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Expiratory Muscle Strength Training in patients After Total Laryngectomy; A Feasibility Pilot Study

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Abstract

Objectives: Expiratory muscle strength training (EMST) is a threshold based device-driven treatment for improving expiratory pressure. EMST proved to be effective in different patient groups to improve cough function. To date, EMST has not been tested in the total laryngectomy population (TL).

Methods: This prospective, randomized case-series study examined feasibility, safety, and compliance of EMST in a group of TL participants and its effects on pulmonary function, physical exertion, fatigue, and vocal functioning. Ten TL participants were included in the study to perform a 4 till 8 weeks of EMST. Objective and subjective outcome measures included manometry, spirometry, cardio pulmonary exercise testing (CPET), voice recordings, and patient reported outcome measures. Group means were reported and estimates of the effect are shown with a 95% confidence interval, using single sample t-tests.

Results: Nine participants completed the full study protocol. Compliance to the training program was high. All were able to perform the training, although it requires adjustments of the device and skills of the participants. Maximum expiratory pressure (MEP) and vocal functioning in loudness improved over time. After EMST no changes were seen in other objective and subjective outcomes.

Conclusions: EMST appears to be feasible and safe after total laryngectomy. MEP improved over time but no improvement in the clinically relevant outcome measures were seen in this sample of relatively fit participants. Further investigation of the training in a larger group of participants who report specifically pulmonary complaints is recommended to investigate if the increase in MEP results in clinical benefits.

Level of Evidence: 4

Keywords
head and neck cancer, total Laryngectomy, cough, bronchoesophagology, voice, clinical outcomes research

Introduction

Total laryngectomy (TL), which involves surgical removal of the larynx, leads to lifelong changes in voice, swallowing and airway. Pulmonary driven speech can be re-established with insertion of a voice prosthesis, also called tracheoesophageal speech.1 Compared to healthy individuals the voices of tracheoesophageal speakers have a rough voice quality, reduced loudness, and limited range.2

After TL pulmonary condition is affected as air entering the lungs via the stoma is not warmed and humidified by the nose and upper respiratory tract, which leads to impaired mucociliary clearance. Impaired mucociliary function is the main cause of pulmonary complaints such as increased mucus production and forced mucus expectoration after TL.3,5 Warming and humidifying the inhaled air is a key factor in improving pulmonary condition. Over the years several options were developed: external humidifiers, stoma cloths (eg, bibs), and heat-moisture-exchange devices (HME-devices).5-8 Both stoma cloths and HME-devices are proved to be effective in everyday life and can reduce pulmonary problems in this patient group.8-11 Nevertheless, pulmonary complaints including increased mucus production and forced mucus expectoration are still present after TL.12,13

The altered anatomy results in an physiological altered cough function after TL. Removal of the larynx eliminates the ability to generate subglottic pressure prior to cough onset. Cough requires high expiratory airflows to aerosolize and remove material that is unable to be removed by
mucociliary action. Cough “strength” is determined by the 
ability to generate high expiratory pressures immediately 
prior to cough onset and by the volume of air that is expelled 
from the airways. With the absence of the ability to build 
up subglottic pressure, it is assumed that after a TL increased 
cough strength can only be achieved by increasing the vol-
ume and speed of cough expiratory airflow. To date, cough 
function after TL and the potential benefit of rehabilitation 
techniques have not been studied.

A well-known rehabilitation technique to improve 
cough function is expiratory muscle strength training 
(EMST). Recently, the use of EMST has been evaluated in 
several studies, including different patient groups such 
as Parkinson’s disease, multiple sclerosis, sleep 
apnea, head and neck cancer patients with dysphagia, 
stroke, amyotrophic lateral sclerosis, supracricoid 
partial laryngectomy, and healthy participants. In sev-
eral populations, to date, EMST has been shown to increase 
expiratory pressure generation by 30% to 150%, with an 
average increase of approximately 50% in a 4-week period 
of time. Most of the clinical studies cited above aimed at improving cough strength to improve clearing 
of aspiration of oral intake or saliva. EMST has not been tested in the TL population.

The main objective of the present study is to evaluate 
feasibility, safety, and compliance of EMST in individuals 
who have undergone TL. Subsequently, objective and sub-
jective outcomes of the effects of EMST on pulmonary 
function, physical exertion, fatigue, and vocal functioning 
are assessed.

