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Integrated and Device-Based Endotracheal Tube Stabilisation During General Anaesthesia: A Systematic Review and Meta-analysis

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Abstract

Background. Adhesive tape is still the usual way of holding an orotracheal tube in place during general anaesthesia. Tube migration, accidental extubation, endobronchial intubation and pressure injury to the face and lips nevertheless remain familiar hazards, and they are most likely when the patient is prone or lateral or when the head is shared with the surgical team. Commercial tube holders have been available for some years, and integrated devices that combine securement with a bite block, an eye shield or a suction port have appeared more recently. The reviews published so far deal with the intensive care unit; no one has yet synthesised the intraoperative question.

Methods. We followed PRISMA 2020. PubMed/MEDLINE, Embase, Cochrane CENTRAL, Scopus, Web of Science and CINAHL were searched from inception with no language limit, together with trial registries and the reference lists of included papers. We accepted randomised and non-randomised comparative studies of patients receiving general anaesthesia through an orotracheal tube, provided a device-based or integrated system was compared with adhesive tape or with another device. Clinically relevant intraoperative displacement was the primary outcome. We appraised randomised trials with RoB 2 and the non-randomised study with ROBINS-I, and pooled dichotomous data as odds ratios and risk ratios using DerSimonian-Laird random-effects models with the Hartung-Knapp-Sidik-Jonkman adjustment. Certainty was graded with GRADE.

Results. Six comparative operating-theatre studies were eligible. Only two, together enrolling 104 patients, reported dichotomous displacement counts that could be combined, and both favoured the device. The random-effects odds ratio was 0.05 (95% CI 0.001 to 1.49; p = 0.083) with substantial heterogeneity (I^2 = 79.4%), and the risk ratio was 0.14 (95% CI 0.01 to 2.57). Fixed-effect estimates reached significance (OR 0.12, 95% CI 0.04 to 0.39; RR 0.39, 95% CI 0.20 to 0.76), the difference reflecting a two-study model that contains a zero cell. A single trial measuring displacement continuously reported a mean difference of −3.00 mm (95% CI −5.98 to −0.02). Accidental extubation and endobronchial intubation were rare and reported inconsistently. In absolute terms 708 per 1000 with tape corresponds to 102 per 1000 with a device (95% CI 4 to 783), and the larger contributing trial had a post hoc fragility index of 1. Certainty was very low for every outcome.

Conclusions. Every study that measured tube movement found less of it with a device than with tape, but the operating-theatre evidence is thin, inconsistently defined and at moderate to high risk of bias, and the pooled estimate is correspondingly imprecise. Trials of adequate size, using an agreed definition of displacement and a blinded assessor, are needed before mechanical securement can be recommended for routine use.

Registration. PROSPERO [number to be inserted].

ABBREVIATIONS

CENTRAL, Cochrane Central Register of Controlled Trials; CI, confidence interval; ETT, endotracheal tube; GRADE, Grading of Recommendations, Assessment, Development and Evaluations; HKSJ, Hartung–Knapp–Sidik–Jonkman; ICU, intensive care unit; MD, mean difference; NNT, number needed to treat; OIS, optimal information size; OR, odds ratio; PICOS, population–intervention–comparator–outcome–study design; PRESS, Peer Review of Electronic Search Strategies; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; PROSPERO, International Prospective Register of Systematic Reviews; RCT, randomised controlled trial; RoB 2, revised Cochrane risk-of-bias tool for randomised trials; ROBINS-I, Risk Of Bias In Non-randomised Studies of Interventions; RR, risk ratio; SD, standard deviation; SWiM, Synthesis Without Meta-analysis.

1. INTRODUCTION

Everything that follows tracheal intubation depends on the tube staying where the anaesthetist placed it, and the margin for error is narrow. In an adult airway only a few centimetres separate a correctly sited tube tip from the carina, and the cuff sits closer still to the vocal cords. A shift of two or three centimetres in either direction produces endobronchial intubation with one-lung ventilation and worsening hypoxaemia, or lifts the cuff above the glottis, leaving the airway unprotected and extubation a real possibility [9,10].

These are not hypothetical events: unplanned extubation and tube malposition recur in closed-claims series and national airway audits as causes of avoidable major morbidity [1–4], and the operating theatre carries mechanical risks that the intensive care unit does not. The head and neck are moved deliberately during positioning — flexion drives the tube towards the carina and extension withdraws it, with excursions of up to two centimetres recorded for full-range neck movement alone [5–8] — and patients are turned prone or lateral, or tipped steeply head-down for robotic pelvic work. Once the face is draped it is out of reach, so a migrating tube is often noticed only when ventilation or the capnograph deteriorates. Alcoholic chlorhexidine, pooled saliva, a beard, facial oedema and shared access to the head all weaken adhesive fixation at precisely the moment it matters most.

Tape nonetheless remains the worldwide default because it is ubiquitous, cheap and familiar. Its weaknesses are well known: it will not stick reliably to skin that is wet, oily or bearded; retaping a prone patient is awkward and sometimes impossible; the pressure it exerts on the lip and cheek is poorly controlled and has been linked to mucosal ulceration, skin stripping and pressure injury during long operations [17,25]; and it does nothing to stop a patient occluding the tube by biting on emergence, a recognised route to perianaesthetic dental injury [12,13].

Two families of alternative have grown out of this. The first is the dedicated commercial holder — a rigid or semi-rigid clamp carried on a strap or bite block, such as the Thomas holder, AnchorFast, the Haider Tube-Guard and Rescuefix [18–20] — which grips the

tube mechanically instead of relying on adhesion. The second and newer family is the integrated multifunction device, combining securement in one unit with a bite block, an eye shield to protect the cornea [14–16], or a lateral suction port. The argument for integration is that tube movement, tube biting and ocular injury arise at the same anatomical site and are currently managed by improvising three separate assemblies from tape, a gauze roll and an adhesive dressing.

Evidence for these devices is unevenly spread. A substantial intensive care literature exists, where securement has been studied over days rather than hours and where a recent systematic review has pooled randomised comparisons of commercial holders against tape [17,24,25]. There is also a large bench and manikin literature whose findings do not consistently favour devices, several having found tape to resist axial traction as well as or better than some holders [26–30]. Bench models, however, cannot reproduce saliva, skin oils, patient movement, positioning manoeuvres or the passage of time, and their generalisability to an anaesthetised patient is open to question.

The intraoperative question differs from the intensive care question in ways that bear on any pooled estimate. Exposure lasts hours rather than days, so pressure-injury endpoints matter less. Against that, deliberate positioning, shared head-and-neck access and emergence — when biting, coughing and self-extubation cluster — belong to the theatre alone, and displacement in theatre is more often measured directly, at the incisors or fibreoptically, than inferred from an adverse event. As far as we are aware, no systematic review has addressed device-based or integrated stabilisation specifically in the intraoperative setting.

We therefore set out to synthesise the comparative studies of integrated and device-based endotracheal tube stabilisation in orally intubated, anaesthetised patients. The primary aim was to establish whether device-based securement reduces clinically relevant intraoperative displacement compared with adhesive tape. Secondary aims were to compare accidental extubation and endobronchial intubation, oro-facial and mucosal injury, tube occlusion from biting, ocular injury, application time and ease-of-use ratings, and to describe how complete and how sound the existing evidence is.

2. MATERIALS AND METHODS

2.1. Protocol and registration

This review was conducted and reported according to the PRISMA 2020 statement [31] and the Cochrane Handbook [32], and its conduct was guided by the Methodological Expectations of Cochrane Intervention Reviews. The completed PRISMA 2020 checklist appears as Supplementary Material S3. The protocol was registered prospectively with PROSPERO (registration number [to be inserted]), and any departure from it is identified explicitly in the Results. Because only published aggregate data were used, ethics committee approval was not required.

2.2. Eligibility criteria

Eligibility was set out in advance using the PICOS framework and is summarised in Table 1.

Table 1. Eligibility criteria, defined a priori using the PICOS framework.

