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ORIGINAL ARTICLE

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A novel clip-on device for electromagnetic tracking in endobronchial ultrasound bronchoscopy

Arne Kildahl-Andersen[a,b], Erlend Fagertun Hofstad[c], Karlijn Peters[d], Gregory Van Beek[d], Hanne Sorger[b,e], Tore Amundsen[a,b], Thomas Langø[c,f] and Håkon Olav Leira[a,b]

[a]St Olavs Hospital, Trondheim University Hospital, Trondheim, Norway; [b]Department of Circulation and Medical Imaging, Faculty of Medicine, Norwegian University of Science and Technology (NTNU), Trondheim, Norway; [c]Department of Health Research, SINTEF Digital, Trondheim, Norway; [d]Delft University of Technology, Delft, The Netherlands; [e]Department of Medicine, Levanger Hospital, Nord-Trøndelag Health Trust, Levanger, Norway; [f]Department of Research, St. Olavs Hospital, Trondheim University Hospital, Trondheim, Norway

ABSTRACT

Introduction: The established method for assessment of mediastinal and hilar lymph nodes is endobronchial ultrasound bronchoscopy (EBUS) with needle aspirations. Previously, we presented an electromagnetic navigation platform for this purpose. There were several issues with the permanent electromagnetic tracking (EMT) sensor attachment on the tip of the experimental EBUS bronchoscope. The purpose was to develop a device for on-site attachment of the EMT sensor.

Material and methods: A clip-on EMT sensor attachment device was 3D-printed in Ultem™ and attached to an EBUS bronchoscope. A specially designed ultrasound probe calibration adapter was developed for on-site and quick probe calibration. Navigation accuracy was studied using a wire cross water phantom and clinical feasibility was tested in a healthy volunteer.

Results: The device attached to the EBUS bronchoscope increased its diameter from 6.9 mm to 9.5 mm. Average preclinical navigation accuracy was 3.9 mm after adapter calibration. The maneuvering of the bronchoscope examining a healthy volunteer was adequate without harming the respiratory epithelium, and the device stayed firmly attached.

Conclusion: Development, calibration and testing of a clip-on EMT sensor attachment device for EBUS bronchoscopy was successfully demonstrated. Acceptable accuracy results were obtained, and the device is ready to be tested in patient studies.

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Electromagnetic navigation; endobronchial ultrasound; convex probe endobronchial ultrasound; ultrasound calibration; navigated EBUS

Introduction

Lung cancer is the most common cause of cancer-related death with a five-year survival <15% in Europe [1]. For lung cancer diagnosis and staging, a thorough investigation of lymph nodes along the trachea is overly important, as the level of cancer spread to these nodes is the main determinator for curative or non-curative treatment.

Endobronchial ultrasound bronchoscopy (EBUS) is the established method for assessment of hilar and mediastinal lymph nodes. EBUS allows for lymph node sampling, using ultrasound-guided, transbronchial needle aspirations (TBNA). EBUS-TBNA is a widely performed and safe procedure with a high diagnostic yield [2].

In lung cancer staging, the high diagnostic yield of EBUS-TBNA depends on ability to conduct several needle aspirations. For patients with several, closely situated lymph nodes the most malignant-appearing node from positron emission tomography and computed tomograph (PET-CT) must be sampled. The optimal number of punctures per lymph node is three to five [3], i.e., the bronchoscopist must navigate to the same lymph node many times, at the same time avoiding lengthy procedure duration with often poor video vision. As the nodes may look quite similar in the EBUS image, the operator will most probably be helped by a concurrent display of the bronchoscope position in the PET-CT images.

To improve the sampling precision and accuracy, image guidance systems based on preprocedural CT scans are frequently used [4]. In bronchoscopy, these systems mainly rely on position tracking tools equipped

CONTACT A. Kildahl-Andersen kildahla@yahoo.no Department of Thoracic Medicine, St. Olavs Hospital, Trondheim University Hospital, Postboks 3250 Sluppen, Trondheim 7006, Norway.

with electromagnetic tracking (EMT) sensors, passed through the bronchoscope's work channel. This approach is not feasible in EBUS bronchoscopy, as the single work channel is used by the TBNA needle.

Based upon the open-source navigation research platform CustusX [5], our group has developed the first EBUS bronchoscopy electromagnetic (EM) navigation system [6]. The system includes automated methods for airway and lymph node segmentation [7,8], as well as a centerline-based patient-to-image registration [9]. A graphical user interface with both video, ultrasound (Figure 1(a)), virtual bronchoscopy or CT (Figure 1(b,c)) can be obtained. The purpose of having EM navigation in EBUS bronchoscopy is to provide an anatomical guide for the apprentice bronchoscopist, to make navigation less video-dependent as blurring of the video lens during sampling may shorten procedure duration and thereby reduce the diagnostic yield.

