Development and use of a non-biomaterial model for hands-on training of endoscopic procedures

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Background: Endoscopic submucosal dissection (ESD) and peroral endoscopic myotomy (POEM) are recently developed techniques that have the potential to significantly improve clinical outcomes. However, training opportunities on these techniques remain limited. To address this issue, we developed a novel *ex-vivo* ESD/POEM training model. Our aim in this paper is to describe the model and provide preliminary evidence of promising feasibility to improve access to ESD/POEM training.

Methods: The model was developed using polyvinyl alcohol hydrogel, which can easily be modified to reproduce the stiffness of the different intestinal layers, namely the mucosa, submucosa, and muscle layer.

Results: A training workshop, using our *ex-vivo* model, was held for 28 residents. Satisfaction and feasibility in using the *ex-vivo* model for endoscopic training were evaluated by using a self-report questionnaire. All participants were satisfied with their training experience (100% satisfaction rate), with 27 of the 28 participants reporting that the model was feasible in replicating all components of the ESD/POEM technique (96.4% feasibility rate).

Conclusions: Based on this feedback, we propose that our non-biomaterial model has the feasibility to provide an effective endoscopy education tool and a satisfactory training experience.

Keywords: Endoscopic submucosal dissection (ESD); peroral endoscopic myotomy (POEM); hands-on; achalasia; endoscopy

Submitted Nov 01, 2016. Accepted for publication Dec 22, 2016.
doi: 10.21037/atm.2017.01.27
View this article at: http://dx.doi.org/10.21037/atm.2017.01.27

Introduction

The development of endoscopic submucosal dissection (ESD) for early gastrointestinal carcinoma and peroral endoscopic myotomy (POEM) for achalasia are outstanding recent developments in therapeutic endoscopy (1-4). The benefits of these minimally invasive curative treatments could be extended to more patients if training opportunities were more widely available to gastroenterologists and surgeons to ensure safe performance.

Presently, training methods for endoscopic procedures use live animals or extracted animal intestines (5,6). The many barriers related to the use of animals for education have, therefore, limited the availability of endoscopic training workshops. These barriers include: difficulty with infection control; the need for specialized endoscopes for animals; cost associated with obtaining additional endoscopes that are only used with the biomaterial model and not humans; variation in the quality and accessibility to animal models in different countries and states; and ethical issues associated with the

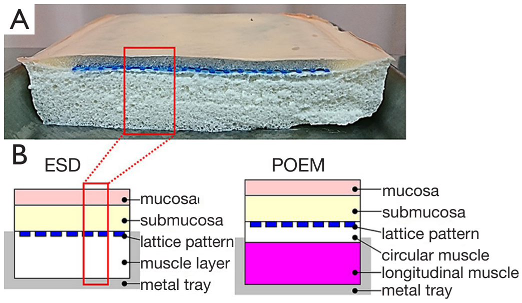

Figure 1 A sectional view of the PVA-hydrogel sheet, with labeling of the intestinal layers for the ESD (A) and POEM models shown in (B).

use of animal models for clinical training and research. To circumvent barriers associated with the use of animal models, in 2016, we developed a new non-animal *ex-vivo* training model for ESD and POEM (7,8). The aim of our paper is to describe our novel model and report on feedback received after a hands-on endoscopic training workshop for ESD/POEM using our model.

Methods

Development of a non-biomaterial training model for ESD/POEM

The development of the *ex-vivo* ESD/POEM training model 'EndoGel' was a joint research project between SunArrow Limited and Niigata University. The sheet was developed using polyvinyl alcohol hydrogel (PVA-H). PVA-H, which is largely comprised of water, has a high conductivity and has been shown to be suitable for therapeutic endoscopic procedures, such as mucosal incision, submucosal dissection, and muscle layer myotomy. Moreover, the mechanical properties of PVA-H can be easily modified to achieve the appropriate stiffness to model the intestine. Specifically, each PVA-H layer can be created with a different concentration and tension, and attached together to model each intestinal layer (*Figure 1*). The first layer is the mucosa in which initial lesion marking and circumferential incision are performed. The second layer is the submucosa, which can expand with submucosal injection. Submucosal dissection for ESD or tunneling for POEM can be performed in the same way as they would be performed in patients. The third layer is the muscle layer. The surface of the muscle layer in the model includes a 'lattice pattern', with a white 5 cm × 3 mm rectangle used as an indicator of the direction or width of the submucosal dissection performed in the ESD procedure or tunneling in the POEM procedure. In the POEM model, the muscle layer is composed of two types of smooth muscle layers, the inner circular muscle layer and the outer longitudinal muscle layer, with the inner circular muscle selectively dissected during POEM myotomy training (*Figure 2*).

The disposable return electrode (ERBE Elektromedizin GmbH, Tübingen, Germany) is attached below the hydrogel sheet and is connected to a high-frequency generator (VIO 300D; ERBE). The hydrogel sheet is fixed onto an original box, with an over-tube prepared on another original stand. In the original box, the hydrogel sheet can be fastened to any side depending on the clinical case being simulated. To simplify the set-up of the model, an original board was also developed, allowing the model to be fixed on a table without adhesive taping (*Figure 3*).

Wearing a mask in a ventilated simulation room is recommended although the toxicity of smoke generated during the training is far below the level causing harmful effect to the human body.

