

## ORIGINAL ARTICLE

# Functional and Physiological Outcomes from an Exercise-Based Dysphagia Therapy: A Pilot Investigation of the McNeill Dysphagia Therapy Program

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**ABSTRACT.** Crary MA, Carnaby GD, LaGorio LA, Carvajal PJ. Functional and physiological outcomes from an exercise-based dysphagia therapy: a pilot investigation of the McNeill Dysphagia Therapy Program. *Arch Phys Med Rehabil* 2012;93:1173-8.

**Objective:** To investigate functional and physiological changes in swallowing performance of adults with chronic dysphagia after an exercise-based dysphagia therapy.

**Design:** Intervention study: before-after trial with 3-month follow-up evaluation.

**Setting:** Outpatient clinic within a tertiary care academic health science center.

**Participants:** Adults (N=9) with chronic (>12mo) dysphagia after unsuccessful prior therapies. Subjects were identified from among patients referred to an outpatient dysphagia clinic. Subjects had dysphagia secondary to prior treatment for head/neck cancer or from neurologic injury. All subjects demonstrated clinical and fluoroscopic evidence of oropharyngeal dysphagia. No subject withdrew during the course of this study.

**Interventions:** All subjects completed 3 weeks of an intensive, exercise-based dysphagia therapy. Therapy was conducted daily for 1h/d, with additional activities completed by subjects each night between therapy sessions.

**Main Outcome Measures:** Primary outcomes were clinical and functional change in swallowing performance with maintenance at 3 months after intervention. Secondary, exploratory outcomes included physiological change in swallow performance measured by hyolaryngeal elevation, lingual-palatal and pharyngeal manometric pressure, and surface electromyographic amplitude.

**Results:** Clinical and functional swallowing performances improved significantly and were maintained at the 3-month follow-up examination. Subject perspective (visual analog scale) on functional swallowing also improved. Four of 7 subjects who were initially feeding tube dependent progressed to total oral intake after 3 weeks of intervention. Physiological indices demonstrated increased swallowing effort after intervention.

**Conclusions:** Significant clinical and functional improvement in swallowing performance followed a time-limited (3wk) exercise-based intervention in a sample of subjects with chronic dysphagia.

Physiological changes after therapy implicate improved neuromuscular functioning within the swallow mechanism.

**Key Words:** Deglutition; Deglutition disorders; Exercise; Physiology; Rehabilitation.

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**D**YSPHAGIA INTERVENTION aims to increase safe and adequate oral intake of food and liquid. Diet modification and compensatory postures focus on protecting the airway during swallowing. These strategies do not aim to improve the impaired swallow mechanism. Strategies focused on improving the impaired swallowing mechanism often incorporate some form of exercise. The goal of exercise approaches is to increase safe oral intake by improving physiological aspects of the swallow mechanism. Literature reviews have implied a positive benefit from exercise-based approaches to swallow rehabilitation.<sup>1,2</sup> Furthermore, recent efforts reflect the inclusion of specific exercise principles in swallow rehabilitation. For example, Robbins et al<sup>3</sup> used a progressive lingual strength program and demonstrated positive change in stroke patients with dysphagia. Crary et al<sup>4</sup> used surface electromyography (sEMG) biofeedback to systematically strengthen swallowing activity in patients with chronic dysphagia after stroke or head/neck cancer treatment. Shaker et al<sup>5</sup> used isometric and isotonic head lift activities to strengthen the submental musculature, with resulting improvement in upper esophageal sphincter opening. Each of these approaches incorporates some exercise principles (primarily increasing resistive load), but none include multiple exercise principles (eg, specificity, resistive load, speed, variability, recovery) into a single dysphagia rehabilitation program.