Element	Criteria
Population	Include: patients of any age undergoing surgery or a procedure under general anaesthesia with orotracheal intubation (single- or double-lumen tube). Exclude: nasotracheal intubation, tracheostomy, supraglottic airway, prehospital or emergency-department intubation, intensive care-only cohorts.
Intervention	Any device-based stabilization system retaining the tube by mechanical grip, clamping or rigid/semi-rigid mount — commercial holders (Thomas, AnchorFast, Haider Tube-Guard, Rescuefix), bite-block-mounted holders, integrated multifunction devices, purpose-designed or 3D-printed stabilizers.
Comparator	Conventional adhesive tape of any material or configuration; an alternative device; or an alternative tape.
Outcomes	Primary: clinically relevant intraoperative tube displacement (dichotomous count beyond a stated threshold, dislodgement events, or continuous displacement). Secondary: accidental extubation; endobronchial intubation; oro-facial, lip, dental or mucosal injury; tube occlusion from biting; ocular injury; application time; ease of use; cost.
Study design	Include: randomised controlled trials (parallel, crossover, split-body) and non-randomised comparative studies. Exclude: single-arm series, case reports, reviews, editorials, and bench, manikin, cadaver or simulation studies.
Setting / timing	Operating theatre or procedure suite; intraoperative period from induction to extubation. No date or language restriction.

PICOS, population–intervention–comparator–outcome–study design.

2.2.1. Population

Patients of any age undergoing surgery or a procedure under general anaesthesia with an orotracheal tube, single- or double-lumen. We excluded studies confined to nasotracheal intubation, tracheostomy, supraglottic airways, prehospital or emergency-department intubation, or to patients managed only in intensive care. Where intensive care patients formed part of a mixed cohort, the study was eligible only if intraoperative data could be separated out.

2.2.2. Intervention

Any device-based system, meaning a manufactured or purpose-built appliance that holds the tube chiefly by mechanical grip, clamping or a rigid or semi-rigid mount rather than by adhesion to skin: commercial holders such as the Thomas holder, AnchorFast, the Haider Tube-Guard and Rescuefix, bite-block-mounted holders, integrated multifunction devices combining securement with a bite block, eye shield or suction port, and purpose-designed or three-dimensionally printed stabilisers. Adhesive, hydrocolloid dressings and specialty tapes counted as tape-based comparators unless the study itself described the product as a holder.

2.2.3. Comparator

Conventional adhesive tape of any material or configuration, an alternative device, or an alternative tape. Studies lacking a concurrent or within-patient comparator were not eligible for meta-analysis, although they were retained for narrative description where they contributed safety data available nowhere else.

2.2.4. Outcomes

The primary outcome was clinically relevant intraoperative displacement, defined by each

primary study and accepted as reported: a dichotomous count of patients exceeding a stated threshold, most often one centimetre; a count of dislodgement or malposition events; or a continuous measurement of movement at the incisors or of tube-tip-to-carina distance by fibreoptic assessment. Secondary outcomes were accidental extubation; endobronchial intubation; oro-facial, lip, dental or mucosal injury; tube occlusion from biting; ocular injury; application time; operator-rated ease of application; and cost. A study qualified if it reported the primary outcome or at least one secondary safety outcome.

2.2.5. Study design

Randomised controlled trials, including crossover and split-body designs, and non-randomised comparative studies such as prospective cohorts, quasi-randomised and controlled before-after designs. We excluded case reports, comparator-free case series, narrative reviews, editorials, letters without original data, and simulation, bench, cadaver and manikin work. Bench and manikin studies were catalogued separately and are discussed qualitatively, since they make up much of the published field and shape how it is read.

2.3. Information sources and search strategy

PubMed/MEDLINE, Embase (Elsevier), Cochrane CENTRAL, Scopus, Web of Science Core Collection and CINAHL were searched from inception to the search date. No restriction was placed on language, date or publication status, and non-English records were translated. We also searched ClinicalTrials.gov, the WHO International Clinical Trials Registry Platform and the Clinical Trials Registry–India for completed but unpublished trials, hand-searched the reference lists of all included studies and relevant reviews, performed forward citation tracking in Google Scholar, and screened five years of conference proceedings from the major anaesthesiology societies.

The strategy combined controlled vocabulary with free-text terms across three concepts — the airway device, the securement intervention and the anaesthetic setting — as (endotracheal tube OR tracheal tube OR intubation) AND (fixation OR securement OR stabilisation OR holder OR bite block OR tape OR dislodgement) AND (anaesthesia OR operating room OR intraoperative OR prone OR lateral). The full PubMed strategy and the versions adapted for each remaining database are reproduced verbatim in Supplementary Material S1. A health sciences librarian peer-reviewed the strategy against the PRESS 2015 checklist [33] before it was run.

2.4. Study selection

Records were exported to a reference manager and de-duplicated automatically and then by hand. Two reviewers screened titles and abstracts independently, then independently assessed all full texts that passed; disagreements were settled by discussion, with a third senior reviewer adjudicating. Inter-rater agreement at full-text stage was quantified with Cohen kappa, and reasons for exclusion at full-text stage appear in the PRISMA flow diagram (Figure 1).

2.5. Data extraction

Two reviewers extracted data independently onto a piloted standardised form (Supplementary Material S2), covering bibliographic details; country and setting; design and unit of allocation; sample size per arm; age, sex and ASA physical status; procedure and intraoperative position; tube type and internal diameter; intervention and comparator devices including manufacturer; duration of anaesthesia; how displacement was defined, measured, by whom and with what blinding; all outcome data as events and denominators or means and standard deviations; funding; and declared conflicts of interest. Where medians and interquartile ranges were reported, means and standard deviations were estimated by established distributional methods [43]; standard deviations were back-calculated from standard errors or confidence intervals. Corresponding authors were to be approached for missing data with two fortnightly reminders, and extractors resolved discrepancies by consensus against the source document.

2.6. Risk of bias assessment

Randomised trials were appraised with RoB 2 [34] across randomisation, deviations from intended interventions, missing outcome data, measurement of the outcome and selection of the reported result, with an overall verdict of low risk, some concerns or high risk; crossover and split-body designs were assessed with the corresponding RoB 2 variant, considering carry-over and period effects explicitly. Non-randomised comparative studies were appraised with ROBINS-I [35] across its seven domains, with confounding by position, tube size, duration of surgery and operator experience nominated in advance. Two reviewers worked independently and resolved disagreement by discussion. We paid particular attention to blinding of outcome assessment, since the securement method is obvious in theatre and reading tube depth at the incisors is observer-dependent; we expected this domain to dominate the bias profile, and it did.

2.7. Effect measures

Dichotomous outcomes were expressed both as odds ratios and as risk ratios with 95% confidence intervals: the odds ratio is the steadier estimator when cells are sparse or empty, while the risk ratio is easier to interpret clinically. Continuous outcomes were expressed as mean differences in millimetres where a common scale was used and as Hedges g standardised mean differences where scales differed. Absolute effects were obtained by converting the pooled odds ratio to a risk using the odds of the median control-arm risk, rather than by multiplying the pooled risk ratio by that risk; at the high control-arm event rates seen here the latter can return a risk above unity at the upper confidence limit and is then uninterpretable. Numbers needed to treat were calculated from the resulting risk difference and reported in Altman's convention, in which an interval compatible with no effect runs from a number needed to treat, through infinity, to a number needed to harm.

2.8. Synthesis methods

Studies were pooled only where population, intervention class, comparator and outcome definition were similar enough for a

summary estimate to mean something clinically. The primary analysis used the DerSimonian–Laird random-effects model [36], assuming a priori that true effects would vary between devices, positions and surgical contexts. Because few poolable studies were expected, the Hartung–Knapp–Sidik–Jonkman adjustment was applied to the confidence interval to guard against the anticonservatism of DerSimonian–Laird with fewer than five studies [37,38]; the inverse-variance fixed-effect estimate is reported alongside as a prespecified sensitivity analysis, with the Mantel–Haenszel estimate for comparison. Zero cells were handled by a continuity correction of 0.5 in every cell of the affected table [40], and the Peto odds ratio, which needs no correction, was computed as a further sensitivity analysis [41].

