### Clinical Data and Resource Booklet





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Dear Researchers and Clinicians,

We, at Aspire Respiratory Products, would like to express our sincere gratitude to all those who have dedicated their time and effort to furthering our understanding of the 4 Ds\* and their treatment options. Your invaluable research and expertise have helped improve the quality of life for countless individuals.

We are pleased to present you with our latest reference booklet containing abstracts of the most recent peer-reviewed research, articles, and studies supporting the use of EMST devices to improve respiratory muscle strength for patients suffering from dysphagia, dysphonia, dysstusia, and dyspnea\* resulting from natural aging, neuromuscular disease, stroke, and other patient conditions.

We believe that the information contained in this reference booklet will be of great assistance to healthcare professionals seeking to provide the best possible care for their patients. We have also included helpful resources and tips to help users achieve the best possible outcomes when using our EMST devices

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We invite you to visit our website, www.emst150.com, for additional information and resources related to our products and their benefits. As always, we are committed to providing the highest level of support to all those who use our products, and we look forward to continuing our work together to improve the lives of individuals.

Once again, thank you for your dedication and contributions to this important field of research.

Sincerely,

Gail Wiley President

Gail Wiley

Aspire Respiratory Products

### Contents























Parkinson's Dysphagia Cough

OSA



Voice







**IMST** 

Quality of Life





Allen, J., Astin, R., Smith, C., Banks, D., & Turner, C. (2020). "Expiratory muscle strength training improves measures of pressure generation and cough strength in a patient with myotonic dystrophy type 1" Neuromuscular Disorders, 30(9), 750-755.







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van Sluis KE, Kornman AF, Groen WG, et al. Expiratory Muscle Strength Training in patients After Total Laryngectomy; A Feasibility Pilot Study. Annals of Otology, Rhinology & Laryngology. 2020;129(12):

# Expiratory muscle strength training improves measures of pressure generation and cough strength in a patient with myotonic dystrophy type 1

Case Reports Neuromuscul Dis

Jodi Allen <sup>1</sup>, Ronan Astin <sup>2</sup>, Christina Smith <sup>3</sup>, Donna Banks <sup>3</sup>, Chris Turner

Affiliations

PMID: 32861531 DOI: 10.1016/j.nmd.2020.07.003

### **Abstract**

Expiratory muscle strength training (EMST) exercise programmes aim to improve respiratory function by increasing the force generating capability of expiratory muscles by resistance training. In neuromuscular conditions, in which cough flow generation is often decreased, there is increasing interest in EMST as a therapeutic intervention. We present data showing efficacy of EMST in a patient with adult onset Myotonic Dystrophy Type 1 (DM1). A domiciliary training programme (5 days per week over 32 weeks) resulted in increases in maximum expiratory mouth pressure (from 15 cmH20 to 38 cmH20) and peak cough flow (300 L/min to 390 L/min).

Improvements were also seen in maximum inspiratory mouth pressure (26 cmH2O to 52 cmH<sub>2</sub>O) and sniff nasal inspiratory pressure (40 cmH2O to 69 cmH2O).

No changes were detected in speech or swallowing. This novel study demonstrates that cough flow generation in DM1 may be increased by a programme of expiratory muscle training. A clinical trial of EMST in DM1 is warranted.

Keywords: Cough peak flow; Dysphagia; Expiratory muscle strength training; Maximum expiratory pressure; Myotonic dystrophy type 1.

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### **Research Article**

### Voluntary Cough Effectiveness and Airway Clearance in Neurodegenerative Disease

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### **ABSTRACT**

**Purpose:** Voluntary cough dysfunction is highly prevalent across multiple pa-tient populations. Voluntary cough has been utilized as a screening tool for swallowing safety deficits and as a target for compensatory and exercise-based dysphagia management. However, it remains unclear whether voluntary cough dysfunction is associated with the ability to effectively clear the airway.

**Method:** Individuals with neurodegenerative disorders performed sameday voluntary cough testing and flexible endoscopic evaluations of swallowing (FEES). Participants who were cued to cough after exhibiting penetration to the vocal folds and/or aspiration with thin liquids during FEES met inclusion criteria. One-hundred and twenty-three trials were blinded, and the amount of residue before and after a cued cough on FEES was measured with a visual analog scale. Linear and binomial mixed-effects models examined the relationship between cough air-flow during voluntary cough testing and the proportion of residue expelled.

**Results:** Peak expiratory flow rate (p = .004) and cough expired volume from the entire epoch (p = .029) were significantly associated with the proportion of aspiration expelled from the subglottis. Peak expiratory flow rate values of 3.00 L/s, 3.50 L/s, and 5.30 L/s provided high predicted probabilities that  $\geq 25\%$ ,  $\geq 50\%$ , and  $\geq 80\%$  aspirate was expelled. Accounting for depth of aspiration significantly improved model fit (p < .001).