The McNeill Dysphagia Therapy Program (MDTP) is a systematic, exercise-based therapy framework for the treatment of dysphagia in adults.<sup>6,7</sup> MDTP focuses on progressive strengthening and coordination of swallowing with progression toward normalization of swallowing behavior. MDTP pursues exercise specificity by focusing on swallowing activity across a hierarchy of tasks that systematically introduce principles of progressive resistance and load, variability, and maintenance. Intensity of exercise is incorporated both by the volume of work (number of swallows) completed in a treatment session and by the manipulation of volume and viscosity of materials swallowed. In prior studies we demonstrated both the safety and functional

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## List of Abbreviations

DSW	Digital Swallowing Workstation
FOIS	Functional Oral Intake Scale
MASA	Mann Assessment of Swallowing Ability
MDTP	McNeill Dysphagia Therapy Program
μRMS	microvolt root mean square
sEMG	surface electromyography
VAS	visual analog scale

benefit of MDTP combined with adjunctive neuromuscular electrical stimulation in chronic, treatment-refractory dysphagia in adult patients.<sup>6</sup> We also noted physiological improvement in swallow performance after therapy in the form of increased laryngeal elevation during swallowing.<sup>6</sup> Subsequently, we reported that MDTP without an adjunctive modality produced clinical and functional outcomes superior to those with traditional therapy approaches supplemented with sEMG biofeedback.<sup>7</sup>

In the present study, we examined a wider range of clinical and functional outcomes compared with our prior studies. Specifically, we included analysis of videofluoroscopic swallowing examinations and a patient-focused outcome (visual analog scale [VAS]). As a secondary, exploratory aim we evaluated physiological change in the swallow mechanism after MDTP intervention. MDTP is designed as an exercise-based intervention specific to swallowing activity. Moreover, patients with chronic dysphagia are expected to demonstrate weakness within the swallow musculature related to underutilization of swallowing muscles. Thus, the focus of the physiological swallow assessment was to evaluate change in movement and strength of oral and pharyngeal swallow components immediately after MDTP. We hypothesized that physiological changes would reflect greater strength and increased movement in swallow function after treatment. Finally, we evaluated effect maintenance via a 3-month follow-up evaluation of functional and physiological outcomes.

## METHODS

### Participants

Between November 2006 and September 2009, patients presenting to an outpatient dysphagia clinic in a tertiary care, academic health center were considered for participation in an outpatient dysphagia intervention. The focus of subject selection was to include individuals who demonstrated severe and chronic functional impairments in swallow abilities in the absence of anatomic deficit or surgical alteration. Inclusion criteria included the following: clinically significant dysphagia defined as a score of 5 or less on the Functional Oral Intake Scale (FOIS)<sup>8</sup> and a score of 178 or less on the Mann Assessment of Swallowing Ability (MASA)<sup>9</sup>; fluoroscopic evidence of pharyngeal dysphagia, defined as impaired movement of swallow structures (hyolaryngeal excursion, pharyngeal constriction, pharyngoesophageal segment opening) and/or aspiration or postswallow residue; chronic dysphagia, defined as >12 consecutive months of clinically significant dysphagia symptoms; received prior dysphagia therapy but no participation in any swallowing therapy within 3 months preceding MDTP intervention; cognitive abilities sufficient to participate in interactive and intense dysphagia therapy, defined as a score of >23 on the Mini-Mental State Examination<sup>10</sup>; and willingness to participate in both clinical and physiological evaluation of swallowing performance, to attend 3 consecutive weeks (15 sessions) of therapy, and to return for follow-up evaluation at 3 months after therapy. This study was reviewed and approved by our institutional review board. All subjects were fully informed and signed an institutional review board-approved consent form.

### Dysphagia Intervention: MDTP

MDTP treatment sessions followed a standard 3-week protocol described previously.<sup>6,7</sup> Subjects were taught a single swallow strategy (swallow hard in a single swallow). Clinicians instructed as needed and determined advancement or regression on a hierarchy of materials based on each subject's performance. Bolus consistency and volume were manipulated across various materials as eating rate and amount of oral

intake were progressively advanced. During therapy sessions, clinicians recorded successful swallow attempts characterized by absence of expectoration or clinical signs of aspiration. Based on in-treatment performance, each subject completed nightly homework that consisted of oral ingestion of materials successfully swallowed during therapy. Each subject completed a dietary record of food or liquids consumed each night, noting any difficulties or concerns. The treating clinician reviewed these records during the subsequent therapy session to ascertain compliance with the home activities and to identify any difficulties that may have occurred outside the therapy environment.

