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ORIGINAL RESEARCH

Clinical Proof of Concept for Stabilization of Tracheostomy Tubes Using Novel DYNAtraq Device

Mauricio Orozco-Levi[1–3], Carlos Reyes[4], Neikel Quintero[1], Diana Tiga-Loza[1–3], Mabel Reyes[1–3], Sandra Sanabria[5], Camilo Pizarro[4], Juan De Hoyos[5], Norma Serrano[6], Victor Castillo[5,7], Alba Ramírez-Sarmiento[1–3,6]

[1]Respiratory Department, Hospital Internacional de Colombia, Fundación Cardiovascular de Colombia (FCV), Floridablanca, Santander, Colombia; [2]Group of Research in Muscle, Training and Lung Diseases (EMICON), Ministerio de Ciencia y Tecnología (MINCIENCIAS), Bogotá, Cundinamarca, Colombia; [3]Department of Medicine, and Facultad de Ciencias Médicas y de la Salud, Universidad de Santander (UDES), Bucaramanga, Santander, Colombia; [4]Department of Critical Care, Hospital Internacional de Colombia, Fundación Cardiovascular de Colombia (FCV), Floridablanca, Santander, Colombia; [5]Bioengineering Research Group, Fundación Cardiovascular de Colombia (FCV), Floridablanca, Santander, Colombia; [6]Research Center, Fundación Cardiovascular de Colombia (FCV), Floridablanca, Santander, Colombia; [7]CEO, Fundación Cardiovascular de Colombia (FCV), Floridablanca, Santander, Colombia

Correspondence: Mauricio Orozco-Levi, Respiratory Department, Hospital Internacional de Colombia, Fundación Cardiovascular de Colombia, Calle 155A no. 23-58, El Bosque, Floridablanca, Santander, Colombia, Tel +57 3175741421, Email mauricioorozco@fcv.org

Introduction: Tracheostomy is one of the most common surgical strategies in intensive care units (ICU) and provides relevant clinical benefit for multiple indications. However, the complications associated with its use range from 5 to 40% according to different series. The risk of these complications could be reduced if fixation strategies and alignment of the tracheostomy tube with respect to the tracheal axis are improved.

Aim: To build a functional device of technological innovation in respiratory medicine for the fixation and alignment of tracheostomy cannula (acronym DYNAtraq) and to evaluate its feasibility and safety in a pilot study in mechanically ventilated patients.

Methods: Study carried out in four phases: (1) design engineering and functional prototyping of the device; (2) study of cytotoxicity and tolerance to the force of traction and push; (3) pilot study of feasibility and safety of its use in tracheostomized and mechanically ventilated patients; and (4) health workers satisfaction study.

Results: The design of the innovative DYNAtraq device included, on the one hand, a connector with very little additional dead space to be inserted between the cannula and the ventilation tubes, and, on the other hand, a shaft with two supports for adhesion to the skin of the thorax with very high tolerance (several kilograms) to pull and push. In patients, the device corrected the malpositioned tracheostomy tubes for the latero-lateral ($p < 0.001$) and cephalo-caudal angles ($p < 0.001$). Its effect was maintained throughout the follow-up time ($p < 0.001$). The use of DYNAtraq did not induce serious adverse events and showed a 70% protective effect for complications ($RR = 0.3$, $p < 0.001$) in patients.

Conclusion: DYNAtraq is a new device for respiratory medicine that allows the stabilization, alignment and fixation of tracheostomy tubes in mechanically ventilated patients. Its use provides additional benefits to traditional forms of support as it corrects misalignment and increases tolerance to habitual or forced movements. DYNAtraq is a safe element and can reduce the complications of tracheostomy tubes.

Keywords: mechanical ventilation, tracheostomy, DYNAtraq, alignment, tubes

Introduction

Tracheostomy is a common and beneficial surgical and prosthetic procedure in intensive care patients. Approximately 10% of patients with mechanical ventilation require it.[1–4] Tracheostomy offers benefits to respiratory mechanics such as maintaining a patient airway, reducing the mechanical load of the system on the respiratory muscles, and facilitating strategies for both airway care and earlier weaning from mechanical ventilation.[5] Therefore, the main indications for tracheostomy are both the

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prevention of prolonged ventilation and failed extubation. Some studies have shown that tracheostomy can decrease the incidence of ventilator-acquired pneumonia, decrease ICU stay, decrease mortality, or decrease direct costs of care.[6,7]

However, tracheostomy can cause or be associated with multiple complications, some intraoperative and others postoperative.[8–11] Its incidence varies between 5–53%, and among them hemorrhage, pneumothorax, subcutaneous emphysema, displacement of the cannula, accidental decannulation, tracheal stenosis, tracheoesophageal fistula, obstruction of the cannula lumen, peristomal skin lesions,[12] stomal and lower respiratory infections, tracheal ring fracture,[13] among others. Of these, the most frequent complications are not very relevant, such as scant stomal bleeding. Although tracheostomy is safe, attributable mortality has been reported to be around 1.4% of patients.[14] Rarely, life-threatening complications have been reported, such as injuries to the trunk of the brachiocephalic artery or even hypoxic-ischemic encephalopathy associated with anomalous displacement of the cannula during changes in position in patients (especially in obese patients).[15–18]

The most used method for fastening tracheostomy tubes is a band or cord that goes around the neck, passes through two eyelets at the base of the tube (one on each side), and is tied or attached by Velcro with the fundamental intention to prevent accidental decannulation. However, this fastening is defective because it does not provide any physical support against lateral or longitudinal traction, nor does it provide a guarantee of fixed alignment of the cannula. This defect is even more evident with changes in the patient's position or the movements of the ventilator circuit tubing. Cannula malposition and decannulation are known and reported events, but several others are underreported such as dynamic obstruction of the tracheostomy tube (in up to 92% of cases) and formation of locoregional inflammatory granulation tissue (in 15%), which in turn are associated with a longer duration of MV.[19,20] Consequently, air leaks, alterations in ventilatory flows, increased respiratory work, dyspnea, limitation for weaning from the tracheostomy, decreased quality of life and risk of respiratory infections or late complications (tracheal stenosis) can be observed.[20,21,22]

The perception was that in the real clinical environment there was an opportunity for improvement and innovation of a new device for the management and reduction of risks related to tracheostomy tubes, especially their displacement and misalignment. This is very relevant in the ICU setting where mechanical ventilation can be prolonged and associated with serious complications. The objective was to determine the physical, material and ergonomic characteristics of an external device that would provide added value to the usual techniques of conventional fastening and fixation of tracheostomy cannulae, as well as to create and test the functionality of the device in a pilot study in patients hospitalized in the ICU, tracheostomized and mechanically ventilated, and to evaluate their safety both in terms of materials and connection elements to the respiratory circuit and adhesion to the chest. The device was named with the acronym DYNAtraq.

