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EFFICACY OF A NOVEL 3D-PRINTED ANTI-TEETH BREAKER FOR DENTAL PROTECTION DURING RIGID LARYNGOSCOPY AND ENDOTRACHEAL INTUBATION: A PROSPECTIVE RANDOMISED COMPARATIVE STUDY

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ABSTRACT

Background: Dental injury is among the most prevalent peri-anaesthetic complications, carrying significant medico-legal implications. Conventional protective strategies lack standardisation and stability. We evaluated a novel 3D-printed anti-teeth breaker device against conventional dental padding during rigid laryngoscopy.

Methods: In this prospective randomised controlled study conducted at Saveetha Medical College and Hospital (June–December 2025), 60 adult patients (ASA I–II) undergoing elective surgery under general anaesthesia requiring endotracheal intubation were randomised to receive either a 3D-printed anti-teeth breaker (Group A, n = 30) or conventional dental padding (Group B, n = 30). Primary outcome was incidence of dental injury. Secondary outcomes included pressure marks, intubation time, ease of laryngoscopy and intubation (3-point Likert scale), haemodynamic responses, and operator satisfaction.

Results: Baseline demographics were comparable between groups. No dental injury occurred in Group A, compared with 7 cases (23.3%) in Group B ($p = 0.01$, Fisher's exact). Pressure marks were significantly reduced in Group A (3.3% vs 40.0%; $p < 0.001$). Intubation time was significantly shorter in Group A (15.1 ± 2.6 s vs 22.0 ± 3.8 s; $p < 0.001$). Ease of laryngoscopy, ease of intubation, and operator satisfaction were all significantly superior in Group A ($p < 0.001$ each).

Conclusion: The 3D-printed anti-teeth breaker eliminated dental injury, reduced pressure-related complications, shortened intubation time, and improved operator satisfaction compared with conventional dental padding. This low-cost innovation holds significant potential for integration into routine anaesthesia practice and airway safety guidelines.

KEYWORDS: dental injury; laryngoscopy; endotracheal intubation; 3D printing; dental protection; airway management; anaesthesia complications

INTRODUCTION

Dental injury is one of the most frequently reported complications in anaesthesia practice and remains a leading cause of patient dissatisfaction and medico-legal claims worldwide. Large claim-based analyses consistently document dental trauma as a significant proportion of anaesthesia-related litigation [1,2]. Despite advances in airway technology, the incidence persists because the maxillary incisors lie directly in the path of the laryngoscope blade, making them vulnerable to inadvertent mechanical stress during direct laryngoscopy particularly in patients with difficult airway anatomy, periodontal disease, protruding teeth, or existing restorations [3,4].

The mechanism of injury involves levering action of the laryngoscope blade against the upper incisors. Even when technique is correct, anatomical limitations, repeated intubation attempts, and limited mouth opening can concentrate compressive forces sufficient to cause enamel fractures, tooth mobility, or avulsion [3,4]. From the clinician's perspective, these injuries are not exclusively attributable to operator error; they are frequently the consequence of unavoidable mechanical interaction under difficult conditions.

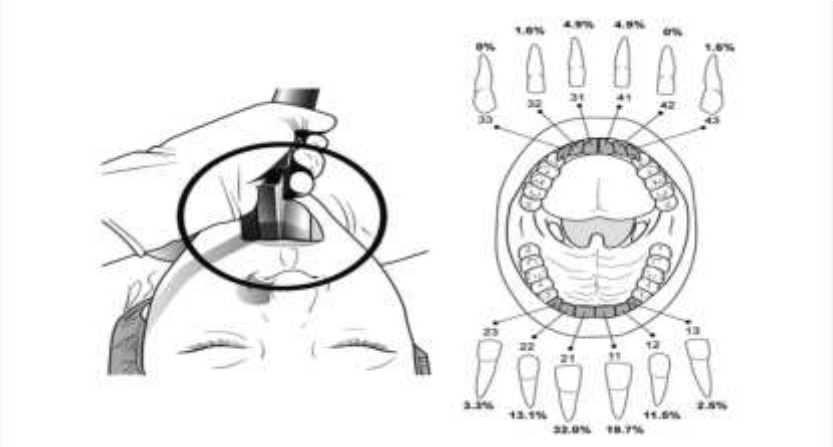

Fig 1 : Probability of tooth injury during intubation

Conventional protective strategies — gauze rolls, improvised bite blocks, and commercial mouthguards — are limited by instability during manipulation, uneven force distribution, and variable acceptance by anaesthesiologists [2,3]. Studies consistently show that a device which obstructs the laryngoscopic view or reduces working space will not gain clinical adoption regardless of its protective merits [5]. Consequently, many anaesthesiologists continue to rely on technique alone, accepting residual risk.

