Article

The Safety and Efficacy of Expiratory Muscle Strength Training for Rehabilitation After Supracricoid Partial Laryngectomy: A Pilot Investigation

Annals of Otology, Rhinology & Laryngology
2019, Vol. 128(3) 169–176

DOI: 10.1177/0003489418812901
journals.sagepub.com/home/aor
SAGE

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Abstract

Objectives: Expiratory muscle strength training (EMST) is a safe, effective intervention that can be performed at home and may be beneficial for individuals with voice and swallowing disorders. To date there have been few studies of EMST in the head and neck cancer population, and there are no previous reports of its use after supracricoid partial laryngectomy (SCPL). The current prospective clinical pilot study was undertaken to determine the safety and efficacy of a 4-week treatment program.

Methods: Six participants were recruited who had previously undergone SCPL, were medically stable, and had no contraindications for use of the device. At baseline, objective respiratory measurements were collected, dietary status was recorded, and participants were asked to complete a series of validated self-report instruments relating to voice, swallowing, breathing, and cough. Following the completion of treatment, baseline measures were repeated, and participant feedback was solicited.

Results: The majority of individuals found the device easy to use (83%) and beneficial (83%). The side effects of treatment were relatively minor and included dizziness, muscle inflammation, and vocal fatigue. There were improvements in 2 measures from before to after treatment, namely, an average 21% increase in peak cough flow (from 371.67 to 451.33 L/min) and a 38% decrease on the Dyspnea Index (from 6.17 to 3.83). Other measures showed inconsistent changes.

Conclusions: EMST appeared to improve cough strength and reduce dyspnea symptoms after SCPL. Further study of the relative efficacy of EMST compared to other rehabilitation protocols after SCPL is needed.

Keywords

partial laryngectomy, dyspnea, cough, voice, swallowing, rehabilitation

Introduction

Supracricoid partial laryngectomy (SCPL) is a technique first developed in Europe that has gained widespread use as a surgical treatment for laryngeal cancer.[1,2] SCPL has been demonstrated to be an oncologically sound alternative to total laryngectomy in select patients and may also be used in patients as a salvage procedure after radiation therapy.[3-5] Postoperatively, the majority of patients are decannulated and do not require a feeding tube.[6] Compared with total laryngectomy, SCPL avoids the need for a permanent tracheostoma, and because voicing is achieved using the patient's native anatomy, the procedure also avoids the need for an alternative vibratory sound source for verbal communication. However, even after extensive rehabilitation, many individuals have long-term symptoms of dysphagia and dysphonia.[7-11] Despite numerous published reports of functional outcomes, there is little consensus regarding the timing or optimal standard of care postoperatively,[6] and very few studies have systematically examined the potential benefit of newer rehabilitative techniques.

Recent studies have shown that expiratory muscle strength training (EMST) is a safe, effective intervention that can be performed at home by individuals with voice and swallowing symptoms using a simple, inexpensive device.[12] During EMST, patients are trained to forcefully

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Figure 1. Expiratory muscle strength training device.

expire through device containing a 1-way spring-loaded valve (Figure 1). The adjustable valve blocks airflow until sufficient expiratory pressure is achieved, which opens the valve and allows air to pass through it. Valve adjustments are calibrated to varying levels of maximum expiratory pressure (MEP), allowing the airflow resistance to be adjusted to a suitable level for the individual, which can then be gradually increased over time. Preliminary data suggest that EMST may benefit individuals with a variety of neurologic etiologies resulting in dysphagia[13-16] and dysphonia.[17] To date, however, there is little information about the efficacy of this intervention in the head and neck cancer (HNC) population. The objectives of the present study were as follows:

- to determine feasibility and tolerance for successful completion of a 4-week EMST program in individuals who have undergone SCPL;
- to explore the potential benefit of EMST for improving respiratory muscle and cough strength, as well as subjective symptoms of voice, swallowing, dyspnea, and cough; and
- to explore participant perspectives on using the EMST device.

