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MBS Measurement Tool for Swallow Impairment—MBSImp: Establishing a Standard

Bonnie Martin-Harris, PhD,
Department of Otolaryngology-Head and Neck Surgery, Medical University of South Carolina, 135 Rutledge Avenue, MSC 550, Charleston, SC 29425-5500, USA

Evelyn Trammell Institute for Voice and Swallowing, Medical University of South Carolina, Charleston, SC, USA

Department of Communication Sciences & Disorders, Medical University of South Carolina, Charleston, SC, USA

Evelyn Trammell Voice & Swallowing Center, Saint Joseph's Hospital of Atlanta, Atlanta, GA, USA

Martin B. Brodsky, PhD,
Department of Otolaryngology-Head and Neck Surgery, Medical University of South Carolina, 135 Rutledge Avenue, MSC 550, Charleston, SC 29425-5500, USA

Evelyn Trammell Institute for Voice and Swallowing, Medical University of South Carolina, Charleston, SC, USA

Department of Communication Sciences & Disorders, Medical University of South Carolina, Charleston, SC, USA

Yvonne Michel, PhD,
Department of Speech Pathology, Medical University of South Carolina, Charleston, SC, USA

College of Nursing, Medical University of South Carolina, Charleston, SC, USA

Donald O. Castell, MD,
College of Medicine, Medical University of South Carolina, Charleston, SC, USA

Melanie Schleicher, MS,
Evelyn Trammell Voice & Swallowing Center, Saint Joseph's Hospital of Atlanta, Atlanta, GA, USA

John Sandidge, MS,
Evelyn Trammell Voice & Swallowing Center, Saint Joseph's Hospital of Atlanta, Atlanta, GA, USA

Rebekah Maxwell, MEd, and

harrisbm@musc.edu.
Present Address: M. B. Brodsky Johns Hopkins Hospital, Baltimore, MD, USA

Evelyn Trammell Institute for Voice and Swallowing, Medical University of South Carolina, Charleston, SC, USA

Department of Communication Sciences & Disorders, Medical University of South Carolina, Charleston, SC, USA

Julie Blair, MA
Evelyn Trammell Institute for Voice and Swallowing, Medical University of South Carolina, Charleston, SC, USA

Department of Communication Sciences & Disorders, Medical University of South Carolina, Charleston, SC, USA

Abstract

The aim of this study was to test reliability, content, construct, and external validity of a new modified barium swallowing study (MBSS) tool (MBSImp) that is used to quantify swallowing impairment. Multiple regression, confirmatory factor, and correlation analyses were used to analyze 300 in- and outpatients with heterogeneous medical and surgical diagnoses who were sequentially referred for MBS exams at a university medical center and private tertiary care community hospital. Main outcome measures were the MBSImp and index scores of aspiration, health status, and quality of life. Inter- and intrarater concordance were 80% or greater for blinded scoring of MBSSs. Regression analysis revealed contributions of eight of nine swallow types to impressions of overall swallowing impairment ($p \leq 0.05$). Factor analysis revealed 13 significant components (loadings ≥ 0.5) that formed two impairment groupings (oral and pharyngeal). Significant correlations were found between Oral and Pharyngeal Impairment scores and Penetration-Aspiration Scale scores, and indexes of intake status, nutrition, health status, and quality of life. The MBSImp demonstrated clinical practicality, favorable inter- and intrarater reliability following standardized training, content, and external validity. This study reflects potential for establishment of a new standard for quantification and comparison of oropharyngeal swallowing impairment across patient diagnoses as measured on MBSS.

Keywords

Dysphagia; Swallowing; Videofluoroscopy; Diagnostic tool; Reliability; Deglutition; Deglutition disorders

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The research literature is dense with measurement methods used to estimate the presence and degree of oropharyngeal and esophageal swallowing dysfunction. At the time of this publication, there are over 9700 citations in Medline of human studies and measurement methods of normal swallowing and swallowing disorders from 1950 to 2007. These methods are directed toward gaining objective indexes of the timing [1–7], pressure [8–17], range [18–20], and strength [21–23] of structural movements, bolus flow patterns [1, 24–27], bolus clearance and efficiency [12, 28], airway protection [29, 30], and sensation [31–34]. These studies have established a strong theoretical framework of the nature of swallowing abnormalities and the clinical value of this work has been unprecedented. However, it is difficult to compare the results of these studies because of the inattention to internal and

external validity of these swallowing measures and to the impracticality of many for routine clinical application.

The modified barium swallowing study (MBSS) is a videofluoroscopic examination of swallowing function. This evaluation method is often considered the instrument of choice by the majority of practicing swallowing clinicians because it permits the visualization of bolus flow in relation to structural movement throughout the upper aerodigestive tract in real time. The MBSS also permits detection of the presence and timing of aspiration, i.e., entry of ingested material below the level of the true vocal folds into the trachea, and assists in identifying the physiologic and often treatable cause(s) of the aspiration [35–38]. Furthermore, clinicians are able to observe the effects of various bolus volumes, bolus textures, and compensatory strategies on swallowing physiology [39].

The most recent omnibus survey of the American Speech Language Hearing Association [40] indicated that 92% of speech-language pathologists (SLPs) working in hospital settings and 100% in residential health-care settings regularly serve individuals with swallowing disorders, yet the degree and type of training in MBSS interpretation is highly varied and in some cases alarmingly sparse [41]. The most frequently observed ICD-9 code (diagnosis) observed by SLPs is dysphagia, representing 27.52% of all claims made to the Centers for Medicare and Medicaid Services. Swallowing and Feeding Disorders is also the most commonly occurring type of clinical episode reported by SLPs representing 38.4% of all patient encounters [42]. In 2004, the Centers for Medicare and Medicaid Services reported over 203,000 claims for MBSSs (CPT 92611) totaling almost $21 million. These data are striking in view of the fact that most SLPs are using the MBSS as the primary examination tool in formulating their impressions about the presence and severity of swallowing disorders, diet recommendations, and treatment planning in the absence of standardized protocols and measures for describing the type and severity of the swallowing impairment. This lack of standardization leads to ambiguous reporting of results, potential inaccuracies in assessment and selection of management strategies, and gaps in service delivery from the examining swallowing clinician, the referring SLPs, physician(s), nurses, and dietitians. Furthermore, there has been no external validation demonstrating the relationship of the type and severity of oropharyngeal swallowing impairment with health indicators such as liquid/food intake restriction, aspiration pneumonia, poor health status, and quality of life across patient groups.