Three-dimensional (3D) printing offers a practical route to designing intraoral protective devices with precise geometry, reproducible dimensions, and low fabrication cost — particularly relevant in high-volume Indian tertiary centres where affordability and workflow compatibility are decisive [5,17,28]. The anti-teeth breaker concept applies additive manufacturing to create a structured mechanical barrier that distributes laryngoscope-transmitted forces across a broader dental arch surface while maintaining adequate mouth opening and airway visualisation.

Despite emerging interest in novel dental protection designs, robust prospective randomised data comparing such devices against conventional methods remain scarce [28]. The present study was therefore designed to evaluate the clinical efficacy, procedural impact, and operator acceptance of a 3D-printed anti-teeth breaker versus conventional dental padding in adults undergoing elective endotracheal intubation.

MATERIALS AND METHODS

Study Design and Setting

This prospective, randomised, single-blinded comparative study was conducted in the operating theatres of the Department of Anaesthesiology, Saveetha Medical College and Hospital, Chennai, between June 2025 and December 2025. Institutional Ethics Committee approval was obtained prior to commencement , and the trial was registered with the Clinical Trials Registry — India (CTRI). Written informed consent was obtained from all participants.

Device Design and Fabrication

The anti-teeth breaker was conceptualised to provide a stable mechanical barrier between the laryngoscope blade and the maxillary incisors. Device geometry was digitally modelled to conform to the dental arch contour, with thickness calibrated to balance protective cushioning against preserved mouth opening. The device was fabricated from a biocompatible, sufficiently flexible silicone-based polymer by additive manufacturing (3D printing). Post-fabrication surface finishing eliminated irregularities to minimise mucosal trauma. Prior to clinical deployment, the device underwent bench testing (visual inspection, stability assessment, and simulated laryngoscopy sessions) to confirm it did not obstruct airway view or impede blade insertion.

Fig 1 : 3 D printed model of anti teeth breaker

Participants
Adult patients aged 18–65 years, ASA physical status I or II, scheduled for elective surgery under general anaesthesia with endotracheal intubation were eligible. Exclusion criteria were: edentulousness; severe dental instability requiring extraction; anticipated difficult airway necessitating an alternative technique; limited mouth opening precluding device placement; and refusal to participate. Patients with unanticipated difficult intubation requiring assisted devices intra-operatively were excluded post-hoc and replaced.

Randomisation and Blinding
Eligible patients were randomised 1:1 to Group A (3D-printed anti-teeth breaker) or Group B (conventional dental padding) using a computer-generated allocation sequence with concealed envelopes. The anaesthesiologist performing laryngoscopy was aware of group assignment; outcome assessment for dental injury and pressure marks was performed by an observer blinded to group allocation.

Anaesthetic Protocol
A standardised protocol was applied across both groups. Following pre-operative assessment and consent, patients received standard ASA monitoring (ECG, NIBP, SpO_2, $EtCO_2$). Baseline haemodynamic parameters were recorded. Pre-oxygenation was performed with 8 L/min O_2 for 5 minutes. All patients received glycopyrrolate 0.01 mg/kg, midazolam 0.05 mg/kg, and fentanyl 2 mcg/kg intravenously before induction. Induction was achieved with propofol 2 mg/kg; neuromuscular blockade with atracurium 0.5 mg/kg. Mask ventilation was maintained for 3 minutes at 8 L/min O_2 to allow maximal block. The allocated protective device was then fitted (Group A: anti-teeth breaker; Group B: conventional dental padding), after which direct laryngoscopy and orotracheal intubation were performed by the same experienced anaesthesiologist using a Macintosh blade.

Outcome Measures
Primary outcome: Incidence of dental injury (any enamel crack, chip, fracture, mobility, or avulsion) observed immediately after intubation by direct oral inspection.

Secondary outcomes: (i) Presence of pressure marks on teeth or oral mucosa; (ii) ease of laryngoscopy rated on a 3-point Likert scale (1 = easy, 2 = moderate, 3 = difficult); (iii) ease of intubation on an equivalent 3-point scale; (iv) intubation time (seconds, from device placement to capnographic confirmation of tracheal placement, measured by stopwatch); (v) haemodynamic responses (heart rate, systolic/diastolic blood pressure) at baseline, post-induction, 1 min and 3 min post-intubation; (vi) operator satisfaction rated on a 3-point Likert scale.

