Endoscopic Horizon Stabilization in Natural Orifice Translumenal Endoscopic Surgery: A Randomized Controlled Trial

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Abstract

Background. Spatial orientation in natural orifice translumenal endoscopic surgery (NOTES) has been identified as a potential barrier to clinical application. We aim to evaluate a triaxial inertial sensor and software that automatically corrects any movements on the roll axis of the flexible endoscope, allowing for stabilization of the image horizon during NOTES operations in a randomized controlled trial. *Methods*. A total of 18 participants (11 surgeons/7 gastroenterologists) performed a transgastric task in the ELITE simulator, which included navigation to the appendix and gallbladder, diathermy of the appendix base and gallbladder fossa, and clipping of the cystic duct using a single-channel gastroscope. Each participant performed the task twice with randomization to horizon stabilization occurring at the second attempt. The primary end point was change in overall performance (time taken and errors made) between the first and second attempt, and secondary end points were absolute performances in the second attempt and subjective evaluation. *Results*. Without horizon stabilization, there was a median improvement of 42.4% in time taken and 38% in number of errors made from the first to the second attempt; however, with the software turned on, there was a statistically significant deterioration of 4.9% (P = .038) in time taken and an increase in errors made of 183% (P = ns). *Conclusions*. Although the software corrects the view to that preferred during surgery, the endoscopic control mechanism as well as the exit point of the instrument are altered in this process, leading to a deterioration of overall performance. Potential solutions include deploying intermittent horizon stabilization or using a robotic interface to achieve fully aligned perceptual-motor control.

Keywords

NOTES, robotic surgery, flexible endoscopy, SILS/single-site surgery, interventional endoscopy, image-guided surgery

Introduction

In the White Paper published in 2006[1] by the Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR) working group, 12 fundamental challenges to the safe introduction of natural orifice translumenal endoscopic surgery (NOTES) were identified. Maintaining spatial orientation was recognized as one of these challenges and identified as an essential requirement for any NOTES surgical system. Disorientation in NOTES can occur through prolonged navigation with inadequate views, when the operator is working in a retroflexed position (image is upside down), or during off-axis visualization. When performing a surgical procedure, it is customary to have a stable view, with the contour of the liver parallel to the horizon. This is what is taught in surgical training, and it has been shown that surgical performance degrades as this view is lost.[2] A solution proposed in the White Paper was electronic image stabilization/inversion.

Recently, Fowler et al[3] evaluated a spatial orientation device consisting of an electromagnetic tracker within the endoscope to display the 3-dimensional imaging of the shape and orientation of the endoscope. They reported favorable outcomes in a simple porcine transgastric

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Figure 1. A. Overview of the abdominal components of the ELITE simulator with gastrotomy site visibly marked by sutures. B. Experimental setup with unaltered endoscopic view. Flexible endoscope with inertial measurement unit mounted at the tip (C and D).

navigational task when using this device compared with controls. However, since the publication of the White Paper only 2 publications have proposed solutions to the problem of image rotation. Tang et al[4] described a live video manipulator software that could perform instant video rotation, vertical or horizontal video inversion, mirror imaging, and digital zooming. They reported good image quality of the manipulated images in transvaginal NOTES procedures in this observation and the feasibility trial; however, they did not perform any usability or comparative evaluations. Holler et al[5,6] described endoscopic orientation correction using a triaxial inertial sensor at the endoscope tip. They performed an evaluation of this micro-electromechanical system–based image rectification system in a comparative porcine study with a task involving transabdominal grasping of needle markers in the 4 abdominal quadrants visualized by a flexible endoscope using a transsigmoidal NOTES access. They reported an increased performance with an inferred reduction of complexity of the task when it was performed with automatic horizon stabilization.

The aim of this study was to compare performance of a more complex, simulated transgastric NOTES procedure with and without the use of automatic horizon stabilization in a cohort of surgeons and gastroenterologists.

Methods

Participants

In all, 18 participants (11 surgeons/7 gastroenterologists) were recruited to participate in this randomized controlled trial at Imperial College, London. Participants were either senior residents or attendings. Surgeons had a minimum experience of 50 laparoscopic operations as primary operators and were all familiar with basic endoscopy; however, none had advanced endoscopic experience, and gastroenterologists had performed a minimum of 200 flexible endoscopic procedures. Participants were shown a standardized presentation illustrating the experimental task as well as some images of the ELITE simulator and an information leaflet before signing appropriate consent to participate.