A swallowing disorder is typically a combination of physiologic impairments that occurs during eating and drinking, impacts related body systems, is life-changing, and potentially life-threatening [43–47]. It is mandated, therefore, that health-care providers seek ways to optimize the safety, accuracy, and appropriateness of evaluation methods used in patients with dysphagia. The present study was directed toward testing the internal and external validity of a MBSS swallowing evaluation tool (MBSImp) in patients referred for MBSS evaluations, determining the reliability of measures made utilizing the MBSImp, and depicting relationships between severity of swallowing impairment and aspiration, diet recommendations, nutrition, health status, and quality of life.

The objectives of the study included the following: (1a) Establish the content validity of the literature-based components of swallowing function included in the proposed tool. (1b) Organize the functional components into a standardized assessment tool, the MBS Impairment tool (MBSImp). (2) Establish the inter- and intrarater reliability of the scored components on the MBSImp made by trained speech-language pathologists. (3) Establish the construct validity of the MBSImp to derive a parsimonious set of components of swallowing impairment that contribute to variation in swallowing impairment in dysphagic patients. (4) Examine the external validity of the MBSImp via the relationship of impairment scores to the presence of penetration/aspiration, and external indicators of diet modifications/restriction, nutrition, health status, and quality of life.

Methods

Content Validation

Expert judgment is often based on a panel's synthesis of evidence from experimental research described in the literature, and on the clinical experience and knowledge of panel members in the validation of selected items for test tools under development in the absence of a gold-standard set (i.e., 100% specificity/100% sensitivity) [48]. The initial goal of our project was to reach consensus regarding the literature-based physiologic components of oropharyngeal and cervical esophageal swallowing that should be evaluated during a MBSS. A trained and content-neutral facilitator employed the Delphi method to accomplish this process [48]. The process encouraged the exchange of ideas and information and enabled each participant to have equal input by preventing bias due to position, status, or dominant personalities. A multidisciplinary panel of ten members (speech-language pathology, 6; otolaryngology, 1; gastroenterology, 1; radiology, 1; physiatry, 1) responded independently to a specific set of questions, prepared by the principal investigator, relating to the proposed components and their operational definitions (i.e., scores) and the inclusion and importance of the proposed test methods and measures. At the time of the consensus meeting, the facilitator organized and presented the experts' responses. The experts were asked for additional input based on the results of the initial inquiry to allow for revision of their initial responses. The process was repeated until 100% agreement was achieved or responses became stable. Stability was defined as agreement among the experts for items showing no greater than one divergent vote across three rounds of voting.

Organizing the Tool

Seventeen components of swallowing impairment (test items) and their observational scores remained at the conclusion of the 8-h session (Table 1). The operational definitions for the component scores represented a unique observation of either structural movement, bolus flow, or both and were converted to a set of Likert scales (Fig. 1).

Training and Reliability

Participating SLPs included ten clinicians with a minimum of 3 years postgraduate experience in conducting and evaluating MBSSs: six from the Medical University of South Carolina (MUSC) and four from Saint Joseph's Hospital of Atlanta (SJHA). The PI, a certified and licensed SLP with over 20 years of experience in the interpretation of MBSSs

and who is a Board Recognized Specialist in Swallowing and Swallowing Disorders (BRS-S) by the ASHA, trained the SLPs. She provided 8 h of group didactic training (i.e., two 4-h sessions) in the implementation and scoring of the MBSImp. In addition, the SLPs participated in 4 h of independent study using an interactive CD-ROM (Radiographic Interpretation of Swallowing Disorders), which the PI developed and published in 2000 and 2004 to assist SLPs in reading videofluoroscopic images of swallowing [49]. This CD was peer-reviewed according to the standards outlined by the Continuing Education Unit of the ASHA. The SLPs practiced the MBSImp scoring system independently for an additional 10 h on the 38 exams.

Fifteen previously recorded MBSSs were randomly selected by the PI to assess interrater and intrarater reliability using the MBSImp scoring system. The PI scored the 15 MBSSs using the MBSImp scoring system, and these scores were considered the "standard" for clinician training. The same 15 MBSSs were then scored by each of the trained SLPs using the MBSImp scoring system. The concordance (% exact agreement) of MBSImp component scores between the "standard" and the SLPs' scores was calculated. If concordance fell below 80%, the MBSImp scale scores were reviewed for areas of disagreement. Based on this review, the MBSImp training continued until the SLPs achieved a minimum of 80% agreement which demonstrated that the training was successful. The SLPs were trained to consistently (intrarater) and accurately (interrater) score based on comparison to the standard.

Standardization of the Procedure and Protocol

The dose and image quality of the fluoroscopic equipment at the two participating sites, MUSC and SJHA, were standardized. The fluoroscopes used for this study were surveyed by a certified medical physicist. The image intensifier input dose was measured using the techniques described by the International Electrotechnical Commission (IEC) [50]. These values were compared to ensure that they were within the standards of the IEC. The fluoroscopic input dose was measured using the methods described by the FDA in CFR 21 [51]. The image quality was standardized by imaging the Leads Test Object TO.10, a contrast detail phantom designed to compare image quality across multiple units [51]. The dose to a standard patient was calculated for the two sites using the measurements described in the "Handbook of Selected Tissue Doses for the Upper Gastrointestinal Fluoroscopic Examination" [52].

All subjects were imaged in an upright, seated, or standing position. To help patients who had medical conditions that caused weakness, balance, or judgment problems which may have impacted their safety during the exam, a specialized and standardized chair (Hausted® VIC, Steris) was used when necessary to maintain an upright posture. The patients were initially positioned in the lateral view, and regions of visualization included the oral cavity, pharyngeal cavity, larynx, and cervical esophagus. The fluoroscopic angle was 70° and the visualization field included the lips anteriorly, nasal cavity superiorly, cervical spinal column posteriorly, and the entire pharyngoesophageal segment (PES) inferiorly [35, 37, 53–55]. The larynx was in full view within this visualization field. The MBSS took place in a standard radiology fluoroscopy suite. The fluoroscope was activated by the radiologist for

a few seconds before and after the administration of the barium substances by the SLP. The fluoroscope was deactivated shortly after the bolus tail had exited the cervical esophageal region. Following swallows of thin liquid barium, nectar-thick liquid barium, honey-thick liquid barium, pudding-thick barium, and a one-half portion of a Lorna Doone shortbread cookie coated with 3-ml pudding-thick barium with views in the lateral plane, patients were turned and viewed from the anterior-posterior plane. Patients were presented with one 5-ml teaspoon of nectar-thick liquid barium and one 5-ml teaspoon of pudding-thick barium for SLPs to make judgments regarding symmetry of bolus flow, pharyngeal wall contraction, and symmetry of structure and function. The total radiation exposure averaged 3–5 min, an amount typically encountered in an upper gastrointestinal series.

