Research Square

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Efficacy of a 3D-Printed Personalized Artificial Airway Fixation Device in Obese Intensive Care Unit Patients: A Randomized Controlled Trial

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Abstract

Background

Securing an artificial airway in obese patients is a significant clinical challenge due to anatomical factors, leading to high rates of tube displacement and pressure injuries. This study aimed to develop a personalized artificial airway fixation device using three-dimensional (3D) printing technology and to evaluate its clinical efficacy in this population.

Methods

In this single-center, two-arm randomized controlled trial, 66 obese patients (body mass index ≥ 28 kg/m²) requiring orotracheal intubation in an intensive care unit in China were randomly assigned (1:1) to a personalized 3D-printed fixation device designed from 3D facial surface scans (intervention group, n = 33) or a commercial fixation device (control group, n = 33). The primary outcome was endotracheal tube displacement (proportion with no displacement on a 5-level scale). Secondary outcomes were local skin irritation and airway management safety indicators (heart rate and pulse oxygen saturation [SpO_2] fluctuations and duration of irritative coughing during nursing procedures). Patients, nursing staff, and outcome assessors were not blinded; data analysts were blinded.

Results

All 66 patients were analyzed. The intervention group demonstrated significantly superior fixation efficacy, with 88% (29/33) of patients experiencing no displacement compared with 24% (8/33) in the control group (risk difference 63.6 percentage points, 95% confidence interval 41.0 to 77.2; $P < 0.001$); no unplanned extubation or other adverse events occurred. Local skin irritation was less frequent in the intervention group (3% vs. 24%; $P = 0.027$, Fisher's exact test). During nursing procedures, the intervention group showed significantly smaller fluctuations in heart rate ($\beta = -3.57$) and SpO_2 ($\beta = -0.96$), and shorter durations of irritative coughing ($\beta = -0.76$) ($P < 0.001$ for all).

Conclusions

Compared with a commercial device, the 3D-printed personalized artificial airway fixation device provided more stable tube fixation and reduced local skin irritation in obese intensive care unit patients, while improving procedural safety during nursing care. Larger multicenter trials with blinded outcome assessment are warranted.

Trial registration:

ClinicalTrials.gov, NCT07349433. Registered September 12, 2025. Retrospectively registered.

Background

Establishing an artificial airway is a critical life-saving intervention for critically ill patients requiring mechanical ventilation [1]. However, maintaining stable and secure endotracheal tube fixation, one of the most important nursing measures for preventing tube displacement and unplanned endotracheal extubation [2], remains a persistent challenge in intensive care nursing. Unplanned endotracheal extubation is a severe nurse-sensitive adverse event, with reported incidence rates of 3.0%–16.0% outside China and 4.5%–22.1% in China. It is directly associated with ventilator-associated pneumonia, prolonged mechanical ventilation, and mortality rates reaching 10–25% [3]. Furthermore, suboptimal fixation methods frequently contribute to medical device-related pressure injuries and oral mucosal trauma, which complicate care and compromise patient safety [4, 5].

Securing the endotracheal tube is particularly problematic in patients with obesity, a population that constitutes an increasing proportion of intensive care unit admissions [6, 7]. Obesity introduces specific anatomical and physiological challenges for airway management. Anatomically, obesity alters craniofacial and cervical morphology, often characterized by a shortened neck, redundant submental and facial adipose tissue, and obscured bony landmarks [6, 8]. These structural variations make it exceedingly difficult to achieve an effective seal and stable anchor with conventional fixation devices. Physiologically, obese patients typically present with reduced functional residual capacity and higher baseline oxygen consumption. Consequently, if unplanned endotracheal extubation occurs, they are highly susceptible to rapid, life-threatening hypoxemia. Given the higher incidence of difficult reintubation in this population, secure initial airway fixation is of paramount importance.

Traditional fixation methods, such as adhesive tape combined with a bite block, often fail in this population. The yielding nature of facial adipose tissue, coupled with excessive diaphoresis and oral secretions common in obese patients, rapidly degrades tape adhesion [5]. Although commercial endotracheal tube holders (e.g., the Thomas™ Tube Holder, AnchorFast Guard, or Haider Tube-Guard) can reduce tube movement compared with adhesive tape [9], their rigid, uniform configurations fail to accommodate the anatomical diversity of obese patients. To achieve a functional seal with these generic devices, nurses must often apply excessive tension to the securing straps. This uneven pressure distribution creates localized high-pressure points on prominent facial areas. When combined with the altered skin microclimate within deep facial folds, this localized mechanical load significantly increases the risk of facial and mucosal medical device-related pressure injuries [10, 11]. Because mechanically ventilated intensive care unit patients often require prolonged intubation, this continuous high-pressure contact leads to rapid tissue ischemia and breakdown, and high body mass index has been identified as a risk factor for endotracheal tube-related pressure injuries [12].

