The Application of Surface Electromyographic Biofeedback in Dysphagia Rehabilitation in Acute Stroke

Archer, Sally Katherine

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The Application of Surface Electromyographic Biofeedback in Dysphagia Rehabilitation in Acute Stroke.

By

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2013

Centre of Human and Aerospace Physiological Sciences

School of Biomedical Sciences

King’s College London

Submitted in partial fulfilment of the requirements of the

Degree of Doctor of Philosophy

of King’s College London
Abstract

Dysphagia is common after stroke and leads to worse outcome. Previous studies have claimed benefits of biofeedback with surface Electromyography (sEMG) in swallowing therapy, but due to methodological weaknesses the findings are difficult to interpret. Feasibility studies are lacking regarding its application in therapy.

Current approaches in dysphagia therapy in stroke were examined through a nationwide survey of Speech and Language Therapists (n=138). Variability in practice and poor uptake of existing guidelines and evidence was revealed, highlighting the need for more research and measures to promote consistency and best practice. The commonly used Kay Digital Swallow Workstation was validated against a reference sEMG system and found to provide appropriate measurement of amplitude of muscle activity, justifying its use in swallow biofeedback and in subsequent studies of this thesis.

The reliability of submental swallowing sEMG amplitudes was found to be poor in 14 stroke and 85 healthy participants, confirming the need to normalise data for fair comparison. Normalising data to the mean normal swallow amplitude significantly reduced variability, supporting its use as a normalisation reference measure.
No age-related changes were found in the variability of muscle activity for swallowing or the ability to increase submental activity for the effortful swallow (ES) in 85 healthy participants. Dysphagic acute stroke patients and healthy controls significantly increased submental muscle activity for the ES compared to the normal swallow (NS) and for the ES with sEMG biofeedback than without. A questionnaire found that participants considered the ES was significantly easier with sEMG biofeedback. Limited inter-rater agreement was found between SLTs’ clinical assessment of the ES and there was no relationship between clinical rating and sEMG measurements. A pilot Randomised Controlled Trial (RCT) investigating the effect of the ES with and without sEMG biofeedback in dysphagic acute stroke patients (n=10) demonstrated feasibility of the study protocol.

These studies confirm the potential benefit of incorporating sEMG biofeedback with the ES for dysphagic acute stroke patients and justify a subsequent RCT to determine its effect on outcome.
Acknowledgements

My heartfelt gratitude goes to my supervisors Prof Di Newham and Dr Christina Smith. Di, thank you for allowing me the freedom to explore my own ideas but always being available and willing to give expert hands-on help and insightful guidance when I needed it. Christina, thank you for adding so much to the team with your knowledge that encompasses both the clinical and academic worlds of dysphagia. Thank you to both of you for being so prompt in your feedback and for your support and friendship on both an academic and personal level.

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The PhD journey has been so much more enjoyable because of the company of my fellow students (present and past). Special thanks to my tea buddy Dr Matt Liston for always having time for a chat and imparting such useful advice in such an unassuming way. To Mar Omar for understanding the trials of combining studying
with motherhood and for making me feel so cared for (and well fed!) and to Mel Fleming for always understanding where I am coming from when I run things past you, especially during the write up period.

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Abbreviations and Symbols

Symbols

Probability notes are indicated by asterisks to indicate statistical significance. For consistency, a given alpha level is assigned the same number of asterisks throughout the thesis:

- *p<0.05
- **p<0.01
- ***p<0.001

Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
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<tbody>
<tr>
<td>Ag/AgCl</td>
<td>Silver/Silver Chloride</td>
</tr>
<tr>
<td>A to D</td>
<td>Analogue to digital</td>
</tr>
<tr>
<td>BMI</td>
<td>Body Mass Index</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence interval</td>
</tr>
<tr>
<td>CPG</td>
<td>Central Pattern Generator</td>
</tr>
<tr>
<td>CV</td>
<td>Coefficient of variation</td>
</tr>
<tr>
<td>DALY</td>
<td>Disability adjusted life years</td>
</tr>
<tr>
<td>DF</td>
<td>Degrees of freedom</td>
</tr>
<tr>
<td>DSW</td>
<td>Digital Swallow Workstation</td>
</tr>
<tr>
<td>EMG</td>
<td>Electromyography</td>
</tr>
<tr>
<td>FB</td>
<td>Feedback</td>
</tr>
<tr>
<td>FEES</td>
<td>Fibreoptic Endoscopic Evaluation of Swallowing</td>
</tr>
<tr>
<td>FOIS</td>
<td>Functional Oral Intake Scale</td>
</tr>
<tr>
<td>fMRI</td>
<td>Functional magnetic resonance imaging</td>
</tr>
<tr>
<td>Hz</td>
<td>Hertz</td>
</tr>
<tr>
<td>IQR</td>
<td>Interquartile range</td>
</tr>
<tr>
<td>Ln</td>
<td>Log transformed (natural log)</td>
</tr>
<tr>
<td>MASA</td>
<td>Mann Assessment of Swallow Ability</td>
</tr>
<tr>
<td>MCA</td>
<td>Middle Cerebral Artery</td>
</tr>
<tr>
<td>MEG</td>
<td>Magnetoencephalography</td>
</tr>
<tr>
<td>MUAP</td>
<td>Motor unit action potential</td>
</tr>
<tr>
<td>MVC</td>
<td>Maximum voluntary contraction</td>
</tr>
<tr>
<td>N</td>
<td>Newtons</td>
</tr>
<tr>
<td>NMES</td>
<td>Neuromuscular electrical stimulation</td>
</tr>
<tr>
<td>------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td>OR</td>
<td>Odds ratio</td>
</tr>
<tr>
<td>PAS</td>
<td>Penetration Aspiration Scale</td>
</tr>
<tr>
<td>PICA</td>
<td>Posterior Inferior Cerebellar Artery</td>
</tr>
<tr>
<td>RCP</td>
<td>Royal College of Physicians</td>
</tr>
<tr>
<td>RCSLT</td>
<td>Royal College of Speech and Language Therapists</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised controlled trial</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>Research and Development</td>
</tr>
<tr>
<td>SD</td>
<td>Standard deviation</td>
</tr>
<tr>
<td>SE</td>
<td>Standard error</td>
</tr>
<tr>
<td>sEMG</td>
<td>Surface Electromyography</td>
</tr>
<tr>
<td>SENIAM</td>
<td>Surface electromyography for the non-invasive assessment of muscles</td>
</tr>
<tr>
<td>SIG</td>
<td>Special Interest group</td>
</tr>
<tr>
<td>SLT</td>
<td>Speech and language therapist</td>
</tr>
<tr>
<td>SS</td>
<td>Sum of squares</td>
</tr>
<tr>
<td>SSL</td>
<td>Swallow Signals Lab</td>
</tr>
<tr>
<td>TDCS</td>
<td>Transcranial direct current stimulation</td>
</tr>
<tr>
<td>TMS</td>
<td>Transcranial magnetic stimulation</td>
</tr>
<tr>
<td>VFS</td>
<td>Videofluoroscopy</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
</tr>
<tr>
<td>WNL</td>
<td>Within normal limits</td>
</tr>
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</table>
Chapter 1  
Introduction

1.1 Normal Swallowing

Human swallowing is a highly complex neuromuscular process enabling oral nutrition and hydration. It consists of a range of interdependent sensory inputs and motor responses and involves up to 32 paired muscles and six cranial nerves (Perlman and Christensen, 1997). Both swallowing and respiration share the same anatomical pathway superiorly so the effectiveness and efficiency of swallowing are critical for airway protection. (Martin-Harris and McFarland, 2013).