Experimental Task

The task was performed in the ELITE (Endoscopic-Laparoscopic Interdisciplinary Training Entity) box trainer simulator (Figure 1).[7,8] The ELITE is a full-size replica model of a human female torso, including a gas-tight abdominal wall and transgastric and transrectal access routes to the peritoneal cavity. It contains a complete modular organ package with the ability to perform electrocautery at the base of the appendix and plane between the liver and the gallbladder. It has been evaluated previously in the context of simulated NOTES surgery, and face and construct validation have been established.[7,8]

Participants used a standard single-channel gastroscope (GIF XQ-240, Olympus, Japan). The task consisted of 7 steps:

1. exiting from the stomach via a gastrotomy previously formed and marked by sutures into the peritoneal cavity;
2. navigating to and identifying the appendix;

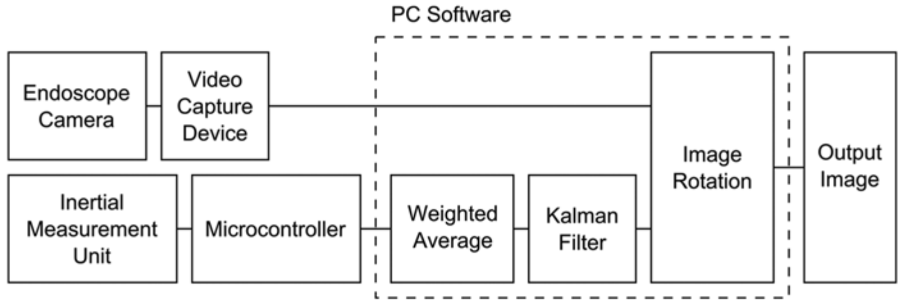

Figure 2. Schematic of horizon stabilization setup.

3. touching the appendix base using a needle-knife (RX Needle Knife XL, Ref 4584, Boston Scientific, IN) to simulate diathermy;
4. navigating to and identifying the gallbladder in retroflexion;
5. applying an endoscopic clip to the cystic artery using an endoscopic clip applicator (Resolution Clip, Ref 2261, Boston Scientific, MA);
6. touching the plane between the gallbladder and liver using a needle-knife (RX Needle Knife XL, Ref 4584, Boston Scientific, IN) to simulate diathermy; and
7. exiting the peritoneal cavity into the stomach.

A scrub nurse was available to aid the operator in changing instruments, opening and closing the clip applicator, and deploying/retracting the needle-knife only. Performance was assessed by time taken to complete each step of the task and number of errors made. An error was recorded when an instrument (needle-knife or clip applicator) was deployed by the operator and came into contact with anything other than the intended target. Each attempt was recorded digitally, and evaluation of performance was by 2 assessors blinded to participant group.

Each participant performed the task twice: once without horizon stabilization software activated and a second time at which point they were randomized to horizon stabilization or control. Randomization was performed using a computer-generated randomization sequence, and participants were randomized by allocation of a concealed envelope in a 50:50 allocation ratio.

End Points

The primary end point was the change in overall performance between the first and second attempt (time taken and errors made), and secondary end points were absolute performances at the second attempt and subjective evaluation of the horizon stabilization software. Secondary analysis assessed differences between specialties and levels of experience.

Horizon Stabilization Software

The first technical description of horizon stabilization in the context of flexible endoscopic surgery was by Holler et al[5]; they used an inertial measurement unit (IMU) externally mounted to the tip of the endoscope, and this is the method used in this study.

The IMU measures the pose of the endoscope with respect to gravity. A video capture device is used to digitize the endoscopic video stream and transfer the images to a host PC. These are subsequently rotated in software, given the measured pose of the endoscope, to maintain a static horizon. The IMU measures 5 × 15 × 2 mm and consists of a 3-axis micro-electromechanical system accelerometer. An ATmega328 8-bit microcontroller (Atmel, CA) is used for communication between the IMU and the PC. The microcontroller serves to arrange the accelerometer data returned by the IMU into packets for transfer to the PC; no processing of sensor data is performed on the microcontroller. The IMU communicates with the microcontroller using a 2-wire I^2C digital communication protocol, with the accelerometer sampling rate set at 400 Hz. Four wires must be passed along the shaft of the endoscope from the IMU to the microcontroller, 2 for communication and 2 for power. The microcontroller communicates with the PC over a virtual serial port, requiring a standard USB cable to connect the 2 devices. A schematic of this setup is illustrated in Figure 2.