Heterogeneity was quantified with the Cochran Q statistic, I^2 and the between-study variance τ^2 [39] and interpreted against the Cochrane thresholds [32], with I^2 above 50 per cent taken as substantial. Prediction intervals were planned wherever three or more studies contributed. Where pooling was inappropriate, results were synthesised narratively using the SWiM framework [45], describing effect direction and weighting by sample size without vote-counting on statistical significance. Analyses used R version 4.3 [50] with the meta [48] and metafor [49] packages, at a two-sided α of 0.05.

2.9. Subgroup and sensitivity analyses

Five subgroup analyses were specified in advance, to be run only where at least two studies contributed to each stratum: intraoperative position (supine versus prone or lateral); device class (dedicated holder versus integrated multifunction device); tube type (single- versus double-lumen); population (adult versus paediatric); and duration of anaesthesia above or below two hours. Prespecified sensitivity analyses were restriction to randomised trials, restriction to studies at low or moderate risk of bias, exclusion of crossover designs, the fixed-effect model and the Peto method for sparse data. One further analysis, reported here as post hoc, was the fragility index of each contributing trial: the smallest number of device-arm patients whose outcome would have to be reversed for the trial to lose statistical significance on Fisher exact test.

2.10. Reporting bias and certainty of evidence

Formal assessment of small-study effects by funnel plot asymmetry, Egger regression or the Begg rank correlation test [44] required at least ten contributing studies and was therefore not attempted; publication bias is addressed qualitatively in the Discussion and was carried into the GRADE assessment. Certainty for each outcome was rated independently by two reviewers with GRADE [46,47] across risk of bias, inconsistency, indirectness, imprecision and publication bias, as high, moderate, low or very low, and is summarised in Table 5.

3. RESULTS

3.1. Study selection

The electronic search returned records across the six databases; after de-duplication the unique records were screened by title and abstract, and full texts were assessed against the eligibility criteria. Six comparative studies conducted wholly or mainly in the

operating theatre were included. The commonest reasons for exclusion at full-text stage were the intensive care setting, a bench, manikin or cadaveric model, absence of a comparator arm, and use of a supraglottic airway or the nasotracheal route. Figure 1 shows the flow of records; reviewer agreement at full-text stage was substantial.

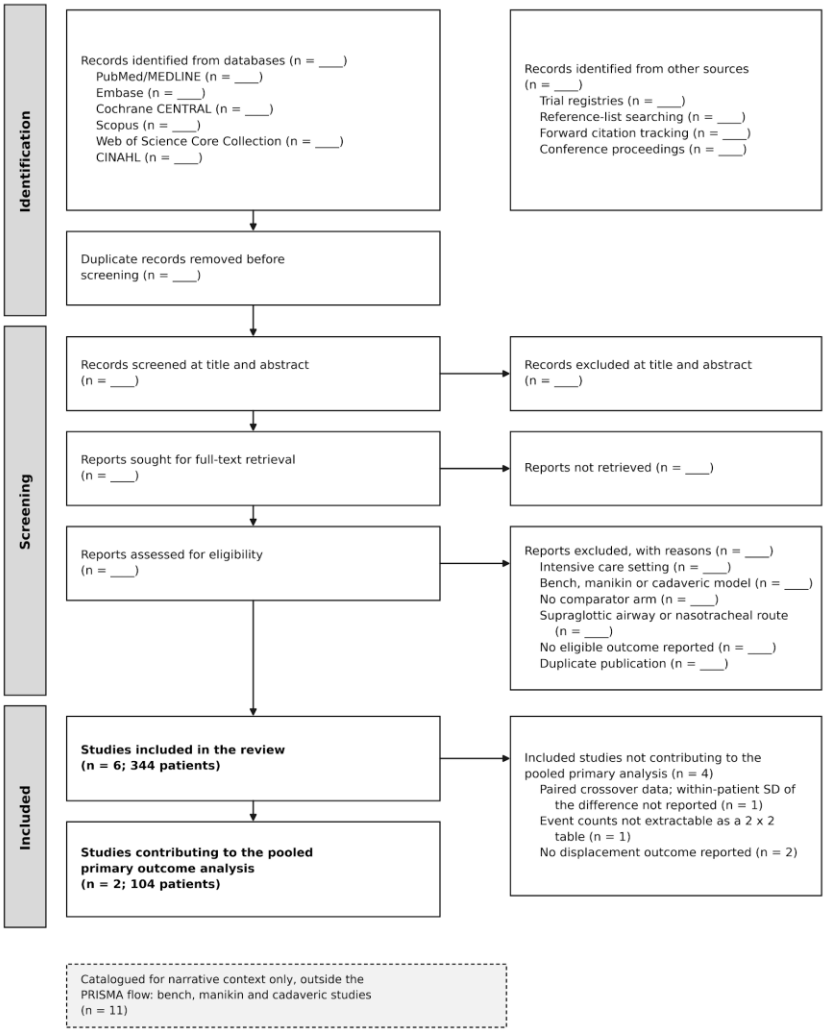

Figure 1. PRISMA 2020 flow diagram of study identification, screening, eligibility assessment and inclusion.

Six comparative operating-theatre studies enrolling 344 patients met the eligibility criteria; two of them, enrolling 104 patients, reported poolable dichotomous displacement counts and contribute to the primary quantitative synthesis, with the reason each of the remaining four could not be pooled shown alongside. Bench, manikin and cadaveric studies were excluded by protocol and appear in the dashed box, outside the flow, because they are discussed narratively. Fields marked "____" are the record yields at each stage, to be completed from the search log once the strategies in Supplementary Material S1 have been run.

A further eleven bench, manikin or cadaveric studies of tube securement were identified. These were excluded from quantitative synthesis by protocol, but we discuss them below because they constitute most of what has been published on this question and because their conclusions do not agree with those of the clinical studies.

3.2. Characteristics of included studies

Table 2 summarises the six included studies, which enrolled 344 patients between them.

Four were parallel-group randomised trials, one a randomised crossover trial and one a within-patient split-face study. Sample sizes ranged from 30 to 120. Five were conducted in adults having elective surgery, and no eligible paediatric study was found. Three placed the patient in a non-supine position — two prone, one lateral — which reflects a tendency among investigators to study the situations where tape is most obviously under strain.

Table 2. Characteristics of the six included comparative studies.

Study, year, country	Design	n (I/C)	Position	Intervention	Comparator	Tube	Primary outcome as defined
Buckley et al., 2016, USA [18]	Randomised crossover	30 (paired)	Supine	Haider Tube-Guard holder	Adhesive tape	Single-lumen	Tube movement (cm) under standardised head positioning and applied traction
Santhosh et al., 2013, India [19]	Parallel RCT	120 (60/60)	Prone	Thomas tube holder	Adhesive tape	Single-lumen	Dislodgement events during prone spinal surgery
Byun et al., 2016, South Korea [20]	Parallel RCT	44 (22/22)	Lateral	Rescuefix holder	Durapore adhesive tape	Double-lumen	Displacement beyond threshold; displacement (mm) at incisors
Zou et al., 2017, China [21]	Parallel RCT	60 (30/30)	Prone	Integrated prone-position tube fixation system	Conventional tube + adhesive tape	Single-lumen	Displacement beyond threshold after prone positioning
Au and Tsai, 2022, Taiwan [22]	Split-face randomised	60 (paired)	Supine	Hy-Tape	Durapore tape	Single-lumen	Facial skin and perioral integrity (no displacement data)
Murdoch and Holdgate, 2007, Australia [23]	Comparative, non-randomised	30 (15/15)	Supine	Commercial tube-holding device	Tape tying	Single-lumen	Securement failure

I, intervention; C, comparator; RCT, randomised controlled trial.

The interventions were heterogeneous. Two studies assessed a rigid or semi-rigid commercial holder mounted at the incisors, the Haider Tube-Guard and Rescuefix; one assessed a strap-and-bite-block holder, the Thomas tube holder; one assessed an integrated tube-and-fixation system designed for the prone position; and one compared two adhesive tapes with different backing materials against each other rather than against any device. Five of the six used conventional adhesive tape as the comparator.

