Novel 3-D Printable Aspiration Device "SPUTA VACUUMER" Designed to Minimize Invasion

Naoyuki Ishikita

***Abstract*—*Goal:* The purpose of this study is to develop a minimally invasive sputum aspiration device. *Methods:* The current general method is to insert a suction catheter into the trachea. However, sufficient suction cannot be obtained unless the catheter reaches the target. A new connection device "SPUTA VACUUMER" has been invented. The effectiveness of the SPUTA VACUUMER is tested in this study. *Results*: After manually inflating the lungs, the device applies suction pressure to the entire lungs. Peripheral sputum or foreign matter is effectively moved to the upper respiratory tract. *Conclusions:* "SPUTA VACUUMER" is minimally invasive, simple and cost effective. The device can be manufactured with a 3D printer and the plastic injection molding model received pharmaceutical approval in Japan in 2021. It is currently being used in clinical settings. It can be operated by non-skilled personnel and may be performed in space and improve astronauts' quality of life.**

***Index Terms*—3D printing, airway secretion clearance therapies, foreign matter suctioning, sputum suctioning, vacuuming.**

***Impact Statement*— The SPUTA VACCUMER is a 3D printable device that can remove sputum and foreign matters without inserting a suction catheter into the trachea.**

I. Introduction

TRACHEAL suctioning is the most basic and important medical procedure to remove dyspnea caused by secretions and obstructions of the airway. There is a clinical guideline on airway suctioning by the American association for Respiratory Care (AARC) based on the clinical review [1]. At present the general sputum or foreign matter aspiration method is to blindly insert a suction catheter connected to a suction tube into the trachea. However, a sufficient suction effect cannot be obtained unless the tip of the catheter reaches the target. A bronchoscope can be used to deliver a suction effect to the site of sputum. However, bronchoscopy requires a high degree of skill, takes time, and cannot reach deep into the bronchi. Stimulating a cough by deep insertion of a catheter to move up sputum or foreign matter is not only painful but also has a risk of serious complications such as cerebrovascular disorder due to elevated blood pressure and airway injuries [1]. Chest physiotherapy such as body squeezing or postural drainage has a potential danger of bone fracture especially when these procedures are performed by non-physical therapists [2]. The Mechanical In-Exsufflation (MI-E) is well known as a "Cough Assist", which is minimally invasive and short-time sputum aspiration machine [3]. This device is similar to an artificial ventilator, but after inflating the lungs with positive pressure, it instantly switches to negative pressure to reproduce the airflow of a cough, and by continuing to apply negative pressure, the lungs are squeezed, sputum and foreign matter in the respiratory tract can be moved to the upper respiratory tract (through vacuuming). However, the machine is expensive and difficult to operate without training. The objective of this study is to develop a minimally-invasive and low-cost sputum or foreign matter aspiration method and device.

Manuscript received 15 October 2022; revised 11 December 2022, 28 December 2022, 29 January 2023, and 21 February 2023; accepted 21 February 2023. Date of publication 24 February 2023; date of current version 7 September 2023. This work was supported in part by the Japan Agency for Medical Research and Development (AMED) under Grant 20he0522005j0001. The review of this article was arranged by Editor Ilaria Cinelli.

The author is with the Niigata National Hospital, Kashiwazaki, Niigata 945-0847, Japan (e-mail: ishikita.naoyuki.vj@mail.hosp.go.jp).

Digital Object Identifier 10.1109/OJEMB.2023.3248875

II. Materials and Methods

Manual In-Exsufflation "Vacuuming" was devised that was based on the established method of the Mechanical In-Exsufflation; see Fig. 1. After inflating the lungs, the suction tube is brought into close contact with the airway management device to deflate the entire lungs and move sputum and foreign matter up the air ways.

The suction tube is a hose that connects the suction pump and the suction catheter, not a medical device for sectioning sputum. Therefore, a special tool was needed to adhere to the airway securing device and transmit negative pressure to the lungs, and the SPUTA VACUUMER was born; see Fig. 2.

