Published in final edited form as:

Surg Endosc. 2013 May ; 27(5): 1607–1616. doi:10.1007/s00464-012-2637-1.

Needs Analysis for Developing a Virtual Reality NOTES Simulator

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Abstract

Introduction and Study Aim—Natural orifice transluminal endoscopic surgery (NOTES) is an emerging surgical technique that requires a cautious adoption approach to ensure patient safety. High fidelity virtual reality-based simulators allow development of new surgical procedures and tools and train medical personnel without risk to human patients. As part of a project funded by the National Institutes of Health, we are developing a Virtual Transluminal Endoscopic Surgery Trainer (VTEST™) for this purpose. The objective of this study is to conduct a structured needs analysis to identify the design parameters for such a virtual reality-based simulator for NOTES.

Methods—A 30-point questionnaire was distributed at the 2011 NOSCAR meeting to get responses from the experts. Ordinal logistic regression and the Wilcoxon rank sum test were used for analysis.

Results—A total of 22 NOTES experts participated in the study. Cholecystectomy (CE, 68%) followed by appendectomy (AE, 63%) (CE vs AE, $p=0.0521$) was selected as the first choice for simulation. Flexible (FL, 47%) and hybrid (HY, 47%) approaches were equally favorable compared to rigid (RI, 6%) with $p<0.001$ for both FL vs RI and HY vs RI. The transvaginal approach was preferred 3 to 1 to the transgastric. Most participants preferred two channel (2C) scopes (65%) compared to single (1C) or three (3C) or more channels with $p<0.001$ for both 2C vs 1C and 2C vs 3C. The importance of force feedback and the utility of a virtual NOTES simulator in training and testing new tools for NOTES were rated very high by the participants.

Conclusion—Our study reinforced the importance of developing a virtual NOTES simulator and clearly presented expert preferences. The results of this analysis will direct our initial development of the VTEST™ platform.

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Disclosure Dr. Kai Matthes: Endosim, LLC (Ownership), Ovesco Endoscopy USA Inc. (Consultation, equipment support), Olympus America Inc. (Equipment support). Arun Nemani and Drs. Ganesh Sankaranarayanan, Woojin Ahn, Masayuki Kato, Daniel B. Jones, Steven Schwaitzberg and Suvarnu De have no conflicts of interest or financial ties to disclose.

Keywords

NOTES; Natural orifice surgery; transgastric; transvaginal; virtual reality; simulator

Introduction

Natural Orifice Transluminal Endoscopic Surgery (NOTES) is an emerging surgical technique that has come a long way from the first procedure performed on a swine by Kallo et al. [1], to the human trials that are currently undergoing in the USA and around the world [2]. Apart from being a scarless procedure with cosmetic appeal, the NOTES technique has several proposed advantages, including shorter hospital stays, less post-operative pain and fewer hernias and wound infections [3].

Realizing the potential of this emerging technology, members from the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and The American Society for Gastrointestinal Endoscopy (ASGE) have established a working group called the Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR) in 2005. Since then, the working group has funded several peer-reviewed proposals on NOTES, established and maintained a registry for the human NOTES cases and organized several national and international meetings. A similar foundation called EURO-NOTES has also been established in Europe.

NOTES procedure, in its pure form is performed using only a flexible scope without laparoscopic assistance. Hybrid NOTES procedures are performed with laparoscopic assistance using either flexible or rigid scopes. Performing NOTES may require a multidisciplinary team with expertise in both laparoscopy and endoscopy. In the highly-cited whitepaper [4], eight fundamental problems to be addressed in order to make the NOTES a feasible procedure were identified. They included access to peritoneal cavity, gastric (intestinal) closure, prevention of infection, development of a suturing/anastomotic device, maintenance of spatial orientation, development of a multitasking platform, management of iatrogenic intraperitoneal complications and identification of physiologic untoward events. Rattner et al. [4] stressed that training is very critical in this nascent technology since poor outcomes by physicians not thoroughly trained in NOTES procedures could lead to premature regulatory intervention.

