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## **Research Report**

# Quantitative assessment of oral phase efficiency: validation of the Test of Masticating and Swallowing Solids (TOMASS)

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### Abstract

*Background:* The Test of Masticating and Swallowing Solids (TOMASS) has been developed to provide clinicians with objective data regarding the efficiency of oral phase function and solid bolus ingestion.

*Aims:* To determine if the TOMASS will detect changes in the oral phase of swallowing imposed by topical anaesthesia, thus providing validation of its clinical utility.

*Methods & Procedures:* Per the standard protocol, 10 healthy participants ate one-quarter of an Arnotts Salada<sup>TM</sup> biscuit. The number of bites per cracker, number of masticatory cycles, number of swallows and total time taken were recorded at baseline, following application of topical oral anaesthetic; this was additionally compared with a post-anaesthetic condition. Median and interquartile range (IQR) were calculated. Wilcoxon signed-rank tests were conducted to evaluate trial effect, and Friedman's tests were used to detect differences in the number of bites, number of swallows, number of chews and time taken to eat the crackers.

*Outcomes & Results:* Results indicated that the number of both bites and swallows did not significantly change across conditions ( $\chi^2(2) = 0.105$ , p = 0.949,  $\chi^2(2) = 1.357$ , p = 0.507); however, the number of chews for the anaesthetic condition was significantly higher when compared with the baseline (p = 0.02) and post-anaesthesia conditions (p = 0.02). Further, the durations of ingestion in the anaesthetic condition were significantly longer than the baseline (p = 0.01) and post-anaesthesia (p = 0.01) conditions. Across all measures, there were no differences between baseline and post-anaesthesia conditions.

*Conclusions & Implications:* Although further exploration is required, these early data suggest the TOMASS is a sensitive measure in the evaluation of the oral-phase preparation of solid textures.

Keywords: deglutition, mastication, solids, anaesthesia, assessment, dysphagia.

#### What this paper adds

#### What is already known on the subject

The TOMASS may improve objectivity when testing solid bolus ingestion, and normative data exist in healthy adults.

#### What this paper adds to existing knowledge

The TOMASS has not been evaluated with regard to its sensitivity at detecting changes in disordered swallowing. Oral anaesthesia was used to mimic dysfunction in order to compare within-subject changes in performance using this test.

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

This study provides important validation of the TOMASS, which appears to be sensitive to changes in solid bolus ingestion as a result of the application of oral anaesthetic.

#### Introduction

Objective identification and assessment of dysphagia within clinical populations is necessary to promote best practice in decision-making and improve patient outcomes. Objective testing is crucial for reducing complications, such as aspiration pneumonia (Hinchey et al. 2005), and may aid in preventing reductions in quality of life caused by unnecessary diet modification (Nguyen et al. 2005). The initial assessment of dysphagia is typically based on a number of subjective rating scales of behavioural observations (Martino et al. 2009, Trapl et al. 2007). A basic oromotor examination is typically carried out as a component of this evaluation to ascertain qualitatively the integrity of the neuromuscular system involved in swallowing (Reddy et al. 1990). Collation of this information, alongside observation of bolus ingestion, leads clinicians to decisions about the presence or absence of swallowing difficulties. The accuracy of this important first assessment and subsequent management decisions depend largely on the experience of the clinician because the tests are purely subjective.

Hughes and Wiles (1996) recognized this limitation, and in response, developed a timed test of water swallowing. This water swallow test evaluates a patient's ability to ingest 150 ml of water and provides a broad sample of normative data to which patients' oropharyngeal swallowing abilities can be compared. Although this timed test of water swallowing has proven valuable in identifying some types of swallowing impairment, a test that would challenge oral bolus preparation and manipulation might provide additional value. The newly developed Test of Masticating and Swallowing Solids (TOMASS) was designed to be easily administered during bedside evaluation, providing the clinician with objective data regarding the efficiency of the oral phase function and solid bolus ingestion (Huckabee et al. 2018). To complete the TOMASS, participants ingest one-quarter of an Arnotts Salada<sup>TM</sup> biscuit 'as quickly as is comfortably possible'. The number of bites per cracker, number of masticatory cycles, number of swallows and total time taken are then recorded. Importantly, however, further validation of this test is indicated to discriminate between expected and disordered oral phase function.

