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# Design and performance evaluation of a 3D-printed transoral tracheal intubation fixation device

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## Abstract

Effective fixation of the endotracheal tube is essential to prevent displacement, unplanned extubation, and pressure injuries (PIs), which remain common complications with traditional fixation methods. Advances in three-dimensional (3D) printing technology offer opportunities to design personalized devices that may improve airway security and patient outcomes. However, no prior study has evaluated the use of 3D-printed fixation devices as an alternative to traditional methods. We aim to design and evaluate the effectiveness of an endotracheal tube fixation device produced using 3D printing technology in patients receiving mechanical ventilation. In a single-center, prospective, non-concurrent, controlled cohort trial, patients with an expected duration of mechanical ventilation exceeding 24 hours were stratified into an observation group (using a 3D-printed device; $n$ = 51) and a control group (using a traditional device; $n$ = 97). The primary endpoints were tracheal tube displacement and unplanned endotracheal extubation (UEE). The incidence of endotracheal tube displacement was 1/51 (1.9%) in the observation group vs. 12/97 (12.4%) in the control group (odds ratio [OR]: 6.28, 95% confidence interval [CI]: 1.91–21.05), yielding a 99% probability of benefit (POB). UEE incidence was 0/51 in the observation group, whereas it was 4/97 (4.1%) in the control group (OR: 5.26, 95% CI: 1.08–26.31), yielding a 98% POB. Lip PI occurred in 0/51 patients in the observation group vs. 10/97 (10.3%) patients in the control group (OR: 8.72, 95% CI: 2.11–35.98), yielding a 99% POB. The observation group exhibited significantly higher nurse satisfaction scores compared to the control group ($p = 0.015$). There were no significant differences in facial PI between the two groups. These findings suggest that the 3D-printed device reduced the incidence of tracheal tube displacement, UEE, and lip PI, while improving nurse satisfaction.

***Keywords:*** Endotracheal tube; Fixation; Pressure injury; Three-dimensional printing; Tracheal tube displacement

## 1. Introduction

Endotracheal intubation is the primary method of establishing an artificial airway in critically ill patients, providing optimal conditions for suctioning the airway and preventing aspiration.[1] Secure fixation of the orotracheal tube is critical for maintaining adequate respiratory function. Common clinical methods for securing endotracheal tubes include the use of adhesive tape, cotton straps, and commercially available fixation devices. Despite their widespread use, these methods are prone to inducing complications, such as displacement of the endotracheal tube, lip pressure injury (PI), and facial PI.[2] Displacement of the endotracheal tube by only 2 cm can result in insufficient ventilation.[3] The transportation of critically ill patients and the implementation of other intensive care technologies also pose significant threats to airway stability, requiring greater effort to maintain the correct position of the endotracheal tube.[4] In addition to endotracheal tube displacement, unplanned endotracheal extubation (UEE) frequently occurs in intensive care units (ICUs), with a reported incidence ranging from 1% to 43%.[4,5] UEE can result in a series of adverse complications, such as laryngeal injury, bronchospasm, arrhythmia, hypoxic brain injury, and death.[6] Skin injuries of the lips, head, and face are common nursing complications.[7] These complications not only increase pain in patients but also reduce their tolerance to tracheal intubation, prolong the length of hospital stay, and increase healthcare expenses.[8] With the development of three-dimensional (3D) printing technology, its application in the medical industry has expanded, enabling personalized customization.[9,10] To our knowledge, this study represents the first attempt to develop a 3D-printed tracheal tube fixator and conduct a comparative analysis with conventional methods.

Therefore, we developed a novel device using 3D printing technology, which has been authorized by the China National Intellectual Property Administration (patent No.: ZL202222274621.1). The present study evaluated the performance of this 3D-printed device in patients undergoing mechanical ventilation. We hypothesized that the 3D-printed fixation device would reduce tube displacement, UEE, and lip PI while improving nurse satisfaction.

## 2. Materials and methods

### 2.1. Study design

This single-center, prospective, non-concurrent, controlled cohort study was designed to compare the efficacy of a novel 3D-printed device (Figure 1A) with that of a traditional counterpart (Figure 1B) in critically ill adult patients requiring intubation and mechanical ventilation for a minimum duration of 24 hours. It is important to note that the fixation device used in this study serves solely as an external stabilizer for the intraoral segment of the endotracheal tube. The device has minimal contact with the mucosal surface and does not enter or interact with deeper tissues. All endotracheal tubes used in this study were standard commercially available products (Wellead, China) approved by the National Medical Products Administration and inserted via the oropharyngeal route. This study was approved by the Institutional Review Board of the Shanghai Ninth People's Hospital, School of Medicine, Shanghai Jiaotong University (No. SH9H-2023-T119-2). The trial was registered in the Research Registry (ID: 11697).

