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Feasibility of a Novel Optoacoustic Device to Precisely Localize Endotracheal Tube Positioning in a Cadaver Model

Napoleon Roux, Chandler Sours, Jeffrey Lodermeier, Jason Pasley, Sarah Wade, Catriona Miller, Samuel Galvagno, Raymond Fang

November 2016

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14. ABSTRACT

Due to the high likelihood of injury caused by improperly placed intubations and the movement of endotracheal tubes (ETTs) during transport, there is a great need for compact, user-friendly devices that are able to non-invasively detect the location of an ETT. Therefore, the objective of this study was to validate a novel optoacoustic device (OAD) as a feasible tool to precisely localize ETT position within the trachea using a cadaver model. Cadavers (n=24) were intubated with ETTs, and the location of the ETT was assessed using the novel OAD, the Prospiria™. A surgical dissection was then performed to ascertain the actual position of the internal optical input within the ETT. Results provide support that the novel OAD is able to accurately detect the location of the internal optical input within 2 cm of its actual location ($p<0.001$). While this OAD is able to detect the location of the ETT, ensuring its location below the vocal cords and above the carina, significant alterations need to be made to the design of the device to make it more compact and user friendly before it can be easily used in the field.

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Endotracheal tube, localization, optoacoustic

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1.0 EXECUTIVE SUMMARY

Incorrect endotracheal tube (ETT) placement results in increased patient morbidity and mortality. Currently used methods for verifying ETT position all have inherent limitations. with the majority of the methods requiring extensive equipment and expertise that are often absent in far-forward locations or during en route care. Due to the high likelihood of injury caused by improperly placed intubations and the migration of ETTs during patient transport, there is a great need for compact, user-friendly devices that are able to non-invasively detect the location of an ETT. Therefore, the primary objective of this study was to validate the novel optoacoustic device (OAD), the Prospiria™, as a feasible tool to precisely localize ETT position within the trachea using a fresh cadaver model.

Fresh cadavers (n=24) were intubated with ETTs and the location of the internal optical input (IOI) was assessed using the novel OAD, the Prospiria. Palpation of the cricothyroid membrane was performed and the OAD was placed at this surface anatomical position. The cricothyroid membrane was chosen as it is the most superficial portion of the airway that is both inferior enough to the vocal cords (to prevent ETT cuff herniation) and superior enough from the carina (to prevent mainstem intubation). The IOI was then passed down the ETT until the highest signal was obtained by the OAD strategically placed at the cricothyroid membrane. A needle was then inserted through the airway at the site of highest detected signal as to represent an external landmark. The IOI cable was also marked at the proximal portion of the ETT to ensure the cable was not moved during airway dissection. Next, a separate physician performed surgical dissection in each cadaver to ascertain the actual position of the IOI within the ETT. Distances between the OAD localization of the IOI and the surgical dissection as well distances to other anatomical landmarks were obtained.

The mean distance between the location of the IOI based on the OAD localization and the location of the ETT based on the surgical dissection for the 24 cadavers was 8.83 mm (± 9.45 standard deviation), which is significantly smaller than 20 mm ($p<0.001$). However, because the study procedures were still being defined during the first lab, and a preliminary analysis suggested that the accuracy of the device improved over the course of the study, a secondary analysis was conducted on the final 20 cadavers with uncompromised data. The mean distance between the location of the IOI based on the OAD detection and the location of the IOI based on the surgical dissection was 6.55 mm (± 8.22 mm standard deviation), which is again significantly smaller than 20 mm ($p<0.001$). Furthermore, there was no significant difference between the IOI to carina distance or the IOI to thyroid cartilage distance between the OAD localization and surgical dissection. The agreement in the distance between the IOI and the carina based on the OAD localization and the surgical dissection can be further visualized in the Bland-Altman plot using the pre-defined clinically acceptable difference of 2 cm.

Our results provide initial evidence that the novel OAD, the Prospiria, is able to detect the ETT location accurately within a fresh cadaver model. By targeting the most superficial portion of the airway, the cricothyroid membrane, we improved the detection of the internal optical input with the OAD. This anatomical landmark also served as a reliable structure for correct placement of the ETT, since placing the proximal portion of the ETT cuff here ensured that the tube was distal to the vocal cords yet the ETT tip was proximal to the carina. While the Prospiria OAD is able to accurately detect the location of an ETT, significant alterations need to occur to the design of the device to make it more compact and user friendly. Additionally, since signal degradation occurs in cold cadaveric models, larger studies in live models with a more

field-ready OAD may show further improvement in the accurate detection of ETT location. This study provides evidence that the utilization of optoacoustic technology is a viable and reliable method of determining ETT location. Furthermore, development of this technology, especially for patient transport or in lieu of traditional methods of determining ETT location, may decrease the likelihood of injury caused by improperly placed or displaced ETTs.