Previously, the EMT sensor was placed on the EBUS bronchoscope's exterior [6,10], permanently fixed by glue and an endoscopy rubber wrap. The concerns were lack of reusability and the longevity of the modification of an advanced medical instrument, and the solution was impaired by risk of sensor breakage under procedures and during bronchoscope sterilization.

The purpose of this study was to develop and test a clip-on device, designed for temporal attachment of the EMT sensor to the EBUS bronchoscope exterior. The hardware requirements were:

- Robust and consistent attachment of the EM sensor to maintain position accuracy.
- Safe removal, to prevent endoscope damage.
- The device should allow for standard sterilization procedures.
- The material and design should not risk vocal cord and airway injury.

Furthermore, we describe the development and testing of the compulsory image-to-EMT sensor calibration procedure. A procedure intended to be quick as to make EM navigation with EBUS more available in the clinic.

Material and methods

This proof-of-concept study consisted of four distinct steps:

- Construction of an EMT sensor attachment clip-on device.
- Construction of an ultrasound-to-sensor calibration adapter.

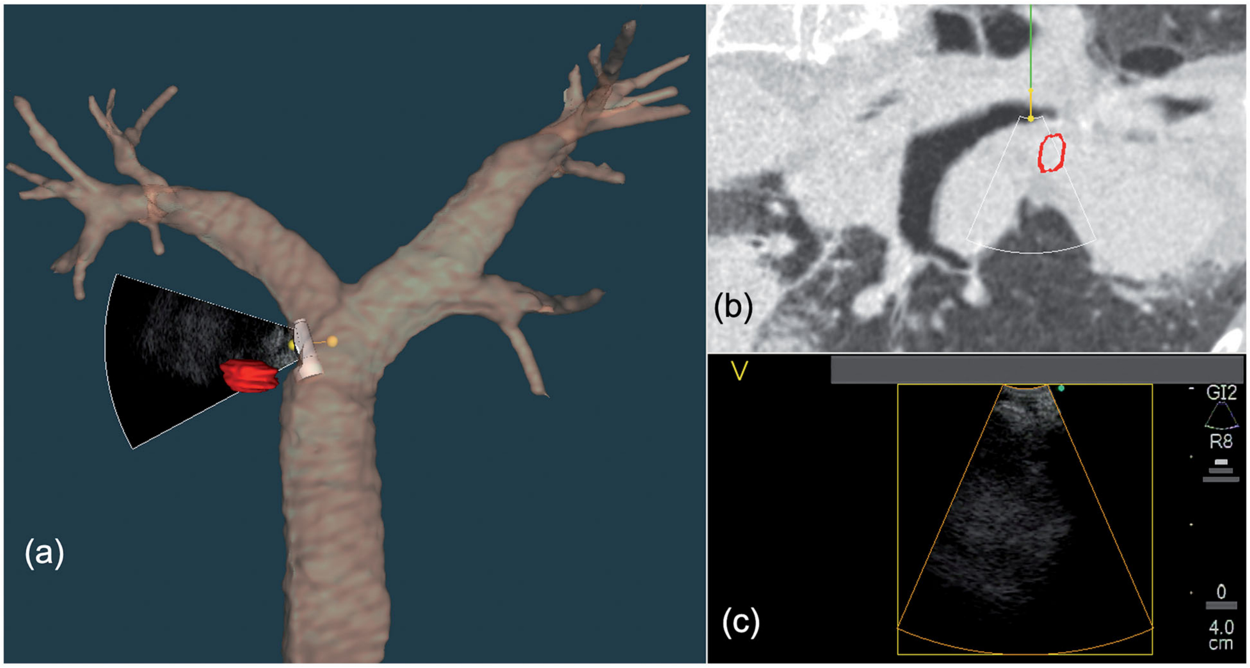

Figure 1. Graphical user interface of intraoperative guiding system CustusX showing real-time EBUS bronchoscopy with electromagnetic tracking. (a) Virtually displayed EBUS ultrasound probe with image sector. Bronchial tree with enlarged lymph node segmented from preoperative CT imaging data. (b) CT view resembling ultrasound image plane. (c) Ultrasound from the EBUS bronchoscope.

- Development of an ultrasound-to-sensor calibration method, including navigation accuracy analysis.
- Lung phantom and human testing.