Methods

Patent of the Device

This study summarizes the process of conceptual design, functional prototyping, final deliverable and evaluation of the efficacy in humans of a tracheostomy cannula fixation and alignment device in mechanically ventilated patients, called DYNAtraq. In the absence of similar devices and due to its beneficial and preventive effect for the alignment and fixation of tracheostomy cannulae, this device has received a patent as an invention model (ref. NC2016/0002057 Resolution 17,691 of the Superintendence of Industry and Commerce, Colombia) due to its novel nature, in the absence of similar devices on the market.

Ethical Considerations

The study protocol was reviewed and approved by both the Institutional Review Board and the Ethics committee (Ethics Committee of the Cardiovascular Foundation of Colombia, CEI-FCV); certificate ref. 361 December 2014 and ref. 390, January 2016 for phases 1 and 2; certificate ref. 482, August 2019 for phase 3. For the present study, seven intubated and mechanically ventilated patients were included (Table 1). The regulations of the World Medical Association for Research on Humans (Helsinki Declaration) were complied with. Instrumentation was always in accordance with the rules of good clinical practice. Participation in the study included informed and written consent from the close responsible family members of each intubated individual (next of kin). The Written Informed Consent Sheet was signed by the next of kin after reading and

Table 1 General Characteristics of the Study Population

Patients, n (%)		7 (100%)
Age (years)	Median (SD)	54 (15)
Sex	Males, n (%)	6 (85.7)
BMI (kg/m^2)	Median (SD)	30.3 (5.8)
Comorbidities	Yes n (%)	6 (85.7)
Days of Stay in ICU	Days, median (min-max)	21 (11–89)
Duration of mechanical ventilation	Days, median (min-max)	22 (9–71)
Tracheostomy timing	Days, median (min-max)	13 (6–50)
DYNAtraq device usage time	Days, median (min-max)	10.9 (1–45)
Before installing DYNAtraq device		
Lateral-lateral deviation of the tracheal axis	Degrees, median (min-max)	13 (6–50)
Cephalocaudal deviation of the tracheal axis	Degrees, median (min-max)	17 (5.1–37.1)
After installing DYNAtraq device		
Lateral-lateral deviation of the tracheal axis	Degrees, median (min-max)	2.4 (0.4–7)
Cephalocaudal deviation of the tracheal axis	Degrees, median (min-max)	5.6 (1.9–9.6)
Adverse events	Excoriation /laceration, n (%)	0
	Flictena, n (%)	0
	Erithema, n (%)	0
	Pressure Ulcer, n (%)	0
Difficulties with the DYNAtraq device	Deformation, n (%)	1 (14.3)
	Failure in adherence to skin, n (%)	4 (57.1)
	Fracture, n (%)	0

Notes: General descriptive variables of patients included in the pilot study to evaluate the DYNAtraq device in patients in intensive care unit. Safety variables of the device is also described.

knowing the objectives, techniques to be used and any inconvenience that participation could cause. The patient's next of kin have provided informed consent for the images to be published. Patient confidentiality was always respected. The study was registered in clinicaltrials.gov (identifier NCT04668742). The present study includes the interim analysis conducted before data collection has been completed for the clinical trial. The authors intend to share with other unidentified individuals.

Pre-DYNAtraq Prototypes

In 2016, our research group validated the "FixTraq" design. In the pilot test, the incidence of angular malposition of the tracheostomy cannula in the ICUs of the HIC and the FCV was determined by means of a digital measurement application on a photographic image without the need for contact with the patient and with a precision equal to a conventional goniometer. As determined by experimental comparison, the finding was that more than 80% of the cannulae were poorly angled. Additionally, in a before-and-after intra-subject comparative analysis, it was reported that FixTraq was effective in correcting the position of tracheostomy tubes, both in terms of cephalocaudal and latero-lateral angles, specifically the longitudinal axis (cephalo -caudal) from 46° to 81° with a percentage change of 56% ($p=0.014$), while regarding the angle of lateral rotation of the cannula with respect to the midline (transverse axis), the device allowed obtaining a change from 52° to 70°, equivalent to a change of 32% ($p<0.001$). The correct position of the tracheostomy cannula was achieved in 83% of the cases, which contrasts with only 2% when they did not have the device ($p<0.01$). However, the rupture of the prototypes due to the traction of the ventilation tubes and the movements of the patients led to a redesign of the prototype with flexible and dynamic elements. Therefore, the new name of DYNAtraq refers to the settings of the current, final version (Figures 1–3).

Production of the DYNAtraq Device

Device prototypes were built by 3D printing using SolidWorks 3D Modeling Software (SolidWorks Corp., Dassault Systèmes, SA (France), conventional printing material (polylactic acid), and printing software (KISSlicer Cubeit; Printer: 3D Systems, Cubex Duo model, 2013 (USA). Subsequently, the mold was manufactured in mechanized steel (Leadwell

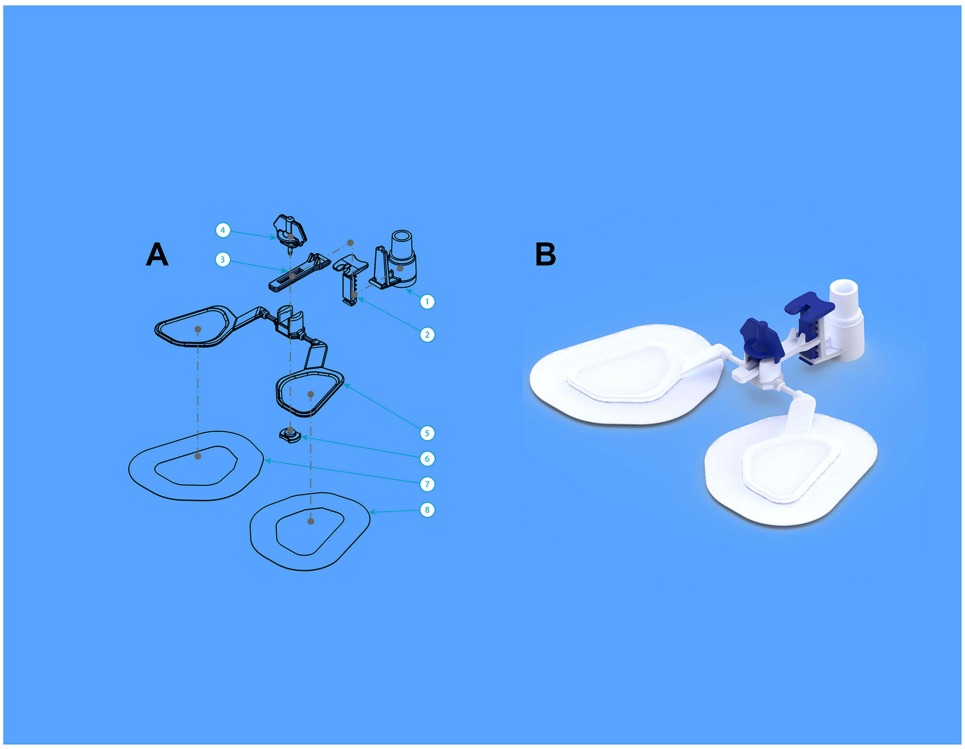

Figure 1 (**A**) Representative figure of the industrial design drawings of DYNAtraq device. The intention of taking the DYNAtraq device to the molding, injection, clinical validation and future commercialization process has required all the necessary plans being designed in accordance with current regulations. These design drawings were also necessary to file the patent application. For more details on the respective plans, please contact the principal investigator. (**B**) Three-dimensional space graphic design of DYNAtraq device.
Notes: (1) male and female 15 mm coupling; (2) adjustable connector hook; (3) adjustable horizontal rail; (4) trim butterfly; (5) thoracic base support; (6) left and (7) right paddles; (8) double-sided hypoallergenic adhesive-tape ring.

