2021 43rd Annual International Conference of the
IEEE Engineering in Medicine & Biology Society (EMBC)
Oct 31 - Nov 4, 2021. Virtual Conference

CathSym: Device and Method to Bring Haptic Feedback to Urinary Catheterization Training.

Nicholas Marjanovic, Cristian Luciano PhD and Craig Niederberger MD, *Member, IEEE*

Urinary catheterization is one of the most widely taught procedures in the medical field. Current simulation-based training methods allow the students to be trained on non-realistic mannequins that do not adequately develop their psychomotor skills. This lack of proper training translates into increased likelihood of the medical professional causing damage to the patients' urethra in the form of false passages when faced with a difficult catheterization. The leading cause of this damage is the overuse of force that diverts the catheter head into the soft tissue. With the emergence of haptic feedback and virtual training into the medical field, we aimed to design and build a novel haptics-based mixed reality simulation trainer for teaching urinary catheterization. We developed a software system accompanied with a customized haptic feedback device to help the user train in various catheterization scenarios to gain experience for improving their psychomotor skills and teach them to navigate blockages and other anatomies in the urethra. Our simulation platform has the potential to adequately provde the trainees with realistic force and visual feedback that are representative of what the user might experience in real world Foley catheterization.

.

I. Introduction

Urinary Catheterization is one of the most widely done medical procedures in the medical environment. Roughly 5 million patients are catheterized in a year in the United States alone(1,2). The purpose of this procedure is to allow unobstructed passage in the urethra for urine to flow freely from the bladder in cases where the patient cannot release by themselves. Situations where catheterization is needed are when the patient does not have control of their bladder muscle or if a blockage is present in the urethra in the form of a stricture, tumors, and stones, amongst others. Placement of a catheter is taught in the early stages of medical training, whether it be a nurse of a doctor. Training mechanisms usually entails using a low fidelity mannequin made of plastic and silicone. The main purpose of simulation-based training is to teach the bare basics of Foley catheterization, while only focusing on keeping the sterile field during the procedure. Due to the lack of realistic mannequins, development of the psychomotor skills of the trainees is done over the course of their medical career on real patients (3). It has been shown that roughly 70% of urethral trauma incidents in hospitals can be connected to an individual that is still learning proper placement of a urinary catheter. The most common form of urethral trauma that is induced amongst learners is a false passage. A false passage occurs when excess force is exerted onto a catheter which moves the catheter head around a blockage and embeds it into the wall of the urethra causing a tear of the lining. Occurrences of false passages introduce an open wound to bacterial environment of the urethra possibly causing complications such as infection and sepsis. Studies have shown that medical training with advanced simulators that include haptic feedback, allows the trainees to advance their knowledge quicker and with higher confidence when faced with real scenarios outside of simulation training (4,5,6). The purpose of this study is to create an advanced training platform with realistic haptic feedback. Through a literature review, it is deduced that 15N of force should be the general threshold for during catheterization to prevent tissue damage. This system also features a visual feedback component to visualize the 3D virtual anatomy and catheter and guide the trainee during the simulated procedure. The aim is to teach the trainee, not just how to perform a catheterization, but also temper their psychomotor skills to the task, so when they are faced with real scenarios, they have some sense of the correct forces and proper technique to use to have a correct placement without complications.

Methods

A. Creation of Virtual Catheterization Environment

To act as the central hub of training, a virtual environment was created that would give visual feedback to the trainee in real time. This software will also facilitate the computational bandwidth to calculate catheter position and forces that are

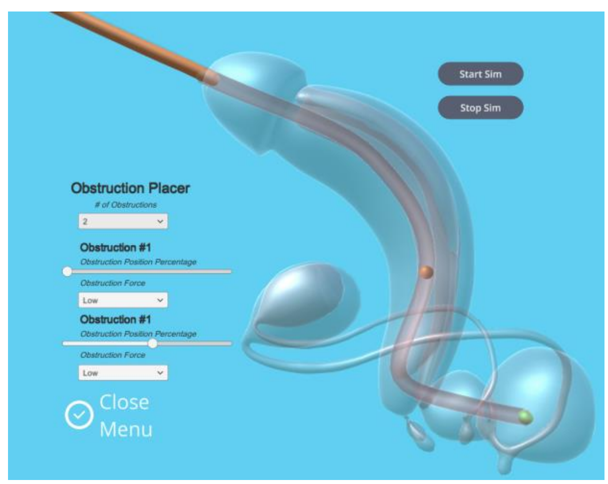

Figure 1. Visual Feedback Simulation

sent back and forth from and to the haptic feedback portion of the system. The software library used to code this

