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Low-cost female catheterization simulator for increasing anatomical accuracy and clinical competency of insertion

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Abstract

This paper presents the development of a low-cost female urinary catheterization simulator for training nurses. An egg shaped structure was 3D printed to house the trainer. A sixteen-ounce clear plastic bottle simulated the bladder. A duck bill valve simulated the bladder's internal valve and was installed in a 3D-printed washer and glued to the bottle lid. The urethra and vagina were cast in a block of Dragon Skin Fx-Pro. The labia majora and labia minora were also cast in Dragon Skin and attached as a patch to the exterior of the 3D-printed egg. A 1.5mm membrane was added over the urethra to eliminate the leakage when the catheter entered the duck bill valve. Additionally, tubing was added to the bottom of the bladder bottle to refill the bottle more rapidly. General feedback from nurses at a local hospital and faculty in a College of Nursing provided feedback including 1) color and shape of the vulva was realistic, 2) trainer helped detect the entry of urine into the catheter when entering bladder, 3) balloon inflation in the bladder bottle was realistic, 4) simulator provides a viable method for teaching and assessing performance. This feedback can provide technical reassurance. The material costs for one trainer was $27.96, excluding the one-time costs of $28.23 for patterns and molds.

Keywords: Catheterization, Simulator, Training nurses

1. Introduction

Urinary catheters are one of the most commonly used medical devices in hospitals with approximately 25% of inpatients catheterized (Blatt etal, 2017). Urology catheterization training programs have been shown to improve confidence in catheterization insertions (Kashefi etal, 2008). The most reported mechanism of injury was by inadvertent balloon inflation in the urethra or false passage creation during insertion (Bhatt etal, 2021). Bhatt etal identified the need for ongoing education and more practical supervision in clinical practice. Furthermore, procedural inaccuracies can increase the risk of catheter-associated urinary tract infections (CAUTIs) (Chuang etal, 2021).

1.1. Background and literature review

Ozdemir and Kaya (2023) stated that although urinary catheterization is taught in the first year of many nursing programs, students may not have had the opportunity to achieve an expected level of competency or to maintain their competencies throughout their academic program. Additionally, nursing graduates have difficulty maintaining urinary catheterization procedural requirements (Frost and Delaney, 2019). Therefore, nursing students must know how to perform urinary catheterization properly and have skills based on sterile principles before graduation (Gonzalez and Cole, 2014). Nursing educators should use laboratories and clinical simulations more effectively to enhance urinary catheterization knowledge and skills (Ozturk and Dinc, 2014). Hanshaw etal (2020) further identify the outcomes of clinical simulation as contributing to higher level thinking in participants.

Hospital-based educators are tasked with ensuring newly graduated nurses and new hires are competent in the skill of inserting a urinary catheter as part of clinical orientation. Assessment of this competency is part of the nurse's permanent record and a mandatory component of most clinical environments due to the penalties associated with CAUTIs. Centers for Medicare and Medicaid Services (CMS), a major payor source in the US healthcare system, launched a Hospital-Acquired Condition (HAC) Reduction System that links quality of care and patient outcomes to payment. Hospitals that have a higher incidence of hospital-acquired complications, as identified by CMS, may incur penalties, and receive lower rates of reimbursement (CMS, n.d.). Though CMS periodically updates the list of HACs, CAUTI has remained on the list due to its high incidence, cost, and preventability. Nurses can mitigate the risk of CAUTIs through modifiable variables such as achieving competency in the skill of inserting and managing urinary catheters.

Kang etal (2022) identified that simulation-based training can have an impact on the reduction of HACs; specifically, CAUTIs. Pelly etal (2020) conducted a literature review of low-cost models in urology. Twenty urology training simulation models were identified as being than $150. These six models included bladder catheterization trainers. The authors concluded a need for further validation or assessment of the transferability of skills to clinical practice since simulation has become a cornerstone in clinical skills education.

