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Improving Hands-Free Speech Rehabilitation in Laryngectomized Patients with a Moldable Adhesive

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Objective: This study aims to assess the product performance of a new moldable peristomal adhesive with corresponding heating pad designed to facilitate and improve automatic speaking valve (ASV) fixation for hands-free speech in laryngectomized patients.

Methods: Twenty laryngectomized patients, all regular adhesive users with prior ASV experience, were included. Study-specific questionnaires were used for data collection at baseline and after two weeks of moldable adhesive use. The primary outcome parameters were adhesive lifetime during hands-free speech, use and duration of hands-free speech, and patient preference. Additional outcome parameters were satisfaction, comfort, fit, and usability.

Results: The moldable adhesive enabled ASV fixation adequate for hands-free speech in the majority of participants. Overall, the moldable adhesive significantly increased adhesive lifetime and duration of hands-free speech compared to participants' baseline adhesives ($p < 0.05$), regardless of stoma depth, skin irritation, or regular use of hands-free speech at baseline.

The participants who preferred the moldable adhesive (55% of participants) experienced a significant increase in the adhesive lifetime (median of 24 h, range 8–144 h) and improved comfort, fit, and ease of speech.

Conclusion: The moldable adhesive's lifetime and functional aspects, including the ease of use and custom fit, are encouraging outcomes and enable more laryngectomized patients to use hands-free speech more regularly.

Key Words: automatic speaking valve, hands-free speech, peristomal adhesive, speech rehabilitation, total laryngectomy.

Level of Evidence: 4

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INTRODUCTION

After total laryngectomy (TL), a surgical procedure where the larynx and vocal cords are removed, the natural voice is lost and the patient breathes through a permanent tracheostoma at the base of the neck. These physical changes can lead to daily functional problems such as frequent coughing, excessive mucus production, and difficulties in sleeping, olfaction, swallowing, and communication, impacting the patient's quality of life (QoL).[1–5]

Especially the altered voicing and related speech rehabilitation problems have a negative effect on the patient's self-image, social participation, and independence.[5–9] Laryngectomized patients often remain dependent on others to manage their day-to-day communication disabilities.[6] Patients are also dependent on the knowledge of their healthcare professionals and their insurance system on what speech rehabilitation options are feasible for them, affecting their speech outcomes and QoL.[6,10–12] Among these options, voice prosthesis rehabilitation represents the gold standard.[10,13,14]

The ultimate goal in post-laryngectomy voice prosthesis speech rehabilitation is achieving regular hands-free speech with an automatic speaking valve (ASV). The ASV closes automatically during tracheoesophageal speech and thus eliminates the need to occlude the tracheostoma with a finger or hand. The use of an ASV, therefore, frees up the patient's hands, enabling immediate verbal reaction and reducing the emphasis on the

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patient's disability, because the patient does not point with his finger to his stoma.[15–17] Despite the clear benefits, regular ASV use is currently achieved by only 20% of laryngectomized patients, mainly due to challenges in achieving a durable and airtight ASV fixation.[15–20] Most laryngectomized patients use a peristomal adhesive to secure the ASV in their tracheostoma opening.[21,22] The high phonation pressures that are exerted on the adhesive during hands-free speech, as well as skin irritation, mucus formation, and perspiration, cause the adhesives to detach prematurely.[16,18,20–25] This is intensified in case of a mismatch between the adhesives and the (individual's) peristomal anatomy.[21,23,25] Alternative fixation devices, such as intratracheal cannulas or buttons, are less commonly used.[17,23,26]

When the fixation method can be adapted or customized to the peristomal anatomy, this could potentially improve ASV fixation and use.[16,21–23,25,27,28] A wide range of peristomal adhesives are currently on the market to cater to the various stoma shapes and needs of laryngectomized patients.[27] However, achieving a durable airtight ASV fixation is still challenging.