Swallowing has traditionally been described as occurring in four stages: the oral preparatory, oral, pharyngeal and oesophageal stages (Logemann, 1998), with some models also including the pre-oral phase, in which sensory stimulation and cognitive processing lead to increased saliva production and modify behaviour in anticipation of swallowing (Leopold and Kagel, 1997). In the oral preparatory stage, the food is tasted and manipulated by the lips, buccal muscles, tongue and teeth to form a bolus, which is mixed with saliva, while the soft palate is in contact with the tongue to contain the bolus in the mouth and to enable ongoing respiration. Once the bolus is adequately prepared, it is propelled posteriorly in the oral phase with a stripping movement of the tongue, while the lips and the buccal muscles contract and the soft palate elevates to allow the bolus to enter the pharynx (Dodds, 1989). In the pharyngeal stage, the tongue base forces the bolus into the pharynx and the...
nasopharynx is sealed by elevation of the soft palate and approximation with the posterior pharyngeal wall, preventing nasal regurgitation (Figure 1.1) (Miller, 2008).

Before the bolus can reach the laryngeal level, which leads to the trachea and the lungs, the submental muscles (Figure 1.2) contract while the mandible is stabilised in a closed position, causing upward and anterior movement of the hyoid and larynx known as hyo-laryngeal excursion (Kim and McCullough, 2008). Respiration is paused and airway closure is achieved by vocal and ventricular fold closure and also by passive inferior folding of the epiglottis with approximation to the arytenoids, caused by the traction force of the hyo-laryngeal movement (Figure 1.1) (Perlman
et al., 1997). Coordinated contraction and relaxation of the pharyngeal constrictor muscles shortens the pharynx and assist the tongue in creating superior positive pressure to propel the bolus further downwards and clear the pharynx of residue. The upper oesophageal sphincter, which is tonically closed at rest to prevent ingestion of air and entry of gastro-oesophageal refluxate into the airway (Shaker and Shaker, 2013), relaxes and is pulled open by the hyo-laryngeal excursion (Miller, 2008). With the associated drop in pressure, together with the superior drive from the tongue and pharyngeal muscles, the bolus is propelled through the upper-oesophageal sphincter into the oesophagus, where peristalsis projects it towards the stomach (McConnel, 1988). On completion of the pharyngeal stage, the soft palate, tongue and pharynx relax, the hyoid and larynx return to their resting positions and respiration resumes (Broniatowski et al., 1999, Perlman and Christensen, 1997, Huckabee and Pelletier, 1999, Martin-Harris et al., 2005).

Figure 1.2: The submental muscle group consists of the mylohyoid, geniohyoid and the anterior belly of the digastrics muscles from Drake et al. (2010)
The interrelated and coordinated movements of swallowing occur rapidly, with an average duration of 1.5 seconds from oral stage to laryngeal descent in healthy swallowing (Zhang et al., 2012). The overlap and variation in the timing of these events (Zhang et al., 2012, Martin-Harris et al., 2007), together with their interdependence mean that dividing the swallow into distinct phases is arguably artificial (Martin-Harris et al., 2005). Instead the swallow has been described as a single pressure driven event in which the oropharynx is a single tube with four different valves (the lips, velopharyngeal port, larynx and upper oesophageal sphincter) and the coordinated control of this closed system enables the necessary generation of pressure to transport and clear the bolus safely (Perlman and Christensen, 1997). However it is conceptualised, the swallow is an undisputedly complex, dynamic activity which is necessarily finely tuned to enable effective and safe nutrition, hydration and airway protection.

1.1.1 Neural Control of Swallowing

The oral preparatory and oral phases of swallowing are predominantly under conscious cortical control (Miller, 1982). Conversely the pharyngeal swallow has historically been described as a reflex mediated at the brainstem level by a “central pattern generator” (CPG), following studies of anaesthetised and decerebrate animals in which swallows were elicited with electrical or mechanical stimulation (Doty and Bosma, 1956, Sinclair, 1970). The CPG includes two main groups of nuclei located in the medulla oblongata and the ventrolateral medulla adjacent to the nucleus ambiguus (Mittal, 2011). Stimulation of the oropharynx leads to sensory
information being relayed via cranial nerves (CN V, VII, IX and X) to the CPG which initiates a set pattern of behaviour and automatically transmits motor commands via cranial nerves (V, VII, IX, X and XII) to the pharyngeal muscles to initiate a swallow (Malandraki et al., 2011, Dodds, 1989). However, more recent research incorporating a variety of neuro-imaging and electrophysiological techniques and including studies of dysphagic patients with cortical and subcortical damage has led to the neural control of swallowing being redefined as a more complex patterned response (Miller, 2008, Robbins et al., 2008, Humbert and German, 2013). Cortical representation of swallowing has been found to be bilateral but asymmetric, with dominance of one hemisphere that is unrelated to handedness (Li et al., 2009, Lowell et al., 2012, Doeltgen et al., 2011b, Hamdy et al., 1996). Studies have consistently shown that many regions are involved in swallowing, with activity in the primary motor and sensory cortices, pre-motor and supplementary motor areas, the anterior cingulate and insular cortices and the internal capsule (Hamdy et al., 1999, Martin et al., 2001, Humbert et al., 2009, Humbert and German, 2013, Lowell et al., 2012, Li et al., 2009, Galovic et al., 2013, Gonzalez-Fernandez et al., 2008).

The involvement of multiple areas and levels of the brain in swallowing suggests reciprocity of control in which different levels modulate one another (Humbert and German, 2013). This is also indicated by the ability to initiate a pharyngeal swallow through pharyngeal stimulation (i.e. bottom-up control) (Miller, 2008) and also the ability to modify a pharyngeal swallow with different manoeuvres (i.e. top-down
control) (Wheeler-Hegland et al., 2008). Intentionally altering swallowing behaviour may increase cortical representation, a theory supported by the finding that volitional swallowing leads to increased activation in the primary motor cortex compared with reflexive swallowing (Doeltgen et al., 2011b).

