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Clinical Feasibility Study of ProTrach DualCare a New Speaking Valve with Heat and Moisture Exchanger for Tracheotomized Patients

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Objective: The aim of this study was to evaluate the clinical feasibility of the ProTrach DualCare (Atos Medical, Hörby, Sweden), a device combining a hands-free speaking valve and a Heat and Moisture Exchanger (HME) for tracheotomized patients.

Study Design: A non-randomized, prospective single center feasibility study.

Methods: Sixteen adult tracheotomized patients were included. Participants were asked to test the DualCare for two weeks while continuing their normal activities. After these two weeks, participants could choose whether or not to take part in the long-term evaluation. The EuroQOL-5D, Borg scale and questionnaires on speaking, pulmonary function and patient preference were used. During the long-term evaluation, a minor redesign was implemented and all participants were asked to test the new device again for one week, with a potential long-term evaluation. Eleven decided to participate.

Results: The device was well-tolerated. Speaking noise was reduced ($p = 0.020$) and speech was considered to sound more natural compared to previously used devices according to the users ($p = 0.020$). Overall 11 participants preferred the DualCare to their standard device. No serious adverse events were reported.

Conclusion: Overall, 11 of 16 participants preferred the DualCare to their standard speaking valve or HME. Users of the DualCare were able to use hands free speech with the benefits of an HME and the device was considered clinically feasible and has the potential to improve quality of life of tracheotomized patients.

Key Words: ProTrach DualCare, Speaking valve, HME, hands free, tracheotomized.

Level of Evidence: 2b

INTRODUCTION

The upper airways humidify, warm, and filter inhaled air. When a tracheostoma is created, upper airways are bypassed. A Heat and Moisture Exchanger (HME) substitutes the loss of the upper airway function by conditioning incoming air with the moist and heat of expiratory air.¹⁻³ The use of an HME is known to reduce mucus production, coughing, shortness of breath, forced expectoration, stoma cleaning, and chest infections.⁴⁻⁷

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ATOS Medical was sponsor of this study. The Department of Otorhinolaryngology—Head & Neck Surgery, University Medical Center Groningen received a research grant for the first author. The University Medical Center Groningen performed data management and the statistical analysis of the results independently.

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To speak, a tracheotomized patient needs to redirect the air through the vocal cords by occluding the tracheostomy tube. This can be done by occluding the opening of the tube with a finger or by pressing on an HME. A hands-free speaking valve can also be used to enable hands-free speech.

Being able to speak hands free is important as it facilitates non-verbal communication and the use of both hands simultaneously with speaking. Also, patients do not emphasize their handicap by pointing at the stoma as is done when using a finger to occlude the stoma. A hands-free speaking valve can also reduce secretions and improve olfaction.⁸ Some studies reported reduced aspiration as well.⁹⁻¹² Others didn't find reduced aspiration.^{13,14}

To compensate for the loss of upper airway function and the loss of normal voice in tracheotomized patients, the ProTrach DualCare was developed, a device combining a hands-free speaking valve and an HME. Before the development of the DualCare, patients had to choose between using an HME or a hands-free speaking valve. There are other speaking valves with an incorporated HME.¹⁵ However in these devices there is no bi-directional flow and thus the HME is not conditioned.¹⁵ The DualCare combines a speaking valve and a fully functional HME in one device using two modes: the speaking mode and the HME mode. The airflow in both modes is shown in Figure 1. In speaking mode, the membrane functions as a bias-closed speaking valve. This means the membrane is closed and opens only

