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Efficacy of a novel swallowing exercise program for chronic dysphagia in long-term head and neck cancer survivors

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Abstract

Background: The efficacy of rehabilitative exercises for chronic dysphagia treatment in head and neck cancer survivors has not been studied extensively and is ambiguous.

Methods: A prospective clinical phase II study using an intensive strength training program was carried out in 17 head and neck cancer survivors with chronic dysphagia. Both swallow and nonswallow exercises were performed for 6–8 weeks with a newly developed tool allowing for progressive muscle overload, including chin tuck, jaw opening, and effortful swallow exercises. Outcome parameters were feasibility, compliance, and parameters for effect.

Results: Feasibility in terms of the program completion rate was 88%. Compliance with the exercises was 97%. After the training period, chin tuck, jaw opening, and anterior tongue strength had substantially improved. All but 1 patient reported to benefit from the exercises.

Conclusion: Feasibility and compliance were high. Some objective and subjective effects of progressive load on muscle strength and swallowing function could be demonstrated.

KEYWORDS

chin tuck, dysphagia, head and neck cancer, jaw opening, radiotherapy, rehabilitation, strength training

1 | INTRODUCTION

Dysphagia is a significant complication in patients treated with radiotherapy (RT) or concurrent chemoradiotherapy

(CRT) for advanced head and neck cancer. It may increase in severity over time, even years after treatment, as a result of progressive fibrosis and/or nonuse atrophy after radiation to the swallowing musculature and structures.^{1–8} Given its

associated morbidity and devastating impact on physical and emotional wellbeing, there is a great demand for targeted, evidence-based dysphagia management.^{9,10} Growing evidence supports the benefit of preventive swallowing therapy to reduce the incidence and severity of dysphagia after CRT, although not all studies demonstrate an effect depending on the chosen endpoints, and the reported effect sizes are generally small.^{11–17} Moreover, also posttreatment swallowing rehabilitation is potentially effective for reducing laryngeal penetration and/or aspiration in patients with chronic dysphagia.^{18–24}

Several swallowing interventions are applied for dysphagia, varying from compensatory techniques (eg, postural changes and diet/bolus modifications) to rehabilitative techniques that aim to strengthen the swallowing musculature. Rehabilitative techniques include swallowing maneuvers, such as the effortful swallow,^{25–27} and nonswallow exercises, such as tongue strengthening exercises and the Shaker (head-lift) exercise.^{18,28} Swallow exercises are used during the swallow with the aim to increase the success of the swallow itself by training the involved muscles.^{25,29} Nonswallow exercises aim to improve the range of motion and strength of the swallowing and neck musculature (ie, the tongue or suprahyoid musculature), whereas allowing patients to progress through a training protocol safely, without limitations that may be imposed during actual swallowing.²⁹

Typically, repetitive exercises are used based on methods applied in sports medicine.^{30–33} The exercises should be built on all principles (ie, specificity, individuality, and overload) that adhere to strength or endurance training.^{29,30,32–35} Swallowing is considered a submaximal muscular activity. This means that the muscular strength generated to successfully complete the swallowing act is less than the so-called 1-repetition maximum (1RM; ie, the maximal force that can be generated by the swallowing muscles in a single repetition).^{30,32} Consequently, most strength training regimens start with an initial resistance of 60%–75% of 1RM.^{19,31,36} To maximize improvements over time, the application of the progressive muscle overload principle during the exercise period has to be an essential part of such a training regimen.^{29,32,35} Recently, Langmore and Pisegna³⁵ (2015) reported that increasing or decreasing the resistive load of swallowing is still an elusive challenge.

Based on the positive experiences with a jaw mobilization device (TheraBite, Atos Medical, Sweden) that showed good compliance and cost-effectiveness,^{13,37} recently, an adapted device was developed that enables both swallow and nonswallow exercises. The device allows adaptation to individual patient's capacity, and, thus, for applying progressive overload during the training program. Moreover, it provides adequate tactile feedback during the exercises, and visual feedback on the resistance level.³⁸ The effectiveness and

feasibility of this Swallow Exercise Aid (SEA)-based exercise regimen has been demonstrated in a prospective study in senior healthy subjects.³⁸ Compliance seemed to be high (86%), and there was a significant increase of swallowing muscle strength and volume, anterior tongue strength, and increased mouth opening after 6 weeks of intensive swallowing training. Although these results are promising, it remains to be demonstrated whether patients with chronic dysphagia in whom the targeted, often atrophied and/or fibrosed muscle groups are trainable with such a tool, and whether increased strength indeed has an impact on swallowing function. Many studies have tested the effects of training on normal, healthy individuals,^{39–42} but not in patients with dysphagia.³⁵ Therefore, as a next step, a prospective clinical study was conducted in a cohort of patients with head and neck cancer with chronic, therapy-resistant dysphagia, with the primary purpose to assess the feasibility and compliance, and the secondary purpose was to establish the short-term efficacy of this SEA-based strength-training protocol.

2 | MATERIALS AND METHODS

The present study was designed as a multicenter, uncontrolled, prospective clinical phase II study. The study was undertaken at the Departments of Head and Neck Oncology and Surgery of The Netherlands Cancer Institute – Antoni van Leeuwenhoek (Amsterdam) and the Radboud University Medical Center (Nijmegen), both in The Netherlands. The study was approved by the local ethical committees of both institutes, and informed consent was obtained from each participant before inclusion. The study followed the guidelines of the Helsinki Declaration.

2.1 | Patients

During the enrollment period (November 2014 to December 2015), patients with chronic, therapy-resistant dysphagia, and in complete remission after treatment with RT or concurrent CRT for advanced head and neck cancer, were recruited at the outpatient clinics of both institutes. The dysphagia had to be persistent for at least 1 year, despite previous targeted swallowing exercise programs. The diagnosis of dysphagia was based on the presence of penetration and/or aspiration (Penetration-Aspiration Scale [PAS] ≥ 4) on at least 1 bolus on recent (< 3 months) videofluoroscopy, and/or on a seriously limited intake of a normal diet (Functional Oral Intake Scale [FOIS] ≤ 4 ; ie, feeding tube dependency). At the end of the enrollment period, 18 patients were included and signed informed consent. Median age at baseline was 65 years (range 42–74 years); median weight was 69 kg (range 45–98 kg); and median body mass index (BMI) was 22 (range 16–31).