Though academic agencies can charge nursing students a "clinical fee" that may, in part, cover the recurring cost of purchasing durable medical equipment, individual training kits, and clinical supplies, healthcare agencies must budget for this expenditure within the cost of onboarding and education of nurses. The Joint Commission (2017), an accrediting body for healthcare agencies, requires each agency to provide all nurses with orientation and competency assessments to ensure safety and compliance with evidence-based guidelines such as sterile techniques. Utilization of training equipment that is cost-effective and anatomically correct is likely to enhance compliance in the area of clinical skill education and validation.

Gillis etal (2020) developed a low-cost male catheterization trainer. Sixty-four students were asked to evaluate the physical attributes of the trainer, realism of the experience, and how well the model increased competence and confidence. Over 90% of the students indicated a 4 or 5 on the Likert scale for anatomical domains of structure, color, shape, size, material and overall. Ninety percent of the students indicated a 4 or 5 on simulation realism domains of stabilizing catheter and balloon inflation. Inserting catheter, advancing catheter and appearance of urine were also less than 90%. Students rated the trainer as effective in increasing their confidence in performing a catheterization (4.48+-0.62 out of 5) and preparing for insertion on a real patient (4.15+-0.76).

Rodriguez etal (2014) conducted a study of 173 students and concluded that simulation is a training method that helps improve the confidence of medical students perform a bladder catheterization (significantly higher after training $p<0.001$). Student confidence levels before and after a urinary catheterization simulation increased from 15% to 87% for men and from 10% to 94% for women.

Todsen etal (2013) found that catheterization skills were retained at six weeks following simulation training. A study by Gonzalez and Sole (2014) concluded that a one-time competency validation using a simulator is not enough skill mastery for retention. Urinary catheter insertion is a high-risk skill and should be afforded ample time for practice. The study revealed that the most frequent breach in aseptic technique was cleaning the urethral meatus (54%).

The College of Nursing (CoN) and the Systems Management and Production (SMAP) Center have been working for several years developing a variety of trainers and simulators. Several of these trainers were a lumbar puncture trainer (Black-Mead etal, 2023), a patch (labia majora) for a pelvic trainer (Showalter etal, 2024) and a computer simulation of endobronchial (Zephyr) valves in the bronchial airways (Lakin etal, 2023).

Typically, a team is established for each project and consists of 1) a researcher from the SMAP Center who provides technical support and mentoring, 2) a faculty member from the College of Nursing who serves as the subject matter expert and 3) students, generally from science and engineering, who do the design and fabrication. At the beginning of the project the team defines the problem and establishes the design requirements. The team meets throughout the project for feedback from the nursing faculty and to ensure that the project goals are being satisfied. Prototypes are often made for testing and evaluation.

1.2. Research objective

The research objective of this project was to develop a low-cost female catheterization simulator that could be easily replicated for nurse training on the skill of urinary catheter insertion. Specifications included cost-effectiveness, anatomical accuracy, and physiologic correctness that mimics urinary valves and urinary return for confirmation of placement. Though students have not yet utilized these manufactured models, the product was utilized in a community hospital during an orientation and skills review for nurses. As these simulators were constructed to accommodate use by community clinical partners and future nursing students in the CoN. durability was added to the specifications.

Included in this paper are the design requirements and specifications of the simulator, the detailed development of the simulator, the use of the simulator by practicing nurses and faculty, nurse feedback on the realism of the catheterization procedure, and the value of the trainer as a teaching tool for increasing procedural accuracy, confidence, and competency.

1.3. Previous research

The University of Alabama in Huntsville has previously developed the following nursing trainers that were presented at previously International Multidisciplinary Modeling & Simulation Multiconferences (EMSS and IWISH):

1) Development of needle injection pads (Lioce etal, 2021).

2) 3D printed model of arteries and veins from the heart (Lioce etal, 2022).

3) Lumbar puncture trainer (Black-Mead etal, 2023).

4) Pelvic exam trainer (Showalter etal. 2024).

These papers focused on the fabrication of the trainers, trainer usage and nursing faculty and student feedback.