The composite material of the connecting device is ABS plastic. The size of the lower end of the lumen is slightly over 15 mm, the same diameter as the outer diameter of the tracheal cannula and endotracheal tube. This is to prevent suffocation due to incorrect connection, and it can be easily removed by releasing the hand. The lumen is conical or stepped for quick connection of the suction catheter after vacuuming. A holder is provided on the outer periphery of the lower end of the connector to fix the suction tubes together.

Vacuuming procedure is as follows:

1) Auscultation

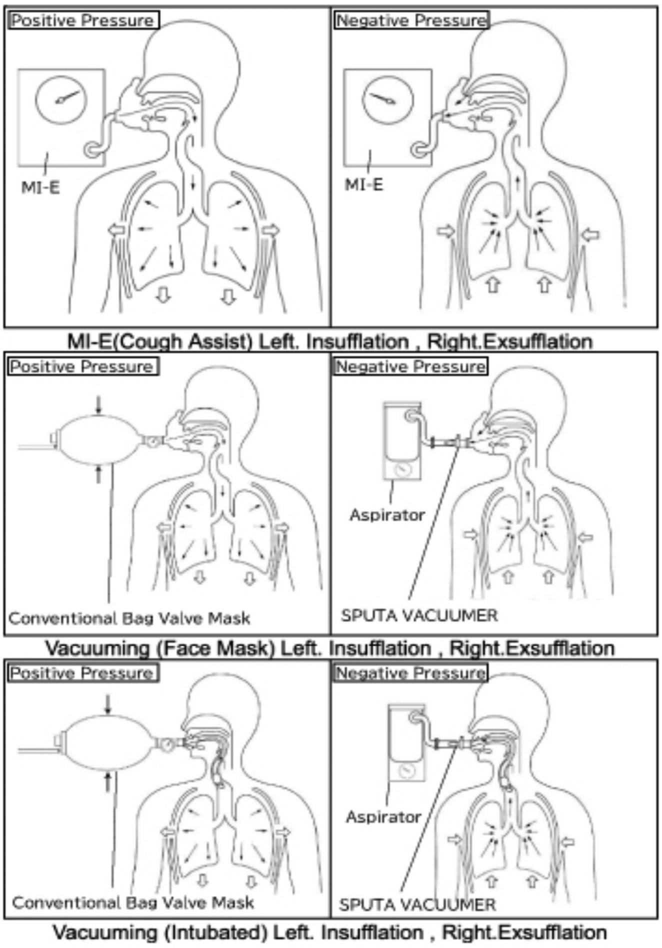

Fig. 1. Suction concept of vacuuming method.

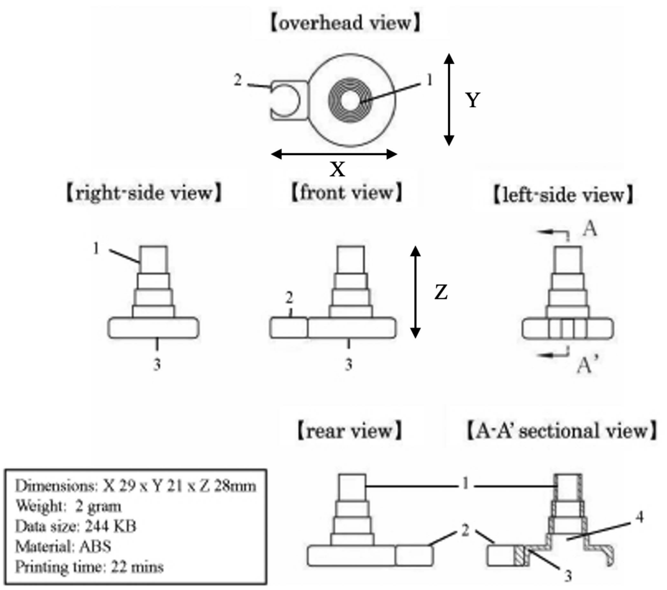

Fig. 2. Design of "SPUTA VACUUMER" (3D Printed model). (1) Suction tube connection port, (2) Suction tube binding holder, (3) Adhesion part with the airway securing device, (4) Suction catheter connection port.

