PHILIPPINE JOURNAL OF OTOLARYNGOLOGY-HEAD AND NECK SURGERY VOL. 41 NO. 1 JANUARY – JUNE 2026

TracheoSense: Innovation in Endotracheal Tube Cuff Pressure Monitoring with a Three-Dimensional Printed Electronic Manometer-Syringe Device

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ABSTRACT

Objective: To design and validate *TracheoSense*, a 3D-printed manometer-syringe device for measuring endotracheal tube (ETT) cuff pressure, by assessing its accuracy and precision compared with a commercially available standard manometer.

Methods:

Design: Instrument Innovation
Setting: Tertiary Private Training Hospital
Participants: None

Results: The study compared the *TracheoSense* device with the VBM Analog Manometer, the reference standard, for measuring cuff air volume at target pressures of 20 and 30 cmH2O across tracheal model diameters of 19 mm, 21 mm, and 23 mm. At 20 cmH_2O, mean cuff volumes measured by *TracheoSense* ranged from 4.04 ± 0.09 mL to 5.82 ± 0.07 mL, with coefficients of variation (CV) between 1.15% and 2.18%, and minimal bias compared to the reference device (–0.02 to 0.09 mL). At 30 cmH_2O, mean volumes ranged from 4.51 ± 0.11 mL to 6.31 ± 0.23 mL, with CVs of 1.62% to 3.58% and biases between –0.07 and 0.02 mL.

Conclusion: The *TracheoSense* 3D-printed manometer-syringe device demonstrated comparable accuracy and precision in measuring ETT cuff pressures when compared with a commercially available analog manometer. These results support this device as a reliable and practical tool for cuff pressure monitoring.

Keywords: *airway management; intubation; printing, three-dimensional; manometry; syringes*

Airway management is a critical component of otorhinolaryngology practice, and an integral part of this is the accurate measurement of endotracheal tube (ETT) cuff pressure. Maintaining cuff pressure within the recommended range of 20 to 30 cmH2O is essential to ensure effective airway sealing without compromising airway protection.[1] Pressures above this threshold may impair tracheal perfusion, leading to increased risk of tracheal stenosis,[2,3] whereas pressures below this range can increase the risk of aspiration and ventilator-associated pneumonia.[4] However, in reality, achieving optimal cuff pressure in clinical practice can be challenging, with one study reporting that only 27% of measured pressures fell within the recommended range.[5]

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Disclosures: The authors signed disclosures that there are no financial or other (including personal) relationships, intellectual passion, political or religious beliefs, and institutional affiliations that might lead to a conflict of interest

Presented at the 4th Asia Pacific Laryngology Association (APLA) Congress and 3rd International Pediatric Airway Surgery Symposium, Tolip El Nargess Hotel, Cairo, Egypt, November 14-16, 2024; and the 68th Philippine Society of Otolaryngology-Head and Neck Surgery Annual Convention, EDSA Shangri-La Hotel, Mandaluyong, Philippines, December 6-8, 2024.

Data Availability and Sharing Statement: Datasets generated and analyzed are included in the published article.

Traditionally, ETT cuff pressure is monitored using both subjective (manual) and objective (commercial or handmade manometer) methods, each with varying levels of accuracy. Among manual techniques, the loss-of-resistance syringe has been shown to be more accurate than pilot balloon palpation.[6] However, these manual techniques remain less accurate than objective means.[7] Objective methods, including disposable or repurposed manometers adapted from aneroid sphygmomanometers, old ventilator manometers, and even home-brewed cuff inflators, have demonstrated innovative and low-cost alternatives.[8-13] However, some of these approaches often lack rigorous validation, and their accuracy and reliability remain inferior to commercially available devices. In the Philippines, subjective techniques remain the most used in practice due to limited availability and relatively high cost of commercial manometers. Therefore, developing a 3D-printed manometer could provide a practical and accessible way of objectively assessing cuff pressure.

In this study, we aimed to design a 3D-printed manometer-syringe device, *TracheoSense*, and evaluate its performance against a commercially available standard by assessing the accuracy, precision, and reproducibility of endotracheal tube cuff pressure measurements in different 3D-printed tracheal models.

METHODS

This experimental study was conducted at a tertiary private hospital to develop a 3D-printed manometer-syringe device and validate its performance versus a commercially available cuff manometer using 3D-printed trachea models. As the study utilized models rather than patients, no human participants were involved.