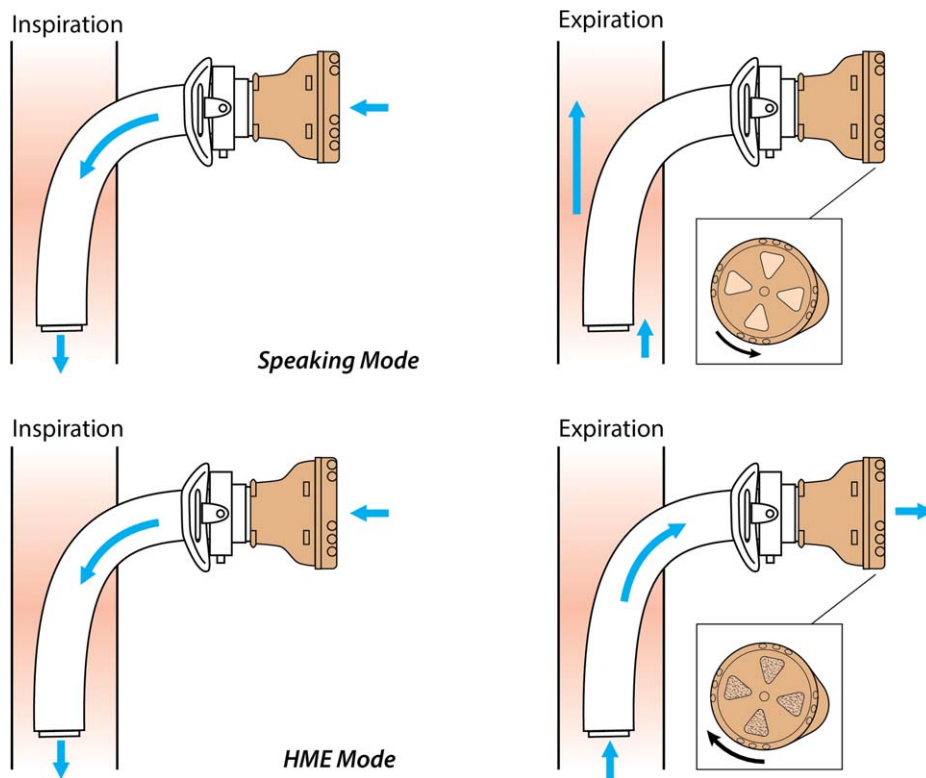


Fig. 1. DualCare™ in speaking mode and HME mode (courtesy Atos Medical).

during inhalation. The HME is not conditioned in this mode, comparable with the other devices. When the HME-mode is activated by turning the lid of the DualCare (Figure 3), the membrane is slid away from the openings. Air can flow in and out through the cannula, conditioning the HME with the exhaled air.

Van den Boer et al compared several speaking valves with integrated HME in an ex vivo study. They concluded no speaking valve offers humidification function in speaking mode. The ProTrach DualCare is the only speaking valve offering an HME mode, enabling a significant increase in humidification.¹⁵

Combining both features in one device is expected to improve compliance with an HME (in hands-free speaking valve users) and thereby enhancing quality of life by improving pulmonary rehabilitation, and patient satisfaction by using a hands-free speaking valve (in HME users). This study was conducted to determine the clinical feasibility of the ProTrach DualCare, leading to a redesign in the process.

MATERIALS AND METHODS

Participants

This study was performed at the University Medical Center Groningen. Inclusion criteria were: at least 18 years old, tracheotomized, spontaneously breathing, and able to use a speaking valve. Exclusion criteria were: inability to operate and remove the device, mechanical ventilation, severe aspiration, tidal volume of less than 100 ml, laryngectomized patients, severe upper airway obstruction, or thick and copious mucus production. The inclusion process is shown in Figure 2. The study took place from September 2013 to April 2014.

Investigational Product

The ProTrach DualCare (ATOS Medical, Hörby, Sweden) consists of two parts. A re-usable speaking valve and a disposable HME (Fig. 3).

The DualCare Speaking Valve must be assembled to the HME Cassette. The HME is available for 22 mm and 15 mm diameter connectors. The humidification properties and air pressure drops are the same for both HME sizes.