**Conclusions:** These findings suggest that voluntary cough airflow is associated with cough effectiveness to clear aspiration from the subglottis, although aspira-tion amount and depth may play an important role in this relationship. These findings provide further support for the clinical utility of voluntary cough in the management of dysphagia.

Correspondence to James C. Borders: jcb2271@tc.columbia.edu. *Dis-closure:* The authors have declared that no competing financial or non-financial interests existed at the time of publication.

### RESEARCH ARTICLE

### Expiratory Muscle Strength Training for Therapy of Pharyngeal Dysphagia in Parkinson's Disease

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ABSTRACT: Background: Pharyngeal dysphagia in Parkinson's disease (PD) is a common and clinically relevant symptom associated with poor nutrition intake, reduced quality of life, and aspiration pneumonia. Despite this, effective behavioral treatment approaches are rare. Objective: The objective of this study was to verify if 4 week of expiratory muscle strength training can improve pharyngeal dysphagia in the short and long term and is able to induce neuroplastic changes in cortical swallowing processing. Methods: In this double-blind, randomized, controlled trial, 50 patients with hypokinetic pharyngeal dysphagia, as confirmed by flexible endoscopic evaluation of swallowing, performed a 4-week expiratory muscle strength training. Twenty-five participants used a calibrated ("active") device, 25 used a sham handheld device. Swallowing function was evaluated directly before and after the training period, as well as after a period of 3 month using flexible endoscopic evaluation of swallowing. Swallowing-related cortical activation was measured in 22 participants (active: sham; 11:11) using whole-head magnetencephalography.

Results: The active group showed significant improvement in the flexible endoscopic evaluation of swallowing–based dysphagia score after 4 weeks and after 3 months, whereas in the sham group no significant changes from baseline were observed. Especially, clear reduction in pharyngeal residues was found. Regarding the cortical swallowing network before and after training, no statistically significant differences were found by magnetencephalography examination.

**Conclusions:** Four-week expiratory muscle strength training significantly reduces overall dysphagia severity in PD patients, with a sustained effect after 3 months compared with sham training. This was mainly achieved by improving swallowing efficiency. The treatment effect is probably caused by peripheral mechanisms, as no changes in the corti-cal swallowing network were identified.

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Key Words: Parkinson's disease; FEES; oropharyngeal dysphagia; swallowing therapy; rehabilitation

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<sup>†</sup>The first 2 authors contributed equally to this work.

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### **ORIGINAL ARTICLE**



### Expiratory Muscle Strength Training for Drooling in Adults with Parkinson's Disease

Naomi Cocks<sup>1,2</sup> Jonathan Rafols<sup>3</sup> Elizabeth Embley<sup>3</sup> Kylie Hill<sup>1</sup>

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### **Abstract**

One of the most debilitating symptoms of advanced Parkinson's disease is drooling. Currently, the main treatment that is offered for drooling is botulinum toxin injections to the saliva glands which have a number of side effects and do not treat the causes of drooling, such as impaired swallowing and lip closure. This study explored the effect of an alternative therapy approach for drooling that aimed at improving the swallow, expiratory muscle strength training (EMST). Sixteen participants received EMST over a 6- to 8-week period. Measurements were taken pre- and post-training for drooling (Sialorrhea Clinical Scale for Parkinson's Disease; SCS-PD), swallowing, lip strength and peak cough flow. Measures of drooling, swallow-ing and peak cough flow were stable over pre-training assessments and improved following training (p < 0.01). The most conservative estimate of the within-group change for SCS-PD was -2.50 (95% confidence interval -3.22 to -1.22). No adverse effects were reported and participants gave high satisfaction ratings for the training. A programme of EMST offers promise as a therapy to reduce drooling for people with Parkinson's disease. Adequately powered randomised controlled trials of EMST are now needed.

**Keywords** Parkinson's disease · Drooling · Therapy

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### **GUIDELINES**

### Diagnosis and treatment of neurogenic dysphagia – S1 guideline of the German Society of Neurology

Rainer Dziewas<sup>1,2\*</sup>, Hans-Dieter Allescher<sup>3</sup>, Ilia Aroyo<sup>4</sup>, Gudrun Bartolome<sup>5</sup>, Ulrike Beilenhoff<sup>6</sup>, Jörg Bohlender<sup>7</sup>, Helga Breitbach-Snowdon<sup>8</sup>, Klemens Fheodoroff<sup>9</sup>, Jörg Glahn<sup>10</sup>, Hans-Jürgen Heppner<sup>11</sup>, Karl Hörmann<sup>12</sup>, Christian Ledl<sup>13</sup>, Christoph Lücking<sup>14</sup>, Peter Pokieser<sup>15</sup>, Joerg C. Schefold<sup>16</sup>, Heidrun Schröter-Morasch<sup>17</sup>, Kathi Schweikert<sup>18</sup>, Roland Sparing<sup>19</sup>, Michaela Trapl-Grundschober<sup>20</sup>, Claus Wallesch<sup>21</sup>, Tobias Warnecke<sup>1</sup>, Cornelius J. Werner<sup>22</sup>, Johannes Weßling<sup>23</sup>, Rainer Wirth<sup>24</sup> and Christina Pflug<sup>25</sup>

