3-DMED® 4-in-1 Silicone Training Aid for Practicing Laparoscopic Skills and Tasks: An Evaluation

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ABSTRACT

Objective: We developed a simple, inexpensive model to simulate four reconstructive laparoscopic procedures: pyeloplasty, vesicourethral anastomosis, bladder injury repair, and partial nephrectomy.

Materials And Methods: Liquid silicone was evenly applied in layers to a mold to create the 4-in-1 model. A questionnaire evaluating face and content validity of the 4-in-1 model was distributed to postgraduate urologists participating in a mini-residency program at the University of California, Irvine, and in the 2006 American Urological Association Hands-On course on reconstructive laparoscopic pyeloplasty. Tensiometric studies were performed on the silicone model to determine tear-through tension compared to porcine tissues.

Results: A total of 56 postgraduate urologists used the 4-in-1 model and completed an evaluation questionnaire. Ninety-one percent (51/56) and 86% (48/56) agreed that the model is helpful for practicing laparoscopic pyeloplasty and urethrovesical anastomosis, respectively. Urologists who were experienced in either performing laparoscopic pyeloplasty (N=6) or robotic-assisted and/or laparoscopic prostatectomy (N=11), would recommend this model to surgeons in training. Overall, 86% (48/56) and 89% (50/56) of all participants would recommend this model for training postgraduate surgeons and residents, respectively. The 4-in-1 model was more resistant to tear-through than the porcine urethra, renal parenchyma and bladder neck, while the portions of the model representing the bladder and the collecting system were, respectively, more fragile.

Conclusion: We present a versatile model for practicing laparoscopic and robotic suturing and knot-tying skills used in four reconstructive urologic procedures. Our results support the face and content validity of this model for performing pyeloplasty and vesicourethral anastomoses.

INTRODUCTION

Laparoscopic pelvic trainers and simulators play an important role in the acquisition of laparoscopic skills. These tools enable urologists to hone their skills in intracorporeal suturing and knot tying for myriad reconstructive procedures.[1,2] These reconstructive procedures most commonly include: (1) laparoscopic cystorrhaphy, (2) pyeloureteral anastomosis for a ureteropelvic junction (UPJ) obstruction, (3) vesicourethral anastomosis after a radical prostatectomy, and (4) collecting system closure and renal parenchyma repair following a partial nephrectomy.

However, while exercises in pelvic trainers allow a urologist to develop basic suturing and knot tying abilities, they provide insufficient training because they do not resemble certain unique intraoperative urologic conditions. A unique limitation in laparoscopic urologic training is the lack of practice opportunities in the clinical setting. Unlike cholecystectomy in general surgery, there is no simple laparoscopic urologic operation through which a urologist may begin to acquire even simple laparoscopic skills before performing more complex reconstructive procedures. Likewise, computer-driven procedure specific simulators to date are both expensive and at present limited to only cholecystectomy and herniorrhaphy. Currently, there is no inexpensive readily accessible inanimate model that would allow the repetitive practice of specific reconstructive urological procedures in their entirety within the confines of a pelvic trainer.

Herein, we describe a simple, inexpensive, and versatile model (3-DMED® 4-in-1 silicone model) developed at the University of California, Irvine (UCI). This is the first model to address procedure specific training in four laparoscopic reconstructive urologic procedures. Both content and face validity of this model were evaluated for two of these reconstructive procedures (i.e. pyeloplasty and vesicourethral anastomosis).

MATERIALS AND METHODS

MODEL PREPARATION: Liquid silicone was applied evenly to a mold pretreated with a releasing agent. The mold's largest diameter was 7 cm. with an overall length of 9.5 cm. The lower half consisted of a 7 cm. long cylindrical tube with a diameter of 8 mm. In making the model, additional coats of silicone were applied to representative areas of the mold to create thicker "tissue" in an attempt to replicate the differences one would find clinically.

METHOD OF MODEL USE: The 3-DMEd® 4-in-1 model (Figures 1A and B) was used to simulate the following four reconstructive procedures: cystorrhaphy, vesicourethral anastomosis, pyeloplasty and partial nephrectomy reconstruction.