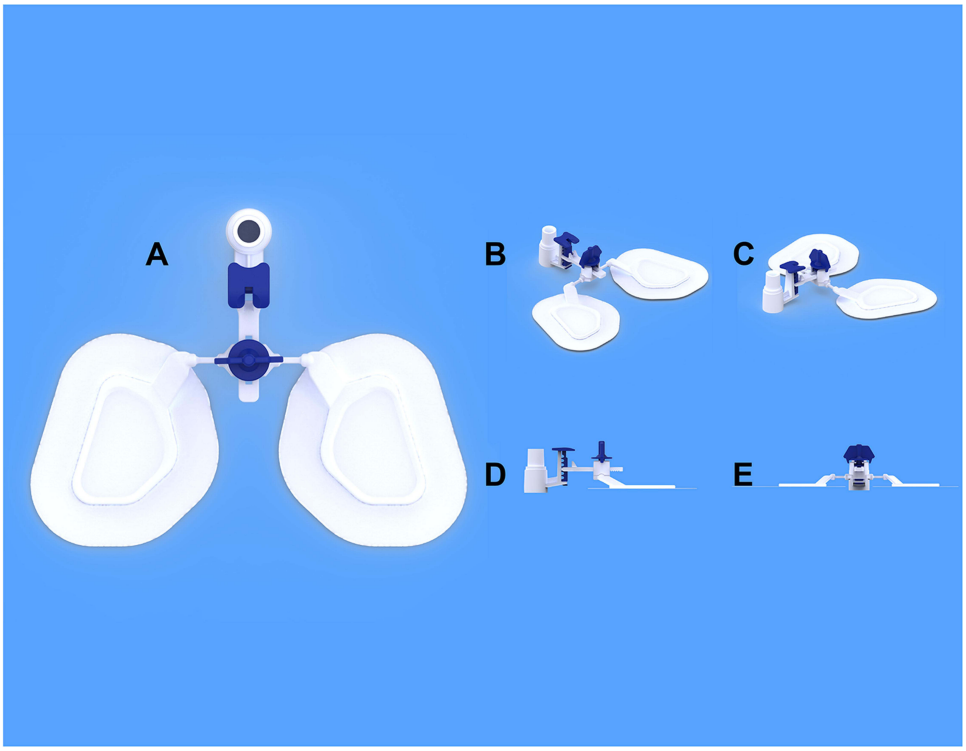

Figure 2 Specialized 3D graphic design of the end of the DYNAtraq device. (**A**) Frontal plane view; (**B** and **C**) obliquus plane view; (**D**) sagittal plane view; (**E**) axial plane view.

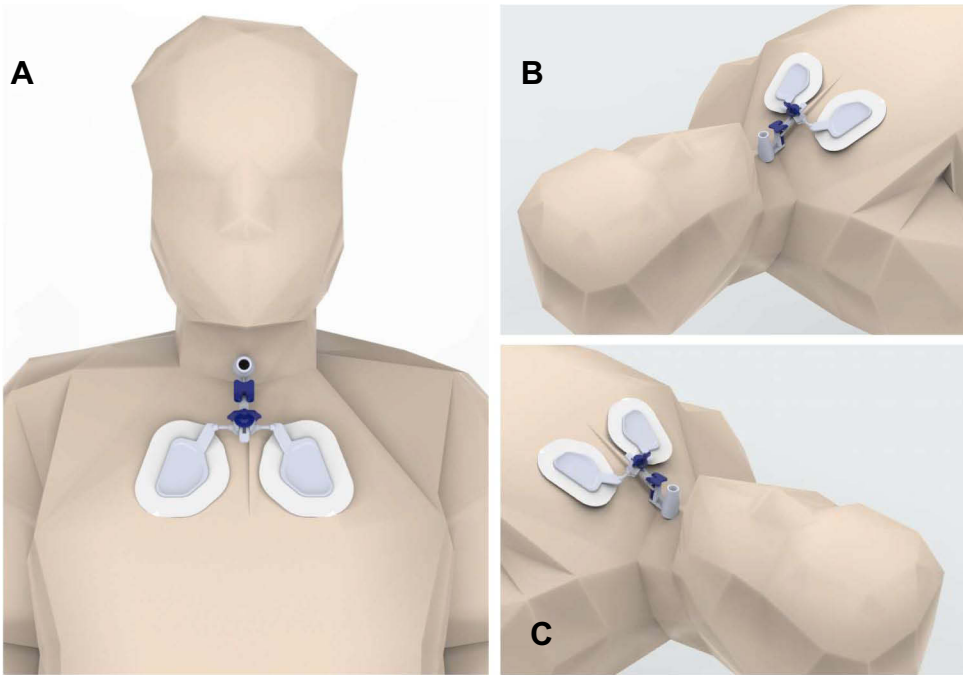

Figure 3 Conceptual model of DYNAtraq device evaluated in life-size human manikins. (**A**) Frontal plane view; (**B**) and (**C**) oblicuous plane view.

V30, 2003). The block was obtained in high quality steel in order to couple it with the plastic injection machine (Boy, 50T2 factory, Neustadt, Germany, 1998). The final product was subjected to quality tests, dimensional verification, functionality and adjustment of the injected parts (Figure 2).

Cytotoxicity Study of Materials and Production Processes of DYNAtraq

The potential cytotoxic effects of the DYNAtraq prototype sample were evaluated. The study was performed in accordance with the specifications of ISO-10993-5, Biological Evaluation of Medical Devices-Part 5: Tests for in vitro cytotoxicity. The cytotoxicity assay is a colorimetric-type assay that quantitatively measures cell viability and proliferation after exposure to device extracts or solutions. Tetrazolium salts are used to assess cell death. The metabolic activity of the cells causes the reduction of these salts in an insoluble substance called formazan which is in the form of crystals, due to the action of the succinate dehydrogenase enzyme. The color change is subsequently quantified by means of spectrophotometry. Absorbance values that are lower than cell controls indicate a reduction in cell capacity, while higher absorbances indicate an increase in cell capacity. A decrease in the number of living cells leads to decreased metabolic activity due to the sample. This decrease correlates directly with the amount of formazan formed and this correlation is measured by absorbance at a wavelength of 570nm. Three replicates of DYNAtraq were performed, using three 96-well plates with semi-confluent cell layers. An extraction was performed for each of the entered replicas, using MEM (Minimal Essential Medium) at 37°C for 24 hours, a negative control and a positive control as the extraction vehicle, according to the specifications of the ISO 10993–12 standard. The sample extract was dosed at a concentration of 100%, 75%, 50%, 25% and 12.5% diluted in the extraction vehicle.

