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Effects of Strengthening Exercises on Swallowing Musculature and Function in Senior Healthy Subjects: a Prospective Effectiveness and Feasibility Study

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Abstract Head and neck cancer (HNC) patients may develop dysphagia due to muscle atrophy and fibrosis following chemoradiotherapy. Strengthening of the swallowing muscles through therapeutic exercise is potentially effective for improving swallowing function. We hypothesize that a customized Swallow Exercise Aid (SEA), developed for isometric and isokinetic strengthening exercises (against resistance), can help to functionally strengthen the suprahyoid musculature, which in turn can improve swallowing function. An effectiveness/feasibility study was carried out with ten senior healthy volunteers, who performed exercises 3 times per day for 6 weeks. Exercises included chin tuck against resistance (CTAR), jaw opening against resistance (JOAR), and effortful swallow exercises with the SEA. Multidimensional assessment consisted of measurements of maximum chin

tuck and jaw opening strength, maximum tongue strength/endurance, suprahyoid muscle volume, hyoid bone displacement, swallowing transport times, occurrence of laryngeal penetration/aspiration and/or contrast residue, maximum mouth opening, feasibility/compliance (questionnaires), and subjective swallowing complaints (SWAL-QOL). After 6-weeks exercise, mean chin tuck strength, jaw opening strength, anterior tongue strength, suprahyoid muscle volume, and maximum mouth opening significantly increased ($p < .05$). Feasibility and compliance (median 86 %, range 48–100 %) of the SEA exercises were good. This prospective effectiveness/feasibility study on the effects of CTAR/JOAR isometric and isokinetic strengthening exercises on swallowing musculature and function shows that senior healthy subjects are able to significantly increase swallowing muscle strength and volume after a 6-week training period. These positive results warrant further investigation of effectiveness and feasibility of these SEA exercises in HNC patients with dysphagia.

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Introduction

Swallowing in general, and the various phases of this process (oral, pharyngeal, and esophageal), requires a complex interaction between the muscles in the tongue, floor of mouth, pharynx, and larynx [1–3]. This intricate physiologic course of muscle events and interactions is at risk in patients treated for head and neck cancer (HNC), and swallowing impairment/dysphagia is not uncommon in these patients. It can be caused by the tumor extension

itself, but maybe even more so, by tissue reactions resulting from surgical resections or (organ preserving) chemoradiotherapy (CRT), e.g., radiation fibrosis or changes in innervation of the swallowing musculature. Additionally, the occurrence of acute mucositis, fibrosis, xerostomia, pain, and trismus often cause severe swallowing problems, which, in turn, limit oral intake and may require nasogastric tube feeding [4–7].

Tongue strength also plays a role in the swallowing physiology, particularly in the oral phase of the swallow [8–10]. In patients treated with primary CRT, lingual strength is reduced, which further limits oral and pharyngeal structural movement during the swallow [11]. As a result, the swallowing muscles are no longer actively used and might eventually atrophy [12], affecting both oral and pharyngeal phase swallowing function, especially in the long term.

Recently, more attention has been drawn to prevention of non-use atrophy in patients with advanced HNC undergoing CRT. In compliant patients, implementation of preventive (swallowing) exercises has demonstrated to improve post-treatment swallowing function and quality of life [13–17]. These exercises include range of motion or resistance exercises (with or without medical devices such as the TheraBite[®] device), the (super-)supraglottic swallow [1, 18, 19], the effortful swallow [1, 20, 21], the Mendelsohn maneuver [19, 22], the Masako (tongue-holding) maneuver [21], and the Shaker (head-raising) exercise [23]. Especially the latter has proven to be effective in strengthening the suprahyoid musculature and reducing swallowing problems [24, 25], but with the major drawback that the exercise should be carried out in a supine position. This appears to be quite strenuous, and compliance with this exercise is less due to sternocleidomastoid muscle discomfort, especially in elderly, frail patients [26, 27].

As an alternative therapeutic intervention for patients who find the Shaker exercise in the supine position physically challenging, Yoon et al. investigated another exercise to activate the suprahyoid musculature: the chin tuck against resistance (CTAR) [27]. This exercise involves tucking the chin as hard as possible on a rubber ball, which is placed between the chin and chest. The authors state that it can be carried out for both isometric and isokinetic tasks, and it would allow elderly/frail patients to perform the exercises based on their current strength level, without having to be strong enough to perform a head lift from the supine position. As such, it could qualify as an alternative to the Shaker exercise and potentially improve exercise compliance [27].

The TheraBite[®] device, originally developed for passive range of motion exercises in irradiated patients with trismus and/or patients with mandibular hypomobility [28,

29], can also be used in HNC patients to aid swallowing exercises during CRT treatment. With this device, it appears to be possible to improve hyo-laryngeal elevation and swallowing muscle maintenance, and thus functional swallowing ability [15, 16].

Based on the positive experience with the TheraBite as an exercise tool with good compliance [15, 16], and the idea to combine proven isometric and isokinetic strength exercises in a single useful handheld device that is applicable in a seated position, we developed a new Swallow Exercise Aid (SEA). The device consists of commercially available and customized components, to enable exercises against variable/increasing resistance, allowing adaptation to individual performance improvement, and to provide adequate tactile feedback. In this way, a variation of exercises can be performed, which have the potential to functionally strengthen the suprahyoid and pharyngeal muscles relevant for swallowing. The effectiveness and feasibility/compliance of an exercise protocol using this device was studied in healthy subjects with a multidimensional assessment protocol.