To address the inherent conflict between standardized medical equipment and individual patient anatomy, personalized approaches are required. Three-dimensional (3D) printing, or additive

manufacturing, enables the rapid prototyping of patient-specific medical devices based on precise anatomical data [13, 14]. This study aimed to integrate 3D surface scanning and printing technology to develop and evaluate a novel, personalized artificial airway fixation device tailored to the facial contours of obese intensive care unit patients. We hypothesized that a custom-fitted device would optimize pressure distribution and anatomical conformity, thereby reducing endotracheal tube displacement and local skin irritation while improving procedural safety and nursing workflows.

Methods

Development of the 3D-printed artificial airway fixation device

Research and development team

An 8-member interdisciplinary research and development team was assembled. The project was led by the head nurse of the Department of Critical Care Medicine, who was responsible for overall protocol design, member training, and quality supervision. The team lead also provided an in-depth analysis of the limitations of traditional airway fixation methods based on clinical problems identified during tracheostomy care. The team comprised: one department director for research guidance and clinical safety oversight; one associate chief physician for risk assessment and interdepartmental collaboration; three senior staff nurses responsible for clinical implementation, data collection, and efficacy evaluation, who also systematically reviewed comfort and safety issues of existing methods based on patient observations; and two technicians from the hospital's 3D Printing Center, responsible for 3D scanning of patient head/neck data, model reconstruction, device design, and final 3D printing. There was no patient or public involvement in the design, conduct, or reporting of this study.

Limitations of traditional artificial airway fixation methods

Traditional fixation methods, particularly in obese patients, present several issues: (1) Insecure fixation and high dislodgement risk: Traditional tape fixation has poor adhesion, elasticity, and breathability, often losing adhesiveness due to sweat or secretions, leading to loosening. For obese patients with thick neck fat and unique anatomy, traditional devices fit poorly, resulting in a high risk of tube displacement or unplanned endotracheal extubation during coughing or turning, exacerbated by traction from ventilator circuits. (2) High complication rates: Prolonged pressure and contact from tape or devices are primary causes of pressure injuries and allergic reactions on the face, mouth corners, and neck. For tracheostomy patients, traditional ties (e.g., cotton twill tape) lack elasticity and harden when moist, causing poor comfort and increasing the risk of skin maceration and erosion. (3) Impaired clinical nursing: Conventional methods often obscure the lips and surrounding skin, hindering patient observation. Furthermore, during oral care, the operational space is restricted to prevent tube displacement, making thorough cleaning difficult and increasing the risk of oral complications. (4) Lack

of individualized design: Most existing devices are standardized products, failing to meet the individualized needs of diverse patients, especially obese or pediatric patients and those with maxillofacial deformities, thus limiting their clinical application.

Structural and material design

The 3D-printed artificial airway fixation device developed in this study was designed exclusively for the orotracheal intubation clinical scenario. Patient-specific head and neck surface data were rapidly acquired using a handheld 3D scanner, forming the basis for 3D modeling and design. For materials, a medical-grade, silicone-like soft and hard resin combination was used for integrated printing. The main body of the device was printed with rigid material. The inner surface, which contacts the patient's skin, was printed using a soft, skin-friendly material and featured a porous structure designed via topological optimization. This design ensures a snug fit to the patient's facial contours while maintaining breathability and comfort. Antibacterial material was incorporated into the inner wall (contact surface) to prevent local skin infections or eczema caused by perspiration. The tube fixation component utilizes a circular clasp design, also lined with soft material, to secure the tube firmly without causing damage or slippage. Overall fixation is achieved via an adjustable elastic strap at the back. Figure 1 shows the personalized 3D-printed orotracheal intubation fixation device and a standardized commercial fixation device in clinical use, highlighting the difference in contour conformity, the movable dual-track design, and the integrated feeding tube groove.

Functional design

The device integrates the following innovative features to address clinical problems: (1) Personalized, precision fit: Based on the patient's own 3D data, the design fundamentally solves the problem of insecure fixation caused by poor conformity. (2) Movable dual-track design: The orotracheal fixation device features curved dual tracks designed according to the patient's lip curvature. The tube-securing clasp can slide safely along these tracks, allowing the endotracheal tube to be moved from one side of the mouth to the other. This design facilitates oral care and inspection and allows for observation of lip color and skin condition without removing the fixation device.