Construction of the EMT sensor attachment clip-on device

The requirements for the clip-on device were secure attachment of the EMT sensor to maintain consistent position accuracy and prevent patient harm. Furthermore, safe removal must be assured, thus preventing endoscope damage. The material and design should not risk vocal cord and airway injury.

The clip-on device was developed to fit an off-the-shelf EMT sensor (Aurora 6-DOF Probe, Straight Tip, Standard, Northern Digital Inc., Waterloo, ON, Canada) to a regular, widely available convex probe EBUS bronchoscope, the Olympus BF-UC180F (Olympus, Tokyo, Japan). Ultem^{TM} 1010 resin (Stratasys Inc., Eden Prairie, MN, USA) was chosen as material for the clip-on device, as it is approved for medical devices and can be used for 3D-printing. It is a high-strength thermoplastic and can operate in high temperature environments including steam autoclaving, thus lowering the risk of airway microbiology contamination.

The clip-on device was developed as an iterative process. The shape and size of the EBUS probe were measured using a digital caliper. Based on the measurements the clip-on device was designed using Google Sketchup (Alphabet Inc., Mountain View, CA, USA), before a sample model was 3D printed using an Original Prusa 3D printer (i3 MK3, 3D Mate, Prague, Czechia). The sample model was evaluated by attaching it, with the EMT sensor, to the EBUS bronchoscope. Any mismatch in the fitting of the clip-on device was fixed by adjustments in the 3D model before another model was 3D printed.

The EBUS bronchoscope has an outer end diameter of 6.9 mm. The optimal inner diameter of the clip prototype was found to be 6.88 mm to fit properly without damaging the surface of the bronchoscope. A clip wall thickness of 1.00 mm was chosen, being a trade-off between device tensile strength and the bronchoscope's extended diameter. Design and dimensions of the clip-on EMT sensor attachment device are shown in Figure 2. The clip follows the circumference of the bronchoscope. Along the length of the bronchoscope an extended part is designed with a groove for the EMT sensor.

After 3D-printing, the device was polished and brushed under a microscope to remove any sharp edges. Before testing in human, we ran the clip through ten cycles of autoclave without any visible breakage or tears.

Construction of an ultrasound-to-sensor calibration adapter

The purpose of the EBUS probe calibration adapter is to fixate the EBUS tip in a repeatable position for probe calibration. A 3D-printed prototype of Polylactic acid (PrimaValue^{TM}, PrimaCreator, Malmö, Sweden) is shown in Figure 3(a–c) and was made using an Original Prusa 3D printer. The adapter is designed as a channel for the bronchoscope proximal to the ultrasound probe and with an open space which allows for ultrasound imaging during probe calibration. To prevent translational motion, the adapter consists of several protrusions and a gap shaped around the bronchoscope's balloon attachment

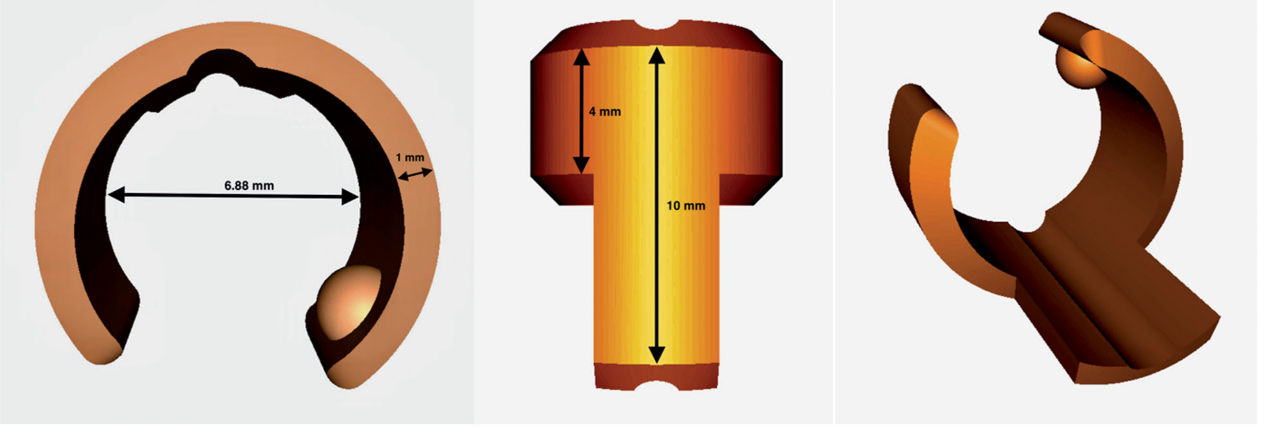

Figure 2. The clip-on EMT sensor attachment device modelled with estimated dimensions before 3D printing. To protect the EMT sensor, the device has an extended part with a groove for the EMT sensor (radius 0.7 mm). Space is created between the extended part and bending section of the bronchoscope to prevent damage due to bending.

