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Research Report

The Test of Masticating and Swallowing Solids (TOMASS): reliability, validity and international normative data

Maggie-Lee Huckabee†‡, Theresa McIntosh†‡, Laura Fuller†‡, Morgan Curry†‡, Paige Thomas†‡, Margaret Walshe§, Ellen McCague§, Irene Battel§¶, Dalia Nogueira||, Ulrike Frank#, Lenie van den Engel-Hoek** and Oshrat Sella-Weiss††‡‡

†Swallowing Rehabilitation Research Laboratory at the Rose Centre for Stroke Recovery and Research, Christchurch, New Zealand

‡Department of Communication Disorders, The University of Canterbury, Christchurch, New Zealand

§Department of Clinical Speech and Language Studies, Trinity College Dublin, University of Dublin, Dublin, Ireland

¶Fondazione Ospedale di Neuroriabilitazione IRCCS San Camillo, Venice, Italy

||Instituto Universitário de Lisboa (ISCTE-IUL), Business Research Unit (BRU-IUL), Lisbon, Portugal

#Department of Cognitive Neurolinguistics, Swallowing Research Lab, University of Potsdam, Potsdam, Germany

**Donders Centre for Neuroscience, Department of Rehabilitation, Radboud University Medical Center, Nijmegen, the Netherlands

††Department of Communication Disorders, Ono Academic Collage, Kiryat Ono, Israel

‡‡Department of Communication Disorders, University of Haifa, Haifa, Israel

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Abstract

Background: Clinical swallowing assessment is largely limited to qualitative assessment of behavioural observations. There are limited quantitative data that can be compared with a healthy population for identification of impairment. The Test of Masticating and Swallowing Solids (TOMASS) was developed as a quantitative assessment of solid bolus ingestion.

Aims: This research programme investigated test development indices and established normative data for the TOMASS to support translation to clinical dysphagia assessment.

Methods & Procedures: A total of 228 healthy adults (ages 20–80+ years) stratified by age and sex participated in one or more of four consecutive studies evaluating test–retest and interrater reliability and validity to instrumental assessment. For each study the test required participants to ingest a commercially available cracker with instructions to ‘eat this as quickly as is comfortably possible’. Further averaged measures were derived including the number of masticatory cycles and swallows per bite, and time per bite, masticatory cycle and swallow. Initial analyses identified significant differences on salient measures between two commercially available crackers that are nearly identical in shape, size and ingredients, suggesting the need for separate normative samples for specific regional products. Additional analyses on a single cracker identified that the TOMASS was sensitive at detecting changes in performance based on age and sex. Test–retest reliability across days and interrater reliability between clinicians was high, as was validation of observational measures to instrumental correlates of the same behaviours. Therefore, normative data are provided for the TOMASS from a minimum of 80 healthy controls, stratified by age and sex, for each of seven commercially available crackers from broad regions worldwide.

Outcomes & Results: Analyses on a single cracker identified Arnott’s Salada, and that TOMASS measures were sensitive for detecting changes in performance based on age and sex. Interrater and test–retest reliability across days were high, as was validation of observational measures to instrumental correlates of the same behaviours. Significant differences were identified between two commercially available crackers, nearly identical in shape, size and ingredients, thus normative samples for specific regional products were required. Normative data were then acquired for the TOMASS from a minimum of 80 healthy controls, stratified by age and sex, for each of seven commercially available crackers from broad regions worldwide.

Address correspondence to: Maggie-Lee Huckabee, The University of Canterbury Rose Centre for Stroke Recovery and Research, Leinster Chambers, Level One, 249 Papanui Road, Merivale, Christchurch 8042, New Zealand; e-mail: maggie-lee.huckabee@canterbury.ac.nz

Conclusions & Implications: The TOMASS is presented as a valid, reliable and broadly normed clinical assessment of solid bolus ingestion. Clinical application may help identify dysphagic patients at bedside and provide a non-invasive, but sensitive, measure of functional change in swallowing.

Keywords: deglutition, assessment, mastication, swallowing, timed, solid.

What this paper adds

What is already known on the subject

Non-instrumental swallowing assessment is typically based on qualitative rather than quantitative assessment of observed behaviour, thus identification of impairment may be inaccurate and outcome assessment may be poorly sensitive to change.

What this paper adds to existing knowledge

The TOMASS is documented as being a valid, reliable and broadly normed quantitative clinical assessment of solid bolus ingestion.

What are the potential or actual clinical implications of this work?

Clinical application of the TOMASS may help identify dysphagic patients at bedside and provide a non-invasive measure of rehabilitation recovery.

Introduction

Accurate identification of dysphagia is crucial for reducing complications such as aspiration pneumonia; it also circumvents decreased quality of life resulting from unnecessary diet modification. Conclusions regarding the presence of dysphagia are drawn initially from clinical swallowing assessments. These assessments most often include an evaluation of oral structure and function, a cranial nerve examination and observation of oral intake, and are based predominantly on subjective binary decisions or severity scales of behavioural observations. This may be sufficient for identification and referral for instrumental assessment in the case of more pronounced impairment. However, in patients with less obvious clinical presentation, the distinction between impaired and unimpaired function may be less evident. Clinical measures that are objective and quantifiable would very likely increase clinical accuracy and decision-making if normative values were available for comparison. Additionally, qualitative judgements of swallowing fail to assess adequately outcome measurement following rehabilitation in either research or clinical practice. Quantitative clinical measures would serve as a valuable metric of functional recovery for some aspects of swallowing.

Hughes and Wiles (1996) recognized this need and, in response, developed the Timed Water Swallowing Test (TWST) to provide quantifiable information on clinical assessment. This test consists of ingestion of either 100 or 150 ml of water from an open cup, with the instructions to drink 'as quickly as is comfortably possible' (110). The number of swallows and total time required for ingestion of the liquid are recorded, along

with subjective observations such as drooling, coughing or vocal quality changes. From the raw data, three quantitative indices are calculated: average volume per swallow (ml/swallow), average time per swallow (s/swallow) and what the researchers termed swallowing capacity (ml/s). In the initial study, the authors derived normative data from 181 healthy participants, with a minimum of 10 men and 10 women in each 10-year band between 20 and 80 and over 80 years. They also included data from a subgroup of patients with motor neuron disease who demonstrated significantly reduced swallowing capacity and volume per swallow. Although this assessment is limited in diagnostic specificity—it provides information about efficiency and speed of swallowing but not pathophysiological characteristics—it has proven a sensitive tool for identifying the presence of impairment in a variety of neurological conditions (Ertekin *et al.* 2000, 2002, Lin *et al.* 2000, Wu *et al.* 2004).