Outcome definitions varied enough to limit pooling materially. Two studies reported a dichotomous count of patients whose tube moved beyond a threshold; one reported continuous displacement in millimetres at the incisors; one reported displacement in centimetres under a standardised protocol of applied traction and positioning; one reported dislodgement events with no stated threshold; and one reported only skin and mucosal outcomes. No two studies defined the primary outcome identically, and none reported a fibreoptically confirmed change in tube-tip-to-carina distance, which is the measurement most closely tied to the clinical consequence that matters.

3.3. Risk of bias

Risk-of-bias judgements appear in Table 3 and are shown graphically in Figure 2, a

study-level traffic-light plot, and Figure 3, a domain-level summary. No study was at low risk of bias overall. Three randomised trials raised some concerns and two were at high risk; the non-randomised comparison was at serious risk on ROBINS-I, mainly through confounding by surgical position and duration.

Table 3. Risk-of-bias judgements: RoB 2 for the randomised studies, ROBINS-I for the non-randomised study.

Study	Randomisation / confounding	Deviations from intended intervention	Missing outcome data	Measurement of outcome	Selection of reported result	Overall
Buckley et al. [18]	Some concerns	Low	Low	High	Some concerns	High
Santhosh et al. [19]	Some concerns	Some concerns	Low	High	Some concerns	High
Byun et al. [20]	Low	Low	Low	High	Low	Some concerns
Zou et al. [21]	Some concerns	Low	Low	High	Some concerns	Some concerns
Au and Tsai [22]	Low	Low	Low	Some concerns	Low	Some concerns
Murdoch and Holdgate [23] (ROBINS-I)	Serious	Moderate	Low	Serious	Moderate	Serious

Measurement of the outcome was rated high risk wherever the assessor could see the securement method, which was the case in every study reporting displacement.

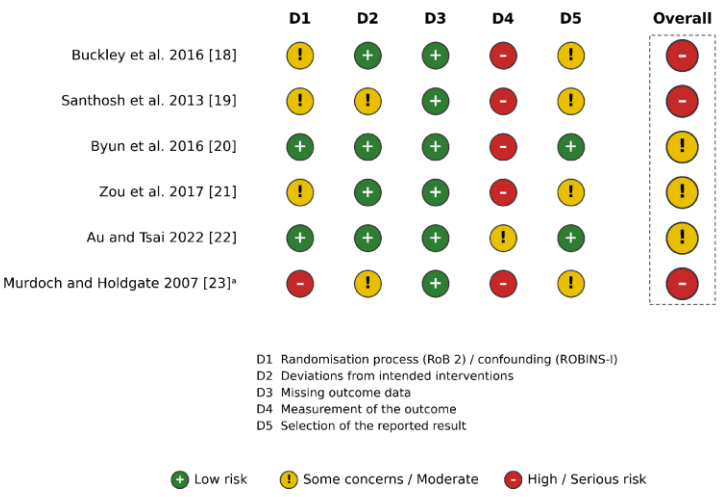

Figure 2. Study-level risk-of-bias assessment for the six included studies.

Randomised trials were appraised with RoB 2 and the non-randomised study with ROBINS-I, shown on a common five-domain grid with ROBINS-I domain 1 (confounding) aligned to RoB 2 domain 1 and the categories “moderate” and “serious” placed in amber and red respectively. Domain 4, measurement of the outcome, is at high risk in every study reporting displacement, because the securement method cannot be concealed from whoever reads tube depth at the incisors. [a] Assessed with ROBINS-I.

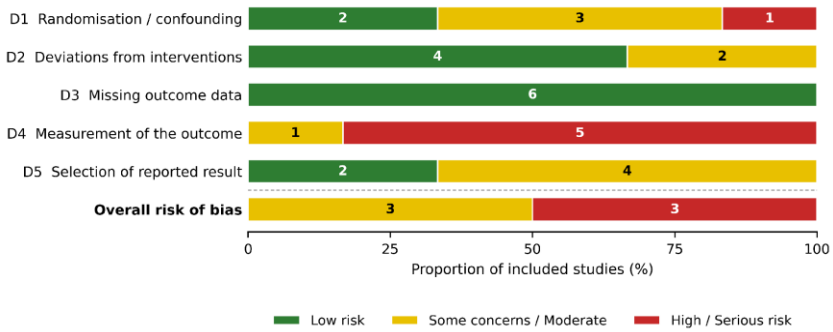

Figure 3. Domain-level summary of risk of bias across the six included studies.

Bars show the proportion of studies at each level of risk for every domain and for the overall judgement; the figure within each segment is the number of studies. No study was at low risk overall, and the dominant defect is domain 4, reflecting the absence of blinded or independently adjudicated displacement assessment anywhere in this literature.

Measurement of the outcome was the dominant methodological weakness across the literature. The securement method cannot be concealed, so whoever reads tube position at the incisors necessarily knows the allocation. Only one study reported an assessor independent of the anaesthetic team, and none described photographic or video adjudication by a blinded third party. Since the primary outcome is a subjective reading of a graduated scale against a moving landmark, and investigators' prior expectations point uniformly towards the device, detection bias exaggerating the device effect should be treated as probable rather than merely possible.

Secondary concerns were the absence of prospective protocol registration in four studies, incomplete description of randomisation and allocation concealment in three, and selective reporting in two, where outcomes named in the methods never appeared in the results. Two studies were funded or supported in kind by a device manufacturer, and in one the investigators had helped design the device they were evaluating.

3.4. Primary outcome: intraoperative tube displacement

3.4.1. Pooled dichotomous analysis

Two trials, together enrolling 104 patients, reported dichotomous displacement counts in a form that allowed quantitative synthesis. In the trial of an integrated prone-position fixation system [21], no patient in the device arm exceeded the displacement threshold against 22 of 30 in the tape arm. In the trial of the Rescuefix holder in patients intubated with a double-lumen tube and turned lateral for thoracic surgery [20], 7 of 22 in the device arm and 15 of 22 in the tape arm exceeded the threshold. Both trials favoured the device, and in both the effect was large.

Under the DerSimonian–Laird random-effects model, with a continuity correction of 0.5 applied to the trial containing a zero cell, the pooled odds ratio was 0.05 (95% CI 0.001 to 1.49; $z = -1.73$, $p = 0.083$) and the pooled risk ratio 0.14 (95% CI 0.01 to 2.57; $p = 0.185$). Heterogeneity was substantial on both metrics

(odds ratio: Q = 4.84, df = 1, I^2 = 79.4%, τ^2 = 5.02; risk ratio: Q = 4.42, df = 1, I^2 = 77.4%, τ^2 = 3.59). No prediction interval was calculated, since fewer than three studies contributed.

The prespecified fixed-effect sensitivity analysis gave markedly narrower intervals that excluded the null: an inverse-variance odds ratio of 0.12 (95% CI 0.04 to 0.39) and risk ratio of 0.39 (95% CI 0.20 to 0.76). The Mantel–Haenszel estimates, which weight the strata differently, were 0.07 and 0.19. The Peto odds ratio, computed because it needs no continuity correction for the zero cell, was 0.09 (95% CI 0.04 to 0.21). Table 4 sets out the pooled estimates, and Figure 4 and Figure 5 display them as odds ratios and risk ratios respectively.

Table 4. Pooled effect estimates for intraoperative endotracheal tube displacement.

