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DESIGN INSIGHT

Performance analysis for difficult airway equipment: Standardising for success

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SUMMARY

Equipment design and selection can contribute to the success or failure of difficult airway management. However, evaluative systems for providing the relative performance data for bougie introducers to help inform these choices do not exist outside of bespoke studies. This paper discusses the design development of an innovative tip pressure and shape retention testing system. Working with a design activity model, a set of stringent criteria to inform the manufacture of the testing systems were produced. Once implemented, this testing method can inform future equipment selection to improve procedure success rates and thereby reduce patient complications.

Key Words

Airway management; bougie introducers; difficult airway; difficult intubation; testing systems;

INTRODUCTION

Airway management and intubation procedures continue to challenge anaesthetists. Current equipment does not always provide optimum solutions; serious complications can potentially occur if an airway is not secured quickly.

To aid difficult intubations, various types of equipment are available, with the most common being a bougie introducer. The Gum Elastic Bougie is widely accepted as the gold standard device, however, there are many similar devices on the market, some of which demonstrate increased tip pressures.[1] Other limitations associated with bougie-aided intubation include: limited shape retention, high insertion and retraction forces, and restricted directional control movement. Nevertheless, to date there is no standard protocol for testing bougies.

Many devices complete the same procedural tasks, although little evidence supports their selection other than personal preference or designated hospital suppliers. Many devices have not undergone any formal testing in accordance with the United Kingdom's Difficult Airway Society's ADEPT principles.[2] ADEPT has formulated advice underlining evidence-based principles, defining minimum evidence requirements to inform purchasing and selection decisions. The ADEPT guidance protocol concludes:

> *All airway-related equipment under consideration must fulfil the minimum criterion that there exists for it at least one source of 'Level 3b' trial evidence concerning its use, published in peer-reviewed scientific literature.*[2]

Developing testing systems analysing device performance in studies would inform users of optimum equipment. Equipment used can vary based on experience, skillset, and operator training. Creating testing systems that provide objective, statistically relevant data to aid with decision-making would be a major advancement.

Two testing systems were designed to help inform device selection:

1. **Tip Pressure Testing System:** evaluating the forces applied at the bougie tip, considering the grip location.
2. **Shape Retention Testing System:** tracking and accurately measuring the shape retention capabilities of bougies; considerations include bend location, angle of bend and position vs time tracking.

SUMMARY

The need for designing accurate testing systems stems from studies such as Hodzovic et al.[1], and Annamaneni et al.[3], who attempt to evaluate various bougies, but fail to consider factors that could influence data accuracy. To improve validity of collected data in future studies, it is necessary to design new testing systems that accurately

record and track various elements simultaneously. The following should be considered:

1. Accuracy of equipment used to record data; ie, maximum measurement ranges, load-cell capabilities and full-scale deflection accuracy (%FSD).
2. Regulating/standardising the amount of pressure applied to shape the bougie.
3. Repeatability of positional tracking of a bougie.
4. Angle and orientation of the bend of the bougie.
5. Adaptability of the testing system ensuring accurate and statistically relevant testing data can be collected regardless of the devices brand.

Many design factors can now be resolved by designing accurate testing systems with interchangeable components, combined with using data acquisition software or health outcome measurement systems that record, track, and analyse data.

When designing the Tip Pressure Testing System, the following design requirements were implemented:

1. Incorporating suitable pressure sensors or ultra-thin, single-element, capacitive sensors that accurately and reliably quantifies forces.
2. Suitable load cells with appropriate maximum measurement ranges, load-cell capabilities and %FSD that link to accurate data acquisition software.
3. Adaptable transportable system that remains calibrated and standardised upon setup.

When designing the Shape Retention Testing System, the following design requirements were implemented:

1. Adaptable system, calibrated to collect reliable and accurate testing data.
2. Interchangeable components standardising system setup regardless of the equipment's diameter and length.
3. Repeatable testing system with pre-configured variables adaptable for the bespoke product range.
4. Recordable accurate camera tracking with interchangeable angle measurement grids to record different measures over clinically relevant ranges.
5. Accurate camera/video tracking with fixed frame rates and appropriate field of view (FOV) to track bend angles, tip movements, speed of movement, and shape retention.
6. LED lighting to reduce the effects of ambient light.
7. Logic-based programming system ensuring that the testing system is reset to a home position, providing a protocol of standard movements.
8. Post-processing capabilities to re-analyse data and adjust into alternative formats.

LESSONS LEARNED

Focused Design Approach

Many designers fail, regardless of the product, due to a lack of focused approach during design and testing. To support the design process, it is important to follow a structured design methodology and formulate a product design specification; this is critical for product evaluative testing phases.

During the design of the Tip Pressure and Shape Retention Testing Systems, Pugh's Total Design Activity Model[4] was considered. Predefining a design methodology mapped to the specification promotes an optimum total design activity, ensuring successful design and manufacture activities; this is crucial when considering evaluative testing phases for these devices.

Designing accurate testing systems provides the opportunity to complete detailed product reviews of existing bougies and future devices produced for the market. By doing so, it is possible to conduct a complete analysis of the market that informs the following:

1. Contribute testing data that informs likelihood of successful device operation, providing recommendation for optimum equipment selection.
2. Inform users of product ranges that offer improved intubation efficiency.
3. Ensure manufacturers avoid producing poorly designed, higher risk devices; ie, devices with increased tip pressures influenced by material selection.
4. Increase overall performance and safe use of devices within the sector contributing to increased procedure success rates for first time intubation.

Reviewing existing literature, including testing methods used in several studies,[1,3,5] it has been possible to design improved testing systems, thus providing a system that can provide accurate data instead of comparable data. Testing data collected from the tip pressure and shape retention testing systems will allow anaesthetists to make informed decisions on equipment selection.

Improvement in intubation practice relies on influencing change in several areas, not just equipment design, but teaching/tutoring methods, training environments, team

dynamics, and psychological and communication considerations. A full assessment of equipment, using adaptable testing systems with stringent protocols would provide significant insight into recommended equipment selection, thus improving the success rates of procedures and reducing patient complications.

DESIGN INSIGHT

Failure to secure the airway on induction of anaesthesia can result in death and disability. Most anaesthetists would consider bougies essential equipment for safe anaesthesia.

Bougies are manually manipulated prior to use to match the curve of the patient's airway from mouth to trachea. If the bougie does not retain its shape, it cannot be adjusted in-situ and it must be removed. This is time consuming in a time-critical process. Bougies are also associated with complications. This is related to pressure applied through the bougie tip as it is placed in the patient's airway. The flex and feel of a bougie is important as the anaesthetist uses tactile feedback to recognise correct placement in the trachea and to prevent damage to the tissues.

A common frustration amongst anaesthetists is the variation in the characteristics of flex or the inability to hold shape when there is a change in manufacturer. Standardised testing would be a new innovation and would certainly be an improvement on the current situation.

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CONFLICTS OF INTEREST

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ETHICS COMMITTEE APPROVAL

Not required.