Accelerated Stability Study

A total of five DYNAtraq samples were subjected to accelerated aging at a temperature of 55°C and humidity of 70%. The test was carried out until obtaining an aging equivalent to 1.6 years. The methodology is carried out according to the American Society for Testing and Materials (ASTM) F1980-7:2011 standard. After accelerated aging, sterility tests were carried out according to the United States Pharmacopeia USP.

Tensile Evaluation of the Connectors Using Dynamometry

An accidental disconnection of the device would represent a serious adverse event with serious consequences for the patient. It is believed that a tensile load on the cannula and DYNAtraq connector can cause disconnection if the geometry of this connector does not meet the capacities required to maintain the installation with standard devices implemented. To evaluate the maximum tensile load tolerated by the DYNAtraq connector before disconnecting from the cannula was compared with referent universal 15 mm connectors of ventilatory circuits. Three prototypes were used, which were subjected to longitudinal axial loads. A dynamometer (Imada Z2-44, Imada Inc, Northbrook, IL, USA) was used to record the peak load (KgF) required to disconnect the connectors from the cannula.

Evaluation of the Perception of Health Personnel Regarding the Use of the Device

An anonymous paper survey was conducted on health personnel (physicians, nurses, therapists, nursing assistants) who work in the intensive care units where the device was used on patients. Eight questions were included, evaluated on a 5-point Likert-type scale ranging from totally disagree to totally agree, aimed at investigating the perception of the device in terms of innovation, need for implementation, size, shape, security, ease of use, and potential reduction of tracheostomy complications. In addition, the level of recommendation for the use of the device was inquired about, as well as the suggestions and possibilities for improvement.

Results

Final Components of the DYNAtraq Device

The device design was based on fundamental concepts of respiratory medicine in mechanically ventilated patients. It was conceived and designed to constitute an ergonomic external element of four components with complementary functions: (1) a universal female-male connector to connect the tracheostomy cannula and the mechanical ventilator tubing simultaneously; this connector represents the interface that transfers the cannula support to the rest of the device; (2) an axis of rotation that allows flexo-extension movements of the connector on the longitudinal body axis; (3) an adjustable rail with longitudinal displacement; (4) and two wide-based lateral supports to be adhered to the skin of the thorax. These components merit the following comments. The connector has universal measurements so that it can be connected to the proximal (extracorporeal) portion of tracheostomy tubes, without increasing the dead space of the external ventilation circuit. This connector is mechanically based on the same pressure clamping principle as the ventilator's own circuits. The union axis of the connector with the rail was designed to allow the flexo-extension movements of the neck to have no resistance. The central rail with longitudinal slide allows the health professional to locate the device in the most appropriate position to orient and align the cannula with the connector and the lateral supports. Finally, the lateral supports have a wide base to reduce the risk of pressure injuries, and they have patches with certified adhesive for fixing to the skin of the chest (Figures 2 and 3).

Accelerated Stability and Cytotoxicity Studies of the DYNAtraq Device

The viability percentage of cells exposed to 100% concentration of the extract in the three samples analyzed was 79.1%, 82.2% and 91.1%, respectively, obtaining a mean of 84.2% with a standard deviation of 6.2%. According to the international standard ISO 10993–5, a medical device is not considered cytotoxic if its viability is greater than 70%. All the dilutions of the extract of the analyzed samples present a percentage of viability greater than 70%, for which the sample is considered NOT cytotoxic for the cell line L929 mouse fibroblasts, according to the ISO 10993–5 standard. The sterility tests carried out after the accelerated aging of the devices were negative at 14 days of incubation, therefore it is concluded that DYNAtraq retains its sterility condition after 1.6 years of storage. (Figure 4).

Tensile Evaluation of the Connectors

A mean 7.5 KgF was needed to disconnect a referent 15 mm connector, whereas an average of 11.1 KgF was needed to disconnect the connector of the DYNAtraq (p=0.00135) (Figure 5).

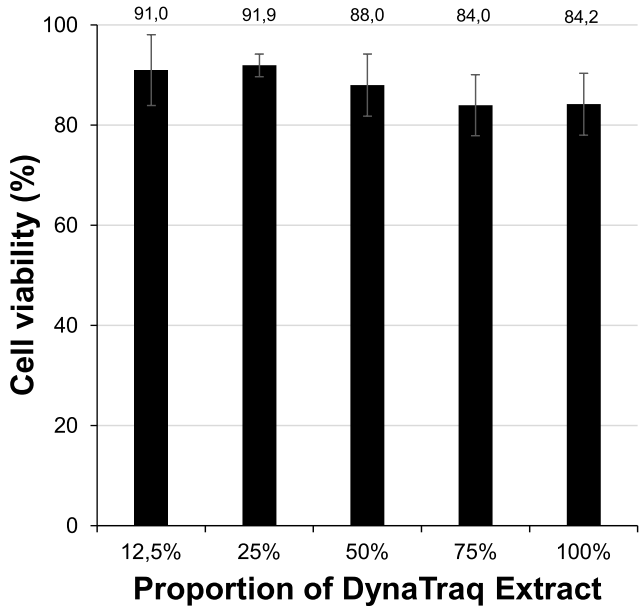

Figure 4 Cytotoxicity tests. The cytotoxicity test was carried out following the international standard ISO 10993–5. The extraction process was carried out according to ISO 10993–12. Different concentrations of the extract (100%, 75%, 50%, 25% and 12.5%) were exposed to the L929 cell line for 24 hours. Bars represent mean (SD) of the viability obtained in triplicate experiments.

