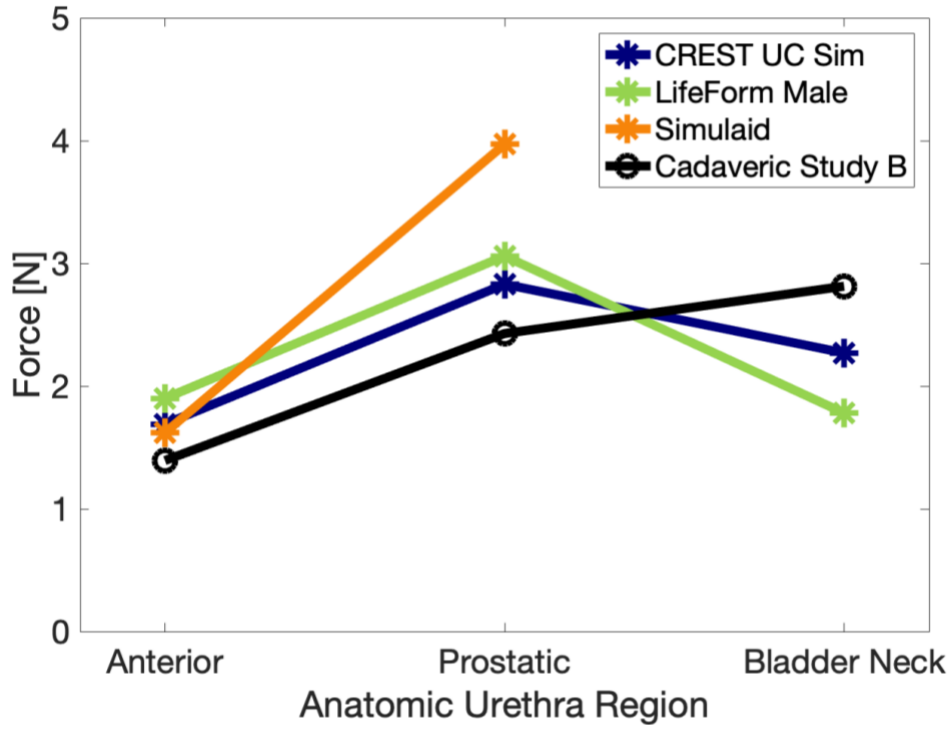


Figure 55: Simulator Comparison Study – Averaged Data for each Commercial Simulator (N=3) + UW Cadaver Study B Average points.

Table 27: Simulator Comparison Study Average Force per Push + UW Cadaveric Study B Average

FORCES [N]						
Push #	Depth [mm]	CREST UC Sim	LifeForm Male	Simulaid Male	Cadaveric Study B Average	Anatomic Region
1	65.9	1.03	1.37	0.67	1.39 +/- 0.61	Anterior
2	117.5	1.61	1.50	1.47		
3	171.5	2.44	2.83	2.72		
4	201.0	2.72	3.82	3.38	2.43 +/- 0.85	Prostatic
5	243.7	2.94	2.30	4.56		
6	284.1	2.51	2.06	-	2.81 +/- 1.1	Bladder Neck
7	316.1	2.18	1.46	-		
8	363.1	2.12	1.83	-		

Table 28: Simulator Comparison Study Average Force per Anatomic Region + UW Cadaveric Study B Average

FORCES [N]				
Anatomic Region	CREST UC Sim	LifeForm Male	Simulaid Male	Cadaveric Study B Average
Anterior	1.69	1.90	1.62	1.39 +/- 0.61
Prostatic	2.83	3.06	3.97	2.43 +/- 0.85
Bladder Neck	2.27	1.78		2.81 +/- 1.1

4.4.5 *Discussion*

The execution of the simulator study led to drawing some qualitative conclusions regarding the simulators. The Life/Form Male repeatedly had difficulty allowing the catheter through if there was too much lubricant. The Life/Form Male created a vacuum-like obstruction during the 4th and 5th pushes which is clear from the force spike. The Life/Form Male allowed the catheter to be hubbed; however, the Simulaid Male trainer did not allow the catheter to be inserted past the 5th push distance (24.3cm) before an obstruction was. During insertion into the CREST Sim, there were no notable issues during insertion.

Due to the limited sample size used in this study there was no statistical analysis performed to compare the outcomes of these devices. A larger, more inclusive study should be performed in the future to expand upon the comparisons of commercially available simulators. From the data collected some observations can be drawn. A plot to draw comparison between the three simulators with the average forces of the UW Cadaver Study B (black line) is included in Figure 55. The Simulaid Male is difficult to compare due to the failure successfully to hub the catheter on any attempt. From the data collected from the Simulaid Male, it suggests a higher force is required to place the catheter than for the Life/Form Male or the CREST UC Sim. Comparing the Simulaid Male to the Cadaveric Data, the Simulaid simulator (3.97N) required almost double the force when

compared to the cadaveric prostatic anatomic urethra (2.43+/- 0.85N). The Life/Form male had previously been noted to show great variability in force results (above in section 3.3). This test did not present a wide data spread, but revealed around push 4 (20cm) the force curve spiked (3.82N). Comparing the Life/Form Male to the other two simulators, it follows a similar force curve of the CREST UC Sim (with the exception of the spike at push 4). When compared to the cadaveric data, the Life/Form Male yielded higher forces at the prostatic urethra region (3.06N) and lower forces in the bladder neck region (1.78N). Lastly, comparing the CREST UC Sim test to the cadaveric data, the CREST UC Sim yields a similar force curve (1.69N, 2.83N, 2.27N) and falls within the range of the standard deviation of the cadaveric data (1.39 +/- 0.61N, 2.43+/- 0.85N, 2.81 +/- 1.1N).

Chapter 5. CONCLUSIONS

5.1 SIMULATOR DEVELOPMENT

The research and development of the CREST Urethral Catheter Simulator occurred over the last 2.5 years at CREST. The process included creating or modifying existing molds and extensive trial and error with many materials and construction methods to yield a final product. Through collaborations and testing within CREST and external groups, the CREST UC Sim is considered a complete product as of March 2020.

This device was first originally disclosed at the UW Bioengineering Capstone Symposium in May of 2019. The CREST UC Sim's record of innovation was finalized in September of 2019. The CREST UC Sim won a variety of awards at pitch events during the 2019-2020 academic year, including: UW School of Medicine Innovator of the Year Pitch Competition, UW Buerk Center 60 second Fast Pitch Contest, and 1st Prize at the UW SEBA Student Technology Showcase 2020.

5.2 FORCE MEASUREMENT INSTRUMENT

Through rapid prototyping and design modification, the new UW *Force Measurement Instrument* was developed and tested to compare force readouts to the originally designed UMN Force Measurement Instrument. Once validated, the UW *Force Measurement Instrument* was shipped back to UMN for their future data collection efforts and employed at the UW in our cadaveric, simulator, and future human studies.

5.3 LUBRICATION STRATIFICATION STUDY

The lubrication stratification study was a novel study designed and executed by myself and my research team to evaluate the effect of intraurethral lubrication on the force required to place a urinary catheter. A few prior studies to evaluate the force of urethral catheter placement have been published, but none have investigated the specific effect lubricant has on the force curve of catheter placement. This study was clinically motivated to provide an evidence-based recommendation for the minimum amount of lubricant to be used in standard male catheter insertion procedures.

Study A and B were designed to evaluate the two lubrication assumptions. The first is that lubrication is additive, thus as you add more lubricant to the urethra you can sum the totals over multiple insertions to equal 10mL after 5 trials. The second is that lubrication is not additive, thus the only effect the lubricant has on the insertion is based on the amount put in immediately before the catheter placement. From the results of Study A, we can suggest with confidence going further that lubrication is additive and that there is a point to which the addition of more lubricant does not change the force required to place the catheter. We call this point the hyper-lubricated state.

The two groups of linear models created from this data are proposed options for the relationship between lubrication applied and the force response over each anatomic region. Visually, Fit 2

leads to a more reasonable curve as the fitted lines do not cross the x-axis as seen in Fit 1. Although the adjusted R^2 values for the two fits are very low, Fit 1 yields higher adjusted R^2 values overall. These two linear models are not to be used in a clinical application, as there is no clear conclusion from the results and further exploration into this comparison should be done in the future.

These statistical results suggest there are significantly higher urethral catheter insertion forces with 2mL of intraurethral lubricant versus a hyper-lubricated state, whereas no difference was seen at 4mL or more. These results suggests that at least 4mL of lubricant should be used for routine male catheterization.

5.4 Average Male Urethral Catheter Force Curve

The data collected during Study B was used to calculate the average force curve when placing a urinary catheter in a deceased human male. A linear model was fit to the anatomic regions vs lubrication condition data to confirm that Study B did not have a relationship with increasing lubrication values once the hyper-lubricated condition was reached. This was confirmed when the curve for each anatomic region failed to yield a slope that was significantly different from 0 which allowed for the assumption to be applied that all of study B attempts were “equal” and each trial can be considered a replication of the hyper-lubricated condition.

From this string of assumptions, we propose that the average force of male catheter insertion for each anatomic region in a hyper-lubricated state including penile, prostatic, and bladder neck are 1.39 +/- 0.61N, 2.43 +/- 0.85N, and 2.81 +/- 1.11N, respectively.

5.5 CREST Sim Verification Study

The comparison of the CREST Sim V4 to the UW Cadaveric data was the crux of the aims achieved in this work. The same insertion protocol for the UW Cadaveric Study was performed on the CREST Sim V4 to compare the forces of insertion and test the realism of the simulator. The two-sample T-Test performed here reported a minimally significant difference between the penile anatomic regions between the two groups ($p = 0.0396$), but given the significance level was changed to 99%, this would not yield a significant result. Thus, we conclude that the CREST Sim force curve is not significantly different from that of the cadaveric study force curve presented in this work.

5.6 Commercial Simulator Force Comparisons

A simple force collection study was performed on three different urethral catheter simulators. Using the *Force Measurement Instrument* and following a consistent lubrication scheme (1mL before each insertion) each simulator was tested over 5 trials. When comparing the results of this study to the UW Cadaveric Study B data the Life/Form Male and the CREST UC Sim were in the range of forces required to place a urinary catheter at each of the anatomic regions.

Chapter 6. FUTURE WORK

6.1 FURTHER CADAVERIC STUDIES

More cadaveric data studies should be performed to be to further verify these findings. Continuing the same protocol will yield an increased number of trials to compare against which will allow for power analysis of the results and a more reliable result to take conclusions from. Ideally, a higher number of donors will help better understand the lubrication effect and general force curve of the average male catheter placement.

Additionally, we would like to expand our study into the collection of female catheterization data. Female catheterization is a shorter procedure and less data points will be collected for each subject as there will not be more than one insertion attempt per donor contrary to the 10 insertions performed on the male subjects. This data will be utilized when creating a female urethral catheter simulator in the future.

6.2 LIVE-PATIENT STUDY UW + UMN

The University of Washington and the University of Minnesota plan to continue to work towards the collection of live patient force insertion data. UMN has had their IRB approved for the last year. UW was able to get their IRB approved in February of 2020 (STUDY00007828: Urinary Catheterization Force Measurement and Analysis) with hopes of beginning live patient collection during the Spring Quarter of 2020. Due to the COVID-19 pandemic event our group was unable to begin live patient collection during the timeline of this work.

Synergistic efforts between UW and UMN will continue, with the hope that a joint publication will result from this work and potentially find implications for clinical practice guidelines.

6.3 COMMERCIALIZATION OF THE CREST URETHRAL CATHETER SIMULATOR

The CREST Urethral Catheter Simulator has reached the completion of the research and development efforts. In June of 2019, the Record of Innovation(ROI) was filed and completed through CoMotion. See Table 29 for the identifying information of this ROI. This ROI can now be licensed through external companies and entities to begin the mass production of the simulator for commercialization efforts going forward.

Table 29: Identifying Information for ROI of CREST Urethral Catheter Simulator

Record of Innovation (ROI) Reference Number: 4594
Title of Innovation: High-Fidelity Urethral Catheter Simulator
Date Entered: June 27, 2019

BIBLIOGRAPHY

1. Catheter-associated Urinary Tract Infections (CAUTI). https://www.cdc.gov/hai/ca_uti/uti.html (2015).
2. Bhatt, N. R. *et al.* A prospective audit on the effect of training and educational workshops on the incidence of urethral catheterization injuries. *Canadian Urological Association Journal* **11**, E302-6 (2017).
3. Davis, N. F. *et al.* Incidence, Cost, Complications and Clinical Outcomes of Iatrogenic Urethral Catheterization Injuries: A Prospective Multi-Institutional Study. *Journal of Urology* **196**, 1473–1477 (2016).
4. Kotsis, S. v & Chung, K. C. Application of the "see one, do one, teach one" concept in surgical training. *Plastic and reconstructive surgery* **131**, 1194–1201 (2013).
5. Vozenilek, J., Huff, J. S., Reznek, M. & Gordon, J. A. See One, Do One, Teach One: Advanced Technology in Medical Education. *Academic Emergency Medicine* **11**, 1149–1154 (2004).
6. Canales, B. K., Weiland, D., Reardon, S. & Monga, M. Urethral catheter insertion forces: a comparison of experience and training. *International braz j urol : official journal of the Brazilian Society of Urology* **35**, 84 (2009).
7. Ling, X. & Kowalewski, T. M. *Mechanical Characteristics of Male Urethral Catheterization: Simulator and Cadaveric Donor Study*. (2019).
8. Summary of Recommendations Guideline for Prevention of Catheter-Associated Urinary Tract Infections (2009). https://www.cdc.gov/infectioncontrol/guidelines/cauti/recommendations.html (2009).
9. Croke, L. Best practices for indwelling urinary catheter use in the surgical population. *AORN Journal* **109**, P7–P8 (2019).
10. University of Ottawa. Urinary Catheter Insertion. https://www.med.uottawa.ca/procedures/ucath/ (2003).
11. Urethral Catheterisation (Male). https://www.medistudents.com/en/learning/osce-skills/genitourinary/urethral-catheterisation-male/ (2017).
12. Muctar, S. The importance of a lubricant in transurethral interventions. *Urologe* **31**, 153–155 (1991).
13. Wilson, M. Catheter lubrication and fixation: interventions. *British journal of nursing (Mark Allen Publishing)* **22**, 566, 568 (2013).
14. Villanueva, C. & Hemstreet III, G. P. Difficult male urethral catheterization: a review of different approaches. *International braz j urol* **34**, 401–412 (2008).
15. Ahluwalia, A., Rossiter, D. & Menezes, P. Urinary catheterisation: Indications, technique and managing failure. *InnovAiT* **11**, 29–34 (2017).
16. Urinary Catheter Types and Being Part of the Insertion Team. https://www.ahrq.gov/hai/quality/tools/cauti-ltc/modules/implementation/education-bundles/indwelling-urinary-catheter-use/catheter-insertion/licensed-staff/slides.html (2017).
17. Willson, M. *et al.* Nursing Interventions to Reduce the Risk of Catheter-Associated Urinary Tract Infection: Part 2Staff Education, Monitoring, and Care Techniques. *Journal of Wound Ostomy & Continence Nursing* **36**, (2009).

18. Laschinger, S. *et al.* Effectiveness of simulation on health profession students' knowledge, skills, confidence and satisfaction. *International Journal of Evidence-Based Healthcare* **6**, 278–302 (2008).
19. Rauen, C. A. Simulation as a Teaching Strategy for Nursing Education and Orientation in Cardiac Surgery. *Critical Care Nurse* **24**, 46–51 (2004).
20. Papanikolaou, I. G. *et al.* Changing the way we train surgeons in the 21th century: A narrative comparative review focused on box trainers and virtual reality simulators. *European Journal of Obstetrics and Gynecology and Reproductive Biology* vol. 235 13–18 (2019).
21. Nathwani, J. N. *et al.* Resident performance in complex simulated urinary catheter scenarios. *Journal of Surgical Research* **205**, 121–126 (2016).
22. Todsen, T. *et al. Short-and long-term transfer of urethral catheterization skills from simulation training to performance on patients*. http://www.biomedcentral.com/1472-6920/13/29 (2013).
23. Derisa Battick, A. *ScholarWorks Enhancing Urinary Catheter Skills Among Clinically Practicing Nurses*. http://scholarworks.waldenu.edu/dissertations (2018).
24. Kohler, T. S., Yadven, M., Manvar, A., Liu, N. & Monga, M. *The Length of the Male Urethra*. *The Length of the Male Urethra International Braz J Urol* vol. 34.
25. Mayo Clinic Staff. Benign prostatic hyperplasia (BPH). https://www.mayoclinic.org/diseases-conditions/benign-prostatic-hyperplasia/symptoms-causes/syc-20370087 (2019).
26. *AMS 800 Operating Room Manual*. (2017).
27. Hudoba, M. W., Lilly, B. & Castro, J. *Design of a Modified Slip Casting Procedure for the Single Step Manufacture of Sealed Silicone Balloons Graduate Program in Mechanical Engineering*. (2011).
28. *3D Guidance trakSTAR User Guide*. www.ndigital.com (2017).
29. Kim, B. S. *et al.* Prostatic urethral length as a predictive factor for surgical treatment of benign prostatic hyperplasia: a prospective, multiinstitutional study. *Prostate international* **7**, 30–34 (2019).
30. Reuter, V. E. & Al-Ahmadie, H. A. 11 - Urethra. in *Urologic Surgical Pathology (Fourth Edition)* (eds. Cheng, L., MacLennan, G. T. & Bostwick, D. G.) 534-548.e5 (Content Repository Only!, 2020). doi:https://doi.org/10.1016/B978-0-323-54941-7.00011-6.
31. Jacob, S. Chapter 4 - Abdomen. in *Human Anatomy* (ed. Jacob, S.) 71–123 (Churchill Livingstone, 2008). doi:https://doi.org/10.1016/B978-0-443-10373-5.50007-5.
32. Carlson, B. M. Chapter 13 - The Urinary System. in *The Human Body* (ed. Carlson, B. M.) 357–372 (Academic Press, 2019). doi:https://doi.org/10.1016/B978-0-12-804254-0.00013-2.
33. Lierse, W. Male Urethra. in *Applied Anatomy of the Pelvis* (ed. Lierse, W.) 171–174 (Springer Berlin Heidelberg, 1987). doi:10.1007/978-3-642-71368-2_9.
34. McCallum, R. W. The adult male urethra: normal anatomy, pathology, and method of urethrography. *Radiologic clinics of North America* **17**, 227–44 (1979).
35. Yamada, Y. 47 - Cancer of the Male Urethra and Penis. in *Leibel and Phillips Textbook of Radiation Oncology (Third Edition)* (eds. Hoppe, R. T., Phillips, T. L. & Roach, M.) 996–1001 (W.B. Saunders, 2010). doi:https://doi.org/10.1016/B978-1-4160-5897-7.00048-2.

36. Schenkman, N. S. Male Urethra Anatomy. *eMedicine* https://emedicine.medscape.com/article/1972482-overview (2016).
37. C, R. H. & K, A. F. An Anatomic Study of the External Urethral Sphincter in Relation to Prostatic Surgery. *Journal of Urology* **61**, 591–603 (1949).
38. Krishnamoorthy, V. & Joshi, P. B. Length of urethra in the Indian adult male population. *Indian journal of urology : IJU : journal of the Urological Society of India* **28**, 297–299 (2012).
39. Gray H: Anatomy of the Human Body. in (ed. Lea & Fiberger) (1985).
40. Willed Body Program. https://www.uwmedicine.org/school-of-medicine/about/willed-body-program.

Chapter 7. APPENDIX

APPENDIX A

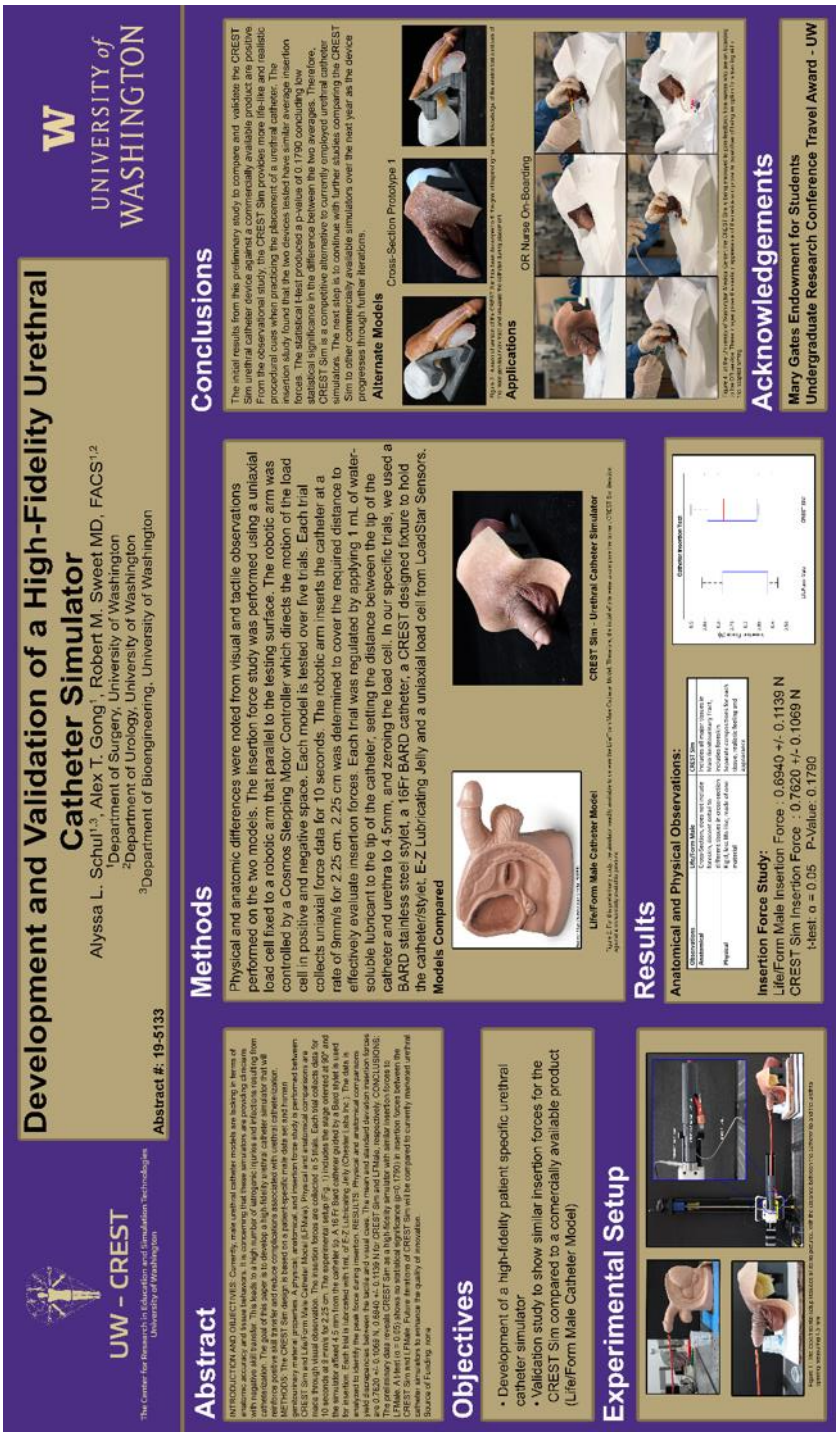


Figure A1: Poster from AUA 2019 Conference.

Abstract

INTRODUCTION AND OBJECTIVES:

Currently, male urethral catheter models are lacking in terms of anatomic accuracy and tissue behaviors. It is concerning that these simulators are providing clinicians with negative skill transfer. This leads to a high number of iatrogenic injuries and infections resulting from catheterization. The goal of this paper is to develop a high-fidelity urethral catheter simulator that will reinforce positive skill transfer and reduce complications associated with urethral catheterization.

METHODS:

The CREST Sim design is based on a patient-specific male data set and human genitourinary material properties. A physical, anatomical, and insertion force study is performed between CREST Sim and Life/Form Male Catheter Model (LFMale). Physical and anatomical comparisons are made through visual observation. The insertion forces are collected in 5 trials. Each trial collects data for 10 seconds at 9 mm/s for 2.25 cm. The experimental setup (Fig. 1) includes the stage oriented at 90° and the simulator affixed 4.5 mm from the catheter tip. A 16 Fr Bard catheter guided by a Bard stylet is used for insertion. Each trial is lubricated with 1mL of E-Z Lubricating Jelly (Chester Labs Inc.). The data is analyzed to identify the peak force during insertion.

RESULTS:

Physical and anatomical comparisons yield discrepancies between the tactile and visual cues. The mean and standard deviation insertion forces are 0.7620 ± 0.1069 N, 0.6940 ± 0.1139 N for CREST Sim and LFMale, respectively.

CONCLUSIONS:

The preliminary data reveals CREST Sim as a high-fidelity simulator with similar insertion forces to LFMale. A t-test ($\alpha = 0.05$) shows no statistical significance ($p=0.1790$) in insertion forces between the CREST Sim and LFMale. Future iterations of CREST Sim will be compared to currently marketed urethral catheter simulators to enhance the quality of innovation.

Figure A2: Abstract from AUA 2019 Conference.

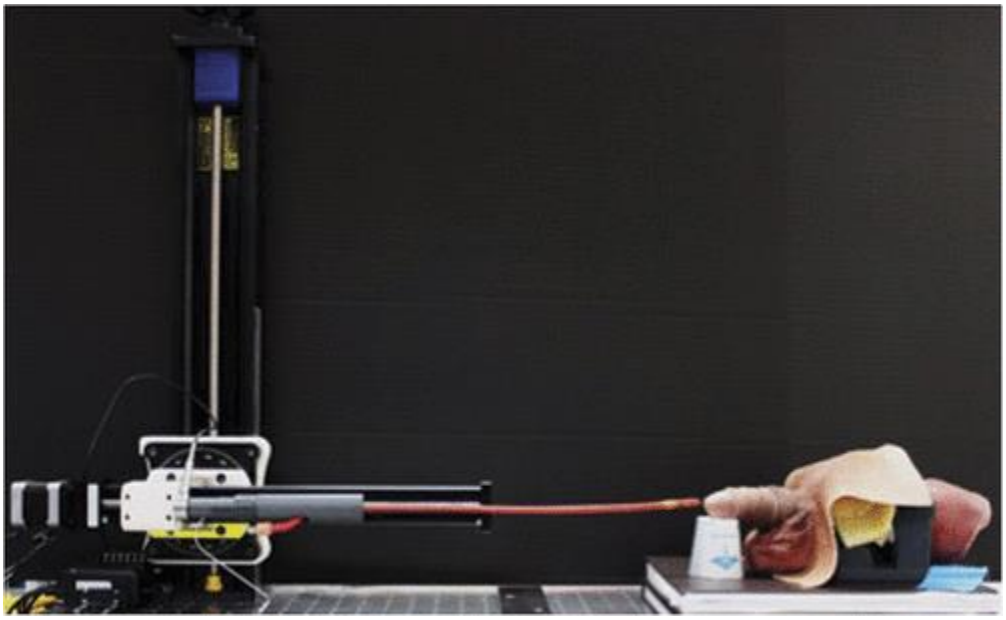


Figure A3: Image 1 from AUA 2019 Conference Abstract Submission.

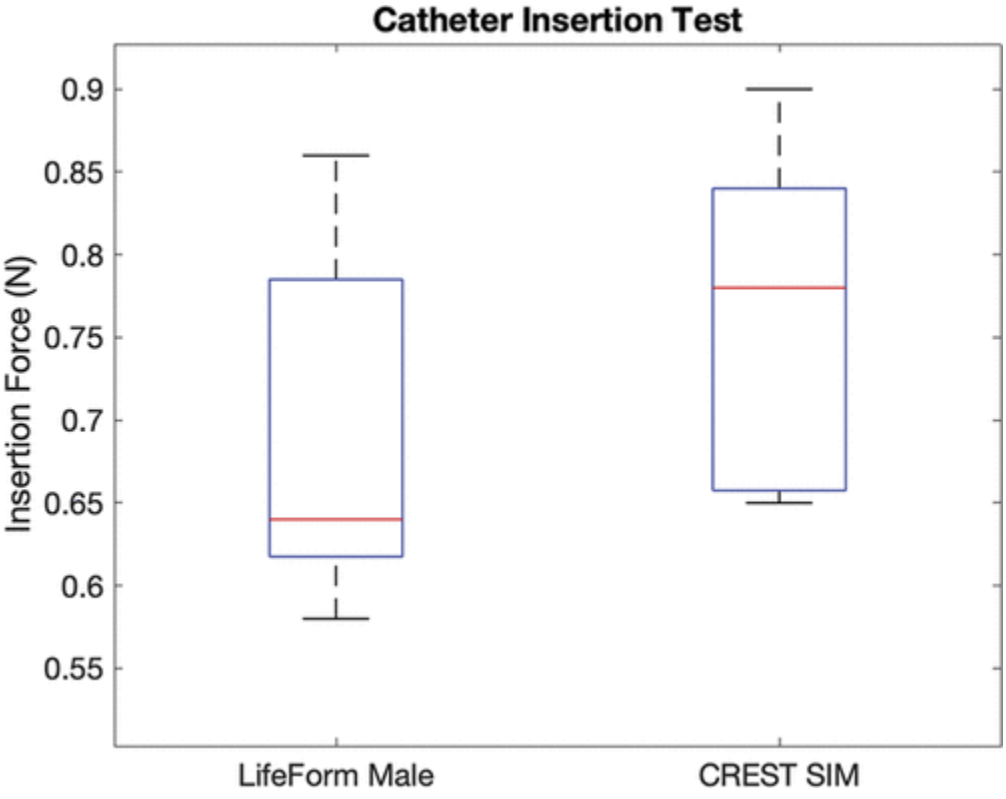


Figure A4: Image 2 from AUA 2019 Conference Abstract Submission.

APPENDIX B

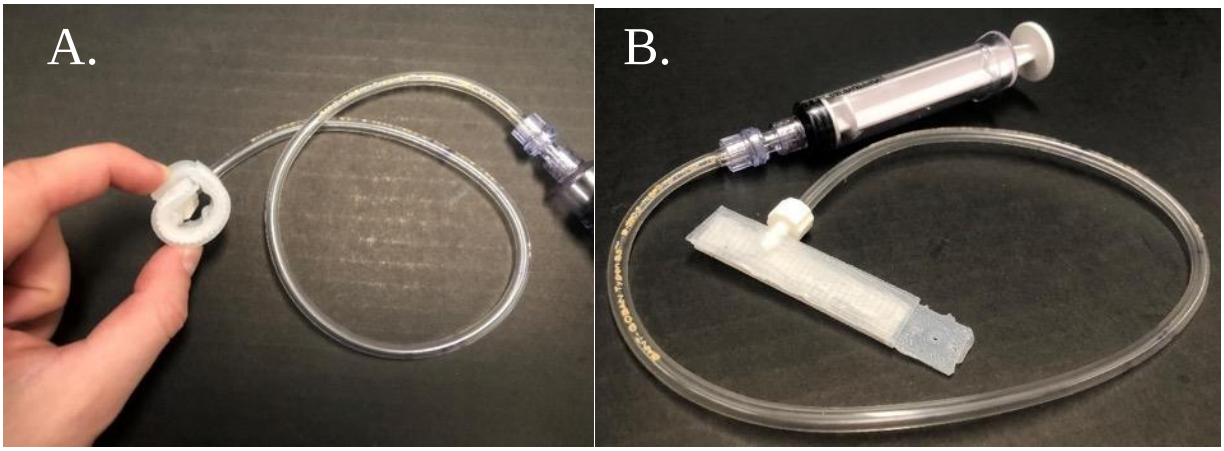


Figure B1: A.) Sphincter Device clasped around itself. B.) Sphincter Device constructed/assembled.