### 2.2. Study participants

Patients admitted to the ICU of the participating hospital between January 2023 and June 2023, who needed endotracheal intubation and met all predefined inclusion criteria, were enrolled in the present study. The enrolled patients were allocated to two groups according to their admission time. Patients admitted between January and March 2023 were included in the control group and treated using traditional fixation methods (Figure 1D), while those admitted between April and June 2023 were included in the experimental group and fitted with the 3D-printed fixation device (Figure 1C). Both groups of patients had their fixation devices replaced routinely, with each operation performed by nurses who had worked in the department for more than 2 years. Suctioning of sputum and oral secretions was performed as needed for patients in both groups.

Inclusion criteria included (i) patients aged 18 years and above; (ii) patients who underwent tracheal intubation; and (iii) patients who signed informed consent forms, either personally or via their family members.

The exclusion criteria were (i) patients who had undergone endotracheal intubation for more than 12 hours prior to ICU admission; (ii) patients with a history of skin or oral mucosal diseases; (iii) patients who had undergone nasotracheal intubation; (iv) patients who were allergic to adhesive tape; and (v) patients with a history of mental disorders who were unable to cooperate.

The withdrawal criteria were (i) patients who underwent mechanical ventilation for <24 hours; (ii) patients who abandoned the treatment during the trial; and (iii) patients or family members who voluntarily requested withdrawal during the trial.

### 2.3. Finite element analysis

The 3D structural design file of the tracheal tube fixation device was first exported in X-T format, then imported