Materials and Methods

The present study was designed as an uncontrolled prospective effectiveness and feasibility study with a 6-week follow-up period, and was undertaken at the Department of Head and Neck Oncology and Surgery of the Netherlands Cancer Institute—Antoni van Leeuwenhoek in Amsterdam, the Netherlands.

Participants/Volunteers

The study population consisted of ten healthy, male subjects without history of swallowing impairment or other dysphagia symptoms (median total SWAL-QOL score at baseline 4.5, which is below the defined cut-off score of 14 by Rinkel et al. for swallowing problems [30]). Median age at baseline was 60 years (range 52–73 years); median weight was 88 kg (range 70–92 kg). This age and gender group was chosen to mimic the age distribution of the HNC patient population [31, 32], and because HNC occurs more frequently in males than in females, with a ratio ranging from 3:1 to 4:1 [31, 32]. Moreover, in this way, gender was not an effect modifier in this small-scale effectiveness and feasibility study. See Table 1 for volunteers' characteristics at baseline.

The Swallow Exercise Aid

The SEA was constructed with commercially available parts, i.e., the TheraBite Jaw Mobilization device

Table 1 Volunteers' characteristics ($N = 10$)

Subject	Gender	Age (years)	Weight (kg)	FOIS (score)	Follow-up	Assessments
Subject 1	M	52	70	7	6 weeks, 2 days	All
Subject 2	M	66	88	7	6 weeks, 2 days	No MRI
Subject 3	M	67	91	7	6 weeks, 2 days	All
Subject 4	M	61	80	7	6 weeks, 2 days	All
Subject 5	M	54	88	7	6 weeks, 2 days	All
Subject 6	M	73	92	7	6 weeks, 2 days	All
Subject 7	M	56	87	7	6 weeks, 2 days	All
Subject 8	M	61	88	7	6 weeks, 2 days	All
Subject 9	M	57	82	7	4 weeks, 4 days	All
Subject 10	M	58	88	7	6 weeks, 2 days	All

Age and weight are assessed at baseline

FOIS functional oral intake scale

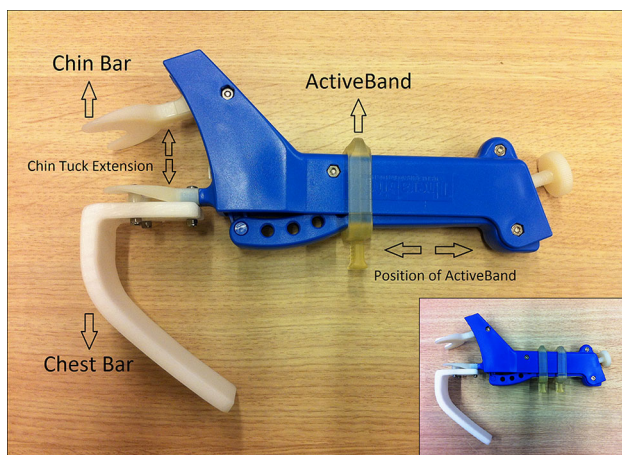


Fig. 1 Swallow Exercise Aid (SEA) with ActiveBand, chin tuck and jaw opening extension, chin bar, and chest bar; inset shows possible addition of a second ActiveBand to further increase resistance

complemented with one or two TheraBite ActiveBands made out of silicone rubber (Atos Medical, Hörby, Sweden), and subsequently remodeled by our Institute's technician by adding a chest bar to one of the mouthpieces of the TheraBite (see Fig. 1). The ActiveBand can be placed at various, marked positions around the handle. The force required to compress the chin bar onto the chest bar with one ActiveBand in the maximum position, according to the manufacturer's specifications, is 50 Newton (N). If a subject had enough strength with one ActiveBand at its maximum position to complete the set of exercises, a second ActiveBand was added at any one of the marked positions. This configuration allows progressive overload, which is a prerequisite for effective strength training [33].

Intervention

The training program consisted of three exercises, visualized in Fig. 2:



Fig. 2 Swallowing Exercise Aid (SEA) exercises (printed with permission of subject). *Top left* start position; *bottom left* exercise 1; chin tuck against resistance (CTAR) exercise; *top right* exercise 2; jaw opening against resistance (JOAR) exercise; *bottom right* exercise 3; effortful swallow exercise with 50 % of maximum closure

The first exercise, the CTAR exercise, was performed by pressing the chin downwards against the chin bar, while keeping the mouth closed, until the chin bar reached the chest bar attachment (providing tactile feedback). In this way, the exercise—comparable to the Shaker [23] and the

'ball' CTAR exercise [27]—focused on training the suprahyoid muscles.

The second exercise, the jaw opening against resistance (JOAR) exercise, was performed by pressing the mandible down while opening the mouth, to again compress the chin bar onto the chest bar. Given that suprahyoid muscles participate in opening the jaw [34], this exercise focused not only on the suprahyoid muscles, but also on other jaw opening musculature.

The third exercise, the effortful swallow exercise, was performed with the chin placed on the chin bar (pressed downwards for approximately 50 %), whereby the subjects were asked to swallow with the mandible down and mouth closed, comparable to the formerly described TheraBite swallowing exercise [15]. This exercise is hypothesized to not only stimulate the suprahyoid and jaw muscles involved in mouth opening, but also the pharyngeal musculature, comparable to an effortful swallow [1, 20, 21].

Exercise Protocol

All subjects were asked to perform the SEA exercises three times per day for 6 weeks. Prior to participation, subjects received a written instruction sheet. They were instructed to hold the SEA in their preferred hand, to place the chest bar onto the sternum without excessive pressure, and to place the chin onto the chin bar. The ActiveBand was placed on the (individual) indicated position of the device, to ensure a specified amount of resistance.