Fabrication of the *TracheoSense* device

A. Materials

The materials for constructing the *TracheoSense* device included a 3D printer (Bambu Lab P1P, Bambu Lab, Kowloon Bay, Hong Kong, China), which utilized ESUN PLA+ black filament 1.75mm diameter (eSUN®, Shenzhen Esun Industrial Co., Ltd, Shenzhen, China). The 3D printing process was managed using Bambu Studio version 1.8.4 (Bambu Lab, Kowloon Bay, Hong Kong, China) as the slicer software (converts the 3D models into printable instructions for the printer). For the creation and refinement of the 3D model, Autodesk Fusion 360 (Autodesk, San Francisco, California, USA) was employed. This Computer-Aided Design (CAD) software allowed for the precise development of the model based on the exact measurements and dimensions of the electronic components that would be integrated into the device. Refining the 3D model was done by iterating through several design modifications to address common issues such as post-print shrinkage and alignment mismatches. Adjustments in tolerances and wall thickness were necessary to achieve an optimal balance between stability and ease of assembly. The finalized models were exported as Standard Triangle Language (STL) files, widely accepted for 3D printing, ensuring compatibility with various 3D printers and that they would be accurate and reliable for anyone attempting to reproduce the device. There were five 3D printed parts: main-shell, backplate, syringe-clamp, sensor-mount, and Luer lock adapter. Another part made of eSUN Green thermoplastic polyurethane (TPU), 1.75mm (ESUN, Shenzhen Esun Industrial Co., Ltd, Shenzhen, China), a semi-flexible material similar to most smartphone cases, was the sensor seal which would act to prevent any air leaks from the modified infusion set tube to couple with the sensor. The battery was a compact 600 mAh lithium-ion battery (DEAH, AliExpress, Shenzhen, China) with a connector compatible with the TTGO T-Display ESP32 development board (LILYGO, Shenzhen, Guangdong, China). *Figure 1* shows the overall components used to assemble the main body of the device, including the syringe holder, backplate, main-shell, battery, TTGO T-Display ESP32, micro vibration motor, digital barometric pressure sensor module, sensor mount, sensor seal, infusion tube, and screws.

Materials and components necessary for the assembly, along with their respective cost estimates are detailed in *Table 1*.

B. Procedure

Assembly of the *TracheoSense* device began with preparation of the 3D-printed components.

1. Preparation of 3D-printed components: Once the STL files were processed through the slicer software, the parts were printed using the specified PLA+ filament at Bambu Lab stock profiles at 0.12mm profiles for eSUN PLA+. The PLA+ filament was chosen over other options such as standard PLA, ABS, or PETG due to its balance of durability, reduced brittleness, and ease of handling in a typical clinical 3D printing setup, and PLA+ is generally more robust than standard PLA, which may not withstand regular handling as well.[14]
2. Integration of electronic parts: The electronic components, including sensors, wiring, and an ESP32 microcontroller, were carefully soldered. This involved aligning the parts on a soldering board (where electronic components are soldered to create electrical circuits), making precise connections, and verifying the integrity of each solder joint. The connections from the battery to the sensor as well as the vibration motor (Generic, 6.5x20mm Micro Built-in Vibration Motor, Shopee, Shenzhen, China) were established. The inclusion of a microcontroller (ESP32) in the *TracheoSense* device enabled the integration of advanced functionalities that analog devices lack. The microcontroller helped capture real-time pressure data, displaying it on a digital interface, and enhancing the accuracy and reliability of measurements through software-based calibration. The *TracheoSense* device also used a pressure sensor to measure the cuff pressure accurately. The sensor provided continuous

pressure readings which were processed by the microcontroller and displayed on an LCD. This setup enabled the device to offer digital precision in pressure measurement, which analog devices cannot provide. The sensor integration also supported the development of an affordable yet accurate monitoring tool.

3. Mounting components: *(Figure 2)* Once the electronic components were assembled and tested, the final construction involved mounting these components into the 3D-printed housing. The parts were securely fastened using screws or adhesives as appropriate, ensuring that all connections were stable and that the internal components were well-protected within the device's enclosure. Once the main ESP32 display was positioned in the main-shell, the rest of the components could follow by first sliding the sensor assembly into the notches on the main-shell, followed by placing the body and vibration motor on top. The backplate assembly was completed by screwing in the syringe-clamp and the backplate. The rest were screwed into the remaining holes to couple with the main-shell assembly that was previously made.
4. Installation of infusion tubes: The infusion tubes were cut to any desired length as long as the male end of the Luer lock was exposed where the Luer lock adapter was then installed and the green TPU sensor seal was pre-attached. *Figure 3* also shows the actual device and exposes the buttons and screen user interface (UI). The procedure is summarized in a flowchart shown in *Figure 4*.
5. Programming the microcontroller: The research team programmed the microcontroller to handle specific tasks, such as reading pressure from the sensor, calibrating the output, and displaying the pressure data on an LCD screen. This programming ensured that the device provided real-time pressure readings and maintained accuracy, comparable to the traditional analog manometer. The coding also included calibration processes to keep the readings precise and consistent over time.