1.2 Oropharyngeal dysphagia

Dysphagia is the impairment of swallowing and while there is a functional interrelationship between all stages of the swallow (Gullung et al., 2012), ‘oropharyngeal dysphagia’ specifically indicates any problem between the lips and the upper oesophageal sphincter (Logemann, 1998). It has a diverse range of aetiologies, including neurological, myogenic and structural causes which lead to anatomical and/or physiological impairments (Koidou et al., 2013). It is common, affecting 23% of independently living adults over 70 years of age who were registered on an inner-city primary care centre database (Serra-Prat et al., 2011), 53% of nursing home residents (Park et al., 2013) and 13% of all adult inpatients at general teaching hospitals (Groher and Bukatman, 1986).

Patients with oropharyngeal dysphagia may present with difficulties controlling, preparing or transporting the bolus, an inability or delay in initiating a swallow, difficulties clearing the mouth and pharynx of food/fluid, leading to a build up of residue, and/or reduced airway protection, with entry of saliva and/or ingested material into the airway above (penetration) and/or below the vocal folds.
Oropharyngeal dysphagia is typically managed by speech and language therapists (SLTs) who will conduct a thorough case history and clinical swallowing assessment, including cranial nerve examination and trials with different food and fluid boluses, and may then recommend and conduct an instrumental swallowing assessment such as a videofluoroscopy (modified barium swallow) or fibreoptic endoscopic evaluation of swallowing (FEES) and make recommendations for safe nutrition and hydration and/or to improve swallow function (The Royal College of Speech and Language Therapists, 2005).

1.3 Stroke

The World Health Organisation (WHO) define stroke as a clinical syndrome of presumed vascular origin, typified by rapidly developing signs of focal or global
disturbance of cerebral functions lasting more than 24 hours or leading to death (World Health Organization, 1978). About 15 million people have a stroke each year, and it is a leading cause of mortality worldwide, with 5.5 million deaths annually. It is also a leading cause of disease burden, accounting for 4.5% of disability adjusted life years (DALYs) in low and middle income countries and 6.3% of DALYs in high income countries (Lopez et al., 2006). It has a long-term impact with 10-20% of first-time stroke survivors continuing to have moderate to severe disability at 10 years (Wolfe et al., 2011). The most common type of strokes are due to cerebral infarction (85%), with 10% due to haemorrhage and 5% due to subarachnoid haemorrhage (Intercollegiate Stroke Working Party, 2012).

1.4 Dysphagia in Stroke

1.4.1 Incidence

Dysphagia is common after stroke; Flowers et al. (2013) reported an incidence of 45% in a retrospective review of 250 patients with first-time ischaemic stroke and similarly Smithard (2007) found an incidence of 44% in 1188 first-time stroke patients assessed with a water screening test. Studies that have used instrumental swallowing assessments typically report a higher incidence; Daniels et al. (1998) diagnosed dysphagia in 65% of 55 consecutive acute stroke patients on videofluoroscopy and Hamdy et al. (1998) identified dysphagia in 71% of 28 unilateral hemispheric stroke patients. This increased reported incidence following instrumental assessment may relate to the frequency of silent aspiration post
stroke (i.e. aspiration with no overt clinical sign), reportedly occurring in 67% (Daniels et al., 1998), which may lead to dysphagia being missed on clinical assessment. Correspondingly dysphagia was identified in 51% of 128 acute stroke patients from clinical assessment and 64% of the same sample with videofluoroscopy (Mann et al., 1999).

1.4.2 Consequences

Dysphagia is associated with a threefold increase in the risk of pneumonia post stroke, rising to an 11 fold increase if the patient is known to aspirate (Martino et al., 2005). It has been identified as an independent predictor of mortality and is associated with poor nutrition, dehydration, increased length of stay and institutionalisation (Smithard et al., 2007, Smithard et al., 1996, Crary et al., 2013, Galovic et al., 2013). Feeding tube dependency or the need for a modified diet is associated with poor quality of life one year after stroke (Kwok et al., 2006) and a large population-based study of 3689 stroke patients found the presence of dysphagia was a predictive factor for depression (Ayerbe et al., 2011), which affects around 30% of patients up to 10 years after stroke (Ayerbe et al., 2013). Furthermore a focus group study including participants with post-stroke dysphagia found that dysphagic individuals report that psychological consequences including fear, embarrassment, frustration and lack of control outweigh the physiological consequences of dysphagia (Martino et al., 2009). Appropriate management of dysphagia following stroke is therefore essential to reduce its burden.
1.4.3 Recovery

There is variability in the reported rates of recovery of swallow function after stroke. Smithard et al. (1997) reported that 51% of 121 consecutive acute stroke patients were dysphagic at clinical assessment within 24 hours of admission, with 27% dysphagic at seven days and 10% at six months. Finestone et al. (2002) found that 27% of 48 dysphagic first-time stroke patients had returned to their normal diet by three weeks and by three months 75% had done so. Daniels et al. (2000) reported that 93% of 56 patients diagnosed with dysphagia on clinical assessment had returned to their normal diet by the point of hospital discharge, although the length of stay was not stated. However, there is evidence that determining recovery of swallow function from clinical assessment or diet tolerance may miss persistent impairment. Mann et al. (1999) found that 87% of 128 acute stroke patients studied prospectively had returned to normal diet by six months despite 50% showing ongoing clinical signs of dysphagia and 81% continuing to present with signs on videofluoroscopy.

The clinical predictors of swallowing recovery in stroke were investigated in a retrospective study of 65 acute stroke patients (Schroeder et al., 2006); an increased number of clinical features of dysphagia present on initial swallowing assessment was associated with poor swallowing outcomes at six months, but presence of aphasia, hemispatial neglect and different lesion location were not. Conversely, Terre and Mearin (2009) found that recovery did relate to lesion location with 58% of 12 patients with posterior vascular territory lesions continuing...
to aspirate at one year compared with just 12% of 8 patients with anterior territory lesions. Although the small numbers in this study make it difficult to interpret the findings, they could be explained by the potential effect of posterior circulation damage on the swallowing CPG. Presence of aspiration, dysarthria, more severe stroke, loss of consciousness, intubation and bilateral infarcts were all significantly associated with dysphagia at discharge in a retrospective study of 323 first-time ischaemic stroke patients (Kumar et al., 2012). Lesion size and severity of stroke and/or having a simultaneous lesion in the frontal operculum and insular cortex were predictive of having a persistent risk of aspiration seven days after stroke on clinical assessment in 94 acute first-time stroke patients (Galovic et al., 2013). Taken together, these findings indicate that unsurprisingly patients who have more severe strokes and/or have more severe dysphagia have worse prognosis for swallow recovery, with a potential adverse impact of specific lesion sites. While the majority of patients will regain swallow function by six months, the significant sequelae of dysphagia mean that methods to reduce the impairment and speed up recovery are warranted.