A benefit of this test is the ease of administration using internationally accessible materials: water. However, the test is limited by the inability of some patients to ingest thin liquids safely and the lack of challenge of the oral phase of swallowing, particularly bolus mastication and preparation. Thus, an accompanying tool that specifically emphasizes oral bolus preparation would be of clinical value, particularly in populations where oral phase deficits predominate and influence the consequent pharyngeal response.

Orolingual manometry measures have been used to quantify aspects of the oral phase of swallowing. The amount of pressure the tongue can generate, along with its subsequent movements, plays a key role in

masticatory function and allows a cohesive bolus to be manipulated and maintained during transfer from the oral cavity into the pharynx. Research has also shown that tongue pressure measures are significantly decreased for patients with dysphagia as compared with those without (Stierwalt and Youmans 2007, Tsuga *et al.* 2011, Hamanaka-Kondoh *et al.* 2014). Although limited normative data exist for orolingual pressure, specifically tongue to palate pressure (Hewitt *et al.* 2008), and there is an association between isometric orolingual pressure and swallowing pressure (Robbins *et al.* 1995), this technique requires specialized instrumentation for measurement and does not directly assess functional ingestive behaviour.

A number of researchers have examined functional masticatory parameters in small control populations. In a study of 11 healthy individuals, Hiiemae *et al.* (1996) found that the total masticatory cycle for one bite of food, on average, ranged from 17.58 to 24.47 s, depending on the food texture, with the average masticatory cycle lasting between 0.58 and 0.82 s. In a later study of 10 individuals, Hiiemae and Palmer (1999) confirmed these findings, reporting an average of 22.8 s to consume an 8 g sample of peanuts and 23.61 s to consume the same size sample of shortbread. Similarly, Palmer *et al.* (2007) found that eight participants, with a median age of 23 years, required 19.6 s, on average, to consume an 8 g piece of shortbread. Within this time, they swallowed twice on and completed 23 masticatory cycles, each of which took 0.76 s, all averaged data. Although they begin to fill a gap in the literature, these studies do not address the lack of large-scale norms, stratified by age and gender that can be used clinically in dysphagia assessment.

In the absence of a valid and reliable measure of masticatory function, the Test of Masticating and Swallowing Solids (TOMASS) was developed for use in a treatment study for swallowing impairment associated with Parkinson's disease (Athukorala *et al.* 2014), extending on the TWST by using the same methods but with a solid bolus texture. The test requires ingestion of a single Arnott's Salada™ cracker with the instructions to eat this 'as quickly as is comfortably possible' (Athukorala *et al.* 2014: 1365). Data were collected on number of discrete bites taken to ingest the cracker, number of masticatory cycles per bite and number of swallows per bite. Although the skill-based treatment provided to this small sample of 10 patients resulted in significant improvement on the TWST, there were no significant changes on the TOMASS as a function of treatment. However, Athukorala and colleagues noted that baseline data on the TOMASS were within the range of normal, based on limited normative data that were available at the time of the study. Importantly, interrater reliability for measurement of TOMASS data was reported to

be high, with intraclass correlation coefficients ranging from .83 to .99 across all measures (Athukorala *et al.* 2014). Additionally, surface electromyography (EMG) measures derived from the masseter muscles were highly correlated with visual observation of chewing cycles, with the average Pearson correlation coefficient across four measurement sessions at $r = .93, p < .05$ (Athukorala 2012).

Aim

The purpose of this programme of study was to establish further the newly developed TOMASS for use in clinical assessment. The first phase of the study evaluated age, gender differences and trial effects in test performance for two very similar crackers. Additional analyses included test-retest and interrater reliability, and validity of observational measurements when compared with instrumental correlates, using a single cracker available to the Australasian market. In the second phase of the study, normative data were collected and summarized by age and gender using readily available crackers available to commercial markets in Australia/New Zealand, North America, Ireland/UK, Italy/Portugal, Germany, the Netherlands and Israel.

Methods

Participants and projects

In phase 1 of the research programme, 228 healthy participants, with no reported history of dysphagia or neurological disease, were recruited from the general public for participation in four related projects. For the first project, designed to evaluate for a trial effect, age and gender differences, and cracker differences, 84 healthy adults were recruited with a minimum of 10 male and 10 female participants within each 20-year band between 20 and 80 years, and aged > 80 years. These participants were then compared with a second group consisting of 80 participants, also balanced for age and sex to evaluate for differences in cracker type. For the second project, which evaluated test-retest and interrater reliability, 40 additional participants (20 men), again equally distributed across the same four age bands, were recruited. The third project, which evaluated the validity of the TOMASS to instrumental measures, recruited an additional 24 participants across the same four age bands with an equal number of men and women in each age group.

In phase 2 of the research programme, normative databases were established for ingestion of commercially available crackers in seven broad regions worldwide. For each database, summarized in table 1, a minimum of 80 participants were recruited, stratified across age and gender.

Table 1. Participant and cracker-type summary for each of seven regional datasets

	Cracker	Gender	20–40	40–60	60–80	80+	Subtotal	Total
New Zealand/ Australia	Arnotts Salada™	M	17	15	15	15	62	124
		F	17	15	15	15	62	
North America	Nabisco Saltine™	M	10	10	10	10	40	80
		F	10	10	10	10	40	
Ireland/ United Kingdom	Carr's Table Water™	M	10	12	10	10	42	85
		F	12	11	10	10	43	
The Netherlands	Albert Heijn Basic™	M	20	21	21	—	62	126
		F	20	22	22	—	64	
Germany	DeBeukelaer Tuc Classic™	M	17	13	11	15	56	121
		F	13	17	16	19	65	
Italy/Portugal	Gran Pavesi™	M	39	28	36	31	134	285
		F	32	34	51	34	151	
Israel	Osem Golden™	M	13	19	18	10	60	126
		F	17	21	18	10	57	

All participants were self-reported to be healthy with no history of dysphagia, head and neck, neurological or gastroenterological illness or injury. Informed written consent was obtained from each participant and all protocols were approved and conducted in accordance with the ethical standards of the relevant University or Regional Human Ethics Committee.