Currently training in NOTES procedures can be done using porcine models, cadavers and ex vivo model-based simulators. While pigs are available and have anatomies similar to humans, they are expensive and require IACUC approval. Similarly, cadavers are expensive and far fewer in number to be useful for repeated training. Even in the case of ex-vivo models, which don't require an IACUC approval, they still need to be constantly replenished. On the other hand, Virtual Reality (VR) simulators do not require replenishing materials and can provide objective performance measures. In the cases of training for laparoscopic, endoscopic and other procedures, several commercial simulators have already been successfully adopted, such as MIST-VR, Simbionix Lap-Mentor and GI-Mentor, Cath Sim® vascular access simulator, AccuTouch® Endovascular simulator, and AccuTouch® Endoscopy simulator.

Realizing the potential of developing a virtual reality simulator for NOTES, the National Institute of Health (NIH) has funded a four year research grant lead by researchers from the Rensselaer Polytechnic Institute, Troy, NY and including surgeons and other researchers from the Beth Israel Deaconess Medical, Cambridge Health Alliance and the Tufts University, Boston, MA to develop a VR-NOTES simulator.

The objective of this work is to perform a structured needs analysis to identify the critical design parameters for a VR-NOTES simulator.

Materials and Methods

A 30-point questionnaire that covered a variety of topics, including background and experience (Table 1); procedure, approach and preferences (Table 2); instruments and tool preferences (Table 3); and preferences on the VR-NOTES simulator (Table 4) were distributed at the 2011 Annual Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR) after securing an IRB exemption from RPI. Since the initial plan for the VR-NOTES simulator was to develop the models and training for both transgastric and transvaginal NOTES appendectomy procedures using flexible instruments, NOTES appendectomy specific questions were also included in the distributed questionnaire.

At the end of the 2011 NOSCAR meeting, the questionnaire was collected for analysis. Statistical analysis on the data was performed using SPSS 18.0 statistical software package (IBM Inc.). Both ordinal logistic regression and the Wilcoxon rank sum test were used to interpret the data.

Results

The expert group was defined as participants at the NOSCAR meeting. NOTES experts (n=23) completed the questionnaire, out of which 17 (77%) were general surgeons, four (18%) were gastroenterologists and one (4.5%) was a thoracic surgeon. The clinical experience of the participants ranged from less than five years to more than 30 years (Figure 1). The highest number of hybrid NOTES procedures performed by the participants were on porcines (17 cases), followed by humans (12 cases), cadavers (9 cases) and dogs (2 cases) and sheep (1 case), Figure 2. For the pure (non-hybrid) procedures, the majority were performed on porcines (16 cases) followed by humans (7 cases), cadavers (5 cases) and dog (1 case), Figure 3. Regarding the question about the procedures that the participants had performed on live human patients, cholecystectomy was the most with eight cases followed by colectomy (four cases), appendectomy (two cases), diagnostics (two cases), POEM (two cases) and one case in each lung biopsy and transgastric peritoneoscopy (Figure 4). Eight of the participants reported no human experience.

When given a choice of procedures to be simulated in the VR-NOTES simulator, the majority of the participants chose cholecystectomy (CE, 68%) followed by appendectomy (AE, 63%) (CE vs. AE, $p=0.0521$). Colectomy (CL, 27%), tubal ligation (TL, 18%) and nephrectomy (NT, 4.5 %) came as the other choices for the procedures (Figure 5). For NOTES appendectomy, participants preferred to perform the surgery using flexible instruments (FL, 47%), using a hybrid procedure (HY, 47%), or using only rigid instruments (RI, 6%) (FL vs. RI, HY vs. RI, both $p<0.001$) (Figure 6).

For the question on the choice of transvaginal (TV), transgastric (TG) and transrectal (TR) approaches for the NOTES appendectomy, 11 participants (65%) chose TV with nine participants indicating the ability to close the access site and one participant each for device preference and instrument as reasons for choosing this particular route. Six participants (35%) chose TG based on angle of view (TV vs TG: $p=0.52$). Four participants chose not to answer this question and none of the participants selected the TR approach for the NOTES appendectomy. Given the preference of training on a live animal or a VR simulator with realistic interface and force feedback (Figure 7), 12 (55%) of the participants preferred both choices, six (27%) participants preferred the VR simulator, five (22%) participants chose the live animal and one (4.5%) participant didn't select either of the choices.

There was no preference regarding the brand of endoscope for the VR-NOTES simulator (85% answered No, $p < 0.001$), although most of the participants preferred a two channel endoscope (2C, 65 %) as opposed to single channel (1C, 17 %) or three or more channels (3C, 17 %) (2C vs. 1C and 2C vs. 3C, both $p < 0.001$). The majority of the participants (95%) agreed that the VR-NOTES simulator should be capable of working with prototype devices.