2.0 INTRODUCTION

Approximately 20 million endotracheal intubations are performed annually in the United States [1]. Incorrect endotracheal tube (ETT) placement occurs in an estimated 15.5% of intubations under emergency pre-hospital conditions [2]. These incorrect placements potentially increase patient morbidity and mortality. Improper ETT placements, occult tube migrations, and routine daily radiographs, which are used to verify tube placement in intubated patients, add healthcare costs of $650 million per year to U.S. hospitals [1,2]. Current methods of assessing ETT position include chest radiography, end-tidal carbon dioxide ($EtCO_2$) detection, fiber-optic videoscopic evaluation, and physical examination. Only physical examination and $EtCO_2$ detection are readily available to medical personnel in the pre-hospital setting or during en route care; however, neither method provides information on the actual location of an ETT other than its gross presence in the airway itself. On the other hand, chest radiography and fiber-optic bronchoscopy are better able to localize the ETT, but require specialized equipment and clinical expertise that are rarely present in the pre-hospital or en route care setting. Because of limitations inherent to all current ETT localization methods, a simple, rapidly accessible method of localizing ETT placement precisely within the trachea would result in a significant patient safety advancement [3-6]. Recently, investigators demonstrated in animal models that a novel optoacoustic device (OAD) was able to detected ETT location with sub-millimeter resolution [7]. In addition to being easy to operate, this device is lightweight and compact. Therefore, this device may have the potential to be manufactured into a compact and field-ready instrument that would be functional in a wide variety of austere, far-forward, and pre-hospital settings.

The primary objective of this human cadaveric study was to validate the novel OAD, Prospiria™, as a feasible tool to precisely localize ETT position within the trachea. A secondary objective was to identify how human neck surface anatomy landmarks such as the thyroid cartilage, carina, and cricothyroid membrane relate to proper underlying ETT placement. ***We hypothesized that the novel OAD would be able to precisely localize the ETT position within the trachea as confirmed by surgical dissection in a human cadaver.*** This hypothesis was tested through the following specific aims:

Specific Aim 1: Assess the accuracy of a novel OAD to precisely localize the ETT position by comparing the OAD localization to the visualized ETT position confirmed by surgical dissection

Specific Aim 2: Identify how human neck surface anatomy landmarks such as the thyroid cartilage, carina, and cricothyroid membrane relate to proper underlying ETT placement

3.0 BACKGROUND

ETT insertion is the “gold standard” definitive method of airway management in trauma patients. The 2015 American Heart Association advanced cardiovascular life support guidelines and the 2012 Joint Theater Trauma System clinical practice guideline for trauma airway management both recommend confirmation of tracheal intubation after tube insertion to exclude esophageal or endobronchial intubation [8,9]. When unaddressed, esophageal intubation results in hypoxemia, regurgitation, aspiration, cardiac dysrhythmia, anoxic brain injury, and ultimately death [1-6]. In addition to improper placement, accidental ETT dislodgement or migration can also commonly occur as a result of inadequate ETT fixation, patient movements, secretions, or procedures. Inadvertent extubations are especially disastrous during casualty transport when clinical expertise and resources are limited. In the intensive care unit, at least 20% of all critical events are airway related [10]. Furthermore, studies evaluating intubations performed by paramedics report ETT misplacement may be as high as 15.5% [2].

Current methods verifying ETT position—chest radiography, $EtCO_2$ detection, fiber-optic videoscopic evaluation, and physical examination—all have inherent limitations. Chest radiography and fiber-optic evaluation require equipment and expertise generally unavailable in austere environments such as the far-forward battlefield, aeromedical environment, or other pre-hospital settings. Chest radiography is not immediate even in the hospital setting and requires radiation exposure. Additionally, two-dimensional chest radiography cannot definitely exclude an esophageal intubation. For example, one study found that chest radiography was able to detect only 14% of patients needing tube repositioning [11]. An additional method, fiber-optic bronchoscopy, requires clinical expertise and specialized equipment and may be limited by massive secretions, blood, or gastric contents. Furthermore, this procedure may not be well tolerated by patients with high airway pressure requirements and is also associated with the risk of inadvertent tube dislodgement. Physical examination has relatively low sensitivity for determining ETT position (primarily trachea vs. esophagus only) and is limited in noisy environments such as experienced during aeromedical evacuation. On the other hand, $EtCO_2$ confirms tube placement within the airway, but provides no information regarding the tube’s precise location within the trachea. $EtCO_2$ detection may also prove ineffective in determining ETT position in certain clinical circumstances, such as non-perfusing cardiac function, mainstem intubation, or regurgitation of carbonated fluids [3-6]. For example, during cardiac arrest and other states of severe malperfusion and shock, carbon dioxide may not be detected due to varying perfusion to the lungs, and ETT placement cannot be confirmed by this method.