Nicholas Marjanovic (phone:3129962335, email:nmarja2@uic.edu), Cristian Luciano PhD, and Craig S. Niederberger MD are with the University of Illinois at Chicago, Chicago, IL, USA - 60612

978-1-7281-1178-0/21/$31.00 ©2021 IEEE

environment was the Unity 3D visualization system. Unity is a robust environment that allows for 3D and 2D game development and is one of the gold standards. To communicate bidirectionally with the haptic device and computer, a Unity plugin called Uduino was integrated to manage the communication with the rotary encoder, force sensor, and servo motor. This plugin allowed communication between the Unity software and Arduino 2560 processing unit. Data from the Unity sketch was sent to the processing unit to give commands to the haptic feedback device based on feedback needed. The processing unity used Uduino to relay information from the rotary encoder and force sensor to the Unity software. For the virtual representation of the penis, a 3D penile phantom and urethra was imported into the environment (Fig.1) that will be the representation of real world interactions that the trainee imparts via the haptic device. A plugin for Unity called DreamTek Splines was used for creation of a virtual urethra inside the penis model that the catheter can interact with using the physics in Unity. A virtual catheter was modeled using the plugin OBI Ropes in Unity. This catheter is allowed to move freely into the urethra and the hilt is connected to a sudo "hand" that applies the force to move it. This "hand" is actually moved via the rotary encoder that senses the movement of the real catheter by the user. To introduce strictures and blockages into the model, DreamTek Splines has the built in ability to add "triggers" to a spline that is part of the urethra. With these triggers, the trainee or supervisor can set the position of the urethra in which they want to experience the phenomenon. In the software, we added the functionality for the user to also specify the haptic feedback amount when a blockage or stricture is reached in the virtual environment. In combination with Uduino and DreamTek Splines, the haptic feedback device received real time information from Unity on when and how much force to apply to the real world catheter. To assess when the user is applying excess force to the real catheter and urethra, a system was made to gauge the movement of the catheter while under force. A test was done to chart the excess force needed to move the real catheter at various applied haptic forces. When the needed haptic force is applied, the rotary encoder sensed any excess movement of the catheter and determines wether that constitutes an excess amount of force applied in that scenario and is classified as a dangerous force. The system software tracked the average amount of force over time the user asserts into the system, as well as how much excessive force is applied. Time to completion is also taken and saved in a master file for the current user alongside the previously mentioned parameters allowing for tracking progress over time.

B. Construction of Penile Phantom Mannequin

The interface between the user and haptic feedback device was modeled after the current training penile phantom that trainees are accustomed to using. A mold was created from the mannequin using silicone of durometer O-30 from SmoothOn. After curing, the mannequin was removed from the silicone to reveal the mold for the phantom model. The phantom was created by pouring silicone from SmoothOn into the mold that was sprayed with mold release. A flexible silicone tube was inserted into the mold to recreate the urethra of the penile phantom for the catheter to pass through. After curing, the phantom was removed from the mold. A frame was 3d printed using PLA to hold the phantom in an upright position, as well as facilitate the mating of the haptic feedback device behind the phantom. The phantom was presented to urologists and nurses for evaluation on realism and comments indicated this model was adequate for training purposes.

B. Construction of Catheter Measurement System and Calibration

This system integrated a haptic feedback device with a visual feedback component for the benefit of tracking and giving feedback to the trainee. To accurately give feedback, the catheter was needed to be accurately tracked as it was inserted into the penile model. A mechanism was created that involves the catheter entering a pathway behind the penile phantom and pass by a toothed wheel that is coupled to a rotary encoder. The rotary encoder has a resolution of 2000 pulses per revolution which allowed for high accuracy in measuring the distance that catheter has moved into the penile phantom. To keep constant contact with the distance module for accurate distance measurement, the tip of the catheter had a extra silicone length of tubing to extend it into the penile phantom through to the distance module. To calibrate the rotary encoder system, a tubular ruler was 3D printed with 5mm increments. The ruler was passed by the rotary encoder in 5mm increments and the voltage output was documented to create a conversion equation for the encoder distance. Voltage from the rotary encoder system is read and analyzed by the processing unit which was interfaced to a central computer for interpretation in the visual feedback software.

