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Construction of a prototype for the development of compact electric medical suction equipment: Investigation focusing on suction pressure, battery, size and weight reduction, and portability

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Abstract

Most suction care patients must be prepared to perform suction in any place, at any time. Further, many suction care patients also require ventilators or oxygen and must equip their wheelchair or portable bed with all necessary equipment when moving from place to place. The total weight of them is very heavy and places a major strain on those assisting with moving the patient. Therefore, the authors wondered whether it would be possible to develop electric medical suction equipment that can be used safely and conveniently while on outings with the same suction pressure as existing suction equipment, but with a reduced size and weight (hereafter referred to as "compact suction equipment"). The authors have created the prototype using parts already on the market toward the development of a compact suction equipment. The prototype was found to have suction pressure and battery functioning equivalent to existing suction equipment while reducing the total weight by -18.3% to -29.3%. Ongoing studies following each step of the medical device development process will be necessary to confirm the safety and practicality and further reduce the size.

Ⅰ. Introduction

Many patients and disabled persons are unable to expel sputum or swallow saliva on their own, for a number of reasons, including congenital or acquired illnesses or disorders, or disabilities resulting from an accident. While there is no accurate data on adults in Japan, a FY2015 survey by the Ministry of Education, Culture, Sports, Science and Technology (MEXT) on medical care in special needs schools found that there were 4,158 needed "oral/nasal suction (up to but not including the pharynx) ".[1] The number of individuals, both children and adults, requiring oral, nasal, respiratory tract, or tracheal suction (hereafter referred to as "suction care patients") is expected to increase every year accompanying advances in medical care and improvements to the home medical care system[2].

Most suction care patients constantly carry the

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supplies necessary for suction, such as electric medical suction equipment and suction tubes, with them during their daily life and outings as they must be prepared to perform suction in any place, at any time. Further, many suction care patients also require ventilators or oxygen and must equip their wheelchair or portable bed with all necessary equipment when moving from place to place. The total weight of them is very heavy and places a major strain on those assisting with moving the patient [3].

Therefore, the authors wondered whether it would be possible to develop electric medical suction equipment that can be used safely and conveniently while on outings with the same suction pressure as existing suction equipment, but with a reduced size and weight (hereafter referred to as "compact suction equipment"). In this study, the authors investigated device materials and components suitable for compact suction equipment using parts already on the market focusing on suction pressure, battery, size and weight reduction, and portability to create a compact suction equipment prototype (hereafter referred to as "the prototype").

Ⅱ. Objective

This study aimed to investigate device materials and components suitable for compact suction equipment focusing on suction pressure, battery, size and weight reduction, and portability to create a prototype using parts existing on the market.

Ⅲ. Ethical considerations

This study was conducted on the basis of a collaborative research contract, after review as a joint study with a private organization by the Akita University Acceptance of External Funding Deliberation Committee (Sciences #858, 2015/10/30). It was also confirmed that there were no conflicts of interest between researchers, that all components used were on the market, and that there was no infringement on intellectual property or the Patent Act. There are no other companies that have a COI relationship to disclose.

Ⅳ. Method

The compact suction equipment to be developed in this study qualifies as a medical device[4]. Kikuchi et al.[5] describe the following five general stages of medical device development. In this study, we considered the exploration stage to be "the stage of exploring techniques and materials and confirming the directionality and concept of the product to be developed. In other words, the step of considering the feasibility of the project"[5] aimed to create a prototype.

1. Study period

November 2015 to March 2016

2. Establishing features and performance necessary for compact suction equipment

We established the following features and performance after considering the features needed in compact suction equipment with reference to existing suction devices.