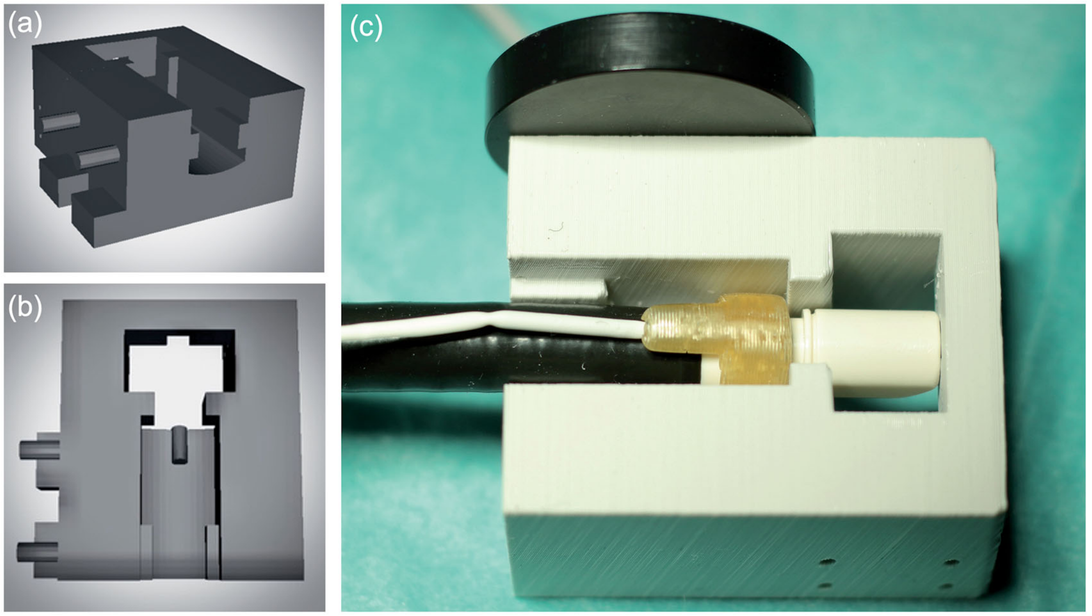

Figure 3. (a,b) 3D design of the calibration adapter. (c) The EBUS probe with an EMT sensor (white) locked with the clip-on device and placed inside the 3D-printed adapter with an EM sensor attached (black disk).

site at the distal end. A spike, which fits in the instrument channel outlet of the distal end, was made to prevent rotation of the EBUS probe. On one side of the adapter there is an attachment for a reference EMT sensor to be used during calibration. As for the clip, described above, the calibration adapter was developed as an iterative process. It was designed in Google Sketchup, 3D-printed and evaluated, before the design was optimized several times.

Ultrasound calibration

Attachment of an EMT sensor to an EBUS bronchoscope used in an image guidance system requires a calibration process to ensure that the ultrasound image is aligned to the rest of the navigation images. The calibration method is a two-step process: The first part is for calibration of the adapter itself, and only needs to be performed once. The second part is the calibration of the sensor to the bronchoscope using the adapter, performed shortly before each bronchoscopy. The software method was implemented in the in-house CustusX navigation system [5].

Calibration of the calibration adapter

The spatial relation between the ultrasound image and the EMT sensor attached to the adapter (${}^{US}M_A$) is found. This calibration method has previously been described generically [11] and specifically for EBUS [6].

Key to calibration is a small plastic sphere (11.5 mm in diameter) in a water tank with known position in the EM field, relative to an EMT reference sensor (Figure 4(a)). The EBUS scope was clicked into the calibration adapter, and the adapter was attached to a six-axis robotic arm (UR5, Universal Robots, Odense, Denmark). The adapter with the ultrasound probe was moved slowly (1mm/s) through the plane of the convex probe ultrasound at nine evenly distributed positions, with two opposite directions for each position. This resulted in 18 acquisitions of corresponding real-time ultrasound and spatial data of the imaged sphere in relation to the sensor on the calibration adapter. In each ultrasound acquisition the center of the sphere was found. Then the calibration matrix was calculated by minimizing the distance between the sphere center positions in the ultrasound image coordinate system and in the coordinate system of the EMT sensor on the adapter.