### **Abstract**

**Introduction:** Neurogenic dysphagia defines swallowing disorders caused by diseases of the central and peripheral nervous system, neuromuscular transmission, or muscles. Neurogenic dysphagia is one of the most common and at the same time most dangerous symptoms of many neurological diseases. Its most important sequelae include aspiration pneumonia, malnutrition and dehydration, and affected patients more often require long-term care and are exposed to an increased mortality. Based on a systematic pubmed research of related original papers, review articles, international guidelines and surveys about the diagnostics and treatment of neurogenic dysphagia, a consensus process was initiated, which included dysphagia experts from 27 medical societies.

**Recommendations:** This guideline consists of 53 recommendations covering in its first part the whole diagnostic spectrum from the dysphagia specific medical history, initial dysphagia screening and clinical assessment, to more refined instrumental procedures, such as flexible endoscopic evaluation of swallowing, the videofluoroscopic swallowing study and high-resolution manometry. In addition, specific clinical scenarios are captured, among others the management of patients with nasogastric and tracheotomy tubes. The second part of this guideline is dedicated to the treatment of neurogenic dysphagia. Apart from dietary interventions and behavioral swallowing treatment, interventions to improve oral hygiene, pharmacological treatment options, different modalities of neurostimulation as well as minimally invasive and surgical therapies are dealt with.

**Conclusions:** The diagnosis and treatment of neurogenic dysphagia is challenging and requires a joined effort of different medical professions. While the evidence supporting the implementation of dysphagia screening is rather convincing, further trials are needed to improve the quality of evidence for more refined methods of dysphagia diagnostics and, in particular, the different treatment options of neurogenic dysphagia.

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### Respiratory muscle training increases respiratory muscle strength and reduces respiratory complications after stroke: a systematic review

Kênia Kp Menezes <sup>1</sup>, Lucas R Nascimento <sup>1</sup>, Louise Ada <sup>2</sup>, Janaine C Polese <sup>1</sup>, <u>Patrick R</u> Avelino <sup>1</sup>, Luci F Teixeira-Salmela <sup>1</sup>PMID: 27320833DOI: 10.1016/j.jphys.2016.05.014

### **Abstract**

**Question:** After stroke, does respiratory muscle training increase respiratory muscle strength and/or endurance? Are any benefits carried over to activity and/or participation? Does it reduce respiratory complications?

**Design:** Systematic review of randomised or quasi-randomised trials.

Participants: Adults with respiratory muscle weakness following stroke.

**Intervention:** Respiratory muscle training aimed at increasing inspiratory and/or expiratory muscle strength.

**Outcome measures:** Five outcomes were of interest: respiratory muscle strength, respiratory muscle endurance, activity, participation and respiratory complications.

**Results:** Five trials involving 263 participants were included. The mean PEDro score was 6.4 (range 3 to 8), showing moderate methodological quality. Random-effects meta-analyses showed that respiratory muscle training increased maximal inspiratory pressure by 7 cmH2O (95% CI 1 to 14) and maximal expiratory pressure by 13 cmH2O (95% CI 1 to 25); it also decreased the risk of respiratory complications (RR 0.38, 95% CI 0.15 to 0.96) compared with no/sham respiratory intervention. Whether these effects carry over to activity and participation remains uncertain.

**Conclusion:** This systematic review provided evidence that respiratory muscle training is effective after stroke. Meta-analyses based on five trials indicated that 30minutes of respiratory muscle training, five times per week, for 5 weeks can be expected to increase respiratory muscle strength in very weak individuals after stroke. In addition, respiratory muscle training is expected to reduce the risk of respiratory complications after stroke. Further studies are warranted to investigate whether the benefits are carried over to activity and participation.

**Registration:** PROSPERO (CRD42015020683). [Menezes KKP, Nascimento LR, Ada L, Polese JC, Avelino PR, Teixeira-Salmela LF (2016) Respiratory muscle training increases respiratory muscle strength and reduces respiratory complications after stroke: a systematic review. Journal of Physiotherapy62: 138-144].