Cystorrhaphy: The ovoid body of the model, representing the bladder wall, was incised longitudinally or transversely and repaired with a running suture (Figures 2A and 2B).

Vesicourethral Anastomosis: The body of the model (representing the bladder) was "dismembered" from the lower tubular portion (representing the urethra). A laparoscopic "vesicourethral" anastomosis was then performed by reconnecting the two together. Either an interrupted or a running van Velthoven-type suture was placed. The suture was secured with either a Lapra-Ty (Ethicon Endo Surgery, Cincinnati, OH) clip or an intracorporeal knot (Figures 3A and 3B) to mimic actual established standard techniques[3].

Pyeloplasty: Alternatively, these same dismembered segments were aligned transversely, on the base of a pelvic trainer, to simulate a right or left–sided dismembered pyeloplasty (the body of the model represents the renal pelvis and the cylindrical portion represents the ureter). In this regard, the surgeon could incise, spatulate, and dismember the "ureter" prior to performing the pyeloureteral anastomosis. A van Velthoven-type of suture was used to perform a continuous non-locking anastomotic stitch joining the pelvis and ureter. (Figures 4A and 4B).

Partial nephrectomy: The flat base of the model served as the bed of the excised "renal parenchyma." A 3-5 cm. incision in the middle of this area simulated the open collecting system which was closed with a running suture (Figure 5A) while the exterior edges of the flat surface simulated the renal capsule and parenchyma that were closed, over bolsters, with interrupted sutures (Figures 5B and 5C).[4,5]

ASSESSMENT OF FACE AND CONTENT VALIDITY: During the 2006, American Urological Association (AUA) Hands-On reconstructive laparoscopic pyeloplasty course and the UCI Mini-Residency for Robotic Assisted Laparoscopic Prostatectomy (RALP) training course, participants had the opportunity to use the 4-in-1 model to learn and practice two laparoscopic reconstructive procedures in a pelvic trainer (i.e., pyeloureteral and vesicourethral anastomoses). Immediately following these courses, the participants were asked to complete a questionnaire to assess the face and content validity of the model. The participants were also asked to rate their experience in a scale of 1 to 5: 1-novice (0-1 cases performed clinically) up to 5-expert (>20 cases done clinically). No questions pertaining to cystorrhaphy or partial nephrectomy were included in the survey because these were not taught during the two study training courses. The responses to each question were analyzed using SPSS software.

TENSIOMETRY STUDY: The Interface® Force Transducer (Scottsdale, Arizona, USA) was used to compare the tensile, tear-through strengths of the 4-in-1 model to their counterparts in the pig model. The 4-in-1 model's bladder neck, urethra, anterior bladder wall, collecting system, ureteral wall, and renal parenchymal edge were contrasted with the equivalent porcine tissues. The thickness of each of these areas was measured using an electronic caliper (Mitutoyo 6" Digital Caliper, Digimatic Mycal E-Z Caliper, Japan). A 3-0 Monocryl suture (Ethicon Surgical, Sommerville, NJ) was passed 5 mm. from the edge of the model or tissue to be tested. The other end was anchored to the tensiometer and pulled with increasing force until the suture tore through the model. The highest tensile pressure at which tear-through occurred was recorded. A total of 10 tests were performed on each tissue and on each part of the model. The mean thickness and tensile tear-through strengths of the 4-in-1 model and porcine tissue were compared using the student's T-test.

RESULTS

A total of 56 urologists participated in the study and completed the questionnaire. Among these, 6 and 11 had completed > 20 cases of laparoscopic pyeloplasty and urethrovesical anastomosis, respectively and were rated at the expert level of experience.