### Functional and Physiological Evaluations of Swallowing

Before therapy, immediately after therapy, and 3 months after the conclusion of therapy, participants completed functional and physiological evaluations of swallowing performance. Functional swallowing evaluations included the MASA, FOIS, VAS reflecting patient perspectives on swallow ability, and videofluoroscopic swallowing assessment. Physiological evaluations included lingual-palatal pressure, pharyngeal manometry, and submental sEMG.

**Functional evaluation.** *Clinical swallowing performance: MASA.* The MASA is a psychometrically validated clinical examination for swallowing performance.<sup>11</sup> This clinical assessment is numerically scored with a total of 200 possible points. Prior research has indicated that a score of 178 or less is indicative of clinically significant dysphagia.<sup>9</sup>

*Functional swallowing performance: FOIS.* The FOIS is a psychometrically validated scale to describe the type and amount of daily oral intake by patients with dysphagia.<sup>8</sup> This tool has been used extensively in clinical studies of dysphagia and dysphagia outcome.<sup>12-16</sup> Prior research has used a score of 5 or less on this scale to reflect a clinically significant reduction or alteration in oral intake.<sup>6,7</sup>

*Patient perception: VAS.* This technique is frequently used as a measure of patients' perception of their abilities.<sup>17,18</sup> In this case series, subjects were presented with a 100-mm line anchored by the semantically opposite statements "no swallow ability" and "no swallow difficulty." The VAS score was the distance from the zero end in millimeters.

*Fluoroscopic swallowing assessment.* Each subject was given 5mL and 10mL of thin liquid and pudding barium sulfate contrast (Varibar<sup>a</sup>) to swallow. Materials were delivered to the mouth by syringe, and the subject was asked to hold the bolus until instructed to swallow. Each fluoroscopic examination was recorded on a digital video disk and later transferred digitally to computer files. The computer video files were rated by 2 judges according to the scoring criteria described by Mann et al,<sup>19</sup> resulting in a weighted median score for each examination.

**Physiological evaluation.** *Biokinematic analysis.* To obtain measures of hyoid and laryngeal elevation during swallowing, videofluoroscopic studies were digitized, deidentified, and assigned a computer-generated random number. For each material swallowed, 2 frames were selected from the digitized videos. One frame represented the preswallow position of the hyoid bone/larynx. The second frame depicted the maximum upward and anterior displacement of each structure. Each image was analyzed using ImageJ (image processing and analysis in JAVA).<sup>b</sup> With the use of a digital cursor, a line was initially drawn between the anterior-inferior corner of the second and fourth cervical vertebrae. This line was rotated to a true vertical position. Subsequently, 3 points were manually selected on each image to measure hyoid/larynx elevation: (1) the anterior-inferior corner of C4, which served as an anchor point; (2) the anterior-inferior point of the hyoid bone; and (3) the anterior-inferior subglottic corner of the larynx.

ImageJ provides the horizontal and vertical values (x, y) of each manually selected point on the image. The extent of

hyoid/larynx elevation was measured using the following formula:  $(y_2 - y_1) - (C_4y_2 - C_4y_1)$ . In this formula,  $y_1$  represents the vertical point in the resting position, and  $y_2$  represents the point of maximum elevation of each structure. All measures were completed in reference to a 20-mm calibration referent positioned on the lateral neck.