2. Materials and Methods

The design specifications for the female catheterization simulator were:

- Realistic look and feel of the vulva to promote respectful and anatomically correct manipulation of the labia.
- Include the following structures of the vulva: labia majora, labia minora, clitoris, urethral opening and vaginal opening.
- Diameter of urethra 8mm and length is approximately 4-5 cm through Dragon Skin block.
- Diameter of the vagina 16mm and length is approximately 1.5inches.
- Gravity feed to simulate urine from the bladder into the catheter.
- Clear plastic bladder bottle to allow visualization of the catheter in the bladder and the deployment of the balloon. Bottle length should allow for the catheter to continue in the bladder bottle for approximately 5cm.
- Cost goal of $25 in materials.

The standard procedure of a urinary catheter begins with set-up of sterile supplies, manipulation of the external genitalia to visualize the urinary meatus, and cleansing the area to decrease the risk of introducing pathogens into the urethra or bladder. The catheter is grasped approximately 5cm from the tip. The patient takes a deep breath and slowly exhales while the catheter tip is inserted 5cm until urine flow starts. The catheter is then inserted another 2.5-5 cm to make certain the catheter tip is in the bladder. As the urine enters the perforated tip of the catheter, it can be visualized flowing through the tubing of the catheter (Feneley etal, 2015). Though nurses are trained to find the urinary return into the clear tubing as confirmation of correct placement in patients, simulator trainers rarely provide the opportunity for the learner to visualize the internal anatomy of the bladder in order to identify the catheter-to-urine contact point as traditional trainers are made of an opaque material.

Fusion360 software was used to design the various parts and create the STL (stereolithography) files which were downloaded to the 3D printer. The PLA (polylactic acid) parts were printed on a Prusa-i3 with a build volume of 25x21x21cm.

Dragon Skin FX-Pro silicone rubber (Smooth-On 2024) was used for all cast parts. Dragon Skin is a soft, stable, high-performance silicone rubber designed for creating silicone makeup appliances and skin effects. Smooth-on Slacker (PartS) was added to change the feel of the silicone rubber to a softer, more flesh-like material. It also alters the rebound properties of the silicone rubber, making it feel more like human tissue. The formulation of the catheterization block was 1PartA: 1PartB and 0.50PartS.

During a previous development of the pelvic examination simulator (Showalter etal, 2024) an obese and pregnant woman's labia majora was developed with a realistic look and feel. The Dragon Skin formulation was 1 PartA:, 1PartB and 0.75PartS. A slight modification was made to reduce the fullness and size of the labia majora to represent a normal female (Figure 1).

Furthermore, it is important for learners to have exposure to simulated patients of diverse and underrepresented populations such as variations of size, weight, and ethnicity. The labia patches were colorized using Smooth-On SilcPig flesh tone silicone color pigment to ensure diverse ethnic populations were represented in the training events.

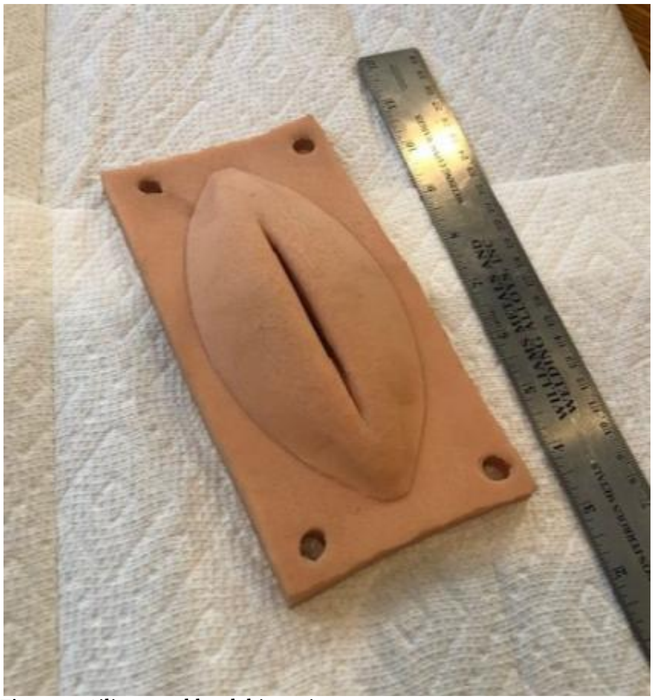

Figure 1. Silicone rubber labia majora.