Content validity. Ninety-one percent (51/56) of respondents rated the model as helpful in learning the suturing techniques of a laparoscopic dismembered pyeloplasty (Table 1). These included 73% (22/30) of the novice participants and 100% (18/18) of all the other participants with average to expert rating in laparoscopic pyeloplasty. Only 7% (2/30) of the novices rated the model as poor or below average (Table 2). Furthermore, of the 50 participants who responded, 96% (48/50) agreed that the model was helpful in practicing urethrovesical anastomosis inclusive of 96% (24/25) of the novices and 100% (24/24) of all the participants with average to expert rating in laparoscopic or robotic prostatectomy. (Table 3).

Face validity. Of the 56 respondents, 86% (48/56) would recommend this training model to postgraduate surgeons and 89% (50/56) considered the model as potentially helpful to residents (Table 1). All of the expert urologists (with >20 case experience) in either pyeloplasty (6/6) or vesicourethral anastomosis (11/11) recommended that surgeons and residents use this model for laparoscopic training in these two specific procedures.

Tensiometry study. The mean wall thickness and tension tear-through strengths of the model and the porcine tissues are summarized in Table 6. The thickness of the 4-in-1 model positively correlated with the corresponding tear-through strength. The 4-in-1 model had statistically significant higher tear-through strengths than the porcine tissue in all aspects except in the anterior bladder wall and the collecting system (Table 4).

DISCUSSION

Numerous studies have been published describing structural animate and inanimate models for laparoscopic training in either pyeloplasty or vesicourethral anastomosis.[6-11] With any model, the key question relates to the validity of these procedural trainers. The initial evaluation addresses face and content validity, and then other validity tests can be applied (e.g. construct, concurrent, and predictive).[12,13,14]

Content validity refers to the model's representation of the actual task to be performed (*Does it teach what it is supposed to teach?*). In this regard, participants were asked to assess whether they were able to realistically practice the methods of laparoscopic pyeloplasty and vesicourethral anastomosis on the 4-in-1 model.

Face validity, on the other hand, determines whether the model represents what it is designed to represent. In this study, it refers to the expert urologists' evaluation of the model after they have used it; i.e. whether they felt that it would be helpful for training others in laparoscopic pyeloplasty and vesicourethral anastomosis. This is the most important aspect of face validity; that of getting the experts' assessment of an instrument's applicability.

Animal training models have been proposed by various authors. Nadu and colleagues originally described a model for training in urethrovesical anastomosis, constructed of chicken skin set in a laparoscopic training box.[6] The chicken skin was fashioned into a 4-cm long tube over a 16F catheter with another piece of skin folded over to simulate a bladder. A "bladder neck" was made by cutting a 1 cm. orifice in the folded edge of the bladder. The time to perform the model anastomosis significantly decreased, after 20 sessions, resulting in a significant improvement in manual dexterity in laparoscopic manipulation of the needles, sutures, and fragile tissues. Other investigators used Nadu's model to further evaluate its construct validity among medical students,[8] urology residents in training,[9] and postgraduate urologists.[7,10]

Another investigator used the esophagogastric junction of a chicken to simulate the vesicourethral junction.[11] It was a good representation of the bladder and urethra and appeared to have good construct validity. However, when using this particular model, certain issues need to be addressed. While this and other animal tissue models are relatively inexpensive, they must be replenished after each use. Due to contamination of the pelvic trainer and suturing instruments, strict bactericidal cleaning of these training tools is mandatory. Further, in the United States, although the use of chicken skin is not forbidden in the laboratory, the sale of fowl with intact intestinal components is regulated by the United States Department of Health and Human Services because the avian digestive tract may harbor certain diseases such as the avian influenza virus; making the use of this esophagogastric model not easily accessible to the American surgical training programs.

