### **Original Article**

## Comparison of the Effectiveness of Two Types of Commercial Endotracheal Tube Holders, with the Conventional Method in a Manikin Model

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### Abstract

**Background:** Endotracheal intubation is employed to create a safe airway in patients requiring mechanical ventilation. The relatively high prevalence rate of unplanned displacement of the endotracheal tube (ETT) can be associated with serious complications. This study was conducted to evaluate the effectiveness of a newly designed tube holder in Iran (Irafit), the Thomas ETT holder and the traditional method using adhesive tape.

**Materials and Methods:** The present manikin-based study was performed on the human mannequin. For this purpose, the mannequin was first subjected to oral intubation by a skilled emergency medicine specialist. Then, three methods of adhesive tape, Irafit-ETT holder, and Thomas-ETT holder were used. The mean of displacement in width of the mouth, length of the ETT, and depth as well as ETT removal was recorded.

**Results:** The results of the present study revealed that the displacement in depth was significantly less in the Irafit-ETT holder as compared with the other two groups following the application of a tug (P < 0.001). The displacement in the length of the ETT with and without the application of a tug was significantly less in the Irafit-ETT holder and Thomas-ETT holder groups as compared with the adhesive tape group (P < 0.001).

**Conclusion:** According to the results of the present study, it can be stated that both ETT holder devices (Thomas vs. Irafit) were not distinct in terms of displacements in length and width; however, the Iranian model was more successful in minimizing the displacement in depth.

Keywords: Adhesive tape, Anesthesia, Endotracheal, Endotracheal Intubation, ventilation

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### INTRODUCTION

Airway management is one of the most sensitive and significant issues in medicine and a great challenge for any anesthesiologist or emergency medicine specialist. The purpose of the artificial airway is to facilitate suctioning, relieve upper airway obstruction, prevent aspiration, and allow effective ventilation.<sup>[1]</sup>

Following successful intubation of endotracheal tube (ETT), it is essential to secure the ETT to prevent its movement, which may lead to the removal of the tube. For various reasons such

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as patient movement, restlessness or noncooperation of the patient, rupture of the ETT cuff, coughing, transfer of the patient (from prehospital to hospital, or from one hospital to another or to different wards of a hospital), and other incidences, unplanned removal or displacement of ETT can occur at any time.<sup>[2-4]</sup> Unplanned removal or displacement of ETT has been reported from 7% to 25%<sup>[5-7]</sup> and can have detrimental effects including local trauma and aspiration of oral and gastric secretions and eventual mortality.<sup>[2]</sup> In addition, excessive pressure on the surrounding tissues due to securing

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Nasr Isfahani, et al.: The effectiveness of two types of commercial ETT-holders

ETT can result in sores and mucosal damage. This is a direct result of securing the device, which generates pressure points that ultimately lead to a reduction in local tissue perfusion.<sup>[8]</sup>

Therefore, the prevention of ETT movement is one of the most important priorities in target patients. A wide range of techniques and devices have been exploited to achieve the goal of securing ETT; however, there is limited evidence to support either method or device.<sup>[9,10]</sup>

There are several traditional methods of using adhesive tape or cloth tape with several techniques available for each to secure the ETT.<sup>[11]</sup> Although commercially-made ETT-holding devices have been offered more than 20 years ago and 15 FDA devices are presently available in the U.S. market, they are still much more common.<sup>[5]</sup>

Despite the large number of devices available, little research has been performed on their efficiency. Some studies suggest commercial ETT-securing devices as an alternative with minimal equivalent efficacy using adhesives.<sup>[5,12]</sup> Another study considered the priority of using a device in comparison with the traditional method of adhesive tape,<sup>[13]</sup> and another study did not distinguish between these methods.<sup>[14]</sup>

The unplanned displacement of the tube more commonly occurs in the case of transferring an intubated patient from one stretcher or bed to another. A sharp lateral force might be applied to the ETT as a result of unexpected involvement of the breathing circuit tubing. Therefore, the effectiveness of a commercially-available device as compared with the traditional method using cloth tape in securing ETTs to prevent the displacement following a lateral force was examined. The Thomas ETT holder (TETH) (Laerdal AS, Norway) was employed considering the availability factor.

As Iran is one of the developing countries and access to foreign samples of these tube holder devices is not possible in some regions, in addition to the utilization of the traditional method of adhesive tape and the foreign tube holder (e.g., Thomas tube holder), the Iranian sample of tube holder (Irafit-ETT holder) was also used in the present study. The Iranian model, as compared with the foreign model (TETH), has a smaller volume, and a section has been anticipated at its top to secure the nasogastric tube (NGT).