Methods

Patients were recruited in Oregon Health and Science University's Department of Otolaryngology–Head & Neck Surgery after institutional review board approval. All participants met the following criteria: having undergone SCPL at Oregon Health and Science University, being currently cancer free and medically stable, being at least 1 month after decannulation and having a healed tracheostoma, no longer requiring tube feedings, not having an upper respiratory infection or intubation in the past 30 days, having adequate cognition for participation as identified by scores on Short Portable Mental Status Questionnaire,[18] not currently or likely to become pregnant, and having no ear conditions that would interfere with use of the device. Authorization was requested from a treating physician if a participant had any of the following: high blood pressure or a cardiac condition, any pulmonary or respiratory condition (eg, asthma, chronic obstructive pulmonary disease, emphysema, and gastroesophageal reflux disease). In addition, the head and neck surgeon who had performed SCPL in all participants (J.S.) provided approval prior to enrollment.

Descriptive Characteristics

Medical and surgical information was collected from the electronic medical record. Baseline dietary status was assessed using the Functional Oral Intake Scale,[19] a 7-point clinician-rated scale developed for use with patients with dysphagia. Baseline frailty was assessed using the Reported Edmonton Frailty Scale,[20] a self-reported measure that has been shown to be valid in comparison with various other measures of health and functional status.

Objective Respiratory Measures

Baseline MEP was measured prior to training. Each participant's nose was occluded with a nose clip during testing. MEP measurements were completed using the MicroRPM pressure meter (Becton, Dickinson and Company, Franklin Lakes, New Jersey, USA) coupled to a flanged mouthpiece. Participants were instructed to inhale as deeply as possible and blow into the manometer tube quickly and forcefully. Verbal encouragement was provided to ensure maximal effort during the task. The average of 3 values was used to set the participant's resistance level on the EMST device for the subsequent training. Maximum inspiratory pressure (MIP) was assessed using the same protocol across 3 trials but with the instruction to inhale through the manometer tube quickly and forcefully, following maximal exhalation. Peak cough flow (PCF) was assessed using a disposable peak flow meter (TruZone; Monaghan Medical Corporation, Syracuse, New York, USA) with a measurement range of 60 to 800 L/min. Participants were seated upright in a comfortable position

and then instructed to "take a maximal deep breath and cough once as hard as you can." Data for 3 single volitional coughs were collected with a 1-minute rest period between each.

Participant Self-Reported Measures

Four validated surveys were used to assess patient-rated symptoms, including the Eating Assessment Tool,[21] a 10-item measure of dysphagia validated in individuals with swallowing disorders; the Voice-Related Quality of Life instrument,[22] a 10-item self-administered questionnaire that evaluates the impact of a voice disorder on day-to-day activities; the Cough Severity Index,[23] a 10-item self-reported measure of symptoms of chronic cough that has been shown to be valid, reliable, and suitable for clinical measurement of outcomes; and, the Dyspnea Index,[24] a 10-item instrument with good reliability and validity designed to quantify symptoms of upper airway dyspnea that can also be used to measure treatment outcomes.

EMST Study Protocol: Feasibility, Safety, and Adherence

During the initial appointment, blood pressure and oxygen saturation were monitored to ensure the safety of the protocol. The EMST program was then initiated using the EMST 150 (Aspire Products, Atlanta, Georgia, USA). The device is available for home use in the United States without a prescription and can be used independent of supervision. The treatment protocol was consistent with that used in previous research.[15] Participants were instructed to put on a nose clip, take a deep breath, hold their cheeks lightly to reduce labial leakage, blow as hard as they could into the device, and identify that air was flowing freely through the device once they reached threshold pressure (Figure 2). Each participant was instructed on a home exercise plan that included completing 5 sets of 5 repetitions 5 days out of the week. Because of the geographic distance of the participants from our facility, weekly face-to-face follow-up visits were not completed. However, weekly phone follow-up was conducted to ensure compliance with the protocol and also to ascertain any problems or symptoms experienced. Medical records were reviewed for adverse events, and adherence was self-reported using a weekly tracking form.

Posttreatment Assessment

The participants were instructed to return for reassessment at the end of the 4-week program. At that time, MIP, MEP, and PCF were reassessed. In addition, the 4 self-report surveys were readministered, the clinician reassigned a value for the Functional Oral Intake Scale on the basis of patient report, and the participants were interviewed about their experiences with the treatment protocol.