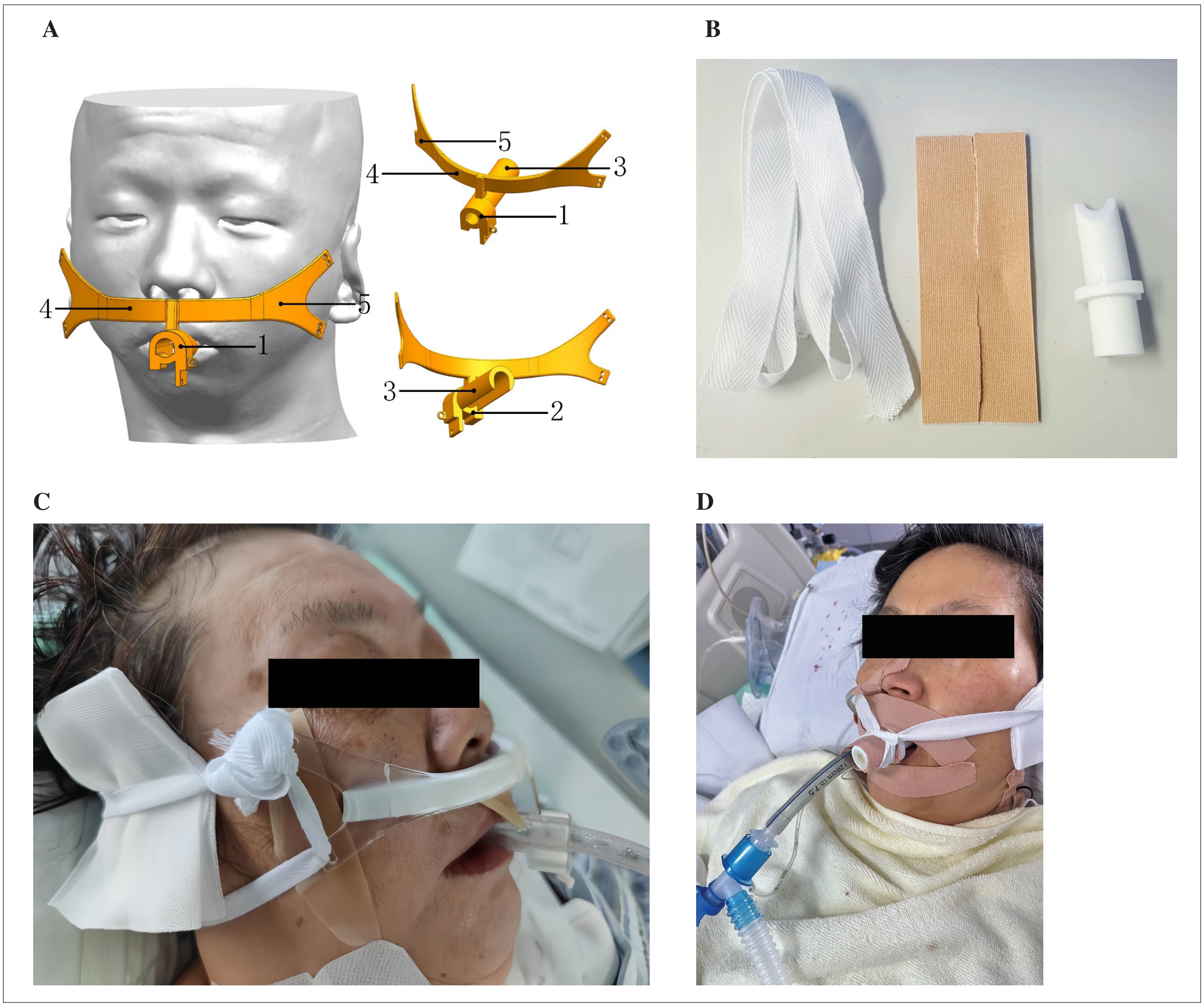


**Figure 1.** Design and application examples of the 3D-printed fixator and traditional fixation method. (A) Schematic diagram of the 3D-printed endotracheal tube fixation device. The number 1 refers to the upper limit stop; 2 refers to the lower limit stop; 3 refers to the tooth pad; 4 refers to the curved bend section; and 5 refers to the branch section. (B) Schematic diagram of the traditional endotracheal tube fixation device. (C) Patient wearing the 3D-printed endotracheal tube fixation device. (D) Patient wearing the conventional endotracheal tube fixation device.

into ANSYS Workbench 19.2 software for subsequent simulations. The material was defined as Clear 10, a photosensitive resin, with the parameters summarized in Table 1.

Automatic meshing was applied to generate the finite element mesh. In the boundary condition settings, the strap holes at both ends of the bracket were defined as "fixed supports," while loads were applied upward, downward, and laterally to the inner walls of the circular holes to simulate stresses exerted by the human body. For mesh-independence testing, a load of 2 N was used. For mechanical performance evaluation, a clinically relevant load of 5 N was applied.

### 2.4. Facial parameters data collection

The patients' facial parameters were measured, including the distance from the philtrum to the bottom of the chin (H), the distance between the left and right wisdom teeth (D), and the acute angle of the face in the supine position (a) to establish the curve of the retainer. One-third of the distance from the incisors to the mandibular angle was measured to determine the mouthpiece length. The collected facial parameter data were provided to a 3D printing technician for digital modeling of the fixation device.

### 2.5. Three-dimensional modeling

The patients' computed tomography scan DICOM images were imported into Mimics Research 19.0 (Materialise,

**Table 1. Finite element mechanical analysis parameters for tracheal tube fixation devices**

| Category | Value | Unit |
|---|---|---|
| Young's modulus | 2880 | MPa |
| Poisson ratio | 0.4 | - |
| Bending strength | 84 | MPa |
| Tensile strength | 56 | MPa |

Belgium) software to reconstruct a 3D model of the patients' lips and cheeks. The model was then calculated and exported in STL format for modeling.

### 2.6. Three-dimensional printing

Clear 10 resin (Uniontech, China) was selected as the printing material, and the splint thickness was set to 3.5 mm. Magics 24.0 (Materialise, Belgium) was used for slicing, with a layer thickness of 0.1 mm. Finally, the file was imported into a 3D printer (Uniontech, China), and the device was printed. Auxiliary materials, such as pads and straps, were then added to complete the production.

### 2.7. Device usage

After completing the endotracheal intubation, the tube was slid into the U-shaped groove of the fixator until it reached the space between the upper and lower incisors. The lower limit stop was inserted to secure the endotracheal tube in place. The securing strap was passed through a small opening at the other end of the fixator, wrapped around the patient's occipital region and neck, and tied securely in place (Figure 2A & B).

### 2.8. Patients' data collection

A comprehensive dataset was collected, including the following variables: age, sex, height, weight, Acute Physiology and Chronic Health Evaluation II score, ethnicity, duration of mechanical ventilation, patient complications, and clinical recovery status. The aforementioned data were retrieved from the hospital's electronic case management system. The research procedure is illustrated in Figure 3.

### 2.9. Study outcomes

The primary outcomes were tracheal tube displacement and UEE. Tracheal tube displacement was defined as tube dislodgement or a positional change exceeding 1.5 cm[11];

The secondary outcomes were (i) the incidence of endotracheal intubation-related PI, which was assessed by evaluating the integrity of the oral mucosa, tongue, and facial/cranial skin and confirmed by members of the hospital's PI prevention team; (ii) mechanical ventilation duration; and (iii) the satisfaction of the nursing staff. Based on a literature review and expert consultations, a questionnaire was designed to assess nurses' satisfaction with the two fixation methods. The Cronbach's α coefficient of the questionnaire was 0.942, and the overall content validity index was 0.979. The questionnaire encompassed six dimensions: fixation stability, operational convenience, hygiene condition, aesthetic appearance,