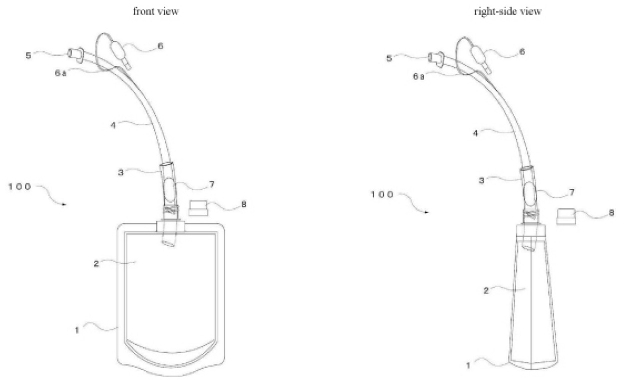

Fig. 3. Sputum suction training model lung. 100. Model lung for sputum suction training, (1) Transparent container with spout: Yume Pack DP16-GN1000 1000 ml 130 $\times$ 80 $\times$ 240 mm (inner diameter 16 mm), (2) Low rebound sponge, (3) Transparent hose: Sanyo Kasei transparent vinyl hose TM-1517D 50T 15 $\times$ 17 mm (4) Tracheal intubation tube, (5) Connector, (6) Pilot balloon, (6a) Inflation tube, (7) Cuff, (8) Cap.

2) Pressure ventilation (+40cmH_2O for 3 seconds to improve hypoxia and atelectasis)
3) Vacuuming (-60 kPa for 3 seconds)
4) Pressure ventilation (+40cmH_2O for 3 seconds to return the lungs to their normal state)
5) Auscultation
*Repeat 1. - 5. until recovered

A simple lung sputum suction model was developed [4] for learning the principles of vacuuming and for training physicians, nurses, and caregivers; see Fig. 3. This model lung consists of a transparent container with a spout heat-sealed with a resin sheet, a porous cushioning material inside the container, a transparent hose inserted into the spout, and a tracheal intubation tube inserted into the transparent hose. The model lung is infused with simulated sputum that is colored and viscosity adjusted and pieces of plastic having a diameter of 1.75 mm as foreign matter. The model lung is made of a transparent material, and it is possible to see where the simulated sputum and foreign matter is accumulated.

As a general suction method, a 10 French Gauge of suction catheter (Top Co., Ltd.) was connected to a universal bubble tube (Nippon Covidien Inc.) and used.

The suction source used was wall piping from our hospital. The suction volume of the suction pump was 1.26 m^3/min at 3.7 kW of power (Central Uni Co., Ltd.), and the suction pressure was kept at -60 kPa.

III. Results

In the conventional established suction method, when a suction pressure was applied after inserting the suction catheter, the model lung did not deflate, and no movement of simulated sputum or foreign matter was observed.

In the vacuuming method, when suction pressure was applied, peripheral simulated sputum and foreign matter began to move to the upper level by compression of the model lung, and almost all of the simulated sputum was removed within 5 seconds. The