Materials

Several commercially available crackers were utilized for this research programme. The Arnott's Salada™ cracker was used in all studies and is readily available throughout New Zealand and Australia. Each cracker weighs 3.75 g with dimensions of 5 cm². The Nabisco Saltine™ cracker was selected for comparison with the Salada. This cracker weighs 16 g with dimensions of 5 cm² and is readily available across North America. Both crackers contain unbleached flour (wheat flour, niacin, reduced iron, thiamine, mononitrate (vitamin B1), riboflavin (vitamin B2), and folic acid, soybean oil, partially hydrogenated cottonseed oil, sea salt, salt, malted barley flour, baking soda and yeast) and are identical in size, shape and appearance. Exact proportions of ingredients were not supplied by the manufacturer on request. However, the Saltine cracker is perceptually slightly more crumbly and dry. Further normative data were collected using the Carr's Table Water™ cracker (Ireland and the UK), Albert Heijn Basic™ cracker (the Netherlands), DeBeukelaer Tuc Classic™ cracker (Germany), Gran Pavesi™ cracker (Italy and Portugal), and the Osem Golden™ cracker (Israel). The crackers chosen from the Netherlands and Italy/Portugal were very similar, but not identical, in ingredients, size and perceptual characteristics with the previously described Salada. The DeBeukelaer Tuc Classic cracker (5 × 6.5 cm, 3.75 g)

and the Osem Golden cracker (6.7 × 4.3 cm, 3.6 g) are both larger and perceptually similar, while the Carr's Table Water cracker (6 cm diameter; 3.5 g) is smaller and perceptually drier than the other crackers.

Objective measures of mastication and swallowing in study 3 were collected using surface electromyography (sEMG), acoustic and nasal airflow functions of the Kay Pentax Digital Swallowing Workstation.

Data collection

For all studies, including normative database development, the TOMASS was carried out in the following manner. Participants, seated comfortably, were asked to eat a single portion of the cracker 'as quickly as is comfortably possible and when you have finished, say your name out loud'. They were advised not to talk during ingestion. However, speaking their name on completion of the entire cracker was used as a marker of task completion and oral cavity clearance. Participants were carefully observed and the number of bites was determined by how many discrete segments of cracker the participant placed in their mouth, while the number of swallows was recorded based on visual observation of movement of the thyroid cartilage. Both measures were manually recorded on a data-collection sheet. The number of masticatory cycles was counted through observation of jaw movements; a lap function on a digital stopwatch was used to mark each masticatory cycle. Timing was initiated when the cracker passed the bottom lip and was stopped when the participant said their name. For all participants, the above procedure was carried out a second time.

For the study of reliability, 40 participants ingested the Arnott's Salada cracker twice in a single session, using the same method of data collection and allowing for water ingestion to clear the oral cavity and moisten

mucosa before and between the two trials. To evaluate test–retest consistency, data collection was repeated on three consecutive days. During one session only, two raters were present to make independent measures of participant performance as an assessment of interrater reliability.

For the study of validity, 24 participants ingested the Arnott's Salada cracker twice in one session. Participants then returned after a period of at least 24 h at which they completed the TOMASS twice more. A glass of water was offered to participants prior to the first trial as well as between the two trials. Objective measures were collected with sEMG electrodes placed over the masseter and submental muscles, nasal prongs to detect respiratory phase and a stethoscope secured over the lateral aspect of the thyroid cartilage to detect swallowing acoustics. All data recorded using the Kay-Pentax Digital Swallowing Workstation. All sensors were placed on the right side of the participant's face to allow optimal viewing for the researcher who was positioned to the left of the participant. Objective measurement of one masticatory cycle was determined by the point at which the sEMG amplitude for masseter activity was at maximum and for submental muscles was at minimum, followed by a reversal of these signals, indicating jaw closure and opening. A swallowing event was denoted by the presence of swallowing apnoea in the respiratory waveform, accompanied by a peak in the submental muscle sEMG activity. The acoustic signal was used as additional confirmation of swallowing; however, a strong acoustic signal was not clearly detected in all participants. The objective measure for time taken was from the first chew recorded by sEMG until the time in which there was a large acoustic signal indicating that the participant had said their name to indicate that they had finished.

Data preparation and statistical analysis

In addition to the raw data of number of discrete bites, masticatory cycles, swallows per cracker and total time required for ingestion, several additional derived measures were calculated, similar to those derived for the TWST. These measures included averaged number of masticatory cycles per bite (number of masticatory cycles/number of discrete bites), averaged number of swallows per bite (number of swallows/number of discrete bites), averaged time per bite (number of discrete bites/total time), time per masticatory cycle (total time/number of masticatory cycles), and time per swallow (total time/number of swallows).

Two general linear model one-way, fixed-factor multivariate analyses of variance (MANOVAs)—one based on data from the first trial, and one on data from the second trial—were conducted on all variables to

compare the data between the two crackers (Arnott's Salada and Nabisco Saltine). An a priori decision was made that if no significant difference was identified between crackers, all subsequent analyses would be completed on the combined data from both crackers. If a significant difference between data on any raw data measure was identified, subsequent analyses would be completed for each cracker independently. A *t*-test was then conducted to evaluate for a trial effect between first and second trials. General linear model, two-way, fixed-factor MANOVAs were then completed to evaluate the influence of age and gender on all variables. The reported *p*-values represent application of Bonferroni correction for multiple comparisons when appropriate.

Cronbach's alpha and mixed-model intraclass correlation coefficients using single measure methods were derived for the raw data only to evaluate test–retest consistency of performance across the three sessions and interrater reliability between two raters in a single session.

Intraclass correlation coefficients using single measure methods were calculated to evaluate validity of behavioural measures when compared with instrumental assessment. Analysis was also conducted to determine the interrater reliability between two raters evaluating the objective data.