Therefore, the present study aimed at comparing the ETT movement generated by the lateral force after fixation of the tube with one of the three methods of adhesive tape, Irafit-ETT holder, and Thomas-tube holder to evaluate the effectiveness of these three methods and achieve an unbiased option to fix ETT with the least complications.

## MATERIALS AND METHODS

### Study design and setting

This study was a manikin-based study conducted in Isfahan, Iran. The protocol of the study was approved by the ethics committee of Isfahan University of Medical Science (Approval Number: IR.MUI.MED.REC.1398.096). The present study was performed on the human mannequin at Al-Zahra Hospital in Isfahan.

### **Procedure**

A human mannequin was used in the present study to compare the effectiveness of the Irafit-ETT holder, the Thomas tube-holder (Laerdal Medical Company), and the traditional method of fixing the ETT with adhesive tape. The mannequin was subjected to oral intubation by an experienced emergency medicine specialist. The distal end of the ETT was impregnated with lidocaine gel to provide a tracheal-like environment. Then, the cuff of the ETT was filled to 25–30 cm H2O.

Then, three practical methods of adhesive tape, Irafit-ETT holder [Figure 1], and Thomas-ETT holder [Figure 2] were used to fix the ETT. The Iranian model ETT holder is similar to the foreign model having PP (mouth piece), Expanded polyethylene (foam), and Nylon (strap) materials.

The mentioned tube holder enjoys the following characteristics: latex-free, nonsterile, disposable-for single use of no more than 24 h, and fits airway device sizes 6.5 mm (Inner Diameter)-42 mm (Outer Diameter). It should be noted that the Iranian model (Irafit-ETT holder), as compared with the foreign model (TETH) has a smaller volume and a section anticipated at its top to secure the NGT.

The present test was performed in three directions of left, right, and tug test in front of the patients by all three methods of adhesive tape, Iranian tube holder, and Thomas-ETT holder.

A tape with a width of 12 mm and a length of 1 m was used in the traditional method of adhesive tape. In this method, the tape was passed under the patient's neck and fixed on the patient's face after knotting on the ETT so that two fingers could move easily between the tape and the patient's face.

With the application of weights and pulleys on both sides

In this part of the test, on the right side of the mannequin, a place was considered for installing the pulley. After installing the pulley, the nylon thread was passed from one end to the ETT and from the other end over the pulley and attached to the weight [Figure 3a-c]. The test was then performed in two stages.



Figure 1: The Iranian tube-holder (Irafit-endotracheal tube holder)

Nasr Isfahani, et al.: The effectiveness of two types of commercial ETT-holders



Figure 2: The Thomas tube-holder (the foreign model)

### Without the application of a tug (static tug test)

The weight was attached to the nylon thread, which moved freely on the pulley. In this condition, no tug was applied to it. After the weight remained constant, the degree of displacement in the depth of the mouth was recorded in this condition.

### With the application of a tug

In this condition, the pulley was rotated 360° once and then released slowly. After the weight remained constant, the degree of displacement in the depth of the mouth was measured.

It should be noted that the above-mentioned tests were performed separately with weights of 750 g and 1000 g, and all the steps were repeated on the left side of the mannequin, and the displacement was measured and recorded in the same way.

# With the application of weights and pulleys at the front (tug test)

In the next part, tug test was performed. The position of pulley installation, in this case, was exactly in front of the face of the mannequin After installing the pulley, the nylon thread was passed from one end to the ETT and from the other end over the pulley and attached to the weight [Figure 3d-f]. The test was then performed in two stages.

### Without the application of a tug (static tug test)

The weight was attached to the nylon thread, which moved freely on the pulley. In this condition, no tug was applied to it. After the weight remained constant, the degree of displacement in the depth of the mouth was recorded.

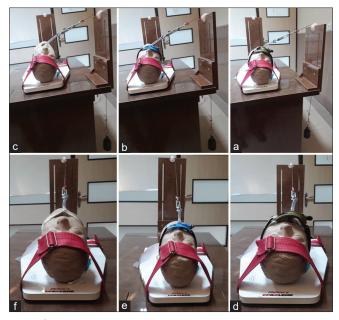
#### With the application of a tug

In this condition, the pulley was rotated 360 degrees once and then released slowly. After the weight remained constant, the degree of displacement in the depth of the mouth was measured.