Trial design and setting

This study was a single-center, two-arm, parallel-group, superiority randomized controlled trial with a 1:1 allocation ratio. A convenience sample of 66 obese patients receiving artificial airway management in the intensive care unit of Tangdu Hospital, Fourth Military Medical University (Xi'an, China), from August 10, 2024, to May 31, 2025, was enrolled. Eligible patients were randomly assigned to an intervention group or a control group.

Participants

Inclusion criteria were: (1) age between 18 and 80 years; (2) meeting clinical indications for orotracheal intubation; (3) body mass index (BMI) ≥ 28 kg/m², the cut-off value for obesity in Chinese adults [15]; (4) intact skin around the mouth, cheeks, and neck prior to intubation; (5) expected intubation duration exceeding 12 hours; and (6) patient or legal guardian provided informed consent. Exclusion criteria were: (1) history of psychiatric diagnosis; (2) presence of laryngeal injury; (3) pre-existing facial skin breakdown or oral disease; and (4) two or more intubations during the current hospitalization.

Sample size

The primary outcome of this study was the rate of "no endotracheal tube displacement" (defined as Level 1 on the displacement scale). Based on the results of our pilot study, the estimated no-displacement rates for the intervention and control groups were 82.4% and 46.3%, respectively. Assuming a two-sided significance level (α) of 0.05 and a statistical power (1-β) of 0.80, the effective sample size required was determined to be 27 patients per group. To account for a predicted 15% dropout rate during the trial, the total planned sample size was adjusted to 64 patients (32 per group).

Randomization and allocation concealment

The random allocation sequence was generated by an independent statistician not involved in recruitment or intervention delivery, using a computer-generated random number table (simple randomization without blocking or stratification). Allocation was concealed using sequentially numbered, opaque, sealed envelopes. Once a patient (or their legal guardian) provided written informed consent, the research coordinator opened the envelope in sequence to assign the participant to either the intervention or control group.

Interventions

Both groups received standardized airway nursing care in the intensive care unit, including oral hygiene every 6–8 hours, regular repositioning for pressure-area care, and standardized sedation and analgesia management.

Control group

Patients received traditional artificial airway fixation. A commercially available fixation device was used. The endotracheal tube was passed through the central hole, and after confirming the depth, a screw cap was tightened from the side. A fixation strap was passed around the neck, threaded through a small hole on the opposite side, and fastened.

Intervention group

Patients received the personalized 3D-printed artificial airway fixation device designed in this study. The personalized, sterilized 3D-printed device was applied. Its soft inner surface was fitted to the patient's facial contour. After the endotracheal tube was inserted and depth confirmed, it was secured into the

central clasp. If a gastric or enteral feeding tube was present, it could be placed in the dedicated upper groove. The posterior adjustable elastic strap was passed around the patient's head, adjusted to an appropriate tightness, and fastened.

Blinding

Due to the distinct physical appearance and operational nature of the 3D-printed device versus commercial fasteners, blinding of patients, clinical nursing staff, and outcome assessors was not feasible. However, the data analysts were blinded to the group assignments. All trial data were de-identified before analysis, and statistical processing was conducted by a third-party statistician unaware of the group allocation. Two uniformly trained nurses collected data for all outcome measures.

Outcome measures

The primary outcome was endotracheal tube displacement. The secondary outcomes were local skin irritation and airway management safety indicators; adverse events were also recorded.

Primary outcome: endotracheal tube displacement or extubation

A 5-level scale was used for assessment [16]: Level 1, no displacement (endotracheal tube depth at the incisors or distance to the lip corners unchanged); Level 2, mild displacement (endotracheal tube depth change < 1 cm at the incisors or < 1 cm shift at the lip corners); Level 3, moderate displacement (endotracheal tube depth change 1–2 cm at the incisors or 1–2 cm shift at the lip corners); Level 4, severe displacement (endotracheal tube depth change > 2 cm at the incisors); and Level 5, unplanned extubation. Tube position (insertion depth at the incisors and position at the lip corners) was measured at every nursing shift until extubation, and each patient was classified according to the highest displacement level recorded.

Local skin irritation

The contact area was inspected daily and recorded for skin irritation or allergic reaction, categorized as "Yes" or "No".

Airway management safety indicators

(1) Duration of irritative coughing: The duration (seconds) of continuous coughing or choking during each nursing procedure (oral care and device change) was recorded.

(2) Patient heart rate (HR) and pulse oxygen saturation (SpO_2) during nursing: HR (bpm) and SpO_2 (%) were monitored and recorded before and after each nursing procedure.