Dirven et al. (2013) presented an improvement in an adhesive lifetime when using an additional custom-molded external neck brace that applies external backpressure to the neck during hands-free speech.[28] Another possible, but not widely used, fixation technique is the Provox® Freehands Support™ system (Atos Medical AB, Malmö, Sweden), in which the adhesive is supported around the stoma using a sternal device. In some patients, the use of an intratracheal button or cannula in combination with an adhesive or the Provox® LaryClip™ (Atos Medical AB, Malmö, Sweden) enables airtight fixation for hands-free speech.[17,26]

To facilitate and improve ASV fixation without using additional fixation devices, a custom moldable peristomal adhesive was developed. When heated, this adhesive can be modeled by the patients to their stoma shape. When the adhesive has cooled down, it retains its shape, providing a personalized fit and stability during hands-free speech.

This study evaluates the product performance of the moldable peristomal adhesive during hands-free speech and patient preference after two weeks of use. This study aims to assess if the moldable adhesive can improve the adhesive lifetime, use, and duration of hands-free speech and give clues for which patient group the moldable adhesive is a valuable addition to the wide range of peristomal adhesives.

MATERIALS AND METHODS

Patients

A total of twenty laryngectomized patients were included: ten patients were included at The Netherlands Cancer Institute (Amsterdam, The Netherlands), and ten patients at the Gemelli IRCCS University Hospital (Rome, Italy). The study was approved by the Ethical Committee of both centers and informed consent was obtained from all patients. Patient characteristics can be found in Table I. There were no statistically significant variations between the patient characteristics from the two centers. The median age was 67 years (range 49–80 years), and the median time because TL was 41.5 months (range 7–271 months). All included patients were rehabilitated with a voice prosthesis, used an adhesive and a heat and moisture exchanger (HME) on a daily basis, and had prior experience with ASV use. Ten of the patients regularly used an ASV (>4 days a week): eight of these patients used the ASV every day for an average of 9.6 h a day. The ten other patients preferred using manual stoma occlusion only, as they experienced problems with the fixation or achieving adequate phonation or voice quality while using an ASV in combination with an adhesive.

TABLE I.
Patient Characteristics (n = 20 Laryngectomized Patients).

Gender [*n*]	*Male*	19
	Female	1
Age [years]	*Median*	67
	Range	49–80
Post TL [months]	*Median*	41.5
	Range	7–271
Neck dissection [*n*]	*No*	4
	Unilateral	3
	Bilateral	13
(Chemo) radiotherapy [*n*]	*Pre-operative RT*	8
	Post-operative RT	8
	Pre-operative CRT	1
	Post-operative CRT	3
Stoma shape and depth [*n*]	*Flat*	7
	Flat and irregular	6
	Deep	5
	Very deep and irregular	2
Type of speech rehabilitation [*n*]	*HME (manual occlusion)*	20
	+ regular use of hands-free speech (ASV use >4 days/week)	10
Baseline adhesive, used during hands-free speech [*n*]	*Provox StabiliBase*	8
	Provox StabiliBase Optiderm	1
	Provox Life Stability	9
	Provox Life Standard	2

Abbreviations: ASV, automatic speaking valve; CRT, chemo radiotherapy; HME, Heat and Moisture Exchanger; RT, radiotherapy; TL, total laryngectomy.

Moldable Peristomal Adhesive and Heating Pad

The moldable peristomal adhesive (Atos Medical AB, Malmö, Sweden) consists of a 1 cm wide thermoplastic ring around the HME/ASV adapter, covered with a protruding acrylic adhesive material (Fig. 1). When the moldable adhesive is heated to 60°C inside the heating pad for five minutes, the thermoplastic ring becomes malleable and facilitates modeling of the adhesive to the shape of the neck and tracheostoma. As the adhesive cools down, it loses its malleability and retains its molded shape.

Study Design

Participants were asked to use the moldable adhesive for two weeks with their regular adhesive application and removal routine. During inclusion, the participants received instruction on how to use the moldable adhesive and heating pad and were provided with all necessary study products.

Study-specific structured questionnaires (see Supplementary Materials) were completed by the participants at baseline and after two weeks' use to assess their preference and the product performance of the moldable adhesive, compared to the participants' baseline adhesive.

