GYNECOLOGY

Development and validation of a laparoscopic hysterectomy cuff closure simulation model for surgical training

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BACKGROUND: The number of robotically assisted hysterectomies is increasing, and therefore, the opportunities for trainees to become competent in performing traditional laparoscopic hysterectomy are decreasing. Simulation-based training is ideal for filling this gap in training. **OBJECTIVE:** The objective of the study was to design a surgical model for training in laparoscopic vaginal cuff closure and to present evidence of its validity and reliability as an assessment and training tool.

STUDY DESIGN: Participants included gynecology staff and trainees at 2 tertiary care centers. Experienced surgeons were also recruited at the combined International Urogynecologic Association and American Urogynecologic Society scientific meeting. Participants included 19 experts and 21 trainees. All participants were recorded using the laparoscopic hysterectomy cuff closure simulation model. The model was constructed using the an advanced uterine manipulation system with a sacrocolopexy tip/vaginal stent, a vaginal cuff constructed from neoprene material and lined with a swimsuit material (nylon and spandex) secured to the vaginal stent with a plastic cable tie. The uterine manipulation system was attached to the fundamentals of laparoscopic surgery laparoscopic training box trainer using a metal bracket. Performance was evaluated using the Global Operative Assessment of Laparoscopic Skills scale. In addition, needle handling, knot tying, and incorporation of epithelial edge were also evaluated. The Student t test was used to compare the scores and the operating times between the groups. Intrarater reliability between the scores by the 2 masked experts was measured using the interclass correlation coefficient.

RESULTS: Total and annual experience with laparoscopic suturing and specifically vaginal cuff closure varied greatly among the participants. For the construct validity, the participants in the expert group received significantly higher scores in each of the domains of the Global Operative Assessment of Laparoscopic Skills Scale and for each of the 3 added items than did the trainees. The median total Global Operative Assessment of Laparoscopic Skills Scale score (maximum 20) for the experts was 18.8 (range, 11-20), whereas the median total Global Operative Assessment of Laparoscopic Skills Scale score for the trainees was 10 (range, 8-18) (P = .001). The overall score that included the 3 new domains (maximum 35) was 33 (range, 18-35) for the experts and 17.5 (range, 14-31.5) for trainees (P = .001). For the face validity testing, the majority of the study participants (32 [85%]) agreed or strongly agreed that the model is realistic and all participants agreed or strongly agreed that the model appears to be useful for improving technique required for this task. For the interrater reliability, the scores assigned by each observer had an interclass correlation coefficient of 0.8 (95% confidence interval, 0.7—0.93). **CONCLUSION:** This model is easily constructed and has an acceptable cost. We have demonstrated evidence of construct validity. This is a valuable education tool that can serve to improve skills, which are essential to the gynecological surgeon but are often lacking in residency training because of national changes in practice patterns.

Key words: laparoscopic hysterectomy, surgical simulation, vaginal cuff closure

V aginal cuff dehiscence after hysterectomy is an uncommon complication but one that is associated with serious morbidity. It is reported to occur in 0.13% of vaginal hysterectomies, 0.2% of abdominal hysterectomies, 0.64% of total laparoscopic hysterectomies, and 1.64% of robotic hysterectomies. The rate appears to be higher after laparoscopic and robotic hysterectomy, and therefore, it is critical to address the training in the surgical skills necessary for this task.

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0002-9378/\$36.00 © 2016 Elsevier Inc. All rights reserved. http://dx.doi.org/10.1016/j.ajog.2015.11.023 As the number of robotically assisted hysterectomies is increasing, gynecological trainees may have fewer opportunities to become competent in performing hysterectomies using a conventional laparoscopic approach. Simulation-based training is ideal for learning and practicing a skill that is complex yet repetitive, particularly when the surgical volume is lacking.

There are many ways to close the cuff laparoscopically, but we prefer free suturing because of its simplicity, low cost, and transferrable skill set. Laparoscopic suturing is a skill that can be applied in multiple venues beyond vaginal cuff closure: myomectomy, paravaginal defect repair, Burch urethropexy, and cystotomy repair. Unfortunately, there is a paucity of low-fidelity simulators for training learners in gynecology. These models are meant to accelerate learning

while improving the safety and quality of care in the operating room. Prior to performing any surgical procedure on patients, surgical trainees should know how to perform the steps required and be confident in their abilities. One way to bridge the gap in knowledge and technical skills is through simulation.