Adverse events

Adverse events were defined as device-related skin breakdown, severe localized allergic reactions, or secondary airway trauma resulting from unplanned extubation. The contact area was inspected daily by

researchers to identify and record any such unintended events.

Statistical analysis

All data were analyzed using R software (version 4.5.0). Normality of continuous data was assessed using the Shapiro-Wilk test. Normally distributed data were described as mean ± standard deviation and compared using independent-samples t-tests. Non-normally distributed data were described as median (interquartile range) [M (P_{25}, P_{75})] and compared using the Wilcoxon rank-sum test. Ordinal data were compared using the Wilcoxon rank-sum test. Categorical data were described as frequency (percentage) [n (%)] and compared using the chi-squared test or Fisher's exact test (when any expected frequency was < 5). For binary outcomes, the risk difference (Newcombe hybrid score method) and risk ratio with 95% confidence intervals (CIs) were also calculated.

For airway management safety indicators, which constituted repeated measures data, Generalized Estimating Equations (GEE) were used. In the GEE models, patient ID was the cluster variable, a normal distribution family with an identity link was selected, an exchangeable (compound symmetry) working correlation matrix was assumed (assuming equal correlation between any two observations within the same patient), and robust (sandwich) standard errors were used to calculate 95% CIs and Wald *z* tests. In all models, the group (Intervention vs. Control) was the predictor variable, with the control group as the reference. The model coefficient β represents the mean difference of the intervention group relative to the reference group. Statistical analyses were conducted in accordance with the intention-to-treat principle. For the primary outcome, any instances of loss to follow-up or missing data were addressed using the multiple imputation method. All statistical tests were two-sided, and a *P*-value < 0.05 was considered statistically significant.

Ethics and trial registration

This study was approved by the Medical Ethics Committee of Tangdu Hospital, Air Force Medical University (Fourth Military Medical University) (approval number: HLXJSXYW-2024-04), which reviewed and approved the protocol on August 10, 2024 (approval letter issued on September 2, 2024). Prior to participation, written informed consent was obtained from all patients or their legal guardians. The trial was retrospectively registered at ClinicalTrials.gov (NCT07349433; https://clinicaltrials.gov/study/NCT07349433) on September 12, 2025, because the nursing research team was initially unaware that prospective registration was required for a trial of a non-drug nursing intervention. The trial is reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) 2025 statement [17].

Results

Participant flow and baseline characteristics

Of the 92 patients assessed for eligibility, 26 were excluded, and 66 obese patients were randomized, with 33 in the intervention group and 33 in the control group (Fig. 2). All patients received the allocated

intervention, none were lost to follow-up, and all 66 patients were included in the analysis of the primary outcome; therefore, no imputation of missing data was required. There were no statistically significant differences ($P > 0.05$) between the two groups in baseline characteristics, including age, sex, BMI, duration of intubation, and Braden pressure sore risk score, indicating that the groups were comparable (Table 1).

Figure 2 CONSORT flow diagram of participant recruitment, randomization, follow-up, and analysis

Table 1
Baseline characteristics of patients in the two groups

Feature	Groups		Statistic	*P*-value[2]
	Intervention Group **N = 33[1]**	**Control Group** **N = 33[1]**		
Age (years)	62.1 ± 13.9	55.9 ± 13.5	$t = 1.84$	0.071
Sex			$\chi^2 = 0.67$	0.415
Male	25 (76%)	22 (67%)		
Female	8 (24%)	11 (33%)		
Body Mass Index (kg/m²)	28.4 (28.2, 29.5)	28.4 (28.2, 29.4)	$W = 595.00$	0.521
Duration of Intubation (hours)	254.86 ± 158.44	220.21 ± 133.40	$t = 0.961$	0.340
Braden Pressure Sore Risk Score	14.79 ± 1.88	14.76 ± 1.85	$t = 0.066$	0.948
Intubation Depth (cm)	22.53 ± 1.50	22.28 ± 1.22	$t = 0.738$	0.463
[1]Data are presented as mean ± standard deviation; M (P_{25}, P_{75}); n (%)				
[2]Statistics are from Two Sample t-test; Wilcoxon rank sum test; Pearson's Chi-squared test				

Primary outcome: endotracheal tube displacement

The fixation efficacy in the intervention group was significantly better than in the control group ($W = 188.00$, $P < 0.001$). In the intervention group, 88% (n = 29) of patients experienced Level 1 (no displacement) fixation, compared to only 24% (n = 8) in the control group ($\chi^2 = 27.13$, $P < 0.001$; risk difference 63.6 percentage points, 95% CI 41.0 to 77.2; risk ratio 3.63, 95% CI 1.96 to 6.71). Conversely, 15% (n = 5) of patients in the control group experienced Level 3 (moderate displacement), while none did in the intervention group. No severe displacement (Level 4) or unplanned extubation (Level 5) occurred in either group (Table 2).