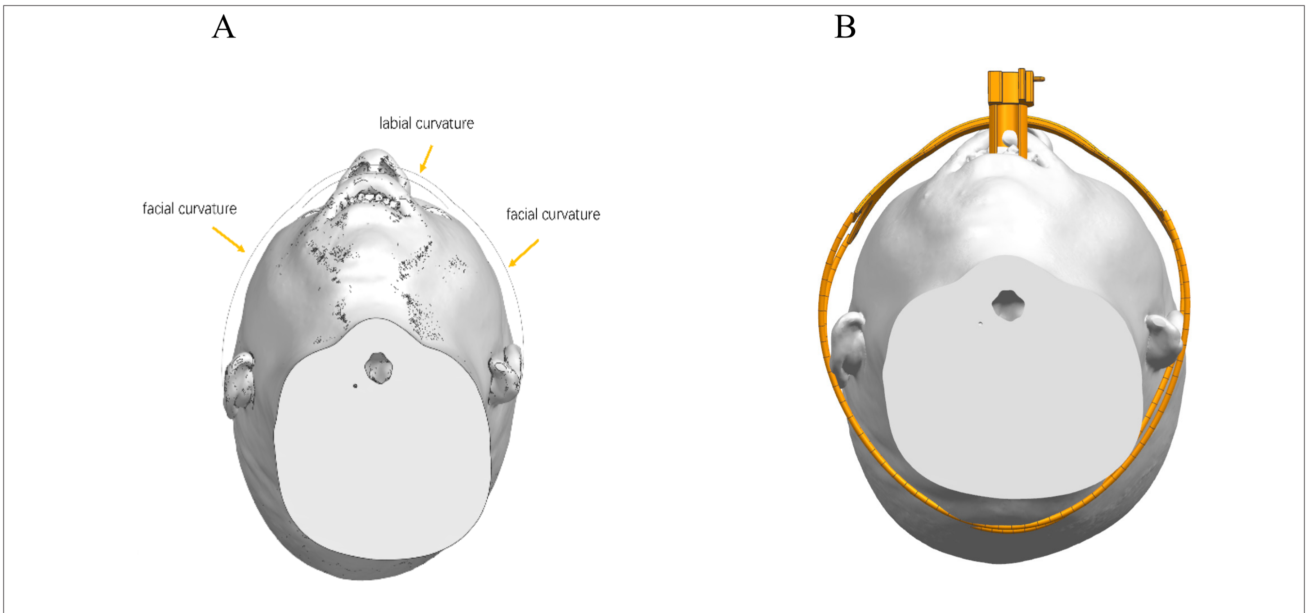


**Figure 2.** Curvature characteristics and design scheme of the wearable 3D-printed tracheal tube fixation device. (A) Wearable device curvature. (B) Design scheme.

