

**Reliability of the Iowa Oral Performance Instrument:
Measuring tongue and handgrip strength and endurance
in young and elderly adults**

By

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BSpPath (Hons)

A thesis submitted in fulfilment of the requirements for the degree
of Doctor of Philosophy (Human Physiology)
in the School of Biomedical Sciences and Pharmacy, Faculty of Health and Medicine,
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Declaration

The thesis contains no material which has been accepted for the award of any other degree or diploma in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text. I give consent to the final version of my thesis being made available worldwide when deposited in the University's Digital Repository, subject to the provisions of the Copyright Act 1968.

Signed .

U Valerie Jean Adams

Date *3 March 2014*



ACKNOWLEDGEMENT OF AUTHORSHIP

I hereby certify that the work embodied in this thesis contains a published paper/s/scholarly work of which I am a joint author. I have included as part of the thesis a written statement, endorsed by my supervisor, attesting to my contribution to the joint publication/s/scholarly work.

Chapters 1 and 2 were written with editorial support of my supervisors.

For Chapter 3, I conducted the systematic review and meta-analysis and wrote the first draft.

For Chapters 4, 5, 6, and 7, I designed all aspects of the projects in collaboration with my supervisors. I conducted all measurements, analysed all data and wrote the first draft of all four chapters. This was followed by editorial support from my supervisors.

Chapter 8 was written with editorial support of my supervisors.

Signed ...

Valerie Adams

Signed .

Primary Supervisor: Professor Robin Callister

Dated: 26/7/13

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Abstract

Appropriate tongue strength is essential for the oral and pharyngeal phases of swallowing and contributes to the formation, placement, and manipulation of a bolus within the oral cavity and propulsion into the pharynx. Examination of tongue strength is a frequent component of the clinical assessment of swallowing by speech-language pathologists. Such assessment is based usually on subjective judgement of the force being applied by the tongue against resistance provided by the speech-language pathologist's fingers resting against the cheek or a tongue depressor. This method raises concerns regarding the reliability of tongue strength measurements due to an inability to eliminate assessor bias and the variability introduced by multiple assessors in most clinical environments.

This thesis presents the results of research that examined investigations of objective measurement of tongue strength and endurance as well as handgrip strength and endurance. Two studies were conducted using the same methods. Healthy young (21 males: 30 females) and elderly (6 males: 24 females) participants underwent anterior and posterior tongue and handgrip strength and endurance assessments using the Iowa Oral Performance Instrument (IOPI) on four occasions separated by approximately two weeks. Strength assessments consisted of three attempts to exert maximal isometric force. Sustained isometric endurance assessments consisted of one attempt to sustain 50% of maximal isometric force. Three statistical analyses providing different indices of reliability were used. Random and systematic change outcomes through sampling error and learning effects were assessed using change in the mean between sessions. Within-subject variation was determined using typical error expressed as a coefficient of variation, which represents the technical and biological sources of error in measurement within participants. Rank order repeatability of the

results among trials was investigated using intraclass correlation coefficients (ICC, r). Additional exploratory strategies were conducted with maximum tongue (anterior and posterior positions) and handgrip strength values analysed using three approaches: 1) the highest of the three trials in the session; 2) the average of the three trials in the session; and 3) the average of the two highest trials in the session.

The key findings are that tongue and hand isometric strength measurements obtained using the IOPI demonstrate excellent reliability for analysis of groups when a familiarisation session is provided prior to clinical evaluation. Further, performing multiple trials within an assessment session with consistency criteria is an additional strategy to improve the reliability of these strength measurements. These strategies also improve the sensitivity of the IOPI measurements for evaluating strength improvements and the effectiveness of interventions in individuals. Multiple attempts resulting in some consistency in the maximum values obtained should be attained to establish that a true representation of current maximal strength is obtained. Further investigation is required to determine the reliability of tongue and hand endurance measures using the IOPI.

The effects of age and sex on measures of tongue and handgrip strength using the IOPI were examined. Participants recruited were categorised into three groups: young, mid-aged and elderly. The results from this study found that tongue and hand strength were influenced by age with no differences between young and mid-aged groups, however large reductions in strength were apparent in the elderly group. In addition and as expected, males were stronger than females in all age groups including the elderly cohort.

As a result of the poor reliability of sustained isometric tongue endurance measures, an additional study assessing repeated isometric tongue endurance was conducted. Healthy young participants underwent anterior and posterior tongue strength

and endurance assessment on four occasions alternating bulb positions separated by a period of one day. For this assessment of endurance, the IOPI was set to 90% of the participant's maximal strength and participants were asked to perform repeated contractions at the target force for as long as possible by pressing their tongue against the roof of their mouth repetitively. The key findings of this study are that although isometric tongue strength measurements obtained using the IOPI demonstrated acceptable reliability, repeated isometric tongue endurance measurements obtained during the same sessions were not reliable. This is also consistent with our findings that sustained isometric tongue endurance tests do not meet the standards of reliability necessary to be recommended for use.

In summary, all studies in this thesis found that tongue and handgrip strength measurements across all ages are reliable when measured using the IOPI. However, tongue and handgrip endurance values were found to be highly variable and cannot be recommended. Future research may be directed at identifying protocols that result in reliable measures of tongue and handgrip endurance.



Preface

Results reported in the dissertation have been published in scientific journals as well as presented at scientific meetings. These publications and presentations to date are listed below.

Publications

Peer Reviewed Papers Published in Scientific Journals (IF = Impact Factor)

- * **Adams, V.**, Mathisen, B., Baines, S., Lazarus, C., & Callister, R. (2014). Reliability of measurements of tongue and hand strength and endurance using the Iowa Oral Performance Instrument in healthy adults. *Dysphagia*, 29(1), 83-95. **IF=1.938**
- * **Adams, V.**, Mathisen, B., Baines, S., Lazarus, C., & Callister, R. (2013). A systematic review and meta-analysis of measurements of tongue and hand strength and endurance using the Iowa Oral Performance Instrument (IOPI). *Dysphagia*, 28(3), 350-369. **IF=1.938**
- * **Adams, V.**, Callister, R., & Mathisen, B. (2011). Using tongue-strengthening exercise programs in dysphagia intervention. *Asia-Pacific Journal of Speech, Language & Hearing*, 14(3), 139-146.

Peer Reviewed Papers Submitted to Scientific Journals (Accepted)

- * **Adams, V.**, Mathisen, B., Baines, S., Lazarus, C., & Callister, R. (January, 2014). Reliability of measurements of tongue and hand strength and endurance using the Iowa Oral Performance Instrument in young, mid-aged and old-older adults. *Disability & Rehabilitation*. **IF=1.541**

- * **Adams, V.**, Mathisen, B., Baines, S., Lazarus, C., & Callister, R. (January, 2104). Effects of age and sex using the Iowa Oral Performance Instrument to measure tongue and handgrip strength in healthy and elderly adults.
International Journal of Speech-Language & Hearing. **IF=1.176**

Abstracts of Scientific Papers Presented at Conferences

- * **Adams, V.**, Mathisen, B., Baines, S., Lazarus, C., & Callister, R. (2013). Reliability of measurements of tongue strength and endurance using the Iowa Oral Performance Instrument with healthy adults. The Dysphagia Research Society 21st Annual Scientific Meeting (**International:** Seattle, USA)
- * **Adams, V.**, Mathisen, B., Baines, S., Lazarus, C., & Callister, R. (2013). Reliability of measurements of tongue and hand strength and endurance using the Iowa Oral Performance Instrument in the frail elderly in a residential aged-care facility. The Dysphagia Research Society 21st Annual Scientific Meeting (**International:** Seattle, USA)
- * **Adams, V.**, Mathisen, B., Baines, S., Lazarus, C., & Callister, R. (2012). A systematic review and meta-analysis of measurements of tongue and hand strength and endurance using the Iowa Oral Performance Instrument (IOPI). Speech Pathology Australia National Conference (**National:** Hobart, Australia)

Abstracts of Scientific Posters Presented at Conferences

- * **Adams, V.**, Mathisen, B., Baines, S., Lazarus, C., & Callister, R. (2013). Reliability of measurements of tongue strength and endurance using the Iowa Oral Performance Instrument with healthy adults. Speech Pathology Australia National Conference (**National:** Gold Coast, Australia)

- * **Adams, V.,** Mathisen, B., Baines, S., Lazarus, C., & Callister, R. (2012).
Determining the optimal duration and intensity of tongue strengthening exercise
in older adults with dysphagia. 1st Congress of European Society of Swallowing
Disorders (**International:** Leiden, The Netherlands)

- * **Adams, V.,** Mathisen, B., Baines, S., Lazarus, C., & Callister, R. (2012).
Evaluation of the effects of tongue strengthening exercises in people with
swallowing difficulties. Speech Pathology Australia National Conference
(**National:** Darwin, Australia)

- * **Adams, V.,** Mathisen, B., Baines, S., Lazarus, C., & Callister, R. (2011).
Evaluation of the effects of tongue strengthening exercises in people with
swallowing difficulties. 8th Asia-Pacific Society for Study of Speech, Language
and Hearing (**International:** Christchurch, New Zealand)



Chapter 1: Introduction

“The human tongue in its uses and functions is the most comprehensive organ in the entire body. With the exception of the heart, it is the most muscular organ of the system”

Gibbons, 1898 (p. 869) [1]

1.1 Background

Swallowing is one of the most complex neuromuscular processes in the body. This process involves intricate co-ordination between various physiological systems of the body including the brain and nervous system, the respiratory and gastrointestinal systems, and in particular, the muscles involved in each system. Any condition, e.g. stroke, traumatic brain injury, head and neck cancer, and degenerative diseases in young and older adults, that weakens or damages the muscles and nerves used for swallowing may cause dysphagia. Dysphagia is defined as a difficulty or partial inability to swallow as a result of injury to: (a) the parts of the brain that control the muscles involved in swallowing; (b) the cranial nerves that control the muscles of swallowing; or (c) the muscles themselves [2]. Difficulty in swallowing can cause food to enter the airway, resulting in choking, pulmonary problems, inadequate nutritional intake and hydration, weight loss, and increased risk of mortality and morbidity.

Deficits in swallowing can occur when any one or more of five cranial nerves (CN) are affected. The trigeminal nerve (CN V) controls the motor supply to the muscles involved in mastication and the general sensation to the face. The facial nerve (CN VII) controls taste to the anterior two-thirds of the tongue and motor function to the lips. The glossopharyngeal nerve (CN IX) provides general sensation to the posterior third of the tongue and motor function to the pharyngeal constrictors. The vagus nerve (CN X) provides sensation to the larynx and motor function to the soft palate, pharynx,

larynx, and oesophagus. The hypoglossal nerve (CN XII) controls motor supply to the intrinsic and extrinsic muscles of the tongue [3].

Impairment in lingual functioning can negatively affect swallow functioning. An improvement in the mobility and strength of the tongue can result in an increased ability to improve nutritional oral intake and general health status. For this reason, exercises designed specifically to strengthen the tongue may prove to be an integral part of a dysphagic therapy care plan [4]. It is only through the complex co-ordination of the tongue muscles, as well as interactions with other structures (e.g. soft and hard palate, jaw, hyoid bone, oropharyngeal walls), that the tongue achieves its optimal swallowing action [5]. The critical role played by the tongue in swallowing is well recognised. It has been referred to as the ‘principle mobile agent’ or the ‘primary manipulator’ providing the essential functions of oral bolus formation, containment of a bolus within the oral cavity, propulsion of the bolus into the pharynx, and oropharyngeal bolus transport. The tongue, being a unique organ composed almost entirely of muscle, is crucial in generating the propulsive force required to propel food and fluid into the pharynx. Tongue strength can be assessed to determine how well the individual is able to generate enough propulsive force to transport food and fluids from the oral cavity to the pharynx.

Whilst subjective clinical measures (e.g. oral-motor assessment) are the most common clinical methods used by speech pathologists for assessing tongue strength, objective measures are the most reliable and valid methods for the evaluation of tongue function in terms of muscle performance [6]. One objective method that has been used successfully in research studies on oral phase swallowing function in dysphagic populations is the use of the Iowa Oral Performance Instrument (IOPI) (Figure 1.1) [7].

This simple hand-held device is able to measure the strength and endurance of the tongue (in kPa) when the bulb is pressed against the roof of the mouth. Placement of the air-filled bulb in the anterior and posterior positions on the tongue and based on the evidence of the differences in the regions of composition of lingual muscle. Previous research has found that a greater percentage of muscle tissue in the posterior tongue may respond favourably to exercise compared to the anterior tongue location [8,9]. Furthermore, the use of both tongue regions for pressure generation during swallowing has been documented, warranting further exploration of the effects of exercise at both tongue sites [10].



Figure 1.1 Iowa Oral Performance Instrument

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In this figure, the tongue bulb (left, blue) is shown connected to the device and the handgrip bulb (brown) is shown on the right.

Whilst the main focus of this research is on the IOPI, it is also of interest to note that while there have been other studies of tongue pressure measures reported in the literature, data has been collected using other instruments. Of these, there is most data available using an array of either 2 or 3 air-filled bulbs that are fixed with glue to the palate e.g. the KayPENTAX Digital Swallowing workstation (KayPENTAX, Montvale, NJ, USA). Descriptive statistics for maximum isometric pressures measures have been reported using this equipment. In addition, there are other papers by authors using different designs of tongue-pressure sensors. A table summarising the citations found in which pressures were measured using other instruments are presented in Table 1.1. While measures taken in the same individuals with the IOPI and the KayPENTAX system are similar with respect to amplitude (when the necessary conversions from kPa to mmHg are made), caution should be observed in generalising normative measures across instruments.

Table 1.1. Summary of studies using KayPENTAX Digital Swallowing Workstation, the Madison Oral Strengthening Therapeutic device, and other devices to measure tongue strength

Device	Study Name	Year
KayPENTAX Digital Swallowing Workstation		
	Ball, S., Idel, O., Cotton, S., & Perry, A. R. [11]	2006
	Butler, S. G., Stuart, A., Leng, X., Wilhelm, E., Rees, C., Williamson, J., Kritchevsky, S. B. [12]	2011
	Crary, M. A., Carnaby, G., & Groher, M. E. [13]	2007
	Fei, Ti., Polacco, R.C., Hori, S. E., Molfenter, S. M., Peladeau-Pigeon, M., Tsang, C., & Steele, C. M. [14]	2013
	Hind, J. A., Nicosia, M. A., Roecker, E. B., Carnes, M. L., & Robbins, J. [15]	2001
	Lenius, K., Carnaby-Mann, G., & Crary, M. [16]	2009
	Nicosia, M. A., Hind, J. A., Roecker, E. B., Carnes, M., Doyle, J., Dengel, G. A., & Robbins, J. [10]	2000
	Robbins, J., Gangnon, R. E., Theis, S. M., Kays, S. A., Hewitt, A. L., & Hind, J. A. [17]	2005
	Robbins, J., Kays, S. A., Gangnon, R. E., Hind, J. A., Hewitt, A. L., Gentry, L. R., & Taylor, A. J. [18]	2007
	Steele, C. M., Bailey, G. L., & Molfenter, S. M. [19]	2010
	Steele, C. M., Bailey, G. L., Molfenter, S. M., Yeates, E. M., & Grace-Martin, K. [20]	2010
	Steele, C. M., & Huckabee, M. L. [21]	2007
	White, R., Cotton, S., Hind, J., Robbins, J., & Perry, A. R. [22]	2009
	Yeates, E. M., Steele, C. M., & Pelletier, C. A. [23]	2010
	Yoshida, M., Groher, M. E., Crary, M. A., Carnaby Mann, G. D., & Akagawa, Y. [24]	2007
	Yoshikawa, M., Yoshida, M., Tsuga, K., Akagawa, Y., & Groher, M. E. [25]	2010
Other devices		
	Kieser, J., Bolter, C., Raniga, N., Waddell, J. N., Swain, M., & Farland, G. U. Y. [26]	2011
	Ono, T., Hori, K., & Nokubi, T. [27]	2004
	Tsuga, K., Maruyama, M., Yoshikawa, M., Yoshida, M., & Akagawa, Y. [28]	2011
	Tsuga, K., Yoshikawa, M., Oue, H., Okazaki, Y., Tsuchioka, H., Maruyama, M., Yoshida, M., & Akagawa, Y. [29]	2012
	Utanohara, Y., Hayashi, R., Yoshikawa, M., Yoshida, M., Tsuga, K., & Akagawa, Y. [30]	2008
	Yano, J., Kumakura, I., Hori, K., Tamine, K. I., & Ono, T. [31]	2012
Madison Oral Strengthening Therapeutic (MOST) device		
	Hewitt, A., Hind, J., Kays, S., Nicosia, M., Doyle, J., Tompkins, W., Gangnon, R., & Robbins, J. [32]	2008

1.2 Overview of thesis

In Chapter 2, a review of the literature introduces relevant investigations into the relationship between the tongue and swallowing, in particular, tongue strength and endurance in healthy and clinical populations across all ages.

Isometric tongue strengthening has received attention as a viable option in swallow rehabilitation. The original concept for this thesis was to conduct an intervention-based study on different regimes designed to provide exercise to the tongue in stroke and head and neck cancer patients to improve the individual's tongue strength sufficiently to enable them to eat and drink safely and effectively. A literature review on the effects of ageing on swallowing, and exercise on dysphagia rehabilitation after stroke is presented in Chapter 2 and was published in the *Asia-Pacific Journal of Speech-Language Pathology*.

Chapter 3 provides a systematic review and meta-analysis of measurements of tongue and hand strength and endurance using the IOPI and published in *Dysphagia*. This review evaluated the utility of the IOPI as an effective tool for assessments of both tongue and hand strength and endurance in healthy and clinical populations. It also investigated the effects of age and sex on the measured values, the impact of clinical conditions, and evaluated the use of the IOPI as an intervention tool to improve tongue strength and/or endurance.

The reliability of the IOPI in assessing tongue and hand strength and endurance is evaluated in Chapter 4 with healthy adults and in Chapter 5 with a cohort of elderly adults. These chapters determined the reliability of the IOPI of tongue and handgrip strength and endurance measurements, and whether prior familiarisation was necessary to obtain reliable results. In addition, also provided in this chapter was a calculation of the minimal change in strength and endurance required to be indicative of a change

greater than measurement error. Results from Chapter 4 have been reviewed and resubmitted to *Dysphagia*. Findings from Chapter 5 have been submitted to the journal *Disability & Rehabilitation*.

The effects of age and sex on tongue and handgrip strength using the IOPI with participants from the healthy and elderly cohorts were examined in Chapter 6. An article based on these results has been submitted to the *International Journal of Speech Language Pathology*.

Unlike the excellent reliability of values for tongue and handgrip strength found in Chapters 5 and 6, the reliability of tongue and handgrip endurance measurements was not established and required further investigation. The results of a further study to examine the reliability of repeated isometric tongue endurance in a group of healthy young adults is provided in Chapter 7.

This thesis concludes in Chapter 8 with a general summary of the findings of the studies and their wider significance. Directions for further research are also suggested.



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Figure 1.1 Iowa Oral Performance Instrument (IOPI)

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Chapter 2: Using Tongue-Strengthening Exercise Programs in Dysphagia Intervention

The original idea for this thesis was to conduct an intervention study to assess and evaluate the effects of exercises to strengthen the tongue in people with swallowing difficulties in stroke and head and neck cancer populations. In July 2009, we sought ethical approval to undertake research within the major hospital governed by the local health service. Our application was declined on three occasions and it took seventeen months to obtain final approval (November 2010). It later became evident that the reluctance to approve this study was due to a lack of support and co-operation by key staff in the required hospital departments. As a result of these barriers, a decision was made to change the thesis project to investigate the reliability of measurements of tongue and handgrip strength and endurance using the IOPI in both healthy young and elderly populations. The literature review presented in this chapter was completed to inform the original project.

2.1 Introduction

The purpose of swallowing is to transport food and saliva safely from the mouth to the stomach but a myriad of diseases and conditions may affect this basic function. Dysphagia is the term used when the normal swallow is disrupted. Any condition that weakens or damages the muscles and nerves used for swallowing may cause dysphagia e.g. stroke, traumatic brain injury, central nervous system infection, head and neck cancer, and degenerative diseases in young and older adults [33,34]. Difficulty in swallowing can cause food to enter the airway, resulting in respiratory difficulties, inadequate nutritional intake and hydration, weight loss, reduced quality of life, and

increased mortality and morbidity. Tongue strength exercise is a relatively new therapeutic tool for dysphagia. Evidence suggests that exercise therapy designed to strengthen the tongue has the potential to improve swallowing in people with dysphagia [35,36,17,18]. The primary objective of this review is to examine the effectiveness of tongue strengthening exercises in the prevention of long-term swallowing dysfunction after stroke or head and neck cancer. Recommendations regarding the use of strengthening exercises in dysphagia management, and suggestions for future research will also be discussed.

2.2 Swallowing

Swallowing is one of the most complex neuromuscular processes in the body. It involves precise co-ordination between physiological systems including the nervous system, the respiratory and gastrointestinal systems, as well as the specific muscles involved in each system [5]. Eating or drinking are done without being aware of the sequence of events that occurs in taking food or liquid (bolus) into the mouth, and transferring it safely to the stomach. For individuals with normal swallow function the experience of food or liquid ‘going down the wrong way’ and the resultant reflexive coughing is a common reality, however in people with a swallow dysfunction this process can be challenging. Dysphagia is the term used when the normal swallow is disrupted.

Many structures of the head and neck work together for successful swallowing, one such structure that plays a critical role in this process is the tongue. The tongue has an entirely muscular composition and provides the major propulsive force for food manipulation and transport [17]. As a result it performs significant functions in the oral preparatory, oral transit, and pharyngeal phases of swallowing [37]. For normal tongue function to take place both the motor and sensory systems of the tongue must be intact

[5]. Eight sets of muscles, innervated by the hypoglossal nerve (CNXII), are responsible for the complex movements performed by the tongue [38] and it is this complex co-ordination of intrinsic and extrinsic muscles, in addition to interactions with other structures (e.g. palate, jaw, hyoid bone, oropharyngeal walls) that allows the tongue to perform these functional movements in swallowing [5]. Impairment to the intrinsic and extrinsic muscles through injury such as stroke, or through the process of natural healthy aging, can cause deficits in tongue strength, movement and co-ordination. They are commonly found in individuals with dysphagia, and considered to be a primary cause of swallowing disorders [5].

2.3 The effect of aging on swallowing

Age-related changes place older adults at risk for dysphagia for two reasons. Firstly, during the process of natural healthy aging older individuals are likely to have decreased body muscle size and strength (sarcopenia) [39], and some compromise in neural co-ordination leading to a reduction in the physiologic and neural mechanism that controls swallowing function (presbyphagia) [40]. These age-related changes increase the risk for disordered oropharyngeal swallow (dysphagia). Secondly, the prevalence of disease also increases with age, and dysphagia is a comorbidity of many age-related diseases and/or their treatments [40]. Cerebral insults e.g. stroke are more common in the older population where the chance of having a stroke approximately doubles for each decade of life after age 55 [41]. These cerebral insults often result in significant damage to the neural circuitry leading to a loss of neural control of striated muscle including a lack of activation of the tongue muscles that are critical in swallowing. Muscle atrophy, which accompanies the loss of neural activation, results in further deficits in tongue strength and reduces the force that propels food and fluids into the oropharynx.

2.4 The effects of exercise on dysphagia rehabilitation after stroke

The emphasis on rehabilitation for survivors after stroke should centre on the recovery of active movement, assisted flexibility and muscle strength, particularly during the early months of recovery [42]. Whilst survivors of stroke may vary widely in age, degree of disability, level of motivation, and the number and severity of co-morbidities and secondary conditions, the specific exercise prescription should be individualised with a focus on improving functional capacity [42]. According to the National Stroke Foundation Clinical Guidelines for Stroke Management (2010) [43], the optimal time to commence exercise following stroke remains ‘the sooner the better’ as rehabilitation is a holistic process that should begin immediately post-stroke with the aim being to optimise recovery and foster the return of the individual after stroke back into their community. This is exemplified by studies [44,45] which have concluded that early intervention using active rehabilitation should be used to provide individuals with as much therapy for dysphagia as can be tolerated to aid recovery. Indeed, in a review of the effects of augmented exercise therapy time after stroke, Kwakkel et al.(2004) concluded that early implementation of intensive stroke rehabilitation was associated with enhanced and faster improvement of function after stroke [46]. Although this study evaluated the effects of exercise therapy in patients after stroke on activities of daily living (ADL), gait, and dexterity, it is probable that early exercise intervention would be equally successful for improving swallowing dysfunction in adults after stroke.

Recent advances in the treatment of dysphagia have investigated using exercise as a means of swallowing rehabilitation [47]. The exercise principles used in other physical rehabilitation or athletic training used to strengthen weak limbs may be applied to dysphagia rehabilitation. For example, to restore the functional use of a limb, a physiotherapist may start by retraining the essential components of the task with

isolated strength training with manual facilitation, assistance and gravity elimination until the patient has the strength and motor control to perform the task independently [48]. The same principle applies in swallowing rehabilitation. For example, tongue-strengthening therapy may begin with isometric contractions or low force movements, and then progress to task-specific exercises while encouraging the patient to use more challenging levels of resistance (higher intensity) throughout the therapy program. Indeed, intensive exercise programs appear to have a positive impact on long-term motor rehabilitation leading to a therapy-induced recovery after stroke [18].

Teaching targeted muscles to increase in strength over the course of an exercise regime requires regular adjustment of the resistance level. By progressively loading the major muscles involved in swallowing, there is the potential for significant improvements in swallowing function [48]. Preliminary findings have indicated that a lingual exercise program, using resistance to increase strength, is a reliable and effective treatment for dysphagia in persons living after stroke [47,17,18]. Tongue strength training programs in dysphagia rehabilitation may be more effective if they are tailored to target the specific activation patterns required during various swallowing movements. For example, if the goal is to improve the dynamic force during tongue base retraction at the initiation of the pharyngeal swallow, then the strength-training task would be aimed at targeting rapid force generation. Similarly, targeting sustained static contraction during treatment may aid the endurance of muscles required during consecutive swallows [48].

2.5 Tongue-strengthening exercises: The evidence

Studies of exercise-training with individuals following stroke support the use of exercise to improve mobility and functional independence and to prevent or reduce further long-term disease and functional impairment [48]. For this reason, exercises

designed specifically to strengthen the tongue may prove to be an integral part of a dysphagic therapy plan as an improvement in the mobility and strength of the tongue can result in an increased ability to improve eating and general health status [4]. Indeed, the weakness that occurs in limb muscles is replicated in the head and neck musculature, and this may be reversed with exercise [10,49]. This gives food for thought that elderly individuals with age-related disease as well as sarcopenia may improve to a greater extent than the responsiveness demonstrated by healthy individuals. Non-speech oro-motor exercise (NSOMEs) to improve swallowing function in the dysphagic population is a widely used practice by speech-language pathologists with the tongue being a common target for exercises using resistance, e.g. a tongue depressor, to increase strength [50].

Primary studies of resistance exercise therapy were conducted with healthy adults to determine if tongue strength could be improved in individuals with no history of swallow impairment [35,17]. One such study conducted by Robbins and her colleagues in 2005 reported positive changes in tongue strength after an 8-week program of progressive resistance exercises in 10 healthy men and women aged over 70 years. Demonstrating the capacity to improve tongue strength in healthy adults provided the motivation to explore the effects of lingual exercise on people with dysphagia secondary to stroke. Clark et. al. (2009) [35] examined 39 healthy adults with mean age of 38 years using sequential or concurrent training conditions. Exercises including elevation, protrusion and lateralisation of the tongue were used with results indicating that by incorporating tongue movements in several directions as well as resistance into the exercise program there was potential to increase lingual strength as well as increase lingual protrusion and lateralisation strength.

Evidence supporting intensive tongue strength exercise in dysphagia rehabilitation has been shown in several research studies [36,18]. To validate this theory Robbins and her team (2007) investigated the effects of progressive resistance lingual exercises on swallowing outcomes in 10 stroke patients with dysphagia. The main finding of this study was that stroke patients with dysphagia were able to increase tongue strength after an 8-week program of resistance exercises for the tongue and hold that improvement over the 8-week period of the study. They also showed a significant improvement in swallowing function and dysphagia-specific QOL measures, with beneficial changes to their social lives and dietary intake.

Further research was conducted to determine if resistance exercise would benefit other dysphagic populations. Kays et al., (2008) [36] investigated the use of an 8-week isometric exercise program of progressive resistance for the tongue with 10 stroke and 8 myopathy patients. Findings indicated that both groups, thus providing further evidence that tongue strength exercise has the ability to improve swallow function in other dysphagic populations, achieved significant increases in tongue strength. These studies provide evidence that resistance exercise has the capacity to increase tongue muscle strength in dysphagic populations. A summary of strength-training regimens for the oropharyngeal musculature and swallowing-related outcomes for the studies mentioned above is provided in Table 2.1.

Table 2.1 Summary of strength-training regiments for the oropharyngeal musculature and swallowing-related outcomes

STUDY	SUBJECTS	PROTOCOL	OUTCOMES	RESULTS
Robbins et al. (2005) [17]	10 healthy adults (70–89 yrs) 10 ischaemic stroke patients (6 acute, 4 chronic)	8 weeks Isometric lingual exercise 10 repetitions (3 × day, 3 days/ week)	Baseline, 2, 4, 6, & 8 wks Max. isometric pressure Max. swallowing pressure Lingual volume (MRI) Bolus flow Quality of Life (SWAL-QOL) Dietary level	Increased isometric strength Increased swallowing pressures for liquid and semisolid boluses Reduced penetration for liquids 5.1% mean increase in lingual volume
Clark, O’Brien, Calleja, & Corrie (2009) [35]	39 healthy adults (18–67 yrs)	Baseline, 9 weeks Isometric lingual exercise— sequential or concurrent 30 repetitions in sets of 10, 7 days/week— elevation, protrusion, lateralisation	Lingual strength and cheek strength assessed weekly	Increased lingual strength Increased lingual protrusion and lateralization strength Small increase in lingual elevation strength
Robbins et al. (2007) [18]	10 ischaemic stroke patients (6 acute, 4 chronic) (51–90 yrs)	8 weeks Isometric lingual exercise 10 repetitions (3 × day, 3 days/ week)	Baseline, 4 & 8 weeks Max. isometric pressure Max. swallowing pressure Lingual volume (MRI) Bolus flow (VFSS) Quality of Life (SWAL-QOL) Dietary level	Increased isometric strength Increased swallowing pressures Reduced penetration for liquids Increase in lingual volume in two patients
Kays, Porcaro, Gangnon, Hind, & Robbins (2008) [36]	10 stroke & 8 myopathy adults	8 weeks Isometric lingual exercise — anterior and posterior tongue 10 repetitions (3 × day, 3 days/ week)	Baseline, 4 & 8 weeks Max. isometric pressure Max. swallowing pressure Lingual volume (MRI) Pene. Asp. (VFSS)	Increased lingual strength for anterior/posterior for stroke & posterior for myopathy Increased lingual volume -> increased tongue mass

2.6 Conclusion

Although exercise principles used in physical rehabilitation and sports training have been gaining increasing attention in dysphagia rehabilitation, future studies should focus on developing more optimal programs from these principles. A number of research studies [35,36,17,18] have attempted to determine the appropriate resistance required to strengthen tongue muscle as well as determining the number and frequency of repetitions, the frequency of sessions, the duration of the program, and the specific exercises (tongue muscle movements) necessary. Recent research for the management of dysphagia in older adults has led to the development of progressive resistance training programs with more rigorous programs of intensive exercise showing promise as interventions for reducing swallowing problems [47].

However, several questions remain. Namely, when is the best time to start exercise? How intensive does this exercise program have to be for optimal results to be obtained? How can the muscles used in swallowing be strengthened? What are the characteristics of the patients on whom it is likely to be most beneficial? Are there patients who are unlikely to benefit? Do the exercise program characteristics matter e.g. how much force, intensity, frequency, duration? Do these program characteristics depend on particular patient characteristics? The challenge for future researchers is to develop the exercise prescription guidelines for these exercise programs to ensure sufficient frequency, intensity and duration of the training stimulus to result in sufficient improvement in tongue strength and swallowing function to have positive implications for the outcomes of dysphagia interventions.



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Chapter 3: A systematic review and meta-analysis of measurements of tongue and hand strength and endurance using the Iowa Oral Performance Instrument (IOPI)

3.1 Introduction

In the early 1990s, new tools to measure the pressure generated by contact between the tongue and palate were developed which offered speech-language pathologists an objective means of assessing tongue strength and endurance. One such tool was the IOPI, which has been used primarily in the USA over the past two decades. The IOPI was originally developed to examine the relationships between tongue strength or endurance and speech motor control, and has subsequently been extended to examine relationships with swallowing. Over this time a number of research studies have been conducted using the IOPI on both healthy and clinical populations, which provide data that can be used to establish normative IOPI values for tongue strength and endurance, as well as to investigate the possible influences of age, sex and medical condition on these values [51-53,38,54,8,55-62,49,63-75,37].

The IOPI is a portable, hand-held device that uses an air-filled pliable PVC tongue bulb (approximately 3.5cm long and 1.2cm in diameter (with an approximate internal volume of 2.8ml) connected via an 11.5cm clear PVC tube to measure peak pressure exerted on the tongue bulb measured in kilopascals (kPa). It contains pressure-sensing circuitry, a peak-hold function, and a timer. Researchers have used this device in many studies to measure tongue strength and endurance with excellent inter-rater reliability [75,37]. Currently it is one of the most commonly used measurement techniques available to objectively measure tongue strength and endurance [76]. A hand

bulb has also been developed for use with the IOPI, which provides a means of assessing hand in addition to tongue strength and endurance.

3.1.1 Aims and objectives

The primary aim of this systematic review was to evaluate the utility of the IOPI as an effective tool for assessments of both tongue and hand strength and endurance in healthy and clinical populations, and if possible, to identify representative values of these measures. Secondary aims were to investigate the effects of age and sex on the measured values, the impact of clinical conditions, and to determine the use of the IOPI as an intervention tool to improve tongue strength and/or endurance. Meta-analyses to consolidate these effects were conducted where appropriate.

3.2 Methods

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [77] and the Consolidated Standards of Reporting Trials (CONSORT) Statement [78] guided the conduct and reporting of this review.

3.2.1 Eligibility criteria

A systematic computer-based search of 21 databases (Table 3.1) and Google Scholar was conducted for the period between January 1990 and April 2012. The search terms used were: “*Iowa Oral Performance Instrument*” or “*IOPI*”. The search was limited to publications in English and peer-reviewed journals. An additional search of the databases using “*tongue strength*” was conducted to ensure maximum inclusion of potential articles. All reference lists in selected journal articles were screened for further potentially relevant articles that met the eligibility criteria. The first authors of two relevant journal articles [69,37] were contacted in April and June 2012 to obtain participant numbers, sex balance, and standard deviations from those studies to allow them to be included in the review. Eligible studies included cross-sectional, time series,

prospective cohort, and randomised controlled studies that provided values for tongue or hand strength or endurance measured by the IOPI, or evaluated the IOPI as an intervention tool on measures of strength/endurance in healthy or disordered populations. Exclusion criteria were studies that did not use the IOPI as a measurement device; were abstracts, theses, posters or conference papers; or contained no relevant data.

Table 3.1

A systematic computer-based search of electronic databases and vendors

Cochrane Library (Wiley InterScience)

CINAHL

EBSCO (Academic Search Complete, Communications & Mass Media Complete, Education Resources

Complete, Health Source: Nursing, Masterfile Premier, Psyc & Behavioural Sciences Collection,

SportsDiscus)

Embase (Elsevier)

Linguistics Language Behavior Abstracts (LLBA)

Medline

OVID

Proquest

PubMed

ScienceDirect

Scopus

Springerlink

Taylor & Francis

Web of Knowledge (Science Citation Index; Social Science Citation Index)

3.2.2 Study selection

After duplicates were deleted, eligibility assessment was performed independently in an unblinded standardised manner by the first author (VA), with any uncertainties resolved by a second author (RC). Retrieved records were screened for relevance and inclusion by title and abstract.

3.2.3 Data extraction process and data items

All data were extracted from the studies by one author (VA). If available, statistics such as 95% confidence interval (CI) or standard error (SE) were converted to the required form (mean $\pm$ standard deviations (SD) according to the calculations outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Sections 7.7 and 16.1.3.2) [79]. Information extracted included: (1) authors and year of publication; (2) setting; (3) groups if appropriate; (4) number of participants; (5) sex; (6) mean age; (7) age range; (8) means and standard deviations (SD) of IOPI measures; (9) outcomes of any comparisons between groups and whether *p* values were reported; (10) effect size of any comparisons; and (11) a clear population description (healthy or with disorders).

Studies that were published post-2000 used the second-generation IOPI tongue bulbs (soft vinyl blue silicone bulbs attached to a polyethylene tube, with a 2mm inside diameter). Studies measuring tongue strength published prior to 2000 were further examined to determine bulb texture and colour. Because of slightly different internal volumes and surface areas, pressure values obtained from first-generation clear air-filled tongue bulbs or latex bulbs must be multiplied by 0.87 to be comparable to the present data [70]; this correction was made where required to the values reported in this review. Whether this correction adequately addresses all variations in the materials in the early years is uncertain.

3.2.4 Risk of bias in intervention studies

Risk of bias was assessed for randomised controlled trials and prospective cohort studies by two authors (VA and RC) using a 10-item quality checklist adapted from the Consolidated Standards of Reporting Trials (CONSORT) statement [80]. In the case of disagreement, discussion took place until a consensus was reached. The items and explanations of the scoring for each item are reported in Table 3.2. Each item was scored with a '1' for 'yes' or '0' for 'no'. The studies were then classified as having a low (score ≥ 6) or high risk of bias (score ≤ 5).

3.2.5 Summary measures and synthesis of results

The primary outcome measures for this review were the means $\pm$ SD of the IOPI measures (tongue and hand strength [kPa] and endurance [seconds]) for the described population samples. Differences between population groups and the effects of intervention studies were examined using statistical comparisons, and effect sizes such as Cohen's *f*. Meta-analyses of healthy participants with outcomes for tongue strength (kPa) and tongue endurance (seconds) were conducted on eligible evaluation studies. Results were pooled in separate meta-analyses using RevMan 5.1.4 for Windows. All data were continuous and reported on the same scale for age and sex. The aggregate result was calculated as the weighted mean difference (WMD) between age and/or sex. Funnel plots to assess publication bias were generated if greater than 10 studies were included in the meta-analyses [79]. Meta-analysis was deemed inappropriate if results from fewer than three studies were compatible for analysis.

Table 3.2

A 10-item quality checklist scale and explanation of scoring for randomised control trials

Indicator	Quality marker
Study design	Controlled trial * Cohort Study Retrospective case control or single-subject design Case series Case study
Blinding	Assessors blinded * Assessors not blinded or not stated
Sampling/allocation	Random sample adequately described * Random sample inadequately described Convenience sample adequately described Convenience sample inadequately described or hand-picked sample or not stated
Group/participant comparability	Groups/participants at baseline on important factors (between-subject design) or participant(s) adequately described (within-subject design) * Groups/participants not comparable at baseline or comparability not reported or participant(s) not adequately described
Outcomes	At least one primary outcome measure is valid and reliable * Validity unknown, but appears reasonable; measure is reliable Invalid and/or unreliable
Significance	p value reported or calculable * p value neither reported or calculable
Precision	Effect size and confidence interval reported or calculable * Effect size or confidence interval, but not both, reported or calculable
Intention to Treat (controlled trials only)	Analysed by intention to treat * Not analysed by intention to treat or not stated

*Indicates highest level of quality

3.3 Results

3.3.1 Study selection

A search across 21 databases yielded a total of 295 articles that were identified for inclusion in the review (Figure 3.1). An additional 47 articles were identified from searching the reference lists of included articles. After adjusting for duplications, 162 remained. Of these, 126 studies were excluded, as they did not meet the eligibility criteria. The full texts of the remaining 42 articles were examined in greater detail. Four of these articles did not meet the inclusion criteria, as they did not provide IOPI data on tongue or hand strength or endurance. Thirty-eight studies met the inclusion criteria and were included in the systematic review.

3.3.2 Study characteristics

Of the 38 included studies, 36 were conducted in the United States; one in Brazil and one in Taiwan. The collective sample size was 1729 participants with 882 males (51%) and 847 females. Participants consisted of 53% healthy people and 47% from disordered populations (Parkinson's Disease (PD), head and neck cancer (HNC), Multiple Sclerosis (MS), Motor Neuron Disease (MND), traumatic brain injury (TBI), nasopharyngeal cancer (NPC), oculopharyngeal muscular dystrophy (OPMD), cerebrovascular accident (CVA), Developmental Apraxia of Speech (DAS), Developmental Verbal Dyspraxia (DVD). The majority of participants were recruited from the community (24%); clinics (21%); no setting stated (21%); hospitals (16%); schools or university (13%); or from other research projects (5%). Age ranges included children and adolescents (3 to 17 years) and adults (18 to 96 years). Included studies were classified as evaluation studies 87% ($n = 33$) or intervention studies 13% ($n = 5$).

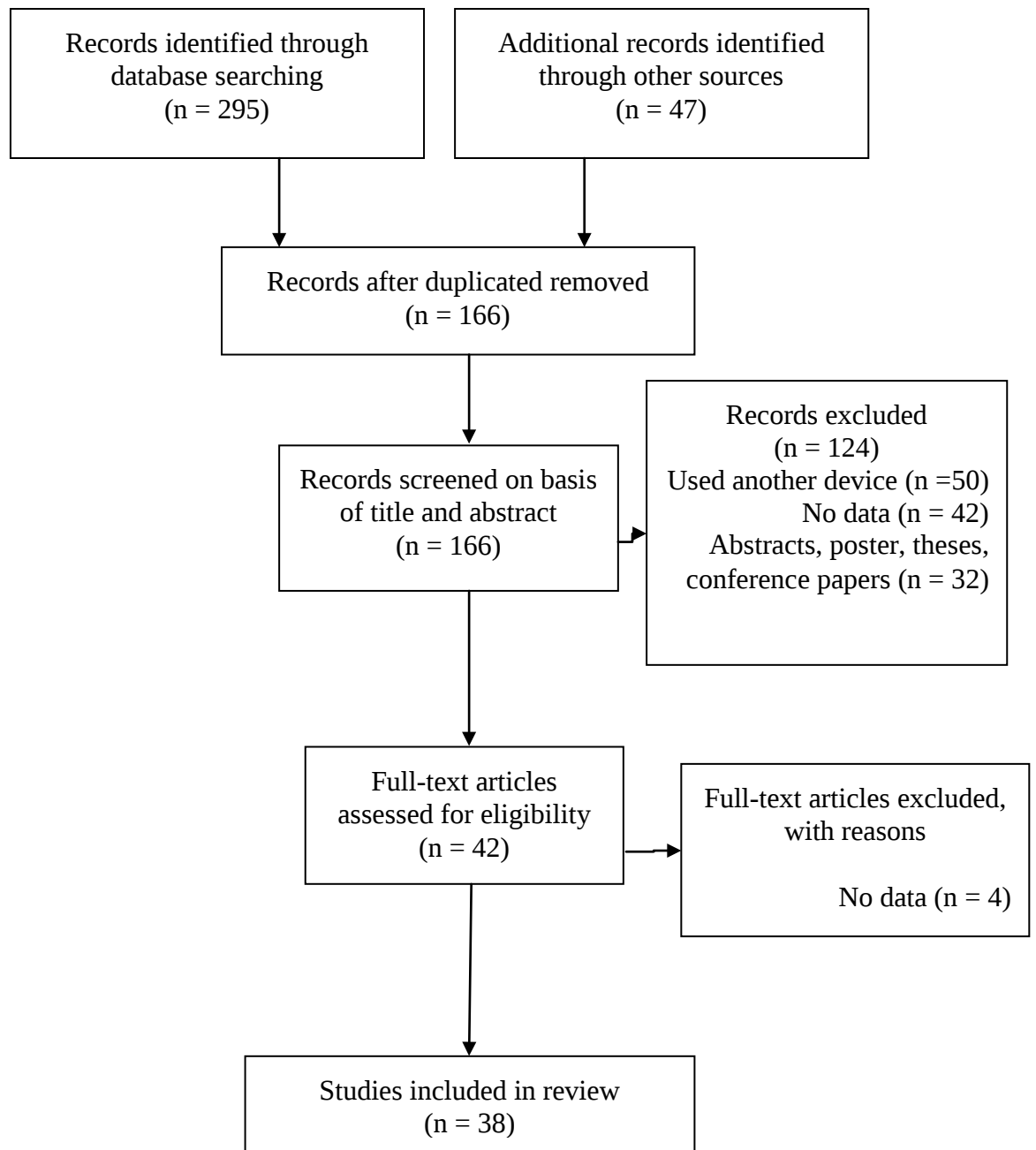


Figure 3.1. A flowchart of the literature search of databases

3.4 Evaluation studies

3.4.1 Tongue strength in healthy populations

Sixteen studies (adults $n = 14$ and children $n = 2$) reported measures of tongue strength (in kPa) in healthy individuals (Table 3.3). Mean values ranged from 43 to 78 kPa in healthy adults. Twelve studies reported data for healthy adult males and females; mean values for tongue strength in healthy males ranged from 49.25 ± 18.64 to 73.33 ± 12.03 kPa compared to moderately lower values for healthy females (37.00 ± 11.36 to 66.96 ± 11.60 kPa) at similar ages. Values of tongue strength in the healthy adult population have been reported primarily for anterior elevation and secondarily for posterior elevation. Reports of other tongue strength measures using the IOPI (i.e. lateralisation and protrusion) were not considered for this review. Three studies [8,53,54] measured tongue strength in both the anterior and posterior positions. Two studies [53,8] investigated tongue strength anteriorly and posteriorly and reported values 4 – 9 kPa below the norm. Tongue strength measured in the anterior position (56.50 ± 13.60 to 73.33 ± 12.03 kPa) was typically stronger than in the posterior position (52.00 ± 15.20 to 55.75 ± 13.58 kPa). In addition, findings from these three studies indicated that males (57.50 ± 15.10 to 73.33 ± 12.03 kPa) were stronger than females (56.50 ± 13.60 to 61.27 ± 14.80 kPa) anteriorly but not posteriorly.

One study [62] reported values of tongue strength that were much lower than those reported by previous studies of healthy participants. Measures of tongue strength in this study were obtained while simultaneously recording from intramuscular electrodes inserted into the muscles of the tongue. No pre-electrode-insertion measures were obtained but one female participant was measured when only a few electrodes were inserted (value of 43 kPa) and again with all electrodes in place (29 kPa); a substantial decrease in tongue strength was observed with more electrodes, which

Table 3.3
Studies investigating tongue strength and endurance in healthy participants

					Tongue Strength (kPa) (mean ± SD)			Tongue Endurance (s) @ 50% Pmax (mean ± SD)		
Study name	Year	Age range (y)	N	Sex	M & F across age groups	Males	Females	M & F across age groups	Males	Females
ADULT STUDIES										
IOPI website										
young						65.00	60.00	35.00		
old						65.00	60.00	35.00		
Robin et al. * [63]										
Trumpeters		18-48	12	8M, 4F	65.25 ± 11.74					
Control		18-49			65.98 ± 12.70					
Debaters		16-17	5	3M, 2F	77.63 ± 4.17					
Control		16-17			76.76 ± 6.00					
Robbins et al. * [49]										
young - blade		22-33	24	24M	56.12					
- dorsum		67-83			48.02					
- tip					43.76					
old - blade					43.07					
- dorsum					39.32					
- tip					40.72					

Study name	Year	Age range (y)	N	Sex	Tongue Strength (kPa) (mean ± SD)			Tongue Endurance (s) @ 50% Pmax (mean ± SD)		
					M & F across age groups	Males	Females	M & F across age groups	Males	Females
Crow & Ship * [38]	1996	19-39	99	52M, 47F	65.85 ± 17.30	65.08 ± 18.90	56.29 ± 19.60	43.90 ± 21.30		
		40-59			65.42 ± 23.60			41.90 ± 24.30		
		60-79			60.47 ± 17.30			48.00 ± 40.80		
		80-96			46.72 ± 13.30			45.20 ± 25.50		
Solomon et al. * [71]	1996	18-23	12	6M, 6F	60.47 ± 9.62	67.14 ± 9.13	53.80 ± 10.09			
Solomon et al. [66]	2002	19-26	10	5M, 5F	61.29 ± 8.80	65.82 ± 10.64	56.76 ± 6.45			
Solomon et al. [68]	2004	20-38	10	2M, 8F	61.60 ± 9.88		61.75 ± 9.53			
Youmans et al. [75]	2006	20-39	90	45M, 45F		64.00 ± 2.03	55.90 ± 1.86			
		40-59				72.00 ± 13.40	55.70 ± 12.50			
		60-96				63.90 ± 11.80	59.10 ± 14.00			
						56.10 ± 11.60	52.90 ± 10.70			
Palmer et al. [62]	2008	24-37	7	4M, 3F		49.25 ± 18.64				
		21-30					37.00 ± 11.36			

Study name	Year	Age range (y)	N	Sex	Tongue Strength (kPa) (mean ± SD)				Tongue Endurance (s) @ 50% Pmax (mean ± SD)			
					M & F across age groups		Males		Females		M & F across age groups	
Vitorino et al. [73]	2010		75	35M, 40F	56.59 ± 2.73		56.81 ± 1.36		56.37 ± 4.07		15.72 ± 2.29	16.23 ± 2.11
young		20-40					58.18 ± 7.07		57.05 ± 8.48		15.12 ± 6.73	17.30 ± 10.03
middle		41-60					55.46 ± 7.69		60.06 ± 7.24		18.25 ± 7.32	17.60 ± 6.35
old		61-80					56.80 ± 6.87		52.00 ± 5.00		13.80 ± 2.05	13.80 ± 3.03
Kays et al. [8]	2010		22	10M, 12F								
young		20-35										
(anterior)							59.20 ± 5.20		67.80 ± 10.60		40.20 ± 14.00	37.50 ± 11.80
(posterior)							50.00 ± 7.90		62.50 ± 14.50		26.00 ± 19.50	29.60 ± 9.30
old		65-82										
(anterior)							62.60 ± 8.80		50.30 ± 11.10		29.60 ± 12.50	34.30 ± 19.30
(posterior)							61.40 ± 7.50		49.00 ± 12.60		24.20 ± 13.60	24.40 ± 14.40
Neel et al. [58]	2011		57	29M, 28F	65.28 ± 12.04		69.35 ± 10.85		61.00 ± 10.10		37.85 ± 9.69	25.45 ± 3.18
young males		20-40					74.10 ± 11.80				31.00 ± 17.40	
old males		22-40					64.80 ± 12.10				44.70 ± 28.40	
young females		42-78							64.60 ± 9.80			23.20 ± 9.20
old females		42-74							57.20 ± 7.60			27.70 ± 17.70
Gingrich et al. [54]	2012	18-34	30	15M, 15F								
(anterior)							73.33 ± 12.03		61.27 ± 14.80			
(posterior)							53.60 ± 14.33		50.07 ± 14.44			

Study name	Year	Age range (y)	N	Sex	Tongue Strength (kPa) (mean ± SD)			Tongue Endurance (s) @ 50% Pmax (mean ± SD)		
					M & F across age groups	Males	Females	M & F across age groups	Males	Females
Clark et al. [53]	2012	18-89	171	88M, 83F						
All males (anterior)						57.50 ± 15.10				
(posterior)						52.00 ± 15.20				
All females (anterior)							56.50 ± 13.60			
(posterior)							53.60 ± 14.20			
young (anterior)		18-29			55.80 ± 13.50					
(posterior)					52.30 ± 13.20					
middle (anterior)		30-59			62.80 ± 13.00					
(posterior)					57.90 ± 16.70					
old (anterior)		60-89			51.00 ± 15.00					
(posterior)					47.40 ± 16.70					
CHILD STUDIES										
Potter et al. (2009a) [81]		3-5	48	24M, 24F	28.50 ± 8.77					
Potter et al. (2009b) [82]		3-17	148	71M, 77F		48.08 ± 18.85	38.16 ± 8.14			

* values in these studies multiplied by 0.87

explains the low values reported in this study. Males (range 34 to 72 kPa, mean 49 kPa) were again found to be stronger than females (range 32 to 50 kPa, mean 37 kPa).

Maximum tongue strength was observed to decrease with increasing age in nine studies involving healthy adults [49,75,73,37,58,8,38,83,54]. Results from these studies indicated that the oldest adults were, on average, 10 - 15 kPa lower than young adults. Two studies investigated tongue strength in healthy children. Potter et al. (2009a) studied children aged 3 - 5 years and found tongue strength increased with age ($p < 0.001$) [81]. Potter et al. (2009b) reported tongue strength in children and adolescents (3 - 17 years) and found significant differences in tongue strength with age up to 10 years, after which no significant age-related differences were observed [82].

3.4.2 Tongue strength in populations with disorders

Seventeen studies (adults $n = 15$ and children $n = 2$) reported measures of tongue strength (in kPa) in populations with a disorder (Table 3.4). The main disorders were PD ($n = 5$), HNC ($n = 3$) and OPMD ($n = 2$). Mean values for PD ranged from 44.26 ± 3.22 kPa to 55.11 ± 13.82 kPa with higher tongue strength values in males than females. Three studies investigated HNC [55-57] with values ranging from 37.05 ± 14.42 kPa to 56.00 kPa. Lazarus et al. (2007) reported that mean maximum tongue strength was not significantly different to pre-treatment at one month after treatment but did increase significantly at 6- and 12- month post-treatment. Two studies investigated OPMD [61,59] with values much lower (19.50 ± 0.71 kPa to 26.90 ± 7.80 kPa) than healthy controls and those with other disorders such as PD.

Table 3.4
Studies investigating tongue strength and endurance in populations with a disorder

						Tongue strength (kPa) (mean ± SD)			Tongue endurance (s) (mean ± SD)		
Study name	Year	Medical Condition	Age range (y)	N	Sex	M & F across age groups	Males	Females	M & F across age groups	Males	Females
ADULT STUDIES											
Lazarus et al. * [55] (baseline) (1 mth) (3 mth) (6 mth) (12 mth)	2007	HNC	29-78	46	35M, 11F	47.00 ± 9.80 41.70 ± 8.22 51.00 ± 10.12 57.50 ± 10.12 54.70 ± 8.54					
Lazarus et al. [56]	2000	HNC Control	38-72 36-77	13 13	10M, 3F 10M, 3F	37.05 ± 14.42 60.15 ± 3.68			40.62 ± 24.67 37.77 ± 3.18		
Lazarus et al. [57]	2002	HNC Control	72 72	1 1	1M 1M		56.00 30.00			4.00 13.00	
Chang et al. [51]	2008	NPC Control	33-63 30-65	12 12	11M, 1F 11M, 1F	56.67 ± 9.35 64.50 ± 12.57			24.58 ± 10.72 18.75 ± 6.22		
Neel et al. [59]	2006	OPMD Control	57-67 61,67	8 2	2M, 6F 2F		19.50 ± 0.71	24.67 ± 9.09 50.50 ± 0.71			

Study name	Year	Medical Condition	Age range (y)	N	Sex	Tongue strength (kPa) (mean ± SD)			Tongue endurance (s) (mean ± SD)		
						M & F across age groups	Males	Females	M & F across age groups	Males	Females
Palmer et al. [61]	2010	OPMD	50-76	11	3M, 8F		26.90 ± 7.80	26.90 ± 7.80			
		Control	52-76	9	4M, 5F		57.40 ± 10.40	57.40 ± 10.40			
Solomon et al. [69]	1994	PD	43-71	3	1M, 2F		53.00	49.50		6.00	50.00
		Control	43-64	3	1M, 2F		70.00	51.50		25.00	37.50
Solomon et al. [67]	1995	PD	46-73	19	10M, 9F		52.98 ± 19.93	50.07 ± 16.79		23.23 ± 11.14	34.32 ± 47.69
		Control	49-74	19	10M, 9F		63.25 ± 10.66	56.94 ± 9.68		23.14 ± 11.58	28.90 ± 11.44
Solomon et al. [70]	2000	PD	56-81	16	12M, 4F		48.25 ± 10.04	47.75 ± 10.21		21.10 ± 9.52	22.20 ± 20.81
		Control	55-93	16	12M, 4F		53.75 ± 6.18	60.75 ± 14.95		38.46 ± 32.05	32.05 ± 9.84
Solomon [64]	2006	PD	40-75	12	9M, 3F		55.11 ± 13.82	49.00 ± 20.42			
		Control	48-74	15	8M, 7F		63.75 ± 13.96	57.00 ± 7.59			
Robin et al. [84]	1991	TBI	26	1	1F			38.28		25.00	
		Control	20-49	26	5M, 21F	61.77				36.31 ± 10.13	
Yeates et al. * [74] (anterior) (posterior)	2008	TBI, HNC, CVA	50-72	3	3M		45.25 ± 19.37				
							42.24 ± 21.95				
Clark et al. * [6]	2003	Various	19-95	63	28M, 35F	32.75 ± 18.44					

Tongue strength (kPa) (mean ± SD)									Tongue endurance (s) (mean ± SD)		
Study name	Year	Medical Condition	Age range (y)	N	Sex	M & F across age groups	Males	Females	M & F across age groups	Males	Females
Solomon et al. * [65]	2008	Various	18-78	44	40M, 4F		43.18 ± 20.00	48.25 ± 13.82		38.28 ± 24.57	32.00 ± 21.83
Stierwalt & Youmans [72]	2007	Various	26-91	50	16M, 26F		42.89 ± 15.60	31.03 ± 15.85		49.85 ± 52.27	37.77 ± 37.30
		Control	26-90	50	16M, 26F		63.24 ± 13.86	57.15 ± 13.50		42.77 ± 16.14	37.15 ± 30.55
CHILD STUDIES											
Robin et al. [84]	1991	DAS, DVD	8-10	5	4M, 1F	40.02			9.10 ± 4.84		
		Control	6-12	6	4M, 2F	56.55			24.03 ± 4.13		
Stierwalt et al. [85]	1996	TBI	6-17	23	14M, 9F		56.24 ± 18.67	36.05 ± 13.58		14.50 ± 14.47	8.78 ± 10.54
		Control	6-17	23	14M, 9F		64.44 ± 11.82	47.56 ± 9.73		38.14 ± 17.10	24.00 ± 19.91

* No control group used

HNC=Head or neck cancer; NPC=Nasopharyngeal cancer; OPMD=Oculopharyngeal muscular dystrophy; PD=Parkinson's Disease; TBI=Traumatic brain injury; DAS=Developmental apraxia of speech; DVD=Developmental verbal dyspraxia

3.4.3 Tongue endurance in healthy populations

Tongue endurance (reported in seconds) was measured isometrically at 50% of maximal tongue strength ($P_{\max}$) in the anterior position (unless otherwise stated) and reported in four studies (Table 3.3) in healthy people. Effects of age on tongue endurance in males and females in four age groups (young, middle-aged, older, and elderly) was examined [38]. Regardless of age or sex, overall mean tongue endurance was 44.80 ± 28.00 s, and no significant differences in tongue endurance with age were observed ($p = 0.67$). Mean tongue endurance values ranged from 15.72 ± 5.86 to 37.85 ± 23.55 s for males and 16.23 ± 7.07 to 36.35 ± 11.74 s for females, with no significant age effects in either males ($p = 0.61$) or females ($p = 0.33$). A comparison of tongue endurance in two age groups (20 - 35y and 65 - 82y) and in two positions on the tongue (anterior and posterior) was conducted [8]. Significant differences in tongue endurance were observed in the anterior compared to the posterior position ($p = 0.0005$) but no significant age or sex differences were reported. Neel et al. (2011) examined tongue endurance in males and females in two age groups (20 - 40y and 42 - 78y). Males had higher values than females ($p < 0.03$) and there was a trend for older adults to have higher values than younger adults ($p < 0.10$). The mean values for each subgroup were older males (44.70 ± 28.40 s), younger males (31.00 ± 17.40 s), older females (27.70 ± 17.70 s) and younger females (23.20 ± 9.20 s). Vitorino et al. (2010) examined three age groups (20 - 40y; 41 - 60y; and 61 - 80y), and their tongue endurance measures were lower than those in other studies, however no significant differences were reported across age ($p > 0.05$) or sex ($p > 0.05$). Robin et al. (1992) investigated tongue endurance in individuals with high skills levels with their tongues (trumpet players and debaters). Although values were not provided (other than in a figure), they reported that both debaters and trumpet players had substantially higher values than healthy controls.

3.4.4 Tongue endurance in populations with disorders

Ten studies (adults $n = 9$ and children $n = 1$) measured tongue endurance (in seconds) isometrically at 50% of maximum tongue strength in populations with disorders (Table 3.4). Five disorders accounted for most of those measured: PD, HNC; OPMD; NPC; TBI. Three studies measured endurance with values ranging from 6.00 to 23.23 ± 11.14 s compared to a control group (23.14 ± 11.58 to 38.46 ± 32.05 s). Females in PD studies (22.20 ± 20.81 s) were better able to hold 50% maximum tongue strength than males (21.10 ± 9.52 s). Stierwalt and Youmans (2007) examined various medical conditions including 29 participants following CVA with males reporting longer endurance times (49.85 ± 52.27 s) than females (37.77 ± 37.30 s) [86]. No endurance data was available for individuals following CVA. One study [84] investigated children (DAS, DVD) with males (14.50 ± 14.47 s) having better endurance than the females (8.78 ± 10.54 s). Males in the control group (38.14 ± 17.10 s) also had longer endurance times than female controls (24.00 ± 19.91 s). This study also reported that children with DVD and/or DAS (9.10 ± 4.84 s) were not able to hold an endurance level similar to the control group (24.03 ± 4.13 s) [84].

Comparisons with healthy control groups indicate that populations with disorders have significantly lower tongue endurance, with the magnitude of the decrease dependent on the specific medical condition; this is demonstrated in a study examining OPMD in older adults by Palmer et al. (2010). Compared to a control group, the OPMD group showed a decrease in tongue endurance however it was not significant [61].

3.4.5 Hand strength in healthy populations

Only three studies (adults $n = 2$ and children $n = 1$) reported hand strength (kPa) in healthy individuals (Table 3.5). Such a small number of studies provides little basis for the establishment of normative hand strength values in healthy adults. Crow and

Ship (1996) investigated the effects of age and sex in healthy adults with males (155.10 ± 44.60 kPa) stronger ($p < 0.001$) than females (123.60 ± 27.20 kPa). Younger adults had the highest values (165.00 ± 43.80 kPa), followed by middle-aged (157.70 ± 34.10 kPa), older (129.00 ± 35.30 kPa), and elderly (110.00 ± 33.20 kPa) groups. Mean hand strength across broader age groups was also reported (140.43 ± 36.60 kPa) with a significant difference in strength ($p < 0.01$) between individuals aged greater than 59 years and younger age groups. Robin et al. (1992) reported hand strength values for trumpet players (157.34 ± 25.74 kPa) and a control group (171.58 ± 23.32 kPa) with significance observed ($p < 0.0001$). A debaters group (171.35 ± 13.20 kPa) showed values that were also significant ($p < 0.0002$) when compared to a control group (181.13 ± 23.32 kPa). Potter et al. (2009a) reported mean hand strength of 48.41 ± 8.18 kPa in 48 children aged 3 to 5 years [81].

Table 3.5
Studies investigating hand strength and endurance in a healthy population

Study name	Year	Age range (y)	N	Sex	Hand Strength (kPa) (mean ± SD)			Hand Endurance (s) (mean ± SD)		
					M & F across age groups	Males	Females	M & F across age groups	Males	Females
ADULT STUDIES										
IOPI website					150.00		140.00		40.00 - 60.00 40.00 - 60.00	
Robin et al. [63]	1992									
Trumpeters		18-48	12	8M, 4F	157.35 ± 25.74					
Control		18-49			171.58 ± 23.32					
Debaters		16-17	5	3M, 2F	171.35 ± 13.20					
Control		16-17			181.13 ± 23.32					
Crow et al. [38]	1996	19-96	99	52M, 47F		155.10 ± 44.60	123.60 ± 27.20		74.20 ± 38.30	90.30 ± 49.80
		19-39			165.00 ± 43.80			72.30 ± 44.30		
		40-59			157.70 ± 34.10			88.50 ± 39.60		
		60-79			139.00 ± 35.30			84.20 ± 46.60		
		80-96			110.00 ± 33.20			72.60 ± 50.50		
CHILD STUDY										
Potter et al. [81]	2009a	3-5	48	24M, 24F	48.41 ± 8.18					

3.4.6 Hand strength in populations with disorders

Five studies (adults) reported measures of hand strength (in kPa) in populations with medical conditions (Table 3.6), primarily PD. Two studies [67,70] examined hand strength in older adults with PD. Solomon et al. (1995) reported that male values (131.20 ± 29.84 kPa) were stronger than females (94.83 ± 35.36 kPa) but not as strong as the age and sex matched control groups (males 150.08 ± 34.13 and females 120.64 ± 25.16). Solomon et al. (2000) also reported values for males and females with PD (140.33 ± 23.46 kPa and 98.25 ± 14.31 kPa respectively), however these were not significantly different ($p = 0.362$) to male and female control group participants (136.58 ± 23.75 kPa and 101.75 ± 24.88 kPa respectively).

3.4.7 Hand endurance in healthy populations

Two studies (adults $n = 1$ and children $n = 1$) measured hand endurance in seconds at 50% of maximum hand strength. One study [38] measured hand endurance in healthy adults (Table 3.5). Mean hand endurance regardless of age was 79.40 ± 45.25 s, and there were no significant differences in hand endurance with age whether analysed with all participants ($p = 0.41$), or for males ($p = 0.38$) or females ($p = 0.56$). Mean values reported for different age groups were middle-aged adults (88.50 ± 39.60 s), adults (84.20 ± 46.60 s), elderly adults (72.60 ± 50.50 s) and younger adults (72.30 ± 44.30 s). There was a trend ($p = 0.08$) for females to sustain hand endurance longer (90.30 ± 49.80 s) than males (74.20 ± 38.30 s). Robin et al. (1991) examined hand endurance in 26 healthy adults and six healthy children. Children sustained hand endurance for an average of 24.03 ± 4.13 s while adults averaged 36.31 ± 10.13 s ($p < 0.05$).

Table 3.6
Studies investigating hand strength and endurance in populations with a disorder

Study name	Medical Condition	Age range (y)	N	Sex	Hand strength (kPa) (Mean ± SD)			Hand Endurance (s) (Mean ± SD)	
					M & F across ages	Males	Females	Males	Females
ADULT STUDIES									
Robin et al. (1991) [84]	TBI	26	1	1F			132.00		56.00
	Control	20-49	26	5M, 21F	110.00				56.49 ± 13.70
Solomon et al. (1994) [69]	PD	43-71	3	1M, 2F		273.00	131.75	33.00	67.50
	Control					156.00	147.50	24.00	45.00
Solomon et al. (1995) [67]	PD	46-72	19	10M, 9F		131.20 ± 29.84	94.83 ± 35.36	44.81 ± 45.95	46.50 ± 18.48
	Control					150.08 ± 34.13	120.64 ± 25.16	41.67 ± 21.98	48.72 ± 20.24
Solomon et al. (2000) [70]	PD	56-81	16	12M, 4F		140.33 ± 23.46	98.25 ± 14.31	53.18 ± 20.79	63.40 ± 39.48
	Control					136.58 ± 23.75	101.75 ± 24.88	57.38 ± 16.19	60.63 ± 50.63
O'Day et al. (2005) [60]	PD	52 – 79	10	10M					
	day 1					105.90 ± 32.93			
	day 2					106.10 ± 28.93			
	day 3					110.50 ± 38.55			
	day 4					109.20 ± 31.62			
	day 5					111.70 ± 38.67			
	Control								
	day 1					133.20 ± 25.62			
	day 2					139.30 ± 25.27			
	day 3					136.90 ± 24.03			
	day 4					134.20 ± 23.71			
	day 5					137.50 ± 18.09			

Study name	Medical Condition	Age range (y)	N	Sex	Hand strength (kPa) (Mean ± SD)		Hand Endurance (s) (Mean ± SD)		
					M & F across ages	Males	Females	Males	Females
CHILD STUDY									
Robin et al. (1991) [84]	DAS, DVD	8-10	5	4M, 1F				11.57 ± 6.96	
	Control	6-12	6	4M, 2F				48.00 ± 10.14	

HNC=Head or neck cancer; NPC=Nasopharyngeal cancer; OPMD=Oculopharyngeal muscular dystrophy; PD=Parkinson's Disease; TBI=Traumatic brain injury;

DAS=Developmental apraxia of speech; DVD=Developmental verbal dyspraxia

3.4.8 Hand endurance in populations with disorders

Five studies (adults $n = 4$ and children $n = 1$) reported measures of hand endurance in populations with disorders (Table 3.6). Three studies examined PD [67,69,70]. Solomon et al (1994) reported three case studies (one male and two females) and found reduced or abnormal findings for hand endurance. Solomon et al. (1995) reported values for males (44.81 ± 45.95 s) and females (46.50 ± 18.48 s) with a statistically significant difference between PD and control groups ($p = 0.025$). Solomon et al. (2000) reported values for males (53.18 ± 20.79 s) and females (63.40 ± 39.48 s) with no significant difference between the disordered and control groups ($p = 0.805$). Stierwalt et al. (1996) measured hand endurance in 23 children with TBI compared to a control group and found a significant difference between groups ($p = 0.0001$) [85]. One study [84] reported a value of 11.57 ± 6.96 s for children aged 8 to 10 years with DAS, which was significantly different ($p < 0.05$) to the healthy control group (48.00 ± 10.14 s). This study also reported values for one female with TBI (56.00s) and found a comparable result to a control group (56.49 ± 13.70 s) (no p value reported).

3.5 Results of meta-analyses

Meta-analyses were conducted for tongue strength and endurance for age and sex. Funnel plot comparison for meta-analyses 2, 3 and 4 were not generated as less than 10 studies were included. Meta-analysis was deemed inappropriate for younger participants (< 60 years) vs. older participants (60+ years) for males and females as results from fewer than three studies were compatible for analysis.

3.5.1 Tongue strength : Meta-analysis 1

In total, males ($n=425$) and females ($n=391$) (total 816) from 17 studies with ages ranging from 19 to 96 years were included. The studies were statistically heterogeneous ($\text{Tau}^2 = 20.05$; $\chi^2 = 112.78$, $df = 16$, $P < 0.00001$, $I^2 = 86\%$), so the

random effects model was used. Meta-analysis (Figure 3.2) revealed statistically significant greater tongue strength in males compared to females (WMD 5.21kPa [2.26, 8.17; 95% CI], $Z = 3.46$, $p = 0.0005$). As this meta-analysis used a random-effect estimate funnel plot comparison for tongue strength to assess publication bias was not generated even though greater than 10 studies were included. Random-effects estimates give greater relative weight to smaller studies and may lead to wider CIs [79].

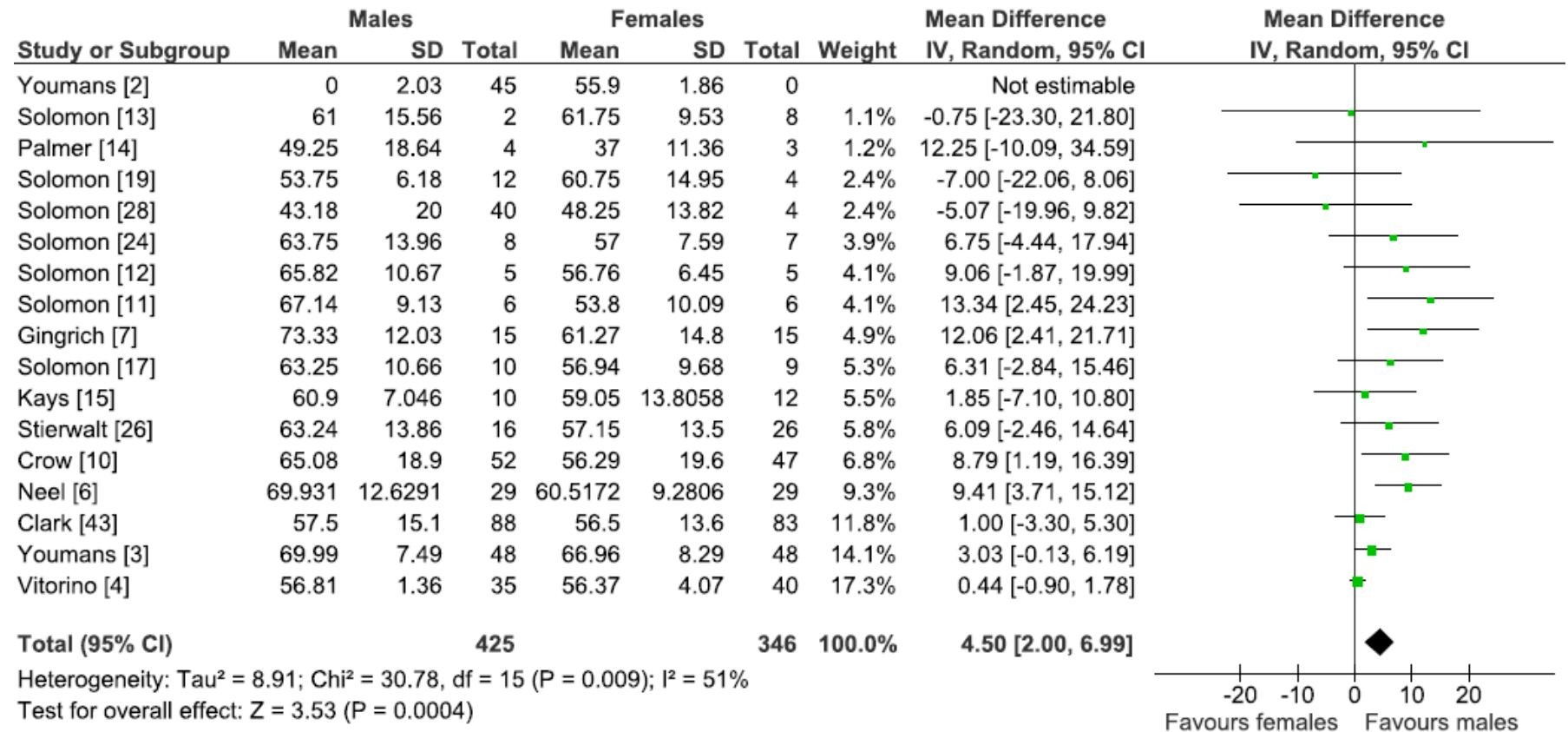


Figure 3.2. Forest plot of comparison: Tongue Strength by Age and Sex, Males vs. Females.

Note. References listed above in square brackets [] relate to the publication provided in the systematic review published in 2013.

3.5.2 Tongue strength : Meta-analysis 2

Two age groups were considered: (< 60 years = younger and 60+ years = older). Data from adults less than 60 years ($n = 484$) were compared to adults 60+ years ($n = 275$) (total 759) from eight studies. The studies were not statistically heterogeneous ($\chi^2 = 3.54$, $df = 7$, $p = 0.83$, $I^2 = 0\%$), so the fixed effects model was used. Meta-analysis (Figure 3.3) revealed statistically significant greater tongue strength in adults less than 60 years compared to adults 60+ years (WMD 8.30 kPa [6.37, 10.23], $Z = 8.43$ ($P < 0.00001$)).

3.5.3 Tongue strength : Meta-analysis 3

Two age groups were considered (< 60 years = younger and 60+ years = older) for males. In total, younger males ($n = 93$) vs. older males ($n = 63$) (total 156) from five studies were included. Studies were not statistically heterogeneous ($\chi^2 = 7.83$, $df = 4$ ($P = 0.10$); $I^2 = 49\%$), so the fixed effects model was used. Meta-analysis (Figure 3.4) revealed that younger males had significantly stronger tongue strength than older males (WMD 8.00 kPa [4.92, 11.08; 95% CI], $Z = 5.09$ ($P < 0.00001$)).

3.5.4 Tongue strength : Meta-analysis 4

Two age groups were considered (< 60 years = younger and 60+ years = older) for females. In total, younger females ($n = 80$) vs. older females ($n = 53$) (total 133) from four studies were included. Studies were not statistically heterogeneous ($\chi^2 = 5.40$, $df = 3$ ($P = 0.14$); $I^2 = 44\%$), so the fixed effects model was used. Meta-analysis (Figure 3.5) revealed that younger females had significantly stronger tongue strength than older females (WMD 9.43 kPa [5.57, 13.28; 95% CI], $Z = 4.79$ ($P < 0.00001$)).

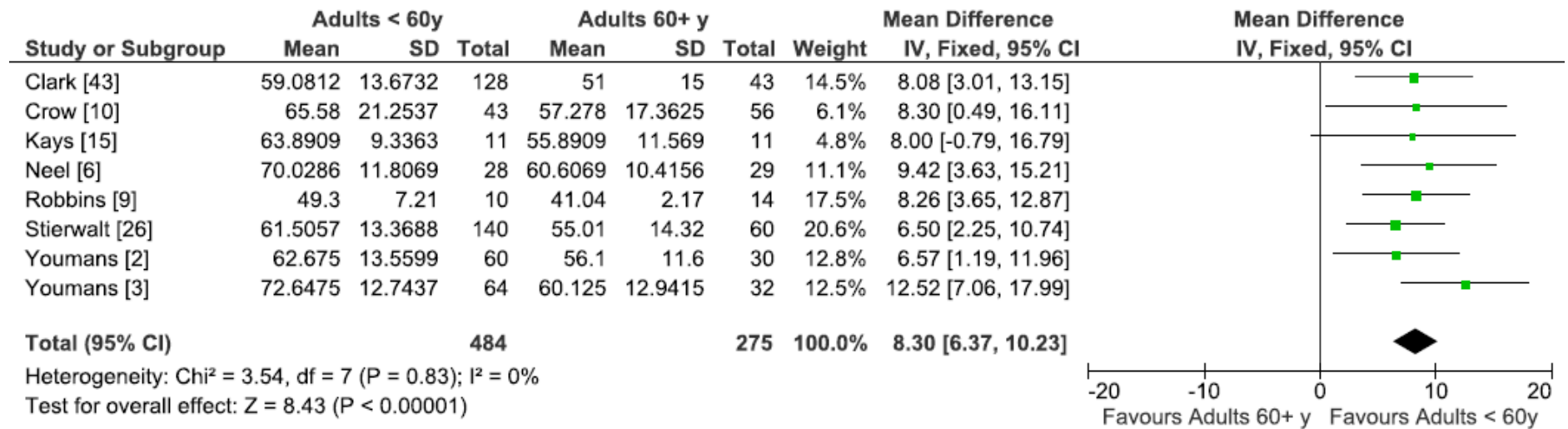


Figure 3.3. Forest plot of comparison: Tongue Strength by Age and Sex, Adults < 60y vs. Adults 60+ y.

Note. References listed above in square brackets [] relate to the publication provided in the systematic review published in 2013.

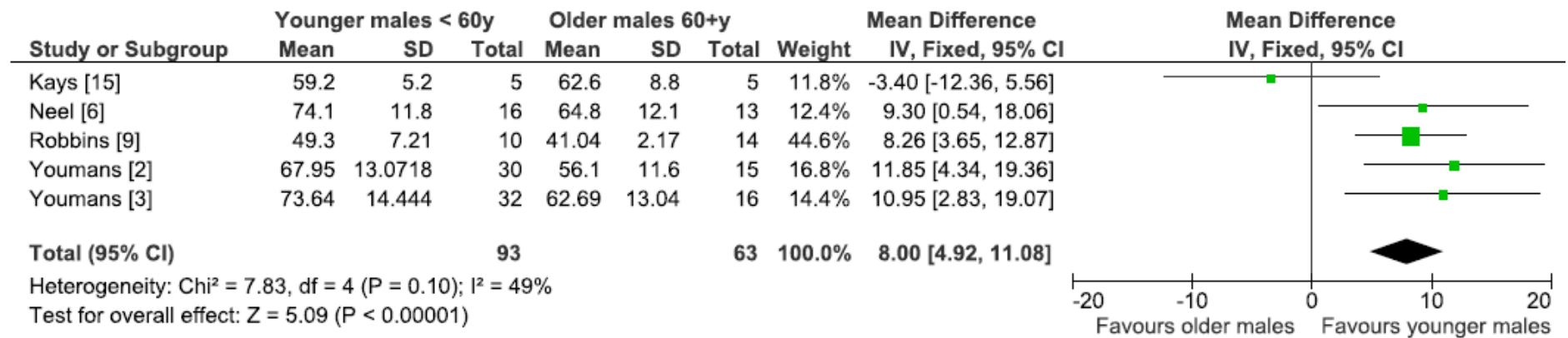


Figure 3.4. Forest plot of comparison: Tongue Strength by Age and Sex, Younger males vs. Older males.

Note. References listed above in square brackets [] relate to the publication provided in the systematic review published in 2013.

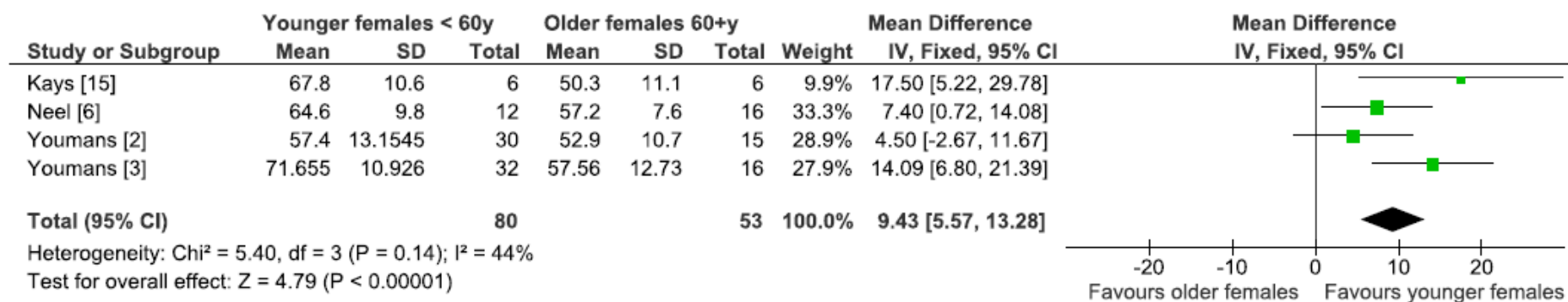


Figure 3.5. Forest plot of comparison: Tongue Strength by Age and Sex, Younger females vs. Older Females.

Note. References listed above in square brackets [] relate to the publication provided in the systematic review published in 2013.

3.5.5 Tongue endurance : Meta-analysis 1

One meta-analysis was conducted with 112 males and 119 females (total 231) from six studies included. The evaluation studies were statistically heterogeneous ($\chi^2 = 7.37$, $df = 5$, $p = 0.19$, $I^2 = 32\%$), so the fixed effects model was used. Meta-analysis (Figure 3.6) revealed no statistically significant difference in tongue endurance between adult males and females across all ages (WMD -0.40 seconds [-1.39, 0.58; 95% CI], $Z = 0.80$, $p = 0.42$).

3.6 Intervention studies

Five studies investigated the effects of interventions on the strength and endurance of the tongue (Table 3.7). Two RCTs [35,87] used the IOPI as both an intervention and evaluation tool, and evaluated the effects of tongue-strengthening exercises on tongue strength and endurance in healthy adults. The third RCT [88] randomised participants to five tongue training groups (strength, endurance, power, speed, and no training) and used the IOPI for the measurement of tongue strength, endurance and power, but not speed, pre- and post-training. Participants in the two prospective cohorts studies [17,18] used the IOPI to measure tongue strength and endurance following an eight-week tongue-strengthening exercise program in older-adult healthy and stroke populations.

Studies varied in the following areas: age groups (18 - 67y, 19 - 57y; 20 - 29y, 51 - 90y, 70 - 89y), medical condition (healthy, stroke); sex imbalance (more females than males); study duration (4, 8 or 9 weeks); participant group size (10, 31, 31 and 39); frequency of measurements (time series, fortnightly, or monthly); exercise program (10 repetitions 3 times/day on 3 non-consecutive days; 10 repetitions 3 times/day for 7 days/week; 10 repetitions 5 times/day for 5 days/week; or 3 sessions per week on 3 non-consecutive days for 4 weeks). Outcome measures (tongue strength and

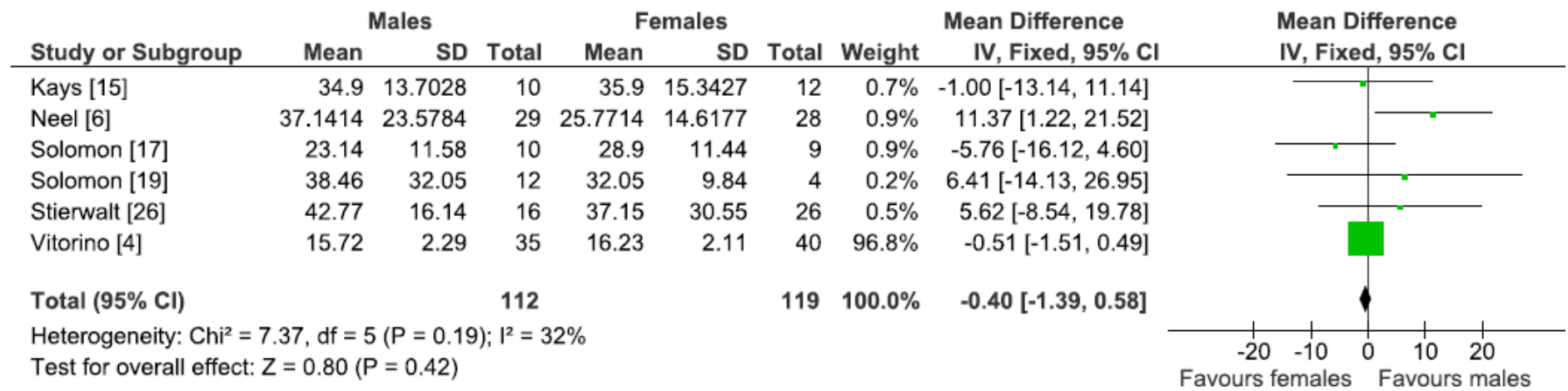


Figure 3.6. Forest plot of comparison: Tongue Endurance by Age and Sex, Males vs. Females.

Note. References listed above in square brackets [] relate to the publication provided in the systematic review published in 2013.

endurance; only tongue strength; or tongue strength and endurance within specific training groups); tongue bulb position (anterior only, or anterior and posterior); and training specificity (directional exercise – elevation, protrusion, lateralisation, or none) were reported. The RCT by Clark (2012) differed from the other four intervention studies in that it reported Cohen's *d* values as well as *p* values.

3.6.1 Tongue strength

Four studies examined tongue strength pre- and post-tongue-strengthening exercise programs (Table 3.7). Lazarus et al. (2003) investigated the effects of IOPI or tongue depressor exercise training in young adults (20 - 29y); the responses of the two exercise intervention groups did not differ and when combined showed significant improvements from baseline (64.40 ± 8.71 kPa) to four weeks (73.10 ± 7.33 kPa) compared to a no-exercise control group ($p = 0.04$). Robbins et al. (2005) examined the effects of six weeks IOPI exercise training in older adults (70 - 89y). Significant increases in tongue strength were observed from baseline to four weeks ($p = 0.002$) and baseline to six weeks ($p = 0.001$), with the following values (in kPa) reported: baseline (41.00; range 36 - 46); two weeks (44.00; range 39 - 49); four weeks (47.00; range 43 - 51); and six weeks (49.00; range 45 - 53). Clark et al. (2009) examined the effects of nine weeks of training using three different directional exercise conditions (elevation, protrusion and lateralization) on tongue strength measured with the IOPI in healthy adults (18 - 67y). Training effects were reported at three and nine weeks. Significant increases in strength were observed with a 6% change in elevation strength ($p < 0.001$) compared to 26.6% for lateralisation ($p < 0.001$) and 13.4% for protrusion ($p < 0.001$). Clark (2012) examined the specificity of exercise training effects using the IOPI in healthy adults (19 - 57y). Large ($d = 1.06$) improvements in strength were observed for the strength-training group only.

3.6.2 Tongue endurance

Two intervention studies investigated the effects of exercise training on tongue endurance (Table 3.7). Lazarus et al. (2003) examined the effects of IOPI or tongue depressor exercise training on tongue endurance in young adults (20 - 29y), and showed a trend to improve from baseline (25.00 ± 14.21 s) to four weeks (34.40 ± 31.62 s) ($p = 0.10$). Dosage included 10 repetitions completed five times per day for five days per week for four weeks with each repetition held for two seconds and performed in four directions (i.e. left, right, on protrusion, and on elevation).

Clark (2012) assessed tongue endurance using the IOPI to determine the effects of four different types of exercise training, including elevation exercises, which required the tongue to be pressed against the hard palate just behind the alveolar ridge with maximum effort. Dosage included 30 repetitions for 7 days per week in sets of 10 repetitions for three sets of elevation, protrusion and lateralisation. Clark (2012) found that endurance training had a large effect ($d = 1.29$) on isotonic tongue endurance (repetitions) but no effect on isometric endurance.

Table 3.7
Studies investigating the use of the IOPI in intervention studies

Study name	Study Design	Groups	Health Status	Age groups (y)	n	Sex	Tongue strength (kPa) (mean ± SD)		Tongue endurance (s) (mean ± SD)	
							Baseline	Post-exercise	Baseline	Post-exercise
ADULT STUDIES										
Robbins et al. (2005) [17]	Prospective cohort	IOPI	Healthy	70-89	10	4M, 6F	41.00	49.00		
Clark et al. (2009) [35]	RCT		Healthy	18-67	39	17M, 22F				
		TD Elevation					59.63 ± 14.12			
		TD Protrusion						66.65 ± 14.50		
		TD Lateral						66.46 ± 14.13		
								66.45 ± 14.91		
Lazarus et al. (2003) [87]	RCT		Healthy	20-29	31	12M, 23F				
		TD					64.80 ± 9.48	74.00 ± 7.59	29.70 ± 16.44	43.70 ± 43.96
		IOPI					63.90 ± 6.96	72.10 ± 6.64	20.80 ± 10.75	26.00 ± 9.49
		IOPI & TD					64.40 ± 8.71	73.10 ± 7.33	25.00 ± 14.21	34.40 ± 31.62
		Control					69.80 ± 17.71	71.20 ± 17.08	17.90 ± 8.22	18.40 ± 8.54
Clark (2012) [88]	RCT		Healthy	19-57	25	3M, 22F				
		IOPI					65.80 ± 14.97	82.60 ± 13.39	45.20 ± 10.28	45.40 ± 10.16
		Strength trg					65.60 ± 15.19	73.00 ± 18.40	81.20 ± 32.41	77.20 ± 12.09
		Endurance trg					60.20 ± 17.98	66.60 ± 17.05	71.60 ± 30.22	71.40 ± 12.58
		Power trg					72.80 ± 14.72	80.40 ± 20.11	62.80 ± 9.07	64.40 ± 12.70
		Speed trg					66.80 ± 13.18	73.60 ± 10.06	62.40 ± 5.18	59.80 ± 14.48
		Control								
Robbins et al. (2007) [18]	Prospective cohort	IOPI	Stroke	51-90	10	5M, 5F				
		Anterior					35.6	51.7		
		Posterior					30.2	54.6		

TD = Tongue depressor; RCT = randomised control trial

3.6.3 Risk of bias in intervention studies

The results of the 10-item risk of bias analysis for the five intervention studies are presented in Table 3.8. Inter-rater reliability for the risk of bias items between two reviewers (VA and RC) indicated a high level of agreement across all items (percentage agreement 100%, Cohen's $\kappa = 1$). Each study received a point for each indicator that met the quality criteria. For the three randomised controlled trials, all eight-quality indicators were relevant, leading to a maximum quality score of 8. For the other study designs, where an intention-to-treat analysis was not applicable, the highest quality score was seven. Randomisation was described adequately and performed in two studies [35,88] and a control group (randomised participants) was included in two studies [88,35,87]. Assessor blinding was carried out in only one study [35]; baseline characteristics were reported and at least one primary outcome measure was valid and reliable in all five studies [88,35,87,17,18]; *p* values were reported in five studies [35,87,17,18]. Effect sizes and/or precision estimates (e.g., 95% CIs) were reported in two studies [18]; magnitude of effect size was determined in two studies [88] using Cohen's benchmarks for small, medium, and large effects as 0.2, 0.5, and 0.8, respectively [89]. Summary results for individual study groups were presented in all studies cited. One study [35] indicated a low risk of bias with six of the eight quality markers. Four studies [87,88,18] and Robbins et al. (2005) had a higher risk of bias for four and three quality markers respectively.

Table 3.8
Risk of bias assessment of intervention studies

Studies	Did the study include a true control group (randomised participants not a comparison group)?	Were the assessors blinded to treatment allocation at baseline and post-test?	Was the randomisation procedure adequately described and carried out?	Were the subjects at baseline adequately described?	Was at least one primary outcome measure valid and reliable?	Did the study report or calculate a <i>p</i> value?	Did the study report effect size or confidence intervals?	Did the study report a power calculation and was the study adequately powered to detect intervention effects?
Clark et al. (2009) [35]	1	1	1	1	1	1	0	0
Clark (2012) [88]	1	0	1	1	1	1	1	1
Lazarus et al. (2003) [87]	1	0	0	1	1	1	0	0
Robbins et al. (2007) [18]	0	0	0	1	1	1	1	0
Robbins et al. (2005) [17]	0	0	0	1	1	1	0	0

1 = yes; 0 = no

Score of 0 - 5 = high risk of bias; score of 6 - 8 = low risk of bias

3.7 Discussion

This review systematically examined the state and quality of the evidence for the use of the IOPI to measure strength and endurance of the tongue and hand in healthy populations and those with a range of medical conditions. A systematic search of the scientific literature published since 1991 yielded 38 studies that addressed this purpose. The IOPI was used mostly for tongue strength (38 studies) and endurance (15 studies) measurement; relatively few studies measured hand strength (9 studies) or endurance (6 studies). Most of the studies used the IOPI as an evaluation tool, although four studies also used it as an intervention tool. Half the studies were conducted in healthy people, mostly in adults. Most of the other participants had disorders associated with dysphagia, such as PD or HNC. In healthy populations, both age and sex influence the tongue strength values obtained, but there is no sex difference in tongue endurance values.

3.8 Consolidation of results

3.8.1 Tongue strength

The IOPI has been most widely used to measure tongue strength, which was the rationale for its original development [84]. Tongue strength can be measured in different tongue positions, and anterior measurements produce higher values than posterior measurements. Measures of tongue strength taken in the anterior position showed that males typically generate higher values than females, but this difference appears to be absent or substantially reduced when posterior measurements are used [54,8,53]. Issues about where the bulb is in the mouth on recording tongue strength are important to note because of the possibility of slippage in the anterior and posterior positions. The average discrepancy between male and female values of tongue strength in healthy populations was 5.2 kPa, as suggested previously [7].

Age also influenced the values obtained, with strength increasing with age in children [81,82] and decreasing with age in adults [49,38,75,37,73,53,58,8,54]. A wide range of tongue strength values have been reported even in healthy populations, no doubt reflecting the influences of the age and sex of the population sampled. Values ranged from 49 to 73 kPa for males and 37 to 67 kPa for females. The analysis of younger (<60 years) compared to older adults indicated an average difference of 8 kPa for males and 9 kPa for females. There are likely to be differences between other age groups as well, but insufficient data exist at present to determine the magnitude of any differences. For future research studies, the age and sex effects on values mean that randomisation to groups should consider stratifying by age and sex.

For clinical practice, there is a need to develop sex-based normative data in a number of age bands, including children and adolescents. Also, a systematic investigation of tongue strength and endurance in adults and children with medical conditions is required as there are limited normative values for individuals with a medical condition.

Three studies conducted in healthy populations reported lower than typical tongue strength measures. Palmer et al. (2008) obtained much lower values during measurements obtained when intramuscular electrodes were inserted into specific muscles of the tongue. It is likely that the presence of the electrodes caused discomfort with muscle contractions altering their performance and reducing maximal strength performance. The second study by Vitorino (2010) examined tongue strength in Portuguese speakers with males (58.20 ± 7.10 kPa) and females (57.10 ± 8.50 kPa) showing 11% lower tongue strength compared to English speakers. The inclusion of a small number ($n = 10$) of older Portuguese speakers may have contributed to the lower values as tongue strength has been shown to decrease in older people. The third study

by Robbins et al. (1995) measured strength at different positions on the tongue (blade, dorsum, tip) in young (22 to 33y) and old (67 to 83y) healthy adults. Despite the values being lower than those reported in many other studies the same trends were observed where older adults had lower tongue strength compared to younger adults.

3.8.2 Tongue endurance

Of the 16 evaluation studies in healthy participants, five measured tongue endurance, which was measured mostly in the anterior position. A wide range of values was observed, but there were no clear sex or age effects on tongue endurance. Two of the five included studies reported values lower than other studies included in this review. Vitorino (2010) reported mean tongue endurance as 16.20 ± 8.57 s. There is no clear explanation for these low values. Neel et al. (2010) reported values that were below the suggested normative range for males (37.85 ± 23.55 s) and for females (25.45 ± 14.11 s). Kays et al. (2010) reported endurance values measured in the anterior position for both males and females, but observed that lower endurance values were obtained from posterior measurements.

3.8.3 Hand strength

Few studies have reported hand strength measured by the IOPI. In general, males tend to have higher values than females, and younger adults higher values than older adults. Populations with a disorder also had lower hand strength values than healthy controls. There is a clear need for further studies to determine representative values for healthy sex-based age groups.

3.8.4 Hand endurance

Duration of hand endurance at 50% of maximum hand strength is not well established. Only one study investigated isometric hand endurance in only healthy

individuals [38]. No significant sex or age effects were observed. Data from this study and the control group data in Table 5 indicate large variation in hand endurance values.

3.8.5 *Studies in populations with a disorder*

Most of the studies to date have been conducted in participants with PD, OPMD or head or neck cancer. Within each of these populations there are still too few data to gain a clear quantitative indication of the types of values that would be typical of these conditions. Most surprisingly, few studies have been conducted using the IOPI in stroke patients or many of the other neurological conditions. Thus, there is wide scope to establish IOPI values for tongue and hand strength and endurance in clinical populations.

3.8.6 *Intervention studies*

Five studies [87,17,18,35,88] used the IOPI as an evaluation tool in intervention research. Four of these studies [17,87,88,18] examined the effects of using the IOPI as a tongue-exercise training device, but no studies have used it as a training device for the hand. These studies clearly indicate that the IOPI can be an effective device for improving tongue strength, and possibly tongue endurance. There is now substantial scope to develop training protocols to address particular tongue strength or endurance deficits. The IOPI is also an effective tool to quantify the impact of tongue training interventions on tongue strength and endurance. There is also clearly potential to use the IOPI to track recovery after interventions or to provide better monitoring of loss of strength or endurance in progressive diseases.

The IOPI appears to be an effective tool to quantify the impact of tongue training interventions on tongue strength and endurance. Randomising participants to groups, including control groups, blinding the assessors, and performing and reporting sample size calculations could clearly improve the quality of reporting of these

intervention studies. There is also room to improve the precision of measures by providing confidence intervals, or at a minimum, standard deviations. Also, the reporting of effects sizes would be beneficial to provide clear objective indications of the magnitude of any effects. Future studies should address these problems to prevent potential reporting bias.

3.9 Strengths and Limitations

There are several strengths to this review: the conduct and reporting of this review is aligned with the PRISMA statement for reporting of systematic reviews and meta-analyses; a comprehensive search strategy across multiple databases with no date restrictions; high agreement levels for quality assessments; and detailed data extraction to allow for comparisons between studies. However, the review also has some limitations. Unpublished literature was not located. This may have resulted in an over-representation of positive treatment effects (i.e., publication bias) in this review. Additionally, due to limited translation resources, only articles published in English were included. Therefore, it is possible that some studies addressing the use of the IOPI were not found. The studies investigating tongue and hand strength and endurance differed across many of the variables examined, including age groups; medical conditions; sex imbalance; study duration; group sizes; evaluation periods; exercise programs; IOPI bulb position; and training specificity. This inconsistency makes it difficult to determine the effect of these variables on outcomes and to compare effects across studies.

3.10 An application for clinical research and routine clinical practice

Based on the findings from this review, there is some evidence supporting the IOPI as an effective tool for research. The IOPI has primarily been used as an evaluation device, and it requires more investigation to determine its effectiveness as an

intervention tool to improve strength or endurance for both adults and children with swallowing problems. There is enormous potential to improve patient outcomes in clinical practice by using a standardised assessment instrument such as the IOPI, which is relatively inexpensive and capable of providing objective measures of tongue strength and endurance rather than relying on the speech-language pathologist's clinical assessment, especially when multiple staff are making assessments. The IOPI has recently been approved by the Australian Therapeutic Goods Administration for use in both research and clinical practice, which may increase the number of studies conducted outside the USA. There is a need to establish clearly relationships between tongue strength and endurance measures and swallowing function and performance in a range of populations. Also the reliability of these strength and endurance measures has not yet been reported.

3.11 Discussion

There is clear evidence indicating the effectiveness of the IOPI for the measurement of tongue and hand strength and endurance. This evidence is strongest for strength measurements, and is best established for measurements of tongue strength. There is a clear need to establish population specific representative values to gain maximum benefit from the use of these measures with this device.

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Chapter 4: Reliability of measurements of strength and endurance using the Iowa Oral Performance Instrument in healthy adults

4.1 Introduction

Appropriate tongue strength is essential for the oral and pharyngeal phases of swallowing and contributes to the formation, placement, and manipulation of a bolus within the oral cavity and propulsion into the pharynx [75]. Examination of tongue strength is a frequent component of the clinical assessment of swallowing by speech-language pathologists. Such assessment is based usually on subjective judgement of the force being applied by the tongue against resistance provided by the speech-language pathologist's fingers resting against the cheek or a tongue depressor. This method raises concerns regarding the reliability of tongue strength measurements due to an inability to eliminate assessor bias and the variability introduced by multiple assessors in most clinical environments. A number of tools have been designed to quantify objectively measures of tongue strength and endurance for research purposes and for routine clinical practice. Such tools have been used to study tongue strength across a range of ages [38,56,10,49,63,84,70,85,72,75,90], in both healthy and clinical populations, and have led to the development of a significant body of literature that documents values of tongue strength. Previous research has determined that the IOPI is the most commonly used of these measurement devices to assess tongue strength [76]. Therefore, it is essential to establish the reliability of measurements obtained with the IOPI. In addition to isometric tongue strength, the IOPI can also be used to measure isometric tongue endurance, and the reliability of this measure should also be determined.

The reliability of a measurement is the reproducibility of the values obtained over multiple test sessions. If measures are reliable, there is little error in the measurement and we can have confidence in the values obtained. There are two main types of reliability: inter-rater and test-retest (intra-rater). Inter-rater reliability assesses the degree to which values are consistent when obtained using different assessors. Test-retest reliability assesses the extent to which the values obtained are consistent from one administration to another, and is performed by one assessor under the same test conditions on multiple occasions. These results provide an indication of the precision or variability with which these measures can be obtained. If this is known, it can be considered in determining the use of a particular measurement tool or interpretation of the values obtained. It is important to be able to differentiate between typical measurement error and real changes being assessed, such as whether a person's condition is improving or deteriorating or if a treatment is having the desired effect, and this is facilitated by a comprehensive evaluation of test-retest reliability. Reliable tests on a number of people over multiple test sessions have the following characteristics: there is little or no change in the group means of the sessions (differences may indicate learning effects); there is little or no within-subject variation over the sessions; and there is a strong test-retest correlation between the sessions [91].

A number of studies have investigated inter-rater reliability of tongue strength using the IOPI [67,56,92,70,6,75,55,93,65,37,61,58] in a range of populations. Typically, values obtained by novice users of the IOPI were compared to those of an experienced user. The measure of reliability was the correlation between values obtained from different users. The inter-rater correlation coefficients were all stronger than $r = 0.75$ with one exception; Solomon et al. (2008) reported $r = 0.535$ in a dysarthric population [65]. Youmans and Stierwalt (2006) also compared the group

means between assessors and found no significant difference [75]. Only one study (Palmer 2010) reported inter-rater reliability for tongue endurance, with a perfect correlation ($r = 1$) between assessors [61].

Nine studies have reported test-retest reliability of tongue strength [55,92,6,51,93,65,58,70]. Robin et al. (1991) provided the first report describing the test-retest variability as low (implying reliability was high) based on the small size of an individual participant's standard deviations [84]. Subsequent studies [67,55,92,70,6,75,51,93,65,37,61,58,54] reported strong correlations as measures of test-retest reliability with correlation coefficients ranging from $r = 0.76$ to $r = 0.99$. Only one study (Chang et al (2008)) reported tongue endurance test-retest reliability ($r = 0.99$) [51].

In addition, Lazarus et al (2000) reported that assessors had to meet pre-established criteria of at least $r = 0.76$ for inter-observer reliability and $r = 0.90$ for test-retest reliability prior to conducting study assessments of tongue strength. In addition, it should be noted that the highest tongue strength value obtained was used in all these investigations of the reliability of IOPI tongue strength measures. In summary, inter-rater and test-retest reliability of the IOPI measurement of tongue strength have been reported but there has been almost total reliance on correlation coefficients as the measure of reliability. Consequently, whether the values obtained change consistently with familiarisation (identifiable by a % change in the mean of a group of people) over several sessions has not been identified. Further, the magnitude of any within-subject variation (typical error) that needs to be accounted for in interpreting clinical improvement has not been investigated.

As well as measuring tongue strength and endurance, the IOPI has an additional attachment that allows measurement of hand strength and endurance. Handgrip strength

is an important predictor of functional decline associated with normal aging and is often used to characterise the general strength of individuals [94]. Consequently, it is appropriate to assess the reliability of the IOPI for handgrip strength and endurance at the same time as tongue strength and endurance; only Robin et al [84] indicated that these handgrip strength measures had low variability.

The primary aim of this study was to determine the test-retest reliability of the IOPI as a tool for assessments of both tongue and handgrip strength and endurance in a healthy population. A secondary aim was to identify characteristics of assessments that improve the reliability of these strength and endurance measurements for both research and clinical practice.

4.2 Methods

4.2.1 Study Design

Healthy adults underwent anterior and posterior tongue and handgrip strength and endurance assessment using the IOPI on four occasions separated by approximately one week. Strength assessments consisted of three attempts to exert maximal isometric force. Endurance assessments consisted of one attempt to sustain 50% of maximal isometric force. Participants were randomised to perform tongue or hand measurements first. One investigator (VA) provided all instructions to the participants and conducted all the tests. Three measures of reliability were assessed according to Hopkins [91]. Exploratory secondary analyses were also conducted to determine whether single peak or mean strength values were more reliable, and to identify other protocol strategies that influence the reliability of these strength and endurance measures.

4.2.2 Participants

Healthy adults were recruited from staff and students at The University of Newcastle. Participants completed a health and medical history questionnaire to

determine their eligibility. Participants were included if they ranged in age from 18 to 60 years, and were healthy with no previous or current swallowing or hand problems. Study exclusion criteria were a history of swallowing problems; an abnormal oral structure and function; any history of neurologic, respiratory or gastrointestinal impairment; any current or previous major injury to the tongue or hand; any tongue piercings; difficulty placing an instrument on the tongue; or a history of seizures. The University of Newcastle Human Research Ethics Committee approved the study and written informed consent was obtained from all participants prior to participation.

4.2.3 Instrumentation

Tongue strength and endurance assessments were collected using the current version (2.2) of the IOPI by placing a small, air-filled bulb longitudinally along the hard palate. The IOPI is a portable, handheld tool containing pressure-sensing circuitry, a peak-hold function, and a timer. It uses a blue air-filled PVC tongue bulb (approximately 3.5cm long and 1.2cm in diameter) which is pliable and has an approximate internal volume of 2.8ml. The bulb was connected to the IOPI via an 11.5cm PVC connecting tube with the pressure exerted against the bulb measured and displayed in kilopascals (kPa). Unlike earlier versions of the IOPI, which showed the green light as the middle light in a row of lights, the current model used in this study has the green light as the top light (100%). Handgrip strength and endurance were measured by placing a handgrip pressure bulb in the centre of the palm of the dominant hand, with the fingers wrapped around it. Participants were instructed not to press the bulb with the fingertips as this may create artificial increases in pressure. The handgrip bulb is made of soft rubber with a small air-filled bulb that was immersed in an incompressible viscous fluid in the middle. Visual feedback to participants for assessment of endurance was achieved by the light-emitting diode (LED) display on the IOPI screen. To ensure

accuracy of measurement, calibration was checked once a week as recommended in the IOPI manual.

4.2.4 Procedure

Participants were seated in an upright position in a straight-backed chair for the duration of the testing performed at the university. Testing was conducted at various times during the day and participants were not required to fast prior to the assessment. Maximum tongue and handgrip strength and endurance measures were obtained following a previously documented procedure [84,63] with the order of tests randomised using a web-based random assignment generator. Attempts allowed in the first session included one or more non-maximal practice trials to ensure the participant understood the task. Participants were provided with instructions for all tasks and verbal encouragement was given during each of the trials. All study participants were given verbal encouragement by the investigator saying “Push, push, push!” or “Squeeze, squeeze, squeeze”. Maximum strength ($P_{\max}$) was determined as the highest pressure recorded of the three trials [49]. The length of the endurance trial was measured in seconds using a stopwatch. Cessation of the endurance trial occurred when one of the following occurred: 1) 50% of $P_{\max}$ (represented by a green LED) could not be maintained for more than 2 s; 2) 80% of the $P_{\max}$ (represented by the second red light below the green LED) could not be maintained for more than 0.5 s; or 3) the pressure dropped sharply [92].

Tongue strength and endurance

Tongue strength and endurance data were collected in two bulb positions, the antero-median and the postero-median. To obtain antero-median measures, the IOPI bulb was placed in the centre of the tongue directly behind the front teeth (Figure 4.1).

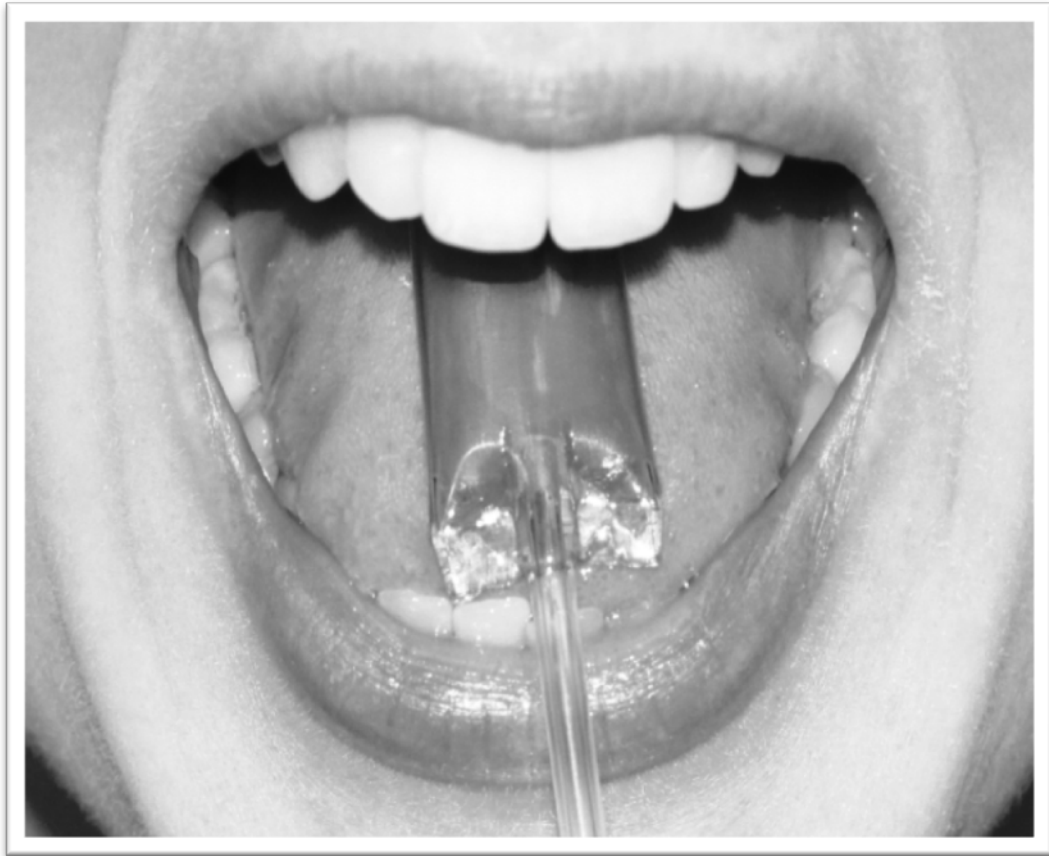


Figure 4.1. Anteromedian position of the IOPI bulb in the oral cavity.

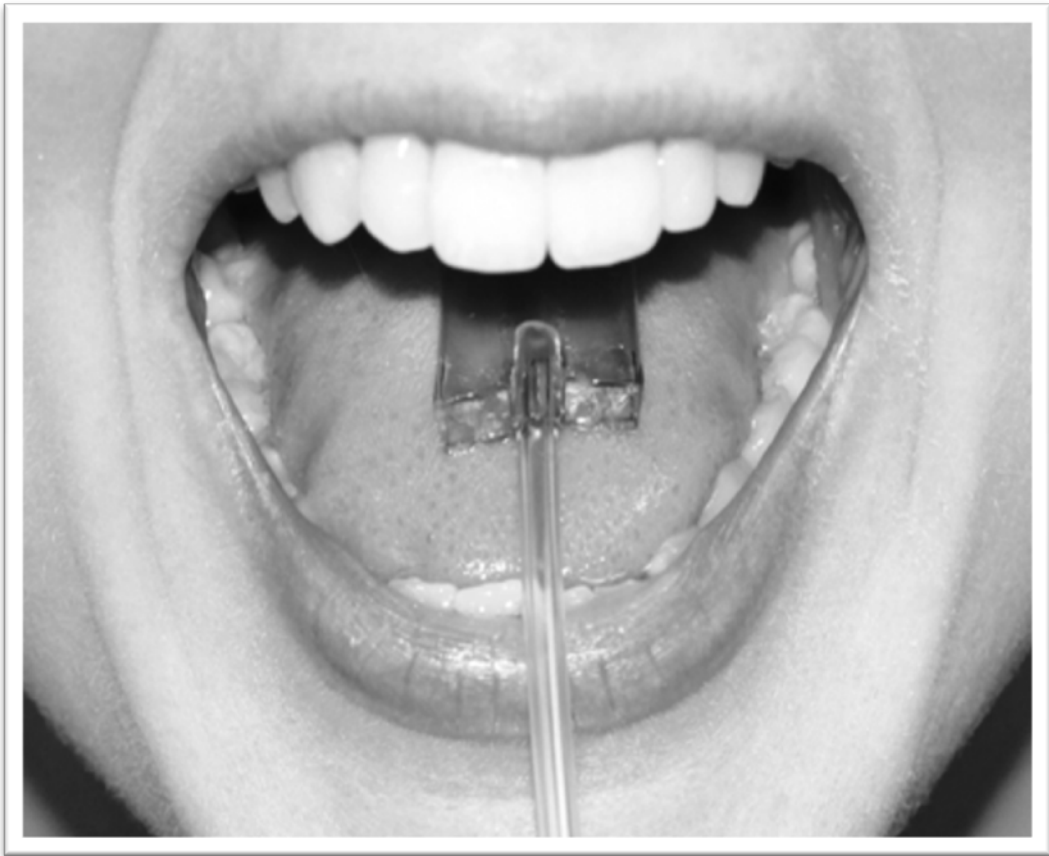


Figure 4.2. Posteromedian position of the IOPI bulb in the oral cavity

The postero-median position was defined by placing the straight edge of the IOPI bulb parallel to the anterior edge of the individual's back molars (Figure 4.2). Individual bulb placement using these landmarks allowed for a standardised placement in relation to normal structures within the oral cavity. Each participant was shown a picture of the correct bulb placement plus a standardised verbal description of the placement at the beginning of each testing session. The investigator then observed the placement prior to each measurement and further directions provided if necessary. While individual anatomy across participants varied (palatal shape and height of the palatal vault), standardised instruction and placement demonstrations were used to ensure the bulb location was as consistent as possible. Once the bulb was in the correct position in the oral cavity, participants were given instructions to push the bulb against the roof of their mouth with their tongue as hard as possible. Maximum tongue strength involved three consecutive trials each of approximately two-second duration, with a short rest between trials while the investigator recorded the peak pressure measurement. No participant had a hypersensitive gag response with the bulb in the posterior position.

For endurance, the IOPI was set to 50% of the participants' maximal tongue strength and participants were required to press the bulb with the tongue against the roof of the mouth as hard as required to maintain the target force for as long as possible. Only one measurement of each anterior and posterior endurance measure was taken during each session. Timing was started when the pressure reached its target force as indicated by the appearance of a green light located on the right side of the device and participants were able to monitor their performance via the LED array.

While collecting tongue strength and endurance measures, the contributing role of the jaw has been questioned. The jaw provides structural support for the articulators, particularly the tongue and it has been suggested that tongue measures may include

contributions from both the tongue and the jaw. This relationship was the basis of an investigation by Solomon and Munson (2004) [68] who examined tongue strength and endurance with 10 healthy adults where the jaw was unconstrained or constrained with a bite block. Results showed that measures of tongue function were lower when the jaw was constrained than when the jaw was unconstrained. Solomon and Munson (2004) determined that maximal measures of tongue strength and endurance were best assessed with an unconstrained jaw. Therefore, the jaw was unconstrained during all measurement tasks for this study.

Handgrip strength and endurance

The investigator (VA) ensured the correct position of the bulb within the hand (Figure 4.3) and participants were given instructions to squeeze the bulb as hard as possible with the whole hand for 1-2 seconds [7]. Maximum hand strength involved three consecutive trials of approximately one-second duration each, with a short rest between trials while the investigator recorded the peak pressure measurement. For hand endurance, the IOPI was set to 50% of the participant's maximal hand strength and participants were required to squeeze the bulb as hard as required to maintain the target force for as long as possible. The timing procedure was the same as for tongue endurance.

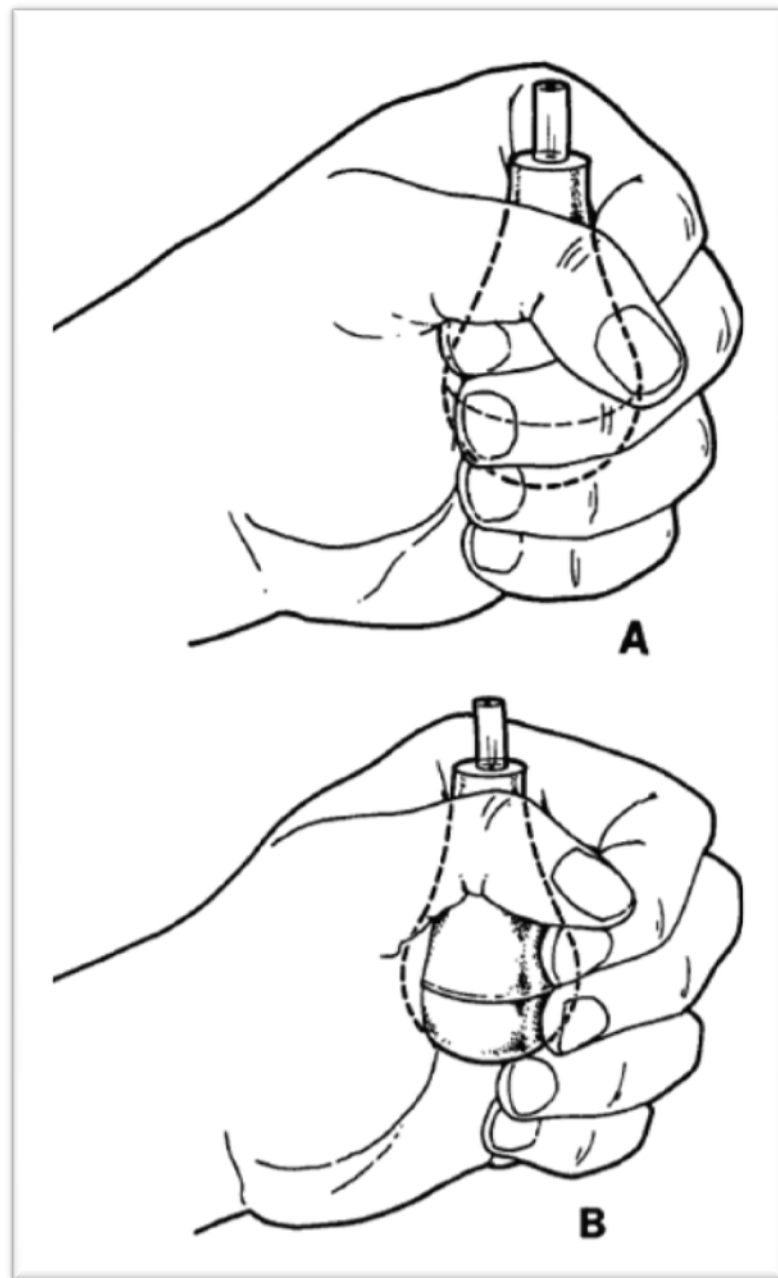


Figure 4.3. A. Standard posture for hand bulb. B. Incorrect posture for hand bulb. Note that finger tips are pushing on bulb.

Note. From IOPI Medical. Copyright © 2011 IOPI Medical LLC. Reproduced with permission

4.2.5 Data management and analysis

All data were entered into Microsoft Excel (Microsoft Windows XP Professional, Version 5.1.2600) for data management and then exported into appropriate analysis programs. Participant characteristics were analysed using a statistical software program (SPSS Statistics 20) and descriptive statistics are presented as a mean $\pm$ SD.

All reliability measures were analysed using a reliability spreadsheet developed by Hopkins and designed to assess the precision of measurement [95]. Three statistical analyses providing different indices of reliability were used. Random and systematic change outcomes through sampling error and learning effects were assessed using % change in the mean between sessions. Within-subject variation was determined using typical error expressed as a coefficient of variation (%) as follows:

typical error = $[(sdiff/\sqrt{2})/\text{mean}]/100$ where *sdiff* is the standard deviation of difference scores between two trials. This measure represents technical and biological sources of error in measurement within participants. Rank order repeatability of the results among trials was investigated using intraclass correlation coefficients (ICC, *r*). An acceptable level of variability in test measures is up to the researcher to determine, however values for reliability measures are a % change in the mean and typical error between sessions of less than 5% (desirable) or 10% (acceptable), and ICC levels above 0.8 (desirable) and 0.6 (acceptable) [91]. The magnitude of any change was assessed by effect sizes using: large ($d > 0.8$); medium ($d = 0.5$ to 0.79); small ($d = 0.2$ to 0.49); and anything smaller than $d = 0.19$ was regarded as insubstantial or trivial [89].

When three strength trials of a measure are conducted in a session, there is uncertainty regarding which of these values should be used in evaluation, and in this study, whether this choice altered the reliability of the measures. Maximum tongue (anterior and posterior positions) and handgrip strength values were analysed using

three approaches: 1) the highest of the three trials in the session; 2) the average of the three trials in the session; and 3) the average of the two highest trials in the session. Further, when three strength trials were conducted in a session, it is possible that the values will vary substantially. There is greater confidence that a true measure of maximal strength has been obtained in a session if the variation between the two highest values is small. Therefore, additional exploratory analyses were conducted in subsets of participants where the two highest values obtained for a measure in a session varied by ≤ 5 kPa for tongue strength and ≤ 15 kPa for handgrip strength. Participants were included in this additional analysis if they met the criteria in all four sessions. If the maximal strength values obtained varied substantially between sessions, and the maximum strength obtained in the session was used to set the force target to assess endurance, then substantial variation has been introduced to the endurance assessment. Therefore, a secondary analysis of the reliability of endurance assessments was conducted in a subset of participants where the maximal force used to set the 50% target force varied by ≤ 5 kPa for tongue strength and ≤ 15 kPa for handgrip strength across all four sessions.

Following the reliability analysis, the ‘minimum-raw-change required’ was determined to give an indication of the magnitude of change in a value needed for a meaningful change in the tested group mean with 95% confidence if such changes are to be used as outcome measures in intervention studies [91]. This value can also be used to determine sample sizes for future studies. This figure was calculated using the session 1 test mean multiplied by the percentage typical error between sessions 1-2 (upper 95% CI) [96]. A second calculation was performed based on the session 2-3 data and compared to the first calculation.

4.3 Results

Fifty-one participants (21 males and 30 females) were recruited. All participants met the inclusion criteria and no potential participants met any exclusion criteria.

Characteristics of the participants are presented in Table 4.1. The mean ($\pm$ SD) time between assessments sessions was 12 ± 9 (range 5-21) days.

Table 4.1

Characteristics of participants (n = 81); data are Mean ± SD

	Age (years)	Weight (kg)	Height (cm)	BMI^a (kg.m⁻²)
Healthy adults (n = 51)				
- Males	29.6 ± 9.3	79.3 ± 8.3	180.3 ± 6.8	24.4 ± 2.3
- Females	27.3 ± 8.2	64.0 ± 11.3	166.8 ± 5.0	23.0 ± 3.7
- All Participants	28.2 ± 9.3	70.3 ± 12.7	172.3 ± 8.8	23.6 ± 3.3
Elderly adults (n = 30)				
- Males	88.0 ± 4.8	73.9 ± 12.2	1.74 ± 5.0	24.5 ± 4.2
- Females	89.2 ± 5.3	64.8 ± 13.9	1.58 ± 5.3	26.1 ± 5.1
- All Participants	88.9 ± 5.2	66.6 ± 13.9	1.61 ± 8.5	25.7 ± 4.9

Note. BMI = Body Mass Index^a

4.3.1 Tongue and hand strength analysis

Analysis based on highest maximum strength value from three trials

Reliability statistics for the highest of three trials in each session for tongue (anterior and posterior) and hand strength are presented in Table 4.2. Similar reliability patterns were observed for both the tongue and hand strength measures.

Change in the mean

For anterior tongue strength, the % change in the mean was largest between sessions 1-2 and substantially smaller in subsequent sessions. The mean difference between sessions 1-2 was 1.02 kPa (95% confidence interval (CI): -1.27 - 3.31). Analysis by paired *t*-test showed that the difference between sessions 1-2 was not significant ($p = 0.375$), and the magnitude of this difference was determined to be trivial ($d=0.08$) using effect size. The mean differences between sessions 2-3 (0.04 kPa; 95% CI: -1.49 - 1.57) and sessions 3-4 (0.17 kPa; 95% CI: -1.56 – 1.21) were also not statistically significant ($p = 0.96$ and $p = 0.80$, respectively) and were trivial in magnitude (effect sizes were $d = 0.003$ and $d = 0.07$, respectively).

For posterior tongue strength, the % change in the mean was also largest between sessions 1-2 and substantially smaller between sessions 2-3 and 3-4. The mean difference between sessions 1-2 was 1.26 kPa (95% CI: -0.99 – 3.50; $p = 0.267$), and the magnitude of this difference was trivial ($d = 0.16$). The mean differences between sessions 2-3 (0.08 kPa; 95% CI: -1.55 – 1.39) and sessions 3-4 (0.14 kPa; CI: -1.68 – 1.95) were also not statistically significant ($p = 0.915$ and $p = 0.880$, respectively; effect sizes: $d = 0.003$ and $d = 0.01$, respectively).

For handgrip strength, the % change in the mean was also largest between sessions 1-2 and substantially smaller in subsequent sessions, although the magnitude of variation was higher with handgrip strength compared to tongue strength. The mean

difference ($p = 0.05$) between sessions 1-2 was 8.02 kPa (95% CI: 0.01 -16.03), which was small in magnitude ($d = 0.22$), whereas mean differences between sessions 2-3 (2.56 kPa; 95% CI: -3.73 – 8.87; $p = 0.416$; $d = 0.02$) and sessions 3-4 (0.52 kPa; 95% CI: -6.27 – 5.21; $p = 0.854$; $d = 0.03$) were trivial.

These results indicate good reliability for group assessments of tongue and hand strength; also, one familiarisation session provided improved reliability of the values obtained in healthy adults.

Table 4.2
 Test-retest reliability of tongue and handgrip strength measures using highest value of 3 trials in 51 participants

Outcome Measure	Session 1	Session 2	Session 3	Session 4		Change in Mean (%)	95% CI	Typical error as CV (%)	95% CI	Mean-typical error as CV (%)	95% CI	ICC (r)	95% CI	Min. change score (kPa)
Tongue strength (kPa)														
Anterior	57.3 ± 11.8	58.3 ± 12.4	58.3 ± 11.5	58.1 ± 10.1	Session 2-1	1.70	-2.4 - 5.9	10.80	8.9 - 13.5	8.20	7.2 - 9.5	0.77	0.63 - 0.86	7.74
					Session 3-2	0.40	-2.2 - 3.0	6.80	5.7 - 8.5			0.90	0.83 - 0.94	4.96
					Session 4-3	0.10	-2.3 - 2.7	6.40	5.3 - 8.0			0.89	0.81 - 0.94	
Posterior	53.9 ± 12.4	55.2 ± 12.0	55.1 ± 11.5	55.2 ± 11.8	Session 2-1	2.50	-1.9 - 7.2	11.80	9.8 - 14.9	10.50	9.2 - 12.1	0.79	0.66 - 0.87	8.03
					Session 3-2	0.30	-3.0 - 3.8	8.90	7.4 - 11.2			0.86	0.76 - 0.92	6.18
					Session 4-3	0.00	-3.9 - 4.0	10.50	8.7 - 13.2			0.79	0.66 - 0.87	
Hand Strength (kPa)	151.7 ± 35.9	159.7 ± 38.4	160.3 ± 39.6	161.7 ± 38.9	Session 2-1	5.00	-0.8 - 11.0	15.20	12.6 - 19.3	12.90	11.3 - 14.9	0.69	0.51 - 0.81	29.28
					Session 3-2	2.10	-2.6 - 7.1	12.60	10.5 - 15.9			0.91	0.64 - 0.87	25.39
					Session 4-3	-0.70	-4.5 - 3.3	10.30	8.5 - 13.0			0.90	0.74 - 0.91	

Typical error

In general, the typical error based on the highest value of the three trials was > 10% and therefore higher than the criterion standard for acceptable for all three strength measures between sessions 1 and 2. Typical error decreased after the first session for all strength measures however only anterior tongue strength typical error clearly met the criterion for acceptability.

Intraclass Correlation Coefficient (ICC)

The ICCs for strength ranged from acceptable to desirable levels, again with higher ICCs being achieved following session 1. All measures of tongue strength showed good reliability as indicated by correlation coefficients considered large to very large (0.77 – 0.90). Measures of handgrip strength also showed good reliability and were considered large to very large (0.69 – 0.91) [96].

Analyses using the average of two or three trials

Additional reliability analyses were conducted using the average of the three trials in each session or the average of the highest two values obtained. Little difference was observed between these two approaches, and only data from the average of the highest two trials are presented in Table 4.3. Similar patterns of response to those obtained using the average of three values (Table 4.4) was observed regarding improved reliability after session 1, again supporting the benefits of familiarisation. Some small reductions in typical error using an average value compared to a single maximum value were observed.

Table 4.3
 Test-retest reliability of tongue and handgrip strength measures using average value of 2 highest trials in 51 participants

Outcome Measure	Session 1	Session 2	Session 3	Session 4		Change in Mean (%)	95% CI	Typical error as CV (%)	95% CI	Mean-typical error as CV (%)	95% CI	ICC (r)	95% CI	Min. change score (kPa)
Tongue strength (kPa)														
Anterior	55.3 ± 11.5	56.6 ± 12.0	56.9 ± 11.6	56.3 ± 10.3	Session 2-1	2.30	-1.2 - 6.0	9.30	7.7 - 11.6	7.20	6.4 - 8.3	0.83	0.71 - 0.90	6.41
					Session 3-2	0.60	-1.5 - 2.8	5.60	4.7 - 7.0			0.93	0.88 - 0.96	3.96
					Session 4-3	-0.60	-3.0 - 1.8	6.30	5.2 - 7.9			0.90	0.84 - 0.94	
Posterior	51.8 ± 12.3	54.0 ± 12.2	53.6 ± 11.7	53.9 ± 11.9	Session 2-1	4.40	-0.2 - 9.2	12.10	10.0 - 15.2	10.60	9.3 - 12.2	0.80	0.67 - 0.88	7.87
					Session 3-2	-0.20	-3.3 - 3.0	8.20	6.8 - 10.3			0.89	0.81 - 0.93	5.56
					Session 4-3	0.20	-3.9 - 4.5	11.10	9.2 - 14.0			0.79	0.65 - 0.87	
Hand Strength (kPa)	146.2 ± 31.7	150.5 ± 32.8	153.7 ± 32.8	155.0 ± 34.4	Session 2-1	2.60	-2.1 - 7.5	15.00	12.8 - 18.3	12.30	11.0 - 13.8	0.66	0.50 - 0.77	26.75
					Session 3-2	2.60	-1.2 - 6.4	11.80	10.1 - 14.3			0.78	0.66 - 0.85	21.52
					Session 4-3	0.60	-2.4 - 3.6	9.40	8.0 - 11.3			0.85	0.77 - 0.90	

Table 4.4
Test-retest reliability of tongue and handgrip strength measures using average value of 3 trials in 51 participants

Outcome Measure	Session 1	Session 2	Session 3	Session 4		Change in Mean (%)	95% CI	Typical error as CV (%)	95% CI	Mean-typical error as CV (%)	95% CI	ICC (r)	95% CI	Min. change score (kPa)
Tongue strength (kPa)														
Anterior	53.4 ± 11.8	54.8 ± 11.9	55.3 ± 11.8	55.0 ± 10.4	Session 2-1	2.60	-1.0 - 6.4	9.50	7.9 - 12.0	7.60	6.7 - 8.7	0.84	0.74 - 0.91	6.41
					Session 3-2	1.20	-1.2 - 3.7	6.20	5.2 - 7.8			0.93	0.87 - 0.96	4.27
					Session 4-3	-0.10	-2.6 - 2.5	6.70	5.6 - 8.4			0.90	0.83 - 0.94	
Posterior	50.2 ± 12.4	52.2 ± 12.1	52.1 ± 11.8	52.0 ± 11.8	Session 2-1	4.20	-0.6 - 9.2	12.40	10.3 - 15.7	10.90	9.6 - 12.6	0.80	0.68 - 0.88	7.88
					Session 3-2	0.30	-2.8 - 3.6	8.30	6.9 - 10.4			0.90	0.83 - 0.94	5.43
					Session 4-3	-0.40	-4.6 - 4.0	11.50	9.6 - 14.5			0.79	0.66 - 0.87	
Hand Strength (kPa)	138.0 ± 26.5	143.3 ± 29.0	146.9 ± 29.8	149.6 ± 32.1	Session 2-1	3.40	-1.8 - 8.8	13.70	11.3 - 17.2	11.50	10.1 - 13.3	0.68	0.49 - 0.80	29.28
					Session 3-2	2.90	-1.3 - 7.3	11.10	9.2 - 14.0			0.78	0.65 - 0.87	23.74
					Session 4-3	1.50	-2.1 - 5.1	9.30	7.7 - 11.7			0.84	0.73 - 0.90	

Additional criteria to reduce typical error

As described above, % change in the mean and ICC indicators of reliability met the acceptable criteria but typical error levels were generally higher than acceptable. Therefore, an exploratory analysis was conducted with a subset of the data with the following additional criteria: for tongue strength, participants (anterior: $n = 28$ and posterior: $n = 25$) with the average of the two highest values within a session differing by ≤ 5 kPa, and for hand strength ($n = 28$), values differing by ≤ 15 kPa were included (Table 4.5). The primary impact of the additional criteria was to reduce the typical error to acceptable or even desirable levels after session 1. This has important implications for the reliability of values obtained when monitoring individuals rather than groups.

Minimum change score required

This value indicates the minimum magnitude of change in a variable required for the change to be meaningful, for example, following an intervention, and depends in part on the reliability of the measurements. As can be observed in tables 4.2, 4.3 and 4.4, the minimum raw change required is much higher if the first session is used for the determination compared to data from a subsequent session, again reinforcing the advantages of familiarisation. The second observation is that using the additional criteria of having at least two measures within 5 kPa (tongue) or 15 kPa (hand) provides a further reduction in the minimum raw change required to be meaningful.

Table 4.5
 Test-retest reliability of tongue and handgrip strength measures using average value of 2 highest trials that are ≤ 5 kPa (tongue) or 15kPa (hand) apart

Outcome Measure	Session 1	Session 2	Session 3	Session 4		Change in Mean (%)	95% CI	Typical error as CV (%)	95% CI	Mean-typical error as CV (%)	95% CI	ICC (r)	95% CI	Min. change score (kPa)
Tongue strength (kPa)														
Anterior (n=28)	56.1 ± 11.2	58.2 ± 12.6	58.8 ± 12.7	57.4 ± 11.0	Session 2-1	3.50	-2.1 - 9.5	10.70	8.4 - 14.9	7.10	6.0 - 8.7	0.76	0.52 - 0.88	8.36
					Session 3-2	1.10	-1.4 - 3.6	4.50	3.6 - 6.2			0.96	0.90 - 0.98	3.61
					Session 4-3	-1.8	-4.1 - 0.5	4.40	3.5 - 6.0			0.95	0.91 - 0.98	
Posterior (n=25)	54.8 ± 11.5	57.0 ± 11.8	57.3 ± 12.0	57.4 ± 11.6	Session 2-1	4.20	-1.8 - 10.6	10.70	8.3 - 15.2	7.80	6.5 - 9.6	0.78	0.56 - 0.90	8.33
					Session 3-2	0.60	-2.5 - 3.7	5.40	4.2 - 7.6			0.94	0.86 - 0.97	4.33
					Session 4-3	0.30	-3.2 - 3.9	6.30	4.9 - 8.9			0.91	0.80 - 0.96	
Hand Strength (kPa) (n=28)	146.2 ± 31.7	141.6 ± 30.7	143.3 ± 26.2	145.5 ± 31.4	Session 2-1	2.60	-2.1 - 7.5	15.00	12.8 - 18.3	12.30	11.0 - 13.8	0.66	0.50 - 0.77	26.75
					Session 3-2	2.00	-0.8 - 4.8	6.30	5.2 - 8.2			0.92	0.88 - 0.96	11.61
					Session 4-3	0.90	-2.3 - 4.2	7.50	6.1 - 9.7			0.88	0.79 - 0.93	

4.3.2 Tongue and hand endurance analysis

Reliability statistics for tongue (anterior and posterior) and hand endurance are presented in Table 4.6. Similar reliability patterns were observed for both tongue and hand endurance measures.

Analysis based on endurance values with all participants

Change in the mean

For anterior tongue endurance, the % change in the mean was not necessarily improved with subsequent sessions. The mean difference between sessions 1-2 was -2.49 s (95% CI: -4.86 – -0.12) which although small (effect size $d = 0.28$) was statistically significant ($p = 0.04$). The mean differences between sessions 2-3 (1.04 s; 95% CI: -1.33 – 3.48; $p = 0.37$; $d = 0.13$, trivial) and sessions 3-4 (1.55 s; 95% CI: -0.53 – 3.63; $p = 0.140$; $d = 0.18$, trivial) were not statistically significant.

For posterior tongue endurance, the % change in the mean was largest between sessions 1-2 and substantially smaller between sessions 2-3 and 3-4. The mean difference between trials 1-2 was 0.47 s (95% CI: -1.36 – 2.30; $p = 0.607$; $d = 0.06$, trivial). The mean differences between sessions 2-3 (0.59 s; 95% CI: -1.24 – 2.41) and sessions 3-4 (0.12 s; CI: -1.46 – 1.69) were also not statistically significant ($p = 0.520$ and $p = 0.881$, respectively) and were trivial in magnitude (effect sizes were $d = 0.07$ and $d = 0.01$, respectively).

For handgrip endurance, the % change in the mean was also largest between sessions 1-2 and substantially smaller in subsequent sessions, although the magnitude of variation was higher with handgrip endurance compared to tongue endurance. The mean difference between sessions 1-2 was -6.77 s (95% CI: -15.45 -1.92; $p = 0.12$), which was small in magnitude ($d = 0.26$) whereas the mean differences between sessions 2-3

(1.20 s; 95% CI: -6.11 – 8.50; $p = 0.744$; $d = 0.03$) and sessions 3-4 (-0.92 s; 95% CI: -7.83 – 5.99; $p = 0.790$; $d = 0.03$) were trivial.

Typical error

In general, the typical error based on the highest value of the three trials was > 10% and therefore higher than the criterion standard for acceptable for all three endurance measures. Typical error improved after the first trial with reduced variation most noticeable in posterior tongue endurance. Although anterior tongue endurance and handgrip endurance typical errors showed improvement following session 1, the typical errors of all endurance measures were considered unacceptable.

Intraclass Correlation Coefficient (ICC)

The ICCs ranged from unacceptable to acceptable levels, again with higher ICCs being achieved following session 1 for posterior tongue and hand endurance. All trials of tongue endurance showed moderate reliability as indicated by correlation coefficients considered small to medium (0.47 – 0.79). Trials of handgrip endurance also showed poor reliability and the correlations were considered small to medium (0.27 – 0.72) [96].

These results indicate moderate reliability for group assessments of posterior tongue and hand endurance following one familiarisation session, but poor reliability of individual measurements for all endurance assessments.

Table 4.6
Test-retest reliability of tongue and handgrip endurance measures in 51 participants

Outcome Measure	Session 1	Session 2	Session 3	Session 4		Change in Mean (%)	95% CI	Typical error as CV (%)	95% CI	Mean-typical error as CV (%)	95% CI	ICC (r)	95% CI	Min. change score (s)
Tongue endurance (s)														
Anterior	14.6 ± 9.9	12.2 ± 7.9	13.2 ± 9.0	14.8 ± 7.6	Session 2-1	-15.50	-30.8 - 3.1	65.10	52.1 - 86.5			0.54	0.31 - 0.71	12.63
					Session 3-2	1.80	-19.7 - 29.2	81.90	65.0 - 110.4	70.80	60.7 - 84.7	0.47	0.23 - 0.66	13.47
					Session 4-3	31.80	8.0 - 60.8	64.80	51.9 - 86.1			0.56	0.34 - 0.72	
Posterior	10.4 ± 8.1	10.8 ± 7.1	11.4 ± 8.2	11.5 ± 8.7	Session 2-1	11.30	-8.6 - 35.4	63.90	51.2 - 84.8			0.62	0.42 - 0.76	8.82
					Session 3-2	2.50	-12.6 - 20.3	49.60	40.0 - 64.9	53.10	45.8 - 62.9	0.73	0.57 - 0.83	7.01
					Session 4-3	-1.70	-15.2 - 13.9	44.90	36.4 - 58.6			0.79	0.66 - 0.87	
Hand endurance (s)	60.4 ± 26.6	53.6 ± 24.6	54.8 ± 33.9	53.9 ± 26.3	Session 2-1	-11.50	-25.0 - 4.4	51.60	41.6 - 67.7			0.27	0.00 - 0.51	40.89
					Session 3-2	-2.50	-13.0 - 9.1	32.90	26.8 - 42.3	43.10	37.4 - 50.9	0.72	0.55 - 0.83	22.67
					Session 4-3	3.00	-10.8 - 19.0	43.70	35.5 - 57.0			0.53	0.30 - 0.70	

Endurance analyses using values of maximal strength ≤ 5 kPa or 15 kPa apart

Additional reliability analyses were conducted using the participants where the maximum strength values across sessions were consistently ≤ 5 kPa apart for tongue strength and ≤ 15 kPa for hand strength (Table 4.7). Using this approach, % change in the mean values for posterior tongue and hand endurance improved following session 1 and met either desirable or acceptable levels. Little improvement was observed using this approach for anterior tongue endurance. In general, typical error was much higher than the criterion standard of acceptable, i.e., $> 10\%$ for all three endurance measures, ranging from 52.1% – 78.2% for anterior; 38.8% – 54.6% for posterior; and 25.7% – 45.1% for the hand.

Minimum raw change required for endurance measures

As can be observed in Table 4.6, the minimum change score required was generally higher if data from the first session was used compared to the subsequent session, again reinforcing the advantages of familiarisation, although the impact of this was most notable for hand endurance. The second observation is that using the additional criteria of reducing the variation of the strength value to within 5 kPa (tongue) or 15 kPa (hand) between sessions provided a further reduction in the minimum raw change required only for anterior tongue endurance.

Table 4.7
Test-retest reliability values of tongue and handgrip endurance values from participants whose peak tongue and handgrip strength values were $\leq 5\text{kPa}$ (tongue) and $\leq 15\text{kPa}$ (hand) apart over test sessions

Outcome Measure	Session 1	Session 2	Session 3	Session 4		Change in Mean (%)	95% CI	Typical error as CV (%)	95% CI	Mean-typical error as CV (%)	95% CI	ICC (r)	95% CI	Min. change score (s)
Tongue endurance (s)														
Anterior (n=28)	15.5 $\pm$ 10.6	12.0 $\pm$ 8.1	14.9 $\pm$ 9.3	14.7 $\pm$ 6.6	Session 2-1	-19.10	-40.6 - 9.7	74.30	55.1 - 113.0			0.46	0.12 - 0.71	17.52
					Session 3-2	20.50	-12.2 - 65.5	78.20	57.9 - 119.5	68.60	56.1 - 88.4	0.46	0.11 - 0.71	14.34
					Session 4-3	13.80	-9.6 - 43.2	52.10	39.3 - 77.0			0.66	0.38 - 0.83	
Posterior (n=25)	13.1 $\pm$ 9.5	12.8 $\pm$ 6.6	12.6 $\pm$ 7.7	14.0 $\pm$ 9.7	Session 2-1	7.80	-16.4 - 39.1	54.60	40.6 - 83.4			0.55	0.21 - 0.78	10.93
					Session 3-2	-5.30	-21.8 - 14.7	38.80	29.2 - 57.8	47.10	38.6 - 60.7	0.69	0.41 - 0.85	7.40
					Session 4-3	6.50	-15.0 - 33.4	47.20	35.2 - 71.2			0.65	0.36 - 0.83	
Hand endurance (s) (n=28)	60.3 $\pm$ 23.3	59.5 $\pm$ 23.5	60.8 $\pm$ 30.5	55.9 $\pm$ 21.9	Session 2-1	-3.20	-21.1 - 18.7	45.10	34.2 - 66.0			0.25	-0.13 - 0.57	39.80
					Session 3-2	-0.60	-12.3 - 12.7	25.70	19.8 - 36.5	38.20	31.8 - 48.0	0.79	0.59 - 0.90	21.72
					Session 4-3	-5.80	-22.2 - 14.2	42.00	31.9 - 61.1			0.52	0.18 - 0.74	

4.4 Discussion

The key findings of this study are that tongue and hand isometric strength measurements obtained using the IOPI demonstrate excellent reliability for analysis of groups when a familiarisation session is provided prior to clinical evaluation. Further, performing multiple trials within an assessment session with consistency criteria is an additional strategy to improve the reliability of these strength measurements. It should be noted that further testing to investigate multiple trials in clinical populations would be of interest as these populations have less motor stability than healthy individuals. These strategies also improve the sensitivity of the IOPI measurements for evaluating strength improvements and the effectiveness of interventions in individuals. Unlike the excellent reliability for hand and tongue strength measures, the reliability of the tongue and hand endurance measurements were generally unsatisfactory and requires further investigation.

The test-retest correlation coefficients for tongue strength observed in this study were similar to those reported previously [51,6,55,58,93,92,65,68] where correlation coefficients ranged between 0.75 and 0.99. Previous studies only compared the results of two sessions whereas the current study looked at the values obtained across four sessions. No previous studies reported changes in the means or indications of typical error therefore this is the first study to provide these important indices of IOPI measurement reliability. Chang et al (2008) are the only investigators to have previously reported the reliability of tongue endurance measurements. In contrast to the extremely high correlation ($r = 0.99$) value they obtained, the correlations in the current study are poor. Some possible reasons for this discrepancy are provided below. This suggests a need for further investigation of the reliability of tongue endurance values and the circumstances that contribute to more reliable values. Although Robin et al [84] stated

that IOPI handgrip strength measures had low variability no quantified measure of reliability was reported, therefore the current study provides the first measures of reliability of IOPI handgrip strength and endurance measures.

The findings of this study have important applications for both researchers and clinicians. For researchers, the small to trivial changes in the means and high ICCs indicated the excellent reliability of the tongue and handgrip strength measures for group analysis. For all the IOPI strength measures, reliability was improved by one familiarisation session to more desirable levels. The implications of this finding for people who are afforded only one opportunity to have their tongue strength tested before an intervention is that a greater increase in the value of the measure post-intervention is required before it can be concluded that real improvement has occurred. Other strategies to provide some familiarisation within the first session such as additional trials may be preferable to the participant being required to return on another day. An important consequence of a reduction in variation is that the magnitude of change required to be regarded as meaningful (minimum change score values) is reduced, which has additional benefits for researchers in reducing the sample size required in research studies. Familiarisation typically reduced the magnitude of change in strength that would be meaningful by approximately 50%.

The question of whether the single highest strength value [75,62,37,8,73,53,88,54,6] or an average of multiple trials [6] should be used was also investigated, as both have been reported in the literature. Differences between these approaches were small, and no approach was preferred for analysis of group data. One consideration is that there are practical reasons for not including one poor trial value in the assessment; therefore, the maximum value or the mean of the two highest values would be preferred. When consideration is given to the impact of improving within-

session consistency of values (i.e., at least two values within a criterion range such as $< 5\text{kPa}$ for tongue strength), there were small improvements in the reliability of the strength measures, particularly for handgrip strength, which importantly improves confidence that reliable maximum values have been obtained.

For clinical practice, the typical error analysis is the most important of the reliability measures as this provides an indication of the variability within an individual between sessions. Typical error was higher than the acceptable standard between the first two sessions but was reduced by familiarisation and by using the average of the highest two of three values taken in a session. It was further improved by using within session consistency criteria to better establish that at least two similar near maximal force values have been obtained in a session. This suggests that in a clinical situation, more than three attempts may be required to meet the consistency criterion.

In contrast to the acceptable reliability demonstrated for tongue and hand strength, the reliability of tongue and handgrip endurance measurements was not established. Changes in the mean values were above 10% between trials 1-2, although they did decrease following subsequent trials. Typical errors were unacceptably large and ICC values were weak to moderate for both tongue and hand endurance. Therefore, further exploratory analysis was conducted to improve the reliability of endurance measures. Using the between session consistency criteria of having at least two strength measures within 5 kPa (tongue) or 15 kPa (hand) of each other resulted in acceptable reliability for posterior tongue and hand endurance but little improvement in anterior tongue endurance. However, this approach excluded most participants from the analysis, which limits confidence in this strategy.

The method of data collection, i.e., using 50% of maximal tongue strength in each session as the endurance target, may have contributed to the unsatisfactory

endurance results obtained. A previous study by Solomon, Robin, & Luschei (2000) assessed isometric tongue strength and endurance during a sustained submaximal effort in 16 people (12 males: 4 females; range: 54 to 84 years) with mild to severe Parkinson disease and an age-matched healthy control group [70]. In the study, the authors set a definition for analysing endurance (a steep drop in pressure; pressure signal was $> 40\%$ and $< 50\%$ of $P_{\max}$ for two seconds (s); or pressure signal was $< 40\%$ of $P_{\max}$ for 0.5s. The study also explained how changes in stability over time during a fatiguing task were measured from the endurance trials (determined by measuring five 3-second segments of each trial). The authors found no difference in stability between the experimental and control groups and cannot attribute differences in endurance to a problem with stability. They did not investigate reliability for endurance. An alternative would be to set the endurance target at 50% of the maximal tongue strength achieved in session 1. Therefore, further investigations of the reliability of tongue and hand endurance measurements need to be undertaken, and considerations should be given to protocols and methodological strategies that could improve reliability.

The current study investigating the reliability of tongue and hand strength and endurance using the IOPI had a number of strengths. Three measures of reliability were used in the analyses providing indices of systematic and random error, with implications for both group and individual applications. An appropriate sample size was used for this analysis, and the population included healthy males and females across an age range from 18-60 years.

However, there were some limitations. Inter-rater reliability was not investigated as only one investigator provided instructions to the participants and conducted the tests. Therefore, this study should be regarded as the first step in establishing the reliability of the IOPI. Although the validity and clinical relevance of these strength

measures have yet to be established, ensuring that measures used in clinical studies are of high reliability allows for effective investigation of strength and its relationships to the functional demands of the individual. Finally, there are other devices to assess tongue strength on the market such as the MOST device [32], and the KayPENTAX Digital Swallowing Workstation. These devices have been developed for evaluating the maximum force or pressure output at different locations on the tongue and can be used to help diagnose and strengthen weakened tongue muscles and the reliability of those devices needs to be established in a comparable manner to this investigation.

In summary, we have determined that the IOPI is reliable for the measurement of tongue and hand strength, but not endurance. A familiarisation session is recommended to improve the precision of the assessment. Future studies should ensure that marking the IOPI connecting tube with tape or black marker pen once the lips were closed may be a strategy to further improve the within session placements and recording that length could possibly improve inter-session placements. Multiple attempts resulting in some consistency in the maximum values obtained should be provided to establish that a true representation of current maximal strength is obtained. Further investigation is required to determine the reliability of tongue and hand endurance measures using the IOPI.

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Chapter 5: Reliability of measurements of strength and endurance using the Iowa Oral Performance Instrument in elderly adults

5.1 Introduction

Frailty is a term used to describe the condition of people who have lost functional abilities and are likely to deteriorate further, and is common in older age [97]. Although there are commonly used definitions of old age, there is no general agreement on the age at which a person becomes old. According to the United Nations World Population Prospects (United Nations, Department of Economic and Social Affairs, Population Division, 2013) the population aged 60 or over are “the elderly”. Sarcopenia (loss of body mass and strength) is a critical component of frailty and contributes to the loss of muscle strength.

The tongue, made primarily of muscle, is one of the principle articulators and during speech it moves rapidly from one position to the next. In order to accomplish precise placement for accurate speech production, the neuromotor system must operate with sufficient strength and without excessive fatigue so that accurate placement of the tongue occurs within an appropriate timeframe [63]. There is a relationship between tongue strength and speech such that abnormally low tongue strength has been associated with reduced intelligibility [98,99,84]. Further, the loss of muscle mass and motor units with age may not only affect strength but also the precision of motor control, which may reduce the reliability of force production.

Strength measurements are a common indicator of the extent of frailty. Tools that can reliably measure muscle strength in an elderly population are valuable. Grip

strength, for example, is widely used for strength assessment and has demonstrated associations with frailty [100]. The hand is the most active and important part of the upper extremity and the anatomy and functional biomechanics of the hand are extremely complex. Hands undergo many physiological and anatomical changes associated with ageing, though very little is understood on the effects of normal aging on adult hand function and dysfunction. Clinicians, therapists, and researchers need to understand both normal and abnormal hand functioning, including age-related functional deterioration [101].

Examination of tongue strength is a frequent component of the clinical assessment of swallowing by speech-language pathologists. These measurements have traditionally relied on subjective methods to estimate tongue strength and co-ordination, such as the force being applied by the tongue against resistance provided by the speech-language pathologist's fingers resting against the cheek or against a wooden tongue depressor. This approach raises concerns regarding the reliability of tongue strength measurements due to assessor bias and the variability introduced by multiple assessors in a range of clinical environments.

A number of tools have been designed to objectively quantify measures of tongue strength and endurance for research purposes and for potential use in routine clinical practice. The IOPI is the most commonly used of these measurement devices to assess tongue strength. A hand bulb allows the IOPI to be used to measure handgrip strength as well as tongue strength. The IOPI can also be used to measure isometric tongue and hand endurance.

A number of studies have provided indications of the test-retest and inter-rater reliability of the IOPI in healthy populations [67,56,92,70,6,75,55,93,65,37,61,58], where the inter-rater correlation coefficients were all stronger than $r = 0.75$, however no

studies have investigated its reliability in an elderly population. A difference in reliability measures between adults and elderly individuals could be explained by a loss of body mass and strength as the individual ages. Findings from a systematic review by Adams and colleagues in 2013 found that maximum tongue strength was observed to decrease with increasing age in nine studies involving healthy adults [2–4, 6, 7, 9, 10, 15, 36]. Results from these studies indicated that maximum tongue strength of the oldest adults was, on average, 10–15 kPa lower than that of young adults.

Although previous reliability studies have included elderly participants, no previous studies have examined the reliability of the IOPI in an exclusively elderly population. Also, many reliability studies assess at only two time points and do not establish whether the results obtained after two sessions will not change further with continued familiarisation. The possibility of such effects from increased experience in performing a task is the reason this study undertook multiple measures over a number of weeks. The potential impact of familiarisation may be especially important in elderly populations for whom assessments demanding precise motor control are required and for whom new task mastery may take more experience.

Typically, values obtained by novice users of the IOPI were compared to those of an experienced user. The measure of reliability was the correlation between values obtained from different users. The inter-rater correlation coefficients were all stronger than $r = 0.75$ with one exception; Solomon et al. (2008) reported $r = 0.535$ in a dysarthric population [65]. Youmans and Stierwalt (2006) also compared the group means between assessors and found no significant difference [75]. Only one study (Palmer 2010) reported inter-rater reliability for tongue endurance, with a perfect correlation ($r = 1$) between assessors [61].

Nine studies have reported test-retest reliability of tongue strength [55,92,6,51,93,65,58,70]. Robin et al. (1991) provided the first report describing the test-retest variability as low (implying reliability was high) based on the small size of an individual participant's standard deviations [84]. Subsequent studies [67,55,92,70,6,75,51,93,65,37,61,58,54] reported strong correlations as measures of test-retest reliability with correlation coefficients ranging from $r = 0.76$ to $r = 0.99$. Only one study (Chang et al (2008)) reported tongue endurance test-retest reliability ($r = 0.99$) [51].

In addition, Lazarus et al (2000) reported that assessors had to meet pre-established criteria of at least $r = 0.76$ for inter-observer reliability and $r = 0.90$ for test-retest reliability prior to conducting study assessments of tongue strength. In addition, it should be noted that the highest tongue strength value obtained was used in all these investigations of the reliability of IOPI tongue strength measures. In summary, inter-rater and test-retest reliability of the IOPI measurement of tongue strength have been reported but there has been almost total reliance on correlation coefficients as the measure of reliability. Consequently, whether the values obtained change consistently with familiarisation (identifiable by a % change in the mean of a group of people) over several sessions has not been identified. Further, the magnitude of any within-subject variation (typical error) that needs to be accounted for in interpreting clinical improvement has not been investigated.

The primary aim of this study was to determine the test-retest reliability of the IOPI as a tool for assessments of both tongue and handgrip strength and endurance in a sample of an elderly population in an aged-care setting. As more than one trial of strength measurement is usually obtained, it is not clear whether the highest value, the average of multiple values, or the average of the two highest values should be used in

strength evaluation. Therefore, a secondary aim was to identify whether the choice of strength measure used influenced the reliability of these strength measurements for both research and clinical practice.

5.2 Methods

5.2.1 Study Design

Participants underwent anterior and posterior tongue and handgrip strength and endurance assessments using the IOPI following a previously documented procedure [84,63,102] on four occasions with each session separated by 14 days. Maximum tongue and handgrip strength assessments involved three consecutive trials each of approximately two-second duration. For endurance, the IOPI was set to 50% of the participant's maximal strength with only one measurement of endurance obtained during each session. Maximum tongue and handgrip strength assessments involved three consecutive trials each of approximately two-seconds duration. For endurance, the IOPI was set to 50% of the participant's maximal strength with only one measurement of endurance obtained during each session. Participants were randomised to perform tongue or hand measurements first. Strength measurements were always performed before endurance measurements to reduce the effect of the endurance assessment on strength performance. One investigator (VA) provided all instructions to the participants and conducted all the tests. Three measures of reliability were assessed according to Hopkins [91]. Exploratory secondary analyses were also conducted to determine whether single peak or mean strength values were more reliable, and to identify other protocol strategies that influence the reliability of these strength and endurance measures.

5.2.2 Participants

Elderly adults were recruited from a residential aged-care facility in Newcastle, NSW, Australia. Participants completed a health and medical history questionnaire to determine their eligibility. Participants were included if they were residing at the facility, with no previous or current swallowing or hand problems. Study exclusion criteria were: a history of swallowing problems; abnormal oral structure and function (e.g. resulting from surgical intervention); a history of neurologic, respiratory or gastrointestinal impairment; cognitive impairment; head or neck cancer; any current or previous major injury (e.g. surgery) to the tongue or hand; or difficulty placing an instrument on the tongue. The University of Newcastle Research Ethics Committee approved the study and written informed consent was obtained from all participants prior to participation.

5.2.3 Instrumentation

Tongue strength and endurance assessments were collected using the current version (2.2) of the IOPI by placing a small, air-filled bulb longitudinally along the hard palate. The IOPI is a portable, handheld tool containing pressure-sensing circuitry, a peak-hold function, and a timer. It uses a blue air-filled PVC tongue bulb (approximately 3.5cm long and 1.2cm in diameter) which is pliable and has an approximate internal volume of 2.8ml. The bulb was connected to the IOPI via an 11.5cm PVC connecting tube with the pressure exerted against the bulb measured and displayed in kilopascals (kPa). Unlike earlier versions of the IOPI, which showed the green light as the middle light in a row of lights, the current model used in this study has the green light as the top light (100%). Handgrip strength and endurance were measured by placing a handgrip pressure bulb in the centre of the palm of the dominant hand, with the fingers wrapped around it. Participants were instructed not to press the bulb with the

fingertips as this may create artificial increases in pressure. The handgrip bulb is made of soft rubber with a small air-filled bulb that was immersed in an incompressible viscous fluid in the middle. Visual feedback to participants for assessment of endurance was achieved by the light-emitting diode (LED) display on the IOPI screen. To ensure accuracy of measurement, IOPI Medical recommends checking the accuracy of the IOPI pressure reading each month using a procedure described in the manual. This is performed by slowly increasing the compression of the tongue bulb against the surface of a postal weighing scale; when the scale reaches 4 lb (1.82 kg) the IOPI should read 42 ± 2 kPa. If outside this range the IOPI needs to be returned to the supplier for recalibration.

5.2.4 Procedure

Participants were seated in an upright position in their own chair or in a straight-backed chair for the duration of the testing performed at the facility. Testing was conducted at various times during the day and participants were not required to fast prior to the assessment. Participants were provided with instructions for all tasks and verbal encouragement was given during each of the trials. All study participants were given verbal encouragement by the investigator saying “Push, push, push!” or “Squeeze, squeeze, squeeze”. Tongue strength and endurance data were collected in two bulb positions, the antero-median and the postero-median. To obtain antero-median measures, the IOPI bulb was placed in the centre of the tongue directly behind the front teeth. The postero-median position was defined by placing the straight edge of the IOPI bulb parallel to the anterior edge of the individual’s back molars. Each participant was shown a picture of the correct bulb placement plus a standardised verbal description of the placement at the beginning of each testing session. The investigator then observed the placement prior to each measurement and further directions provided if necessary.

5.2.5 *Data management and analysis*

Although version 2.2 of the IOPI used in this study has the capability to download data through a data analogue output, strength and endurance values were taken directly from the IOPI screen and recorded on data sheets. All data were then entered into Microsoft Excel (Microsoft Windows XP Professional, Version 5.1.2600) for data management and then exported into appropriate analysis programs. Participant characteristics were analysed using a statistical software program (SPSS Statistics 20) which provided descriptive statistics and are presented as a mean $\pm$ standard deviation (SD).

To assess the primary aim, regarding the reliability of the strength and endurance measures, three statistical analyses providing different indices of reliability were used: change in the mean; typical error; and intraclass correlation (ICC). To assess the secondary aim regarding the choice of strength measure on reliability, all the above reliability analyses were replicated using the highest of three trials, the average of three trials, and the average of the two highest trials. All reliability measures were analysed using a reliability spreadsheet developed by Hopkins and designed to assess the precision of measurement [95].

Three measures of reliability (change in the mean between sessions, typical error, and intraclass correlation coefficients) were assessed according to Hopkins [91]. An acceptable level of variability in test measures is up to the researcher to determine, however established values for reliability measures are a % change in the mean and typical error between sessions of less than 5% (desirable) and 10% (acceptable), and ICC levels above 0.8 (desirable) and 0.6 (acceptable) [91]. The magnitude of any changes between tests was assessed by effect sizes as follows: large ($d > 0.8$); medium ($d = 0.5$ to 0.79); small ($d = 0.2$ to 0.49); and smaller than $d = 0.19$ deemed

insubstantial or trivial. Exploratory secondary analyses were also conducted to determine whether single peak or mean strength values were more reliable, and to identify protocol strategies that influence the reliability of these strength and endurance measures in this population.

5.3 Results

Thirty participants (6 males and 24 females) were recruited. All participants met the inclusion criteria and no potential participants met any exclusion criteria. Characteristics of the participants are presented in Table 5.1. The time between assessments sessions was 14 days.

Table 5.1

Characteristics of participants ($n = 30$), data are Mean $\pm$ SD

	Age (years)	Weight (kg)	Height (m/cm)	BMI* (kg.m⁻²)
Males ($n=6$)	88.0 $\pm$ 4.8	73.9 $\pm$ 12.2	1.7 $\pm$ 5.0	24.5 $\pm$ 4.2
Females ($n = 24$)	89.2 $\pm$ 5.3	64.8 $\pm$ 13.9	1.6 $\pm$ 5.3	26.1 $\pm$ 5.1
All participants	88.9 $\pm$ 5.2	66.6 $\pm$ 13.9	1.6 $\pm$ 8.5	25.7 $\pm$ 4.9

* BMI = Body Mass Index

5.3.1 Tongue and hand strength analyses

For anterior tongue and handgrip strength using the highest of the three trials, the % change in the mean was largest between sessions 1-2 and substantially smaller in subsequent sessions (Table 5.2). Between sessions 1 and 2, the % change in the mean based on the highest value of the three trials was higher than the criterion standard for desirable (> 5%) or acceptable (> 10%) for these strength measures but all met the criterion for desirable with familiarisation. No significant changes in the means between sessions were observed for any strength measures and the magnitude of these changes was small to trivial (Table 5.3). These results indicate good reliability for group assessments of anterior tongue and hand strength but suggest that one or more familiarisation sessions improve the reliability of the values obtained in elderly adults.

For posterior tongue strength, the % change in the mean between sessions was more variable (Table 5.2). No tongue or hand strength typical error values met the criterion for acceptability, which indicates that individual measures are less reliable than group measures. All measures of strength indicated medium to strong (0.59 – 0.96) correlation coefficients with higher ICCs being achieved following session 1. Additional reliability analyses were conducted using the average of the trials in each session and the average of the highest two values obtained (Table 5.2). Little difference was observed between these two approaches.

Table 5.2

Exploration of test-retest reliability of strength measures using highest of 3 trials, mean of 3 trials, and mean of highest 2 trials in 30 participants

Outcome Measure	Session 1	Session 2	Session 3	Session 4		Change in Mean (%)	95% CI	Typical error as CV (%)	95% CI	Mean-typical error as CV (%)	95% CI	ICC (r)	95% CI	
Highest of 3 trials														
Tongue strength (kPa)														
Anterior	26.9 ± 11.0	28.8 ± 10.4	29.4 ± 10.8	29.9 ± 11.5	Session 2-1	11.50	-5.8 - 32.1	37.70	29.0 - 53.7	35.80	30.2 - 44.9	0.68	0.43 - 0.83	
					Session 3-2	3.10	-8.7 - 16.3	25.70	20.0 - 36.0				0.77	0.58 - 0.89
					Session 4-3	-2.60	-19.3 - 17.4	42.80	32.8 - 61.4				0.59	0.29 - 0.78
Posterior	25.6 ± 10.6	25.3 ± 10.3	26.7 ± 10.2	27.9 ± 10.8	Session 2-1	-0.60	-16.9 - 19.0	40.40	31.1 - 57.9	33.80	28.5 - 42.3	0.77	0.57 - 0.88	
					Session 3-2	8.90	-5.3 - 25.3	30.40	23.5 - 42.9				0.84	0.69 - 0.92
					Session 4-3	3.50	-9.8 - 18.8	29.90	23.1 - 42.1				0.81	0.65 - 0.91
Hand strength (kPa)														
Hand strength (kPa)	57.7 ± 19.9	60.5 ± 18.8	60.0 ± 18.7	61.2 ± 20.1	Session 2-1	8.90	-4.7 - 24.5	28.80	22.3 - 40.5	19.20	16.3 - 23.7	0.79	0.60 - 0.89	
					Session 3-2	-1.80	-8.0 - 4.8	13.10	10.3 - 18.0				0.94	0.88 - 0.97
					Session 4-3	0.80	-5.2 - 7.2	12.30	9.7 - 16.9				0.96	0.91 - 0.98

Outcome Measure	Session 1	Session 2	Session 3	Session 4		Change in Mean (%)	95% CI	Typical error as CV (%)	95% CI	Mean- typical error as CV (%)	95% CI	ICC (r)	95% CI
Mean of 3 trials													
Tongue strength (kPa)													
Anterior	23.2 ± 10.3	25.4 ± 9.9	25.7 ± 9.7	26.9 ± 10.7	Session 2-1	14.60	-4.1 - 36.9	40.10	30.8 - 57.3	38.10	32.1 - 47.9	0.71	0.74 - 0.91
					Session 3-2	3.10	-9.5 - 17.3	27.80	21.6 - 39.1			0.78	0.59 - 0.89
					Session 4-3	0.60	-17.4 - 22.4	45.20	34.6 - 65.0			0.56	0.26 - 0.76
Posterior	21.9 ± 9.7	22.6 ± 9.5	23.1 ± 9.9	25.1 ± 10.5	Session 2-1	7.60	-12.5 - 32.3	47.80	36.5 - 69.1	37.90	31.9 - 47.5	0.74	0.52 - 0.87
					Session 3-2	4.90	-9.2 - 21.1	31.30	24.2 - 44.2			0.84	0.68 - 0.92
					Session 4-3	6.80	-8.3 - 24.2	33.30	25.7 - 47.2			0.80	0.62 - 0.90
Hand strength (kPa)	53.0 ± 18.4	56.0 ± 18.0	60.0 ± 18.7	57.1 ± 19.5	Session 2-1	9.20	-5.0 - 25.6	30.30	23.5 - 42.8	20.30	17.2 - 25.0	0.79	0.60 - 0.89
					Session 3-2	7.10	0.1 - 14.4	13.50	10.6 - 18.5			0.94	0.88 - 0.97
					Session 4-3	-6.50	-12.5 - 0.00	13.40	10.6 - 18.5			0.95	0.90 - 0.98

Outcome Measure	Session 1	Session 2	Session 3	Session 4		Change in Mean (%)	95% CI	Typical error as CV (%)	95% CI	Mean-typical error as CV (%)	95% CI	ICC (r)	95% CI
Mean of highest 2 trials													
Tongue strength (kPa)													
Anterior	24.9 ± 10.7	27.1 ± 10.2	27.5 ± 10.2	28.3 ± 11.1	Session 2-1	13.90	-4.3 - 35.6	39.10	30.1 - 55.9	36.80	31.0 - 46.2	0.69	0.44 - 0.84
					Session 3-2	2.90	-8.9 - 16.2	25.90	20.2 - 36.3		0.78	0.60 - 0.89	
					Session 4-3	-1.50	-18.8 - 19.4	44.00	33.7 - 63.3		0.57	0.27 - 0.77	
Posterior	23.8 ± 10.0	24.4 ± 10.0	25.0 ± 10.3	26.8 ± 10.9	Session 2-1	4.50	-13.6 - 26.3	43.20	33.1 - 62.1	34.90	29.4 - 43.7	0.75	0.55 - 0.88
					Session 3-2	5.20	-8.2 - 20.6	29.60	22.9 - 41.6		0.85	0.71 - 0.93	
					Session 4-3	6.10	-8.1 - 22.3	31.10	24.0 - 43.9		0.81	0.64 - 0.90	
Hand strength (kPa)													
Hand strength (kPa)	55.3 ± 18.5	58.3 ± 18.5	58.1 ± 18.3	59.1 ± 20.0	Session 2-1	8.50	-5.2 - 24.2	29.20	22.6 - 41.1	19.40	16.5 - 24.0	0.79	0.60 - 0.89
					Session 3-2	-1.00	-7.4 - 6.0	13.60	10.7 - 18.8		0.94	0.88 - 0.97	
					Session 4-3	0.20	-5.6 - 6.4	12.00	9.5 - 16.5		0.96	0.92 - 0.98	

Table 5.3.
Changes in tongue and hand strength between sessions analysed by paired t-tests in 30 participants

	Session	Mean Diff (s)	95% CI	<i>p</i> value *	Effect size (<i>d</i>)
Anterior	1-2	1.87	-1.41 – 5.14	0.25	0.17
	2-3	0.63	-2.45 – 3.72	0.68	0.00
	3-4	0.53	-2.76 – 3.83	0.74	0.26
Posterior	1-2	-0.30	-3.13 – 2.71	0.47	0.11
	2-3	1.43	-2.11 – 4.97	0.41	0.02
	3-4	1.17	-2.07 – 4.41	0.84	0.20
Hand	1-2	2.83	-3.36 – 9.03	0.36	0.15
	2-3	-0.50	-3.70 – 2.70	0.75	0.03
	3-4	1.13	-2.42 – 4.69	0.52	0.02

* $p < 0.05$ is statistically significant

5.3.2 Tongue and hand endurance analyses

Reliability statistics for tongue (anterior and posterior) and handgrip endurance are presented in Table 5.4. None of the endurance measurements showed the desired consistency as demonstrated by the highly variable percentage changes in means, mean-typical errors, and ICC values. Although changes in the means were not statistically significant and the magnitude of changes were small to trivial, this may partially reflect the variability (Table 5.5) The ICCs for endurance ranged from unacceptable to acceptable levels, with higher ICCs being achieved following session 1 for hand endurance. All measures of tongue endurance showed poor reliability as indicated by correlation coefficients considered trivial to medium (-0.01 – 0.60). These results indicate poor reliability for group assessments (% change in the means, ICCs) and individual assessments (typical error) of tongue and hand endurance, which were not made more reliable with familiarisation of the IOPI.

Table 5.4
Test-retest reliability of endurance measures in 30 participants

Outcome Measure	Session 1	Session 2	Session 3	Session 4		Change in Mean (%)	95% CI	Typical error as CV (%)	95% CI	Mean-typical error as CV (%)	95% CI	ICC (r)	95% CI
Tongue endurance (s)													
Anterior	4.7 ± 3.8	4.2 ± 3.2	5.0 ± 3.4	6.3 ± 4.8	Session 2-1	-6.70	-28.6 - 22.0	61.40	45.8 - 92.7			0.47	0.11 - 0.72
					Session 3-2	16.80	-13.5 - 57.7	73.00	54.2 - 110.8	64.00	52.4 - 82.3	0.30	-0.07 - 0.60
					Session 4-3	13.40	-11.9 - 46.0	57.00	42.6 - 85.5			0.58	0.26 - 0.78
Posterior	4.6 ± 4.0	4.6 ± 3.3	4.4 ± 2.8	5.3 ± 3.9	Session 2-1	-0.70	-22.0 - 26.5	54.20	40.6 - 81.0			0.60	0.60 - 0.80
					Session 3-2	0.80	-27.4 - 40.0	84.10	62.3 - 128.4	70.00	57.3 - 90.4	-0.01	-0.37 - 0.35
					Session 4-3	26.80	-5.6 - 70.2	69.30	51.4 - 105.8			0.22	-0.19 - 0.54
Hand endurance (s)													
	23.8 ± 17.1	26.3 ± 23.9	24.1 ± 24.3	27.3 ± 21.7	Session 2-1	2.50	-26.5 - 43.0	87.90	65.3 - 133.5			0.52	0.20 - 0.74
					Session 3-2	-7.10	-30.5 - 24.3	73.50	55.1 - 109.7	69.80	57.8 - 89.9	0.64	0.37 - 0.81
					Session 4-3	21.30	-0.4 - 47.8	45.30	34.7 - 65.3			0.81	0.64 - 0.90

Table 5.5

Changes in tongue and hand endurance between sessions analysed by paired t-tests in 30 participants

	Session	Mean Diff (s)	95% CI	<i>p</i> value *	Effect size (<i>d</i>)
Anterior	1-2	-0.53	-2.11 – 1.04	0.50	0.15
	2-3	0.63	-1.18 – 2.44	0.48	0.19
	3-4	0.23	-1.91 – 2.37	0.83	0.05
Posterior	1-2	1.03	-1.67 – 3.73	0.44	0.19
	2-3	-1.70	-4.45 – 1.05	0.22	0.39
	3-4	0.47	-1.11 – 2.05	0.55	0.16
Hand	1-2	-2.43	-4.40 – 9.25	0.47	0.12
	2-3	-3.83	-16.95 – 9.28	0.56	0.17
	3-4	-3.23	-12.81 – 6.35	0.50	0.17

* $p < 0.05$ is statistically significant

5.4 Discussion

The key findings of this study are that tongue and hand isometric strength measurements obtained using the IOPI demonstrate acceptable reliability for group assessments in the elderly, especially when a familiarisation session is provided prior to clinical evaluation. Considerable variability in the tongue strength measures of individuals was observed as indicated by typical error whereas handgrip strength measures of individuals were more reliable. Unlike the high reliability of the tongue and hand strength measures, the reliability of the tongue and hand endurance measurements was generally unsatisfactory.

No previous studies have reported on the reliability of the IOPI strength and endurance measures in an elderly population. Only one previous study [102] has reported changes in the means or indications of typical error as measures of reliability of the IOPI. In a younger population, tongue and hand strength measures met desirable criteria for changes in the means with familiarisation and the initial variation was less than in the elderly in this study [102]. This suggests that familiarisation may have a greater benefit in the elderly. Typical error values were substantially higher for tongue strength in the elderly compared to a younger population (25 - 40% in elderly; 4 - 15% in younger) but only slightly higher for hand strength. The test-retest correlation coefficients for tongue and hand strength observed in this study (range: 0.77 and 0.97) were similar to those reported previously [6,103,70,75,102] in younger populations.

The current study also investigated whether the single highest strength value [75,62,37,8,73,53,88,54,6] or an average of multiple trials [6,104] should be used, as both have been reported in the literature. Overall, it does not appear that one approach is more clinically useful than another and from a practical standpoint, it would be easier to use the maximum of three trials as a calculation is not required. For clinical practice, the

typical error analysis is the most important of the reliability measures as this provides an indication of the variability within an individual between sessions. Typical error was higher than the recommended standard of less than 10% variation [91], however the relatively low values of strength compared to younger populations means that small absolute strength changes result in greater percentage variability. It is plausible however that higher variability in the elderly is suggestive of greater motor instability as they are experiencing sarcopenia probably at differing rates and possibly with sex effects. Therefore, further investigations of the practical utility of the IOPI to assess tongue and handgrip strength in clinical environments with elderly populations of > 80 years are needed to ascertain its applicability in this context.

In contrast to the acceptable reliability demonstrated for tongue and handgrip strength, the reliability of tongue and handgrip endurance measurements was not established. The method of data collection, i.e., using 50% of maximal tongue strength in each session as the endurance target, may have contributed to the unsatisfactory endurance results obtained. Using 50% of maximal strength in session 1 as the target force for subsequent sessions may result in more reliable assessments of endurance. Similar to the current study, a previous investigation of the reliability of IOPI tongue and hand endurance measures found that these were not reliable using the same protocol [102]. These findings suggest that using the IOPI to assess tongue and handgrip strength may be appropriate but that IOPI measures of tongue and handgrip endurance using the protocol used in this study is not useful in younger or elderly populations.

The current study had a number of strengths. Three measures of reliability were used in the analyses providing indices of systematic and random error, with implications for both group and individual applications. An appropriate sample size was used for this analysis, and the population included elderly males and females across an age range

from 79 - 97 years. However, there were some limitations. Inter-rater reliability was not investigated as only one investigator provided instructions to the participants, conducted the tests, and performed all the analyses. More variability was observed in the posterior compared to anterior tongue strength measures, which may reflect greater variation in placement of the tongue bulb. Marking the IOPI connecting tube with tape or marker pen once the lips are closed and measuring this distance for subsequent assessments may improve the positioning of the tongue bulb within the oral cavity and may result in more consistent inter-session tongue-bulb placements especially for posterior tongue measurements. Therefore, this study should be regarded as the first step in establishing a level of reliability of the IOPI in an elderly population. Ensuring that measures used in clinical studies are of high reliability allows for effective investigation of strength and its relationships to the functional demands of the individual although the validity and clinical relevance of these strength measures have yet to be established. Further, although these elderly participants showed adequate competency in having their tongue strength and endurance collected, this may be more difficult or inappropriate with people with problems such as dementia and/or co-morbid mental health problems as they may not understand the instructions necessary, or cope with bulb placement.

In summary, we have determined that the IOPI is reliable for the measurement of tongue and hand strength, but not endurance in an elderly population. Familiarisation is recommended to improve the precision of the strength assessments and more attempts or more frequent sessions may be beneficial. Multiple attempts resulting in some consistency in the maximum values obtained could be provided to establish that a true representation of current maximal strength is obtained. The availability of an objective, quantifiable, and reliable method for measuring tongue and handgrip strength, using the IOPI, makes it possible to establish ranges of strength in an elderly population. Further

investigation is required to establish the reliability of tongue and handgrip endurance measures using the IOPI in the elderly.

Conflict of interest

The authors have no conflict of interest.

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No funding was received for the completion of this study.

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Chapter 6: Effects of age and sex on measurements of tongue and handgrip strength using the Iowa Oral Performance Instrument

6.1 Introduction

Appropriate tongue strength is essential for the oral and pharyngeal phases of swallowing and contributes to the formation, placement, and manipulation of a bolus within the oral cavity and propulsion into the pharynx [75]. Examination of tongue strength is a frequent component of the clinical assessment of swallowing by speech-language pathologists and a number of tools have been designed to objectively quantify measures of tongue strength for research purposes and for clinical practice. Such tools, for example, KayPENTAX Digital Swallowing Workstation, the Madison Oral Strengthening Therapeutic (MOST I and II) as well as handy probe devices have been used to study tongue strength in both healthy and clinical populations. However, previous research has determined that the IOPI is the most commonly used of these measurement devices to assess tongue strength [76].

A number of studies have documented isometric tongue strength as a result of age and sex in healthy individuals using the IOPI across a range of ages [38,55,10,49,63,84,70,85,72,75,90], although few data are available on those over 80 years of age. In normal aging, strength decreases due to muscle atrophy and motor neuron loss [8] and is most evident after age 60 years. This may lead to ‘frailty’, which is a term used to describe a range of conditions in older people, including general debility and possibly cognitive impairment reflecting multisystem physiological change. The changes contributing to frailty do not always lead to a disease, hence some

individuals, usually the very elderly, are frail without a specific life threatening illness [105,106].

The effects of age on tongue strength have been examined in nine studies [53,38,8,58,49,72,73,75,37] which divided adult participants into groups consisting of approximately 20-year intervals although the precise age groups have not been consistent among studies. Groups have been classed as younger, mid-aged, older, and elderly and associated with the following age ranges: younger (18-29y; 19-39y; 20-35y; 20-39y; 20-40y), mid-aged (30-59y; 40-59y; 41-60y) and older/elderly (60-79y; 60-89y; 60-96y; 61-80y; 65-82y; 67-83y). Five studies [53,72,73,75,37] divided participants into three age groups; three studies examined two age groups [8,58,49]; and one study [38] used four groups. The majority of these studies found that there were significant differences in maximum tongue strength between age groups with the older group having lower tongue strength compared to the younger and mid-aged groups although three studies found no differences between age groups (18,21,22). Interestingly, in a study by Clark (2012) which examined anterior and posterior tongue strength over three age groups (18-29y; 30-59y; 60-89y) [53] the comparisons revealed that for anterior tongue strength, the mid-aged group was stronger on average than the younger and older groups. For posterior strength, the mean of the mid-aged group was greater than the older group, but not the younger group.

Most of the above studies also demonstrated that males have higher tongue strength values than female participants [38,8,58,49,72,73,75,37]. In contrast, Clark (2012) found that females were stronger than males for tongue strength measured in the posterior bulb position [53] and three studies [8,58,73] found no evidence that tongue strength differed between males and females. Also, the relative loss of muscle mass and strength with age has been reported to be similar for males and females [107].

Handgrip strength is an important predictor of functional decline associated with normal aging and is often used to characterise the general strength of individuals [94]. As well as measuring tongue strength, the IOPI device has an attachment that allows measurement of handgrip strength. A systematic review of the literature by Adams et al. [108] determined that two studies have reported IOPI-measured handgrip strength in healthy adults [38,63]. Crow and Ship (1996) found that a younger age group had higher values of hand strength than mid-age or older age participants. The authors also found a significant relationship between hand strength and age in males and females, and that males were consistently stronger than females [38].

Previous studies have examined the test-retest reliability of the IOPI measurements of tongue and hand strength and reported correlation coefficients between 0.75 and 0.99 but these studies were conducted mostly in healthy young and mid-aged adults [67,56,92,70,6,75,55,93,65,37,61,58]. No studies have examined the test-retest reliability of IOPI strength measures in elderly populations yet this may be the age group where it will be most widely used.

The primary aims of this study were to further investigate the effects of age and sex on tongue and hand strength measured by the IOPI, and to provide an indication of representative values for the elderly (>75 years). Secondary aims were to investigate the relationships between tongue and hand strength as well as examine the effects of age on the reliability of IOPI strength measurements.

6.2 Methods

6.2.1 Study Design

All participants underwent anterior and posterior tongue and handgrip strength assessments using the IOPI on four occasions separated by 1-2 weeks. Strength assessments consisted of three attempts to exert maximal isometric force on each

occasion. Investigations of the effects of age and sex on the strength values were based on the measurements obtained during the second test session to account for the effects of familiarisation as determined previously [102]. Measurements across the four sessions were used for comparison of the reliability of the IOPI strength measurements with age.

6.2.2 Participants

Data were obtained from two groups of participants as described in more detail previously [102]. Healthy young to mid-aged adults (aged 18 – 60 years) were recruited from staff and students at The University of Newcastle, and elderly adults (aged >75 years) were recruited from residents at an aged-care facility in Waratah, NSW, Australia. Each participant completed a health and medical history questionnaire to determine their eligibility, which required no past or current problems with swallowing or hand function. Study exclusion criteria were a history of swallowing problems; abnormal oral structure or function; a history of neurologic, respiratory or gastrointestinal impairment; any current or previous major injury to the tongue or hand; any tongue piercings; difficulty placing an instrument on the tongue; or a history of seizures. The University of Newcastle Human Research Ethics Committee approved the study and written informed consent was obtained from all participants prior to participation.

6.2.3 Procedure

Participants were seated in an upright position in a straight-backed chair for the duration of the testing. Participants were not required to fast prior to the assessment. The order of tests (tongue or hand) was randomised using a web-based random assignment generator. Attempts allowed in the first session included one or more non-maximal practice trials to ensure the participant understood the task. Participants were

provided with instructions for all tasks and verbal encouragement was given during each of the trials. All study participants were given verbal encouragement by the examiner. Maximum strength ($P_{\max}$) was determined as the highest pressure recorded of the three trials [49].

6.2.4 Instrumentation

Tongue and handgrip strength assessments were collected using the current version (2.2) of the IOPI with maximum tongue strength measures obtained following a previously documented procedure [84,63].

Tongue strength

Tongue strength data were collected in two bulb positions, anterior and posterior, with bulb placement using specific landmarks, which allows for a standardised placement in relation to normal structures in the oral cavity outlined in previous studies [102]. Each participant was shown a picture of the correct bulb placement plus a standardised verbal description of the placement at the beginning of each testing session. The investigator then observed the placement prior to each measurement and directions provided if necessary. While individual anatomy across participants varied (palatal shape and vault), standardised instruction and placement demonstrations were used to ensure the bulb location was as consistent as possible.

Once the bulb was in the correct position in the oral cavity, participants were given instructions to push the bulb against the roof of their mouth with their tongue as hard as possible. Maximum strength ($P_{\max}$) was determined as the highest pressure recorded of the three trials [49]. No participants suffered a gag response with the bulb in the posterior position. While collecting tongue strength measures, the contributing role of the jaw has been questioned. Solomon and Munson (2004) determined that maximal

measures of tongue strength were best assessed with an unconstrained jaw. Therefore, the jaw was unconstrained during all measurement tasks for this study [68].

Handgrip strength

The correct position of the bulb within the hand was ensured by one investigator (VA) and participants were given instructions to squeeze the bulb as hard as possible with the whole hand and not the fingertips [102]. Maximum hand strength involved three consecutive trials each of approximately 1-2 seconds duration, with a short rest between trials while the investigator recorded the peak pressure measurement.

6.2.5 Data management and analysis

All data were entered into Microsoft Excel (Microsoft Windows XP Professional, Version 5.1.2600) for data management and exported into appropriate analysis programs (SPSS for Windows 20; reliability spreadsheets). Descriptive statistics are presented as mean $\pm$ SD. Participants were categorised by age (young 18-29y; mid-aged 30-60y; elderly >75y) and sex. Two-way between-subject analyses of variance (ANOVA) with Bonferroni corrections were used to investigate age (young vs. mid vs. elderly), sex (male vs. female) effects, and their interaction on tongue and handgrip strength. For the analysis of pressure variable differences between anterior and posterior tongue strength, and hand strength, repeated measures analyses of variance (ANOVAs) were performed separately by bulb with factors of sex and age. Effect sizes (ES) for differences between groups were calculated using Cohen's *d* with the magnitude of differences interpreted as described below. Pearson correlation coefficients were used to investigate relationships between tongue (anterior, posterior) and handgrip strength, between the strength measures and age.

All test-retest reliability measures were analysed using a reliability spreadsheet developed by Hopkins and designed to assess the precision of measurement [95]. Three

statistical analyses providing different indices of reliability were used. Random and systematic change outcomes through sampling error and learning effects were assessed using % change in the mean between sessions. The magnitude of any change was assessed by effect sizes using: large ($d > 0.8$); medium ($d = 0.5$ to 0.79); small ($d = 0.2$ to 0.49); and anything smaller than $d = 0.19$ was regarded as insubstantial or trivial [89]. Within-subject variation was determined using typical error expressed as a coefficient of variation (%) as follows: typical error = $[(sdiff/\sqrt{2})/\text{mean}]/100$ where *sdiff* is the standard deviation of difference scores between two trials. This measure represents technical and biological sources of error in measurement within participants. Rank order repeatability of the results among trials was investigated using intraclass correlation coefficients (ICC, *r*). An acceptable level of variability in test measures is up to the researcher to determine, however recommended values for reliability measures are % change in the mean and typical error between sessions values of less than 5% (desirable) or 10% (acceptable), and ICC levels above 0.8 (desirable) and 0.6 (acceptable) [91].

6.3 Results

A total of eighty one adults comprised of 34 younger (18-29 years), 17 mid-aged (30-57 years) and 30 older (79-97 years) participants were recruited. Six sub-groups were established for analysis: young males ($n = 14$), young females ($n = 20$), mid-aged males ($n = 7$), mid-aged females ($n = 10$), older males ($n = 6$) and older females ($n = 23$). Characteristics of the participants by age and sex are presented in Table 6.1. No participants reported problems with swallowing. Elderly participants indicated either full/partial top or bottom false dentition (80%) or own teeth (20%) and tongue strength and endurance testing was conducted with dentition in situ. All participants reported a negative history for neurologic, respiratory or gastrointestinal impairment. Several

medical conditions were noted in the elderly, with hypertension, osteoarthritis, osteoporosis, and ischaemic heart disease being the main conditions. Some elderly participants reported slight problems with hand function related to their medical condition but were still able to complete the task. Caution should be observed when comparing results from the young group with the mid-aged group, as there was a clear bias towards the younger age group with a mean of 39 years.

Table 6.1
 Characteristics of participants by age and sex, data are Mean $\pm$ SD

	Age (years)	Weight (kg)	Height (cm)	BMI ^a (kg.m ⁻²)
Younger adults				
Males (n=14)	23.3 $\pm$ 2.9	77.8 $\pm$ 6.0	180.0 $\pm$ 7.0	23.9 $\pm$ 2.4
Females (n=20)	22.9 $\pm$ 3.4	59.6 $\pm$ 7.6	166.1 $\pm$ 5.2	23.0 $\pm$ 3.7
All Participants	23.1 $\pm$ 3.1	67.1 $\pm$ 11.4	171.8 $\pm$ 9.1	22.6 $\pm$ 2.8
Middle-aged adults				
Males (n=7)	42.1 $\pm$ 9.2	82.6 $\pm$ 11.4	179.8 $\pm$ 7.9	25.7 $\pm$ 4.2
Females (n=10)	36.0 $\pm$ 8.2	72.7 $\pm$ 12.8	168.1 $\pm$ 4.3	25.5 $\pm$ 1.9
All Participants	38.5 $\pm$ 8.9	76.7 $\pm$ 12.9	172.9 $\pm$ 8.3	25.6 $\pm$ 3.3
Elderly adults				
Males (n=6)	88.0 $\pm$ 4.8	73.9 $\pm$ 12.2	174.0 $\pm$ 5.0	24.5 $\pm$ 4.2
Females (n = 24)	89.2 $\pm$ 5.3	64.8 $\pm$ 13.9	160.7 $\pm$ 8.5	26.1 $\pm$ 5.1
All participants	88.9 $\pm$ 5.2	66.6 $\pm$ 13.9	161.0 $\pm$ 1.0	25.7 $\pm$ 4.9

^a BMI=Body Mass Index

6.3.1 Analysis of tongue and handgrip strength by age and sex

Anterior tongue strength

A two-way between-subjects ANOVA was used to investigate the effects of age and sex on anterior tongue strength. There were significant age ($F(2,75) = 52.992, p < 0.001$) and sex ($F(1,75) = 4.016, p = 0.049$) effects but no age by sex interaction ($F(2,75) = 1.934, p = 0.152$) (Table 6.2). Men were significantly stronger than women regardless of age (ES $d = 0.74$). Employing Bonferroni post-hoc tests, no differences were found between the younger and mid-aged age groups ($p = 0.238$) but both these age groups were significantly stronger, approximately two-fold, than the older age group ($p < 0.001$). There was a significant strong negative correlation between anterior tongue strength and age ($r = -0.786, N = 81, p < 0.01$). The scattergram (Figure 6.1) shows that the data points are reasonably well distributed along the regression line, in a linear relationship with no outliers.

Table 6.2

Sex differences for strength measures x session 2 data, Mean $\pm$ SD in 81 participants

Outcome measures	All	Male	Female
Anterior tongue strength			
- young	59.7 $\pm$ 11.0	65.6 $\pm$ 12.1	55.5 $\pm$ 8.0
- mid-aged	54.2 $\pm$ 9.3	55.1 $\pm$ 10.6	53.6 $\pm$ 8.9
- elderly	28.4 $\pm$ 9.4 *	31.3 $\pm$ 7.5 *	28.1 $\pm$ 9.8 *
- All ages	58.3 $\pm$ 12.4	63.8 $\pm$ 13.9	54.4 $\pm$ 9.7
Posterior tongue strength			
- young	56.4 $\pm$ 11.5	61.4 $\pm$ 13.7	52.8 $\pm$ 8.4
- mid-aged	51.9 $\pm$ 9.6	50.6 $\pm$ 10.1	52.8 $\pm$ 9.7
- elderly	26.3 $\pm$ 8.2 *	27.2 $\pm$ 6.5 *	26.0 $\pm$ 9.4 *
- All ages	55.2 $\pm$ 12.0	58.4 $\pm$ 13.5	52.9 $\pm$ 10.5
Hand strength			
- young	161.4 $\pm$ 32.3	183.4 $\pm$ 28.7	146.0 $\pm$ 25.2
- mid-aged	153.7 $\pm$ 39.3	179.1 $\pm$ 40.2	136.0 $\pm$ 28.7
- elderly	59.9 $\pm$ 17.7 *	68.7 $\pm$ 12.4 *	57.7 $\pm$ 18.3 *
- All ages	159.7 $\pm$ 38.4	183.9 $\pm$ 35.6	142.8 $\pm$ 30.7

* Significant difference to other age groups

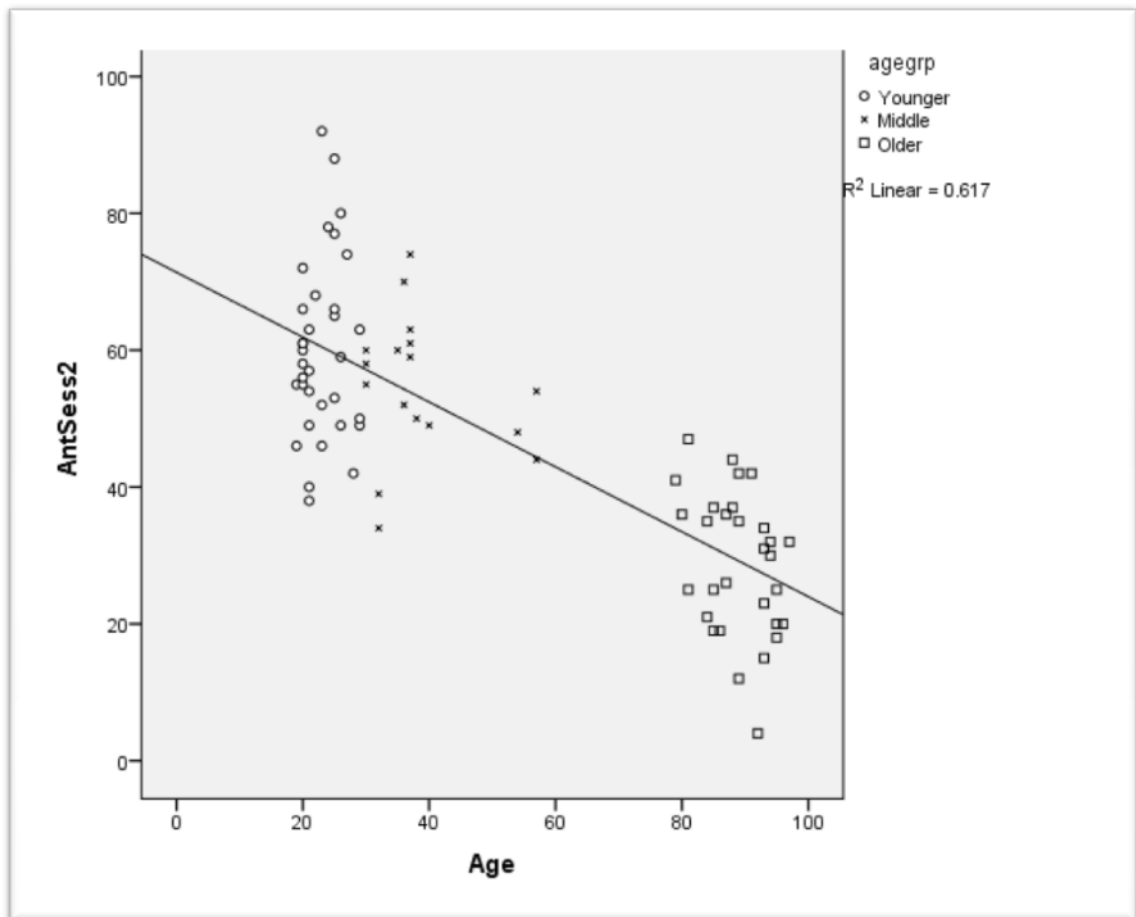
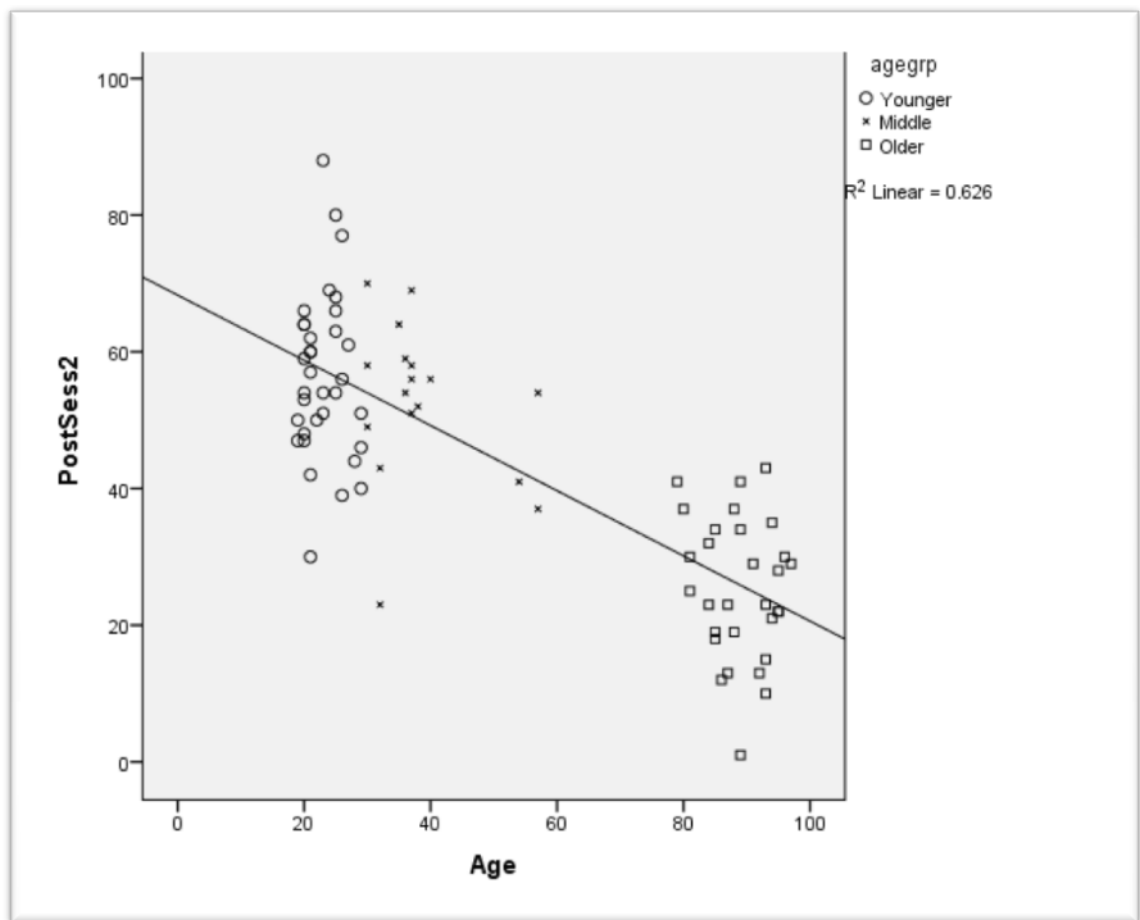


Figure 6.1. Anterior tongue strength session 2 (in kPa) plotted against participant age (in years)

Posterior tongue strength

Analysis of posterior tongue strength found a significant effect of age ($F(2,75) = 51.423$, $p < 0.001$), but no effect of sex ($F(1,75) = 0.871$, $p = 0.354$) and no age by sex interaction ($F(2,75) = 1.509$, $p = 0.228$) although males were stronger than females based on effect size (ES $d = 0.58$) (Table 6.2). Bonferroni post-hoc tests found that the younger and mid-aged age groups were significantly stronger (also approximately two-fold) than the older age group ($p < 0.001$) but there was no difference between the younger and mid-aged groups ($p = 0.477$). There was a strong negative correlation between posterior tongue strength and age ($r = -0.772$, $N = 81$, $p < 0.01$). The scattergram (Figure 6.2) shows that the data points are reasonably well distributed along the regression line, in a linear relationship with no outliers.



Hand strength

Analysis of hand strength found significant effects of age ($F(2,75) = 88.101, p < 0.001$) and sex ($F(1,75) = 17.349, p < 0.001$), with the age by sex interaction term at $F(2,75) = 3.104, p = 0.051$. Males were significantly stronger than females (ES $d = 0.94$) and this sex difference tended to be greater for the young (25%) and mid-aged (32%) groups than the elderly (19%) (Table 6.2). There was no difference in hand strength between the young and mid-aged groups ($p = 0.384$) but both these groups were significantly stronger (2.5 times) than the elderly ($p < 0.001$). There was a strong negative correlation between hand strength and age ($r = -0.796, N = 81, p < 0.01$). The scattergram (Figure 6.3) shows that the data points are reasonably well distributed along the regression line, in a linear relationship with no outliers.

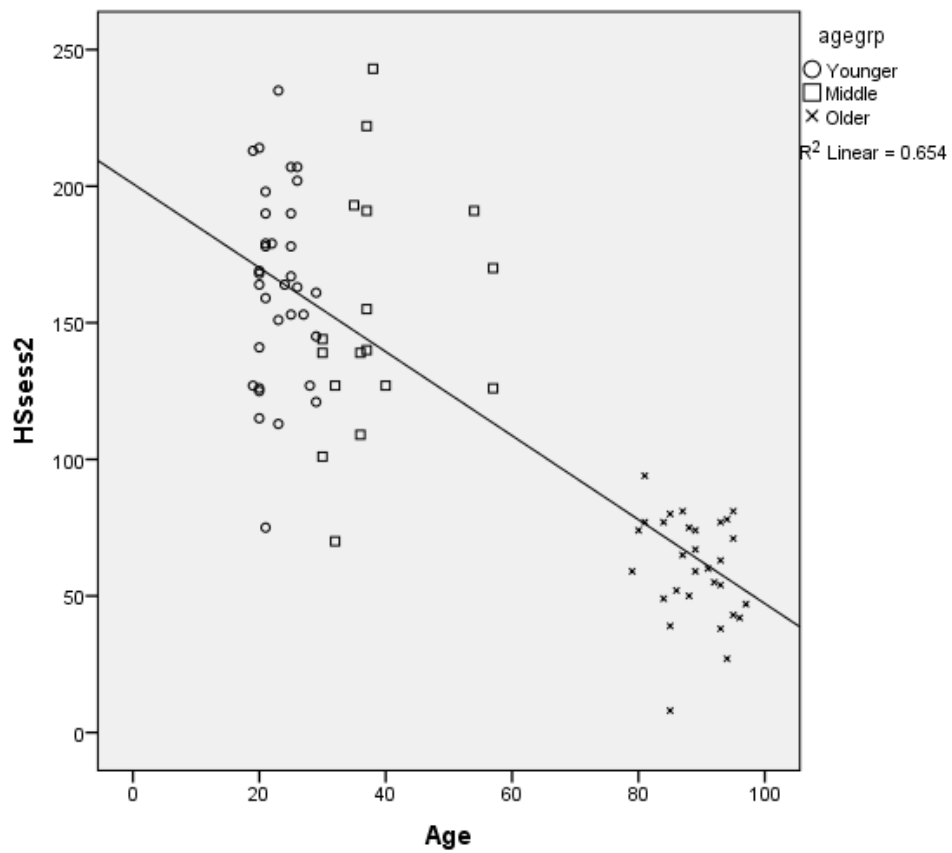


Figure 6.3. Hand strength session 2 (in kPa) plotted against participant age (in years).

Relationships between tongue and hand strength

As expected, a very strong correlation ($0.925, p < 0.001$) was found between anterior and posterior tongue strength. Strong correlations were found between hand strength and both anterior ($0.744, p < 0.001$) and posterior tongue strength ($0.719, p < 0.001$). Similar results were found for males with an almost perfect correlation ($0.965, p < 0.001$) between anterior and posterior tongue strength, and strong correlations were found between hand strength and anterior ($0.638, p < 0.001$) and posterior ($0.648, p < 0.001$). For females, there was a very strong correlation ($0.893, p < 0.001$) between anterior and posterior tongue strength, and stronger correlations between hand strength and anterior ($0.752, p < 0.001$) and posterior ($0.723, p < 0.001$) tongue strength compared to males.

Effects of age on the reliability of IOPI strength measurements

Comparison of the reliability of IOPI-measured tongue and hand strength are shown in Table 6.3. For anterior tongue strength, the % change in the mean between sessions met the desirable criteria for reliability after one session whereas the elderly group benefitted from a familiarisation session. None of the changes in means between sessions were significant ($p > 0.05$) and all were trivial in magnitude. The typical error values were much higher for the elderly compared to the young and mid-aged participants, indicating there is much greater variability between sessions within individuals in the elderly. The ICCs indicated moderate to strong correlations meeting the criteria for acceptable (elderly) to desirable correlations. The increased variability in the elderly mean that larger changes are needed to be confident of meaningful changes. Similar reliability results were observed for posterior tongue strength with greater variability in the elderly, although there was also some increase in variability in the mid-aged group.

Table 6.3
Comparison of the reliability of IOPI-measured tongue and handgrip strength in 81 participants

Outcome Measure	Session 1	Session 2	Session 3	Session 4		Change in Mean (%)	95% CI	p value	effect size (d)	Typical error as CV (%)	95% CI	Mean-typical error as CV (%)	95% CI	ICC (r)	95% CI
Tongue strength (kPa) - Anterior															
Young	59.2 ± 11.2	60.1 ± 13.1	59.9 ± 12.2	59.5 ± 10.7	Session 2-1	0.90	-3.8 - 5.9	0.53	0.07	10.20	8.2 - 13.7	7.90	6.8 - 9.5	0.78	0.60 - 0.88
					Session 3-2	0.10	-3.5 - 3.8	0.87	0.01	7.60	6.1 - 10.2			0.88	0.77 - 0.94
					Session 4-3	-0.30	-2.7 - 2.2	0.57	0.04	5.10	4.1 - 6.8			0.93	0.87 - 0.97
Mid-aged	53.4 ± 12.3	54.7 ± 10.3	55.2 ± 9.6	53.7 ± 8.5	Session 2-1	3.30	-4.9 - 12.1	0.54	0.12	12.00	8.8 - 18.8	9.10	7.4 - 12.0	0.75	0.43 - 0.90
					Session 3-2	1.00	-2.5 - 4.7	0.61	0.05	5.00	3.7 - 7.7			0.95	0.86 - 0.98
					Session 4-3	-2.20	-8.2 - 4.1	0.31	0.16	9.00	6.6 - 14.0			0.79	0.51 - 0.92
Elderly	26.9 ± 11.0	28.8 ± 10.4	29.4 ± 10.8	29.9 ± 11.5	Session 2-1	11.50	-5.8 - 32.1	0.25	0.18	37.70	29.0 - 53.7	35.80	30.2 - 44.9	0.68	0.43 - 0.83
					Session 3-2	3.10	-8.7 - 16.3	0.68	0.06	25.70	20.0 - 36.0			0.77	0.58 - 0.89
					Session 4-3	-2.60	-19.3 - 17.4	0.74	0.05	42.80	32.8 - 61.4			0.59	0.29 - 0.78

Outcome Measure	Session 1	Session 2	Session 3	Session 4		Change in Mean (%)	95% CI	p value	effect size (d)	Typical error as CV (%)	95% CI	Mean-typical error as CV (%)	95% CI	ICC (r)	95% CI
Tongue strength (kPa) - Posterior															
Young	55.8 ± 12.8	56.5 ± 12.1	56.6 ± 12.6	56.5 ± 11.9	Session 2-1	1.70	3.0 - 6.6	0.59	0.06	10.00	8.0 - 13.4	8.90	7.6 - 10.6	0.84	0.70 - 0.92
					Session 3-2	0.20	-2.7 - 3.2	0.81	0.01	6.10	4.9 - 8.1			0.93	0.87 - 0.97
					Session 4-3	0.00	-4.6 - 4.8	0.90	0.01	10.00	8.0 - 13.3			0.81	0.66 - 0.90
Mid-aged	50.2 ± 11.2	52.6 ± 11.7	52.0 ± 8.3	52.7 ± 11.4	Session 2-1	4.20	-5.9 - 15.4	0.29	0.21	15.10	11.0 - 23.8	13.40	10.9 - 17.8	0.71	0.36 - 0.88
					Session 3-2	0.50	-8.2 - 10.1	0.73	0.06	13.30	9.7 - 20.9			0.71	0.36 - 0.88
					Session 4-3	0.00	-7.8 - 8.5	0.67	0.07	11.80	8.7 - 18.5			0.74	0.42 - 0.90
Elderly	25.6 ± 10.6	25.3 ± 10.3	26.7 ± 10.2	27.9 ± 10.8	Session 2-1	-0.60	-16.9 - 19.0	0.91	0.02	40.40	31.1 - 57.9	33.80	28.5 - 42.3	0.77	0.57 - 0.88
					Session 3-2	8.90	-5.3 - 25.3	0.41	0.14	30.40	23.5 - 42.9			0.84	0.69 - 0.92
					Session 4-3	3.50	-9.8 - 18.8	0.47	0.11	29.90	23.1 - 42.1			0.81	0.65 - 0.91

Outcome Measure	Session 1	Session 2	Session 3	Session 4		Change in Mean (%)	95% CI	<i>p</i> value	effect size (<i>d</i>)	Typical error as CV (%)	95% CI	Mean-typical error as CV (%)	95% CI	ICC (r)	95% CI
Hand Strength (kPa)															
Young	146.8 ± 30.1	163.4 ± 34.9	165.7 ± 37.1	166.6 ± 37.7	Session 2-1	10.90	2.2 - 20.5	0.02	0.41	18.20	14.4 - 24.6			0.45	0.13 - 0.68
					Session 3-2	1.40	-2.8 - 5.8	0.49	0.06	9.00	7.2 - 12.0	12.3	10.6 - 14.8	0.87	0.76 - 0.93
					Session 4-3	0.30	-3.2 - 4.0	0.76	0.02	7.50	6.0 - 10.0			0.91	0.83 - 0.95
Middle-aged	155.5 ± 42.8	152.2 ± 44.6	150.1 ± 42.0	151.9 ± 40.4	Session 2-1	-2.7	9.5 - 4.6	0.42	0.08	10.50	7.7 - 16.4			0.90	0.74 - 0.96
					Session 3-2	0.8	-6.1 - 4.7	0.66	0.08	7.80	5.7 - 12.1	9.30	7.6 - 12.3	0.94	0.85 - 0.98
					Session 4-3	1.7	4.9 - 8.6	0.60	0.09	9.50	7.0 - 14.9			0.90	0.75 - 0.96
Elderly	57.7 ± 19.9	60.5 ± 18.8	60.0 ± 18.7	61.2 ± 20.1	Session 2-1	8.90	-4.7 - 24.5	0.36	0.15	28.80	22.3 - 40.5			0.79	0.60 - 0.89
					Session 3-2	-1.80	-8.0 - 4.8	0.75	0.03	13.10	10.3 - 18.0	19.20	16.3 - 23.7	0.94	0.88 - 0.97
					Session 4-3	0.80	-5.2 - 7.2	0.52	0.06	12.30	9.7 - 16.9			0.96	0.91 - 0.98

For handgrip strength, the mid-aged group demonstrated the least variation whereas both the young and elderly groups had greater changes in the means between sessions 1-2 but subsequently met the desirable criteria for reliability. For the young group, analysis by paired sample *t*-test found the mean difference between sessions 1-2 was 13.71 kPa (95% CI: 2.71 – 24.70) was significant ($p = 0.02$), although small in magnitude ($d = 0.41$), whereas mean differences between sessions 2-3 (2.29 kPa; 95% CI: -4.33 – 8.92; $p = 0.49$; $d = 0.06$) and sessions 3-4 (0.91 kPa; 95% CI: -5.02 – 6.85; $p = 0.76$; $d = 0.02$) were trivial. The typical error for hand strength in the elderly was greater than for the young and mid-aged groups, but was substantially less than the variation in tongue strength. In contrast to tongue strength, the meaningful change score for hand strength was much smaller in the elderly compared to the young and mid-aged.

6.4 Discussion

This study had a number of aims and the findings are summarised as follows. Tongue and hand strength were influenced by age with no differences between young and mid-aged groups but large reductions in strength in the elderly. Males were stronger than females in all age groups including the elderly. To the authors knowledge IOPI data for tongue and hand strength have been obtained in an elderly population with a mean age of 89 years for the first time. Strong correlations were observed between both tongue strength measures and hand strength. The test-retest reliability of IOPI strength measurements are influenced by age and a familiarisation session is more important for the reliability of these assessments in the elderly compared to younger populations.

Both tongue and hand strength values are influenced by age as clearly demonstrated by the strong correlations between the strength measures and age. Young and mid-aged individuals had greater maximum tongue and handgrip strength than elderly individuals. Although this is not surprising, the magnitude of the difference was

substantial with the mean tongue strength values in the young and mid-aged groups twice as high as those in the elderly age group. This loss of tongue strength in older age likely contributes to an increase in swallowing problems in the elderly although interestingly the populations studied reported no swallowing problems and the ability to eat a range of foods. The values obtained in the current study were much lower (range: 26-29 kPa) than previous studies (range: 47-65 kPa) of the elderly, which is most likely due to our age group being much older, and possibly frailer as they were residents of an aged-care facility. No difference in tongue strength was observed between the young and mid-aged groups in this study. Although the range of ages in the mid-aged groups was 30 to 57 years it was clearly biased towards the younger end of the range with the mean age of 39 years. The current study found that young and mid-aged males (tongue strength range: 51-66 kPa) and young and mid-aged females (tongue strength range: 53-56 kPa) were close to or within the range of tongue strength values determined in previous studies (55-77 kPa and 55-73 kPa, respectively).

Differences in hand strength with age were also substantial with the young and mid-aged groups more than twice as strong as those of the elderly group. Similarly hand strength in the elderly group was only approximately 60% of that found in a previous study (110 kPa) investigating an elderly population, however that study did not report their findings by sex [38]. In comparison, the current study found that hand strength was lower for elderly males (69 kPa) and females (58 kPa) and again this substantial deficit in older age contributes to the frailty typically observed in this population.

Males were stronger than females for all the strength measures independent of age. The extent of this strength difference was greatest with hand strength (29%) compared to anterior (17%) and posterior (10%) tongue strength. Sex-related strength differences were not always evident in the age subgroups for all the strength measures,

in part due to small participant numbers in many subgroups. Differences in strength between males and females were most evident in anterior tongue and hand strength, and least evident in posterior tongue strength and in the mid-aged group.

Studies have previously included elderly participants but usually in very small numbers and the data have been reported as part of much wider age ranges [53,38,8,73,75,37]. Consequently, this is the first study to provide some representative IOPI strength data for those over 79 years of age. Although our cohort of men was small, we obtained data from a good sized sample of elderly women ($n=24$) relative to the sample size of many previous studies which ranged in numbers from 7 to 16 participants [53,38,58,75,37]. Importantly we have established that it is possible to get good and reliable tongue and hand strength data on this age group, which could have important clinical applications. As expected, there were extremely strong correlations between the two tongue strength measures. Of interest is the strength of the correlations between hand and tongue strength measures. Hand strength is often used as an indication of health-related strength, particularly the loss of strength related to illness or frailty.

The current study also investigated the effects of age on the reliability of IOPI strength measurements. Three measures of reliability were used in the analyses providing indices of systematic and random error, with implications for both group and individual applications [91]. Measures of reliability provided interesting results: % change in the mean values ranged from acceptable to desirable with the young and mid-aged groups meeting the desirable criterion for all strength measures. In contrast, while the elderly group met the desirable criterion for anterior tongue strength it only met the acceptable level for posterior tongue and hand strength. For clinical practice, the typical error analysis is the most important of the reliability measures as this provides an

indication of the variability within an individual between sessions. Typical error was higher than the acceptable standard between the first two sessions but was reduced by familiarisation with the use of IOPI. ICCs for all groups showed good reliability for individual assessments. One limitation of this study was that we did not have a 60-80 year age group and the mean age of the mid-aged group (30-60 years) was 39 years. However a number of studies [53,38,8,58,49,72,73,75,37] have previously reported on these age groups, and the current study provides data that complements these previous studies.

In summary, the results from the current study provide data from healthy younger, mid-aged and elderly participants that contribute to our knowledge of tongue and hand strength measures obtained from the IOPI. A familiarisation session is recommended to improve the precision of these assessments, particularly in older participants.

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Chapter 7: Measures of repeated isometric tongue endurance in healthy adults

7.1 Introduction

Fatigue is one of the most common chronic conditions reported by older adults [8], with effects on eating and drinking as well as other activities of daily living. For example, elderly adults report that it takes them longer to eat a meal and this may have an effect on an individual's ability to maintain a healthy weight and to perform a safe and effective swallow [8]. The tongue, comprised almost entirely of muscle, is the primary propulsive agent to accomplish oropharyngeal swallowing. Appropriate tongue strength is essential for the oral and pharyngeal phases of swallowing as the tongue contributes to the formation, placement, and manipulation of a bolus within the oral cavity and propulsion into the pharynx [75]. Muscle endurance is described as being able to maintain a required or expected force. Further, it may be functionally defined as “the time to task failure for a sustained isometric contraction performed at a submaximal intensity” [109] or the inability to produce a target force with repeated contractions. Decreases in muscle endurance can indicate fatigue which may also be characterised by a clear decrease in the ability to exert appropriate or target muscle force, independent of whether the force can be sustained [110]. Fatigue can be influenced by a variety of task-dependent mechanisms (e.g., type of contraction, exercise intensity).

Studies of the relationship between tongue strength and endurance have been documented using the IOPI [108]. The IOPI is the most commonly used measurement technique to assess isometric tongue strength and endurance [76] but has demonstrated

appropriate test-retest (intra-rater) reliability only for tongue strength [102].

Measurements of sustained isometric tongue endurance lack reliability (as shown in Chapters 5 and 6), as indicated by high variability when measured using the three measures of reliability as recommended by Hopkins [91]. Tongue endurance may be measured in two ways: sustained isometric, which requires tongue muscle contraction to be held in one position for a length of time; or repeated isometric, which involves brief isometric contractions that are performed repeatedly [88]. The reliability of this repeated isometric tongue endurance measure has not been reported and remains to be determined. Repeated isometric tongue endurance measurement may be more representative of the requirements for the tongue force production needed for prolonged speech or the repeated swallowing efforts associated eating a meal or drinking a fluid.

Primarily, the majority of research studies have used sustained isometric tongue endurance measures performed at 50% of maximum isometric tongue strength with healthy adults [38,63,72] and, particularly in terms of speech intelligibility, in populations with a medical condition [51,111,56,103,70]. Solomon, Robin, & Luschei (2000) assessed isometric tongue strength and endurance during a sustained submaximal effort in 16 people (12 males: 4 females; range: 54 to 84 years) with mild to severe Parkinson's disease (PD) and an age-matched healthy control group [70]. Only tongue endurance was significantly less for the group with PD than the healthy control group indicating that tongue weakness and fatigue may influence speech in this population. A recent study by Clark (2012) used the IOPI and assessed repeated isometric tongue endurance contractions in 25 healthy adults at 50% of maximum tongue strength and found that most participants could repeat these contractions (more than 100) for several minutes, although they did report significant fatigue with this task [88].

In spite of there being a large number of published studies in which the IOPI has been used, there is no published evidence to confirm test-retest reliability of the IOPI as a device to measure repeated isometric tongue endurance [11]. Therefore, we have identified the need to determine the reliability of this tongue performance measure in a non-clinical population before using the IOPI as an assessment tool with individuals with dysphagia. This study will provide information about the reliability and skill acquisition of the IOPI as a tool for measuring tongue endurance. If the IOPI is reliable in measuring repeated isometric tongue endurance, it could be a valuable tool for assessing and monitoring individuals during interventions in which tongue endurance may change.

The primary aim of this study was to evaluate the utility of the IOPI as an effective tool for assessment of repeated isometric tongue endurance in a healthy population using 90% of an individual's maximum tongue strength, and if reliable, to determine representative values of these measures. A secondary aim was to assess the rate of any skill acquisition i.e., the number of sessions of tongue endurance assessments for the results to become reliable if values improve with multiple assessment sessions.

7.2 Methods

7.2.1 Study Design

Healthy adults underwent anterior and posterior tongue and handgrip strength and endurance assessment using the IOPI on four occasions separated by approximately one week. Strength assessments consisted of three attempts to exert maximal isometric force. Endurance assessments consisted of one attempt to sustain 90% of maximal isometric force. One investigator (VA) provided all instructions to the participants and conducted all the tests. Three measures of reliability were assessed according to

Hopkins [91]. Exploratory secondary analyses were also conducted to determine whether single peak or mean strength values were more reliable, and to identify other protocol strategies that influence the reliability of these strength and endurance measures.

7.2.2 Participants

Healthy adults were recruited at the University of Newcastle. Each participant completed a health and medical history questionnaire to determine his or her eligibility. Participants were included if they ranged in age from 22 to 37 years, and were healthy with no previous or current swallowing problems. Study exclusion criteria were a history of swallowing problems; abnormal oral structure and function; a history of neurologic, respiratory or gastrointestinal impairment; any current or previous major injury to the tongue; any tongue piercings; any difficulty placing an instrument on the tongue; or a history of seizures. The University of Newcastle Human Research Ethics Committee approved the study and written informed consent was obtained from all participants prior to participation.

7.2.3 Instrumentation

Tongue strength and endurance assessments were collected using the current version (2.2) of the IOPI by placing a small, air-filled bulb longitudinally along the hard palate. The IOPI is a portable, handheld tool containing pressure-sensing circuitry, a peak-hold function, and a timer. It uses a blue air-filled PVC tongue bulb (approximately 3.5cm long and 1.2cm in diameter) which is pliable and has an approximate internal volume of 2.8ml. The bulb was connected to the IOPI via an 11.5cm PVC connecting tube with the pressure exerted against the bulb measured and displayed in kilopascals (kPa). Unlike earlier versions of the IOPI, which showed the green light as the middle light in a row of lights, the current model used in this study has

the green light as the top light (100%). Handgrip strength and endurance were measured by placing a handgrip pressure bulb in the centre of the palm of the dominant hand, with the fingers wrapped around it. Participants were instructed not to press the bulb with the fingertips as this may create artificial increases in pressure. The handgrip bulb is made of soft rubber with a small air-filled bulb that was immersed in an incompressible viscous fluid in the middle. Visual feedback to participants for assessment of endurance was achieved by the light-emitting diode (LED) display on the IOPI screen. To ensure accuracy of measurement, calibration was checked once a week as recommended in the IOPI manual.

7.2.4 Procedure

Participants underwent anterior and posterior tongue strength and endurance assessment using the IOPI following the procedure as previously documented [84,63,102] on four occasions alternating anterior and posterior tongue bulb positions separated by a period of one day. Maximum tongue strength assessment involved three consecutive trials each of approximately two-second duration; the maximum of the three values obtained was used to determine the endurance force target for that session. For assessment of endurance, the IOPI was set to 90% of the participant's maximal strength and participants were asked to perform repeated contractions at the target force for as long as possible by pressing their tongue against the roof of their mouth repetitively.

Three measures of reliability (change in the mean between sessions, typical error, and intraclass correlation coefficients) were assessed according to Hopkins [91]. An acceptable level of variability in test measures is up to the researcher to determine, however established values for reliability measures are a % change in the mean and typical error between sessions of less than 5% (desirable) and 10% (acceptable), and

ICC levels above 0.8 (desirable) and 0.6 (acceptable) [91]. The magnitude of any changes between tests was assessed by effect sizes as follows: large ($d > 0.8$); medium ($d = 0.5$ to 0.79); small ($d = 0.2$ to 0.49); and smaller than $d = 0.19$ deemed insubstantial or trivial [89].

7.2.5 Data management and analysis

All data were entered into Microsoft Excel (Microsoft Windows XP Professional, Version 5.1.2600) for data management and exported into appropriate analysis programs. Participant characteristics were analysed using a statistical software program (SPSS Statistics 20), which provided descriptive statistics and are presented as a mean $\pm$ SD. All reliability measures were analysed using a reliability spreadsheet developed by Hopkins and designed to assess the precision of measurement [95]. A metronome set at 80 beats per minute was used as an example to set the correct speed of contractions.

7.3 Results

Seventeen participants (7 males and 10 females; aged 22-37 years) were recruited. All participants met the inclusion criteria. Characteristics of the participants are presented in Table 7.1. The mean ($\pm$ SD) time between assessments was 6.5 ± 5.0 days (anterior) and 7.6 ± 5.2 days (posterior).

Table 7.1
Characteristics of participants (n = 17), data are Mean ± SD

	Age (years)	Weight (kg)	Height (cm)	BMI^a (kg.m⁻²)
Healthy adults (n = 17)				
- Males	28.0 ± 5.2	76.6 ± 7.1	179.0 ± 6.9	23.9 ± 1.5
- Females	28.9 ± 6.0	62.9 ± 6.5	166.3 ± 6.3	22.8 ± 2.7
- All Participants	28.5 ± 5.5	68.5 ± 9.5	172.0 ± 0.1	23.2 ± 2.3

Note. BMI = Body Mass Index^a

7.3.1 Tongue strength analyses

Data for anterior tongue strength using the highest of the three trials in each session are shown in Table 7.2. Between all sessions, the % change in the mean was lower than the criterion standard for desirable ($> 5\%$) for these strength measures. Typical error values met the criterion for acceptable following session 2 and ICC values met the criterion of desirable over all sessions. For posterior tongue strength, the % change in the mean and typical error met the criteria for acceptable with ICC values between sessions meeting the criterion for desirability (Table 7.2). These results are consistent with the reliability assessments of tongue strength demonstrated in Chapters 5 and 6.

Table 7.2

Test-retest reliability of tongue strength measures using highest value of 3 trials in 17 participants

Outcome Measure	Session 1	Session 2	Session 3	Session 4		Change in Mean (%)	95% CI	Typical error as CV (%)	95% CI	Mean-typical error as CV (%)	95% CI	ICC (r)	95% CI	Min. raw score change (kPa)
Tongue strength (kPa)														
Anterior	58.2 ± 15.1	57.1 ± 14.9	56.1 ± 12.4	55.7 ± 14.5	Session 2-1	-0.90	-9.1 - 8.0	12.60	9.2 - 19.8			0.87	0.67 - 0.95	11.52
					Session 3-2	-0.90	-8.3 - 7.0	11.10	8.2 - 17.4	10.80	8.8 - 14.3	0.85	0.64 - 0.94	9.94
					Session 4-3	-1.70	-7.4 - 4.3	8.50	6.2 - 13.2			0.92	0.80 - 0.97	
Posterior	53.0 ± 14.4	53.3 ± 11.3	53.9 ± 13.3	55.2 ± 14.6	Session 2-1	1.90	-4.3 - 8.4	9.00	6.6 - 13.9			0.91	0.76 - 0.96	7.37
					Session 3-2	0.20	-5.8 - 6.5	8.80	6.5 - 13.7	8.40	6.9 - 11.1	0.91	0.76 - 0.97	7.30
					Session 4-3	1.90	-3.3 - 7.4	7.50	5.6 - 11.7			0.94	0.85 - 0.98	

7.3.2 Tongue endurance analyses

Reliability statistics for repeated isometric tongue (anterior and posterior) endurance are presented in Table 7.3. None of the endurance measurements showed the desired consistency as indicated by highly variable percentage changes in means, mean-typical errors, and ICC values. Although changes in the means were not statistically significant, the magnitude of changes ranged from trivial to medium, which partially reflects the variability. The ICCs for endurance ranged from unacceptable to acceptable levels. All measures of repeated isometric tongue endurance showed poor reliability as indicated by correlation coefficients considered trivial to medium (0.12 – 0.53). These results indicate poor reliability for group assessments (% change in the means, ICCs) and individual assessments (typical error) of tongue endurance, which were not made more reliable with familiarisation.

Table 7.3

Test-retest reliability of isotonic tongue endurance measures at 90% of maximum tongue strength in 17 participants

Outcome Measure	Session 1	Session 2	Session 3	Session 4		Change in Mean (%)	95% CI	Typical error as CV (%)	95% CI	Mean-typical error as CV (%)	95% CI	ICC (r)	95% CI
Tongue endurance (s)													
Anterior	8.3 ± 7.6	17.3 ± 20.1	11.6 ± 10.2	24.2 ± 28.6	Session 2-1	79.80	-2.1 - 230.2	117.40	76.6 - 240.3			0.44	-0.10 - 0.77
					Session 3-2	-22.40	-53.4 - 29.3	96.80	64.9 - 185.2	117.90	88.7 - 177.8	0.47	-0.02 - 0.77
					Session 4-3	51.00	-19.5 - 183.3	137.60	90.5 - 273.2			0.28	-0.21 - 0.66
Posterior	10.5 ± 9.9	11.4 ± 9.2	17.7 ± 23.2	13.6 ± 13.6	Session 2-1	41.80	-18.2 - 145.8	90.40	58.7 - 189.5			0.40	-0.24 - 0.78
					Session 3-2	5.60	-41.9 - 91.6	107.60	69.8 - 224.3	129.20	96.2 - 205.7	0.53	0.01 - 0.81
					Session 4-3	0.10	-53.6 - 116.0	177.30	112.4 - 384.7			0.12	-0.40 - 0.57

7.4 Discussion

The key findings of this study are that although isometric tongue strength measurements obtained using the IOPI demonstrate acceptable reliability, repeated isometric tongue endurance measurements obtained during the same sessions are not reliable. The ability to develop submaximal force of the tongue repeatedly has clear functional applications for tasks such as swallowing and speech, and the ability to identify any limitations or decline in this ability would be clinically important [88]. The lack of established tests or reports of the development or use of such muscle endurance tests suggests that it has been difficult to identify reliable assessments of tongue muscle endurance, which is consistent with the findings of this study. This is also consistent with our previous findings that sustained isometric tongue endurance tests do not meet the standards of reliability necessary to be recommended for use [102].

Substantial additional investigation is required to develop better protocols for both repeated and sustained isometric tongue endurance tests. A limitation of the current study was that the target force was established independently in each session, and although the strength measures on which the target force was calculated were reliable, this does introduce an additional source of variation. A suggestion for future investigation would be to base the target force on the maximum strength identified in the first session and then performing the endurance test in the subsequent sessions with the same target force.

Further exploration of other avenues to reduce error is also required. Measurement of tongue strength prior to endurance assessment may be most useful in confirming a consistent position of the bulb within the oral cavity. Providing feedback to participants of their previous performance and encouraging them to better that target may be beneficial. Use of a metronome to provide the rate at which repetitions should

be repeated would keep the work to rest uniform between tests and individuals, and potentially reduce variation.

The percentage of maximum strength at which the endurance test is conducted also requires additional investigation. Pilot testing prior to this study identified that using 50% of maximum strength, which has been used in a number of studies for sustained isometric endurance tests, results in many minutes of test duration with little fatigue (but possible loss of concentration) when testing repeated isometric tongue endurance. Consequently, 90% of maximum strength was chosen but there may be a target force that is much more reliable. The reliability of the tongue strength measures were similar to those reported in Chapters 5 and 6 as well as those reported previously [6,103,70,75,102]. This provides additional support for the reliability of the IOPI tongue strength measurements.

In summary, this study should be regarded as the first step in developing a reliable repeated isometric tongue endurance test using the IOPI. A number of sources of variation that could be reduced have been identified. Additional research may then provide clinicians with a protocol for using the IOPI as a suitable device to measure tongue endurance.

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Chapter 8: Summary

8.1 Literature review outcomes

While anticipating that the original project would proceed I reviewed the literature pertinent to the topic (Chapter 2) which showed that the IOPI has been the most widely used device to measure tongue strength. The design of the original project for this thesis required the measurement of tongue strength, and the IOPI was identified as a potentially suitable tool. At the time, the IOPI was very new in Australia and not yet approved for clinical use. A systematic review and meta-analysis (Chapter 3) was conducted in order to understand the application of the IOPI to the data. The key findings from this review revealed a wide range of tongue strength values reported in healthy populations, no doubt reflecting the influences of the age and sex of the populations sampled. Tongue strength values decreased as age increased in adults; male strength values were greater than those obtained from age-matched female participants; healthy adults were typically stronger than those with a medical condition; and the anterior portion of the tongue was stronger than the posterior. In summary, this review found clear evidence indicating that the IOPI was an effective tool for the measurement of tongue and to a lesser extent, hand strength. By comparison, few studies had reported its use for tongue or handgrip endurance. The limited investigation of the reliability of the IOPI was also identified as part of this review.

8.2 Studies of tongue and handgrip strength

A review of the literature in relation to the reliability of IOPI measures is provided in the introduction to Chapter 4. The need for test-retest reliability of the IOPI as a tool for assessments of both tongue and handgrip strength and endurance in a healthy population led to the studies reported in Chapters 4, 5, 6 and 7. The key findings in regards to tongue and handgrip strength assessments are summarised as follows:

1. Excellent reliability was demonstrated for tongue and handgrip strength measures using the IOPI in a young to mid-aged healthy population.
2. Acceptable reliability was demonstrated for group assessments of tongue and handgrip strength in the elderly.
3. Greater variability in the tongue strength measures was observed whereas hand strength values were more reliable in the elderly.

8.2.1 Recommendations to improve reliability

1. A familiarisation session is recommended to improve the precision of these assessments.
2. Multiple attempts resulting in some consistency in the maximum values obtained is recommended to establish that a true representation of current maximal strength is obtained.

8.2.2 Strengths

This series of studies investigating the reliability of tongue and handgrip strength and endurance using the IOPI had a number of strengths.

1. Three measures of reliability were used in the analysis providing indices of systematic and random error for both group and individual applications.
2. An appropriate sample size was used with healthy males and females ranging across a suitable age group (healthy: 18-60 years and elderly: 79-97 years).

8.2.3 Limitations

1. A lack of a 60-80 year age group. As tongue strength has been documented to decrease after the age of 60 years, investigating tongue strength in that age group may provide answers that have implications in the clinical environment.
2. A small cohort of elderly males ($n = 6$) was recruited.

3. The healthy age range from 30-60 years was biased toward the 30-40 years age band.
4. Inter-rater reliability was not investigated as only one investigator provided instructions to the participants and conducted the tests. Therefore, this study should be considered the first step towards establishing the reliability of the IOPI.
5. The connecting tube of the IOPI was not marked with tape or marker pen. Marking the IOPI connecting tube with tape or marker pen once the lips are closed and measuring this distance for subsequent assessments may improve the positioning of the tongue bulb within the oral cavity and may result in more consistent inter-session tongue-bulb placements especially for posterior tongue measurements.

8.3 Effects of age and sex on tongue and handgrip strength

As well as investigating healthy and elderly adults, this project examined the effects of age and sex on tongue and handgrip strength in healthy young, mid-aged and elderly adults. The key findings are summarised as follows:

1. Data for tongue and hand strength have been obtained in an elderly population with a mean age of 89 years for the first time.
2. Strong correlations were observed between both tongue strength measures and hand strength.
3. Tongue and hand strength were influenced by age with no differences between young and mid-aged groups but large reductions in strength were noted in the elderly adults.
4. Males were stronger than females in all age groups including the elderly.
5. The test-retest reliability of IOPI strength measurements are influenced by age.

6. A familiarisation session is more important for the reliability of these assessments in the elderly compared to younger populations.

8.4 Studies of tongue and handgrip endurance (Chapters 4, 5 and 7)

Unlike the excellent reliability for tongue and handgrip strength measures the reliability of the tongue endurance measurements was generally unsatisfactory and requires further investigation. Most of the research into tongue endurance measured sustained isometric tongue endurance at 50% of maximum tongue strength and the results from Chapters 4 and 5 found that measures of tongue endurance using a sustained isometric contraction were unsatisfactory and unreliable. An alternative to sustained tongue endurance is repeated tongue endurance. Only one previous study [88] has assessed tongue endurance in this way. In an attempt to try to make tongue endurance more reliable, a small study was designed using maximal tongue strength ($P_{\max}$) and repeated isometric endurance at 90% of $P_{\max}$.

Investigations have revealed that no studies have reported on the reliability of the IOPI measuring repeated isometric tongue endurance in a healthy population. Many common issues between sustained and repeated isometric endurance values were revealed. % change in the mean values above the criterion of 10% between sessions 1-2 were found, although there was a decrease in variation following session 1. Typical errors, or the variation shown within an individual's values, were unacceptably large and ICC values ranged from weak to moderate. This indicates that IOPI-measured endurance values cannot be recommended using the protocols investigated in these studies.

8.4.1 Strengths

Two approaches to the assessment of tongue endurance were investigated.

1. A sustained isometric contraction method.

2. A repeated isometric contractions method.

8.4.2 Limitations

1. Target force was established independently in each session, and although the strength measures on which the target force was calculated were reliable, an additional source of variation was introduced by potentially changing the target force each time.
2. The factors that contribute to the variability in the endurance measures need to be identified so that strategies to control them can be developed. One possible explanation may be that only one measurement of endurance was collected whereas three measures of strength were taken. This difference in protocol could contribute to the larger variation in the endurance measures.
3. The requirements for clinician reaction in starting and stopping the stopwatch may also be a source of variability in the endurance measurement.

8.5 Significance of the project and future directions

This series of studies has enhanced our understanding of appropriate applications of one of the most widely used objective devices for the measurement of tongue strength and endurance. The reliability analysis framework used should form the basis of comparable investigations of reliability of all other tongue strength and endurance measurement devices. Having established the reliability of the IOPI strength measures it is now necessary to investigate relationships between tongue strength and speech and swallowing disorders. Further studies comparing strength values in healthy and clinical populations using the IOPI are now justified. Applications of IOPI tongue strength measures to monitor changes in performance with tongue strengthening interventions appear justified. Establishing reliable protocols for tongue endurance measurement requires considerable research focus. In addition, the clinical implication

of tongue endurance requires greater investigation. The original idea for this thesis was to evaluate the effects of tongue strengthening exercises in people with swallowing difficulties such as those with stroke, and individuals in the head and neck cancer populations. As this project did not proceed, this is still an area of research investigation that is important to pursue.



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Appendix A: Study One - Participant Consent

Appendix A: Consent form – Study One

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Consent Form (V1 – 31/08/11)

Reliability of measurements of tongue strength and endurance and handgrip strength and endurance using the Iowa Oral Performance Instrument

Investigators: Prof Robin Callister (Project Supervisor); A/Prof Bernice Mathisen, A/Prof. Surinder Baines, A/Prof Cathy Lazarus, Valerie Adams (Research Student)

I agree to participate in the above research project and give my consent freely. I understand that the project will be conducted as described in the Information Statement, a copy of which I have retained.

I understand I can withdraw from the project at any time and do not have to provide any reason for withdrawing.

I consent to:

- Attend 4 assessment sessions at The University of Newcastle
- Have my tongue strength and endurance assessed by having a tongue bulb placed in my mouth and push it against the roof of my mouth as hard as possible
- Have my handgrip strength and endurance measured by squeezing a rubber bulb as hard as I can
- Complete a questionnaire describing my health status related to neurological/cognitive problems, any history of respiratory problems, oral status, smoking, any gastrointestinal problems, current medications, any history of non-oral feeding, nutrition/dietary intake, any history of swallowing problems, any current or previous major injuries to my tongue or hand, and previous participation in speech pathology or hand function rehabilitation programs.

I understand that my personal information will remain confidential to the researchers and that data collected from my participation may be used in journal publications, conference presentations and theses. My refusal to participate or withdrawal from the study will not affect my relationship with The University of Newcastle. I have had the opportunity to have questions answered to my satisfaction. I have the right to withdraw my information at any time.

Print Name: _____

Signature: _____ **Date:** _____

Phone: _____ **E-mail** _____

Appendix B: Study One - Information Statement

Appendix B: Participant Information Statement

Chief Investigator:
Professor Robin Callister
Senior Lecturer, Human Physiology
School of Biomedical Sciences & Pharmacy
Faculty of Health
The University of Newcastle
Callaghan NSW 2308
Phone: (02) 49215650
Facsimile: (02) 49217407
E: Robin.Callister@newcastle.edu.au

Student Researcher:
Valerie Adams (0413 016 021)

Information Statement (V1 – 31/08/11)

Reliability of measurements of tongue strength and endurance and handgrip strength and endurance using the Iowa Oral Performance Instrument

Investigators: Prof Robin Callister (Project Supervisor); A/Prof Bernice Mathisen, A/Prof. Surinder Baines, A/Prof Cathy Lazarus, Valerie Adams (Research Student)

You are invited to take part in the research study identified above which is being conducted by researchers from the University of Newcastle, La Trobe University and the Beth Israel Medical Center in New York. Ms Adams is conducting the research as part of her Doctor of Philosophy degree in Biomedical Sciences/Speech Pathology under the supervision of Professor Robin Callister, Associate Professor Bernice Mathisen, Dr Surinder Baines and Associate Professor Cathy Lazarus.

Why is this research being done?

The importance of knowing an individual's tongue strength is clinically useful for deciding whether tongue weakness is involved in swallowing problems. People with swallowing difficulties are at risk of life-threatening problems such as dehydration, malnutrition, and airway obstruction. This study will be the first step in evaluating the reliability (whether it provides the same information with repeated measurements) of a measurement tool called the Iowa Oral Performance Instrument (IOPI) to be used for swallowing research. This tool can also be used to measure handgrip strength and endurance and the reliability of these measurements will also be assessed.

Who can participate in the research?

You are invited to participate in this research if you are aged 18 - 60 years.

This research project is not suitable for you if:

- you have any history of swallowing problems
- you have any current or previous major injuries to your tongue
- you have any tongue piercings
- you have difficulty placing an instrument on your tongue
- you have a history of seizures

What choice do you have?

Your decision to participate is entirely voluntary and only those who give their informed consent will participate in this project. If you decide to participate you may withdraw from the project at any time and no reason for your decision is required. Non-participation or withdrawal from this study will not change any relationship you have with the university and will not disadvantage you in the future.

Where will the project take place?

All tongue strength measures will be done in the Human Performance Laboratory (room HPE2-8) in the HPE building on the Callaghan campus of the University of Newcastle.

What would you be asked to do?

If you agree to participate in this project you will be asked to have your tongue strength and endurance and handgrip strength and endurance assessed on 4 occasions, each a week apart, and to complete a questionnaire. Each strength assessment will take 2 seconds with a 60 second rest between measurements.

1. Tongue Strength Assessment:

Each week will involve three recorded assessments. You will be asked to place a small sterile air-filled bulb between your tongue and hard palate and to press against the bulb with your tongue as hard as you can.

2. Tongue Endurance Assessment:

Each week will involve one assessment. You will be asked to place the air-filled bulb between your tongue and hard palate and to squeeze the bulb with your tongue as hard as you can. A handheld, portable device that shows visual feedback via a column of lights on how much force is generated will be used. You will be required to develop a pressure that makes the top (green) light come on and keep it on for as long as possible.

3. Handgrip Strength Assessment:

Each week will involve three recorded assessments. Hand strength is measured by recording the maximum pressure you can exert on a special hand bulb when you squeeze it with your hand as hard as possible.

4. Handgrip Endurance Assessment:

Each week will involve one assessment. You will be asked to place the air-filled bulb in your hand and to squeeze the bulb with enough force that the top (green) light of the measurement device comes on and to keep it on for as long as possible.

Questionnaire:

You will also be asked to complete a questionnaire that indicates your age, sex, medical history relevant to your tongue and hand, any current or previous major injuries to your tongue, mouth or hand, and whether you have participated in any speech pathology or hand function rehabilitation programs.

How long does it take?

The first assessment will take approximately 20 minutes, to allow for data entry, assessment and completion of the questionnaire. Subsequent sessions will take 10-15

minutes. Your total commitment time over the period of the study will be approximately one hour.

What are the risks and benefits of participating?

When we measure your tongue strength and endurance, you will be asked to place a small air-filled bulb into your mouth. If you report any discomfort, Ms Adams who is a speech pathologist will stop the procedure and you may leave the study. We do not anticipate or expect any serious risks to arise from your participation. We do not anticipate that you will gain any health benefit from your participation in this study.

How will your privacy be protected?

The information you provide will be treated with the same respect for privacy and confidentiality expected of all medical information collected about you when you visit your local doctor. Your test data will be recorded under a code number and all your data will be stored under this number. No information from either questionnaires or testing procedures will be reported in an individual manner; your data contributes to a pool of information from which conclusions are drawn. A master copy of participant names and number codes will be held by the chief investigator so that subjects can be re-identified if required at a later date. Only the research team will have access to the data, which will be locked in Professor Callister's office at the university. Your data will be stored for a minimum of 5 years.

How will the information collected be used?

Measurements will be obtained during your visits to the laboratory. The data will be entered into a computer spreadsheet under a code number so that it is not identifiable by name. You have the right to withdraw your data at any time. You will be provided with your own data and you may choose to receive a summary of the results of the project at the end of the study either by email or by mail if you prefer.

The data will be used to:

- Determine whether tongue strength and endurance or handgrip strength and endurance measured by the IOPI measurement tool changes with repeated tests
- Determine whether sex and/or age have an influence on these measures
- Develop normative data for healthy individuals on these assessments

Results from this study will be presented at national and international conferences, and published in international journals. The results will also be reported in Ms Adams' PhD thesis. Only group data are published or presented, not your individual data.

What do you need to do to participate?

Please read this Information Sheet carefully and be sure you understand its contents before you consent to participate. If there is anything you do not understand, or you have questions about the study, please contact Valerie on 0413 016 021 or Prof Robin Callister on 49215650.

Alternatively, you can contact the researchers by emailing:

- Robin.Callister@newcastle.edu.au
- Val.Adams@uon.edu.au

Thank you for taking the time to consider this invitation.

Professor Robin Callister
Chief Investigator
The University of Newcastle

Valerie Adams
Postgraduate Research Student
The University of Newcastle

Date:

Research Team

Dr Surinder Baines
The University of Newcastle
Phone: 0249215643

A/Professor Bernice Mathisen
LaTrobe University
Phone: 03 54447473

A/Professor Cathy Lazarus
Beth Israel Medical Center
USA

E: Surinder.Baines@newcastle.edu.au

E: Bernice.Mathisen@latrobe.edu.au

E: clazarus@chpnet.org

This project has been approved by the University's Human Research Ethics Committee, Approval No. H-2011-0286. Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Human Research Ethics Officer, Research Office, The Chancellery, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia, telephone (02) 49216333, email Human-Ethics@newcastle.edu.au.

Appendix C: Study One - Screening Questionnaire

Appendix C: Screening Questionnaire

Chief Investigator:
Professor Robin Callister
Senior Lecturer, Human Physiology
School of Biomedical Sciences & Pharmacy
Faculty of Health
The University of Newcastle
Callaghan NSW 2308
Phone: (02) 49215650
Facsimile: (02) 49217407
E: Robin.Callister@newcastle.edu.au

Student Researcher:
Valerie Adams (0413 016 021)

Questionnaire (V1 – 31/08/11)

Reliability of measurements of tongue strength and endurance and handgrip strength and endurance using the Iowa Oral Performance Instrument

Investigators: Prof Robin Callister (Project Supervisor); A/Prof Bernice Mathisen, A/Prof. Surinder Baines, A/Prof Cathy Lazarus, Valerie Adams (Research Student)

Name: _____

This page will be removed once your code number is placed on the questionnaire.

Date: _____

Age: _____

Sex: _____

Do you have a history of swallowing problems?

Yes ☐ No ☐

Do you have any past or current injuries to your tongue?

Yes ☐ No ☐

Do you have any difficulty placing an instrument on your tongue?

Yes ☐ No ☐

Do you have a history of seizures?

Yes ☐ No ☐

Have you required any speech pathology?

Yes ☐ No ☐

Do you have a history of respiratory problems? e.g. pneumonia

Yes ☐ No ☐

Do you smoke?

Yes ☐ No ☐

Do you have any neurological or cognitive issues?

Yes ☐ No ☐

Do you have any problems with your nutritional or dietary intake?

Yes ☐ No ☐

Do you have any history of non-oral feeding? e.g. intubation

Yes ☐ No ☐

Do you have any gastrointestinal problems? e.g. reflux

Yes ☐ No ☐

Do you have any problems with your handgrip function?

Yes ☐ No ☐

Have you ever had rehabilitation for a hand injury?

Yes ☐ No ☐

Appendix D: Study One - Research Flyer

HOW STRONG IS YOUR TONGUE?

DO YOU WANT TO FIND OUT?

Researchers from the Faculty of Health at The University of Newcastle are inviting people to participate in a study to determine the reliability of a device used to measure tongue strength and endurance as well as handgrip strength and endurance.

We are looking for individuals who:

- Are aged 18-60 years
- Are healthy with no swallowing or hand problems

Participation involves having your tongue strength and endurance measured using the Iowa Oral Performance Instrument (IOPI). We will also measure your handgrip strength and endurance.

If you would like to participate in this study or obtain more information, please contact:

Ms Val Adams (PhD student researcher)

E Val.Adams@uon.edu.au

T 0413 016 021

Project Supervisor: Professor Robin Callister

Priority Research Centre for Physical Activity and Nutrition

Robin.Callister@newcastle.edu.au

Complaints about this research

This project has been approved by the University's Human Research Ethics Committee, Approval No. H-2011-0286. Should you have concerns about your rights as a participant in research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Human Research Ethics Officer, Research Office, The Chancellery, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia, telephone (02) 49216333, email Human-Ethics@newcastle.edu.au.

RESEARCH

STUDY

www.newcastle.edu.au

Appendix E: Study Two - Participant Consent

Appendix E: Consent Form – Study Two

Chief Investigator:
Professor Robin Callister
Senior Lecturer, Human Physiology
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Faculty of Health
The University of Newcastle
Callaghan NSW 2308
Phone: (02) 49215650
Facsimile: (02) 49217407
E: Robin.Callister@newcastle.edu.au

Student Researcher:
Valerie Adams (0413 016 021)

Consent Form (V2 – 19/03/12)

Determining the reliability of the Iowa Oral Performance Instrument in measuring strength and endurance of older adults in an aged-care facility

Investigators: Prof Robin Callister (Project Supervisor); A/Prof Bernice Mathisen, A/Prof. Surinder Baines, A/Prof Cathy Lazarus, Valerie Adams (Research Student)

I agree to participate in the above research project and give my consent freely.

I understand that the project will be conducted as described in the Information Statement, a copy of which I have retained.

I understand I can withdraw from the project at any time and do not have to give any reason for withdrawing.

I understand that my personal information will remain confidential to the researchers.

I consent:

- ☐ To have my tongue strength and endurance measured
- ☐ To have my hand strength and endurance measured
- ☐ To complete a questionnaire at specific time periods during the study
- ☐ To allow the researchers to access to my medical records at the nursing home to obtain information on my age, height, weight, medical conditions, and current diet.
- ☐ I would like to receive a summary of the research project at the end of the study.

By signing below I am indicating my consent to participate in the research project conducted by Professor Robin Callister, A/Professor Bernice Mathisen, A/Prof Surinder Baines, A/Professor Cathy Lazarus and Mrs Valerie Adams as it has been described to me in the Information Statement, a copy of which I have retained.

Print Name: _____

Signature: _____ **Date:** _____

Appendix F: Study Two - Information Statement

Appendix F : Information Statement – Study Two

Chief Investigator:
Professor Robin Callister
Senior Lecturer, Human Physiology
School of Biomedical Sciences & Pharmacy
Faculty of Health
The University of Newcastle
Callaghan NSW 2308
Phone: (02) 49215650
Facsimile: (02) 49217407
E: Robin.Callister@newcastle.edu.au

Student Researcher:
Valerie Adams (0413 016 021)

Information Statement (V2 – 19/03/12)

Determining the reliability of the Iowa Oral Performance Instrument in measuring strength and endurance of older adults in an aged-care facility

Investigators: Prof Robin Callister (Project Supervisor); A/Prof Bernice Mathisen, A/Prof. Surinder Baines, A/Prof Cathy Lazarus, Valerie Adams (Research Student)

You are invited to take part in the research study identified above which is being conducted by Valerie Adams from the School of Biomedical Science and Pharmacy at The University of Newcastle. Valerie is conducting the research as part of her Doctor of Philosophy in Biomedical Science/Speech Pathology degree under the supervision of Professor Robin Callister, Associate Professor Bernice Mathisen, Dr Surinder Baines, and Associate Professor Cathy Lazarus.

Why is this research being done?

Tongue strength and endurance

Tongue strength and endurance are important for swallowing. People with swallowing difficulties associated with poor tongue strength and endurance are at risk of problems such as not being able to eat a healthy diet and possibly choking on food. This study will evaluate the reliability (whether it provides the same information with repeated measurements) of a new measurement tool used for swallowing research. We will determine whether measurements of tongue strength and endurance are the same when repeated on multiple occasions or whether you improve.

Hand strength and endurance

We will also make the same measurements of your hand strength and endurance with the same measurement device. People with swallowing problems often have other medical problems associated with muscle weakness, which may affect their hand strength and endurance.

Who can participate in the research?

You are invited to participate in this research if you are a resident at the Maroba Nursing Home, Edith St, Waratah, NSW.

Unfortunately this research is not suitable for you if you have:

- problems with your memory or language (e.g. dementia)
- current or previous major injuries to your tongue
- difficulty placing the measurement device on your tongue
- a history of seizures

What choice do you have?

Your decision to participate is entirely voluntary and only those who give their informed consent will participate in this project. If you decide to participate you may withdraw from the project at any time and no reason for your decision to withdraw is required. Non-participation or withdrawal from this study will not change any relationship you have with your place of residence and will not disadvantage you in the future.

Where will the project take place?

All measurements will be obtained at the Maroba Nursing Home, Waratah.

What would you be asked to do?

If you agree to participate in this project you will be asked to:

1. Provide information about your sex, age, height, weight, medical history and diet. This will be obtained by questionnaire and by obtaining information from your medical records at the nursing home. The student researcher will provide assistance for you to complete the questionnaires, and obtain the requested information from your medical file under the supervision of nursing home staff.
2. Complete a questionnaire about your food (and swallowing if required) every two weeks for 8 weeks.
3. Have assessments of the strength and endurance of your tongue and hand measured every two weeks for 8 weeks. Tongue and hand strength measurements will be performed 3 times with at least 60 seconds rest between efforts. Endurance measurements will be taken once each session at 50% of your maximum tongue and hand strength. (See table below)

<i>Measure</i>	<i>Instructions</i>
Tongue strength	Use the front of your tongue to squeeze a small disposable air-filled bulb against the roof of your mouth as hard as you can.
Tongue endurance	Use the front of your tongue to squeeze the air-filled bulb against the roof of your mouth keeping the green lights on for as long as possible.
Hand strength	Squeeze a hand bulb between the fingers and palm of your preferred hand as hard as you can.
Hand endurance	Squeeze a hand bulb between the fingers and palm of your preferred hand keeping the green lights on for as long as possible.

How long does it take?

The first session will take approximately 30 minutes, to allow for completion of the questionnaires as well as the tongue and hand measurements. Subsequent sessions will take ~ 20 minutes each. Your total commitment time over the period of the study will be about 2 hours.

What are the risks and benefits of participating?

When we measure your tongue strength and endurance, you will be asked to place a small disposable air-filled bulb into your mouth. If you find it uncomfortable or unpleasant, Ms Adams will stop the procedure and you do not have to continue. We do not anticipate or expect any problems to arise from your participation.

We also do not anticipate that you will gain any direct benefit from your participation in this study in terms of increasing your tongue or hand strength, or endurance of your tongue or hand. The understanding gained from your participation may benefit other people in the future.

How will your privacy be protected?

The information you provide will be treated with the same respect for privacy and confidentiality expected of all medical information collected about you when you visit your local doctor. Your test data will be recorded under a code number and all your data will be stored under this number. No information from either questionnaires or testing procedures will be reported to another person (other than yourself) in an individual manner; your data contributes to a pool of information from which conclusions are drawn. Only the research team will have access to the data, which will be locked in Professor Callister's office at the university. Your data will be stored for a minimum of 5 years.

How will the information collected be used?

The data will be entered into a computer spreadsheet under a code number so that it is not identifiable by name. You have the right to withdraw your data at any time. You will be provided with your own data and you may choose to have this placed in your medical file at the nursing home. You may also choose to receive a summary of the results of the project at the end of the study.

The results of this study will be presented at national and international conferences, and published in international journals. The results will also be reported in Ms Adams' PhD thesis. Only group data will be published or presented, not your individual data.

What do you need to do to participate?

Please read this Information Sheet carefully and be sure you understand its contents before you consent to participate. If there is anything you do not understand, or you have questions about the study, please contact Valerie on 0413 016 021 or Professor Robin Callister on 49215650. If you wish to participate, let Valerie know on one of her visits to the nursing home.

Alternatively, you can contact the researchers by emailing:

- Robin.Callister@newcastle.edu.au
- Val.Adams@uon.edu.au

Thank you for taking the time to consider this invitation.

Professor Robin Callister
Chief Investigator
The University of Newcastle

Valerie Adams
Postgraduate Research Student
The University of Newcastle

Date:

Supervisory Team

Dr Surinder Baines
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Surinder.Baines@newcastle.edu.au

Assoc. Prof. Bernice Mathisen
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Assoc. Prof. Cathy Lazarus
Beth Israel Medical Center, USA
Phone: 0011 1 2128446943

Email: clazarus@chpnet.org

Complaints about this research

This project has been approved by the University's Human Research Ethics Committee, Approval No. H-2012-0012. Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Human Research Ethics Officer, Research Office, The Chancellery, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia, telephone (02) 49216333, email Human-Ethics@newcastle.edu.au.

Appendix G: Study Two - Screening Questionnaire

Appendix G: Screening Questionnaire – Study Two
Version 2 (19 March 2012)

Determining the reliability of the Iowa Oral Performance Instrument in measuring strength and endurance of older adults in an aged-care facility

Name: _____ Date: _____

This page will be removed once your ID code is recorded on the questionnaire.

ID Code: _____

Date: _____

Age: _____ Sex: _____

Dominant hand: LEFT / RIGHT

Please answer the questions below.

Do you have a history of any swallowing problems? Yes ☐ No ☐

Do you have any past or current injuries to your tongue? Yes ☐ No ☐

Will you have any difficulty placing a small bulb on your tongue? Yes ☐ No ☐

Do you have a history of seizures? Yes ☐ No ☐

If you answered YES to any of these four questions, you are unable to participate in this study. Thank you for responding.

If you answered NO to the above questions, you may be able to participate in this study. Please continue with the following questions.

Have you ever required any speech pathology? Yes ☐ No ☐

Do you have a history of respiratory problems? e.g. pneumonia Yes ☐ No ☐

Do you smoke or have you quit smoking in the last year? Yes ☐ No ☐

Do you have any problems remembering or thinking clearly? Yes ☐ No ☐

Do you have any problems with what you can eat or drink? Yes ☐ No ☐

Do you have any history of being fed through a tube? Yes ☐ No ☐

Do you have any gastrointestinal problems? e.g. reflux Yes ☐ No ☐

Do you wear false teeth? Yes ☐ No ☐

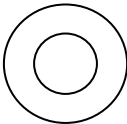
Do your teeth limit your ability to eat some foods? Yes ☐ No ☐

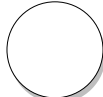
Appendix H: Study Two - Food Texture Screener

Appendix H : Food Texture Screener

Date	
Participant No.	
Week of visit (Baseline, 2, 4, 6, 8)	
Swallowing difficulties reported Y / N If yes, conduct SWAL-QOL	
Food intake – NGT, PEG	

TEXTURES SELECTED

	A	B	C	D
FOOD	Soft	Minced & moist	Smooth pureed	Normal
				
FLUID	Level 150 Mildly thick	Level 400 Moderately thick	Level 900 Extremely thick	Normal
				

	ALL	$\frac{1}{2}$	$\frac{1}{4}$	NOTHING	COMMENTS
BREAKFAST 	☐  ☐	☐  ☐	☐  ☐	☐  ☐	
Mid-morning snack 	☐  ☐	☐  ☐	☐  ☐	☐  ☐	
LUNCH 	☐  ☐	☐  ☐	☐  ☐	☐  ☐	
Mid afternoon snack 	☐  ☐	☐  ☐	☐  ☐	☐  ☐	
DINNER 	☐  ☐	☐  ☐	☐  ☐	☐  ☐	

**Appendix I: Using tongue-strengthening exercise programs in
 dysphagia intervention**

**Appendix J: A systematic review and meta-analysis of
measurements of tongue and hand strength and endurance using
the Iowa Oral Performance Instrument (IOPI)**

**Appendix K: Reliability of measurements of strength and
endurance using the Iowa Oral Performance Instrument in
healthy adults**