Local skin irritation

The incidence of local skin irritation was significantly lower in the intervention group (3%, n = 1) than in the control group (24%, n = 8) (risk difference − 21.2 percentage points, 95% CI -38.2 to -4.4; risk ratio 0.13, 95% CI 0.02 to 0.94). This difference was statistically significant (Fisher's exact test, $P = 0.027$) (Table 2). No adverse events (device-related skin breakdown, severe localized allergic reactions, or secondary airway trauma) occurred in either group.

Table 2
Comparison of outcome indicators between the two groups

Outcome	**Groups**		**Statistic**	***P*-value[2]**
	Intervention Group	**Control Group**		
	N = 33[1]	**N = 33[1]**		
Tube Displacement / Extubation			*W* = 188.00	**< 0.001**
Level 1	29 (88%)	8 (24%)		
Level 2	4 (12%)	20 (61%)		
Level 3	0 (0%)	5 (15%)		
Level 4	0 (0%)	0 (0%)		
Level 5 (unplanned extubation)	0 (0%)	0 (0%)		
Local Skin Irritation			—	**0.027**
Yes	1 (3%)	8 (24%)		
No	32 (97%)	25 (76%)		
[1]Data are presented as n (%)				
[2]Statistics are from Wilcoxon rank sum test; Fisher's exact test (no test statistic shown)				

Airway management safety indicators

Results from the GEE model analysis are presented in Table 3. A total of 8401 nursing procedures were analyzed (4424 in the intervention group and 3977 in the control group). Compared to the control group, the intervention group showed a significantly lower magnitude of change in vital signs and a shorter duration of coughing during nursing procedures. Specifically, the mean heart rate fluctuation per procedure was 8.28 ± 4.06 bpm in the intervention group and 11.96 ± 5.56 bpm in the control group (β = -3.57, 95% CI -4.88 to -2.26, z = -5.35, $P < 0.001$). The mean fluctuation in SpO_2 was 1.46 ± 1.12% versus 2.37 ± 1.46% (β = -0.96, 95% CI -1.32 to -0.60, z = -5.29, $P < 0.001$), and the mean duration of irritative coughing was 2.21 ± 0.81 s versus 3.02 ± 1.17 s (β = -0.76, 95% CI -1.05 to -0.47, z = -5.08, $P < 0.001$).

Table 3
Generalized estimating equation analysis of airway management safety indicators

Outcome	Predictor	Coefficient β[1]	95% CI	Statistic	*P*-value[2]
Heart Rate Fluctuation (bpm)	Intervention vs. Control	-3.57	-4.88 to -2.26	z=-5.35	**< 0.001**
SpO_2 Fluctuation (%)	Intervention vs. Control	-0.96	-1.32 to -0.60	z=-5.29	**< 0.001**
Irritative Coughing Duration (s)	Intervention vs. Control	-0.76	-1.05 to -0.47	z=-5.08	**< 0.001**

[1]Estimated mean difference (intervention minus control), from GEE with an exchangeable working correlation and robust standard errors; 8401 nursing procedures (intervention, 4424; control, 3977) from 33 patients per group

[2]Wald z-test

Discussion

The findings of this randomized controlled trial demonstrate that a personalized, 3D-printed artificial airway fixation device provides superior clinical outcomes compared to standardized commercial devices in obese intensive care unit patients. The intervention significantly improved fixation stability, decreased the incidence of local skin irritation, and optimized physiological parameters during nursing care.

Anatomical conformity enhances fixation stability

Unplanned endotracheal extubation is a critical quality indicator in intensive care nursing, with improper securement recognized as a major precipitating factor [18]. Anatomical features inherent to obesity—such as hypertrophied facial adipose tissue and altered mandibular contours—compromise the anchoring efficacy of standardized tube holders, making this population particularly vulnerable to tube displacement [19]. In our study, 88% of patients in the intervention group maintained optimal endotracheal tube positioning without displacement, compared to only 24% in the control group. This improvement is primarily attributable to the device's customized facial interface. By utilizing 3D scanning, the device achieves exact topological conformity to the individual's facial geometry. This personalized fit eliminates the micro-gaps common with rigid commercial devices, creating a uniform contact area. Consequently, kinetic forces generated by patient coughing, repositioning, or ventilator circuit traction are absorbed and dispersed evenly across the facial surface, rather than causing the device to shift. Given the high rates of difficult intubation and the severe risks associated with emergency reintubation in obese patients, maximizing fixation stability through anatomical adaptation represents a vital enhancement to patient safety [6].

