

An innovative tissue model for robot-assisted radical hysterectomy and pelvic lymphadenectomy

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Objective: The purpose of this study was to evaluate a new tissue model and to conduct a questionnaire survey to assess its feasibility for robot-assisted radical hysterectomy, colpotomy, and pelvic lymph node dissection training. Methods: Sixteen gynecologists (12 males, 4 females; mean age: 47.1 years; all attending doctors with an average experience of 9.3 robot-assisted surgeries) were trained in robotassisted radical hysterectomy, colpotomy, and pelvic lymphadenectomy using a new uterine and pelvic lymph node model (mainly composed of PVA) from Fasotec Inc. The participants were trained by the author using a dual console. They performed all surgical procedures following the author's instructions. The time required for completion of the surgeries was measured. The surgical skills of the participants were evaluated by the author using the operative performance rating scale recommended by the American College of Surgeons. After training, the participants answered a questionnaire for the assessment of the model and the training using a 5-point Likert scale. Results: We found that the mean time taken for radical hysterectomy, colpotomy, and pelvic lymphadenectomy was 57.3 minutes (range: 45-75 minutes), 12.2 minutes (range: 8-17 minutes), and 60.7 minutes (range: 45-70 minutes), respectively; the total time taken was 136.5 minutes (range: 98-162 minutes). The questionnaire survey revealed that this model followed pelvic anatomy and was practically trainable. Conclusion: This is the first report of a tissue model relevant to the uterus and the pelvic lymph nodes, and robot-assisted training using this model was considered effective.

Keywords

Robotic training; Tissue model; Radical hysterectomy; Pelvic lymphadenectomy; Colpotomy; Uterine cervical cancer

1. Introduction

Over the past few years, the number of robot-assisted surgeries has rapidly increased in Europe, the United States, and Asia [1, 2]. Robot-assisted surgery offers a three-dimensional (3D) field of view and permits the use of easy-to-operate forceps, thereby allowing for greater precision. In Japan, robot-assisted surgeries have been performed for cervical cancer, uterine cancer, and benign uterine diseases [3]. Since 2018, robot-assisted surgeries for the latter two have been covered by insurance. Therefore, the opportunities for performing such surgeries are increasing. However,

the adoption of gynecological robot-assisted surgery has been slower in Japan than in the United States and Europe, and quality training is necessary to promote safe robot-assisted surgery. Although training using live pigs and cadavers is practical, there are issues regarding animal welfare, availability of dedicated facilities, and cost.

2. Materials and methods

A uterine and pelvic lymph node model manufactured by Fasotec Inc. (Chiba, Japan) was used as the tissue model in this study. The designer of this model is an engineer with experience in computer development. A reproducible overall image of the system is shown in Fig. 1; there is a patent on this item. This model is mainly composed of a synthetic polymer called polyvinyl alcohol (PVA). PVA is highly hydrophilic, soluble in warm water, and can be cut with an electrocautery scalpel due to its high hydration content. It is also highly elastic and has a similar texture to the texture of the human body. The size of this uterine model is similar to that of the human uterus, complete with the bladder, rectum, ureter, ovaries, uterine arteries, deep uterine veins, large vessels, and obturator nerves in the pelvis (Figs. 2,3). The spaces between the tissues were covered with a special yellow gel to expose various anatomical structures. The tissue model was fixed in a special training box, which had several holes, allowing the insertion of a camera and a pair of forceps from any position (Fig. 4).

The da Vinci Si and Xi (Intuitive Surgical, Inc., Sunnyvale, CA, USA) were used as the operating instruments. Monopolar curved scissors, a pre-sized bipolar, and Cadiere forceps were used for the first, second, and third arms, respectively. Figs. 5,6,7,8,9 show the manipulation and dissection that were performed during the training.

In total, 16 participants underwent training for robot-assisted surgery using this model. The training was divided into five sessions (each session, including three or four participants), and the author provided guidance and conducted an evaluation. The author had 23 years of experience as a gynecologist and had performed 2500 open hysterectomies, 2000 laparoscopic hysterectomies, and 300 robot-assisted

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hysterectomies. Additionally, among the radical hysterectomies the author has performed, 300 procedures involved laparotomy, 120 involved laparoscopy, and 25 involved robot-assisted surgery.



Fig. 1. Overall view of the model.

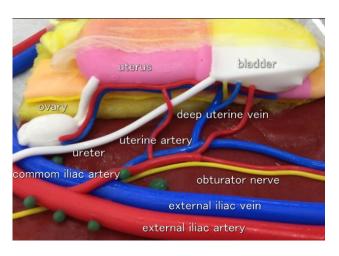


Fig. 2. The model's anatomical arrangement, which is covered with a yellow gel.