The novel OAD used in this study was the Prospiria, which uses lasers to generate sound waves to determine the position of “labeled” ETTs within millimeters of accuracy. Laser optoacoustic imaging combines the merits of optical tomography (high optical contrast) and ultrasound imaging (minimal scattering of acoustic waves) to yield high contrast, sensitivity, and resolution. Laser optoacoustics has developed as a technique for tissue characterization and for diagnostic imaging [12-15]. Optoacoustic techniques utilize sensitive detection of laser-induced ultrasonic waves, which travel without scattering through tissue in a straight line from the source to the transducer. Transmission of ultrasound signals without scattering differentiates optoacoustic measurements from pure optical measurements, in which both incident and returning optical signals are scattered. The depth of the optoacoustic target vessel can be precisely calculated from the time required for the signal to return and the speed of sound through tissue. Time-resolved detection of the pressure profiles by ultrasound transducers and analysis of the pressure signals facilitate high-resolution reconstruction of axial optoacoustic images [12-19] at depths as great as 8 cm with spatial resolution ≤ 0.5 mm [18-20] and can reconstruct optoacoustic images.

The method currently in development using optoacoustics involves placing the optical input in a fiber-optic cable within the ETT at a specified depth. This internal optical input (IOI) is located at the tip of the fiber-optic cable. Tracheal tissue absorbs light and emits sound. Those sound waves travel without scattering. Sensors found in the optoacoustic device detect those sound waves, and the software determines the position of the ETT [7].

The objective of this study was to determine the success rate of an OAD to verify the position of the IOI within an ETT using a prototype OAD, the Prospiria. The cricothyroid membrane was chosen as the targeted superficial anatomical position because it is well below the vocal cords (to prevent ETT cuff herniation and subsequent extubation) and well above the carina (to prevent mainstem intubation).The OAD was placed at the cricothyroid membrane while the IOI was passed down the ETT until the highest signal was captured. Success rate will be determined by comparing the actual location of the IOI assessed by the Prospiria with that visually confirmed by surgical dissection. The desired location for the ETT is 2 cm below the vocal cords, where the top of the ETT cuff is at the level of the cricothyroid membrane while the tip of the ETT is 2.5-4 cm above the carina. Future modifications of this technology would therefore have the IOI incorporated just proximal to ETT cuffs. Those verifying proper ETT placement would then be able to adjust the ETT until the highest signal was detected at the cricothyroid membrane.

4.0 METHODS

4.1 Cadaver Model

ETTs were placed in fresh cadavers by an anesthesiologist or respiratory therapist. Mallinckrodt ETTs (6.0 mm and 7.0 mm) were used for all intubations. All cadavers were removed from the freezer prior to the experimental procedures to allow for the trachea to warm to a more physiologically relevant temperature. Only cadavers with normal airway anatomy were included in this study. Cadavers less than 18 years of age or with evidence of a surgical airway (i.e., tracheostomy or cricothyroidotomy), trauma involving the face, jaw, or neck, or obvious congenital craniofacial abnormalities were excluded.

4.2 Study Procedures

Based on a previous randomized trial that established ideal ETT depth in 160 patients, all male cadavers had the ETT secured at 22 cm at the incisors and all female cadavers had the ETT secured at 20 cm at the incisors [21,22]. ETT position was confirmed by direct visualization with video-assisted laryngoscopy. After intubation, the ETT was secured with sutures to prevent movement during airway manipulation. The desired location of an ETT cuff is 2 cm below the vocal cords, with the top of the ETT cuff at the level of the cricothyroid membrane. Alternatively, the desired distance from the ETT tip to the carina is approximately 2.5-4 cm. This depth ensures that the ETT tip does not engage a mainstem bronchus and that the ETT cuff lies below the level of the vocal cords. The ETT position was determined sequentially using the internal laser source OAD.

First, the cricothyroid membrane was palpated. The sensor of the OAD was placed at the cricothyroid membrane. The IOI cable was then passed down the ETT until the highest signal was captured by the sensor at the cricothyroid membrane. The cable was marked at the proximal portion of the ETT. Additionally, a needle was placed at the cricothyroid membrane. The needle served as the surface position representative of the highest captured signal and to further stabilize the ETT during surgical dissection (Figure 1A). Next, a separate physician performed surgical dissection in each cadaver to ascertain the actual position of the IOI within the ETT (Figure 1B). Following dissection, the following measurements were recorded: (1) needle (representing maximum detected OAD signal location from the surface) to cricothyroid membrane, (2) IOI of the OAD cable tip (representing true OAD signal location) to cricothyroid membrane, (3) cricothyroid membrane to superior portion of the thyroid cartilage (representing distance to vocal cords), (4) IOI of the OAD cable tip to superior portion of the thyroid cartilage, (5) cricothyroid membrane to carina, and (6) length of OAD cable tip. In addition, the following distances were calculated from the recorded data: (1) distance between the cable tip and the needle, (2) distance from the cable tip to the carina (representing the true OAD signal location), (3) distance from the needle (representing the maximum detected OAD signal location) to the carina, and (4) distance from the needle (representing the maximum detected OAD signal) to the thyroid cartilage.