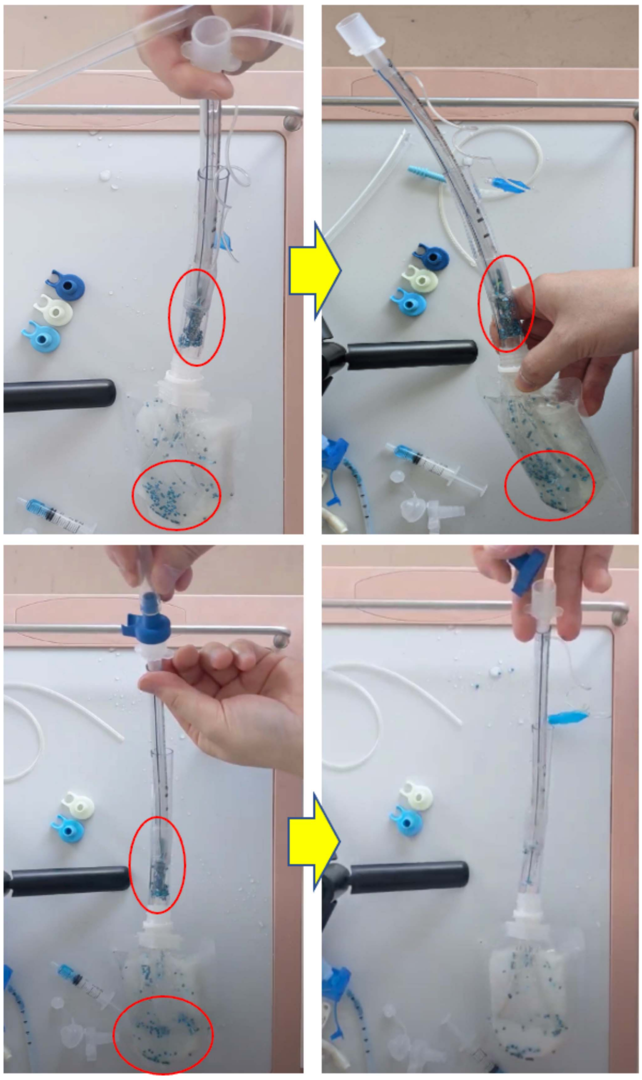

Fig. 4. Upper row: Conventional method, Lower row: Vacuuming method. Foreign matter in the airways are circled.

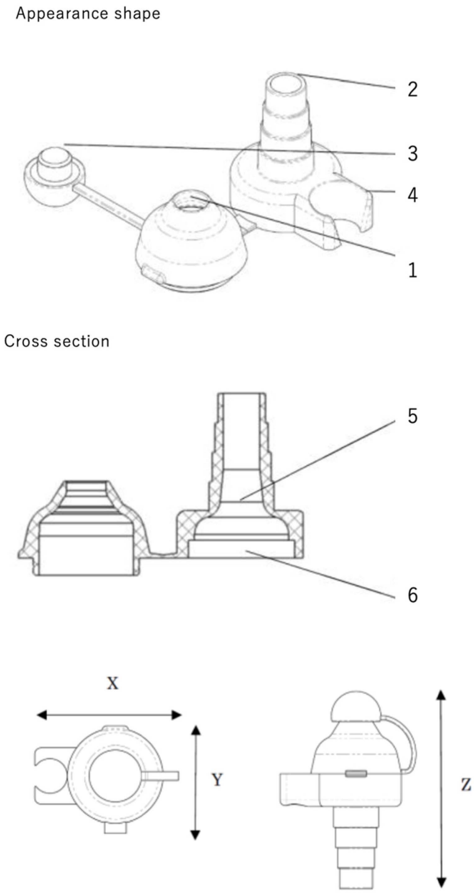

Fig. 5. Design of "SPUTA VACUUMER" (Mass production model) Dimensions: X 33 × Y 24 × Z 48 mm, Weight: 4 g (1) Nasal suction port, (2) Suction tube connection port, (3) Lid, (4) Suction tube binding holder, (5) Suction catheter connection port, (6) Adhesion part with the airway securing device.

foreign matter moved along with the upward movement of the moisture, and more than half of the foreign matter was removed; see Fig. 4.

IV. Discussion

It was demonstrated that the SPUTA VACCUMER device can remove sputum and foreign matter without inserting a suction catheter into the trachea. The method can be assumed to be safe as its manual operation is based on the existing and established MI-E method. The MI-E method has been used by non-medical workers not only in hospitals but also in home care. As no special skills or qualifications are required to operate the device, the SPUTA VACCUMER device has the potential to be used in these settings.

As a non-invasive procedure, the potential for physical injury to the airway is eliminated. In the current MI-E method, discomfort (sore throat / ear pain, runny nose) due to increased pressure when the machine is activated has been observed. The SPUTA VACCUMER has no rapid positive / negative pressure change so such discomforts are less likely.