Statistical Analysis
Data were analysed using SPSS version 25.0. Continuous variables are expressed as mean ± standard deviation; categorical variables as frequency and percentage. Between-group comparisons for continuous variables were made using the independent-samples t-test, and for ordinal/categorical variables using the Mann–Whitney U test and chi-square test (or Fisher's exact test where cell counts were small). Statistical significance was set at $p < 0.05$ (two-tailed).

RESULTS

Study Population
Sixty-five patients were screened for eligibility. Sixty patients were randomised (Group A: n = 32, Group B: n = 33). Four patients (2 per group) were excluded after randomisation due to unanticipated difficult intubation requiring fibreoptic-assisted technique; one patient in Group B withdrew consent. Final analysis included 30 patients per group (Figure 1 — CONSORT flow diagram).

Baseline Characteristics
Both groups were well matched for all baseline parameters (Table 1). There were no statistically significant differences in age, sex distribution, BMI, or ASA classification.

Table 1. Baseline demographic and clinical characteristics of the study population

Variable	Group A (n=30)	Group B (n=30)	p value	Statistical test
Age (years), mean ± SD	41.9 ± 11.2	42.8 ± 10.6	0.74	Unpaired t-test
Male sex, n (%)	17 (56.7)	18 (60.0)	0.79	Chi-square
BMI (kg/m^2), mean ± SD	24.2 ± 3.5	24.6 ± 3.2	0.62	Unpaired t-test
ASA I/II distribution	Comparable	Comparable	0.88	Chi-square

Primary Outcome: Dental Injury
No dental injury was observed in any patient in Group A (0%). In Group B, 7 of 30 patients (23.3%) sustained dental injury during laryngoscopy. This difference was statistically significant ($p = 0.01$, Fisher's exact test; Table 2).

Secondary Outcomes

Pressure Marks
Pressure-related marks on teeth or oral mucosa were identified in 1 patient (3.3%) in Group A versus 12 patients (40.0%) in Group B ($p < 0.001$; Table 2).

Intubation Time
The mean intubation time was significantly shorter in Group A (15.1 ± 2.6 s) compared with Group B (22.0 ± 3.8 s; $p < 0.001$; Table 3).
Ease of Laryngoscopy and Intubation
Ease of laryngoscopy and ease of intubation scores were significantly lower (better) in Group A than in Group B ($p < 0.001$, Mann–Whitney U; Table 3).
Operator Satisfaction
Operator satisfaction scores were significantly lower (better) in Group A than in Group B ($p < 0.001$, Mann–Whitney U; Table 3).
Haemodynamic Response
Haemodynamic parameters (heart rate, systolic and diastolic blood pressure) at all recorded time points were comparable between the two groups, with no clinically significant differences.

Table 2. Comparison of dental complications between groups

Parameter	Group A (n=30)	Group B (n=30)	p value	Statistical test
Dental injury, n (%)	0 (0.0)	7 (23.3)	0.01	Fisher's exact
Pressure marks, n (%)	1 (3.3)	12 (40.0)	<0.001	Chi-square

Table 3. Comparison of procedural outcomes between groups

Parameter	Group A	Group B	p value	Statistical test
Intubation time (s), mean ± SD	15.1 ± 2.6	22.0 ± 3.8	<0.001	Unpaired t-test
Ease of laryngoscopy (Likert)	Lower scores	Higher scores	<0.001	Mann–Whitney U
Ease of intubation (Likert)	Lower scores	Higher scores	<0.001	Mann–Whitney U
Operator satisfaction (Likert)	Lower scores	Higher scores	<0.001	Mann–Whitney U