Subjects were administered standardized, commercial preparations of barium contrast agents (Varibar® E-Z-EM, Inc.) that included: thin liquid barium (two trials of 5-ml cup sip, sequential swallows from cup); nectar-thick liquid barium (5-ml cup sip, sequential swallows from cup), honey-thick liquid barium (5 ml), pudding-thick barium (5 ml), and a one-half portion of a Lorna Doone shortbread cookie coated with 3-ml pudding-thick barium. The smallest liquid volumes selected for administration and scoring in this investigation are considered representative of standard practice, safe and manageable by even the most severely dysphagic patients who are carefully observed in the controlled radiology environment during the MBS [37]. The larger, thicker, and solid boluses were given only if the patient demonstrated adequate airway closure and pharyngeal clearance on the thin 5-ml boluses. The barium textures administered were dependent on observations made early in the examination procedure by the SLP and radiologist and on observations of the patient's cognitive status and swallowing physiology/airway protection mechanisms. The average duration for the patient's participation during the MBS procedure, including set-up and positioning, was 15 min.

Study Sample, Recruitment, and Consent

Subjects eligible for this study included all patients (inpatients and outpatients) referred by a physician to the MUSC Evelyn Trammell Institute for Voice and Swallowing and the Evelyn Trammell Voice & Swallowing Center (SJHA). Three hundred subjects were recruited consecutively by physician referral for a MBSS from all hospital services due to concerns of swallowing impairment during the course of the patient's normal medical management. The only exclusion criterion for this study was the absence of a physician order for a MBSS. The only consideration for consent was the later use of the recorded MBSS video for data analysis. The examining SLP interpreted the examination and based the management recommendation on their usual practice pattern. The exams were not scored at the time the study was conducted. Outside the scope of this study, the SLP clinician proceeded with rehabilitation strategies such as bolus volume modification, compensatory maneuvers, and postures that optimized airway protection and bolus clearance, when necessary, based on the nature of the patient's swallowing dysfunction [35, 37, 53–55]. The SLP clinician also communicated diet and feeding recommendations per the usual scope of practice to swallowing team members, including physicians, nursing, and dietitian staff.

This study was approved by the Institutional Review Boards of MUSC and SJHA. The MBSS performed within the scope of care was not the experiment of this project; the analysis and scoring methodology of the video record was the focus of the experiment. Data generated from this study did not influence patient care and was deidentified before scoring procedures occurred long after the examination and the surveys explained below were completed.

Data Capture

The data were recorded using digital video imaging (computer movie file recordings). A high-resolution videofluoroscopic recording device was used for signal acquisition and digital storage and retrieval of the swallowing data. The Digital Swallowing Workstation™ (DSW) (Model 7200 KayPENTAX, Lincoln Park, NJ) recorded each MBSS directly to computer storage media for instantaneous retrieval and playback of exams at full video resolution. Videofluoroscopic recordings were made with a resolution of 30 frames per second. All digitally recorded videos were saved on the DSW following completion of the MBSS and were archived to DVD and stored in the central lab at MUSC.

Image Analysis

All studies related to this project were converted from the DSW's native format to a universal digital video format (.mpg). All converted MBSSs were then collected and deidentified by the study coordinator for randomized distribution on CD-ROM to the SLP raters for scoring. The 300 studies were divided among ten SLPs at the two study sites (150 studies each), with each SLP rater receiving 30 studies for scoring.

Scoring

The 17 components and their operational definitions were organized into a tool, the MBSImp. Each score was characterized by a distinguishable observation or score. Scales ranged from 3 to 5 points. Figure 1 shows one example of a 5-point scaled component. Each swallow type (each bolus consistency and volume) was scored because the study set out to establish the contribution of each swallow type to the SLP's overall impression of the integrity of each swallowing component. When a particular texture level could not be administered because of patient safety issues related to concerns about significant aspiration or poor bolus clearance, the SLP rated that texture the most severe score for the individual component. An overall impression (OI) score of each component across all bolus consistencies and volumes was recorded to represent the “real-world” practices of swallowing clinicians. The contribution of variation in OI score by each bolus volume and consistency swallow was tested.

Contribution of Swallow Consistency/Mode to Overall Impression Scores

Seventeen linear regression analyses were performed to measure the contribution of the swallow trials to the OI score of the 17 swallowing components. Each of the nine swallow types were designated as independent predictors of the dependent OI component score and were entered simultaneously in the analysis. The threshold of statistical significance of the regression coefficient calculated for each of the nine swallow trials was set to 0.05.

Construct Validity

A confirmatory factor analysis using principal component extraction and varimax rotation with Kaiser normalization was conducted to empirically determine the number of factors supported by the data. Factor loadings greater than 0.5 were considered significant.

External Validation: Association of MBSImp Scores and External Indicators

The relationship between measures of impairment (oral and pharyngeal) and external indicators were explored using correlational statistics. Pearson's correlation coefficient was used for continuous variables and Spearman's correlation coefficient was used for ordinal variables.

Penetration-Aspiration Scale—Observed aspiration, as measured by a validated and reliable aspiration index, the Penetration-Aspiration (PA) Scale [56, 57], was measured using an 8-point scale. The clinician's rating for each swallow trial considered bolus path, depth of penetration/aspiration, and patient response (Table 2).

Texture Grade/Intake Mode—The oral intake/modification(s) recommended by the examining SLP (i.e., recommendation was not made by the SLP who participated in the blind scoring) following the MBSS was recorded. Ten possible combinations of intake status and diet grade were developed and rank-ordered on a scale from lowest to highest dietary restriction (Table 3). The items are rated from 0 being no restriction to 9 being the most severe restriction with no food or liquid to be given by mouth. This rank ordering was based on previous research that related greater thickness and higher textures to greater intake restriction [37]. Then, the ranking was reviewed by an expert panel and found to be a reasonable representation of the gradient of thickness/texture and restriction.

Nutritional Status—To better understand if the severity of swallowing impairment relates to a reduction in current nutritional status, a common clinical indicator of nutritional status, body mass index (BMI),was calculated for each patient. BMI describes the relative weight for height and is significantly correlated with total body fat content (Table 4). BMI is calculated by dividing the weight in pounds by height in inches squared [BMI = weight (kg) ÷ height $(m)^2$] [58]. The height and weight of the patient was obtained by the SLP and the BMI was calculated. These measurements were obtained on the same day as the MBS exam on the hospital floor for inpatients, and in the Radiology Department for outpatients. In addition, the Patient-Generated-Subjective Global Assessment (PG-SGA) was used (Table 5). The PG-SGA is a scored categorical and continuous measure that takes into consideration the patient's medical history in addition to height and weight to determine risk for malnutrition [59].