Reduction of local skin irritation

Medical device-related pressure injuries are significant adverse events in critical care, and endotracheal tubes are among their most common causes, accounting for 37.5% to 61.4% of such injuries in intensive care units [20]. In this study, the incidence of local skin irritation in the intervention group was markedly lower (3%) than in the control group (24%). Sustained mechanical loading that exceeds capillary closing pressure leads to tissue ischemia [21], and standardized devices often exert disproportionate peak interface pressures on prominent facial areas to maintain their position. By maximizing the contact surface area, the 3D-printed device may redistribute and reduce peak interface pressure. Furthermore, obese patients are highly susceptible to moisture-associated skin damage due to excessive diaphoresis and deep skin folds. To address this, the inner layer of the 3D-printed device utilized a porous, topologically optimized structure combined with an antibacterial, skin-friendly resin, which was designed to promote air circulation, manage microclimate moisture, and limit bacterial colonization [22]. Because interface pressure was not measured, these mechanisms remain hypothetical, and whether the device also reduces medical device-related pressure injuries requires confirmation in future studies.

Optimization of nursing workflow and procedural safety

The device demonstrates notable clinical value through its positive impact on nursing ergonomics and procedural safety. Routine airway management, particularly oral care and endotracheal tube repositioning, is physically demanding and poses a transient risk for accidental extubation. Traditional care methods necessitate loosening the securement device to access the oral cavity or shift the tube, which frequently stimulates the tracheal mucosa, triggering irritative coughing, sympathetic nervous system activation, and hemodynamic fluctuations [23]. The 3D-printed device features an innovative "movable dual-track" design that allows nurses to slide the endotracheal tube smoothly from one side of the mouth to the other without breaking the primary facial seal or detaching the device. Our data indicate that this continuous securement significantly reduced the duration of irritative coughing and minimized fluctuations in heart rate and SpO_2 during nursing interventions. By streamlining oral care and potentially eliminating the need for a second nurse to manually stabilize an unsecured endotracheal tube, the device may reduce the cognitive and physical burden on critical care staff. However, nursing workload and procedure time were not directly measured in this study.

Strengths and limitations

This study highlights the clinical translation of a nurse-led clinical innovation, advancing from the identification of a specific clinical problem to the bedside deployment of a tailored intervention utilizing 3D printing technology. However, several limitations must be acknowledged. First, the single-center design and relatively small convenience sample may limit the generalizability of the findings. Second, because the devices were visually distinct, patients, nursing staff, and outcome assessors could not be blinded, which may have introduced performance and detection bias. Third, skin outcomes were recorded as local skin irritation (yes/no) rather than staged pressure injuries, and interface pressure was

not measured. Fourth, obesity was defined using the Chinese criterion (BMI ≥ 28 kg/m²) [15], and at least three-quarters of the participants had a BMI below 30 kg/m²; therefore, the findings may not be generalizable to patients with more severe obesity or to settings in which obesity is defined as BMI ≥ 30 kg/m². Fifth, the trial was registered retrospectively. Sixth, the logistical requirements of 3D printing—specifically the time required for data acquisition, modeling, and printing—currently preclude its use in emergency intubations, restricting its application to patients already stabilized in the intensive care unit, and the cost-effectiveness of the device was not evaluated. Finally, while the short-term efficacy is promising, longitudinal follow-up is necessary to evaluate the device's impact on the incidence of ventilator-associated pneumonia and overall intensive care unit length of stay.

Conclusions

The personalized artificial airway fixation device, developed via 3D printing technology, provides a safe, stable, and anatomically appropriate securement solution for obese patients in the intensive care unit. By conforming precisely to individual patient anatomy, the device effectively reduces endotracheal tube displacement and local skin irritation. Furthermore, its ergonomic design facilitates nursing procedures and is associated with smaller physiological fluctuations during care. As additive manufacturing becomes more accessible in clinical settings, integrating patient-specific 3D printing into critical care nursing practice holds significant potential to elevate the standard of care for anatomically challenging patient populations. Larger multicenter trials with blinded outcome assessment are needed to confirm these findings.