For transluminal access for both the TG and TV approaches (Figure 8), 86% of participants chose the needle knife and access/closure device followed by tunnel/submucosal flap technique (81%), balloon (72%), guide wire (63%), trocar insertion (36%), hydro-dissection (31%) and manual incision (27%).

Similarly, the results from the choice of achieving hemostasis are shown in Figure 9. More than 90% of the participants chose the endoclips, followed by suturing device (81%), bipolar cautery (72%), monopolar cautery (59%), ultrasonic energy (54%), argon plasma coagulation (40%), cograsper (36%), RF and multipolar coagulation device (both 27%) and epinephrine injection (4.5%).

Figure 10 shows the results from the choice of the participants for the methods of specimen retrieval in the VR-NOTES simulator. Seventy-seven percent of the participants chose snare followed by retrieval nets (50%), basket (50%), rat tooth/alligator forceps (45%) and endocatch bag (13%).

For the choice of methods for transluminal closure in the VR-NOTES simulator, the results are shown in Figure 11. Most of the participants (90%) chose the suturing device, followed by endoclips (63%), stapling device and over-the-scoop clip (both 50%), T-tags (45%), access/closure device (36%) and manual closure (27%).

The mean and the standard deviations from the responses for the 5-point Likert scale questions are shown in Table 5. Overall, all of the questions were highly rated with the lowest mean score of 3.0 for the question on the importance of having the cul-de-sac closure simulation in the VR-NOTES simulator. The participants rated the importance of including the gastric wall closure highly as well as the importance of the VR-NOTES simulator as a trainer for various NOTES procedures, developing new procedures and testing new instruments in addition to the inclusion of force and torque feedback in the VR-NOTES simulator.

Discussion

From the responses to our questionnaire, cholecystectomy was rated as the most widely performed procedure by the participants. Published human and animal trials also support this conclusion [2, 5–8]. According to Comber et al., [7], a total of 961 cases of transvaginal cholecystectomies have been reported in literature, performed mostly using a hybrid (with laparoscope assistance) approach followed by transvaginal appendectomy with clinical results on 113 patients that were reported so far. A search of the currently registered NOTES human trials at the ClinicalTrials.gov database shows that out of 18 active human trials, four are on both NOTES cholecystectomy and appendectomy procedures. While there are seven ongoing human trials on NOTES cholecystectomy alone, only one human trial is conducted on NOTES appendectomy. The multi-center (six institutions in USA) randomized controlled study sponsored by NIOSCAR is also on comparing NOTES and laparoscopic cholecystectomy outcomes.

Of the various access routes to perform NOTES, transvaginal access is the most preferred due to the removal of risk associated with the leakage of intestinal contents due to imperfectly closed access site [9]. Though transgastric was a preferred route during the

many initial NOTES trials, issues related to gastrotomy closure have limited the use of this route. Similarly, the transrectal route is highly susceptible to contamination from fecal bacteria load [10]. The feedback from participants also indicates a similar trend with more than 65% participants preferring the transvaginal approach compared to 35% for the transgastric method. The majority of the cases reported for appendectomy using transvaginal and transgastric routes used a hybrid NOTES approach with a flexible scope [7]. Likewise, in our study only 6% of the participants preferred NOTES using rigid instruments for appendectomy while 47% preferred using flexible instruments and hybrid NOTES.

Performing NOTES requires a multi-disciplinary team due to the expertise needed in laparoscopy and interventional gastroenterology [11]. Current training paradigms for NOTES consist in using either artificial or ex-vivo tissue simulation models. The ELITE (Endoscopic-Laparoscopic Interdisciplinary Training Entity) developed by MITI (Klinikum Rechts der Isar, Germany), is a full synthetic, latex based ex-vivo surgical training model for laparoscopic surgery, combined endoluminal/endocavitary procedures ("hybrid surgery") and NOTES [12]. The full size replica of a human female torso in ELITE includes a gas-tight abdominal wall with intra-abdominal organs based on a latex compound and provides various accesses to the abdomen. The ELITE simulator model has shown to have evidence for construct validity for training in NOTES for a peritoneoscopy procedure via a trans-sigmoidal approach [13]. More recently, it has also been validated for trans-sigmoidal NOTES cholecystectomy [14].