TABLE 1 Patients' and treatment characteristics at baseline (N = 17)

Patient No.	Tumor				Treatment				Nutritional status				Pneumonia ≥ 2 last y
	Sex	Age	Location	TNM	Year	RT	Dose	Chemo	FOIS	PRG	Weight	BMI	
1	M	42	Oropharynx	T4N2c	2007	IMRT	68 Gy	yes	1	yes	85	22.8	no
2	M	71	Oropharynx	T2N1	1987	2D	60 Gy	no	6	no	72	24.9	no
3	M	71	Parotic gland	TxN3	2013	IMRT	70 Gy	yes	1	yes	76	24.3	no
4	M	58	Oropharynx	T3N2a	2008	IMRT	70 Gy	yes	2	yes	45	16.1	yes
5	M	71	Hypopharynx	T1N1	1984	2D	68 Gy	no	1	yes	70	21.8	yes
6	M	71	Oral cavity	T2N1	1984	2D	60 Gy	no	4	no	98	30.9	no
7	M	62	Oropharynx	T2N0	2014	IMRT	66 Gy	no	2	no	72	21.7	no
8	V	60	Oropharynx	T3N2c	2004	IMRT	70 Gy	yes	6	yes	67	23.3	yes
9	V	61	Hypopharynx	T2N1	2004	IMRT	70 Gy	yes	7	no	48	17.2	yes
10*	M	65	Oropharynx	T4N3	2014	IMRT	68 Gy	yes	5	no	58	19.6	no
11	M	69	Neck metastasis	TxN1	2012	IMRT	39 Gy	no	6	no	65	20.5	no
12*	M	65	Hypopharynx	T2N1	2007	3D	68 Gy	no	7	no	62	21.6	yes
13*	M	74	Oropharynx	T2N0	2003	3D	68 Gy	no	6	no	62	18.1	yes
14*	V	67	Oropharynx	T3N2c	2000	3D	68 Gy	no	6	no	76	29.7	no
15*	M	65	Larynx	T3N2c	2002	3D	68 Gy	no	3	yes	76	24.0	yes
16	M	46	Oropharynx	T4N2	2011	IMRT	70 Gy	yes	4	no	82	24.0	no
17	V	72	Oral cavity	T2N0	1999	3D	60 Gy	no	6	no	59	21.2	yes

Abbreviations: 2D, two-dimensional radiotherapy; 3D, three-dimensional radiotherapy; BMI, body mass index; FOIS, Functional Oral Intake Scale; IMRT, intensity-modulated radiotherapy; PRG, percutaneous radiologic gastrostomy; RT, radiotherapy.

Note: Patients indicated by an asterisk (*) were included at the Radboud University; all other patients were included at the Netherlands Cancer Institute.

2.2 | Treatment

All patients had completed a full dose of 60-70 Gray (Gy) as target volume to the primary tumor, except for 1 patient who had received treatment with a total dose of 39 Gy as planned target volume. Elective nodal areas were given a total dose of 44 Gy. One patient was reirradiated and had received an additional dose of 46 Gy with a boost to 56 Gy 1 year after initial treatment because of local recurrence. The prescribed dose was delivered in 30-35 fractions, as 2D conventional RT in 3 patients (18%), as 3D conventional RT in 5 patients (29%), or as intensity-modulated radiotherapy (IMRT) in 9 patients (53%). Concurrent chemotherapy was given in 8 patients (44%). Patients treated surgically for head and neck cancer, except for any kind of neck dissection, were excluded. With a median of 119 months (10 years) posttreatment, patients were well past the stages of recovery of acute toxicity. In Table 1, the patient and treatment characteristics at baseline are shown.

2.3 | The Swallow Exercise Aid

The technical and functional features of the SEA have been described extensively before.³⁸ In short, the SEA is constructed on the basis of the TheraBite Jaw Mobilization device, modified with an added chest bar to the lower mouthpiece (see Figure 1). It is complemented with an ActiveBand that can be placed at various marked positions around the handle. To increase resistance, the ActiveBand can be moved per position toward the final position 6. The force required for compressing the chin bar onto the chest bar with one ActiveBand around the handle ranges from 4 Newton in position 1 (minimal resistive load) to 50 Newton in position 6 (maximal resistive load; see Table 2). If required, a second ActiveBand can be added to further increase resistance. This configuration enables the progressive overload needed for effective strength training.³²

2.4 | Intervention

The training program consists of 3 (nonswallow and swallow) exercises, visualized in Figure 2.

FIGURE 1 Swallow Exercise Aid with ActiveBand, chin tuck and jaw opening extension, chin bar, and chest bar [Color figure can be viewed at wileyonlinelibrary.com]

The first exercise, the chin tuck against resistance (CTAR) exercise, is performed by pressing the chin downward against the chin bar, while keeping the mouth closed, until the chin bar reaches the chest bar attachment (providing tactile feedback). This exercise, which is comparable to the Shaker^{18,25,28} and another CTAR exercise,⁴³ is directed at the suprahyoid muscles, and aims at improvement of hyolaryngeal elevation and upper esophageal sphincter (UES) opening.

The second exercise, the jaw opening against resistance (JOAR) exercise, is performed by pressing the mandible down while opening the mouth, again compressing the chin bar against the chest bar. This exercise targets the jaw opening musculature, including the suprahyoid muscles, and aims at improvement of hyoid elevation, amount of UES opening, and time for pharynx passage.²³

The third exercise, the effortful swallow exercise, is performed with the chin placed on the chin bar (pressed downward for 50%), whereby the subjects swallow with the mandible down and mouth closed, comparable to the

FIGURE 2 Swallowing Exercise Aid exercises (printed with permission of patient). Top left: start position; top right: exercise 1; chin tuck against resistance exercise; bottom left: exercise 2; jaw opening against resistance exercise; bottom right: exercise 3; effortful swallow exercise with 50% of maximum closure [Color figure can be viewed at wileyonlinelibrary.com]

formerly described TheraBite swallowing exercise.¹³ This exercise is hypothesized to also stimulate the pharyngeal musculature, to increase tongue base retraction, and decrease the amount of pharyngeal residue, comparable to an effortful swallow.^{25–27}

The proposed effects and related measures of the 3 exercises with the SEA are demonstrated in Table 3.⁴⁴

2.5 | Exercise protocol

Before participation, the patients visited the clinical investigator and received a written instruction sheet. To allow for the calculation of test-retest reliability of the chin tuck and jaw opening strength measurements, muscle strength testing was performed during that first visit. After a 3-week interval, the patients again visited the investigator for the actual instruction visit, and they received the necessary instruments. They were instructed to hold the SEA device in their preferred hand, to place the chest bar onto the sternum without excessive pressure, and to place the chin onto the chin bar. Subsequently, all baseline measurements were performed, including the muscle strength tests. During the exercise period, the patients visited the clinical investigator for mid-term evaluations (including muscle strength tests) after the first week, and subsequently every 2 weeks. A diagram of all clinical visits is shown in Appendix A.