1) Suction pressure and battery capacity

Although negative pressure for tracheal suction in adults generally should not exceed -20kPa[6], it is essential to be able to quickly apply maximum suction pressure if there is a risk of airway obstruction by vomit or other substances. According to the Japanese Industrial Standards (JIS) JIST7208-1 "Medical Suction Equipment—Part 1: Electric Suction Equipment—Safety Requirements" [7], the battery "must be able to operate for a minimum of 20 minutes and a suction pressure of at least -40kPa during that time." The JIS do not stipulate a maximum suction pressure. Accordingly, the suction pressure was established as -80kPa ±10%, the highest maximum suction pressure of any existing suction equipment.

2) Size and weight reduction and portability

A total weight of 2kg or below, including all accessories, was established to allow the apparatus to be operated with one hand and to be worn over the shoulder. In addition to the above, goals of a design which allows stress-free use even when on outings, adjustable suction pressure, easy to clean/

sterilize, and a price per unit of around 10,000 yen were established.

3. Investigations for the realization of necessary features and performance

1) Suction pressure and battery capacity

(1) Investigation of suction pressure and power consumption for different pumps

Considered small, capable of maintaining suction power, and readily available four pumps, were selected as parts to use in the experiment (Table 1). The lightest and cheapest apparatus on the market in Japan as of 2015, "Shin-Ei Industries Power Smile KS-700" (hereafter referred to as "KS-700"),[8] was selected as existing suction equipment for comparison. The KS-700 pump connection was removed and the device operated with the experimental parts listed above in its place to measure suction pressure, current fluctuation levels, and time to maximum suction pressure with a DC regulated power supply (KENWOOD: PA18-2A). Suction performance was also visually confirmed using artificial sputum (Kyoto Kagaku, Co., Ltd.).

(2) Investigation of the battery

The current value at which the equipment could be operated for 30 minutes on a single full charge was calculated from experiment Ⅳ -3-1). Batteries of different shapes and current values were selected as parts for use in the experiment. Similarly, as in experiment Ⅳ - 3-1), only the battery portion of the KS-700 was replaced with the experimental part to measure maximum suction pressure and time to maximum suction pressure.

2) Size and weight reduction and portability

(1) Selection of exterior design and parts to use in the prototype

Concerning parts to be used in the prototype, parts that were both relatively cheap and readily available for purchase were chosen from among parts already on the market. Then an exterior design that could both store the necessary parts and be transported easily was considered.

(2) Confirmation of prototype operation

Maximum suction pressure and time to maximum suction pressure were measured to confirm the operation of the prototype. Suction performance was also visually confirmed using tap water and artificial sputum. The final comparison between the prototype and existing suction equipment was made using the "Shin-Ei Industries Minic-SII" (hereafter referred to as "Minic-SII") [8], an apparatus with a slightly higher maximum suction pressure than the KS-700.

(3) Investigation of the storage bag

A storage bag for carrying the prototype was selected from among products on the market found using an online search of shoulder bag and waist pouch type bags that would allow suction operations to be performed while the device was being carried. A bag made of a waterproof or easily cleaned material, with a design allowing operations to be carried out as conveniently as possible, capable of being fastened to the body to prevent movement of the suction bottle, allowing storage of small items such as disinfecting wipes or suction tubes, and which would not directly transmit vibrations when the prototype was operating, was considered optimal when making the selection.

Ⅴ. Results

1. Results of investigation of suction pressure and power consumption for different pumps

Of the four pumps selected, TZX512/V12-8015(b) was capable of a maximum suction of -80kPa and reached this maximum suction pressure the fastest in 27 seconds. Multiple trials were completed, and no difference was observed (Table 1). Although suction using artificial sputum found the suction power of the TZX512/V12-8015(b) to be somewhat inferior to the KS-700 pump, it was capable of maintaining unchanging pressure. Thus, the TZX512/V12-8015(b)

Table 1　Maximum suction pressure and power consumption for different pumps

	Model	Max suction pressure	Power consumption (A)	Time to max suction pressure (sec)	
Comparator	KS-700	−80kPa	1.10～1.55	13	
a	D2028B	−70kPa	0.48～0.80	28	
b	TZX512/V12-8015	−80kPa	0.72～1.10	27	※
c	TM22-A6-V6003	−60kPa	0.16～0.40	80	
d	DSA-2F-12	−40kPa	0.14～0.40	42	

※12 sec to −70kPa

pump was used in the prototype.