While this test emphasizes the oral phase, it may also be useful in evaluating abnormalities in subsequent phases of swallowing, and enables comparison with normative data across the age span (Huckabee *et al.* 2018). Given the interrelation between the phases of swallowing, dysphagia across oral as well as pharyngeal phases may be sensitive to alterations measured by this test, although ongoing research is indicated to elucidate this further.

#### Topical anaesthesia mimics dysphagia

Sensory input plays a key role in the swallowing process (Steele and Miller 2010) and is vital during the oral phase to provide feedback regarding mastication, ensuring a bolus is manipulated until it is of a safe consistency for swallowing (Takahashi et al. 2007). Reduction of oral sensation has been shown to affect tongue pressure measures negatively. In a study of eight healthy individuals (aged 26-31 years), Yagi et al. (2008) reported application of a surface anaesthetic to the interdental papillae-affected tongue pressure measurements during swallowing of a liquid bolus. They noted an increase in the duration of tongue pressure, with a longer period between maximum tongue pressure and offset of tongue pressure in the anaesthetic condition as compared with pre-anaesthetic. In the anaesthetic condition, a decrease in the maximum pressure and the pressure integral were also observed. Similarly, Fujiki et al. (2001) found that applying a surface anaesthetic to the tongue resulted in decreased contact between the palate and the tongue, alongside weaker posterior propulsion by the tongue. This led to delayed bolus transport into the pharynx. As these studies highlight, oral phase measurements may be sensitive to altered oral sensation following provision of surface anaesthesia.

Surface anaesthetics have also been shown to affect other parameters of oral deglutition. Mansson and Sandberg (1975) examined the effects of an oral anaesthetic on dry swallowing capabilities. Using a control group and an experimental group, they found a statistically significant increase in total swallowing time with the application of an anaesthetic, yet no increase in swallowing time was noted in the control group. Several subsequent studies have examined the effects of oral anaesthesia on swallowing capabilities with a water bolus. Using a Hughes and Wiles (1996) timed water swallow test, the application of a topical oral anaesthetic resulted in reduced swallowing speed and increased inter-swallow interval with no effect on swallowing capacity (Chee et al. 2005). Similarly, Teismann et al. (2007) observed that application of oral pharyngeal anaesthetic caused short-term dysphagia in 10 healthy participants and

resulted in reduced swallowing speed. In contrast to Chee *et al.* (2005), Teismann *et al.* (2007) also noted a decrease in swallowing capacity and reduced volume per swallow with the anaesthetic condition.

The aim of the present study was to evaluate the sensitivity of the TOMASS to changes in swallowing secondary to oral anaesthesia. Based on prior research using the timed water swallow test, we hypothesized significant inefficiencies in time and swallowing capacity under an anaesthetic condition. If it is found to be sufficiently sensitive in this and subsequent studies, the TOMASS may be a useful tool in the screening and monitoring of patients at risk of dysphagia.

#### Materials and methods

Ten healthy participants (five males) aged 19–24 years (median age = 21 years, 7 months), with no reported history of dysphagia or neurological disease, were recruited from the general public. The protocol was approved by regional human ethics committees (Ref. UC/2013/30) and informed written consent was obtained from each participant. Formal sample size calculations were not undertaken as this was an initial pilot study; participants were recruited through convenience sampling.

The TOMASS was developed to evaluate swallowing features that are heavily influenced by ingestion of solid textures. The test was implemented using a standard method, as described previously (Huckabee et al. 2018). Participants, seated comfortably, ingested one section of an Arnotts Salada<sup>TM</sup> cracker 'as quickly as is comfortably possible'. Each dry cracker weighed 14 g with dimension of 5 cm<sup>2</sup> and had ingredients including wheat flour, vegetable oil, salt, yeast, baking powder, sugar, malt extract (from barley). The participants were advised not to talk during ingestion and to count mentally the number of swallows required to consume the whole cracker. As a marker of task completion and perceptual oral clearance, participants were asked to say their name audibly when they had consumed the entire cracker.

Participants were carefully observed and the following measures were recorded:

- Number of masticatory cycles was counted through observation of jaw movements.
- Number of bites per cracker was determined by counting how many discrete segments of cracker the participant placed in their mouth.
- Number of swallows was recorded based on observed superior movement of the thyroid cartilage and was confirmed through comparison with participant recollection.