Ethical Considerations

The study was approved by the Medical Ethical Committee of the University Medical Center Groningen. Signed informed consent was obtained from all participants. The study was monitored for patient safety and data validation.

Methods

The ProTrach DualCare was compared to the pre-study device(s) (speaking valves and/or HMEs) used by the participants. Structured, study-specific questionnaires were completed by the participants at the start of the study and after two weeks of using the new device with the 15 and/or 22 mm HME, and after the optional long-term evaluation of three months. The three-month period was chosen as earlier reports have shown significant changes in airway function are seen from the use of an HME after this period of time.¹⁶

During the long-term evaluation, it was discovered that some patients had issues with stickiness of the valve ($n = 4$). This was successfully addressed by a slight redesign.

At the time of the redesign, 9 out of 16 patients were still included in the long-term part of the study. All 16 participants were asked if they were interested in trying the redesigned valve. The nine patients still in the study and two patients that had discontinued after the short-term evaluation agreed

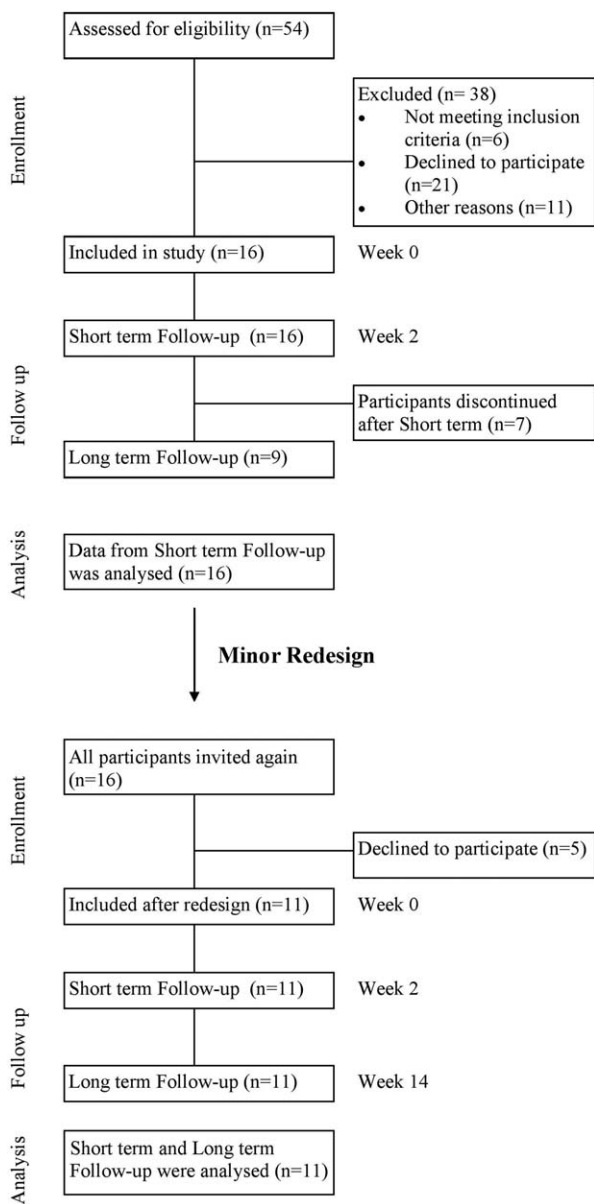


Fig. 2. Inclusion process.

to do so. With these 11 patients, the study was started again, with a one week short-term follow-up, and an optional long-term evaluation of three months. After the first week, data that could potentially have been influenced by the new design were collected again and replaced the earlier collected data. This was data on breathing resistance, HME function, swallowing, smell, and patient satisfaction. Other data that were collected prior to redesign are still considered valid.

Only participants testing the final version completed the long-term questionnaire at three months. Questionnaires addressed speaking, swallowing, coughing, mucus production, breathing, sleeping, olfaction, appearance, satisfaction, practical aspects, and handling of the device. Answers were reported on a 3- or 5-point Likert scale or were quantitative. To determine overall satisfaction a scale from 1 to 10 was used.

