Digestive Endoscopy 2025; 37: 541–547 doi: 10.1111/den.15001

Techniques and Innovation

Virtual-reality endoscopic navigation system in mediastinal natural orifice transluminal endoscopic surgery (with video)

Masaya Uesato,[1] Senri Umetsu,[2] Akira Nakano,[1] Mayuko Kinoshita,[1] Toshiya Nakaguchi[3] and Hisahiro Matsubara[1]

[1]Department of Frontier Surgery, Chiba University Graduate School of Medicine, [2]Graduate School of Science and Engineering and [3]Center for Frontier Medical Engineering, Chiba University, Chiba, Japan

The approaches to mediastinal surgery are open thoracic, thoracoscopic, and mediastinoscopy. However, using natural orifice transluminal endoscopic surgery (NOTES) would be minimally invasive if the mediastinum is reached via the esophagus. One disadvantage of NOTES was no information outside the wall. We focused on the electromagnetic tracking solution. The sensor position in the space created by the magnetic field generator can be determined. We performed a computed tomography (CT) of a pig before constructing the target mediastinal organs in 3D. The pig was placed in the magnetic field space, and the endoscope with the sensor was subsequently inserted orally and synchronized with the 3D image. By simultaneously viewing the actual and the virtual endoscopic image in 3D, the mediastinum can be visualized through the esophagus. We determined six points in advance in the 3D images, and the esophageal lumen closest to the esophagus from the points was marked with a clip under the endoscope. The CT scans showed that the mean error between the clip position and the closest point from the target point to the esophagus was 4.7 mm across three trials. We named this system the virtual-reality endoscopic navigation system (VENaS). VENaS can help determine the shortest distance to the point away from the esophagus and the 3D relation with the surrounding organs during esophageal endoscopy, and also displays gravity direction and an overhead view, thereby making it easy to approach areas with tumors or malformations in the mediastinum and increasing the realism of mediastinal NOTES.

Trial registration: UMIN-CTR and jRCT are trials involving humans. This study is not applicable because it involves animals. The approval number given to this study by the Animal Care Facility is #20136-03.

Key words: esophagus, mediastinum, natural orifice transluminal endoscopic surgery, navigation system, virtual reality

INTRODUCTION

THE APPROACHES TO mediastinal surgery are open thoracic, thoracoscopic, and recently, mediastinoscopy. However, using a technique called natural orifice transluminal endoscopic surgery (NOTES) would be the least invasive if the mediastinum is reached via the esophagus. In 2004, Kalloo *et al.*[1] introduced NOTES as a technique in which an endoscope is inserted through a physiological opening to artificially perforate the luminal organ wall for diagnosis and treatment outside the wall. This technique is expected to reduce postoperative pain and adhesions, eliminate complications related to the surgical wound, and improve cosmetic appearance.

However, NOTES presents unique technical and safety issues. In a NOTES white paper compiled by the Natural Orifice Surgery Consortium for Assessment and Research, a NOTES research organization, they described 12 potential barriers that should be resolved in clinical practice.[2] Among them, reliable closure of the artificial perforation should be ensured. In 2007, Sumiyama *et al.*[3] reported submucosal endoscopy with a mucosal flap (SEMF) technique wherein a tunnel was created under the esophageal mucosa, the muscularis propria was incised at the distal end, and the scope could enter the mediastinum. The SEMF facilitates closure of the esophagostomy incision because the mucosa acts as a sealed flap.[4] In 2007, Pasricha *et al.*[5] performed an experimental endoscopic esophageal myotomy in pigs using SEMF. In 2008, Inoue *et al.* performed the first per-oral endoscopic myotomy (POEM) in humans,[6] which is now widely used as a safe treatment for esophageal achalasia. Thus, a procedure similar to the prototype of NOTES is currently implemented in clinical practice, indicating the feasibility of NOTES via transesophageal access.