Poulakis and colleagues devised an innovative non-animal, inanimate training model using a Gore-Tex® vascular graft for teaching laparoscopic vesicourethral anastomosis.[15] In a study involving a single urologist, the first 30 laparoscopic radical prostatectomies were assessed. During the first 15 procedures, the surgeon had no systematic training outside of the operating room. During the subsequent 15 cases, the surgeon followed a systematic simplified daily program of training which consisted of intracorporeal suturing and knot tying in a linear and circular anastomosis using the Gore-Tex® graft. The skill task training and the operative procedures were video recorded, reviewed, and evaluated by two independent surgeons experienced in open radical prostatectomy for time, global performance errors, and quality of the anastomosis. Logarithmic regression analysis showed a steady improvement in time and accuracy of the suturing skills and there was a statistically significant improvement in the time, accuracy, and the quality of the watertight anastomosis of the last 15 clinical laparoscopic radical prostatectomies compared to the first 15 clinical procedures. The authors suggested that this experience perhaps had an element of predictive validity, however it is also likely that the quality of anastomoses in the latter patients improved over time as a result of the surgeon's continuing practice and advancement on the learning curve, despite the preoperative practice sessions. One drawback of this model however, is the overall expense of the material. A 10mm. 40cm. Gore-tex® vascular graft which was used in this study costs at least $400 based on the most recent 2007 catalogue. Another is the lack of similarity of Gore-Tex® to the bladder neck and urethral tissues.

An effective simulation model should as closely as possible mimic the anatomical intraoperative reality; as such, the model should accurately represent the visual space and real time characteristics of the procedure, be capable of being positioned similar to the arrangement of the tissues at the real surgical site such that the access of the instruments to the surgical site is similar to the clinical situation, and provide realistic tactile feedback.[17] The 4-in-1 silicone model incorporates these various characteristics. Firstly, it closely resembles the size and shape of the human bladder and urethra making it a realistic vesicourethral anastomosis model. The average volume of the human bladder is about 400 cc and the mold used for the 4-in-1 model has an average volume of 300 cc. The hollow ovoid shape of the 4-in-1 model also mimics a dilated renal pelvis associated with a UPJ obstruction during a dismembered pyeloplasty. The similarity of the 4-in-1 model to the bladder and renal pelvis is based on its overall flexibility and pliability. Incisions in this part of the model can also vary in direction, posing a variety of suturing challenges for the trainee. A partial cystectomy can be performed on the model and the edges can be sewn together while simultaneously maintaining tension on the knot to approximate the edges, similar to the in vivo situation. The 4-in-1 model was also designed such that it may be anchored to an angled board within the pelvic trainer in order to mimic the actual surgical approach to the vesicourethral junction when the patient is in a 45-degree Trendelenburg position or to the ureteropelvic junction when the patient is in a lateral decubitus position (Figure 1A). This ability to vary the position of the model on the pelvic trainer creates geometric challenges that a surgeon usually encounters in the actual patient; duplication of these visuo-spatial challenges in the training laboratory may therefore help to improve efficiency in the operating room.[17]

A more recent development was use of the 4-in-1 model for teaching and practicing partial nephrectomy (Figure 1B). The 4-in-1 model provides a format to practice a running suture closure of the model's collecting system; in addition placement of surgical bolsters and suturing these in place via the model's edges with a series of interrupted sutures simulates the closure of the renal parenchyma over surgical bolsters. The model can again be positioned at a variety of angles to stimulate various approaches to the partial nephrectomy including right vs. left side, and upper pole vs. lower pole.[4,5]

The 4-in-1 model is the first model to provide content and face validity for both laparoscopic pyeloplasty and laparoscopic vesicourethral anastomosis. It is also the first model to allow practice of cystorrhaphy and partial nephrectomy. Furthermore, by removing the sutures after every exercise, the various procedures can be repeated several times on the same 4-in-1 model. Based on our personal experience and the participants' use of the model in our mini-residency program, we estimate that at least 40 vesicourethral anastomoses or pyeloplasties can be performed before having to use a new 4-in-1 model.

While animal models or cadavers provide a more realistic procedural training environment, the expense of these one-time use models is all too often prohibitive.[16,19] The average cost of the use of a cadaver at our medical center is $2500; while the cost of a pig for the skills training laboratory is $348, exclusive of transportation, anesthesia, room time, and personnel. While the use of chicken skin or other non-vital animal tissues is low cost (a whole chicken costs approximately $5 or $1.75 per pound); the setup time for each model, the post-use clean-up time, and the single use nature of these models remain a drawback.