TABLE 2 Estimated resistance in Newton at various positions of the ActiveBand

Baseline chin tuck strength, 1RM	Position of ActiveBand	Estimated resistance (60%-70% of 1RM)
0-12 N	1	1-8 N
13-24 N	2	9-16 N
25-36 N	3	17-25 N
37-50 N	4	26-34 N
51-65 N	5	35-44 N
66-80 N	6	45-54 N

Abbreviations: 1RM, one repetition maximum; N, Newton.

TABLE 3 Summary of proposed effects and related measures of the three swallow and non-swallow exercises with the SEA (partly adapted from Dysphagia Management in Adults and Children, by Groher and Crary⁴⁴).

Technique	Performance	Intent	Target musculature	Physiology	Outcomes	Assessment
Chin tuck against resistance	Isokinetic and isometric chin tuck against resistance with SEA	Reduces postswallow aspiration	Suprahyoid musculature	Improved elevation and anterior excursion of the hyolaryngeal complex; improved UES opening	Less aspiration	Swallowing muscle strength; PAS; hyoid displacement; PROs.
Jaw opening against resistance	Isokinetic and isometric jaw opening against resistance with SEA	Reduces postswallow aspiration	Jaw opening musculature including suprahyoid muscles	Improved elevation and anterior excursion of the hyolaryngeal complex; improved UES opening	Less aspiration	Swallowing muscle strength; PAS; hyoid displacement; maximum mouth opening; PROs.
Effortful swallow	Swallow against resistance with SEA	Increases lingual force on bolus	Suprahyoid and pharyngeal musculature	Increased tongue-palate pressures; increased duration of swallow; increased tongue base retraction	Less pharyngeal residue	Amount of residue scores; tongue strength and endurance; PROs.

Abbreviations: PAS, Penetration-Aspiration Scale; PROs, patient-reported outcomes; SEA, Swallow Exercise Aid; UES, upper esophageal sphincter.

Republished as adapted from Groher M, Crary M. Treatment for Adults. In: Dysphagia 2nd Edition Clinical Management in Adults and Children Book. Ch. 10, pp 225–225. (St Louis, MO: Mosby; 2015), © 2015, with permission from Elsevier.

The ActiveBand was placed on the appropriate position of the device to ensure a specified amount of resistance, based on the most recent chin tuck strength (see Table 2). The individual starting position of the ActiveBand was determined following the principle of 1RM, (ie, for this study, the maximum chin tuck strength assessed at baseline, see below). A force of approximately 60%–70% of the 1RM was used as initial resistance.³² Subsequently, progression of intensity was based upon interim swallowing strength measurements and self-perceived exertion.

Comparable with the Shaker exercise,²⁸ the CTAR and JOAR exercises were performed both as isometric and isokinetic exercises. The isokinetic exercises were performed 30 times consecutively at a fixed pace of 1 second per contraction, with the aim to improve maximal muscle strength.³² The isometric exercises were performed 3 times, maintained for 60 seconds, with a 60-second rest period between each of the 3, with the aim to improve endurance of sustained muscle activity.³² These 2 exercises were carried out first, with a 60-second rest period between each session. Subsequently, the effortful swallow exercise was performed 10 times consecutively as an isokinetic flexion, after another 60-second rest period. The total duration of the 3 exercises is 25 minutes per session.³⁸

All patients were asked to perform the SEA exercises 3 times daily for at least 6 weeks and for a maximum of 8 weeks, which is based on Burkhead et al³² (2007), who suggested that at least 5 weeks of strength training are needed before a meaningful gain in strength in skeletal muscles can be achieved. Patients were asked to record their performances by using tally sheets in a special exercise log (see Appendix B). When patients felt the exercises became too easy, they were allowed to advance the ActiveBand to the next position in consultation with the clinical investigator. Patients were instructed to cease the exercises if they felt discomfort or pain in the chest/chin or in/around their temporomandibular joint during the exercises.

2.6 | Multidimensional assessment

The outcome parameters were recorded before participation (at baseline) and 2 days after the practice period (posttraining). Primary outcome parameters were feasibility and compliance of this SEA-based strength training protocol in this cohort of patients with head and neck cancer with chronic dysphagia. Secondary outcome measures were parameters to obtain an estimate of effect: maximum chin tuck and maximum jaw opening strength, maximum tongue strength/endurance, maximum mouth opening, presence of laryngeal penetration or aspiration, oral intake, hyoid bone displacement, subjective swallowing complaints, and general health status.

FIGURE 3 Muscle strength test setup with an adapted ophthalmic examination frame and a dynamometer (Microfet) fixed at the chin rest (printed with permission of patient). Left: measurement 1 (mouth closed, comparable to chin tuck against resistance exercise); right: measurement 2 (mouth opened, comparable to jaw opening against resistance [JOAR] exercise). Note: If patients feel more comfortable during the JOAR exercise, they may also hold the handle bars [Color figure can be viewed at wileyonlinelibrary.com]

2.7 | Feasibility and compliance

Feasibility of the SEA exercises (eg, ease of handling of the device, practicality of the progressive exercise regimen, familiarity with the exercises, and occurrence of adverse events) was monitored with a study-specific questionnaire (see Appendix C for a translation in English). It was considered to be more or less equal to the program completion rate. Compliance with the SEA exercises (in terms of exercise adherence) was monitored interim by the clinical investigator and at the posttreatment assessment point with tally sheets from the daily exercise log (Appendix B).