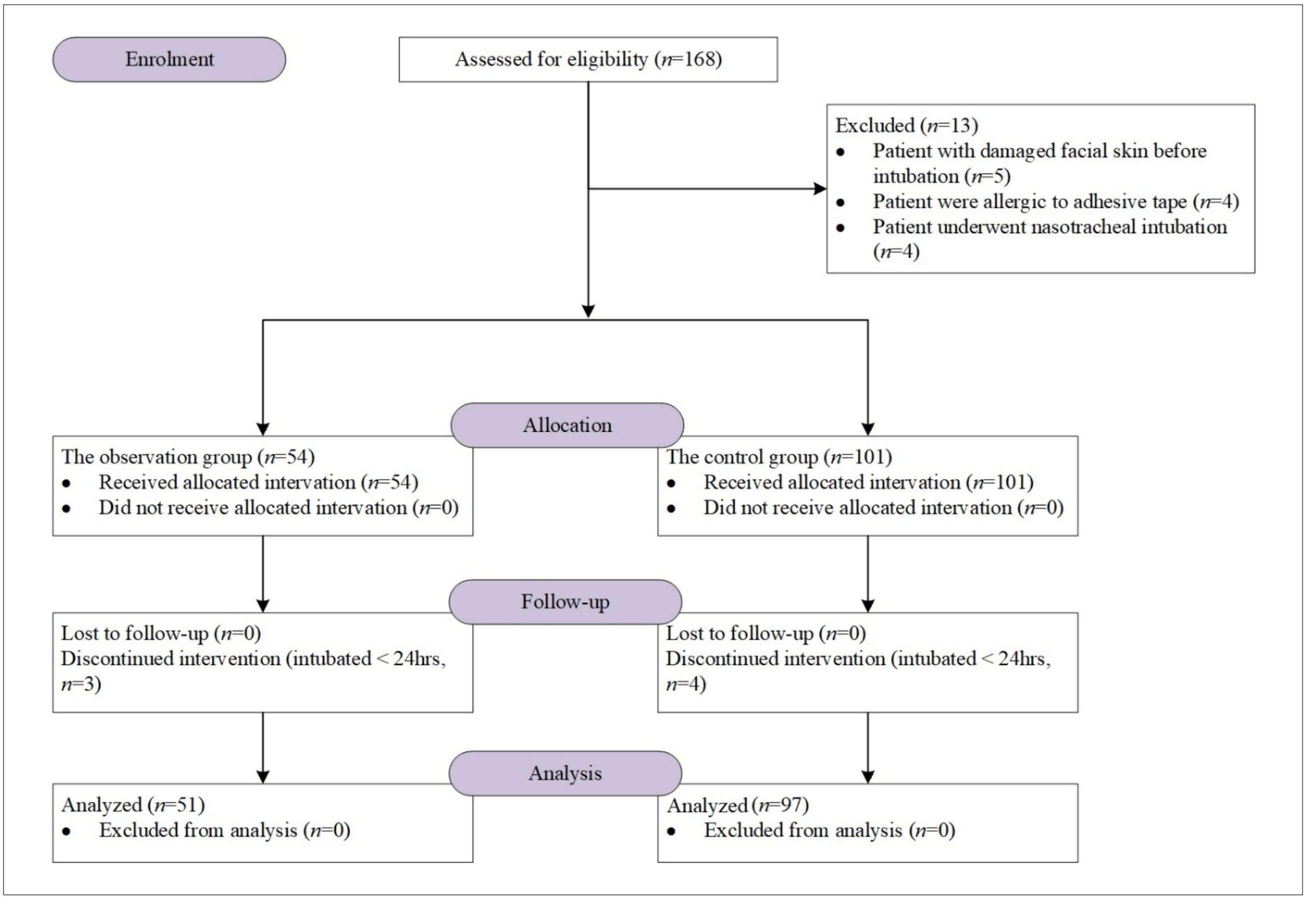


**Figure 3.** Flow diagram of enrolment and randomization of patients

adjustment frequency, and degree of interference with other operations. A five-point Likert scale was adopted for satisfaction scoring, where "Strongly Satisfied" was scored 5, "Satisfied" as 4, "Neutral" as 3, "Dissatisfied" as 2, and "Strongly Dissatisfied" as 1. Higher scores indicate greater satisfaction (Table S1).

### 2.10. Statistical analysis

Continuous variables were first tested for normality using the Shapiro–Wilk test. Variables following a normal distribution were presented as mean ± standard deviation (SD), whereas those with a non-normal distribution were expressed as median (interquartile range). Between-group comparisons of continuous variables were performed using an independent sample *t*-test for normally distributed data or a Mann–Whitney *U* test for non-normally distributed data. Categorical variables were summarized as counts (percentages). The Pearson's $\chi^2$ test was used for intergroup comparisons when the expected frequency of all cells in the contingency table was ≥5; otherwise, Fisher's exact test was applied to avoid statistical bias caused by sparse data. Bayesian logistic regression models were constructed to analyze the primary outcomes (tracheal tube displacement & UEE) and secondary categorical outcomes (lip/facial PIs). A non-informative prior distribution (normal distribution: mean=0, SD = 1.645) was adopted to minimize prior influence on the results. Posterior odds ratios (ORs) and their corresponding 95% confidence intervals (CIs) were estimated to quantify the effect size. The posterior probability of benefit (POB) was defined as the percentage of posterior samples where the OR (control group vs. observation group) exceeded 1. For the continuous secondary outcome (nurse satisfaction score), between-group comparison was conducted using the independent sample *t*-test, and the results were presented as mean ± SD. All statistical analyses were performed using R software (version 4.3.1; R Foundation for Statistical Computing, Austria). Bayesian inference was implemented using the Stan software (version 2.32.2). For frequentist statistics, statistical significance was set at a two-sided *p*-value < 0.05; for Bayesian statistics, a 95% CI was used.

## 3. Results

### 3.1. Basic characteristics of the study participants

A total of 51 patients were allocated to the observation group and 97 to the control group after applying the inclusion, exclusion, and withdrawal criteria. The two groups were well-matched in terms of baseline characteristics, with no significant between-group disparities (Table 2).

### 3.2. Finite element analysis

Under upward, lateral, and downward loading, the maximum local stresses of the fixation device were 1.258, 2.496, and 1.258 MPa, respectively, with corresponding maximum displacements of 49.6, 239.3, and 49.6 μm. Stress concentration was most pronounced under lateral loading, whereas upward and downward loading produced the lowest stress concentrations (Figure 4). In all directions, the local stresses remained below both the fracture and yield strengths, confirming the safety and reliability of the device. The maximum local deformation was 239.3 μm, which is within clinically acceptable limits and lower than the material's fracture elongation threshold (7.5%).

### 3.3. Clinical outcomes

The incidence of endotracheal tube displacement was 1.9% (1/51) in the observation group, as compared with 12.4% (12/97) in the control group. Utilizing a neutral prior probability, the OR was 6.28 (95% CI: 1.91–21.05), and the corresponding probability of clinical benefit was determined to be 99%. UEE incidence was 0% (0/51) in the observation group, whereas it was 4.1% (4/97) in the control group. The OR was estimated to be 5.26 (95% CI: 1.08–26.31), yielding a POB of 98% (Table 3).