All participants had never undergone training using this model. They followed the author's instructions and performed a radical hysterectomy, colpotomy, and pelvic lymphadenectomy using this model. All procedures were timed. The participants' knowledge and training were assessed by the author using the operative performance rating scale (OPRS) as per the recommendations of the American College of Surgeons [4]. The evaluation items included general criteria (instrument handling, respect for tissue, time and motion, flow of operation, and knowledge of specific procedure) and procedure-specific criteria (hysterectomy, colpo-

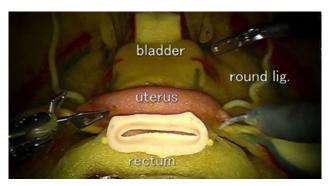


Fig. 3. Head view of the model.

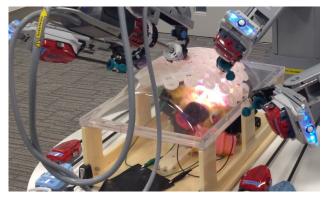


Fig. 4. The model is fixed in its original box and docked with the da Vinci Si system.

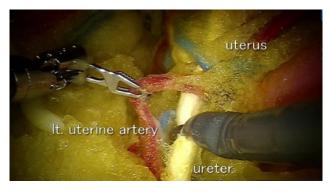


Fig. 5. The left uterine artery is tractioned, and the ureter is separated.

tomy, and lymphadenectomy). The results were scored on a scale of 1–5 (1 = poor, 2 = fair, 3 = good, 4 = very good, and 5 = excellent).

After completing the training, the participants were asked to complete a satisfaction survey questionnaire to evaluate the tissue model and the training process; all responses to this questionnaire were scored using a 5-point Likert scale (1 = poor, 3 = good, and 5 = excellent).

2.1 Statistical analysis

All statistical analyses were performed using SPSS version 26 (IBM Analytics, Armonk, NY, USA). An analysis of variance was performed for all scores obtained from the satisfac-

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Fig. 6. Colpotomy simulation.



Fig. 7. The vaginal vault is sutured with Vicryl.

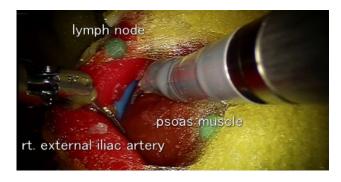


Fig. 8. The psoas muscle is separated, and a right external iliac lymphadenectomy is performed.



Fig. 9. The obturator nerve is identified, and the closed lymph node is removed.

Table 1. Characteristics of the participants.

Characteristics	Data
Age (years)	
Mean	47.1
Range	35-60
Gender (n)	
Female	4
Male	12
Medical level	
Attending physician	16
Specialty	
Gynecology	16
Average experience with robotic-surgery cases	
Mean	9.3
Range	0-50

Table 2. Training time (minutes).

Radical hysterectomy	
Mean	57.3
Range	45-75
Colpotomy	
Mean	12.2
Range	8-37
Lymphadenectomy	
Mean	60.7
Range	45-70
Total	
Mean	136.5
Range	98-162

tion survey questionnaire and the OPRS. Values of p < 0.05 were considered statistically significant (two-tailed). Intragroup differences in the continuous variables were analyzed using an independent sample t-test or the Mann-Whitney U test, depending on the normality of the data.

3. Results

Table 1 shows the characteristics of all participants. All 16 participants (12 men and 4 women; mean age: 47.1 years) were gynecologists who had served as attending physicians at their institutions. The mean experience of the gynecologists with robot-assisted surgery was 9.3 cases (Table 1). The mean operative time for robot-assisted surgeries using this model was 57.3 minutes (range: 45–75 minutes) for radical hysterectomy, 12.2 minutes (range: 8–17 minutes) for colpotomy, and 60.7 minutes (range: 45–70 minutes) for lymphadenectomy. The total time taken to complete all tasks was 136.5 minutes (range: 98–162 minutes) (Table 2).

Each physician's training was evaluated by the author using the OPRS (Table 3). The average scores for the general criteria were as follows: (i) instrument handling: 3.13, (ii) respect for tissue: 3.62, (iii) time and motion: 3.31, (iv) flow of operation: 3.5, and (v) knowledge of specific procedure: 4.13. The overall performance was scored at 3.38. The av-

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Table 3. Operative Performance Rating Scale.

General criteria	*Score (1-5)
Instrument handling	3.13
Respect for tissue	3.62
Time and motion	3.31
Flow of operation	3.5
Knowledge of specific procedure	4.13
Overall performance	3.38
Procedure-specific criteria	
Hysterectomy	3.25
Colpotomy	3.5
Lymphadenectomy	3.25
Total score	31.0

^{*}(1 = poor, 2 = fair, 3 = good, 4 = very good and 5 = excellent). Date are presented as median.

erage scores for the procedure-specific criteria were as follows: (i) hysterectomy: 3.25, (ii) colpotomy: 3.5, and (iii) lymphadenectomy: 3.25.

The total median score was 31.0 (range: 28.3–32.8). This score was categorized into two groups: one with a total score of 27–30 and another with a total score of 31–36; and the Mann-Whitney U test was performed. Significant intergroup differences were noted in terms of respect for tissue (p < 0.008), flow of operation (p < 0.015), overall performance (p < 0.008), radical hysterectomy (p < 0.049), colpotomy (p < 0.015), and lymphadenectomy (p < 0.049). Similarly, a comparison of operative time between the two groups revealed a significant difference in the time required for colpotomy (p < 0.02).

After the training, a questionnaire survey was conducted to assess the level of satisfaction. Scores were obtained for questions regarding the model and the training process (Table 4). The model was scored as follows: (i) actual anatomy: 4.75, (ii) tissue flexibility, grasping, and traction: 4.38, (iii) use of energy sources: 4.22, (iv) radical hysterectomy: 4.69, (v) colpotomy: 4.88, (vi) pelvic lymph node dissection: 4.82, and (vii) cost: 4.06. The training was scored using questions regarding: (i) whether the participants believed the training would improve their actual surgical skills: 4.88, (ii) whether the dual console was effective: 4.94, and (iii) whether the participants would like to repeat the training: 4.88.

The total median score was 47.5 (range: 44.5–48.0). This score was classified into two groups, one with 40–47 points and the other with 48–49 points, and the Mann-Whitney U test was performed. There were significant intergroup differences in the repeatability of the actual dissection (p < 0.025), energy source (p < 0.015), radical hysterectomy (p < 0.09), and cost (p < 0.007). Subgroup analyses were performed within the study groups for operative time and model satisfaction. Comparisons were made between male and female surgeons, young and old, experienced and inexperienced surgeons. Regarding operative time, surgeons who had experienced more than 5 cases had shorter operative times than inexperienced surgeons (p < 0.025). No significant difference

was observed in the other comparisons.

Regarding satisfaction with the model, no significant differences were observed upon comparison between other groups.

4. Discussion

The purpose of this study was to evaluate a new tissue model and conduct a questionnaire survey to assess the feasibility of conducting robot-assisted training for radical hysterectomy, colpotomy, and pelvic lymph node dissection.

The questionnaire results revealed that the tissue model could accurately portray the pelvic anatomy and could be used for practical training. The participants could be trained perform the most complicated procedures of gynecological surgery, namely, radical hysterectomy and lymph node dissection. The mean time for completing radical hysterectomy, colpotomy, and pelvic lymphadenectomy is shown in Table 2. For reference purposes, the console time for robot-assisted radical hysterectomy, colpotomy, and pelvic lymphadenectomy, which the author performed on 25 actual cervical cancer patients, was 117.3 minutes, 10.5 minutes, and 50.3 minutes, respectively. The time taken for all tasks was 189.7 minutes. Although a simple comparison was not performed, we observed minimal differences between the time taken using the model and the actual operative time for colpotomy, and there was a 60-minute difference between the two times for radical hysterectomy. The operative time for colpotomy may not have been significantly different because colpotomy is a relatively simple operation. The difference in operative time for radical hysterectomy was probably due to the time required for hemostasis and dissection of the tissue around the ureter and the cardinal ligament, which are necessary procedures during the actual surgery. As supplementary information, the time taken for laparotomy and laparoscopy in each of the last 25 cases managed by the author is as follows: the total operative time for a recent laparotomy and laparoscopy was 179.7 minutes (range: 147-219 minutes) and 171.1 minutes (range: 142-195 minutes), respectively.

The main component of the training model used in this study is PVA. Recently, mitral valvuloplasty, cardiac, and renal models have been created using PVA. Further, 3D printers have been used to create molds of actual organs, and PVA has been used to create accurate tissue models. These models are used by cardiac surgeons and urologists for training [5, 6]. These tissue models have been found to be ideal for training, as they have a realistic appearance and texture. The price of this model is approximately \$1000. The cost is slightly high because it is handmade and detailed. The model is portable and can be used for training at any facility. If the demand for these training models increases and machines can be used for their mass production, the cost may be lowered. While this model is basically for a single-time use only, it can still be used for colpotomy after hysterectomy has already been performed. After use, it can be disposed as normal combustible waste.

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Table 4. Evaluation of the tissue model (questions 1–7) and training (questions 8–10).