Comparable with the Shaker exercise [23], the CTAR and JOAR exercises consist of both isometric and isokinetic strength exercises. The isokinetic exercises were performed 30 times consecutively at a fixed pace of 1 s per contraction. The isometric exercises were performed three times, maintained for 60 s, with a 60 s rest period between each of the three. These two exercises were carried out first, with 60 s rest between each session. Subsequently, the effortful swallow exercise was performed ten times consecutively, after another 60 s rest period. The total duration of the three exercises was estimated to be 15 min per session.

For the exercise prescription, only start-intensity was specified for individual subjects based on baseline strength assessments (dynamometry and 30-repetition maximum). Progression of intensity was based on self-perceived exertion; all subjects were instructed that the exercises should be perceived as strenuous, inducing substantial local muscle fatigue, and to increase resistance whenever they felt able to (that is: if they could complete the exercise without substantial exertion).

Subjects received three daily SMS text messages as a reminder to practice and were asked to record their

performances by using tally sheets in a special exercise log. All subjects were instructed to stop the exercises if they felt discomfort or pain on the chest/chin or in/around their temporomandibular joint during the exercises.

Multidimensional Assessment

All outcome parameters were recorded prior to participation (at baseline) and two days after the 6-week practice period (post-training). The total duration of the multidimensional assessment protocol was estimated to be 60 min per session. Primary outcome parameters were maximum chin tuck/jaw opening strength, maximum tongue strength/endurance, suprahyoid (swallowing) muscle volume, and hyoid bone displacement (HBD).

Muscle Strength

Muscle strengths were measured with a 'handheld' dynamometer (Microfet™, Biometrics, Almere, the Netherlands) mounted into an adapted ophthalmic examination frame (see Fig. 3), to avoid variations in head and chin position and to ensure consistent compression. A superior fixed belt stabilized the subject's head, and the height of both the chin rest and the superior belt could be adjusted to the subject's dimensions. Subjects 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). The dynamometer digitally measured the maximal isometric chin tuck/jaw opening strength in Newton. Both measurements were

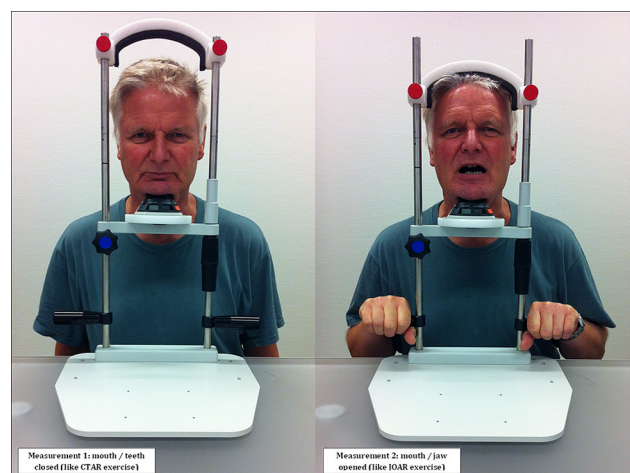


Fig. 3 Muscle strength test setup with an adapted ophthalmic examination frame and a dynamometer (Microfet™) fixed at the chin rest (printed with permission of subject). *Left* measurement 1 (mouth closed, comparable to CTAR exercise); *right* measurement 2 (mouth opened, comparable to JOAR exercise)

preceded by one familiarization session, in order to exclude learning curve effects and to improve reliability of the values obtained [35]. After the familiarization session, both measurements were repeated three times, with a 60-s rest period between the trials. The mean maximum pressure of the highest two of three values was calculated and used as the subjects' maximum chin tuck/jaw opening strength [35]. Test–retest reliability with intraclass correlation coefficient (ICC(2,1)) of this setup was assessed in 14 (different) volunteers. The maximal chin tuck strength showed an ICC(2,1) of 0.98 (95 % CI 0.93–0.99), and the maximal jaw opening strength showed an ICC(2,1) of 0.97 (95 % CI 0.92–0.99) (which means a maximal measurement error of 17 N for chin tuck strength and 18 N for jaw opening strength in this SEA sample).

Tongue Strength and Endurance

The Iowa Oral Performance Instrument (IOPI) was used to measure maximum tongue pressures (at anterior and posterior locations) and endurance by means of a small air-filled bulb. There is ample evidence to support this tool for evaluating (isometric) tongue strength and endurance [33, 36]. Subjects had to press their tongue upwards on the air-filled bulb, in order to squeeze the bulb against the hard palate. Pressures were expressed in kPa and digitally displayed on the device. After one familiarization session, three trials of maximum (anterior and posterior) tongue pressure were obtained for each subject, with a 2-min rest period between the trials. The mean maximum pressure of the highest two of three values was calculated and used as the subjects' maximal (anterior/posterior) tongue strength. Also endurance measures were analyzed at anterior tongue location following the strength task, after a break of at least 5 min. Subjects were asked to maintain 50 % of their maximal tongue strength as long as possible.