All physiological measures for this study were completed using the KayPentax Digital Swallowing Workstation (DSW)<sup>c</sup> and Swallowing Signals Laboratory (Model 7100).<sup>c</sup> All data were recorded digitally on the DSW and later analyzed offline. **Lingual-palatal pressure.** Lingual-palatal pressure during swallowing was measured from 3 air-filled bulbs affixed on the hard palate with Stomahesive.<sup>d</sup> Bulbs were 8mm apart and mounted on a silica strip. The anterior bulb in this array was placed on the alveolar ridge just posterior to the maxillary incisors, locating the posterior bulb anterior to the junction of the hard and soft palates. The disposable bulb array was calibrated to record a range from 0 to 750mmHg. In this study, we focused on the anterior and posterior lingual palatal pressures, because these may be important in initiating oral transit of bolus materials and in delivering materials into the oropharynx. **Pharyngeal manometry.** Manometric swallow pressures were measured with a 100-cm-long, solid-state manometric catheter,<sup>e</sup> 2.1mm in diameter, with 3 pressure transducers. The catheter was calibrated to record a pressure range from -50 to 250mmHg. The catheter was passed transnasally under videoendoscopic guidance until the middle sensor had entered the upper esophageal sphincter and a high pressure zone was recorded. Subsequently, the catheter was slowly withdrawn until the resting pressure dropped at the middle sensor and increased in the distal sensor. With the catheter in this position, swallows typically resulted in a characteristic "M-wave" shape.<sup>20</sup> If an M-wave was noted, the catheter was anchored to the exterior nose with tape, and this location was used to obtain manometric data during swallowing. If no M-wave was obtained during swallowing, the catheter was anchored to the exterior nose at the location where increased resting pressure was observed at the distal sensor and the middle sensor was visible (endoscopic inspection) in the inferior hypopharynx.

**Surface electromyography.** sEMG signals associated with swallowing were recorded from the submental region using a single, 3-point, circular, dry, disposable electrode with a 2.25-inch diameter (UniPatch<sup>f</sup>). Sampling rate was 500Hz. The raw signal was filtered and integrated using factory set parameters (bandpass filtered between 50 and 250Hz and integrated with a time constant of 50ms), and rectified. sEMG data were depicted as microvolt root mean square ( $\mu$ RMS). Before recording sEMG data, an acceptable resting baseline amplitude of  $<4\mu$ RMS was verified for each subject.<sup>21</sup> From the amplitude trace of each swallow attempt, the average amplitude (average amplitude level for duration of swallow) was noted in  $\mu$ RMS.

**Detraining effect.** Detraining is the reversal of physiological adaptation to exercise. For each physiological measure we noted the presence or absence of any overt detraining effect. A detraining effect was considered to be present when the average value of a measurement at the 3-month assessment significantly reversed direction (reduced or increased depending on the measure) from significant changes observed in the post-MDTP assessment.

**Swallowed materials.** Participants swallowed 5mL and 10mL of thin liquid and pudding. Gatorade<sup>g</sup> was used as the thin liquid and combined with Resource Thicken-Up<sup>h</sup> to make pudding material. Viscosity properties of these materials were evaluated with a viscometer<sup>i</sup> using the Brookfield Small Sample adapter<sup>i</sup> or Couette geometry. The size of the spindle and the torque range of the viscometer were changed to allow for the different rheologic properties of these samples. True shear

rate was determined using the method of Krieger and Elrod.<sup>22</sup> Pudding does not have a constant viscosity. Rather, it is pseudoplastic. Higher shear rates result in decreased viscosity. The pudding sample demonstrated an "n" value of approximately .21. For reference, a constant viscosity sample (Newtonian) would have an n value of 1.0. Smaller numbers indicate increasing pseudoplasticity. The pudding sample had a "K" value of over 75,000mPa\*s. In contrast, viscosity of the thin liquid sample was calculated at 1.16mPa\*s at 20°C (just slightly more viscous than water at the same temperature). Both materials in turn were placed into a 20-mL syringe and placed in the participant's mouth in measured amounts (5mL and 10mL).

Once the materials were placed in the participant's mouth, the participant was instructed to breathe quietly through the nose. Each physiological channel was monitored to ascertain that baseline levels were demonstrated with the bolus being held in the mouth. Once baseline activity levels were demonstrated, the participant was instructed to swallow. All physiological data were recorded on the DSW during the respective examinations. A blinded assessor subsequently measured these examinations. In the case of multiple swallows per a single bolus, only the initial swallow attempt was measured.