C. Construction of Haptic Feedback Device and Calibration

To develop the required psychomotor skills for performing Foley catheterization under a realistic scenario, a haptic feedback system was needed to apply feedback force to the catheter as the trainee passes certain points in the urethral path. To provide quick haptic response to catheter behavior, a clamping mechanism was employed. The clamp portion was designed and then 3D printed in PLA material. The clamping force is supplied via a high torque servo motor with precise angle control. This servo motor is interfaced to the AtMEGA 2560 processing unit (Figure 2.) that allows for servo positional data to be sent back and forth in real time. The catheter being inserted into the phantom passed through into the clamping mechanism via a guide passage. When haptic feedback is requested by the visualization software, the processing unit sends a signal to the servo to clamp down on the catheter. To accurately assess the force being exerted onto the catheter, a 4 lb. Flexiforce force sensor was place on one of the claws of the clamping mechanism. To calibrate the force sensor, the manufacturer recommends a procedure whereas a known force is placed on the force sensor and the output voltage read over a course of several known forces to create a calibration curve of force versus output voltage(7). A circuit consisting of a non-inverting operational amplifier with set voltage and feedback resistance was attached to the force sensor to gather the electrical signal. A ForceOne load cell calibration device (Figure 3)(8) was used in this study to calibrate the force. 20 Newtons was applied to the force

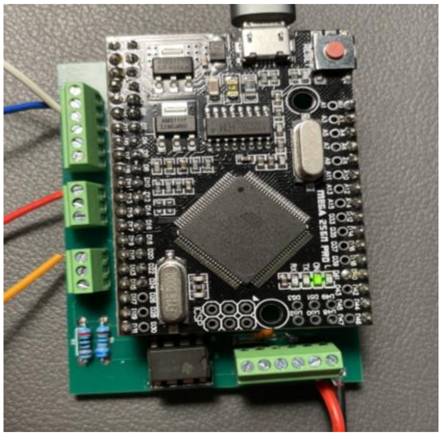

Figure 2. ATMega 2560 processing unit

sensor, at the same time a potentiometer was used to change the reference voltage so the output voltage was set to the 5 volts at maximum force. A force of 0 to 20 N in 0.5 N increments was applied to the force sensor, with its output voltage recorded by the processing unit. With the force to voltage conversion data, regression analysis can now be used to interpolate an unknown force using the acquired voltage value. To test real world use of the sensor, a random force was applied 15 times to the sensor to gauge its accuracy in response. When the virtual catheter encounters a stricture or another form of blockage, a clamping force is applied to the real catheter that is proportional to the stopping force dictated by the virtual software. To assess whether the user is applying a force magnitude above the safe threshold, the movement of the catheter is constantly monitored by the rotary encoder. If movement is sensed at an unsafe speed and amount with the

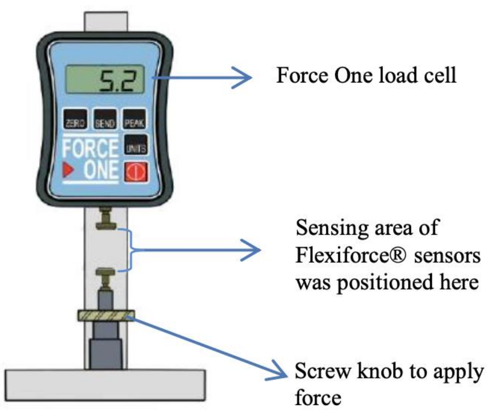

Figure 3. ForceOne device for force sensor calibration (8)

clamp engaged, the device will register this as excess force. To calibrate the haptic feedback device to accurately detect forces applied to the catheter, the ForceOne unit was turned onto its side and attached to a moving sled. The catheter length was placed into the haptic device and the tip was attached to the tip of the ForceOne unit. A clamping force of 1N to 20N in 1N increments was applied to the catheter. The ForceOne unit attached to the sled was then pulled until a movement was detected by the device. The pulling force recorded by the ForceOne unit at each clamping force was recorded and regression analysis was used to create an force equation. This data was used to assess whether the user is applying excess amounts of force when the haptic device introduced a force to the catheter mimicking obstruction. To test the accuracy of the system, random stopping forces where applied to the catheter and haptic device. The ForceOne unit was used on the catheter to test the amount of force needed to move the catheter.

Finally, the training system was tested by 4 medical professionals with different years of experience to provide feedback of the device as well as score them based on their current skill levels based on experience. For this test we gauged the average force they applied during training as well as the number of excess force events.