### 1.4.4 Mechanisms of swallow recovery

Neuroplasticity is the central nervous system’s ability to adapt and reorganise following injury (Martin, 2009) and there is increasing evidence that experience-dependent cortical reorganisation is fundamental to regaining function after stroke (Robbins et al., 2008, Kleim and Jones, 2008, Hamdy et al., 1998, Fraser et al., 2002). A seminal study of 28 patients using transcranial magnetic stimulation (TMS) and
videofluoroscopy one and three weeks after initial hemispheric stroke found that dysphagic patients who recovered swallow function presented with increased motor representation of the pharynx in the unaffected hemisphere, whereas patients with persistent dysphagia did not, suggesting that reorganisation of the intact hemisphere has an important role in swallow recovery (Hamdy et al., 1998). A more recent magnetoencephalography (MEG) study of 37 patients eight days after initial stroke found reduced cortical activation in the primary sensory and motor areas in both the affected and contralesional hemispheres during swallowing in a subgroup of 19 dysphagic patients. Conversely, non-dysphagic patients had extensive bilateral activation that was comparable to healthy controls. Furthermore, brainstem stroke patients showed right lateralisation of sensorimotor cortical activation, which was stronger in those without dysphagia, potentially indicating cortical reorganisation compensating for subcortical damage (Teismann et al., 2011). These studies suggest that activation and reorganisation of the unaffected hemisphere after stroke is essential for both protecting and restoring normal swallow function.

1.5 Treatment of oropharyngeal dysphagia

In the management of dysphagia, there has traditionally been a focus on recommending compensatory techniques, e.g. altering food/fluid consistencies and/or posture, to prevent aspiration without changing swallow physiology (Bisch et al., 1994). However, more recently the focus has shifted to techniques aimed at
restoring swallowing ability (Robbins et al., 2008), and this thesis will centre particularly on behavioural rehabilitative treatments.

### 1.5.1 Principles of treatment

Motor learning is the formation of a new motor pattern via practice. This can refer to learning a completely new movement or the adaptation of a pre-learned one. In motor learning through adaptation, behaviour is modified with repeated practice in response to error feedback, which leads to the recalibration of a motor pattern to meet different demands, e.g. with variations in the rate, force or direction of movement (Bastian, 2008). As such, the nervous system is highly flexible in responding to new situations and this type of motor learning is relevant in dysphagia rehabilitation post stroke as the patient needs to relearn how to swallow safely and effectively in the context of their newly impaired sensorimotor system. Adaptive motor learning of hyolaryngeal excursion during swallowing has been shown in response to a single session of electrical stimulation that induced contraction of the infrahyoid muscles as a form of resistance in healthy participants (Humbert and German, 2013). Treatments that encourage adaptive motor learning may therefore help dysphagic patients compensate for impairment and therefore improve their swallow function.

In addition treatments are recommended that are structured according to the principles of exercise physiology, including intensity, where an exercise must force
the neuromuscular system beyond the normal level of activity in order to drive improvement, task specificity and transference, where training in one task impacts on performance of another (Burkhead et al., 2007). These treatments aim to increase the strength, rate or coordination of specific movements for swallowing or the swallow itself while maximising neuromuscular plasticity. Resistance training in the healthy and stroke populations is known to increase the number of motor units recruited and the rate and coordination of recruitment, leading to shifts in muscle fibre type and muscle hypertrophy, with resultant increased strength, coordination and precision of movement (Ryan et al., 2011, Duchateau et al., 2006). There is evidence that strength training induces corticomotor adaptation, with unilateral limb training leading to significantly increased strength bilaterally, coupled with increased ipsilateral primary motor cortex excitability (Goodwill et al., 2012). Indeed the principles considered to drive neuroplastic changes overlap with those established in the field of exercise training. Kleim and Jones (2008) outline 10 principles of neural plasticity: use it or lose it, use it and improve it, specificity, repetition, intensity, time, salience, age, transference and interference.

1.5.2 Non-behavioural swallowing therapy

Broadly, rehabilitative swallowing interventions can be categorised as behavioural and non-behavioural. Non-behavioural interventions have been described as those in which the patient is a passive recipient of treatments which focus on neurostimulation with the aim of increasing excitability of the motor cortex; these include peripheral electrical, peripheral sensory and cortical stimulation (Martin,
Pairing peripheral pharyngeal electrical stimulation with repetitive TMS, in a combined technique termed paired associative stimulation, has been shown to increase excitability of corticomotor projections to the pharyngeal muscles (Michou et al., 2012b, Michou et al., 2013). Furthermore, improvements in airway protection and swallowing timings measured on videofluoroscopy were shown immediately following one session of the technique in six dysphagic patients who were 9-160 weeks post stroke (Michou et al., 2012b). Results of further studies of this new treatment are awaited to determine its role in clinical practice.

A commonly used treatment for sensory impairment in swallowing is thermal-tactile stimulation (Lim et al., 2009). However, the few studies that have examined its efficacy do not support its use in stroke-related dysphagia (Power et al., 2006, Rosenbek et al., 1998). Neuromuscular electrical stimulation (NMES) has received considerable attention as a treatment option for dysphagia, with the aim of increasing the sensory stimulation for swallowing and/or stimulating the motor nerves for muscle contraction (Humbert et al., 2012). However, the evidence is unclear and conflicting with respect to its efficacy (Lim et al., 2009, Bülow et al., 2008, Permsirivanich et al., 2009, Park et al., 2012, Heck et al., 2012).

Cortical stimulation has been described as “priming” the brain to make the most of behavioural therapy (Cassidy et al., 2013). Non-behavioural and behavioural swallowing treatments can therefore be combined to maximise the effects of each
Improvements in motor learning and retention have been shown when brain stimulation with transcranial direct current stimulation (TDCS) is combined with upper limb training in chronic stroke patients (Lefebvre et al., 2012). Significant improvements in dysphagia severity were found as a result of TDCS combined with mixed behavioural swallowing therapy compared with behavioural therapy alone in a randomised control trial of 20 sub-acute stroke patients (Shigematsu et al., 2013). Therefore there is justification to determine behavioural methods that exploit and enhance neural plasticity and improve performance alongside non-behavioural techniques (Kleim, 2011).