The EuroQOL-5D was used to assess influence on general Quality of Life.¹⁷ This instrument is a multilingual validated instrument in which scores on five health-care dimensions

(mobility, self-care, daily activities, pain/discomfort and anxiety/depression) are recorded.¹⁷ From this data, a balanced health care index is derived in accordance with the EuroQOL guidelines.¹⁸

Borg scales were used to investigate impact of the device on breathing. The Borg scale is an ordinal scale ranging from 0 to 10 on which participants indicate their currently perceived breathing exertion.¹⁹

Analysis

Frequencies were explored using the Kolmogorov-Smirnov test. Normal distributed frequencies are shown as the mean \pm standard deviation and were analyzed using the paired T-test. Non-parametric values are presented as the median (inter quartile range) and were analyzed using the Wilcoxon-Signed rank test. Questions using a Likert Scale rendered ordinal data. These data were analyzed using the Wilcoxon Signed Rank test. The Borg scale outcomes are categorical and are shown as median (inter quartile range). Comparative questions were completed after using the DualCare. Because these are one sample ordinal data, the One Sample Wilcoxon Signed Rank test was used to analyze these data. The median compared to was 2 (neutral).

RESULTS

Sixteen tracheotomized participants were entered into the study, 11 males and 5 females. Before the study, 11 participants used a speaking valve during the day. Six participants used an HME (sometimes changing between an HME and speaking valve). One participant used no device at all. During the night, 13 participants used an HME and 3 participants no device (Table I). The



Fig. 3. From top to bottom: Assembled DualCare™, Twisting function of DualCare™, 22mm and 15mm HME.

TABLE I.
Device Use at Baseline

Participant	Age in years	Time between tracheotomy and study	Pre-study HME day	Pre-study Speaking valve day	Pre-study device night	Tested re-design
1	58	2 years	FreeVent Combi*	FreeVent Combi	TrachPhone	Yes
2	64	5 years	FreeVent Combi*	FreeVent Combi	Provox XtraFlow	No
3	66	5 years	Provox Xtraflow	None	None	Yes
4	74	2 years	FreeVent Combi*	FreeVent Combi	Xtramoist	No
5	34	5 years	Provox Xtraflow	FreeVent Combi	Provox Xtraflow	Yes
6	63	7 years	TrachPhone	None	TrachPhone	Yes
7	43	1 year	Provox Xtraflow	None	Provox Xtraflow	Yes
8	50	1,5 years	FreeVent Combi*	FreeVent Combi	Provox Xtraflow	Yes
9	44	11 years	None	None	None	Yes
10	53	11 years	Provox Xtraflow	None	Provox Xtraflow	No
11	66	10 years	FreeVent Combi*	FreeVent Combi	Provox Xtraflow	Yes
12	62	9 years	None	Freevent	None	Yes
13	83	1,5 years	FreeVent Combi*	FreeVent Combi	Provox Xtraflow	No
14	51	1 year	Spiro*	Spiro	Provox Xtraflow	Yes
15	73	5 years	Provox Xtraflow	Freevent Combi	Provox Xtraflow	Yes
16	52	2 years	FreeVent Combi*	FreeVent Combi	Provox Xtraflow	No

*HME in these devices is not functional as no inspired air flows through the device, the HME is therefore not conditioned. HME = Heat and Moisture Exchanger.

age of participants ranged from 34 to 83 with a mean of 58.5 years old. The indications for tracheotomy were tracheal stenosis (3), laryngeal paralysis (8), and laryngeal stenosis by respiratory papillomatosis, edema, trauma or Myasthenia Gravis (5).