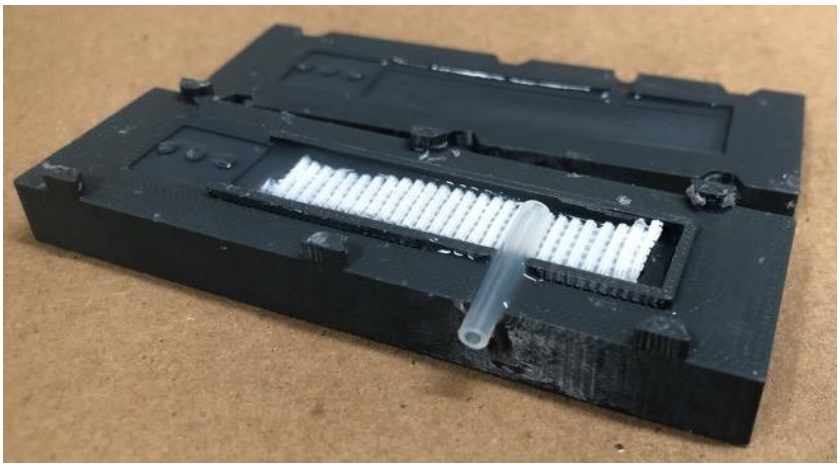


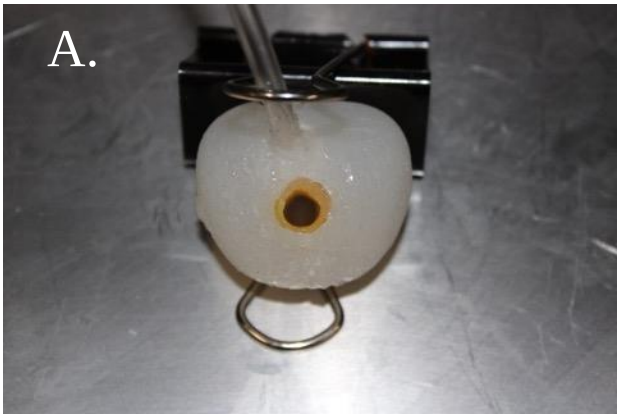
Figure B2: Sphincter Device 2-Part Mold filled following creation methods.

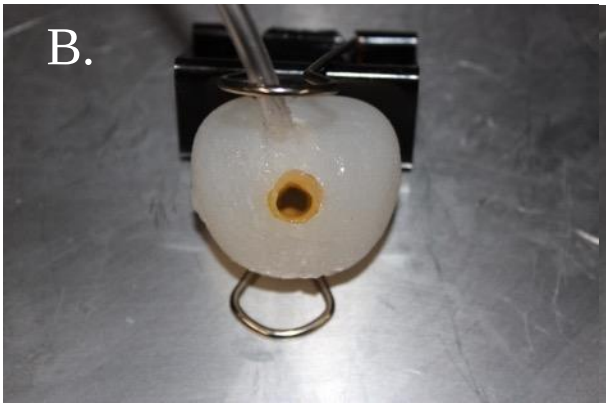
Figure B3: Another constructed sphincter device without a luerlock syringe attached.

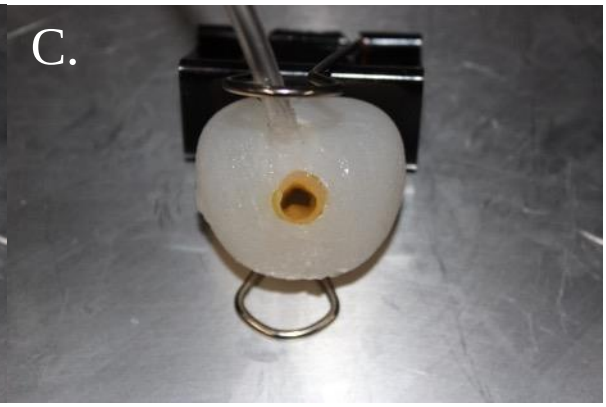
APPENDIX C

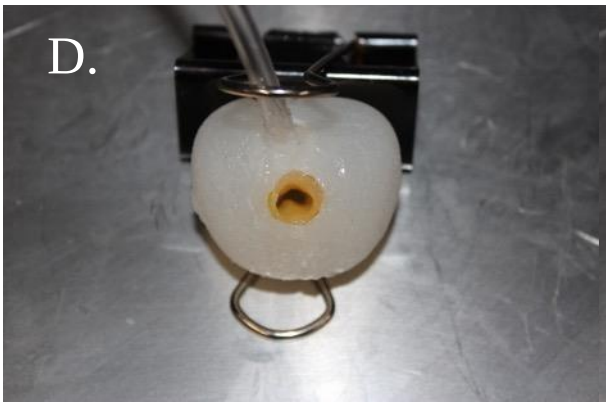
Figure C1: Urethra Core mold + Sphincter Device combination to create prostatic sphincter.

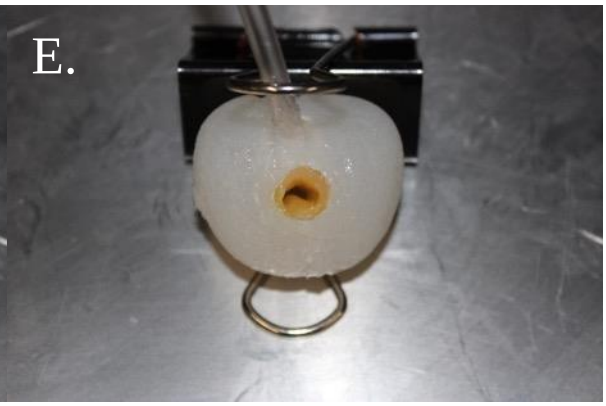
APPENDIX D











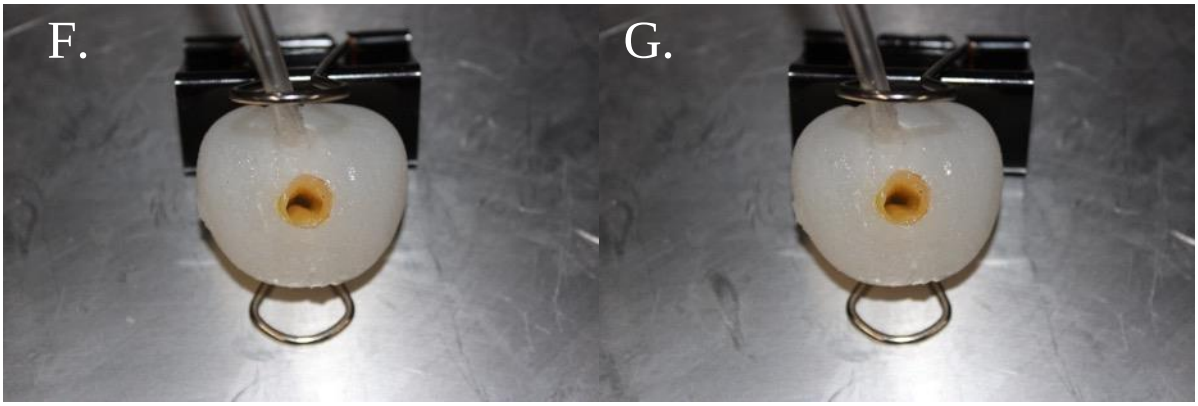


Figure D1: Sphincter Occlusion Study Images: A.) baseline B.) 0.5mL C.) 1.0mL D.) 1.5mL E.) 2.0mL F. 2.5mL G.) 3.0mL.

APPENDIX E

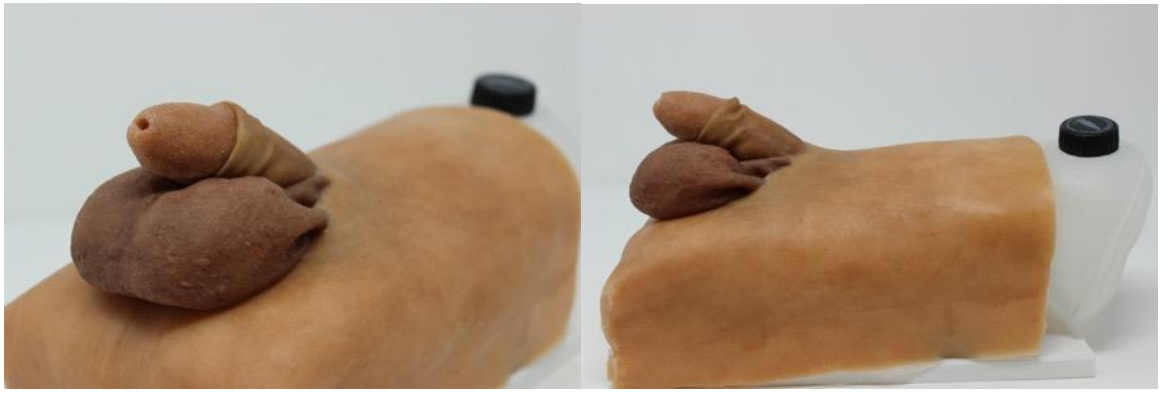


Figure E1: Images of CREST UC V4 – Circumcised Model

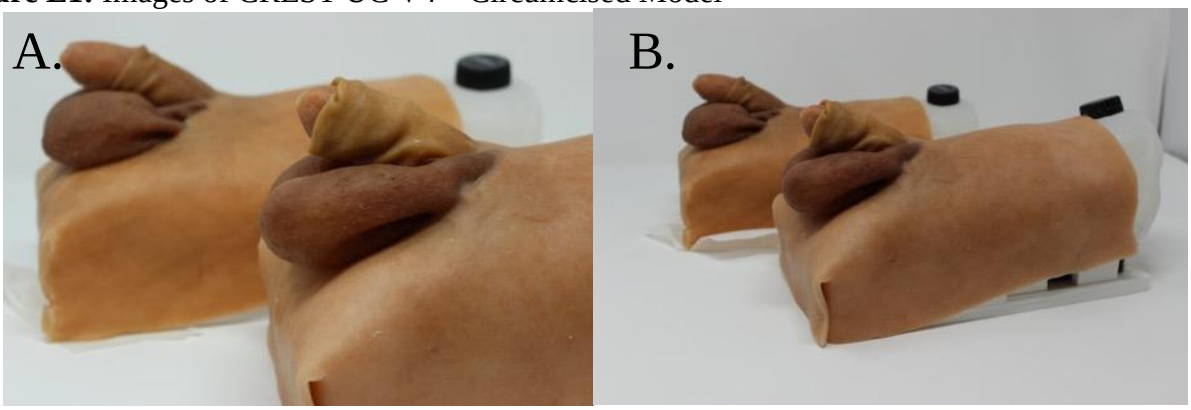


Figure E2: Images of CREST UC V4 – Circumcised + Uncircumcised Model(close up(A.) and full-model(B.)).

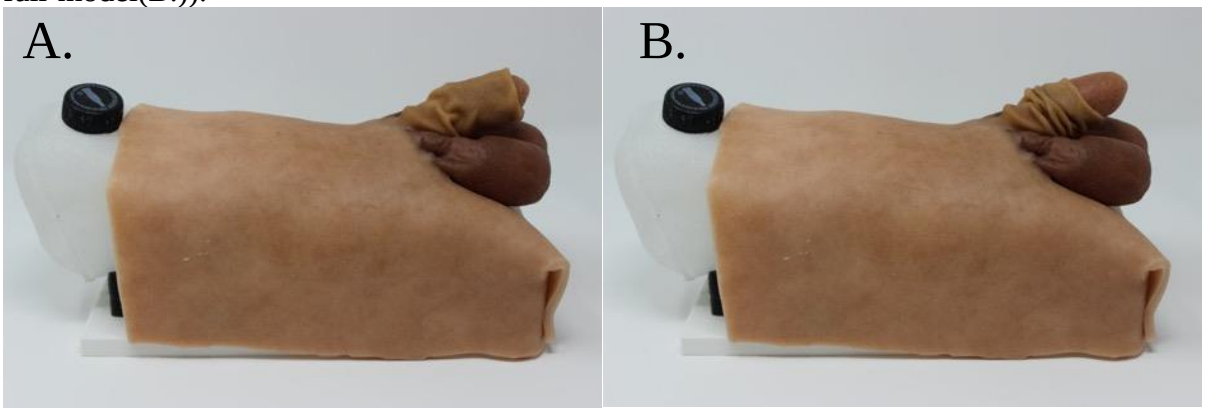


Figure E3: Images of CREST UC V4 – Uncircumcised Model with modular foreskin feature highlighted. A.) Foreskin is relaxed forward. B.) Foreskin is retracted for access to glans.

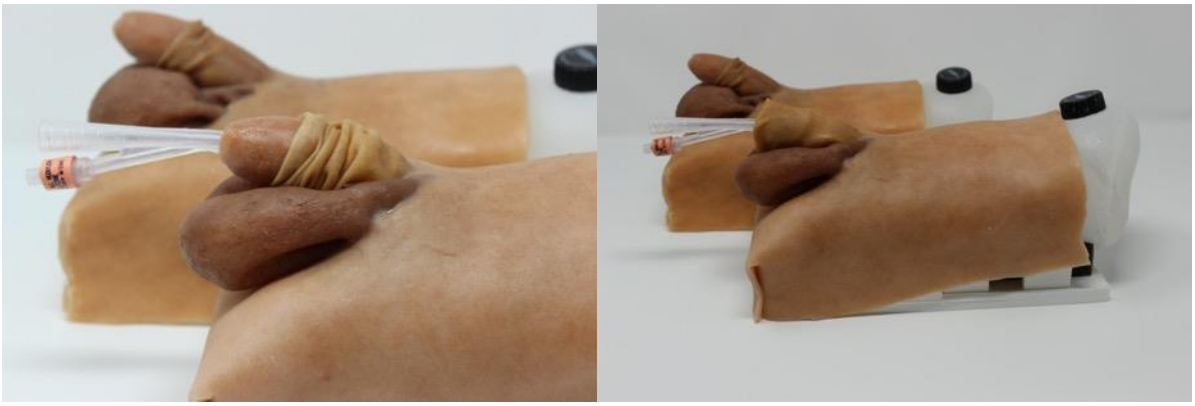


Figure E4: Additional images of the CREST UC Sim V4 with a catheter placed in the circumcised model.

APPENDIX F

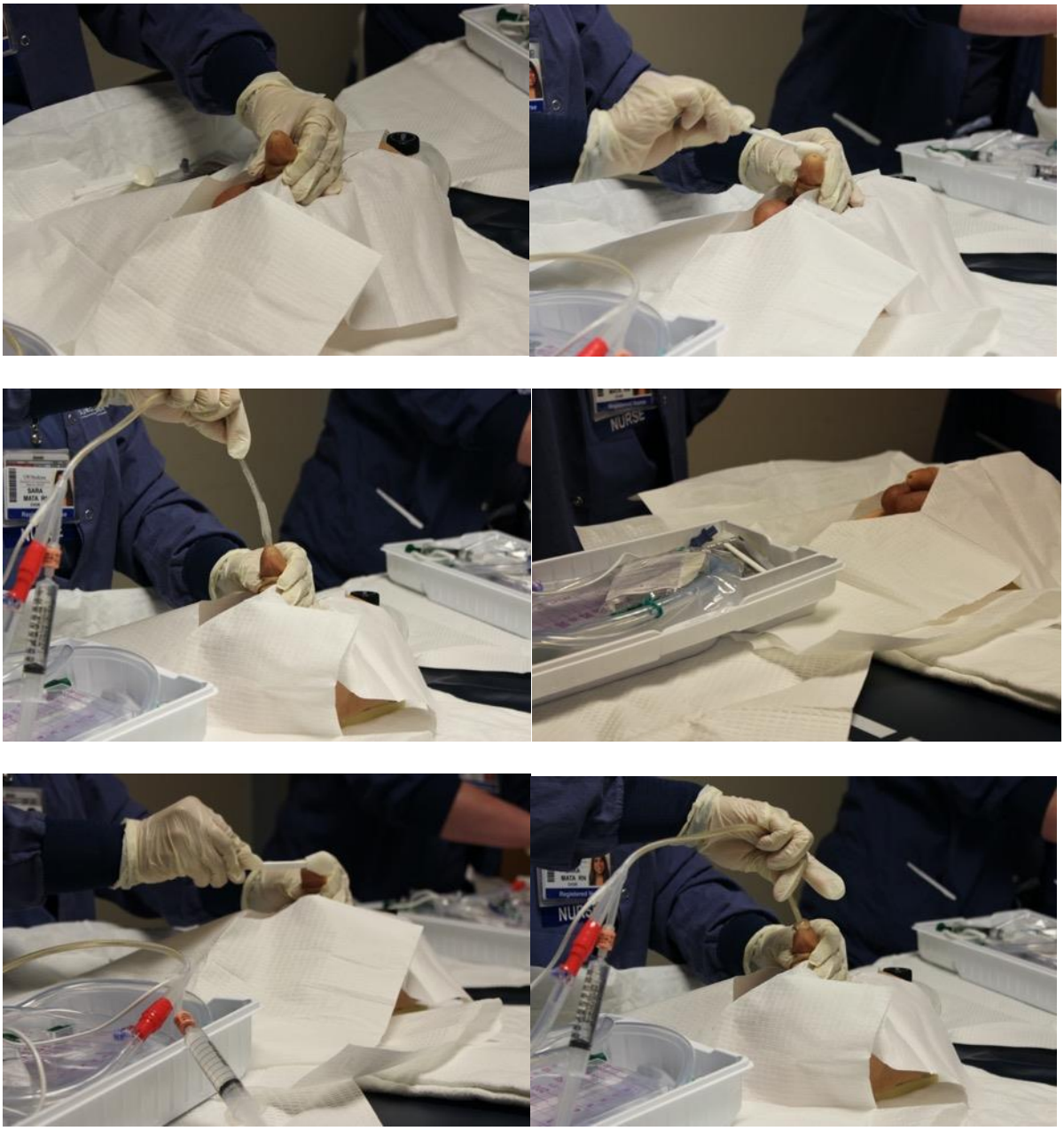


Figure F1: OR Nurse On-Boarding Images part 1.

Figure F2: OR Nurse On-Boarding Images part 2.

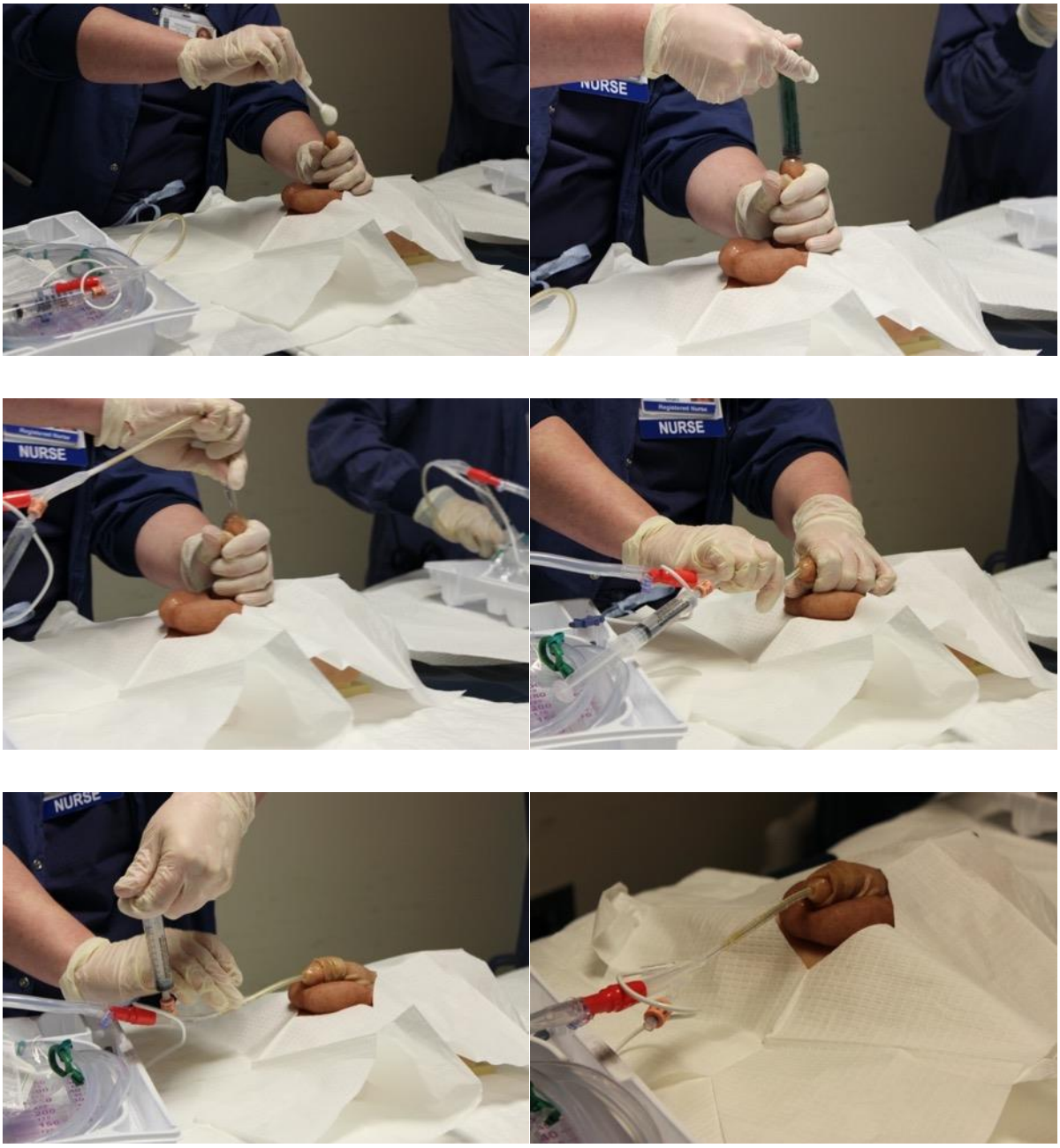


Figure F3: OR Nurse On-Boarding Images part 3.

APPENDIX G

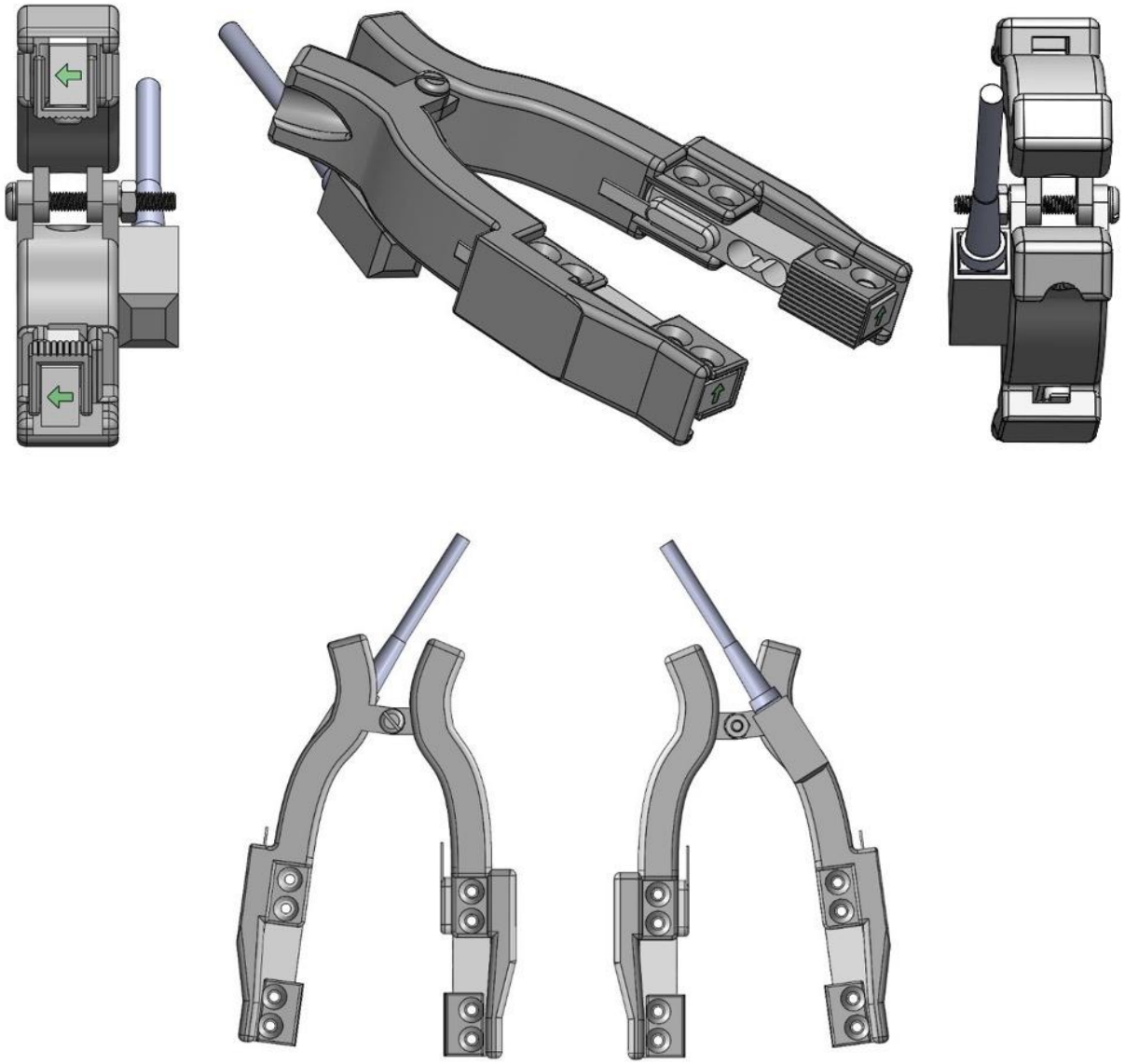


Figure G1: Multi-view images of the *Force Measurement Instrumen*t with the inclusion of the TrakSTAR sensor.

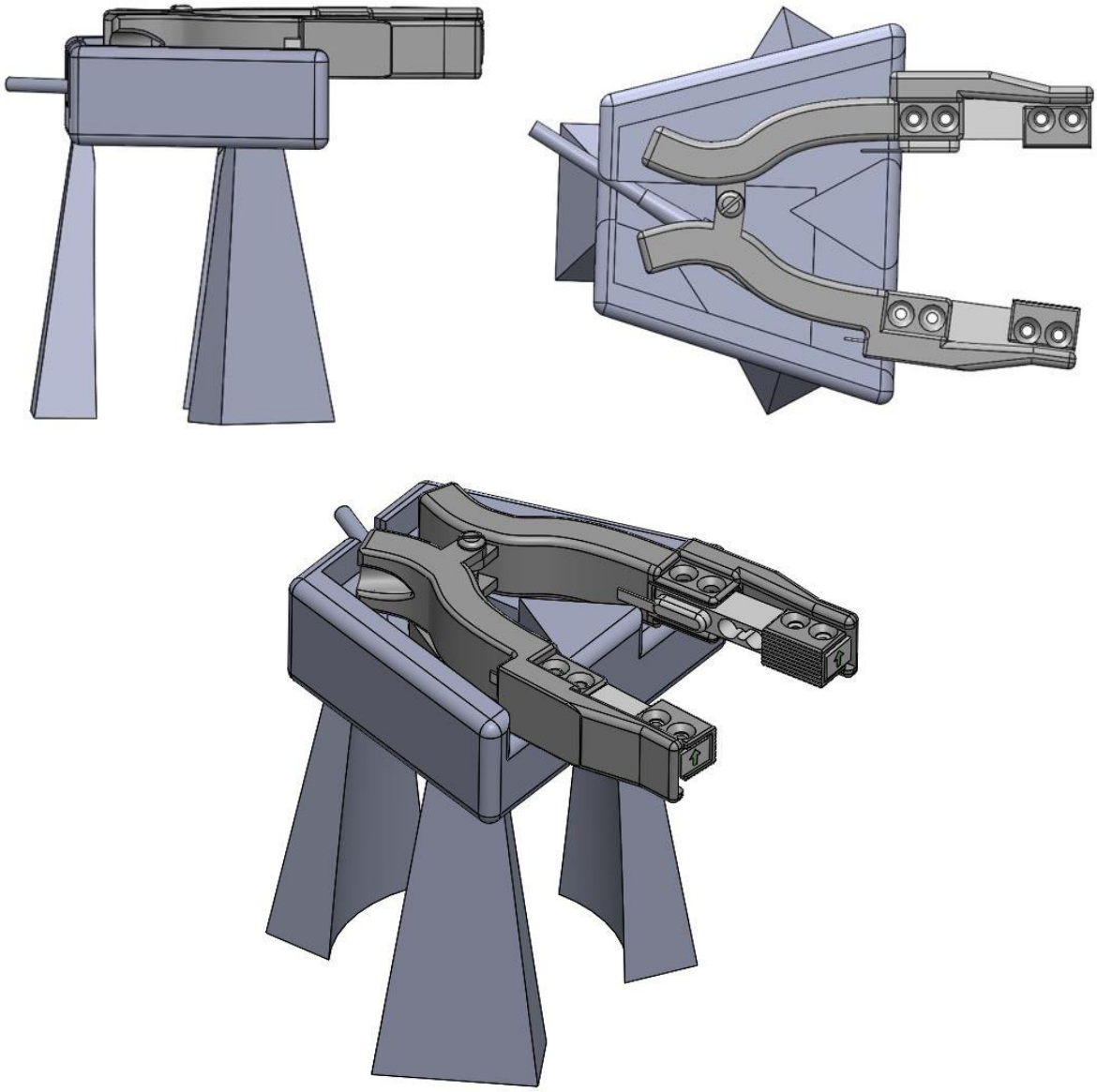


Figure G2: Multi-view images of the *Force Measurement Instrumen*t on the calibration stand.

APPENDIX H

Calibration Sketch must be used on both load cells in the instrument

Current Orientation of Loadcells and Pins

VPins/GreySide/Bone/tinyV -->

DAT 20

CLK 18

Calibration Guess with GLOVE: -954000

Without Glove : -1022000

UMN TONGS

Flat 21 18 1063000

V 20 19 1063000

Flat Face --> DAT 21

CLK 19

Calibration Guess: -947000

without glove: -964000

New weights with hooks:

50g -> 50.698g

20g -> 20.702g

10g -> 10.649g

```
/*
#include "HX711.h" //This library can be obtained here http://librarymanager/All#Avia_HX711
#define LOADCELL_DOUT_PIN  20 // Change according to which cell you are testing either 20 or 21
#define LOADCELL_SCK_PIN  18 // Change according to which cell you are testing either 19 or 18
HX711 scale;
float calibration_factor = -934000; //Initial guesses from previous calibrations SEE ABOVE
   //    Take note of variation if changed  //
void setup() {
  Serial.begin(9600);
```

```
  Serial.println("HX711 calibration sketch");
  Serial.println("Remove all weight from scale");
  Serial.println("After readings begin, place known weight on scale");
  Serial.println("Press + or a to increase calibration factor");
  Serial.println("Press - or z to decrease calibration factor");
  scale.begin(LOADCELL_DOUT_PIN, LOADCELL_SCK_PIN);
  scale.set_scale();
  scale.tare();    //Reset the scale to 0
 // long zero_factor = scale.read_average(); //Get a baseline reading
 // Serial.print("Zero factor: "); //This can be used to remove the need to tare the scale. Useful in permanent scale projects.
 // Serial.println(zero_factor);
 // We don't use the zero_factor in the code //
}
void loop() {
  scale.set_scale(calibration_factor); //Adjust to this calibration factor
  Serial.print("Reading: ");
  Serial.print(scale.get_units()*(0.453592), 6); // Change to SI lb / 1 * kg / lb  --> ,6 = # of units shown
  Serial.print("kg"); //Change this to kg and re-adjust the calibration factor if you follow SI units like a sane person
  Serial.print(" calibration_factor: ");
  Serial.print(calibration_factor);
  Serial.println();
  if(Serial.available())
  {
    char temp = Serial.read();
    if(temp == '+' || temp == 'a')
      calibration_factor += 1000;
    else if(temp == '-' || temp == 'z')
      calibration_factor -= 1000;  } }
```

APPENDIX I

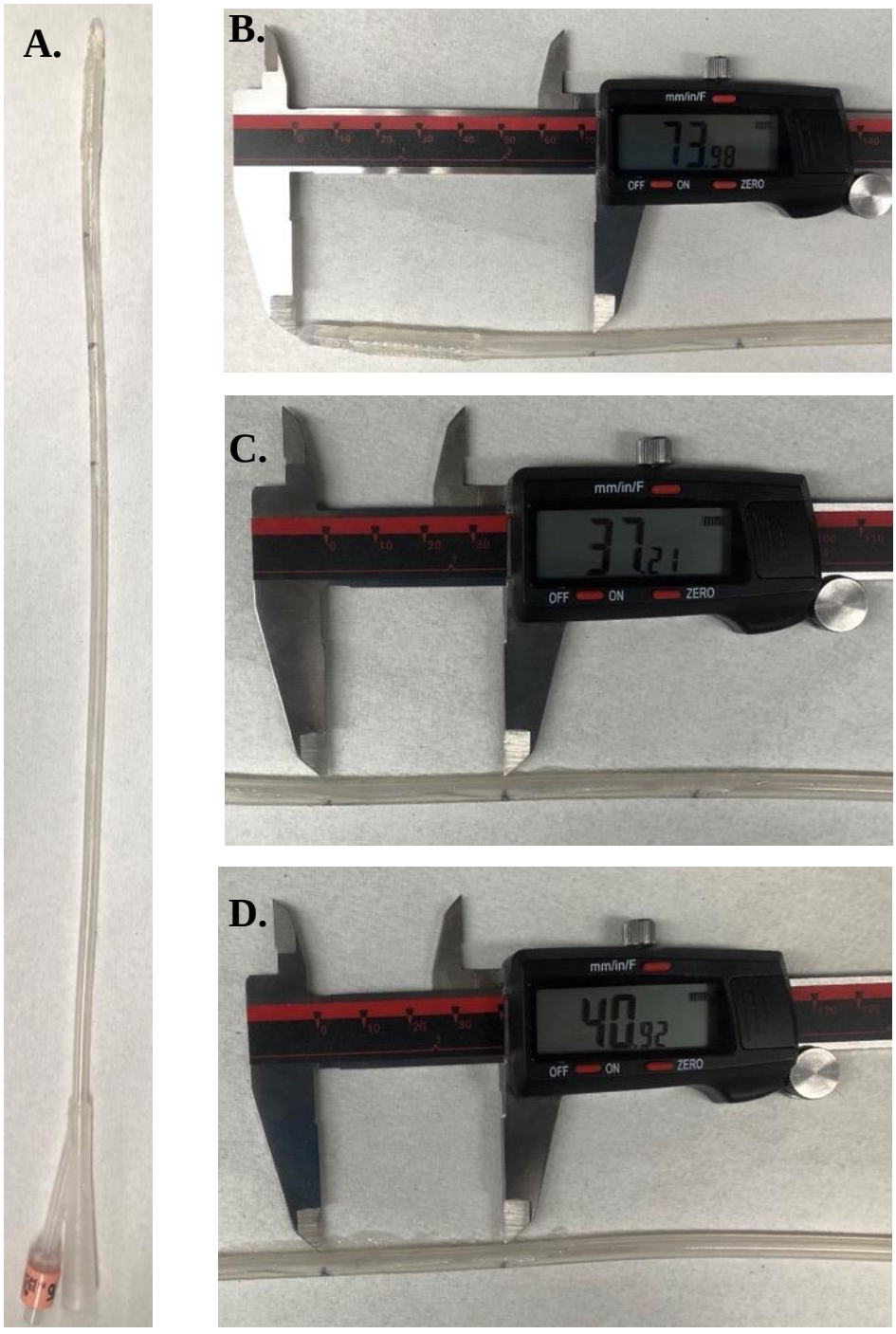


Figure I1: TrakSTAR location verification study. A.) Image of marked catheter B.) Measurement – 1 C.) Measurement – 2 D.) Measurement – 3.

