Bi-stable Expanding Bougie

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Introduction

EXISTING DEVICES

A combination of two devices is used during intubation procedures: an endotracheal tube (ETT) and a bougie. The bougie is a stiff plastic rod that is inserted into the throat first. The ETT is a hollow PVC tube that can then be slid over the bougie. As shown in Fig. 1, a balloon cuff on the ETT is then inflated with air to hold the device in position during procedures.

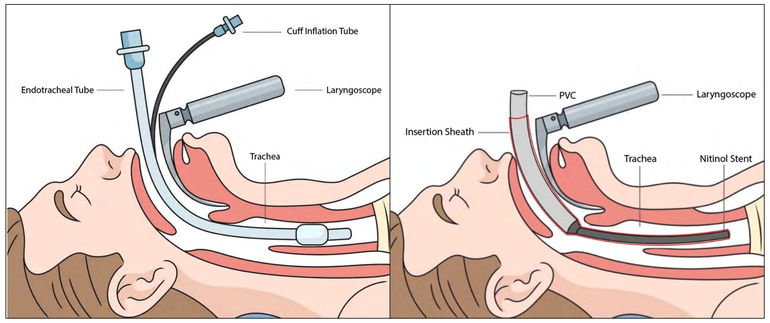

Fig. 1: The existing ETT during use (left), and the new replacement device during use (right).

OUR DESIGN

We designed one device that provides the functionality of both the bougie and the ETT. As shown in Fig. 2, our design consists of 4 main parts: a nitinol stent capable of expanding and collapsing, a CarboSil dip coating, a helically-perforated sheath, and a PVC tube.

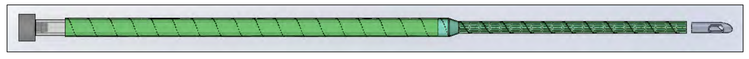

Fig. 2: A model of the complete device, including (from left to right): a universal attachment, PVC tube, green polyolefin perforated sheath, blue CarboSil coating, laser cut nitinol stent, and Murphy's eye attachment.

WHY NITINOL

Nitinol (NiTi) is a nickel-titanium alloy that is widely used in the medical device industry. Famous for its superelastic properties, NiTi has the ability to undergo huge amounts of elastic deformation. This prevents plastic deformation during stent expansion (Fig. 3) and compression.

Fig. 3: A laser cut, heat treated, and expanded sample of the stent in nitinol.

Methods

FINITE ELEMENT ANALYSIS

Multiple stent designs (Figures 4-6) were analyzed, placing a force in the axial direction, to compare the maximum stress and displacement in each model.

Stent Iteration	Max Von Mises Stress (kPa)	Maximum Displacement (mm)	Deformation Scale Factor
Stent Design #1	7.54	9.07	6.63
Stent Design #2	2.55	3.01	19.9
Stent Design #3	5.77	5.77	10.43

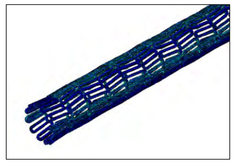

Fig. 4: Stent Design #1.

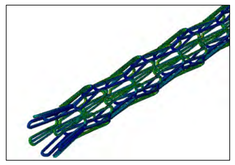

Fig. 5: Stent Design #2.

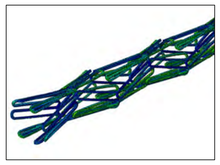

Fig. 6: Stent Design #3.

MANUFACTURING

The steps required to manufacture the device are:

1) Laser cut the NiTi stent (Fig. 7).
2) Heat treat the stent in its maximum expanded state (Fig. 8).
3) Attach the stent to the PVC extension (using Loctite 4011).
4) Dip coat the stent in CarboSil polymer (Fig. 10).
5) Slide the stent into the perforated sheath to compress it.
6) Insert universal attachment piece into the PVC tube.

Fig. 7: A laser cut stent, after being deburred and acid etched.

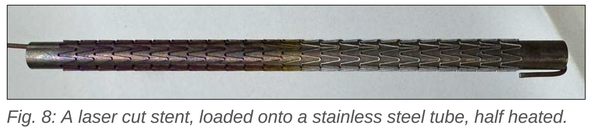

Fig. 8: A laser cut stent, loaded onto a stainless steel tube, half heated.

Fig. 9: Molten salt bath for heating.

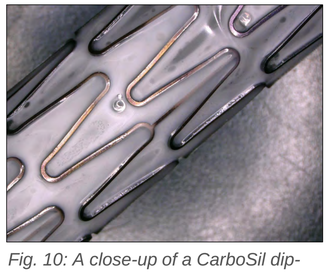

Fig. 10: A close-up of a CarboSil dip-coated stent.

Results

TESTING

The Young's modulus of the final device was found using a simply supported beam deflection test. The average value shown in Fig. 11 was found to be below the desired metric. Refer to the conclusion for a table of the metrics. To meet this goal, the NiTi stent geometry can be easily modified in the future to increase stiffness.

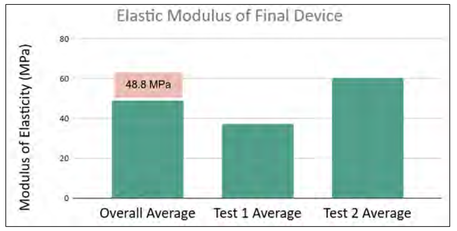

Fig. 11: Elastic modulus data of the final device, from simple beam deflection testing.

Device retrieval force testing was completed with a pull test through an airway mannequin using a force gauge. The average pull force was well below the maximum specification (Fig. 12).

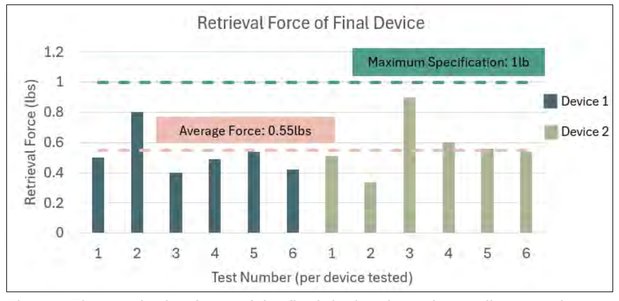

Fig. 12: The extubation force of the final device, based on pull tests using a force gauge and an airway mannequin.

CONCLUSION

Each of the design metrics for this project, shown below, were met with the exception of the Young's modulus. The modulus can be improved with future stiffer NiTi stent iterations.

#	Metric	Target	Units	Actual
1	Tensile Strength	> 57	N	61.4
2	Compressed OD	6 - 8	mm	7.2
3	Change in Length	< 10	mm	0.1
4	Young's Modulus	305 - 425	MPa	48.8
5	# Insertion Motions	≤ 4	count	2
6	Expanded OD	> 10	mm	10.2