### **Data collection**

It should be noted that the above-mentioned tests (in three directions of left, right, and front tug test (with and without the application of a tug)) were performed five times in 1 day. Thus, 45 tests were performed on each device. The interval between the two tests was about 1-2 min. In all tests, the displacement of more than 4 cm of the ETT was considered as the exit of the ETT.

It should be noted that to prevent bias, the face of the mannequin was covered with a nylon cover. After performing every five



**Figure 3:** The position of the mannequin and implementation of the test with weights and pulleys (a and d): Using pulleys and weights from the right and front sides in the adhesive-band method (b and e): Using pulleys and weights from the right and front sides in the Iranian tube-holder method (c and f): Using pulleys and weights from the right and front sides in the foreign Thomas endotracheal tube holder method

tests on the device, the ETT was removed, the mannequin was thoroughly cleaned, and all steps were performed for the next test from the beginning. Furthermore, intubations were performed by a single emergency medicine specialist, and ETT displacement was recorded by an experienced nursing doctor who was unaware of the purpose of the study.

### Statistical analysis

Finally, the collected information was entered into SPSS software (version 22; SPSS Inc., Chicago, Ill., USA). The mean  $\pm$  standard deviation and median interquartile range indices were used to present the data. According to the results of Shapiro–Wilk test indicating the abnormal data distribution, the Mann–Whitney test was used to compare the means of displacements in two groups. In all analyses, the significance level was considered to be <0.05.

### RESULTS

### Displacement in width

The results of the present study showed that ETT displacement in the width of the mouth was observed in all three types of ETT holders.

### **Displacement in depth**

### Without the application of a tug

The evaluation of ETT displacement in depth indicated that the displacement in depth from the right side without the application of a tug in the Irafit-ETT holder group with two weights of 750 g and 1000 g with a mean of  $0.23 \pm 0.26$  mm and  $0.23 \pm 0.37$ , respectively, was significantly less than that of

the Thomas-ETT holder group with two weights of 750 g and 1000 g with a mean of  $1.70 \pm 0.84$  mm and  $3.96 \pm 1.54$  mm, respectively, and that of the adhesive tape group with two weights of 750 g and 1000 g with a mean of  $1.36 \pm 0.29$  mm and  $3.16 \pm 1.67$  mm, respectively (P < 0.001). In addition, there was no significant difference in terms of the displacement in depth from the right side without the application of a tug between the Thomas-ETT holder and adhesive tape groups (P > 0.05). Moreover, displacement in depth from the left side without the application of a tug with the weight of 750 g in the Irafit-ETT holder group did not differ significantly from that of the Thomas-ETT holder group, and the Thomas-ETT holder group also did not differ significantly from the adhesive tape group with the 1000 g weight (P > 0.05). However, in other pairwise comparisons of these holders, it was found that the displacement in depth from the left side without the application of a tug in the adhesive tape group was more than that of the Irafit-ETT holder and Thomas-ETT holder groups (P < 0.001).

#### With the application of a tug

In addition, the displacement in depth from both left and right sides with the application of a tug in the Irafit-ETT holder method was significantly less than that of the other two groups (P < 0.001). It is also worth mentioning that with the

increase of weight from 750 g to 1000 g in the Iranian ETT holder, the displacement in depth had not changed much either from the left or right side; however, a significant increase was observed in the displacement in the depth of Thomas-ETT holder and adhesive tape [Table 1 and Figure 4].

### Displacement in depth in the tug test method

Finally, the evaluation of ETT displacement in depth also indicated that the displacement in depth with and without the application of a tug and in both 750 and 1000 gr weights in Irafit-ETT holder and Thomas-ETT holder groups was significantly less than that of the adhesive tape group (P < 0.001). However, the displacement in depth was not significantly different between the Irafit-ETT holder and Thomas-ETT holder groups [Table 2 and Figure 5]. In addition, it should be noted that two ETT removals occurred with the application of a tug and with two weights of 750 and 1000 g.