Presence of Aspiration Pneumonia—Aspiration pneumonia (ICD-9: 507.0) was confirmed by documentation in the patient's medical record by an attending physician or consulting pulmonologist. The physician used diagnostic criteria for aspiration pneumonia that have been tested and reported and which are listed in Table 6 [60, 61].

Functional Health Status—The SF-6 Health Survey [62] measures six of the eight generic functional health concepts included in the SF-36: physical functioning, role functioning, pain, general health perceptions, social functioning, and general mental health. In the SF-6, each health concept is measured using a single-item measure. Each single-item measure correlates significantly with its long-form-parent scale (range = 0.71–0.83), and the average length of time to administer the SF-6 is less than 3 min [62]. Respondents first completed the SF-6 immediately before the MBS test.

Quality of Life The SWAL-QOL is a 44-item tool consisting of ten multi-item scales (food selection, burden, mental health, social functioning, fear, eating duration, eating desire, communication, sleep, and fatigue) [63, 64]. Higher scores on each scale are associated with better quality of life. It takes respondents an average of 14 min to complete the SWAL-QOL. All of the SWAL-QOL scales exhibit internal consistency and test-retest reliability. The SWAL-QOL was completed by the patient just before the MBS test.

Results

Data were collected on 345 subjects throughout the study. Because of missing data from incomplete forms and difficulty with transfer and analysis of the MBSS, data for 300 subjects were analyzed in the final data set. In the combined sample of 300 subjects between the two sites (MUSC and SJHA), there were 59% male, 41% female, 78% Caucasian, 19% African-American, 1% Asian, and 2% unknown or unreported. MUSC recruited and analyzed 58% of the subjects, SJHA recruited and analyzed 42% of the subjects. The distribution of demographics is summarized in Table 7. The medical diagnoses related to the subjects' swallowing disorders were distributed into the following broad medical service classifications: 23% Pulmonary, 21% Head and Neck Cancer, 16% Neurology, 12% Gastroenterology, 9% Cardiothoracic, 5% General Otolaryngology, 3% Neurosurgery, 3% Oncology (other than Head and Neck), 3% General Practice, 2% Endocrine, and <1% each in Orthopedics, Trauma, General Surgery, Rheumatology, Vascular, and unknown/ unreported.

Contribution of Swallow Consistency/Mode to Overall Impression Scores

The most striking result to emerge from the data was the salient contribution of the 5-ml thin bolus and the 5-ml nectar bolus to OI scores in both Oral and Pharyngeal Factors. Together, these two swallow trials contributed to the clinicians' OI scores on 14 of the 15 swallowing component scores. Boluses of 5-ml thin liquid barium contributed to all scores with the exception of lip closure, bolus preparation/mastication, and tongue base retraction. Boluses of 5-ml nectar-thick liquid barium, however, contributed to lip closure and tongue base retraction but, similar to 5-ml thin, did not contribute to bolus preparation/mastication scores. The data also demonstrated that the cup-sip thin trial contributed to one OI Oral Factor score, initiation of the pharyngeal swallow, and four OI Pharyngeal Factor scores that included soft palate elevation, laryngeal elevation, laryngeal closure, and pharyngeal stripping wave. Cup-sip nectar and sequential nectar swallows each contributed to only one OI score, initiation of the pharyngeal swallow and LE, respectively. The 5-ml honey swallow contributed to two Oral (bolus transport/ lingual motion, oral residue) and two

Pharyngeal (PES opening and tongue base retraction) OI scores. The 5-ml pudding teaspoon swallow contributed to two Oral (bolus transport, oral residue) and three Pharyngeal (laryngeal elevation, anterior hyoid motion, and PES opening) IO impairment scores. The cookie swallow contributed to only Oral Factor OI scores (lip closure, hold position/tongue control, and bolus preparation/mastication). A summary of these findings is presented in Table 8.

Construct Validity

Two components that were recommended by the panel, pharyngeal contraction (13) and esophageal clearance (17), were obtained from the anterior-posterior viewing plane. The number of patients who were able to complete the anterior-posterior view with sufficient visibility, however, fell below the required number of observations necessary for factor analysis. Therefore, these two components were not included in the factor analysis. This analysis confirmed a two-factor solution as given below (Table 9). Factor loadings for lip closure (1) and soft palate elevation (7) were all below threshold and were not included. One factor (Oral, in italics) included the OI component scores that related to oral tongue function. The other factor (Pharyngeal, in bold) included the OI component scores related to pharyngeal clearance and airway protection.

The analysis resulted in factors that were linear combinations of the significant components. The coefficients are the factor loadings in this linear combination (sum). Since the significant coefficients were all of a similar magnitude, they were converted to the constant = 1. Using this summing process, total possible Oral Factor score = 20 and total possible Pharyngeal Factor score = 23. Figures 2 and 3 demonstrate approximately normal distributions of the Oral and Pharyngeal Factor OI component scores.

Association of MBSImp Scores and External Indicators

PA Scale Scores—To capture frequency and severity of penetration and aspiration over the nine swallow trials, PA Scale scores were summed over all nine swallow trials. The sum for subjects that had higher frequency and severity was higher than for subjects with lower frequency and severity. Higher results revealed that the averaged PA Scale scores were modestly negatively skewed, indicating that most patients scored within the normal range (scores = 1–2) despite the presence of moderate to severe swallowing impairment scores (Fig. 4). While significant correlations were found between PA Scale scores and Oral Impairment ($r = 0.27$, $R^2 = 0.07$, $p < 0.0005$) and between PA Scale scores and Pharyngeal Impairment ($r = 0.22$, $R^2 = 0.05$, $p < 0.0005$), PA Scale scores explained less than 10% of the variation in Oral and Pharyngeal Impairment.

Diet Modifications—A total of 41 patients who had a feeding tube or parenteral feedings for nonswallowing reasons were excluded from the diet analysis. The ten recommended diet restrictions were collapsed into five categories because of low frequency (Figs. 5, 6). Data showed a significant correlation between Oral Impairment scores ($r = 0.47$, $R^2 = 0.22$, $p < 0.0005$) and Pharyngeal Impairment scores ($r = 0.54$, $R^2 = 0.29$, $p < 0.0005$) with the dietary recommendation/ restriction made by the examining SLP.