In contrast, completely inanimate plastic-based models are commercially available for surgical skills training, such as the Bristol Urological Institute Pyeloplasty and Nephrectomy Trainer (Limbs & Things Inc., Savannah, GA); this model costs approximately $137 per unit. The same company also makes the Clinical Male Pelvic Trainer that costs more than $2000. This model has penis, bladder and prostate elements but its validity and use in practicing urethrovesical anastomosis has yet to be tested to the best of our knowledge. In contrast, the cost of the material for the production of the 4-in-1 model including labor expenses is $34 per model.

Presently, there are several limitations to the 4-in-1 model. First, the 8-mm caliber of the cylinder is too large for the ureteral portion of the model, albeit perfect for the urethral portion of the model. Secondly, the thickness of the different parts of the model has not yet been standardized. In this regard, the model is anatomically incorrect since the normal ureter has a thickness of 2-3 mm, the normal bladder wall is 7-8 mm, while the renal pelvis is 3-4 mm. Third, the tensile strength of the model in its present state does not mimic the tensile strength of the respective porcine tissues and has yet to be compared to normal human tissues. The next generation of the 4-in-1 model will be revised to address each of these concerns.

In the Minimally Invasive Surgery Education Center at the University of California, Irvine, the 4-in-1 model is routinely used to practice all four reconstructive laparoscopic procedures during a Mini-Residency training course.[18] Future studies will be directed to compare performance of residents during skills training on the 4-in-1 model, to their performance in a “gold” standard animal model or cadaver procedure in order to obtain concurrent validity testing for each of the four procedures. In addition, testing of construct and predictive validity is being planned now that both face and content validity of this model have been confirmed for both the pyeloplasty and vesicourethral anastomosis models. Face and content validity testing for the cystorrhaphy and partial nephrectomy is currently being performed. Lastly, an instruction manual is currently being written to facilitate the proper use of this model.

CONCLUSION

The 3-DMed® 4-in-1 model provides an inexpensive, versatile model for learning four reconstructive laparoscopic urologic procedures. For this model, content and face validity have been demonstrated for both laparoscopic pyeloplasty and laparoscopic vesicourethral anastomosis.

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APPENDIX

QUESTIONNAIRE FOR ASSESSMENT OF FACE AND CONTENT VALIDITY AND PARTICIPANTS' LEVEL OF EXPERIENCE.

1. Did the model help you learn the suturing technique of a laparoscopic pyeloplasty?

   (Yes ____ No ____)

2. Did the model help you learn the suturing technique of a laparoscopic vesicourethral anastomosis?

   (Yes ____ No ____)

3. Would you recommend surgeons in training to use this model?

   (Yes ____ No ____)

4. Would you recommend residents in training to use this model?

   (Yes ____ No ____)

5. On a scale of 1-5 please rate the value of the model for improving your suturing technique in laparoscopic pyeloplasty. (1-poor, 2, 3-average, 4, 5-excellent)

6. On a scale of 1-5 please rate the value of the model for improving your suturing technique in laparoscopic urethrovesical anastomosis. (1-poor, 2, 3-average, 4, 5-excellent)

7. Please rate your clinical experience in performing laparoscopic pyeloplasty from 1-5.

   1 (0-1 cases performed clinically) up to 5 (>20 cases performed clinically)

   _____1 (novice) _____2 _____3 (average) _____4 _____5 (expert)

8. Please rate your clinical experience in performing robotic and or laparoscopic prostatectomy.

   1 (0-1 cases performed clinically) up to 5 (>20 cases performed clinically)

   _____1 (novice) _____2 _____3 (average) _____4 _____5 (expert)

TABLES

TABLE 1. SUMMARY OF RESPONSES TO QUESTIONS 1 TO 4 (ASSESSMENT OF FACE AND CONTENT VALIDITY)