### DISCUSSION

The results obtained from three ETT fixing (securing) methods of adhesive tape, Thomas-ETT holder, and Irafit-ETT holder revealed that the Irafit-ETT holder had significantly the lowest ETT displacement in comparison with the other

Table 1: Determination and comparison of	of the mean displacement in depth	in three types of endotracheal tube holders

The use of weights and pulley from sides	Weight (g)	Thomas-ETT holder	Irafit-ETT holder	Adhesive tape	<b>P</b> <sub>1</sub>	<b>P</b> <sub>2</sub>	<b>P</b> <sub>3</sub>
Without the application of a tug from the right side	750	1.70±0.84, 2.00 (1.00-2.00)	0.23±0.26, 0 (0-0.5)	1.36±0.29, 1.20 (1.10-1.70)	< 0.001	0.267	< 0.001
	1000	3.96±1.54, 5.00 (2.10-5.00)	0.23±0.37, 0 (0-0.5)	3.16±1.67, 2.10 (2.00-5.00)	< 0.001	0.148	< 0.001
Without the application of a tug from the left side	750	0.33±0.48, 0 (0-1)	0.09±0.18, 0 (0-0.2)	1.43±0.65, 1.50 (0.70-2.00)	0.486	< 0.001	< 0.001
	1000	0.67±0.59, 1.00 (0-1.00)	0.08±0.17, 0 (0-0)	0.75±0.19, 0.70 (0.60-1.00)	0.006	0.713	< 0.001
With the application of a	750	2.5±0.73, 2.5 (2.00-3.00)	0.07±0.17, 0 (0-0)	1.12±0.45, 1.10 (1.00-1.30)	< 0.001	< 0.001	< 0.001
tug from the right side	1000	8.73±0.59, 9.00 (8.00-9.00)	0.07±0.17, 0 (0-0)	2.03±0.09, 2.00 (2.00-2.10)	< 0.001	< 0.001	< 0.001
With the application of a tug from the left side	750	0.70±0.45, 1.00 (0-1.00)	0.05±0.13, 0 (0-0)	2.12±0.23, 2.10 (2.00-2.40)	0.001	< 0.001	< 0.001
	1000	1±0.46, 1.00 (1.00-1.50)	0±0, 0 (0-0)	2.11±0.09, 2.10 (2.00-2.20)	< 0.001	< 0.001	< 0.001

Data is shown as means±SD and median (IQR).  $P_1$ : Comparison of the Thomas-ETT holder group with the Irafit-ETT holder group,  $P_2$ : Comparison of the Thomas-ETT holder group with the adhesive tape group,  $P_3$ : Comparison of the Irafit-ETT holder group with the adhesive tape holder group, ETT: Endotracheal tube, IQR: Interquartile range, SD: Standard deviation

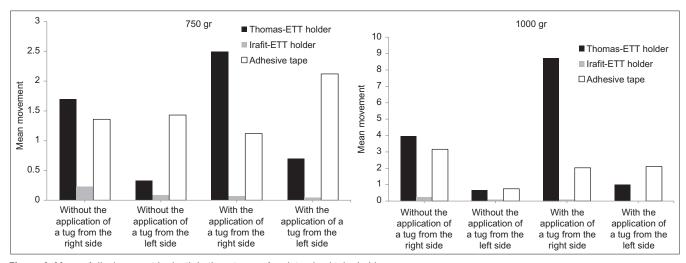


Figure 4: Mean of displacement in depth in three types of endotracheal tube holders