Table 1. Materials and estimated costs for device assembly (PhP)

Material	Cost-estimate (PhP)
Polymer: Polylactic Acid (ESUN PLA+) Black 1.75mm (ESUN, Shenzhen Esun Industrial Co., Ltd, Shenzhen, China)	700.00
Polymer: Thermoplastic polyurethane (ESUN TPU) White 1.75mm (ESUN, Shenzhen Esun Industrial Co., Ltd, Shenzhen, China)	1300.00
3D Printer: Bambulab P1P (Kowloon Bay, Hong Kong)	38,995.00
Battery: Lithium Polymer - 3.7V 600mAh Rechargeable Battery Cell (DEAH, AliExpress, Shenzhen, China)	265.00
10mL Syringe (Terumo) (Terumo Philippines Corporation, Biñan Laguna, Philippines)	15.00
3-way Stopcock (UNIMEX)(Unimex, Inc., Philippines)	71.00
Pressure Sensor: 3.3-5V 0-40KPa Digital Barometric Pressure Sensor Module Liquid Water Level Controller Board (Makerlabs, Manila, Philippines)	62.00
Microcontroller assembly with Thin Film Transistor (TFT) Display: ESP32 Lilygo (Shenzhen, China) (LILYGO, Shenzhen, Guangdong, China)	409.11
Tubes: Infusion set - Microset (Prime, Shopee, Philippine Medical Supplies, Philippines)	29.00
10pcs M2 x 8mm screws (To Suy Bolts Center, Manila, Philippines)	20.00

Table 2. Air volume measurements by TracheoSense and reference device at varying target pressures and tracheal diameters, including mean (mL), standard deviation, coefficient of variation, and bias (mL).

Target pressure (cmH2O)	Tracheal diameter (mm)	Mean (mL) Tracheo Sense	Mean (mL) Reference device	SD Tracheo Sense	SD Reference Device	CV (%) Tracheo Sense	CV (%) Reference device	Bias (mL)
20	19	4.04	4.13	0.09	0.17	2.18	4.19	0.09
20	21	5.07	5.04	0.10	0.09	1.97	1.75	-0.02
20	23	5.82	5.89	0.07	0.11	1.15	1.79	0.07
30	19	4.51	4.44	0.11	0.09	2.34	1.98	-0.07
30	21	5.44	5.47	0.09	0.10	1.62	1.83	0.02
30	23	6.31	6.24	0.23	0.22	3.58	3.50	-0.07

Fabrication of the Three-dimensional Tracheal Models

A. Materials

The three-dimensional tracheal models were fabricated using a Bambu Lab P1P 3D printer (Bambu Lab, Kowloon Bay, Hong Kong, China) with eSUN white TPU filament, 1.75 mm in diameter (eSUN®, Shenzhen Esun Industrial Co., Ltd, Shenzhen, China). Model design, scaling, and refinement were carried out using Autodesk Fusion 360 (Autodesk, San Francisco, CA, USA), while slicing and print preparation were performed in Bambu Studio version 1.8.4 (Bambu Lab, Kowloon Bay, Hong Kong, China). A Creative Commons CC BY 4.0 International licensed tracheal model served as the reference for fabrication.[15] For simulation of intubation, a size 6.5 endotracheal tube (ETT) was used with the printed models.

