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Concurrent and predictive validation of robotic simulator Tube 3 module

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Purpose: We previously described a new procedure specific module (Tube 3) to allow the practice of vesicourethral anastomosis after robot-assisted radical prostatectomy. Herein, we report a predetermined proficiency level of Tube 3 and preliminary validation to explore whether this new module can lead to performance improvement in the da Vinci system.

Materials and Methods: Eight urology residents and three urology fellows performed the Tube 3 module 1 hour daily for 7 days. The learning curve was depicted through a scatterplot and the stable point was identified through the cumulative sum chart. Concurrent and predictive validations were performed with the da Vinci system. The mean time to complete the task and end product rating score between Tube 3 training group and no Tube 3 training group were compared.

Results: Concerning the learning curve, about 41 repetitions comprising about 5 hours were needed to achieve this stable point when the mean time to complete Tube of 384 seconds was set as a target. With regarding to the concurrent and predictive validation, there significant differences were evident in the mean time to complete 16 needle passages and the vesicourethral anastomosis and the end product rating score.

Conclusions: The virtual reality (VR) simulator can yield sufficient improvement in technical performance in Tube 3 within 5 hours. The acquired proficiency can be transferable to the vesicourethral anastomosis using the da Vinci system.

Keywords: Computer simulation; Learning curve; Robotics

INTRODUCTION

In spite of the wide adoption of robotic surgery, training tools for robotic operation have been developed slowly and have not been officially established [1,2]. This insufficient training may expose an excessive number of patients to the inherent risk in the early learning curves of inexperienced surgeons [3,4].

Besides animal lab and bench models, virtual reality (VR) simulators have been intoduced as one of the risk-free training methods [2,5,6]. VR simulators have been validated and shown encouraging results, still most modules in the VR simulators are limited to the basic skills and general familiarization with the da Vinch system (Intuitive Surgical Inc., Sunnyvale, CA, USA) [1,2,7]. In this regard a procedure-specific module for the VR simulator is need [1-3].

Previously, we developed the procedure specific module (Tube 3) and the Tube 3 module specialized to practice

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vesicourethral anastomosis (VUA) which is one of the most complex steps in robot-assisted radical prostatectomy [2]. In previous face and content validations results, about 80% of surgeons agreed that this module reflected the technical skills required to perform the VUA and that it can be useful for VUA training in robot-assisted radical prostatectomy. Herein, we report preliminary results on whether this new module can lead to performance improvement in bench model using the synthetic material. In addition, to be included in the training curriculum and credentialing process, achieved predetermined proficiency level should be suggested, so we also suggest the predetermined proficiency level of the Tube 3 through the learning curve.

MATERIALS AND METHODS

For the learning curve analysis, 11 subjects with no previous robotic experience participated in this prospective study after receiving approval from the institutional review board at our institution. These inexperienced subjects consisted of eight urology residents and three urology fellows. The Participants performed the Tube 3 module 1 hour daily for 7 days. The training schedule was based on previous study about effective training [8]. Tube 3 was developed specifically to practice VUA performance with the participation of the Mimic technology (Mimic Technologies, Seattle, WA, USA) [2]. The goal of tube 3 module is to practice effective needle passage 8 times for the bladder and 8 times in urethra in turn. A detailed description of the Tube 3 module has been previously provided [2]. Performance data were recorded by a built-in scoring algorithm in the Mimic dV-Trainer. To evaluate the predetermined proficiency level, the learning curve was depicted using a scatterplot, and the stable point was identified through a cumulative sum (CUSUM) chart.

For the concurrent and predictive validation, the Tube 3 training group (group 1) who achieved at the pleatau of Tube 3 module performed the dry lab exercise using the da Vinci system. Five subjects who were available to participate in this additional study were included as the group 1. The no Tube 3 training group (group 2) comprised five residents who did not perform Tube 3 module. And post graduated year of subjects in groups 1 and 2 were described in Table 1. Warm-up exercises consisted of "pick and place" and "peg board" to familiarize participants with robot system, which involved EndoWrist manipulation, clutch pedaling, and camera handling [9].