Nasr Isfahani, et al.: The effectiveness of two types of commercial ETT-holders

Table 2: Determination and comparison of the mean displacement in depth in three types of endotracheal tube holders							
Weight (g)	Thomas-ETT holder	Irafit-ETT holder	Adhesive tape	<b>P</b> <sub>1</sub>	<b>P</b> <sub>2</sub>	<b>P</b> <sub>3</sub>	
750	0.03±0.07, 0 (0-0)	0.03±0.07, 0 (0-0)	1.57±0.30, 1.50 (1.30-1.80)	-	< 0.001	< 0.001	
1000	0.03±0.07, 0 (0-0)	0.06±0.14, 0 (0-0)	2.26±0.11, 2.30 (2.20-2.30)	0.744	< 0.001	< 0.001	
750	1.00±0.21, 0 (0-0)	0.01±0.05, 0 (0-0)	2.63±0.57, 2.60 (2.00-3.05)	0.512	< 0.001	< 0.001	
1000	1.00±0.21, 0 (0-0)	0, 0 (0-0)	2.78±0.79, 2.50 (2.27-3.00)	0.367	< 0.001	< 0.001	
	Weight (g) 750 1000 750	Weight (g) Thomas-ETT holder   750 0.03±0.07, 0 (0-0)   1000 0.03±0.07, 0 (0-0)   750 1.00±0.21, 0 (0-0)	Weight (g) Thomas-ETT holder Irafit-ETT holder   750 0.03±0.07, 0 (0-0) 0.03±0.07, 0 (0-0)   1000 0.03±0.07, 0 (0-0) 0.06±0.14, 0 (0-0)   750 1.00±0.21, 0 (0-0) 0.01±0.05, 0 (0-0)	Weight (g) Thomas-ETT holder Irafit-ETT holder Adhesive tape   750 0.03±0.07, 0 (0-0) 0.03±0.07, 0 (0-0) 1.57±0.30, 1.50 (1.30-1.80)   1000 0.03±0.07, 0 (0-0) 0.06±0.14, 0 (0-0) 2.26±0.11, 2.30 (2.20-2.30)   750 1.00±0.21, 0 (0-0) 0.01±0.05, 0 (0-0) 2.63±0.57, 2.60 (2.00-3.05)	Weight (g) Thomas-ETT holder Irafit-ETT holder Adhesive tape P1   750 0.03±0.07, 0 (0-0) 0.03±0.07, 0 (0-0) 1.57±0.30, 1.50 (1.30-1.80) -   1000 0.03±0.07, 0 (0-0) 0.06±0.14, 0 (0-0) 2.26±0.11, 2.30 (2.20-2.30) 0.744   750 1.00±0.21, 0 (0-0) 0.01±0.05, 0 (0-0) 2.63±0.57, 2.60 (2.00-3.05) 0.512	Weight (g) Thomas-ETT holder Irafit-ETT holder Adhesive tape P1 P2   750 0.03±0.07, 0 (0-0) 0.03±0.07, 0 (0-0) 1.57±0.30, 1.50 (1.30-1.80) - <0.001	

Data is shown as means±SD and median (IQR).  $P_1$ : Comparison of the Thomas-ETT holder group with the Irafit-ETT holder group,  $P_2$ : Comparison of the Thomas-ETT holder group with the adhesive tape group,  $P_3$ : Comparison of the Irafit-ETT holder group with the adhesive tape holder group, ETT: Endotracheal tube, IQR: Interquartile range, SD: Standard deviation

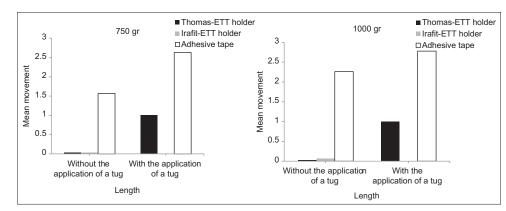


Figure 5: Mean of displacement in depth in three types of endotracheal tube holders

two methods following the lateral force with and without the application of a tug. In more detail, the results of this study indicated that the displacement in depth following the lateral force with the application of a tug from both right and left sides in the Irafit-ETT holder was significantly less than that of the Thomas-ETT holder and the adhesive tape. Following the Iranian tube holder, the degree of movement in depth in the foreign ETT holder was less than that of the adhesive tape method. In fact, it can be stated that the use of the adhesive tape method had the least safety in movement and displacement. With regard to the displacement in depth induced by the application of weights without the application of a tug, it was also found that although in general, the degree of displacement in all three methods was less than the case with the application of weights with the application of a tug, still the least displacement in depth from both left and right sides was obtained from the Iranian ETT holder. In this test, no significant difference was found between the two methods of foreign ETT holder and adhesive tape. In other words, it is not possible to differentiate between the foreign commercial model of the ETT holder and the traditional adhesive tape method following the lateral force without the application of a tug. These results were still valid by changing the weights and increasing their weights.

In addition, the evaluation of the depth displacement in the tug test (in which the lateral force was applied from the front of the mannequin) revealed that there was no significant difference between the Iranian and foreign ETT holder samples with regard to ETT displacement in depth following the lateral force (with two weights of 750 g and 1000 g)

with and without the application of a tug. Moreover, both of the mentioned devices in comparison with the traditional method of adhesive tape had the least displacement in length. In other words, it can be stated that the foreign and Iranian samples were not different from each other in terms of displacement in depth although the Iranian model of this device was more successful in minimizing the displacement in depth. Moreover, two ETT removals in the tug test method occurred with the application of a tug and with two weights of 750 and 1000 g.