Finally, normative data were established for participants ingesting each cracker, calculated by age and gender as mean and 95% confidence interval for number of bites, number of masticatory cycles and number of swallows per cracker as well as total time. Further normative data were calculated for the derived measures of masticatory cycles per bite, swallows per bite, time per bite, time per masticatory cycle and time per swallow.

Results

Study 1: Cracker, trial, age and gender effects

Salada versus saltine comparison

For both the first and second trials of the TOMASS there were significant differences between crackers for most, but not all, measures (table 2). In general, the group ingesting the Salada cracker took more discrete bites, required more masticatory cycles and swallows, and more time to ingest the cracker than the group ingesting the Saltine cracker.

Trial effect. Paired *t*-tests compared data from the first trial with data from the second trial on all variables. Three of the four raw data measures (discrete bites: $t = -3.29$, $p < .01$; masticatory cycles: $t = -2.14$, $p = .035$; and swallows per cracker: $t = -2.62$, $p = .01$) were significantly different between the first and second

Table 2. Summary of the statistical output for the evaluation of trial, age and gender effects

Measure	Cracker effect						Age Effect						Sex Effect														
	Trial 1			Trial 2			Salada			Saltine			Salada			Saltine											
	Salada ^a	Saltine ^a	F	F	P	Salada ^a	Saltine ^a	F	F	P	F	F	P	F	F	P	F	F	P								
Raw data per cracker	2.81	2.59	1.34	1.34	.25	3.13	2.51	8.65	8.65	<.01	25.0	28.83	<.01	41.48	27.63	<.01	59.75	44.68	13.51	<.01	21.97	10.1	<.01	5.51	7.99	<.01	
#discrete bites																											
#masticatory cycles	3.57	2.68	14.41	14.41	<.01	3.9	2.5	33.24	33.24	<.01	7.32	11.638	<.01	7.38	5.29	<.01	53.39	35.80	21.22	<.01	19.97	23.39	<.01	7.2	12.07	<.01	
#swallows																											
total time (in sec)	23.65	19.38	7.10	7.10	<.01	22.98	18.96	6.27	6.27	.01	0.01	3.68	.02	13.9	7.01	<.01											
Average events per bite	1.46	1.14	7.42	7.42	<.01	1.5	1.06	13.12	13.12	<.01	1.85	1.16	.33	7.86	4.11	<.01											
Average time per event (in sec)	21.17	15.34	15.51	15.51	<.01	19.96	14.68	18.71	18.71	<.01	0.41	.79	.50	7.53	3.66	<.01											
#masticatory cycle	.90	.82	7.97	7.97	<.01	.90	.79	14.36	14.36	<.01	0.64	4.20	<.01	.39	.86	<.01											
swallow	16.13	14.24	3.36	3.36	.07	15.54	14.70	.61	.61	.43	4.71	.43	.73	.69	.004	.41											

Note: ^aMean values.

trials, with a tendency toward slower, less efficient performance on the second trial. No significant differences were identified for total time to ingest and the derived measures ($p > .05$). However, as a trial effect was evident on several measures of the raw data, normative data and all subsequent reliability and validity analyses were completed only on the first trial.

Age and sex effects. Multivariate analysis of variance with age and sex as fixed factors revealed a significant main effect of both variables (age: $F = 5.15, p < .001$; sex: $F = 3.56, p < .001$); but no significant age and gender interaction ($p = .07$). Post-hoc testing of individual variables (table 2) revealed a significant age effect for the four raw data variables of discrete bites, masticatory cycles, swallows per cracker and total time to ingest the cracker. However, none of the derived measures was significantly different as a function of age with the exception of number of swallows by time. Post-hoc analyses and evaluation of normative data (tables 3 and 4) suggest increased biomechanical movements and time associated with increased age.

The effects of sex were significant across all variables (discrete bites, masticatory cycles and swallows per cracker, total time to ingest, masticatory cycles per bolus, and swallows per bolus) with the exception of the derived measures of average time per masticatory cycle and average time per swallow. In general, post-hoc analyses and evaluation of normative data (tables 3 and 4) reveals that male participants took fewer bites, chewed and swallowed less, and took a shorter amount of time than age equivalent females.

Study 2: Interrater and test-retest reliability

Within-session trial effect

The trial effect observed in the first study was also present in this analysis. Significant differences, all at $p < .01$, were found between trials for masticatory cycles ($t = 4.99, d.f. = 119, p < .01$), swallows ($t = 3.43, d.f. = 119$) and total time ($t = 5.35, d.f. = 119$). The number of discrete bites taken from each cracker did not differ as a function of trial ($t = 1.645, d.f. = 119, p = .103$) The second trial consistently exhibited fewer masticatory cycles and swallows, as well as faster total time. As with prior studies, subsequent analyses were conducted only on the first trial of each session.

Interrater

Cronbach's α for all measures between raters were $> .90$, indicating a high level of internal consistency. This is supported by ICC values $> .98$ for all measures indicating a near perfect relationship between the two

Table 3. TOMASS normative data consisting of mean and 95% confidence intervals by age and gender for Arnott's Salada™ cracker

