Evaluation of a Novel Prototype Medical Device for Performing Percutaneous Dilatational Tracheostomy

Yuan Tang[1], Yufeng Li[1], Glen Cooper[1], Brendan A. McGrath[2], Andrew Weightman[1]
[1]School of Engineering, University of Manchester, Manchester, United Kingdom
[2]Manchester University Foundation Trust Wythenshawe Hospital Intensive Care Unit, Manchester, United Kingdom
Email: andrew.weightman@manchester.ac.uk

Summary

Percutaneous Dilatational Tracheostomy (PDT) is one of the most dangerous procedures frequently performed on intensive care unit patients. To simplify the procedure and potentially improve safety, we created a novel medical device (TrachyPen). This study conducted experiments on porcine tissue *in-vitro* to robotically evaluate the insertion and dilation force profiles of TrachyPen and compare them with the Ciaglia Blue Rhino (CBR) dilator, used in clinical practice currently. Results illustrated a smaller stoma and insertion force from TrachyPen use, compared with CBR. This study provides evidence for the potential feasibility of using TrachyPen to perform PDT puncture and dilation.

Introduction

Percutaneous Dilatational Tracheostomy (PDT) is frequently performed at the intensive care unit bedside [1]. Perioperative movements of instruments, especially inserting and removing the needle and dilators, may cause severe complications in around 10% of total patients [2]. To reduce the complications associated with PDT instruments and improve the procedure, we proposed a prototype medical device called TrachyPen and the concept of using it for robotic PDT in previous study [3]. Either used robotically or manually, TrachyPen combines the PDT puncture and dilation into a single step to eliminate the use of multiple instruments and their complex operations. The conceptual design was evaluated in [3] and this research focuses on the experimental validation of insertion and dilation force profiles of TrachyPen, which aims to test its safety level and feasibility.

Methods

The experiment setup is illustrated in Fig. 1. Experiments were conducted on porcine back skin samples (thickness $4 \pm 1\ mm$, cut from meat for human consumption) to evaluate the force characteristics of TrachyPen during PDT and compare it with CBR (Cook Critical Care, Europe), the dilator currently used in clinical practice. Samples were fixed mechanically on a 3D printed test rig. A robot (Franka Robotics GmbH, Munich, Germany) was used to perform simulated PDT dilations on tissue samples using predefined trajectories. The insertion force peak was recorded by a sensor and the stoma length created was measured by a caliper. Results were explored using SPSS 24. Group differences were tested with independent t-tests.

Results and Discussion

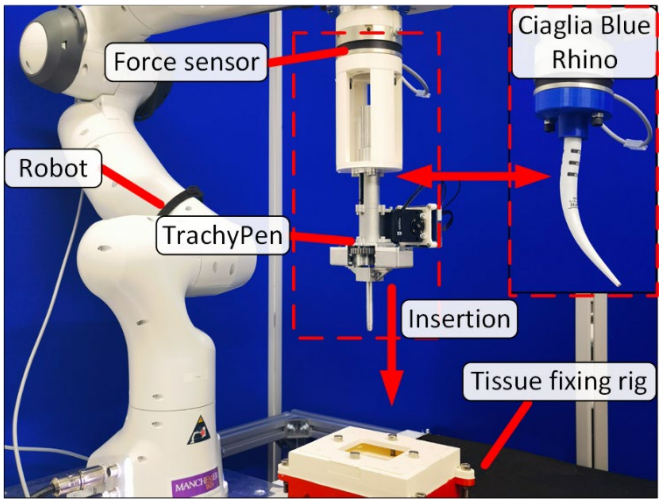

Figure 1: Experimental setup. TrachyPen and CBR were installed on the robot to perform simulated insertions on porcine back skin samples.

In total, 25 TrachyPen and 25 CBR dilations were successfully undertaken. There was a significant difference between the resulting stoma lengths and also the peak insertion force between the two techniques (Table 1). During the CBR insertion, the pushing force gradually increased along with the diameter of the CBR segment entering the stoma. TrachyPen's insertion pattern is similar to the blunt dilator but with a larger force. All trials of TrachyPen insertions experienced an increase in the insertion force when the dilator arms were pressing on the skin surface. The TrachyPen design could be improved by making the dilator arms tip sharper, which could ease the skin penetration.

Conclusions

TrachyPen has demonstrated the potential feasibility to be used for performing PDT procedures robotically without applying excessive stoma or force.

References

[1] Durbin et al. (2005). *Res. Care*; **50 (4)**: 483-487.
[2] Ambesh et al. (2002). *Anes & Anal*; **95 (6)**: 1739-1745.
[3] Tang et al. (2024). 9th *EMBEC*: 298-307.

Table 1: Experiment outcome of simulated PDT dilation using TrachyPen and Ciaglia Blue Rhino.

	Number of trials	Sample thickness (mm)	Stoma length (mm)	P value of stoma length	Insertion force peak (N)	P value of force peak	Dilation force (N)	Blunt insertion force (N)
Blue Rhino	25	4.2 ± 0.4	16.17 ± 2.05	<0.001	69.01 ± 8.42	<0.001	--	24.35 ± 3.17
TrachyPen	25	4.0 ± 0.5	13.65 ± 1.64		53.44 ± 8.07		94.69 ± 4.15	--