The EASIE-R™ (Endosim, LLC, Berlin MA) is an ex-vivo tissue model based simulator that can be used for training in endoscopic, laparoscopic and NOTES procedures. It uses porcine specimens which are secured in a box and altered to resemble human anatomy. Multiple gastrotomies and colostomies can be performed with a single specimen in the EASIE-R™. Hybrid NOTES procedures can also be performed by using a dome lid with a laparoscopic port. The EASIE-R model has been tested extensively at various national and international NOTES courses and at the SAGES learning center since 2008. In a study comparing the EASIE-R™ and ELITE simulators conducted at the SAGES learning center, the subjective rating provided by the participants who performed various NOTES procedures such as transluminal access/closure, appendectomy, distal pancreatectomy, nephrectomy and cholecystectomy showed that the EASIE-R™ simulator outperformed the ELITE in various categories including visual realism, tissue pliability and anatomic correlation compared to humans [15]. The EASIE-R™ simulator has also been successfully used for team simulation for NOTES [16].

Training and assessment is an important part of the surgical training curriculum [17]. Currently, no credentialing system exists for NOTES, unlike for laparoscopic and endoscopic surgeries [18–20]. Vassiliou et al. [21], developed an assessment tool for NOTES called FITNESS (Formative Intraoperative Tool for NOTES Evaluation of Surgical Skills) that has undergone limited validation. The assessment consisted of six items scored by NOTES experts on a Likert scale from 1 to 5 including Access (A), Navigation and Orientation (NO), Visualization and Stabilization (VS), Instrument Manipulation and Targeting (IMT), Closure (C) and application of Surgical Principles (SP). Though preliminary validation established evidence for reliability and construct validity, more studies need to be performed before FITNESS could be used as an assessment tool for NOTES.

The ELITE and EASIE-R™ simulators, though useful for training in NOTES, require constant replenishing of materials. Moreover, the performance measures are subjective in nature. In addition, the FITNESS, though could be used as a credentialing system for NOTES, is actually based on a subjective rating system. In contrast, VR surgical simulators

have several advantages including objective performance measures, no need for replenishments, local and remote telementoring and the ability to test various tools and new technologies before applying them to human patients. VR surgical simulators are already used for training in basic laparoscopic procedures [22], laparoscopic adjustable gastric banding [23] and many other procedures. They are part of most skill and simulation laboratories in various teaching hospitals in the USA and around the world.

Though VR simulators exist for many procedures, none currently exists for the simulation of NOTES. The VR-NOTES that is being developed by us is the first simulator of its kind that can be exclusively used for training in NOTES procedures. NOTES is a relatively new procedure and there is still a lot of technical hurdles including new procedural techniques and new tools that need to be addressed to facilitate widespread adoption. The utility of a VR-NOTES simulator beyond just training is to act as a testbed for new procedures and tools in a safe environment without risk to human patients. The development of a VR-NOTES simulator, however, offers unique challenges compared to other VR surgical simulators. These include realistic modeling of multilayered hollow organs, realistic simulation of the interaction of flexible surgical tools and soft tissues, the evaluation of the physiology of pneumoperitoneum as well as the evaluation of the integrity of gastronomy closure [24]. The VTEST™ that is currently being developed is designed to address all of the above issues.

The usefulness of such a simulator for NOTES is expressed by the participants in our study with a 55% preference for both VR and live animals as well as 27% of the participants preferring the VR simulator exclusively, compared to 22% choosing live animals for training. Furthermore, the participants rated highly (mean score of 4.0 on a 5-point Likert scale) the importance of the virtual reality NOTES simulator for training in NOTES procedures. Another important aspect of such a simulator is its ability to provide multiple views and test new designs without the need for fabricating the devices. The participants in our survey have expressed a strong desire to see such features in the virtual simulator. To this end, we plan to incorporate the option of providing two videos, one from the endoscope and another from a laparoscope while performing the NOTES procedure. We anticipate that such a feature would enable mastering triangulation while using a flexible endoscope. We also plan to provide an option of global view (view of endoscope from outside the body with transparent internal organs) in addition to the endoscope for training in driving the flexible endoscope. The VTEST™ simulator would also allow loading models using standard Computer Aided Design (CAD) supported file formats. So any new design features such as new tools and endoscope designs such as Direct Drive System (Boston Scientific) [25], Endosamurai (Olympus) etc. could be tested very easily in our simulator. The participants have also rated very highly the above proposed features in our virtual simulator.