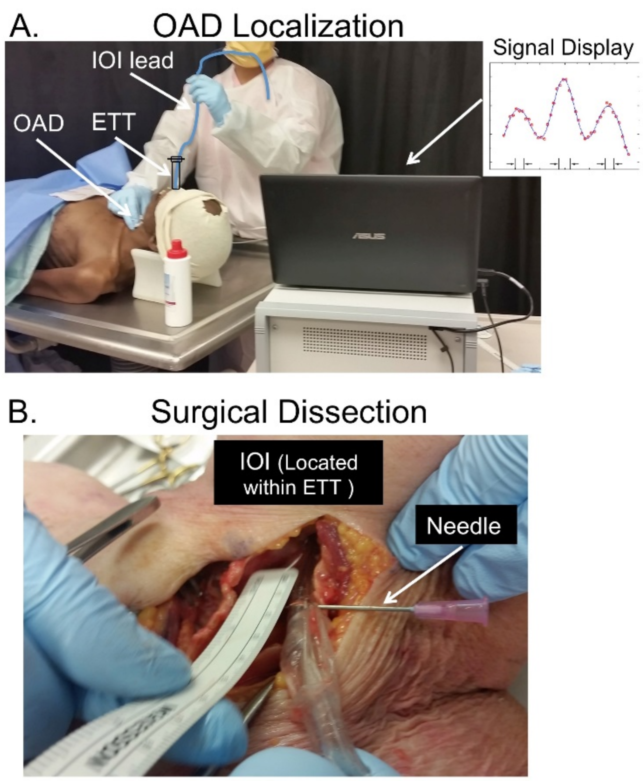

Figure 1. Study procedures.

4.3 Data Analysis

The accuracy of the device was assessed by determining the distance between the location of the IOI (cable tip) based on the OAD detection (represented by the needle) and the location of the IOI based on the surgical dissection. Based upon the clinical expertise of the principal investigators, a distance of less than 2 cm (or 20 mm) was determined to be clinically acceptable error in the device. A one-sample t-test was used to determine if the mean distance between the OAD localization and the surgical dissection was in fact less than 20 mm. The agreement between OAD localization and surgical dissection was visualized using the Bland-Altman plot. In addition, the distance from the carina and the thyroid cartilage to the needle (based on OAD localization) and to the IOI (surgical dissection) was determined. Paired t-tests were be used to compare means; a value of $p<0.05$ was considered statistically significant.

5.0 RESULTS

5.1 Initial Results

As noted in the previously submitted quarterly reports, the first 12 cadavers dissected as part of this protocol were unable to be used because of missing information due to an oversight in the data collection sheet. These 12 cadavers are not included in this report. Upon revision of the data collection sheet for this study, 24 additional cadavers were dissected and included in this report.

This analysis was initially conducted on all measurements completed upon the correction of the initial data collection form (n=24 cadavers). The 24 cadavers consisted of 12 male cadavers and 12 female cadavers. The mean distance between the location of the IOI based on the OAD localization (represented by the needle) and the location of the ETT based on the surgical dissection was 8.83 mm (± 9.45 standard deviation [SD]), which is significantly smaller than 20 mm ($p<0.001$) (Figure 2).

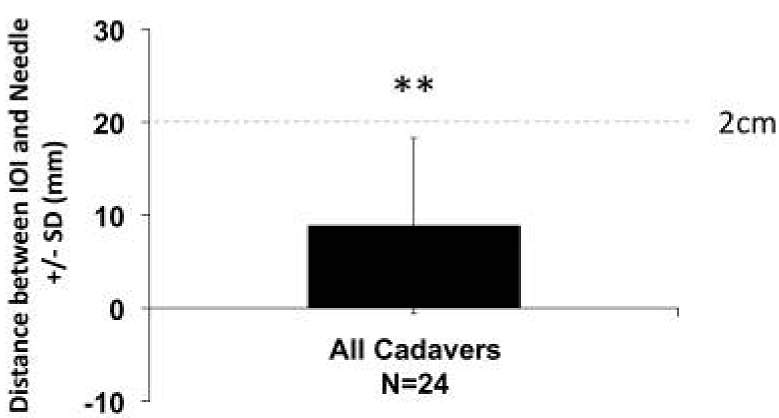

Figure 2. Mean distance between OAD localization and surgical dissection for all cadavers (n=24).

During the first few labs, however, the study investigators noted that procedures still required some correction and that the device was not as easy to use as initially anticipated. These issues were especially prevalent during the first lab conducted with the updated procedures. The signal took less time to capture and less manipulation of the IOI cable was required when the sensor was placed at the cricothyroid membrane. For this reason, we were interested in investigating if the accuracy of the device improved over the course of the study as the investigators became more familiar with the device and the procedures. Data from the 24 cadavers were collected over nine labs conducted at the University of Maryland, Baltimore between April 2015 and September 2015. First, we divided the nine labs chronologically into three groups, with Group 1 consisting of results from labs 1-3 (n=7), Group 2 consisting of results from labs 4-6 (n=8), and Group 3 consisting of results from labs 7-9 (n=7). A repeated measures analysis of variance was used to determine if the accuracy of the device was different between these three groups (Figure 3). The results of this analysis of variance demonstrate that there is a significant difference ($F=5.36$; $p=0.013$) between the accuracy of the device over the course of these three groups of lab. Tukey's honest significant difference post hoc tests show that Group 1 (the first three labs completed) had a significantly lower accuracy ($p<0.05$) compared to Group 3 (the final three labs completed), suggesting that over time the investigators' ability to use the device to collect accurate measurements improved. Furthermore, it was noted that the variability of the accuracy of the measurements reduced over the course of the study as shown by a reduction in the standard deviation of the measurements over the three groups (Figure 4).