1.5.3 Behavioural swallowing therapy

The aim of behavioural therapy techniques is to restore swallowing ability by improving the physiological components of swallowing, including muscle strength, duration, coordination and timing (Burkhead et al., 2007). While there are yet to be studies that have specifically investigated cortical reorganisation as a result of common behavioural swallowing exercises, there is a growing body of evidence of the neuroplastic effects of oral motor training (Arima et al., 2011, Svensson et al., 2006, Svensson et al., 2003, Kothari et al., 2013, Boudreau et al., 2013, Sessle et al., 2007, Boudreau et al., 2007). The relevant studies are summarised in Appendix 1. Short periods of tongue training have been shown to increase corticomotor excitability in both fMRI and TMS studies of healthy participants, with changes evident in primary motor areas up to a week after training, associated with increased training success (Arima et al., 2011, Svensson et al., 2003, Svensson et al.,
and indicating the importance of the neuroplastic principle of time (Kleim and Jones, 2008). Furthermore, interventions that incorporate motor skill training, consistent with the principle “use it and improve it” (Kleim and Jones, 2008), have been shown to drive cortical neuroplasticity most effectively (Kothari et al., 2013). The concept of task specificity is supported by tongue-training studies that have shown changes in tongue primary motor cortex but not the swallow area (Sessle et al., 2007, Avivi-Arber et al., 2011). These studies are small and yet to be replicated in patient populations, but they provide a strong basis for more research investigating the neuroplastic effects of other behavioural interventions specifically targeting swallowing. While this research is awaited, there is an accepted theory that behavioural treatments that focus on driving cortical reorganisation by complying with the principles of neural plasticity, while following established theories of exercise physiology, are considered most likely to improve functional outcome (Kleim and Jones, 2008, Robbins et al., 2008, Kleim, 2011, Burkhead et al., 2007)

1.5.3.1 Evidence for behavioural therapy

A recent Cochrane review (Geeganage et al., 2012) of dysphagia treatments post stroke included five studies (423 patients in total) that assessed the outcome of behavioural dysphagia therapy and reported significantly reduced dysphagia (OR 0.52; 95% CI 0.30 to 0.88; p=0.01) and a non-significant reduction in length of stay and chest infection as a result of behavioural swallowing therapy. This represents considerable progress from the previous Cochrane review on this subject in 1999 which concluded that there was insufficient evidence to draw reliable conclusions
However, the latest review by Geegenage et al. (2012) also concluded that it was unclear which components of the therapies were beneficial and therefore recommended more research to guide practice.

A recent study of 50 dysphagic patients within the first six months post stroke indicated improved functional swallowing status and quality of life measures as a result of a mixed dysphagia exercise programme compared with “conventional swallowing therapy” consisting of thermo-tactile stimulation (Kang et al., 2012). However there was no random allocation into groups or blinding and therefore there is a considerable risk of confounding and bias in this study. Carnaby et al. (2006) performed a more robust randomised controlled trial of dysphagia therapy in 306 stroke patients and found a consistent trend towards more favourable outcomes, e.g. return to normal diet and lower incidence of swallowing-related medical complications, in patients who were assigned a programme of swallowing intervention compared with those receiving “usual care” from the attending physician. The intervention package delivered was multi-factorial and patient specific; however information is not provided on the specific content, intensity or format of the sessions. Therefore, while these findings are promising with respect to the benefit of therapy, they do not provide the clinician with sufficient guidance on how to treat an individual patient.
Other studies have examined the effect of individual therapy approaches and promising results have been reported from case series of a lingual exercise programme on swallowing recovery, particularly incorporating biofeedback from oral pressure sensors (Yeates et al., 2008, Robbins et al., 2007). Furthermore, as outlined in section 1.5.3 above, just one hour of tongue training has been shown to increase corticomotor excitability in fMRI and TMS studies of healthy participants, with neuroplastic changes evident in primary motor areas up to a week after training, associated with increased training success (Arima et al., 2011, Svensson et al., 2003, Svensson et al., 2006). However, there were mixed results of a tongue strength and accuracy training programme in six dysphagic traumatic brain injury patients, with an overall improvement in aspiration but a deterioration in pharyngeal clearance, despite improvements in tongue strength (Steele et al., 2013). Therefore until studies are completed with control groups, random allocation and blinding, the evidence for tongue strength training in improving swallowing remains unclear.

The Shaker or “head-lift” exercise is a prescriptive programme incorporating both isotonic and isometric exercises with task progression and was found to lead to significantly improved swallow function and return to oral diet in a cross-over study of 27 dysphagic patients of mixed aetiologies (Shaker et al., 2002). A subsequent multi-centre randomised control trial in dysphagic patients of mixed aetiologies indicated physiological benefits of both the Shaker exercise and “traditional swallowing therapy”, consisting of a mixed programme of exercise and
compensatory strategies (Logemann et al., 2009). However, this study failed to recruit sufficient numbers to draw reliable conclusions, with outcome data only available on 11 patients, despite recruiting from seven centres.

Lip strength training has been described as improving swallowing function, but this has yet to be investigated in stroke beyond a retrospective study of 30 stroke patients without a control group or blinding (Hagg and Anniko, 2008). Other commonly used techniques, for example the effortful swallow (ES) (see 1.6) the massako or “tongue-hold” and the Mendelsohn manoeuvre, have been shown to beneficially alter the biomechanics of the swallow during their execution (Huckabee et al., 2005, Wheeler-Hegland et al., 2008, Doeltgen et al., 2011a, McCullough et al., 2012, McCullough and Kim, 2013, Fujiu-Kurachi et al., 2013), but are yet to be subject to controlled trials in which their benefit as individual rehabilitative techniques are examined. Expiratory muscle strength training (EMST) tasks have been shown to increase submental muscle activity compared with normal swallowing in healthy participants (Wheeler et al., 2007) and a randomised control trial in 72 Parkinson’s disease patients showed significant improvements in hyolaryngeal function and improved airway protection on videofluoroscopy after a four week EMST programme compared with sham therapy (Troche et al., 2010). Studies are awaited that examine this technique in stroke patients. The McNeill Dysphagia Therapy Programme aims to incorporate exercise principles to systematically drive neuroplastic changes and improvement, such as task progression (use it and improve it), specificity and intensity, and has been
recommended as an effective dysphagia treatment (Carnaby-Mann and Crary, 2010, Crary et al., 2012). The patient is asked to perform “hard swallows” and a hierarchy of feeding tasks is followed. However, while the principles of this technique appear sound, the existing evidence comes from studies that are small, retrospective, include mixed populations with selective allocation, lack blinding or control groups (Crary et al., 2012, Lan et al., 2012) and/or are confounded by marked differences in treatment dose between groups (Carnaby-Mann and Crary, 2010).

Taken together, several studies have suggested that behavioural dysphagia therapy improves swallow function in stroke patients; however the literature is dominated by low quality evidence. Further research is indicated that addresses some of the methodological issues of previous studies, incorporating a prospective, clear protocol with control groups, blinding, randomisation and the use of validated outcome measures. Furthermore the effects of specific exercises need attention in order to determine their role in reducing the burden of dysphagia.

1.6 The Effortful Swallow Exercise

The “effortful swallow” (ES) is a dysphagia exercise commonly recommended by SLTs (Carnaby et al., 2006, Peck et al., 2010). It is a task-specific exercise (Kleim and Jones, 2008, Robbins et al., 2008, Burkhead et al., 2007) as the patient is typically instructed to swallow and to “squeeze hard with all of your swallowing muscles” (Logemann, 1998). The exercise aims to increase posterior tongue base movement,
drive the bolus more efficiently through the pharynx, reduce post-swallow residue and decrease the incidence of aspiration (Yeates et al., 2010, Hind et al., 2001).