Results

Advanced hands-on workshop using the ex-vivo ESD/POEM training model

On July 2016, we held a non-biomaterial endoscopic hands-on workshop at Niigata University for resident doctors working in the Niigata prefecture. Twenty-eight residents, having a range of medical experience of 1 to 3 years, participated in the workshop. Training using the non-biomaterial model was conducted using the same endoscope, high-frequency generator, and therapeutic devices as used for patients. Using a self-report questionnaire, participants provided feedback regarding their satisfaction with using the non-biomaterial model for training ('satisfied' or 'not satisfied'). Participants also provided feedback on the feasibility ('feasible' or 'not feasible) of performing procedures, including lesion marking, circumferential mucosal incision and submucosal dissection. All attendees were satisfied with the training received using the non-biomaterial model (100% satisfaction), with 27 of the 28 participants indicating that all procedures could be performed (96.4% feasibility).

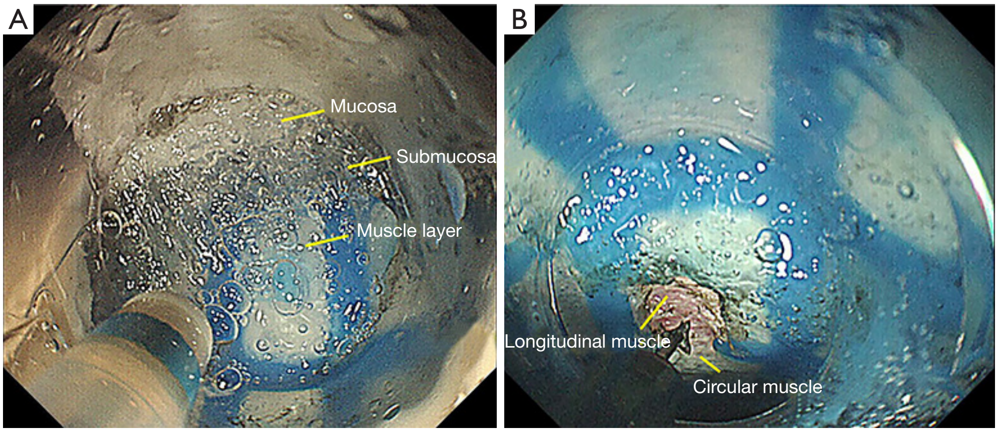

Figure 2 Training of endoscopic procedures using the EndoGel^{TM}. (A) Endoscopic view of a submucosal dissection (ESD) using the EndoGel^{TM}. The submucosa is progressively dissected; (B) endoscopic view of a peroral endoscopic myotomy (POEM) using the EndoGel^{TM}, where the inner circular muscle is selectively dissected while the outer longitudinal muscle remains intact.

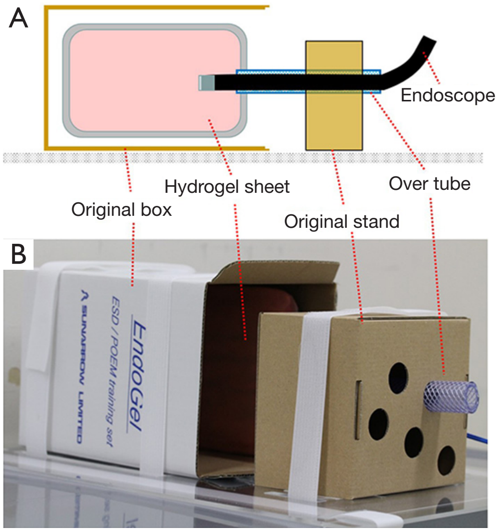

Figure 3 The schematic representation of the set-up for endoscopic training using the EndoGel^{TM} model is shown in (A). The complete set-up of the EndoGel model on the fixed original board is shown in (B).

Conclusions

Prior to the development of our EndoGel model, no practical models were available to train surgeons in the use of therapeutic endoscopy. A silicon-based artificial simulator was previously reported (9). However, as silicon is a stiff material, submucosal injection could not be performed in the simulator, although it is a necessary procedure to complete prior to submucosal dissection in ESD or tunneling in POEM. Animal models, which have traditionally been used for training, also do not adequately simulate the human intestine, with different histological features in porcine gastric models and different degree of ESD difficulty having been reported, depending on the lesion (10). Moreover, difficulty in training for the POEM procedure using a porcine esophagus model has also been reported due to the thinness of the submucosa (11). Therefore, the idea of using an artificial material, which has a high conductivity and softness, is clinically acceptable for the training of therapeutic endoscopy.

The feedback provided by the attendees in our hands-on workshop underlines the satisfaction and feasibility of using our non-biomaterial model for ESD/POEM training. Therefore, we consider our model to be effective for therapeutic endoscopy education in any facility equipped for endoscopy, rather than only in those with endoscopic units specialized for animal use. Our EndoGel model holds promise to extend access to endoscopy training, which would improve the therapeutic use of ESD and POEM worldwide. Furthermore, improvement of this initial model based on users' requests is underway. Therefore, in the near future, the EndoGel model would further better simulate actual practice.

Acknowledgements

This study was supported by SunArrow Limited.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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Cite this article as: Sato H, Mizuno KI, Sato Y, Hashimoto S, Hayashi K, Ikarashi S, Honda Y, Yokoyama J, Terai S. Development and use of a non-biomaterial model for hands-on training of endoscopic procedures. Ann Transl Med 2017;5(8):182. doi:10.21037/atm.2017.01.27