2.8 | Swallowing muscle strength

Muscle strengths for chin tuck and jaw opening (exercises 1 and 2) were measured in Newton, using a “handheld” dynamometer (Microfet; Biometrics, Almere, The Netherlands) mounted into an adapted ophthalmic examination frame (see Figure 3) to avoid variations in head and chin position and to ensure consistent compression.³⁸ A superior fixed belt stabilized the patient’s head, and the height of both the chin rest and the superior belt could be adjusted to the patient’s dimensions. Patients were instructed to sit straight, and to press their chin down on the dynamometer as powerful as possible, once with their mouth and teeth closed (like the CTAR exercise), and once by opening their jaw/mouth (like the JOAR exercise). Both measurements were preceded by one familiarization session, in order to exclude learning

curve effects and to improve reliability of the values obtained.⁴⁵ After the familiarization session, both measurements were repeated 3 times, with a 60-second rest period between the trials. The mean maximum pressure of the highest 2 of 3 values was used as the patients’ maximum chin tuck/jaw opening strength.⁴⁵

Test-retest reliability coefficients (intraclass correlation coefficient [ICC] 3.2) for this setup were 0.89 (95% confidence interval [CI] 0.70-0.93) for maximal chin tuck strength and 0.97 (95% CI 0.90-0.99) for maximal jaw opening strength in these 18 patients. This implies a smallest detectable change of 15 Newton for chin tuck strength and 7.5 Newton for jaw opening strength in this sample.

2.9 | Tongue strength and endurance

The Iowa Oral Performance Instrument (IOPI) was used to measure maximum tongue pressures and endurance (exercise 3) by means of a small air-filled bulb.^{32,46} Patients had to press their tongue upward on the air-filled bulb in order to squeeze the bulb against the hard palate. Pressures (at anterior and posterior locations) were expressed in kPa and digitally displayed on the device. After one familiarization session, 3 trials of maximum (anterior and posterior) tongue pressure were obtained for each patient, with a 2-minute rest period between the trials. The mean maximum pressure of the highest 2 of 3 values was used as the patients’ maximal (anterior/posterior) tongue strength. In addition, endurance measures were analyzed at anterior tongue location after the

strength task, after a break of at least 5 minutes. Patients were asked to maintain 50% of their maximal tongue strength as long as possible.

2.10 | Videofluoroscopy

Videofluoroscopy (VFS) was used for objective assessment of all phases of the swallowing physiology, according to the protocol of Logemann⁴⁷ (1998). In brief, the swallowing act was recorded in with the patient in the upright position in a lateral field of view. The consistencies and amounts used were 3 and 10 cc thin liquid, 5 cc thickened liquid, and an Omnipaque coated piece of gingerbread. Each bolus was repeated twice, resulting in a total of 8 swallows per patient per assessment.

Swallowing function was evaluated with the validated PAS score,⁴⁸ ranging from 1 to 8 (score 1 = material does not enter the airway, to score 8 = material enters the airway, passes below the vocal folds, and no effort is made to eject). If a patient aspirated on 2 consecutive boluses of thin liquid of the same volume, larger volumes of thin liquid were not administered anymore. Similarly, if boluses of more solid food were deemed not to be safe (ie, high likelihood of severe aspiration), these boluses were avoided. Other VFS parameters, such as presence of contrast residue and anterior/superior hyoid bone displacement, were also assessed. The overall “presence of residue” score ranges from 0 to 3 (score 0 = no residue, to score 3 = residue above and below the vallecula, with minimal residue judged as normal).^{47,49} Hyoid bone elevation and anterior excursion were defined as the anterior/superior distance travelled by the hyoid bone to the point of maximal displacement during a swallow from its position during hold.^{50,51} It was measured according to the methods described previously.⁵²

The PAS and amount of residue scores were scored by 2 evaluators independently: the first author and the participating speech-language pathologist (SLP). Both evaluators were blinded to preintervention or postintervention status of the swallow study. Subsequently, the scores were reviewed in a consensus meeting, under maintained blinding, and the consensus scores were used for analysis. For hyoid bone displacement, 10% of the measurements (stills of all consistencies in lateral view preintervention and postintervention) were repeated by the first author (to assess intrarater reliability), and 10% were reviewed by the SLP (to assess interrater reliability). Measurements were deemed in concordance if pairwise testing showed a >95% chance of measuring clinically indistinguishable values in the 2 measurement sessions.^{22,38}

2.11 | Oral intake and nutritional status

Oral intake was assessed with the FOIS and nutritional status with BMI and weight change. The FOIS ranges from 1-7

with score 1 = nothing by mouth, to score 7 = total oral diet without restrictions.

2.12 | Mouth opening

Maximum mouth opening was measured in millimeters with the disposable TheraBite range of motion scale. Two measurements were performed at both assessment points, with the highest value recorded as the maximum mouth opening. Trismus was defined as a maximal interincisal opening of ≤ 35 mm.⁵³

2.13 | Patient-reported outcomes

Subjective swallowing complaints were recorded pretraining and posttraining with the validated Dutch version of the 44-item Swallowing Quality of Life (SWAL-QOL) questionnaire.⁵⁴ The SWAL-QOL assesses patients' swallowing impairment based on 10 quality of life domains, each ranging from 0-100 with a higher score indicating more impairment. Feasibility and compliance were assessed with a structured study-specific questionnaire (see Appendix B for the English translation of this questionnaire). The study-specific questionnaire also contained a rating of global perceived benefit, and an open question to specify what the experienced benefit was. Additionally, health status was assessed with the EuroQOL-5D questionnaire (EQ-5D) questionnaire to provide a simple, generic measure of health for clinical and economic appraisal.⁵⁵ The EQ-5D consists of a descriptive system comprising 5 dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) with 3 levels (no problems, some problems, and severe problems) for each dimension, and a visual analog scale recording the respondent's self-rated health on a vertical visual analog scale ranging from 0-100.⁵⁵

2.14 | Statistical analyses

The aimed sample size was 20 patients with head and neck cancer, based on the previous improvements (Cohen's $d > 0.6$) demonstrated in the healthy volunteer sample.³⁸ In this way, the study would have 80% power to detect an effect size (Cohen's d) of 0.70 with a power of 80% and an alpha of 0.05, while allowing for a 10% attrition rate, using a paired t test. For all outcome measures, descriptive statistics were generated. Data from muscle strength tests, IOPI measurements, VFS, mouth opening, and questionnaires of the total study population were summarized as medians and median differences, with 95% CIs for the median differences obtained with bootstrapping. Statistical analysis was performed using the Statistical Package of Social Sciences (SPSS) software version 23.0.