3. Results and Discussion

An egg-shaped structure was 3D printed to hold the simulator (Figure 2). The structure had a rectangular hole to hold the Dragon Skin trainer. A circular hole was added to support the bladder bottle.

Two thin plates with two pegs were 3D printed in PLA and glued on the structure to hold the top and bottom of the vulva (Figure 2).

Openings were cast in a block of Dragon Skin to simulate the urethra and vagina (Figure 3). The diameter of the urethra was 8mm and the length approximately 5cm, while the diameter of the vagina was 16mm and length approximately 1.5 inches. Both openings tapered to a smaller opening for more realism.

A 33mm (7/8inch) diameter hole was cut into the bladder plastic bottle lid. A washer was 3D printed to hold the duck bill valve (Figure 4). Super glue was used to adhere the washer to the bottle lid. Super glue with cyanoacrylate was used to adhere the washer to the Dragon Skin block. An additional bead of E6000 surrounded the opening between the valve and lid to avoid any water leakage. Plumber tape was also wrapped around the bladder bottle to eliminate any water leakage.

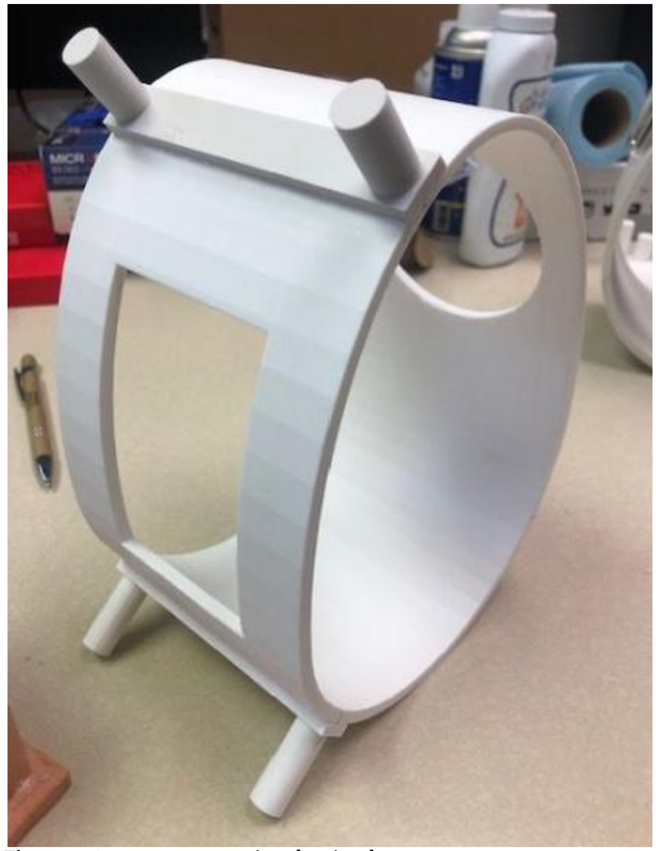

Figure 2. Structure supporting the simulator.