 Table 1. Median (interquartile range—IQR) across the conditions and trials

Condition	Trial	Number of bites	Number of chews	Number of swallows	Duration of ingestion
Baseline	1	2	40.0	4.5	41.745
		(1.75)	(15.75)	(2.00)	(5.13)
Anaesthesia		2	53.5	3.0	71.640
		(1.50)	(23.25)	(1.00)	(41.97)
Post-anaesthesia		2	34.5	2.5	28.235
		(1.75)	(12.75)	(1.00)	(10.95)
Baseline	2	2	36.0	3.0	32.575
		(0.75)	(8.50)	(0.00)	(6.83)
Anaesthesia		2	51.5	3.0	53.795
		(1.50)	(34.25)	(0.75)	(33.07)
Post-anaesthesia		2	39.0	2.5	26.950
		(2.00)	(8.50)	(1.00)	(5.53)

Table 2. Results of the Wilcoxon signed-rank test comparing the effect of the trial on the different measures for all conditions

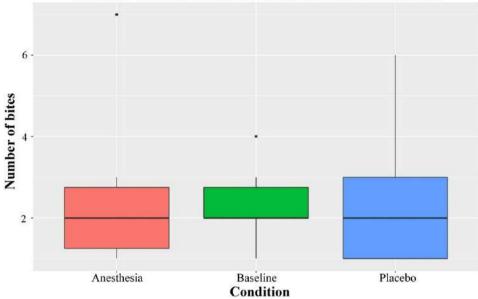
Condition	Measure	<i>p</i> -value	Effect size
Baseline	Number of bites	0.257	-0.254
	Number of chews	0.635	-0.106
	Number of swallows	$0.047^{*}$	-0.443
	Duration of ingestion	$0.002^{*}$	-0.693
Anaesthesia	Number of bites	0.414	-0.183
	Number of chews	1	0
	Number of swallows	0.527	-0.141
	Duration of ingestion	0.038*	-0.464
Post-anaesthesia	Number of bites	1	0
	Number of chews	0.373	-0.199
	Number of swallows	0.655	-0.100
	Duration of ingestion	0.625	-0.109

Note: \**p* < 0.05.

 Duration of ingestion was timed from the moment the participant first bit into the cracker until they indicated that they had completely finished by stating their name out loud.

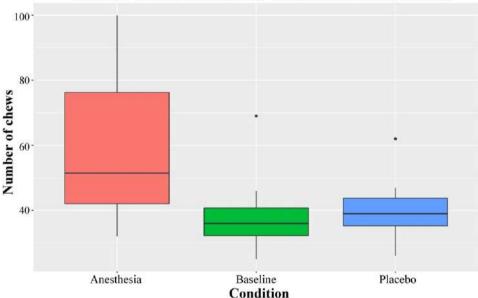
Following completion of the task participants were given a glass of water to clear residual cracker from their oral cavity before the above procedure was carried out a second time to evaluate for trial effect.

To anaesthetize the oral mucosa, 0.8 ml of the topical anaesthetic gel ZAP<sup>TM</sup> (benzocaine 18% w/w and tetracaine 2% w/w) were syringed onto the centre of the participant's tongue by a registered dentist. The participant was instructed to swirl the gel in their mouth until their oral cavity was coated, then expectorate any residual without swallowing. The product information sheet advised that benzocaine produced anaesthesia within 30 s of application to mucosal tissue, and tetracaine ensured maintenance of an anaesthetized state for at least 15 min (www.medsafe.govt.nz). After 6 min, all participants reported that their tongue and oral cavity were



Number of bites under the three different conditions

Figure 1. Number of bites under the three different conditions. [Colour figure can be viewed at wileyonlinelibrary.com]

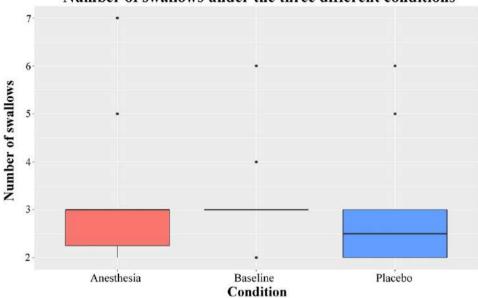


Number of chews under the three different conditions

Figure 2. Number of chews under the three different conditions. [Colour figure can be viewed at wileyonlinelibrary.com]