Sixteen participants completed the short-term part of the study. Nine participants decided to continue in the long-term follow-up. At this stage, a redesign was implemented after which 11 out of the original 16 participants decided to continue in the study. Only the questions relevant after redesign were completed again and replaced the earlier answers. Therefore, some answers will have an N of 16 while others have an N of 11. Regarding the device itself, results show that 13 of the 16 participants (81%) liked the option to choose between HME and Speaking mode and this functionality was used by all participants. At the end of the study, participants switched between modes with a median of 30 times per day (range 8–40). The median number of hours the product was used in speaking mode was 7.5 (range 4.0–12.0) and in HME mode median 6.0 (range 3.0–7.5). When the DualCare was not used, mainly during the night, most participants used their regular HME.

When comparing the DualCare to the device they were using before the study, participants reported significantly less stoma pain ($p = 0.046$), significantly better voice and speech sound ($p = 0.020$), significantly less noise during speech ($p = 0.020$), significantly less noise when breathing in HME and speaking mode ($p = 0.014$ and $p = 0.025$, respectively) and a significantly more natural sounding voice ($p = 0.034$).

For breathing, different questions were completed. Breathing exertion was scored using the Borg scale. Results show that breathing in HME mode is significantly

easier than breathing through the device used before the study ($p = 0.006$). Not surprisingly, breathing through the HME mode is also significantly easier than breathing through speaking mode ($p = 0.017$). Results were confirmed when participants were asked to compare breathing resistance in HME mode and speaking mode with breathing resistance of their pre-study device using the Borg scale. (Table II)

When comparing to the device they were using before the study, participants reported lower breathing resistance with the DualCare in HME mode ($p = 0.034$, $n = 15$) and higher breathing resistance in Speaking mode ($p = 0.020$, $n = 15$).

Participants were also asked if they experienced shortness of breath when climbing stairs, when walking on level ground and when resting. Significantly less shortness of breath was reported while climbing stairs with the DualCare compared to the pre-study device ($p = 0.011$, $n = 11$).

When participants were asked about breathing, coughing and mucus, two significant results were found:

TABLE II.
Results Borg Scale

	Subgroup	Borg scale
Baseline ($n = 11$)*	Total	2.0 (0.0–2.5)
	HME users ($n = 5$)	2.00 (0.75–2.75)
	Speaking valve users ($n = 5$)	0.00 (0.0–2.0)
Final version DualCare ($n = 11$)	In HME mode	0.5 (0.0–1.0)
	In speaking mode	1.0 (0.5–3.0)

*1 patient did not use any device at baseline.
HME = Heat and Moisture Exchanger.

TABLE III.
EuroQOL 5D Mean Index Scores and Mean VAS Scores

	Pre-Study Device (N = 11)	Final DualCare 3-Month Follow-Up (N = 11)
Mean Index scores (SD)	0.72 (0.26)	0.76 (0.21)
Mean VAS (SD)	71 (15)	68 (20)

SD = standard deviation; VAS = visual analog scale.

less discomfort breathing dry air ($n = 16$, $p = 0.031$) and less dry coughs during the night when comparing the DualCare to the pre-study device ($n = 16$, $p = 0.039$).

The EuroQol-5D was completed at the start of the study using the pre-study device and the DualCare. Index scores and visual analog scale (VAS) score for the pre-study device and the DualCare are displayed in Table III. No significant differences were found.

Participants were asked to describe their experiences in free text. The main advantages that were reported for the DualCare were: voice quality, “more air” or easier breathing, less noise, and ability to combine two devices in one. The main disadvantages reported for the DualCare were: leakage around the cannula when in speaking mode (compared to pre-study HME); sometimes the device loosening from cannula while coughing; not being able to speak immediately when in HME mode, and the breathing direction being straight forward (an HME has side openings for breathing).

All 11 participants testing the final (= actual) device preferred the DualCare to their pre-study device. This is 69% of the original inclusion.