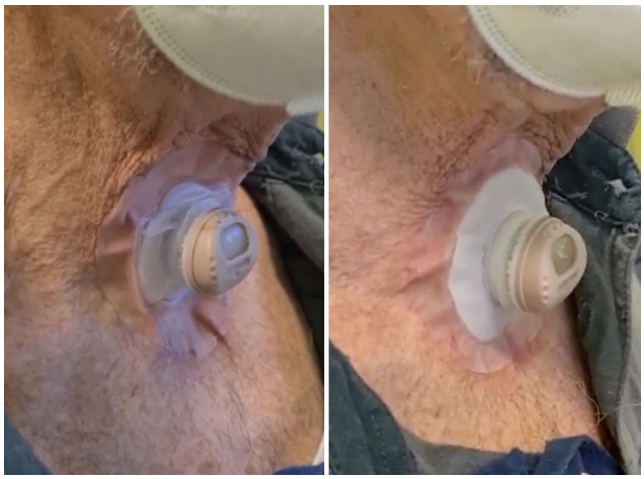

Fig. 1. Lateral view of a baseline adhesive (Provox StabiliBase, left image) and moldable adhesive (right image) during phonation with a hands-free automatic speaking valve (ASV).

Product performance was defined as:

- Adhesive lifetime during hands-free speech use [hours]
- Use of hands-free speech [days/week]
- Duration of hands-free speech [hours/day]

Questions regarding satisfaction, comfort, fit, and usability (scored on a 5-point Likert scale), stoma depth, and skin irritation, assessed by the participants themselves, were included, as these parameters were expected to influence product performance and patient preference.[21,25,27]

In addition, during the instruction, the main researchers (ML, YL) observed the participants' handling of the heating pad and the application of the moldable adhesive. After the first and second weeks, participants were contacted by telephone to detect any problems with the study products or changes in adhesive routine during the study period.

Statistical Analysis

Statistical analyses were performed using IBM SPSS Statistics for Windows, version 27.0 (IBM Corp., Armonk, N.Y., USA). The analysis included descriptive measurements, such as medians and crosstabs.

Variables were tested with a Kolmogorov–Smirnov test to determine whether the data were normally distributed. Based on this outcome, non-parametric tests were chosen to analyze the data. A Mann–Whitney U test and Kruskal-Wallis test were used to assess the association between the two preference groups (preference for either the baseline adhesive or moldable adhesive) and product performance, stoma depth, regular use of hands-free speech and skin irritation, and between product performance and the experienced comfort, fit, and usability. A Wilcoxon signed ranks test was used to compare differences in the product performance and satisfaction between the participants' baseline adhesive and moldable adhesive.

A Fisher's exact test was used to assess the association between preference groups (preference for either baseline adhesive or moldable adhesive) and stoma depth, regular use of hands-free speech, and skin irritation.

Spearman's rank correlation coefficient was used to investigate the correlation between the duration of hands-free speech on adhesive lifetime.

A two-tailed p-value <0.05 was considered statistically significant for all statistical analyses.

RESULTS

Eighteen participants completed the entire study. During the study period, one participant discontinued the study after one week. This participant, having used the moldable adhesive every day, had comparative adhesive lifetime outcomes with the moldable adhesive as with the baseline adhesive but stopped prematurely because of the necessity of using the heating pad. Because this participant had completed all study assessments, according to the intention to treat principle, the outcomes of this participant were included in all analyses. One participant only completed the post-study questionnaire regarding product performance, but not on satisfaction, comfort, fit, and usability of the moldable adhesive. Because these participants had completed either the full study period or all study assessments, according to the intention to treat principle, the collected outcomes of these participants were included in the analyses.

Patient Preference and Satisfaction

Of the 20 participants, 11 participants (55%) preferred the moldable adhesive, eight participants (40%) preferred their baseline adhesive, and one participant (5%) had no preference between adhesives. No association was found between patient preference and stoma depth, skin irritation, or regular use of hands-free speech at baseline. There is an association between patient preference and product performance (see paragraph 'Product performance').

The 19 participants rated their satisfaction both at baseline and at the end of the study on a 5-point Likert scale (with 1 meaning 'not at all', 2 'a bit', 3 'neutral', 4 'quite' and 5 'very much') gave the baseline adhesive an average satisfaction score of 2.7 and the moldable adhesive an average score of 3.5 ($p = 0.053$).