Muscle Volume

Magnetic resonance imaging (MRI) at 3 Tesla (Philips Achieva release 3.2.1, Philips Medical Systems, Best, The Netherlands) was used to visualize the swallowing muscles in the oral cavity and pharynx [16]. A dedicated 16-channel SENSE neurovascular coil was used. Both T1 (Turbo Spin Echo (TSE), TRA:TR/TE:1761/10, ETL:6, recon voxel: $0.5 \times 0.5 \times 1.5$ mm, FOV:100x100x91, 2 nex; SGT:TR/TE:1490/10 ms, ETL:7, recon voxel: $0.5 \times 0.5 \times 1.5$ mm, FOV: $100 \times 200 \times 91.2$ nex; COR:TR/TE:877/10, ETL:7, recon voxel: $0.28 \times 0.28 \times 1.5$ mm, FOV: $99 \times 110 \times 180$, 3 nex) and 3D T2 (Vista COR:TR/TE:1874/200 ETL:66, recon voxel: $0.4 \times 0.4 \times 0.75$, FOV: $100 \times 110 \times 181$, 3 nex) were acquired. Total duration of the MRI-investigation was 20 min. Subjects were

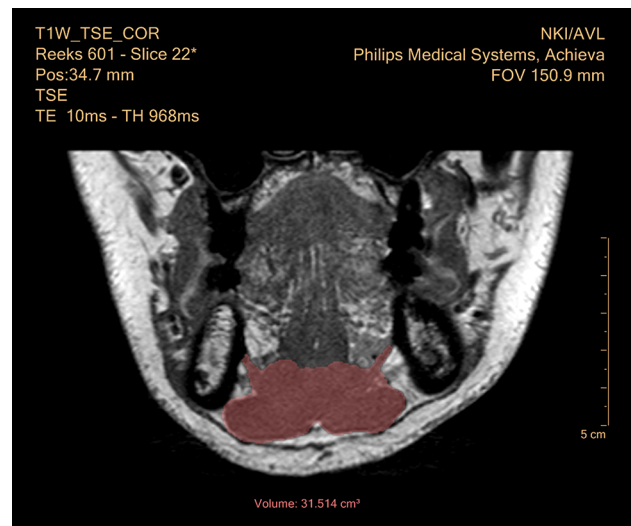


Fig. 4 Graphic representation of delineated suprahyoid muscle contour with corresponding volume calculation in the coronal orthogonal plane assessed with MRI

instructed to lie down while keeping their tongue (relaxed) to the lower teeth during scanning. The acquired images were stored unto a PACS Workstation (Carestream Health Inc, Rochester, USA). Post-processing (volume measurements) was done using the Philips Intellispace Portal Tumor Tracking Application (Philips Medical Systems, Best, the Netherlands). With this application, the contours of the muscle groups were delineated in three orthogonal planes (T1 coronal, transversal, and sagittal), and controlled with overlying T2 images. As an example, in Fig. 4, a graphic representation of the delineated muscle contour with corresponding volume calculation in the coronal orthogonal plane is shown. Muscle volumes of the suprahyoid muscles (the combination of the geniohyoid, mylohyoid, and digastric (anterior belly) muscles) were determined. It appeared that the measurements of individual muscles were not practical, because of three reasons: the individual muscles are not easily distinguished from each other with MRI (especially the geniohyoideus and mylohyoideus), the individual muscles are small, therefore measuring will have a relatively large inherent variability and inaccuracy, and third: they can functionally be considered as one group, and we supposed an equal reaction to exercise.

Videofluoroscopy Swallowing Parameters

Videofluoroscopy (VFS) is a validated method for objective assessment of all phases of the swallowing physiology [1]. The swallowing act was recorded in a lateral field of view encompassing the lips anteriorly, the cervical vertebrae posteriorly, the soft palate superiorly, and the lower end of the cervical esophagus inferiorly. The consistencies

and amounts used were 1, 3, 5, and 10 cc thin liquid, 3 and 5 cc paste liquid, and a Omnipaque coated piece of gingerbread. Subjects were instructed to sip and wait for a verbal cue from the clinical investigator before swallowing, with clear instructions to sip as usual, without excessive force. The primary outcome measure was anterior/superior HBD, which is defined as the anterior/superior distance traveled by the hyoid bone to the point of maximal displacement during a swallow from its position during hold [37, 38]. Measures were done based on the methods of these authors, by ‘subtracting’ the still of hyoid elevation start time (HEST) from that of maximum hyoid elevation time (MHET). HEST is defined as the time between the first superior-anterior displacement of the hyoid bone that results in a swallow minus the time of the first movement of the head of the bolus past the posterior nasal spine (onset of pharyngeal transit). MHET is defined as the time between the frame in which the hyoid bone had reached its maximum superior-anterior excursion during the swallow, and again pharyngeal transit onset time [39]. Other VFS parameters assessed were the presence of laryngeal penetration and/or aspiration [40], and occurrence of contrast residue.

Additional outcome parameters in the multidimensional assessment protocol were mouth opening, subjective swallowing complaints, and feasibility and compliance of/with the SEA exercises. Maximum mouth opening was measured in millimeters using disposable TheraBite range of motion scales. Subjective swallowing complaints were recorded pre- and post-training with the 44-item Swallowing Quality of Life (SWAL-QOL) questionnaire [41], which assesses patients’ swallowing impairment based on ten QoL domains, each ranging from 0 to 100 with a higher score indicating more impairment. Feasibility of the SEA exercises (use of the exercise regimen, familiarity with the exercises, and occurrence of adverse events) was monitored with a study-specific questionnaire. Compliance with the SEA exercises was monitored with tally sheets in a daily exercise log.

Imaging Assessment Procedures

Both MRI and VFS assessments were done by two assessors independently: the first author and one dedicated head and neck radiologist (for MRI; JT), or the participating SLP (for VFS; LvdM). For MRI, both assessors were blinded to pre- or post-intervention status of the image. The delineated muscle volumes were reviewed in a consensus meeting, while maintained blinding, and the consensus volumes were used in the analysis. For VFS categorical measurements, a similar blinded consensus procedure was followed, in this respect with the participating SLP. For VFS anterior and superior HBD assessments, 10 % of the measurements (stills of all consistencies in lateral view pre-

and post-intervention) were repeated by the first author (as a measure of intrarater reliability), and 10 % were reviewed by the SLP (as a measure of interrater reliability). Measurements were deemed in concordance if pairwise testing showed a greater than 95 % chance of measuring statistically indistinguishable values in the two measurement sessions [25].