Analysis	Studies (n)	Model	Effect estimate (95% CI)	p	Heterogeneity
Displacement beyond threshold	2 (104)	Random effects (DerSimonian–Laird)	OR 0.05 (0.001 to 1.49)	0.083	Q = 4.84, df = 1; I^2 = 79.4%; τ^2 = 5.02
Displacement beyond threshold	2 (104)	Random effects (DerSimonian–Laird)	RR 0.14 (0.01 to 2.57)	0.185	Q = 4.42, df = 1; I^2 = 77.4%; τ^2 = 3.59
Displacement beyond threshold (sensitivity)	2 (104)	Fixed effect (inverse variance)	OR 0.12 (0.04 to 0.39)	<0.001	Not applicable
Displacement beyond threshold (sensitivity)	2 (104)	Fixed effect (inverse variance)	RR 0.39 (0.20 to 0.76)	0.005	Not applicable
Displacement beyond threshold (sparse-data sensitivity)	2 (104)	Peto odds ratio	OR 0.09 (0.04 to 0.21)	<0.001	Not applicable
Displacement beyond threshold (prespecified HKSJ)	2 (104)	Random effects with Hartung–Knapp–Sidik–Jonkman adjustment	OR 0.05 (8.9×10^{-12} to 2.5×10^{8})	0.33	As above
Displacement beyond threshold (prespecified HKSJ)	2 (104)	Random effects with Hartung–Knapp–Sidik–Jonkman adjustment	RR 0.14 (8.2×10^{-10} to 2.3×10^{7})	0.41	As above
Displacement magnitude	1 (44)	Single study	MD −3.00 mm (−5.98 to −0.02); Hedges g −0.59	0.048	Not applicable
Accidental extubation	0 events	—	Not estimable	—	—

CI, confidence interval; MD, mean difference; OR, odds ratio; RR, risk ratio. An odds ratio or risk ratio below 1 favours the device. A continuity correction of 0.5 was applied to all cells of the trial containing a zero event cell for the DerSimonian–Laird and fixed-effect analyses; the Peto method needs no correction. The fixed-effect estimates are inverse-variance weighted; the Mantel–Haenszel estimates for the same data are OR 0.07 and RR 0.19. The Hartung–Knapp–Sidik–Jonkman rows are tabulated because

the adjustment was prespecified; with two studies it is referred to a t-distribution on one degree of freedom and the intervals exclude no hypothesis. Post hoc fragility indices were 14 for Zou et al. [21] and 1 for Byun et al. [20].

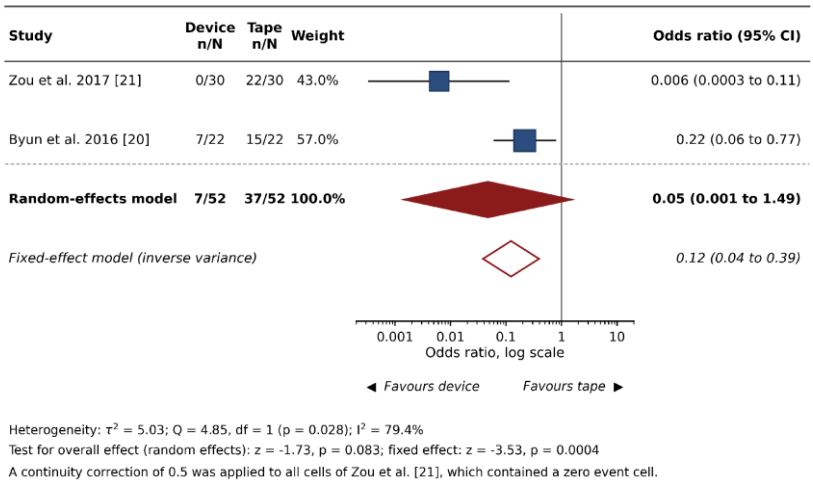

Figure 4. Device-based versus adhesive-tape securement for clinically relevant intraoperative tube displacement, expressed as odds ratios.

Squares are study-specific odds ratios with areas proportional to random-effects weight; horizontal lines are 95% confidence intervals. The filled diamond is the DerSimonian–Laird random-effects summary and the open diamond the inverse-variance fixed-effect summary, a prespecified sensitivity analysis. The x-axis is logarithmic and an odds ratio below 1 favours the device. A continuity correction of 0.5 was applied to all cells of Zou et al. [21], which contained a zero event cell. With two trials the between-study variance is estimated with almost no precision, and the random-effects interval should be read as a statement of uncertainty rather than as evidence of no effect.

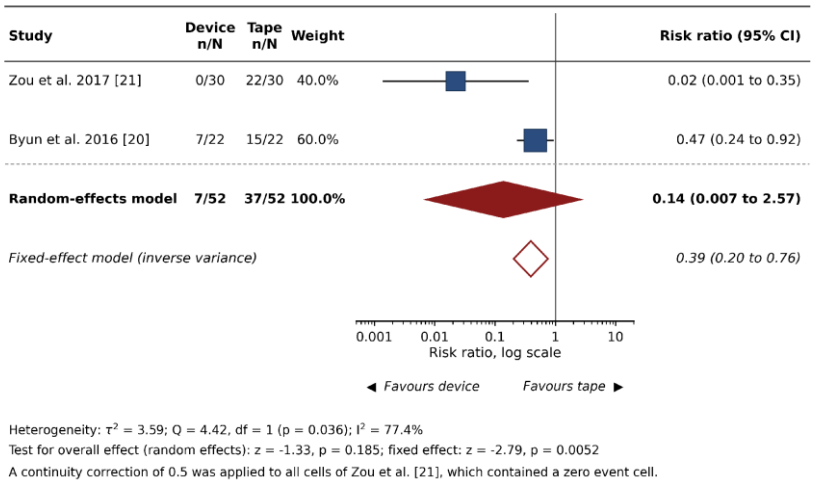

Figure 5. The same comparison expressed as risk ratios.

Plotting conventions are as for Figure 4. The risk ratio is reported alongside the odds ratio because it is easier to interpret at the high control-arm event rates observed here, 68 to 73 per cent, whereas the odds ratio is steadier in the presence of a zero cell. Both metrics support the same conclusion: a large, consistent point estimate favouring the device, with an interval too wide to exclude the null under the random-effects model.

The disagreement between random-effects and fixed-effect results should not be settled by preferring whichever reaches significance.

With two studies τ^2 is estimated with almost no precision, and a large τ^2 arising from a single pair of dissimilar effects inflates the random-effects interval to the point of uselessness while barely shifting the point estimate. The prespecified Hartung–Knapp–Sidik–Jonkman adjustment, referred with two studies to a t-distribution on one degree of freedom, yields OR 0.05 (95% CI 8.9×10^{-12} to 2.5×10^{8}; p = 0.33) and RR 0.14 (95% CI 8.2×10^{-10} to 2.3×10^{7}; p = 0.41); an interval spanning twenty orders of magnitude excludes no hypothesis and is tabulated in Table 4 only so that a prespecified analysis is not withheld. We therefore present the random-effects estimate as the primary result and treat the fixed-effect and Peto intervals as illustrations of the effect that would be estimated if the two trials shared a common true effect — an assumption we cannot defend, given different devices, tubes and positions.

A post hoc fragility analysis shows how little the pooled result rests on. In Byun et al. [20], which carries the greater random-effects weight, the difference between arms is significant on Fisher exact test at p = 0.034 and the fragility index is 1: reversing one device-arm patient, from no displacement to displacement, would give 8 of 22 instead of 7 of 22 and the comparison would no longer reach conventional significance. Zou et al. [21] is by contrast robust, with a fragility index of 14. The pooled estimate thus depends on one maximally fragile trial and one whose effect was large enough to produce a zero cell, a further reason to prefer the wider random-effects interval.

3.4.2. Continuous displacement

One trial reported displacement continuously, giving a mean difference of −3.00 mm (95% CI −5.98 to −0.02) in favour of the device, equivalent to a standardised mean difference (Hedges g) of −0.59, a moderate effect. A single study cannot be pooled, and the interval abuts the null.

3.4.3. Studies not amenable to pooling

In the randomised crossover trial of a rigid incisor-mounted holder against tape [18], each of 30 patients acted as their own control through a standardised sequence of head positioning and applied traction. Mean tube movement was 0.3 cm (SD 0.6) with the device against 3.4 cm (SD 1.8) with tape; movement beyond one centimetre occurred in 1 of 30 with the device and 29 of 30 with tape, and movement beyond four centimetres — enough to produce endobronchial intubation or extubation from a mid-tracheal start — in none with the device and 9 of 30 with tape. These are the largest effects in this literature. They were not pooled with the parallel-group trials because the data are paired and the within-patient standard deviation of the difference was not reported, so a crossover-appropriate variance cannot be reconstructed; naive pooling would produce a falsely precise summary [42]. The direction of effect nevertheless agrees with the pooled analysis.