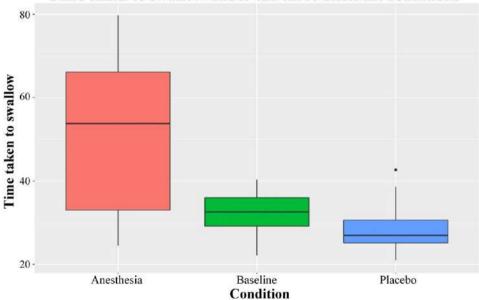
subjectively judged to be in an anaesthetized state. The protocol for TOMASS was carried out two subsequent times; participants ingested a glass of water between the consumption of the two sections of cracker. Data were recorded as previously described. Subsequent to a 30-min wait, participants all subjectively reported that sensation within the oral cavity had returned to baseline. Participants were then asked to ingest two final crackers following the above-mentioned procedure for TOMASS. Again, the participants rinsed with a glass of water between the two crackers; the same measures were recorded.

Raw data parameters included the number of bites, number of swallows, number of chews and duration of ingestion. Non-parametric statistics were used due to the small sample size in the study and non-Gaussian distribution of the data. Median and interquartile range (IQR) were calculated for the four measures under the



Number of swallows under the three different conditions

Figure 3. Number of swallows under the three different conditions. [Colour figure can be viewed at wileyonlinelibrary.com]



Time taken to swallow under the three different conditions

Figure 4. Time taken to swallow under the three different conditions. [Colour figure can be viewed at wileyonlinelibrary.com]

three conditions (namely baseline, anaesthesia and postanaesthesia) and two trials. A Wilcoxon signed-rank test was conducted on each measure to evaluate the trial's effect. Friedman's test, similar to the parametric repeated-measures analysis of variance (ANOVA), was used to detect differences in the number of bites, number of swallows, number of chews and time taken to eat crackers across the three different conditions. When the overall effect from the Friedman's test was significant, post-hoc comparisons were made using a Wilcoxon signed-rank test. To account for multiple comparisons, p-values were adjusted using a false discovery rate (FDR) step-down procedure; significance was reached when the adjusted p-value < 0.05.

#### Results

Median and IQR for all measures across the three different conditions and the two trials are reported on table 1.

Table 3. Results of the Friedman test for all measures across the different conditions

Variable	Chi-squared	d.f.	<i>p</i> -value
Number of bites	0.105	2	0.949
Number of chews	11.421	2	$0.003^{*}$
Number of swallows	1.357	2	0.507
Duration of ingestion	12.200	2	$0.002^{*}$

Note: \*p < 0.05.

Table 4. Post-hoc comparisons for the number of chews and duration of ingestion

Condition	Number of chews <i>p</i> -value	Duration of ingestion <i>p</i> -value
Baseline–anaesthesia	0.024*	$0.006^{*}$
Baseline–post-anaesthesia	0.610	0.105
Anaesthesia–post-anaesthesia	0.016*	$0.006^{*}$

Note: \**p* < 0.05.

Comparisons with a Wilcoxon signed-rank test were used to determine the trial effect between the first and second trials across conditions. There were significant differences between trials 1 and 2 for the number of swallows and duration of ingestion in the baseline condition, and duration of ingestion for the anaesthesia condition, with fewer swallows and a faster time on the second trial. No significant differences between trials were found in other measures (table 2). As a result, subsequent analyses were performed only on the second trial of all measures, with the initial trial considered to be a practice trial.

Regarding the evaluation of the condition effect for the four measured variables, box plots comparing the three different conditions for the measures are shown in figures 1–4.

Results of the Friedman test are depicted in table 3. Results indicated that the number of bites and number of swallows did not significantly change across the three conditions  $\chi^2(2) = 0.105$ , p = 0.949,  $\chi^2(2) = 1.357$ , p = 0.507. The number of chews and duration of ingestion were significantly different for the three conditions.

As the Friedman's test indicated significant differences for the number of chews and duration of ingestion, post-hoc multiple comparisons were conducted for these two measures to identify differences between the conditions. According to the Wilcoxon signed-rank post-hoc tests, the number of chews for the anaesthetic condition was significantly higher when compared with the baseline and post-anaesthesia conditions. No significant differences were found between baseline and post-anaesthesia conditions. Duration of ingestion in the anaesthetic condition was significantly longer than the baseline and post-anaesthesia conditions. Adjusted *p*-values are shown in table 4.

#### Discussion

The TOMASS was developed as a simple objective tool for bedside evaluation (Huckabee *et al.* 2018). This measure was based on the timed water swallow test developed by Hughes and Wiles (1996), a well-established, valuable clinical tool used to quantify the efficiency of swallowing during liquid ingestion. The TOMASS was intended to provide the clinician additional useful information regarding masticatory efficiency and swallowing of solid foods; however, the sensitivity of this measure to disordered states was previously unknown. Critically, this study provided preliminary validation of the sensitivity of the TOMASS by measuring aspects of swallowing before and after the application of topical oral anaesthetic.

First, the present results reveal no significant difference between baseline and post-anaesthesia conditions. These results indicate the TOMASS is sensitive to the detection of changes in the oral environment from baseline to anaesthesia of the oral mucosa, as well as from an anaesthetized state back to a post-anaesthetic condition. Further, these results indicate topical anaesthetic likely did mimic the sensory loss observed in dysphagia, as found in previous studies (Teismann et al. 2007). Second, Wilcoxon signed-rank post-hoc testing revealed a significantly higher number of chews and duration of ingestion for the anaesthetic condition when compared with the baseline and post-anaesthesia conditions. Interestingly, the IQRs of both the number of chews and duration were noted to be markedly increased in the anaesthesia condition as compared with the baseline and post-anaesthesia conditions. This may reflect a decrease in oral processing of food and swallowing efficiency as a result of the decreased sensory input during task performance.

These promising results align with existing research using topical anaesthetic. The increase in duration noted in this study is similar to other findings which reported a reduction in swallowing speed (Chee et al. 2005, Mansson and Sandberg 1975, Teismann et al. 2007). Interestingly, Teismann et al. (2007) detected changes in performance using similar research methods; oropharyngeal anaesthesia was administrated before carrying out Hughes and Wiles' (1996) water swallow test. These researchers observed that application of oral pharyngeal anaesthetic reduced swallowing speed in 10 healthy participants. However, in contrast to Teismann et al. (2007), who observed a decrease in swallowing volume with anaesthesia, the present study documented no difference in the number of swallows per cracker. Yagi et al. (2008) reported the application of a surface

#### The Test of Masticating and Swallowing Solids (TOMASS)

anaesthetic during swallowing of a liquid bolus (n = 8). They noted an increase in the duration of tongue pressure, with a longer period between maximum tongue pressure and offset of tongue pressure in the anaesthetic condition as compared with pre-anaesthetic. In the anaesthetic condition, a decrease in the maximum pressure and the pressure integral were also observed. The present results, including statistically significant differences between each condition for the duration of ingestion, align with these prior findings. However, while these initial findings are promising, further studies will be required across a wider range of age and functional ability of participants, including, importantly, geriatric populations.

As with all research, this study is not without its limitations. It uses a small sample of healthy young adults; ongoing studies will be required on a larger number and more diverse age range of participants. It remains unclear how the anaesthetic state may have affected salivary function; the role of salivation in the speed of oral preparation of this dry cracker cannot be discounted. Further, dental status was not formally investigated; however, given the young age and general health of the participants, it is likely dentition was functional in all participants. Further research validating the TOMASS against instrumental tools, such as a videofluoroscopic swallowing study, is indicated to understand the relationship between alterations in TOMASS measures with functional degradation of oral and, importantly, pharyngeal swallowing biomechanics.

#### Conclusions

These early data suggest that the TOMASS is a sensitive measure for the evaluation of the oral-phase preparation of solid textures. Though further research is indicated, existing international normative data across age and gender (Huckabee *et al.* 2018) and the present validation of this technique indicate the TOMASS is likely to be a valuable quantitative adjunct to increase standardization within routine clinical swallowing evaluations.

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