2. Results of investigation of the battery

Based on the results of V -1, the current value at which the equipment could be operated continuously for 30 minutes on a single full charge when using the TZX512/V12-8015(b) pump was measured and found to be 720 to 1100mA (Table 1). Therefore, a battery capacity of around 1100mAh, capable of supplying 1100mA for one hour, was concluded to be ideal. Thus, a nickel-metal hydride battery (RA-H2/3A10R2WR16) and a nickel-cadmium battery pack (CU-J964), which feature different shapes and current values, were selected (Table 2). Comparison to the KS-700 found that all could reach a suction pressure of -80kPa. As a result of shapes and weight, the nickel-metal hydride battery was used in the prototype.

3. Results of investigation of exterior design and parts to use in the prototype

A total of 25 parts were selected for use in the prototype (Table 3). Investigation of the exterior design of the prototype resulted in a box shape, the equipment was built into an “all-purpose case manufactured by Takachi Electronics Enclosure Co., Ltd.” To allow the battery to be changed out, the equipment was built into two separate boxes, one for the main device and one for the battery (Figure 1, Figure 2). The suction bottle (a collection bottle into which suctioned materials flow) and safety bottle (an empty bottle preventing suctioned materials from entering the device directly) were attached to the exterior for easy replacement (Figure 3).

4. Results of confirmation of prototype operation

Confirming the operation of the prototype found that it reached -80kPa in approximately 15 seconds. Further, successful suction was visually confirmed in experiments with suction of both water and artificial sputum. There were negligible visible differences when comparing the prototype and the Minic-SII.

5. Results of investigation of the storage bag

Two bags with different designs were selected as a result of the investigation. These were the multifunctional waist bag “Belldine Marib select ”

Table 2　Results of investigation of the battery

	Nickel-metal hydride battery	Nickel-cadmium battery pack
Model number	RA-H2/3A10R2WR16	CU-J964
Nominal capacity (mAh)	1600	1000
Nominal voltage (V)	12	12
Weight (g)	226	238
Dimensions (mm)	84×27×33	248×30×15
Max suction pressure	−80kPa	−80kPA
Time to max suction pressure (sec)	23	27
Appearance		

Table 3　List of parts used in the prototype and their placement

No	Part	Model number	Count	Placement
1	SMC vacuum pressure gauge	GZ46-K-01-C	1	Main device structure
2	PISCO tube fitting, female straight 1/8ϕ	PCF4-01	1	Main device structure
3	Compact switch valve, toggle type	MSHRT3	1	Main device structure
4	AS ONE gas wash bottle PC100ml	1-7404-01	1	Safety bottle
5	AS ONE gas wash bottle PC250ml	6-129-01	1	Suction bottle
6	AS ONE gas wash bottle PC500ml	6-129-02	1	Suction bottle
7	CKD silencer one-touch type 455LPM	SLW-H6	1	Main device structure
8	Inline filter －ϕ50	2-9067-02	1	Main device structure
9	PISCO tube fitting union straight	PU8	3	Connection
10	PISCO tube fitting bulkhead union ϕ8	PM8	1	Connection
11	PISCO tube fitting mini type elbow ϕ4	PL4-０１M	1	Main device structure
12	Vibration control rubber	VD2-1510M4	2	Main device structure
13	Hose clamp	HOSBS28N	1	Main device structure
14	Pump fixation jig	(self made)	1	Main device structure
15	Takachi TWS type plastic case with silicon protector	TWS13-7-18	1	Main device external housing
16	Takachi TWS type plastic case with silicon protector	TWS7-5-13	1	Battery external housing
17	Marushin Electric Mfg. Co., Ltd. DC power jack 2A13.5Vϕ5.5Φ1.0	MJ-19	2	Battery structure
18	PFE tubing ϕ4-2.5	SFT0425-20-C-L1	1	Tubing
19	PFE tubing ϕ6-4	SFT0640-20-C-L1	1	Tubing
20	PFE tubing ϕ8-6	SFT0860-20-C-L1	1	Tubing
21	PISCO reducing nipple	PIG8-6	1	Main device structure
22	PISCO tube fitting mini type cross B ϕ6.4	PZB6-4M	1	Main device structure
23	NKK rocker switch (lighted type)	JW－S11RKKM	1	Main device structure
24	Push-on cable	SR5R2-100P	1	Battery structure
25	Battery fixation band	(self made)	2	Battery structure