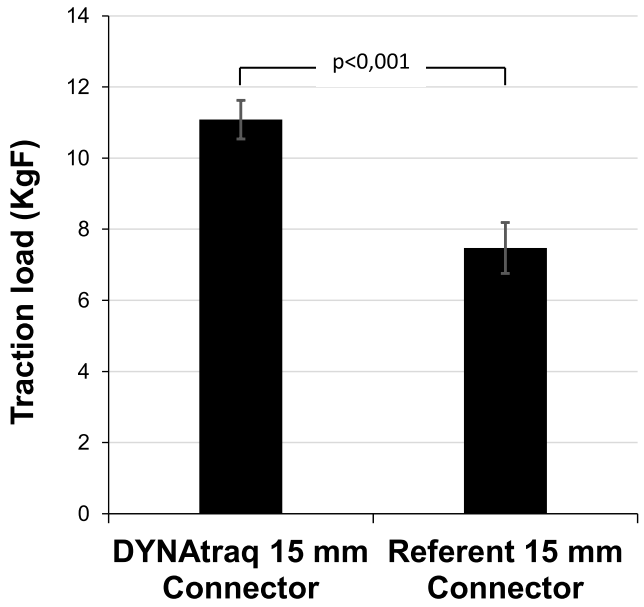

Figure 5 Tensile loads tolerated by the connectors before disconnection from the tracheostomy tube. Under experimental laboratory conditions, high values (several KgF) were recorded for both the DYNAtraq 15mm connector and the reference connector before they were disconnected from the tracheostomy tube. Bars represent the mean (SD) value of the studies performed in triplicate for both connectors.

Results of the Use of the DYNAtraq Device in Humans

The patients included in the pilot study of the device were selected from those hospitalized, tracheostomized and receiving mechanical ventilation due to medical indications for various reasons. All patients were of legal age, most with multiple comorbidities, and most of the male gender. Most of them had a prolonged stay in the ICU. All had been tracheostomized in the previous 6 or more days and had been mechanically ventilated for 9 more days (Table 1).

Measurements (degrees) of the alignment of the proximal end of the cannula with respect to the sternum (longitudinal axis) or the interclavicular line (lateral axis) showed a high range, some up to 50° and 37°, respectively, when evaluated without the intervention of the researchers (Table 1). Characteristically, the cannulas show a high mobility to the movements induced by the tubes of the ventilation circuit, which we call the "dance" of the tracheostomy, with ranges of up to 70–80 degrees in both axes. The DYNAtraq device was easily connected to all tracheostomy tubes by interfacing it with the ventilator circuit. The most appropriate position was defined by the evaluator, including alignment criteria in their axes in the face of less perceived resistance (Figures 6 and 7). The lateral supports were stuck to the skin of the thorax and the residual displacement angles were measured, which decreased significantly to maximum values of 10° when faced with longitudinal or lateral external load (Table 1). The median time of use of the DYNAtraq was 10 days (median). The ventilatory parameters did not deteriorate and, on the contrary, in some patients the flow-volume curves improved with the installation of the device, apparently due to better alignment in relation to the trachea (data not

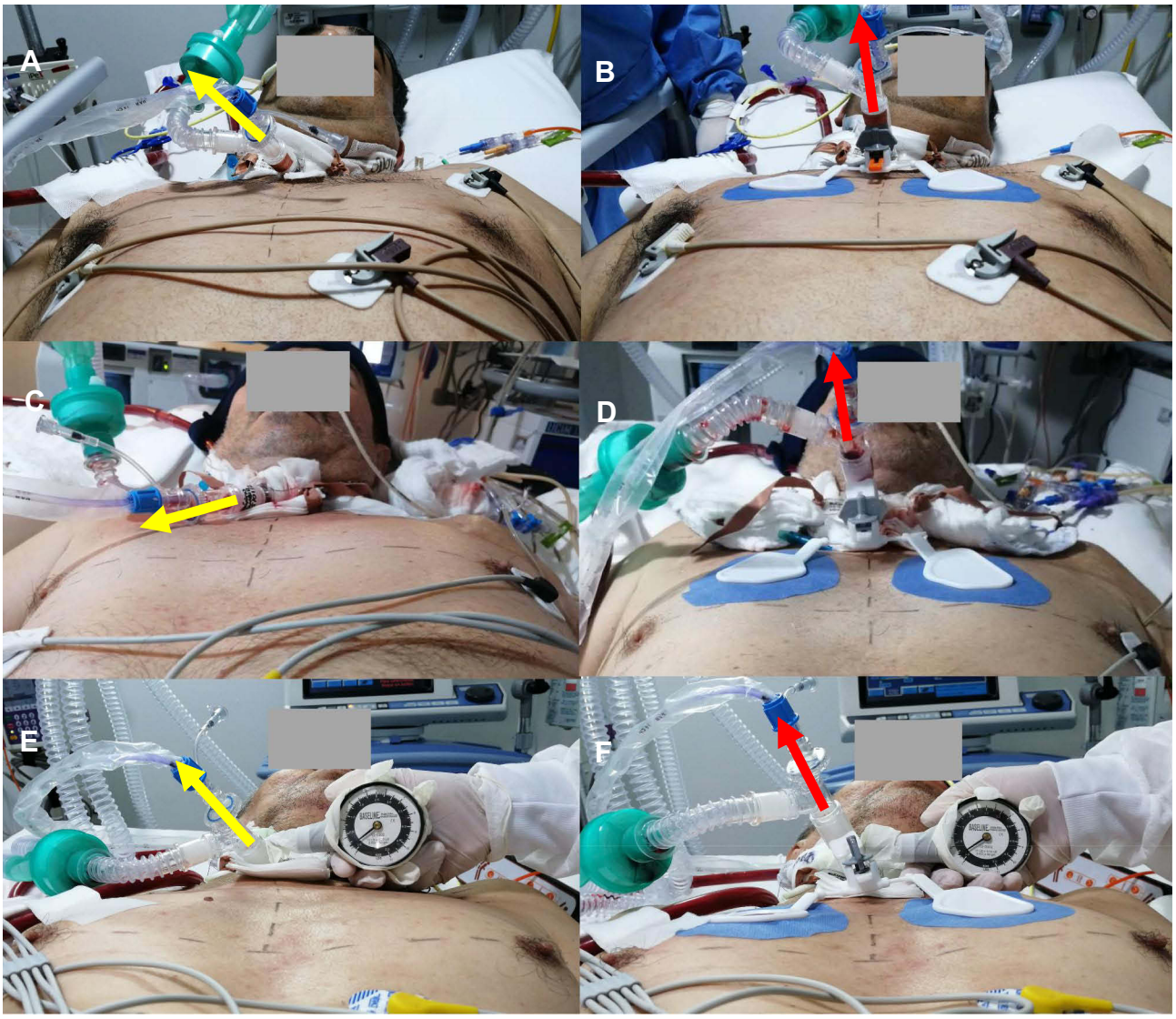

Figure 6 Comparisons Between Sequential Photographs Taken Prior To And After The Placement Of The DYNAtraq Device In Ventilated Patients. Sequential pictures from three selected patients to show cephalo-caudal view of intrasubject comparisons prior to and after the placement of the DYNAtraq device. Pictures (**A, C** and **E**) represent the referent caudal-cephalic photographs patients without the device, whereas pictures (**B, D** and **F**) show caudal-cephalic photographs of the same patient once the device has been placed on the chest taking the midline of the sternum for reference. Color code: (Yellow arrows): axis of the tracheostomy tube alignment at baseline (without the device) position; (Red arrows): axis of the tracheostomy tubes using the DYNAtraq device. It is also shown in (**E** and **F**) pictures the degree of lateral misalignment in a patient in the face of equivalent left to right push loading on the tracheostomy tube. Note that the device offers greater tolerance to the pushing load as it is deduced from a lower angular displacement despite of an equivalent external load.