**Keywords:** Physical therapy; Respiratory muscle training; Strength; Stroke; Systematic review.

### Journal of Oral Rehabilitation

Journal of Oral Rehabilitation 43; 364-372

# Effects of expiratory muscle strength training on oropharyngeal dysphagia in subacute stroke patients: a randomised controlled trial

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SUMMARY Expiratory muscle strength training (EMST) involves forcible blowing as a means of generating high expiratory pressure, against adjustable resistance. EMST has recently been introduced potential treatment as а This study was performed to dysphagia. investigate the effects of EMST on the activity of suprahyoid muscles, aspiration and dietary stages in stroke patients with dysphagia. Twenty-seven stroke patients with dysphagia were randomly divided into two groups. The experimental group performed EMST with a 70% threshold value of maximal expiratory pressure, using an EMST device, 5 days a week for 4 weeks. The placebo group trained with a sham device. The EMST regime involved 5 sets of 5 breaths through the EMST device for a total of 25 breaths per day. Activity in the suprahyoid muscle group was measured using surface electromyography (sEMG). Further, penetration-aspiration scale (PAS) was used to assess the results of the videofluoroscopic swallowing study (VFSS).

In addition, dietary stages were evaluated using the Functional Oral Intake Scale (FOIS). The experimental group exhibited improved suprahyoid muscle group activity and PAS results, when compared to the placebo group. Following intervention, statistical analysis indicated significant differences in measured suprahyoid muscle activity (P = 0.01), liquid PAS outcomes (P = 0.03) and FOIS results (P= 0.06), but not semisolid type PAS outcomes (P = 0.32), between the groups. This study confirms EMST as an effective treatment for the development of suprahyoid muscle activity in stroke patients with dysphagia.

Additionally, improvements in aspiration and penetration outcomes were observed.

KEYWORDS: aspiration, dysphagia, expiratory muscle strength training, stroke, suprahyoid muscles

Accepted for publication 31 December 2015



### **Journal of Preventive Medicine & Healthcare**

### **Review Article**

# Expiratory Muscle Strength Training for Dysphagia in Chronic Obstructive Pulmonary Disease: A Meta-analysis and Systematic Review

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#### **Keywords**

- Swallowing (
  - COPD
- Meta-analysis
- Dysphagia
- Respiratory muscle strength training

### **Abstract**

**Background**: Chronic obstructive pulmonary disorder (COPD) negatively impacts respiratory function which may lead to breathing disorders (dyspnea) and swallow disorders (dysphagia). Device driven expiratory muscle strength training (EMST) programs improves these disorders in patients with a variety of diseases.

**Purpose**: A systematic and meta-analytic review was conducted to determine the feasibility of EMST as a treatment of dysphagia for COPD patients. The following three areas of research were reviewed: (1) Studies comparing swallow function in patients with COPD compared to healthy controls. (2) Studies examining the efficacy of EMST with a device as a treatment for dyspnea in patients with COPD. (3) Studies examining the efficacy of EMST with a device as a dysphagia treatment in patients with peripheral and central nervous system disorders.

**Method(s)**: Literature searches of electronic databases were conducted between August 2015 to February 2016. Two independent investigators assessed the studies based on inclusion criteria and study quality.

**Result(s)**: A moderate effect size revealed that patients with COPD have impaired swallow function compared to the healthy controls. A moderate effect size revealed that patients with COPD using EMST with a device had greater improvement in lung function compared to patients with COPD in a control group. An effect size of 1.39 revealed that the participants using an EMST device showed greater improvement in swallow function compared to a control group.

**Conclusion**: The results support EMST as a dysphagia treatment for patients with COPD. Higher levels of evidence-based research within this area is needed.

Abbreviations: COPD: Chronic Obstructive Pulmonary Disorder; EMST: Expiratory Muscle Strength Training; IMST: Inspiratory Muscle Strength Training; RCT: Randomized Control Trials

### **ORIGINAL ARTICLE**



### Using Ultrasound to Document the Effects of Expiratory Muscle Strength Training (EMST) on the Geniohyoid Muscle

Barbara R. Pauloski<sup>1</sup> · Kacey M. Yahnke<sup>1,2,3</sup>

Received: 6 February 2021 / Accepted: 8 June 2021 / Published online: 16 June 2021 © The Author(s), under exclusive licence to Springer Science+Business Media, LLC, part of Springer Nature 2021

### **Abstract**

Expiratory muscle strength training (EMST) is an exercise program designed to strengthen the muscles of expiration by increasing expiratory load during breathing exercises using either resistive or pressure threshold devices. Previous research has shown that EMST may increase submental suprahyoid muscle activity as measured with surface electromyography. The impact of EMST on submental muscles is of interest to those who treat dysphagia. The purpose of this study was to determine whether the cross-sectional area of the geniohyoid muscle changes as observed with ultrasound during a 5-week EMST program performed at 75% of maximum expiratory strength using the EMST150 device in healthy adults. Ten healthy adults participated in the 5-week program. Maximum expiratory pressure (MEP) and cross-sectional area of the geniohyoid muscle were measured weekly. Geniohyoid crosssectional area was measured from ultrasound images recorded in the coro-nal plane. Repeated Measures ANOVA was used to determine whether there were significant changes among the dependent variables over the study period. Both MEP and geniohyoid area increased significantly in response to a 5-week program of EMST. EMST in healthy adults is effective at strengthening the geniohyoid muscle as reflected by significantly increased cross-sectional area measured with B-mode ultrasound. This is the first study to document weekly change in muscle mor-phology as a result of EMST. Increasing geniohyoid muscle mass and consequent strength through a program of EMST may be beneficial for persons with pharyngeal stage dysphagia resulting from reduced hyolaryngeal elevation, reduced laryngeal closure, or reduced UES opening.