The procedure time is longer than that for MI-E as less power is used. However, in the absence of set up time, the total operating time is less using the SPUTA VACCUMER. Moreover, the costs associated with the procedure are significantly lower.

Potential patients for the SPUTA VACCUMER include intraoperative and postoperative ICU-managed patients, patients with reduced cough function (neurological / muscular disease patients, patients who have undergone total laryngectomy, premature infants, newborns, etc.), patients who need removal of foreign bodies in the airway. In March 2020, the SPUTA VACCUMER mass production model was developed in Japan with government support to treat pneumonia caused by the spread of the COVID-19 pandemic [5]; see Fig. 5. Subsequently, the SPUTA VACCUMER was approved as a Class I medical device in Japan in July 2021. In terms of future applications, the SPUTA VACCUMER is 3D printable and so may be used for space missions where sufficient medical equipment and personnel with advanced medical skills are not available [6]. In a separate project, the data for 3D printable ventilators has been sent to the International Space Station, where astronauts successfully printed the medical device [7]. This method of producing medical devices on demand is of great benefit for space missions. The SPUTA VACCUMER 3D model can be produced in Space by astronauts in the same manner.

For the SPUTA VACCUMER the time required for vacuuming differs depending on lung capacity, body weight, and lung compliance, and we believe that clinical research is necessary to further enhance the effect of the device. By using a negative pressure manometer for the aspirator or using EIT (electric impedance tomography) for the patient, it is possible to observe the expansion and contraction of the lungs, and it is thought that a correlation in this data can be established.

V. Conclusion

“SPUTA VACUUMER (Mass production model)” was developed with government support and approved as a Class I medical device in Japan in July 2021. In this paper, we presented a sputum suction training model; see Fig. 3. For space missions, the SPUTA VACUUMER is 3D printable and can be operated by those who do not have advanced medical skills.

In summary, “SPUTA VACUUMER” has a range of benefits. It can be installed relatively easily and relatively cheaply, while maintaining the usefulness and safety of conventional MI-E. Therefore, the risk of developing asphyxiation and pneumonia in postoperative ICU patients and neuromuscular disease patients may be reduced.

Furthermore, subsequent reduction in the use of drugs may reduce the incidence of resistant bacteria, shorten hospital stays, and lower medical costs. It will also become an indispensable and powerful tool for astronauts who have to deal with the lack of adequate equipment. Further studies are needed to investigate a broader range of benefits.

Acknowledgment

The author would like to thank Newton Co., Ltd. and Mr. Takayuki Fujita of Coshell Lab. under technical cooperation.

References

[1] T. C. Blakeman, “AARC clinical practice guidelines: Artificial airway suctioning,” *Respir. Care*, vol. 67, no. 2, pp. 258–271, 2022.

[2] S. K. Li, “Investigation of the frequency and force of chest vibration performed by physiotherapists,” *Physiotherapy Can.*, vol. 60, no. 4, pp. 341–348, Nov. 2008.

[3] J. R. Bach, “Airway secretion clearance by mechanical exsufflation for post-poliomyelitis ventilator-assisted individuals,” *Arch Phys. Med. Rehabil.*, vol. 74, no. 2, pp. 170–177, 1993.

[4] N. Ishikita, “Model lung for sputum suction learning,” Accessed: Jun. 8, 2022. [Online]. Available: https://patentimages.storage.googleapis.com/6c/89/37/14ce23274e2e07/JP3238599U.pdf

[5] N. Ishikita, “Suction-target guide pipe and suction-target suction system,” Accessed: Jul. 9, 2020. [Online]. Available: https://patentscope2.wipo.int/search/ja/detail.jsf?docId=JP349194475&_cid=JP1-L99T2N-25112-1

[6] P. D. Hodkinson, “An overview of space medicine,” *Prehosp. Care*, vol. 119, no. 1, pp. 143–153, 2017, doi: 10.1093/bja/aex336.

[7] N. Ishikita, “Examination of usefulness of 3D printed inhalation anesthesia aid device (VapoJet) for future manned space missions,” *Jpn. J. Anesthesiol.*, vol. 68, pp. 133–143, Nov. 2019.