### Statistical Analysis

Means and SDs were computed for all variables. Mean differences between baseline and posttherapy assessments were evaluated using *t* tests. Mean differences between posttherapy and 3-month assessments were evaluated using *t* tests to identify significant detraining effects. Statistical comparisons were completed using SPSS version 17.0.<sup>j</sup> In addition, Hedges' *g* for a single group precomparison/postcomparison was used to estimate effect size for functional outcomes.

## RESULTS

### Participant Demographics

Nine patients participated in MDTP treatment during the course of the study. Seven participants were men, and the mean age  $\pm$  SD of all participants was  $55.89 \pm 16.34$  years. Most participants had dysphagia secondary to treatment for oropharyngeal cancer ( $n=6$ ). Among these, all subjects had been treated with radiotherapy; no surgical cases were included. The remaining participants demonstrated dysphagia secondary to either neurologic deficit ( $n=2$ ) or a combination of neurologic and cancer treatment deficits ( $n=1$ ). Duration of dysphagia averaged 3.6 years, with a range from 14 months to 7 years. All participants had received prior swallowing therapy without functional improvement. At the initiation of MDTP intervention, 7 of 9 participants were dependent on nonoral tube feeding.

### Functional Outcomes

Improvement in MASA scores was noted in all participants. The average increase from baseline to post-MDTP assessment was 17 points ( $P=.002$ ). This clinical improvement was maintained through the 3-month follow-up period. FOIS scores (mean  $\pm$  SD) improved from a baseline of  $2.11 \pm 1.27$  to  $4.56 \pm 1.74$  post-MDTP, and all participants increased functional oral intake ( $P<.001$ ). This functional improvement was maintained for all but 1 subject at the 3-month follow-up assessment (FOIS mean  $\pm$  SD,  $4.71 \pm 1.97$ ). VAS scores improved from a mean of 25.00 at baseline to 60.56 post-MDTP ( $P<.001$ ). These gains were maintained at the 3-month follow-up assessment. Scores from the fluoroscopic evaluation demonstrated improvement (lower scores) from baseline (.150) to post-MDTP (.133), but this change did not reach statistical significance. Im-



Table 1: Change in Functional Status After Dysphagia Therapy With MDTP Protocol

Outcome Measure	Baseline	Post-MDTP	P	Effect Size (Hedges' g)	3-Month Follow-up	P	Effect Size (Hedges' g)
MASA	158.78±13.18	175.22±15.87	.002	0.94	177.57±16.50	.670	.130
FOIS	2.11±1.27	4.56±1.74	<.001	1.42	4.71±1.97	.172	.074
VFE score	0.150±0.066	0.133±0.091	.370	0.177	0.131±0.72	*	*
VAS	25.00±16.93	60.56±27.83	<.001	1.26	53.14±33.33	.378	-.212
Gastric feeding tube dependency (count)	7	3	†	0.93 <sup>‡</sup>	3	*	*

NOTE. Values are mean ± SD or as otherwise indicated.

Abbreviation: VFE, videofluoroscopic evaluation.

\*Given the lack of significant change at the post-MDTP assessment or absence of change to 3-month assessment, no statistical comparison was completed for follow-up.

†No statistic completed on this change.

‡One group (pre-post) log odds ratio with external correlation (Hedges' g conversion).

provement on fluoroscopic evaluations was maintained at the 3-month follow-up assessment (.131). Finally, at baseline, 7 of 9 participants were dependent on nonoral feeding for nutrition/hydration. After MDTP, only 3 patients remained partially dependent on nonoral feeding. At 3 months, all 4 subjects who became feeding tube independent post-MDTP had their feeding tubes removed (table 1).