Statistical Analyses

Descriptive statistics were generated for all outcome measures. Data from muscle strength tests, IOPI measurements, MRI, VFS, and questionnaires of the total study population were summarized as medians and median differences, whereby 95 % confidence intervals for the median differences were obtained with bootstrapping. Wilcoxon signed-rank tests were used to compare the repeated measurements. A two-sided p value of 0.05 was considered to indicate statistical significance. Statistical analysis was performed using Statistical Package of Social Sciences (SPSS) software version 20.0.

Results

For 9 subjects, the post-intervention multidimensional evaluation protocol was carried out two days after the 6-week exercise period. In one subject, this had to be done already after four and a half weeks since he had professional commitments abroad. All collected data are shown in Table 2. In the following paragraphs, the most relevant/significant results are described in more detail.

Muscle Strength

After 6-weeks of swallowing training, median chin tuck strength significantly increased with 38.5 N (95 % CI 20.3–59.4 N; $p = .005$), from a median of 82.0 N to a median of 120.5 N. The median jaw opening strength significantly increased with 52.1 N (95 % CI 28.9–89.5 N; $p = .005$), from a median of 82.3 to 134.4 N. The individual improvements are visualized in Figs. 5 and 6.

Tongue Strength and Endurance

Median anterior tongue strength (IOPI) significantly increased with 2.9 kPa (95 % CI –1.0 to 9.0 kPa; $p = .016$), from a median of 57.4 kPa to a median of 60.3 kPa. There was a trend for posterior tongue strength increase with a median increase of 1.3 kPa (95 % CI –1.0 to 7.0 kPa; $p = .080$). The increase in anterior tongue endurance with a median of 8.5 s was not statistically significant ($p = .126$).

Table 2 Data collection per subject before and after the 6-week exercise period

	S01	S02	S03	S04	S05	S06	S07	S08	S09	S10	Median	Median difference	95 % CI difference	<i>p</i> value
Chin tuck strength (N)														
Pre	198.5	81.0	51.0	63.0	228.5	83.0	78.0	132.0	126.5	100.0	82.0			
Post	242.4	99.2	93.4	118.1	238.9	142.4	112.5	152.3	132.0	189.5	132.0	38.5	20.3 to 59.4	<i>p</i> = .005
Jaw opening strength (N)														
Pre	128.5	70.5	36.5	55.0	232.0	69.0	94.0	96.5	54.0	100.0	82.3			
Post	229.8	117.0	87.8	107.9	283.4	145.0	102.1	125.4	120.0	189.5	122.7	52.1	28.9 to 89.5	<i>p</i> = .005
Ant. tongue strength (kPa)														
Pre	70.5	54.5	57.0	55.0	74.5	58.5	45.5	49.0	60.0	57.5	57.4			
Post	72.0	65.0	58.0	64.0	73.5	57.5	57.0	54.0	61.5	62.0	61.8	2.9	-1.0 to 9.0	<i>p</i> = .016
Post. tongue strength (kPa)														
Pre	75.0	75.5	57.5	64.0	63.5	47.0	49.5	47.5	56.0	53.5	56.8			
Post	76.5	76.5	57.5	64.0	70.0	46.0	56.5	45.5	60.0	63.5	61.8	1.3	-1.0 to 7.0	<i>p</i> = .080
Ant. tongue endurance (s)														
Pre	44	30	30	31	24	106	71	19	27	29	30.0			
Post	53	29	61	32	35	260	41	16	47	37	39.0	8.5	-3.0 to 20.0	<i>p</i> = .126
Suprahyoid muscle mass (cm ²)														
Pre	27.3	x	24.1	22.5	32.1	26.8	29.5	26.8	27.4	22.2	26.8			
Post	29.5	x	27.5	23.8	34.3	32.9	34.1	29.6	30.8	23.4	29.6	2.9	1.3 to 4.6	<i>p</i> = .008
Mouth opening (mm)														
Pre	42	67	56	61	52	49	60	48	51	46	51.5			
Post	42	70	56	64	52	53	64	50	52	52	52.5	2.5	0.0 to 4.0	<i>p</i> = .018
Ant. HBD 1 cc thin liq. (mm)														
Pre	8.19	13.57	7.76	12.33	10.14	9.73	12.6	9.98	9.47	8.83	9.9			
Post	12.09	15.45	7.96	7.61	11.58	13.7	9.19	14.97	14.45	8.83	11.8	1.7	-3.4 to 2.9	<i>p</i> = .173
Sup. HBD 1 cc thin liq. (mm)														
Pre	22.25	15.56	6.2	13.32	13.85	20.74	13.1	17.09	24.42	14.73	15.1			
Post	14.33	22.35	15.05	14.4	22.71	15.91	28.72	9.56	27.36	27.69	19.1	4.9	-1.9 to 13.0	<i>p</i> = .169
Ant. HBD 3 cc thin liq. (mm)														
Pre	8.62	11.58	8.28	11.35	12.18	9.3	14.61	11.87	8.97	13.03	11.5			
Post	13.43	12.2	9.29	8.41	9.86	15.91	11.58	14.97	x	11.64	11.6	0.6	-2.9 to 3.8	<i>p</i> = .594
Sup. HBD 3 cc thin liq. (mm)														
Pre	17.99	14.76	10.34	13.32	14.36	22.86	14.11	19.47	13.96	14.3	14.3			
Post	12.53	21.13	14.61	12.4	22.71	16.35	25.93	4.57	x	26.49	16.3	4.3	-3.7 to 11.8	<i>p</i> = .594
Ant. HBD 5 cc thin liq. (mm)														
Pre	14.51	9.57	7.25	9.87	12.68	9.3	13.1	9.98	7.97	13.87	9.9			
Post	14.78	11.79	10.18	9.6	13.71	15.46	12.78	15.8	13.42	11.64	13.1	1.6	-0.3 to 2.6	<i>p</i> = .093
Sup. HBD 5 cc thin liq. (mm)														
Pre	21.97	19.55	4.14	15.3	13.85	28.78	20.15	12.35	14.45	13.04	14.9			
Post	12.09	24.38	16.83	6.79	27.42	15.46	22.34	2.5	34.58	27.29	19.6	3.5	-9.9 to 13.5	<i>p</i> = .386
Ant. HBD 10 cc thin liq. (mm)														
Pre	15.84	10.78	8.8	11.35	14.7	9.73	15.62	8.08	6.97	13.03	11.1			
Post	15.67	10.98	9.73	11.2	14.57	15.46	13.57	14.97	5.68	11.24	12.4	-0.1	-1.8 to 0.6	<i>p</i> = .959
Sup. HBD 10 cc thin liq. (mm)														
Pre	7.09	20.74	5.17	9.87	16.38	21.16	21.16	13.29	10.97	14.3	13.8			
Post	13.88	28.44	16.83	11.6	27.42	16.35	30.33	0	26.84	25.69	21.3	8.4	1.7 to 11.4	<i>p</i> = .093
Ant. HBD 5 cc thick liq. (mm)														
Pre	13.76	10.38	9.31	15.3	20.79	9.3	15.12	9.5	9.47	15.98	12.1			
Post	17.02	12.6	11.51	10.8	15.85	15.46	10.78	14.14	18.58	15.65	14.8	2.2	-4.5 to 3.3	<i>p</i> = .445