Participants in our survey have expressed that they don't have any preference on the brand of the endoscope simulated but most of them wanted the standard two channel scope for operating in the virtual simulator. As a result, in our initial version of the VTEST™ simulator, we will use models of two-channel flexible scopes for performing NOTES procedures. We plan to add the options of including more than two channels in our subsequent versions. Similarly, for transluminal access, we plan to model the needle knife, access/closure device and balloon as an option and endoclips, as well as the suturing device and bipolar cautery as an option for hemostasis. Furthermore, for specimen retrieval we plan to provide snare, retrieval nets and basket as options in the VTEST™ simulator, as well as suturing device and endoclips for access closure.

Haptic enabled VR simulators not only provide high visual fidelity but also are capable of providing accurate force feedback to the users. The participants in our study have rated highly

the importance of feeling forces and torques while performing NOTES procedures. Consequently, the VTEST™ simulator will also have a realistic hardware interface with motors and gears to provide force and torque feedback to the users when operating with endoscope. To this end, we plan to perform a series of experiments on pigs with instrumented tools and force sensors to measure the range of forces felt while performing NOTES procedures and use that data for the design of our hardware interface.

As a first step in developing the VTEST™ simulator, the structured need analysis provided guidelines for many features that need to be incorporated for training in the NOTES procedure. Most importantly, there is a general agreement that the VR simulation testbed would be a valuable tool in this emerging field of NOTES. High fidelity force feedback with realistic interface should also be part of the simulator. Since technological hurdles make it difficult to perform pure NOTES procedures, the simulator should be capable of simulating both pure and hybrid procedures. Though the initial plan for the VR-NOTES simulator is to develop models and training for transgastric and transvaginal appendectomy procedures, the results from our questionnaire show that cholecystectomy should also be simulated since it is currently the most widely performed NOTES procedure. As a second step, we are undertaking task analysis for NOTES appendectomy and cholecystectomy procedures to find significant simulation steps and objective performance measures that need to be incorporated in the VTEST™ simulator. We also plan to perform a follow up questionnaire study at the 2012 NOSCART to assess any change in perception from the community and validate our initial steps.

Acknowledgments

This work was supported by the NIBIB/NIH grant # R01EB009362.

References

1. Kalloo AN, Singh VK, Jagannath SB, Niiyama H, Hill SL, Vaughn CA, et al. Flexible transgastric peritoneoscopy: a novel approach to diagnostic and therapeutic interventions in the peritoneal cavity. *Gastrointestinal Endoscopy*. 2004; 60(1):114–7. PubMed PMID: 1525. [PubMed: 15229442]
2. Moris DN, Bramis KJ, Mantonakis EI, Papalampros EL, Petrou AS, Papalampros AE. Surgery via natural orifices in human beings: yesterday, today, tomorrow. *American Journal of Surgery*. 2012; 204(1):93–102. PubMed PMID: 1509. [PubMed: 22206853]
3. Huang C. Natural orifice transluminal endoscopic surgery: New minimally invasive surgery come of age. *World Journal of Gastroenterology*. 2011; 17(39):4382. PubMed PMID: 1546. [PubMed: 22110263]
4. Rattner D, Kalloo A. ASGE/SAGES Working Group on Natural Orifice Translumenal Endoscopic Surgery. October 2005. *Surgical Endoscopy*. 2006; 20(2):329–33. PubMed PMID: 1222. [PubMed: 16402290]
5. Auyang ED, Santos BF, Enter DH, Hungness ES, Soper NJ. Natural orifice transluminal endoscopic surgery (NOTES(®)): a technical review. *Surgical Endoscopy*. 2011; 25(10):3135–48. PubMed PMID: 1512. [PubMed: 21553172]
6. Chukwumah C, Zorron R, Marks JM, Ponsky JL. Current Status of Natural Orifice Translumenal Endoscopic Surgery (NOTES). *Current Problems in Surgery*. 2010; 47(8):630–68. PubMed PMID: 58. [PubMed: 20620259]
7. Coomber RS, Sodergren MH, Clark J, Teare J, Yang G-Z, Darzi A. Natural orifice transluminal endoscopic surgery applications in clinical practice. *World journal of gastrointestinal endoscopy*. 2012; 4(3):65–74. PubMed PMID: 1507. [PubMed: 22442743]
8. Targarona EM, Maldonado EM, Marzol JA, Marinello F. Natural orifice transluminal endoscopic surgery: The transvaginal route moving forward from cholecystectomy. *World journal of gastrointestinal surgery*. 2010; 2(6):179–86. PubMed PMID: 1518. [PubMed: 21160871]