TABLE 4 Strength training data per patient before and after the training period

Patient		ActiveBand Position	Swallowing muscle strength		Tongue strength & endurance			Mouth opening MIO, mm
			CTAR, Newton	JOAR, Newton	Anterior (kPa)	Posterior (kPa)	Endurance, s	
1	Pre	4 - 3	40.0	25.0	34.5	37.0	22	21
	Post	6 - 5	71.5	55.5	47.0	48.0	29	21
2	Pre	4 - 4	46.5	48.5	32.5	29.5	48	40
	Post	6*- 6*	84.0	108.5	34.0	29.0	43	41
3	Pre	4 - 2	45.5	16.0	33.5	28.5	44	15
	Post	6 - 6	92.5	34.5	40.0	37.5	28	15
4	Pre	2 - 2	0	0	39.5	35.0	55	20
	Post	4 - 4	0	0	65.0	32.0	51	21
5	Pre	3 - 3	33.5	25.0	39.0	35.0	20	38
	Post	6 - 6	63.0	103.0	42.0	36.5	25	37
6	Pre	2 - 2	8.5	17.0	48.5	30.5	12	37
	Post	5 - 6	33.0	57.5	43.0	41.5	42	38
7	Pre	6 - 4	71.5	47.0	66.0	52.5	36	54
	Post	6*- 6*	85.0	84.5	69.0	38.5	38	55
8	Pre	1 - 2	4.5	13.0	15.5	14.0	40	37
	Post	5 - 5.5	6.0	21.5	17.0	15.5	41	35
9	Pre	1 - 2	0.5	7.5	45.0	42.0	37	48
	Post	5 - 5	2.0	7.0	51.5	47.5	51	51
10	Pre	3 - 4	31.5	38.0	18.0	10.5	22	29
	Post	6 - 6	49.5	51.5	15.5	12.5	34	30
11	Pre	3 - 3	29.0	28.0	35.5	12.5	5	51
	Post	6 - 5	37.5	32.5	35.5	10.0	3	54
12	Pre	4 - 3	59.0	21.5	30.5	31.0	11	33
	Post	6 - 5	69.5	43.5	32.5	29.0	11	33
13	Pre	4 - 2	39.5	10.5	63.0	47.0	14	31
	Post	6 - 5	56.0	43.5	70.0	53.5	12	40
14	Pre	3 - 2	5.0	2.0	27.5	25.5	12	20
	Post	6 - 6	7.5	22.0	22.5	28.5	37	21
15	Pre	3 - 2	21.5	22.5	31.0	33.0	31	42
	Post	6 - 5.5	16.0	52.0	36.5	40.5	30	43
Median (95% CI) pre			31.5 (7–45)	21.5 (11–28)	34.5 (31–42)	31 (27–36)	22 (12–39)	37 (25–41)

(Continues)

TABLE 4 (Continued)

Patient	ActiveBand Position	Swallowing muscle strength		Tongue strength & endurance			Mouth opening MIO, mm
		CTAR, Newton	JOAR, Newton	Anterior (kPa)	Posterior (kPa)	Endurance, s	
Median (95% CI) post		49.5 (12–72)	43.5 (27–58)	40.0 (33–49)	36.5 (29–42)	34 (27–42)	37 (26–42)
Median (95% CI) change		13.5 (2–30)	22.0 (11–35)	3.0 (0–7)	2.0 (-1–8)	1.0 (-2.0–9.5)	1.0 (0–1.0)

Abbreviations: ANT, anterior; CI, confidence interval; CTAR, chin tuck against resistance; END, endurance; JOAR, jaw opening against resistance; MIO, maximal interincisal opening; POST, posterior.

Note: Patients 2 and 7 were able to add a second ActiveBand on (position 2 of) the SEA at the end of the exercise period. The position of the ActiveBand was specified for exercises 1 and 2. For exercise 3, the same resistance as used for exercise 2 was applied.

3 | RESULTS

Although the aim was to include 20 patients, due to the strict inclusion criteria, only 17 patients could be included during the planned study period of 1 year. Of these 17 patients, 2 patients withdrew from the study. One patient decided to withdraw from the study after the second baseline assessment point before starting the exercise program. The second patient decided to resign from the study after 3 weeks of exercise because of substantial pain around the temporomandibular joint during the exercises. There was no obvious substrate for that discomfort, but the patient still opted out. Hence, 15 of 17 patients completed the exercise program, resulting in a program completion rate of 88%. All collected data are shown in Tables 4 and 5. In the following paragraphs, the most relevant results ($n = 15$) are described in more detail.

3.1 | Feasibility and compliance

Patients executed, as intended, the exercises minimally for 6 weeks and maximally for 8 weeks (mean 47 days; median 45 days; range 40–56 days). All but 1 patient had practiced at least 1 session daily during the exercise period. The total duration of the exercises was reported to be 20–30 minutes per session. The patients were familiar with the exercises after a median of 1 week. One patient reported the exercises as “very unpleasant,” 4 patients as “a bit unpleasant,” 8 patients as “neither pleasant nor unpleasant,” and 2 patients as “a bit pleasant.” The median compliance in terms of adherence to the 3 daily exercise sessions was 97% (range 86%–100%). At the start of treatment, 6 patients reported (some) muscle pain around their temporomandibular joints during the exercises, which disappeared within 1 hour after completing the exercises in all of them. There was 1 patient with an episode of aspiration pneumonia during the first week of the trial period.

3.2 | Muscle strength

All patients started at position 2–4 of the ActiveBand and all but 3 (patients 4, 8, and 9) had ultimately reached position 6.

Two patients (2 and 7) were able to go past position 6 by adding a second ActiveBand to further increase resistive load. At the end of treatment, an increase in median chin tuck strength of 13.5 Newton (95% CI 2.0–29.5 Newton) was observed, from a median of 31.5 Newton (95% CI 6.8–45.4 Newton) at baseline to a median of 49.5 Newton (95% CI 11.8–71.5 Newton) posttreatment (effect size with Cohen's $d = 0.7$). The median jaw opening strength increased with 22 Newton (95% CI 11.0–35.3 Newton) from a median of 21.5 Newton (95% CI 10.5–28.0 Newton) at baseline to a median of 43.5 Newton (95% CI 27.3–57.5 Newton) at the end of treatment (Cohen's $d = 1.8$). The individual improvements are visualized in Figures 4 and 5.