Statistics

Comparisons between individual variables were performed using the Mann-Whitney *U* test, and correlations of continuous variables were determined by nonparametric linear regression. Statistical analyses were performed

Table 1. Performance of Participants at Both Attempts With Randomization Groups.[a]

	Attempt 1, All Participants, n = 18		Horizon Stabilization Group, n = 9					Group Without Horizon Stabilization, n = 9				
			Attempt 1		Attempt 2			Attempt 1		Attempt 2		
	Time	Errors	Time	Errors	Time	Error	Percentage Change	Time	Errors	Time	Errors	Percentage Change
Overall, n = 18	620	2.5	571	3	796	3	4.9[b]	728	2	350	1	−42.4
Surgeons, n = 11	748	3	643	3	805	3	−15.4	832	3	431	1.5	−35.3
Gastroenterologists, n = 7	568	2	457	3	579.5	5.5	22.5	568	2	335	1	−42.4

[a]Time is given in seconds, and all values are presented as medians. Percentage change is based on a calculation of the median of all individual participants' percentage change in time between attempts, which explains the difference between median time per event in the horizon stabilization group (positive) and overall median change (negative).
[b]$P < .05$.

using SPSS v18.0 (SPSS Inc, Chicago, IL). Differences were considered statistically significant at $P < .05$.

Results

Primary End Point

When horizon stabilization was turned off, there was a median improvement of 42.4% in time taken and 38% in the number of errors made from the first to the second attempt; however, with the software turned on, there was a statistically significant deterioration of 4.9% (P = .038) in time taken and an increase in errors made of 183% (P = .689). The second attempt was performed faster with the software turned off (median 350 vs 796 s; P = .085) with overall fewer errors made (median 1 vs 3; P = .079). These results are illustrated in Table 1. As the data were nonparametric, the difference between median performance metrics between the attempts was used to compare the groups. The overall percentage change is, therefore, the median of all the participants within that group, which explains the discrepancy in median time per attempt (positive) and median percentage change (negative) overall and in the surgery group.

Secondary End Points

Gastroenterologists performed the task faster than surgeons at the first attempt (median 748 vs 568 s; P = .026), with no difference in errors made (median 2 vs 3; P = .645); however, there was no difference in time taken or errors made at the second attempt, and there was no difference in overall improvement (learning) between the attempts (41 vs 21.4%; P = .821).

The performance of both groups at the first attempt is presented in Table 1. Note, as described above, that the calculation of median percentage change from the first to the second attempt is based on the median of individual participants' change in time between attempts and is, therefore, different from an overall median change, which is likely to amplify the difference between the groups further. For gastroenterologists, although both performance parameters were superior without horizon stabilization, these did not reach statistical significance. Similarly for surgeons, performance was more favorable without the horizon stabilization software. The median change between the attempts for surgeons with the horizon stabilization software was an improvement of 15.4%, although the mean change was actually −78.5%.

There was no statistically significant correlation between time taken and experience as first laparoscopic operator (ρ = 0.096; P = .708), laparoscopic assistant (ρ = 0.168; P = .505), or total number of flexible endoscopy procedures performed (ρ = −0.310; P = .211). There was also no statistically significant correlation between number of errors made and experience as first laparoscopic operator (ρ = −0.090; P = .724), laparoscopic assistant (ρ = −0.122; P = .631), or total number of flexible endoscopy procedures performed (ρ = 0.142; P = .575).

Subjectively, all participants randomized to horizon stabilization complained of 2 problems. The underlying reason was that the endoscopic controls did not correspond to the conventional movements while viewing the rectified image—that is, "up" did not correspond to up—and furthermore, they did not remain constant throughout the task because they were dependent on the orientation of the endoscope. Second, the exit point of the instruments (usually at 7 o'clock on the monitor) was altered and variable depending on endoscope position.

Discussion

The results of this randomized controlled trial indicate that overall performance in this simulated transgastric NOTES task actually deteriorates with the use of horizon stabilization software. Participants reported significant problems using horizon stabilization, mainly concerning navigation control and instrument exit point. It appears that the effects of these changes outweighed any benefit in performance from the presumed increased likelihood of maintaining spatial orientation as a result of horizon stabilization.

One way of overcoming this problem may be to have twin monitors, with the rectified and unaltered images next to each other; so during navigation, the operator can rely on the unaltered image to guide control of the endoscope. This would, however, mean that navigation would sometimes occur without a straight horizon, perhaps degrading performance compared with a corrected view. However, the obvious reason for failure of the horizon stabilization software in this experiment is the fact that endoscope and tool control are coupled via the endoscope, and the real benefits of this technology are likely to be seen when these are decoupled. A more elegant solution, however, would be to decouple the visuomotor control axis by using a robotic endoscope interface. This would allow for correction of the motor control because the image is manipulated to stabilize the horizon, thereby realizing the full benefits in orientation of a stable horizon while maintaining a customary control mechanism. This highlights the importance of developing improved mechatronically controlled devices with seamless instrumental control if NOTES is to make a realistic impact on the future of minimally invasive surgery.