Sex	Age	TEST OF MASTICATING AND SWALLOWING SOLIDS: Arnott's Salada™ cracker																	
		Discrete bites per cracker		Masticatory cycles per cracker		Swallows per cracker		Total time (in sec)		Masticatory cycles per bite		Swallows per bite		Time per bite (in sec)		Time per masticatory cycle (in sec)		Time per swallow (in sec)	
		Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.
Males	20-40	1.76	1.30-2.23	36.53	30.36-42.70	2.35	1.87-2.83	29.22	24.70-33.74	25.13	18.78-31.49	1.54	1.10-2.00	19.63	15.21-24.06	.82	.76-.88	15.08	10.37-19.79
	40-60	1.93	1.44-2.42	41.60	34.60-48.60	3.00	2.11-3.89	36.49	30.74-42.24	23.87	18.93-28.81	1.89	1.15-2.64	21.10	17.09-25.11	.90	.82-.98	13.01	10.73-15.28
	60-80	2.33	1.79-2.87	60.67	50.51-70.82	3.20	2.41-3.99	51.26	40.53-61.99	28.87	21.09-36.65	1.44	1.13-1.76	24.06	17.69-30.43	.84	.77-.92	16.99	14.46-19.52
Females	80+	3.40	2.65-4.15	89.73	70.52-108.94	4.00	2.73-5.27	84.76	63.13-106.39	28.99	23.04-34.95	1.27	.88-1.66	28.79	19.33-38.24	.95	.80-1.11	24.12	17.15-31.09
	20-40	2.71	2.31-3.10	45.94	38.72-53.16	3.18	2.65-3.70	40.84	32.68-49.01	18.37	14.54-22.21	1.30	.91-1.70	16.44	12.45-20.42	.89	.79-.99	13.62	11.87-15.36
	40-60	3.13	2.55-3.72	52.93	45.10-60.77	3.53	2.91-4.16	46.79	36.75-56.83	18.10	15.08-21.13	1.17	1.06-1.27	15.70	13.53-17.88	.89	.78-1.00	13.79	11.62-15.97
80+	60-80	3.27	2.94-3.60	63.33	53.21-73.46	4.07	3.19-4.94	60.37	49.24-71.51	19.89	16.05-23.73	1.28	.97-1.58	19.04	14.84-23.25	.95	.85-1.05	14.70	12.59-16.82
	80+	4.33	3.75-4.91	104.33	81.85-126.82	4.67	3.79-5.55	90.08	70.11-110.06	24.51	20.28-28.74	1.09	.93-1.25	20.92	17.87-23.97	.85	.78-.93	19.44	15.67-23.21

Table 4. TOMASS normative data consisting of mean and 95% confidence intervals by age and gender for the Nabisco Saltine™ cracker

Sex	Age	TEST OF MASTICATING AND SWALLOWING SOLIDS: Nabisco Saltine™ cracker																	
		Discrete bites per cracker		Masticatory cycles per cracker		Swallows per cracker		Total time (in sec)		Masticatory cycles per bite		Swallows per bite		Time per bite (in sec)		Time per masticatory cycle (in sec)		Time per swallow (in sec)	
		Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.
Males	20-40	1.40	.90-1.90	30.80	25.25-36.35	1.70	.94-2.46	23.42	17.74-29.09	24.05	20.18-27.92	1.30	.62-1.98	18.15	13.36-22.74	.79	.64-.95	15.73	12.23-19.23
	40-60	1.40	1.03-1.77	34.30	23.18-45.42	2.20	1.26-3.14	28.04	15.46-40.62	26.20	16.16-36.24	1.65	.93-2.37	20.70	13.15-28.26	.81	.67-.96	13.22	11.25-15.19
	60-80	2.10	1.69-2.51	41.50	33.94-49.07	2.40	1.90-2.90	30.66	25.22-36.09	21.77	13.18-30.36	1.20	.90-1.50	16.35	9.29-23.41	.75	.67-.83	13.70	10.43-16.98
Females	80+	3.70	3.11-4.29	54.30	41.68-66.92	3.40	2.50-4.30	44.29	35.62-52.96	14.65	11.94-17.35	.91	.71-1.12	12.08	9.89-14.28	.83	.76-.90	14.17	11.20-17.14
	20-40	2.10	1.47-2.72	40.30	30.80-49.80	2.30	1.71-2.89	26.40	21.44-31.35	20.70	16.73-24.67	1.20	.85-1.55	14.83	9.46-20.20	.68	.56-.81	12.25	9.79-14.72
	40-60	3.20	2.46-3.94	53.40	41.66-65.14	2.50	1.80-3.20	36.41	29.21-43.62	17.37	13.49-21.24	.81	.59-1.04	11.80	9.63-13.97	.69	.63-.76	16.36	11.73-20.99
80+	60-80	2.80	2.50-3.10	39.50	32.75-46.26	2.90	2.49-3.31	37.71	31.52-43.90	13.28	11.97-16.60	1.03	.96-1.11	13.58	11.38-15.78	.97	.83-1.11	13.24	10.92-15.56
	80+	4.00	3.42-4.58	63.60	50.39-76.21	4.00	3.42-4.58	59.50	51.20-67.80	16.08	12.98-19.17	1.00	1.00-1.00	15.23	12.95-17.51	.99	.78-1.21	15.23	12.95-17.51

raters. Data for individual measures are summarized in table 5.

Test-retest reliability

Test-retest reliability was also very high. Cronbach's α ranged from .94 to .99 with ICC values between .83 and .98 suggesting a high level of internal consistency. Data for individual measures are summarized in table 4.

Study 3: Validity

The ICC value between objective and behavioural measures of the number of masticatory cycles was .99 with a 95% confidence interval from .98 to .99 ($F(d.f. = 95) = 142.26, p < .001$). For number of swallows, the ICC was .85 with a 95% confidence interval from .79 to .90 ($F(d.f. = 95) = 12.57, p < .001$). The ICC for time was .99 with a 95% confidence interval from .91 to 1.0 ($F(d.f. = 95) = 634.51, p < .001$).

The ICCs for the reliability of two independent raters of the instrumental measures were greater than .95 for the number of masticatory cycles and time taken. The ICC for interrater reliability of the number of swallows recorded by instrumental assessment was .73.

Study 4: Normative data

Normative data represented by the mean and 95% confidence interval for the TOMASS during the first trial ingestion of each of the targeted crackers are displayed for the following crackers: Arnott's Salada (table 3), Nabisco Saltine (table 4), Carr's Table Water (table 5), Gran Pavesi (table 6), DeBeukelaer Tuc Classic (table 7), Albert Heijn Basic (table 8), and Osem Golden (table 9). Normative data are stratified by age and sex.

Discussion

The TOMASS is a newly developed quantitative measure of discrete components of solid bolus texture ingestion with normative data from a population of healthy controls. Strong interrater and test-retest reliability across sessions is demonstrated, as well as strong measurement validity when clinical assessment is compared with instrumental correlates. Therefore, normative data are provided for ingestion of commercially available crackers that are easily accessible in North America, Australasia and much of Europe.