QUESTIONS	*Number of respondents (%)*			
	Yes	No	Don't know	TOTAL
No. 1. Helps to learn suturing techniques of laparoscopic pyeloplasty?	51 (91)	3 (5.4)	2 (3.6)	56 (100)
No. 2. Helps to learn suturing techniques of laparoscopic vesicourethral anastomosis?	48 (86)	2 (3.6)	6 (10.7)	56 (100)
No. 3. Would recommend surgeons in training to use this model?	48 (86)	3 (5.4)	5 (8.9)	56 (100)
No. 4. Helpful for resident in training for laparoscopic suturing?	50 (89)	2 (3.6)	4 (7.1)	56 (100)

TABLE 2. EVALUATION OF THE 3-Dmed® 4 IN 1 MODEL ACCORDING TO THE LEVEL OF EXPERTISE IN LAPAROSCOPIC PYELOPLASTY

Level of laparoscopic experience in laparoscopic pyeloplasty	1-Poor	2	3-Average	4	5-Excellent	No rating	TOTAL (%)
1 Novice	1	1	10	8	4	6	30 (53.6)
2				3	2		5 (8.9)
3				4	4		8 (14.3)
4				4			4 (7.1)
5 Expert (>20 cases)					6		6 (10.7)
Level of expertise not mentioned			3				3 (5.4)
TOTAL	1 (1.8)	1 (1.8)	13 (23.3)	19 (33.6)	16 (28.6)	6 (10.7)	56 (100)

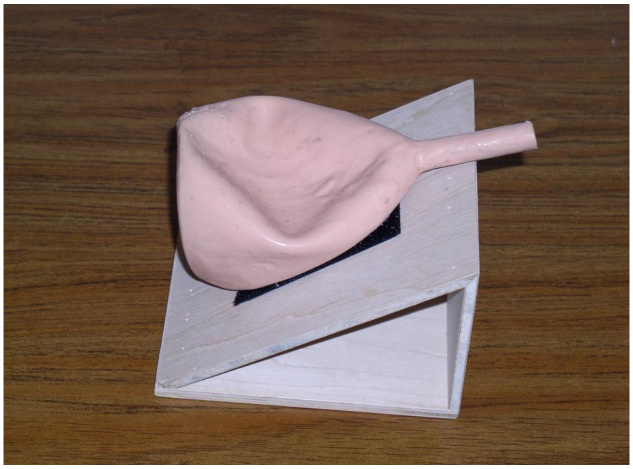
TABLE 3. EVALUATION OF THE 3-Dmed® 4 IN 1 MODEL ACCORDING TO THE LEVEL OF EXPERTISE IN LAPAROSCOPIC OR ROBOTIC PROSTATECTOMY

Level of laparoscopic experience in laparoscopic prostatectomy	1-Poor	2	3-Average	4	5-Excellent	No rating	TOTAL (%)
1 Novice		1	9	15			25 (44.6)
2			2	2			4 (7)
3			2				2 (3.5)
4				2	5		7 (12.5)
5 Expert (>20 cases)					11		11 (19.6)
Level of expertise not mentioned	1					6	7 (12.5)
TOTAL	1 (1.8)	1 (1.8)	13 (23.3)	19 (33.6)	16 (28.6)	6 (10.7)	56 (100)

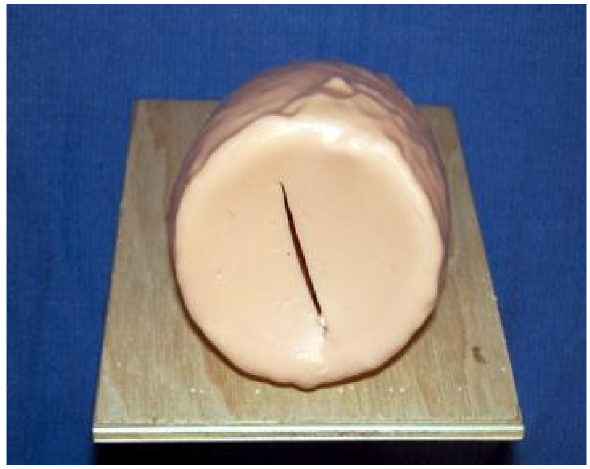
TABLE 4. COMPARISON OF WALL THICKNESS AND TEAR STRENGTHS OF THE SILICONE 3-DMED® 4-IN-1 AND PORCINE TISSUES.