**Keywords** Expiratory muscle strength training  $\cdot$  Geniohyoid  $\cdot$  Maximum expiratory pressure  $\cdot$  Healthy adults  $\cdot$  Ultrasound  $\cdot$  Deglutition  $\cdot$  Deglutition disorders

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### Effects of vocal exercises on the treatment of dysphagia: integrative review

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### **ABSTRACT**

Purpose: To verify the available evidence on the effect of vocal exercises on the treatment of dysphagia.

**Research strategy:** A bibliographic survey was carried out in the PubMed, LILACS, SciELO and MEDLINE databases, with no restrictions on the publication period.

**Selection criteria:** Original articles, case studies and/or literature reviews published in Portuguese and/or English, available electronically in full and addressing clinical treatment with vocal exercises in adults and elderly with dysphagia. Publications repeated by the databases, with a population of children, individuals who did not present the diagnosis of dysphagia, with vocal exercises without specification, with exclusive swallowing exercises, articles and/or abstracts without the possibility of access by institutional platforms, and studies with animal model were excluded.

**Results**: A total of 2,356 articles were found, of which, after the eligibility criteria were applied, 08 were selected for the final sample. To evaluate the effects of vocal exercises, the studies used clinical evaluation, videofluoroscopy, videoendoscopy and electromyography. Regarding the effects of vocal exercises on swallowing, it was observed that the techniques of plosive sound, buoyancy, semi-occluded vocal tract, basal sound, vocal modulation, overarticulation, the Lee Silverman Voice Treatment method® and the use of expiratory muscle strength training exercises showed positive effects in the rehabilitation of dysphagia.

**Conclusion**: It was observed that studies with expiratory muscle strength training (EMST), Lee Silverman method (LSVT<sup>®</sup>) and traditional vocal exercises demonstrated positive effects in the treatment of dysphagia. However, it has not yet been possible to prove the level of evidence in all studies.

Study carried out at Universidade Federal de Pernambuco – UFPE – Recife (PE), Brasil.

Conflict of interests: No

Authors' contribution: ATLQ and FGB were responsible for collection, analysis, interpretation of data and article writing; TLS and CRX were responsible for analysis and interpretation of data, writing and review of the article; AOCG was responsible for conception, study design, analysis and interpretation of data, writing and review of the article

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### The effects of COVID-19 on respiratory muscle performance: making the case for respiratory muscle testing and training

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SARS-CoV-2 infection itself may cause damage to the respiratory muscles and may contribute to the acute and persistent dyspnoea in patients with COVID-19. Respiratory muscle testing and training appears to be important for patients with COVID-19. https://bit.ly/3vxwKGG

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### **Abstract**

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syndrome (SARS-CoV-2) Severe respiratory coronavirus 2 acute multiorgan infection results in damage primarily mediated by viral infiltration via angiotensin-converting enzyme-2 receptors on the surface of cells. A primary symptom for many patients is exertional dyspnoea which may persist even beyond recovery from the viral infection. Respiratory muscle (RM) performance was hypothesised severity of coronavirus contributing factor to the 2019 such as dyspnoea, and outcomes. This was (COVID-19) symptoms, attributed to similarities between patient populations at elevated risk for severe COVID-19 symptoms and those with a greater likelihood of baseline RM weakness and the effects of prolonged mechanical ventilation. More recent evidence suggests that SARS-CoV-2 infection itself may cause damage to the RM, and many patients who have recovered report persistent despite having mild cases. normal lung undamaged lung parenchyma. These more recent findings suggest that the role of RM in the persistent dyspnoea due to COVID-19 may be more substantial than originally hypothesised. Therefore, screening for RM weakness and providing interventions to improve RM performance appears to be important for patients with COVID-19. This article will review the impact of SARS-CoV-2 infection **RM** performance on clinical recommendations for screening RM performance and provide treatment interventions.





## Aspiration and swallowing in Parkinson disease and rehabilitation with EMST

A randomized trial



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### **ABSTRACT**

Objective: Dysphagia is the main cause of aspiration pneumonia and death in Parkinson disease (PD) with no established restorative behavioral treatment to date. Reduced swallow safety may be related to decreased elevation and excursion of the hyolaryngeal complex. Increased submen-tal muscle force generation has been associated with expiratory muscle strength training (EMST) and subsequent increases in hyolaryngeal complex movement provide a strong rationale for its use as a dysphagia treatment. The current study's objective was to test the treatment outcome of a 4-week device-driven EMST program on swallow safety and define the physiologic mechanisms through measures of swallow timing and hyoid displacement.