Table 2 continued

	S01	S02	S03	S04	S05	S06	S07	S08	S09	S10	Median	Median difference	95 % CI difference	<i>p</i> value
Sup. HBD 5 cc thick liq. (mm)														
Pre	12.19	21.54	2.06	3.94	9.28	30.89	10.59	11.39	9.96	15.98	11.0			
Post	6.27	24.38	13.72	8.8	23.99	18.56	21.55	0	25.29	19.67	19.1	4.3	-4.3 to 11.3	<i>p</i> = .333
Ant. HBD paste liq. (mm)														
Pre	14.38	11.18	8.28	13.82	19.27	11.85	11.59	12.35	11.97	17.66	12.2			
Post	15.67	15.45	14.17	12.8	16.72	19	12.38	x	x	18.06	15.6	1.0	-1.0 to 5.1	<i>p</i> = .161
Sup. HBD paste liq. (mm)														
Pre	8.66	20.07	-0.49	11.71	15.55	19.69	12.92	7.21	8.04	8.79	10.8			
Post	9.78	16.59	11.77	11.01	26.44	11.74	23.86	x	x	19.44	14.9	6.2	-2.2 to 11.5	<i>p</i> = .161
Hyoid elevation start time (s)														
Pre	0.42	-0.36	-0.09	-0.03	-0.2	0.15	0.24	0.05	-0.13	0.17	0.04			
Post	0.42	0.12	-0.07	0.34	0.31	0.33	0.23	0.42	0.07	0.13	0.22	0.1	-0.0 to 0.4	<i>p</i> = .093
Max. hyoid elevation time (s)														
Pre	1.16	0.57	0.55	1.03	0.71	0.76	0.68	0.84	0.43	0.85	0.77			
Post	0.94	0.59	0.49	0.81	0.82	0.88	0.74	0.98	0.4	0.72	0.74	-0.1	-0.2 to 0.0	<i>p</i> = .241
Total SWAL-QoL score														
Pre	22.9	8.9	0	1.8	47.1	7.1	0	16.7	0	0	4.5			
Post	22.9	29.5	0	1.8	56.0	7.1	0	66.6	0	0	4.5	0.0	0.0 to 10.3	<i>p</i> = .109

S01–S10 subject 1 to subject 10, CI confidence interval, N Newton, kPa kilopascal, s seconds, cm³ cc cubic centimeters, mm millimeters, HBD hyoid bone displacement, ant. anterior, sup. superior, liq. liquid, max. maximum, SWAL-QoL score Swallowing Quality of Life score (a higher score means worse quality of life based on swallowing function), x not available

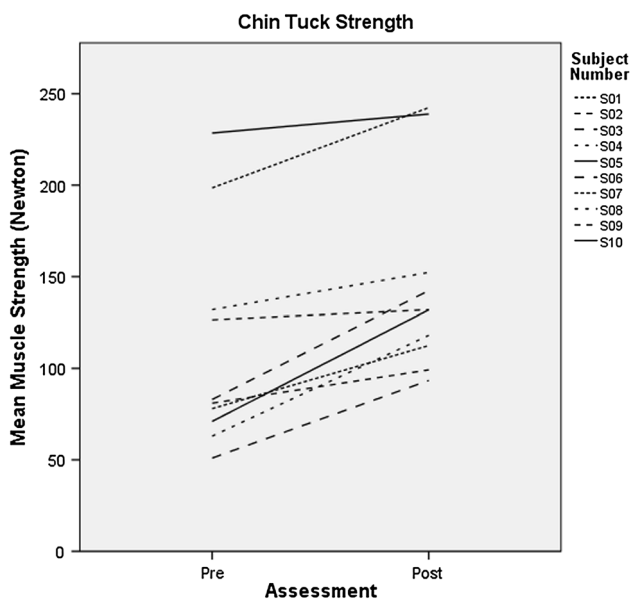


Fig. 5 Change in individual maximum chin tuck strength after the 6-week exercise period