No lip PI occurred in the observation group, whereas 10 out of 97 patients (10.3%) in the control group developed this complication. The OR was estimated to be 8.72 (95% CI: 2.11–35.98), yielding a POB of 99%. The nurse satisfaction scores in the observation group were significantly higher than those in the control group, with respective values of 28.29 ± 1.49 and 22.29 ± 4.79 ($p$ = 0.015). There were no

**Table 2. Comparison of general clinical information between the two patient groups**

| Characteristic | Observation group ($n$ = 51) | Control group ($n$ = 97) | $t/\chi^2$ | $p$-value |
|---|---|---|---|---|
| Age, years (mean ± SD) | 60.73 ± 17.91 | 61.48 ± 21.38 | 0.17 | 0.87 |
| Male sex | 33 (64.7) | 67 (69.1) | 0.29 | 0.59 |
| Body mass index, kg/m$^2$ (mean ± SD) | 23.39 ± 4.78 | 22.55 ± 6.42 | −0.82 | 0.42 |
| APACHE II (mean ± SD) | 13.91 ± 6.55 | 14.39 ± 4.99 | 0.46 | 0.64 |
| Braden score (mean ± SD) | 12.08 ± 3.59 | 11.26 ± 1.56 | 0.35 | 0.93 |
| RASS score (mean ± SD) | 1.06 ± 0.66 | −0.57 ± 0.26 | 1.80 | 0.07 |
| Physical restraint | 50 (98) | 89 (91.7) | 2.31 | 0.13 |
| Duration of mechanical ventilation, hours (mean ± SD) | 44.57 ± 28.12 | 40.46 ± 34.19 | −0.74 | 0.46 |
| Indication for intubation | | | 0.23 | 0.89 |
| Postoperative transfer | 40 (78.4) | 77 (79.4) | | |
| Hemodynamic instability | 3 (5.8) | 4 (4.1) | | |
| Respiratory failure | 8 (15.7) | 16 (16.5) | | |
| Comorbidities | | | | |
| Smoking | 15 (29.4) | 25 (25.7) | 0.07 | 0.78 |
| Alcohol addiction | 11 (21.5) | 16 (16.5) | 0.28 | 0.59 |
| Heart disease | 9 (17.6) | 17 (17.5) | 0.00 | 1.00 |
| Diabetes mellitus | 8 (18.6) | 18 (18.5) | 0.04 | 0.83 |
| End-stage renal disease | 2 (3.9) | 3 (3.1) | 0.00 | 1.00 |
| Cancer | 7 (12.3) | 12 (12.4) | 0.00 | 1.00 |
| Admission type | | | 0.00 | 1.00 |
| Medical | 5 (9.8) | 9 (9.3) | | |
| Surgical | 46 (90.2) | 88 (90.7) | | |

Note: Data presented as $n$ (%), unless stated otherwise.
Abbreviations: APACHE: Acute Physiology and Chronic Health Evaluation; RASS: Richmond Agitation-Sedation Scale; SD: standard deviation.

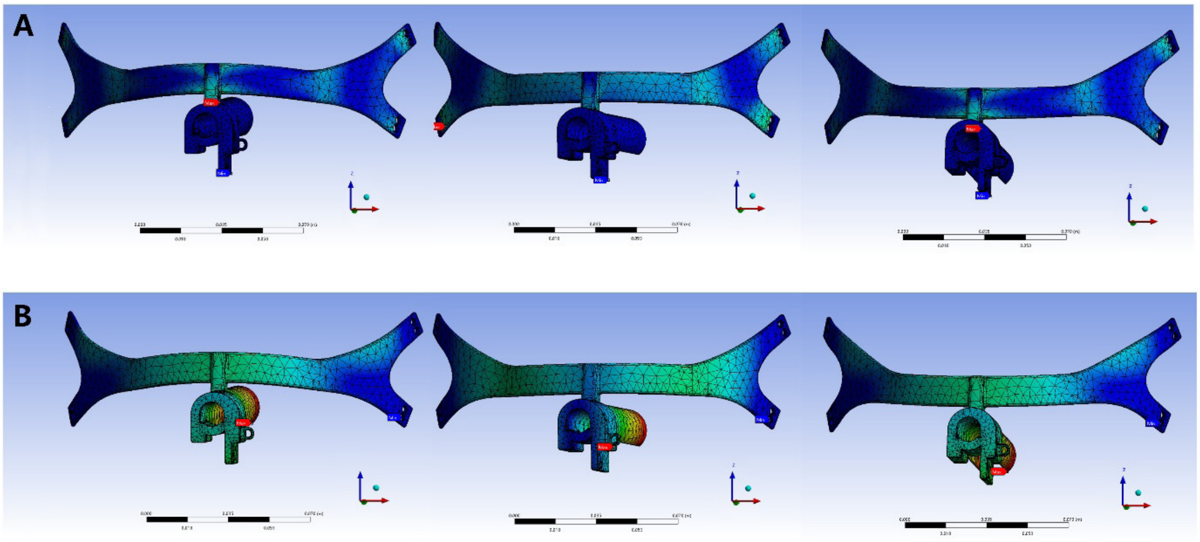


**Figure 4**. Finite element simulation verification of the mechanical properties of the suspended tracheal tube fixator. (A) Local stress distributions. (B) Local displacement distributions.