Nutritional Status—BMI demonstrated no significant correlation with Oral Impairment (r = -0.08, R^2 = 0.02, p = 0.20), but demonstrated a statistically significant, clinically modest correlation with Pharyngeal Impairment (r = −0.21, R^2 = 0.04, p < 0.0005). The PG-SGA demonstrated a statistically significant, clinically modest correlation with Oral Impairment (r = 0.28, R^2 = 0.08, p < 0.0005) and Pharyngeal Impairment (r = 0.20, R^2 = 0.04, p < 0.008).

Health Status—Only two of the six health concepts of the SF-6 survey demonstrated a statistically significant, clinically modest correlation with Oral Impairment and Pharyngeal Impairment: General Health Perception and Oral Impairment (r = 0.17, R^2 = 0.03, p = 0.04) and Pain and both Oral and Pharyngeal Impairment (r = 0.16, R^2 = 0.03, p = 0.046).

Aspiration Pneumonia—No relationship was found between swallowing impairment scores and the presence of aspiration pneumonia. Only 18 of the 300 tested patients presented with the infection at the time of testing.

Quality of Life—Of the ten multi-item scales of the SWAL-QOL, five demonstrated statistically significant, clinically modest correlations with Oral and Pharyngeal Impairment: General Burden with Pharyngeal Impairment (r = −0.21, R^2 = 0.04, p = 0.01), Eating Duration with Oral Impairment (r = −0.24, R^2 = 0.06, p = 0.003), Food Selection with both Oral Impairment (r = −0.028, R^2 = 0.08, p = 0.001) and Pharyngeal Impairment (r = −0.19, R^2 = 0.04, p = 0.024), Communication with both Oral Impairment (r = −0.34, R^2 = 0.12, p < 0.0005) and Pharyngeal Impairment (r = −0.32, R^2 = 0.10, p < 0.0005), and Social Functioning with both Oral Impairment (r = −0.26, R^2 = 0.07, p = 0.002) and Pharyngeal Impairment (r = −0.25, R^2 = 0.07, p = 0.002).

Discussion

A standardized evaluation tool for the videofluoroscopic assessment of swallowing impairment (MBSImp) has been created and rigorously tested in a heterogeneous, representative, cross-sectional sample of patients referred for MBSS; it is based on scored observations of physiologic and bolus flow measures. The MBSImp was characterized by high inter- and intrarater reliability following standardized training for SLP clinicians with a minimum of 3 years of postcertification experience.

The MBS exam has been the instrument of choice for assessing swallowing physiology and determining the course of treatment for the majority of practicing clinicians because of the ability of the procedure to capture swallowing and bolus flow properties throughout the swallowing continuum from mouth to stomach. The examination is performed collaboratively with a radiologist and is relatively noninvasive and well-tolerated by most patients. However, radiation exposure is not a trivial issue and clinicians must take every precaution to minimize the radiation exposure to any patient (and themselves) regardless of age or diagnosis [51, 52]. The evidence is clear from previous studies that swallowing physiology does vary as a function of bolus type, taking into consideration volume, consistency, texture, and taste. Clinicians make use of the known physiologic swallowing adaptations to bolus types in their treatments of the swallowing mechanism [39]. However,

multiple trials of volumes and textures may unnecessarily extend the radiation exposure time if not all trials are needed to identify the type and presence of a swallowing impairment. This study is the first known to demonstrate the unique contribution of standardized varied volumes and textures to overall impressions of swallowing impairment. Eight of the nine bolus types (volumes, consistencies, mode of administration) contributed unique variation to at least some of the 15 components, with the exception of sequential swallowing with thin liquids. This trial did not offer any unique contributions to the clinician's judgment of swallowing impairment in this study sample. Many clinicians use this type of trial in patients who are able to tolerate it in terms of airway protection, particularly in the head and neck cancer patient, because it may offer information regarding the extent of PES distension. It may be the case that if the study sample contained more head and neck patients in whom PES stricture may be a concern, the swallow trial might have made more of a contribution to overall impressions of swallowing impairment. A 5-ml liquid swallow and a 5-ml nectar swallow together, on the other hand, contributed to clinician identification of all physiologic swallowing impairments except bolus preparation/ mastication. This is not surprising given that thin and nectar liquids do not require substantial bolus preparation as defined. If 5-ml liquid boluses (thin- and nectar-thick liquid barium) continue to contribute to judgments of impairment in subsequent studies, these two swallow trials may serve as “screening swallows” that signal the need to progress with or perhaps conclude the MBS exam. This finding certainly speaks to the potentially misguided practice of forgoing the thin-liquid swallow with the perception that the patient will perform better (i.e., less aspiration) on a more viscous bolus. These data suggest that it is possible to miss substantial physiologic information when using such practices. These data, summarized another way, indicate that if clinicians were to employ these standardized swallowing viscosities and volumes, with the exception of the sequential thick-liquid swallow, they would capture each of the validated physiologic components of swallowing.

The physiologic components of swallowing impairment fit a two-factor model that appeared to characterize swallowing function related to oral tongue (i.e., named “Oral” Factor) and to combined pharyngeal clearance and airway protection (i.e., named “Pharyngeal” Factor). It has been demonstrated that when the onsets of temporal components of swallowing are subjected to exploratory factor analysis, only one factor (“oropharyngeal”) resulted because of the interdependency of the onset of one structural movement with another [65]. However, when subjecting physiologic observations of impairment to exploratory factor analysis, a two-factor solution resulted which fits the historically described oral and pharyngeal “phases” of swallow with one exception—initiation of the pharyngeal swallow. Initiation of the pharyngeal swallow is uniquely related to other factors that are highly dependent on movement of the oral tongue. This finding fits with the early work of Logemann and colleagues who demonstrated the contributions of oral tongue movement to the onset of pharyngeal swallowing dynamics [66–69]. It should also be highlighted that soft palate elevation and lip closure did not uniquely relate to either factor. This finding relates to a limitation of the study that may also be considered a strength—heterogeneity of the sample. A heterogeneous sample was desired for the study because the investigator wished to develop a test tool that would be capable of capturing swallowing impairment regardless of a patient's diagnosis. The demographic data discussed in the Results section indicate a solid

representative sample from both a university-based and a tertiary, community-based hospital in the southeastern United States. Clearly, the demographics may differ in specialty hospitals, skilled nursing facilities, rural regions, and Veterans' Administration medical centers. The physiologic components that contribute to overall impressions of impairment may also differ and it is premature to exclude these validated components from MBS exams. If replicated in homogeneous patient groups and across health-care settings, then the components may be redundant and eliminated as necessary observations during the examination.