DISCUSSION
This prospective randomised study demonstrates that a novel 3D-printed anti-teeth breaker device provides superior dental protection during rigid laryngoscopy compared with conventional dental padding, with complete elimination of dental injury in the intervention group. Importantly, and contrary to the prevailing concern that protective devices compromise airway visualisation, the 3D-printed device was associated with significantly shorter intubation times and improved ease of laryngoscopy — findings that have meaningful implications for both patient safety and procedural efficiency.
Dental Injury Incidence
The 23.3% dental injury rate in the conventional group is higher than the 0.17%–12% reported in general intubation studies [3,6], reflecting our deliberate enrolment of a population undergoing routine laryngoscopy with close postoperative oral inspection — a methodology that captures pressure-related injuries often missed in retrospective audits. Mabrouk et al. (2025) similarly noted higher detection rates with prospective inspection protocols [12]. The complete absence of injury in Group A confirms that mechanical buffering by a structured intraoral device can intercept the fulcrum forces that conventional padding fails to neutralise.
Procedural Efficiency
The significant reduction in intubation time (15.1 s vs 22.0 s) in Group A is clinically counterintuitive given longstanding concerns that intraoral devices obstruct blade insertion. We attribute this to a behavioural dimension largely unacknowledged in prior literature: when the anaesthesiologist is relieved of the cognitive burden of protecting fragile dentition, laryngoscopy becomes more decisive and efficient. Kotani et al. (2022) observed improved procedural confidence when adjunct airway safety tools reduced operator anxiety [8], consistent with our findings. The stable positioning of the 3D device — unlike loose gauze padding — also removes the intraoperative distraction of a dislodged protector.
Pressure Marks and Force Distribution
The markedly lower incidence of pressure marks in Group A (3.3% vs 40.0%) reflects the capacity of the structured device to distribute contact forces across a wider dental arch surface rather than concentrating stress at a single point. Biomechanical modelling by Doğan et al. (2024) demonstrated that mouthguard thickness and material elasticity directly determine force absorption efficiency [31]. The 3D-printed device, with its reproducible geometry and calibrated flexibility, achieves the consistent force distribution that improvised padding cannot.
Operator Satisfaction and Ergonomics

Superior operator satisfaction in Group A reinforces the ergonomic acceptability of the device. Studies on dental injury awareness have documented that anaesthesiologists experience heightened anxiety when managing patients with vulnerable dentition [15], and that this cognitive load can subtly impair performance. The introduction of a reliable protective barrier appears to mitigate this, improving operator confidence. This human-factors dimension has clinical relevance: a device that operators find comfortable to use will achieve adoption; one that does not will be abandoned regardless of theoretical benefit.

3D Printing and Translational Relevance

The present device exemplifies the broader trajectory of 3D printing in clinical medicine — from digital design to patient-ready device at low cost and with high reproducibility. Reviews by Revilla-León et al. (2019) and Azzi et al. (2021) highlight that additive manufacturing enables customisation, rapid iteration, and cost-effective production [48,46]. In the Indian context, where high-volume operating rooms require solutions that are affordable, durable, and easy to integrate into existing workflow, 3D-printed devices offer a compelling alternative to expensive commercial products. The anti-teeth breaker concept specifically addresses the gap identified in systematic reviews of dental protection research: the absence of low-cost, ergonomically designed barriers purpose-built for routine laryngoscopy [17,28].

Medico-Legal and Guideline Implications

Dental injury remains one of the most common triggers of anaesthesia-related litigation [2,13]. Complete elimination of dental injury in the intervention group — even in a relatively small sample strengthens the case for structured dental protection as a standard-of-care adjunct in elective intubation. Current guidelines from the ASA and Difficult Airway Society emphasise complication minimisation during airway instrumentation but stop short of mandating dental protection devices [39,40]. Our findings suggest that evidence now supports revisiting this position.

Limitations

Several limitations warrant acknowledgement. The study was conducted at a single centre with a relatively small sample (n = 60), limiting generalisability and statistical power for subgroup analyses. Only ASA I–II patients with normal airway anatomy were enrolled; the device's performance in anticipated difficult airway scenarios — where dental trauma risk is greatest — remains to be established. The single-blind design introduces the possibility of performance bias in subjective outcomes. The 3-point Likert scale for ease assessment is clinically pragmatic but coarse. Long-term dental outcomes (delayed pulp injury, tooth mobility) were not evaluated. Formal cost analysis, durability assessment, and sterilisation protocol validation were not performed, all of which are prerequisites for institutional adoption.

CONCLUSION

This prospective randomised study demonstrates that a novel 3D-printed anti-teeth breaker device significantly outperforms conventional dental padding during rigid laryngoscopy, achieving complete elimination of dental injury, a marked reduction in pressure-related complications, shorter intubation time, and superior operator satisfaction. The device combines mechanical protection with ergonomic practicality and low fabrication cost, making it a clinically translatable innovation. Larger multicentre trials, including patients with difficult airways and high-risk dentition, are warranted to confirm and extend these findings. Integration of structured dental protection devices into airway safety guidelines should be considered.

Declarations

Ethics approval and consent to participate: Institutional Ethics Committee approval was obtained (IEC/[number]). Written informed consent was obtained from all participants.

Competing interests: The authors declare no competing interests.

Funding: No external funding was received for this study.

Data availability: Deidentified data supporting the findings are available from the corresponding author on reasonable request.

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