Materials and Methods

This prospective, randomized case-series study examined 
feasibility of EMST and its effects on pulmonary function 
and voice, in a group of male TL participants, who were at 
least a half year post surgery and, if applicable, post-
operative (chemo) radiation. Participants were screened 
and recruited from the head and neck department of the 
Netherlands Cancer Institute-Antoni van Leeuwenhoek, 
Amsterdam, The Netherlands. Exclusion criteria were: recurrence of head and neck cancer, a history of lung can-
cer, severe asthma, tuberculosis, uncontrolled or untreated 
hypertension, a heart attack in the last year, or abdominal 
hernia. The study was approved by the medical ethical 
review committee of the Netherlands Cancer Institute 
(registration nr. NL60167.031.16.).

Expiratory Muscle Strength Training and 
Adjustment to Use After TL

EMST150 (Aspire Products) is a threshold based device-
driven treatment for improving expiratory pressure generat-
ing capacity. EMST employs a handheld training device 
consisting of a plexiglass tube. Inside the device is a vari-
able tension spring controlling a valve that is calibrated in 
pressure, adjustable from 30 till 150 cmH₂O. When enough 
pressure is developed, the valve opens, allowing air to flow 
through the trainer. The patient is instructed to exhale force-
fully through the device. In this way, EMST targets the rec-
tus abdominis and internal intercostal muscles through a 
program of progressive overloading which is an exercise 
stimulus specific for forceful expiration.

To adjust the use of the EMST150 device for TL partici-
pants, we developed and produced an adaptor to connect the 
device at the adhesive baseplate in front of the tracheos-
toma. This adaptor contains an opening on top to allow 
inhalation which can be occluded manually, a small lumen 
for use of the voice prosthesis plug, and a tube which 
enables connection with a manometer (Figures 1 and 2).

EMST Study Training Protocol

All participants performed 4 weeks of EMST (period A) 
which consisted of five sets of five repetitions across 5 days 
per week. Strength measurements and subsequent adjustment 
of the pressure of the EMST device were performed at base-
line and after each training week. Participants were instructed 
to perform their training sessions at home and log each train-
ing with details in a diary to check compliance. During the
weekly visits to the hospital, the researchers monitored the participants’ compliance by discussing their training results. The pressure of the device was set at approximately 80% of the participant’s mean Maximum Expiratory Pressure (MEP).

In the following 4 weeks (period B), participants were allocated to different protocols depending on the group they were randomized to. Participants in group 1 discontinued the training. Participants in group 2 continued EMST for another 4 weeks, but with a lower frequency of 2 days per week.

Block-randomization in blocks of four with stratification for age was performed with help of Alea software.

Adjustments in training procedures with the EMST150 device were needed. Before each training session, the participants’ voice prosthesis had to be blocked with a plug to avoid air escaping through the voice prosthesis into the esophagus. Participants were instructed to connect the EMST device at the adhesive in front of the tracheostoma, take a deep breath, close the opening on top of the adaptor with a finger, and exhale forcefully into the EMST device until enough pressure was built up to open the valve inside.

### Feasibility, Safety, and Compliance

The main objective of the study was to evaluate feasibility, safety, and compliance with the EMST program. Any difficulties regarding participants’ performance of the training and assessment procedures were documented. Participants were instructed to log every training session and reflect on their experiences in a diary. At the end of the training program participants filled in a short questionnaire on whether they found the training feasible and whether they could stay motivated during the period of training.

### Objective and Subjective Outcome Measures

The effects of EMST on pulmonary function, physical exertion, fatigue, and vocal functioning were assessed with manometry, spirometry, cardio pulmonary exercise testing (CPET), voice recordings, and questionnaires. Time points of the assessments are shown in Table 1. MEP in cmH₂O was obtained with a calibrated digital manometer (Druck DPI 705) connected to the adapter whilst the EMST device was adjusted to the maximum pressure of 150 cmH₂O and connected to the tracheostoma. Participants were instructed to sit, take a deep breath, occlude the adapter, and exhale as forcefully as possible. Peak Expiratory Flow (PEF) in L/min was obtained with a Micro 1 spirometer combined with a Microgard II filter (PT Medical) which was placed directly on the baseplate of the stoma. Participants were instructed to inhale calm but deep and then exhale as forcefully and fast as they could. A series of three forced expirations was used to obtain MEP and PEF, the mean of the three trials was used for the analysis.

Objective and Subjective Outcome Measures:

- **Pulmonary Function**: Measured with spirometry.
- **Physical Exertion**: Assessed during the Cardio Pulmonary Exercise Test (CPET).
- **Fatigue**: Evaluated with questionnaires.
- **Vocal Functioning**: Assessed with voice recordings.