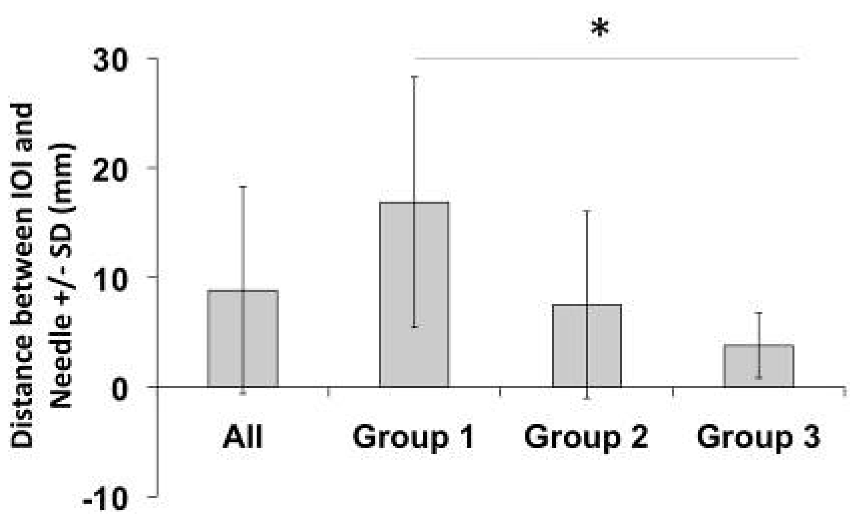

Figure 3. Mean distance between OAD localization and surgical dissections for each chronological group.

Based on these preliminary findings, we plotted the individual data points to further visualize the improvements over the course of the study (Figure 5). Based on the inspection of this information, it was concluded that since the study procedures were still being finalized during the first lab, the data were not necessarily reliable. In addition, part of the data from Group 1 includes data from three cadavers used during the first lab. It was noted that the IOI was not correctly placed within the ETT during dissection of one of the cadavers from the first lab. Therefore, we opted to repeat the initial analysis after removing these questionable data points. The following secondary analysis represents the results of the analysis completed on data collected from the remaining 20 cadavers.

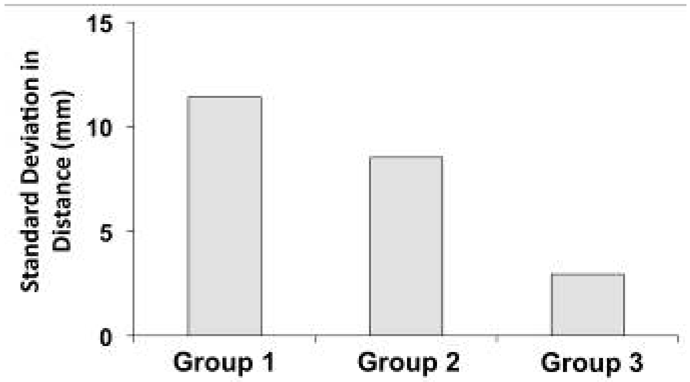

Figure 4. Standard deviation in accuracy over time.

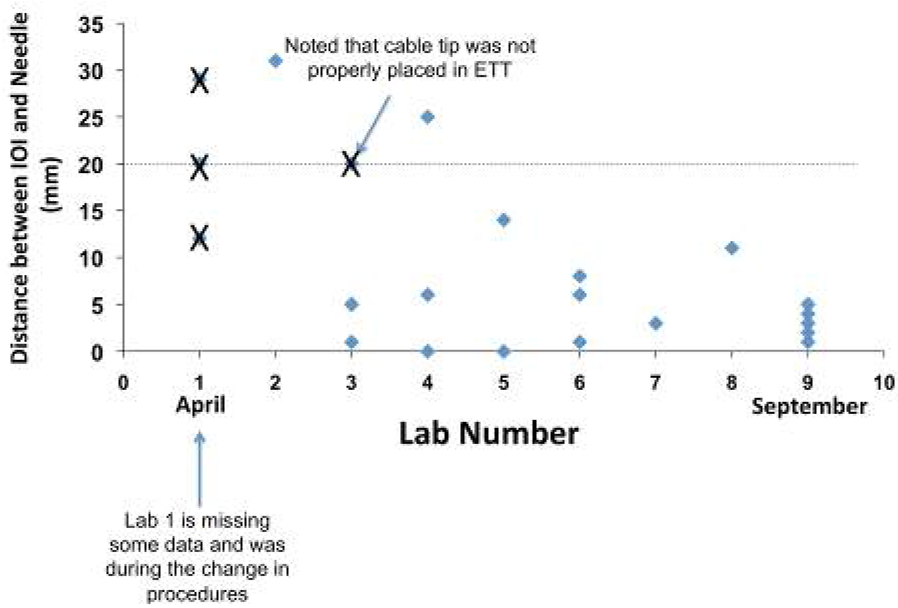

Figure 5. Scatter plot of individual data points across the 9 cadaver labs.