9. Dallemagne B, Marescaux J. NOTES: past, present and future. *Asian Journal of Endoscopic Surgery*. 2010; 3(3):115–21. PubMed PMID: 1529.
10. Dehn T, Austin RCT. Natural orifice transluminal endoscopic surgery (NOTES) - scar free or scary? *Annals of the Royal College of Surgeons of England*. 2009; 91(3):192–4. PubMed PMID: 1533. [PubMed: 19335968]
11. Rattner DW, NOTES SAJCo. NOTES: Where have we been and where are we going? *Surgical Endoscopy*. 2008; 22(5):1143–5. PubMed PMID: 1062. [PubMed: 18414948]
12. Fiolka A, Gillen S, Meining A, Feussner H. ELITE -The ex vivo training unit for NOTES: Development and Validation. *Minimally Invasive Therapy & Allied Technologies*. 2010; 19(5): 281–6. doi: 10.3109/13645706.2010.510673. [PubMed: 20868301]
13. Gillen S, Wilhelm D, Meining A, Fiolka A, Doundoulakis E, Schneider A, et al. The “ELITE” model: construct validation of a new training system for natural orifice transluminal endoscopic surgery (NOTES). *Endoscopy*. 2009; 41(5):395–9. PubMed PMID: 1297. [PubMed: 19418392]
14. Gillen S, Fiolka A, Kranzfelder M, Wolf P, Feith M, Schneider A, et al. Training of a standardized natural orifice transluminal endoscopic surgery cholecystectomy using an ex vivo training unit. *Endoscopy*. 2011; 43(10):876–81. PubMed PMID: 1536. [PubMed: 21833898]
15. Gromski MA, Alkhoury F, Lee S-H, Matthes K. Evaluation of NOTES hands-on courses by surgeons at the SAGES Annual Meeting Learning Center. *Surgical Endoscopy*. 2010; 24:229. [PubMed: 19517174]
16. Tsuda, S.; Matthes, K.; Hill, CS.; Derevianko, A.; Derevianko, T.; Moshin, A., et al. Validation of a High-Fidelity NOTES Simulator for Team Training. *World Congress of Endoscopic Surgery/ SAGES Annual Meeting*; Landover MD. 2010.
17. Tsuda S, Scott D, Doyle J, Jones DB. Surgical Skills Training and Simulation. *Current Problems in Surgery*. 2009; 46(4):271–370. PubMed PMID: 164. [PubMed: 19249439]
18. Fried GM. FLS assessment of competency using simulated laparoscopic tasks. *Journal of gastrointestinal surgery: official journal of the Society for Surgery of the Alimentary Tract*. 2008; 12(2):210–2. PubMed PMID: 1497. [PubMed: 17955315]
19. Soper NJ, Fried GM. The Fundamentals of Laparoscopic Surgery: Its time has come. *BULLETIN OF THE AMERICAN COLLEGE OF SURGEONS*. 2008
20. Vassiliou MC, Dunkin BJ, Marks JM, Fried GM. FLS and FES: Comprehensive Models of Training and Assessment. *Surgical Clinics of North America*. 2010; 90(3):535–58. PubMed PMID: 1527. [PubMed: 20497825]
21. Vassiliou MC, McKenna DT, Kaneva PA, Park P-O, Swain P, Rothstein RI. Development of An Assessment Tool to Measure Technical Skills for NOTES. *Gastrointestinal Endoscopy*. 2009; 69(5):AB306–AB. PubMed PMID: 1542.
22. Duffy AJ, Hogle NJ, McCarthy H, Lew JI, Egan A, Christos P, et al. Construct validity for the LAPSIM laparoscopic surgical simulator. *Surgical Endoscopy*. 2004; 19(3):401–5. PubMed PMID: 217. [PubMed: 15624062]
23. Sankaranarayanan G, Adair JD, Halic T, Gromski MA, Lu Z, Ahn W, et al. Validation of a novel laparoscopic adjustable gastric band simulator. *Surgical Endoscopy*. 2010; 25(4):1012–8. PubMed PMID: 1543. [PubMed: 20734069]
24. Matthes, K.; Sankaranarayanan, G.; Ahn, W.; De, S.; Marescaux, J. Simulator-based Training of NOTES Procedures. In: Kalloo, AN.; Zorron, R., editors. *Natural Orifice Transluminal Endoscopic Surgery: Textbook and Video Atlas*; Wiley-Blackwell: 2012. p. 291-307.
25. Thompson CC, Ryou M, Soper NJ, Hungess ES, Rothstein RI, Swanstrom LL. Evaluation of a manually driven, multitasking platform for complex endoluminal and natural orifice transluminal endoscopic surgery applications (with video). *Gastrointestinal Endoscopy*. 2009; 70(1):121–5. PubMed PMID: 1534. [PubMed: 19394008]