**Figure 1.** EMST150 connected to a baseplate with the adapter and voice prosthesis plug present.

**Figure 2.** EMST150 during practice, connected to the baseplate attached to the tracheostoma. The index finger is used to occlude the opening on top during forced exhalation.
respectively. The best of three attempts was used for each value. All voice recordings were acoustically analyzed with PRAAT software. Self-reported vocal functioning is assessed with the Voice Handicap Index-10 (VHI-10), self-reported fatigue with the Short Fatigue Questionnaire (SFQ), and self-reported pulmonary functioning with the clinical COPD questionnaire (CCQ). 

Statistical Analysis

Due to lack of preliminary data with regard to pulmonary exercise programs in TL patients, there was no meaningful way to perform sample size calculations related to the quantitative outcome. All data was analyzed using SPSS software. Accordingly, no significance tests were performed. Group means were estimated with a 95% confidence interval, using single sample t-tests.

Results

Ten participants were included and signed informed consent. Participants age ranged from 50 to 73 years, and all were tracheo-esophageal speakers (characteristics are presented in Table 2).

Feasibility, Compliance, and Safety

Using the EMST device with help of an adapter on the tracheostoma of the TL participants appeared to be generally feasible. All participants could perform the training. One participant withdrew from the study after 1 week due to unrelated medical reasons. For the remaining nine participants, compliance to the allocated training program was 95.5%. According to the final short questionnaire, participants did not experience problems to stay motivated during the training weeks. Minor problems included leakage of air underneath the adhesive, which was reported by four of the participants. Two participants occasionally experienced dizziness during and shortly after the training. Three participants were not able to plug the voice prosthesis prior to the training, and continued training without plug. From the six participants who did plug their voice prosthesis before training, three mentioned that plugging was a hassle.

Regarding to safety, one adverse event occurred with one of the participants in his fourth EMST training week. After a training session with the EMST, the voice prosthesis was not in situ anymore. A new voice prosthesis was placed and an X-thorax was made which showed that the voice prosthesis was not in the lungs. All participants and the medical ethical review committee were informed.

Objective and Subjective Outcome Measures

Results on pulmonary function, physical exertion, fatigue, and vocal functioning are presented in Table 3. We observed a non-linear increase in the manometry outcome MEP. During the first four training weeks mean MEP increased from 125.5 cmH2O to 174.8 cmH2O during the first 4 weeks (95% CI: baseline 110.4-140.6, 4 week 152.8-196.8). After 4 weeks, MEP stabilized, with no evidence for differences in detraining between group 1 and group 2 (Figure 3). Overall, MEP decreased slightly to a mean of 164.9 cmH2O (95% CI: 141.8-189.0) at the end of the follow-up. Three of the nine participants achieved a MEP-score above 187.5 cmH2O during the first four training weeks. For those participants, training at 80% of the mean MEP was not possible from that moment onward, since the maximum setting of the EMST is 150 cmH2O. These participants continued their training on the maximum setting of the EMST150-device. The three participants who used no plug during training showed increase of the MEP as well.

| Table 1. Overview of the Assessed Outcome Measures per Time Point, Visualization of Period A and B Over Time. |
|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
|                | Wk 0 | Wk 1 | Wk2 | Wk 3 | Wk 4 | Wk 8 |
| **Period A**    |      |      |     |      |      |      |
| Manometry—MEP  | X    | X    | X   | X    | X    | X    |
| Spirometry—PEF | X    | X    | X   | X    | X    | X    |
| Spirometry—VC, FEV1 | X | X |
| CPET—VE/VCO2, Borg exertion, Borg dyspnea scale | X |
| Voice assessment—Vocal range (Hz and dB), MPT | X |
| Short fatigue questionnaire33 | X |
| Clinical COPD Questionnaire34 | X |
| Voice Handicap Index-1032 | X |
| **Period B**    |      |      |     |      |      |      |
|
Abbreviations: CPET, Cardio Pulmonary Exercise Testing; FEV1, Forced Expiratory Volume in the first second; MEP, Maximum Expiratory Pressure; MPT, Maximum Phonation Time; PEF, Peak Expiratory Flow; VC, Vital Capacity.
We observed no effect on spirometry outcome PEF over time (Figure 4). Mean PEF values were 455.9 L/min at baseline and 445.5 L/min after 4 weeks (95% CI: baseline 374.8-537.0, 4 week 356.0-535.0). In this sample, no effect of detraining was seen in PEF after reducing or stopping the training with a mean PEF value of 405.3 at week 8 (95% CI: 318.8-492.0).

No changes over time were found for self-reported pulmonary problems (CCQ), vocal functioning (VHI-10), fatigue (SFQ). No differences were found for outcomes in physical exertion (CPET, Borg scales). Objective assessment of vocal functioning showed no differences in MPT and vocal range in Hz. Exception was dynamic range in dB, which increased from 26.4 dB (95% CI: 21.7-31.0) to 31.9 dB (95% CI: 28.8-35.0) after 4 weeks of training. After period B vocal range in dB returned back to baseline values (mean 27.6 dB 95% CI: 23.1-32.2).