5.2 Secondary Analysis

This analysis was conducted on the data collected on the remaining cadavers (n=20). The 20 cadavers consisted of 11 male cadavers and 9 female cadavers. The mean distance between the location of the ETT based on the OAD and the location of the ETT based on the surgical dissection was 6.55 mm (± 8.22 mm SD), which is significantly smaller than 20 mm ($p<0.001$) (Figure 6).

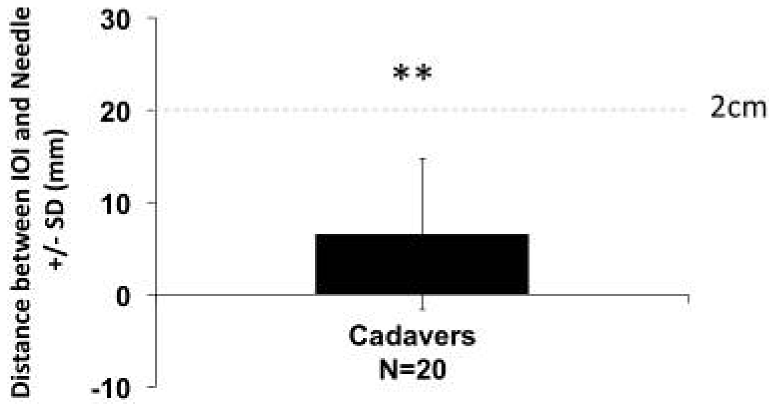

Figure 6. Mean distance between OAD localization and surgical dissection after correction to procedures (n=20).

The average distance between the ETT and carina based upon the OAD localization was 126.6 mm (± 22.3 mm SD). The average distance between the ETT and the carina based upon the surgical dissection was 124.0 mm (± 17.2 mm SD). There was no significant difference between the ETT to carina distance between the two methods (p=0.28) (Figure 7A). The average distance between the ETT and thyroid cartilage based upon the OAD localization was 21.25 mm (± 4.22 mm SD). The average distance between the ETT and the thyroid cartilage based upon the surgical dissection was 23.80 mm (± 8.69 mm SD). There was no significant difference between the ETT to thyroid cartilage distance between the two methods (p=0.28) (Figure 7B).

The agreement in the distance between the ETT and the carina based on the OAD localization and the surgical dissection can be further visualized in the Bland-Altman plot using the pre-defined clinically acceptable difference of 2 cm (Figure 8). Table 1 shows descriptive statistics of the measured and inferred distances.

6.0 DISCUSSION

Healthcare providers are taught that one of the most important factors of patient care is the evaluation and treatment of airways. ETT insertion is the definitive method of airway protection and control in cardiopulmonary arrest or trauma patients. Both the American Heart Association advanced cardiovascular life support guidelines and the Joint Theater Trauma System clinical practice guideline for trauma airway management recommend confirmation of the tracheal intubation after ETT insertion to exclude esophageal or endobronchial intubation [8,9]. When unaddressed, esophageal intubation can result in hypoxemia, regurgitation, aspiration, cardiac dysrhythmia, and finally death [1-6]. Accidental extubation or dislodgement is another common complication, especially as a result of inadequate ETT fixation or patient movements or secretions or during procedures or transports. These issues become even more problematic during trauma casualty transports out of the combat zone to forward echelons of patient care.