DISCUSSION

After redesign, the ProTrach DualCare proved to be clinically feasible. Overall 69% preferred the final (= actual) design of the DualCare to their pre-study device. This is 100% of the participants testing the redesigned device. Most participants liked the possibility to switch between the speaking and HME mode and used this modality consistently. Switching between modes will increase the hours of HME use per day, which can positively influence pulmonary rehabilitation. The fact that patients had less problems breathing in dry air and had less dry coughs per night confirm this positive effect. In this study, no changes in quality of life and no differences in mucus production, coughing, shortness of breath, or forced expectorations were found. The use of an HME is expected to reduce mucus production, coughing, shortness of breath, forced expectoration, and stoma cleaning.^{4,5,16,20} This is associated with improvements in quality of life.^{4,6,20} The lack of HME effects found in this study may thus be the reason no changes in quality of life were found. The lack of HME effects found may be explained by HME use by most participants before the study started, creating a smaller window of possible improvement.

Compared to the pre-study device the DualCare had a comparable or lower breathing resistance. Prigent et al. compared several speaking valves in 10 patients.

This study showed mean Borg scale ratings from 1.6 ± 2.2 to 4.6 ± 2.6 .²¹ The HME mode of the DualCare was rated 0.5 “very, very slight,” the speaking mode was rated 1.0 “very slight.” Considering this, the DualCare is on the lower end of breathing resistance of hands-free speaking valves for tracheotomized patients. In HME mode, the perceived breathing resistance drops to even lower values. This is also shown in the questions on shortness of breath during exercise, where participants indicated a lower breathing resistance in HME mode.

No differences were found in olfaction and swallowing when using the DualCare compared to the pre-study device. Studies have shown improvement of olfaction and reduced aspiration by increased subglottic pressure when tracheotomized patients used a speaking valve.^{8,10,12,21} Others could not confirm reduced aspiration.^{13,14} Some participants in this study already used a speaking valve prior to the study, which could reduce the found effect. Participants may have also used the DualCare in HME mode when eating or drinking, lapsing the benefits of using a bias-closed speaking valve.

With the DualCare, participants indicated significantly better voice and speech sound, less noise during speech and a more natural voice. Also, noise generated when breathing was less. As only participants who preferred the DualCare tested the final version of the device, these outcomes may be an important factor in preferring the DualCare.

Compared to the pre-study device the satisfaction with the DualCare, measured with a VAS score, was significantly better than the pre-study device. As only participants that chose to continue tested the final version of the DualCare, this outcome may be biased. As stated above, no changes in quality of life were found in this study.

As this is a feasibility study, it had limitations. A small group of participants was included in the study, which may lead to bias and underestimation of effects. All the questions asked were analyzed using statistical tests and none of the outcomes were corrected. As 9 of the 11 participant that continued to test the redesign in long-term follow-up preferred the DualCare over their original device and the 5 participants preferring their original device over the DualCare, didn't test the final design of the device, outcome measures based on the redesign of the DualCare may be biased. Finally, all questions were based on participant experience therefore subjective to bias.

This study indicates that the DualCare can decrease breathing resistance, improve voice and speech sound, and improve HME compliance in tracheotomized patients. The switching function of the DualCare is used consistently. This will increase the hours of HME use per day, which can positively influence pulmonary rehabilitation. The fact that patients had less problems breathing in dry air and had less dry coughs per night confirm this positive effect. Patients can benefit from an HME while being able to employ hands-free speech with the same device. Overall 69% preferred the final (= actual) design of the DualCare to their pre-study device. This is 100% of the participants testing the redesigned

device. After redesign, the ProTrach DualCare proved to be clinically feasible.

CONCLUSION

The DualCare is well-tolerated, overall 69% of the participants preferred the DualCare over their pre-study speaking valve or HME. All participants testing the final design of the device preferred the DualCare. No serious adverse events were reported in this study and no device deficiencies were registered after redesign. This study shows the DualCare is clinically feasible. To determine a significant difference in the patient preference a prospective study powered for that purpose is needed.

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