Calibration of the sensor to the EBUS bronchoscope

The second part of the calibration method is performed shortly before each bronchoscopy. The clip-on device secures the EMT sensor on the EBUS bronchoscope, which is placed into the calibration adapter. Then the spatial relation between the two EMT sensors, on the EBUS tip and on the calibration adapter, is measured. Next, the probe calibration is found instantly in the CustusX software. The calculation is performed as:

$$ {}^{US}\boldsymbol{M}_{\boldsymbol{C}} = {}^{US}\boldsymbol{M}_{\boldsymbol{A}} * {}^{A}\boldsymbol{M}_{\boldsymbol{C}} $$

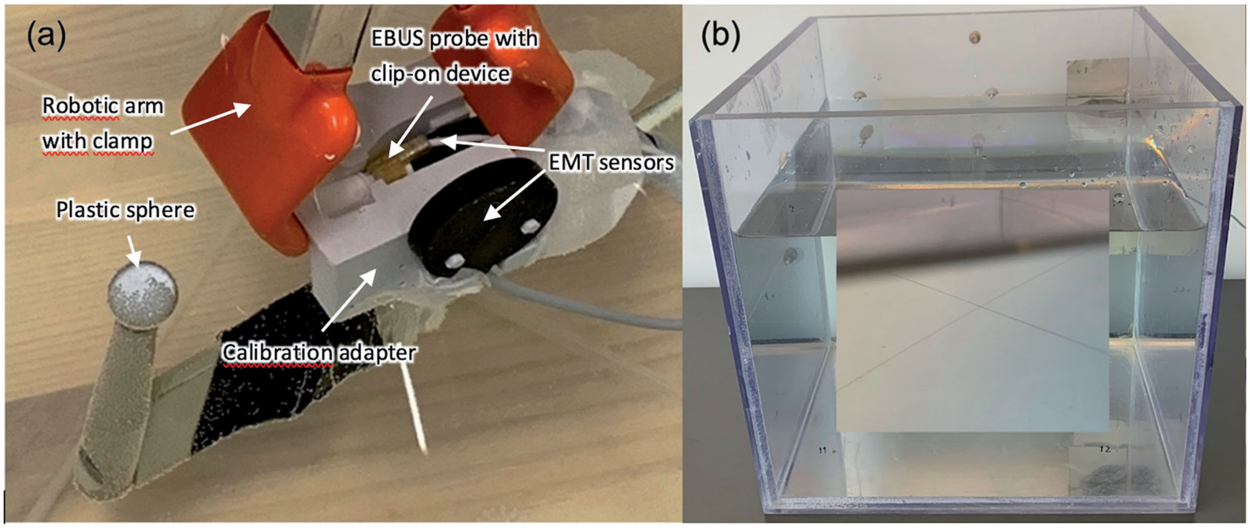

Figure 4. (a) A small plastic sphere in a water tank with known position in the EMT field. Slip pass movements of the calibration adapter and ultrasound probe with a robotic arm for calibration. (b) Water tank phantom with a nylon wire cross used for free-hand ultrasound calibration and accuracy analysis. A close-up picture of the wire cross is superimposed onto the water tank.

where ${}^{US}M_C$ is the transformation matrix from the sensor placed in the clip-on device on the EBUS tip to the ultrasound plane, ${}^{US}M_A$ from the sensor on the calibration adapter to the ultrasound plane (measured once) and ${}^{A}M_C$ from the sensor in the clip-on device to the sensor on the adapter (measured before each procedure).

Navigation accuracy analysis

To measure the navigation accuracy after probe calibration an accuracy phantom was used (Figure 4(b)). The phantom is a $25 \times 25 \times 25\,\text{cm}$ water tank with two nylon wires crossing each other in the middle of the tank. The position of the wire cross is known in the EM coordinate system by an EMT sensor mounted to the phantom and a separate calibration routine for the phantom. The wire cross was first imaged with the calibration adapter placed on the EBUS tip, to measure the system accuracy with the initial, one-time, calibration only. The wire cross was imaged ten times, five in each of two orthogonal directions.

Next, the system accuracy was measured after the preprocedural calibration. In total five calibrations were performed. Before each calibration the clip-on device and tracking sensor on the EBUS tip were taken off and on to resemble a new procedure. After each calibration the wire cross was imaged six times, three in each of two orthogonal directions.

The navigation system accuracy was evaluated by identifying the wire cross in the 3D ultrasound acquisitions in CustusX and comparing them to its physically position within the phantom.

