AMERICAN ACADEMY OF OTOLARYNGOLOGY–HEAD AND NECK SURGERY FOUNDATION

Short Scientific Communication

Otolaryngology–Head and Neck Surgery
1–4

DOI: 10.1177/0194599820982634
http://otojournal.org
SAGE

Improving Hands-free Speech Rehabilitation in Patients With a Laryngectomy: Proof-of-Concept of an Intratracheal Fixation Device

Maartje Leemans, MSc[1], Maarten J.A. van Alphen, PhD[1], Richard Dirven, MD, PhD[1], Gijsbertus J. Verkerke, PhD[2,3], Edsko E.G. Hekman, MSc[3], and Michiel W.M. van den Brekel, MD, PhD[1,4,5]

Abstract

Permanent hands-free speech with the use of an automatic speaking valve (ASV) is regarded as the optimal voice rehabilitation after total laryngectomy. Due to fixation problems, regular ASV use in patients with a laryngectomy is limited. We have developed an intratracheal fixation device (ITFD) composed of an intratracheal button augmented by hydrophilic foam around its shaft. This study evaluates the short-term effectiveness and experienced comfort of this ITFD during hands-free speech in 7 participants with a laryngectomy. We found that 4 of 7 participants had secure ASV fixation inside the tracheostoma during hands-free speech for at least 30 minutes with the ITFD. The ITFD's comfort was perceived positively overall. The insertion was perceived as being mildly uncomfortable but not painful. This proof-of-concept study demonstrates the feasibility of the ITFD that might improve stomal attachment of ASVs, and it provides the basis for further development toward a prototype suitable for long-term daily use.

Keywords

total laryngectomy, speech rehabilitation, hands-free speech, automatic speaking valve, intratracheal fixation, tracheostoma valves

Received October 2, 2020; accepted November 25, 2020.

Permanent hands-free speech with the use of an automatic speaking valve (ASV) is regarded as the optimal voice rehabilitation after total laryngectomy.[1,2] The ASV enables patients with a laryngectomy to speak without using manual occlusion, therefore reducing the emphasis on the patient's disability and improving hygiene and dexterity. However, regular use of hands-free speech with an ASV is limited to only 7% to 37.5% of patients,[2-7] mainly due to problems with achieving airtight ASV fixation in the tracheostoma opening.[2-5,8,9] We have developed an intratracheal fixation device (ITFD) as a potential alternative method to improve ASV fixation and ultimately compliance. In this proof-of-concept study with 7 patients with a laryngectomy, we focused on the short-term effectiveness and experienced comfort of the ITFD.

Patients and Methods

Patients

Seven patients with a laryngectomy who were seen for follow-up in the Netherlands Cancer Institute (NKI) were included after NKI Institutional Review Board approval of this study. Six participants were male, and the mean age was 67 years (range 51-78 years). The majority of the participants (6/7) daily use a peristomal adhesive with a manual occluding heat and moisture exchanger. None of the included participants use an intratracheal button with ASV hands-free speech on a daily basis.

Intratracheal Fixation Device

The ITFD that we developed consists of an intratracheal button (Provox Larybutton; Atos Medical AB) augmented by a hydrophilic polyvinyl acryl foam (Ivalon Nasal Packing; Fabco) around its shaft, secured with a suture string (Vicryl 3.0; Ethicon). The foam exterior expands and softens considerably under the influence of moisture after insertion into the

[1]Department of Head and Neck Oncology and Surgery, Netherlands Cancer Institute–Antoni van Leeuwenhoek, Amsterdam, the Netherlands
[2]Department of Rehabilitation Medicine, University of Groningen, University Medical Center Groningen, Groningen, the Netherlands
[3]Department of Biomechanical Engineering, University of Twente, Enschede, the Netherlands
[4]Institute of Phonetic Sciences, University of Amsterdam, Amsterdam, the Netherlands
[5]Department of Oral and Maxillofacial Surgery, Amsterdam University Medical Center, Amsterdam, the Netherlands

Corresponding Author:
Michiel W.M. van den Brekel, MD, PhD, Department of Head and Neck Oncology and Surgery, Netherlands Cancer Institute–Antoni van Leeuwenhoek, Plesmanlaan 121, Amsterdam, Noord-Holland, 1066 CX, the Netherlands.
Email: m.vd.brekel@nki.nl

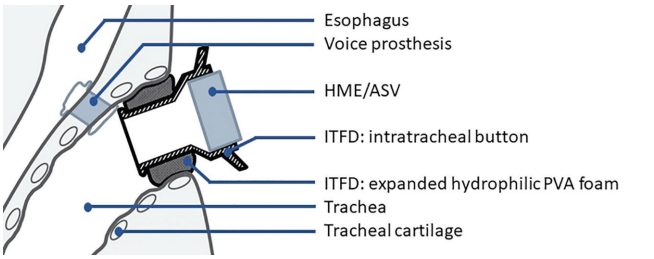

Figure 1. Schematic representation of the positioning of the intratracheal fixation device (ITFD) inside the tracheostoma. ASV, automatic speaking valve; HME, heat and moisture exchanger; ITFD = intratracheal fixation device.

tracheostoma opening, thereby adapting to the tracheostoma morphology (**Figure 1**).

At the NKI's outpatient clinic, a head and neck surgeon assembled the participant-specific ITFDs by adjusting the thickness of the foam exterior and the dimensions of the button. After insertion of the ITFD into the participant's stoma, an ASV was placed into the ITFD and worn for a maximum of 30 minutes or until it was dislodged from the tracheostoma. We monitored the participants on the short-term effectiveness of the ITFD during hands-free speech. Subsequently, participants filled out a questionnaire on the experienced comfort of the ITFD.

Results

The participants' characteristics and results of the observed short-term effectiveness of the IFTD are shown in **Table 1**. We observed that 4 of 7 participants had an effective short-term ASV fixation (30 minutes) inside the tracheostoma during hands-free speech. The remaining 3 participants were unable to obtain effective ASV fixation due to their specific stoma morphology (ie, not device related). The expanded foam exterior did not restrict the lumen of the intratracheal button or the voice prosthesis in 6 of 7 participants (**Figure 2**).

The overall comfort of the ITFD was experienced positively by the participants. The insertion of the ITFD with the dry, compressed foam exterior was experienced by 2 participants as mildly uncomfortable but not painful.

Discussion

This proof-of-concept study shows that the ITFD can provide effective short-term ASV fixation during hands-free speech in a subset of patients with a laryngectomy. Additionally, the ITFD's comfort was overall experienced positively.

This proof-of-concept study focused on the short-term effectiveness and comfort of the ITFD, as made in-house; other aspects of the effectiveness were beyond the scope of this study. Therefore, the long-term effectiveness and comfort of a fully developed and professionally manufactured ITFD are still unknown, as well as the clinical effect of long-term use and repeated use on the tissue of the tracheostoma.

Additionally, the study design had its limitations. The process of fitting the participant-specific ITFD was done more or less in a trial-and-error approach, involving the professional but subjective estimates of the surgeons. In case of an unsuccessful insertion, the dimensions were adjusted. The thickness of the dry, compressed hydrophilic foam exterior proved to be the main restricting factor to a successful insertion because it influences the pliability of the ITFD. Since the ITFD was made in-house, the size of the hydrophilic foam was adjusted with a scalpel, resulting in somewhat irregular material edges and thickness. However, the hydrophilic foam material is intended for mucosal application, and its dimensions can safely be adjusted due to the material's nonshredding property.[10] Another limitation is that the ITFD was inserted only once per participant. It can be expected that insertion becomes easier after a few times of application.

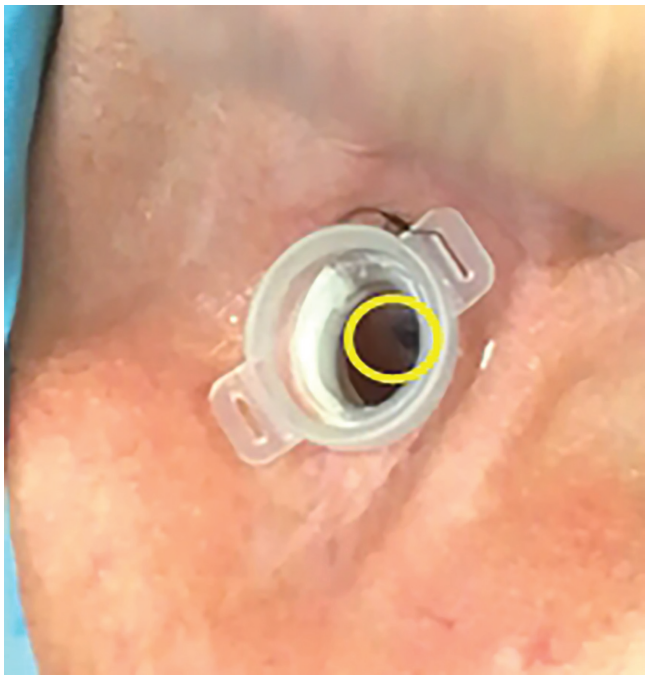

Figure 2. Correct placement of the intratracheal fixation device inside the tracheostoma (participant 3). The circle indicates the placement of the voice prosthesis, which is not obstructed by the device.

The ITFD did not provide effective ASV fixation during hands-free speech in all participants; however, none of the participants are currently able to speak hands-free with the use of a standard intratracheal button. Important parameters influencing the ITFD's success are the stoma morphology and location of the voice prosthesis, which should be studied more extensively to determine the most optimal IFTD design and range of dimensions.

Furthermore, this ITFD can serve as an alternative fixation method to overcome disadvantages of current peristomal and intratracheal fixation methods, such as skin irritation, air leakage, and inadequate tracheostoma fit.[1,2,4,8,11-16]

Conclusion

We conclude that this proof-of-concept study demonstrates the feasibility and comfort of the modified ITFD during

Table 1. Participant Characteristics and Short-term Effectiveness of the ITFD.

				Participant-specific ITFD				
No.	Sex	Age, y	Daily fixation and speech rehabilitation method	Button size, mm[a]	Foam thickness, mm	Effective fixation during hands-free speech?	Removal of ITFD	Additional remarks
1	M	69	Adhesive, HME + ASV	12/8	~7	Yes, ~30 min	Easy manual removal	Full 30-min fixation with forceful hands-free speech, no observed leakage of air.
2	M	51	Adhesive, HME	16/18	~15	No, 0 min	Spontaneous dislodgment out of tracheostoma	ITFD obstructed the voice prosthesis due to a shallow and beveled stoma morphology. Small blood stain observed on foam exterior after removal.
3	M	72	Button, HME	18/8	~7	Yes, ~30 min	Dislodgment out of tracheostoma after very forceful pressure buildup by participant	Full 30-min fixation with forceful hands-free speech, no observed leakage of air.
4	M	78	Adhesive, HME	12/18	~7	Yes, ~30 min	Easy manual removal	Full 30-min fixation with forceful hands-free speech, no observed leakage of air. After removal, foam appeared to not have been completely expanded.
5	M	65	Adhesive, HME + ASV	14/8	~7	Yes, ~30 min	Easy manual removal	Full 30-min fixation with forceful hands-free speech, no observed leakage of air.
6	F	69	Adhesive, HME	12/8	~7	No, <5 min	Spontaneous dislodgment out of tracheostoma	Deep stoma. Peristomal skin and ITFD came forward during hands-free speech. Thus, the participant was not able to gain (forceful) hands-free speech.
7	M	68	Adhesive, HME	14/8	~15	No, 5-10 min	Spontaneous dislodgment out of tracheostoma	~5-10 min of forceful hands-free speech possibly due to specific stoma morphology. Small blood stain observed on foam exterior after removal.

Abbreviations: ASV, automatic speaking valve; F, female; HME, heat and moisture exchanger; ITFD, intratracheal fixation device; M, male.
[a]Diameter/length.

hands-free speech in patients with a laryngectomy and provides a basis for further development toward a prototype suitable for long-term daily use. As the ITFD was not always easy to insert and as stoma morphology and location of the voice prosthesis play a role in its usability, a redesign of the prototype focusing on these aspects will be undertaken, as will an evaluation with long-term use in a larger study population .

Authorship Contributions

Maartje Leemans, study design, data acquisition, analysis, drafting, revision and final approval of the manuscript; **Maarten J.A. van Alphen**, study design, data acquisition, analysis, drafting, revision and final approval of the manuscript; **Richard Dirven,** study design, data acquisition, analysis, drafting, revision and final approval of the manuscript; **Gijsbertus J. Verkerke**, study design, analysis, revision and final approval of the manuscript; **Edsko E.G. Hekman**, study design, analysis, revision and final approval of the manuscript; **Michiel W.M. van den Brekel**, study design, data acquisition, analysis, drafting, revision and final approval of the manuscript.

Disclosures

Competing interests: None.

Sponsorships: None.

Funding source: The Netherlands Cancer Institute's Department of Head and Neck Oncology and Surgery receives a research grant from Atos Medical AB, which contributes to the existing infrastructure for quality-of-life research in the department. Atos Medical AB had no role in the concept, study design, and drafting of this manuscript.

References

1. Dirven R, Hilgers F, Plooij J, et al. 3D stereophotogrammetry for the assessment of tracheostoma anatomy. *Acta Otolaryngol*. 2008;128:1248-1254.
2. Hilgers F, Ackerstaff A. Development and evaluation of a novel tracheostoma button and fixation system (Provox LaryButton and LaryClip adhesive) to facilitate hands-free tracheoesophageal speech. *Acta Otolaryngol*. 2007;126:1218-1224.
3. Lorenz KJ, Groll K, Ackerstaff AH, Hilgers FJ, Maier H. Hands-free speech after surgical voice rehabilitation with a Provox voice prosthesis: experience with the Provox FreeHands HME tracheostoma valve system. *Eur Arch Otorhinolaryngol*. 2007;264(2):151-157
4. Op De Coul BMR, Ackerstaff AH, Van As-Brooks CJ, et al. Compliance, quality of life and quantitative voice quality aspects of hands-free speech. *Acta Otolaryngol*. 2005;125(6): 629-637.
5. Hilgers FJ, Ackerstaff AH, Van As CJ, Balm AJ, Van den Brekel MW, Tan IB. Development and clinical assessment of a heat and moisture exchanger with a multi-magnet automatic tracheostoma valve (Provox FreeHands HME) for vocal and pulmonary rehabilitation after total laryngectomy. *Acta Otolaryngol*. 2003;123(1):91-99.
6. Lansaat L, de Kleijn B, Hilgers F, Laan B, van den Brekel M. A prospective multicenter clinical feasibility study of a new automatic speaking valve for postlaryngectomy voice rehabilitation. *Eur Arch Otorhinolaryngol*. 2017;274(2):1005-1013
7. Tervonen H, Bäck L, Juvas A, et al. Automatic speaking valve in speech rehabilitation for laryngectomized patients. *Eur Arch Otorhinolaryngol*. 2005;262(10):816-820.
8. ten Hallers EJO, Marres HAM, Rakhorst G, et al. Difficulties in the fixation of prostheses for voice rehabilitation after laryngectomy. *Acta Otolaryngol*. 2005;125(8):804-813.
9. Doyle PC, Grantmyre A, Myers C. Clinical modification of the tracheostoma breathing valve for voice restoration. *J Speech Hear Disord*. 1989;54(2):189-192
10. Fabco. Ivalon nasal packing. Accessed August 7, 2020. https://wwwshreyaasnet/pdf/FABCO_Cataloguepdf
11. Moreno M, Lewin J, Hutcheson K, Leone J, Barringer D, Reece G. Tracheostomaplasty: a surgical method for improving retention of an intraluminal stoma button for hands-free tracheoesophageal speech. *Head Neck*. 2010;32:1674-1680.
12. Ackerstaff AH, Hilgers FJ, Balm AJ, Tan IB. Long-term compliance of laryngectomized patients with a specialized pulmonary rehabilitation device: Provox stomafilter. *Laryngoscope*. 1998;108(2):257-260.
13. Hilgers FJ, Ackerstaff AH, Balm AJ, Gregor RT. A new heat and moisture exchanger with speech valve (Provox stomafilter). *Clin Otolaryngol Allied Sci*. 1996;21(5):414-418.
14. van der Houwen EB, van Kalkeren TA, Burgerhof JG, van der Laan BF, Verkerke GJ. In vitro evaluation of the iValve: a novel hands-free speech valve. *Ann Otol Rhinol Laryngol* 2011;120(12):814-819.
15. Lansaat L, de Kleijn B, Hilgers F, Laan B, van den Brekel M. Comparative study between peristomal patches in patients with definitive tracheostomy. *Int Arch Otorhinolaryngol*. 2018; 22(2):130-135.
16. Ackerstaff AH, Hilgers FJ, Aaronson NK, Balm AJ, van Zandwijk N. Improvements in respiratory and psychosocial functioning following total laryngectomy by the use of a heat and moisture exchanger. *Ann Otol Rhinol Laryngol*. 1993; 102(11):878-883.