APPENDIX J

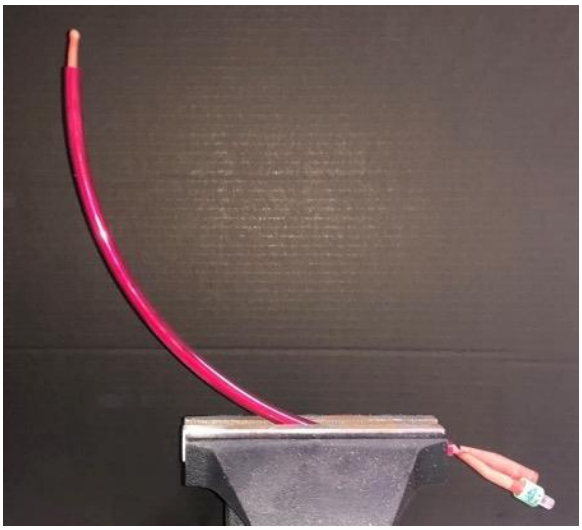


Figure J1: Catheter inserted fully into the analog tube held in place by a vise.

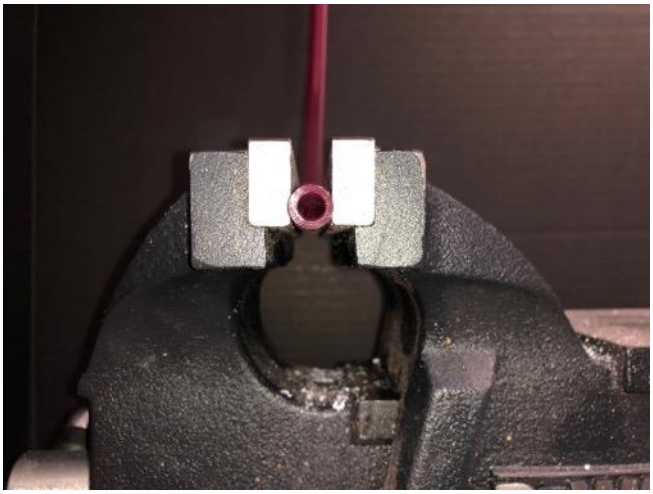


Figure J2: Frontal image of the opening for the analog tube. ID – 6.25 mm OD – 9.5 mm

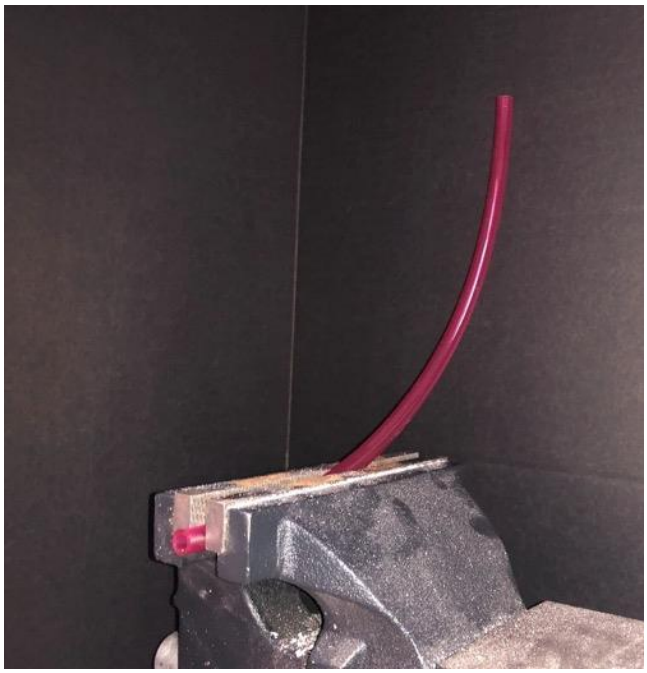


Figure J3: Insertion test setup without the catheter inserted into the tubing.

Figure J4: Image of the tubing used in the test laying flat.

APPENDIX K

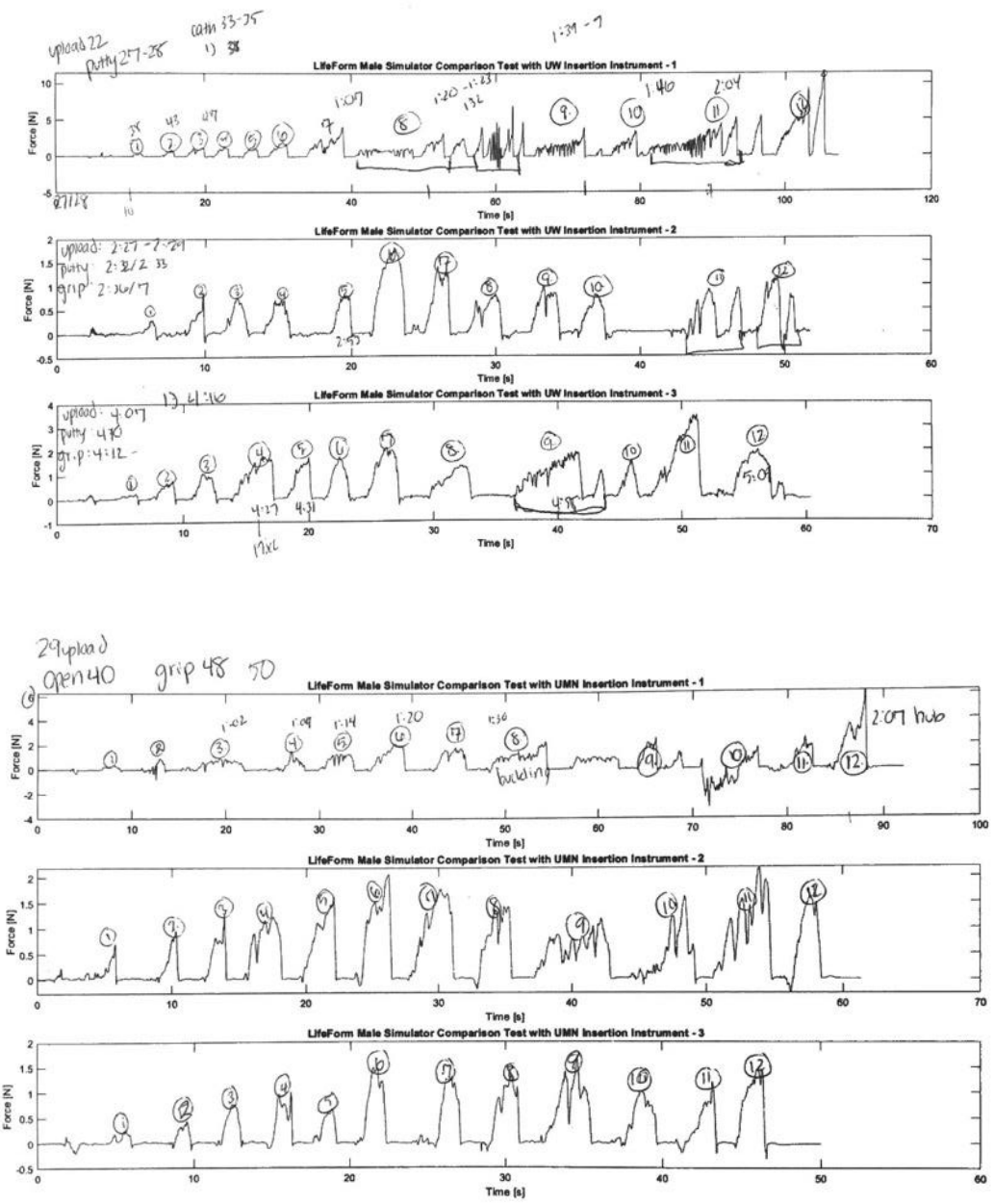


Figure K1: Raw data analysis of the Life/Form Male Study. Peaks are numbered according to which depth they correspond to.

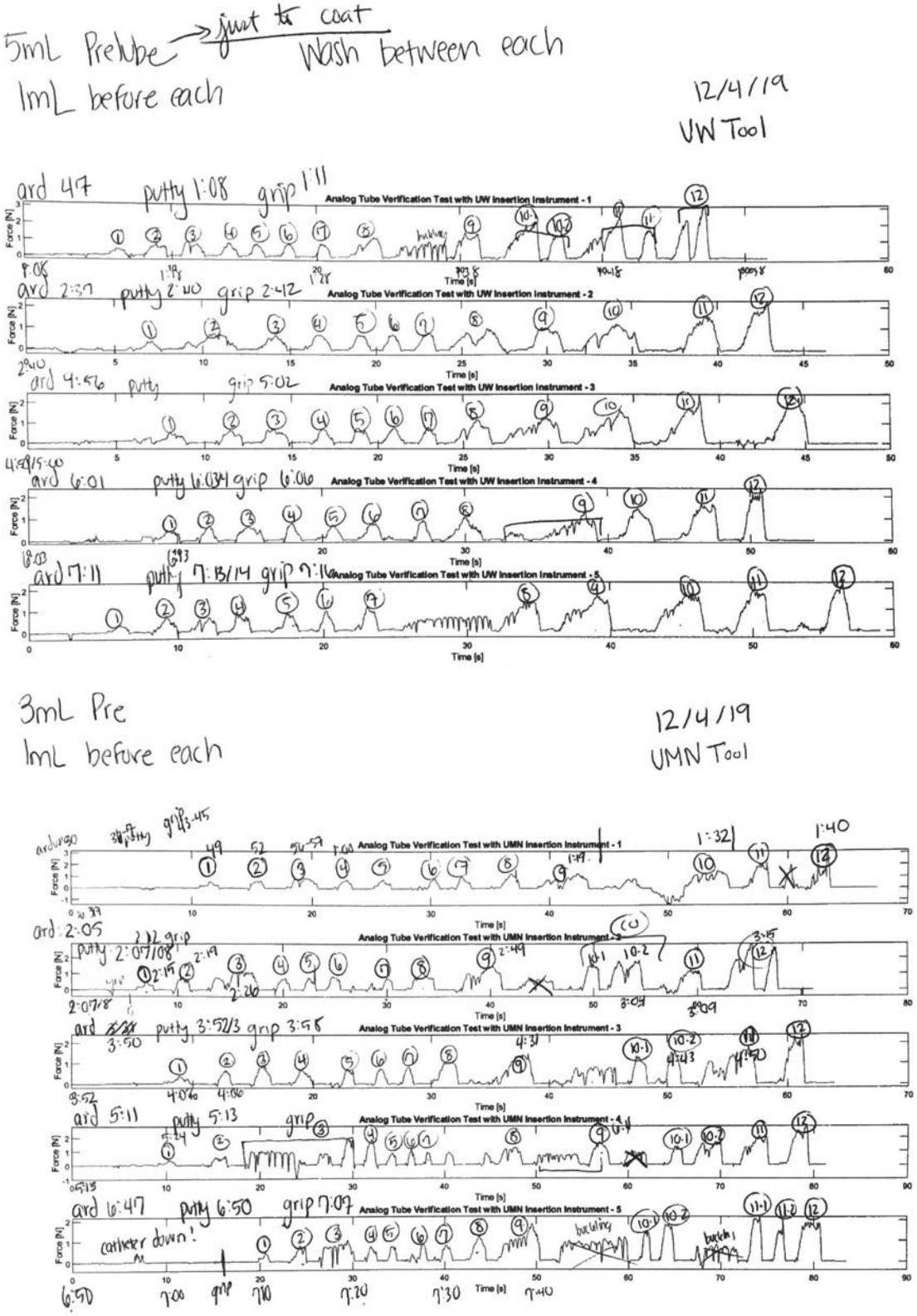


Figure K2: Raw data of analog tube collection. Numbering of the peaks to discern which peak represents which distance pushed.

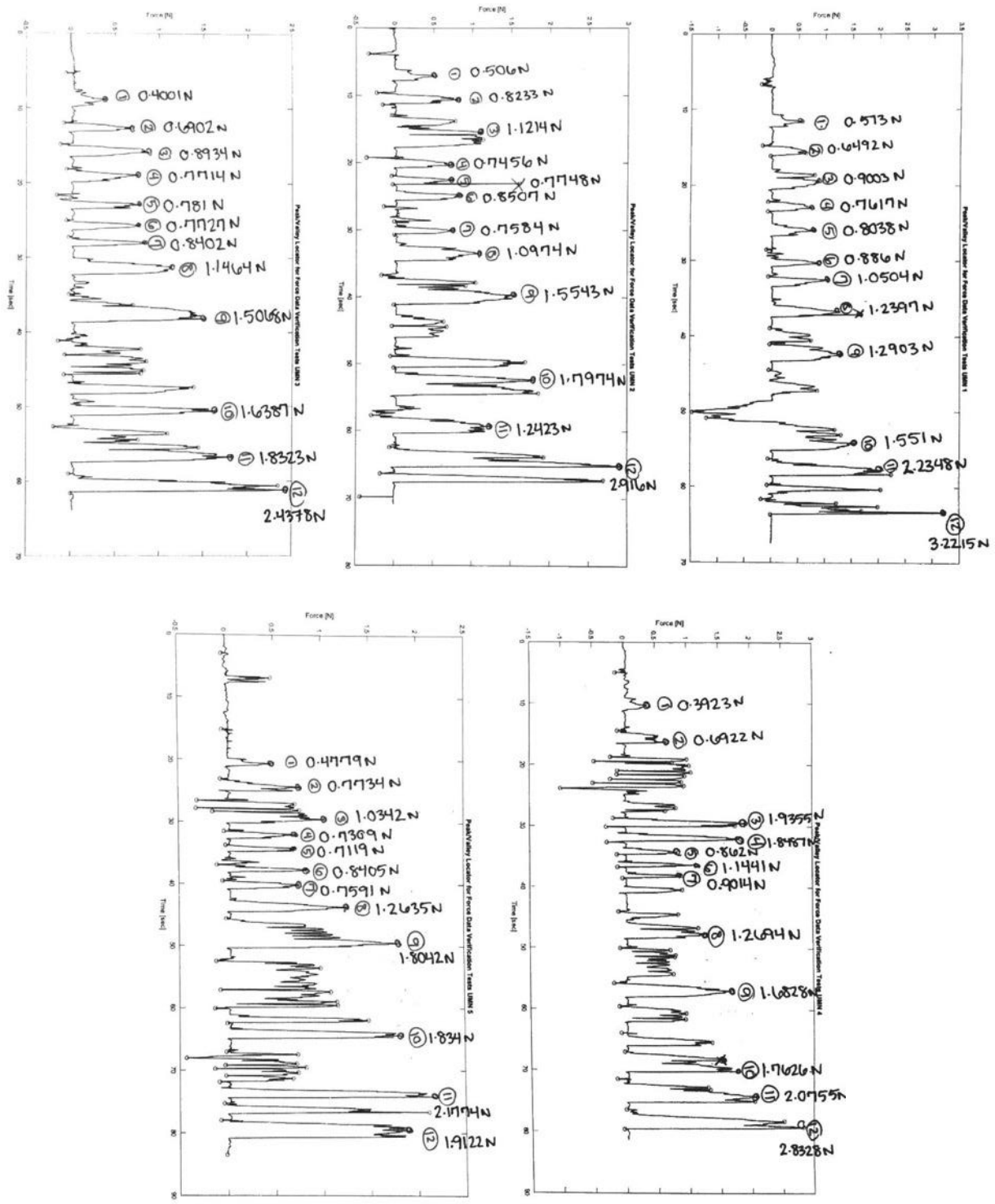


Figure K3: Force Peak Identification for the UMN instrument's 5 trials with the analog tube.

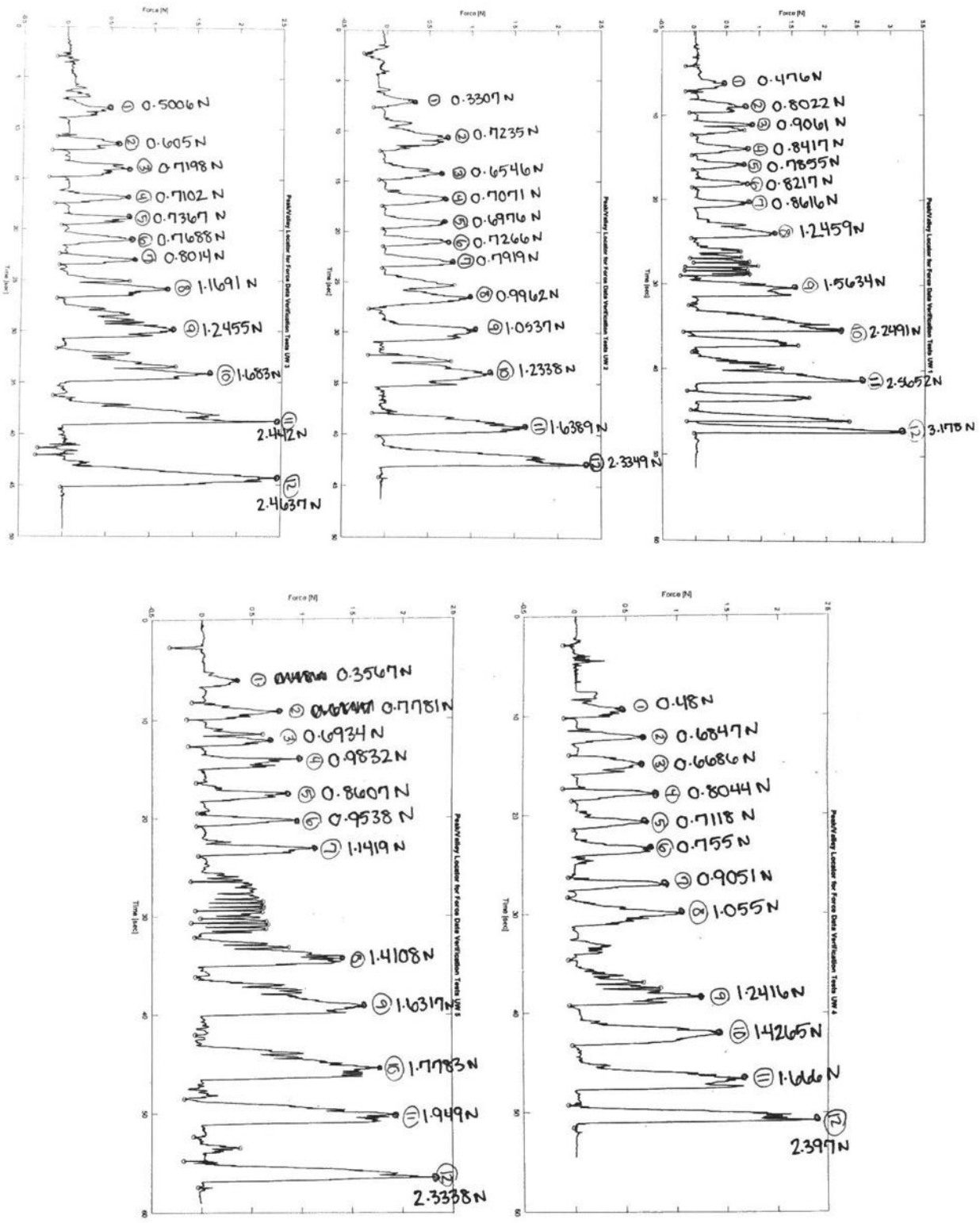


Figure K4: Force Peak Identification for the UW instrument's 5 trials with the analog tube.

APPENDIX L

Willed Body Urethral Catheterization Protocol

Study Team:
Alyssa Schul → Graduate Research Student
Jon Wingate M.D. – Urology Fellow → Research Physician 1
Rishi Sekar M.D. – Urology Resident R4 → Research Physician 2

DON'T EVER USE GLOVES ON COMPUTER

1.) Get called/texted/informed of donor from UW Willed Body
    a. Only able to go on days where Jon Wingate is working in CREST or WISH
    b. These days are:
2.) Arrive at Health Science Building
3.) Gather Insertion Items on HTDB Lab Cart
    a. See "Items to Bring to Study" Document
4.) Meet with Dr. and proceed to the Morgue together
5.) Arrive at the Morgue and discuss with Willed Body staff to be directed to the proper donor
6.) Set up cart of items
    a. Plug into power source
    b. Boot up computer
    c. Connect Data Processing box to Force Measurement Instrument
    d. Connect Data Processing box to Computer
7.) Collect donor info → Using "Willed Body Donor Worksheet" document
8.) Prepare Force Measurement Instrument
    a. Apply a Large Glove over the measurement instrument and secure down
    b. Connect microUSB cable to the Teensy board
    c. Place the measurement instrument in holder to calibrate
    d. Run calibration protocol for instrument
        i. Open Arduino program on computer
        ii. Open the HX711 Calibration Sketch
        iii. Using the 10g, 20g, and 50g weights calibrate each load cell
        iv. Run the sketch for the VClip Load Cell
            1. Record the calibration factor
        v. Run the sketch for the Flat-side Clip Load Cell
            1. Record the calibration factor
    e. Fill in the new calibration factors into HX711_Read_ALS file
    f. Upload sketch to ensure all components are plugged in and ready to capture
        i. Take note of what COM the process is running from
9.) Prepare donor
    a. Unwrap body from plastic if not already done
    b. Begin by removing the catheter if one is placed upon arrival
10.) Prepare Software on laptop for data collection
    a. Putty

i. Load ForceDataCollection – from saved sessions
ii. Ensure the proper COM is being used in the serial window
iii. Click Logging
    1. Choose save as
        a. Namefile : UWDonor#_m/f_Trial_# in the donor's folder
        b. Click save

********** Continue only if donor is prepped, and computer is ready **********
MALE PROTOCOL: Will Run the Test over 5 Conditions (first donor may be more based on data):

Condition 1: 2mL of Lubricant
Condition 2: 4mL of Lubricant
Condition 3: 6mL of Lubricant
Condition 4: 8mL of Lubricant
Condition 5: 10mL of Lubricant

11.) Prepare donor with first condition of lubricant
12.) Prepare the Research Physician to Insert Catheter
    a. Apply the Data Processing Box to the Research Physician's Arm
    b. Hand the Research Physician the Gloved Insertion Tool
    c. Provide the Research Physician with the catheter to be used
    d. Research Physician will orient around the donor
13.) Research Student will prepare to collect Data on computer + begin recording audio session of insertion
14.) When Research Physician is ready, he will verbalize ready to begin
    a. Holding insertion tool in a neutral position for the motion to zero out load cells
15.) The Research Student will then verbalize "OK, collection Begins"
    a. Student will begin to collect force data
16.) The Research Physician will begin to insert the catheter
17.) The research student will move to access the donor, and have a sharpie for marking the catheter as it is being placed after each push and before the regripping of the catheter.
    a. Verbalize any issues, things to note during insertion
    b. VERBALIZE a count of the number of regrips on the catheter (HELPS TO PROCESS)
18.) The Research Physician will finish inserting the catheter and verbalize completion to Research Student
19.) Research Student will stop collecting data on Putty
20.) Research physician will then begin to remove catheter
21.) Research Student will prepare for next data collection
    a. Wipe the catheter clean with a towel/chuck
    b. Change glove for the insertion device
    c. Rename the putty Save file to trial # 2
22.) Prepare for Condition_2
    a. Insert another 2mL of Lubricant into Urethra (assumption the lubrication will be additive)

    b. Re-equip the Force Measurement Instrument to Research Physician

23.) Research Physician signals to Research Student they are ready
24.) Research Student verbalizes force data are being collected
25.) Collect data until Research Physician Signals completion
    a. The research physician will be using the same marked catheter as before and following the insertion schematic of the markings to replicate as close to the same insertion as the initial insertion.
26.) Stop collection on computer programs
27.) Research Student will set up data files for next Condition
28.) Repeat steps 21-30 for Conditions 3 – 5
29.) At the end of condition 5, Inflate the balloon in the bladder of the male donor
    a. Pull balloon until it sits taut
    b. Then mark the catheter at the tip of the penis signifying the length of the urethra from the bottom of the balloon to the exterior of the body.
    c. Write down value on the study worksheet
30.) Collect Biohazard items (3bags)
    a. Catheter in its own bag
    b. Other item syringes, gloves, chucks, plastic bag
    c. Bag for cables and tong device
31.) Save all data, upload to google drive
32.) Unplug from Power source
33.) Grab any other remaining items
34.) Tell Willed Body team the study is completed
35.) Take cart up to CREST
36.) Dispose of Biohazard Bag
37.) Clean Force Measurement Tool and Cables with Cavicide Wipes
38.) Measure catheter used during the study to acquire the distance information travelled for each push on to study worksheet.
39.) Restock used items in prepped insertion box

APPENDIX M

FEMALE PROTOCOL: Run over 1 lubrication condition of dipping the pre-marked catheter into 5mL of lubricant then inserting the catheter until the marks are reached.

1.) Prepare pre-marked catheter prior to coming to Willed Body
2.) Prepare Donor and catheter with lubrication on the Chuck
3.) Prepare the Research Physician to Insert Catheter
    a. Apply the Data Processing Box to the Research Physician's Arm
    b. Hand the Research Physician the Gloved Insertion Tool
    c. Provide the Research Physician with the catheter to be used
    d. Research Physician will orient around the donor
4.) Research Student will prepare to collect Data on computer + begin recording audio session of insertion
5.) When Research Physician is ready, he will verbalize ready to begin
    a. Holding insertion tool in a neutral position for the motion to zero out load cells
6.) The Research Student will then verbalize "OK, collection Begins"
    a. Student will begin to collect force data
7.) The Research Physician will begin to insert the catheter following the separations predetermined on the catheter.
    a. Verbalize any issues, things to note during insertion
    b. VERBALIZE a count of the number of regrips on the catheter (HELPS TO PROCESS)
8.) The Research Physician will finish inserting the catheter and verbalize completion to Research Student
9.) Research Student will stop collecting data on Putty → turn off voice memo recording
10.) Research physician will then inflate the balloon in the bladder and pull taut
11.) Research student will mark the exterior of the catheter to measure the length of the urethra.
    a. When catheter is taken to be measured in lab – write the length on the study worksheet
12.) Research physician will deflate the catheter balloon and remove the catheter.
13.) Collect Biohazard items (3bags)
    a. Catheter in its own bag
    b. Other item syringes, gloves, chucks, plastic bag
    c. Bag for cables and tong device
14.) Save all data, upload to google drive
15.) Unplug from Power source
16.) Grab any other remaining items
17.) Tell Willed Body team the study is completed
18.) Take cart up to CREST
19.) Dispose of Biohazard Bag
20.) Clean Force Measurement Tool and Cables with Cavicide Wipes

21.) Measure catheter used during the study to acquire the distance information travelled for each push on to study worksheet.