Lung phantom and human testing

Lung phantom testing

To confirm that the prototype device was safe and stayed firmly attached, EBUS bronchoscopy with the clip-on device attached was performed on a lung phantom extended with upper airways (Ultrasonic Bronchoscopy Simulator LM-099, KOKEN CO., LTD, Tokyo, Japan).

Human testing

As final part of the study, an EBUS examination was performed on a healthy volunteer. The study was approved by the local ethics committee and informed consent was obtained from the healthy volunteer. The examination was performed without EM navigation and included examination of mediastinal and hilar lymph node stations to check whether the diameter of the combined clip/bronchoscope gave access to all essential areas. The volunteer's airways were closely examined for any injury during the bronchoscopy, and afterward by inspection of the recorded bronchoscopy video.

Equipment for bronchoscopy and electromagnetic position tracking system

- CP-EBUS (Olympus BF-UC180F, Olympus, Tokyo, Japan).
- Video processing unit (Olympus, Evis Excera III CV-190 Plus, Olympus, Tokyo, Japan).
- Light source (Olympus, Evis Excera III CLV-190, Olympus, Tokyo, Japan).

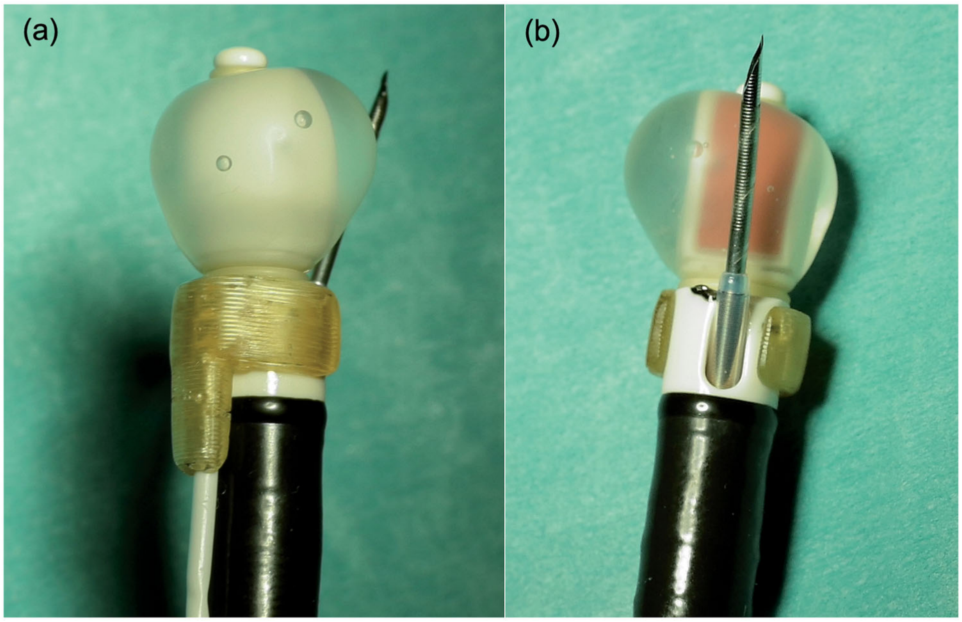

Figure 5. (a) EBUS 3D-printed clip-on device for attaching an electromagnetic sensor, thus making the EBUS bronchoscope suitable for navigation. The sensor is aligned in the clip-on device protruding the upper edge of the bronchoscope on the picture. (b) The attachment of the EBUS 3D-printed clip-on device does not interfere with either the cytology needle, the light source, or the inflatable water balloon.

- Ultrasound processor (Olympus EVIS EUS EU-ME2, Olympus, Tokyo, Japan).
- CustusX (In-house developed open-source research system for image guiding and navigation), http://www.custusx.org [5].
- Aurora® electromagnetic tracking system (Northern Digital Inc. (NDI), Waterloo, ON, Canada).
- Tracking sensor (Aurora 6-DOF Probe, Straight Tip, Standard, Northern Digital Inc., Waterloo, ON, Canada).

Results

Testing of the EM sensor attachment clip-on device

The clip-on EMT device was 3D printed in Ultem™ and after a brushing procedure it was attached to the EBUS bronchoscope. The diameter of the EBUS bronchoscope increased from 6.9 mm to 9.5 mm with the clip-on device attached. The device did not interfere with the inflatable water balloon, cytology needle or light source (Figure 5(a,b)). It was tested repeatedly on a lung phantom extended with the upper airways without falling off.