The TOMASS was derived from procedures established by Hughes and Wiles (1996) for the TWST. As the TWST utilizes ingestion of a water bolus, the TOMASS was developed specifically to challenge ingestion of solid-bolus textures. Although overlap between outcomes on the two tests would be expected,

Table 5. TOMASS normative data consisting of mean and 95% confidence intervals by age and gender for Carr's Table Water™ cracker

Sex	Age	TEST OF MASTICATING AND SWALLOWING SOLIDS: Carr's Water™ Cracker																	
		Discrete bites per cracker		Masticatory cycles per cracker		Swallows per cracker		Total time (in sec)		Masticatory cycles per bite		Swallows per bite		Time per bite (in sec)		Time per masticatory cycle (in sec)		Time per swallow (in sec)	
		Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.
Males	20-40	1.80	1.24-2.36	30.80	21.38-40.22	1.90	1.27-2.53	24.04	17.54-30.54	19.47	12.53-26.40	1.05	.94-1.16	14.39	11.07-17.70	.81	.64-.98	13.83	10.50-17.16
	40-60	2.17	1.27-3.06	35.75	28.12-43.38	1.83	1.24-2.43	28.58	23.29-33.87	21.45	14.24-28.67	.93	.81-1.04	18.21	11.07-25.35	.84	.70-.98	19.13	12.51-25.73
	60-80	2.14	1.56-3.24	47.20	28.54-65.86	2.30	1.23-3.37	39.69	25.61-53.77	21.08	14.72-27.43	.96	.79-1.13	18.09	12.75-23.43	.87	.75-1.0	19.24	14.13-24.35
Females	80+	2.38	1.94-2.81	66.25	50.97-81.53	2.75	1.88-3.62	55.02	42.63-67.42	29.04	19.97-38.11	1.21	.76-1.65	23.69	17.46-29.93	.83	.73-.94	29.55	16.27-26.84
	20-40	2.92	2.49-3.34	42.83	35.89-49.78	3.17	2.80-3.53	34.17	29.78-38.55	15.39	12.23-18.56	1.11	.98-1.24	12.23	9.99-14.45	.84	.68-.99	11.12	9.24-13.00
	40-60	3.45	2.64-4.27	42.55	35.65-49.44	2.91	2.15-3.67	38.97	34.06-43.88	13.15	10.83-15.47	.86	.67-1.05	12.42	9.27-15.56	.94	.80-1.08	15.12	11.46-18.79
60-80	3.67	2.45-4.88	52.78	38.08-67.47	3.22	2.08-4.36	54.23	37.08-71.38	16.73	9.81-23.64	.89	.62-1.34	17.15	10.04-24.25	1.06	.82-1.29	19.00	12.71-25.29	
80+	3.78	3.14-4.42	59.22	48.21-70.23	3.44	2.49-4.39	50.81	39.56-62.06	16.13	13.22-19.03	.88	.72-1.06	13.75	10.98-16.51	.85	.77-.93	16.44	11.61-21.26	

Table 6. TOMASS normative data consisting of mean and 95% confidence intervals by age and gender for the Gran Pavesti™ cracker

Sex	Age	TEST OF MASTICATING AND SWALLOWING SOLIDS: Gran Pavesti Salati™																	
		Discrete bites per cracker		Masticatory cycles per cracker		Swallows per cracker		Total time (in sec)		Masticatory cycles per bite		Swallows per bite		Time per bite (in sec)		Time per masticatory cycle (in sec)		Time per swallow (in sec)	
		Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.
Males	20-40	1.74	1.43-2.06	35.85	31.88-39.81	2.15	1.84-2.46	27.75	24.33-31.17	24.75	21.19-28.31	1.49	1.19-1.70	18.62	16.15-21.08	.78	.73-83	15.31	12.64-17.97
	40-60	1.50	1.21-1.79	35.14	30.33-39.96	2.50	1.92-3.08	28.69	23.21-34.17	26.08	21.86-30.30	1.89	1.43-2.35	20.96	17.46-24.46	.82	.73-90	12.61	10.86-14.36
	60-80	2.19	1.86-2.53	49.19	42.98-55.41	2.53	2.10-2.96	39.61	32.24-46.99	26.49	21.34-31.64	1.29	1.06-1.52	21.09	16.40-23.77	.79	.73-85	17.97	14.46-21.47
Females	80+	2.94	2.44-3.43	62.68	50.70-74.65	3.19	2.51-3.88	52.62	39.91-65.33	24.97	19.92-30.01	1.27	.99-1.56	21.04	15.55-26.52	.84	.75-92	18.58	14.54-22.62
	20-40	2.41	2.04-2.77	41.56	36.69-46.43	2.66	2.28-3.03	35.49	30.35-40.63	19.43	16.80-22.06	1.28	1.03-1.53	16.81	14.04-19.57	.86	.78-95	14.22	12.08-16.36
	40-60	3.00	2.57-3.43	46.71	41.17-52.24	2.85	2.45-3.26	39.49	33.83-45.16	17.97	14.70-21.24	1.08	.85-1.32	14.83	12.52-17.14	.87	.79-96	15.01	13.17-16.85
60-80	3.22	2.88-3.55	56.53	49.17-63.90	2.94	2.59-3.29	50.49	43.27-57.72	18.55	16.56-20.55	1.00	.87-1.13	16.56	14.48-18.64	.90	.84-96	18.56	15.50-21.62	
80+	3.65	3.24-4.06	70.79	59.64-81.94	3.50	2.96-4.04	59.81	50.81-68.80	21.10	17.60-24.60	1.01	.84-1.17	17.45	15.23-19.67	.87	.79-94	19.67	16.09-23.26	

Table 7. TOMASS normative data consisting of mean and 95% confidence intervals by age and gender for the DeBeukeler Tuc Classic™ cracker