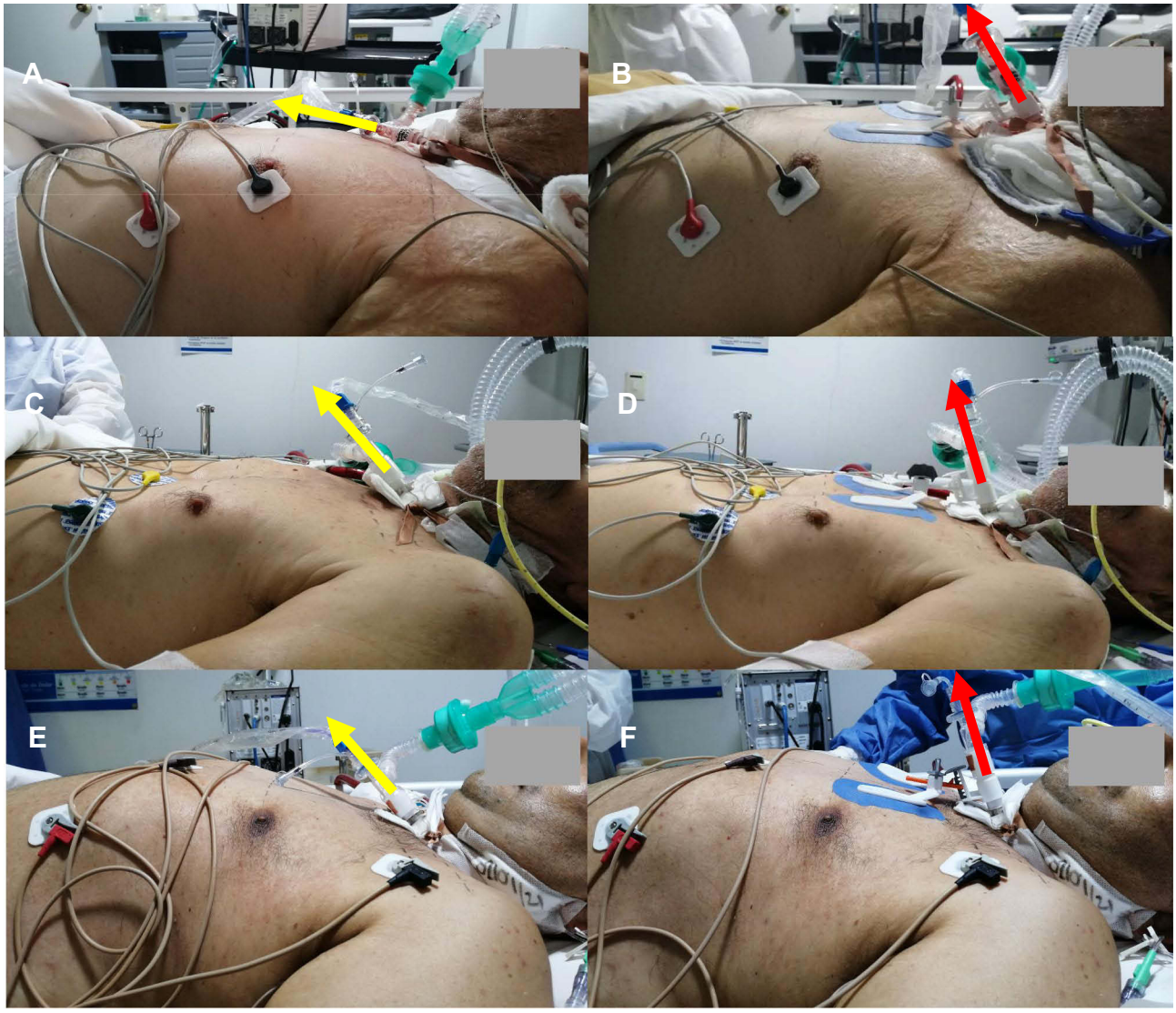

Figure 7 Patient With DYNAtraq Dispositive: Lateral View In Supine Position Comparisons Between Sequential Photographs Taken Prior To And After The Placement Of The DYNAtraq Device In Ventilated PatientS. Sequential pictures from three selected patients to show latero-lateral view of intrasubject comparisons prior to and after the placement of the DYNAtraq device. Pictures (**A, C** and **E**) represent the referent latero-lateral photograph of the patients without the device, whereas pictures (**B, D** and **F**) show latero-lateral photographs of the same patient once the device has been placed on the chest following the interclavicular line reference. Color code: (Yellow arrows): axis of the tracheostomy tube alignment at baseline (without the device) position; (Red arrows): axis of the tracheostomy tubes using the DYNAtraq device.

shown). No adverse events related to or precipitated by the DYNAtraq device were identified. Aspects of partial loss of adhesiveness were identified after several days of use, especially in more diaphoretic patients, which were resolved by changing the adhesive patch. No difficulties were identified or reported with the interpretation of radiological studies (translucent X-ray device) nor with general nutrition care, tracheostomy care, respiratory therapy, bathing care, or general usual medical care.

Results of the Evaluation of the Perception of Health Workers About the Use of the Device

In 71 health workers who were in contact with patients using the device, it was found that most of them perceive DYNAtraq as innovative, necessary for the management of tracheostomy, as well as being easy to use, of an adequate shape and size, can reduce complications and does not interfere with the daily care of patients (Table 2). Additionally, it

Table 2 Perception of Use of the DYNAtraq Device in Health Workers of the ICU

Scale	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree	Total Score
Domains	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**Median (SD)**
DYNAtraq is innovative for tracheostomy management	36 (50.7)	34 (47.9)	1 (1.4)	0	0	4.49 (0.53)
DYNAtraq is easy to use	32 (45.1)	31 (43.7)	8 (11.3)	0	0	4.33 (0.67)
DYNAtraq is required for tracheostomy management	27 (30)	31 (43.7)	13 (18.3)	0	0	4.19 (0.73)
Suitable Shape of DYNAtraq device	29 (40.8)	38 (53.5)	1 (1.4)	3 (4.4)	0	4.31 (0.71)
Suitable size of DYNAtraq device	26 (36.6)	33 (46.5)	5 (7)	7 (9.9)	0	4.10 (0.91)
DYNAtraq device reduce risk of respiratory infections	23 (32.4)	30 (42.3)	17 (23.9)	1 (1.4)	0	4.06 (0.79)
DYNAtraq device reduce tracheostomy complications	34 (47.9)	25 (35.2)	12 (16.9)	0	0	4.31 (0.75)
DYNAtraq device does not interfere with patient care	29 (40.8)	30 (42.3)	7 (9.9)	4 (5.6)	1 (1.4)	4.14 (0.98)

Note: Median (SD) values of sexagesimal scale evaluating the perceptual characteristics including safety variables of the device reported by tens of ICU health workers.

was asked if the health personnel would recommend the use of the device, answering that always 54.9%, almost always 38% sometimes 5.6% and never 1.4%. Among the suggestions for improvement in its use, 8.4% of the respondents mentioned that improvements are required in the adhesive for greater durability, and 7.04% that it should have a smaller size, 1.4% that it could cause dilation of the stoma to be used incorrectly.