The exploratory aim of this study was to determine the relationship between swallowing impairment scores and external indicators of health status and quality of life. It should be clear that these indicators are not synonymous with outcomes. The indicators were measured at the time of the MBS exam. Therefore, the data do not reflect prediction of outcome based on the MBSImp scores. Rather, the relationship of component scores made by the SLP to the general status of the patient was explored. The data indicated that Oral and Pharyngeal MBSImp scores were associated with PA Scale scores. It was surprising, however, that most patients with oral and pharyngeal impairment did not aspirate (i.e., PA Scale scores ≤ 2). PA Scale scores were skewed toward more severe swallowing impairments. One strength of the tool is the ability to capture physiologic impairment outside the scope of aspiration. While the accurate identification of penetration and aspiration is critical to describing the swallowing problem profile, it is only one potential feature of a physiologic swallowing disorder. These data suggest that penetration and aspiration are not necessary or sufficient measures of swallowing impairment. The aim of the MBSS should be to find the impairment or "cause" of any or potential aspiration. Furthermore, swallowing inefficiency may be equally harmful to a patient if it results in compromised nutrition and hydration.

The MBSImp was also shown to correlate with the intake recommendations made by the SLPs. The data in Figure 5 demonstrate that the modified diets recommended by the examining SLPs were strongly associated with the degree of oral and pharyngeal impairment scores made by the scoring SLP. This finding points to the clinical validity of the tool in making intake decisions given that the scoring clinician was blinded to all clinical patient information (cognitive status, medical diagnosis, social circumstances) that usually play a role in intake recommendations made by the examining SLP.

The MBSImp scores were found to correlate significantly with several of the external indicators of health status and quality of life. Although the correlations between the indexes were statistically significant, MBSImp scores contributed only modestly to their variation. The modest correlations found in this study should not be surprising and are consistent with Brenner's proximal-distal continuum model, demonstrating that most aberrations in proximal physiologic indicators (swallowing impairment scores) typically show small relationships with distal indexes of health status and quality of life [70]. This does not connote lack of relevance, however. The unexplained variation in the external indicators may relate to multiple patient/SLP differences such as experience of the scoring clinician, patient diagnosis or natural history of a disease, the referral setting, and/or age of the patient. The degree of the relationships of scores to external indicators, therefore, may differ between large homogeneous groups of patients.

The theme that underscores the importance of this work is the practice of standardization, i.e., standardization of terminology, training, protocol, contrast materials, and quantification of swallowing impairment. This study set out to meet a need for externally validated, standardized measures that quantify and stratify swallowing impairment and are sensitive to detecting change in swallowing function over time. Adaptation of a voluntary standards system will lead to optimization of the patient's quality of care, its safety, its efficacy, and its cost [71]. Standardized practices facilitate interinstitutional exchange of patient data using electronic data collection, aggregation, and reporting systems [71]. The results of this study shows the achievement of a critical strategic step toward standardization of swallowing assessment. Implementation of such standardized training, protocol, contrast materials, and measurements should improve our ability to compare across clinics and clinical laboratories the swallowing impairment exhibited by our dysphagic patients during the course of recovery or physiologic decline associated with progressive neurologic diseases.

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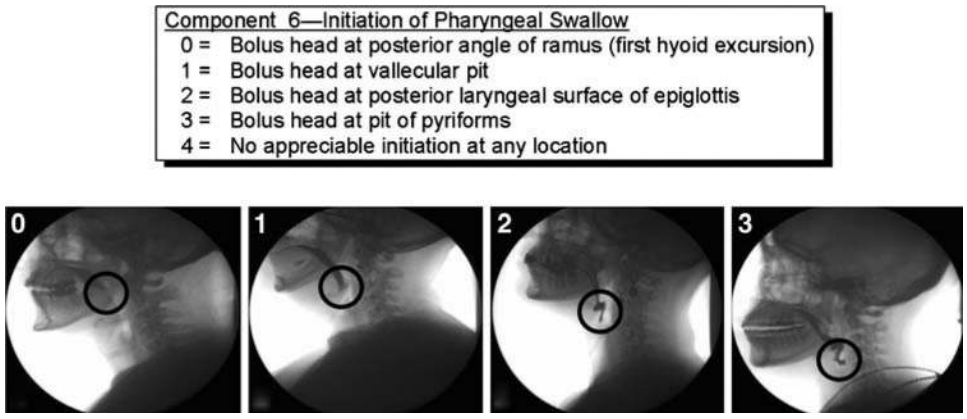

Fig. 1.
Depiction of the operational definition of initiation of the pharyngeal swallow