It is widely accepted that gastroenterologists rely less frequently on a standard horizon view because the tubular structure of the gastrointestinal tract means that standardizing the roll axis rarely makes a difference. Surgeons, however, prefer a standard laparoscopic view when performing minimally invasive surgery.[2] For operative/interventional NOTES procedures, therefore, the ability to aid the operator in obtaining an optimal view will be a requirement for any NOTES-specific platform.

With the use of a single attempt before and after randomization, bias relating to learning to use the horizon stabilization software may naturally be introduced. However, because of the relatively small sample size and to avoid bias resulting from individual variability as much as possible, it was decided to allow all participants to perform the task once and then randomize them to horizon stabilization or control for the second attempt. Although it is accepted that there is an individual variability in learning, it was presumed that this was less significant than individual variability in task performance, and therefore, it was decided to use the change of performance between the first and second attempt as the primary end point.

This study evaluating horizon stabilization did not yield the same results as the initial validation of Holler et al,[9] which concluded it to be beneficial. In their validation, participants were presented with a view of both the rectified and nonmanipulated images during navigation in 4 quadrant peritoneoscopy, and the needle targets were grasped using conventional transabdominal laparoscopic instrumentation, not instruments from the flexible endoscope. The flexible endoscope was used for visualization alone and did not contribute to any further operative maneuvers. Therefore, the benefit derived here is likely to be a result of the correction of the image at the point of the task because we know that laparoscopic performance is optimum with correct orientation of the viewing endoscope.[2]

The fact that there was no difference in second attempt performance based on level of training or specialty is in concordance with published work for tasks involving orientation[3,10] and likely reflects a combination of the relative novelty of the NOTES approach to both surgeons and gastroenterologists as well as the fact that most participants in this study were experienced enough to have reached their innate proficiency in orientation.

To perform horizon stabilization, it is first necessary to align the camera vertically to a plum line or other vertical reference point. This process of 1-time calibration is performed manually and establishes the relationship between the camera and IMU coordinate systems. Because the force of gravity constantly acts on the accelerometer, when the system is at constant velocity, the measured acceleration will have a magnitude of 1*g*. The angle between the current measured vector associated with gravity and the calibration vector is that by which the endoscope image is rotated to stabilize the horizon. However, changes in velocity of the endoscope will produce additional acceleration, which is superimposed with the constant acceleration due to gravity. Because the gravity component is inseparable from this additional component, errors can occur in the angle calculation. Down-sampling of the sensor data is necessary because the sampling rate is much faster than the camera frame rate (400 vs 25 Hz). This data redundancy allows the data to be filtered in order to avoid errors in the angle calculation associated with movement. A weighted average is used[5] because it biases the average of sensor values within 1 image frame toward a magnitude of 1*g*. The weighting for each set of sensor data is inversely proportional to the deviation of their magnitude from 1*g*. Hence, those sensor data values affected by motion are effectively ignored. To avoid unwanted motion in the image from small angle changes caused by sensor noise when the endoscope is stationary, a minimum angle change threshold and Kalman filtering are introduced. This results in a smooth output image free of jerky movements during all types of endoscope manipulation.

An issue with using an IMU for horizon stabilization in its current form is that it has to be secured to the outside of the endoscope, which inevitably leads to an increase in diameter of the overall device. Although no problems were encountered in this simulator study, the increase in size may lead to increased tissue trauma at the gastrotomy site. It is also imperative that the IMU is secured to the endoscope in a fashion that avoids exposing surrounding tissue to the relatively sharp edges of the IMU during navigation. It will be interesting to explore the relative merits and differences between other methods of horizon stabilization as described in the introduction, bearing in mind that simple manual methods such as using 2 endoscopes of differing diameters may provide a very simple solution, which avoids further computer assistance.

The potential benefit of horizon stabilization during NOTES procedures is clear; however, its use is not supported in the context of direct application to current design of flexible endoscopes. The potential uncoupling of the visuomotor axis to allow for conventional endoscopic control should be explored and preferably in the context of a more complex surgical procedure, where the true benefit of maintaining correct orientation and visual alignment can be demonstrated.

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