	Wall Thickness in mm. (Mean ± SD)			Maximal Tear Strengths in lbf. (Mean ± SD)		
	Silicone	Porcine	*p-value*	Silicone	Porcine	*p-value*
Urethra	3.0 ± 0.3	3.0 ± 0.4	0.846	3.0 ± 0.7	2.0 ± 0.4	0.008
Bladder neck	3.5 ± 0.4	2.6 ± 0.2	<.0.005	3.6 ± 0.5	2.7 ± 0.4	0.003
Anterior bladder wall	2.5 ± 0.2	3.5 ± 0.4	<0.005	2.8 ± 0.6	4.9 ± 1.6	0.001
Ureteral wall	1.3 ± 0.2	0.6 ± 0.2	<0.005	1.7 ± 0.7	1.1 ± 0.5	0.08
Collecting system	3.5 ± 0.8	4.4 ± 0.3	0.005	3.7 ± 1.1	5.7 ± 1.5	0.04
Renal parenchyma	4.2 ± 0.5	5.7 ± 0.4	<0.005	3.8 ± 0.6	1.1 ± 0.4	<0.005

FIGURE 1. 3-DMED® 4-IN-1 SILICONE MODEL (A) ON ANGLED PLATFORM FOR SIMULATION OF VESICOURETHRAL ANASTOMOSIS AND (B) DEMONSTRATING FLAT EDGE SIMULATION OF PARTIAL NEPHRECTOMY

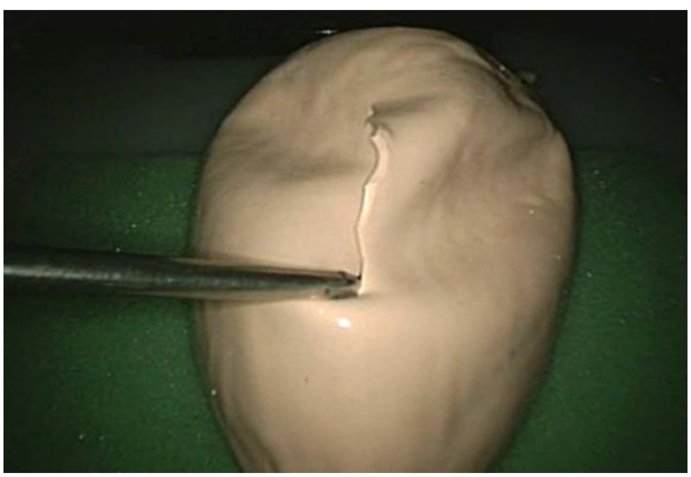


1A

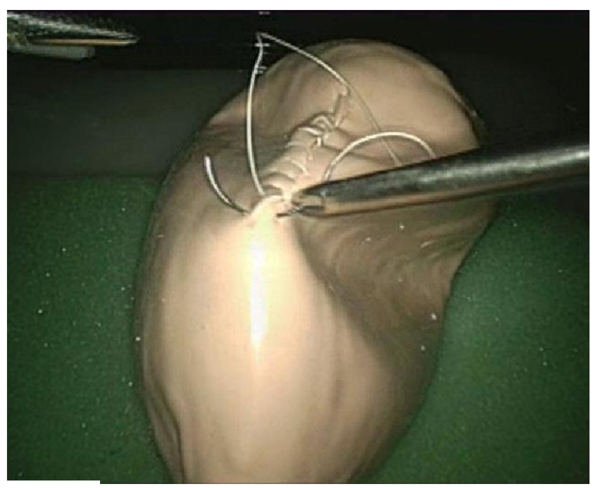


1B

FIGURE 2. SIMULATION OF A CYSTORRHAPHY: LONGITUDINAL CYSTOTOMY (2A) FOLLOWED BY CYSTORRHAPHY (2B)