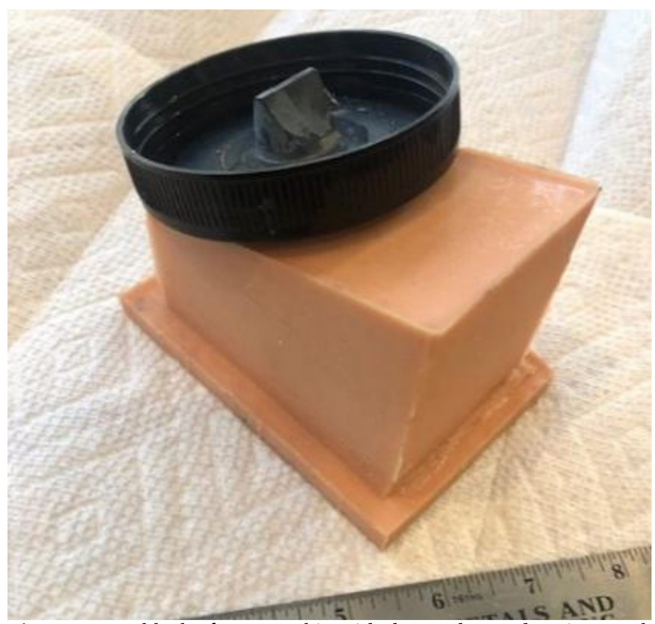

Figure 3. Cast block of Dragon Skin with the urethra and vagina. Duck bill and bottle cap glued to Dragon Skin block

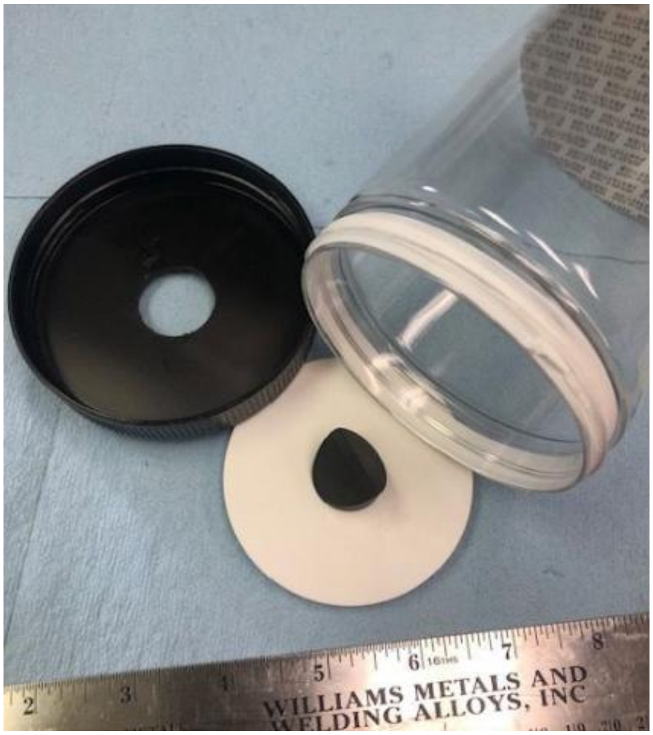

Figure 4. Duck bill valve in washer.

The catheterization simulators were evaluated by nurses in a skills training program at an area community hospital and by faculty at the College of Nursing at the University of Alabama in Huntsville. Nurses were informally asked for feedback on the realism of the catheterization, overall simulation experience, and the value of the simulator as a teaching tool for increasing procedural confidence and competency.

The overall feedback included content surrounding these variables:

- The exterior color and shape of the vulva were very realistic and anatomically correct.
- The simulator helped detect the entry of urine into the catheter when entering the bladder.
- Balloon inflation in the bladder bottle was realistic; allowing for visualization.
- Simulator provides a good method for teaching and assessing performance; can enhance procedural confidence.

One area for improvement regarded the issue of urine leakage after the catheter tip passed through the duck bill valve and entered the bladder bottle. Normally the duck bill valve was closed. The valve became elongated when the catheter passed through as shown in Figure 5. As a result, there was a small void for urine to leak outside the catheter and through the urethra and to drip out of the trainer. The initial trainer assumed that the balloon would seal the void when inflated (Figure 5).