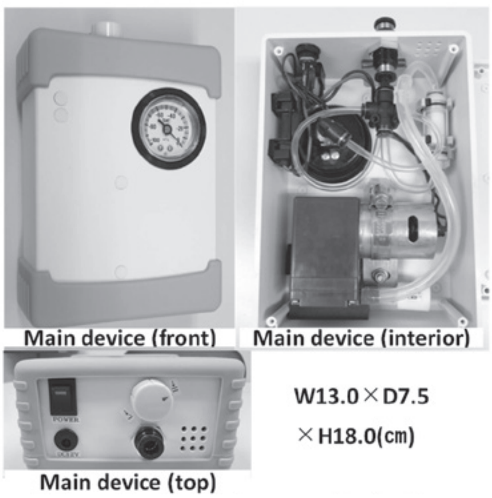

Figure 1　Prototype main device

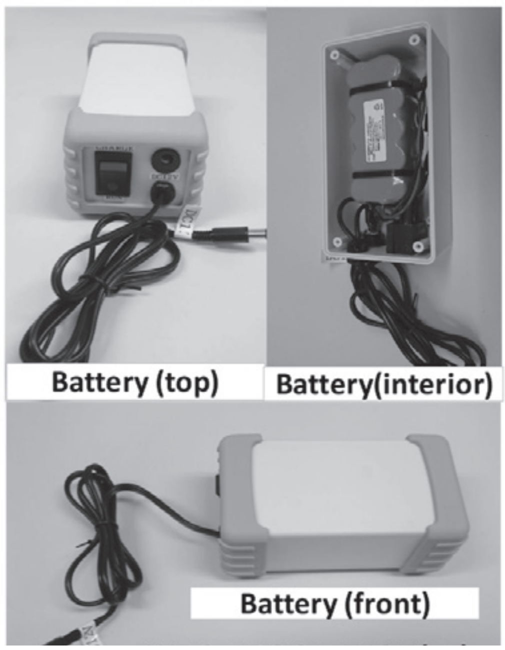

Figure 2　Battery

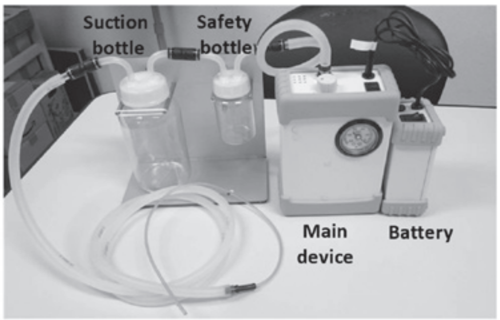

Figure 3　Complete prototype apparatus

Figure 4　Placement of the storage bag

(hereafter referred to as “the waist bag”), most often used for storing fishing tools and camera equipment, and the diaper bag “SKIP HOP Duo Signature Diaper Bags” (hereafter referred to as “the diaper bag”), generally used to store children’s items and often attached to a stroller (Figure 4).The waist bag is capable of holding all pieces of the prototype. This bag stands alone. However, they are too small and there was minimal space to store anything aside from the prototype. The diaper bag can be used to attach it to a wheelchair. The diaper bag is larger than the waist bag. However, it cannot stand on its own. Vibrations from operation of the prototype were not noticeable with both.