2A



2B

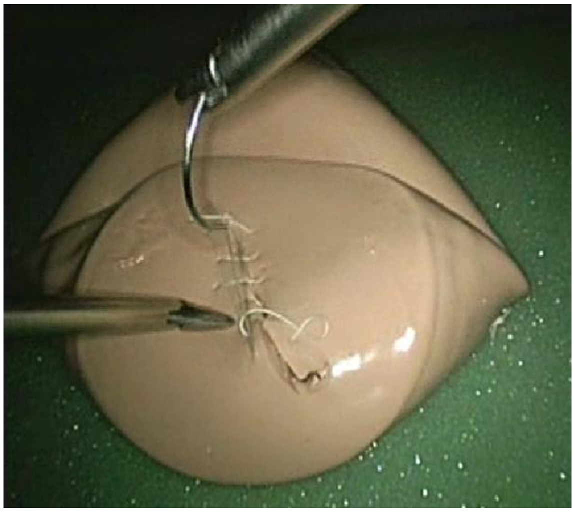
FIGURE 3. SIMULATION OF VESICOURETHRAL ANASTOMOSIS: APPLICATION OF VAN VELTHOVEN STITCH (A) AND COMPLETION OF THE ANASTOMOSIS (B)

3A **3B**

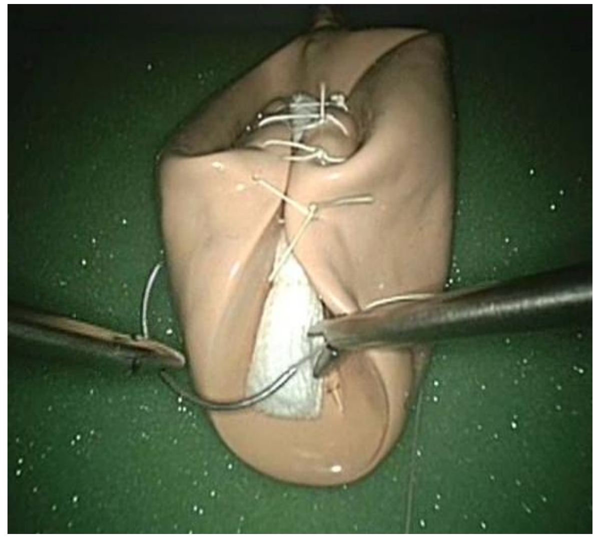
FIGURE 4. SIMULATION OF PYELO-URETERAL ANATOMOSIS IN DISMEMBERED PYELOPLASTY: APPLICATION OF VAN VELTHOVEN STITCH ($A) AND CONTINUOUS POSTERIOR ANASTOMOSIS (4B)

4A **4B**

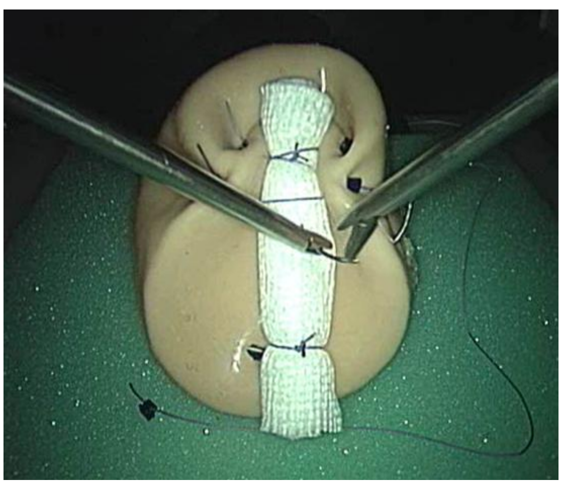
FIGURE 5. SIMULATION OF RENAL COLLECTING SYSTEM REPAIR (5A) AND APPROXIMATION OF THE RENAL PARENCHYMAL EDGE OVER SURGICAL BOLSTERS (5B).



5A



5B



5C