Methods: This was a randomized, blinded, sham-controlled EMST trial performed at an academic center. Sixty participants with PD completed EMST, 4 weeks, 5 days per week, for 20 minutes per day, using a calibrated or sham, handheld device. Measures of swallow function including judgments of swallow safety (penetration–aspiration [PA] scale scores), swallow timing, and hyoid movement were made from videofluoroscopic images.

Results: No pretreatment group differences existed. The active treatment (EMST) group demon-strated improved swallow safety compared to the sham group as evidenced by improved PA scores. The EMST group demonstrated improvement of hyolaryngeal function during swallowing, findings not evident for the sham group.

Conclusions: EMST may be a restorative treatment for dysphagia in those with PD. The mecha-nism may be explained by improved hyolaryngeal complex movement.

Classification of evidence: This intervention study provides Class I evidence that swallow safety as defined by PA score improved post EMST. Neurology® 2010;75:1912–1919

### **GLOSSARY**

**CI** = confidence interval; **EMST** = expiratory muscle strength training; **MEP** = maximum expiratory pressure; **PA** = penetration-aspiration; **PD** = Parkinson disease; **SWAL-QOL** = Swallowing Quality of Life Questionnaire; **UES** = upper esophageal sphincter; **UF** = University of Florida Movement Disorders Center; **VA** = Veterans Affairs.

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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.

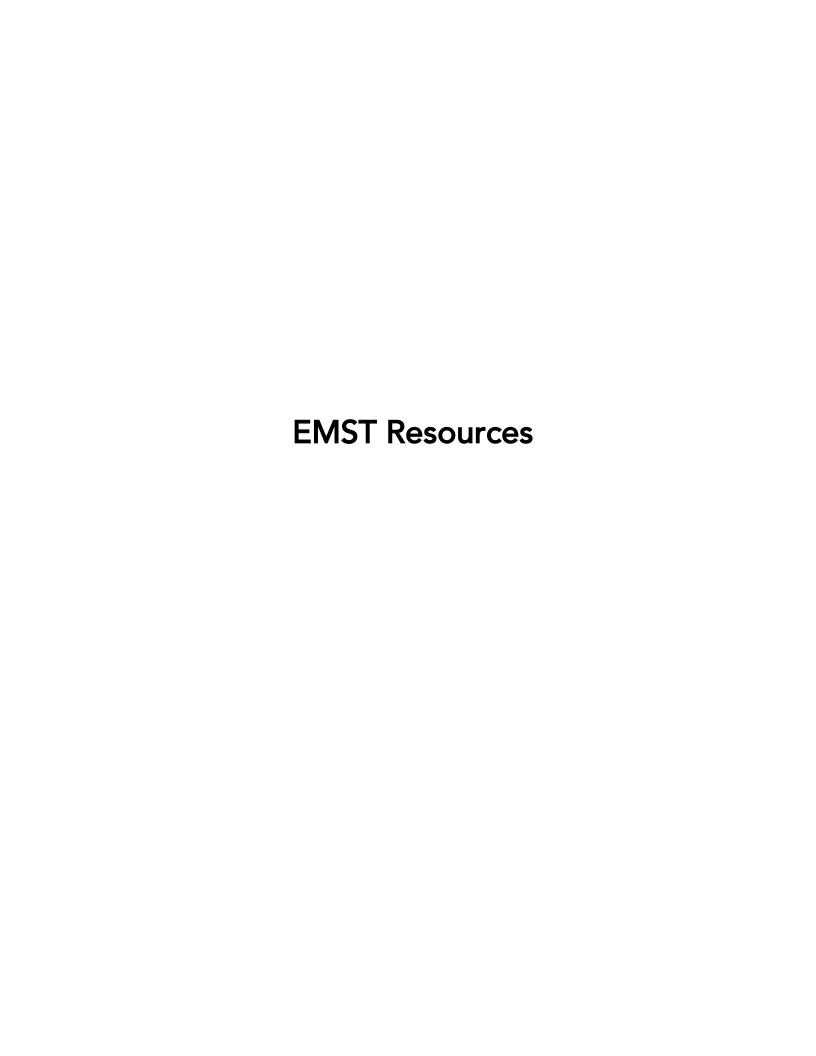
**Results:** Nine participants completed the full study protocol. Compliance to the training program was high. All were able to perform the training, although it requires adjustments of the device and skills of the participants. Maximum expiratory pressure (MEP) and vocal functioning in loudness improved 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





### PRODUCT INFORMATION



The EMST150<sup>TM</sup> is an innovative handheld device that has been scientifically tested for its ability to improve muscle strength. The EMST150 was designed by a team of researchers who understood the impact that muscle weakness can have on a person's overall health. The EMST 150 team recognized that increasing exhaled strength could improve basic breathing related functions such as cough, swallow and speech. The most exciting results to date have been through working with the elderly and individuals suffering from neurological disorders. In clinical trial after trial, the EMST150 produced significant improvements in both healthy individuals and persons with Parkinson's, multiple sclerosis, and other types of neuromuscular disease. We've also found that therapists could use the device with these of patients to strengthen weakened muscles improving breathing, cough, swallowing and speech. And because the EMST150 is is calibrated, therapists can measure and document progress.