It should be noted that the application of a tug was taken into consideration because there is a possibility that due to transferring the patient from one ward to another or changing the sheets by the nurse, the necessary care may not be taken and the tug transferred to the patient might cause ETT removal. Therefore, the tests performed in this study were done with and without the application of a tug.

In this regard, some previous studies have used a technique similar to that of the present study to generate the dynamic force on ETT by hanging the weight via a reel. For example, Murdoch and Holdgate presented a design to make the generated force be perpendicular to the mannequin used for intubation.<sup>[5]</sup> A movement of the ETT of  $\geq 20$  mm was considered to be a remarkable displacement. The twill tape tied with a reef (square) knot and the Laerdal Medical Thomas tube holder were evaluated. ETT movement of  $\geq 20$  mm was allowed by the tape in 61% of the trials. However, the trials with the Laerdal Medical device did not meet failure criteria. The poor reef knot was considered as an explanation for the observed discrepancy.<sup>[5]</sup>

In addition, it should be noted that although knots in the cloth tape were not used in our study, their results were similar to those of the present study in terms of indicating the effective role of the TETH in minimizing ETT displacement. Moreover, another similarity of our findings with those of this study is that the TETH device was easy to use, adjust, or remove. However, loosening or resetting the cloth tape (when tied) or the adhesive tape is difficult if not impossible and may require to be reset.

Tasota *et al.* also found much less movement when using a special ETT Holder (Secure Easy) as compared to adhesive tape.<sup>[13]</sup> Levy and Griego compared adhesive tape, cloth tape, and a different device (Flex Blue) and found no significant differences between them in terms of the ETT movement.<sup>[15]</sup> Another study compared the standard method of tape and bandages with the TETH in mannequins and found that TETH could be used faster and had more durable stabilization than its standard method.<sup>[16]</sup>

The similarity of the previous study with our study was that the use of adhesive tape was revealed to be the riskiest method in ETT removal or displacement. In fact, it can be stated that the use of commercial devices, as compared with adhesive tape, in the field of fixing the intubation tube reduced injuries to patients' lips and face.<sup>[10]</sup>

Another study used Rescuefix as an innovative tube-holder including a flexible flange, which was adapted to each patient's distinctive shape of the face. The findings indicated that there was no significant difference in-depth changes of the trachea between the adhesive tape group and the Rescuefix group. However, Rescuefix significantly reduced the tube displacement as compared to the adhesive tape method.<sup>[12]</sup>

The present study also employed a new sample of ETT holders, which had a longer length and contact surface with ETT than the foreign tube holder, resulting in less ETT displacement. Moreover, the Iranian sample had a section designed to fix NGT, which was not included in the Thomas sample. In addition, the volume and size of the Iranian sample are less than those of the foreign one. Furthermore, the inner pad of the Iranian model is designed to be simpler and cheaper than that of the Thomas model. All the mentioned points are the salient features and differences of the Iranian tube holder in comparison with its foreign counterpart. The results of this study have indicated the effectiveness of the Iranian model in reducing the risk of ETT displacement and removal as much as possible.

#### Limitation

However, it is worth mentioning that according to the initial test of the designed tube holder, this study was performed on human model, which can be one of the weaknesses of this study as the surface of the mannequin, as compared with normal skin, may act differently. Therefore, considering the positive result of this device, it is suggested that future studies evaluate its performance on human samples. In addition, the objective was to move the airway as fast as possible during the ETT movement. Putting more emphasis on the safety of the patients may result in a slowing effect on ETT movement under clinical conditions. Thereby, a long time can be anticipated in actual clinical circumstances.

The mentioned point can be regarded as another limitation of the present study. Moreover, the convenience factor with regard to the application of the devices was not attended to in this study while the mentioned factor may affect the selection of the device and method.

Finally, some of the strengths of the present study are as follows: the evaluation of ETT displacement in right and left sides, with and without the application of a tug, with two different weights, and the repetition of each test five times, which to some extent compensated for the small sample size and the use of mannequins and increased the accuracy of the study.

### CONCLUSION

According to the results of the present study, it can be stated that following the application of the lateral force from sides; displacement in depth in the Irafit-ETT holder model was less than that of the Thomas-ETT holder model and the use of adhesive tape method had the least safety in preventing the movement and displacement. In other words, it can be stated that both ETT holders were not different from each other in terms of the displacement in depth with the application of the lateral force from the front of the mannequin; however, the Irafit model was more successful in minimizing the displacement in depth.

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#### **Conflicts of interest**

There are no conflicts of interest.

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