**Table 3. Clinical outcomes of the two groups**

| Outcomes | No./total no. (%) | No./total no. (%) | Posterior probability of benefit (%) | Posterior OR (95% CI) |
|---|---|---|---|---|
| | Group 1 ($n$=97) | Group 2 ($n$=51) | | |
| Endotracheal tube displacement | 12/97 (12.4) | 1/51 (1.9) | 99 | 6.28 (1.91–21.05) |
| UEE | 4/97 (4.1) | 0/51 (0.0) | 98 | 5.26 (1.08–26.31) |
| Lip pressure injuries | 10/97 (10.3) | 0/51 (0.0) | 99 | 8.72 (2.11–35.98) |
| Facial pressure injuries | 6/97 (6.2) | 2/51 (3.9) | 68 | 1.58 (0.54–4.59) |

Abbreviations: CI: confidence interval; OR: odds ratio; UEE: unplanned endotracheal extubation.

significant between-group differences in the occurrence of facial PIs (**Table 3**).

## 4. Discussion

This study is the first to utilize 3D printing technology in the design and manufacture of tracheal intubation fixators. Our findings revealed that the observation group exhibited a significantly lower incidence of endotracheal tube displacement, UEE, and a marked reduction in lip PI incidence relative to the control group. In contrast, the incidences of facial PI did not differ significantly between the two groups. Furthermore, nurse satisfaction scores were significantly higher in the observation group.

The present study emphasizes the significance of structural strength in maintaining the functional stability and safety of tracheal tube fixation devices.[12] The proposed adjustable retaining clip, incorporating an indentation to fully encircle the tube, was shown to effectively redistribute mechanical loads and mitigate stress concentrations arising from multidirectional displacement. This structural optimization substantially reduced the risk of severe local deformation or fracture of adjacent components, thereby enhancing overall device safety. Finite element mechanical simulation further confirmed that, even under tensile forces equivalent to a 500 g weight, the U-shaped fixation groove exhibited a maximum displacement of only 0.13 mm. This minimal deformation is well within clinically acceptable thresholds, underscoring the device's ability to provide secure and reliable tracheal tube fixation. Collectively, these findings suggest that the optimized design not only meets clinical performance requirements but also offers a practical solution to improving fixation stability and reducing complications associated with tracheal intubation.

Biomechanical analysis provides evidence supporting the optimization of fixation methods for endotracheal intubation. The force required for endotracheal tube displacement and UEE varies with changes in fixation methods and the angle at which the force is applied. Previous studies compared the extubation force required during UEE across seven common fixation methods and found that an integrated system offered the best overall performance in terms of fixation.[4,13] This study focused on an integrated endotracheal tube fixation system that combined a perioral fixation device with a bite block. This increases the force required for extubation and ensures optimal fixation performance. Additionally, its design effectively reduces pressure on the patient's lips, minimizes the risk of pressure ulcers, and enhances patient comfort. It also facilitates oral care procedures for critically ill patients performed by clinical nurses, thereby improving nurse satisfaction ($p = 0.015$).

3D-printed tracheal tube fixation devices are more effective than traditional methods in preventing tube displacement. Incorrect tracheal tube positioning, whether too long or too short, can impair ventilation.[14] If the tube is too long, its tip may enter the right main bronchus, leading to hyperventilation of the right lung, pneumothorax, and other complications. Conversely, if the tube is too short, unplanned extubation may occur, resulting in prolonged mechanical ventilation, airway mucosa damage, increased care requirements for chronic conditions, higher medical costs, and potential complications such as bronchospasm, aspiration pneumonia, arrhythmia, or death.[15] Reducing the incidence of unplanned extubation has become an urgent issue in clinical practice and has been designated as a nursing-sensitive quality indicator.[16] In this study, the bite portion of the 3D-printed tracheal tube retainer enveloped the tracheal tube, reducing the pressure on the lips, gums, and tongue surface. This design effectively prevented patients from dislodging the tube with their tongues, and edentulous patients did not experience movement of the tracheal tube as the dental pad moved up and down. Furthermore, wide fixation straps were wrapped around the occipital and cervical regions to provide stable fixation. The results of this study indicate that the 3D-printed tracheal tube fixation device effectively reduced the incidence of tracheal tube displacement. The device demonstrated superior fixation efficacy compared with the control group.

