V-Scope Extendable Intubation Stylet

C. Ekweghariri[1], C. Grunewald[1], T. Kramcha[1], M. Abdul Rahman[1], G. Atlas[1,2]
[1]Stevens Institute of Technology
Castle Point on Hudson
Hoboken, NJ 07030
[2]University of Medicine and Dentistry of New Jersey
Newark, NJ 07103

Abstract–The V-Scope extendable intubation stylet is designed to be used in conjunction with video laryngoscopy. It has both flexion and extension properties which facilitate tracheal intubation.

I. Introduction

Difficult conditions occur in 10.5% to 18% of all tracheal intubations performed annually in the US. Failed intubations occur in 0.04% to 0.07% of those cases [1]. Video laryngoscopy is being used with increasing frequency in those patients with known, or anticipated, difficult airways. However, airway trauma is often reported with many stylets, including the rigid stylet, when they are used in conjunction with the video laryngoscope [2].

In tracheal intubations with the video laryngoscope, use of the rigid stylet is generally preferred [3]. However, the rigid stylet lacks the softness, flexibility, and maneuverability which are essential characteristics during the tracheal intubation process [2].

The V-Scope extendable intubation stylet, Fig. 1, is designed to compete with the rigid stylet. It is mechanically controlled and expands the usage-range of the video laryngoscope in various scenarios. The stylet creates a safer airway management system by filling the need for a softer, more maneuverable, and more flexible stylet [2]. It provides a safer alternative for tracheal intubation. It also reduces the number of failed intubations, tracheostomies, and morbidity when time is of critical life-saving value.

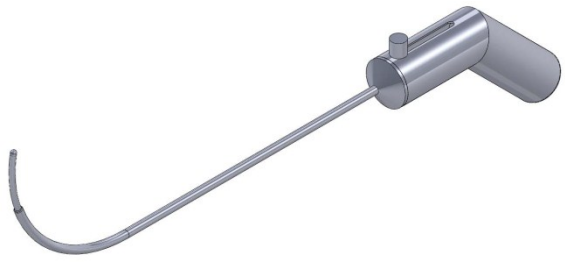

Fig. 1: V-Scope stylet prototype

II. Design & Method

A. Flexion Property

The design incorporates a flexion property which makes the V-Scope stylet more controllable, and efficient, in guiding a tracheal tube into the glottis. The ability of the stylet to flex at its tip is due to the pseudo-elastic properties of a nitinol (nickel titanium) alloy. The nitinol tip is pre-formed, with a radius of 3.4 inches, and is encased in a medical-grade stainless steel sheath. It can extend up to 2.0 inches out of the sheath. As it extends, the nitinol flexes into its original pre-formed or curved shape.

B. Extension Mechanism

The design also incorporates an extension mechanism. This gives the physician greater control during video laryngoscopy intubation. To enable flexion at the stylet's tip, the nitinol alloy must be extended. This extension of the nitinol, through the outer case, allows it to regain its original pre-formed shape. Thus, flexion is created.

The extension is performed by a slide mechanism which is located within the stainless steel handle. The nitinol is attached to this mechanism, extending through the stainless steel outer case. Also, the slide mechanism within the handle retains a tactile feel, which physicians prefer. Once the glottis is observed with the video laryngoscope, the stylet can be inserted into the trachea using the extension mechanism.

C. Testing

Two test protocols, specified in Table I, were constructed to compare the performance of the V-Scope to the rigid stylet. The criteria for each test originated from established successful and safe intubation standards. Intubations exceeding three attempts or 150 seconds in duration were considered to have failed.

TABLE I
Test protocols

Test	Criteria for successful ET intubations
Difficult Airway Test	Pass if intubation time < 150 seconds within 3 attempts.
ANOVA Test	V-Scope intubation time lower than rigid intubation time within 3 attempts.

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1) Difficult Airway Test: The V-Scope stylet was designed to decrease the number of failed intubations. Other available stylets are less efficient in maneuvering through Grade 3 airways (Cormack-Lehane classification). This test would simulate several difficult intubation conditions on mannequins, using this classification system. Success of the stylet would be based on intubation success, number of attempts, and time.

2) ANOVA Test: By comparing the rigid stylet to the V-Scope stylet, the effectiveness of the V-scope stylet could be statistically proven. ANOVA analysis would be performed to demonstrate statistically significant differences between intubation successes, number of attempts at intubation, and intubation time.

III. Results

Results are pending. For the difficult airway test, intubations with the V-Scope stylet are expected to perform within a time limit of 150 seconds and within three attempts. The device is anticipated to demonstrate a success rate above 90% in multiple airway conditions [4]. Optimally, the ANOVA analysis between the rigid stylet and the V-Scope stylet would exhibit a statistically higher rating of successful intubations for the V-Scope stylet, as shown in Fig. 2.

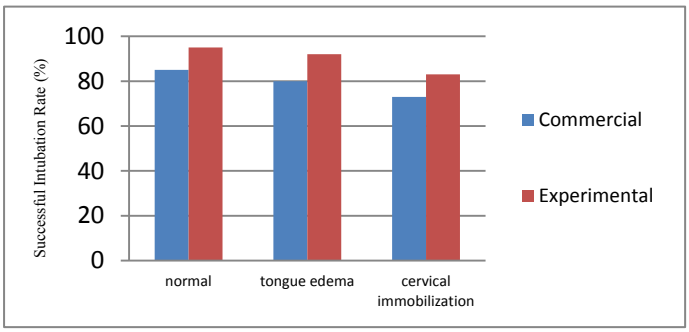

Fig. 2: Hypothetical optimal comparison of a commercial rigid stylet to the experimental V-Scope stylet. Results are pending.

IV. Discussion

The V-Scope extendable intubation stylet is designed to improve the efficiency of tracheal intubations and to decrease the number of failed intubations. It is expected to provide more maneuverability, and greater control, than currently available stylets.

At the conclusion of the difficult airway test, intubations with the V-Scope stylet are expected to have succeeded when used with the video laryngoscope. Furthermore, based on the results of the ANOVA test, the V-Scope stylet is expected to be, at the minimum, statistically comparable to the rigid stylet.

In the future, a secondary control mechanism could be added which would control the angle of flexion of the distal tip. This improvement would also create a motion similar to that seen with fiberoptic laryngoscopes. The slider extension mechanism could also be changed to a trigger mechanism, to further increase maneuverability and ergonomics. Also, a suction port could be incorporated which would clear blood, and other secretions, from the pharynx. This would increase anatomic visibility when using the video laryngoscope.

Acknowledgement

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