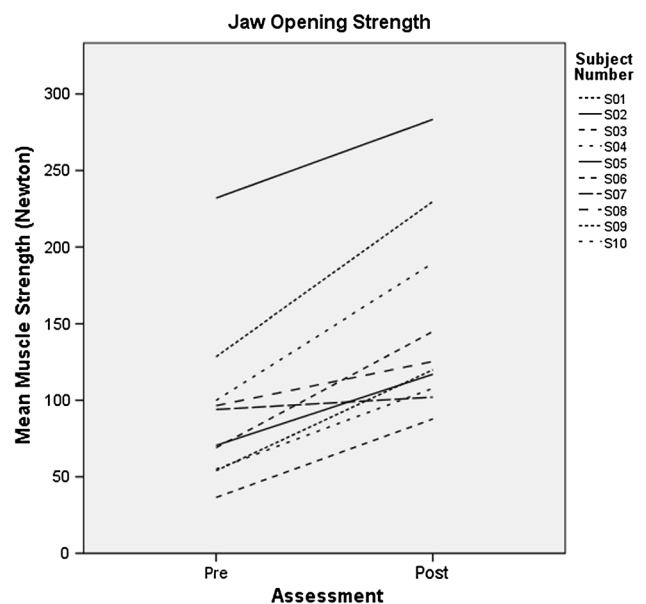


Fig. 6 Change in individual maximum jaw opening strength after the 6-week exercise period

Muscle Volume

After 6-weeks of swallowing training, median suprahyoid muscle volume (the mylohyoid, geniohyoid, and anterior belly of digastric muscles combined) significantly increased with 2.9 cm³ (95 % CI 1.3–4.6 cm³; $p = .008$), from a median of 26.8 cm³ to a median of 29.6 cm³. The individual improvements are visualized in Fig. 7.

VFS Swallowing Parameters

As can be seen in Table 1, HBD outcomes were quite variable over the various consistencies and subjects, and did not differ significantly over time. After the 6-week exercise period, HBD had increased in particular in the superior direction compared to the anterior direction. As an example, the lowest increase was seen for a 5 cc thin liquid swallow (superior HBD increased with a median of 3.5 mm), and the highest increase was seen for a 10 cc thin liquid swallow (superior HBD increased with a median of 8.4 mm). At both assessment points, subjects showed normal swallowing function on the VFS. There was no laryngeal penetration/aspiration or more than normal contrast residue seen after the swallow (this applied to all consistencies). Mean hyoid bone elevation start time and hyoid bone maximum elevation time did not differ significantly between the two assessment points (median difference 0.1 and -0.1 s, respectively).

Additional Outcome Parameters

Although none of the tested subjects had any swallowing complaints, trismus, or dietary limitations, still we found an

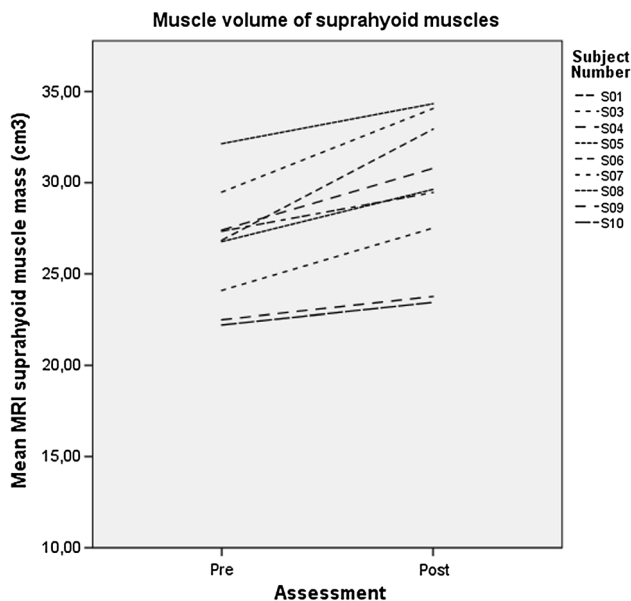


Fig. 7 Change in individual muscle volume of suprahyoid muscles after the 6-week exercise period

increase in mouth opening after the training program. Median maximal inter-incisor opening significantly increased with 2.5 mm (95 % CI 0.0–4.0 mm; $p = .018$), from a median of 51.5 mm to a median of 52.5 mm. There were no subjective swallowing complaints or adverse events. Total duration of the exercises was reported to be 15–20 min. Feasibility of the SEA exercises was considered acceptable, i.e., “time consuming, but doable.” Out of 129 exercise sessions (three times a day during 6 weeks with one additional day at the end of the exercise period), median compliance was 86 % (range 48–100 %). Except for one subject, all participants had at least practiced one session a day, and none of the participants had missed more than two sessions consecutively. Half of the participants added a second ActiveBand during the 6 weeks exercise period, because of increased ease of closing the chin bar onto the chest bar. None of the subjects reported unacceptable discomfort or pain on the chest/chin or in/around their temporomandibular joint during the exercises.