The ES has been shown to elicit significantly higher responses in cortical regions related to swallowing on fMRI when compared with normal swallowing, with the primary motor and sensory areas most consistently active, suggestive of enhanced cortical activation during the task (Peck et al., 2010). This may relate to the increased volitional component of the exercise compared with normal swallowing and is consistent with the increased primary motor cortex excitability for submental corticobulbar projections in TMS studies during volitional versus reflexive swallowing (Doeltgen et al., 2011b). Active training of limb muscles leads to improved performance compared with passive training, with a corresponding increase in primary motor cortex activation and this is suggested to indicate a key role for voluntary drive in neurorehabilitation and motor learning (Lotze et al., 2003). Arguably a benefit of the ES is that it is not only task specific but it also enhances volitional drive.

A series of studies have examined the physiological impact of the ES exercise in healthy participants and there is adequate data indicating it significantly increases oral pressure (Hind et al., 2001, Yeates et al., 2010, Steele and Huckabee, 2007, Fukuoka et al., 2013), pharyngeal pressure and peak submental surface Electromyography (sEMG) amplitudes compared with normal swallowing (Huckabee
et al., 2005, Huckabee and Steele, 2006, Steele and Huckabee, 2007, Takasaki et al., 2011, Yeates et al., 2010, Wheeler-Hegland et al., 2008). Furthermore, it leads to significantly increased superior hyoid movement compared with the normal swallow (NS) (Wheeler-Hegland et al., 2008, Hind et al., 2001). Temporal advantages of the manoeuvre have also been reported which augment and lengthen airway closure and pharyngeal clearance, including significantly reduced hyoid-mandibular space pre-swallow, indicative of early laryngeal elevation (Bülow et al., 1999), significantly longer laryngeal vestibule (airway) closure and duration of upper oesophageal opening (Hind et al., 2001). Other studies have shown that there is relatively faster achievement of peak pharyngeal pressure in the ES than the NS, indicative of faster muscle recruitment (Steele and Huckabee, 2007) and that the ES elicits significantly longer overall oral and pharyngeal pressure generation (Steele and Huckabee, 2007, Hiss and Huckabee, 2005).

In contrast to other studies, Bülow et al. (2002, 2001) found no significant difference in pharyngeal pressure in their videomanometric comparison of normal and effortful thin liquid (barium) swallows in eight patients with pharyngeal dysfunction secondary to stroke (n=6) or head and neck cancer (n=2). However, key methodological issues stand out with these studies; in particular the mixed patient populations represented and the risk of type II error from the small sample sizes. Furthermore, four of the eight patients reportedly “had problems” completing the ES and yet their results were included in the analysis, therefore potentially skewing the results (Bülow et al., 2001, Bülow et al., 2002). The study tasks were not
counterbalanced, which may have led to a fatigue effect, especially considering four different exercises were investigated in the same examination with “at least three” wet swallows of each technique elicited. The instruction for the ES was considerably different to that described in other studies; participants were asked to “swallow very hard while squeezing the tongue in an upward–backward motion toward the soft palate”. This altered trajectory of the tongue is likely to affect generation of pressure within the pharynx (Huckabee et al., 2005).

In response to these conflicting findings, Huckabee and Steele (2006) hypothesised that the method of executing the exercise would have a significant effect on the outcome, so they compared the effect of two different methods of completing the ES on submental sEMG peak amplitude and orolingual and pharyngeal manometric pressure. Healthy female participants aged between 20 and 35 years (n=20) completed the ES without tongue emphasis, with the instruction “as you swallow I want you to squeeze hard with the muscles of your throat, but not use your tongue to generate extra force” and the ES with tongue emphasis, following the instruction “as you swallow, push really hard with your tongue” and the data compared to measurements taken during normal swallowing. Statistically significant effects of ES strategy were observed for all variables investigated and in all cases the tongue-to-palate emphasis produced a significantly greater change from normal swallowing than the tongue de-emphasis technique. This indicates that tongue-to-palate emphasis during effortful swallowing has a greater effect on enhancing the overall motor system performance in the ES.
Taken together, these studies indicate that the ES is a task specific exercise that incorporates overload; that is, in order to complete an ES, the muscles are being worked harder than normal with increased cortical activation. These physiological benefits comply with many of the principles of strength training (Burkhead et al., 2007) and neural plasticity (Kleim and Jones, 2008). However, only one study has specifically investigated the effects of the ES on swallow recovery. Park et al. (2012) reported no significant difference in hyolaryngeal movement or penetration/aspiration as a result of ES training in a randomised control trial of 18 patients >1 month after stroke comparing ES training with ES training coupled with resistance from transcutaneous electrical stimulation to the infrahyoid muscles. The ES combined with electrical stimulation, however, produced significant improvements in hyolaryngeal elevation but not penetration/aspiration. Unfortunately, limited information is provided about key factors that may have influenced recovery, including no information on time since stroke apart from it being more than a month, history of previous stroke or dysphagia or lesion location. Participants were only mildly dysphagic, with the majority scoring ≤3 on the penetration/aspiration scale (PAS) (Rosenbek et al., 1996), indicating that they were not aspirating, which may have led to a ceiling effect. Outcome measures were limited, with no examination of pharyngeal clearance or functional swallowing status. Furthermore, the intensity of treatment was arguably insufficient to drive recovery, consisting of just three sessions of 20 minutes per week for four weeks. The impact of this exercise on the dysphagic population therefore remains to be determined.
1.6.1 Challenges in delivering therapy

A challenge in the treatment of patients with dysphagia is that they rarely perceive that they have a swallowing problem, while those who are aware spontaneously make more modifications to the way they eat/drink and have better outcomes (Parker et al., 2004). Anxiety and fear are common consequences of dysphagia, for which strategies to increase patients’ feelings of control are recommended (Martino et al., 2010). During swallowing therapy, patients work to gain volitional control of previously automatic movements, e.g. the ES, with the aim of restoring airway protection during swallowing. Frequently, patients are asked to learn and practise movements that are novel and/or difficult to monitor as part of behavioural swallowing rehabilitation (Crary et al., 2004).

Feedback is vital for motor learning to be successful as the learner adapts subsequent behaviour according to the difference between the actual and the desired output (Shumway-Cook, 2001, Bastian, 2008, Huang et al., 2008). It is accepted that individuals generate motor commands that will maximise the reward they receive (Huang et al., 2008), so it follows that accurate feedback is essential and the right behaviour is rewarded to shape learning. However, feedback is challenging to deliver in dysphagia therapy when there is no overt sign of successful accomplishment of a target. Clinical swallowing assessments have poor reliability (McCullough et al., 2005) so it likely that feedback provided during therapy may lack validity. This has implications for ensuring that optimal movements are reinforced and for motivating the patient to continue trying.
1.7 Biofeedback

Biofeedback is a method of recording and presenting the performance of an automatic function in order to teach volitional control (Oxford University Press, 2006) and it enables small changes in physiological processes to be noticed and reinforced so that behaviour is modified (Barofsky, 1995). This follows the theory that motor control and learning involves actively discovering the sensory consequences of motor commands, enabling the development of a movement plan to minimise implicit motor costs and maximise rewards (Izawa et al., 2008).