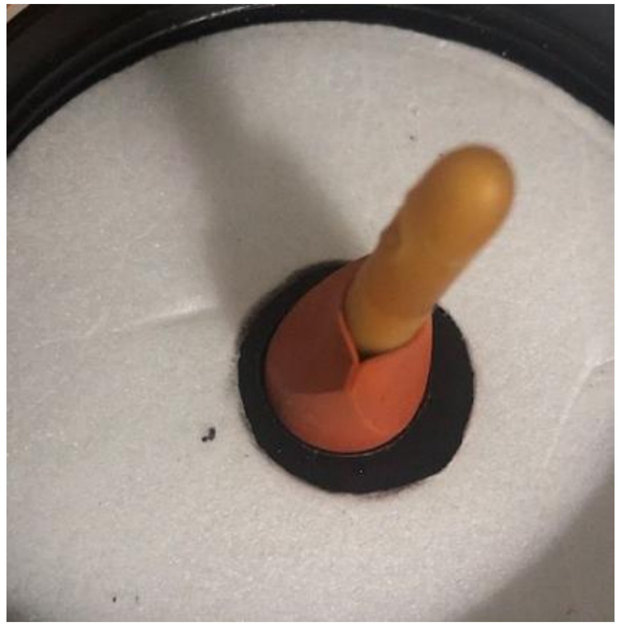

Figure 5. Catheter passing through the duck bill valve.

The solution to the leak was to brush a thin layer of Dragon Skin on the block and install a 1.5mm thick membrane between the block of Dragon Skin containing the urethra and the duck bill valve assembly. A small several-millimeter sized cut was made in the membrane at the opening of the urethra (Figure 6). Thereafter, as the catheter was inserted the cut was stretched and tightly wrapped around the catheter. The membrane completely eliminated the leakage.

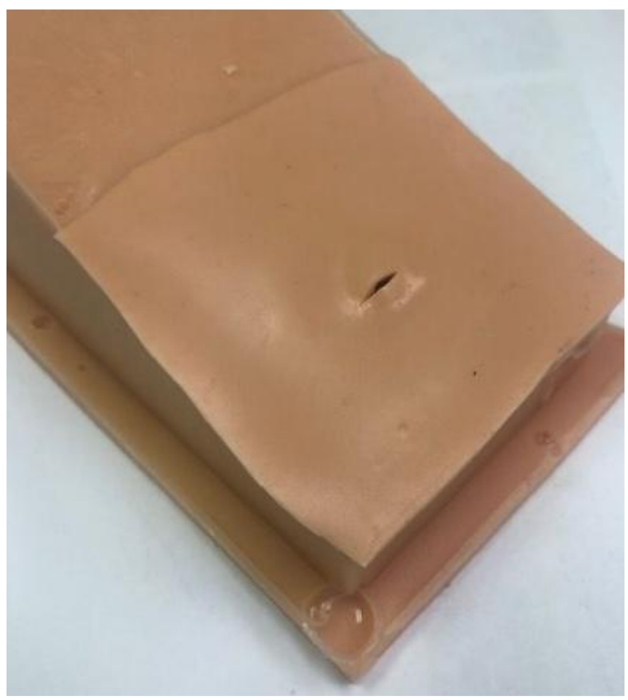

Figure 6. 1.5mm thick membrane installed over the block of Dragon Skin.

Previously, the simulator had to be refilled by unscrewing the bladder bottle from the simulator. However, based on observations, a tube was added to easily refill the bladder bottle rather than unscrewing the bottle. Figure 7 is a close-up of the tubing at the bottom of the bladder bottle.

It was also noted that clogging of the catheter occurred during the simulation when the standard lubricant used to advance the catheter through the urethra in a patient was used. As a result, the urine did not flow through the catheter. However, if the bladder bottle was at a higher elevation the urine flowed freely through the catheter. The solution was to use a lubricant specifically designed for catheterization simulators such as Life/form from Nasco Life (2024).

The total cost of materials for one catheterization simulator was $27.96 (given in Table 1). The one-time material cost for the molds was $28.23.