3.3 | Tongue strength and endurance

Median anterior tongue strength (IOPI) increased with 3.0 kPa (95% CI 0–6.5 kPa), from a median of 34.5 kPa (95% CI 30.5–42.3 kPa) at baseline to a median of 40.0 kPa (95% CI 32.5–49.3 kPa) at the end of treatment. There were no improvements observed for posterior tongue strength or anterior tongue endurance.

3.4 | Swallowing and mouth opening

For thickened liquid swallows, the PAS score had clinically improved in 5 patients (33%): from aspiration to penetration in 3 patients (patients 5, 10, and 12), and from aspiration/penetration to normal swallowing in 2 patients (patients 9 and 15; Table 5 and Appendix D). The PAS scores had clinically deteriorated in 3 patients (patients 6, 7, and 11; 20%). The mean PAS score for thickened liquid swallows showed a small to moderate effect size (Cohen's $d = 0.3$). No clinically relevant improvements in other consistencies or residue scores were observed. There were also no improvements in anterior or superior hyoid bone displacement for the various consistencies used. Based on the FOIS scores, oral intake had improved in 4 patients (patients 2, 6, 10, and 13), and had stayed the same in the remaining 11 patients. There were also 4 patients who had gained some weight after the

TABLE 5 Videofluoroscopic, nutrition, and patient-reported data on swallowing function per patient before and after the training period

Patient	VFS			SSQ				SWAL-QOL					EQ-5D					
	Weight	FOIS	PAS	Residue	Did you benefit?	General Burden	Food selection	Eating duration	Eating desire	Fear of eating	Sleep	Fatigue	Communication	Mental Health	Social Function	Symptom scale	Self-rated health	
1	Pre	85	1	8	3		88	NA	NA	75	100	13	50	63	75	65	NA	75
	Post	85	1	8	3	+	88	NA	NA	75	100	50	25	63	75	65	NA	75
2	Pre	72	6	4	3		38	25	50	58	44	13	17	50	55	25	63	90
	Post	73	7	4	3	-	38	38	63	17	38	0	0	50	30	25	50	90
3	Pre	76	1	8	3		100	NA	NA	100	NA	0	0	75	75	65	NA	70
	Post	76	1	8	3	+	100	NA	NA	100	NA	0	0	75	75	65	NA	60
4	Pre	45	2	8	3		100	50	75	42	75	75	83	25	40	60	71	15
	Post	42	2	8	3	++	100	50	75	42	75	75	83	25	40	60	70	25
5	Pre	70	1	8	3		50	NA	NA	75	NA	0	25	50	56	55	NA	75
	Post	70	1	8	3	++	50	NA	NA	75	NA	0	25	50	56	55	NA	75
6	Pre	98	4	2	3		50	63	25	42	63	63	75	25	45	60	54	60
	Post	98	5	4	3	+	50	38	38	50	69	63	50	75	50	55	52	70
7	Pre	72	2	8	3		100	NA	NA	50	100	0	17	0	55	70	54	60
	Post	72	2	6	3	++	88	NA	NA	50	100	25	0	0	45	70	52	50
8	Pre	67	5	8	3		0	0	0	17	0	38	83	0	0	20	11	75
	Post	69	5	8	3	++	25	0	0	17	19	63	42	38	0	0	30	60
9	Pre	48	7	8	3		0	25	38	33	44	25	33	25	0	0	30	90
	Post	48	7	8	3	+	0	0	63	33	44	25	25	25	0	0	23	90
10	Pre	58	5	8	3		75	88	63	67	6	50	42	100	90	65	46	80
	Post	58	6	7	3	++	63	75	88	42	25	50	33	75	75	65	52	90
11	Pre	65	5	8	3		100	75	100	75	69	50	50	75	80	70	66	60
	Post	65	5	8	3	+	88	50	88	75	50	50	50	50	95	70	55	70

(Continues)

TABLE 5 (Continued)

Patient	VFS			SSQ	SWAL-QOL				EQ-5D								
	Weight	FOIS	PAS	Residue	Did you benefit?	General Burden	Food selection	Eating duration	Eating desire	Fear of eating	Sleep	Fatigue	Communication	Mental Health	Social Function	Symptom scale	Self-rated health
12	Pre	62	6	8	3	38	25	63	33	56	63	67	50	35	25	57	70
	Post	65	6	8	3	50	38	63	8	44	63	33	50	25	25	43	85
13	Pre	62	6	8	3	50	38	100	83	25	25	33	38	5	25	39	50
	Post	62	7	8	3	50	0	75	17	44	38	75	25	0	60	21	75
14	Pre	76	5	8	3	75	50	100	50	56	63	58	75	75	35	68	70
	Post	75	5	8	3	63	63	100	42	38	75	50	50	35	20	57	78
15	Pre	76	3	8	3	75	50	63	50	63	38	50	50	50	65	27	70
	Post	77	3	8	3	63	25	63	33	63	63	50	38	50	50	36	63
Median (95% CI) pre	70	5	8	8	3	63	50	63	54	56	38	46	50	53	58	54	70
		(62–76)	(2–5)	(8–8)	(3–3)	(38–75)	(25–63)	(38–100)	(33–67)	(25–63)	(25–63)	(33–75)	(25–75)	(5–75)	(25–65)	(30–66)	(60–75)
Median (95% CI) post	70	5	8	8	3	63	38	63	42	44	50	33	50	50	55	51	75
		(65–76)	(2–6)	(7–8)	(3–3)	(38–63)	(0–50)	(63–88)	(17–42)	(38–63)	(38–63)	(33–50)	(25–50)	(0–50)	(20–60)	(30–55)	(63–85)
Median (95% CI) change	0	0	0	0	0	0	-13	0	0	0	0	-8	0	0	0	-5	0
		(0–0.8)	(0–1)	(0–0)	(0–0)	NA	(-12–0)	(-25–13)	(0–13)	(-25–0)	(-12–19)	(0–13)	(-25–0)	(-15–0)	(-15–0)	(-13–6)	(0–10)

Abbreviations: CI, confidence interval; EQ-5D, EuroQOL-5D questionnaire; FOIS, Functional Oral Intake Scale; NA, not applicable; PAS, Penetration Aspiration Scale; SSQ, Study-Specific Questionnaire; - means no benefit, + means a little benefit, ++ means quite some benefit, +++ means a lot of benefit; SWAL-QOL, Swallowing Quality of Life questionnaire; VFS, videofluoroscopy.