Figure 1.
Number of years of clinical practice of the participants

Figure 2.
Number of hybrid NOTES procedures performed by the participants

Figure 3.
Number of pure NOTES procedures performed by the participants

Figure 4.

Type of NOTES procedure performed on live human subjects by the participants

Figure 5. Types of NOTES procedure that was preferred by the participants to be simulated in the VR-NOTES simulator

Figure 6. Types of Approach (instruments) preferred by the participants for NOTES appendectomy procedure

Figure 7.
Preference for training in NOTES appendectomy procedure by the participants

Figure 8.
Choice of tools and methods for transluminal access in the VR-NOTES simulator

Figure 9.
Type of tools for hemostasis preferred in VR-NOTES simulator

Figure 10.
Choice of retrieval of the specimen in the VR-NOTES simulator

Figure 11.
Choice of method for transluminal closure preferred in the VR-NOTES simulator

Table 1

Background and Experience Section of the Questionnaire

Question Number	Questions on background and experience
1	I am (Surgeon, Gastroenterologist, Other speciality)
2	I have been in clinical practice for ____ years
3	How many Hybrid NOTES procedures have you performed on the following subjects? (Porcine, Human Subjects, Cadaver, Other species)
4	How many Pure NOTES procedures have you performed on the following subjects? (Porcine, Human Subjects, Cadaver, Other species)
5	Which procedures have you performed with NOTES using live human subjects? (Appendectomy, Cholecystectomy, Nephrectomy, Tubal Ligation, Sigmoidectomy or Colectomy)
6	Which is the single best indication for NOTES to eventually become standard of care?

Table 2**NOTES Procedure, Approach and Preference Section of the Questionnaire**

Question Number	Questions on NOTES procedure, approach and preference in the simulator
7	Which of the following procedures is most relevant for training of NOTES in a simulation environment? (Appendectomy, Cholecystectomy, Nephrectomy, Tubal Ligation, Sigmoidectomy or Colectomy, Other)
8	For NOTES appendectomy, which approach do you prefer? (NOTES using flexible instruments, NOTES using rigid instruments, Hybrid NOTES)
9	Given a choice of transvaginal, transgastric and transrectal approaches for appendectomy (in a female patient), which approach you prefer most and why? (Transgastric, Transvaginal, Transrectal) and (Angle of view, Device preference, Instrument length, Ability to close access site)
10	For training of NOTES appendectomy, which of these environments do you prefer? (Live animal, VR simulator with realistic interface and force feedback, Both, Neither)
11	Rate the importance of a realistic interface with force feedback (haptics) for the NOTES simulator (Likert scale 1(Not important) – 5 (Very important))
12	Rate the importance of feeling torque forces while navigating the endoscope. (Likert scale 1 (Not important) – 5 (Very important))
13	Rate the importance of feeling force while manipulation of instruments (forceps, snare.) through endoscopic channels. (Likert scale 1 (Not important) – 5 (Very important))