Sex	Age	TEST OF MASTICATING AND SWALLOWING SOLIDS: Tuc Classic™ cracker																	
		Discrete bites per cracker		Masticatory cycles per cracker		Swallows per cracker		Total time (in sec)		Masticatory cycles per bite		Swallows per bite		Time per bite (in sec)		Time per masticatory cycle (in sec)		Time per swallow (in sec)	
		Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.
Males	20-40	2.47	1.89-3.05	35.29	30.32-40.26	1.77	1.38-2.15	30.94	25.41-36.47	17.05	13.08-21.06	.88	.60-1.16	15.88	10.09-21.67	.89	.76-1.01	19.26	16.06-22.46
	40-60	2.92	2.35-3.49	37.38	29.55-45.22	2.16	1.30-3.00	34.0	27.27-40.72	12.89	11.69-14.09	.79	.44-1.14	11.74	10.61-12.88	.92	.82-10.2	20.53	13.33-27.75
	60-80	2.27	1.74-2.80	36.64	27.64-45.63	1.45	1.10-1.80	33.55	27.80-39.29	17.85	12.55-23.14	.80	.38-1.22	17.56	10.17-24.96	.98	.73-1.23	25.82	18.20-33.44
Females	80+	2.67	2.13-3.21	49.87	39.97-59.76	2.0	1.58-2.42	39.13	32.53-45.73	19.75	15.24-24.27	.80	.61-1.00	15.56	12.47-18.65	.81	.75-87	21.62	15.94-27.29
	20-40	3.31	2.55-4.06	41.38	34.43-48.34	1.77	1.41-2.13	32.38	28.13-36.64	13.80	10.69-16.91	.64	.36-.91	11.17	7.71-14.43	.80	.73-88	20.15	15.25-25.06
	40-60	3.27	2.82-3.71	35.93	29.95-41.90	2.2	1.38-3.02	33.27	23.80-38.54	11.32	9.41-13.23	.68	.46-.89	10.44	8.89-11.98	.96	.81-1.10	19.11	13.93-24.28
60-80	3.63	2.98-4.27	47.31	38.03-56.60	2.37	1.53-3.22	45.25	37.03-55.47	16.2	9.26-23.14	.70	.48-.93	15.65	9.31-21.98	.99	.89-1.07	26.74	18.66-34.81	
80+	4.0	3.49-4.51	52.84	45.07-60.61	2.63	2.00-3.25	52.80	46.44-59.14	13.54	11.58-15.50	.66	.54-.79	13.49	12.00-14.97	1.06	.90-1.21	23.12	18.78-27.46	

Table 8. TOMASS normative data consisting of mean and 95% confidence intervals by age (20–80 years) and gender for the Albert Heijn Basic™ cracker

Sex	Age	TEST OF MASTICATING AND SWALLOWING SOLIDS: Albert Heijn Basic™																	
		Discrete bites per cracker		Masticatory cycles per cracker		Total time (in sec)		Swallows per bite		Time per bite (in sec)		Time per masticatory cycle (in sec)		Time per swallow (in sec)					
		Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.				
Males	20–39	1.25	1.04–1.46	31.4	25.23–37.57	1.35	1.04–1.66	22.8	18.72–26.88	27.02	21.07–32.98	1.10	.920–1.28	19.53	15.85–23.20	.75	.68–.83	18.71	15.07–22.37
	40–59	1.43	1.09–1.77	34.62	30.4–39.20	1.81	1.22–2.39	27.90	22.72–31.98	27.35	22.72–31.98	1.39	1.03–1.74	21.36	17.86–24.87	.80	.70–.89	18.49	15.01–21.98
	60–79	2.57	1.39–3.75	34.90	37.69–42.12	1.48	1.17–1.78	26.38	21.42–31.35	19.95	13.90–26.00	.92	.61–1.22	14.65	10.39–18.53	.78	.68–.88	20.74	15.41–26.08
Females	20–39	1.9	1.422–2.18	29.95	26.44–33.46	1.95	1.62–2.27	27.1	22.89–31.02	19.80	15.19–24.42	1.22	.92–1.28	17.47	13.09–21.85	.90	.82–.98	15.63	11.58–19.367
	40–59	2.59	2.01–3.16	34.91	31.45–38.37	1.72	1.36–2.09	30.41	26.72–34.10	17.69	12.68–22.69	.87	.56–1.18	15.78	10.94–20.61	.88	.79–.97	21.03	16.56–25.50
	60–79	3.27	2.72–3.82	46.5	40.85–52.15	1.68	1.31–2.05	40.32	35.02–46.62	15.83	12.91–18.74	.57	.42–.78	13.71	11.08–16.34	.87	.80–.94	27.18	23.11–33.24

Table 9. TOMASS normative data consisting of mean and 95% confidence intervals by age and gender for the Osem Golden™ cracker

Sex	Age	TEST OF MASTICATING AND SWALLOWING SOLIDS: Osem Golden™																	
		Discrete bites per cracker		Masticatory cycles per cracker		Total time (in sec)		Swallows per bite		Time per bite (in sec)		Time per masticatory cycle (in sec)		Time per swallow (in sec)					
		Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.	Mean	95% C.I.				
Males	20–39	2.6	1.5–3.7	41.7	30.8–52.8	2.2	1.8–2.7	37.8	29.4–49.5	19.3	13.7–25.8	1.1	.7–1.6	16.0	10.4–21.6	.9	.7–1.0	18.0	13.9–22.0
	40–59	2.6	2.0–2.5	36.0	30.3–41.8	1.6	1.3–2.0	32.1	28.1–36.0	16.1	13.2–19.0	.7	.6–.9	14.4	12.1–16.7	.9	.8–1.0	23.0	16.7–22.8
	60–79	2.6	2.2–3.0	47.3	39.8–55.3	2.5	1.9–3.1	45.6	32.4–58.9	18.5	16.2–20.8	1.0	.7–1.3	17.5	13.6–21.3	.9	.8–1.1	20.3	15.3–25.4
Females	80+	3.4	2.4–4.4	52.5	40.2–64.8	3.0	1.5–4.5	46.9	34.2–59.7	18.2	10.3–26.0	1.0	.5–1.5	15.4	9.9–20.9	.9	.8–1.0	20.6	11.9–29.8
	20–39	3.7	3.3–4.1	42.0	36.0–48.0	3.8	3.2–4.3	42.8	36.6–49.1	11.8	9.9–13.6	1.0	.89–1.2	11.9	10.3–13.6	1.0	.9–1.1	12.0	10.0–14.1
	40–59	3.5	2.9–4.0	51.1	44.3–57.9	3.3	2.8–3.8	50.6	45.0–56.6	15.2	13.3–17.1	1.0	.8–1.2	15.2	13.5–16.9	1.0	.9–1.1	16.8	14.2–19.4
60–79	4.2	3.5–5.0	54.4	46.2–62.7	3.1	2.4–3.8	55.2	47.0–63.5	14.7	11.0–18.4	.8	.6–1.0	15.0	11.3–18.6	1.0	.9–1.2	19.9	15.9–23.6	
80+	3.2	2.5–3.9	55.8	42.3–69.3	2.7	1.9–3.5	65.6	52.8–78.3	18.3	13.9–22.6	.9	.7–1.1	21.9	16.8–27.0	1.2	1.0–1.5	26.6	19.1–34.0	