**Discussion**

To date, this is the first study to investigate feasibility, safety, and compliance of EMST in a group of TL participants.
EMST appears to be somewhat challenging, but feasible. MEP improved over time but this did not seem clinically relevant for this group of relatively fit participants.

Challenges encountered the need for an adapter, skills of the participants with plugging the voice prosthesis, placing the EMST150 with an adaptor on the tracheostoma, and creating an airtight seal. One safety issue occurred with a participant presenting without a voice prosthesis after a training session. Nevertheless, compliance to the training program was high (>95%).

The results show a clear increase in MEP over time in contrast to PEF values in which no change was seen. The increase of MEP as a result of EMST is consistent with both biological rationale and former findings.\textsuperscript{14,16,18,20,22,23,25} Baseline MEP scores were higher than predicted for eight out of ten participants when compared with reference values for healthy adults.\textsuperscript{36} No normative MEP values for TL patients are found. The higher than expected MEP scores might be the effect of frequent coughing and forced expectoration which is present after TL. The high MEP values are in contrast with the study of Hutcheson et al,\textsuperscript{20} in which head and neck cancer patients suffering from chronic aspiration were included. Their group showed reduced average MEPs at baseline.\textsuperscript{20} Palmer et al\textsuperscript{24} reported a good MEP at baseline in their group after partial laryngectomy and reasoned their candidates must have good pulmonary support to tolerate some amount of aspiration during recovery.

**Figure 3.** Individual Maximum Expiratory Pressure (MEP) scores over time in cmH\textsubscript{2}O.

**Figure 4.** Individual Peak Expiratory Flow (PEF) scores over time in liter per minute.
We observed no changes over time for PEF outcomes. Contrary to the MEP scores, baseline scores were lower than predicted for seven participants compared with reference values. No normative values for PEF in TL patients are found. In the group of partial laryngectomy patients performing EMST a significant increase in peak cough flow (L/min) was found, from below normal prior to the intervention to within normal range after training. Peak expiratory flow rate also increased significantly with training in a group of elderly. It is worth questioning why MEP values did not improve in the studied group of TL participants. A possible reason is impaired cough technique. As there is no glottic closure, the higher built up pressure does not lead to increased flow. Besides, no special attention was paid at the exhaling technique (ie, generating the force primarily using the rectus abdominis muscle, and keeping the thorax maximally expanded during the first part of the forced expiration) during the training.

The increase in MEP and vocal range in dB did not lead to an improvement in the clinical relevant outcome measures regarding pulmonary function, physical exertion, fatigue, and vocal functioning. It was disappointing to see that no clinically relevant benefits were found in the self-reported outcome measures. This might be the result of a sample of relatively fit TL participants which showed high baseline values in MEP and who mentioned no specific pulmonary complaints. Despite an improvement in loudness, related to the dynamic range in dB after 4 weeks of training, no changes in self-reported vocal functioning (VHI-10) were seen.

Although this pilot study offered useful insights, there are some limitations which should be mentioned related to the included group, use of EMST device and performance of training and measurements. Because of the small number of participants the results of this first EMST study in a TL group must be interpreted with caution. The outcomes can therefore be interpreted with caution.

For future research, it should be considered to test EMST in a group of TL patients without plugging the voice prosthesis prior to the training. If this also results in improvements, users can be spared the hassle of plugging. Next to this, special attention should be given towards exhaling technique used during the training. It is recommended to assess effectiveness of the training in a large group of participants which includes patients who explicitly report pulmonary problems, less fit elderly participants, and women. Finally, there are still unanswered questions about the association between patients characteristics (eg, time since TL, flap reconstruction, neck dissection etc.) and effectiveness of EMST.

**Conclusion**

This pilot feasibility study indicates that an EMST program is generally safe and feasible in individuals following TL, although it requires adjustments of the device and skills of the participants to perform the training. Compliance to the training program was high. The EMST leads to an increase MEP, no evident changes in PEF outcomes were found. An increase in dynamic range in dB was seen, but this did not result in less reported voice handicap measured with VHI-10. No effects were found in the voice parameters MPT and vocal range in Hz, and ventilatory efficiency during exercise. For this relatively fit group of TL participants, clinical relevant benefits measured with self-reported clinical outcomes could not be determined. It is recommended to assess EMST in a less fit TL population who specifically report pulmonary problems to further investigate potential clinical benefit.

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**Declaration of Conflicting Interests**

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References