Biofeedback has been incorporated into stroke rehabilitation for decades (Basmajian et al., 1975). However, a Cochrane review of 13 studies examining EMG biofeedback in stroke rehabilitation in 2007 (269 participants) concluded that there was insufficient evidence for its use in routine practice (Woodford and Price, 2007). The authors recommended completion of randomised clinical trials using standardised outcome measures. More recently, Stanton et al. (2011) performed a systematic review of studies published up until September 2010 addressing the application of biofeedback specifically during lower limb rehabilitation following stroke and concluded that augmenting treatment with biofeedback leads to improved outcome compared with usual therapy. Improvements in power and control were also found when stroke patients were provided with visual feedback during cycling tasks (Lin et al., 2012). However, biofeedback is referenced within the most recent Royal College of Physicians’ guidance on stroke (Intercollegiate...
Stroke Working Party, 2012), recommending that it should not be used on a routine basis outside the context of research.

1.7.1 Biofeedback and Dysphagia

It has been suggested that incorporating biofeedback into dysphagia therapy would provide the patient with direct information on a complex and subtle process to improve motor control (Nelson, 2007), enabling more active involvement in therapy and providing feedback that both challenges and motivates, thereby improving outcome (Reddy et al., 2000). Increased conscious control for swallowing with biofeedback was implied by the results of an fMRI study in which visual feedback during swallowing led to increased activation in frontal regions, indicating that the feedback directed more attention to motor planning for swallowing (Humbert and Joel, 2012).

Several studies have reported benefits of swallowing therapy with adjunctive sEMG biofeedback in dysphagic stroke patients (Huckabee and Cannito, 1999, Logemann and Kahrilas, 1990, Bogaardt et al., 2009, Crary et al., 2004, Crary, 1995, Bryant, 1991). However, all of these studies are retrospective and/or case studies and none use a control group, blinding or randomisation and the sample sizes are small. Furthermore, most do not follow a specified, structured treatment protocol, used mixed treatments (Reddy et al., 2000, Logemann and Kahrilas, 1990, Crary et al., 2004) and include mixed populations (Reddy et al., 2000, Crary et al., 2004). These
methodological weaknesses limit the interpretation of the reported findings. Robust studies are indicated, with randomisation, control groups and blinding and with clear treatment protocols, in order to provide evidence of the usefulness of biofeedback in the treatment of dysphagic patients. Furthermore it is not known whether dysphagic patients can actually use and interpret biofeedback for swallowing to improve exercise performance, or whether they find it an acceptable part of therapy.

1.8 Surface Electromyography (sEMG)

sEMG provides a non-invasive way of studying muscle activity and has been described as one of the easiest electrophysiological signals to measure, but also one of the hardest to interpret quantitatively (Stegeman and Hermens, 2007). It is used to deliver biofeedback as a graphical representation of muscle activity can be displayed while the patient performs therapy tasks and is particularly applicable with less easily observable contractions or movements (Nelson, 2007).

The sEMG signal is complex, representing the temporal and spatial summation of action potentials generated by several concurrently active motor units. The motor unit action potentials (MUAPs) recorded on the skin surface vary in amplitude, duration and frequency (Basmajian and De Luca, 1985). The frequencies emitted will depend on the innervation ratio of the muscles, motor unit recruitment, along with their repetitive firing patterns (Cram, 2011). With increasing force of muscle
contraction, there is successive activation of additional motor units and an increase in the firing rate of all motor units recruited (De Luca and Contessa, 2012), with a resultant increase in the amplitude of the sEMG signal (Gabriel and Kamen, 2009). This follows the accepted Henneman size principle: when a higher force is required, larger motor units are recruited (Henneman et al., 1965). A shift to the lower frequencies in the sEMG power spectrum is seen in muscle fatigue (Kallenberg and Hermens, 2008, White et al., 2008) when there is increased recruitment of higher threshold motor units with significantly lower firing rate compared with “fresh” muscle (Stock et al., 2012).

1.9 Swallowing and sEMG

sEMG is being used internationally in both swallowing research and clinical practice to provide objective measurement of relevant muscle function and also biofeedback (Huckabee and Steele, 2006, Steele and Huckabee, 2007, Crary et al., 2007, Wheeler-Hegland et al., 2008, Yeates et al., 2010, O’Kane et al., 2010, Coriolano et al., 2012, van den Engel-Hoek et al., 2012, Watts, 2013, Umay et al., 2013). However, its current level of use in the UK is not known. As described above, the existing studies incorporating biofeedback in dysphagia therapy represent weak levels of evidence. Essential precursory information is lacking regarding the role of sEMG in swallowing biofeedback before it should be applied clinically, such as whether patients are actually able to modify the sEMG trace, whether this helps them with exercises and whether they find it an acceptable technique. Furthermore, several fundamental questions with respect to sEMG data
management and its reliability remain to be answered before its role in the objective assessment of swallowing becomes clear.

1.9.1 Normalising swallowing sEMG

In order to compare sEMG data between different participants, sessions or muscles, it is recommended that the measurements are normalised (Stegeman and Hermens, 2007). This is because of many intrinsic and extrinsic factors that can affect the raw signal that are unrelated to the level of muscle activation, for example the amount of fat and skin impedance and the orientation of the muscle fibres in relation to the recording electrodes (De Luca, 1997, Lehman and McGill, 1999). To control for these factors, the EMG measurements are expressed as a percentage of a value taken from a reference contraction from the same muscle within the same recording session (Burden, 2010).

The most common reference used for normalisation in limb muscles is an isometric Maximum Voluntary Contraction (MVC) (Stegeman and Hermens, 2007). However, use of the MVC normalisation method in dynamic activities has been questioned on the basis that it may not produce reliable results (De Luca, 1997) and is not representative of the task being investigated, for example due to differences in the rate and degree of muscle lengthening and shortening (Albertus-Kajee et al., 2010, Balshaw and Hunter, 2012). It is not feasible to accurately elicit or measure an MVC of the submental muscles due to inherent difficulties in measuring force from
these muscles and the possibility of signal contamination from involuntary activation of adjacent muscles (Archer et al., 2012). Furthermore it is difficult to elicit maximum effort in patients with weakness, pain, poor motivation and/or difficulty understanding the task. Therefore different approaches are warranted for normalising swallowing sEMG.