### Physiological Outcomes

Except for kinematic results (n=9), physiological data were available from only 8 subjects. Although all subjects were expected to attempt swallows of both 5mL and 10mL of bolus materials, baseline dysphagia severity was deemed prohibitive to ask all subjects to attempt the larger volume because of safety concerns. In this respect, only 5-mL physiological outcome data are presented. In addition, measurement artifact contributed to data loss for some subjects in 1 or more of the assessments. No physiological outcome is presented unless 5 of 8 subjects provided data on that outcome.

**Biokinematic change.** Both laryngeal and hyoid elevation increased after MDTP. For the thin liquid bolus, post-MDTP average laryngeal elevation nearly doubled ( $P=.013$ ), with no significant detraining effect noted at the 3-month assessment (fig 1). The pudding bolus resulted in an average increase of >5mm of laryngeal elevation (>30% increase from baseline); however, this increase was nonsignificant (data not shown). Changes in hyoid elevation paralleled those observed for laryngeal elevation. Post-MDTP average hyoid elevation more than doubled ( $P=.039$ ) for the thin liquid bolus, with no significant detraining effect noted at the 3-month assessment.

Increases in hyoid elevation observed for pudding materials were nonsignificant (data not shown).

**Lingual-palatal pressure.** Lingual-palatal pressure measured from the anterior tongue increased for both materials after MDTP; however, the only significant increase was noted for pudding material (fig 2). The average increase for the pudding bolus doubled the baseline value ( $P=.025$ ), with no significant detraining effect noted at the 3-month assessment. Average posterior lingual-palatal pressures paralleled those from the anterior tongue. Posterior tongue pressures increased after therapy, with a significant increase observed for the pudding bolus ( $P=.039$ ). No significant detraining effect was observed at the 3-month assessment.

**Pharyngeal manometry.** Average manometric values from the base of tongue region (upper pharynx) for thin liquid decreased nearly 50%, but for the pudding bolus, base of tongue manometric average values increased nearly 50%. Neither of these posttherapy changes was statistically significant (data not shown). Manometric measures from the inferior pharynx demonstrated average reductions for both bolus materials, but these reductions were not statistically significant (data not shown).

**sEMG mean amplitude.** sEMG mean amplitude reflects sustained myoelectric activity over the duration of the swallow event. sEMG mean amplitude values increased for both bolus materials, with the average increase for pudding reaching statistical significance ( $P=.02$ ). Posttherapy increases in sEMG mean amplitude were maintained at the 3-month assessment (fig 3).

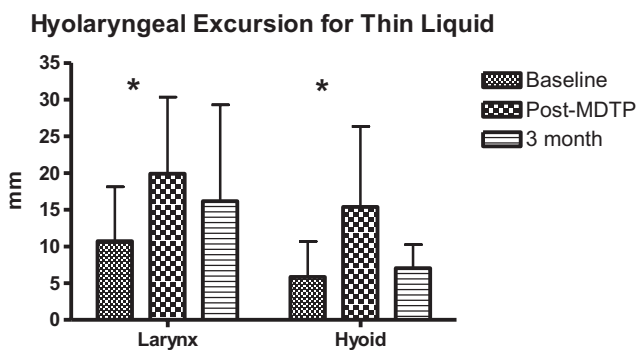


Fig 1. Laryngeal and hyoid excursion (mm) data (n=9) for thin liquid swallows before and after MDTP and at 3-month follow-up assessment. \* $P<.05$ .

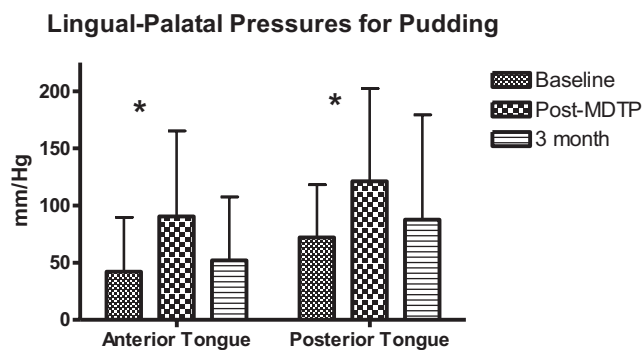


Fig 2. Lingual-palatal pressure (mmHg) data from the anterior and posterior tongue (n=8) for pudding swallows before and after MDTP and at 3-month follow-up assessment. \* $P<.05$ .