Another major problem was the lack of additional information with NOTES, making it unclear where to insert

Corresponding: *Masaya Uesato, Department of Frontier Surgery, Chiba University Graduate School of Medicine, 1-8-1 Inohana, Chuo-ku, Chiba-shi, Chiba 260-8670, Japan. Email: uesato@faculty.chiba-u.jp*
Received 18 September 2024; accepted 13 January 2025.

the endoscope into the digestive tract. Determining the closest point to the target point (TP) in the mediastinum when observing from inside the esophagus is impossible. Moreover, after determining the entry site to the mediastinum from the esophagus, determining whether any vital organs exist outside the esophageal wall at the planned entry site is difficult. However, this was solved through joint research between medicine and engineering, which aimed to obtain accurate information outside the digestive tract in real time. We named the system virtual-reality endoscopic navigation system (VENaS). This study aims to determine the shortest point from inside the esophagus to the TP when observing from inside the esophagus without inserting it in the mediastinum where the TP was located.

PROCEDURE

Study design

WE CONDUCTED THIS study on one pig in the supine position under general anesthesia after obtaining Jichi Medical University's approval for an Ethics Review of Animal Experiments (Approval No. 20136-03). Figure 1 shows the experimental environment. A wooden platform was used on the computed tomography (CT) examination table to fit the position of the pig's mediastinum in the detection area of the sensor. Additionally, the magnetic field generator was placed under the platform.

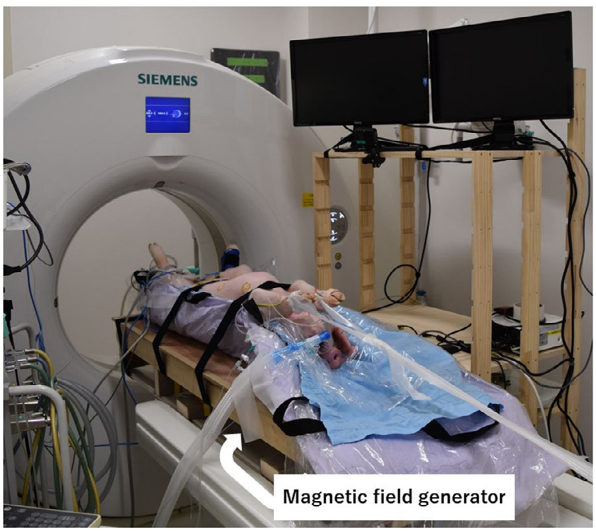

Figure 1 Animal experiment environment. A wooden platform was used on the computed tomography examination table to fit the position of the pig's mediastinum within the detection area of the sensor. The magnetic field generator was placed under the platform.

Six TPs (TP1, superior margin of the aortic arch; TP2, inferior margin of the aortic arch; TP3, tracheal bifurcation; TP4, right upper pulmonary vein esophageal crossing; TP5, right lower pulmonary vein esophageal crossing; TP6, inferior margin of the sternum) were set in advance in 3D CT, a virtual mediastinal endoscopic image. The endoscope was not inserted in the mediastinum where the TP was located. A gastrointestinal endoscopy instructor using a hemostatic clip marked the nearest part of the TP to the esophageal lumen, referring to the virtual mediastinal endoscopic image. Subsequently, the CT image of the pig was obtained under the same conditions as before the marking. We performed three trials. The clips were removed after CT imaging in each trial (Fig. 2).

Measurements

Measurements were obtained after completing the three trials. The errors between the clip tip and correct positions were measured in 3D. The correct position is the intraluminal location of the esophageal wall with the shortest distance from the TP. Three gastrointestinal surgeons marked the clip tip and correct positions on CT images. The allowable error was set at 10 mm.

Statistical analysis

Statistical analysis was performed on 18 measurements. A two-way analysis of variance was performed to assess significant differences between the six TPs and the three trials. P-values <0.05 were considered statistically significant. Statistical analysis was performed using JMP software version 17.2.0 (SAS Institute, Cary, NC, USA).

System configuration

First, the electromagnetic position sensor attached to the tip of the endoscope sends position and rotation information to the host computer. Subsequently, the host computer uses the sensor information to navigate in the virtual space and provide various information. Finally, two images are displayed simultaneously: the real endoscope image of the esophagus on one display and the virtual endoscope image of the mediastinum on the other (Fig. 3).