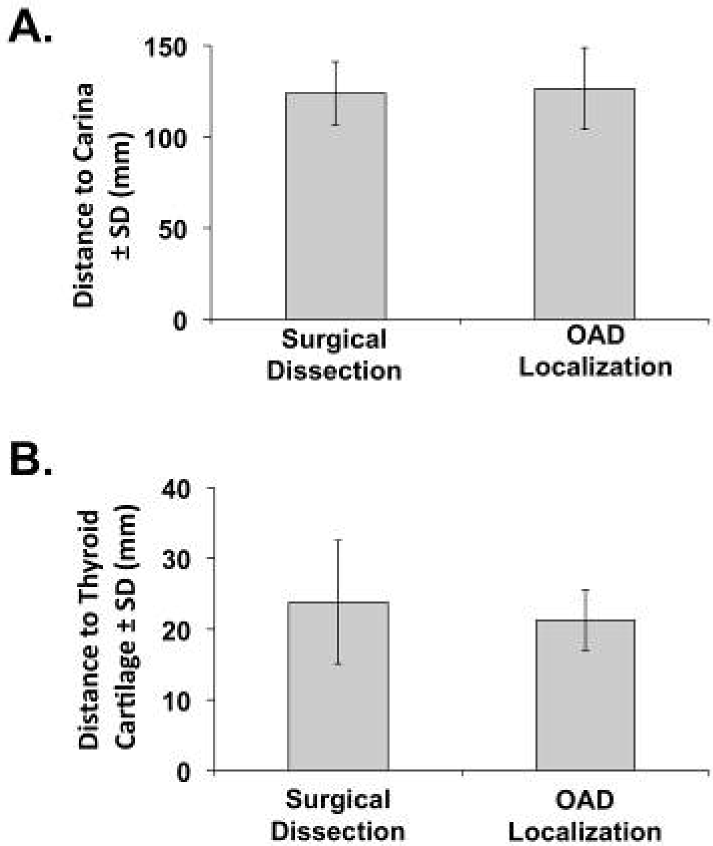

Figure 7. Mean distance from ETT to carina and thyroid cartilage.

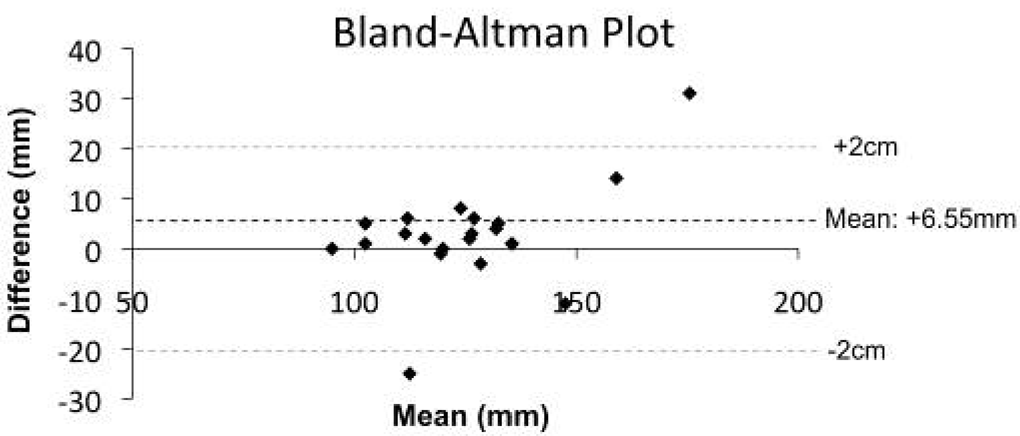

Figure 8. Bland-Altman plot showing distance from ETT to carina.

Table 1. Mean Distance (n=20)

Measurement	Distance (mm) (mean ± SD)	Range (mm)
Cable length	257.80±20.1	202-275
IOI to carina (surgical dissection)	126.60±22.3	95-191
Needle to carina (OAD localization)	124.00±17.2	95-160
Needle to cable tip	6.55±8.22	0-31
Cable tip to cricothyroid membrane	6.75±8.16	0-31
Cricothyroid membrane to thyroid cartilage	21.05±4.22	12-27
IOI to thyroid cartilage (surgical dissection)	23.80±8.69	14-45
Needle to thyroid cartilage (OAD localization)	21.25±4.22	14-27

Correctly determining the location of an ETT in an intubated patient is a constant concern for medical personnel. Whether working as Special Forces medics in austere, far-forward environments or as intensive care unit physicians in robust medical centers, accurate ETT location may prevent disastrous patient outcomes. Approximately 20 million endotracheal intubations are performed each year in the United States [1]. In work evaluating intubations performed by paramedics, there is evidence that ETT misplacement may occur in approximately 15% of cases [2]. Additionally, in the intensive care unit, at least 20% of all critical events are airway related in etiology [10]. The financial burden of improper placement, unintended migration, and current methods of daily placement verification results in additional healthcare costs of $650 million per year to U.S. hospitals [1,2].

Currently used methods for verifying ETT position all have inherent limitations, with the majority of the methods requiring extensive equipment and expertise, which are often absent in far-forward locations or during en route patient transport. The current methods include chest radiography, carbon dioxide detection, fiber-optic evaluation, and physical examination. Chest radiography and fiber-optic evaluation require time, large, expensive equipment, and experienced personnel not always available in the battlefield, during patient transport, or in pre-hospital settings. Chest radiography takes time and increases radiation exposure, and one study was found to detect only 14% of patients needing tube repositioning [11]. Fiber-optic bronchoscopy may prove difficult, with massive secretions, blood, or gastric contents inhibiting the view. Physical examination has proven to have low sensitivity for correctly determining ETT position, especially in noisy environments. It has been reported that 60% of patients with mainstem intubations had bilateral breath sounds [11]. Lastly, carbon dioxide detection may prove ineffective in determining ETT position during situations such as non-perfusing cardiac function, mainstem intubation, or regurgitation of carbonated fluids [3-6].