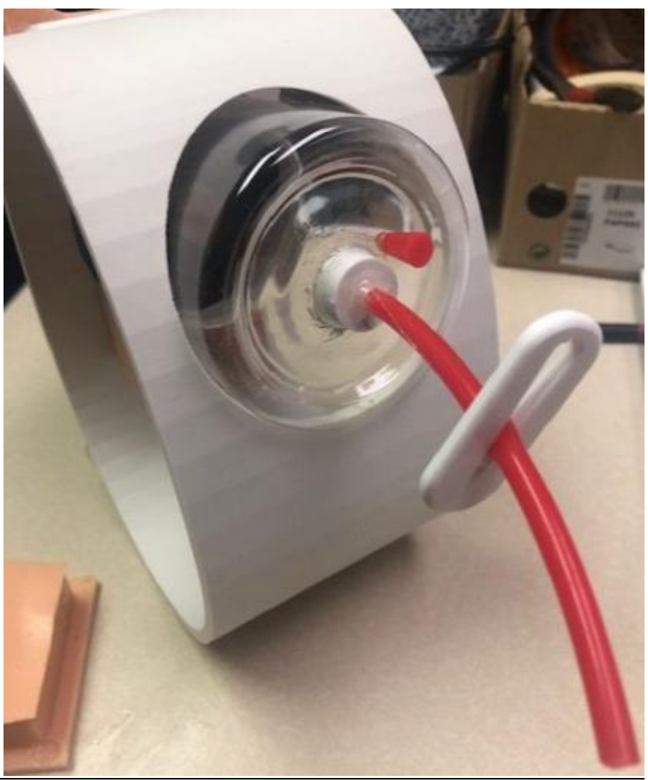

Figure 7. Addition of tubing to refill the bladder bottle.

Table 1. Material costs.

Item	Material	Amount	Cost
Structure	PLA	175g	$5.25
Washers (2)	PLA	18g	$0.54
Slide clamp	PLA	20g	$0.60
Peg plates (2)	PLA	44g	$1.32
Vulva	Dragon Skin	250ml	$7.50
Block (urethra/vagina)	Dragon Skin	328ml	$9.84
Bladder (16 oz bottle)	Purchased	--	$1.43
Duck bill valve	Purchased	_	$1.28
Red tubing and plug	Purchased	--	$0.20
Total material costs for one trainer			$27.96
One-time costs			
Casting block mold	PLA	121g	$3.63
Labia majora pattern	PLA	40g	$1.20
Labia majora mold	Dragon Skin	780ml	$23.40
Total one-time costs			$28.23

4. Conclusions

Figures 8 and 9 show the simulator after the addition of the membrane and the tubing to refill the bladder bottle.

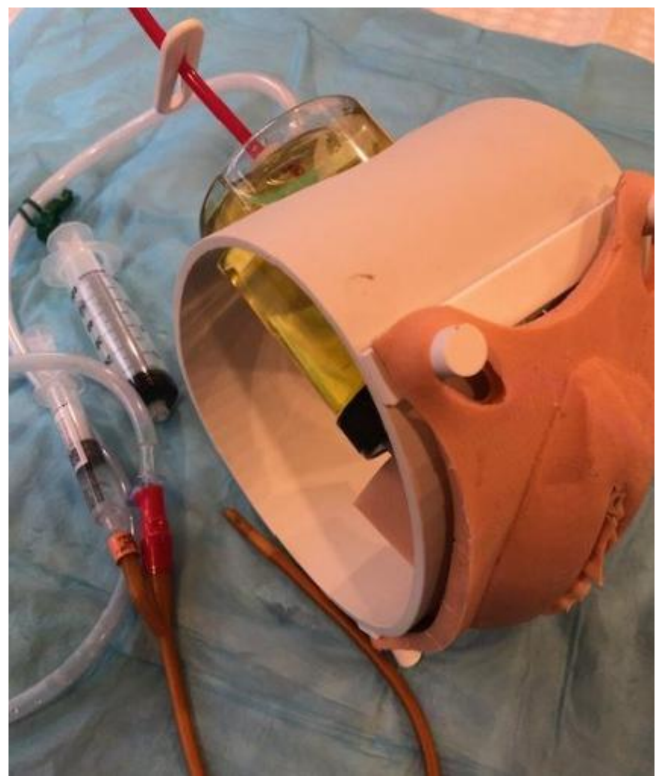

Figure 8. Catheterization trainer assembly with Foley catheter.