The objective of this study was to design a surgical model for training in laparoscopic vaginal cuff closure and to present evidence of its validity and reliability as an assessment and training tool.

Materials and Methods

This study involved 2 tertiary care centers: Hartford Hospital and University of Colorado Anschutz Medical Campus. The study was approved by the institutional review board at both institutions. The study has 2 phases: model construction and validity testing.

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Model construction

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 $158^{[T1]}$

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The model design is demonstrated in the Figure. Materials used for the model were as follows: repurposed RUMI Advanced Uterine Manipulation System (Cooper Surgical, Inc, Trumbull, CT), sacrocolopexy tip/vaginal stent (Cooper Surgical, Inc), and a vaginal cuff constructed from neoprene material and lined with a swimsuit material (nylon and spandex) secured to the vaginal stent with a plastic cable tie.

The setup also includes the Fundamentals of Laparoscopic Surgery (FLS) laparoscopic training box trainer. A similar model with a different attachment was previously developed for training in laparoscopic suturing for sacrocolpopexy, and validity testing was performed.² We elected to use the same model with a different attachment to expand on the utilization of one model for more than one procedure.

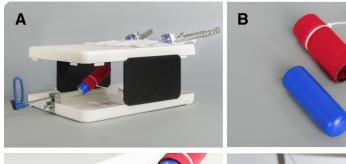
The FLS box trainer was chosen because of its presence in most academic surgical training programs in the United States, and its availability facilitates generalizability and acceptance of the model. The RUMI vaginal manipulator was affixed to the lower portion of the box trainer via a metal bracket (custom made, available upon request). The neoprene material simulates the thickness of the vaginal cuff and the swimsuit material lining simulates vaginal epithelium. The lining is sewn inside the neoprene cuff 1 cm from the edge to optimally simulate the closure technique in which the epithelial edge has to be incorporated into the cuff closure and to serve as a distance marker. The combination of the materials closely represents the pliability of the vaginal tissue, yet the model is durable enough to be reused multiple times.

Materials and their corresponding costs are given in Table 1. The model ideally should be used on a table of adjustable height for ergonomic purposes.

Model acceptability and validity

Eligible participants included gynecology staff and trainees at 2 tertiary care centers. Gynecological surgeons were also recruited at the combined International Urogynecologic Association

FIGURE Laparoscopic vaginal cuff closure simulation model







A, RUMI Advanced Uterine Manipulation System (Cooper Surgical) attached to the FLS box trainer. **B**, Simulated vaginal cuff made of the neoprene and swimsuit material and vaginal manipulator stent. C, Custom bracket attachment. D, View of the simulator in the FLS box.

FLS, fundamentals of laparoscopy.

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and American Urogynecologic Society (AUGS) scientific meeting, on July 22, 2015.

Participants met inclusion criteria if they perform laparoscopic total hysterectomies as part of their training or practice. Participants were divided into 2 groups: experts and trainees. Participants for the experts group were recruited at the AUGS scientific meeting.

Unfortunately, given the change in practice with a shift to supracervical hysterectomies for sacrocolpopexy to minimize the risk of mesh erosion and the practice of vaginal cuff closure via a vaginal approach after a laparoscopic hysterectomy, we could not use the number of annual surgical procedures as our criteria for inclusion for the expert group.

List of materials and corresponding cost

Item	Cost, \$
RUMI Advanced Uterine Manipulation System (repurposed)	100
Sacrocolopexy tip, model SACRO-1	50
Vaginal cuff sleeve ^a	10
Bracket	20
Total ^b	180

FLS, Fundamentals of Laparoscopic Surgery.

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^a Tip cover is made from neoprene material, repurposed from neoprene can holder, \$2.99, makes 2 sleeves; the inner epithelium is made from swimsuit material (nylon and spandex), \$28 for a sheet of fabric sufficient for 14 items. Plastic cable tie, used to attach the sleeve to the plastic tip; \$0.50 per tie. \$7 is added for labor if the tip cover is to be custom made; b Does not include the price for the FLS box trainer, surgical instruments, mesh, and suture.

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