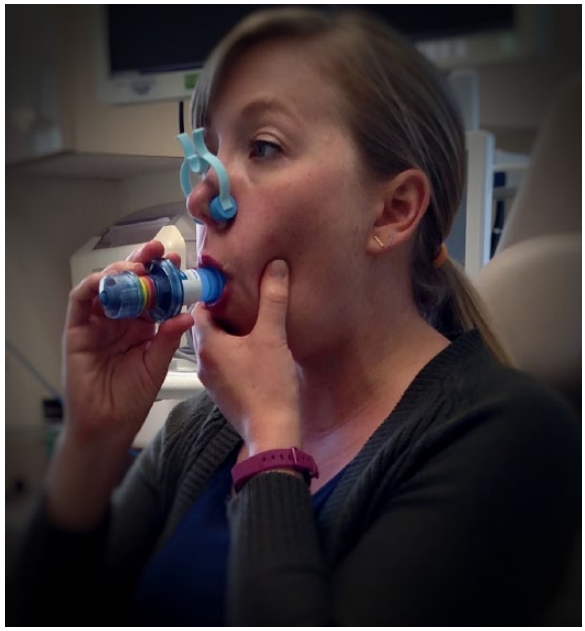

Figure 2. Demonstration of the expiratory muscle strength training device in use.

Statistical Analysis

Participant characteristics, compliance data, and responses to interview questions and responses to self-report tools were summarized descriptively. The Wilcoxon signed rank test was used to compare changes in pre- to posttreatment scores using SPSS version 24 (IBM, Armonk, New York, USA). Because of the exploratory nature of this study and the small sample size, an α level of $P < .10$ was selected to minimize the likelihood of failing to identify clinically significant differences (ie, to minimize the type II error rate),[25] as in similar kinds of clinical pilot studies.[26]

Results

Patient Characteristics

A total of 6 individuals were enrolled in the 4-week program. All participants had undergone SCPL and had 1 arytenoid remaining after cricohyoidoepiglottopexy (n = 5) or cricohyoidopexy (n = 1). Individual characteristics for all participants are shown in Table 1. As indicated by scores on the Functional Oral Intake Scale, all participants were on an oral diet, and only 1 individual had specific food limitations (participant 1 was limiting her intake of thin liquids). On the basis of their scores on the Reported Edmonton Frailty Scale, all participants were classified as "not frail."

Table 1. Participant Characteristics.

Patient	Sex	Age (y)	Tumor Stage	SCPL Type	Months Postoperative	Prior RT	Baseline Diet (FOIS)	Baseline Frailty (REFS)
1	F	67	T2N0M0	CHEP	3	Yes	6	4
2	M	60	rT2N0M0	CHEP	8	Yes	7	4
3	M	67	T3N0M0	CHP	30	No	7	0
4	M	58	rT2N0M0	CHEP	4	Yes	7	2
5	M	67	T1aN0M0	CHEP	5	Yes	7	5
6	M	47	T2N0M0	CHEP	18	No	7	1

Abbreviations: CHEP, cricohyoidoepiglottopexy; CHP, cricohyoidopexy; FOIS, Functional Oral Intake Scale; REFS, Reported Edmonton Frailty Scale; RT, radiotherapy; SCPL, supracricoid partial laryngectomy.

Table 2. Comparison of Pre- and Posttreatment Scores on Objective Respiratory Measures.[a]

	MEP (cm H_2O)		MIP (cm H_2O)		PCF (L/min)	
Patient	Pre	Post	Pre	Post	Pre	Post
1	139.33 ± 6.11	NA	82.33 ± 3.06	NA	256.67 ± 11.55	NA
2	146.33 ± 5.69	122.67 ± 10.02	62.67 ± 5.86	61.67 ± 5.69	353.33 ± 50.33	435.00 ± 40.93
3	113.67 ± 3.51	108.00 ± 13.75	66.00 ± 8.89	43.33 ± 7.37	165.00 ± 32.79	188.33 ± 37.53
4	160.67 ± 10.26	201.67 ± 5.13	117.33 ± 1.53	136.33 ± 7.02	196.67 ± 50.33	386.67 ± 28.87
5	129.33 ± 13.50	152.67 ± 5.69	78.00 ± 6.08	82.67 ± 5.51	536.67 ± 158.22	596.67 ± 30.55
6	126.33 ± 0.58	205.00 ± 19.97	70.67 ± 2.52	70.00 ± 3.00	606.67 ± 20.82	650.00 ± 100.00

Abbreviations: MEP, maximum expiratory pressure; MIP, maximum inspiratory pressure; NA, not assessed; PCF, peak cough flow.
[a]Data are expressed as mean ± SD.