The 10 participants who preferred the moldable adhesive and rated both satisfaction scores gave the moldable adhesive an average satisfaction score of 4.6, which was a significant improvement ($p = 0.011$) compared to their average satisfaction score of 2.7 for their baseline adhesive.

Product Performance

All participants obtained an ASV fixation with the moldable adhesive that was adequate to enable hands-free speech. Regular ASV use (>4 days/week) increased from 50% of the participants at baseline to 85% during the study. At baseline, eight participants used the ASV every day, and during the study, 15 participants used the ASV every day.

Overall, the moldable adhesive significantly increased adhesive lifetime during hands-free speech use (from a median of 4 h to a median of 12 h) as well as the duration of hands-free speech compared to participants' baseline (from a median of 3 h/day to a median of 8 h/day).

These outcomes are illustrated in Figure 2 for the total group and subdivided for adhesive preference. The participants who preferred the moldable adhesive (55% of participants) generally experienced a significant increase in adhesive lifetime during hands-free speech use (to a median of 24 h, range 8–144 h) and duration of hands-free speech (to a median of 8 h/day, range 4–17 h/day). The participants that experienced a comparable moldable adhesive lifetime compared to their baseline adhesive, preferred their baseline adhesive (also influenced by the better-rated usability of their baseline adhesive in this preference group, Table II).

There is a significant strong positive correlation between adhesive lifetime and hands-free speech duration for both the baseline adhesive (Spearman's rank correlation, $r_s = .761$, $p < .0001$) and moldable adhesive ($r_s = .570$, $p < .01$). No association was found between product performance and stoma depth, skin irritation, or regular use of hands-free speech at baseline.

Skin Irritation

During the study period, 12 participants experienced no change, three participants experienced a decrease and five experienced an increase in skin irritation. Of the five participants that experienced an increase in skin irritation during the study period, one got a small pressure ulcer during the first week that cleared up within a day or two, which was similar to his experiences with his baseline adhesive. No association was found between skin irritation and patient preference, product performance or patient characteristics (e.g., rate of radiotherapy).

Comfort, Fit, and Usability

Nineteen participants completed the post-study questionnaire regarding comfort and usability. The results regarding experienced comfort, fit, appearance, and usability of the moldable adhesive and heating pad are shown in Table II.

The heating, modeling, comfort, and removal of the moldable adhesive (Table II questions 1–5) were rated positively by all participants (an average score >3). The participants that preferred the moldable adhesive scored comfort, fit, ease of speech, and confidence significantly higher (Table II, questions 6–9, p-values resp: .008, .019, .001, 0.007).

The heating pad was very intuitive and easy to use (e.g., connecting it to power, placing the moldable

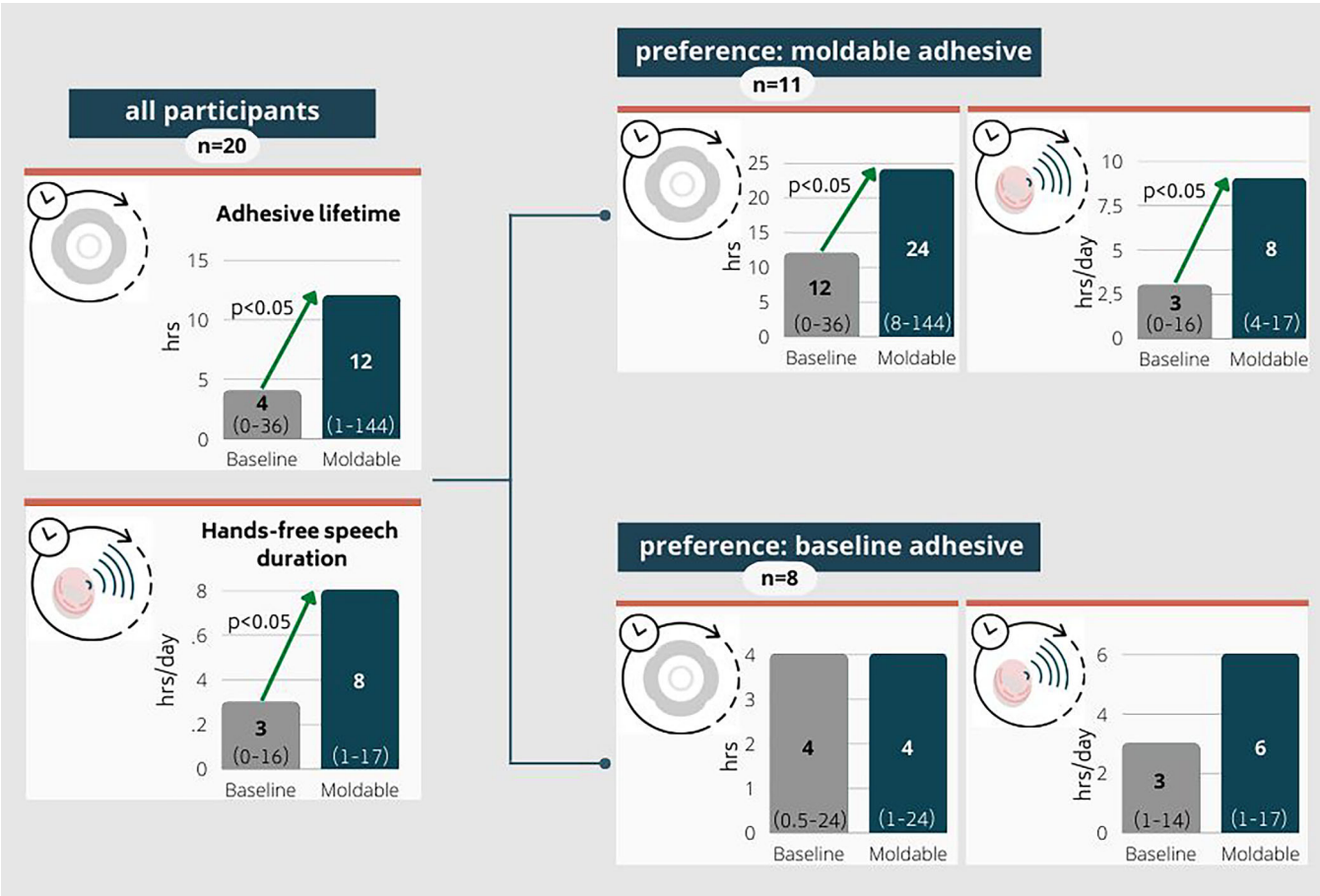

Fig. 2. Product performance and its influence on patient preference between the baseline adhesive and moldable adhesive. Variables are displayed as the median (in bold) and range (min-max). One participant had no preference between adhesives.

TABLE II.
Averaged scores regarding comfort, fit, and usability of the moldable adhesive and heating pad, scored on a 5-point Likert scale (1 meaning 'not at all', 2 'a bit', 3 'neutral', 4 'quite' and 5 'very much').

	Preference: Baseline Adhesive (n = 8)	Preference: Moldable Adhesive (n = 10)	*p*-Value
1. **Heating** the moldable adhesive **was easy**	4.5	4.8	0.364
2. The **temperature** of the moldable adhesive was **comfortable** during the application	4.25	4.7	0.522
3. **Modeling** the moldable adhesive **to the shape** of my neck and stoma was **easy**	4.13	4.7	0.368
4. The moldable adhesive was **comfortable to wear**	3.25	4.5	0.187
5. The moldable adhesive was **easy to remove**	3.38	4.4	0.301
6. The moldable adhesive was **more comfortable** than my usual adhesive(s)	**2.25**	**4.2**	**0.008**
7. The moldable adhesive **fits my stoma shape and neck better** than my usual adhesive(s)	**2.75**	**4.3**	**0.019**
8. **Speaking** with the moldable adhesive **was easier** than with my usual adhesive(s)	**2.00**	**4.6**	**0.001**
9. I **felt very confident** when using the moldable adhesive	**2.5**	**4.4**	**0.007**

Note: Nineteen participants filled out the post-study questionnaire, and one of the participants had no preference for adhesives.

adhesive inside the heating pad, and starting the heating process). Three participants indicated that they found the necessity of using the heating pad inconvenient and preferred their baseline adhesive. These participants did not experience a significant increase in product performance with the moldable adhesive.

DISCUSSION

The moldable adhesive enabled ASV fixation adequate for hands-free speech in the majority of participants. With the moldable adhesive, a significantly increased adhesive lifetime and duration of hands-free speech are seen in approximately half of the participants, regardless of stoma depth, skin irritation, or adhesive and regular use of hands-free speech at baseline. This increase in product performance and the more positively perceived comfort, fit, and ease of speech of the moldable adhesive compared to their baseline adhesive explains the patient preference for the new moldable adhesive. The participants who preferred their baseline adhesive, experience a comparable product performance of the moldable adhesive compared to their baseline adhesive, regardless of stoma depth, skin irritation, or adhesive and regular use of hands-free speech at baseline. In this group, the moldable adhesive's usability, especially the necessity of using the heating pad and the additional time commitment needed for the adhesive application (approximately 5–10 min), had an expected negative influence on moldable adhesive preference.

This study has some limitations and uncertainties. This study only included successful adhesive users with prior ASV experience. We used these inclusion criteria to assess the performance and feasibility of the moldable adhesive compared to a baseline adhesive for ASV use, and to eliminate influences and uncertainties associated with using an adhesive or ASV for the first time. The increased use of an ASV with the new moldable adhesive can partially be explained by the fact that all participants had prior ASV experience and were more motivated to use it, as they participated in a study. However, regardless of the selection bias in including only successful adhesive users, the moldable adhesive still significantly improved the adhesive lifetime in half of the participants compared to their baseline adhesive. In this study, the baseline adhesives that most participants used are already the adhesive types from the range that are specifically designed and recommended for hands-free speech (Provox® StabiliBase™ or Provox® Life™ Stability adhesives). This might explain why no correlation was found between patient preference and adhesive lifetime or stoma depth in this study, in contrast to previous reports with different baseline adhesives.[21,25,27] The use of study-specific questionnaires only gives the best approximation of the product performance (as experienced by the participants) but are not a direct and objective measurement, making a direct comparison of product performance between studies ambiguous. Furthermore, due to the nature of the intervention, it was not possible to blind the participants and researchers. Therefore, this study design as well as the phrasing of the questionnaire could have biased the participants to respond more positively to the questions regarding the new moldable adhesive. An objective or subjective voice assessment as performed in previous clinical trials regarding medical devices to aid hands-free speech,[16,18,19,28] was also not included in the scope of our study. For further studies on this new fixation device, we recommend including objective and subjective voice assessments and visual analog scales with neutral questions to let participants rate product performance in studies regarding the use of ASVs and fixation methods.

Over the past two decades, considerable efforts have been made to improve or develop new fixation devices to allow for adequate ASV fixation and promote regular hands-free speech in laryngectomized patients with a wide variation in stoma morphology, skin condition and preferences in the type of fixation device.[17,26–30] The results of this study are promising for clinical practice. This study indicates that the moldable adhesive is a valuable addition to the wide range of fixation devices already available to laryngectomized patients, as it allows durable and airtight fixation during hands-free speech. Furthermore, the moldable adhesive and heating pad are accessible products: the adhesive can easily and intuitively be heated and applied by laryngectomized patients themselves, achieving an airtight and custom fit without the need for a healthcare

professional or additional fixation devices. Although not assessed in this study, the enhanced fit and adhesive lifetime of the moldable adhesive might also lead to positive results in ASV-naive patients or previously unsuccessful adhesive users. For clinical practice, the moldable adhesive could make it easier for ASV-naive patients to learn hands-free speech by providing more stability and back-pressure to counteract the high phonation pressures. Even for the substantial group of laryngectomized patients who do not and will not use hands-free speech, the moldable adhesive has a great potential to improve their speech and pulmonary rehabilitation and QoL by preventing early air leakage and detachment.

CONCLUSION

The moldable adhesive's lifetime and functional aspects, including the ease of use and custom fit, are encouraging outcomes and enable more laryngectomized patients to use hands-free speech more regularly.

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