Airway Shield
Safer Intubation

PRECLINICAL AND CLINICAL VALIDATION

STUDIES COMPLETED

1. 1st Pre-clinical Study

A preclinical study demonstrating the Airway Shield™´s capacity to reduce exposure to aerosols and droplets in a high-fidelity simulation of endotracheal intubation in a manikin model. This study was conducted by **a single operator** who performed **eight intubations with and without the Airway Shield™.** The results confirmed a significant reduction in respiratory particles during intubation using the device compared to intubation without it. This article was published in a prestigious medical journal.

(https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9553218/).

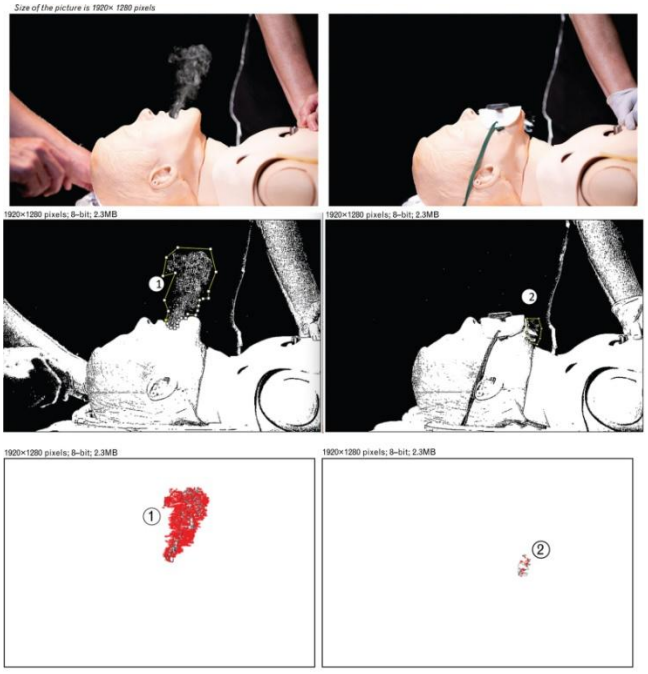


Fig. 1. Data capture and analysis using ImageJ: measurement of aerosol spread during simulated induction and CPR with and without Airway Shield.

2. 2nd Pre-clinical Study

A **randomized cross-over trial with 15 anaesthesiologists** who performed **3 intubations attempts using the Airway Shield™ and 3 using video laryngoscope alone, in a manikin model**. The goal of this study is to **determine** whether intubation by experienced operators using the **Airway Shield™ is non-inferior compared to standard intubation technique**. The results demonstrate a significant reduction in the intubation time when using the medical device compared to the technique without it. Moreover, participants scored the feasibility of intubation with Airway Shield™, reaching a mean value of 9/10 points. (Under revision/pre-print).

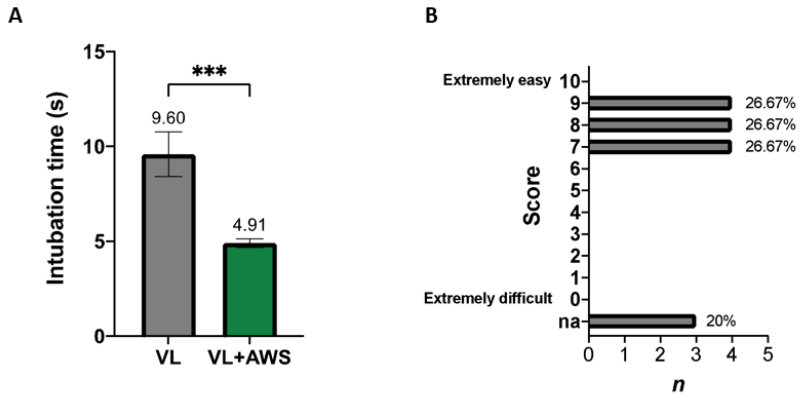


Fig. 2. A) Time to ETI spent by clinicians in the two scenarios: without Airway Shield™ (VL) or with Airway Shield™ (VL+AWS). B) Ease of intubation performed with Airway Shield™ scored by participants on a scale of 0-10.

3. 1st Clinical Study

Pilot study conducted with **20 patients at the Marqués de Valdecilla University Hospital (Santander, Spain)** to test the efficacy and safety of the intubation technique using the device. Although it has not yet been published, preliminary analysis shows that 19 intubations were successful and there were no complications.

Valdecilla
Hospital Universitario Marqués de Valdecilla

Fig. 3. Valdecilla University Hospital logo.

4. 2nd Clinical Study

A **randomized study with 102 patients** and **performed by experienced anaesthesiologists** from **Araba University Hospital (Vitoria, Spain),** who proceeded with endotracheal intubation with **(intervention group) or without Airway Shield™ (control group)**. Preliminary analysis showed no significant differences in intubation times between the two groups and intubation success rate with video laryngoscope and Airway Shield™ of 100%. Moreover, the rate of patients successfully intubated at the first pass was 73%, concluding that the intubation with this device is non inferior to the standard intubation technique.

Osakidetza

Fig. 4. Araba University Hospital logo.

5.- USER LEARNING TEST (ULT STUDY) – UNIVERSITIES IN SPAIN

Unlike many other airway management devices, the Airway Shield™ is easy to learn. We aimed to test this statement with students to determine whether the technique is easier to learn with or without our device. It has involved medicine students from different universities in Madrid, Spain. We are currently analysing the results.

Universidad Europea

Universidad Francisco de Vitoria
UFV Madrid

Fig. 5. Universities taking part in ULT Study

6. TRAUMA STUDY – CLINIC HOSPITAL IN BARCELONA

A randomized crossover trial with a sensorised manikin that measures in Newton the force applied to different anatomical structures when performing endotracheal intubation. The main objective of this study is to demonstrate the dental protection offered by the Airway Shield™ during intubation performed by **26 operators** (including intensivists and anaesthesiologists), who performed a total of 312 intubations attempts, , using two different VLs: the Intersurgical i-View® and the Medtronic McGrath®. A specialized software was developed for real-time data acquisition.

The results showed a 70% reduction in the force applied over the incisors when using the Airway Shield™ compared to intubation without the device. Moreover, the maximum force applied with the Intersurgical I-view decreased by 41% when used in combination with the Airway Shield™, and by 25% when using the Medtronic McGrath in combination with the Airway Shield™, compared to the procedure without the device. Additionally, a 50% reduction in intubation time was also observed when using the Airway Shield™. Finally, a first-pass success rate of 100% was achieved in all intubation attempts using the Airway Shield™, compared to 80% without the device.



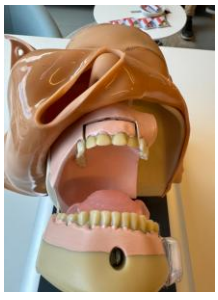


Fig.6. Modified manikin for the trauma study.

7. MULTICENTER STUDY

Currently, we are involved in the preparations for a multicenter, randomized study to compare our device with the two approaches currently used in clinical practice to guide endotracheal intubation: the bougie and the stylet. The trial aims to enroll 750 patients across 10 sites located in Spain, Italy, Poland, Sweden, Qatar, and Brazil.



Fig. 7. Sites participating in our Multicenter Study.