22.) Restock used items in prepped insertion box

APPENDIX N

Version 2 –11/22/19
DONOR #: _____
Physician ID : _____

RETURN TO ALYSSA SCHUL
At CREST Lab in HSB T-293 if found

2019/2020 – UW Willed Body Catheter Insertion Study Worksheet

Donor Age: _____ **Donor Sex:** _____

Donor Day of Death: _____ **Day of Study:** _____

Donor History (if known): _____

_____

Foley Size (in Fr): _____ **Catheter Present at Death?:** _____

Urethral Length (mm): _____ **Catheter Type Used:** _____

Conditions for Males:
Condition 1 → 2 mL
Condition 2 → 4 mL
Condition 3 → 6 mL
Condition 4 → 8 mL total
Condition 5 → 10 mL total
File Path : HTDB → Projects → 2019-2020 Master's → Data → UW_Donor_

Calibration Factors **V-Side LC:**_____ **Flat-Side LC:**_____

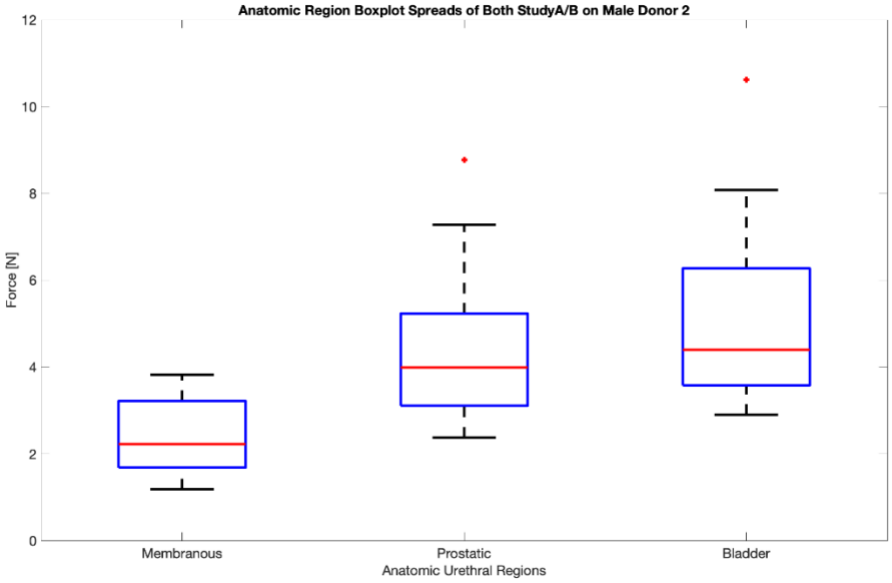
Audio Recording? Y or N **Uploaded?** Y or N

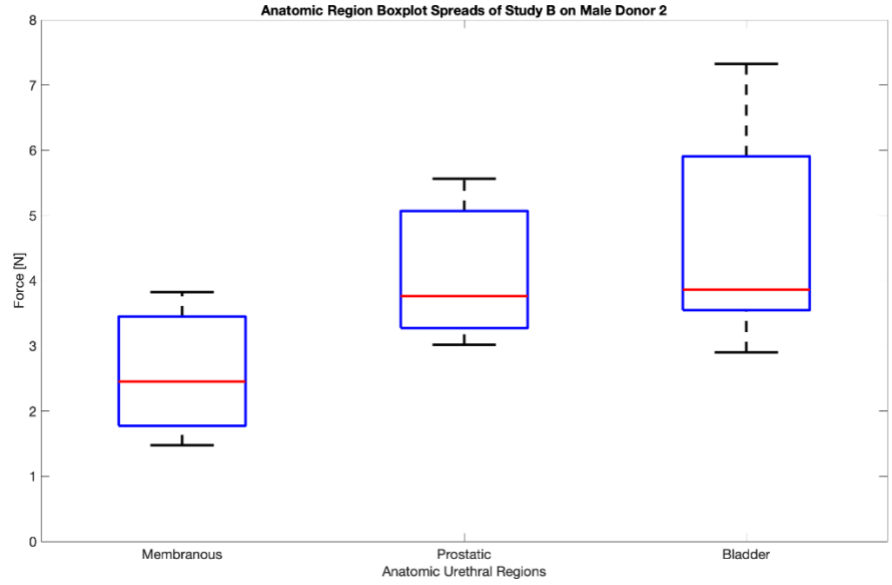
Notes:

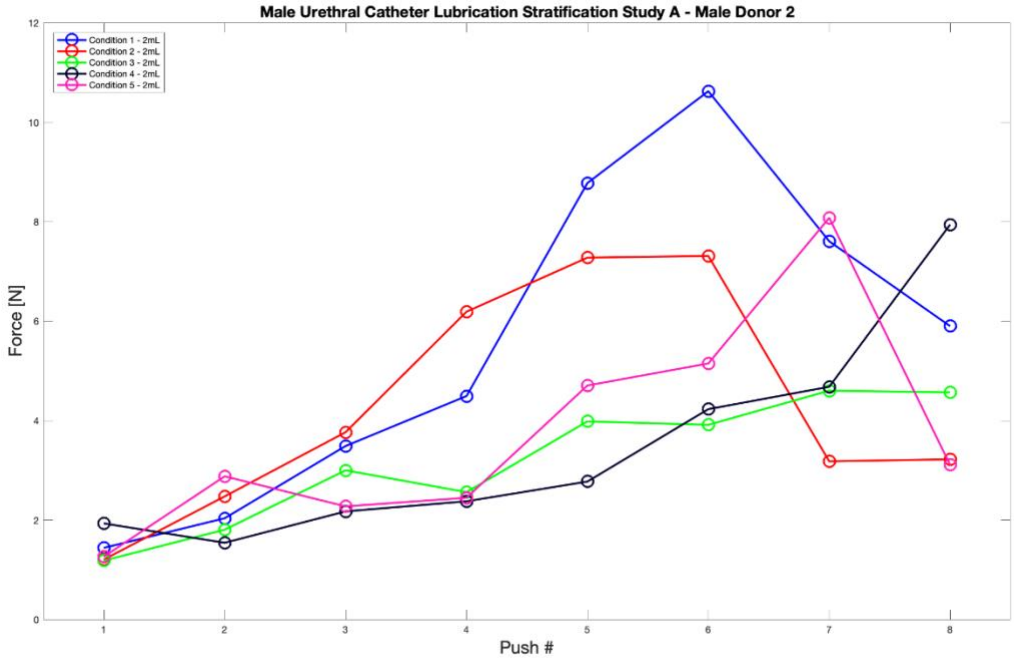
Figure N1: Donor Collection Worksheet template.

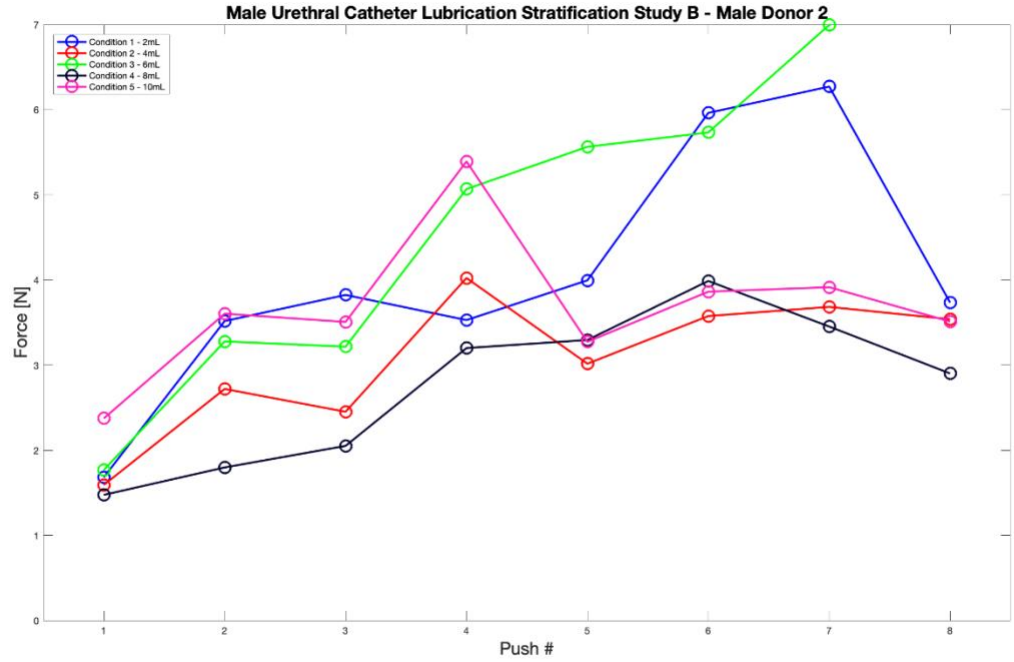
APPENDIX O

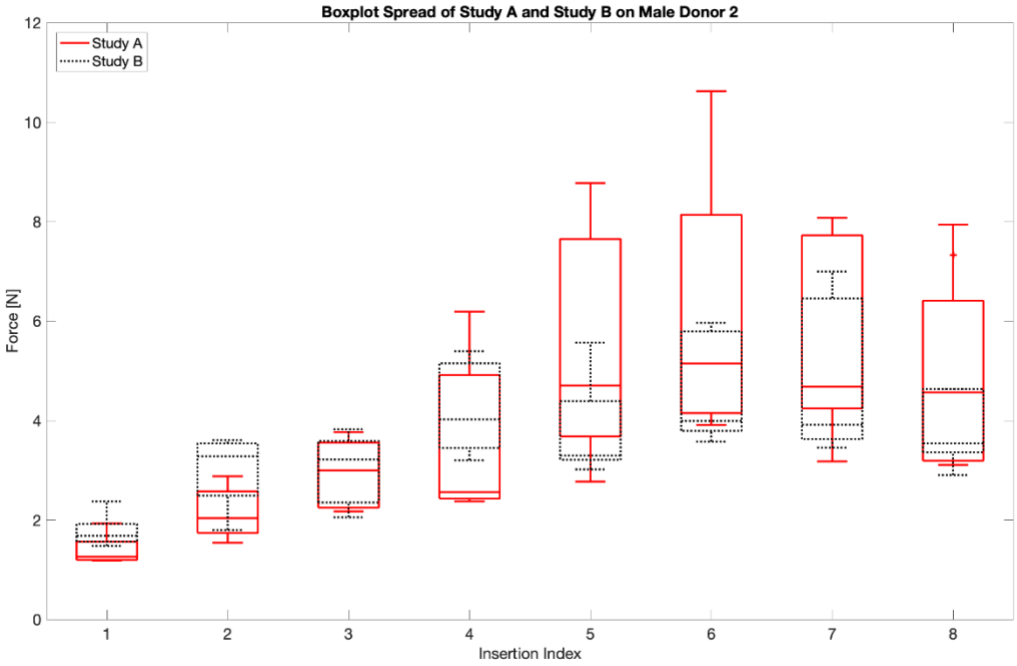
Donor 2

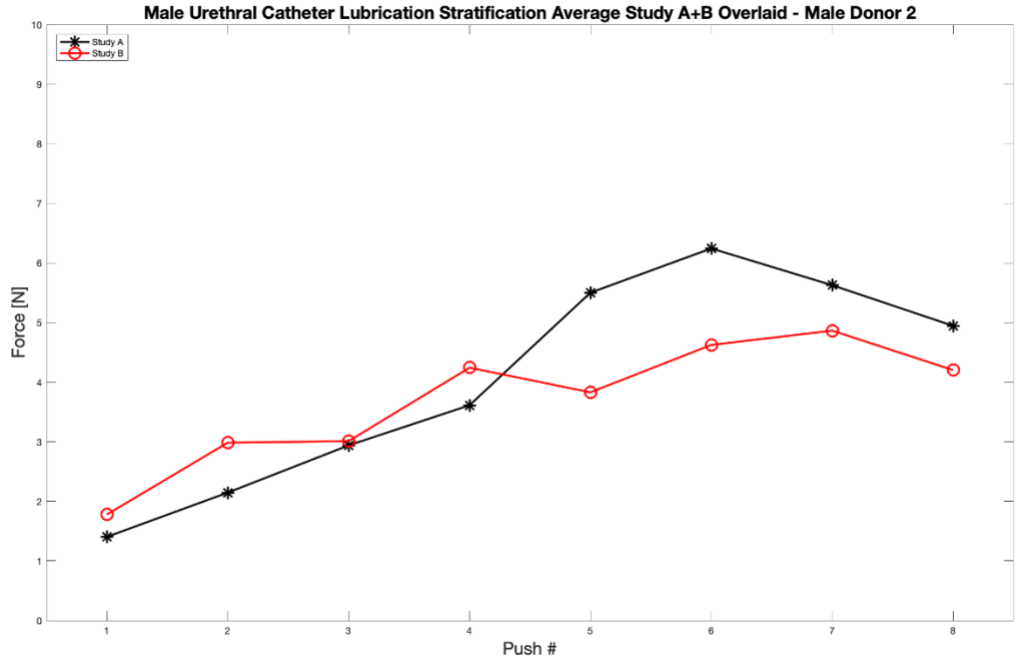


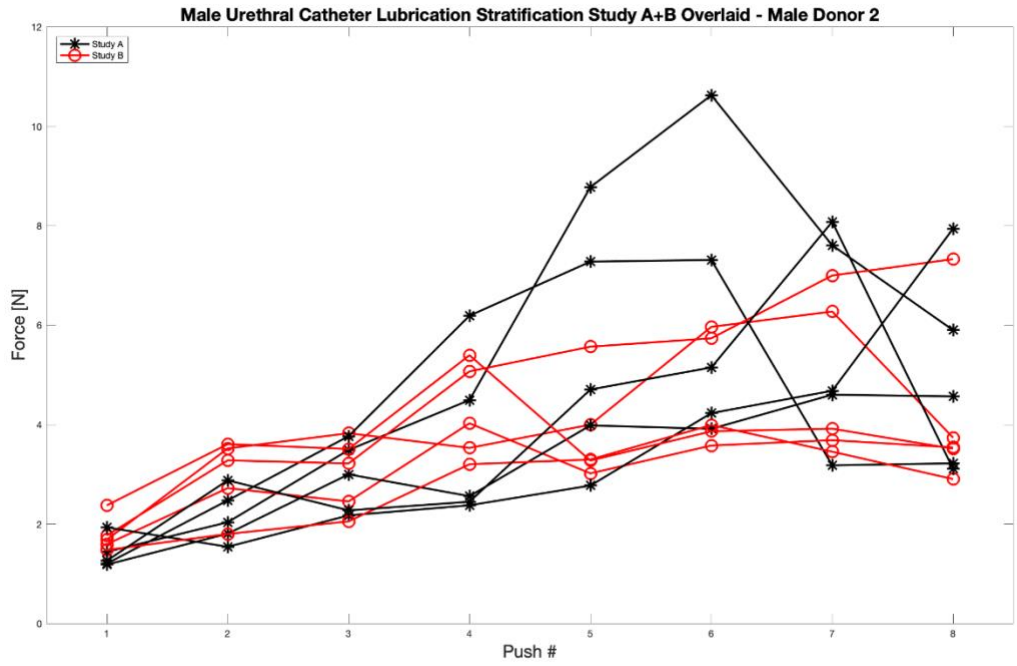



Male Urethral Catheter Lubrication Stratification Study A - Male Donor 2
Condition 1 - 2mL
Condition 2 - 2mL
Condition 3 - 2mL
Condition 4 - 2mL
Condition 5 - 2mL
Force [N]
Push #


Male Urethral Catheter Lubrication Stratification Study B - Male Donor 2
Condition 1 - 2mL
Condition 2 - 4mL
Condition 3 - 6mL
Condition 4 - 8mL
Condition 5 - 10mL
Force [N]
Push #


Boxplot Spread of Study A and Study B on Male Donor 2
Study A
Study B
Force [N]
Insertion Index
0
2
4
6
8
10
12
1
2
3
4
5
6
7
8


Male Urethral Catheter Lubrication Stratification Average Study A+B Overlaid - Male Donor 2
Study A
Study B
Force [N]
Push #
0
1
2
3
4
5
6
7
8
9
10
1
2
3
4
5
6
7
8



Insertion #	Measured	Running Total(mm)	
1	73.04	73.04	
2	32.91	105.95	
3	70.22	176.17	
4	43.99	220.16	
5	34	254.16	
6	46.7	300.86	
7	26.79	327.65	
8	20.06	347.71	Total Catheter Placed
Urethra Length	34	247.6	24.7 cm long urethra tip to bladder
Measurement from tip to end balloon	40.56		

Version 2 –11/22/19
DONOR #: 2M2
Physician ID : 2

RETURN TO ALYSSA SCHUL
At CREST Lab in HSB T-293 if found

2019/2020 – UW Willed Body Catheter Insertion Study Worksheet

Donor Age: 72 **Donor Sex:** M

Donor Day of Death: 1/18/20 **Day of Study:** 1/20/20

Donor History (if known): Intestinal bleed

Foley Size (in Fr): 16Fr **Catheter Present at Death?:** N

Urethral Length (~~mm~~): 24.7cm **Catheter Type Used:** BardEx Silicone 16 Fr

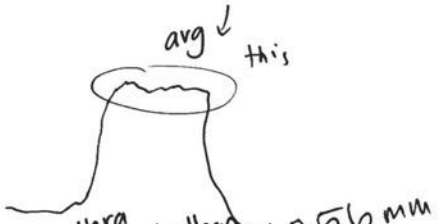
Conditions for Males:
Condition 1 → 2 mL
Condition 2 → 4 mL
Condition 3 → 6 mL
Condition 4 → 8 mL total
Condition 5 → 10 mL total
File Path : HTDB → Projects → 2019-2020 Master's → Data → Male Donors → UW_Donor_2

Calibration Factors V-Side LC: -1030000 **Flat-Side LC:** -960000

Audio Recording? (Y) or N **Uploaded?** (Y) or N

Notes: Study A – 2,2,2,2,2 Study B – 2,4,6,8,10

hard issue w/ hitting had @ end
↳ avg force peak.

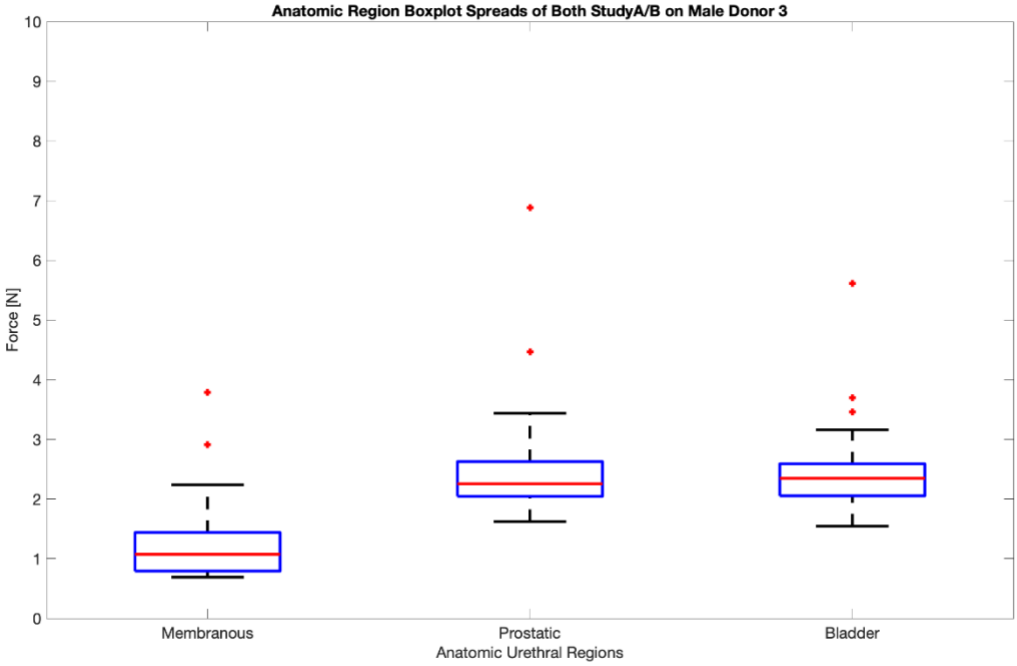


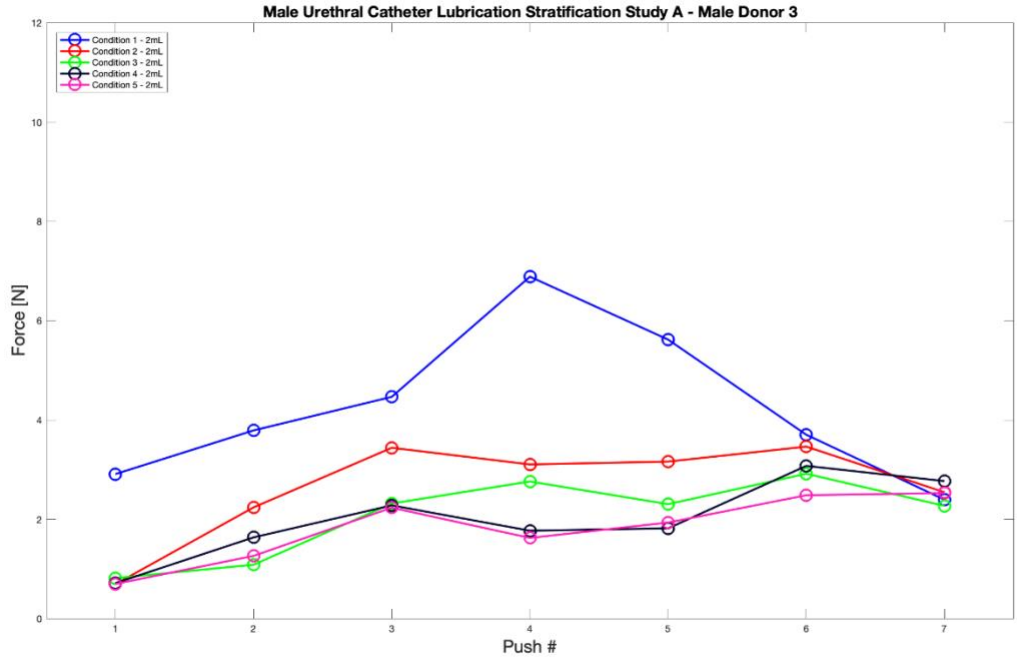
Lengths : based on marks

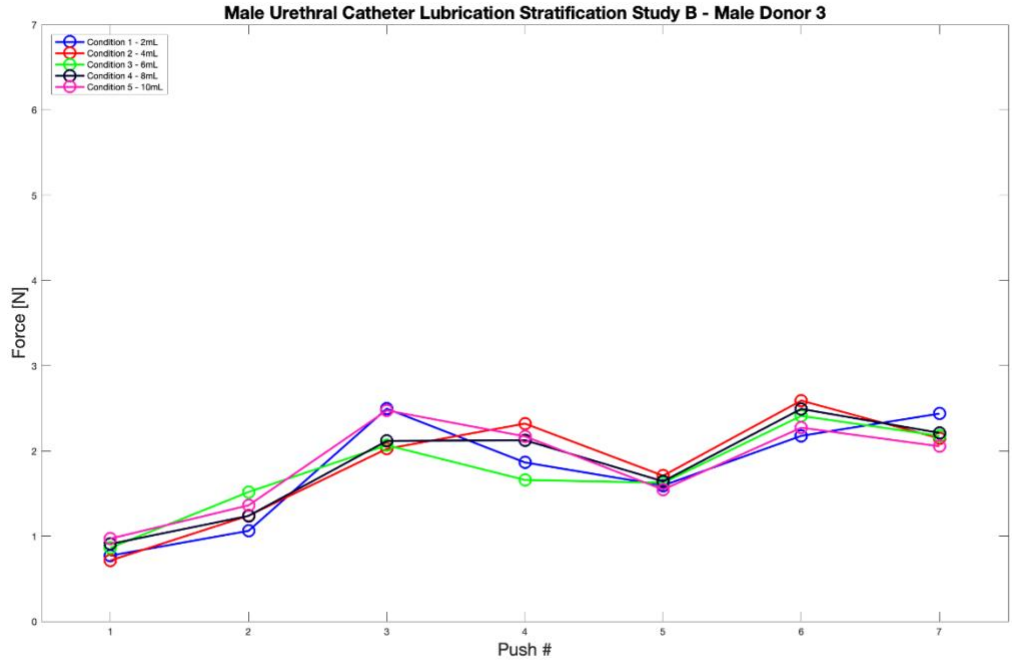
	1	2	3	4	5	6	7	8
Mean	73.04	32.91	10.72	43.99	34	46.7	26.79	20.06

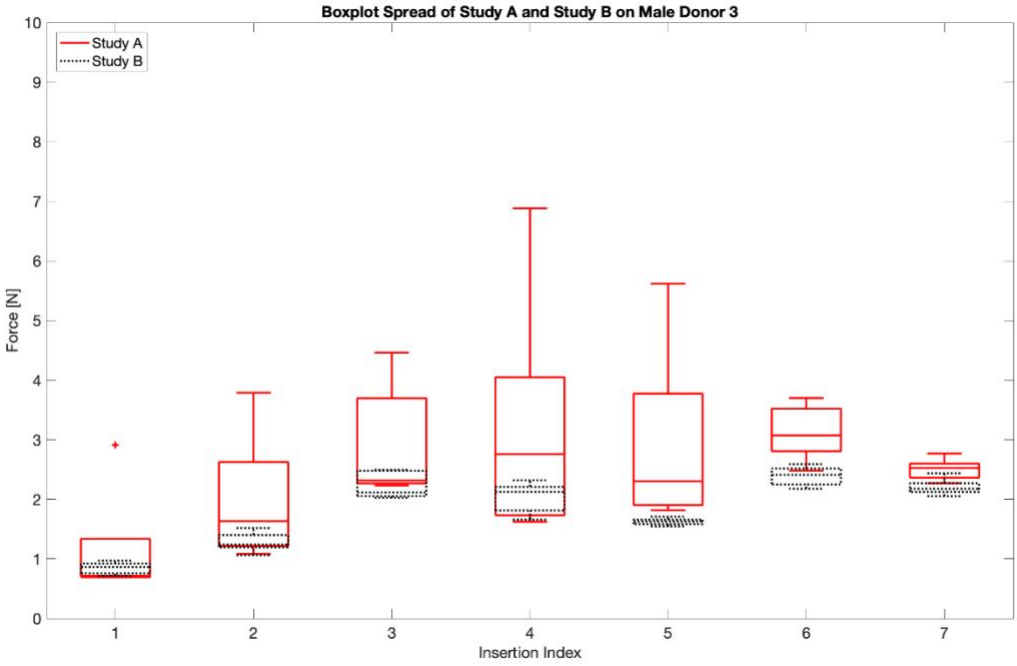
total saved in file as excel : ↳ Prostatic Pushes

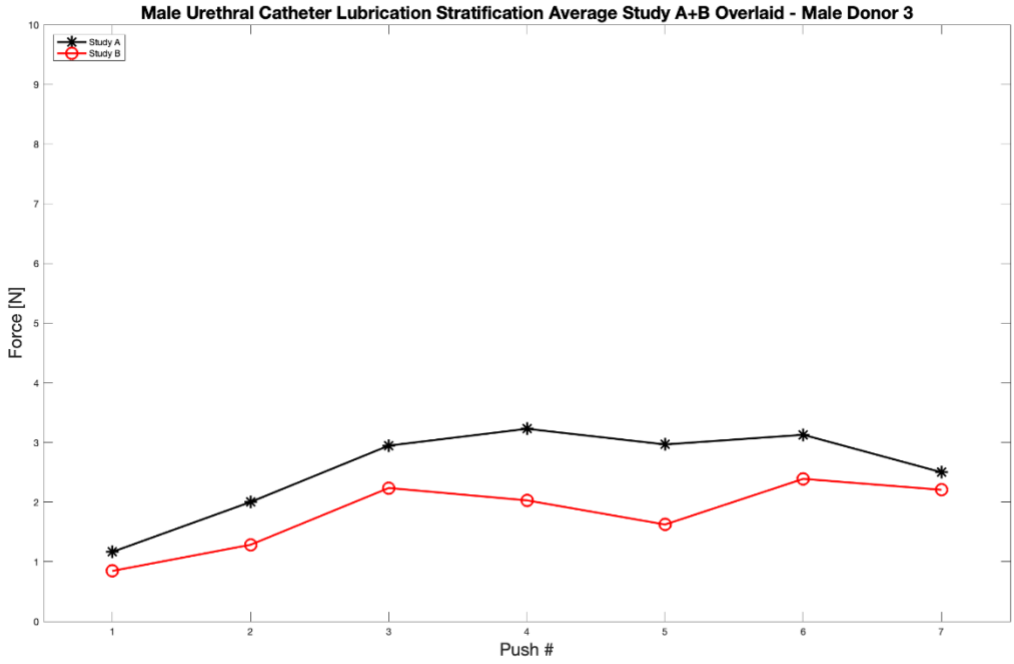
Donor 3

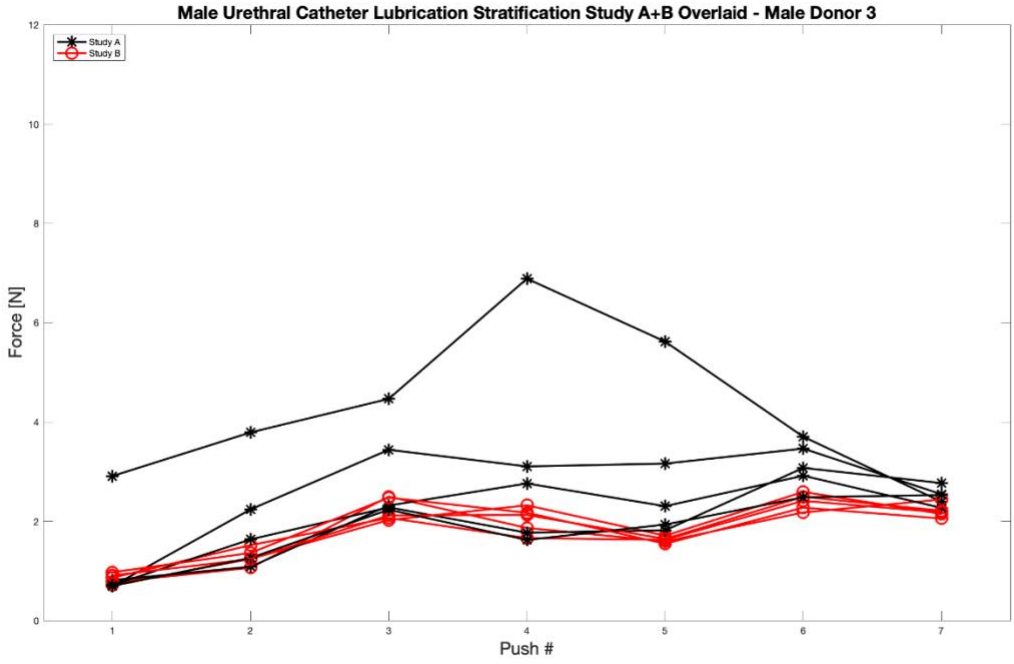

Anatomic Region Boxplot Spreads of Both StudyA/B on Male Donor 3
Force [N]
Membranous
Prostatic
Bladder
Anatomic Urethral Regions


Male Urethral Catheter Lubrication Stratification Study A - Male Donor 3
Condition 1 - 2mL
Condition 2 - 2mL
Condition 3 - 2mL
Condition 4 - 2mL
Condition 5 - 2mL
Force [N]
Push #


Male Urethral Catheter Lubrication Stratification Study B - Male Donor 3
Condition 1 - 2mL
Condition 2 - 4mL
Condition 3 - 6mL
Condition 4 - 8mL
Condition 5 - 10mL
Force [N]
Push #


Boxplot Spread of Study A and Study B on Male Donor 3
Study A
Study B
Force [N]
Insertion Index


Male Urethral Catheter Lubrication Stratification Average Study A+B Overlaid - Male Donor 3
Study A
Study B
Force [N]
Push #


Male Urethral Catheter Lubrication Stratification Study A+B Overlaid - Male Donor 3
Study A
Study B
Force [N]
Push #

Insertion #	Measured	Running Total(mm)	
1	95.64	95.64	
2	55.53	151.17	
3	23.61	174.78	
4	44.31	219.09	
5	55.33	274.42	
6	49.41	323.83	
7	33.02	356.85	
Urethra Length	33.87	162.36	16.2 cm long urethra tip to bladder
Measurement from tip to end balloon	46.29		

Version 2 –11/22/19
DONOR #: 3M
Physician ID : 3

RETURN TO ALYSSA SCHUL
At CREST Lab in HSB T-293 if found

2019/2020 – UW Willed Body Catheter Insertion Study Worksheet

Donor Age: ~~80~~ 96 **Donor Sex:** M

Donor Day of Death: 1/25/20 **Day of Study:** 1/27/20

Donor History (if known): natural causes

Foley Size (in Fr): 16 Fr **Catheter Present at Death?:** N

Urethral Length (mm): 16.2 cm **Catheter Type Used:** 16 Fr Bardex Silicone

Conditions for Males:
Condition 1 → 2 mL
Condition 2 → 4 mL
Condition 3 → 6 mL
Condition 4 → 8 mL total
Condition 5 → 10 mL total
File Path : HTDB → Projects → 2019-2020 Master's → Data → UW_Donor_

Calibration Factors **V-Side LC:** -1030000 **Flat-Side LC:** -960000

Audio Recording? (Y) or N **Uploaded?** (Y) or N

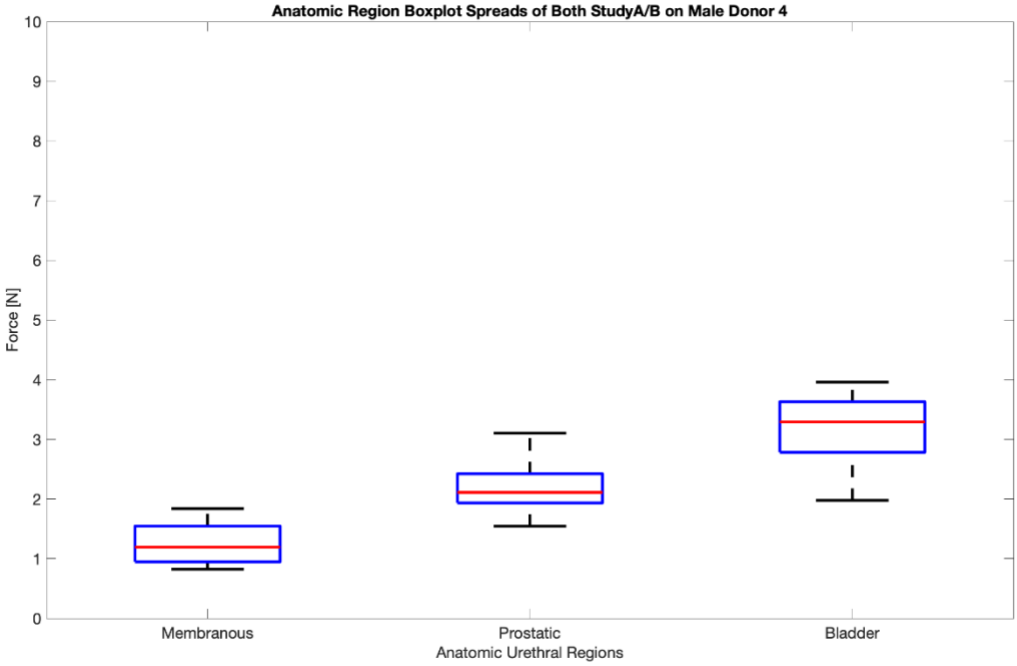
Notes:

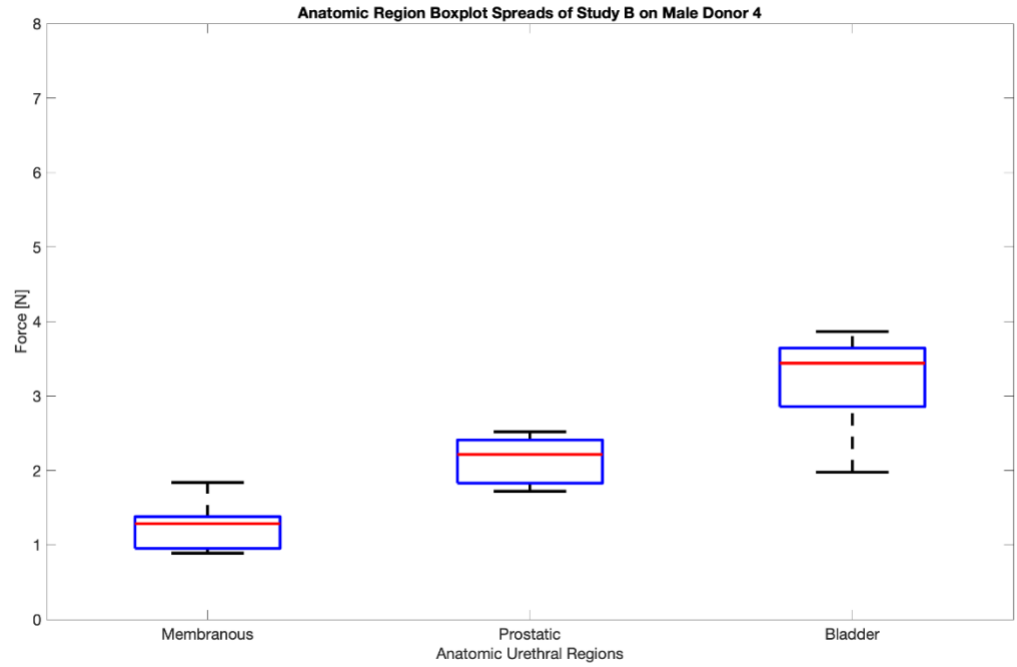
Lengths

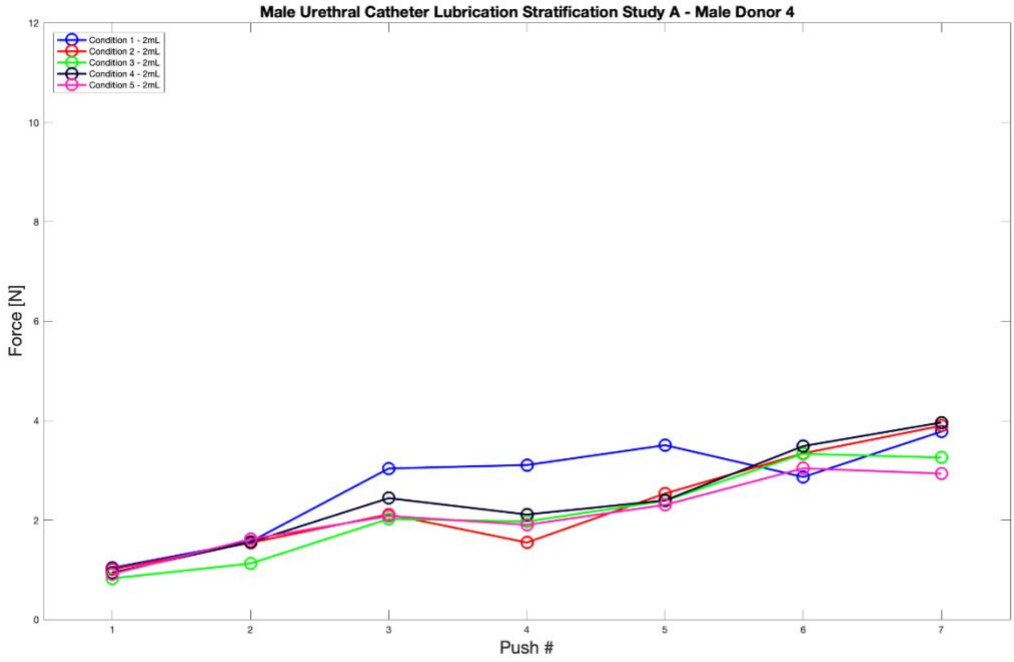
1. 95.64
2. 55.53
3. 23.61 → 33.87
4. 44.13
5. 55.33
6. ~~44.41~~ 49.41
7. 38.02

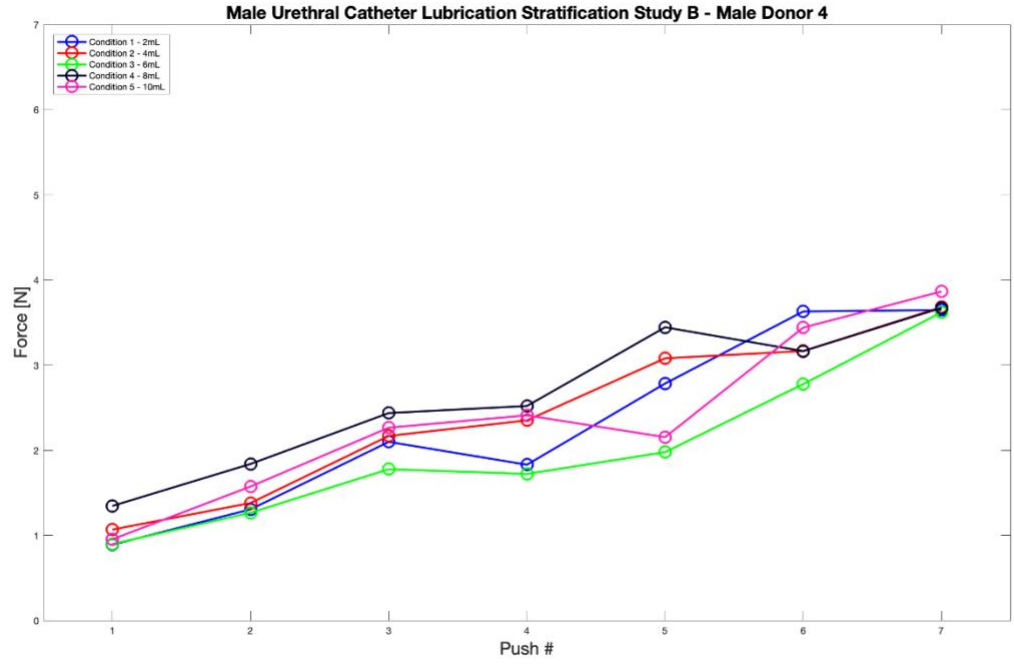
*. 46.29 ← balloon

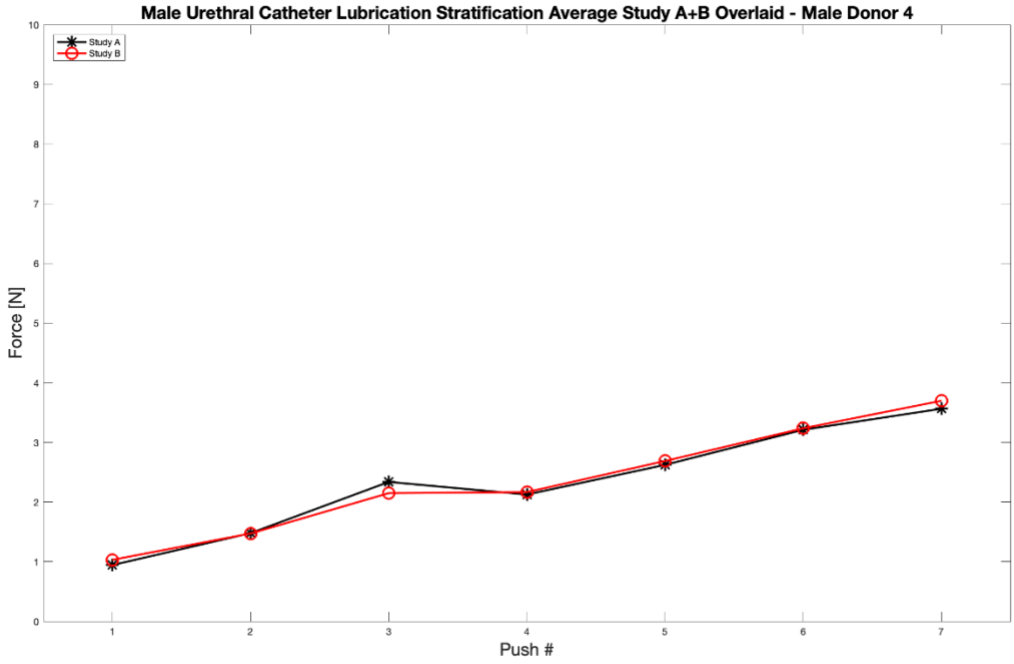
Donor 4

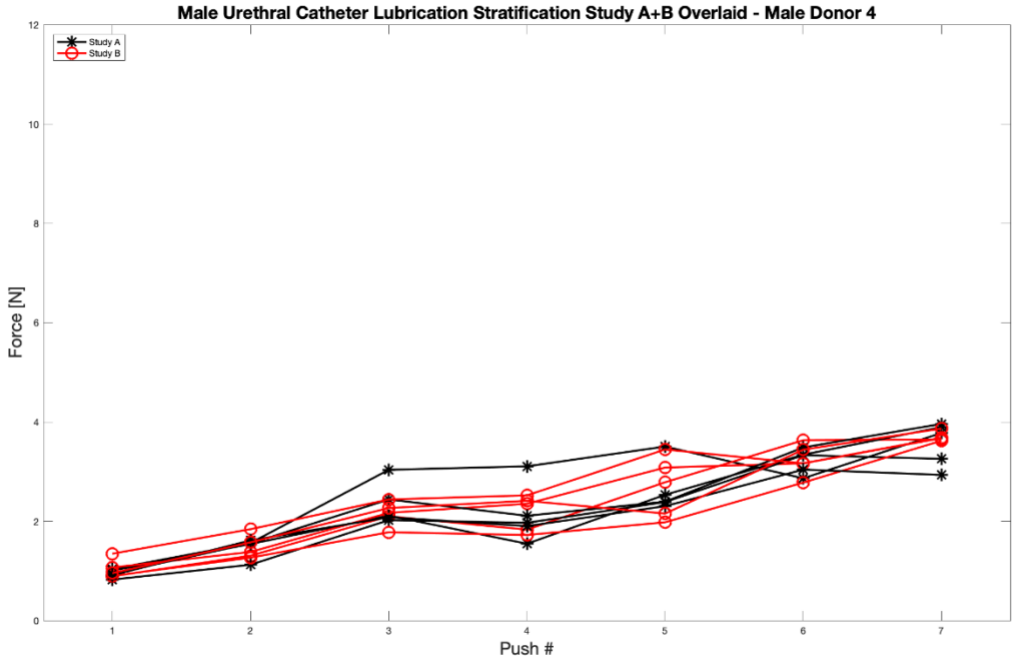

Anatomic Region Boxplot Spreads of Both StudyA/B on Male Donor 4
Force [N]
0
1
2
3
4
5
6
7
8
9
10
Membranous
Prostatic
Bladder
Anatomic Urethral Regions

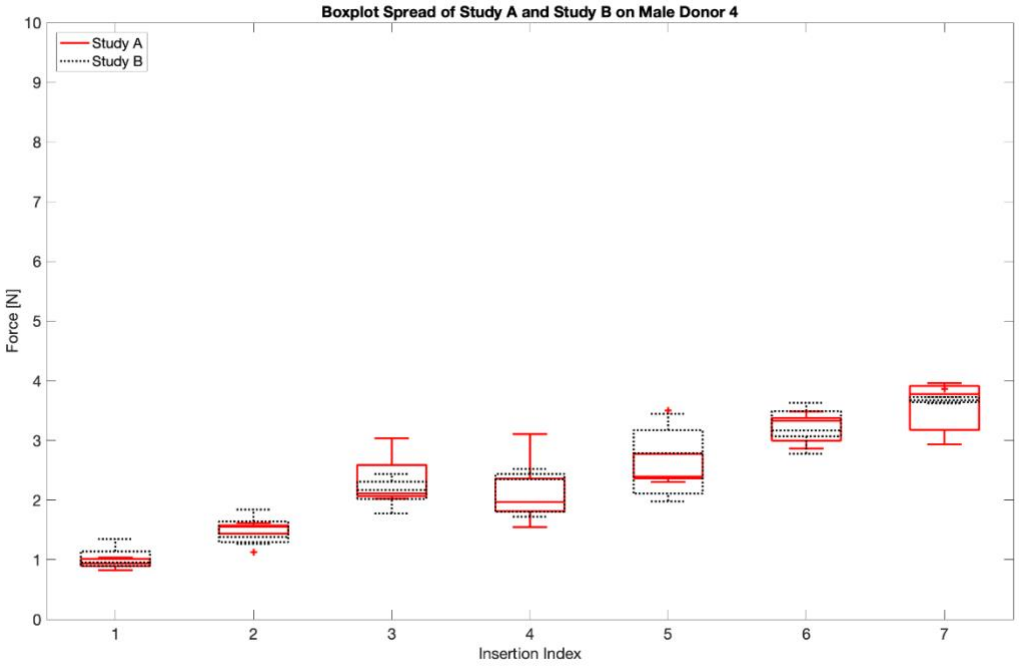

Anatomic Region Boxplot Spreads of Study B on Male Donor 4
Force [N]
0
1
2
3
4
5
6
7
8
Membranous
Prostatic
Bladder
Anatomic Urethral Regions


Male Urethral Catheter Lubrication Stratification Study A - Male Donor 4
Condition 1 - 2mL
Condition 2 - 2mL
Condition 3 - 2mL
Condition 4 - 2mL
Condition 5 - 2mL
Force [N]
Push #


Male Urethral Catheter Lubrication Stratification Study B - Male Donor 4
Condition 1 - 2mL
Condition 2 - 4mL
Condition 3 - 6mL
Condition 4 - 8mL
Condition 5 - 10mL
Force [N]
Push #


Male Urethral Catheter Lubrication Stratification Average Study A+B Overlaid - Male Donor 4
Study A
Study B
Force [N]
Push #


Male Urethral Catheter Lubrication Stratification Study A+B Overlaid - Male Donor 4
Study A
Study B
Force [N]
Push #



Insertion #	Measured	Running Total(mm)	
1	93.4	93.4	
2	61.82	155.22	
3	49.9	205.12	
4	27.15	232.27	
5	46.61	278.88	
6	29.9	308.78	
7	53.88	362.66	
Urethra Length	17.38	175.11	17.5 cm long urethra tip to bladder
Measurement from tip to end balloon	47.39		

Version 2 –11/22/19
DONOR #: 4M
Physician ID : 3

RETURN TO ALYSSA SCHUL
At CREST Lab in HSB T-293 if found

2019/2020 – UW Willed Body Catheter Insertion Study Worksheet

Donor Age: ~~80~~ 86 **Donor Sex:** M

Donor Day of Death: 1/25/2020 **Day of Study:** 1/27/20

Donor History (if known): COPD

Foley Size (in Fr): 16Fr **Catheter Present at Death?:** N

Urethral Length (mm): 17.5cm **Catheter Type Used:** 16 Fr Bardex Silicone

Conditions for Males:
Condition 1 → 2 mL
Condition 2 → 4 mL
Condition 3 → 6 mL
Condition 4 → 8 mL total
Condition 5 → 10 mL total
File Path : HTDB → Projects → 2019-2020 Master's → Data → UW_Donor_

Calibration Factors **V-Side LC:** -1030000 **Flat-Side LC:** -960000

Audio Recording? (Y) or N **Uploaded?** (Y) or N

Notes:

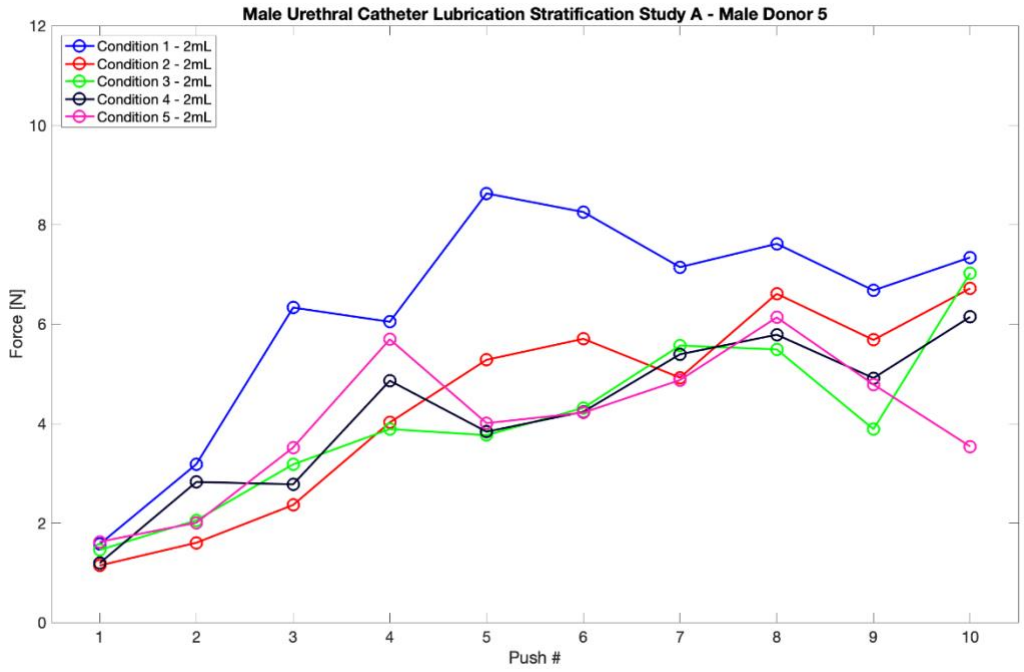
Length

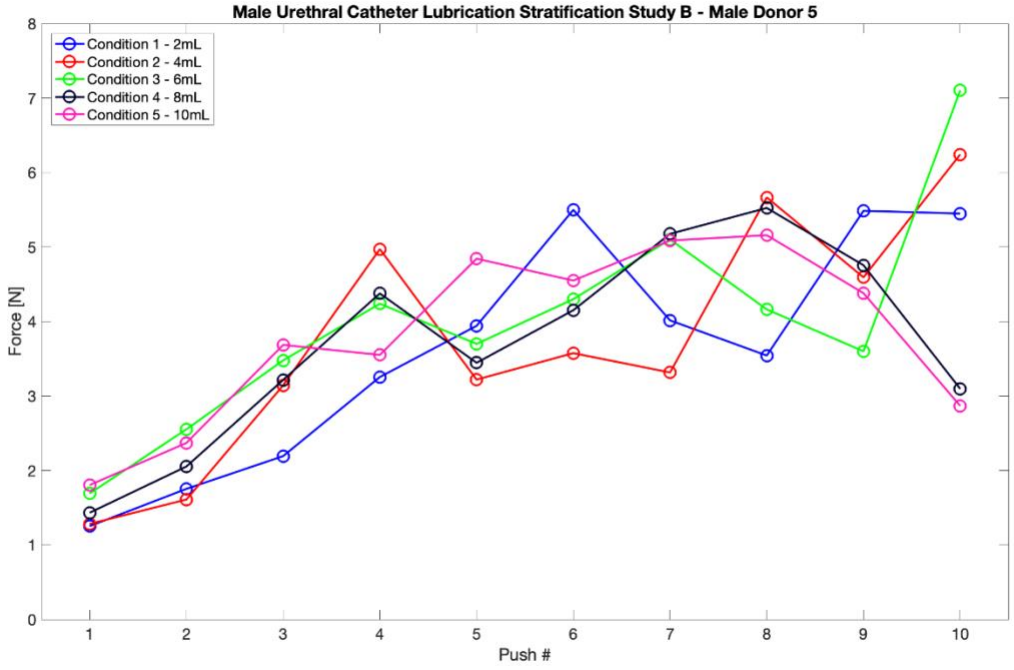
1. 93.40 + measure to urethral length
2. 61.82
3. 49.9 → 17.38
4. 27.15
5. 46.61
6. 29.90
7. 53.88

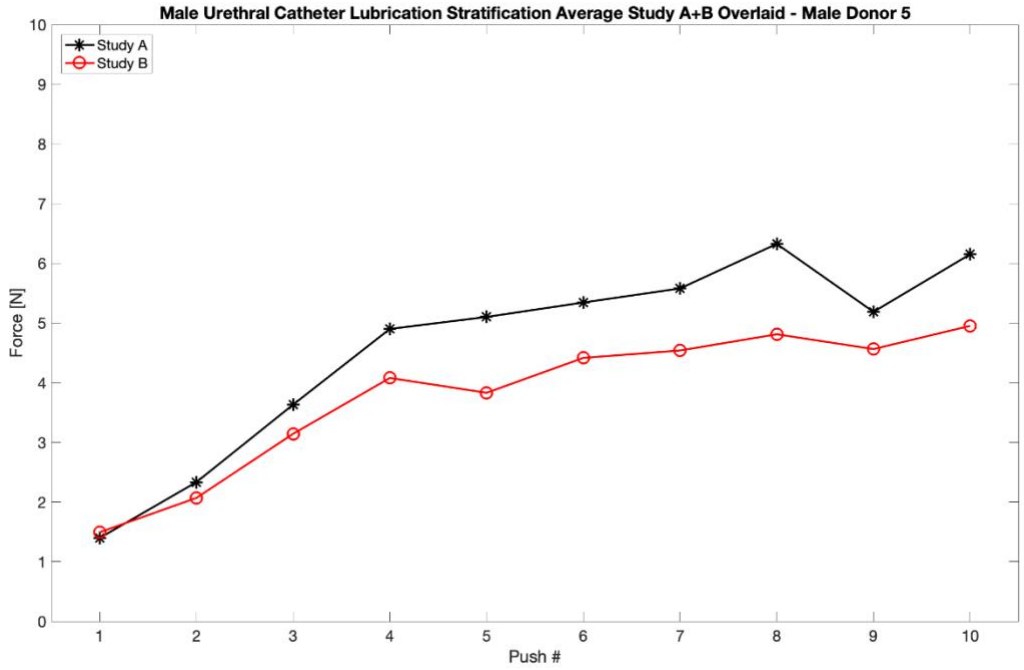
*. 47.89
rubber band on bag

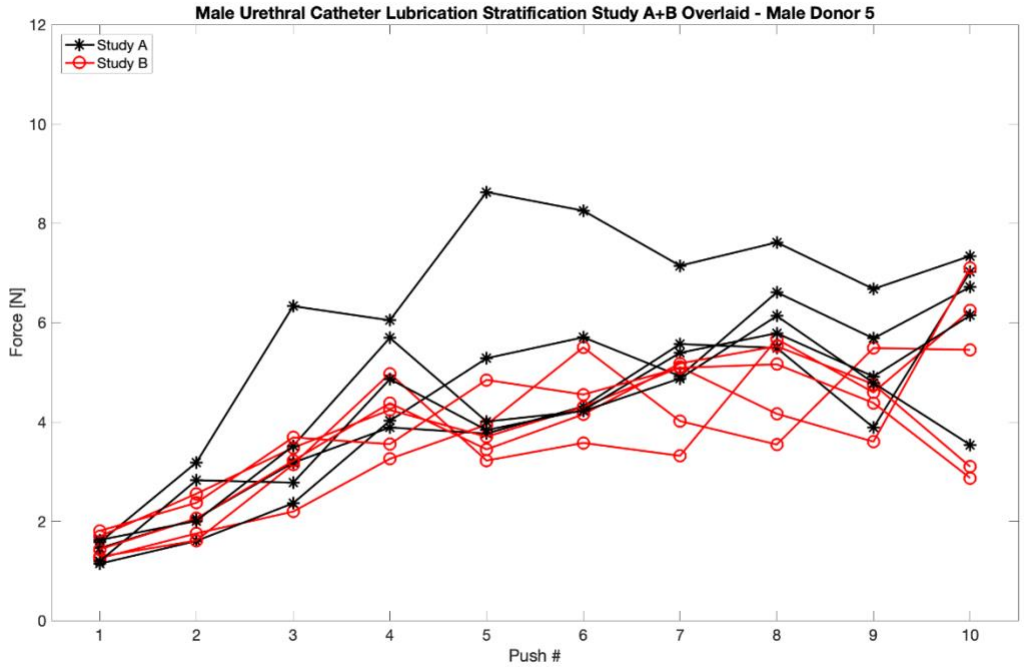
3/ push 4 was prostate

Donor 5


Male Urethral Catheter Lubrication Stratification Study A - Male Donor 5
Condition 1 - 2mL
Condition 2 - 2mL
Condition 3 - 2mL
Condition 4 - 2mL
Condition 5 - 2mL
Force [N]
Push #


Male Urethral Catheter Lubrication Stratification Study B - Male Donor 5
Condition 1 - 2mL
Condition 2 - 4mL
Condition 3 - 6mL
Condition 4 - 8mL
Condition 5 - 10mL
Force [N]
Push #


Male Urethral Catheter Lubrication Stratification Average Study A+B Overlaid - Male Donor 5
Study A
Study B
Force [N]
Push #
0
1
2
3
4
5
6
7
8
9
10


Male Urethral Catheter Lubrication Stratification Study A+B Overlaid - Male Donor 5
Study A
Study B
Force [N]
Push #
0
2
4
6
8
10
12
1
2
3
4
5
6
7
8
9
10

Insertion #	Measured	Running Total(mm)	
1	70.7	70.7	
2	72.5	143.2	
3	57.87	201.07	
4	30.94	232.01	
5	40.83	272.84	
6	22.09	294.93	
7	13.3	308.23	
8	9.3	317.53	
9	12.7	330.23	
10	35.35	365.58	
Urethra Length	5.01	162.78	16.8 cm long urethra tip to bladder
Measurement from tip to end balloon	43.3		

Version 2 –11/22/19
DONOR #: 5M
Physician ID : 1

RETURN TO ALYSSA SCHUL
At CREST Lab in HSB T-293 if found

2019/2020 – UW Willed Body Catheter Insertion Study Worksheet

Donor Age: 89 **Donor Sex:** M

Donor Day of Death: 2/3/20 **Day of Study:** 2/4/20

Donor History (if known): prostate cancer

Foley Size (in Fr): 16 **Catheter Present at Death?:** N

Urethral Length (mm): ~~[illegible]~~ 16.8cm **Catheter Type Used:** 16Fr Bard Ex

Conditions for Males:
Condition 1 → 2 mL
Condition 2 → 4 mL
Condition 3 → 6 mL
Condition 4 → 8 mL total
Condition 5 → 10 mL total
File Path : HTDB → Projects → 2019-2020 Master's → Data → UW_Donor_Male_5

Calibration Factors **V-Side LC:** -1030000 **Flat-Side LC:** -960,000

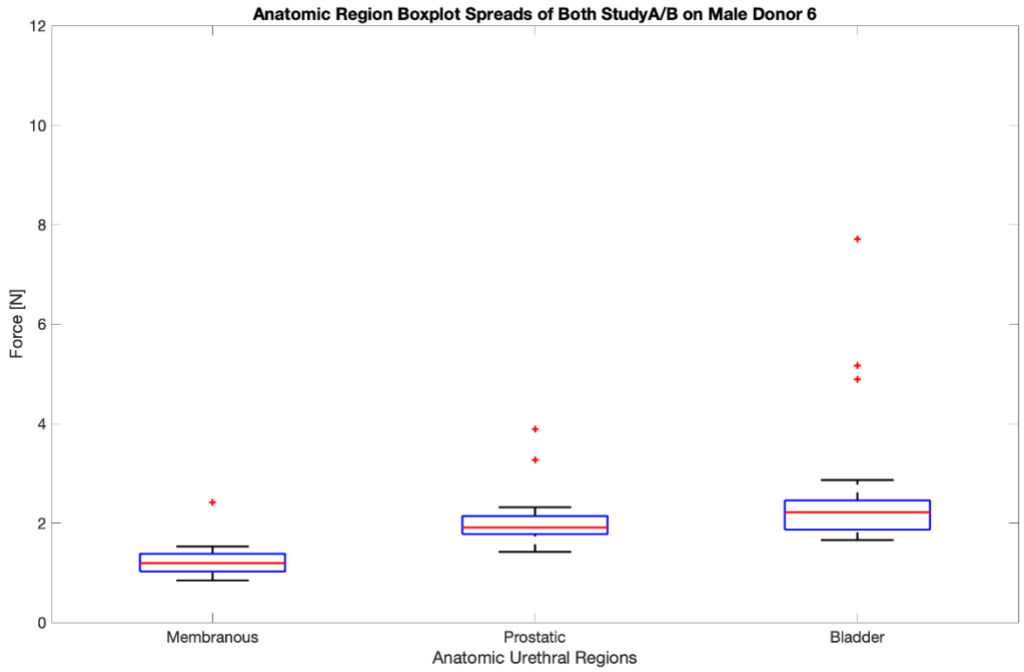
Audio Recording? Y or N **Uploaded?** Y or N

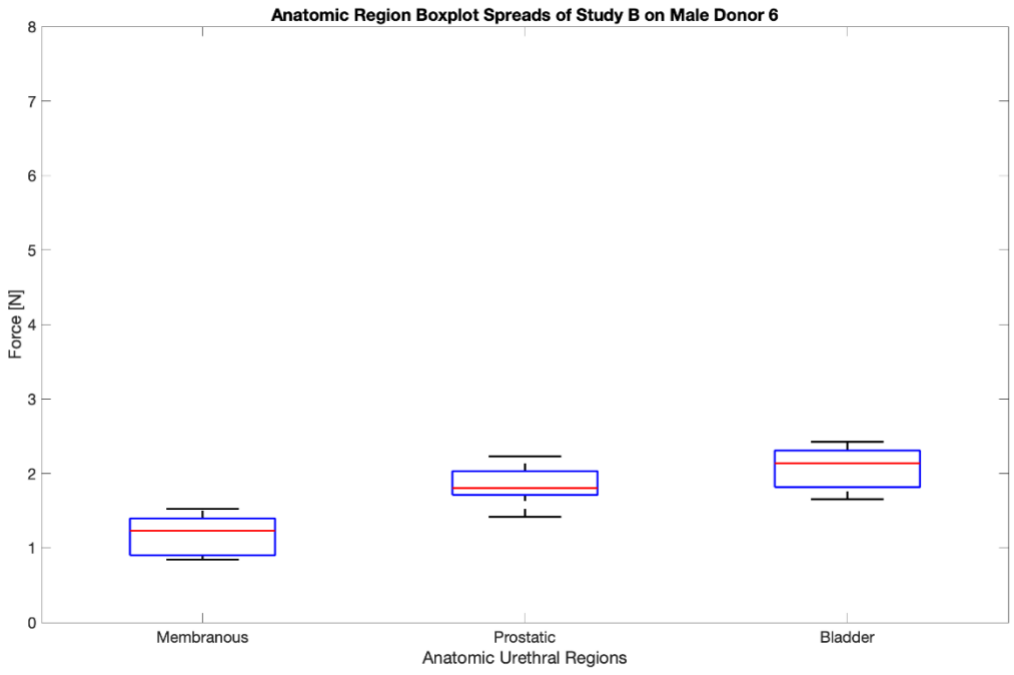
Notes: may not be able to do full cath

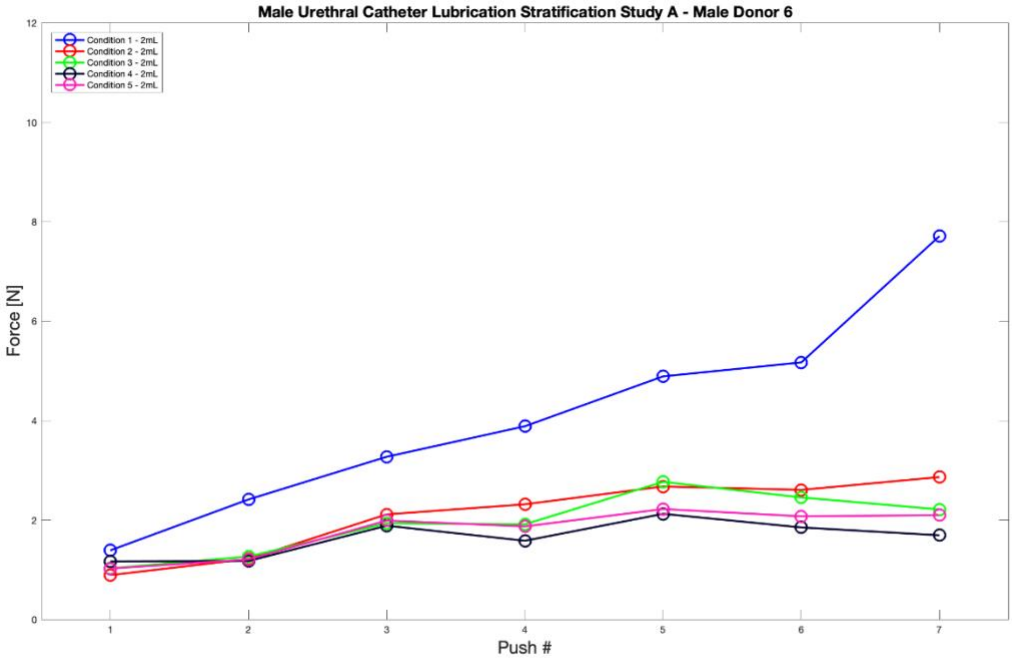
1.	70.7	MM
2.	72.5	uretha length - balloon#
3.	57.87 → 62.88	
4.	30.94	
5.	40.83	
6.	22.09	
7.	[illegible] 13.3	
8.	[illegible] 9.3	
9.	[illegible] 12.7	
10.	[illegible] 35.35	