Note: Patients 3, 4, and 5 were still (completely) feeding tube dependent at the posttreatment assessment point. Hence, the posttreatment SWAL-QOL results were identical to their previous results.

FIGURE 4 Change in individual maximum chin tuck strength after the 6 to 8-week exercise period [Color figure can be viewed at [wileyonlinelibrary.com](#)]

exercise period (patients 2, 8, 12, and 15; Table 5), whereas 2 patients had lost some weight (patients 4 and 14). Mouth opening had slightly increased with a median of 1.0 mm after the training program (95% CI 0–1.0 mm).

3.5 | Patient-reported outcomes

Results of the SWAL-QOL questionnaire, divided per subdomain are shown in Table 5. Overall, no major improvements at the posttreatment assessment point were observed. After a median of 3 weeks, 14 of 15 patients reported to benefit from the exercises, varying from “a little bit” ($n = 6$), to “quite a bit” ($n = 7$), and to “a lot” ($n = 1$). Patients mainly reported more confidence and ease during swallowing (some patients had actually tried to eat meat or bread again), and less coughing/choking during a meal.

Patients’ overall self-rated health, as assessed with the EQ-5D questionnaire, showed a small improvement from a median of 70 to a median of 75 after treatment. There were no improvements on 1 of the 5 dimensions of this questionnaire.

4 | DISCUSSION

This study prospectively investigated the feasibility, compliance, and short-term efficacy of an intensive strength training protocol with a dedicated SEA in patients with head and neck cancer with chronic dysphagia after treatment with (chemo-)radiotherapy, who had been refractory for usual care. Regarding the first purpose of the study, the results showed that the exercises were indeed feasible in the current patient cohort with often atrophied and/or fibrosed swallowing muscles, with almost all patients executing the exercises according to the protocol. The patients were also compliant with the prescribed exercises. Despite their long-lasting dysphagia, they were eager to participate, resulting in high program completion rate (88%), and high compliance with

regard to exercise adherence (97%). The 15 evaluated patients had missed only 0%–14% (median 3%) of the targeted number of exercise sessions. The majority of patients even continued practicing after the study period because they experienced clinical benefits (ie, more confidence and ease during swallowing/eating) since they had started their exercises. The closure of the chin bar onto the chest bar and the option to increase resistance with this band gave biofeedback for patient’s performance. This was supported by anecdotal feedback from our patients, and is a strong point of the device, because it improves patients’ compliance with the exercises.³⁸

Second, with respect to the short-term efficacy of this SEA-based exercise regimen, it can be concluded that the swallowing muscles are still trainable. Results of the strength tests showed substantial improvements in strength of the trained muscles in almost all patients, with a median increase of 13.5 Newton for chin tuck strength, 21.5 Newton for jaw opening strength, and 3.0 kPa for anterior tongue strength. This coincides well with the observation that all but 3 patients had been able to ultimately reach position 6 of the ActiveBand, with 2 of them being able to add a second band.

It should be noted, though, that the posterior tongue strength did not increase much, and that the median increase in chin tuck strength of 13.5 Newton is just below the smallest detectable change of 15 Newton, based on the established reliability, implicating that the observed increase in chin tuck strength cannot be attributed to the exercise regimen with complete confidence. Three patients (patients 4, 8, and 9) showed no major improvements in muscle strength. Their scores remained below 10 Newton, and they were considered “nonresponders.” However, half of the patients achieved an increase in chin tuck strength that well exceeded the smallest detectable change, and the median increase in jaw opening strength of 22 Newton is well above the smallest detectable

FIGURE 5 Change in individual maximum jaw opening strength after the 6 to 8-week exercise period [Color figure can be viewed at [wileyonlinelibrary.com](#)]

change of 7.5 Newton for this test, which indicates that this increase is confidently attributable to the SEA exercises. As compared to the formerly ICC values obtained from healthy subjects,³⁸ the test-retest reliability of the muscle strength assessment setup in the current patient population was good. Hence, the current ICC values indicate that the muscle strength measurement procedure is highly reliable and suitable for future use in individual patients.

Interestingly, the median strengths of 31.5 and 49.5 Newton for chin tuck and jaw opening, respectively, at the posttreatment assessment point were still considerably lower than the >80 Newton achieved by 10 healthy subjects at the pretreatment assessment point in our previous study.³⁸ This was also demonstrated for maximum anterior and posterior tongue strength, with maximum values of 36.5 to 40 kPa in our cohort of patients with head and neck cancer, as compared to values of >60 kPa in healthy subjects.³⁸ This clearly underlines that damaged, atrophied, and/or fibrosed muscles because of radiation loose (part of) their function. One could question whether 6-8 weeks of strength training is enough to achieve sufficient increase in muscle strength for clinical improvements in these (often feeding tube dependent) patients >10-years posttreatment. On the other hand, most increase in muscle strength in the individual patients was observed in the first weeks of treatment. In particular in this stage, central and neuromuscular adaptations (and not yet hypertrophy) do occur. Therefore, the question is whether ongoing training will lead to a further increase in muscle strength, or whether a plateau will be reached after optimization of the remaining muscle function. At least the present study shows that these damaged muscles are, up to a certain point, still trainable.