For concurrent validation, synthetic material (double layer bowel 30-mm outer diameter, length 200 mm; Limbs and Things, Bristol, England) similar to tubes used in

Table 1. The post graduated year (PGY) of participants in groups 1 and 2

Group	Post graduated year					Mean	p-value
	Subject 1	Subject 2	Subject 3	Subject 4	Subject 5		
1	7	6	6	4	2	5	0.287
2	5	5	5	3	2	4	

Group 1, Tube 3 training group; group 2, no Tube 3 training group.

Fig. 1. The synthetic double layer bowel 30-mm OD used for concurrent validation (length 200 mm; Limbs and Things, Bristol, England).

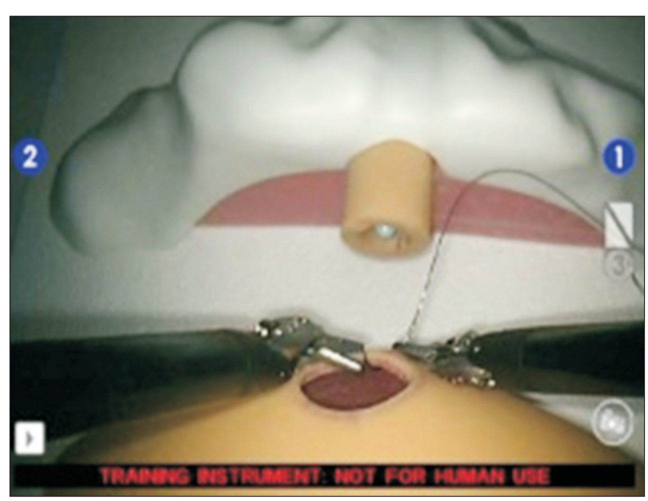

Fig. 2. Vesicourethral anastomosis kit used for predictive validation (Limbs and Things, Bristol, England).

the Tube 3 task was used (Fig. 1). The 16-needle passages without suture material were performed as for Tube 3 module. Each subject performed this task five times and the time to complete the task was recorded. For predictive validation, the VUA kit (Limbs and Things) was used (Fig. 2) and subjects in two groups performed the Van Velthoven manner running VUA five times using double arm needle with single knot [10]. The time to complete each VUA was recorded and end product rating score for the task was measured by a blinded urologist. The end product rating score which Sabbagh et al. [11] used in bench model for laparoscopic VUA was modified for our study. The modified end product rating score used in our study consists of tissue integrity, suture placement, watertightness and overall anastomosis score, where each component is rated from 0 to 5 with a maximum total score of 20. Concurrent and predictive validity were assessed using the Mann-Whitney test comparing the mean time to complete the tasks and end product rating score.

RESULTS

Fig. 3 is a scatter plot of the mean time to complete the Tube 3 task of all of trainees versus the subsequent task number. The mean number of repetitions and the mean time to complete the task at every each 1 hour are presented in Table 2. Fig. 4 shows CUSUM graphs of the mean time to complete. When the mean time to complete the task (384 seconds) was set as a target, about 41 repetitions (about 5 hours) were needed to achieve this stable point which could be interpreted as the predetermined proficiency level.

We provide a detailed description of post graduated year (PGY) of participants in groups 1 and 2 in Table 1. As a result, mean PGY was higher in group 1 (5 years) compared with group 2 (4 years), but there was no statistical difference using the Mann-Whitney test (p=0.287). In the concurrent validation study, comparing group 1 (Tube 3 training group) and group 2 (no Tube 3 training group) there was statistically significant difference in the mean time to complete the 16 needle passages (323 seconds vs. 479 seconds, p=0.016). For the VUA kit task, group 1 performed the anastomosis more quickly than group 2 (774 seconds vs. 1,002 seconds, p=0.009) and there was significantly different in the end product rating score (16.0 vs. 8.2, p=0.009) (Table 3).

DISCUSSION

Robot-assisted laparoscopic radical prostatectomy is

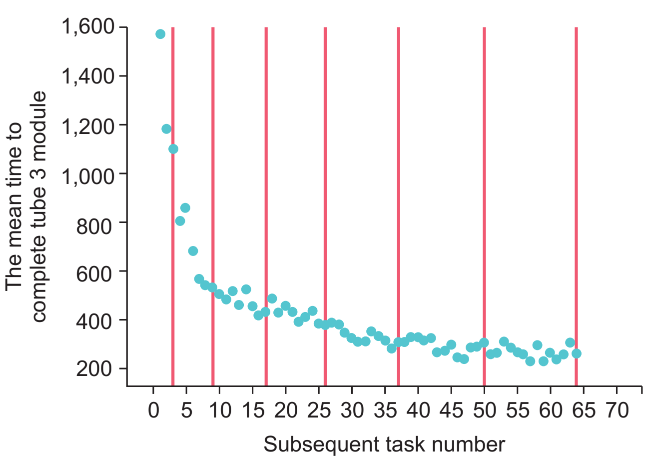

Fig. 3. Learning curve of Tube 3 module using a scatter plot.

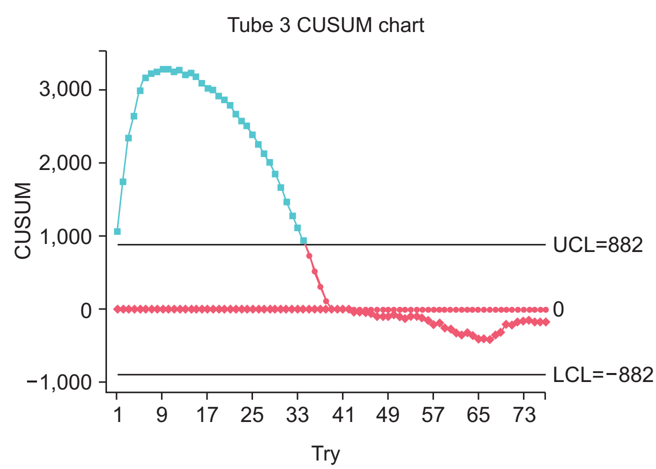

Fig. 4. Cumulative sum (CUSUM) graph of Tube 3 module.

Table 2. Mean number of repetitions and mean time to complete Tube 3 module per hour

Hour	Mean count of repetitions (per 1 h)	Mean time to complete, s (min)
1st	1–3 (3 repetitions)	1,287.7 (21 min 27 s)
2nd	4–9 (6 repetitions)	664.6 (11 min 5 s)
3rd	10–17 (8 repetitions)	475.4 (7 min 55 s)
4th	18–26 (9 repetitions)	423.1 (7min 3 s)
5th	27–37 (11 repetitions)	332.5 (5 min 32 s)
6th	38–50 (13 repetitions)	295.2 (4 min 55 s)
7th	51–64 (14 repetitions)	267.4 (4 min 27 s)

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Table 3. Performance results of Tube 3 training group (group 1) and no training group (group 2) in bench model using synthetic material

Variable	Group 1	Group 2	p-value
Mean time to complete the 16 times needle passage using two bowels (s)	323±68.9	479±42.1	0.016
Mean time to complete VUA kit (s)	774±176.0	1002±92.3	0.009
End product score in VUA (0–20)	16.0±2.24	8.2±0.84	0.009

Values are presented as mean±standard deviation.
VUA, vesicourethral anastomosis.

widely used in urology to treat localized prostate cancer [12-15]. The robot-assisted laparoscopic radical prostatectomy has evolved in the skills and can involve a steep learning curve [6,13]. Although the training methods are necessary for the next generation of robotic surgeons, training tools have not been established and animal lab or bench model have several constraining issues, such as ethical and cost restraints [3,8,11].

The VR simulator can be a useful training tool in familiarizing people with robotic system, in which most tasks are still limited to basic skills including camera handling and, endowrist manipulations [2,3]. The development of more complex procedure-specific modules may be a more useful training tool. Hung et al. [9] suggested that development and validation of procedure-specific modules, such as tumor excision, transection of bladder neck, and reconstruction were essential. Recently, we developed a procedure-specific module for vesciourethral anastomosis and reported excellent face, content, and construct vadalition results [2]. Although Tube 3 was not developed for the all steps of the robot-assisted laparoscopic prostatectomy, this module would be the first procedure specific module for robotic surgey. Although Tube 3 does not contain the suture materials and focuses on the needle passage, participants considered that this module reflects the technical skill required to perform the VUA and is useful for training the VUA step outlined previously [2].