one might also expect points of diversion. The TWST is described as a test of 'swallowing capacity' (Hughes and Wiles 1996: 113); however, observations are made of behaviours that may suggest aspiration events. Aspiration is known to occur more frequently with liquids than solid textures (Robbins *et al.* 1999) rendering this a more sensitive tool to this feature of swallowing pathophysiology. However, ingestion of liquid does not perhaps challenge oral bolus preparation or pharyngeal pressure generation as extensively as a solid texture, which may be a particular weakness when evaluating patients with neuromuscular weakness. Although this assumption requires validation, the TOMASS may more likely identify patients with subtle oral phase impairment, or perhaps specific impairment in bolus transition through the upper oesophageal sphincter. Further research is underway to validate this hypothesis.

Water is readily available and, if measured carefully, is consistent in texture worldwide. The challenge in developing a test for solid bolus textures is in identifying a stimulus item that is available and consistent in size and viscosity worldwide. Use of a food in its natural state is difficult to control for consistency in size and texture (e.g., a ripe versus a very ripe banana cut to size) or may pose significant aspiration risk if the food does not break down with secretions and hold together (e.g., a peanut). A commercially produced product will be consistent across that brand name and product. A cracker requires mastication but will generally mix with secretions in the oral cavity and remain cohesive. An initial analysis was conducted to determine if similar appearing crackers produced similar data. However, our data clearly demonstrate that although the Arnott's Salada and Nabisco Saltine crackers are near identical in size, shape and ingredients, there are differences in swallowing behaviour for some measures. Ingestion of the Arnott's Salada cracker required consistently more bites, more masticatory cycles and more time, behaviour that might suggest a difference in fat content. Interestingly, Arnott's Salada contains 2.8 g of fat whereas the Nabisco Saltine cracker contains no reported fat. One could speculate that cultural or behavioural differences associated with solid texture ingestion in different regions of the world may influence outcomes; however, both groups in this study were New Zealand residents. As there are significant differences in normative data, the measures cannot be combined as a single dataset and independent norms are required for regional products. Thus, normative data are provided for a wide range of crackers that are available across several continents. The methods described in this study can then be replicated to develop normative data for commercially available products where these crackers are not sold.

For the Arnott's Salada and Nabisco Saltine crackers there was a significant within-session trial effect on several of the raw data measures, with the second trial performance generally slower and less efficient than the first for the Salada cracker and the inverse being true on two measures for the Saltine cracker. This relative difference may reflect a methodological inconsistency between crackers. Those ingesting the Saltine cracker were instructed to rinse their mouth with water between trials, thus residual fluid in the oral cavity is likely to have facilitated bolus preparation. This method was not utilized for the Salada cracker; thus, dry mouth on the second trial may have exacerbated slowness in rate of ingestion. However, this same within-session effect was evident in the reliability study when water was ingested between trials of Salada cracker ingestion, lending support to the theory that differences in relative ingredient proportions between crackers may be reflected in swallowing behaviours. Regardless, normative data were reported for the first trial only for which liquid ingestion was not controlled. This is considered to represent a more realistic testing scenario in clinical practice. Incorporating a liquid wash before cracker ingestion may unduly challenge patients who are at greater risk of liquid aspiration. Repeating the test for a second trial would increase the time required for test administration. The within-session differences are inconsistent with cross-session comparisons for the Salada in the test-retest comparison in which very high measurement consistencies were detected; thus, the TOMASS is considered a reliable measure of solid-texture swallowing behaviour when first trials in a given session are compared with normative data.

Finally, although clinical observation is required to count the number of bites, masticatory cycles and swallows, these observations are documented to be highly correlated with instrumental measures of the same behaviour. Thus, the measurements that are collected at bedside provide useful insight into a patient's masticatory and swallowing ability without the need for instrumentation.

Age and sex differences

There are consistent and significant influences of age and sex on the raw data measures and most of the derived measures both the Arnott's Salada and Nabisco Saltine crackers. Although not specifically evaluated for all crackers, it is expected that this trend would remain irrespective of the specific bolus. Thus, when evaluating patients against the normative sample, attention should be paid to age and sex categorization. As a rule, women required more time, more bites and more masticatory cycles than men. Across both men

and women, these measures increased as a function of age. These findings are consistent with prior published research.

The TWST produces similar findings with men reported to ingest fluid with greater average volume per swallow and swallowing capacity than women, and a clear decline in both measures as a function of age (Hughes and Wiles 1996). Specific to bolus preparation, Van der Bilt *et al.* (2010) demonstrated significant differences between the masticatory patterns of old and young participants, resulting in larger particle sizes in boli manipulated by older individuals when compared with younger individuals after the same number of chewing cycles. This may reflect a decrease in the sEMG activity of masticatory muscles (Cecilio *et al.* 2010) and consequent decrease in tongue strength associated with increased age (Stierwalt and Youmans 2007, Tsuga *et al.* 2011, Hamanaka-Kondoh *et al.* 2014).

Limitations

These data represent a relatively small sample of healthy controls, limited in some samples to 10 participants in each cell. Further expansion of norms is indicated. However, despite the small numbers, the TOMASS is sensitive to the detection of expected changes associated with age and sex, with reasonably small confidence intervals. Further investigation into the sensitivity and specificity of the TOMASS for detecting oral and pharyngeal phase dysphagia is warranted.

In the validity study, an acoustic signal was collected to provide further support of swallowing events when paired with submental sEMG and swallowing apnoea seen in nasal airflow. Unfortunately, interpretation of the acoustic signal for swallowing onset was complicated by the acoustics associated with mastication. Ultimately, this was not considered to be detrimental to the analysis as use of sEMG and respiration measures was clear and correlation to observational measures was high.

Conclusions

The TOMASS is presented as an emerging clinical tool for quantification of solid bolus ingestion. Normative data are provided, supported by reliability data and validation to instrumental measures. Investigations of sensitivity and specificity for identification of specific oral and/or pharyngeal dysphagic presentations would be of clinical value.

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