The EMST75™ is a positive expiratory pressure (PEP) medical device with a lower pressure range from 0cmH20 - 75cmH20. The EMST75™ is indicated and prescribed for individuals with neuromuscular diseases with progressive respiratory muscle weakness such as ALS, Parkinson's, and Multiple Sclerosis; patients with chronic obstructive pulmonary disease (COPD); head and neck cancer; stroke; spinal cord injuries; and other conditions that lead to abnormal airway clearance and weakened cough production. PEP therapy has been shown to be medically beneficial for strengthening and opening airways in the lungs and assisting with secretion clearance.



The IA150<sup>™</sup> was created to reverse the airflow of BOTH the EMST150 and the EMST75 devices. With the addition of the IA150, you can now also train inspiratory muscles, the muscles used for breathing in, while maintaining the pressure-thresholds found only with the EMST150<sup>™</sup>. Simply insert the device into the IA 150 and immediately create a dual purpose Inspiratory-expiratory device.

### **CONTACT INFORMATION**

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### Calibration of the EMST150<sup>™</sup> - finding the desired pressure

The EMST150<sup>™</sup> is a pressure-threshold handheld calibrated device that includes a one-way, spring-loaded valve with an adjustable external dial. The valve blocks the flow of air until enough pressure is produced. Once the targeted pressure is produced, the valve opens and air will flow through the device. **The dial allows adjusting the pressure amount in a range between 24 and 150 cmH<sup>2</sup>O.** The pressure-threshold load is based on the patient's maximum expiratory pressure (MEP) .

During training the pressure threshold device is adjusted incrementally to progressively increase the resistance (progressive overload). The expiratory force must be sufficient to open the spring-loaded valve and allow the air flow. If the expiratory force is inadequate, the valve will not open and no air will flow through the device. These mechanics may serve as a biofeedback during the use of the device. The "dose" of EMST is typically defined in terms of the number of repetitions per set, with 5 sets completed each day, 5 days per week with the pressure set at 75% of the patient's MEP and increased each week

### How to find the "number" on the device that corresponds to 75% of MEP

- 1, Set (move) the small screw on the knob to sit on (just above) the number 30. This is  $30 \text{cmH}^20$ . (See figure 1)
- 2, One full turn will take the pressure to 60cmH<sup>2</sup>0. The screw will be sitting on (just above) the number 60, (see figure 2)
- 3, Now, because the *tension is* increasing *with the pressure*, the number of full turns to increase +30cmH<sup>2</sup>0 increases as well. Keeping that in mind, One full turn from 60 will bring the pressure to 75cmH20 (the screw will sit halfway between 60 and 90).
- 4, The same principle applies between 90 and 120cmH<sup>2</sup>0. Two full turns are needed to increase the pressure 30cmH20. Then one full turn from 90 will bring the device to 105cmH20. A second full turn will get you to 120cmH<sup>2</sup>0.

### **WHAT THIS TRANSLATES TO:**

30 up to to 60 cmH 20 -->. 1/4 turn = 7.5 cmH 20 --> 1 full turn = 30 cmH 20 From 60 to 90 cmH 20 --> 1/4 turn = 3.75 cmH 20 --> 1 full turn = 15 cmH 20 From 90 to 120 cmH 20 --> 1/4 turn = 3.75 cmH 20 --> 1 full turn = 15 cmH 20 From 120 -150 ---> 1/4 turn is again = 7.5 cmH 20 --> 1 full turn = 30 cmH 20

Pressure (from-to)	1 full turn =	1/4 turn =
(30-60) cmH20	30 cmH20	7.5 cmH20
(60-90)cmH20	15 cmH20	3.75 cmH20
(90-120) cmH20	15 cmH20	3.75 cmH20
(120-150) cmH20	30 cmH20	7.5 cmH20

TIP: If you are looking for exact values, this table will help you. However, through discussions with clinicians utilizing the device, and well as with those doing research using the EMST150, and based on the average of the numbers in the table above, we have found that using the value of **6cmH20** to represent each **1/4 turn** is the easiest method, while achieving similar results.