EMST Treatment and Compliance

During the initial training session, all participants were able to perform a complete set of the training exercise without significant difficulty. The initial training level of the device was set to 75% of the participant's average baseline MEP and ranged from 90 to 120 cm H_2O across the participants (mean 103 ± 14 cm H_2O). Participants experienced no significant complications during the study. Four participants had perfect compliance with the protocol (100%). Participant 1 did not complete the protocol as prescribed, because of time constraints due to preparations for moving out of state, and she did not return for posttreatment objective measures for this reason. She achieved only 60% compliance over the course of the study but did complete the study questionnaire and posttreatment interview by phone. Participant 6 initially had some difficulty integrating the use of the device with his work schedule and had below-average use during the first week but was able to complete the 5-5-5 protocol during weeks 2 to 4. His overall compliance was 85%.

Pre-Post Objective Respiratory Measures

Comparing the baseline measures for all participants with age- and sex-matched normative data, the baseline MEP and MIP values for all 6 participants were within a normal range.[27] Five of the 6 participants returned for posttreatment objective testing at the completion of treatment (Table 2). Overall, mean MEP increased from 135.3 ± 18.4 cm H_2O at baseline to 158.0 ± 44.4 cm H_2O at follow-up, which was not significant ($P = .35$). Because EMST does not target inspiration, MIP was not predicted to increase from baseline to follow-up, and this proved to be the case. Mean MIP was almost identical, from 78.9 ± 22.2 cm H_2O at baseline to 78.8 ± 35.2 cm H_2O at follow-up ($P = .89$). There was a significant increase in PCF from 371.7 ± 197.6 L/min at baseline to 451.3 ± 183.2 L/min at follow-up ($P = .04$). Mean pre- and posttreatment values for the 3 respiratory measures are displayed in Figure 3.

Pre-Post Participant Self-Reported Measures

On the 4 subjective scales, there was a considerable amount of variability (Table 3). Dysphagia score on the Eating Assessment Tool increased on average from 9.3 ± 7.2 at baseline to 11.2 ± 8.1 at follow-up, indicating a slight, although nonsignificant, worsening of subjective swallowing-related difficulties ($P = .34$). Similar findings were found for voice-related difficulties. Overall, the average Voice-Related Quality of Life score worsened slightly from 66.7 ± 16.6 before treatment to 63.8 ± 20.8 afterward ($P = .10$). Mean score for chronic cough-related symptoms on the Cough Severity Index improved slightly from 7.3 ± 5.7 before treatment to 6.7 ± 6.6 afterward, but this was nonsignificant ($P = .47$). Subjective perceptions of dyspnea on the Dyspnea Index improved from 6.2 ± 7.9 before

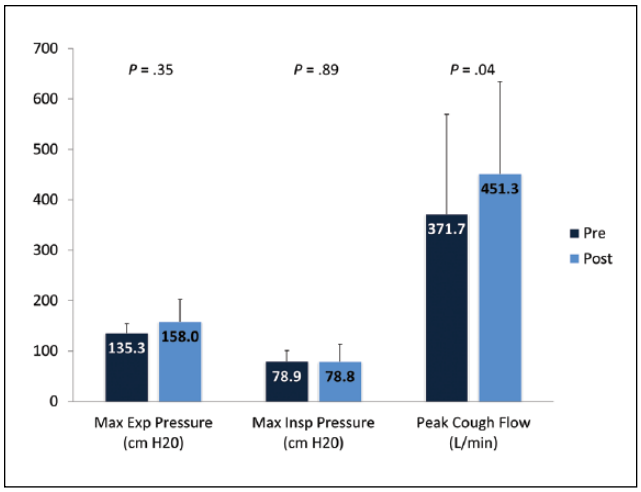

Figure 3. Objective respiratory measures before and after treatment.