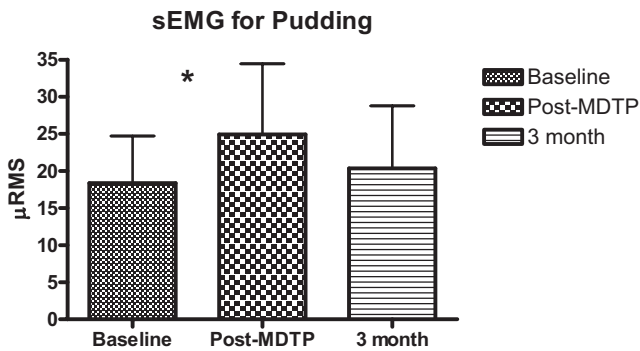


Fig 3. sEMG ( $\mu$ RMS) mean data ( $n = 8$ ) for pudding swallows before and after MDTP and at 3-month follow-up assessment. \* $P < .05$ .

## DISCUSSION

Results from this study supported prior conclusions that MDTP produces significant functional swallowing improvement in a restricted time frame with no dysphagia-related complications during or after therapy. Furthermore, functional improvement was maintained to 3 months. In addition to functional benefit from MDTP, physiological improvement in swallow characteristics was noted in kinematics, swallow pressures, and sEMG analyses of swallow effort.

Functional improvement after MDTP manifested in clinically identified improvements (MASA), increased safe and adequate oral intake (FOIS), patient report of benefit (VAS), and improved performance on videofluoroscopic swallow examination. With the exception of improvement in videofluoroscopic scores, effect sizes for these changes were moderate to strong across measures. Improvement in these domains was consistent with prior results with MDTP and expanded the range of assessed functional benefit from this intervention.<sup>6,7,23</sup> Still, not all subjects demonstrated functional improvement after MDTP. In the present series, 1 subject demonstrated minimal improvement in MASA and FOIS scores immediately after MDTP. At the 3-month assessment, this subject returned to baseline levels on these measures. This single subject was a head/neck cancer survivor treated for oropharyngeal cancer nearly 20 years before therapy. At baseline, he was dependent on a percutaneous endoscopic gastrostomy tube with no oral intake. After intervention, he increased oral intake to fluids with some soft foods, but at 3 months he returned to baseline levels. Subsequent clinical changes suggested that he was impacted by late neuromuscular deterioration related to prior radiotherapy.<sup>24</sup>

The most pronounced physiological changes after therapy in this study were increased lingual-palatal pressures for pudding and increased laryngeal and hyoid elevation for thin liquid. These physiological changes may relate to different aspects of functional swallow improvement. For example, increased lingual-palatal pressures, especially for pudding material, would assist in clearing this material through the upper swallow mechanism. Likewise, increased laryngeal and hyoid excursion for thin liquids may contribute to improved airway protection.<sup>25</sup> Furthermore, increased hyoid and laryngeal excursion, along with increased lingual pressures and higher sEMG amplitudes, suggested increased strength (and resulting movement) within the swallowing musculature. These changes likely reflected a central neuromuscular reorganization, since muscle hypertrophy typically requires longer than the 3-week treatment period.<sup>26,27</sup> Given the short-term intervention from MDTP (3wk), some degree of detraining was anticipated among physiological

measures of swallowing. The degree or time course of detraining has been associated with the length and intensity of the original exercise. Short-term gains (neuromuscular adaptations) detraining more and faster than muscle morphology changes from longer, higher intensity exercise.<sup>28,29</sup> Specific to swallowing musculature, Clark et al<sup>30</sup> reported that 9 weeks of lingual exercise significantly increased lingual strength in young, healthy adults, but that significant reductions in lingual strength (detraining) were noted in as little as 2 weeks after cessation of exercise. In the present study, the lack of a statistically significant reversal in posttreatment physiological gains suggests maintenance of physiological effects after cessation of therapy. It is conceivable that continued oral intake after therapy may represent a form of swallow exercise maintenance. The degree of exercise effect obtained from eating and drinking outside therapy is likely less than that resulting from intense, daily intervention. Still, continued exercise, even at reduced doses, has been shown to minimize detraining effects and maintain function in older adults.<sup>31</sup>