Figure 1



Figure 2



### Calibration of the EMST75 - finding the desired pressure

The EMST75 Lite is a handheld calibrated device that includes a one-way, spring-loaded valve with an adjustable external dial. The valve blocks the flow of air until enough pressure is produced. Once the targeted pressure is produced, the valve opens and air begins to flow through the device. **The dial allows adjusting the pressure amount in a range between 0 and 75 cm H2O.** The pressure-threshold load is based on the patient's maximum expiratory pressure (MEP) which can be obtained using a pressure manometer.

<u>progressively increase the resistance (progressive overload</u>). The expiratory force must be sufficient to open the spring-loaded valve and allow the air flow. The pressure released valve requires a consistent flow of air to remain open. If the expiratory force is inadequate, the valve will not open and no air will flow through the device. These mechanics may serve as a biofeedback during the use of the device. The "dose" of EMST is typically defined in terms of the number of repetitions per set, with 5 sets completed each day, for 5 days per week with the device resistance set at 75% of the patient's MEP and progressed each week

### How to find the "number" on the device that corresponds to 75% of MEP

Turn the green knob so that the small screw on the knob sits on or just above the number 5. (See photo\*) This is 5cmH20. This is where you begin.

One full turn will increase the pressure to 15cmH20. The screw will be sitting on (just above) the number 15. One more full turn will take you to 25cmH20 (the screw will sit halfway between 15 and 35). One more full turn will bring you to 35cmH20.

As the pressure increases on the EMST75, the spring gets tighter and the pressure increases more per turn, Beginning at 35cmH20, one full turn will increase the pressure by 20 cmH20 to 55 cmH20, and one more full turn will take you to the max at 75 cmH20. (The final 2 full turns each represent 20cmH20).

### WHAT THIS TRANSLATES TO:

Between 5 cmH20 to to 35c mH20 ---->. 1/4 turn = 2.5 cmH20 ----> 1 full turn = 10 cmH20

From 35 to 75 cmH20----> 1 /4 turn = 5 cmH20---> 1 full turn = 20 cmH20

Pressure (from-to)	1 full turn =	1/4 turn =
(5-35) cmH20	10 cmH20	2.5 cmH20
(35-75) cmH20	20 cmH20	5 cmH20

\*\*\*IMPORTANT TIP FOR CLINICIANS: If you are looking for exact values, this table will help you. However, through discussions with clinicians utilizing the device and those doing research using the EMST75, coupled with the average of the numbers in the table above, we have found that using the value of 4cmH20 to represent each 1/4 turn is the easiest method for documenting patients' progress, while achieving similar results.



This screw is just to the left of 5cmH20. To begin, move it a to the right to sit on/above the 5. That is the starting point.





### **Precautions and Contraindications**

EMST150 - Respiratory muscle training (RMT) is drug free; suitable for almost anyone and should cause no harmful side effects when used properly. If you have any doubts about the EMST150's suitability, please consult your doctor or therapist.

Please read the following Precautions and Contraindications information to ensure that you use the EMST150 device safely and appropriately:

### **Precautions**

- To prevent the potential transmission of infections, we recommend that you do not share your EMST150 device with other users, including family members. We recommend that you clean the device once a month.
  - The EMST150 is designed for exercising your expiratory muscles.. No other use is intended or implied.
- While training with the EMST150 you should feel resistance, but it should not be painful. If you should feel pain while using any inspiratory or expiratory device, stop immediately and consult your doctor or therapist..

Additionally, the following conditions have been highlighted to advise you to seek guidance from your medical professional before use of an RMST device:

- A history of spontaneous pneumothorax Following a traumatic pneumothorax and/or broken rib, the EMST150 should not be used prior to full recovery.
- In a patient with any CSF drain in place (or need to monitor inter cranial pressure) obtain physician approval/order for EMST/IMST
- Recent facial, oral, neck, skull or chest surgery (including cardiac surgery)or trauma
- Epistaxis
- Esophageal surgery
- Active hemoptysis
- Lung transplant, Lung resection
- For use with tracheostomy patients, the trach cuff must be fully deflated with adequate secretion management; obtain physician order and approval For patients status post recent decanulation, the previous trach site should be completely closed/healed and physician order obtained

### Contraindications:

- Asthma patients who have low symptom perception and suffer from frequent severe exacerbations or with an abnormally low perception of dyspnoea.
- Patients suffering from a ruptured eardrum or any other condition of the ear.
- Patients who are or might be pregnant
- Patients with untreated and uncontrollable reflux
- Patients with untreated and uncontrollable hypertension
- Patients with abdominal hernia or recent abdominal surgery

\*\* For Healthcare professionals: Candidacy for expiratory training is best determined on a case by case basis. A good way to discuss this with the medical team is by using the Valsalva maneuver as an analogy for expiratory training. If Valsalva and generation of intrathoracic and/or intracranial pressures are contraindicated then expiratory training is as well. As always, clinical experience and acumen is of the highest value when using the EMST150 with patients. Always remember: If in doubt, always consult your doctor or therapist.

### Additional Studies, Articles, and Research







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