Discussion

This study describes the conceptualization and technological development of a respiratory medicine device that is justified by the opportunity to improve the care of tracheostomy cannulae in mechanically ventilated patients. The so-called knowledge economy is a determining element in competitiveness and the solution of clinical problems in real life. The first original value proposition of this study was the possibility of solving a specific clinical problem with effective and accessible elements on a large scale for patients mechanically ventilated through tracheostomy tubes. A second value proposition was to consider that the DYNAtraq device could represent an element of technological innovation with a potential invention patent, which was achieved at the level of the Patent Office.

The present investigation has focused on the resolution of the misalignment and displacement of the tracheostomy tubes. The initial insight of the team into opportunities for improvement in clamping and fixation techniques and devices for these tubes was based on detecting problems during patient care in the real-life ICU setting. The usual use (standard of care) of velcro straps or knotted cords around the neck can hold the cannulas but have no real ability to maintain their correct alignment for ventilation when patients change position or the connection tubing to the mechanical ventilator, they create traction and displace the cannula. Therefore, this research becomes a novel scientific contribution that describes and evaluates the invention of the DYNAtraq device to provide additional, non-redundant elements for respiratory medicine in critical patients.

The development of the device had a first phase of conceptual design that allowed the generation of functional prototypes through 3D printers using PLA. These prototypes were evaluated in terms of proportions to human anthropometry and in terms of mobility axes that should be incorporated into the final device. The first prototypes showed that the PLA did not show sufficient flexibility or resistance to deformation, but they allowed identification of the points of maximum inflection before the forces that were exerted during its use in patients in real life. This evidence made it possible to deduce the final characteristics in terms of resistance and the use of more flexible materials for the definitive design of the device. Specifically, a polymer authorized by national and international entities for medical use and with sufficient elasticity and resistance called SBC (Styrene Butadiene Copolymer) was selected. The clinical requirements

were taken to the design by engineering, agreeing on modified angles and couplings in the areas that had previously been documented as having greater tension and risk of rupture. The final design of the DYNAtraq has some well-defined characteristics that deserve to be highlighted. It molded in material approved for external use in humans and a design that provides flexibility for different positions of the tracheostomy cannula. It has a tilting connector that allows flexion and extension movements of the neck. It has two sliding mechanisms that allow adaptation to different morphologies of the chest. It has a connector height adaptation mechanism that allows it to be adapted to the tracheostomy as required by the relationship between the sternum and pectoral muscles with the ostomy stoma. In addition, the central bridge is elevated in such a way that it does not directly contact the sternum, something important in cases of cardiovascular surgery by sternotomy.

The patients included in this study would represent typical populations of adult patients who are usually admitted to medical ICUs in Colombia and other countries. In fact, one of the strengths of the present study has been contemplating the testing of the device in a real clinical setting and therefore directly reflecting the conditions of patients who have required tracheostomy and care in critical care units. These studies allowed the reengineering of the prototype design to culminate in a device of standardized size, resistant, non-invasive, adjustable, useful and relevant for the adequate fixation and orientation of the tracheostomy cannula to the thorax of adult patients.

Clinical perception suggests that there exists an underestimation of the prevalence of malpositioned tracheostomy tubes, which is not a superfluous clinical problem and may be related to both medically and economically relevant outcomes. In fact, to the best of our knowledge, only one study has postulated tracheostomy malposition as a complication. Schmidt et al[20] recently described that malposition was a fairly common complication and that it depends on demographic, clinical and tracheostomy-specific factors, which affect the duration of mechanical ventilation, can occlude the distal end of the tracheostomy tube by making an impression against the posterior wall of the trachea, an can increase hospital stay and mortality.[20] Formation of granulation tissue was observed in 37% of cases.[20]

The DYNAtraq device provides conventional systems with an additional non-redundant fixation technique for tracheostomy tubes with very high tolerance to forced or accidental external pulling or pushing movements. In our laboratory conditions, the connector of the DYNAtraq offers not only similar but even greater tolerance to traction loads before disconnecting from the cannula connector. The evaluation of the tensile resistance of the connector allowed demonstrating that there is no inferiority but even greater resistance when compared to commercial connectors, As far as real life is concerned, this does not imply practical or instrumental difficulties for the clinicians to disconnect it. It is not potentially an obstacle to emergency resuscitation due to that tensile force. It is not estimated that patient safety will be modified when the ventilator has to be urgently disconnected. This connector is V-shaped, which is usual in ventilation devices and tubes, and allows it to disconnect by exerting lateral-longitudinal traction, without requiring disconnect wedges or other disconnecting elements. The adhesives that allow the fastening of the DYNAtraq to the thorax were selected through a comparative process until defining that the reference 1577 3M™ Medical Tape 1577 double sided adhesive provides enough fundamental features for the device. Our studies under laboratory conditions made it possible to demonstrate that the device with its supports adhered to a smooth metal surface tolerates up to several KgF of linear and lateral traction. However, we did not develop forced traction studies of such magnitudes in humans, nor did we have materials that emulate healthy skin for such effects. Given that the device does not have a similar comparator except cord systems or straps around the neck and its usefulness for aligning and fixing tracheostomy tubes has been demonstrated, it is justified to carry out clinical trial-type research to compare its clinical efficacy in the prevention of local complications such as infections, lacerations, bleeding, stoma dilation, mechanical tracheitis, decannulation or dysfunction of tracheostomy tubes, among others. For the purposes of the present study, it was agreed that appropriate position of the tracheostomy cannula should be defined based on two fundamental angles: the longitudinal and the latero-lateral, both with respect to the thorax. The poor position of the cannula in the longitudinal and latero-lateral axis was evidenced in 93% and 75% of the patients, respectively.

The present study has limitations. One of the limitations is the absence of a similar reference device to compare. An additional limitation of the conceptualization and design of the device is that it has been defined for adult tracheostomized patients (young, middle-aged and older) but we have not developed versions for pediatrics or patients with major chest deformities. It is necessary to define the relevance and feasibility of emulating a similar device before being able to extrapolate its use to minors or patients with unusual chest morphologies. The study does not allow evaluating effects

and/or potential adverse events related to the use of the device for weeks or months. The mechanical effect of the device in terms of alignment, fixation and safety was only evaluated in the short term. Finally, we do not have enough information to quantify the clinical benefit or the therapeutic effect in terms of reducing length of hospital stay, days of mechanical ventilation, or decreasing tracheal and stomal complications that in fact justified the design of the device. These questions require progress to another experimental study design to be answered. Likewise, its use may be extended to the environment of home hospitalization, long-stay centers or on an outpatient basis, which implies the need to carry out future studies and continue with the work platform to establish the impact of the device in reducing the risk of tracheal and ventilatory complications in tracheostomized patients.