Due to the large likelihood of damage caused by improperly placed intubations and the movement of ETTs during transport, there is a great need for compact, user-friendly devices that are able to non-invasively detect the location of an ETT. One potential device investigated in this study was the Prospiria, which uses the localization of an optoacoustic signal to determine the location of the ETT within the trachea. The device uses lasers to generate sound waves to determine the position of the ETT within millimeters of accuracy. Laser optoacoustic imaging combines the merits of optical tomography (high optical contrast) and ultrasound imaging (minimal scattering of acoustic waves) to yield high contrast, sensitivity, and resolution. Laser optoacoustics has recently developed as a technique for tissue characterization and diagnostic imaging [12-15]. This technique utilizes sensitive detection of laser-induced ultrasonic waves, which propagate through tissue without scattering. The straight-line wave travels through tissue from input/source to the transducer. Software then determines the position of the input and thus the position of the ETT.

The results of this project provide evidence that the novel OAD, the Prospiria, was able to accurately detect the location of the IOI within 2 cm of the true location within the ETT as determined by surgical dissection. While our investigators faced some challenges defining specific study procedures as well as mastering the use of the device, the data collected on all cadavers (n=24) suggest that the OAD was able to detect the true location of the IOI within an average of 8.83 mm. This accuracy improved when only the data collected following the finalization of study procedures (n=20) were considered, demonstrating that the OAD was able to detect the true location of the ETT within 6.55 mm. Furthermore, no differences were noted in the distance between the true location of the device or the detected location of the device and anatomical landmarks such as the carina or superior portion of the thyroid cartilage. Future modifications of this device would be to incorporate the IOI within the ETT just proximal to the cuff. By using the cricothyroid membrane as the target surface anatomical position, obtaining maximal signal at this location would ensure proper placement of the ETT. The ETT would be far enough from the carina to prevent mainstem intubation while distal enough to prevent ETT cuff herniation and subsequent extubation [23]. Therefore, the results represented in this report provide evidence that the Prospiria OAD has the potential to be used by military personnel to accurately detect the location of the ETT. However, these results must be taken within the context of the limitations of this study.

One of the limitations of the Prospiria is that it is not intuitive to use. Although our investigators received extensive training on the use of the device by the manufacturers, there remained a learning curve in the actual use of the device by our investigators. This can be clearly seen in the fact that the accuracy of the device was significantly improved from the first three cadaver labs to the final three cadaver labs.

In addition, while we are aware that the instrument used in this study was a prototype of the product, the usability of the device would be greatly improved by altering the design of the device. While the optoacoustic device and sensor are relatively compact and lightweight, the remainder of the device used for the localization of the sensor is large and cumbersome, making its use in an austere setting not feasible. Therefore, it is suggested that extensive alterations be made to the design of the instrument before it can be used in far-forward environments. In addition to reducing the size of the device, it is suggested that the software interface be altered to make it more intuitive and user friendly. Additional modifications would be to include the IOI embedded into the ETT just proximal to the cuff. Since signal of the IOI is narrow, the cable required significant manipulation to ensure the signal was directed anteriorly to the sensor. Incorporating the IOI to emit a signal circumferentially around the ETT would allow the user to capture that signal despite what portion of the ETT was directed anteriorly.

Furthermore, it is well accepted that the optoacoustic signal is affected by the temperature of the surrounding tissue. Therefore, one of the limitations of this current study is that the cadaver tissue within the trachea was often much cooler than the temperature of the trachea in a living person. Since the cadavers are stored in a freezer, they were removed from storage and placed in room temperature conditions prior to intubation and measurements with the OAD in an attempt to allow the cadavers to reach more physiologically relevant temperatures. But, it is unlikely that the cadaver tissue reached physiologically accurate temperatures, and we were unable to obtain accurate measurements of the true temperature of the surrounding tissues within these cadavers. However, in spite of cooler temperatures in the cadavers, after modifications to our procedure, we were able to obtain adequate signals from the IOI to the sensor.

7.0 CONCLUSIONS

Our results provide initial evidence that the novel OAD, the Prospiria, is able to detect ETT location accurately within a fresh cadaver model. By targeting the most superficial portion of the airway, the cricothyroid membrane, we improved the detection of the IOI with the OAD. This anatomical landmark also served as a reliable structure for correct placement of the ETT, since placing the proximal portion of the ETT cuff here ensured that the tube was distal to the vocal cords yet the ETT tip was proximal to the carina. While the Prospiria OAD is able to accurately detect the location of an ETT, significant alterations need to occur to the design of the device to make it more compact and user friendly. Additionally, since signal degradation occurs in cold cadaveric models, larger studies in live models with a more field-ready OAD may show further improvement in the accurate detection of ETT location. This study provides evidence that the utilization of optoacoustic technology is a viable and reliable method of determining ETT location. Furthermore, development of this technology, especially for patient transport or in lieu of traditional methods of determining ETT location, may decrease the likelihood of injury caused by improperly placed or displaced ETTs.

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LIST OF ABBREVIATIONS AND ACRONYMS

$EtCO_2$	end-tidal carbon dioxide
ETT	endotracheal tube
IOI	internal optical input
OAD	optoacoustic device
SD	standard deviation