System equipment

For the hardware, the endoscope system was composed of EVIS LUCERA ELITE CLV-290, CV-290, and GIF TYPE Q260 (Olympus Medical Systems, Tokyo, Japan). Frontier FRLN710/WS2 (Inversenet, Kanagawa, Japan) was used as

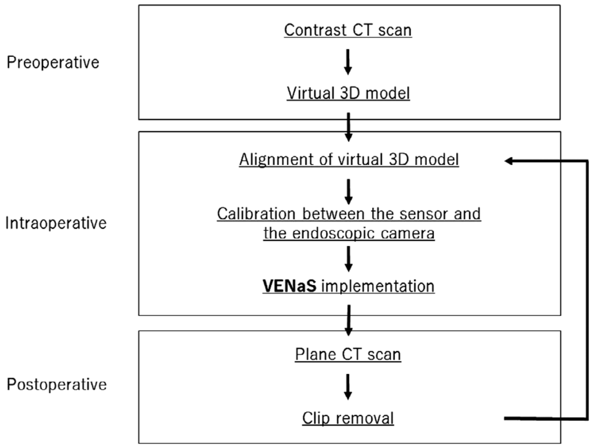

Figure 2 Flow of surgery using virtual-reality endoscopic navigation system (VENaS) and evaluation. The flow of VENaS is divided into two stages: pre- and intraoperative. First, a contrast computed tomography (CT) scan is obtained, as well as the 3D model. At the beginning of surgery, the virtual 3D model is aligned in real space. After the calibration, the surgeon performs the procedure while referring to the virtual endoscopic image of the VENaS. A pig is evaluated by CT, the clips are removed, and the virtual 3D model is synchronized for the next trial.

a host computer, and Aurora (Northern Digital, Waterloo, Canada) was used as an electromagnetic tracking solution[7] consisting of a magnetic field generator and a sensor (Fig. 4). For the software, we mainly used Unity (version 2021.3.31f1) (Unity Technologies, Tokyo, Japan)[8] to simulate the virtual space.

System usage flow

Figure 2 shows the flow of surgery by using VENaS. The flow is divided into two stages: pre- and intraoperative. First, the patient underwent a contrast CT scan preoperatively. Subsequently, the 3D model of the patient was created from the images obtained and placed in virtual space. This time, the cardiovascular and tracheal systems in the mediastinum and the thoracic bones will be constructed in 3D. However, the organs that will be constructed can be determined arbitrarily. At the beginning of surgery, the virtual 3D model is aligned with the patient in real space, and five radiopaque tags (CT-SPOTS #123; FLAIR, Tokyo, Japan) are applied to the patient's skin as fiducial markers. Specifically, the markers in the preoperative CT images are matched with the markers on the patient in real space obtained by an electromagnetic position sensor. After alignment, the sensor and endoscopic camera are calibrated. The sensor is attached to the underside of the endoscope tip, that is the 6 o'clock position when looking at the endoscope from the front. Because of the slight difference in the sensor and camera positions, the distance between the sensor and camera is measured in advance, and correction is performed. After completing the calibration, the surgeon performs the procedure while referring to the virtual endoscopic image of the VENaS.

Navigation features

The navigation function aims to help the surgeon understand the environment outside the wall by presenting multifaceted