Conclusions

The DYNAtraq device is an inventive device that allows tracheostomy cannulas to be held and aligned in height and position by means of sliding rails and supports with adhesion to the skin of the thorax. For its use, awareness or collaboration is not required on the part of the patient, relatives or guardians, since it depends on the health personnel. DYNAtraq is a non-invasive device, ergonomically designed, and both intuitive and simple use. It is injected in innocuous and biocompatible material and its production reflects a low cost. Finally, DYNAtraq does not include antibiotic components, so it is reasonable to consider that it does not exert selection pressure on microorganism. For all the above, we believe that multicenter clinical trials are warranted to assess its clinical impact in terms of prevention of complications such as infections, lacerations, bleeding, stoma dilation, mechanical tracheitis, decannulation or dysfunction of tracheostomy tubes, among others.

Data Sharing Statement

The authors intend to share with other individuals unidentified participant data including demographics, clinical characteristics, and specific data regarding safety and efficacy of the device. Data is available on request from the corresponding author (mauricioorozco@fcv.org).

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Disclosure

The authors MOL, CR and ARS declare to be the inventors with intellectual property of the device. The patrimonial property of the device belongs to the FCV institution. MOL reports grants from the Ministry of Science and Technology of Colombia MINCIENCIAS, during the conduct of the study, and has patent licensed to ref NC2016/0002057. The authors report no other potential conflicts of interest for this work.

References

1. Esteban A, Apezteguía C, Anzueto A, et al.; International Mechanical Ventilation Study Group. Outcome of mechanically ventilated patients who require a tracheostomy. *Crit Care Med*. 2005;33(2):290–298.
2. Fischler L, Erhart S, Kleger GR, Frutiger A. Prevalence of tracheostomy in ICU patients: a nation-wide survey in Switzerland. *Intensive Care Med*. 2000;26(10):1428–1433. doi:10.1007/s001340000634
3. Marchese S, Corrado A, Scala R, et al. Tracheostomy in patients with long-term mechanical ventilation: a survey. *Respir Med*. 2010;104:749–753. doi:10.1016/j.rmed.2010.01.003
4. Che-Morales J, Díaz-Landero P, Cortés-Tellés A. Manejo integral del paciente con traqueostomía. *Neumol Cir Torax*. 2014;73(4):254–262. doi:10.35366/55381
5. Trouillet J, Collange O, Belafia F, et al. Tracheostomy in the intensive care unit: guidelines from a panel of French experts: French society of intensive care and French society of anesthesia and intensive care medicine. *Anaesth Crit Care Pain*. 2018;37(3):281–294. doi:10.1016/j.accpm.2018.02.012
6. Rumbak M, Newton M, Truncale T, Schwartz S, Adams J, Hazard P. A prospective, randomized study comparing early percutaneous dilated tracheostomy with prolonged translaryngeal intubation (delayed tracheostomy) in critically ill medical patients*. *Rev Bras Ter Intensiva*. 2004;32(8):1689–1694.
7. Hyde G, Savage S, Zarzaur B, et al. Early tracheostomy in trauma patients saves time and money. *Injury*. 2015;46(1):110–114. doi:10.1016/j.injury.2014.08.049

8. Freeman B, Morris P. Tracheostomy practice in adults with acute respiratory failure. *Crit Care Med*. 2012;40(10):2890–2896. doi:10.1097/CCM.0b013e31825bc948
9. Garner JM, Shoemaker-Moyle M, Franzese CB. Adult outpatient tracheostomy care: practices and perspectives. *Otolaryngol Head Neck Surg*. 2007;136(2):301–306. doi:10.1016/j.otohns.2006.08.023
10. Cipriano A, Mao M, Hon H, et al. An overview of complications associated with open and percutaneous tracheostomy procedures. *Int J Crit Illn Inj Sci*. 2015;5(3):179. doi:10.4103/2229-5151.164994
11. Pantoja CG, Mora ME, Blasco A. Traqueotomía: indicaciones, técnica y complicaciones. *Libr Virtual Form En ORL*. 2014;21:1–14.
12. Karaca T, Korkmaz F. A quasi-experimental study to explore the effect of barrier cream on the peristomal skin of patients with a tracheostomy. *Ostomy Wound Manag*. 2018;64(3):32–34. doi:10.25270/owm.2018.3.3239
13. Ramírez J, Padilla J, Sánchez-Arias M. Traqueostomía percutánea por dilatación: reporte de 70 casos. *Acta Médica Costarricense*. 2006;48:77–83.
14. Klemm E, Nowak AK. Tracheotomy-related deaths-a systematic review. *Dtsch Arztebl Int*. 2017;16:273.
15. Jacob AM, Jacob AM, V. P. N. Incidence of complications of emergency tracheostomy in a rural medical college setting: a prospective study. *Int J Otorhinolaryngol Head Neck Surg*. 2017;3(3):522–527. doi:10.18203/issn.2454-5929.ijohns20171465
16. Bontempo LJ, Manning SL. Tracheostomy Emergencies. *Emerg Med Clin North Am*. 2019;37(1):109–119. doi:10.1016/j.emc.2018.09.010
17. Bello G, Muzio FD, Antonelli M. Quality of life and complications after percutaneous tracheostomy. In: *Percutaneous Tracheostomy in Critically Ill Patients*. Cham: Springer; 2016:131–147.
18. Readi SR, Gómez AF, Osorio MJ. Open tracheotomy in the intensive care unit. *Rev Otorrinolaringol Cir Cabeza Cuello*. 2015;75(May2008):7–12.
19. Hebert LM, Watson AC, et al. Discussing benefits and risks of tracheostomy: what physicians actually say. *Pediatr Crit Care Med*. 2017;18(12):e592–e597. doi:10.1097/PCC.0000000000001341
20. Schmidt U, Hess D, Kwo J, et al. Tracheostomy tube malposition in patients admitted to a respiratory acute care unit following prolonged ventilation. *Chest*. 2008;134(2):288–294. doi:10.1378/chest.07-3011
21. Swain SK, Acharya S, Das S. Social impact of tracheostomy: Our experiences at a tertiary care teaching hospital of Eastern India. *J Sci Soc* 2020;47:148–52
22. Allgood S, Peters J, Benson A, Maragos C, McIltrot K, Slater T, Akst L, Best SR, Galiatsatos P, Brodsky MB, Brenner MJ, Pandian V. Acquired laryngeal and subglottic stenosis following COVID-19-Preparing for the coming deluge. *J Clin Nurs*. 2021 Aug 8; doi:10.1111/jocn.15992