Abbreviations

3D
Three-dimensional
BMI
Body mass index
CI
Confidence interval
CONSORT
Consolidated Standards of Reporting Trials
GEE
Generalized estimating equations
HR
Heart rate
SpO_2
Pulse oxygen saturation

Declarations

Ethics approval and consent to participate

This study was conducted in accordance with the Declaration of Helsinki. The study protocol was approved by the Medical Ethics Committee of Tangdu Hospital, Air Force Medical University (Fourth Military Medical University) (approval number: HLXJSXYW-2024-04; reviewed and approved on August 10, 2024; approval letter issued on September 2, 2024). Written informed consent to participate was obtained from all patients or their legal guardians before enrollment.

Consent for publication

Written informed consent for the publication of the clinical photographs in Fig. 1 was obtained from the patients or their legal guardians.

Competing interests

The authors declare that they have no competing interests.

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This study was supported by the Fourth Military Medical University. The funder had no role in the study design, data collection, analysis, interpretation of data, or writing of the manuscript.

Author Contribution

LL: conceptualization, methodology, formal analysis, investigation, data curation, writing – original draft, writing – review and editing, and project administration. LY: conceptualization, resources, writing – review and editing, supervision, and project administration. JHL: methodology, software, resources, and visualization. JY: methodology, software, and visualization. HC: methodology and software. HJ: validation and investigation. JML: investigation and data curation. RL: validation. WJ: conceptualization, supervision, and writing – review and editing. All authors read and approved the final manuscript.

Acknowledgements

Not applicable.

Data Availability

The datasets generated and/or analyzed during the current study are not publicly available to protect patient privacy but are available from the corresponding author on reasonable request. De-identified individual participant data, together with the data dictionary and statistical code, will be made available for academic research purposes beginning six months after publication to researchers who sign a data-use agreement. The full trial protocol and statistical analysis plan are available through ClinicalTrials.gov (NCT07349433) or upon reasonable request to the corresponding author.

Clinical trial number

ClinicalTrials.gov NCT07349433; registered on September 12, 2025 (retrospectively registered).

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Figures

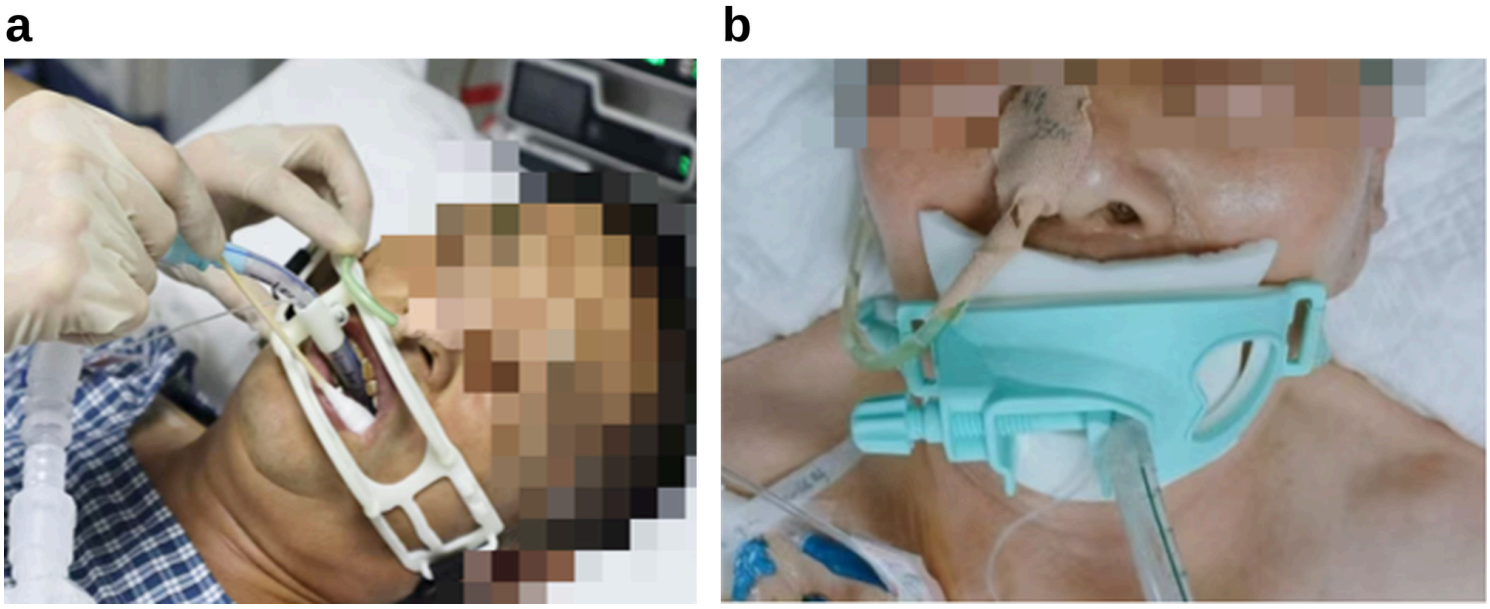


Figure 1

Personalized 3D-printed fixation device and a standardized commercial fixation device in clinical use. **a** Personalized 3D-printed orotracheal intubation fixation device. **b** Standardized commercial fixation device. Patients' faces have been pixelated to protect their privacy.