In this study, this module also showed the excellent concurrent and predictive validation result s in a bench model. In concurrent validation using using similar sized tubes, average time to complete for 16 needle passages was 323 seconds (about 5 minutes), of which less than 384 seconds (about 6 minutes) was the plateau of the Tube 3 module. The mean time to complete the 16 needle passages in the bench model was similar to the time to completion in Tube 3. We may conclude that the training purpose for the needle passage was transferable in the bench model using synthetic material. The final purpose of the Tube 3 development was to perform the Van Velthoven running VUA using double arm needle with a single knot. Previously, we speculated that the learning curve required to perform VUA, which consists of passing through each of the dots marked on the tube, can be shortened if the method by which the needle is held is perfected, if the performer practices passing through the target tissue perpendicularly, and if the performer practices to effectively switch the grip of the needle [3]. Although Tube 3 does not include suturing, approximation of tissue, or tensioning of sutures, participants finished the VUA in bench model in an average 13 minutes. In the first and second trials, participants experienced difficulty because of the suture material, but most participants adjusted to suture material after the first few trials. We might conclude that a novice without robotic experience can finish the VUA in bench model within 17 minutes after sufficient training of the needle passage on each position which was statistically much slower than Tube 3 training group. Especially, in contrast with the Tube 3 group, the end product score for the no Tube 3 training group showed marked tissue injury. This result reflects that accurate passage of the needle in a perpendicular fashion was achieved in the Tube 3 training group as we previously hypothesized.

In our study, we used the bench model using the VUA kit for the predictive validation. Several studies have shown that training on the low fidelity model, such as the bench model, can improve surgical skills, but a higher fidelity model would reflect an operative field similar to real operating situation [11,16-18]. Sabbagh et al. [11] developed a similar task-specific model for VUA during laparoscopic radical prostatectomy recently, and the skills learned on the urethrovesical model transferred to a higher fidelity pig model. For predictive validation, we used a VUA bench model because validation on actural patients could induce ethical problem due to unexperienced participants. We speculate that the outcome can be transfer to a high fidelity model, like an animal model. It will be necessary to see if the present results are reproducible in an animal model.

Beside the concurrent and predictive validation, this study attempted to examine the learning curve of Tube 3. To be incorporated into the curriculum for the training, a predetermined proficiency level of how many repetitions and time are required to gain proficiency is necessary. To obtain proficiency, about 41 repetitions (about 5 hours) were needed to achieve this stable point according to CUSUM graph analysis. A novice can thus be anticipated to gain proficiency if they practice 1 hour daily for five days using the Tube 3 module. Previously, we performed the similar study for the learning curve of Tube 2 task [3]. In that study, to obtain the proficiency, about 4 hours was needed and the average time to complete the task was 150.3 seconds. Considering the complexity of Tube 3, about 384 seconds and 5 hours are intuitively expected. This predetermined proficiency level might be used to guide for training and credentialing process, if this program is incorporated into the curricula for student and resident.

This study has several limitations. Firstly, the VUA kit used in predictive validation was a low fidelity bench model. Validation using high fidelity model such as animal model is needed in the future. Secondly, our major limitation is that this study was not performed as a randomized trial, the difference in the postgraduate year between two groups can result in the different outcome in bench model, despite of the fact that there was no statistical difference in the postgraduate year between two groups. This study is preliminary validation and came from the single institution which was challenging to obtain a sufficient number of experienced participants. The large scale multi-institutional validation study is needed in the near future.

CONCLUSIONS

We reported excellent concurrent and predictive validation results. In addition, we suggested 5 hours and 41 repetitions as a predetermined proficiency level of Tube 3. Although Tube 3 has several flaws regarding VUA training, we believe that the proficiency of this module can shorten the learning curve of the VUA in a risk-free environment. In the future, predictive validation results through the high fidelity model are required to support these results.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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