Discussion

This prospective effectiveness and feasibility study on the effects of this newly assembled SEA, enabling CTAR and JOAR exercises, shows that senior healthy subjects are able to improve and increase swallowing muscle strength and volume after a 6-week training period, even at the absence of swallowing problems. The increases in muscle strength are highly significant and potentially clinically relevant. Moreover, with a median increase of 38.5 and 52.1 N, they exceed the possible measurement error associated with the measurement setup, which was 17 N for chin tuck strength and 18 N for jaw opening strength in this sample, based on the established reliability. Therefore, the observed increase in swallowing muscle strength can be attributed to the 6-week exercise regimen with confidence. On top of that, subjects’ anterior tongue strength and mouth opening significantly increased as well. The positive results found in this study warrant a trial for this SEA in HNC patients with dysphagia.

The results found in this study are more or less in concordance with some earlier studies on strengthening the suprahyoid musculature by JOAR and/or CTAR exercises, applied to improve swallowing function. Wada et al. investigated the effects of the JOAR exercise on decreased upper esophageal sphincter (UES) opening on videofluoroscopy in eight patients with dysphagia while swallowing, and these authors found significant improvements in the extent of upward hyoid bone movement, amount of UES opening and time for pharynx passage after four weeks of training [34]. Although that study population consisted of only eight patients and no objective

assessment of suprahyoid muscle strength was performed, the significant increase in upward movement of the hyoid bone following 4 weeks of practice suggests that the suprahyoid musculature (especially the mylohyoid muscle and anterior belly of the digastric muscles) was strengthened. This would be in line with the significant improved suprahyoid muscle strength (and volume) found in the present study after 6 weeks of comparable JOAR and CTAR exercises, although we did not find a significant increase in HBD, which is not surprising in this group of healthy subjects without swallowing issues.

As already briefly mentioned in the introduction, Yoon et al. recently investigated the CTAR exercise for both isometric and isokinetic tasks in comparison with the Shaker exercise, by measuring maximum and mean surface electromyography (sEMG) activity of the suprahyoid muscles during the exercise regimen [27]. The CTAR exercise was performed by tucking the chin as hard as possible on a rubber ball, placed between the chin and chest. Both exercises resulted in elevated maximum and mean sEMG values, reflecting suprahyoid muscle activity. Given the fact that suprahyoid muscle activity/strength is strongly correlated with hyoid bone displacement [42] and thus an important indicator of swallowing function [34], and given the fact that suprahyoid muscle strength significantly improved in our study, it can be assumed that the CTAR and JOAR exercises with the SEA positively affect swallowing function too. The observed increased suprahyoid muscle volume contributes to this hypothesis. Compared to the Shaker exercise, interestingly, Yoon et al. found that the CTAR exercise with a rubber ball resulted in significantly greater maximum and mean activation levels during the isometric and isokinetic tasks, even though it was reported as less strenuous. This latter fact might further increase compliance with the ball exercise, aside from the advantage that no inconvenient and uncomfortable supine position is needed, which also allows elderly/frail patients to perform the exercises based on their current strength level [27]. The same holds true for the SEA, which has the additional advantage of using one or two elastic silicone ActiveBands to specify and increase the amount of resistance during the exercises. The closure of the chin bar onto the chest bar and the option to add a second elastic band to further increase resistance also give biofeedback for patient's performance. This latter fact was also supported by anecdotal feedback from our volunteers, and might further improve subjects' compliance with the exercises. However, the lack of a structured protocol for exercise progression may have resulted in a sub-optimal training effect. This underscores the potential of the exercise regimen, given the large effect sizes that we observed in this study. In future clinical studies, a structured prescription for exercise

progression may result in even greater gains in muscle strength.

Despite the physiological range of motion during mouth opening, and the fact that all subjects already showed a normal maximum mouth opening (>35 mm) at baseline without swallowing complaints or dietary limitations, there was a small but statistically significant increase in maximum mouth opening after the 6-week exercise period. A following trial in HNC patients (with damaged swallowing muscles) will evaluate if maximum mouth opening can also increase in these patients, following six weeks of swallowing training.

Although submental sEMG recordings are commonly used in the field of dysphagia research and measured sEMG activity is thought to reflect actions of the suprahyoid musculature, we chose not to record sEMG activity. The main reason is that it is not possible to delineate which individual muscle (i.e., mylohyoid, anterior belly of the digastric, geniohyoid, and genioglossus) contributes most to the derived sEMG recordings [43]. Instead, we used muscle volume measurements with MRI, which provides information on possible hypertrophy of the muscles of interest. In addition, MRI might be more useful in a clinical research setting, because in most patients with advanced head and neck cancer, MRIs are readily available for diagnosis and treatment response evaluation.

A limitation of the current study is that assessment of muscle function was limited to maximal muscle strength for the performed exercises. As a result, we cannot be sure how well the increase in swallowing muscle strength results in overall better functional swallowing ability (due to potential specificity effects). Regarding the literature, maximal chin tuck and jaw opening strengths are associated with better swallowing function [27, 34]. However, to better understand how these exercises influence swallowing function, future studies could include measurements of lingua-palatal pressures produced during effortful and non-effortful swallows. Furthermore, the sample size of this preliminary study was limited to ten highly motivated subjects, and therefore, the results should be interpreted with some caution.

Conclusion

This prospective effectiveness and feasibility trial on the effects of CTAR and JOAR isometric and isokinetic strength exercises on swallowing musculature and function shows that senior healthy subjects are able to improve and increase swallowing muscle strength and volume after a 6-week period of extensive swallowing training. The

positive results found in this study warrant a trial with this SEA in HNC patients with dysphagia.

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