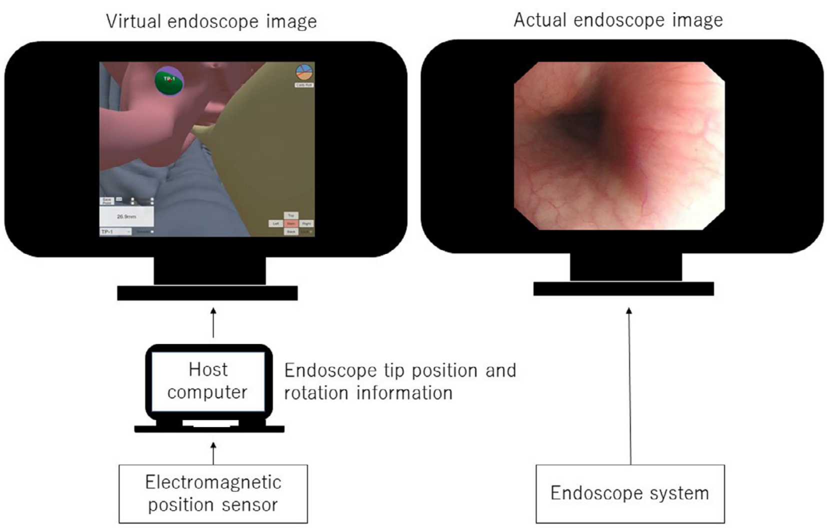

Figure 3 This system displays two images simultaneously: one is the real endoscopic image from the endoscopy system, and the other is the virtual endoscopic image of the mediastinum.

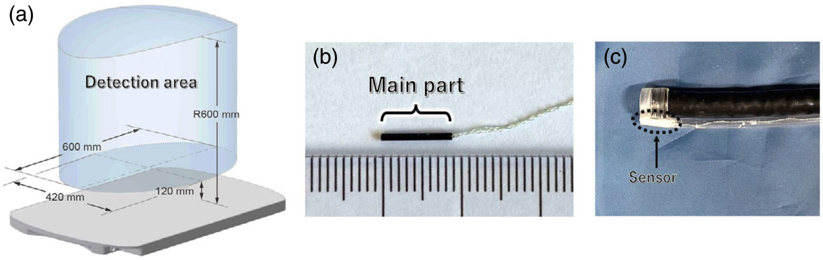

Figure 4 Aurora (Northern Digital, Waterloo, Canada). (a) The magnetic field generator can effectively detect the sensor position in the detection area. (b) The sensor is wired and measures 9.4 mm in length and 0.92 mm in diameter. (c) The sensor is loaded in the attachment (impact shooter (L), TOP Co., Tokyo, Japan) at the endoscope tip.

and visual information and improving the safety and precision of NOTES. The navigation functions of VENaS are broadly divided into four categories: switching the viewpoint, presenting the camera and sensor status, displaying the TP outside the wall, and presenting information on the distance to the TP, and each function is explained in detail (Video S1).

Switching the viewpoint

Because the endoscopic camera usually projects only forward images, it is difficult to understand the relative positional relationship between the endoscope and surrounding organs or the endoscope position in the entire image. Therefore, we introduced a function to switch the viewpoint of the virtual endoscope to the same viewpoint as the real endoscope and to a bird's-eye viewpoint. Using the viewpoint-switching function, the extramural environment can be visualized from different directions, facilitating an understanding of the positional relationship between the additional organs and the endoscope.

Presenting the camera and sensor status

The roll angle of the endoscope camera is presented in real time using the tilt of the arrow, allowing the surgeon to intuitively understand the endoscope posture, even inside a patient, where he/she has difficulty grasping the direction of the camera. In the display of the transit path, a line indicates the trajectory where the sensor has moved, confirming the actual path traveled and the esophagus location. In the sensor value acquisition status display, a red frame is displayed to alert the surgeon when a sensor value is missing, making the surgeon notice unintended sensor movement outside the detection area or the effect of ferromagnetic materials on the magnetic field, even when the surgeon is concentrating on the procedure.

Displaying the TP

We have developed a function that displays TPs outside the wall, which are predefined in the CT image. TP characters and arrows are always displayed at a constant size at the front of the screen without blockage from any organs. Furthermore, a green sphere displayed in the virtual space indicates the 3D positional relationship between the TP and extra organs. The axial plane wherein the TP resides can also be displayed, making the positional relationship between the TP, located far from the esophagus, and the endoscope tip easy to determine.

Presenting information on the distance

The 3D distance from the endoscope tip to the TP is displayed in real time, making it possible to quantitatively search for the nearest-neighbor of the TP in the esophagus. Furthermore, the distance information is presented with sound, with a continuous sound playing when the distance to the TP is <50 mm. The frequency of the continuous sound increases continuously as the distance from the TP decreases. The acoustic presentation of distance information allows the surgeon to intuitively grasp the approach to and departure from the TP without constantly checking the numerical information visually.

RESULTS

Figure 5 shows the error between the clip tip and the correct positions at each TP location. The order of marking was from TP6 to TP1. The mean error was 4.7 mm, and 94.4% of the errors were within the error tolerance (<10 mm). No significant differences were observed among the first, second, and third measurements ($P = 0.434$) or between the TPs ($P = 0.467$). To evaluate the stability of the sensor value acquisition, the percentage of data from the

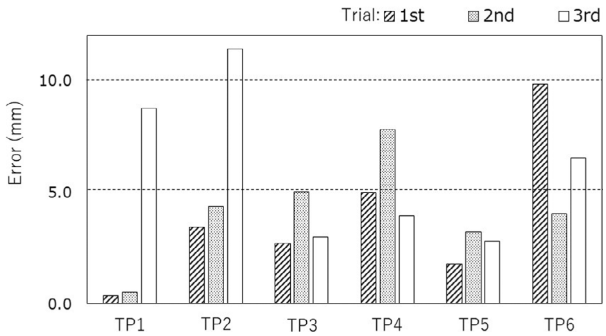

Figure 5 Error between the clip tip position and the correct position at each target point (TP). The experiment was performed thrice, and each is shown separately. The mean error over all points was 4.7 mm, and 94.4% of the errors were within the error tolerance (<10 mm).

electromagnetic position sensor without position information was calculated as the degree of missing sensor values, and was 0.3%.

DISCUSSION

TO EVALUATE THE effectiveness of VENaS in understanding the environment outside the wall, we experimented using a pig in an environment close to a clinical situation. The mean error was 4.7 mm, which was within the acceptable error range, indicating the effectiveness of the developed system and its feasibility in a clinical environment. Although many methods can provide 3D images as a surgical support system,[9–11] our technology is highly novel during digestive endoscopic surgeries, such as NOTES.

Engineering advancements in VENaS

Position sensors are divided into optical and electromagnetic types. The optical sensor requires an optical path between the light source and the receiver. Conversely, the electromagnetic sensor can be used even with obstacles.[12] In addition, the electromagnetic position sensor can detect the position and rotation of the sensor in real time from the voltage generated by the magnetic field. Therefore, we thought that would be suitable for NOTES, which uses a flexible endoscope. Previously, we used deep-learning technology to capture the white line on the endoscope surface with an external camera, measure the distance of the scope movement, and estimate the tip position of the scope.[13] However, the error increased due to scope flexure. Moreover, Aurora[7] can pinpoint the sensor position and orientation within a magnetic field with high accuracy. Because of the small size of the sensor, it can be attached to the tip of a needle or catheter. Therefore, we believe that the sensor attached to the tip of the scope was detected, resulting in a small error. Furthermore, as a surgical support technology, the additional information to virtual endoscopic images, such as the scope orientation, TP position information, overhead images, and sensor reception status, are beneficial in clinical applications.

Clinical implications of our study results

In NOTES, we thought that surgical procedures could be significantly affected if the deviation of the perforation site when approaching the mediastinum from the esophagus exceeded the width of a normal scope (~10 mm). Therefore, we set the target error for the intraesophageal projection information of the mediastinal object position to within 10 mm, which was much smaller than expected, but with high accuracy. The two-way analysis of variance revealed no significant differences among the first, second, or third measurements or between the TPs. This does not indicate that the measurements were not reproducible. If the information obtained from CT scans can be reconstructed more accurately into 3D images, more information could be provided intraoperatively, improving accuracy and safety. Additionally, the construction of a 3D image from a preliminary CT scan can be completed in 20 min by using automation that utilizes deep learning. We are also striving to make this process even faster.