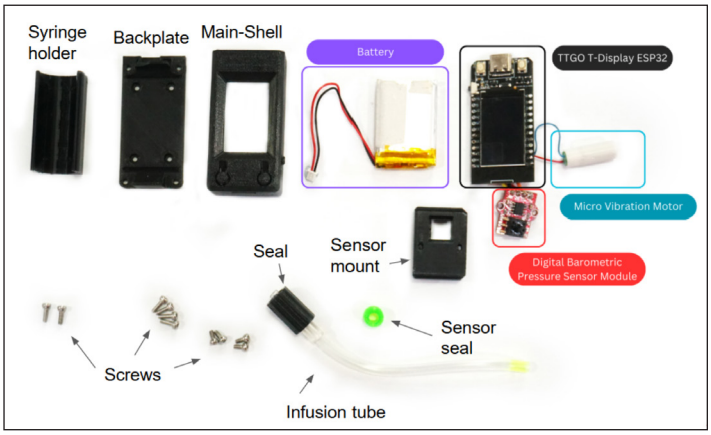

Figure 1. Components of the main body assembly of the manometer device

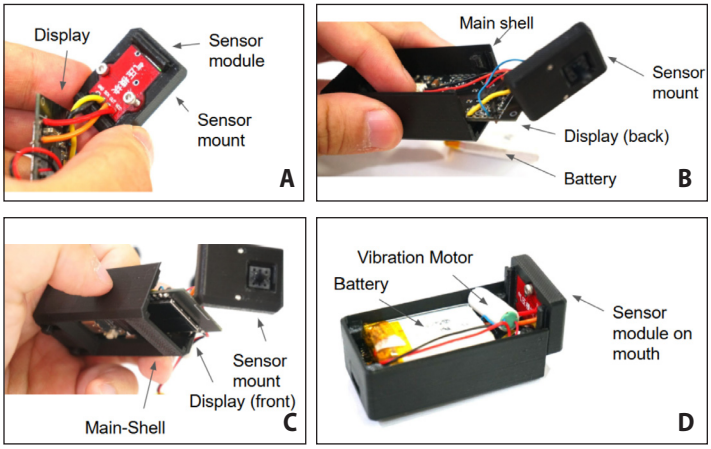

Figure 2. Mounting components: **A.** Mounting the sensor module on the sensor holder; **B.** Sensor module attached to the display on the main-shell (back view); **C.** Front view of the display; and **D.** Installation of the battery and vibration motor

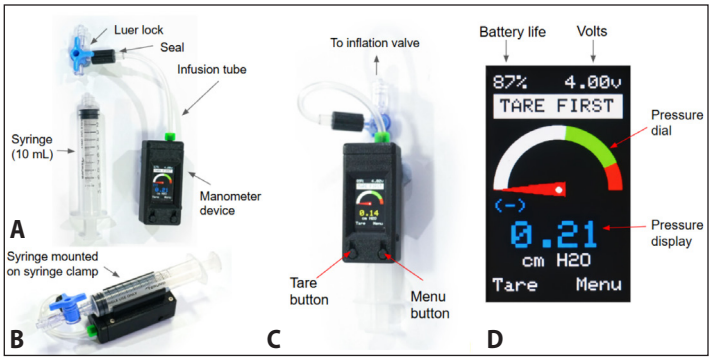

Figure 3. Assembly and interface of the manometer device: **A.** Manometer connected to the infusion tube, with the syringe detached; **B.** Syringe secured to the back of the manometer via the syringe clamp; **C.** End of the 3-way stopcock intended for connection to the ETT inflation valve, and the tare and menu buttons; and **D.** User interface (UI) highlighting the functions of different screen elements

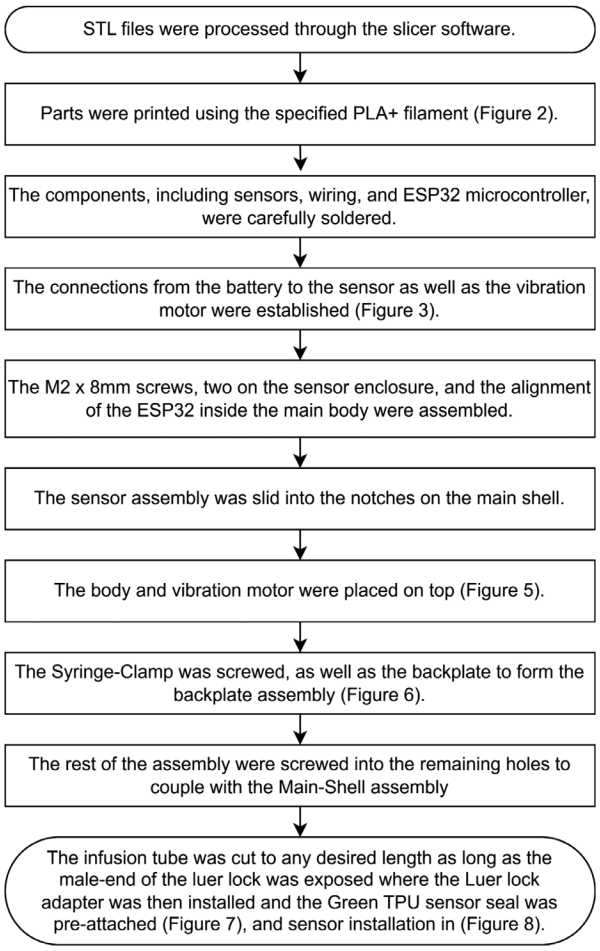

Figure 4. Summary of device assembly

B. Procedure

1. Printing of Tracheal Models: Three tracheal models with inner diameters of 19 mm, 21 mm, and 23 mm were fabricated. *(Figure 5)* These sizes were chosen to represent common tracheal dimensions for adult males (13–25 to 27 mm) and females (10–21 to 23 mm), as reported in normative data obtained from chest radiographs.[16]

Testing the *TracheoSense* 3D printed manometer-syringe device

A. Materials:

1. The materials used for testing included a VBM manometer device (VBM Medicintechnik GmbH, Germany) with an accuracy of ±2 cmH_2O, a Portex® Blue Line® cuffed endotracheal tube size 6.5 (Portex Inc., Keene, NH, USA), the TracheoSense 3D-printed manometer-syringe device, and three-dimensional printed tracheal models with inner diameters of 19, 21, and 23 mm.

B. Procedure:

1. The *TracheoSense* was calibrated with the commercially available manometer and showed equal pressure readings across various pressure readings. This was done by directly connecting the analog manometer to the *TracheoSense*. As the analog manometer was pumped, it showed the same reading between the two devices. This procedure, which represents the standard method of calibrating manometers, was done only once each day of testing, before proceeding with the measurements. This is shown in *Figure 6*.
2. The endotracheal tube was inserted into each tracheal model simulating actual endotracheal intubation with the cuff resting at the level of the second to third tracheal ring. This is shown in *Figure 7*.
3. The endotracheal tube cuff was inflated using the analog manometer. The analog manometer was connected, and the cuff was inflated until a pressure of 20 cmH2O was reached.
4. The volume of air was aspirated using a 10 mL Terumo® syringe (Terumo Corporation, Tokyo, Japan) and recorded.
5. The same procedure was repeated at a target pressure of 30 cmH2O.

These measurements established the optimal range for cuff air volume, which was repeated for three trials on three consecutive days, and the mean air volume was recorded. *Figure 8* shows steps 3-5.

6. Next, the above procedure was repeated utilizing the *TracheoSense* manometer-syringe device. The cuff was reinflated using the syringe connected to the *TracheoSense* and adjusted to achieve pressures of 20 cmH2O and 30 cmH2O.
7. The respective air volumes were measured using a 10 mL syringe and repeated for three tries in three consecutive days, and the mean air volume was recorded. Figure 9 shows the setup with the *TracheoSense* manometer-syringe device with the respective pressures.

In summary, the *TracheoSense* device was calibrated against the analog manometer, showing consistent pressure readings across various levels. The cuff of the endotracheal tube was inflated to target pressures of 20 cmH2O and 30 cmH2O to determine optimal cuff air volumes. This procedure was conducted over three consecutive days with the procedure consistently applied across trials. The measurements were taken using both the analog manometer and the *TracheoSense* device to record the mean air volumes required at the specified pressures. The researchers were able to maintain target pressures consistently during the testing.

Data Analysis

Data analysis was performed using Microsoft Excel 365 (version 2508, Microsoft Corp., Redmond, WA, USA). For each tracheal model diameter (19, 21, and 23 mm) and target cuff pressure (20 and 30 cmH_2O), the mean air volume, standard deviation (SD), and coefficient of variation (CV) were calculated for both the *TracheoSense* and the reference device. Additionally, the bias of *TracheoSense* measurements was determined and the Bland Altman plot generated.

RESULTS

The mean air volumes measured by *TracheoSense* and the reference device at target pressures of 20 and 30 cm H_2O are summarized in *Table 2*. At 20 cmH_2O, *TracheoSense* demonstrated mean volumes of 4.04 ± 0.09 mL, 5.07 ± 0.10 mL, and 5.82 ± 0.07 mL for tracheal diameters of 19, 21, and 23 mm, respectively, with corresponding coefficients of variation (CV) ranging from 1.15% to 2.18%. The bias compared to the reference device was minimal, ranging from –0.02 to 0.09 mL At 30 cmH_2O, mean volumes were 4.51 ± 0.11 mL, 5.44 ± 0.09 mL, and 6.31 ± 0.23 mL across the same tracheal diameters, with CVs between 1.62% and 3.58%, and biases ranging from –0.07 to 0.02 mL. The bar graphs for 20 and 30 cmH_2O (*Figures 10 and 11*, respectively) further illustrate the mean air volumes for each tracheal diameter for both *TracheoSense* and the reference device.

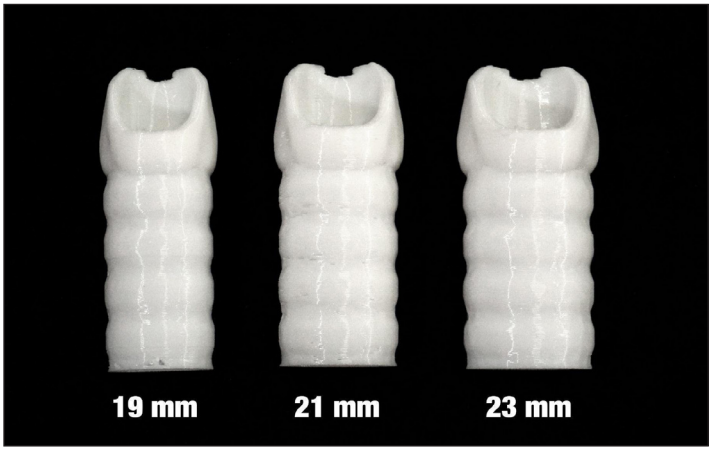

Figure 5. Different trachea models of the following diameters from left to right respectively: 19 mm, 21 mm, 23 mm

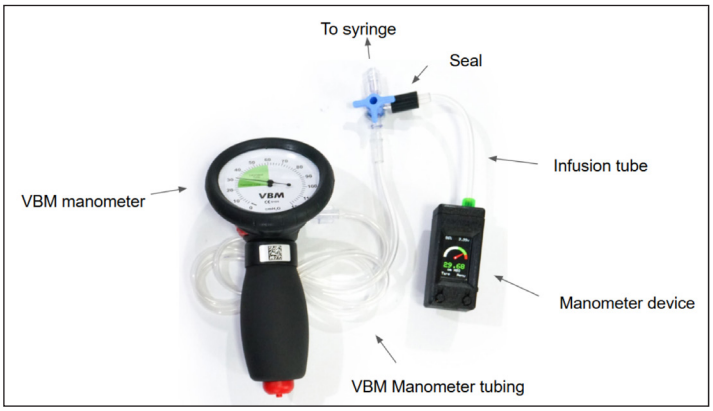

Figure 6. *TracheoSense* calibration setup with the commercially available manometer

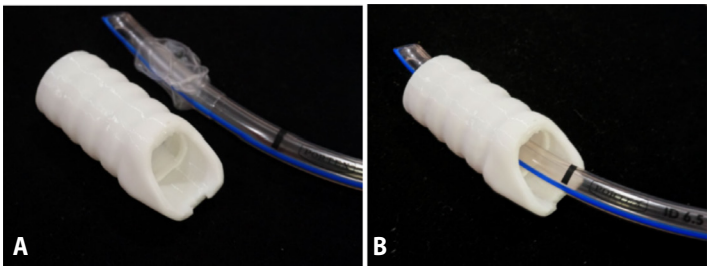

Figure 7. Endotracheal tube placement into the tracheal models

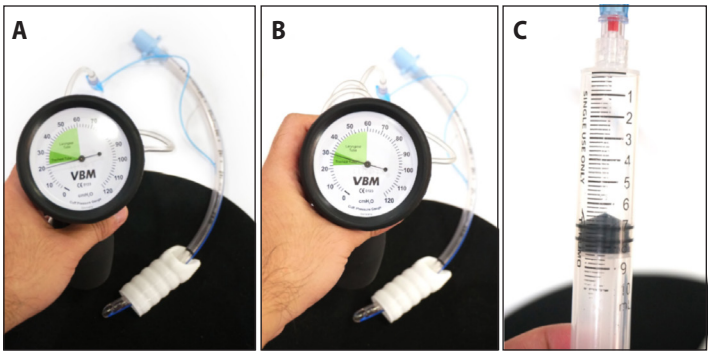

Figure 8. VBM manometer inflated at **A.** 20cm H2O; **B.** 30cm H2O; and **C.** volume aspirated in the syringe from the test

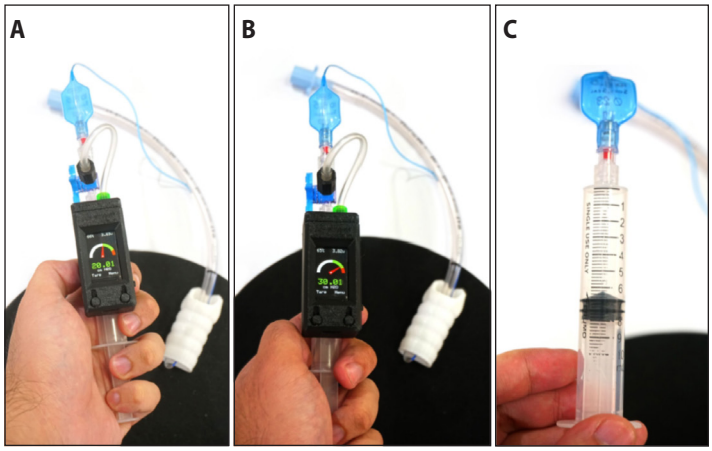

Figure 9. *TracheoSense* inflated at A. 20cm H2O; B. 30cm H2O; and C. volume aspirated in the syringe from the test

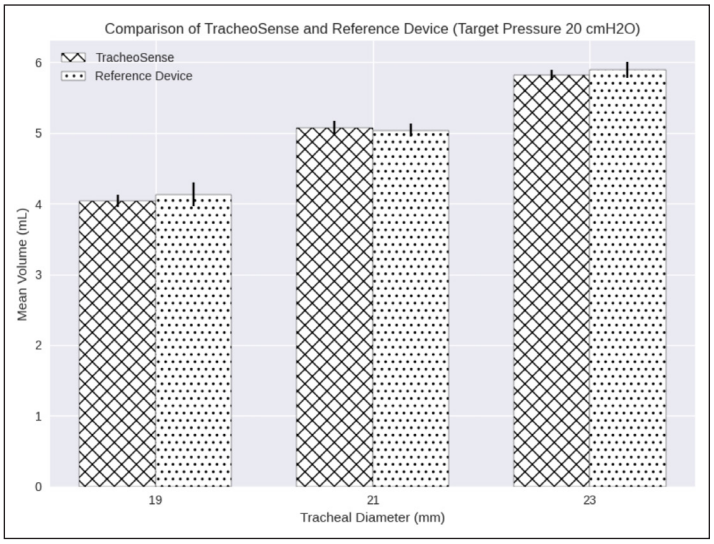

Figure 10. Mean air volume ± SD for each tracheal diameter at 20 cmH_2O

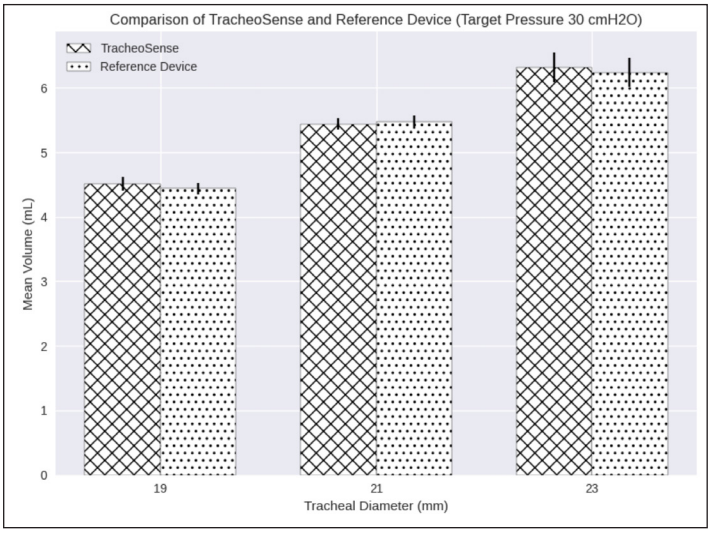

Figure 11. Mean air volume acquired per given tracheal diameter at 30 cmH2O

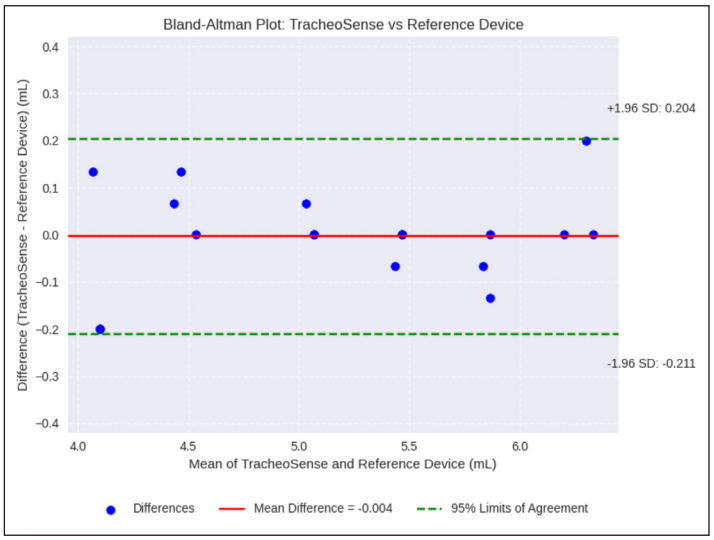

Figure 12. Bland-Altman analysis comparing TracheoSense and the reference device across pressures and tracheal diameters, showing mean bias and 95% limits of agreement

DISCUSSION

This study successfully designed and validated *TracheoSense*, a 3D-printed manometer-syringe device for measuring endotracheal tube (ETT) cuff pressure against a commercially available standard manometer. The accuracy and precision of *TracheoSense* were evaluated using bias, SD and CV, respectively.[8-9] Accuracy was assessed by calculating the mean difference, or bias, which is the systematic difference between the values measured by a test device and those measured by a reference, reflecting the extent to which the test device over- or underestimates true cuff volume. Precision was evaluated using SD and CV, which indicate variability in repeated measurements and consistency relative to the mean, respectively.

The bias of *TracheoSense* relative to the reference device across all tested pressures and tracheal diameters ranged from –0.07 mL to 0.09 mL This indicates that *TracheoSense* neither consistently overestimates nor underestimates cuff volume compared with the reference, suggesting good agreement. Clinically, such differences are negligible, as previous studies have shown that changes in cuff volume of 2–4 mL do not produce significant differences in cuff pressure.[5] Notably, the largest observed bias in our study (0.09 mL at 20 cmH_2O and 19 mm tracheal diameter) is less than 1 mL, which is unlikely to result in a meaningful clinical difference.

Supporting this, the Bland-Altman analysis demonstrated a high level of agreement between *TracheoSense* and the reference device, with a mean difference of –0.004 mL and 95% limits of agreement from –0.211 mL to 0.204 mL, indicating negligible systematic bias. *(Figure 12)* The scatter of points appeared random, with no evident linear or curvilinear trend. At 20 cmH_2O, the bias ranged from –0.02 to 0.09 mL, and at 30 cmH_2O, it ranged from –0.07 to 0.02 mL. Similarly, across

tracheal diameters of 19, 21, and 23 mm, the bias fluctuated slightly but showed no systematic increase or decrease. These findings indicate that changes in target pressure or tracheal diameter do not meaningfully affect the accuracy of *TracheoSense*.

The SDs of *TracheoSense* measurements across all tested tracheal diameters and target pressures ranged from 0.07 to 0.23 mL reflecting its absolute precision. The CV, which standardizes the SD relative to the mean, provides a measure of relative precision and repeatability allowing comparison across different magnitudes of measurement. *TracheoSense* exhibited CVs ranging from 1.15% to 3.58%, all well below the commonly accepted threshold of 5% for acceptable repeatability in volumetric measurements, highlighting its capacity of precise and repeatable measurements. In comparison, the reference device demonstrated slightly higher CV at some points (up to 4.19%), but still within clinically acceptable limits.

The higher volumes measured in our tracheal model compared with in vivo studies (4.0–5.8 mL vs. 2.5–3.3 mL for 20 cmH_2O) can be attributed to the uniform rigidity, lack of tissue compliance, and absence of physiological air leaks in the model. This also explains the steeper pressure-volume slopes observed (*TracheoSense*: 22.7 cmH_2O/mL, reference: 27.8 cmH_2O/mL) and the lower variability in measurements compared with patient studies.[5] Despite these differences, *TracheoSense* reliably reflects relative changes in cuff volume and maintains high accuracy and precision across the tested range.

Compared with other devices, *TracheoSense* shows a more stable bias. For example, a previous study on two disposable airway pressure manometers reported biases ranging from –0.4 to –1.7 cmH_2O, indicating a tendency to overestimate pressures relative to the reference.[9] In contrast, *TracheoSense* did not consistently under- or overestimate across pressures or tracheal diameters. Although the original study did not report CVs, we calculated them from the reported means and SDs, which ranged from 2.4% to 3.7%, comparable to the CVs observed in *TracheoSense* measurements. This suggests that the variability of *TracheoSense* is within the range of commercially available or previously tested cuff pressure devices, supporting its reliability for repeated measurements.

Despite the demonstrated comparable accuracy and precision of *TracheoSense* with the reference device, several limitations should be considered. The study was conducted using a tracheal model, which lacks real tissue compliance, airway dynamics, and physiological air leaks. Only a limited range of tracheal diameters (19, 21, 23 mm) and one tube size were tested, which may not fully represent the diversity encountered in clinical practice. Environmental factors such as temperature, humidity, or patient movement were not assessed, along with the effects of long-term device durability or repeated clinical use. Importantly, in vivo validation in actual patients was not performed, and clinical outcomes related to cuff pressure management were not assessed. Therefore, future research should focus on validating *TracheoSense* in clinical settings to confirm its effectiveness and reliability in real-world use. Since this study relied solely on descriptive statistics, future research incorporating inferential analyses may provide stronger evidence for the relationships and measurement capabilities observed.

The *TracheoSense* 3D-printed manometer-syringe device demonstrated accuracy and precision comparable to a commercially available analog manometer, supporting its potential as a reliable and practical tool for ETT cuff pressure monitoring. Nonetheless, further research is warranted to validate its performance in clinical practice.

ACKNOWLEDGEMENTS

The authors acknowledge the contribution of Dr. Ma. Lourdes Enecilla in internally reviewing the paper.

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