The device itself weighed 0.94kg and the battery 0.42kg. With the suction bottle and suction tube, the waist bag weighed a total of 2.45kg and the diaper bag a total of 2.12kg.

VI. Discussion

1. Suction pressure and battery capacity

Investigations found that the prototype could maintain suction pressure nearly identical to that of existing suction equipment. Further, by constructing the main device and battery in separate cases, the battery can be removed from the device for charging and the device itself can be used for suction while connected to a wall socket if there is access to a residential power source. Having this variety of power sources will enable extended time on outings and widens the range of use in disaster situations as well.

2. Size and weight reduction and portability

Choosing a box shape for exterior design of the main device and battery made for a simple and easy-to-operate product. The total weight of the prototype was -18.3% to -29.3% lighter than the KS-700 equipment (approximately 2.3kg) and its specialized carrying bag (670g) which have a combined total weight of approximately 3.0kg. This study considered two storage bags of differing designs. While both allowed operation of the prototype and had no issues with vibration, advantages and disadvantages were found for each. Price also remains a challenge. Even excluding manufacturing costs, as the prototype was created from parts already on the market, a single device at this stage had a total unit price of just over 20,000 yen. In future investigations of compact suction equipment design and storage bags, it is essential to investigate from a multifaceted perspective with input from users themselves, in order to create options that suit their purposes and needs.

3. Future issues

As discussed above, the creation of this prototype corresponds to the “exploration stage” of medical device development. This stage does “not seek to verify the reliability of data,” but to consider the feasibility of a project[5]. Therefore, this study did not conduct experiments on safety or durability. Surveys on accidents involving portable medical electric suction equipment note that many are due to operation failure and risk endangering the life of the user[9)10)]. To ensure the quality of medical devices, Japan has several laws, such as the Pharmaceutical Affairs Act, in addition to the JIS stipulating requirements that products must meet before they can be manufactured and sold[5]. This means that developing new products takes considerable time. This study is only the first step of the development process. Hereafter, it will be essential to accumulate further data by considering ways to increase the battery capacity, reexamining the parts used, and repeating experiments on suction pressure and consistency in order to further minimize the size and weight, reduce the price, and ensure practicality and safety. It will also be necessary to carry out continuing investigations working toward the completion and commercialization of the device while considering each stage of the development process including inspection based on JIS, clinical trial as a medical device, production of parts for commercialization, and consideration of sales channels.

Ⅶ. Conclusion

The authors have created the prototype using parts already on the market toward the development of a compact suction equipment. The prototype was found to have suction pressure and battery functioning equivalent to existing suction equipment while reducing the total weight by -18.3% to -29.3%. Ongoing studies following each step of the medical device development process will be necessary to confirm the safety and practicality and further reduce the size.

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医療用電動小型吸引器の開発に向けた試作品の作成
－吸引圧，バッテリー，小型軽量化，携帯しやすさを中心とした検討－

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要　旨

吸引を要する者の多くは，いつでもどこでも吸引ができるようにする必要がある．またその中には，人工呼吸器や酸素を必要としている者も多く，移動の際は多くの必要物品を車椅子や移動用ベッドなどに装備する必要があり，介助者の負担も大きい．そこで，外出先でも安全に手軽に使用でき，既存吸引器と同等の吸引圧で，より小型軽量化した医療用電動吸引器（以下，小型吸引器）が開発できないかと考えた．本研究では，小型吸引器の開発に向け，吸引圧，バッテリー，小型軽量化，携帯しやすさを中心に，市販品の既成部品を用い機器の材料や部品の検討を行い，試作品を作成した．その結果，吸引圧，バッテリー共に既存吸引器と同等の機能を持たせつつ，本体，バッテリー，バッグを含む総重量を－18.3% ～－29.3% 軽量化できた．今後，医療機器開発における各開発ステージに沿って，安全性，実用性，更なる小型化に向け継続的な検討が必要である．