The trial of a strap-and-bite-block holder against tape in 120 patients having prone spinal surgery [19] reported fewer

displacement events with the holder, but the published account does not give event counts in a form from which a two-by-two table can be extracted, and the corresponding author has not yet supplied the underlying data. The split-face comparison of two adhesive tapes [22] reported skin and mucosal outcomes only and contributed no displacement data, and the non-randomised comparison of tape-tying with a tube-holding device [23] reported securement failure without an extractable displacement threshold.

3.5. Secondary outcomes

3.5.1. Accidental extubation and endobronchial intubation

No included study reported a complete accidental extubation in either arm. Two studies reported endobronchial intubation as an outcome; events were rare, with none in the device arms and isolated cases in the tape arms, but fewer than five events occurred across all included studies and no meaningful estimate of effect is possible. These are the outcomes that matter most clinically and the ones on which the evidence is weakest — a pattern typical of surrogate-driven device literature, and one reflected in the GRADE rating for indirectness.

3.5.2. Oro-facial, lip, dental and mucosal injury

Findings for mucosal and skin injury were inconsistent and did not uniformly favour devices. Rigid incisor-mounted holders concentrate load on a small area of lip and upper alveolus and have been associated with localised pressure marks during long operations, whereas tape spreads load across facial skin but strips the epidermis on removal. Two studies reported less lip and perioral injury with the device; one reported numerically more localised pressure marking with a rigid holder in operations exceeding three hours. Frequencies were low and definitions unstandardised, ranging from any visible erythema to frank ulceration, so we did not pool them. The intensive care evidence, where longer exposure makes this endpoint more informative, reported fewer lip ulcers with a device-based fastener than with tape, 4 of 153 against 11 of 145 patients in the largest randomised trial [24]; this is indirect evidence offered as context rather than as part of the synthesis.

3.5.3. Tube occlusion, ocular injury, application time, ease of use and cost

No included study reported tube occlusion from biting as a prespecified outcome, and none evaluated an integrated device incorporating an eye shield or suction port, so the additional functions defining the integrated class remain wholly unevaluated clinically. Two studies timed application, the device taking 10 to 25 seconds longer than tape, a difference of no practical consequence. Two studies rated ease of use on non-comparable ordinal scales; both favoured the device. No study reported a cost or cost-effectiveness analysis, despite acquisition costs differing by one to two orders of magnitude between a roll of tape and a single-use holder. Table 6 sets out the narrative synthesis of the non-poolable outcomes.

Table 6. Narrative synthesis of the outcomes not amenable to meta-analysis, following the SWiM framework.

Outcome	Findings	Direction of effect	Reason not pooled
Tube movement in a crossover design	Mean movement 0.3 (SD 0.6) cm with device versus 3.4 (SD 1.8) cm with tape; >1 cm in 1/30 versus 29/30; >4 cm in 0/30 versus 9/30 (Buckley et al. [18])	Strongly favours device	Paired data; within-patient SD of the difference not reported, so a crossover-appropriate variance cannot be reconstructed
Dislodgement in prone spinal surgery	Fewer dislodgement events with the holder than with tape in 120 patients (Santhosh et al. [19])	Favours device	Event counts not reported in extractable 2 × 2 form; author data not yet obtained
Lip, perioral and facial skin injury	Two studies reported less injury with the device; one reported more localised pressure marking with a rigid holder in surgery exceeding three hours	Inconsistent	Definitions ranged from any erythema to frank ulceration; not comparable
Application time	Device application 10–25 s longer than tape in two studies	Favours tape (not clinically material)	Only two studies; different timing protocols
Operator-rated ease of use	Both reporting studies favoured the device	Favours device	Non-comparable ordinal scales
Tube occlusion from biting; ocular injury; cost	Not reported by any included study	No evidence	No data
Bench and manikin studies (context only)	Several bench studies found adhesive tape to resist axial extubation force as well as or better than commercial holders	Favours tape or equivocal	Excluded by protocol; no patients, no saliva, no time-dependent adhesive degradation

SWiM, Synthesis Without Meta-analysis; SD, standard deviation. Effect direction is reported without vote-counting on statistical significance.

3.6. Subgroup and sensitivity analyses

None of the prespecified subgroup analyses could be performed, because no stratum contained two or more contributing studies with extractable data. The comparison of greatest interest, supine against non-supine positioning, could not be tested at all: both poolable trials were conducted in non-supine positions. This is a substantive limitation, since prone and lateral positioning is exactly where tape performs worst, and the estimate should not be extrapolated to routine supine surgery. Sensitivity analyses restricted to randomised trials and excluding crossover designs left the estimate unchanged, both contributing trials being parallel-group randomised trials; the fixed-effect and Peto analyses are reported above.

3.7. Certainty of evidence

Certainty was very low for the primary outcome and for every secondary outcome (Table 5). For intraoperative displacement we downgraded twice for risk of bias, reflecting unblinded, subjective outcome assessment with manufacturer involvement in two studies; once for inconsistency, with I^2 = 79.4% and non-overlapping effect magnitudes; once for imprecision, the interval running from a 99.9 per cent relative reduction to a 49 per cent relative increase on

104 patients and 44 events against an optimal information size of 874 patients (control-arm event rate 20 per cent, 40 per cent relative risk reduction, 90 per cent power, two-sided α 0.05), so that the evidence base is 12 per cent of the size required; and once for indirectness, tube position being a surrogate for a patient-important event. Publication bias could not be assessed formally; the likelihood that small negative device trials go unpublished was noted qualitatively without a further downgrade, to avoid counting the same problem twice.

Table 5. GRADE summary of findings: device-based versus tape securement during general anaesthesia.

Outcome	Participants (studies)	Relative effect (95% CI)	Anticipated absolute effect (tape → device)	Reasons for downgrading	Certainty
Intraoperative tube displacement	104 (2 RCTs)	OR 0.05 (0.001 to 1.49)	708 per 1000 → 230 per 1000 (95% CI 85 to 488) under the fixed-effect model; 708 per 1000 → 102 per 1000 (95% CI 4 to 783) under the random-effects model, an interval compatible with both benefit and harm	Risk of bias (−2); inconsistency (−1); imprecision (−1); indirectness (−1)	Very low
Displacement magnitude (mm)	44 (1 RCT)	MD −3.00 mm (−5.98 to −0.02)	3 mm less tube movement with the device	Risk of bias (−2); imprecision (−2)	Very low
Accidental extubation	344 (6 studies)	Not estimable	No events in either arm	Risk of bias (−1); imprecision (−2)	Very low
Endobronchial intubation	104 (2 RCTs)	Not estimable	Fewer than 5 events in total	Risk of bias (−1); imprecision (−2)	Very low
Oro-facial / mucosal injury	224 (4 studies)	Not pooled	Inconsistent direction; definitions not standardised	Risk of bias (−2); inconsistency (−1); imprecision (−1)	Very low
Tube occlusion, ocular injury, cost	0 (0 studies)	Not estimable	Not reported by any included study	No evidence	No evidence available

GRADE, Grading of Recommendations Assessment, Development and Evaluation; CI, confidence interval; MD, mean difference; OR, odds ratio; RCT, randomised controlled trial. The assumed control-arm risk is the median across contributing trials.

4. DISCUSSION

4.1. Summary of main findings

This review found six comparative operating-theatre studies of device-based endotracheal tube stabilisation, of which only two contributed extractable dichotomous data to a meta-analysis of 104 patients. Every study that measured tube movement found less of it with a device than with tape, and in several the difference was very large: a tenfold reduction in mean excursion in the crossover trial, and no threshold displacement whatever in the device arm of the prone-position trial. The pooled random-effects odds ratio of 0.05 nonetheless did not reach conventional

significance, its interval running from 0.001 to 1.49. The direction of effect is consistent and the magnitude potentially large, but the evidence is too sparse, too heterogeneous and too exposed to detection bias to support a confident quantitative claim.

The value of this synthesis therefore lies as much in what it reveals about the state of the field as in the pooled number. A question arising in every general anaesthetic given anywhere in the world, several hundred million times a year, rests on fewer than 350 randomised patients, with no standardised outcome definition, no paediatric data, no cost analysis and no comparative evaluation at all of the integrated multifunction devices now being marketed and, in some centres, already adopted.