Table 3

NOTES Instruments and Tools Preference Section of the Questionnaire

Question Number	Questions on instruments and tools preference
14	Which flexible endoscope brand and type do you use for NOTES? (Olympus, Pentax, Storz, Fujinon, Other)
15	For the purpose of the VR-NOTES simulator, do you have preference in the brand of the endoscope? (Yes, No)
16	How many number of channels do you prefer in VR-NOTES (1, 2, 3, more than 3 channels)
17	Should the VR-NOTES simulator be capable of working with prototype devices? (Yes, No)
18	The proposed simulator would allow the use of several types of tools and methods to achieve transluminal access for both the approaches. Which of these from the given list would be useful for testing in the simulator? (Needle knife, Balloon, Guide wire, Hydro-dissection, Tunnel/submucosal flap technique, Access/closure device, Manual incision, Trocar insertion, Other)
19	To achieve hemostasis, which of the following tools would you like to see as a choice in the final simulator? (Endoclips, Bipolar cautery forceps, Monopolar cautery forceps, Multipolar coagulation probe, Coagrasper, Suturing device, Ultrasonic energy, RF energy, Argon plasma coagulation, Other)
20	Which of these methods of retrieval of the specimen (ex. Appendix) do you want as a choice in the final simulator? (Snare, Rat tooth/alligator forceps, Snare, Basket, Retrieval nets, Other)
21	Which of these methods of transluminal closure do you want as a choice in the final simulator? (Endoclips, T-tags, Stapling device, Suturing device, Access/Closure device, Over-the-scope clip, Manual closure, Other)
22	The unique feature of the VR simulator is that it can precisely report the integrity of the closure of gastrotomy. In addition to that would you prefer more traditional methods of testing? (Visual inspection, Air leak test, Fluid leak test, Other)

Table 4

Rating on the Preferences in the VR-NOTES Simulator Section of the Questionnaire

Question Number	Questions on rating on the preferences in the VR-NOTES simulator
23	In the initial VR-NOTES simulator, rate how important is it to include the cul-de-sac closure. (Likert scale 1 (Not important) – 5 (Very important))
24	In the initial VR-NOTES simulator, rate how important is it to include the gastric wall closure. (Likert scale 1 (Not important) – 5 (Very important))
25	Rate the importance of the specimen being placed in a bag during retrieval of the organ. (Likert scale 1 (Not important) – 5 (Very important))
26	The VR-NOTES simulator could be capable of providing multiple views to identify the global position of the endoscope (flexures of the endoscope tube as well as the angulated tip). For example, one such view could be the view of endoscope from outside the body with transparent internal organs. Such views might help to find the best spatial orientation of the flexible endoscope to reach the target (appendix in this case). Rate the importance of this functionality in the initial VR-NOTES simulator. (Likert scale 1 (Not important) – 5 (Very important))
27	In the VR-NOTES simulator, multiple endoscopic/ laparoscopic views could be shown in the same screen to learn/train operating in triangulation. Rate the importance of this functionality in the initial VR-NOTES simulator. (Likert scale 1 (Not important) – 5 (Very important))
28	The ultimate goal of the VR-NOTES simulator is to become a testbed for developing and training in new procedures for NOTES in a virtual reality environment. Rate the importance of such a VR testbed for developing new procedures for NOTES. (Likert scale 1 (Not important) – 5 (Very important))
29	Rate the importance of VR-NOTES simulator for training in varying NOTES procedures such as appendectomy, cholecystectomy, tubal ligation etc. (Likert scale 1 (Not important) – 5 (Very important))
30	In the VR-NOTES simulator, various new instrument designs can be tested even before they are fabricated for their effectiveness. Rate the importance of designing/ testing new instruments for the NOTES procedure in the VR-NOTES simulator. (Likert scale 1 (Not important) – 5 (Very important))

Table 5

Likert Scale Questionnaire Responses

Question	Mean $\pm$ Std
Importance of realistic interface and force feedback	3.85 $\pm$ 1.06
Importance of feeling torque while navigating the scope	4.0 $\pm$ 1.06
Importance of feeling forces while manipulating the instruments	3.8 $\pm$ 1.20
Importance of having cul-de-sac closure	3.0 $\pm$ 1.02
Importance of including gastric wall closure	4.54 $\pm$ 0.67
Importance of specimen being placed in a bag during retrieval	3.77 $\pm$ 1.10
Importance of having multiple views to identify the global position of the endoscope	3.59 $\pm$ 1.09
Importance of multiple endoscopic/laparoscopic views to learn/train in triangulation	3.45 $\pm$ 0.91
Importance of VR testbed for training and developing in new procedures for NOTES	4.04 $\pm$ 0.99
Importance of VR-NOTES simulator for training in varying NOTES procedures such as appendectomy, cholecystectomy, tubal ligation etc.	4.0 $\pm$ 1.19
Importance of designing/testing new instruments for the NOTES procedure in VR-NOTES	4.0 $\pm$ 1.11