II. Results

With calibration of the Flexiforce sensor using the ForceOne calibration device, a random force was applied on the sensor 15 times to test the accuracy. We achieved an average accuracy of 1% between applied and measured forces as seen in Table 1. With calibration, this data showed we could accurately assess the force being applied to the force sensor.

Table I: Applied vs. Measured Force with FlexiForce Calibration

Applied Force Average (N)	Measured Force Average (N)	% Difference
8	7.93	0.87

With the integration of the force sensor into the haptic feedback device, we were able to show that the device is capable of applying forces to the catheter within 2% of the required force by the simulation as seen in Table 2.

Table II: Applied vs. Measured Force with Haptic Device Calibration

Applied Force (N)	Measured Force (N)	% Difference
8.01	8.14	1.62

After calibration, a random distance was applied through the haptic device via the rotary encoder 15 times. We were able to achieve an accuracy of 1% within the applied distance as seen in Table 3.

Table III: Applied vs. Measured Distance Calibration

Applied Distance Average (mm)	Measured Distance Average (mm)	% Difference
80.71	81.5	0.97

The participants' performance scores are shown in Table 4. It can be seen that users with less experience showed much higher levels of force applied versus individuals with more years of experience that have used less force with less events of excess force.

Table IV. User Scores From Simulation

User	Average Force Applied to Catheter (N)	# Excess Force Events	Years Experience
#1	13	3	1
#2	8	0	3
#3	10	1	2
#4	7	0	5

III. DISCUSSION

Urinary Catheterization is a core skill taught to medical professional. Current training models were shown to be inadequate in developing the psychomotor skills for Foley catheterization. In turn, incidents involving excess force during urinary catheterization is at a high rate right after initial training. There have been studies that have attempted to create new versions of trainers for catheterization but the common theme amongst them all is that they lack any form of force feedback, which is essential for properly developing the psychomotor skills.

With our system, we aimed to create a visual and haptic feedback device to provide the training with rapid force feedback response and visual stimulus to reinforce the learning experience, so that it may transfer to real-world application. For this study, we really wanted to focus on the accuracy of the force feedback provided, so calibration of the haptic device was paramount to ensure the correct experience was provided. With the use and feedback provided by this preliminary study, we can show that the device is capable of being used in training. Future work into this training system will include an expanded test pool to gather feedback and data on a more diverse user group.

REFERENCES

[1] Igawa, Yasuhiko, et al. “Catheterization: Possible Complications and Their Prevention and Treatment.” *International Journal of Urology*, vol. 15, no. 6, 2008, pp. 481–485., doi:10.1111/j.1442-2042.2008.02075.x.

[2] Canales, Benjamin K., et al. “Urethral Catheter Insertion Forces: a Comparison of Experience and Training.” *International Braz j Urol*, vol. 35, no. 1, 2009, pp. 84–89., doi:10.1590/s1677-55382009000100013.

[3] Gillis, Charlie, et al. “Male Catheter Insertion Simulation Using a Low-Fidelity 3D-Printed Model in Undergraduate Medical Learners.” *DALHOUSIE MEDICAL JOURNAL*, vol. 45, no. 2, 2019, doi:10.15273/dmj.vol45no2.8998.

[4] Manalo, Manuel, et al. “Medical Interns' Knowledge and Training Regarding Urethral Catheter Insertion and Insertion-Related Urethral Injury in Male Patients.” *BMC Medical Education*, vol. 11, no. 1, 2011, doi:10.1186/1472-6920-11-73.

[5] Schout, B. M., et al. “Validation and Implementation of Surgical Simulators: a Critical Review of Present, Past, and Future.” *Surgical Endoscopy*, vol. 24, no. 3, 2009, pp. 536–546., doi:10.1007/s00464-009-0634-9.

[6] Canales, Benjamin K., et al. “Urethral Catheter Insertion Forces: a Comparison of Experience and Training.” *International Braz j Urol*, vol. 35, no. 1, 2009, pp. 84–89., doi:10.1590/s1677-55382009000100013.

[7] “Best Practices for Electrical Integration of the FlexiForce Sensor.” *Tekscan*, 30 Oct. 2020, www.tekscan.com/resources/product-guide/best-practices-electrical-integration-flexiforce-sensor.

[8] Parthiban, Sujeeth, et al. “A Novel Method to Determine Perineal Artery Occlusion among Male Bicyclists.” *PeerJ*, vol. 3, 2015, doi:10.7717/peerj.1477.