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SUMMARY

Airway management and intubation procedures continue to challenge anaesthetists. With current equipment not always providing an optimum solution, this can lead to potential serious complications if an airway is not secured quickly. Improvements in airway devices need to be discussed, designed, tested, and implemented. The implementation of the appropriate smart technologies and materials present an opportunity to resolve key issues with bougie-guided intubation. It is suggested that the development of a novel steerable Bougie could improve current tracheal intubation practice. This proposition is grounded on using the appropriate research and design development strategies combined with a structured methodological approach.

Key Words

Airway management; smart materials; steerable bougie; difficult airway

INTRODUCTION

Difficulty with airway management has potentially serious implications; if the airway is not secured quickly, there will be serious consequences for the patient. A difficult airway is defined as:

*“The clinical situation in which a conventionally trained anaesthesiologist experiences difficulty with facemask ventilation of the upper airway, difficulty with tracheal intubation or both.”*¹

Endotracheal intubation is a procedure with the purpose of intubating a patient in the quickest and safest possible manner, ensuring that air is able to pass freely to and from the lungs, thus allowing a patient to be ventilated. Anaesthetists are often presented with difficult airways, especially in emergency situations, however, unexpected difficulties within planned procedures are not uncommon. Difficult airways require a variety of management techniques, dependent on a patient’s clinical situation.

Complications of unsuccessful airway management can be very serious, including potential mortality.² Although the incidence of death and brain damage from airway management during general anaesthesia is low, reports of major complications during anaesthesia, collected from all UK National Health Service hospitals, suggests that there is room for improvement.³

There are other significant airway-related complications that, in combination, may lead to morbidity and mortality. These include aspiration of gastric contents, laryngospasm, and bronchospasm. Understanding a patient’s clinical situation, regardless of whether the intubation is planned or not, is extremely important. A planned procedure ensures an anaesthetist can review a patient’s medical history, plan for any suggestion of an anticipated difficult airway, and make changes in approach or equipment as needed.

The correct selection and safe use of optimally designed equipment is just one aspect of difficult airway management; recent equipment improvements have been shown to improve airway management success and safety rates.⁴⁻⁵ It is imperative that any equipment used is fit for purpose; causing further complications because of device failure during airway management procedures must be avoided.

One of the most common devices used to aid tracheal intubation is a bougie. This is a long, flexible, relatively

narrow guide rod that has some intrinsic “memory”. Bougies are used as a guide when a direct view of the trachea cannot be obtained. Following the shaping and placement of a bougie, an endotracheal tube can be “railroaded” over the bougie to secure the airway, before the bougie is removed. This process ensures a patient can be intubated when the direct placement of an endotracheal tube would be difficult.

Airway perforation and tissue damage is always a risk during intubation, especially with bougies. Studies have documented forces as low as 0.8N causing injury, thus this presents a significant design challenge.⁶ Overcoming this design challenge has massive potential; namely, the integration of smart systems using smart materials could be one possible solution to combat and improve the safety risks associated with the documented forces experienced during the intubation procedures.

Improving the safety and efficiency of emergency airway devices extends beyond the design and safe use of the device. Considerations should also relate to accurate pre-device testing, the design of teaching/tutorial methods especially for medical students, the design of the teaching space for procedural training, and the interaction behaviours within this space.⁷⁻⁸

Improving existing equipment presents an opportunity to increase the safety and efficiency of procedures within anaesthesia, especially when using a bougie. Common problems with the bougie relate to shape retention, tip pressure forces and steer-ability, amongst others. Improving these aspects of the device will ultimately improve the speed, safety, and performance profile, which is advantageous for the anaesthetist. Using smart materials within new equipment, thus creating a smart system, could solve a number of the identified problems.

The use of smart materials within medical products and applications is not a new concept; there a number of common examples, including stents, grafts, filters, sensors, amongst others. A general definition for a smart material is:

“A smart material is one that reacts to a stimulus in a reproducible way, the reaction, in most cases, also tends to be reversible.”

A material cannot be defined as being “smart” by itself. To be classified as “smart”, a material needs to be integrated into a system. Smart systems typically integrate a variety of objects, including sensors and actuators that respond to environment changes, thus creating an intelligent system.

There are various types of smart materials: shape memory alloys (SMAs), shape memory polymers (SMPs), electroactive polymers (EAPs), quantum-tunnelling composites (QTCs), thermochromic polymers, piezoelectric materials, magnetic shape memory alloys (MSMAs), amongst others.

Smart materials are currently being investigated as a result of a joint research project being undertaken by Nottingham Trent University (NTU), UK, and Nottingham University Hospitals Trust (NUH), UK, for the development of a Novel Steerable Bougie.⁹ The research project focuses on creating a bougie with a steerable tip, which functions using Flexinol® Actuator Wires (Dynalloy, Inc.).¹⁰ These shape memory alloy actuator wires are manufactured from nickel-titanium and can be electrically driven or heated to either flex or shorten, thus contracting within a 2-5 per cent range of the wire length.

Flexinol’s® ability to flex or shorten is a characteristic of certain alloys; these alloys dynamically change their internal structure at certain temperatures, thus demonstrating a controllable movement.

In the proof of concept stage and prototyping of the novel steerable bougie, various shape memory alloys, shape memory polymers, and low-cost artificial muscles were analysed. Tests conducted on these materials showed their properties were extremely dependant on the input parameters used, which resulted in the varying degrees of reaction times, material response, and relaxation times. The control parameters in some cases affected the materials lifespan and in certain cases resulted in failure; Siena et al.⁹ present a selection of these testing results. The selection of the Flexinol® Actuator Wires was made based on the required control parameters for the steerable bougie’s tip, including:

- The ability to have directional control of a steerable tip, 50-60mm in length and 5mm in diameter.

- Curvature control of 120 degrees in at least one plane.
- Positive movement with reaction and relaxation times of one second without exceeding tracheal damaging forces.

The use of SMAs in medical devices is likely to increase as new devices are designed and manufactured; however, SMAs do have some significant drawbacks, as described by Morgan and Broadley.¹¹ One of the most concerning drawbacks relates to the increased brittleness displayed after a period of use and the required power consumption. Therefore, if incorrectly controlled, repeatability and overuse of a SMA-control mechanism could result in device failure. However, if accurate control parameters are used, obtaining repeatable motion especially when considering Flexinol® Actuator Wires,¹⁰ tens of millions of cycles can reasonably be achieved.

Thorough research and design, development strategies have been applied to the development of the new bougie, alongside implementing a structured methodological approach. This will ensure that the designed novel steerable bougie performs as required, giving increased user control and steer-ability functionality, greater shape retention, reduced tip force pressures, and improved intubation times. Validating the design is an important process; verification can be achieved using pre-production prototypes and testing rigs for preclinical testing. Preclinical testing will ensure that any new device will function accurately while in use during clinical trial.

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CONFLICTS OF INTEREST

The authors declare that they have no competing interests.

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ETHICS COMMITTEE APPROVAL

Not required.