Question	Score
1. Was this model similar to the actual anatomy?	4.75
2. Was this model appropriate regarding tissue softness, grasping, or traction?	4.38
3. Did this model use an energy source effectively?	4.22
4. Was this model efficient for radical hysterectomy?	4.69
5. Was this model efficient for colpotomy?	4.88
6. Was this model efficient for pelvic lymph node dissection?	4.82
7. Is the cost of the tissue model adequate?	4.06
8. Do you think the training will improve the actual surgical technique?	4.88
9. Was the dual console training effective?	4.94
10. Would you like to receive the training again?	4.88
Total score	47.5

All questions were graded on a 5-point Likert scale. (1 = poor, 2 = fair, 3 = good, 4 = very good and 5 = excellent; the closer the score is to 5, the more effective the model is for training). Date are expressed as medians.

The mean age of the participants was 47.1 years. In Japan, robot-assisted surgery for gynecology was recently covered by insurance in 2018, and attending physicians have just started performing it. Therefore, doctors who currently require training are attending physicians, not young doctors, which explains the high mean age in our study. Another reason for the high mean age is that radical hysterectomy and pelvic lymphadenectomy are often performed by physicians who are professionally at the level of attending physicians. Although this model can be used to train students and residents, it may be more useful for simple total hysterectomy, rather than for radical hysterectomy.

The author used the OPRS for scoring each doctor's training. The mean experience with robot-assisted surgery for all participants was 9 cases, and the participants were not very familiar with forceps manipulation. However, as gynecologists, they had extensive experience in surgery and were familiar with the anatomy. The learning curve is reportedly 30 cases, and the OPRS scores may improve with future experience [7, 8].

Comparing the present model with other tissue models is difficult. This is because there is currently no tissue model for training surgeons in uterine and pelvic lymph node dissection under robotic surgery. There are models for performing open total hysterectomy [9]; however, these models cannot be used for robot-assisted training because they cannot be towed. There are other reports on tissue models in laparoscopic surgery for vaginal margin suturing training. Moreover, we found a report on a laparoscopic vaginal vault suture model using pig stomachs [10], and a vaginal vault suture training model for vaginal total hysterectomy [11]. These models have a simple structure and are suitable for vaginal suture training; however, they cannot be used for other purposes.

Other training methods include the use of live pigs, which allow surgeons to learn how to prevent and control bleeding from vascular injuries. However, the major disadvantage of training with animals is that there are fundamental anatomical differences between animals and humans, and the pig model is not suitable for total hysterectomy due to the presence of a twin uterus. Training with tissue models using gastric blocks has the following advantages: (1) relatively low cost, (2) availability, and (3) training with these tissue blocks can be performed in various settings. However, there are religious and ethical issues associated with tissue models [12]. Similarly, virtual reality simulators have been reported to be effective for training [13–15]. The initial cost is high; however, the training can be repeated many times. The training includes many basic operations, such as passing a loop through a ring or moving a needle, which is effective for beginners and provides a tool for evaluating basic skills. However, expert physicians often consider this training insufficient because it involves only simple operations.

The strength of this study is that the uterine and pelvic lymph node model in this study could accurately portray the pelvic anatomy, indicating that it can be used for training for complex operations, such as radical hysterectomy. This type of training is often conducted with simple models; therefore, students and residents often learn only basic forceps manipulation and suturing. The strength of this model is that it offers a practical training method that is satisfactory even for attending physicians.

The limitation of this study is that the participants were professionally at the level of attending physicians; students and young physicians were not included. Furthermore, the study evaluated the more specialized procedures of radical hysterectomy and pelvic lymphadenectomy, rather than simple total hysterectomy. This type of training could be useful for students and residents and should be considered in the future, as training for simple total hysterectomy and colpotomy is important, especially for beginners.

Further, it is difficult to determine the effectiveness of using the uterine model after a single training session; therefore, multiple simulations should be conducted. Future studies measuring the effect of training with this model on the performance of the learner in the operating room are war-

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ranted. In addition, we need to continue the validation process to determine the cut-off point for the required number of training sessions.

5. Conclusions

Robot-assisted surgery in gynecology is rapidly expanding worldwide, and better training of surgeons is required. Using this model, we believe it will be possible to provide training for radical hysterectomy, colpotomy, and pelvic lymph node dissection. The model can be used as an effective educational tool for more efficient surgery. By using this model in the future, it may be possible to achieve a faster learning curve in the dry laboratory before preforming the procedures in patients.

Author contributions

KU, YK, RU, AK, MO, HA, and MK designed the research study. KU and YK performed the research study. HM analyzed data. KU and YK wrote the manuscript. All authors made editorial changes to the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

This study was performed in accordance with the institutional guidelines.

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Conflict of interest

The authors declare no conflict of interest.

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