EBUS bronchoscopy on a healthy male volunteer

The EBUS bronchoscope was advanced down to wedge position in the lower lobe of the left lung, demonstrating that all lymph node stations in question could be reached. The maneuverability of the EBUS bronchoscope was not compromised by the EMT sensor clip-on device. Having the device attached did not cause detectable injury to the respiratory epithelium or other complications on the healthy volunteer. The balloon on the EBUS bronchoscope was inflated with saline solution and found to be functional. The clip-on device remained firmly on the bronchoscope during the test procedure.

Navigation accuracy

The average navigation system accuracy measured with the calibration adapter attached to the tip was 3.4 ± 3.5 mm. After the preprocedural calibration, the accuracy was measured to 3.9 ± 3.9 mm. The results from all 40 accuracy measurements are shown in Figure 6.

Discussion

In this study we described the successful development of a 3D printed EMT sensor attachment clip-on device and calibration procedures for navigated convex probe EBUS bronchoscopy. The clip-on device adds to the total diameter of the bronchoscope without disturbing the functionality of the bronchoscopy. Access to lymph node stations was not compromised, partly because the diameter expansion is proximal to the ultrasound probe. No harm was induced to

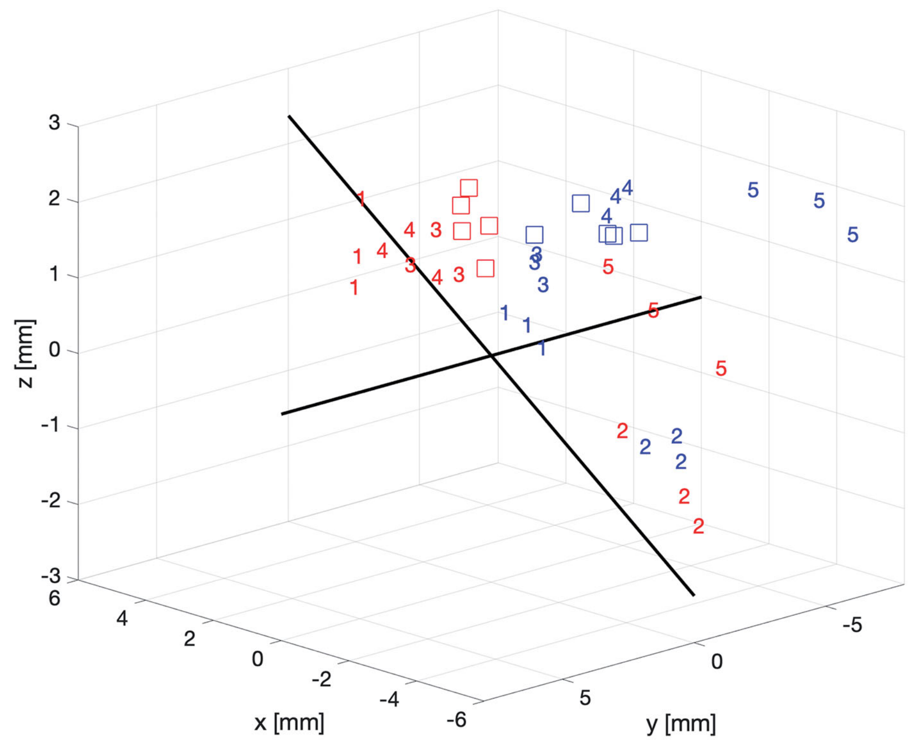

Figure 6. The measured position of the wire cross in the ultrasound image. The squares denote the acquisitions made with the adapter on, while the numbers denote acquisitions made after on-site calibrations (1–5). Red and blue colors denote the two orthogonal acquisition directions.

respiratory epithelium or vocal cord when tested in the healthy volunteer. After adapter calibration the accuracy was measured to 3.9 mm.

The type of material chosen for 3D printing, Ultem™ 1010 resin, has previously been explored as material in 3D-printed surgical instruments used for orthopedic surgery. In a study by Hooper et al., different 3D print materials were compared through steam sterilization and oscillation saw tests; Ultem™ proved to be the least affected material studied [12]. Our experience was coherent to this result, with no visible tears after ten cycles of autoclavation. Despite this we consider the EBUS clip-on device for single use only, at first in the context of research. 3D printing of materials for medical use can reduce cost as the manufacturing is kept in-house. Through experience, improvements can easily be made with easy access to better versions of completed 3D-printed products.