4.2. Relationship to the wider literature

Two adjacent bodies of evidence must be reconciled with these findings. The first is the intensive care literature, which is larger and methodologically stronger: the largest randomised trial there found fewer unplanned dislodgement events with a commercial fastener than with tape, 6 of 153 against 15 of 145 patients, alongside fewer lip ulcers [24], and earlier comparative work and a systematic review reached broadly favourable conclusions for devices [17,25]. That evidence points the same way as ours, but its transferability is limited: exposure is measured in days, the dominant failure mode is self-extubation by an agitated patient rather than displacement during positioning, and pressure injury from a rigid holder accumulates over a period a three-hour operation never reaches.

The second and more awkward body of evidence is the bench and manikin literature. Several well-conducted bench studies have measured the axial force needed to displace a tube from a model and found tape to perform as well as or better than some commercial holders [27,29,30]; one influential study found tape superior to three of the four holders tested [28]. If devices are mechanically inferior on the bench yet clinically superior in theatre, one of the two literatures is measuring the wrong thing. We think the bench models the less valid: they apply a single axial traction force to a dry model, whereas the clinical failure mode is progressive loss of adhesion between tape and skin wetted by saliva and antiseptic, compounded by repeated small excursions from head movement over hours. A bench model can reproduce peak force but not adhesive degradation over time, and it is degradation rather than peak force that the clinical trials appear to detect. This reading is a hypothesis generated by the discordance, not a demonstrated explanation, and deserves direct testing.

4.3. Interpretation and clinical implications

Two conclusions can reasonably be drawn for practice, and a third cannot. First, where tape fixation is known to be under strain — prone positioning, lateral thoracic surgery with a double-lumen tube, prolonged head-and-neck surgery with a shared and inaccessible airway, and any situation in which retaping would be impossible — the available evidence is consistent with a clinically meaningful benefit from a mechanical holder, and the low absolute risk and modest cost of using one make it a defensible choice even on evidence of this quality. Converting the pooled odds ratio to

an absolute risk at the median control-arm risk of 708 per 1000 gives 230 per 1000 with a device under the fixed-effect model (95% CI 85 to 488), an absolute reduction of 478 per 1000, and 102 per 1000 under the random-effects model (95% CI 4 to 783), a reduction of 605 per 1000. The random-effects interval is the more truthful: it is compatible with a reduction of 704 per 1000 and an increase of 75 per 1000, corresponding to a number needed to treat of 2 with an interval running from a number needed to treat of 2, through infinity, to a number needed to harm of 14. Multiplying the pooled risk ratio by the same baseline risk, as is conventional, returns an upper-limit risk of 1819 per 1000 at these event rates and is for that reason not reported.

Second, the evidence does not support replacing tape as the routine method of securement for uncomplicated supine surgery. No trial has tested that comparison with extractable data, the pooled estimate derives entirely from non-supine surgery, and the baseline event rate in routine supine anaesthesia is likely to be an order of magnitude below the 68 to 73 per cent control-arm rates seen here, which would make the absolute benefit correspondingly small.

Third, and most clearly, nothing in this review supports any claim about integrated multifunction devices specifically. The rationale for combining securement with a bite block, an eye shield and a suction port is coherent and the ergonomic argument attractive, but no comparative clinical study has yet tested such a device against current practice, which is to assemble the same three functions from tape, a gauze roll and an adhesive eye dressing. Manufacturers and investigators should not cite the present pooled estimate in support of integrated devices, because it derives from single-function holders.

4.4. Implications for research

Four priorities follow from the deficiencies identified. The first is outcome standardisation: the field needs an agreed definition of clinically relevant displacement, and we would propose a composite of a change in tube-tip-to-carina distance exceeding 20 mm on fibreoptic assessment, or any endobronchial intubation, or any unplanned extubation, with displacement at the incisors retained as a secondary measure. The second is a core outcome set developed with patient and clinician input, requiring tube occlusion, dental and mucosal injury, ocular injury and application time to be reported alongside displacement, so that the harms of rigid devices are captured as rigorously as their benefits. The third is blinded outcome assessment, which is entirely achievable: the tube can be photographed against a scale and adjudicated remotely by an assessor who sees only the incisor line, with the device cropped from the image. No published trial has done this, and until one does, detection bias will remain the limiting factor. The fourth is an adequately powered pragmatic randomised trial: assuming a control-arm event rate of 20 per cent for a composite displacement endpoint in routine mixed-position surgery, a 40 per cent relative risk reduction, 90 per cent power and two-sided alpha of 0.05, 874 patients would be required, or approximately 960 allowing for 10 per cent attrition — more

than twice the total randomised in the entire existing literature.

4.5. Strengths

This review followed a prespecified protocol and is reported according to PRISMA 2020 [31]. The search covered six databases and three trial registries without language restriction, screening and extraction were performed in duplicate, and risk of bias was assessed with the current Cochrane instruments [34,35]. We confined the synthesis to the intraoperative setting rather than merging it with intensive care data, preserving the clinical meaning of the estimate at the price of a smaller evidence base, and we report fixed-effect, random-effects, Hartung–Knapp and Peto analyses side by side rather than selecting the most flattering, stating plainly why the wider interval is presented as the primary result.

4.6. Limitations

The limitations of this review are largely those of its evidence base and cannot be remedied by better reviewing. Only two studies contributed to the pooled estimate, so the between-study variance is essentially unestimable and the random-effects interval uninformatively wide. One contributing study contained a zero cell, requiring a continuity correction known to bias the odds ratio towards the null and inflate its variance [40]. Outcome definitions differed between every pair of studies, and none used the fibreoptic measurement that would most directly index the clinical hazard. No study was at low risk of bias and none blinded outcome assessment. Small-study effects could not be assessed formally with fewer than ten studies, and in a device literature with manufacturer involvement publication bias should be assumed present and to favour the device.

Two further limitations are specific. Both poolable trials were conducted in non-supine positions, so the estimate does not generalise to routine supine anaesthesia. And no included study enrolled children, in whom the tracheal margin for error is smallest, tube movement with head position proportionally greatest, and the physiological case for mechanical securement strongest; the complete absence of paediatric comparative data is the single largest gap in the field.

5. CONCLUSION

Device-based endotracheal tube stabilisation is consistently associated with less intraoperative tube movement than conventional adhesive tape across every comparative study that has measured it, and in the prone and lateral positions the reported effects are large. The pooled random-effects estimate is nonetheless imprecise and does not reach statistical significance, the evidence base comprises fewer than 350 randomised patients with no standardised outcome definition and no blinded assessment, and certainty is very low for every outcome. Mechanical securement is a reasonable and defensible choice where positioning places the airway at risk, but it cannot at present be recommended in place of adhesive tape for routine surgery, and the integrated multifunction devices now entering practice remain entirely untested in comparative clinical research. Adequately powered randomised trials with blinded, standardised outcome assessment are required.

DECLARATIONS

Ethics approval and consent to participate. Not applicable. This review used previously published aggregate data and involved no human participants, human material or human data collected by the authors.

Consent for publication. Not applicable.

Data availability. All data analysed in this review are contained within the published articles cited in the reference list. The full search strategies (Supplementary Material S1), the data extraction form (Supplementary Material S2), the extracted dataset and the analysis code are available from the corresponding author on reasonable request.

CRediT authorship contribution statement. [Author 1]: conceptualisation, methodology, investigation, formal analysis, writing — original draft. [Author 2]: investigation, data curation, formal analysis, writing — review and editing. [Author 3]: investigation, data curation, validation, writing — review and editing. [Corresponding Author]: conceptualisation, methodology, supervision, project administration, writing — review and editing. All authors read and approved the final manuscript and agree to be accountable for all aspects of the work.

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HIGHLIGHTS

- Six operating-theatre trials of device-based tube securement were found; only two could be pooled.
- Wherever tube movement was measured, it was smaller with a device than with tape.
- The random-effects odds ratio of 0.05 (95% CI 0.001 to 1.49) is imprecise and not significant.
- The larger of the two pooled trials has a fragility index of 1, so the result turns on one patient.
- Certainty was very low throughout, and no trial assessed displacement blind.
- Integrated multifunction devices have never been tested against anything in clinical practice.