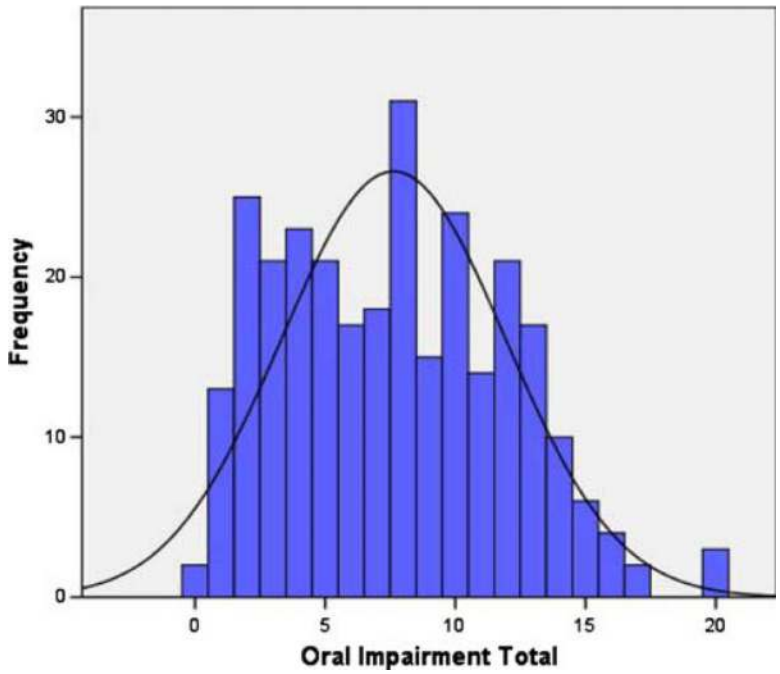

Fig. 2.
Distribution of Oral Impairment total across subjects

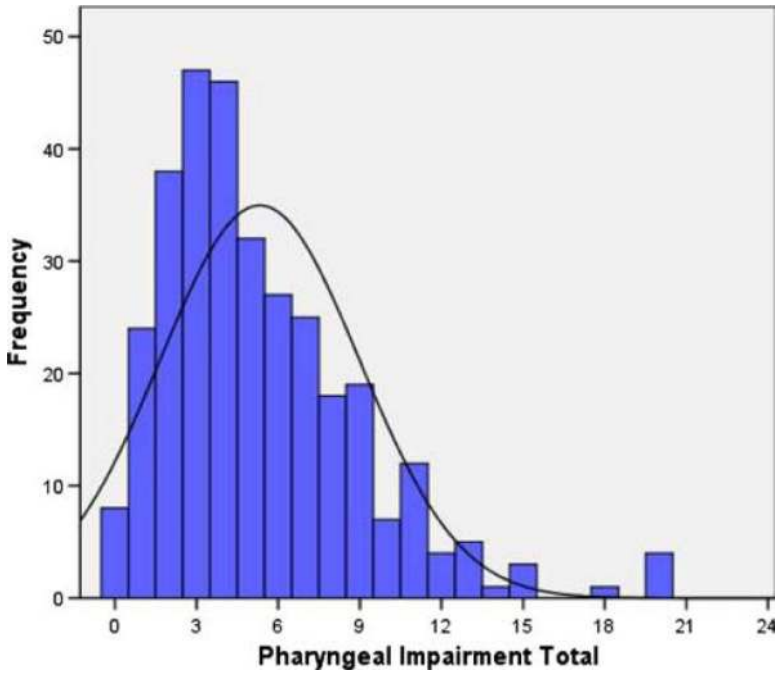

Fig. 3.
Distribution of Pharyngeal Impairment total across subjects

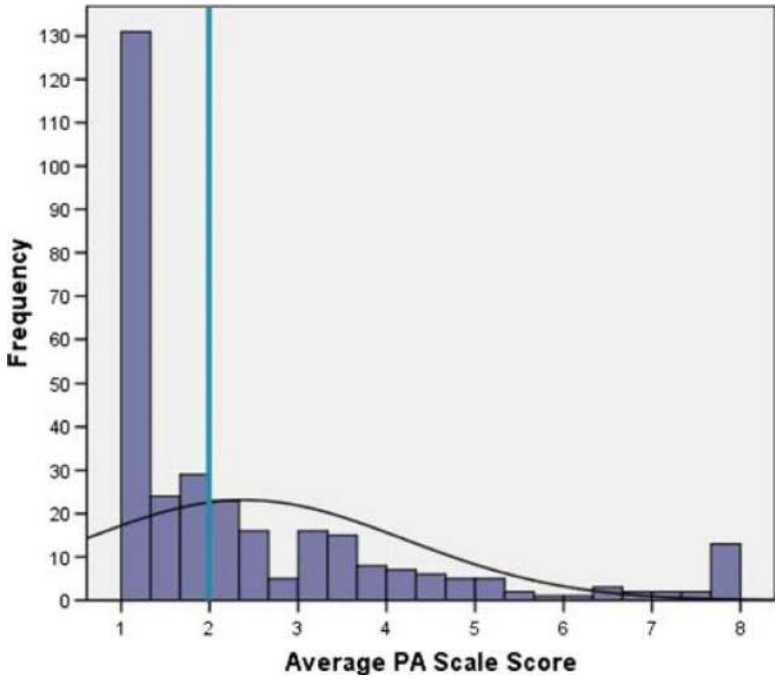

Fig. 4.
Distribution of average PA Scale scores across subjects

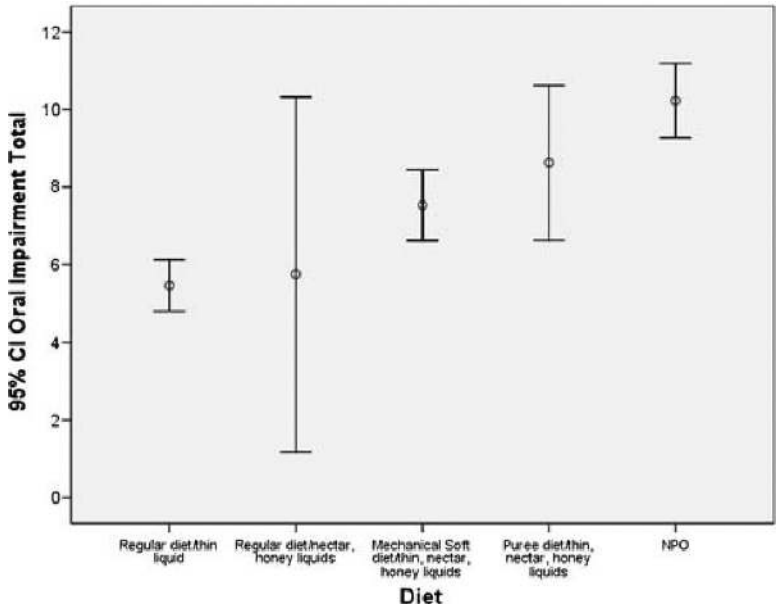

Fig. 5.
Relationship of Oral Impairment total to diet recommendation

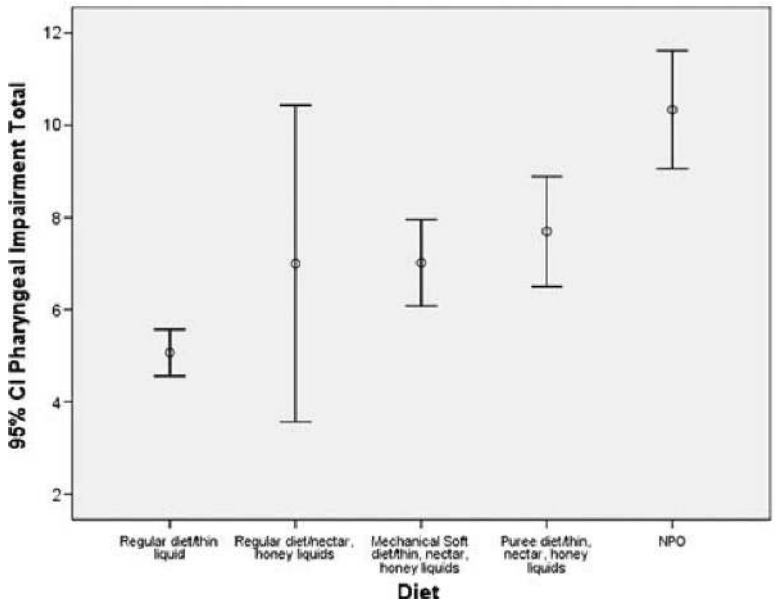

Fig. 6.