The clip-on device is easy to attach to the bronchoscope and remains firmly attached as has been tested repeatedly during lung phantom and navigation accuracy testing. However, we have experienced that forced pressure applied against the front of the clip-on device can make the device tilt, thus harming the EBUS bronchoscope, especially relevant in experiments with less compliant lung phantom material. More of concern during the development process has been the potential of the protruding part of the clip-on device to hook onto the vocal cords during retraction of the bronchoscope. If the bronchoscope is rotated when retracted this could potentially occur. However, retracted in normal manner the clip is facing the posterior wall of the larynx with a wide space between the vocal cords. If troublesome parts in the design are uncovered this could easily be adjusted by modifications to the model before 3D-printing a new version. Navigation systems for radial probe endobronchial ultrasound often have the EMT sensor inside the working channel of the bronchoscope. In our system for convex probe endobronchial ultrasound for mediastinal and hilar lymph nodes, the working channel is free for necessary operational tasks such as blood/mucus suction and TBNA.

An advantage of the calibration method is that the adapter calibration is fast to perform. There is no need of a predesignated EBUS bronchoscope for EM tracking. Any EBUS bronchoscope of the same type could undergo preprocedural adapter calibration, requiring only seconds to perform.

Both the clip-on device and the calibration adapter are especially designed for the chosen EBUS bronchoscope by Olympus. One concern is that small differences in ultrasound transducers could exist even in EBUS bronchoscopes of the same type and from the same producer. As the ultrasound scan sector can be aligned slightly differently from the original adapter calibration, ideally a new calibration of the calibration adapter would have to take place. From a clinical perspective though, the examined lymph nodes are in the ultrasound near field, and a minimal difference in scan sector angulation would not have clinical relevance. EBUS bronchoscopes from other manufacturers and even endoscopic ultrasound (EUS) for the gastrointestinal tract could be calibrated the same way, provided adjustments of the clip-on device are made as endoscope dimensions vary. The calibration adapter design will have to be adjusted as well. However, such adjustments and customization could easily be done with 3D printing.

The navigation accuracy was 3.4 mm, measured with the calibration adapter attached to the EBUS scope and using the sensor on the adapter for navigation. This is slightly higher than in a previous study by Sorger et al. (2.8 mm) [6], where the sensor was permanently attached to the scope tip, and accuracy measured on an airway phantom. The robotic (one-time) calibration consists of several steps contributing to the navigation accuracy [11]: The accuracy of the positioning system, including measurement the position of the sphere in relation to the EMT sensor on the calibration arm. Moreover, the measurement of the relative position of the sensor on the calibration adapter to the sensor on the calibration arm, and identification of the center of the sphere in the ultrasound image contributes to navigation accuracy. The accuracy of the wire cross in the accuracy water tank phantom in relation to the EMT sensor on the phantom also contributes to the measured accuracy.

The variance of the accuracy measurements was significant, as was clearly exemplified with differences in the adapter calibration acquisitions 1 versus 5 (Figure 6). Small variations in ultrasound probe positions during adapter calibration may have contributed to these differences. This could also explain the low accuracy measurement of the calibration adapter itself. To overcome this problem, the fixation of the ultrasound probe must be improved during calibration, which again requires additional improvements on the adapter design.

From a proof-of-principle trial with an in-house phantom model, a system accuracy estimate of 2.8 mm was found [6]. This resembles the mean error observed in target lesion between ultrasound and CT. Transferring the technology to human testing, the mean accuracy increased to 10.0 mm as CT to patient mismatch, cardiorespiratory movements, tissue movement from the ultrasound probe and disturbance from metal objects in the bronchoscopy suite add to the preclinical estimate of accuracy [10]. Similar findings must be anticipated when introducing the click-on device in patient studies. Still, we believe that EM navigation in EBUS procedures could give useful additional guidance when assessing mediastinal lymph nodes, and that an EMT sensor attachment clip-on device is beneficial for the workflow.

The study of possible vocal cord damage from the clip was limited to one male volunteer, and as dimensions in human anatomy varies, testing on more individuals needs to be performed before we can conclude on the safety of the device. In addition, although the clip-on device stuck firmly to the bronchoscope during our experiments, a mechanical strength test will be needed to measure the clip performance objectively. For early clinical use, we will need a surveillance process for vocal cords and other potential surface damage, clip performance, and a possible increased airway infection rate.

Conclusion

Development, calibration and testing of a novel clip-on EMT sensor attachment device for EBUS bronchoscope was successfully demonstrated, using a calibration/lung phantom and a human pilot study. The device and method could be adapted to fit other types of EBUS bronchoscopes or EUS endoscopes.

Given the acceptable accuracy results the clip-on device is ready to be tested clinically in sampling of lymph nodes. Larger patient studies integrating the device into the navigation system will be the next step in our project.

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Disclosure statement

No potential conflict of interest was reported by the author(s).

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ORCID

Arne Kildahl-Andersen http://orcid.org/0000-0002-3911-5222

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