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SUPPLEMENTARY MATERIAL S1. FULL ELECTRONIC SEARCH STRATEGIES

PubMed / MEDLINE (searched from inception to [date])

#1 "Intubation, Intratracheal"[Mesh] OR "Airway Management"[Mesh] OR endotracheal tube*[tiab] OR tracheal tube*[tiab] OR ETT[tiab] OR "double lumen tube*"[tiab] OR intubat*[tiab]

#2 fixation[tiab] OR securement[tiab] OR secure*[tiab] OR stabilis*[tiab] OR stabiliz*[tiab] OR holder*[tiab] OR "tube holder"[tiab] OR "bite block"[tiab] OR biteblock[tiab] OR tape[tiab] OR taping[tiab] OR anchor*[tiab] OR "AnchorFast"[tiab] OR "Tube-Guard"[tiab] OR "Rescuefix"[tiab] OR "Thomas tube holder"[tiab] OR dislodg*[tiab] OR displac*[tiab] OR migrat*[tiab] OR "unplanned extubation"[tiab] OR "accidental extubation"[tiab] OR "unintentional extubation"[tiab]

#3 "Anesthesia, General"[Mesh] OR "Operating Rooms"[Mesh] OR anaesthesia[tiab] OR anesthesia[tiab] OR intraoperative[tiab] OR perioperative[tiab] OR "operating room"[tiab] OR "operating theatre"[tiab] OR surgery[tiab] OR prone[tiab] OR "lateral decubitus"[tiab] OR Trendelenburg[tiab]

#4 #1 AND #2 AND #3

Filters: none. Language: none. Publication type limits: none applied at search stage; excluded at screening.

Embase (Elsevier, Emtree)

#1 'endotracheal intubation'/exp OR 'endotracheal tube'/exp OR (endotracheal NEAR/2 tube*):ti,ab OR (tracheal NEAR/2 tube*):ti,ab

#2 fixation:ti,ab OR securement:ti,ab OR stabilis*:ti,ab OR stabiliz*:ti,ab OR holder*:ti,ab OR 'bite block':ti,ab OR tape:ti,ab OR dislodg*:ti,ab OR displac*:ti,ab OR 'unplanned extubation':ti,ab

#3 'general anesthesia'/exp OR 'operating room'/exp OR intraoperative:ti,ab OR prone:ti,ab OR 'lateral position':ti,ab

#4 #1 AND #2 AND #3

Cochrane CENTRAL

#1 MeSH descriptor: [Intubation, Intratracheal] explode all trees

#2 (endotracheal or tracheal) near/2 tube*:ti,ab,kw

#3 (fixation or securement or stabilis* or stabiliz* or holder* or tape or dislodg* or displac* or extubation):ti,ab,kw

#4 (anaesthe* or anesthe* or intraoperative or "operating room" or prone or lateral):ti,ab,kw

#5 (#1 OR #2) AND #3 AND #4 — in Trials

Scopus

TITLE-ABS-KEY(("endotracheal tube*" OR "tracheal tube*" OR intubat*) AND (fixation OR securement OR stabilis* OR stabiliz* OR holder* OR "bite block" OR tape OR dislodg* OR displac* OR "unplanned extubation") AND (anaesthe* OR anesthe* OR intraoperative OR "operating room" OR prone OR lateral))

Web of Science Core Collection

TS=(("endotracheal tube*" OR "tracheal tube*") AND (fixation OR securement OR stabiliz* OR stabilis* OR holder* OR tape OR dislodg* OR displac*) AND (anesthes* OR anaesthes* OR intraoperative OR "operating room" OR prone))

CINAHL (EBSCO)

(MH "Intubation, Intratracheal+") OR TI/AB ("endotracheal tube*" OR "tracheal tube*") AND TI/AB (fixation OR securement OR stabiliz* OR holder* OR tape OR dislodg* OR displac*) AND TI/AB (anaesthesia OR anesthesia OR intraoperative OR "operating room" OR prone)

Trial registries

ClinicalTrials.gov, WHO ICTRP and CTRI searched with the free-text termsendotracheal tube fixation; tube holder; tube securement; unplanned extubation; bite block. Records of completed trials without a linked publication were followed up by contacting the listed principal investigator.

SUPPLEMENTARY MATERIAL S2. DATA EXTRACTION FORM

Domain	Items extracted
Study identification	First author; year; country; journal; funding source; declared conflicts of interest; protocol or trial registration number and date; whether registration preceded enrolment
Design	Design type (parallel RCT, crossover, split-body, non-randomised comparative); unit of allocation; method of sequence generation; allocation concealment; blinding of participants, personnel and outcome assessors; sample size calculation and its assumptions

Domain	Items extracted
Participants	Number randomised, analysed and lost per arm; age; sex; ASA physical status; body mass index; presence of beard or facial hair; dentition; exclusion criteria
Setting and procedure	Type of surgery; intraoperative position (supine, prone, lateral, Trendelenburg); duration of anaesthesia; whether the head was accessible or draped; intraoperative repositioning events
Intervention and comparator	Device name and manufacturer; mechanism of retention; whether integrated functions (bite block, eye shield, suction port) were present; tape material, width and configuration; who applied the securement and their experience; whether re-application was permitted
Airway details	Tube type (single- or double-lumen); internal diameter; cuff type; initial depth at the incisors; method of confirming initial position
Outcome measurement	Definition of displacement; measurement method (incisor mark, fibreoptic, radiographic); threshold used; timing and frequency of measurement; identity and blinding of the assessor; inter-observer reliability if reported
Outcome data	Events and denominator per arm for each dichotomous outcome; mean and standard deviation (or median, IQR, range) per arm for each continuous outcome; effect estimate and 95% CI as reported by the authors; p values as reported
Adverse events	Accidental extubation; endobronchial intubation; lip, perioral, dental or mucosal injury with its definition; tube occlusion; ocular injury; device failure or need to revert to tape
Resource use	Application time; number of personnel required; unit cost of device and of tape; any formal cost analysis
Extraction metadata	Extractor initials; date; source of each datum (text, table, figure, supplement, author correspondence); any calculation or imputation performed and its method; discrepancies between extractors and their resolution

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SUPPLEMENTARY MATERIAL S3. PRISMA 2020 CHECKLIST

Item	Checklist item	Location in this manuscript
1	Title identifies the report as a systematic review	Title page
2	Structured abstract	Abstract
3–4	Rationale and objectives	Introduction, final two paragraphs
5	Eligibility criteria	Methods — Eligibility criteria; Table 1
6	Information sources	Methods — Information sources and search strategy
7	Search strategy presented in full	Supplementary Material S1
8	Selection process	Methods — Study selection
9	Data collection process	Methods — Data extraction; Supplementary Material S2
10	Data items (outcomes and other variables)	Methods — Eligibility (Outcomes); Supplementary Material S2
11	Study risk of bias assessment	Methods — Risk of bias assessment; Table 3
12	Effect measures	Methods — Effect measures
13	Synthesis methods	Methods — Synthesis methods; Subgroup and sensitivity analyses
14	Reporting bias assessment	Methods — Reporting bias and certainty of evidence
15	Certainty assessment	Methods — Reporting bias and certainty; Table 5
16	Study selection results	Results - Study selection; Figure 1
17	Study characteristics	Results — Characteristics; Table 2
18	Risk of bias in studies	Results — Risk of bias; Table 3
19	Results of individual studies	Results - Primary outcome; Figure 4
20	Results of syntheses	Results — Primary and secondary outcomes; Tables 4 and 6
21	Reporting biases	Results — Certainty of evidence; Discussion — Limitations
22	Certainty of evidence	Results — Certainty of evidence; Table 5
23	Discussion — interpretation, limitations, implications	Discussion
24	Registration and protocol	Title page; Methods — Protocol and registration
25	Support / funding	Declarations
26	Competing interests	Declarations
27	Availability of data, code and other materials	Declarations