Currently, the TP was placed in the CT as a site with anatomical features for experimental purposes, but it should be placed in the area to be treated in reality, such as a tumor or malformation. VENaS has a wide range of applications for mediastinal NOTES, such as nonthoracotomy resection of a single lymph node recurrence after chemoradiotherapy for esophageal cancer, diagnosis of mediastinal tumors, and minimally invasive surgery for pediatric surgical diseases (esophageal tracheal fistula, etc.). Moreover, we believe that it will be useful to confirm the direction of the submucosal tunnel and grasp the position of the gastric blood vessels during POEM for esophageal achalasia. The double-scope method is recommended during POEM to confirm the final destination on the stomach side, which is undoubtedly a good method.[14] However, we are going to use VENaS as a guide for creating submucosal tunnels during POEM in human clinical trials. Using the virtual image, the direction of the axis and final destination of the submucosal tunnel can be set in advance. Because a tunnel can be easily created, this system may also be useful for sigmoid-type achalasia, which is prone to losing track of direction.[15] However, this step is still limited to the esophageal wall, and the next step is NOTES within the mediastinum. CT-guided needle biopsy or ablation has become popular, and some reported combining the real-time position of a needle handle and a marker on the patient to deliver the needle tip from the body surface to the target in augmented reality,[16] assuming that the needle does not deform. VENaS is equipped with a sensor at the tip of the scope, making it possible to create a virtual reality view through a flexible scope.

Recently, in trauma surgery a hybrid emergency room (ER), an ER equipped with CT equipment and operating room functions, has become a hot topic.[17] Patients can rapidly undergo interventional radiology and surgery without moving from one bed to another place, which could be ideally performed if our technology could be implemented in an environment such as a hybrid ER.

Study limitations

Our study has several limitations. The magnetic sensor is stored in an attachment at the endoscope tip. Thus, the attachment shifts, and the position of the sensor changes with long-term use. Moreover, the large error at TP2 and TP1 of the third measurement shown in Figure 5 represents the limit of the experiment. Olympus' UPD-3 (Olympus Medical Systems, Tokyo, Japan) is available on the market, using magnetism to grasp the shape of a colonoscope inside the body. The scope is already integrated with a sensor and has received pharmaceutical approval, so it can be used immediately on humans, which will likely produce stable results.

The best approach is to attach the five radiopaque tags around the observation area. Regarding the mediastinum, shoulders and the upper abdomen on both sides would be ideal. As we did not compare this allocation with random tag attachment, further investigation is required to identify the best tag locations. Furthermore, these tags can be relocated. However, when changing their locations, a new CT scan and calibration should be performed. It takes ~30 s for calibration.

The mean error was 4.7 mm. When the cause was investigated, no change was observed in the overall length of the esophagus between the start and end of the experiment. A slight change was observed in the esophageal length during endoscope insertion, which may be related to air injection and the weight of the endoscope itself. The sensor loss time of 0.3% indicates that the system always works, but one challenge for practical application will be that the detection area is currently limited.

In conclusion, we have developed VENaS, a surgical support technology that will likely benefit mediastinal NOTES. VENaS reflects information about the outside of the esophageal wall in a virtual endoscopic image and can provide this information simultaneously with real endoscopic observation.

ACKNOWLEDGMENTS

THE AUTHORS THANK Dr. Hiroshi Kawahira and Dr. Kazuhiro Endo for the animal experiments at Jichi Medical University.

CONFLICT OF INTEREST

AUTHORS DECLARE NO conflict of interest for this article.

FUNDING INFORMATION

THIS WORK WAS supported by the Japan Society for the Promotion of Science KAKENHI (grant number 23K11864).

ETHICS STATEMENT

APPROVAL OF THE research protocol by an Institutional Reviewer Board: This study was approved by the Animal Experimentation Committee (#20136-03, Jichi Medical University, Tochigi-ken, Japan).

Informed Consent: N/A.

Registry and the Registration No. of the study/trial: UMIN-CTR and jRCT are trials involving humans. This study is not applicable because it involves animals. The approval number given to this study by the Animal Care Facility is #20136-03.

Animal Studies: Animal experiments approved by the Animal Experimentation Committee at Jichi Medical University (#20136-03).