To date, there are no large clinical trials that have studied and proven efficacy for rehabilitative (swallow and/or non-swallow) exercises for their long-term effect in patients with head and neck cancer and chronic dysphagia,^{24,35} except for the Shaker exercise.^{18,25,28} As swallow exercises are applied to make a swallow stronger or faster,²⁹ the advantage of non-swallow exercises is that they allow patients to improve through a training protocol safely without limitations that may be imposed during swallowing, or during NPO status. Especially the combination of swallow and nonswallow exercises, leading to different activation patterns encountered during various swallowing circumstances, may be more effective.³² Obviously, the effortful swallow exercise of the current SEA-based exercise protocol is in concordance with the specificity principle of neural plasticity.^{29,34,35} In addition, the muscle overload principle is applicable to the SEA exercises. By contrast, the amount of load in the Shaker exercise is not easily quantifiable, and cannot be manipulated progressively over the course of treatment.³² Moreover, the sternocleidomastoid muscles are probably significantly more

activated and fatigued during the Shaker exercise than during the SEA exercises.⁴² As swallowing is a submaximal activity,³² whereby increase in muscle volume is not the focal point, for the current study, a resistive load of approximately 60%-70% of the estimated 1RM was maintained as the resistance level. Besides, in this population of patients with head and neck cancer with chronic, severe dysphagia, hypertrophy is not expected.

Unfortunately, the increase in muscle strengths did not result in overall better functional swallowing ability, because the clinical swallowing outcomes (ie, FOIS and PAS scores) and hyoid elevation did not improve after the training period. Apparently, 6-8 weeks of strength training are probably not enough for achieving improvements in clinical end points in this challenging patient population. Although the results of the study-specific questionnaire revealed some improvements, as perceived by the patients themselves (and certainly no harm), these results did not correspond with the improvements in muscle strength. As reported by Langmore et al²⁴ (2015), the suggestion is made that "the simple act of practicing swallowing will improve the patients' skill, ease, and rate of eating, helping them to more safely and efficiently swallow more challenging foods." This is in line with a recent study of Hutcheson et al,⁵⁶ who found in particular small improvements in functional status or quality of life after an individualized, high-intensity swallowing therapy program in more or less the same patient population, with few major improvements, such as tube removal or improved PAS scores. Moreover, the time posttreatment of the current patient cohort is notable (median 10 years after RT). This is a tremendously challenging population, so any functional improvements are likely notable. Despite disappointing swallow-specific change, it may be that the measurable functional change is noteworthy in potentially helping slow functional deterioration that is clinically evident in this population. However, another explanation could be that other muscles involved in swallowing play an important role, or that fibrosis or nerve dysfunction at long term prohibit functional improvement in spite of improved muscle strength.

In conclusion, this study investigated a SEA-based strength training protocol with swallow and nonswallow exercises for the rehabilitation of chronic, therapy-resistant dysphagia in patients with head and neck cancer. Feasibility and compliance seemed to be high and some objective and subjective effects of progressive load on muscle strength and swallowing function were demonstrated, indicating that the swallowing muscles at long term still are trainable. In this extremely challenging group of survivors, the gains in strength are notable and may have a role in slowing functional deterioration even if substantial swallow-specific improvement is not seen. To further study the efficacy and effectiveness of rehabilitative exercises in patients with

chronic dysphagia, larger, prospective studies of longer duration ensuring adequate numbers of patients and structured treatment protocols are needed.^{16,32}

Because significant benefits of preventive exercises during organ-preservation treatment already have been demonstrated,^{14–16,57} and major clinical improvements at long term seem difficult, starting rehabilitation before treatment onset, or at least as soon as possible in case of post-treatment rehabilitation, is preferable. Further, a minimum baseline muscle strength of 10 Newton or higher seems to be required, because the nonresponders all showed baseline muscle strengths below 10 Newton, and the device seemed to work better with the resistance minimally on position 2 or higher. Therefore, as a next step in the validation process of the SEA-based exercise protocol, a following phase III randomized controlled trial in the preventive or early rehabilitation setting of head and neck cancer treatment is planned.

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APPENDIX A: DIAGRAM OF STUDY VISITS

Diagram of study visits / follow-up:

APPENDIX B: PATIENT EXERCISE LOG

M14SEA

Phase-1/2 clinical trial on the treatment of chronic dysphagia in head and neck cancer patients with dedicated strengthening exercises using the Swallow Exercise Aid

Patient Exercise Log

Name:

Date of birth:

Instructions: Please note if you have performed your exercises three times a day during the total exercise period

* If you have performed your exercises less than 3 times a day, please note the number of practice sessions during that day

* If you haven't performed your exercises one day, please leave that day empty

Week		Exercise 1		Exercise 2		Exercise 3	Remarks
1 / 2 / 3 / 4 5 / 6 / 7 / 8		Chin Tuck Against Resistance		Jaw Opening Against Resistance		Effortful Swallow	
		30 x	3 x 60s	30 x	3 x 60s	10 x	
Monday	Morning						
	Afternoon						
	Evening						
Tuesday	Morning						
	Afternoon						
	Evening						
Wednesday	Morning						
	Afternoon						
	Evening						
Thursday	Morning						
	Afternoon						
	Evening						
Friday	Morning						
	Afternoon						
	Evening						
Saturday	Morning						
	Afternoon						
	Evening						
Sunday	Morning						
	Afternoon						
	Evening						

APPENDIX C: STUDY SPECIFIC QUESTIONNAIRE

Name:
Study number:
Date of birth:

Date of record:
Post-treatment assessment

N14SEA
Questionnaire 2

Appendix III. Study-specific questionnaire

Please fill in this questionnaire at the follow-up visit at the end of the exercise period.

- 1) Have you performed your exercises three times a day?
1= yes (continue to question 6)
2= no, I have exercised approximately times a **day**
3= no, I have exercised approximately times a **week**
- 2) After how many days did you stop with your exercises?
After day #:
- 3) Why did you stop with your exercises?
- 4) Did you re-continue your exercises after you having stopped earlier?
1= yes
2= no (continue to question 6)
- 5) After how many days did you re-continue?
After days
- 6) How many days did you perform the exercises in total?
Number of days:
- 7) How did you experience the exercises?
1= very unpleasant
2= a bit unpleasant
3= not unpleasant or pleasant
4= quite pleasant
5= very pleasant
- 8) Can you try to explain why?
- 9) How many days did it take you to get used to the exercises?
Approximately days:
- 10) Did you have the feeling to benefit from the exercises?
1= not at all
2= a little bit
3= quite a bit
4= very much
- 11) If yes, can you try to explain what benefit?
- 12) After how many days, if any, did you notice this benefit?
After days:
- 13) Did you have problems getting used to or performing the exercises?
- 14) What is your general impression of the exercises?
- 15) Would you keep practicing, if recommended by your therapist?
1= yes, absolutely
2= probably
3= probably not
4= no
- 16) General remarks: