# Comparison of non-specialized versus specialized ties for endotracheal tube fixation


**Faculty of social science**
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| **MASTERSTUDIUM I PRE-HOSPITAL CRITICAL CARE**<br>**MASTEROPPGAVE** |
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| **FORFATTER:** Karin Haaland<br><br>**VEILEDER:** Nils Petter Oveland |
| **TITTEL PÅ MASTEROPPGAVE:**<br>**Engelsk tittel:** Comparison of non-specialized versus specialized ties for endotracheal tube fixation.<br><br>**Nordisk tittel:** Sammenligning av ikke- spesialiserte kontra spesialiserte bånd for endotrakeal tubefiksering. |
| **EMNEORD/STIKKORD:**<br>Endotracheal intubation, endotracheal tube, endotracheal securement device, endotracheal tube fixation, tube fixation device. |
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# Acknowledgement

" We are but warriors for the working day" This line from Shakespeare's "Henry V" captures something of the challenges facing those who practice medicine in an Emergency Department(1). They stand on the front line between the hospital and the hostile world of injury, infections and acute illness. The nature and extent of these enemies are not really known until the moment of encounter. And the encounter itself is brief, singular, hugely critical, largely unplanned and full of surprises and uncertainties.

This Master thesis is in two parts: Part 1: The compilation and Part 2: The Article.
The Article is written for publishing in BMC Anaesthesiology, (https://bmcanesthesiol.biomedcentral.com/submission-guidelines/preparing-your-manuscript/research-article). This scientific journal was selected because of the audience within advanced airway management.

Thanks to my supervisor Nils Petter Oveland for including me in his studies and gave me the confidence to test this new idea in my Master thesis. Great teamwork and great guidance from a professional within anaesthesia, research and development.

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...and thanks to my loving family for always giving me patience, support and encouragement.

- ***Karin Haaland***

## Part 1: The Compilation

## Figures



## Tables



## Abbreviations

| | |
|---|---|
| ETI | Endotracheal Intubation |
| ETT | Endotracheal Tubes |
| ICU | Intensive care unit |
| CPR | Cardiopulmonary resuscitation |
| NSD | Norwegian centre of research data (Personvernombudet for forskning) |
| REK | Regional Committees for Medical and Health Research Ethics (Regionale komiteer for medisinsk og helsefaglig forskningsetikk) |
| FHI | Norwegian Institute of Public Health (Folkehelseinstituttet) |
| EBP | Evidence based practice |
| EBM | Evidence based medicine |
| UE | Unplanned extubation |

# 1.0 SUMMARY

**Background and aim**: Endotracheal intubation is performed to secure the airway in patients who require mechanical ventilation. Unplanned extubation is life-threatening and need to be secured to prevented. Various methods and devices have been developed to fixate the endotracheal tube. In this study, we aimed to compare the effectiveness of specialized versus non-specialized fixation devices/ties.

**Methods**: An experimental study on a training mannequin compared four different methods to fixate an endotracheal tube; non- specialized ties such as tape and tube tie against specialized, purpose-built devices such as the Thomas Tube Holder™ and the T2 Wrap™. The study consisted of three parts: pull test, jerk test and user test. The fixation strength and tube dislodgement of each device/ties was measured.

**Results:**
The T2 Wrap™ demonstrated superiority in fixation strength for ETTs compared to tape, tube tie and Thomas Tube Holder™ (p=0,05), in both the pull and user test. In jerk test, all ETTs secured with tape immediately snapped out of the airway, all tubes fixated with tube tie moved on average 24.6 mm, all tubes fixated with Thomas Tube Holder™ 11.8 mm and all tubes fixated with T2 Wrap™ 6.5 mm. Paramedics scored user-friendliness of the Thomas Tube Holder™ and T2 Wrap™ first and second.

**Conclusion:** Our results demonstrate a superiority of using specialized ties (e.g. Thomas Tube Holder™ and T2 Wrap™) compared to non-specialized ties (e.g. tape and tube tie) for endotracheal tube fixation in a simulated clinical setting. We advocate increased use of these devices to prevent unplanned extubations.

**Keywords:** Endotracheal intubation, endotracheal tube, endotracheal securement device, endotracheal tube fixation, tube fixation device

# 2.0 INTRODUCTION

*In this chapter, the background, aim and choice of the topic will be described. The search process is detailed described using PICO and electronical databases. And a summary of previous science.*

## 2.1 Background

The uncontrolled nature of the prehospital environment increases the complexity of airway management and ETI(2). The emergent nature of prehospital ETI, the relatively smaller number of health professionals available at the time for intubation, and the necessity to move the patient heighten the risk for ETT dislodgement in these settings.
Endotracheal intubation (ETI) is one of the most important and common procedures in emergency medicine performed to secure the airway of critically ill and injured patients (3). Unplanned extubation (UE) is a life-threatening event that quickly can lead to oxygen deficit in the blood followed by irreversible brain damage and even death, and in recent years has been a focus of continuous quality improvement programs. While these programs and research have improved the care of the intubated patient, relatively little attention has been given to experimental comparisons between methods for endotracheal tube (ETT) fixation. This problem affects multiple disciplines, notably anaesthesia, critical care, military filed use, emergency medicine and prehospital critical care.

## 2.2 Evidence based practice / medicine

Evidence based practice (EBP) refers to the process that includes finding empirical evidence regarding the effectiveness and/or efficacy of various treatment options and then determining the relevance of those options to specific clients(4). Sackett et al defined evidence-based medicine (EBM) as an integration of best research evidence, clinical expertise, and patient values(5). Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.

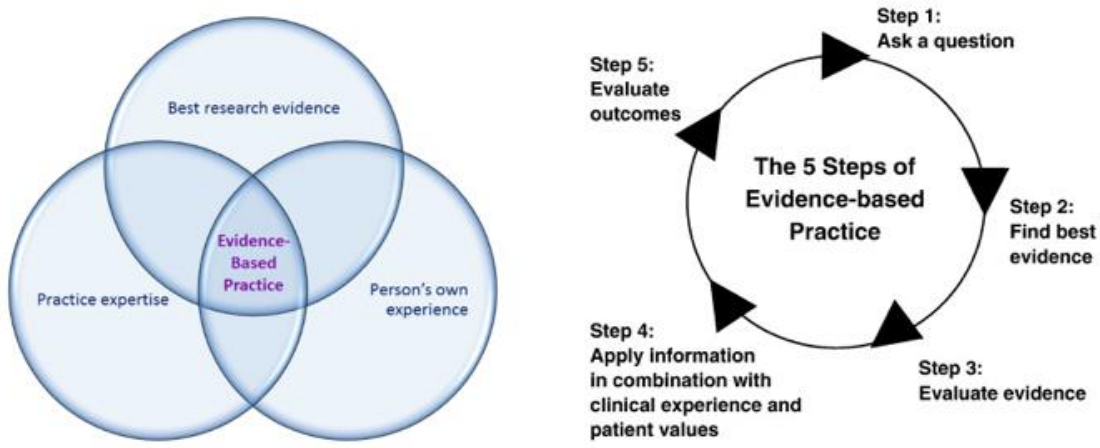


Figure 1: The EBP/ EBM process (Sackett et al 2000, Evidence based medicine(5))

## 2.3 Search description/ PICO

Literature increase is a crucial element in an EBP process, if you have not identified all the relevant studies, you may risk an incorrect conclusion based on the literature (6). Literature increase must be systematic in order to achieve a complementary result as well as be well documented and transparent so that the process is credible and can be repeated with the same result of others.

| | |
|---|---|
| **Databases** | **Chinal, Medline and Cochrane Library** |
| **Keywords** | **Endotracheal tube*, fixation or fixator*, securing or securement or stabili* or restrain*, device* or method* or technique*, tube* or ETT, holder* or tape or tapes or taping or suture* or tie or ties + not infant* or neonate* or new born* or paediatric* or child*.** |
| **Inclusion criteria** | **Patients, manikin or cadavers (patient group)<br>Science literature within the last 15 years<br>Trials with either tape, umbilical tape or the Thomas tube holder.** |
| **Exclusion criteria** | **Infants/ Neonate/ New born/ Paediatric/ Children<br>Other securement devices that are not included in our trial.<br>Research papers or literature older than 15 years** |
| **Study design** | **All** |
| **Intervention** | **Test of tube fixation after endotracheal intubation.** |
| **Endpoint** | **Outcome of test** |

*Table 1: The systematic search (6)*

An advanced literature search was performed in the databases Ovid Medline and Cinahl using a PICO form (Attachment 6, 7, 8). The results from Ovid revealed 177 articles, 164 of these were rejected. Cinahl revealed 52 studies and 4 of these was included in the master thesis (Table 1).

Quality assessment is a part of the systematic review process that can guide the interpretation of the findings and help determine the strength of inferences made from the results.(4) There are three aspects that one must critically deal with when reading scientific articles(6). First, whether the populations, efforts and measurements are professionally relevant and conducted in a professionally sound manner. Secondly, the internal validity will be assessed whether the scientific methods are inverted / implemented in a way that can be trusted. Thirdly, consider whether the results of the study are relevant to own practice. Checklists from Centre for Evidence Based Medicine have been prepared for the evaluation of articles. The purpose of checklists is to ensure that all essential parts of the study method are reported so that it is possible to assess the quality of the study and thus assess the credibility of the study results.

## 2.3 Previous science/ Summary of the literature

### *2.2.1 Clinical trials on a trainer mannequin*

Lovett BP. et al. compared degrees and movement of ETTs secured with 6 different commercial devices. (7) The Dale® was most secure. Murdoch E. et. al. performed a pull test trial testing the Thomas™ tube holder.(8) The tube holder device minimized tube movement in a mannequin when compared with conventional tape tying. Shimizu et al. tested 3 brands of tape with 6 methods, and two ETT holders (Lock Tite™ and Thomas™) with a pulled test (9). The conventional tape method was superiors to the two tested ETT holders. Fisher DF et al. tested several ETT holders in a jerk test.(10) The ETT stability is affected by the type of fixation device used. Davies A et al. compared four different tapes using three different fixation methods in different positions.(11) Durapore silk tape was superior at holding the ETT in place. Kowasawa et al., evaluated how ETT displacement is affected by tape versus tube holder fixation using a compression machine simulation.(12) ETT displacement occurred less with tube holder fixation than with tape.

### *2.2.2 Clinical trials on patients*

Kupas DF. et. al. compared the effectiveness of common airway- securing techniques (differnet tape, tubing, tube holders and manual stabilization/none) in preventing UE in prehospital setting.(2). ETT dislodgement did not occur with woven twill tape. Santhosh et. al. compared tube- taping versus tube- holding device for securing ETT in patients.(13) The ETT was secured either with adhesive tape or a Thomas tube holder™. The Thomas tube holder was more effective than adhesive tape in preventing UE. Hanan et al. studied effectiveness of three techniques twill, adhesive and simple bow.(14). The twill securement technique method was associated with lower times for application and removal of ETT securement. Buckley JC. et. al. compared the Haider tube guard (similar to the Thomas tube holder™) versus adhesive tape.(15) The conclusion was that the Haider Tube-guard can influence the quality of the ETT fixation.

### *2.2.3 Clinical trials on cadavers*

Carlson J. et al. researched tape versus ETT using intubated cadavers secured with either tape or one of 4 commercially available ETT holders.(16) Tape required a significantly larger force to extubate than 3 of 4 ETT holders. Only the Thomas Tube Holder™ secured the ETT better than tape. Owen R., et. al. compared adhesive tape, non- adhesive tape and Thomas tube holder™ in intubated cadaver.(17) Adhesive tape provided the greatest resistance to tube dislodgement, but the Thomas tube™ was quick and effective.

### *2.2.4 Clinical patients with facial issues*

Bodily fluid is present in critical care and emergent situation leading to difficulty when trying to use the more common, traditional methods of tube fixation.(18) Beside posing a difficulty during ventilation and intubation, facial hair also limits reliable tube fixation (19, 20) Agarwal et. al. fixated the tube first with a temporary bandage and then by tape over a plastic rectangle piece. Kajal et. al. used a technique with gauze bandage imposes no traction on the ETT. Patients with facial burns and inhalation injuries who require grafting to the face and neck area present additional challenges: oedema, ventilator requirements and avoiding facial burn debridement (21). A Danish study investigated whether the materials currently used for fixation of the tracheal tube ensured secure fixation in injured trauma patients (22). 14 tubes of 100 were recorded unsatisfactory where of these were reinforced and 5 fixation materials

had to be replaced. The number of insufficient tube fixations locally led to Thomas™ as a standard use of ETT fixation in trauma patients.

## 2.3 Aim of study and Questionnaire

We aim to challenge aspects of current airway management and how we secure ETTs after ETI and reduce the risk of extubation. The use of non- specialized fixation devices has many disadvantages and we hope to elucidate the safety and user-friendliness of current commercial available tube fixation equipment and look at the effectiveness of a newly designed tube fixation device.

In this study, we will compare four different methods to fixate ETTs; non- specialized ties such as tape and umbilical tape (twill) against specialized, purpose-built devises such as the Thomas Tube Holder™ and the T2 Wrap™. We have limited the study to only deal with the three different devices / ties used in our own health service, as well as implementation of the new design. Our results can give us an indication of the optimal fixation procedure of ETTs and potentially change current airway management.

# 3.0 THEORY

The starting point for the research process is a theoretical domain (23). Theories in the social science can vary between abstract general approaches (such as functionalism) and fairly low-level theories to explain specific phenomena. By and large, the theories that are most likely to receive direct empirical attention are those which are at a fairly low level of generality.

*In this chapter the theoretical framework will be presented: the basic theory of advanced airway management including intubation and extubation.*

## 3.1 Critical Advanced Airway Management

The ability to provide critical care and definitive airway management for all patients, regardless of the cause of their presentation, is unique to the specialty of emergency medicine. A patient airway is essential for adequate ventilation and oxygenation. If the patient is unable to maintain the airway, patency must be established by artificial means, such as repositioning, chin lift, jaw thrust, or insertion of an oral or nasal airway. Likewise, the patient must be able to protect against aspiration of gastric contents, which carries significant morbidity and mortality.

## 3.2 Endotracheal intubation

ETI is always indicated during cardiopulmonary resuscitation (CPR) (24). ETT placement during CPR provides effective ventilation and oxygenation, frees the operator's hands from mask ventilation, improves the conditions for chest compression, avoids gastric distensions and aspiration of the gastric contents into the lungs, and allows accurate measurement of end-tidal CO2, which may be critical for assessment of the effectiveness of resuscitation. ETI is the most definitive means or achieving complete control of the airway (the golden standard). A very important step in intubation is to secure the ETT. Inadvertent extubation caused by the patient or someone else is relatively common and can be very traumatic to the patient (25).

## 3.3 Unplanned Extubation

Unplanned extubation may results from movement of or by the patient with an inadequately secured ETT (26). Fastidious attention to securing the tube, providing support for the circuit, and moving the patient and the tube as an integral unit should help to reduce the frequency of this complication. Self – extubations may occur during emergence from anaesthesia when the patient is confused, agitated, or distressed, prompting premature extubation. Reintubation will almost certainly be even more difficult and is different from the original intubation because it is likely to occur in an urgent or emergent setting, with limited information/ equipment. The patient is more likely to be hypoxic, academic, agitated, or hemodynamically unstable, and the procedure may be done in haste.

# 4.0 METHODS

*This chapter presents the methodological framework: study design, trial description, data, participants and the ethical aspects.*

## 4.1 Research Design

The choice of research design must be dovetailed with the specific research question being investigated(4) Another salient matter relevant to the choice of research designs is the nature of the topic and the characteristics of the individuals/ groups being researched. The golden standard of scientific science is randomized controlled trials where participants are randomly assigned to groups in order to receive different interventions, but due to time and resources, a RCT was not planned. For this study we chose a quantitative experimental trial. Quantitative research design is known as the science of numbers, and is also referred to as positivist science. Positivism is underpinned by the ontological belief that there is an objective reality that can be accessed. The aim of positivistic enquiry is to explain, predict and control a reality.

## 4.2 Materials and Methods

### *4.2.1 Materials and trial setup*

In this experimental study, a training mannequin (i.e. Laerdal Medical ALS Simulator) was placed in a supine position with its body and head fixed to a stretcher using safety belts and tape. Further, it was intubated with a pre-lubed ETT with uninflated cuff.

The ETTs were fixated with either tape, tube tie, Thomas Tube Holder™ or T2 Wrap™. With tape (2.5 cm x 4.5 m Tensoplast®, BSN Medical Ltd, Pinetown, South Africa) the ETTs were fixated using a criss-cross pattern around the shaft (i.e. 2 x 20 cm long pieces of tape), and with tube tie (1 cm x 2 m ribbon) around the neck the ETTs were fixated with the knot "Rolling hitch/ Magnus hitch". The fixation with the Thomas Tube Holder™ (Laerdal Medical, Stavanger, Norway) and T2 Wrap™ (novel device under development) were done according to their instruction of use, being thumbscrew and tie wrap devices respectively.


**Figure 2**. Specialized and non– specialized ties/ devices used in the trials.
**A.)** Thomas tube, **B)** T2 Wrap, **C.)** Tape, **D.)** Umbilical tape.

### *4.2.2 Trial description*

**<u>This trial was subdivided into three different tests:</u>**

**1.) Pull test:** The mannequin was intubated and the ETTs fixated at 22 cm at the lower lip using the four different ties, respectively. A rope from the end of the ETT was thread through pole rings and attached to a scale (i.e. a bucket). Furthermore, a digital force gauze (FH 10-500 EXT, Sauter, Albstadt, Tyskland) was placed between the ETT and the pole rings to measure the force (i.e. Newton) applied to the tube. Dumbbells of 1 Kg were put onto the scale in 10 incremental steps. Further, the movement of the ETTs out of the mouth compared

to the basis (i.e. 22 cm at the lip) was marked with a pen alongside the shaft of the tube after each incremental weight-step. Extubation (i.e. endpoint) was defined as complete ETT dislodgement or movement of the tube of at least 69 mm (i.e. the distance where the cuff slipped out of the larynx). The main outcome mm tube displacement was measured alongside the shaft of the tube (i.e. from the 22 cm line to all the marked pen points on the side of the tube) after extubation with a digital slide caliper (Cocraft digital caliper, Clas Ohlson, Insjön, Sweden). The pull test was repeated in 10 separate identical series per device/tie. The setup is shown in **figure 3.**

**2.) Jerk test**

The exactly the same setup as the "Pull test", the dumbbells of 2 kg were dropped from a 20-cm height down into the bucket (i.e. the scale) to give a jerk of the ETTs. The main measurement in this test was the peak of force (i.e. peak Newton) applied to each tube and the main outcome mm tube displacement compared between the four different devices/ties in 10 separate series. Similar endpoint as the "Pull test". The setup is shown in **figure 3.**

**3.) User test**

The user test was performed by 10 experienced paramedics that each intubated and fixated the ETTs tubes using the different devices/ties in four separate realistic simulated scenarios of cardiac arrest. Which ties they used were randomized as the participants had to draw one of four envelopes before each scenario. In the pre-trial period, the participants received a short demo of the new fixation device T2 Wrap. The others were familiar ties used in their prehospital practice (e.g. tape, tube tie and Thomas Tube Holder™). The mannequin was placed in the supine position on the floor of a gym. They were all allowed to use their own methods of fixation, but not given the opportunity to go through guidelines and recommendations for tube fixation. The participants intubated the same mannequin as described and fixated the tubes to their best of their ability using all four different devices/ties. They were timed from laryngoscopy until tube fixation. The fixation strength of each device/tie was measured using the exactly the same method and endpoint described in the "Pull test" (the mannequin was moved from the floor and strapped to the stretcher). Finally, after completing four scenarios each participant had to score their self-experienced user-

friendliness of each device from 0 – 100 (i.e. Visual Analogue Scale) where 100 was best and 0 worst. The setup is shown in **figure 3.**

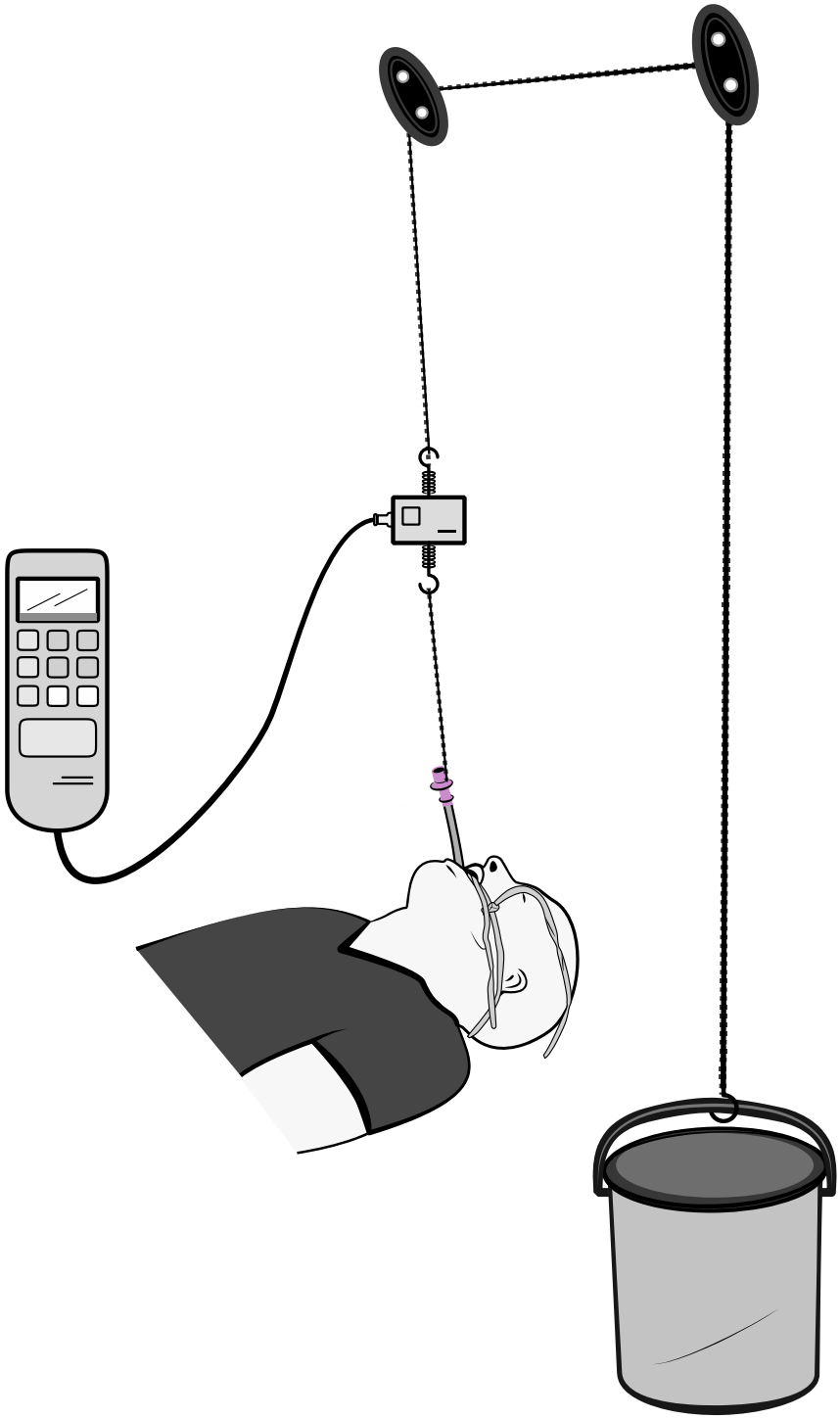

Figure 3: Trial setup used in the 1) Pull test, 2) Jerk test and 3) User test.

## 4.5 Statistical Analysis

The ETT fixation strength was measured in Newton (N) and the tube dislodgement in millimetre (mm) for each trial (i.e. pull, jerk and user test) using the four different devices/ties. We calculated the mean values of force (N) and displacement (mm) with standard deviations for the 10 series of each device/ties. Per definition extubation was given the value 69 mm tube displacement. A tobit model (censored regression model) was used when estimating the linear relationships between the predictive values; weight on scale (i.e. Kg), type of device/tie used and paramedic performing the procedure and the dependent variable (i.e. outcome variable) mm tube displacement. This statistical model is well suited based on the fact that we had a threshold for extubation on 69 mm tube displacement (i.e. censoring from above). Furthermore, we used dummy variable statistics where our four different devices /ties were (categorical predictive variable) were given a binary 0 or 1 number. This was done to compare the three different devices/ties; tape, tube tie and Thomas Tube Holder™ against a reference device T2 Wrap™. We calculated the mean time from laryngoscopy to tube fixation and mean scored user-friendliness (Visual Analogue Scale 0-100) among the 10 paramedics in the user test. All computations were performed using SPSS (IBM SPSS, Armonk, NY)(23).

## 4.6 Validity and Reliability

Criteria used in this quantitative research to evaluate the rigour (authenticity/ credibility/ strength) is reliability and validity(4). Reliability refers to stability of findings whether a finding is reproducible, at other times, by other researchers. Validity represents the truthfulness of findings and is concerned with the integrity of the conclusions that are generated from a piece of research. Internal validity is related “to the issues of whether a method investigates what is purport to investigate”, while external validity relates to “whether the results of a study can be generalised beyond the specific research context”. Quantitative researchers need to be objective and structured to avoid any bias, even though it is difficult to avoid all the bias.

## 4.7 Ethics

Research ethics is finding the balance between the risks associated with a research project and its benefits(4). There are four principles that researchers must adhere to in their research: respecting autonomy, beneficence, non- maleficence and justice.

The trials were performed using a simulation mannequin and did not involve any patients or cadavers. Participants was informed of the aims and methods of the research and asked for their consent. The research participants in the user tests was qualified emergency personnel who voluntarily participated, and the trial was without hazard. Their anonymity and confidentiality was maintained, and person-identifiable material was stored safely and the individual has been identified in the analyses by number (Candidate number 1,2,3). The University of Stavanger and the Stavanger University Hospital's internal rules for good research ethics was followed. Application to REK / NSD was not needed.

# 5.0 RESULTS

## 5.1 Pull test

Ten separate series of measurements with incremental weight gain from 1 to 10 Kg were performed for all the four different ties. A total of 40 measurements were analysed and mean values calculated per Kg level from 1 to 10. The curves of mean mm tube displacement as a function of increasing weight is shown in **Figure 4**.

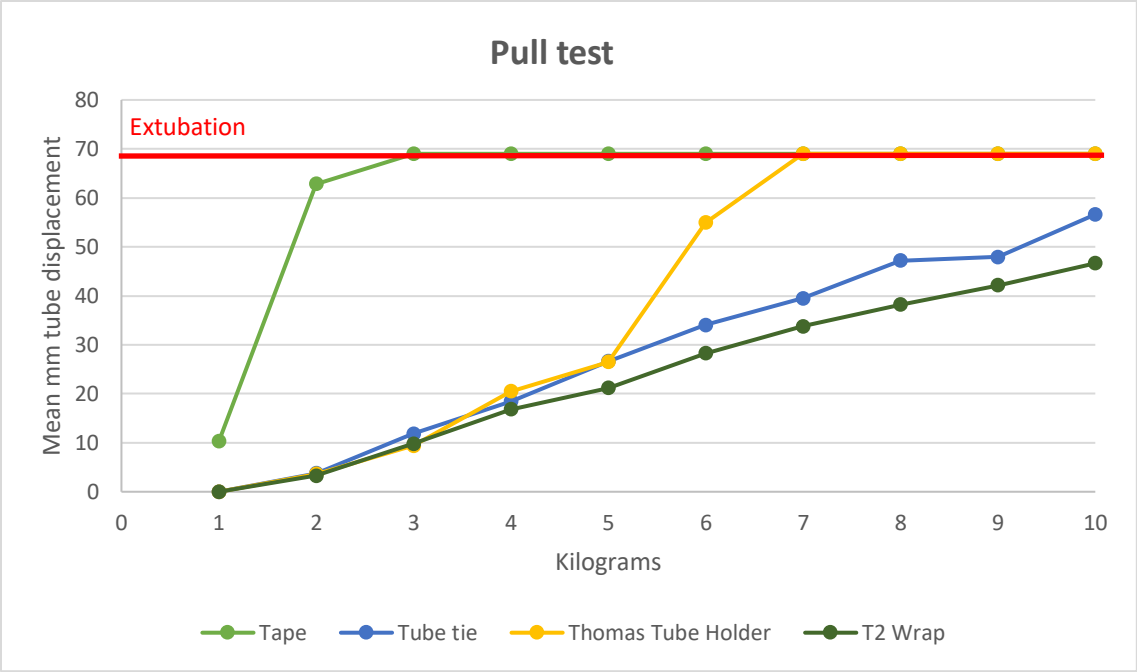


**Figure 4.** Pull test with movement of the ETTs (Y-axis) per Kg increasing weight (x-axis). The different coloured curves represent the four ties used in the trial, and the dots the mean value of mm tube displacement from the 10-separate series. The red line is the threshold of 69 mm representing extubation (i.e. cuff out of the larynx).

Summary of the regression analysis for the pull test is shown in **Table 2**.

**Table 2.** Tobit regression model analysis with dummy variable statistics of pull test.

| Device | Estimate | Standard error | p-value |
|---|---|---|---|
| Tape* | 61.99 | 4.13 | 0.001 |
| Tube Tie* | 5.37 | 2.64 | 0.04 |
| Thomas Tube Holder™* | 22.86 | 2.67 | 0.001 |

* T2 Wrap as reference device.

## 5.2 Jerk test

A total of 40 measurements were analysed and mean values of peak force (Newton) and mm tube displacement calculated. The jerk test demonstrated a consistency in the peak force applied to all the ETTs regardless of device/tie used.

All the results from the jerk test are shown in **Table 3**.

**Table 3.** Results from the 10-series jerk test per device.

| Device | Mean peak force* | Mean mm tube displacement** |
|---|---|---|
| Tape | † | †† |
| Tube Tie | 65.7 | 24.6 |
| Thomas Tube Holder™ | 62.3 | 11.8 |
| T2 Wrap | 64.6 | 6.5 |

* Mean peak force applied to the tube with a single jerk by a 20 cm dumbbell drop. Measured with a digital newton-meter.

** Mean movement of the tube out of the mouth. Measured in millimetre.

† 10/10 extubations. Not able to measure peak force.

†† 10/10 extubations. Mean tube displacement ≥ 69 mm.

## 5.3 User test

**3.) User test**

A total of 40 measurements were analysed and mean values calculated per Kg level from 1 to 10. The curves of mean mm tube displacement as a function of increasing weight is shown in **Figure 5**.

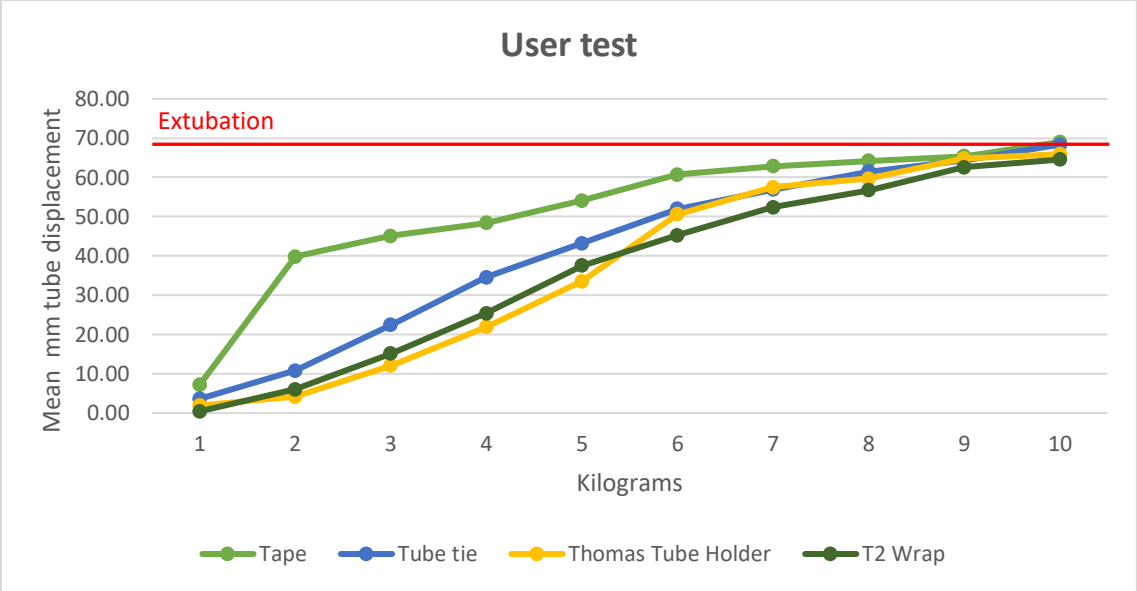


**Figure 5.** User test with movement of the ETTs (Y-axis) per Kg increasing weight (x-axis). The different coloured curves represent the four ties used in the trial, and the dots the

mean value of mm tube displacement from the 10-paramedic series. The red line is the threshold of 69 mm representing extubation (i.e. cuff out of the larynx).
Summary of the regression analysis for the user test is shown in **Table 4**.

**Table 4.** Tobit regression model analysis with dummy variable statistics of user test.

| Device | Estimate | Standard error | p-value |
|---|---|---|---|
| Tape* | 27.61 | 3.40 | 0.001 |
| Tube Tie* | 7.61 | 3.21 | 0.018 |
| Thomas Tube Holder™* | 6.05 | 3.20 | 0.059 |

* T2 Wrap as reference device.

## 5.4 Time and User friendliness

The mean time from laryngoscopy to fixation and the self-scored user-friendliness of the devices/ties are showed in **table 5**.

**Table 5.** Time to fixation and user-friendliness of the four different devices/ties.

| Device | Time (sec)* | User-friendliness score (0-100)** |
|---|---|---|
| Tape | 67 | 35 |
| Tube Tie | 52 | 61 |
| Thomas Tube Holder™ | 47 | 80 |
| T2 Wrap™ | 71 | 72 |

* Mean time from laryngoscopy to fixation among 10 experienced paramedics.

** Visual Analogue Scale (VAS) with 0= low and 100=high user-friendliness.

# 6.0 DISCUSSION

*In this chapter, background, aim, method and previous research findings will be discussed, and critical review of the validity and reliability. The results from the research and comparison between the different devices/ ties are the main topics for discussion in the article, which also describes the limitations for the study.*

Quantitative researcher must consider the degree of confidence desired, the homogeneity of the population, the complexity of the analysis plan, and the expected strength of the relationship they measured(4). We aimed to challenge aspects of current airway management

and how we secure ETTs after ETI and reduce the risk of UE. We compared four different methods to fixate ETTs that we use in our own emergency practice; the non- specialized ties tape and twill tape against the the specialized devices Thomas Tube Holder™ and the T2 Wrap™. We wanted to elucidate the safety and the user- friendliness of current available tube fixations and look at the effectiveness of the new designed innovative fixation device: The T2 Wrap™.

The best way to investigate/ compare different ties/ devices was by using an experimental quantitative study design, both with trials performed by the investigators and experienced paramedics. The strength of this type of research design is that it can give specific answers/ results. The amount of variables is less than in other scientific methods, because the sets promote control of the variables that is being study. This method also let the investigator identify cause of effect. Quantitative data shows measurements that is significant information, statistics and number allows the investigator to draw conclusions. But the weakness of this method is that the results that arise is not necessary representative for same phenomena in the real life. The study participants could act different because they know that they were investigated or perform in a different environment. Therefor to minimize this bias the investigators tried to create a research setting almost equal to a clinical setting. Other bias that could arise in this study was selection bias since the research participants was selected using non- random. Experimental study is a method of contact between the investigator(s) and the study participants which allows possibility of impact. To avoid impact during the tests the participants performed the fixation while the investigator observed at a distance. The pull and jerk test was performed with to researcher present for quality assurance/ double check. This was small randomized experimental trial performed by a small dynamic group of paramedic located in one ambulance department with the same procedures and practice. A larger (randomized controlled) trial with a more extended participants and different profession within anaesthesiology would be the golden standard of this study where researcher bias could be minimized. The advantages of a small experimental study method are that it is affordable and timesaving.

The validity of the data collection is high using both observation and trials in the study, and the test method used was tested with success in previous sciences. Pre-tests were performed before trial start up to make sure that the equipment, set up and the measuring instrument were accurate. The study was supplemented with the participant's individual feedbacks. This

study used a standardized method with registrations and measurements. Although there are some factors that could have led to impair the reliability, human influence for example. Random errors could have occurred at different stages of the research process, especially in the trial process. Only one investigator was in charge of the data collection and analysis which increased the reliability in the study. The trial is well described with detailed information about the set-up, equipment and the approach to the study which suggests that the method can be reused by a new researcher who can produce apparently similar results. In the case of observations, other researchers may observe to see whether the same conclusions will be drawn at the same time.

Previous clinical studies on ETT securement shows no superior method of fixation of ETT. The research articles show an approximately 50/50 result whether specialized/ commercial devices versus non – specialized/ non- commercial devices are best for securing the ETT. 8 studies tested and concluded that the specialized ETT holders had the best results in their trials (7, 8, 12, 13, 15-17, 22). 6 studies concluded in their trials that the non- specialized devices (any type of tape and twill tape) was the best way of securing the ETT, 2 of these concluded that tape was the best (9, 11) and 4 of these studies concluded that the twill tape was best suited (2, 14, 20, 21). Fisher et al concluded that no ideal devices or methods for securing ETT exist(10).

Advanced Cardiac Life support guidelines (2005) recommend either tape or commercial/ specialized holders to secure the ETT(9). But our study and the majority of previous studies don't support tape as the best method to secure the ETT. Santosh et al suggest that tape is clinical useful in the prone position in a in hospital setting, but ETT holder was significant better(13). In Carlson et al study tape outperformed 3 ETT holders, but got beaten by The Thomas tube holder(16). Tape was the most effective way in preventing extubation in the study from Davies et al, but they only tested different types of tapestry and taping methods(11). It seems like the only benefit of tape is that is easily accessible and lowest cost. In our study the tape hade the worst outcome in all three tests, and in the jerk test the taping fixation ended up in extubation in each test. The same results had the study from Shimizu et al where the conventional taping method had the largest extubation force.(9) 97 % of the patients (29/30) experienced clinical significant ETT movement with adhesive tape(15). The tape was not the best way to secure an ETT during chest compressions(27). The study from

Wagner et al the tape tored before the tube underwent significant tube displacement(18). The tape partly or completely separated from the face, or stretched enough to get extubated in our tests. Success criteria for tape was taping around the patient's head, not just a facial typing. Same observational was done by Shimizu et al where wider and longer the tape was, the greater was the extubation force(9).
Emergency medical practitioners are not selective knot tiers and the methods are often a combination of habit, guesswork and tradition(7). This was clearly seen in our study where none of the participants had a specific knot or method for tube tie fixation. 10 paramedic performed 10 different ways of securing the tie, none used the same method as the investigator in pull/ jerk tests. The failure and cause of extubation of the tube tie was stretch and slippage. Some of the knots completely loosened. In the study from Hanan et al 80 % of the patients was most satisfy with the tube tie compared to tape(14). There was no slippage, the mean of skin integrity was lower and lowest score in pain for the tube tie. Studies who tested ETT fixation on patients with beard, facial issues concluded with the tube tie in different combination. (19-21)

Specialized devices are used only a small percentage of intubated patients (7). The total marked for specialized ETT holders is less than 500.000 units, in less than 5 % of intubations. This shows that current practice is not based on previous research evidence. The majority of the research articles investigated in our study conclude that specialized ETT holders are superior in fixating the ETT, including our trial. The ETT significantly reduced the mobility (15). Thomas Tube holder was more effective in preventing tube displacement (13). And had a greater security method especially under transportation (8). Participants was faster to the secure the tube holder and a greater force was also required to move the tub (17).

# 7.0 CONCLUSION

We have demonstrated a superiority of using specialized ties (e.g. Thomas Tube Holder™ and T2 Wrap™) compared to non-specialized ties (e.g. tape and tube tie) for ETT fixation in a simulated clinical setting. The new device T2 Wrap™ prevents clinically significant dislodgement of ETTs compared to other methods of restraint and can decrease the incidence of UE in the field.

# REFERENCE


1. Croskerry P. Patient safety in emergency medicine. Philadelphia, Penn: Wolters Kluwer/Lippincott Williams & Wilkins; 2009.
2. Kupas DF, Kauffman KF, Wang HE. Effect of Airway-Securing Method on Prehospital Endotracheal Tube Dislodgment. Prehospital Emergency Care. 2010;14(1):26-30.
3. Davis B. ROSEN'S EMERGENCY MEDICINE: CONCEPTS AND CLINICAL PRACTICE, FIFTH EDITION. Prehospital Emergency Care. 2004;8(3):334-5.
4. Liamputtong P. Research methods in health : foundations for evidence-based practice. 2nd ed. ed. Melbourne, Australia: Oxford University Press; 2013.
5. Sackett DL, Rosenberg WMC, Gray JAM, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. BMJ. 1996;312(7023):71-2.
6. Lund H, Juhl C, Andreasen J, Møller A. Håndbog i litteratursøgning og kritisk læsning : redskaber til evidensbaseret praksis. København: Munksgaard; 2014.
7. Lovett P, Flaxman A, Stürmann K. The insecure airway: a comparison of knots and commercial devices for securing endotracheal tubes. Academic Emergency Medicine. 2003;10(5):485-6.
8. Murdoch E, Holdgate A. A comparison of tape-tying versus a tube-holding device for securing endotracheal tubes in adults. Anaesthesia and Intensive Care. 2007;35(5):730-5.
9. Shimizu T, Mizutani T, Yamashita S, Hagiya K, Tanaka M. Endotracheal tube extubation force: adhesive tape versus endotracheal tube holder. Respiratory care. 2011;56(11):1825-9.
10. Fisher DF, Chenelle CT, Marchese AD, Kratohvil JP, Kacmarek RM. Comparison of commercial and noncommercial endotracheal tube-securing devices. Respiratory care. 2014;59(9):1315-23.
11. Davies A, Murphy M, Monaghan W, Cushenbery C. Sticky situation: best practice to secure endotracheal tubes in the operating room. International Journal of Advanced Nursing Studies. 2014;3(1):20-3.
12. Komasawa N, Fujiwara S, Miyazaki S, Ohchi F, Minami T. Shifts in Endotracheal Tube Position Due to Chest Compressions: A Simulation Comparison by Fixation Method. The Journal of Emergency Medicine. 2015;48(2):241-6.
13. Santhosh MC, Torgal SV, Pai RB, Roopa S, Santoshi VB, Rao RP. Comparison of tube-taping versus a tube-holding device for securing endotracheal tubes in adults undergoing surgery in prone position. Acta anaesthesiologica Belgica. 2013;64(2):75-9.
14. Hanan Mohammed M, Manal Salah H. Endotracheal tube securements: Effectiveness of three techniques among orally intubated patients. Egyptian Journal of Chest Disease and Tuberculosis. 2015;64(1):183-96.
15. Buckley JC, Brown AP, Shin JS, Rogers KM, Hoftman NN. A Comparison of the Haider Tube-Guard(®) Endotracheal Tube Holder Versus Adhesive Tape to Determine if This Novel Device Can Reduce Endotracheal Tube Movement and Prevent Unplanned Extubation. Anesthesia and Analgesia. 2016;122(5):1439-43.
16. Carlson J, Mayrose J, Krause R, Jehle D. Extubation Force: Tape Versus Endotracheal Tube Holders. Annals of Emergency Medicine. 2007;50(6):686-91.

17. Owen R, Castle N, Hann H, Reeves D, Naidoo R, Naidoo S. Extubation force: A comparison of adhesive tape, non-adhesive tape and a commercial endotracheal tube holder. Resuscitation. 2009;80(11):1296-300.
18. Wagner J, Shandas R, Lanning C. Extubation force depends upon angle of force application and fixation technique: a study of 7 methods. BMC Anesthesiology. 2014;14.
19. Agarwal A, Singh DK, Dinesh C, Pradhan C. Nonconventional way of securing endotracheal tube in bearded individuals. Journal of Anaesthesiology, Clinical Pharmacology. 2011;27(3):425-6.
20. Kajal S, Dhankhar M, Mukherjee S, Arya G. Non traditional method of endotracheal tube fixation in bearded patients undergoing facial and occipital surgeries. Egyptian Journal of Anaesthesia. 2015;31(3):255-7.
21. Sadawarte P, Gadkari C, Bhure A, Lande S. Non conventional way of securing endotracheal tube in a case of facial burns. Journal of Anaesthesiology Clinical Pharmacology. 2013;29(2):267-8.
22. Korsvold EC. Placement and fixation of the endotracheal tube in trauma patients. Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine. 2010;18(1):P25.
23. Bryman A, Cramer D. Quantitative data analysis with SPSS 14, 15 and 16 : a guide for social scientists. London: Routledge; 2009.
24. Section IV The Airway Techniques A2 - by, Edited. In: Hagberg CA, editor. Benumof's Airway Management (Second Edition). Philadelphia: Mosby; 2007. p. 319.
25. Caroline NL, Smith M, Pollak AN, Elling B. Nancy Caroline's emergency care in the streets. 6th ed. ed. Boston: Jones and Bartlett; 2008.
26. Section VI Postintubation Procedures A2 - by, Edited. In: Hagberg CA, editor. Benumof's Airway Management (Second Edition). Philadelphia: Mosby; 2007. p. 1055.
27. Komasawa N, Fujiwara S, Miyazaki S, Ohchi F, Minami T. Shifts in endotracheal tube position due to chest compressions: A simulation comparison by fixation method. Journal of Emergency Medicine. 2015;48(2):241-6.

# 9.0 Attachements

## 9.1 Attachment 1: Registration of the master thesis

**Vedlegg 1: Registrering av masteroppgaven i Pre-Hospital Critical Care**

Forfatter(e):
1) Karin Haaland (Student) Studentnummer: 205367
2) Nils Petter Oveland (veileder)

E-post:

Jeg/vi bekrefter at vi oppfyller forkunnskapskravene for skriving av masteroppgaven:

Signatur(er):
Nils P. Oveland

Veileder (navn, adresse, telefon):

Eventuelle merknader:

Temaområde, problemstilling og metodisk tilnærming:

Tema: Sikring av endo-trakeal tuber.
Problemstilling: Hva er beste metode for å sikre endo-trakeal tuber; tape, bånd eller kommersielle tube-holdere?
Metode: 1) Litteratursøk 2) Praktisk test på sim dukke. Teste tape vs bånd vs diverse kommersiell tube-holdere

Eventuell tilknytning til forskningsmiljøer/prosjekt/praksis:

Navn – tittel: (2) Nils Petter Oveland, MD, phD
Institusjon: Overlege SUS

Registreringsskjema for masteroppgave er levert:
Stavanger 3/5 20 17 Sign. UiS Karin Haaland

Masteroppgave er registrert og tittel (problemstilling) er godkjent:
Stavanger 18/1 20 18 Sign. veileder Nils P. Oveland

33

## 9.2 Attachment 2: Agreement form

**Vedlegg 2: Skjema for avtale i forbindelse med masteroppgave knyttet til offentlig/privat virksomhet**

**Masterstudium i Prehospital Critical Care**

**Avtale i forbindelse med masteroppgave knyttet til offentlig og/eller privat virksomhet.**

**Rammer for masteroppgaven:**

Målsetting med masteroppgaven er at studenten skal tilegne seg vitenskapelig tenkesett og arbeidsmåte, kunne formidle vitenskapelige funn og beherske det vitenskapelige språket knyttet til helsefaget som vitenskapelig område.

Masteroppgaven utgjør 30 studiepoeng og er et selvstendig, individuelt vitenskapelig arbeid, enten i form av en monografi eller artikkelformat. En monografisk oppgave skal være på ca. 17..500 ord. Velges artikkelformat må der i tillegg skrives en kappe som utdyper de teoretiske og metodologiske overveielser som ligger til grunn for artikkelen. Artikkelen har en ramme på ca 5000 ord, og kappen en ramme på 5000 ord.

Student 205367 ~~KARIN HAAHEIM~~ på Masterstudium i Prehospital Critical Care er gitt mulighet til å skrive masteroppgave i samarbeid med følgende virksomhet Validé/Prometheus Medical Nordic

Studentens kontaktperson(er) i virksomheten er Nils Petter Overland

Tema for masteroppgaven: Sikring av endo-trakeal tuber

Arbeidet forventes sluttført i henhold til normal studieprogresjon 15.06.18

Universitetet i Stavanger tilbyr veiledning i tilknytning til arbeidet. Veileder(e) er:
Nils Petter Overland (ekstern veileder)

34

## 9.3 Attachment 3: Approval of project plan

### Vedlegg 3: Godkjenning av prosjektplan

**PROSJEKTPLAN - MASTER I PRE-HOSPITAL CRITICAL CARE**

**Prosjektplan leveres veileder innen 15.oktober** i 7 semester og godkjennes av veileder senest innen **15. november**. Når prosjektplan er godkjent leveres dette skjemaet, signert av student og veileder, til instituttekspedisjonen sammen med kopi av godkjent prosjektplan.

205367 KARIN HEMLAND

Stud.nr. Navn

Adresse

E-postadresse Telefon

**Prosjektplan - tittel:**

"COMPARISON OF SPECIALIZED VERSUS NON-SPECIALIZED TEES FOR ENDOTRACHEAL TUBE FIXATION"

**Prosjektplanen er godkjent / ikke godkjent.**

(Stryk det som ikke passer)

18/1/18 (dato) (sign. veileder) ( sign. student )

36

## 9.4 Attachment 4: Invitation to the study


### Forespørsel om deltakelse i forskningsprosjektet

**Comparison of specialized versus non-specialized ties for endotracheal tube fixation.**

På bakgrunn av din kompetanse innenfor prehospital tjeneste inviteres du til deltakelse i et forskningsstudie i anledning Masteroppgave ved Universitetet i Stavanger.
Bakgrunn for studiet er at uforventet ekstubasjon er livstruende og endotracheal tuber og supraglottis utstyr må sikres optimalt for å forebygge nettopp dette. Ulike metoder og utstyr er utviklet for å fiksere intubasjonstuber, alle med fordeler og ulemper. Tidligere studier viser ingen suverene metoder/utstyr, og har sprikende forskningsresultater. Vi ønsker derfor å kartlegge dette ved blant annet et eksperimentelt studie i vårt eget foretak.

### Hva innebærer studiet?

Studiet omhandler fiksering av de ulike spesialiserte og ikke spesialiserte metodene ambulansetjenesten og luftambulansetjenesten har tilgjengelig for intubasjon, samt implementering av et nytt design. Dette er ikke et prosjekt som skal teste ut den enkeltes ferdigheter eller prestasjoner, dette studiet skal kun teste kvaliteten på utstyret i form av en test i etterkant av kandidatens arbeid. Det krever ingen nye forkunnskaper for å delta i studiet. Potensielle kandidater for studiet er allerede forhåndsplukket for å sikre at deltaker innehar de adekvate kvalifikasjoner som er ønskelig i dette studiet.

### Praktisk informasjon

Studiet vil foregå på Stavanger Ambulansesentral i Mars/ April måned og den enkelte deltaker vil bli forepurt om å foreta 4 ulike intubasjoner og fikseringer med tid mellom hver seanse. Prosjektleder vil derfor prøve å tilstrebe den enkelte deltakers arbeidstid, slik at deltakelse ikke går på bekostning av fritid. Dersom deltakelse ønskes utenom arbeidstid kan dette avtales med prosjektledere.

### Samtykke og personopplysninger

Vedlagt følger samtykkeskjema som undertegnes dersom en ønsker å delta i studiet.
Deltakelse er frivillig og du kan når som helst trekke ditt samtykke.
Personopplysninger er kun for prosjektlederes interesse og vil holdes konfidensielt for andre.
Ingen personopplysninger vil bli publisert eller lagret i etterkant av studiet.

Dersom du har spørsmål til prosjektet kan du kontakte Karin Haaland mob; 91562854

## 9.5 Attachment 5: Consent form

| **Skjema for samtykke til deltakelse i forskningsprosjekt** | |
|---|---|
| **Prosjekttittel**<br>***Comparison of specialized versus non-specialized ties for endotracheal tube fixation.*** | **Masterstudie:**<br>PHCC |
| **Prosjektledere**<br>Student<br>Karin Haaland<br><br>Veileder<br>Nils Petter Oveland | **Utdanningssted**<br>Det samfunnsvitenskapelige fakultetet - Universitetet i Stavanger |

Dette er et eksperimentelt studie som omhandler ulike metoder for å fiksere endotracheal intubasjon på en simuleringsdukke. Studiet innebærer ikke test på mennesker eller dyr.
Det er frivillig å delta i studien. Dersom du ønsker å delta, undertegner du denne samtykkeerklæringen. Om du nå sier ja til å delta, kan du senere når som helst og uten å oppgi noen grunn, trekke tilbake ditt samtykke. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte prosjektleder.

Jeg er villig til å delta i forskningsprosjektet :

| Dato | Underskrift | |
|---|---|---|

Estimert antall totale intubasjoner: 0-50□ 50-200□ 200-2500□ >2500□

Jeg bekrefter å ha gitt informasjon om forskningsprosjektet:

| Dato | Underskrift | |
|---|---|---|

Eventuelle kommentarer:

## 9.6 Attachment 6: Search Description

| | |
|---|---|
| 1 endotracheal tube*.mp. (8103) | Dette er søkelinjen som inkluderer P-en i PICO. Vi forutsetter at referansene inneholder endotracheal tube(s) skrevet fullt ut. |
| 2 (fixation or fixator*).mp. (198500)<br>3 ((securing or securement or stabili* or restrain*) adj3 (device* or method* or technique*)).mp. (10424)<br>4 ((securing or securement or stabili* or restrain*) adj3 (tube* or ETT)).mp. (690)<br>5 ((tube* or ETT) adj3 (holder* or tape or tapes or taping or sutur* or tie or ties)).mp. (480)<br>6 2 or 3 or 4 or 5 (208360) | Disse linjene i blått er søkelinjer for I-en I PICO, altså for festemetoden. Her har jeg brukt Ovids nærhetsoperator. Den heter adj, en forkortelse for adjacency. Se forklaring under, hentet fra Ovids hjelpefil.*<br>Jeg vil ha treff som inneholder fixation ELLER fixator(s), ELLER hvor:<br>- securing ELLER securement ELLER stabili* (dvs. stabilize eller stabilization eller stabilisation osv.) ELLER restrain* (restraint/restraints/ restraining) *står ikke mer enn 2 ord unna* device* ELLER method* ELLER technique*.<br>- eller securing ELLER securement ELLER stabili* ELLER restrain* *står ikke mer enn 2 ord unna* tube* ELLER ett (forkortelsen for endotracheal tube)<br>- ELLER tube* ELLER ett *står ikke mer enn to ord unna* holder* ELLER tape ELLER tapes ELLER taping ELLER sutur* (suture/sutures/suturing) ELLER tie ELLER ties<br>Søkelinje 6 kombinerer søkelinjene 2, 3, 4 og 5 med OR, altså sier vi at det holder at referansen matcher noe innenfor en av disse linjene, ikke alle. OR utvider søket. |
| 7 1 and 6 (261) | Her spesifiserer jeg at jeg vil ha treff som både matcher søkelinje 1 og ett av elementene i søkelinje 6. AND begrenser søket. |
| 8 7 not (infant* or neonat* or newborn* or paediatric* or pediatric* or child*).mp. (177) | Her sier jeg at jeg vil ha treffene fra søkelinje 7 minus de som inneholder ett av ordene i parentesen. Slik skreller vi vekk treff som nevner barn. Viktig å huske at hvis du skal gjøre et søk for en systematisk oversiktsartikkel, for eksempel, så skal man være ytterst varsom med å bruke NOT, siden man da risikerer å gå glipp av relevante treff. |

## 9.7 Attachment 7: Search results for the Ovid search

Ovid Technologies, Inc. Email Service

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Search for: 7 not (infant* or neonat* or newborn* or paediatric* or pediatric* or child*).mp.

Results: 177

Database: Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present>
Search Strategy:
---
1 endotracheal tube*.mp. (8103)
2 (fixation or fixator*).mp. (198500)
3 ((securing or securement or stabili* or restrain*) adj3 (device* or method* or technique*)).mp. (10424)
4 ((securing or securement or stabili* or restrain*) adj3 (tube* or ETT)).mp. (690)
5 ((tube* or ETT) adj3 (holder* or tape or tapes or taping or sutur* or tie or ties)).mp. (480)
6 2 or 3 or 4 or 5 (208360)
7 1 and 6 (261)
8 7 not (infant* or neonat* or newborn* or paediatric* or pediatric* or child*).mp. (177)

## 9.8 Attachment 8: Search results from Cinahl

| Search ID# | Search Terms | Search Options | Last Run Via | Results |
|---|---|---|---|---|
| S10 | S9 not (infant* or neonat* or newborn* or pediatric* or paediatric* or child*) | Limiters - Peer Reviewed<br>Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Advanced Search<br>Database - CINAHL with Full Text | 52 |
| S9 | S3 AND S8 | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Advanced Search<br>Database - CINAHL with Full Text | 91 |
| S8 | S4 OR S5 OR S6 OR S7 | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Advanced Search<br>Database - CINAHL with Full Text | 17,474 |
| S7 | (tube* or ETT) N2 (holder* or tape or tapes or taping or sutur* or tie or ties) | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Advanced Search<br>Database - CINAHL with Full Text | 66 |
| S6 | (securing or securement or stabili?ing or restrain*) N2 (tube* or ETT) | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Advanced Search<br>Database - CINAHL with Full Text | 84 |
| S5 | (securing or securement or stabili* or restrain*) N2 (device* or method* or technique*) | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Advanced Search<br>Database - CINAHL with Full Text | 1,281 |

## 9.9 Attachment 9: Overview Studies

| Author(s), Year | Title | Study design/ Methods | Participators (N) + Patients | ETT devices | The aim of st |
|---|---|---|---|---|---|
| Lovett PB., Flaxman A., Sturmann KM., Bijur P., 2006 | ***"The insecure Airway: A comparison of knots and commercial devices for securing endotracheal tubes."*** | In-vitro experimental design.<br>Jerk tests on a manikin. | N =?<br><br>1 manikin | Commercial devices: Comfit™ (Ackrad), Stabiltube™ (B&B Medical), Tube Restraint® (ErgoMed), ETAD™ (Hollister), Thomas ST™ (STI Medical) and Dale® ETT Holder<br><br>The knots: The Clove Hitch (Clove), Magnus Hitch (Magnus), and the Cow Hitch (Cow). The Cow Hitch is also known as the Lark's Head Hitch. | Compare deg movement of secured with different commercial d and to compa movement of secured with tape tied with different knot (hitches). |
| Carlson J., Mayrose J., Krause R., Jehle D., 2007 | ***"Extubation Force: Tape versus Endotracheal tube holders."*** | Intubated cadavers<br><br>Pull test with a force-measuring device. | N =? | Tape or one of 4 commercially ETT holders. | ETT secured either tape or 4 commercial available ETT holders. |
| Murdoch E., Holdgate A., 2007 | ***"A comparison of tape-tying versus a tube-holding device for securing endotracheal tubes in adults."*** | Pull test on a manikin. | N= 45 Paramedics and critical care doctors<br><br>270 tube fixation were performed (135 tied vs 135 tube holder)<br><br>1 manikin | Cloth tape versus the Thomas Tube holder. | Compare the amount of ET movement res from a fixed l force followin fixation of the |
| R. Owen, N. Castle, H. Hann, D. Reeves, R. Naidoo, S. Naidoo., 2009 | ***"Extubation Force: A comparison of adhesive tape, non-adhesive tape and a commercial endotracheal tube holder."*** | Cadaver<br>Time and force was measured. | N = 36 Senior paramedic students | Adhesive tape, Thomas Tube holder, knotted non-adhesive tape | To determine of three meth securing an endotracheal quickest to ap and which bes protects the pa from accident dislodgement endotracheal |

| | | | | | |
|---|---|---|---|---|---|
| Kupas DF Kauffman KF Wang HE 2010 | ***"Effect of airway-securing method on prehospital endotracheal tube dislodgment"*** | Prospective, observational, multicenter study<br><br>EMS providers structured, closed-response data forms for all ETI attempts during an 18-months period. | N = 42 EMS<br><br>1732 patients | Adhesive tape, (face tape), tape wrapped around the neck (neck tape), woven twill or umbilical tape (twill tape), intravenous or oxygen tubing (tubing), commercial tube holders, and manual stabilization/ none. | Compare the effectiveness common airw securing techn in preventing dislodgment i prehospital se |
| Shimizu T., Mizutani T., Yamashita S., Hagiya K., Tanaka M. 2011 | ***"Endotracheal tube extubation force: Adhesive tape versus endotracheal tube holder."*** | Orally intubated manikin.<br><br>Digital push-pull force gauge for measurement.<br><br>9 different methods of securing ETT. | N = 1 researcher<br><br>One Manikin | 3 brands of tapes: Durapore, Multipore Dry and Wardel.<br>6 methods.<br><br>Commercial devices: LockTite and Thomas tube holder<br>One method. | To determine force required extubate when ETT is secure adhesive tape commercially available ETT holders. |
| Santhosh MC Torgal SV., Pai RB., Roopa S, Santoshi VB., Rao RP. 2013 | ***"Comparison of tube-taping versus a tube- holding device for securing endotracheal tubes in adults undergoing surgery in prone position."*** | Patients undergoing surgery in the prone position who were randomly allocated in two groups with sixty patients each (Group A and B) | N =<br><br>120 patients undergoing surgery | Adhesive tape (Group A) and Thomas tube holder (Group B). | Study the ease application an removal, effe caliber of ET amount of displacement ETT and any injuries with fixation meth |
| Davies A., Murphy M., Monaghan P.W., Cushenbery C., 2014 | ***"Sticky situation: best practice to secure endotracheal tubes in the operating room."*** | Intubated manikin in supine, lateral or prone position.<br>Digital force meter for measurement latteraly | N =?<br><br>Manikin | Four different varieties of commercially tape and three different taping method. | Examine the a of force requi dislodge ETT secured with different tape and taping me |

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| | | right/left or vertically. | | | |
| Fisher DF., Chenelle CT., Marchese AD., Kratohvil JP., Kacmarek RM., 2014 | ***"Comparison of Commercial and Noncommercial endotracheal tube-securing devices."*** | ETT security was tested by measuring distance displaced after a tug. Sensor applied force vertically and horizontally. | N =? | Test of 16 ETT holding devices/ ETT –securing methods in 4 separate tests.<br><br>Commercial: Hollister Anchorfast, Thomas tube holder, Marpac 320 ETT, Marpac 320 ETT with head strap, Teleflex-cushioned, Portex Quickstrap, Ambu ETT (white strap), Ambu ETT (blue strap), Dale stabilock, Precision Medical ETT.<br><br>Noncommercial: Hy-tape, lillehei method, modified lillehei method, rolling hitch knot, clove hitch knot, cow hitch knot. | Compare commercial a noncommerci ETT securing devices. |
| Mohammed HM., Hassan MS., 2014 | ***"Endotracheal tube securements: Effectiveness of three techniques among orally intubated patients."*** | Randomized clinical trial. Data collection: demographic and clinical data sheet, the time profile for ETT fixation method sheet, slippage, external jugular venous pressure ++ | N =?<br><br>90 intubated patients | Tape: Twill, Adhesive and Simple bow | Compare the effectiveness three ETT securement techniques on slippage, exte jugular venou pressure measurement, mucosa and fa skin integrity, intensity and patient satific after the fixat method. |
| Kowasawa N., Fujiwara S., Miyazaki S., Ohchi F., Minami T., 2015 | ***"Shifts in endotracheal tube position due to chest compressions: a simulation comparison by fixed method."*** | Manikin and auto- chest compression machine simulation. Trial performed five times in each setting. | N= 5 (The authors) | No fixation, Durapore tape fixation, Multipore tape fixation, Thomas tube holder. | Evaluate the e of various fix methods on E displacement manikin and a chest compres machine mod |
| J. C. Buckley, A. P. Brown, J. S. Shin, K. M. Rogers, N. | . ***"A comparison of the haider tube-guard endotracheal tube holder versus adhesive tape to*** | A force transducer used to apply linear force on ETT in intubated | N = ?<br>30 patients | Adhesive tape and haider tube guard. | Compare ETT mobility whe securing the E with to differe methods. |

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| N. Hoftman., 2016 | ***determine if this novel device can reduce endotracheal tube movement and prevent unplanned extubation."*** | patients undergoing general anesthesia. | | | |
| J. L. Wagner, R. Shandas, C. J. Lanning., 2013 | ***"Extubation force depends upon angle of force application and fixation technique: a study of 7 methods."*** | Pull test in 13 angles (test points) in a intubated manikin. | N = 1 | 7 different fixation combinations. | Compare diff methods of E restraint to on another and m force required displace an E |
| Agarwal A, Singh DK, Dinesh C, Pradhan C. 2011 | ***"Nonconventional way of securing endotracheal tube in bearded individuals."*** | Case report | N = 3 (The authors)<br><br>1 bearded patient undergoing general anesthesia. | Tape<br>The tube was secured using tape over the plastic rectangle, and next secured with bandage. | Investigate th way of securi ETT in beard individuals. |
| Kajal S, Dhankhar M, Mukherjee S, Arya G. 2015 | ***"Non traditional method of endotracheal tube fixation in bearded patients undergoing facial and occipital surgeries".*** | Case report | N = 4 (The authors)<br><br>2 bearded patients undergoing general anesthesia | Tape<br><br>The end of the bandage was passed under the axilla (properly padded) and brought behind the neck from the other side to fasten it with the other end. To counteract the downward pull, an adhesive tape was wrapped around the tube and fixed on the bridge of the nose. | Investigate th way of securi ETT in beard patients. |
| Sadawarte P, Gadkari C, Bhure A, Lande S. 2013 | ***Non conventional way of securing endotracheal tube in a case of facial burns."*** | Case report | N = 4 (The authors)<br><br>1 patient with facial burns undergoing anesthesia. | Tape<br><br>A 500 ml plastic bottle of an intravenous fluid was cut open into a rectangular piece, and the cut an additional hole for passing suction catheter for intraoral suction Secondly, a sterile gauze pad was placed below the | Investigate th way of securi ETT in facial |

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| | | | | rectangular plastic to avoid trauma to the burnt face. The rectangular shaped plastic served as a smooth surface over the burn area to secure the tube. Finally secured with tape. | |
| Korsvold EC. 2010 | ***"Placement and fixation of the endotracheal tube in trauma patients."*** | Prospective study | N = 100 intubated patients | All<br><br>The method of controlling tube placement, the fixation method used and condition of the patient's face were recorded. | Investigated whether the materials curr used for fixati the tracheal tu ensured secur fixation in inj trauma patien |


1. Croskerry P. Patient safety in emergency medicine. Philadelphia, Penn: Wolters Kluwer/Lippincott Williams & Wilkins; 2009.
2. Kupas DF, Kauffman KF, Wang HE. Effect of Airway-Securing Method on Prehospital Endotracheal Tube Dislodgment. Prehospital Emergency Care. 2010;14(1):26-30.
3. Davis B. ROSEN'S EMERGENCY MEDICINE: CONCEPTS AND CLINICAL PRACTICE, FIFTH EDITION. Prehospital Emergency Care. 2004;8(3):334-5.
4. Liamputtong P. Research methods in health : foundations for evidence-based practice. 2nd ed. ed. Melbourne, Australia: Oxford University Press; 2013.
5. Sackett DL, Rosenberg WMC, Gray JAM, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. BMJ. 1996;312(7023):71-2.
6. Lund H, Juhl C, Andreasen J, Møller A. Håndbog i litteratursøgning og kritisk læsning : redskaber til evidensbaseret praksis. København: Munksgaard; 2014.
7. Lovett P, Flaxman A, Stürmann K. The insecure airway: a comparison of knots and commercial devices for securing endotracheal tubes. Academic Emergency Medicine. 2003;10(5):485-6.
8. Murdoch E, Holdgate A. A comparison of tape-tying versus a tube-holding device for securing endotracheal tubes in adults. Anaesthesia and Intensive Care. 2007;35(5):730-5.
9. Shimizu T, Mizutani T, Yamashita S, Hagiya K, Tanaka M. Endotracheal tube extubation force: adhesive tape versus endotracheal tube holder. Respiratory care. 2011;56(11):1825-9.
10. Fisher DF, Chenelle CT, Marchese AD, Kratohvil JP, Kacmarek RM. Comparison of commercial and noncommercial endotracheal tube-securing devices. Respiratory care. 2014;59(9):1315-23.
11. Davies A, Murphy M, Monaghan W, Cushenbery C. Sticky situation: best practice to secure endotracheal tubes in the operating room. International Journal of Advanced Nursing Studies. 2014;3(1):20-3.

12. Komasawa N, Fujiwara S, Miyazaki S, Ohchi F, Minami T. Shifts in Endotracheal Tube Position Due to Chest Compressions: A Simulation Comparison by Fixation Method. The Journal of Emergency Medicine. 2015;48(2):241-6.
13. Santhosh MC, Torgal SV, Pai RB, Roopa S, Santoshi VB, Rao RP. Comparison of tube-taping versus a tube-holding device for securing endotracheal tubes in adults undergoing surgery in prone position. Acta anaesthesiologica Belgica. 2013;64(2):75-9.
14. Hanan Mohammed M, Manal Salah H. Endotracheal tube securements: Effectiveness of three techniques among orally intubated patients. Egyptian Journal of Chest Disease and Tuberculosis. 2015;64(1):183-96.
15. Buckley JC, Brown AP, Shin JS, Rogers KM, Hoftman NN. A Comparison of the Haider Tube-Guard(®) Endotracheal Tube Holder Versus Adhesive Tape to Determine if This Novel Device Can Reduce Endotracheal Tube Movement and Prevent Unplanned Extubation. Anesthesia and Analgesia. 2016;122(5):1439-43.
16. Carlson J, Mayrose J, Krause R, Jehle D. Extubation Force: Tape Versus Endotracheal Tube Holders. Annals of Emergency Medicine. 2007;50(6):686-91.
17. Owen R, Castle N, Hann H, Reeves D, Naidoo R, Naidoo S. Extubation force: A comparison of adhesive tape, non-adhesive tape and a commercial endotracheal tube holder. Resuscitation. 2009;80(11):1296-300.
18. Wagner J, Shandas R, Lanning C. Extubation force depends upon angle of force application and fixation technique: a study of 7 methods. BMC Anesthesiology. 2014;14.
19. Agarwal A, Singh DK, Dinesh C, Pradhan C. Nonconventional way of securing endotracheal tube in bearded individuals. Journal of Anaesthesiology, Clinical Pharmacology. 2011;27(3):425-6.
20. Kajal S, Dhankhar M, Mukherjee S, Arya G. Non traditional method of endotracheal tube fixation in bearded patients undergoing facial and occipital surgeries. Egyptian Journal of Anaesthesia. 2015;31(3):255-7.
21. Sadawarte P, Gadkari C, Bhure A, Lande S. Non conventional way of securing endotracheal tube in a case of facial burns. Journal of Anaesthesiology Clinical Pharmacology. 2013;29(2):267-8.
22. Korsvold EC. Placement and fixation of the endotracheal tube in trauma patients. Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine. 2010;18(1):P25.
23. Bryman A, Cramer D. Quantitative data analysis with SPSS 14, 15 and 16 : a guide for social scientists. London: Routledge; 2009.
24. Section IV The Airway Techniques A2 - by, Edited. In: Hagberg CA, editor. Benumof's Airway Management (Second Edition). Philadelphia: Mosby; 2007. p. 319.
25. Caroline NL, Smith M, Pollak AN, Elling B. Nancy Caroline's emergency care in the streets. 6th ed. ed. Boston: Jones and Bartlett; 2008.
26. Section VI Postintubation Procedures A2 - by, Edited. In: Hagberg CA, editor. Benumof's Airway Management (Second Edition). Philadelphia: Mosby; 2007. p. 1055.
27. Komasawa N, Fujiwara S, Miyazaki S, Ohchi F, Minami T. Shifts in endotracheal tube position due to chest compressions: A simulation comparison by fixation method. Journal of Emergency Medicine. 2015;48(2):241-6.

## 9.10 Attachment 10: The Tube Tie Wrap ($T^2$ Wrap™)

# Comparison of non-specialized versus specialized ties for endotracheal tube fixation

Study ID:

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## Abstract:

**Background and aim**: Endotracheal intubation is performed to secure the airway in patients who require mechanical ventilation. Uncontrolled extubation is a life-threatening event and endotracheal tubes (ETTs) need to be secured to prevent this hazardous event. In this study, we compare the fixation strength of non-specialized versus specialized ties.

**Method**: A simulation mannequin was intubated and the ETTs fixated using four different ties; tape, tube tie, Thomas Tube Holder™ and the T2 Wrap™. The trial consisted of three parts: a pull test, a jerk test and a user test. The pull and jerk tests were repeated 10 times per device, while the user test was performed by 10 experienced paramedics that intubated and fixated the ETTs using all four different devices/ties in a simulated scenario with cardiac arrest. After fixation, weights (i.e. 1-10 Kg dumbbells) were applied to all the tubes in incremental steps (i.e. pull test and user test) or with a 25 cm drop (i.e. jerk test). The main outcome measure was millimeter tube displacement out of the mouth. Secondary outcomes were force applied to the tubes (newton), time from laryngoscopy to tube fixation (seconds) and user-friendliness of each device (0 – 100).

**Results:** The T2 Wrap™ demonstrated superiority in fixation strength for ETTs compared to tape, tube tie and Thomas Tube Holder™ ($p=0,05$), in both the pull test and user test. In the jerk test, all ETTs secured with tape immediately snapped out of the airway, all tubes fixated with tube tie moved on average 24.6 mm, all tubes fixated with Thomas Tube Holder™ 11.8 mm and all tubes fixated with T2 Wrap™ 6.5 mm, respectively. Paramedics scored the user-friendliness of the specialized ties Thomas Tube Holder™ and T2 Wrap™ first and second.

**Conclusion:** Our results demonstrate a superiority of using specialized ties (e.g. Thomas Tube Holder™ and T2 Wrap™) compared to non-specialized ties (e.g. tape and tube tie) for endotracheal tube fixation in a simulated clinical setting. We advocate increased use of these devices to prevent unplanned extubations.

**Keywords:** Endotracheal intubation, endotracheal tube, endotracheal securement device, endotracheal tube fixation, tube fixation device, extubation.

# INTRODUCTION

The uncontrolled nature of prehospital environments increases the complexity of airway management and endotracheal intubation (ETI)(1). In the field, there are inherent challenges during patient transport where displacement and loss of control of the endotracheal tube (ETT) (i.e. uncontrolled extubation) often occurs with rigorous movement of the patient. The emergent nature for prehospital ETI and the various experience of health professionals performing them, present a significant challenge to airway management and necessitate standard algorithms and use of high-quality equipment to prevent hazardous events.

is one of the most important and common procedures in emergency medicine performed to secure the airway of critically ill and injured patients (2, 3). A very important step in intubation is to secure the ETT (4). Inadvertent extubation is relatively common and can be very traumatic to the patient. Reintubation will almost certainly be even more difficult(5, 6). Unplanned extubation (UE) (i.e. dislodgement of the tube out of the trachea) is a life-threatening event that quickly can lead to oxygen deficit in the blood followed by irreversible brain damage and even death, and in recent years has been a focus of continuous quality improvement programs. While these programs and research have improved the care of the intubated patient, relatively little attention has been given to comparisons between methods for ETT fixation. This problem involves multiple disciplines, notably anaesthesia, critical care, military, emergency medicine and prehospital critical care. The time period before the patient arrive to the hospital is especially vulnerable due to the moving and transportation of the patients, but also at the hospital, ETT securement methods are an important topic.

The currently applied methods and fixation ties can be broadly classified into three groups A.) Adhesive tape, applied to the face and head in a variety of ways, B.) Tube tie (i.e. twill tape or umbilical tape or ribbon), tied around the tube and around the neck and the posterior occiput (back) portion of the head, C.) Specialized ties (i.e. purpose-built commercial devices). There are several known disadvantages and problems with adhesive tapes and tube ties, the main ones being dislodgement (e.g. caused by

detachment of the tape) of the tube and slippage (i.e. movement of knot or tape along the length of the tube). This is especially true for patents with beard, bodily fluids (i.e. blood, vomit, mucus) around the mouth and challenging facial anatomy (e.g. dental prostheses). These problems have been tried solved by specialized ties, but so far clinical studies diverse in their conclusions whether fixation with non-specialized/non-commercial ties or specialized/ commercial ties are best for securing ETTs. Eight studies tested and concluded that the specialized ties such as Thomas™, Dale™ or the Haider™ Tube Holder had superior fixation strength in their trials (7-14). Opposite, six studies concluded that non-specialized ties (i.e. any type of tape and tube tie) was the best way of securing the ETTs, two of which had tape (15, 16) and four (1, 17-19) of which has tube tie as the best method. However, a comprehensive study by Lovett et al. reported that only 500.000 ETTs (less than 5 %) of a total of annually 13-20 million ETIs in the United States were secured with specialized ties. They concluded that commercial devices were under-utilized(7) Although the literature does not identify a superior method for fixation, we know that inadequate restrain of tubes always is the root cause of UE. Therefore, we want to test the fixation strength of non-specialized versus specialized ties commonly used in the prehospital setting; tape, tube tie, the Thomas Tube Holder ™ and the novel T2 Wrap™, respectively.

# OBJECTIVE

To compare four different methods to fixate ETTs; non- specialized ties such as tape and tube tie against specialized, purpose-built devises such as the Thomas Tube Holder™ (i.e. commercially available) and the T2 Wrap™ (i.e. an innovative new tube fixation devise under development). Our results can give us an indication of the optimal fixation procedure of ETTs and potentially change current airway management.

# METHODS

## Ethics

The trials were performed using a simulation mannequin (ALS Simulator, Laerdal Medical, Norway) and did not involve any patients or cadavers. The candidates in the user tests were qualified emergency medical personnel who voluntarily participated. They retained their anonymity throughout the research project. No hazards were identified. The University of Stavanger and the Stavanger University Hospital's internal rules for good research ethics was followed. Application to REK / NSD was not needed.

## Study design

In this experimental study, a training mannequin (i.e. Laerdal Medical ALS Simulator) was placed in a supine position with its body and head fixed to a stretcher using safety belts and tape. Further, it was intubated with a pre-lubed ETT with uninflated cuff. The ETTs were fixated with either tape, tube tie, Thomas Tube Holder™ or T2 Wrap™ **(Figure 1).** With tape (2.5 cm x 4.5 m Tensoplast®, BSN Medical Ltd, Pinetown, South Africa) the ETTs were fixated using a criss-cross pattern around the shaft (i.e. 2 x 20 cm long pieces of tape), and with tube tie (1 cm x 2 m ribbon) around the neck the ETTs were fixated with the knot "Rolling hitch/ Magnus hitch". The fixation with the Thomas Tube Holder™ (Laerdal Medical, Stavanger, Norway) and T2 Wrap™ (novel device under development) were done according to their instruction of use, being thumbscrew and tie wrap devices respectively.

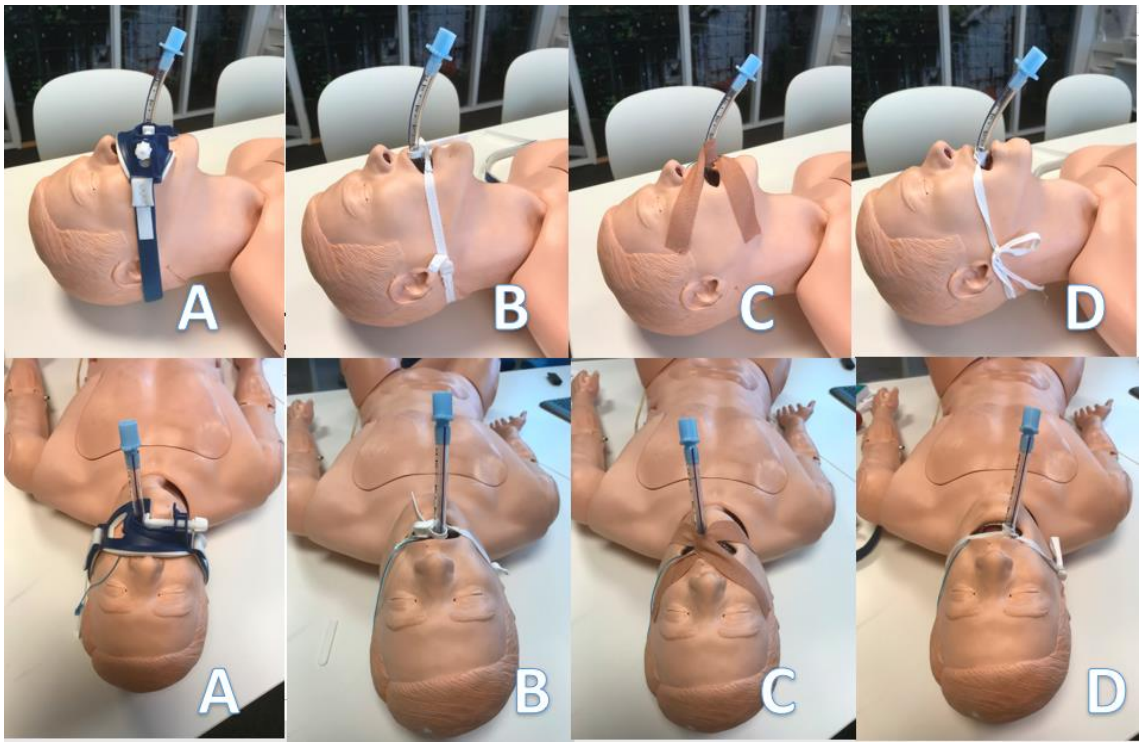


**Figure 1.** The four different ties used; **A)** Thomas Tube Holder™, **B)** T2 Wrap™, **C)** tape and **D)** tube tie.

## Measurements

This trial was subdivided into three different tests:

**1.) Pull test:** The mannequin was intubated and the ETTs fixated at 22 cm at the lower lip using the four different ties, respectively. A rope, in the vertical direction, from the end of the ETT was thread through pole rings and attached to a scale (i.e. a bucket). Furthermore, a digital force gauze (FH 10-500 EXT, Sauter, Albstadt, Tyskland) was placed between the ETT and the pole rings to measure the force (i.e. Newtons) applied to the tube. Dumbbells of 1 Kg were put onto the scale in 10 incremental steps. Further, the movement of the ETTs out of the mouth compared to the basis (i.e. 22 cm at the lip) was marked with a pen alongside the shaft of the tube after each incremental weight-step. Extubation (i.e. endpoint) was defined as complete ETT dislodgement or movement of the tube of at least 69 mm (i.e. the distance where the cuff slipped out of the larynx). The main outcome mm tube displacement was measured alongside the shaft of the tube (i.e. from the 22 cm line to all the marked pen points on the side of the tube) after extubation with a digital slide caliper (Cocraft digital caliper, Clas Ohlson, Insjön,

Sweden). The pull test was repeated in 10 separate identical series per device/tie. The setup is shown in **figure 2.**

**2.) Jerk test**

The exactly the same setup as the "Pull test", the dumbbells of 2 kg were dropped from a 25 cm height down into the bucket (i.e. the scale) to give a jerk of the ETTs. The main measurement in this test was the peak of force (i.e. peak Newton) applied to each tube and the main outcome mm tube displacement compared between the four different devices/ties in 10 separate series. Similar endpoint as the "Pull test". The setup is shown in **figure 2.**

**3.) User test**

The user test was performed by 10 experienced paramedics that each intubated and fixated the ETTs tubes using the different devices/ties in four separate realistic simulated scenarios of cardiac arrest. Which ties they used were randomized as the participants had to draw one of four envelopes before each scenario. In the pre-trial period, the participants received a short demo of the new fixation device T2 Wrap. The others were familiar ties used in their prehospital practice (e.g. tape, tube tie and Thomas Tube Holder™). The mannequin was placed in the supine position on the floor of a gym. They were all allowed to use their own methods of fixation, but not given the opportunity to go through guidelines and recommendations for tube fixation. The participants intubated the same mannequin as described and fixated the tubes to their best of their ability using all four different devices/ties. They were timed from laryngoscopy until tube fixation. The fixation strength of each device/tie was measured using the exactly the same method and endpoint described in the "Pull test" (the mannequin was moved from the floor and strapped to the stretcher). Finally, after completing four scenarios each participant had to score their self-experienced user-friendliness of each device from 0 – 100 (i.e. Visual Analogue Scale) where 100 was best and 0 worst. The setup is shown in **figure 2.**

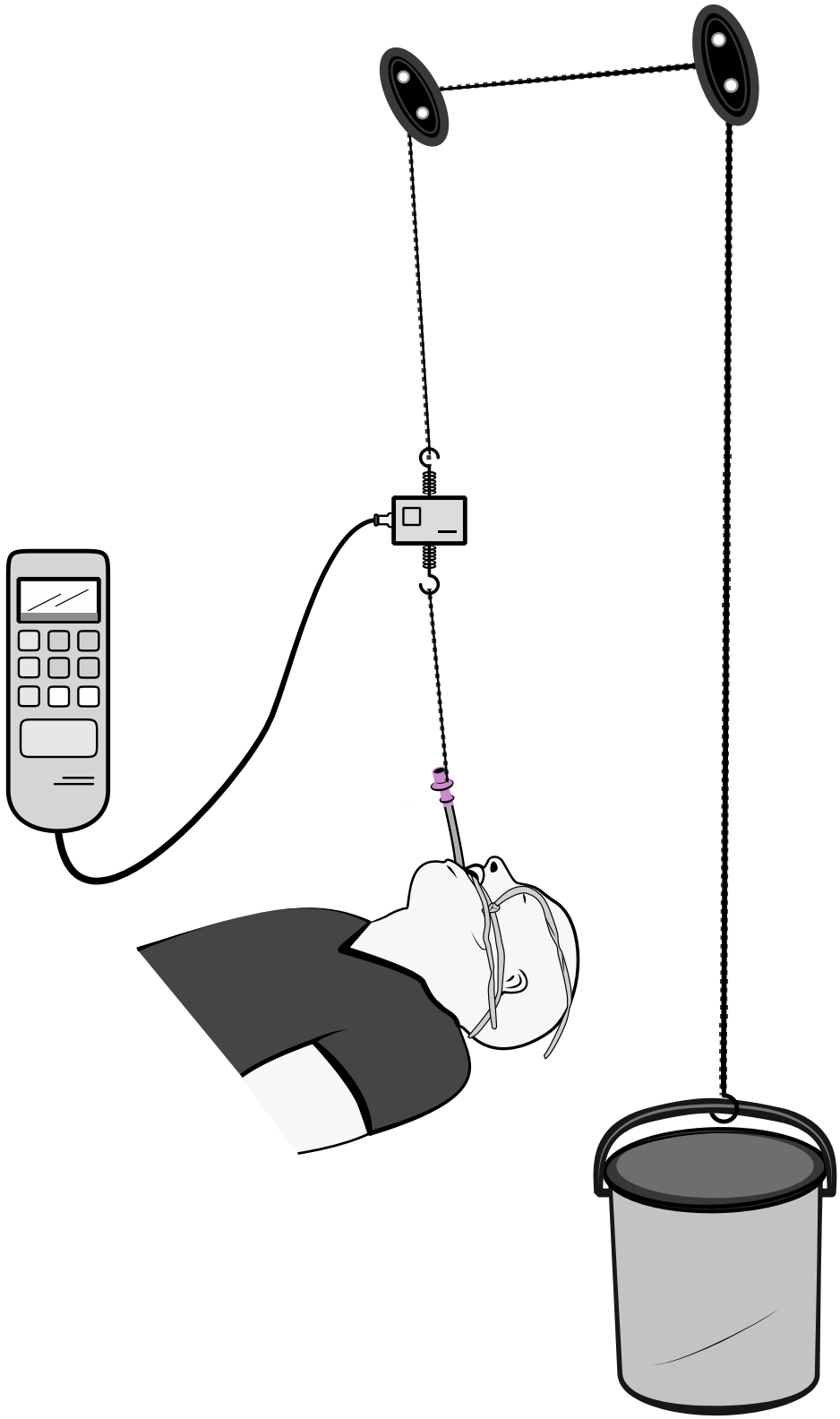

**Figure 2.** Trial setup used in the 1) Pull test, 2) Jerk test and 3) User test.

## Statistical analysis

The main outcome measure in these trials was tube displacement out of the mouth per Kg weight put on the scale. This was measured in millimeters with a digital slide caliper alongside the shaft of the tube. For the jerk test we also measured the peak force (i.e. Newtons) applied to the tubes as 2 Kg dumbbells was dropped into the scale. We calculated the mean values of mm tube displacement per Kg (incremental steps from 1 to 10 Kg) for the 10-separate series (pull test and jerk test) and 10-paramedics series (user test) for each device/tie. Similar, the mean peak force applied to the tube from a 2 Kg dumbbell drop was calculated from the 10-separate series (jerk test). Per definition extubation was movement of the tube until the cuff slipped out of the larynx, and all extubations were given the value 69 mm tube displacement. Therefore, we used a tobit model, also called a censored regression model, when estimating the linear relationships between the predictive values; weight on scale (i.e. Kg), type of device/tie used and paramedic performing the procedure and the dependent variable (i.e. outcome variable) mm tube displacement. This statistical model is well suited based on the fact that we had a threshold for extubation on 69 mm tube displacement (i.e. censoring from above). Furthermore, we used dummy variable statistics where our four different devices /ties were (categorical predictive variable) were given a binary 0 or 1 number. This was done to compare the three different devices/ties; tape, tube tie and Thomas Tube Holder™ against a reference device T2 Wrap™. The results from our tobit regression model analysis are presented as the coefficient of determination called $R^2$ that shows how well the statistical model fits our data. $R^2$ has the value of 0 (0= no linear relationship between the predictive values on the x-axis and outcome value on the Y-axis) up to 1 (1= perfect linear relationship between the predictive values on the x-axis and outcome value on the Y-axis). Furthermore, we present the statistical significance level (i.e. p-value) for the comparison of tape, tube tie and Thomas Tube Holder™ versus the reference device T2 Wrap™. A p-value of 0,05 was used as definition for a significant observed difference in performance between the devices/ties. Finally, we calculated the mean time (seconds) from laryngoscopy to tube fixation and mean scored user-friendliness (Visual Analouge Scale 0-100) among the 10 paramedics in the user test. All computations were performed using SPSS (IBM SPSS, Armonk, NY) and stored on a research computer.

# RESULTS

**1.) Pull test:**

Ten separate series of measurements with incremental weight gain from 1 to 10 Kg were performed for all the four different ties. A total of 40 measurements were analyzed and mean values calculated per Kg level from 1 to 10. The curves of mean mm tube displacement as a function of increasing weight is shown in **Figure 3**.

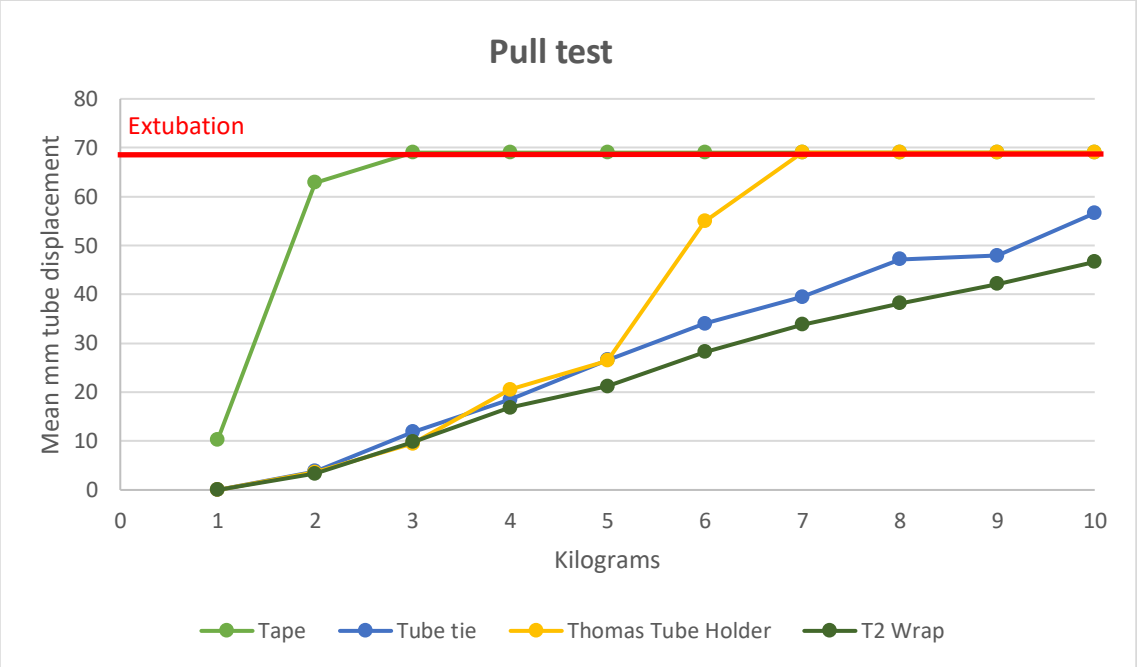


**Figure 3.** Pull test with movement of the ETTs (Y-axis) per Kg increasing weight (x-axis). The different coloured curves represent the four ties used in the trial, and the dots the mean value of mm tube displacement from the 10-separate series. The red line is the threshold of 69 mm representing extubation (i.e. cuff out of the larynx).

The $R^2$ coefficient was 0.73 indicating a linear relationship between our predictive variables (x-axis); weight (kg) and device used (tape, tube tie, Thomas Tube Holder™ and T2 Wrap™) and the outcome variable (Y-axis) mean mm tube displacement. Our $R^2$ value of 0.73 is closer to 1 than 0, and shows that our statistical model is good with

high explanatory power. This means that the variation in outcome data (i.e. mm tube displacement) is more likely to be due to the predictive values than a random unknown factor.

The T2 Wrap™ tie (i.e. reference device) demonstrated superiority in fixation strength for ETTs compared to all the three other ties; tape (p=0.001), tube tie (p=0.04) and Thomas Tube Holder™ (p=0.001). All calculations were statistical significant at the p-value level of 0.05. Looking at individual measurements for tape 9/10 series (2 Kg) and 10/10 series (3 Kg) resulted in extubation, respectively. Similar, for the Thomas Tube Holder™ 6/10 series (6 Kg) and 10/10 (7 Kg >) ended with extubation. No extubation was observed with the tube tie having the knot "Rolling hitch/ Magnus hitch" or with the novel T2 Wrap. Summary of the regression analysis for the pull test is shown in **Table 1**.

**Table 1.** Tobit regression model analysis with dummy variable statistics of pull test.

| Device | Estimate | Standard error | p-value |
|---|---|---|---|
| Tape∗ | 61.99 | 4.13 | 0.001 |
| Tube Tie∗ | 5.37 | 2.64 | 0.04 |
| Thomas Tube Holder™∗ | 22.86 | 2.67 | 0.001 |

∗ T2 Wrap as reference device.

**2.) Jerk test**

Ten separate series of 2 Kg dumbbell-drops (20 cm) were performed for all the four different ties. A total of 40 measurements were analyzed and mean values of peak force (Newton) and mm tube displacement calculated. The jerk test demonstrated a consistency in the peak force applied to all the ETTs regardless of device/tie used. There was no clinical relevant difference in the mean Newton values between tube tie, Thomas Tube Holder™ and T2 Wrap™, except for the lack of measurements from all the 10-series with tape (i.e. all 2 Kg weight drops gave extubation). Again, the T2 Wrap™ was superior to all other devices/ties when looking at mm tube displacement. With a comparable mechanical jerk to the ETTs, the T2 Wrap™ moved only 6.5 mm out of the mouth, nearly ¼ - ½ of the observed distance compared to the tube tie (24.6

mm) and Thomas Tube Holder™ (11.8 mm), respectively. All the results from the jerk test are shown in **Table 2**.

**Table 2.** Results from the 10-series jerk test per device.

| Device | Mean peak force* | Mean mm tube displacement** |
|---|---|---|
| Tape | † | †† |
| Tube Tie | 65.7 | 24.6 |
| Thomas Tube Holder™ | 62.3 | 11.8 |
| T2 Wrap | 64.6 | 6.5 |

* Mean peak force applied to the tube with a single jerk by a 20 cm dumbbell drop. Measured with a digital newton-meter.

** Mean movement of the tube out of the mouth. Measured in millimeter.

† 10/10 extubations. Not able to measure peak force.

†† 10/10 extubations. Mean tube displacement ≥ 69 mm.

**3.) User test**

Ten experienced paramedics intubated the mannequin using all different ties in four repeated scenarios of cardiac arrest. No instructions on how to use each device was given, except for the novel T2 Wrap™. The fixation strength was then tested in exactly the same way as described in the pull test. A total of 40 measurements were analyzed and mean values calculated per Kg level from 1 to 10. The curves of mean mm tube displacement as a function of increasing weight is shown in **Figure 4**.

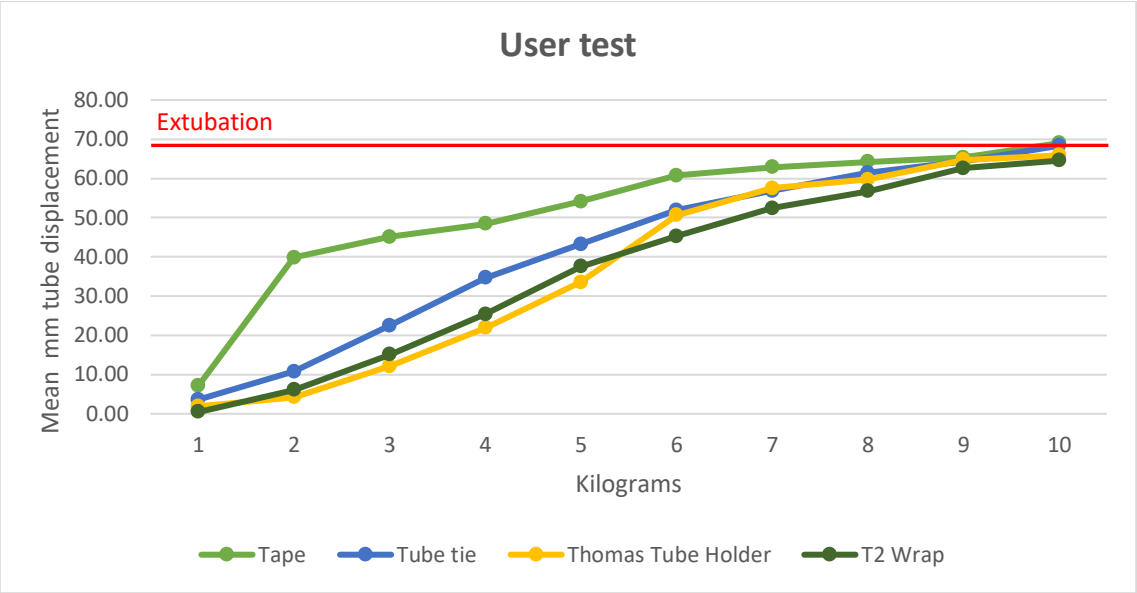


**Figure 4.** User test with movement of the ETTs (Y-axis) per Kg increasing weight (x-axis). The different coloured curves represent the four ties used in the trial, and the dots the mean value of mm tube displacement from the 10-paramedic series. The red line is the threshold of 69 mm representing extubation (i.e. cuff out of the larynx).

The $R^2$ coefficient was 0.69 show a linear relationship between our predictive variables (x-axis); weight (kg), paramedic performing the procedure, device used (tape, tube tie, Thomas Tube Holder™ and T2 Wrap™) and the outcome variable (Y-axis) mean mm tube displacement. The $R^2$ value of 0.69 indicate a statistical model with high explanatory power between the observed variation in outcome data and the predictive variables.

Again, the T2 Wrap™ tie (i.e. reference device) demonstrated better fixation strength for ETTs compared to all the three other ties; tape (p=0.001), tube tie (p=0.018) and Thomas Tube Holder™ (p=0.058), but the latter p-value was slightly above the statistical significance level of 0.050. Therefore, the level of superiority was weaker for the T2 Wrap™ versus the Thomas Tube Holder™ in the user test compared to the pull test, respectively. Looking at individual measurements with tape; 5/10 series (2 Kg), 7/10 series (7 Kg) , 8/10 series (9 Kg) and 10/10 series (10 Kg) resulted in extubation, respectively. Furthermore, for the tube tie 1/10 series (6 Kg), 4/10 series (7 Kg), 5/10 series (8 Kg) and 9/10 series (10 Kg) ended in extubation, with only 1 tube still fixated at the maximum scale of 10 Kg. Similar, for the Thomas Tube Holder™ 1/10 series (3

Kg), 2/10 series (4 Kg), 5/10 series (6 Kg), 7/10 series (7 Kg), 8/10 series (8 Kg) and 9/10 series (9 Kg >) ended in extubation, with only 1 tube still fixated at the end of the trial series. Finally, for the T2 Wrap™, 1/10 series (5 Kg), 2/10 series (7 Kg), 3/10 series (8 Kg), 6/10 series (9 Kg) and 7/10 series (10 Kg) ended in extubation, with 3 tubes still fixated at maximum weight. Summary of the regression analysis for the user test is shown in **Table 3**.

**Table 3.** Tobit regression model analysis with dummy variable statistics of user test.

| Device | Estimate | Standard error | p-value |
|---|---|---|---|
| Tape∗ | 27.61 | 3.40 | 0.001 |
| Tube Tie∗ | 7.61 | 3.21 | 0.018 |
| Thomas Tube Holder™∗ | 6.05 | 3.20 | 0.059 |

∗ T2 Wrap as reference device.

The mean time from laryngoscopy to fixation and the self-scored user-friendliness of the devices/ties are showed in **table 4**.

**Table 4.** Time to fixation and user-friendliness of the four different devices/ties.

| Device | Time (sec)* | User-friendliness score (0-100)** |
|---|---|---|
| Tape | 67 | 35 |
| Tube Tie | 52 | 61 |
| Thomas Tube Holder™ | 47 | 80 |
| T2 Wrap™ | 71 | 72 |

* Mean time from laryngoscopy to fixation among 10 experienced paramedics.

** Visual Analogue Scale (VAS) with 0= low and 100=high user-friendliness of the device/tie.

# DISCUSSION

There is a discrepancy in the literature regarding the ideal device/tie or method for securing ETTs. However, we know that the stability of tubes is affected by the type of fixation device/tie used and that inadequate restrain can lead to unplanned extubations.

An important publication by Lovett et al. compared degree and movement of ETTs secured with six different specialized/commercial devices against ETTs secured with tube tie using three different knots(7). They found specialized devices to be better regardless of tube tie method, and concluded based on consumption statistics, that such fixation devices/ties were under-utilized (less then 5% of all ETTs were fixated with commercial devices). Our study supports their findings showing that specialized ties such as the Thomas Tube Holder™ and the T2 Wrap™ (patented device under development) have a significant better fixation strength in our paramedic user test. However, this result differ from the pull test where the tube tie outperformed the Thomas Tube Holder™ with no extubations after a 10 Kg weight strain. We believe that this is due to the predefined knot "Rolling hitch/ Magnus hitch" used for all the tube in the pull test. Our hypothesis and the reason that we had 10 paramedics perform ETI in a simulated scenario of cardiac arrest is that their ability to fixate ETTs will be affected by multiple factors in a clinical situation, including stress, environment (e.g. indoor with narrow spaces or outdoor with alternating lighting and weather conditions), position of the patient, etc. Based on clinical experience it could be difficult to tie a decent knot in these time critical situations. This suspicion was confirmed when observing the different methods and knots the paramedics used when fixating the ETTs with tube ties, going from 0 extubations in the pull test to 9 out of 10 tubes slipping out of the larynx in the user test. An opposite trend was found for tape with a poor performance in the pull test, that was not observed to a similar degree in the user test (i.e. going from 9 out of 10 > 5 out of 10 extubations at 2 Kg, respectively). Again, when looking at individual creativity for tube fixation, we found that five of the paramedics did not use the "standard" criss-cross tape pattern around the tube (i.e. 2 x 20 cm long pieces of tape), but rather taped the tube around its circumference and then going behind the neck of the patient before anchoring to the tube again. This tape technique is not commonly used, but does resemble a tube tie method and explains the improvement in fixation strength for tape in the user test. However, the overall performance for tape in all three tests is really poor, with minimal ability to withstand movement of ETTs when pulled or jerked. This can to some degree be explain by the lack of adhesiveness against the plastic mannequin "skin". However, the adhesive strength of different tapes is often poor in real patients with beard, bodily fluids (i.e. blood, vomit, mucus) around the mouth and challenging facial anatomy (e.g. dental prostheses). Furthermore, there are

disadvantage with using these non-specialized ties because the insertion depth of the ETTs cannot be adjusted once the tape or tube tie are fixed around the shaft of the tube. Of course the tape or tie can be removed and replaced, but this is a cumbersome procedure increasing the risk of UE due to manual movement of the tube. Also seen is slippage where too loose knots move along the length of the tube, increasing the risk of either extubation or one-lung ventilation (i.e. when the tube is moved down into one of the main bronchia). We therefore advocate a more robust and adjustable method of securing ETTs, ideally having superior fixation strength and a reversible tube locking mechanism. One of the most widely used ties in the prehospital setting is the thumbscrew device Thomas Tube Holder™. It scores high on user-friendliness (VAS score 80/100) and is easy to apply (47 seconds). However, its design with a large physical extension blocks the access to the patient`s mouth. In our study we therefor wanted to test a "hybrid" solution of a tube tie and a cable tie (both non-medical approved devices) called the $T^2$ Wrap™ (**Figure 5**).

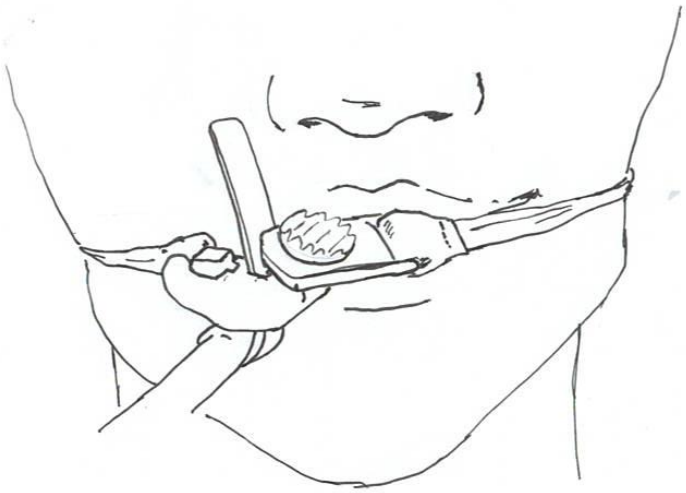

**Figure 5.** Tube Tie Wrap ($T^2$ Wrap™) is a specialized device for securing ETTs with high fixation strength suitable for, but not limited to, emergency and field use. The uniqueness of the device is in the ease-of-use, simplicity, since it only comprises a few parts, it has a structure that enables mounting without unnecessarily moving the

patient's head, and it has a limited physical extension that provides an essentially free access to the patient's mouth.

Defined as the reference device/tie in our tobit regression model, the T2 Wrap™ demonstrated superiority in fixation strength for ETTs compared to all the three other ties at a five percent level of significance (p=0,05), in both the pull test and user test. Our statistical model was satisfactory and showed a relationship among the predictors (i.e. Kg, device/tie used[pull test] and paramedics[user test]) and the outcome mm tube displacement in both the pull test and user test ($R^2$ 0.7 respectively). Although, the paramedic had no previous experience in the use of the T2 Wrap™ it still came out on top with regards to fixation strength. At maximum 10 Kg weight, the mean mm tube displacement in the pull test was only 46.6 mm with no observed tube extubations. The ten paramedics failed to reproduce this result in the user test with 3 tubes still intact in the trachea at 10 Kg. We believe that this is caused by inexperience with use as many of the ETTs did slip because the tie wrap locking mechanism was not tightened enough. This assumption is supported by the slightly increased application time of 71 seconds for the T2 Wrap™ compared to the other ties (e.g. some paramedics were fumbling). However, the paramedics liked its user-friendliness and scored it second only to the Thomas Tube Holder™ (VAS score 72/100). Considering that this is an unfinished product in a proof-of-concept phase, the results are encouraging and call for improvement in design. In the pull test and user test we were able to produce a constant, reproducible traction force. However, the magnitude and nature of force that ETTs are subjected to in day-to-day situations are not known. We believe that the most likely stress to tubes is sudden jerks based on accidents such as drop of connected ventilator bags or movement of the patients in or between beds. We therefore did a jerk test where a 2 Kg dumbbell was dropped 25 cm into the scale. In summary, this test again shows the superiority of specialized ties over tube tie and tape. All devices where subject to the same peak traction force of approximately 64 ± 2 N. All ETTs secured with tape immediately snapped out of the airway, all tubes with tube tie moved on average 24.6 mm and all with Thomas Tube Holder™ 11.8 mm. The T2 Wrap™ only moved 6.5 mm (about a quarter of and half the distance of both the tube tie and Thomas Tube Holder™, respectively).

## Limitations

First, this trial was performed using a simulator mannequin instead of a real patient or cadaver. Using a real patient would be optimal with regards to anatomy and physiology. In our trials, there were no body fluid applied to the mannequin. However, in a real clinical situation blood, vomit, mucus, sweat, dirt, beard, facial hair, loss of teeth, dental prosthesis, facial trauma, burns or fractures may all affect the fixation strength of our four different devices/ties. However, we believe that in these events tape is useless and tube tie challenging since the knot may slip alongside the shaft of the tubes. The specialized devices/ties solve many of these issues because they have a locking system that radially or circumferentially hold the tubes in place in combination with an occipital part that anchor the ETTs around the patient neck.

Second, the new devices used for the trial (T2 Wrap™) was 3D printed where some items or parts had small production errors. This could have affected the fixation strength in our trials.

Third, we only applied traction force in a vertical angle with the mannequin in the supine position, and did not pull or jerk the ETTs in lateral or horizontal direction. Multi-directionally traction force may be a more realistic test to resemble a clinical setting.

Fourth, in the pull and jerk tests the same fixation method for all ETTs was used by a single operator, while the paramedics used individual techniques. Most of the participants had only pre-trial experience in the use of the Thomas Tube Holder™ and therefor had no intentional method for fixation when using tape/ ties. This may have led to user error(s) in the trials, underpowered the user-friendliness scores and increased their application times.

Fifth, our study is limited by the fact that we did not test different fixation tapes on the marked and only used one type and size of ETT (Portex 8.0). More importantly, we did not inflate the cuff in any of the ETTs, because we observed that the friction between the cuff itself and the plastic trachea of the mannequin held the tube in position after the

fixation device failed. In a real patient it is normal to inflate the cuff, but since we were consistent using uncuffed tubes in all of our tests we believe that our results show the true differences in fixation strength. In all tests, the ETTs were fixated at 22 cm and our definition of extubation set to be 69 mm (cuff out of the larynx). This may not be transferable to real patients with anatomic variations.

Last, this is not a large randomized controlled trial, but a small experimental study. Our results and conclusions should be read with that in mind.

# CONCLUSIONS

We have demonstrated a superiority of using specialized ties (e.g. Thomas Tube Holder™ and T2 Wrap™) compared to non-specialized ties (e.g. tape and tube tie) for ETT fixation in a simulated clinical setting. The new device T2 Wrap™ prevents clinically significant dislodgement of ETTs compared to other commonly used methods of restraint and therefore could decrease the incidence of UE in the field.

## Author contributions

Dr. Nils Petter Oveland is the guarantor of the manuscript and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Dr. Oveland: Contributed to the concept and design; analysis and interpretation of the data and the drafting, writing, review, and approval of the manuscript.
Master candidate Karin Haaland: Contributed to the concept and design; responsible for the experiment and acquisition of data and recruitment of participants; analysis and interpretation of the data and drafting and writing the manuscript.

## Declarations of interests

Dr. Oveland has reported to the University of Stavanger (UiS) that he is the inventor of the T2 Wrap™ device and therefore could have future financial income if the device reach the marked. Furthermore, the results of this study is not to be published without dr. Oveland`s written approval. Karin Haaland has reported no conflicts of interests.

## Economy/ Fundings

The project has received 25.000 NOK from the Plogen fund to cover expenses for 3D printing of the new T2 Wrap™ device and other relevant test equipment needed.

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# REFERENCES


1. Kupas DF, Kauffman KF, Wang HE. Effect of Airway-Securing Method on Prehospital Endotracheal Tube Dislodgment. Prehospital Emergency Care. 2010;14(1):26-30.
2. Davis B. ROSEN'S EMERGENCY MEDICINE: CONCEPTS AND CLINICAL PRACTICE, FIFTH EDITION. Prehospital Emergency Care. 2004;8(3):334-5.
3. Rosen P, Marx JA. Rosen's emergency medicine : concepts and clinical practice : Volume two. 5th ed. ed. St. Louis, Mo: Mosby; 2002.
4. Caroline NL, Smith M, Pollak AN, Elling B. Nancy Caroline's emergency care in the streets. 6th ed. ed. Boston: Jones and Bartlett; 2008.
5. Section IV The Airway Techniques A2 - by, Edited. In: Hagberg CA, editor. Benumof's Airway Management (Second Edition). Philadelphia: Mosby; 2007. p. 319.
6. Section VI Postintubation Procedures A2 - by, Edited. In: Hagberg CA, editor. Benumof's Airway Management (Second Edition). Philadelphia: Mosby; 2007. p. 1055.
7. Lovett P, Flaxman A, Stürmann K. The insecure airway: a comparison of knots and commercial devices for securing endotracheal tubes. Academic Emergency Medicine. 2003;10(5):485-6.
8. Murdoch E, Holdgate A. A comparison of tape-tying versus a tube-holding device for securing endotracheal tubes in adults. Anaesthesia and Intensive Care. 2007;35(5):730-5.
9. Komasawa N, Fujiwara S, Miyazaki S, Ohchi F, Minami T. Shifts in Endotracheal Tube Position Due to Chest Compressions: A Simulation Comparison by Fixation Method. The Journal of Emergency Medicine. 2015;48(2):241-6.
10. Santhosh MC, Torgal SV, Pai RB, Roopa S, Santoshi VB, Rao RP. Comparison of tube-taping versus a tube-holding device for securing endotracheal tubes in adults undergoing surgery in prone position. Acta anaesthesiologica Belgica. 2013;64(2):75-9.
11. Buckley JC, Brown AP, Shin JS, Rogers KM, Hoftman NN. A Comparison of the Haider Tube-Guard(®) Endotracheal Tube Holder Versus Adhesive Tape to Determine if This Novel Device Can Reduce Endotracheal Tube Movement and Prevent Unplanned Extubation. Anesthesia and Analgesia. 2016;122(5):1439-43.
12. Carlson J, Mayrose J, Krause R, Jehle D. Extubation Force: Tape Versus Endotracheal Tube Holders. Annals of Emergency Medicine. 2007;50(6):686-91.
13. Owen R, Castle N, Hann H, Reeves D, Naidoo R, Naidoo S. Extubation force: A comparison of adhesive tape, non-adhesive tape and a commercial endotracheal tube holder. Resuscitation. 2009;80(11):1296-300.
14. Korsvold EC. Placement and fixation of the endotracheal tube in trauma patients. Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine. 2010;18(1):P25.
15. Shimizu T, Mizutani T, Yamashita S, Hagiya K, Tanaka M. Endotracheal tube extubation force: adhesive tape versus endotracheal tube holder. Respiratory care. 2011;56(11):1825-9.

16. Davies A, Murphy M, Monaghan W, Cushenbery C. Sticky situation: best practice to secure endotracheal tubes in the operating room. International Journal of Advanced Nursing Studies. 2014;3(1):20-3.
17. Hanan Mohammed M, Manal Salah H. Endotracheal tube securements: Effectiveness of three techniques among orally intubated patients. Egyptian Journal of Chest Disease and Tuberculosis. 2015;64(1):183-96.
18. Kajal S, Dhankhar M, Mukherjee S, Arya G. Non traditional method of endotracheal tube fixation in bearded patients undergoing facial and occipital surgeries. Egyptian Journal of Anaesthesia. 2015;31(3):255-7.
19. Sadawarte P, Gadkari C, Bhure A, Lande S. Non conventional way of securing endotracheal tube in a case of facial burns. Journal of Anaesthesiology Clinical Pharmacology. 2013;29(2):267-8.