REFERENCES

1 Kalloo AN, Singh VK, Jagannath SB *et al*. Flexible transgastric peritoneoscopy: A novel approach to diagnostic and therapeutic interventions in the peritoneal cavity. *Gastrointest Endosc* 2004; **60**: 114–7.
2 Rattner D, Kalloo A, ASGE/SAGES Working Group. ASGE/SAGES working group on natural orifice translumenal endoscopic surgery. *Surg Endosc* 2006; **20**: 329–33.
3 Sumiyama K, Gostout CJ, Rajan E, Bakken TA, Knipschield MA. Transesophageal mediastinoscopy by submucosal endoscopy with mucosal flap safety valve technique. *Gastrointest Endosc* 2007; **65**: 679–83.
4 Moreira-Pinto J, Ferreira A, Rolanda C, Correia-Pinto J. Natural orifice transesophageal endoscopic surgery: State of the art. *Minim Invasive Surg* 2012; **2012**: 896952.

5 Pasricha PJ, Hawari R, Ahmed I *et al*. Submucosal endoscopic esophageal myotomy: A novel experimental approach for the treatment of achalasia. *Endoscopy* 2007; **39**: 761–4.
6 Inoue H, Minami H, Kobayashi Y *et al*. Peroral endoscopic myotomy (POEM) for esophageal achalasia. *Endoscopy* 2010; **42**: 265–71.
7 Northern Digital Inc. Aurora – NDI's premier electromagnetic tracking solution [Internet]. Northern Digital Inc. [cited 2024 Aug 11]. Available from: https://www.ndigital.com/electromagnetic-tracking-technology/aurora/
8 Unity Technologies. *Unity Real-Time Development Platform| 3D, 2D, VR & AR Engine [Internet]*. Tokyo: Unity Technologies, 2005. [cited 2024 Aug 11]. Available from: https://unity.com/ja
9 Chen-Yoshikawa TF, Date H. Three-dimensional image in lung transplantation. *Gen Thorac Cardiovasc Surg* 2018; **66**: 19–26.
10 Bracale U, Iacone B, Tedesco A *et al*. The use of mixed reality in the preoperative planning of colorectal surgery: Preliminary experience with a narrative review. *Cir Esp* 2024; **102**: 36–44.
11 Du C, Li J, Zhang B *et al*. Intraoperative navigation system with a multi-modality fusion of 3D virtual model and laparoscopic real-time images in laparoscopic pancreatic surgery: A preclinical study. *BMC Surg* 2022; **22**: 139.
12 Hagan MJ, Remacle T, Leary OP *et al*. Navigation techniques in endoscopic spine surgery. *Biomed Res Int* 2022; **2022**: 8419739.
13 Uesato M, Sato Y, Kobayashi M *et al*. Development of a navigation system for transesophageal mediastinal surgery using an oral endoscope. *Jpn J Gastroenterol Surg* 2022; **55**: 725–8.
14 Khashab MA, Kumbhari V, Azola A *et al*. Intraoperative determination of the adequacy of myotomy length during peroral endoscopic myotomy (POEM): The double-endoscope transillumination for extent confirmation technique (DETECT). *Endoscopy* 2015; **47**: 925–8.
15 Bechara R, Onimaru M, Ikeda H, Inoue H. Per-oral endoscopic myotomy, 1000 cases later: Pearls, pitfalls, and practical considerations. *Gastrointest Endosc* 2016; **84**: 330–8.
16 Solbiati M, Passera KM, Rotilio A *et al*. Augmented reality for interventional oncology: Proof-of-concept study of a novel high-end guidance system platform. *Eur Radiol Exp* 2018; **2**: 18.
17 Kinoshita T, Yamakawa K, Matsuda H *et al*. The survival benefit of a novel trauma workflow that includes immediate whole-body computed tomography, surgery, and interventional radiology, all in one trauma resuscitation room: A retrospective historical control study. *Ann Surg* 2019; **269**: 370–6.

SUPPORTING INFORMATION

ADDITIONAL SUPPORTING INFORMATION may be found in the online version of this article at the publisher's web site.

Video S1 Virtual endoscopic images of the mediastinum during esophageal endoscopy and the functions of the virtual-reality endoscopic navigation system are shown.