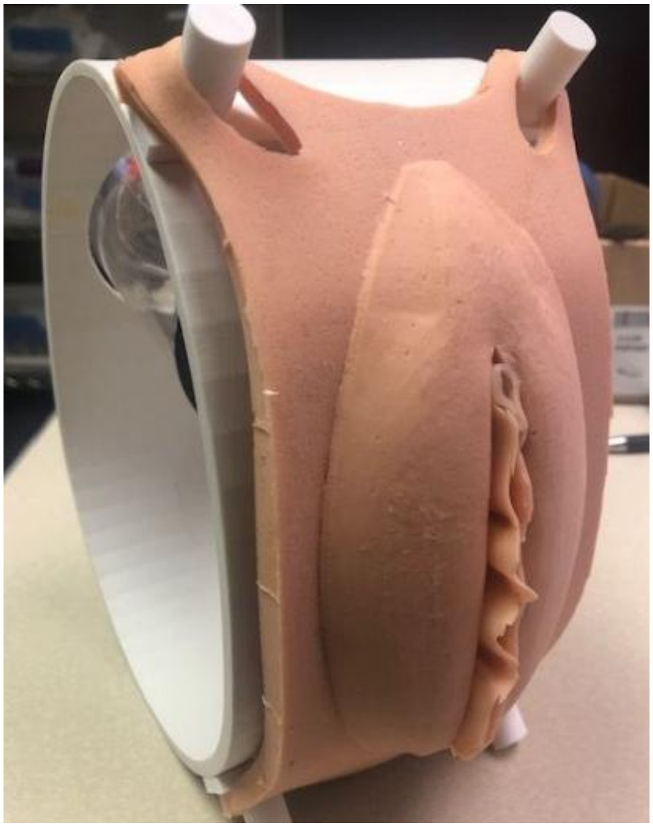

Figure 9. Catheterization trainer assembly.

Two catheterization simulators were provided to the community hospital for continued nursing training. Orientation and skills sessions occurred every two weeks with a portion of the orientation being a skills lab to validate competency of the newly hired RNs/LPNs in their reviewing and using policy and procedure documents to guide clinical skills. Female urinary catheterization was one of these skills.

Though nursing students have not yet utilized this training modality, based on agency utilization and the addition of trainer enhancements, students in the fundamentals course will begin to use this model to learn and practice the skill of inserting a urinary catheter.

The Systems Management and Production Center (SMAP) at the University of Alabama in Huntsville (UAH) is working closely with nursing programs throughout North Alabama to transfer its technologies. Many of these products are available on SMAP's MEDNET (Model Exchange and Development of Nursing and Engineering Technologies) website. Instructions for the fabrication of the catheterization simulator will be added to MEDNET.

In summary:

- The catheterization simulator permitted nurses to visualize the urinary tract and bladder and to promote appreciation for the function of the catheter in the bladder.
- Fluid was retained in the bladder using a duck bill valve that provided a small amount of resistance when the catheter passes through the urinary tract. This was representative of breaching the internal urethral sphincter on a real patient.
- The bladder (urine) drained through the catheter before the balloon was inflated and held snugly in the bladder neck.
- The bladder bottle was clear plastic, allowing the visualization of the inflated balloon and showing the correct length of insertion to reduce urethral injury.
- The labia patch was anatomically correct and allowed for a life-like texture which was helpful in the practice of manipulating external genitalia during the procedure. Many trainers are not anatomically correct and are made of hard materials.
- The material costs for a catheterization simulator was $27.96, ensuring that the design goal of $25 was close to being met. Other trainers can cost considerably more.
- The use of simulators can provide opportunities for skills practice and validation before delivering patient care. The end result is reducing nurse fears.
- Simulators such as catheterization trainers can be an effective tool in teaching and validating basic procedural skills, while also maintaining a low cost.

Areas for future research are:

- Reduce water (urine) leakage. Surprisingly, many of the catheterization trainers are being used without liquid.
- Make the trainer more stable. Generally one student is required to hold the trainer while the other student inserts the urinary catheter.
- Enclose the sides of the trainer which would alter the appearance, add weight and possibly retain some of the water leakage.
- Conduct a structured survey to obtain user feedback.

Acknowledgements

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