Compared with traditional methods, 3D-printed tracheal tube fixation devices resulted in fewer lip PIs. From a mechanical standpoint, patients receiving ventilation are at high risk of developing lip PI.[17] In clinical practice, inappropriate fixation methods can subject the lips and surrounding skin to pressure, friction, and shear forces from the tube and adhesive tape. Additionally, because tracheal tubes are inserted through the mouth, patients often have their mouths continuously open, leading to increased oral secretions.[18] The lip mucosa and surrounding areas are frequently exposed to moisture, impaired blood circulation, prolonged ischemia, hypoxia, and malnutrition, which can result in lip PI. Furthermore, dental pads are often used to assist with fixation after tracheal intubation.[19] Lip pressure ulcers are easily overlooked, regardless of the medical procedure in which dental pads are used. The occurrence of lip pressure ulcers increases patient discomfort and reduces tolerance to tracheal intubation, which is detrimental to the recovery process. Our device has a suspended design that effectively reduces the contact pressure between the lips and the surrounding area. Its integrated design facilitates oral care and suction of oral secretions. In this study, none of the 51 patients in the observation group developed lip pressure ulcers, demonstrating a statistically significant advantage over the control group in preventing them.

The personalized advantages of the 3D-printed fixation device may offer specific benefits for patient populations at higher risk of inadequate tube stabilization or device-related PIs when using conventional fixation methods. Edentulous patients represent a notable subgroup in whom traditional adhesive or bite–block-based devices often fail to achieve secure anchorage due to reduced oral structural support and altered perioral tissue tension. In this population, the absence of dentition increases the likelihood of tube malposition and focal soft-tissue compression. The ability of our device to conform precisely to the patient's maxillofacial contour, as derived from computed tomography imaging, ensures a stable and evenly distributed contact surface, thereby potentially lowering displacement risk while minimizing mucosal loading. Similarly, patients with congenital or acquired facial deformities—such as mandibular defects, maxillofacial asymmetry, post-traumatic abnormalities, or postoperative reconstructive changes—pose a challenge for standardized fixation systems designed for typical craniofacial geometries. Poor fit in these individuals may not only compromise fixation security but also predispose them to high-pressure points and ulceration. Our results support that personalized design can overcome these anatomical limitations by enabling device geometry to mirror patient-specific surface morphology. This tailored fit likely contributed to the observed reduction in lip PIs in the present study and may be even more impactful among patients with distorted soft-tissue contours. Furthermore, critically ill populations with fragile skin, severe cachexia, or long-term mechanical ventilation may also benefit from the improved pressure distribution enabled by individualized support structures. Although our cohort did not specifically stratify these subgroups due to sample size limitations, future studies with targeted enrolment of edentulous patients, those with facial deformities, or patients with impaired tissue integrity are warranted to further clarify the magnitude of benefit. Overall, the personalized nature of the 3D-printed fixation device represents a promising approach to addressing anatomical variability, which has long limited the performance of conventional fixation techniques.

This study had some limitations, including its non-randomized controlled design, single-center nature, and relatively small sample size—factors that may introduce potential bias into the findings. First, selection bias is inherently associated with the non-randomized design, and unmeasured or residual confounding factors cannot be completely mitigated. Second, the non-random assignment precludes the establishment of definitive causal relationships between the intervention (a personalized transoral endotracheal tube fixation device) and primary outcomes. Our findings therefore reflect associative rather than causal links, and their generalizability to broader clinical populations may be constrained. Notably, because the proposed personalized transoral endotracheal tube fixation device represents a novel concept, no comparable customized fixation devices have been reported in the literature to date, rendering the establishment of a parallel control group for direct comparison infeasible. Accordingly, our mechanical simulation experiments primarily evaluated deformation characteristics to demonstrate the device's clinical safety under external mechanical perturbations and its efficacy in preventing deformation-induced tube displacement. Multicenter prospective studies are warranted to further advance the understanding of 3D-printed devices for mechanically ventilated patients. Future research should explore the integration of sensors into 3D-printed fixation devices, which would facilitate real-time monitoring of skin integrity and blood perfusion, with the potential to reduce the incidence of endotracheal intubation-related PIs.

## 5. Conclusion

This study incorporated 3D printing technology into the development of a tracheal intubation fixation device, enabling precise, personalized design to enhance patient safety in artificial airways and reduce the incidence of adverse complications, especially lip PI, thereby demonstrating the effective integration of medicine and 3D printing technology.


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## Conflict of interest

Yongqiang Hao serves as the Editorial Board Member of the journal, but did not in any way involve in the editorial and peer-review process conducted for this paper, directly or indirectly. Other authors declare they have no competing interests.

## Author contributions

*Conceptualization*: Guihua Hao, Yongqiang Hao
*Formal analysis:* Tian Xie
*Investigation:* Yu Guo, Yayuan Tian
*Methodology:* Dinghao Luo, Yu Guo
*Visualization:* Dinghao Luo, Yongqiang Hao
*Writing – original draft:* Guihua Hao
*Writing – review & editing:* Yu Guo, Jingjing Dai, Dinghao Luo, Lili Hou, Yongqiang Hao
All authors read and approved the final version of the manuscript.

## Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki and was approved by the Medical Ethics Committee of the Ninth People's Hospital, Shanghai Jiao Tong University School of Medicine (No. SH9H-2023-T119-2). All patients have signed the written informed consent form.

## Consent for publication

Patients provided informed consent for the publication of the image.

## Availability of data

All data analyzed have been presented in the paper.

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