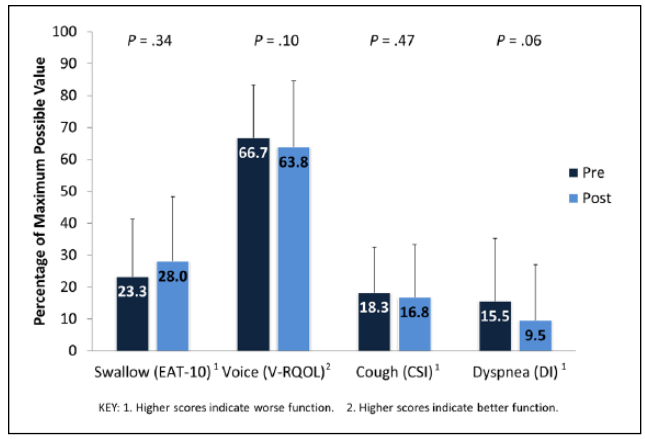

Figure 4. Self-rated quality-of-life scale scores before and after treatment. For ease of comparison, all scores have been converted to percentages of the maximum possible score.

Table 3. Comparison of Pre- and Posttreatment Scores on Self-Report Measures.

	EAT-10		V-RQOL		CSI		DI	
Patient	Pre	Post	Pre	Post	Pre	Post	Pre	Post
1	13	11	77.78	75.00	9	7	2	0
2	19	17	35.00	27.50	18	18	21	18
3	15	24	75.00	55.00	6	10	9	2
4	2	2	65.00	62.50	5	0	3	1
5	3	5	67.50	77.50	2	2	0	1
6	4	8	80.00	85.00	4	3	2	1

Abbreviations: CSI, Cough Severity Index; DI, Dyspnea Index; EAT-10, Eating Assessment Tool; V-RQOL, Voice-Related Quality of Life.

treatment to 3.8 ± 7.0 afterward, which was significant at our chosen α level ($P = .06$). Mean pre- and posttreatment values for the 4 subjective scales are displayed in Figure 4.

Posttreatment Participant Feedback

At follow-up participants were asked about their experiences with the treatment protocol (Table 4). Most individuals found the EMST device easy to use (83%) and considered the device training effective (83%). None of the participants had any recommendations for changes to the treatment protocol itself, and all of the participants found the weekly tracking log helpful. Two individuals reported that the greatest difficulty had been incorporating the treatment protocol into their daily schedule. Three individuals reported side effects from the treatment, namely, symptoms of dizziness and light-headedness initially that improved over time, an increase in dysphonia, and an area of muscular inflammation underneath the xiphoid process that developed during the final week of the protocol. The latter patient was examined by his physician (J.S.), who recommended temporary discontinuation of use of the device and a 2-week course of NSAIDs, and the swelling subsequently resolved. Most individuals (83%) found the treatment program beneficial. In terms of perceived benefits, 1 individual reported an improvement in swallowing, and 3 individuals mentioned improvements in breathing. Only 3 participants planned to continue using the device, however. With regard to the reasons for discontinuing the protocol, 1 individual cited a lack of improvement, and another reported that it was "slightly unpleasant" to use. With regard to why he planned to keep using the device, 1 participant reported "The device helped expand lungs and take deep breaths allowing me to cough up any small stuff." In terms of other feedback about the program, 2 participants reported that using it sooner following their surgery might have been easier to schedule or more beneficial.

Discussion

A number of studies have demonstrated promising results from the use of EMST in patients with dysphagia related to neurogenic pathologies, suggesting improvement in airway protection after use,[13-15] but to date, there is very little information about its efficacy in the HNC population. In a recent retrospective study by Hutcheson et al[28] of 23 patients with chronic aspiration after previous radiation treatment for HNC, there was a significant improvement in both MEP and subjective dysphagia scores after an 8-week program of EMST, and swallowing safety improved significantly on videofluoroscopy. The authors concluded that EMST may be a beneficial adjunct to the current standard of care to improve airway protection in chronic radiation-associated aspirators. As far as we aware, this is the first description of

Table 4. Responses to Yes/No Posttreatment Survey Questions.

Question	Yes	No	Maybe/Don't Know
Did you find the EMST device easy to use?	5	1	0
Was the training you received on how to use the device effective?	5	1	0
Would you suggest any changes to the home training protocol (5 repetitions, 5 days a week, over 4 weeks)?	0	6	0
Was the logbook helpful to track your exercises as you completed them?	6	0	0
Did you experience any negative effects from the EMST program?	3	3	0
Did you find this program to be generally beneficial?	5	1	0
Will you continue to use the EMST device?	3	2	1

Abbreviation: EMST, expiratory muscle strength training.

its use after SCPL and also the first prospective description of its use in any HNC group.