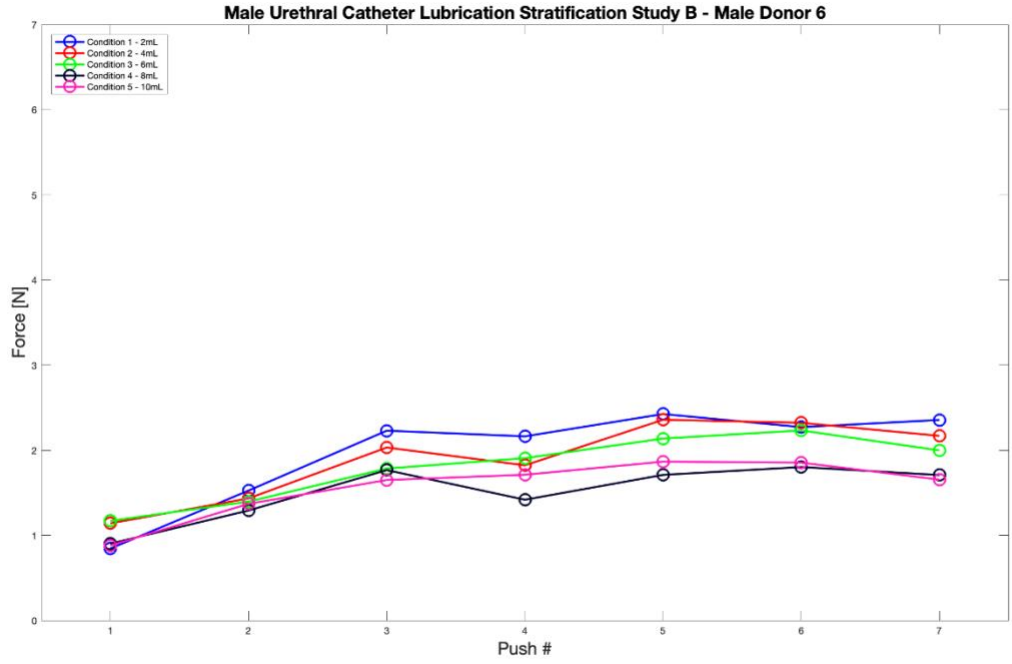
balloon mm=43.3

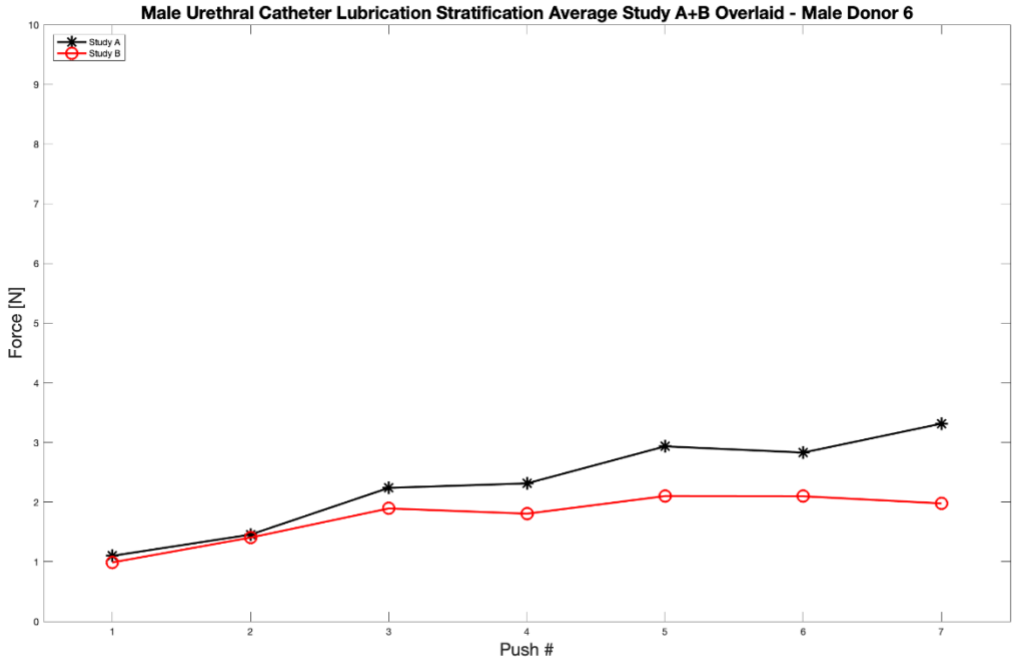
Donor 6

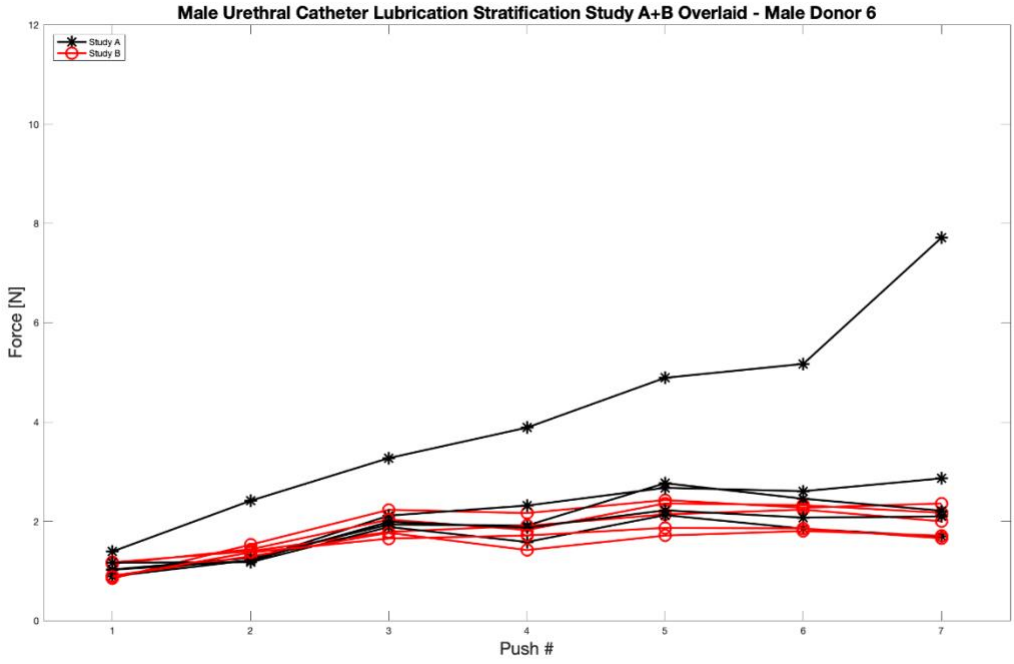

Anatomic Region Boxplot Spreads of Both StudyA/B on Male Donor 6
Force [N]
0
2
4
6
8
10
12
Membranous
Prostatic
Bladder
Anatomic Urethral Regions


Anatomic Region Boxplot Spreads of Study B on Male Donor 6
Force [N]
0
1
2
3
4
5
6
7
8
Membranous
Prostatic
Bladder
Anatomic Urethral Regions


Male Urethral Catheter Lubrication Stratification Study A - Male Donor 6
Condition 1 - 2mL
Condition 2 - 2mL
Condition 3 - 2mL
Condition 4 - 2mL
Condition 5 - 2mL
Force [N]
Push #


Male Urethral Catheter Lubrication Stratification Study B - Male Donor 6
Condition 1 - 2mL
Condition 2 - 4mL
Condition 3 - 6mL
Condition 4 - 8mL
Condition 5 - 10mL
Force [N]
Push #


Male Urethral Catheter Lubrication Stratification Average Study A+B Overlaid - Male Donor 6
Study A
Study B
Force [N]
Push #
0
1
2
3
4
5
6
7
8
9
10
1
2
3
4
5
6
7


Male Urethral Catheter Lubrication Stratification Study A+B Overlaid - Male Donor 6
Study A
Study B
Force [N]
Push #
0
2
4
6
8
10
12
1
2
3
4
5
6
7

Insertion #	Measured	Running Total(mm)	
1	79.95	79.95	
2	65.1	145.05	
3	53.66	198.71	
4	50.48	249.19	
5	53.08	302.27	
6	24.76	327.03	
7	40.03	367.06	
Urethra Length	26.15	178.83	17.9 cm long urethra tip to bladder
Measurement from tip to end balloon	46.03		

Version 2 –11/22/19
DONOR #: 6M
Physician ID : 3

RETURN TO ALYSSA SCHUL
At CREST Lab in HSB T-293 if found

2019/2020 – UW Willed Body Catheter Insertion Study Worksheet

Donor Age: 96 **Donor Sex:** M

Donor Day of Death: 2/5/2020 **Day of Study:** 2/6/2020

Donor History (if known): Pneumonia

Foley Size (in Fr): 16 FR **Catheter Present at Death?:** N

Urethral Length (mm): 17.9 cm **Catheter Type Used:** Bardex All- Silicone

Conditions for Males:
Condition 1 → 2 mL
Condition 2 → 4 mL
Condition 3 → 6 mL
Condition 4 → 8 mL total
Condition 5 → 10 mL total

File Path : HTDB → Projects → 2019-2020 Master's → Data → UW_Donor_ Male- 6- 02062020

Calibration Factors **V-Side LC:** -1030000 **Flat-Side LC:** -960000

Audio Recording? (Y)or N **Uploaded?** (Y)or N

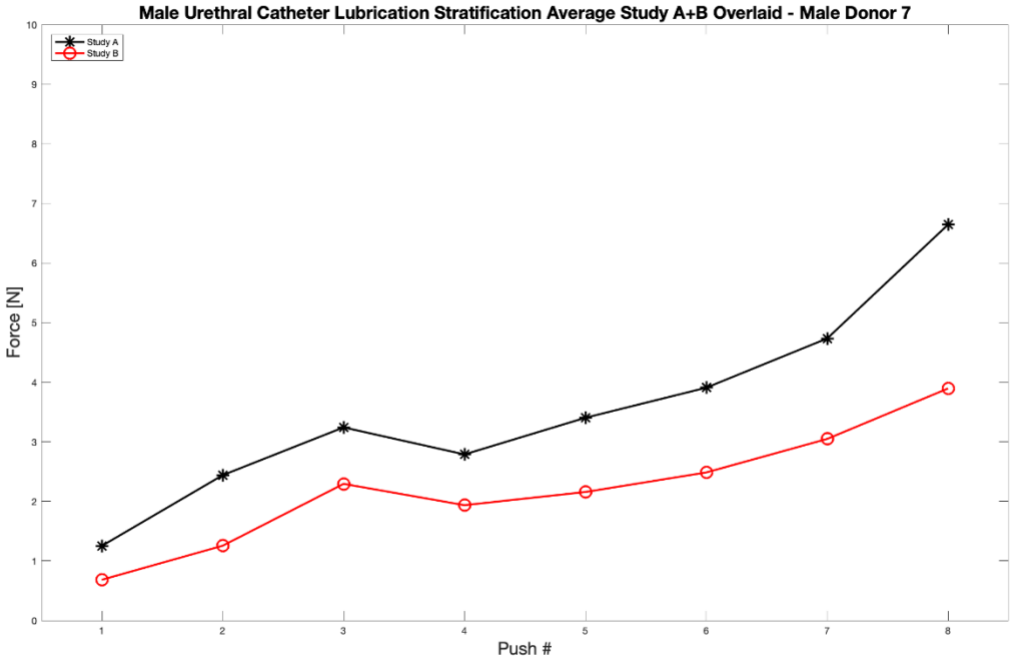
Notes:

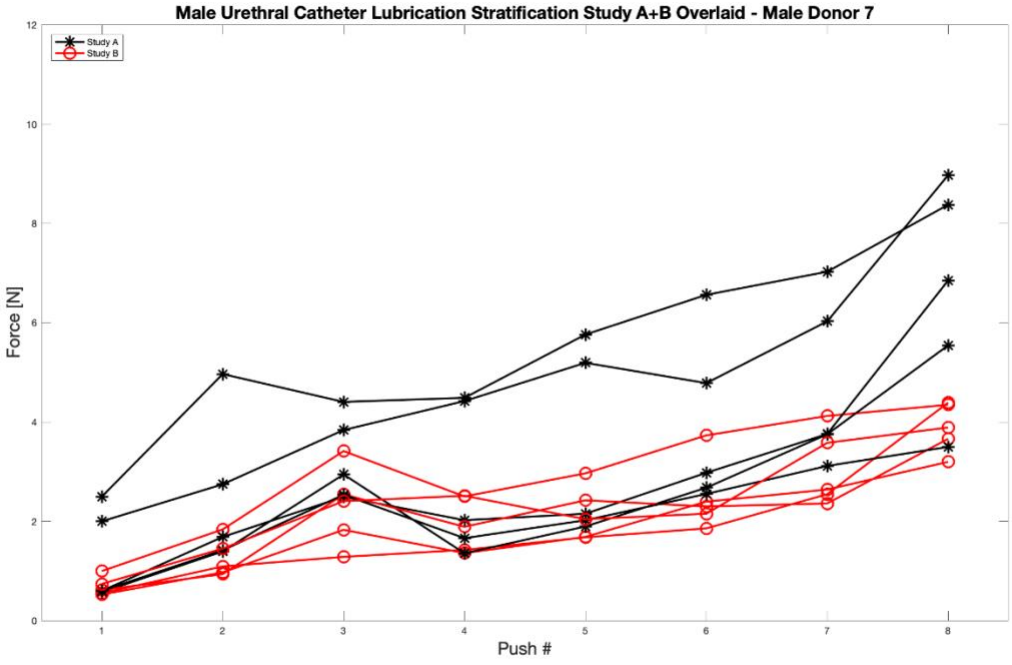
Length (mm)

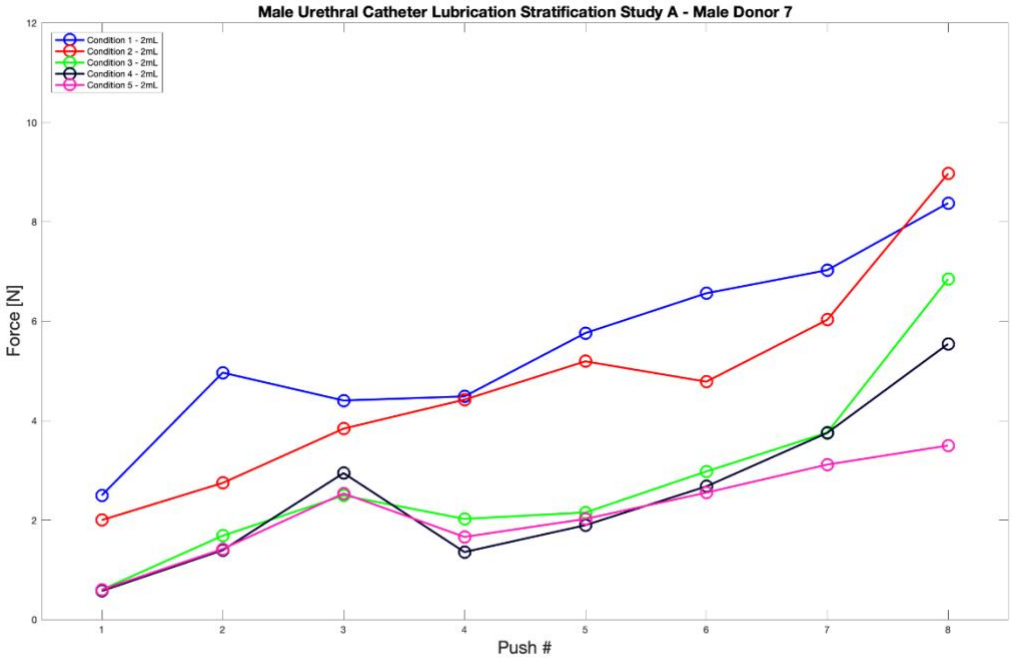
1. 79.45
2. 65.1
3. 53.66 1→3↓ – balloon
   → urethral len→26.15
4. 50.48
5. 53.08
6. 24.76
7. 40.03

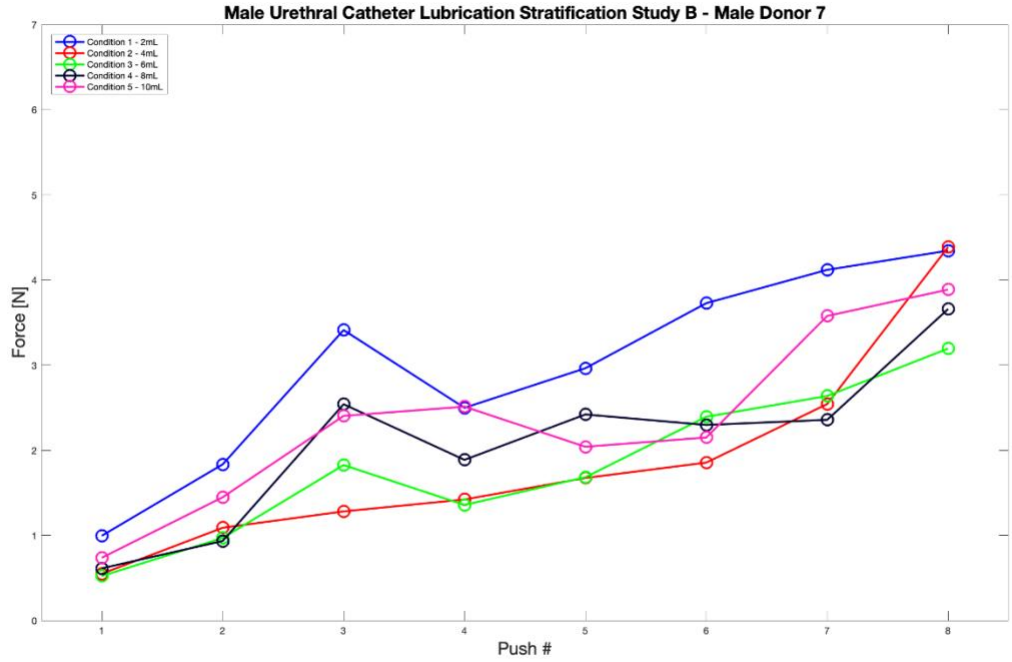
balloon. 46.03

Donor 7


Male Urethral Catheter Lubrication Stratification Average Study A+B Overlaid - Male Donor 7
Study A
Study B
Force [N]
Push #


Male Urethral Catheter Lubrication Stratification Study A+B Overlaid - Male Donor 7
Study A
Study B
Force [N]
Push #


Male Urethral Catheter Lubrication Stratification Study A - Male Donor 7
Condition 1 - 2mL
Condition 2 - 2mL
Condition 3 - 2mL
Condition 4 - 2mL
Condition 5 - 2mL
Force [N]
Push #


Male Urethral Catheter Lubrication Stratification Study B - Male Donor 7
Condition 1 - 2mL
Condition 2 - 4mL
Condition 3 - 6mL
Condition 4 - 8mL
Condition 5 - 10mL
Force [N]
Push #

Insertion #	Measured	Running Total(mm)	
1	82.57	82.57	
2	53.75	136.32	
3	51.07	187.39	
4	48.75	236.14	
5	29.3	265.44	
6	31.55	296.99	
7	26.88	323.87	
8	48.71	372.58	
Urethra Length	N/A unsuccessful full catheter		
Measurement from tip to end balloon			

Version 2 –11/22/19
DONOR #: 7M
Physician ID : 3

RETURN TO ALYSSA SCHUL
At CREST Lab in HSB T-293 if found

2019/2020 – UW Willed Body Catheter Insertion Study Worksheet

Donor Age: 71 **Donor Sex:** M

Donor Day of Death: 2/10/20 **Day of Study:** 2-11-20

Donor History (if known): Gastro Intestinal Cancer

Foley Size (in Fr): _____ **Catheter Present at Death?:** N

Urethral Length (mm): NA - not full cath **Catheter Type Used:** _____

Conditions for Males:
Condition 1 → 2 mL
Condition 2 → 4 mL
Condition 3 → 6 mL
Condition 4 → 8 mL total
Condition 5 → 10 mL total
File Path : HTDB → Projects → 2019-2020 Master's → Data → UW_Donor_

Calibration Factors **V-Side LC:** _____ **Flat-Side LC:** _____

Audio Recording? Y or N **Uploaded?** Y or N

Notes:

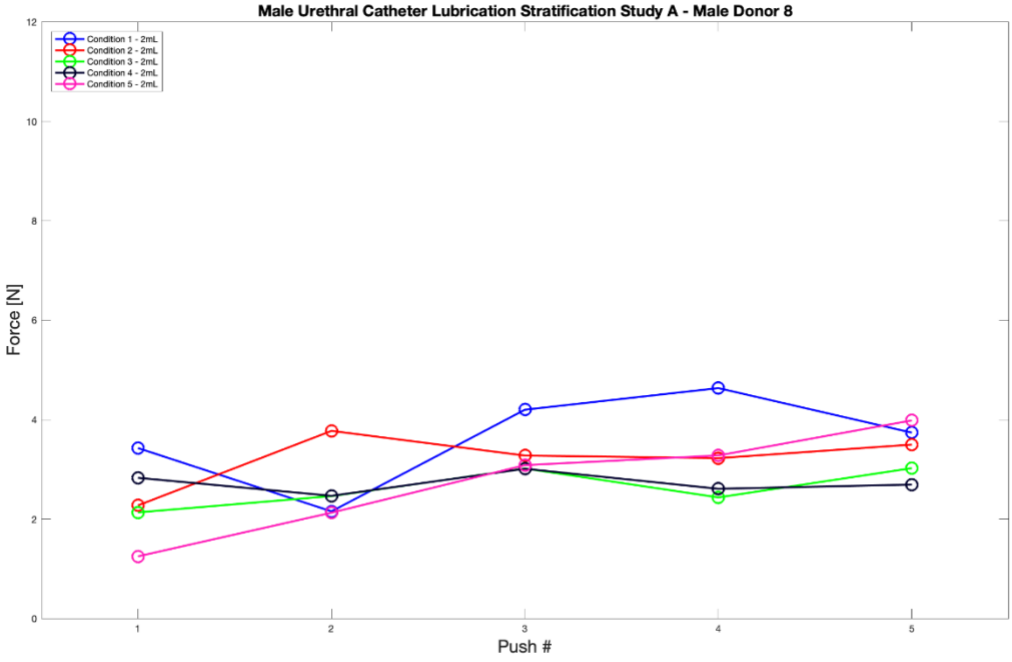
Not Full cath

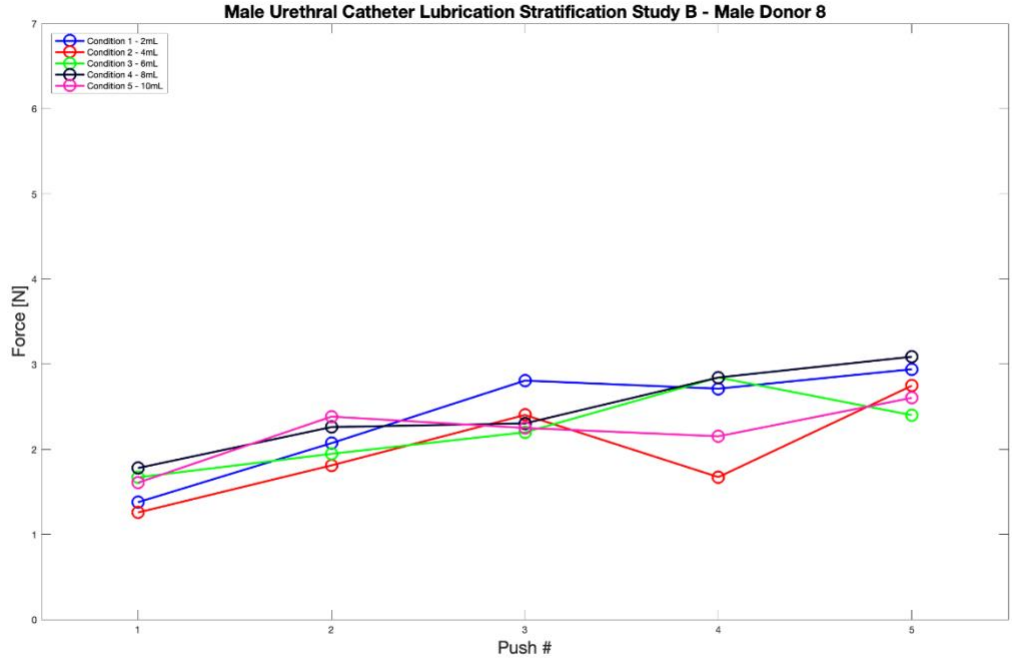
Lengths

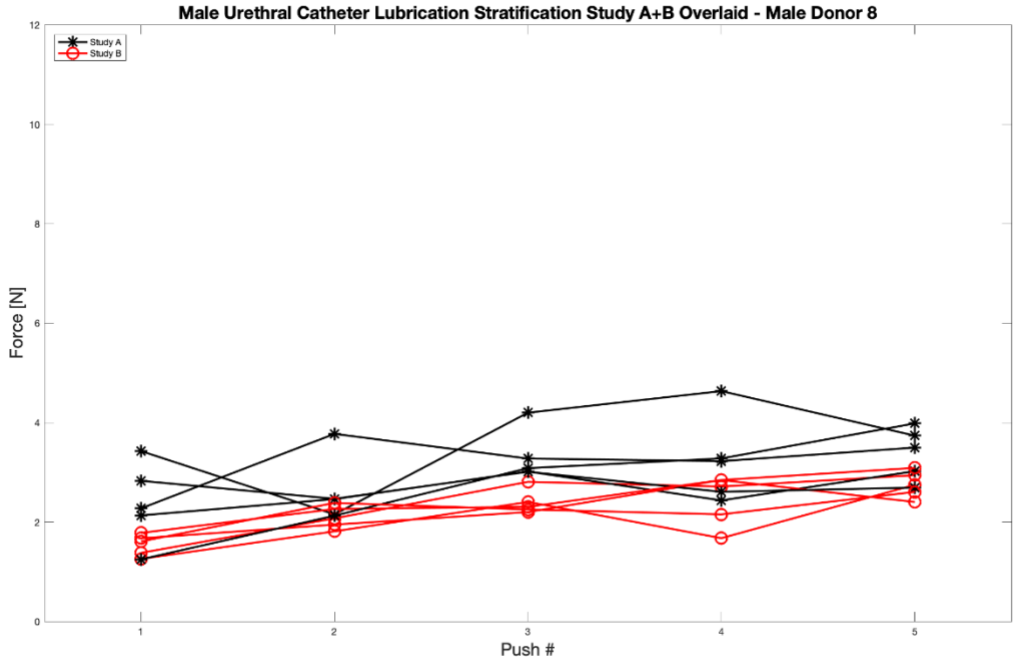
1. 82.57
2. 53.75
3. 51.07
4. 48.75
5. 29.3
6. 31.55
7. 26.88
8. ~~48~~ 48.71

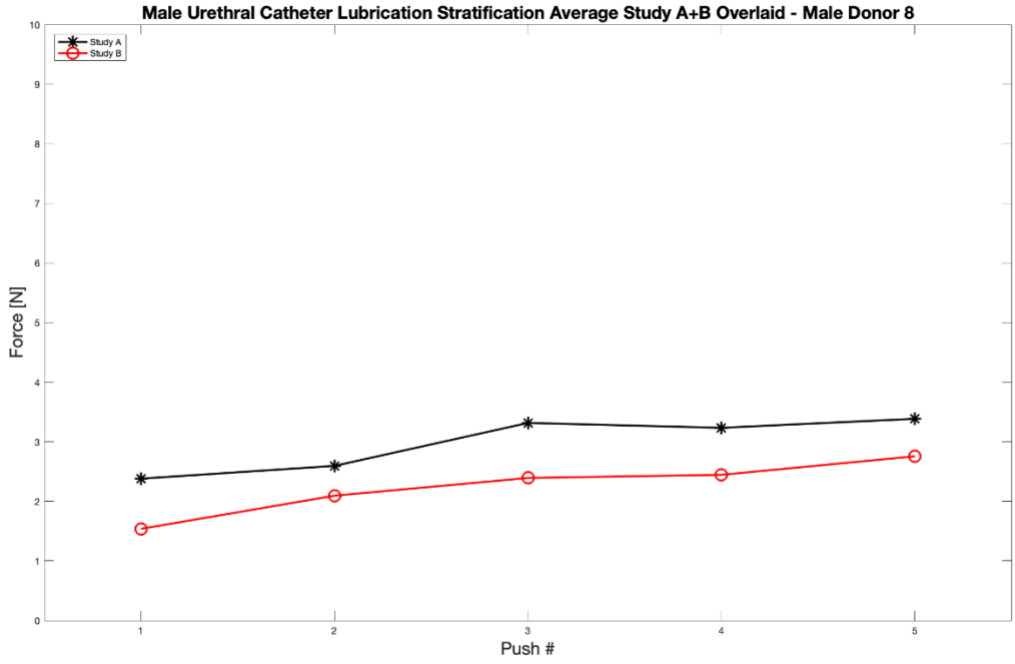
No balloon
No *3

Donor 8


Male Urethral Catheter Lubrication Stratification Study A - Male Donor 8
Condition 1 - 2mL
Condition 2 - 2mL
Condition 3 - 2mL
Condition 4 - 2mL
Condition 5 - 2mL
Force [N]
Push #


Male Urethral Catheter Lubrication Stratification Study B - Male Donor 8
Condition 1 - 2mL
Condition 2 - 4mL
Condition 3 - 6mL
Condition 4 - 8mL
Condition 5 - 10mL
Force [N]
Push #


Male Urethral Catheter Lubrication Stratification Study A+B Overlaid - Male Donor 8
Study A
Study B
Force [N]
Push #
0
2
4
6
8
10
12
1
2
3
4
5


Male Urethral Catheter Lubrication Stratification Average Study A+B Overlaid - Male Donor 8
Study A
Study B
Force [N]
Push #
0
1
2
3
4
5
6
7
8
9
10
1
2
3
4
5

Insertion #	Measured	Running Total(mm)	
1	98.81	98.81	
2	46.8	145.61	
3	40.3	185.91	
4	38.86	224.77	
5	38.7	263.47	Only 26cm of catheter placed
			Prostate obstruction

Version 2 –11/22/19
DONOR #: BM
Physician ID : 3

RETURN TO ALYSSA SCHUL
At CREST Lab in HSB T-293 if found

2019/2020 – UW Willed Body Catheter Insertion Study Worksheet

Donor Age: 71 **Donor Sex:** M

Donor Day of Death: 2/10/20 **Day of Study:** 2/11/20

Donor History (if known): Dementia

Foley Size (in Fr): _____ **Catheter Present at Death?:** N

Urethral Length (mm): _____ **Catheter Type Used:** 16Fr Bardex Silicone

Conditions for Males: only plain
Condition 1 → 2 mL 263.47mm
Condition 2 → 4 mL 26.35cm ish... bending/buckling of urethra signs obstruction
Condition 3 → 6 mL
Condition 4 → 8 mL total
Condition 5 → 10 mL total