## Study Limitations

Case series are valuable clinical research designs to test the safety and effect of interventions.<sup>32</sup> However, small sample sizes can limit the overall power of the analysis and increase the possibility of underidentification of meaningful results (eg, type II error or increased false-negative rate). In addition, the use of multiple statistical tests in this exploratory study may have increased the probability of falsely identifying significant results (eg, type I error or increased false-positive rate). For example, a Bonferroni correction applied to planned comparisons resulted in an adjusted  $P$  value for significance of any outcome of .002. This more conservative significance level would render all physiological changes statistically nonsignificant. Furthermore, based on prior results,<sup>6,7</sup> we had adequate power for the clinical/functional outcomes, but based on a post hoc power analysis, a sample of more than 20 cases would be indicated for even the strongest physiological outcomes (laryngeal and hyoid elevation) to obtain adequate power (80%) with an alpha of .05. Given these limitations, caution should be exercised when interpreting the physiological outcomes of this study. Although the results suggested increased strength and movement of swallow structures with no statistically significant detraining effects noted, these data should be viewed as exploratory until confirmed by larger-sample, controlled comparison studies.

## CONCLUSIONS

The growing body of evidence regarding MDTP intervention for dysphagia in adults indicates a time-efficient functional benefit with physiological improvement in most treated cases.<sup>6,7,24,33</sup> Functional benefit was maintained after intervention and occurred in the absence of dysphagia-related complications during therapy or in the follow-up period. In addition, replication of functional outcomes across studies, including studies from different centers,<sup>23</sup> strengthens claims regarding both the safety and the benefit of MDTP intervention for dysphagia in chronic, treatment-refractory patients. Physiological change posttreatment implicated improved strength of swallow function. Current data indicating physiological improvement in swallowing, combined with related data indicating improved temporal coordination of swallowing after MDTP,<sup>33</sup> support the exercise influence of MDTP on swallowing neuromuscular performance in addition to functional benefit. Still, these preliminary studies are exploratory in nature and lack the rigor of larger controlled studies. From this perspective, the results of the present investigation do not provide adequate evidence to guide clinical care. Rather, they provide direction for subsequent confirmatory research. The next logical

step in the evaluation of MDTP as an effective dysphagia intervention will be the completion of a randomized controlled trial comparing this approach with other approaches in the treatment of dysphagia in adults.

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### Suppliers

- a. EZ EM Inc, 1111 Marcus Ave, Lake Success, NY 11042.
- b. ImageJ; U.S. National Institutes of Health, Bethesda, MD. Available at: <http://imagej.nih.gov/ij/download.html>.
- c. KayPENTAX, 2 Bridgewater Lane, Lincoln Park, NJ 07035.
- d. Stomahesive; ConvaTec U.S. Headquarters, 200 Headquarters Park Dr, Skillman, NJ 08558.
- e. Gaeltec manometer; Medical Measurements Inc, 56 Linden St, Hackensack, NJ 07601.
- f. UniPatch electrodes; Covidien, 15 Hampshire St, Mansfield, MA 02048.
- g. The Gatorade Company, PO Box 049003, Chicago, IL 60604-9003.
- h. Nestle Nutrition online store, <http://www.nestlenutritionstore.com/general-itemdetail.asp?T1=THKENUP+1CAN&SRCCODE=PDS10&gclid=CNWEO7Hvq6gCFRIq7AodtFcvJA>.
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