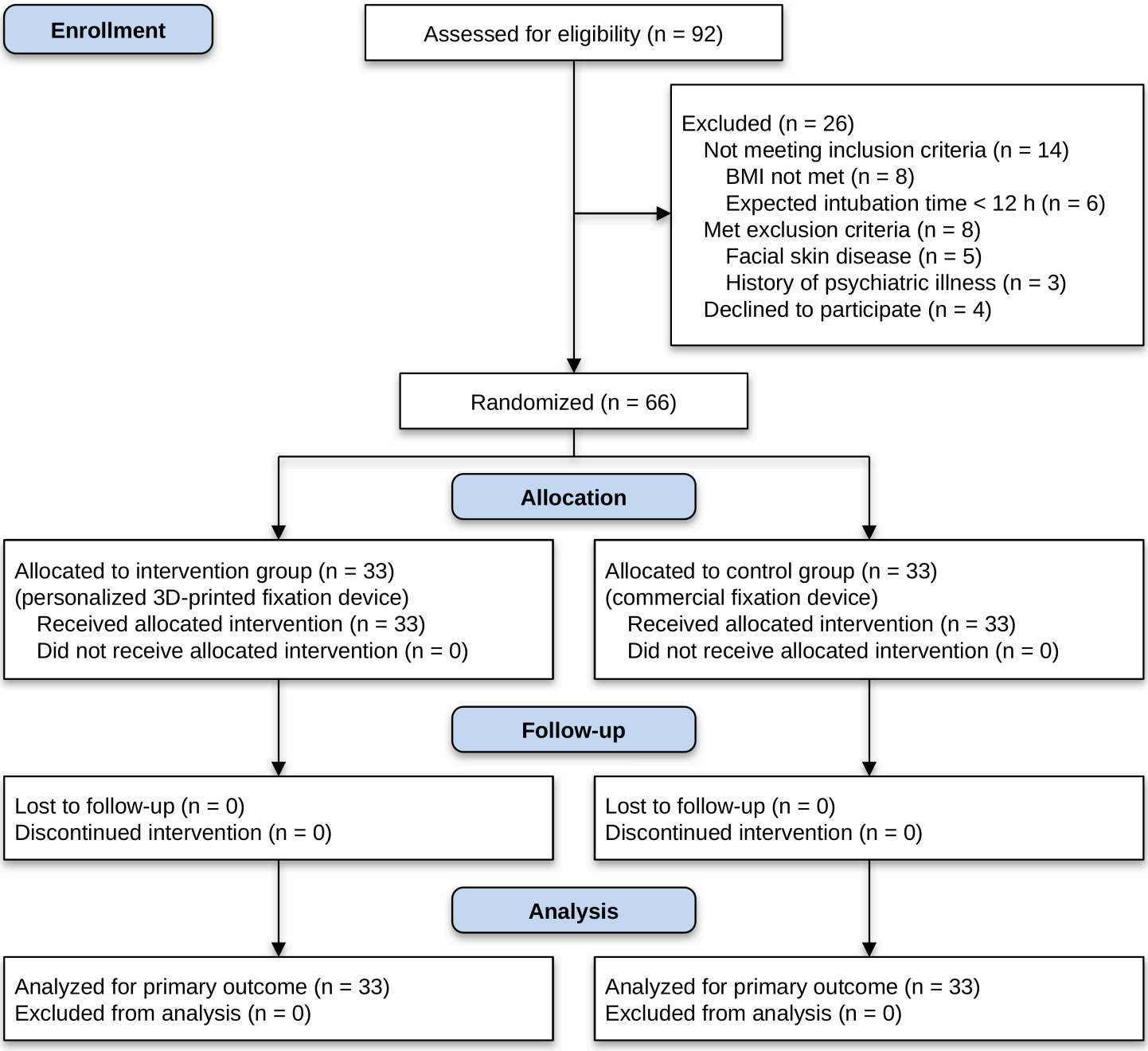


Figure 2

CONSORT flow diagram of participant recruitment, randomization, follow-up, and analysis

Supplementary Files

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- CONSORTchecklist.docx