File Path : HTDB → Projects → 2019-2020 Master's → Data → UW_Donor_

Calibration Factors **V-Side LC:** -1030000 **Flat-Side LC:** -960000

Audio Recording? (Y) or N **Uploaded?** (Y) or N

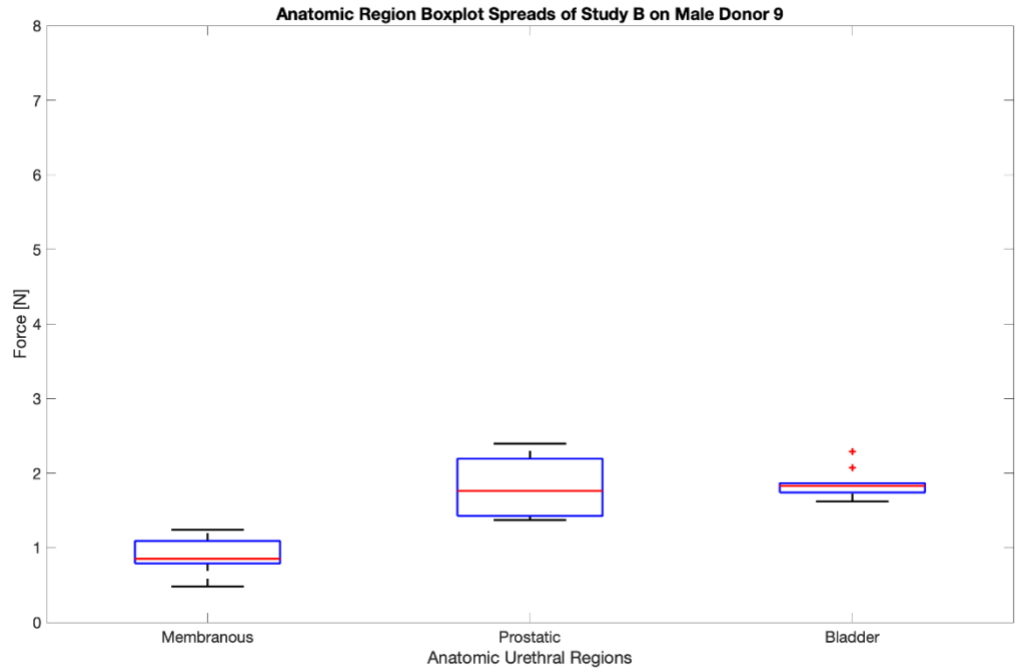
Notes:

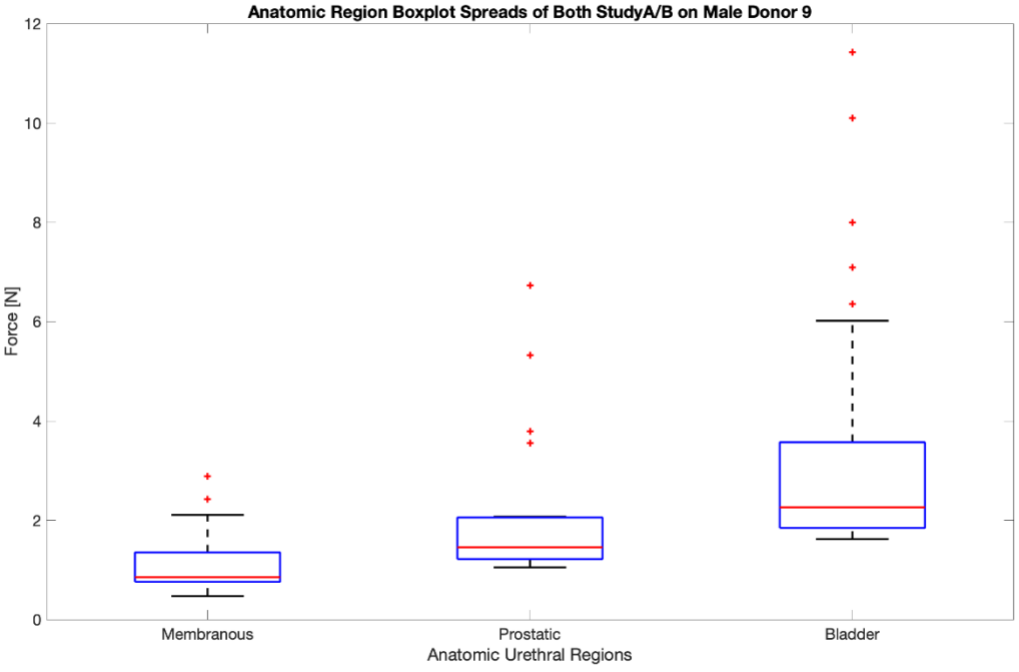
Not fully cath

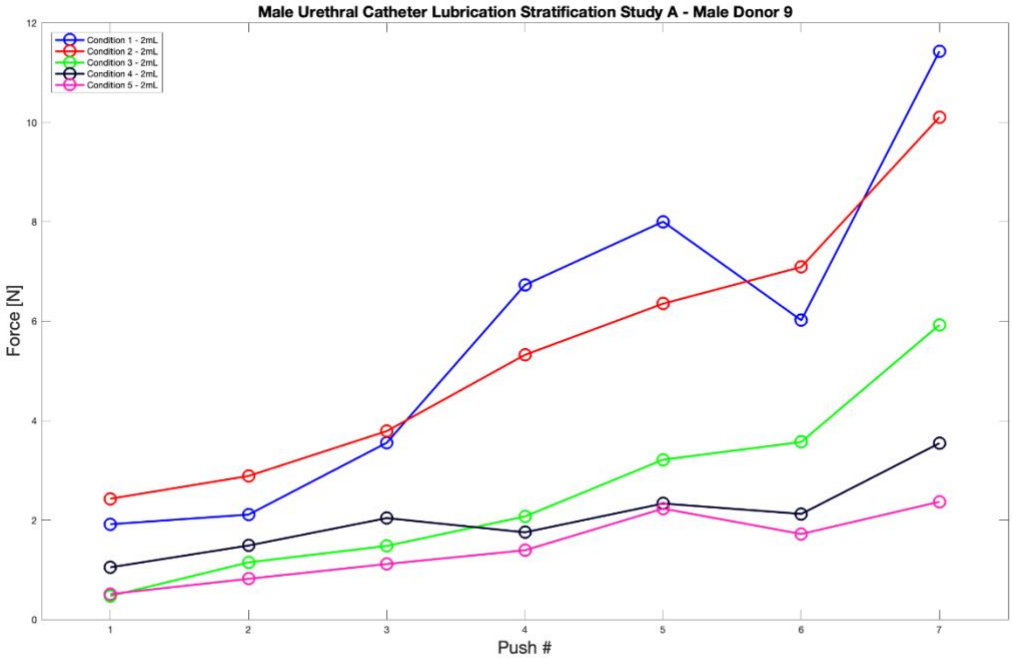
prostate obstruction

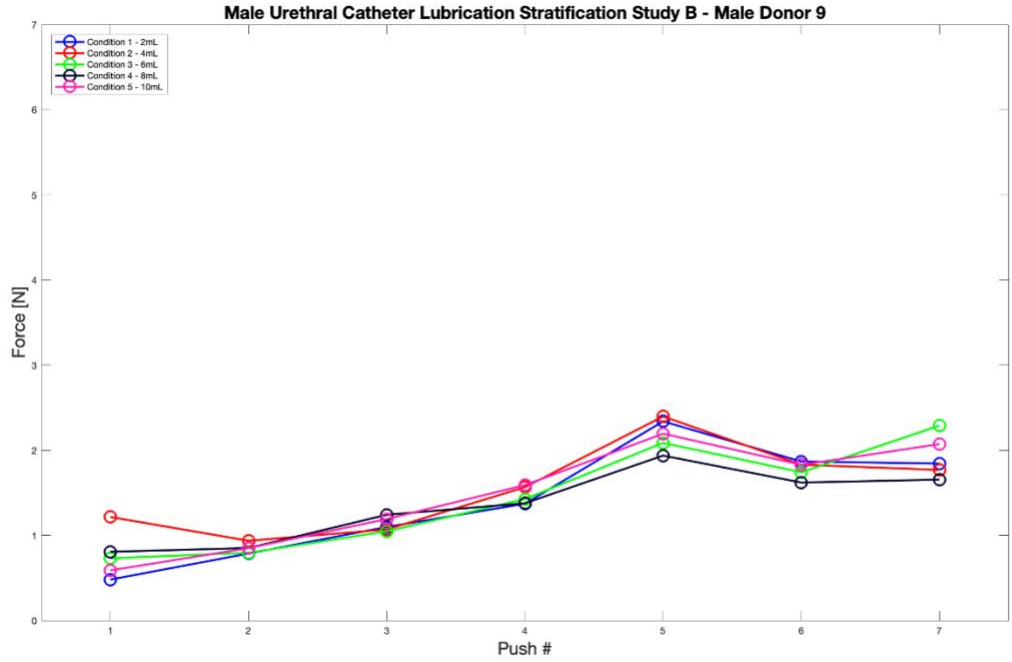
	Length
1.	48.81
2.	46.8
3.	40.3
4.	38.86
5	38.70
6?	right just be to 5.

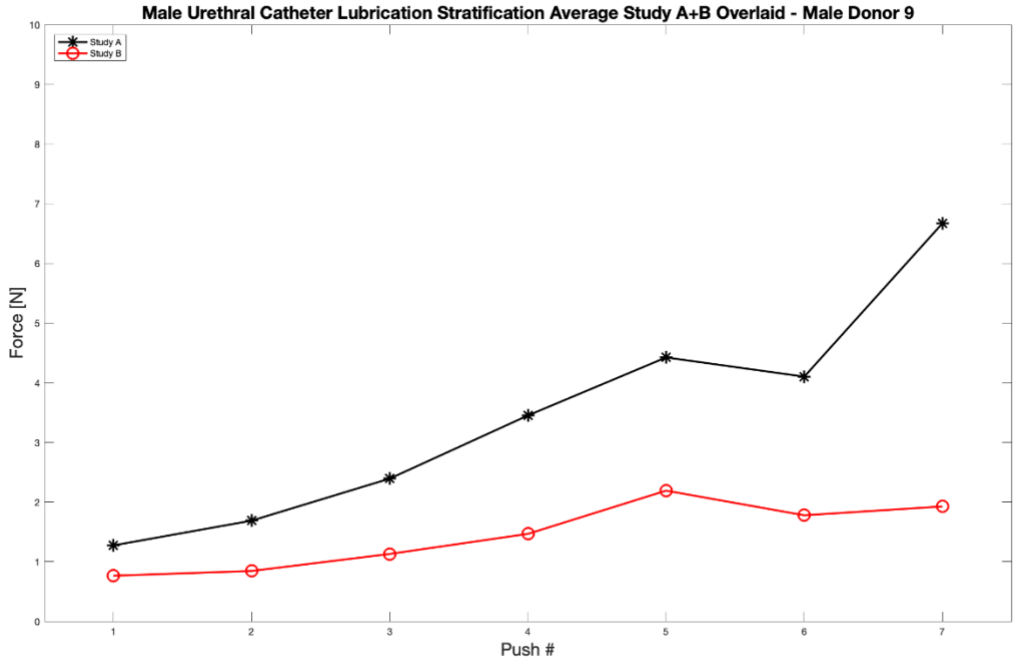
Donor 9

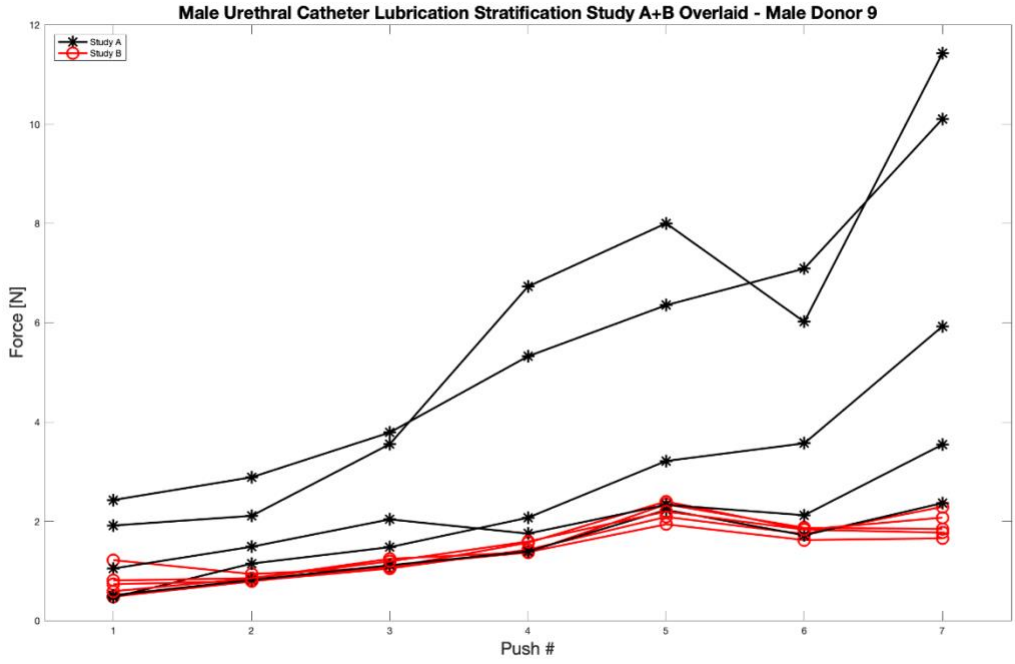

Anatomic Region Boxplot Spreads of Study B on Male Donor 9
Force [N]
0
1
2
3
4
5
6
7
8
Membranous
Prostatic
Bladder
Anatomic Urethral Regions


Anatomic Region Boxplot Spreads of Both StudyA/B on Male Donor 9
Force [N]
0
2
4
6
8
10
12
Membranous
Prostatic
Bladder
Anatomic Urethral Regions


Male Urethral Catheter Lubrication Stratification Study A - Male Donor 9
Condition 1 - 2mL
Condition 2 - 2mL
Condition 3 - 2mL
Condition 4 - 2mL
Condition 5 - 2mL
Force [N]
Push #


Male Urethral Catheter Lubrication Stratification Study B - Male Donor 9
Condition 1 - 2mL
Condition 2 - 4mL
Condition 3 - 6mL
Condition 4 - 8mL
Condition 5 - 10mL
Force [N]
Push #


Male Urethral Catheter Lubrication Stratification Average Study A+B Overlaid - Male Donor 9
Study A
Study B
Force [N]
Push #


Male Urethral Catheter Lubrication Stratification Study A+B Overlaid - Male Donor 9
Study A
Study B
Force [N]
Push #

Insertion #	Measured	Running Total(mm)	
1	71.92	71.92	
2	45.61	117.53	
3	58.01	175.54	
4	54.01	229.55	
5	52.75	282.3	
6	35.53	317.83	
7	46.74	364.57	
Urethra Length	31.6	163.64	16.2 cm long urethra tip to bladder
Measurement from tip to end balloon	43.5		

Version 2 –11/22/19
DONOR #: 9M
Physician ID : 2

RETURN TO ALYSSA SCHUL
At CREST Lab in HSB T-293 if found

2019/2020 – UW Willed Body Catheter Insertion Study Worksheet

Donor Age: 79 **Donor Sex:** M

Donor Day of Death: 2/20/20 **Day of Study:** 2/21/20

Donor History (if known): diabetes, lung cancer

Foley Size (in Fr): 16 Fr **Catheter Present at Death?:** N

Urethral Length (mm): 16.4 cm **Catheter Type Used:** 16Fr BardEx

Conditions for Males:
Condition 1 → 2 mL
Condition 2 → 4 mL
Condition 3 → 6 mL
Condition 4 → 8 mL total
Condition 5 → 10 mL total
File Path : HTDB → Projects → 2019-2020 Master's → Data → UW_Donor_

Calibration Factors **V-Side LC:** -1,030,000 **Flat-Side LC:** -960,000

Audio Recording? (Y) or N **Uploaded?** (Y) or N

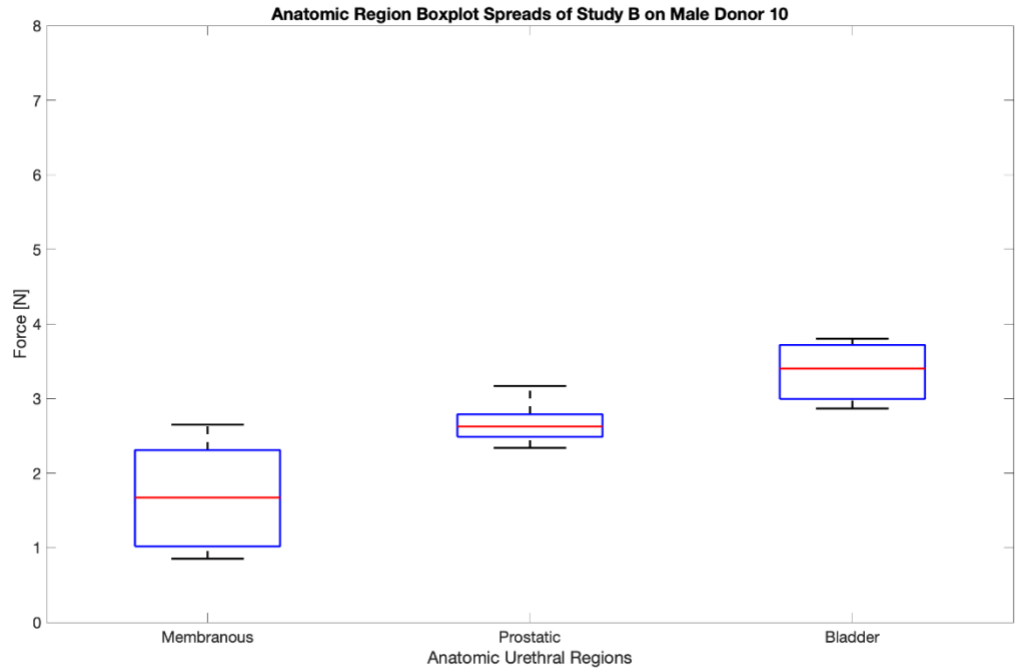
Notes:

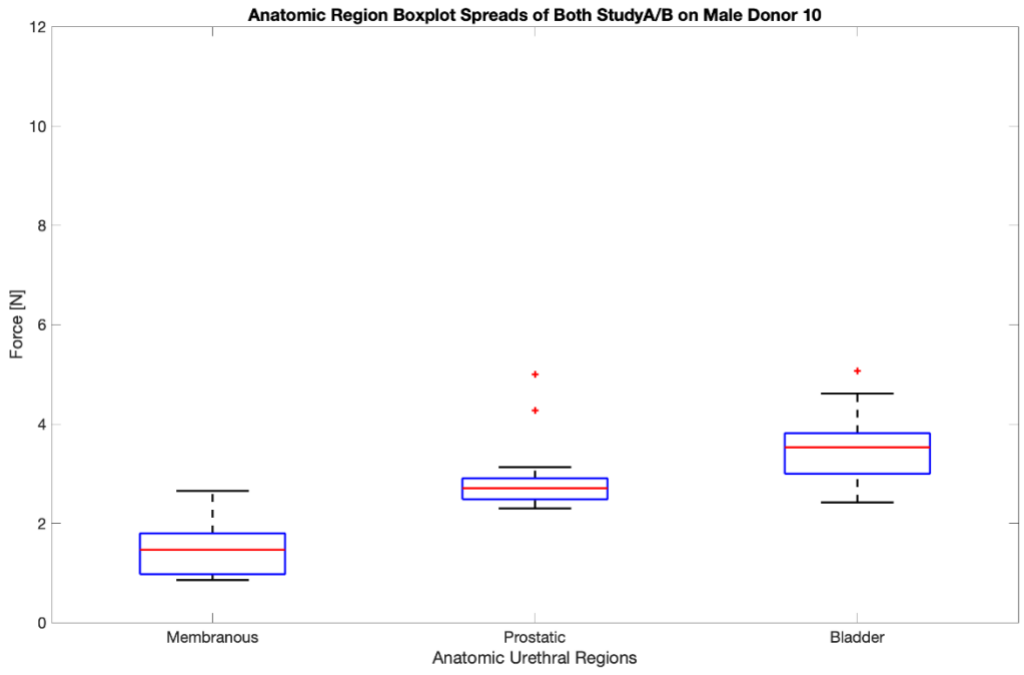
Lengths

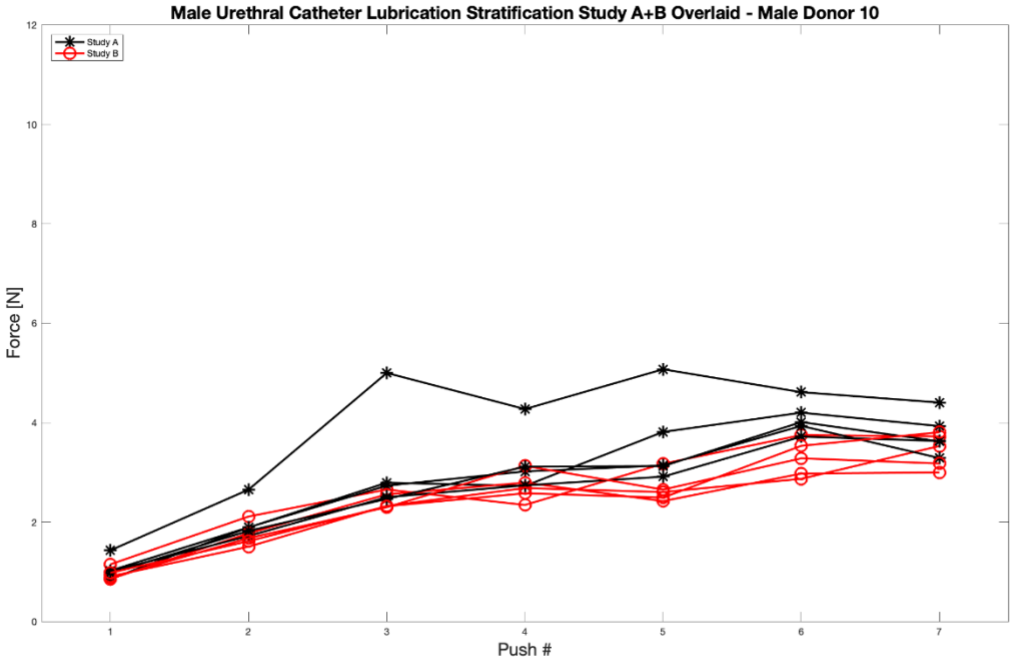
1. 71.92
2. 45.61
3. ~~58.01~~ Within push 4
4. 54.01 → urethra length 31.6
5. 52.75
6. 35.53
7. 46.74

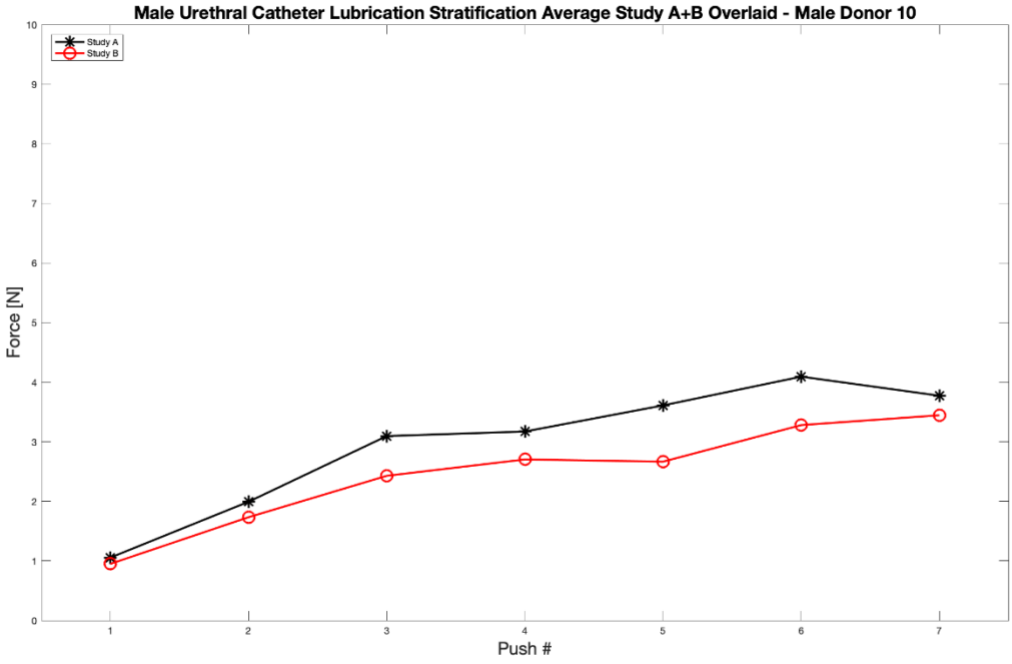
balloon: 43.5

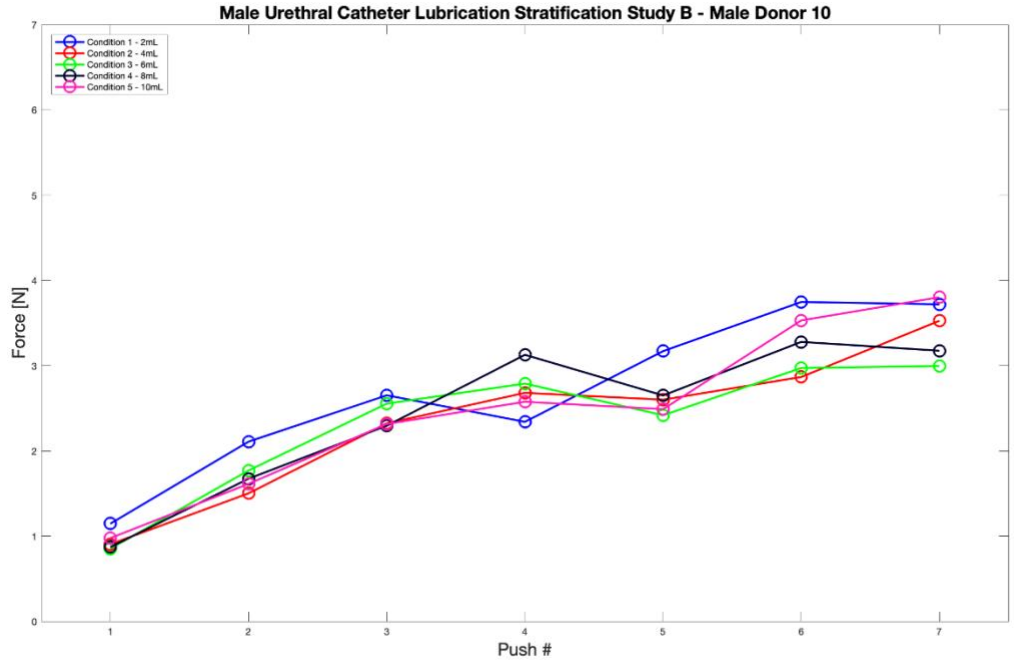
Donor 10

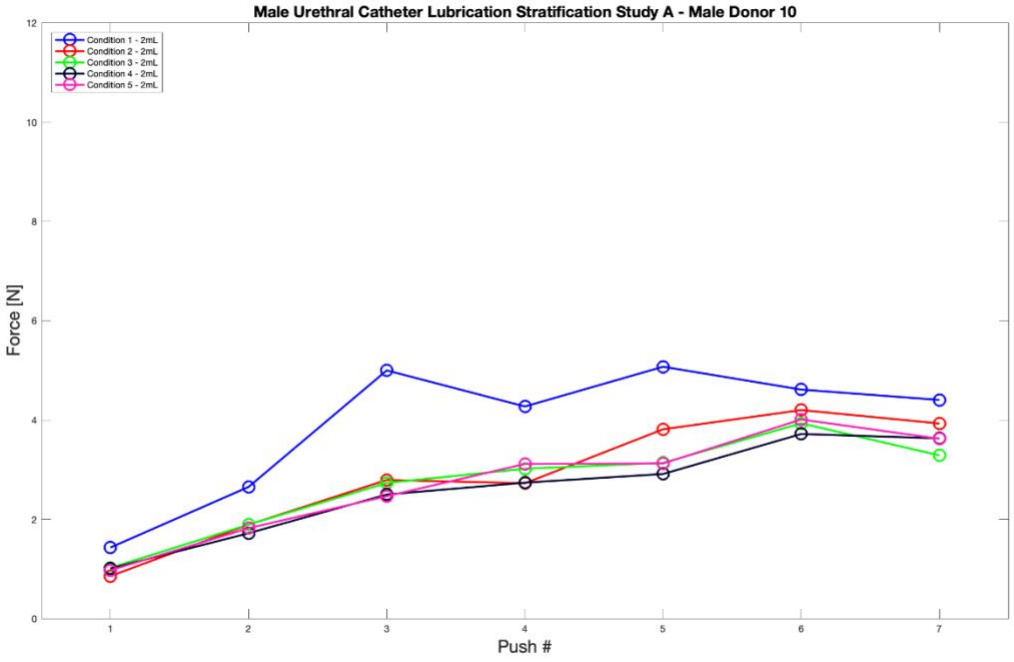

Anatomic Region Boxplot Spreads of Study B on Male Donor 10
Force [N]
0
1
2
3
4
5
6
7
8
Membranous
Prostatic
Bladder
Anatomic Urethral Regions


Anatomic Region Boxplot Spreads of Both StudyA/B on Male Donor 10
Force [N]
0
2
4
6
8
10
12
Membranous
Prostatic
Bladder
Anatomic Urethral Regions


Male Urethral Catheter Lubrication Stratification Study A+B Overlaid - Male Donor 10
Study A
Study B
Force [N]
Push #
0
2
4
6
8
10
12
1
2
3
4
5
6
7


Male Urethral Catheter Lubrication Stratification Average Study A+B Overlaid - Male Donor 10
Study A
Study B
Force [N]
Push #
0
1
2
3
4
5
6
7
8
9
10
1
2
3
4
5
6
7


Male Urethral Catheter Lubrication Stratification Study B - Male Donor 10
Condition 1 - 2mL
Condition 2 - 4mL
Condition 3 - 6mL
Condition 4 - 8mL
Condition 5 - 10mL
Force [N]
Push #


Male Urethral Catheter Lubrication Stratification Study A - Male Donor 10
Condition 1 - 2mL
Condition 2 - 2mL
Condition 3 - 2mL
Condition 4 - 2mL
Condition 5 - 2mL
Force [N]
Push #

Insertion #	Measured	Running Total(mm)	
1	95.64	95.64	
2	55.53	151.17	
3	23.61	174.78	
4	44.31	219.09	
5	55.33	274.42	
6	49.41	323.83	
7	33.02	356.85	
Urethra Length	33.87	162.36	16.2 cm long urethra tip to bladder
Measurement from tip to end balloon	46.29		

Version 2 –11/22/19
DONOR #: 10 M
Physician ID : 3

RETURN TO ALYSSA SCHUL
At CREST Lab in HSB T-293 if found

2019/2020 – UW Willed Body Catheter Insertion Study Worksheet

Donor Age: 88 **Donor Sex:** M

Donor Day of Death: 2/22/20 **Day of Study:** 2/24/20

Donor History (if known): system shutdown / cardiac failure

Foley Size (in Fr): _____ **Catheter Present at Death?:** N

Urethral Length (mm): _____ **Catheter Type Used:** 16 Fr Bard Ex

Conditions for Males:
Condition 1 → 2 mL
Condition 2 → 4 mL
Condition 3 → 6 mL
Condition 4 → 8 mL total
Condition 5 → 10 mL total
File Path : HTDB → Projects → 2019-2020 Master's → Data → UW_Donor_(0

Calibration Factors **V-Side LC:** -1030000 **Flat-Side LC:** -960000

Audio Recording? (Y) or N **Uploaded?** Y or N

Notes:

Slipped in tongs near end

Lengths

1 90.25
2 54.50
3 49.50 → urethra length 32.50
4 39.75
5 49.25
6 42.50
7 34.50

balloon 44.25

APPENDIX P

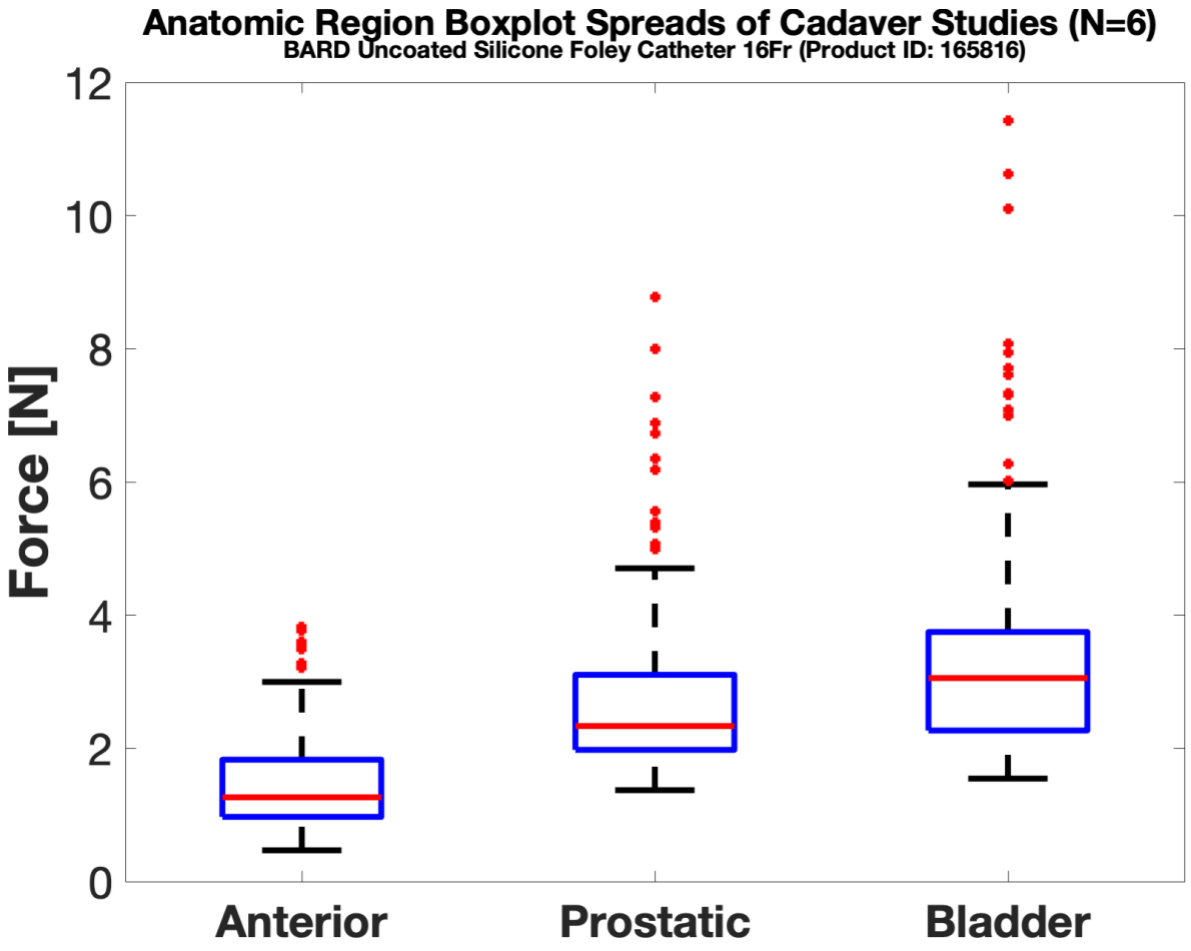
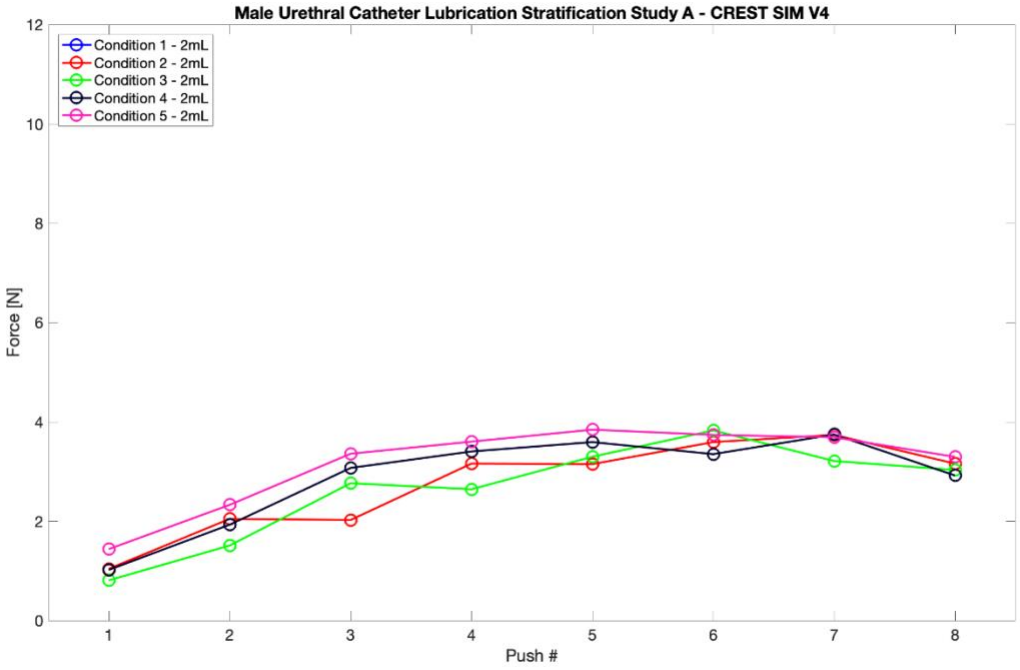
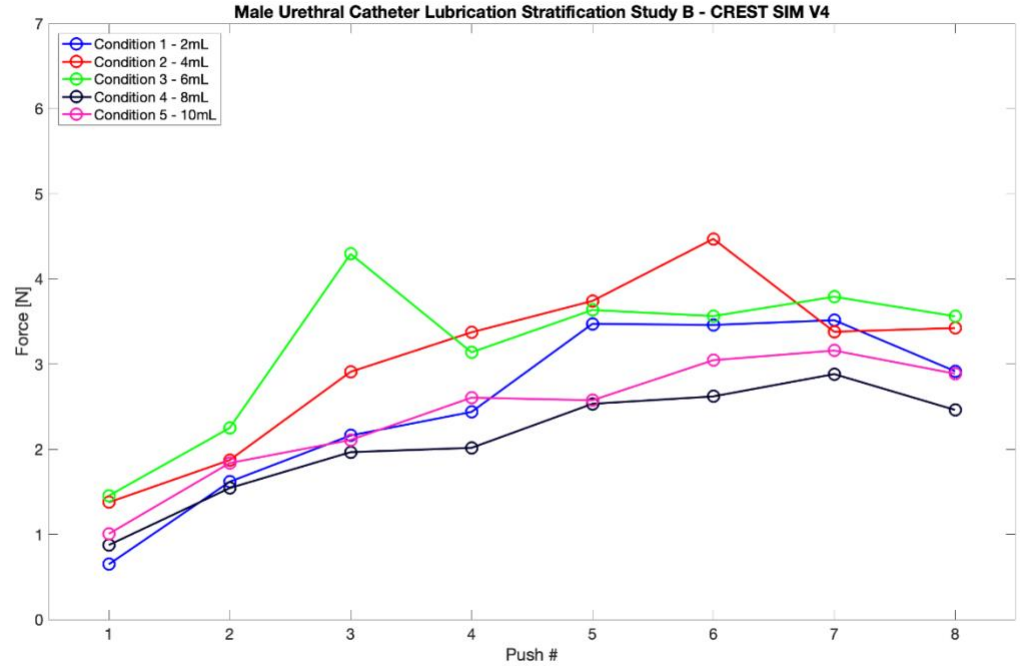


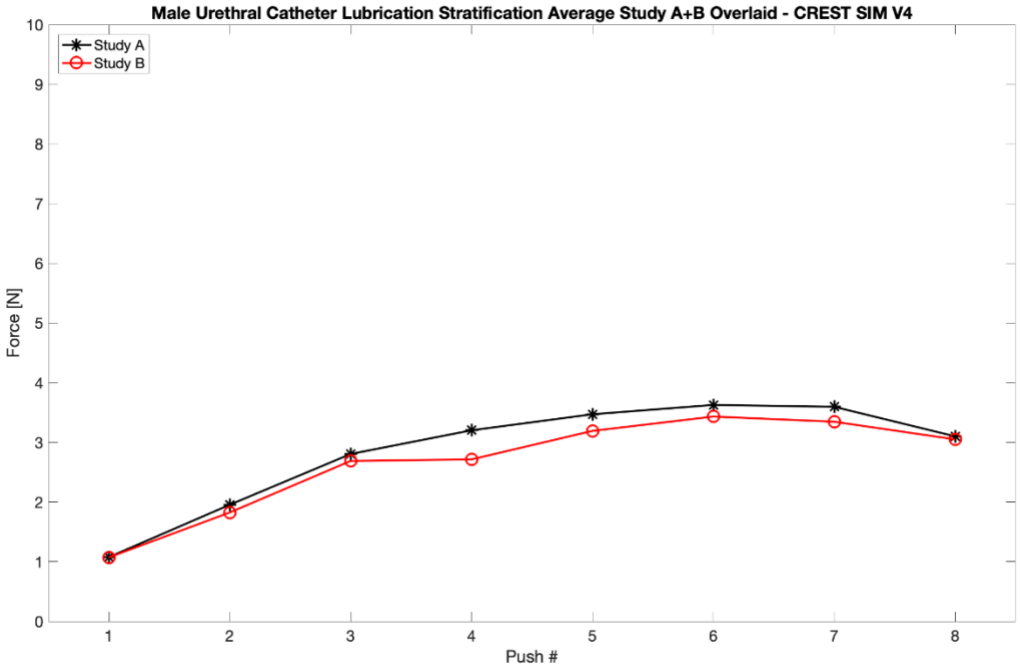
Figure P1: Anatomic Boxplot spread for Study A + Study B Cadaver Results.

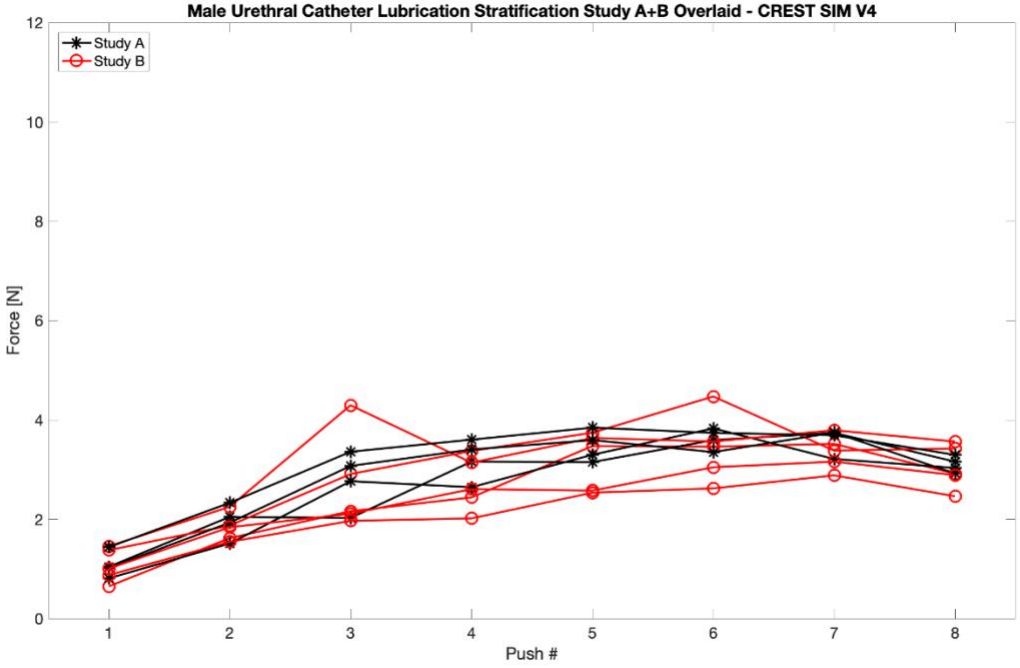
APPENDIX Q

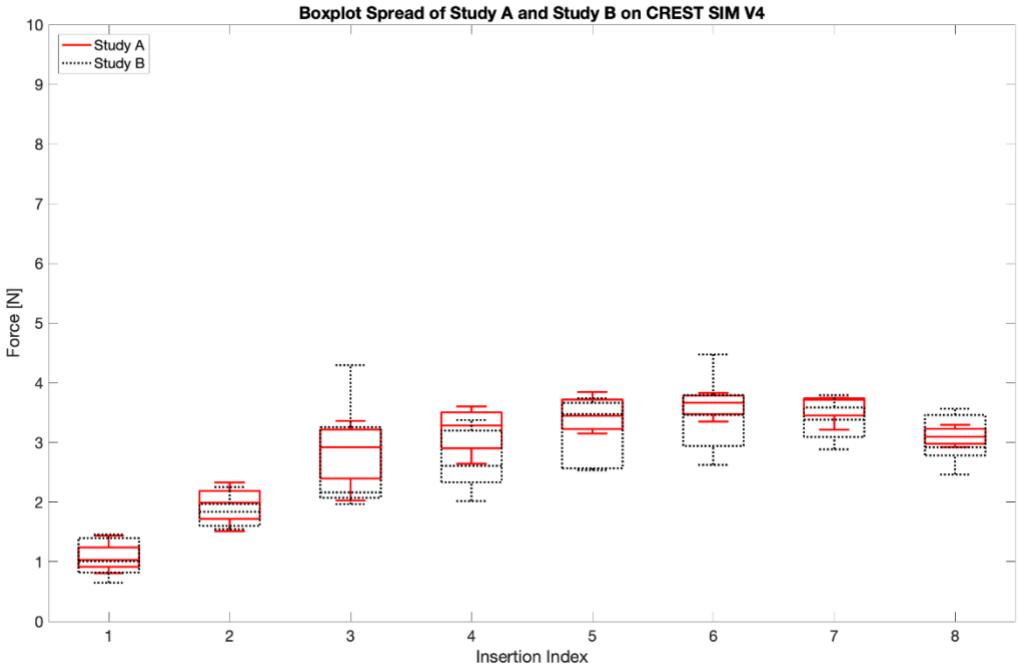
CREST SIM V4 Data Analysis Plots

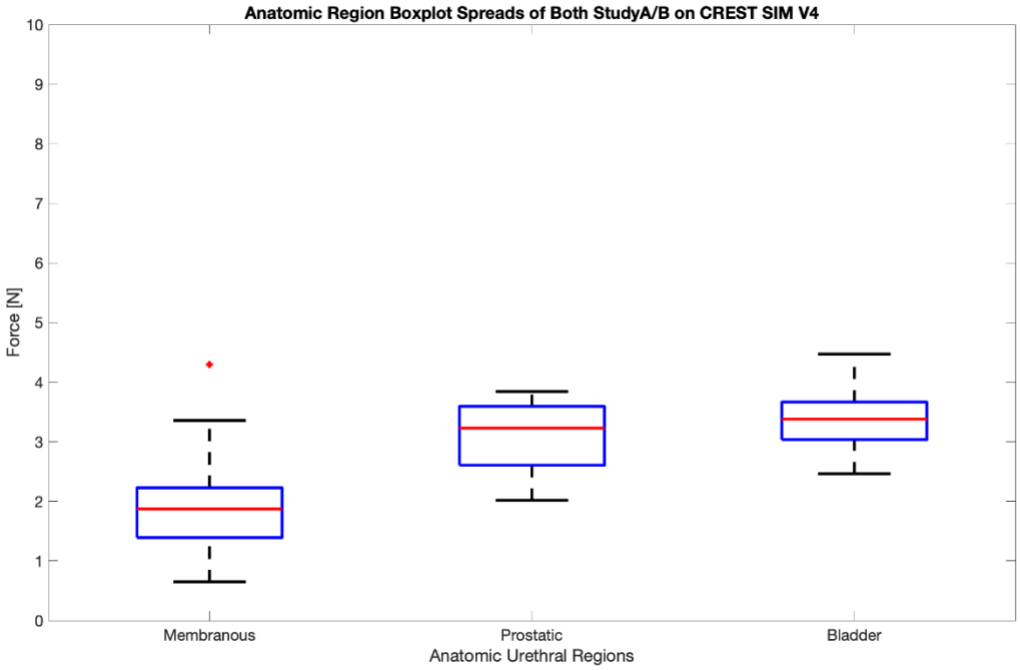


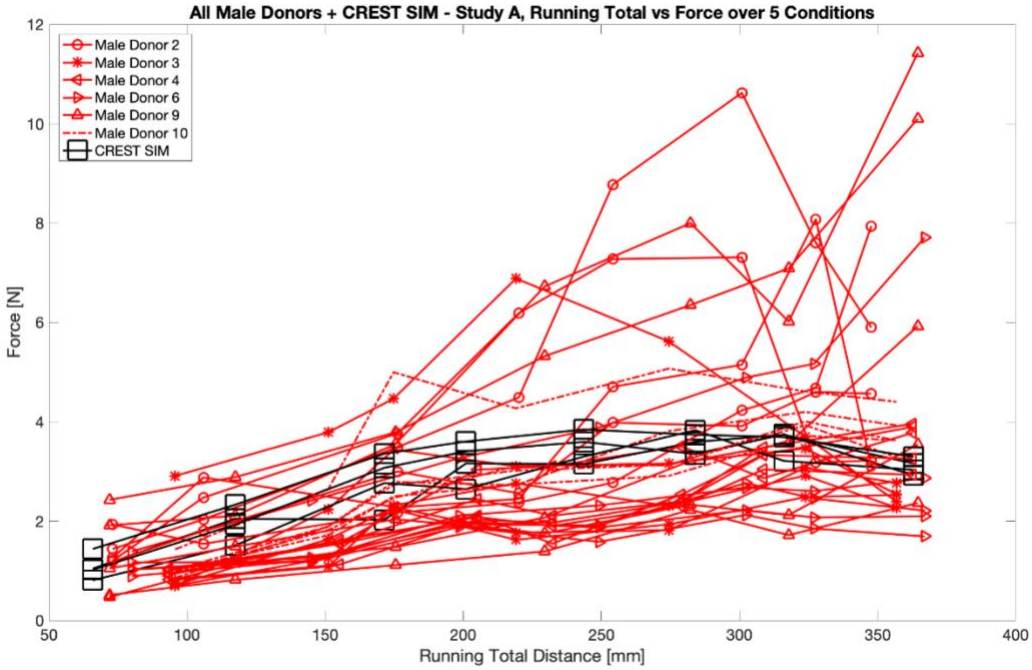


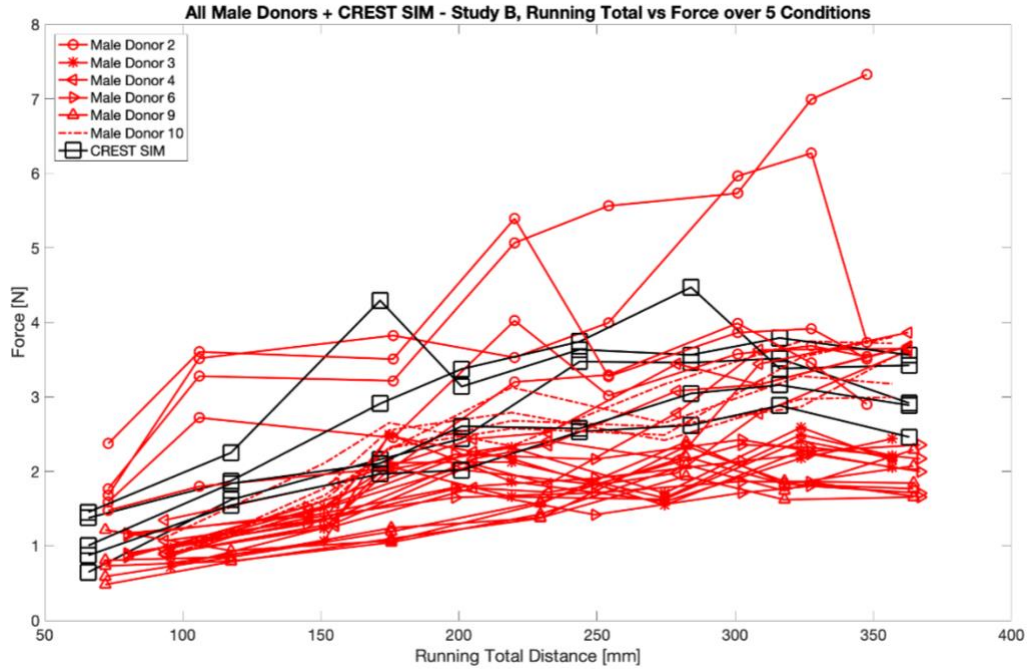

Male Urethral Catheter Lubrication Stratification Average Study A+B Overlaid - CREST SIM V4
Study A
Study B
Force [N]
Push #
0
1
2
3
4
5
6
7
8
9
10
1
2
3
4
5
6
7
8


Male Urethral Catheter Lubrication Stratification Study A+B Overlaid - CREST SIM V4
Study A
Study B
Force [N]
Push #
0
2
4
6
8
10
12
1
2
3
4
5
6
7
8


Boxplot Spread of Study A and Study B on CREST SIM V4
Study A
Study B
Force [N]
Insertion Index
0
1
2
3
4
5
6
7
8
9
10


Anatomic Region Boxplot Spreads of Both StudyA/B on CREST SIM V4
Force [N]
Membranous
Prostatic
Bladder
Anatomic Urethral Regions
0
1
2
3
4
5
6
7
8
9
10


All Male Donors + CREST SIM - Study A, Running Total vs Force over 5 Conditions
Male Donor 2
Male Donor 3
Male Donor 4
Male Donor 6
Male Donor 9
Male Donor 10
CREST SIM
Force [N]
Running Total Distance [mm]


All Male Donors + CREST SIM - Study B, Running Total vs Force over 5 Conditions
Male Donor 2
Male Donor 3
Male Donor 4
Male Donor 6
Male Donor 9
Male Donor 10
CREST SIM
Force [N]
Running Total Distance [mm]

APPENDIX R

Table R1: Depth Insertion Pattern for Simulator Comparison Study

Insertion #	Measured	Running Total(mm)	
1	65.86	65.86	
2	51.6	117.46	
3	54.01	171.47	
4	29.52	200.99	
5	42.68	243.67	
6	40.38	284.05	
7	32	316.05	
8	47.02	363.07	
Urethra Length	33.87	159.05	16.2 cm long urethra tip to bladder
Measurement from tip to end balloon	46.29		

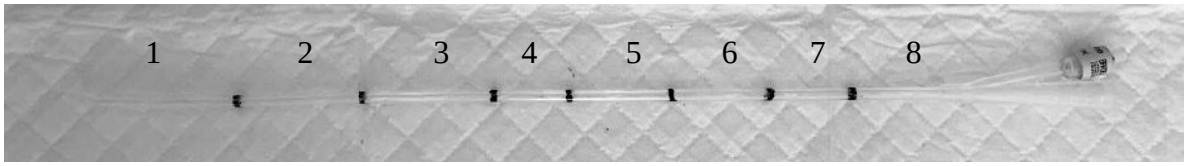


Figure R1: Catheter used for simulator comparison study.

APPENDIX S

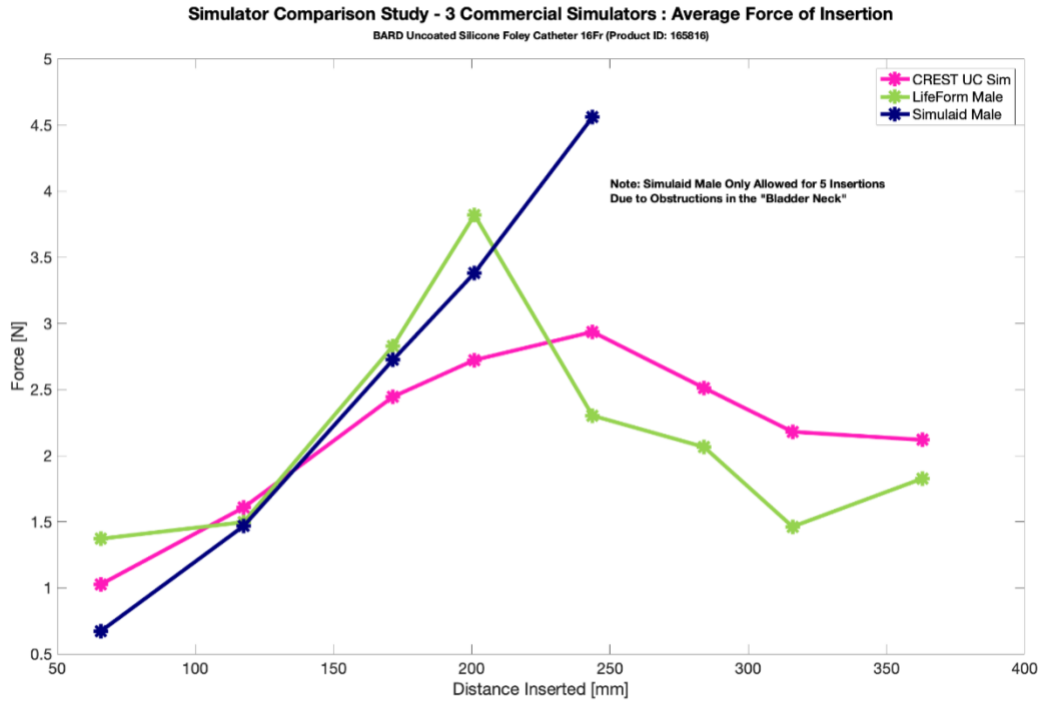


Figure S1: Average force of insertion of the 5 trials for each of the three simulators.

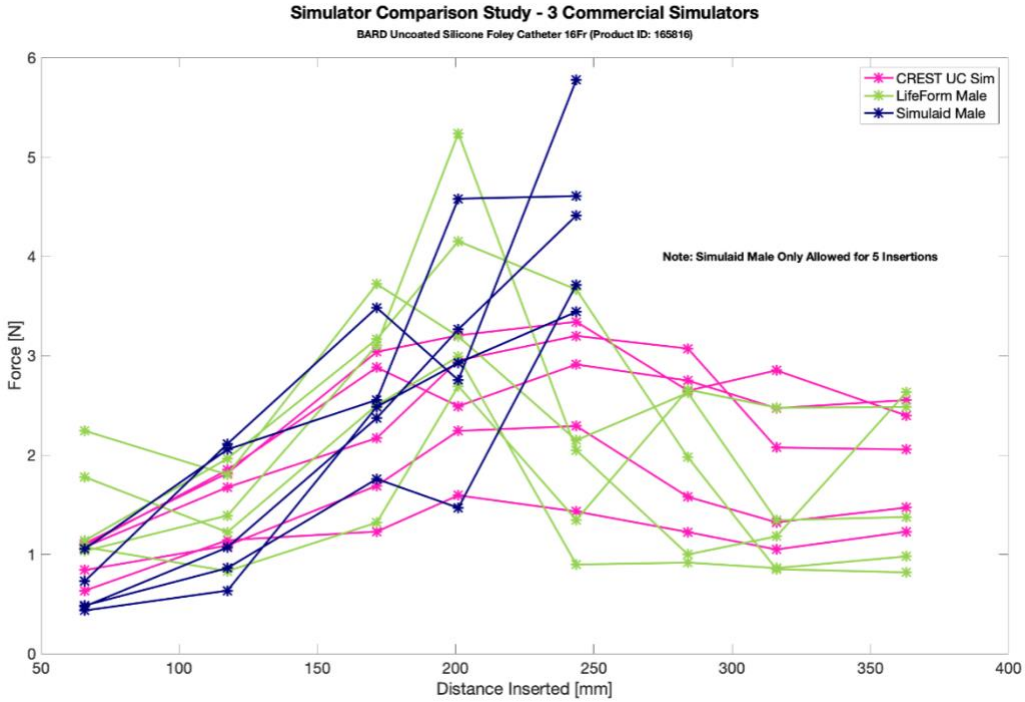


Figure S2: All insertions plotted for the three simulators over the 5 trials. Each separated by the color of the markers.

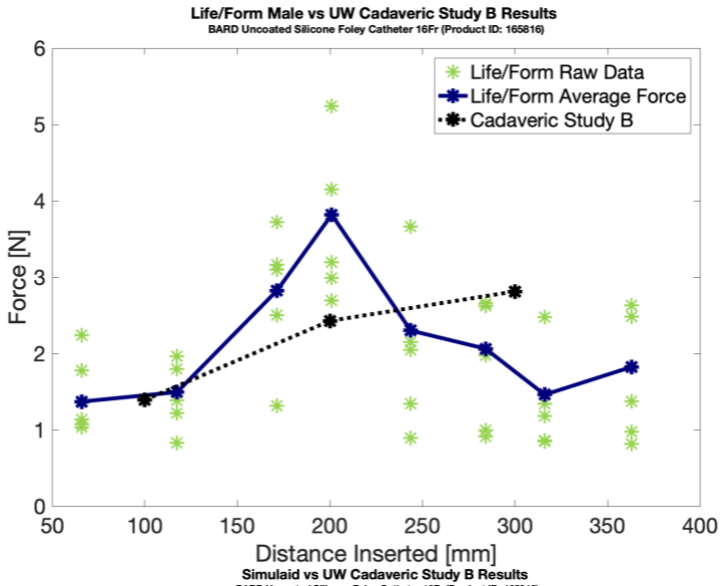


Figure S3: Results for the Life/Form Male simulator study with the Cadaveric Study B results included. Includes average force curve + raw data points to show the data spread.

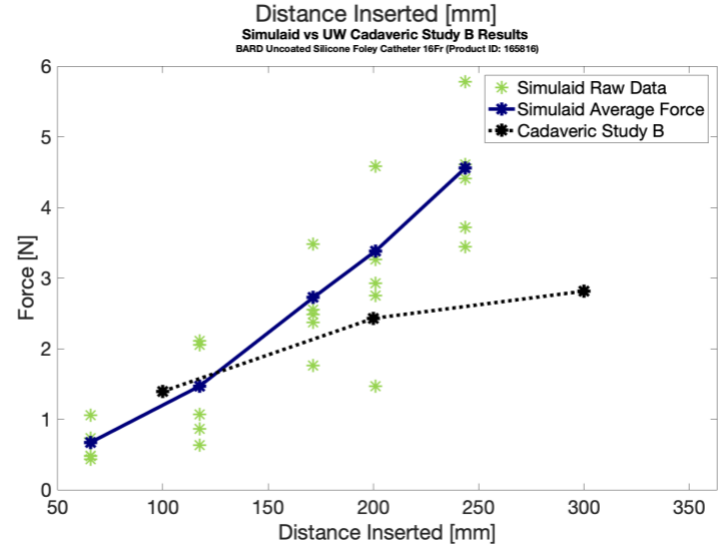


Figure S4: Results for Simulaid Male simulator study with the Cadaveric Study B results included. Includes average force curve + raw data points to show the data spread.

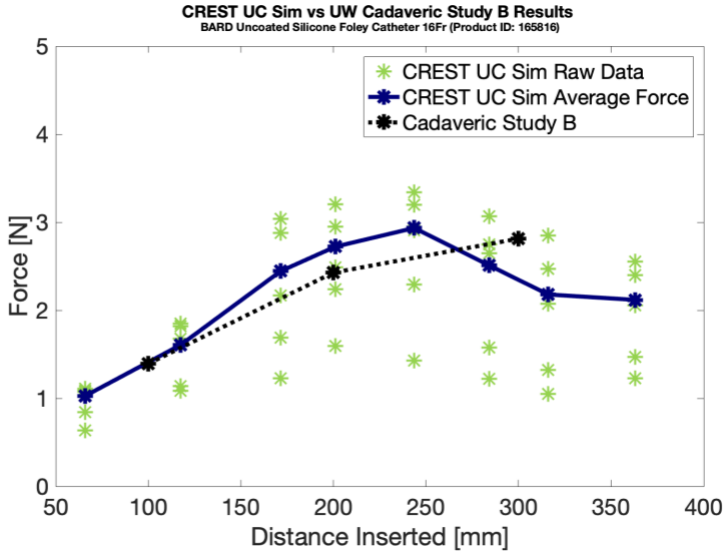


Figure S5: Results for the CREST UC Sim - V4 simulator study with the Cadaveric Study B results included. Includes average force curve + raw data points to show the data spread.