Relationship of Pharyngeal Impairment total to diet recommendation

Table 1

Physiologic swallowing components

1. Lip closure	(Lip C)
2. Hold position/tongue control	(HP)
3. Bolus preparation/mastication	(BP)
4. Bolus transport/lingual motion	(BT)
5. Oral residue	(OR)
6. Initiation of the pharyngeal swallow	(IPS)
7. Soft palate elevation	(SPE)
8. Laryngeal elevation	(LE)
9. Anterior hyoid motion	(HM)
10. Epiglottic movement	(EM)
11. Laryngeal closure	(LC)
12. Pharyngeal stripping wave	(PSW)
13. Pharyngeal contraction	(PC)
14. PES opening	(PESO)
15. Tongue base retraction	(TBR)
16. Pharyngeal residue	(PR)
17. Esophageal clearance in the upright position	(EC)

Table 2

Penetration-aspiration scale

Function	Category	Score	Description
Normal		1	Material does not enter airway
	Penetration	2	Material enters the airway, remains above the vocal folds, no residue
Disordered		3	Material remains above vocal folds, visible residue remains
		4	Material contacts vocal folds, no residue
		5	Material contacts vocal folds, visible residue remains
	Aspiration	6	Material enters the airway, remains above the vocal folds, no residue
		7	Material remains above vocal folds, visible residue remains
		8	Material contacts vocal folds, no residue

Table 3

Possible combinations of diet texture and liquid consistency recommendations

Rating	Diet grade	Liquids
0	Regular diet	Thin liquids
1		Nectar thick
2		Honey thick
3	Mechanical soft diet	Thin liquid
4		Nectar thick
5		Honey thick
6	Puree/dysphagia diet	Thin liquid
7		Nectar thick
8		Honey thick
9	NPO	N/A

Table 4

Body mass index (BMI)

Nutritional status			
Body Mass Index (BMI)		<18.5	Underweight
	$\text{BMI} = \frac{\text{Weight(kg)}}{\text{Height(m)}^2}$	15.5–24.9	Normal weight
	or	25–29.9	Overweight
	$\text{BMI} = \frac{\text{Weight(lbs)} \times 703}{\text{Height(in)}^2}$	30–34.9	Obesity (Class 1)
		35–39.9	Obesity (Class 2)
		≥40	Extreme obesity (Class 3)

Table 5

Patient-generated subjective global assessment triage recommendations based on score

Score	Triage recommendation
0–1	No intervention required at this time. Reassess on routine and regular basis during treatment
2–8	Patient and family education by clinician with pharmacologic intervention if necessary
9–15	Dietitian referral and pharmacologic intervention if necessary
>15	Nutrition support team referral

Table 6

Inclusion criteria for aspiration pneumonia (ICD-9: 507.0)

1. Gravitational segment infiltrate on chest X-ray (posterior segment of upper lobes ± superior segments of lower lobes for recumbent patient, basilar segments for upright patients)
2. Observed aspiration
3. Predisposing conditions for aspiration:
Poor dentition
Alcoholism
Seizure disorder
Loss of consciousness
Vomiting
Neurologic disorders
Reduced mental status
4. Gastric contents suctioned from the endotracheal tube
5. Microbiology
Anaerobes isolated from empyema fluid
Sputum gram stain: 4 + polys, no epithelial cells, and mixed bacteria
Anaerobes from blood culture in appropriate settings
6. Radiographic lung abscess (0.2-cm cavity)
Aspiration pneumonia group must have *one* of the following clusters of criteria:
1 and 2
1 and 3 with nondiagnostic sputum
1 and 4
1 and 5a or 5c
1, 3, and 5b
3 and 6
5 (a, b, or c) and 6

Table 7

Demographics distribution between sites

	MUSC		SJHA	
	Male (%)	**Female (%)**	**Male (%)**	**Female (%)**
Race				
Asian	0.5	0	1.4	0.7
Black/African American	14.1	14.1	4.3	2.8
White	39.8	29.8	58.2	30.5
Unknown/not reported	0.5	1.0	1.4	0.7
Ethnicity				
Hispanic or Latino	0.5	1.0	1.4	0.7
Not Hispanic or Latino	52.9	42.9	58.2	30.5
Unknown/not reported	1.5	1.0	5.7	3.5

Table 8

Statistical significance of independent swallow consistency/mode trials (*p* values)

	LipC	HP	BP	BT	OR	IPS	SPE	LE	HM	EM	LC	PSW	PESO	TBR	PR
Thin: 5 ml by teaspoon		<0.0005		0.006	0.012	<0.0005	<0.0005	<0.0005	<0.0005	<0.0005	<0.0005	<0.0005	<0.0005		<0.0005
Thin: cup sip						0.009	0.008	0.002			0.015	0.010			
Thin: sequential															
Nectar: 5 ml by teaspoon	0.001	0.001				0.009	<0.0005	<0.0005	<0.0005	<0.0005		<0.0005	0.001	0.030	0.009
Nectar: cup sip						0.045									
Nectar: sequential								<0.0005							
Honey: 5 ml by teaspoon				<0.0005	<0.0005								0.001	<0.0005	
Pudding: 5 ml by teaspoon				<0.0005	00.001			0.048	0.004				0.029		
½ Lorna Doone cookie with 3 ml pudding	0.023	<0.0005	<0.0005												

Table 9

Rotated component matrix[a]

Component	Factor loadings	
	1	2
Hold Position/Tongue Control (HP)	0.050	*0.761*
Bolus Preparation/Mastication (BP)	0.283	*0.692*
Bolus Transport/Lingual Motion (BT)	0.100	*0.812*
Oral Residue (OR)	0.146	*0.653*
Initiation of the Pharyngeal Swallow (IPS)	0.154	*0.664*
Laryngeal Elevation (LE)	**0.788**	.232
Hyoid Motion (HM)	**0.788**	.138
Epiglottic Motion (EM)	**0.757**	.087
Laryngeal Closure (LC)	**0.788**	.250
Pharyngeal Stripping Wave (PSW)	**0.558**	.101
Pharyngoesophageal Segment Opening (PESO)	**0.678**	.003
Tongue Base Retraction (TBR)	**0.592**	.476
Pharyngeal Residue (PR)	**0.742**	.231

Extraction method = principal component analysis; rotation method: varimax with Kaiser normalization

Oral factors are indicated in italics

Pharyngeal factors are indicated in bold

[a]Rotation converged in three iterations