SCPL is a complex procedure typically performed at specialty cancer centers in carefully selected patients. As described previously,[29] the standard of care for rehabilitation after SCPL at our facility has many commonalities with that of other similar institutions.[7,30] Early, aggressive rehabilitation including patient education and a combination of compensatory and rehabilitative techniques has been shown to be effective.[30] Patients who receive postoperative rehabilitation are able to resume an oral diet without aspiration more quickly than those who do not.[31] In addition, the use of swallowing strategies taught during rehabilitation can reduce or eliminate aspiration more effectively than dietary modification alone.[7] Although there are many commonalities in previously published studies about the types of interventions typically used, there are also significant gaps, and it is far from clear as to the optimal nature, intensity, or timeline of rehabilitation.[6] To date, there have been relatively few studies of whether newer rehabilitative techniques might be benefit the SCPL population. Two recent studies, both from Brazil, examined the immediate effect of intensive vocal exercises to determine their potential as a rehabilitative technique.[32,33] These studies demonstrate that there is an interest in developing new rehabilitation protocols for this population.

There are a number of limitations to this pilot study, including the small and somewhat heterogeneous sample, the lack of weekly face-to-face follow-up visits over a 4-week period, and the lack objective measures of voice and swallowing. Nonetheless, in our investigation, it appeared that it was feasible for patients to complete a 4-week program of EMST after SCPL with minimal side effects. It had been predicted that objective measures of both cough (PCF) and expiration pressure (MEP) would increase significantly after treatment, but in fact, there was an improvement only in PCF. The reason for the lack of a significant change in MEP is unclear. One possibility is that the candidates for SCPL must have good pulmonary function at baseline in order to be able to tolerate some amount of aspiration during recovery. It is possible that this resulted in a "ceiling effect" for MEP and the Dyspnea Index. Most previous studies have examined the use of EMST in neurogenic populations that had below-average pulmonary function at baseline, likely because of involvement of the respiratory musculature. The mean baseline MEP for the patients in our study was in excess of the values reported in all of the previous intervention studies, including the study of patients with HNC with chronic radiation-induced aspiration.[13,14,16,28] In contrast, values for PCF were below normal at baseline but closer to the normal range following intervention.[34] This finding was also consistent with patient reports of subjective improvement in the efficacy of their voluntary cough after treatment, although there was less improvement in symptoms of "chronic" or involuntary cough as demonstrated by a nonsignificant reduction in Cough Severity Index scores.

It was disappointing that there were not greater improvements in subjective voice- and swallowing-related function, as we had hoped. A number of possible explanations are hypothesized. First, studies of voicing after SCPL have shown considerable variability in which structures are used to achieve phonation.[35] It is possible that these muscles may be more prone to fatigue during EMST, as demonstrated by reports of vocal fatigue and a general decline in Voice-Related Quality of Life score after treatment. Symptoms of vocal fatigue could be indicative of "overtraining" the musculature, which has the potential to be counterproductive.[36] Second, it is possible that our participants achieved less improvement than patients in previous studies because of another difference in their anatomy. Previous studies have reported improvements in laryngeal elevation after EMST, but one of the modifications after SCPL is to elevate the remaining laryngeal structures when performing the "pexy" in order to facilitate postoperative swallowing. It is possible that this may also explain the absence of self-reported swallowing improvement in our study patients. Third, recent physiologic data have suggested that EMST may have a greater impact on the musculature of the soft palate and the pharynx than on the laryngeal musculature,[37] which, if

correct, would suggest that EMST might be less beneficial after SCPL, as these muscles are generally intact. Finally, it is possible that there were improvements in voice and swallowing function that were not perceived by the participants and that objective measures would have been more sensitive in identifying them.

Conclusions

It was possible for patients to complete a 4-week treatment protocol of EMST after SCPL with minimal side effects. The primary benefits appeared to be related to respiration and cough, rather than voice and swallowing. These are not unimportant benefits, however, given the importance of these functions for pulmonary health in a population known to be at risk for aspiration. Further research is indicated into the potential utility of EMST after SCPL compared with other rehabilitation approaches.

Acknowledgments

EMST units were provided free of charge to study participants courtesy of Aspire Products. The manufacturer had no involvement whatsosever in the study design, recruitment of participants, implementation of the study protocol, or the analysis of the study findings.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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