Despite being recommended by international guidelines on sEMG reporting (Stegeman and Hermens, 2007, Merletti, 1999), most sEMG studies of swallowing have not normalised their data (Vaiman, 2007, O’Kane et al., 2010, Coriolano et al., 2012, Crary and Baldwin, 1997, Wheeler et al., 2007, Leow et al., 2007, Vaiman et al., 2004b, Huckabee et al., 2005, Yoshida et al., 2007, Park et al., 2009, Miyaoka et al., 2010). This could lead to misinterpretation of the data as confounding influences on the EMG signal are not controlled. Other studies have normalised swallowing sEMG to the maximum amplitude recorded during tasks (Ding et al., 2002), the mean amplitude recorded during water swallowing (van den Engel-Hoek et al., 2012), the maximum amplitude recorded during a normal saliva swallow (Yeates et al., 2010, Huckabee and Steele, 2006) or a MVC of the swallowing muscles in a non-swallow task (Archer et al., 2012). It is accepted that a good method of normalisation should increase the reliability of the sEMG and particularly reduce the inter-participant variability (Burden et al., 2003, Burden, 2010, Albertus-Kajee et al., 2010, Buckthorpe et al., 2012), but an unreliable reference value may produce data that is less reliable than absolute values (Ball and Scurr, 2010).
Studies of normalisation techniques in limb muscles have suggested that normalising to a sub-maximal force contraction increases the reliability of sEMG data compared with maximum force contractions (Yang and Winter, 1983). It is also recommended that optimal normalisation methods are task-and muscle-specific, so ideally data should be normalised to a contraction that is representative of the task (Ball and Scurr, 2012). Previous swallowing studies that have normalised to swallow amplitudes (van den Engel-Hoek et al., 2012, Yeates et al., 2010, Huckabee and Steele, 2006) follow these principles. It is predicted that normalising to a task with a consolidated pattern such as normal swallowing would increase reliability. However, these methods of normalisation have not been evaluated despite their potential influence on the reliability and sensitivity of measurements.

1.9.2 The reliability of swallowing sEMG

To be sensitive to real change in a participant’s swallowing status, sEMG measurements need to reliable, i.e. similar when repeated under the same conditions in participants in whom no change is expected (Hopkins, 2000). An understanding of intra-participant variability is vital if data is to be used as an assessment or outcome measure. If reliability is poor, there will be low sensitivity and power to detect differences due to treatment or disease (Lachin, 2004). However, no study has yet investigated the reliability of sEMG measurements during swallowing, despite recommending its use in swallowing assessment (Vaiman, 2007, Coriolano et al., 2012, Vaiman et al., 2004a). Swallowing is a highly complex, adaptive motor activity and sEMG from the submental region provides a
composite measure of activity from a group of muscles (the mylohoid, geniohyoid and the anterior belly of the digastric muscles (Palmer et al., 1999). Variability is therefore likely to be greater than for movements involving one muscle group.

Inter-participant variation is seemingly high for non-normalised submental sEMG with standard deviations of 42% of the mean reported in healthy normal swallowing (Coriolano et al., 2012) and a wide interquartile range (32.68 - 94.12 % MVC) in data normalised to the MVC (Archer et al., 2012). This variability in healthy participants throws into doubt the applicability of sEMG amplitude measurements to identify disordered swallowing. However, inter-and intra-participant reliability of optimally normalised swallowing sEMG is not currently known.

1.9.3 Changes in swallowing sEMG with age

If sEMG is to be used as a method of examining and treating disordered swallowing, it is important to understand what to expect in the healthy population so that changes are not misinterpreted as signs of the disease process. Age-related changes in swallow function have been reported on FEES, with a 30% incidence of aspiration recorded in healthy adults aged over 65 years of age compared with zero incidence in young adults (Butler et al., 2009). Different factors have been suggested as contributing to this, with a disruption to the timing of swallowing events commonly described (Ney et al., 2009). There is also evidence of an age-related decline in muscle function for swallowing. Logemann et al. (2000) observed
a reduction in hyoid movement with preserved airway protection during swallowing in a group of healthy older adults and suggested that this indicates reduced neuromuscular reserve. Additionally, pharyngeal peak pressure during swallowing was found to be significantly lower in healthy adults who aspirated compared with non-aspirators (Butler et al., 2011b). Reduced pharyngeal wall thickness and constriction has also been observed in videofluoroscopic studies of healthy older adults, suggesting that the ageing pharynx undergoes structural changes with age which are consistent with atrophy (Aminpour et al., 2011). These findings are consistent with the hypothesis that age-related changes in muscle, i.e. sarcopenia, contributes to the decline in swallow function in healthy ageing.

Despite this, there have been conflicting findings from sEMG studies examining changes in swallowing muscle activity with age. In a comparison of 40 younger (aged 18-35) and 40 older (aged 60+) healthy participants, no significant effect of age was found on either lingual pressure or simultaneous sEMG peak amplitudes during saliva swallowing, although there was a trend towards reduced muscle activity with age (Yeates et al., 2010). No significant effect of age on sEMG amplitudes during swallowing was found in a study of 78 healthy men and women aged 5-65 (van den Engel-Hoek et al., 2012) or in an earlier study of 20 healthy younger adults (aged 18-28 ) compared with 20 healthy older adults (aged 65-85) (Ding et al., 2003). Contrastingly Vaiman et al. (2004b) found a significant decrease in sEMG amplitude during swallowing with age in a large study of 440 healthy adults. Differences in the methodologies of these studies may account for the
contrasting findings. Despite including a large sample across a wide age range, Vaiman et al. (2004b) did not normalise their data to a reference measurement. The maximum age of the subjects in the study by van den Engel-Hoek et al. (2012) was 65, which may have been too young to detect age related changes. In contrast, a significant age-related decrease in oral pressures during swallowing was found in a study with a maximum age of 93 (Hind et al., 2001). Yeates et al. (2010) only included female participants despite evidence that the effects of age on swallowing may be more significant in men (Dantas et al., 2011, Hiss et al., 2004).

Greater variability in sEMG amplitudes with age has been reported in studies of walking which was associated with subtle deterioration in function (Kang and Dingwell, 2009). Studies of hand function have shown that healthy older adults have larger fluctuations in motor output, to which variability of motor unit discharge rate is a significant contributor (Tracy et al., 2005, Jordan et al., 2012). Furthermore, a significant improvement in manual dexterity as a result of training was associated with a significant decrease in motor unit discharge rate variability in healthy older adults (mean age 72.9 (5.8) years) (Kornatz et al., 2005). No study has yet examined whether there is a change in the level of variability of swallow sEMG with age.

There is therefore justification for a further study to determine age-related changes in muscle activity during swallowing using robust methods of sEMG analysis,
including both sexes and a cross section of ages into advanced age and investigating changes in sEMG amplitude and variability.

1.9.4 The effect of age on the ability to increase submental muscle activity during the effortful swallow

Healthy participants have been found to produce significantly increased submental sEMG peak amplitudes during the ES compared with the NS (Huckabee et al., 2005, Huckabee and Steele, 2006, Yeates et al., 2010, Wheeler-Hegland et al., 2008), indicating that normal swallowing is a submaximal behaviour. The difference between normal swallowing and maximum ES has been described as “swallowing reserve” (Yeates et al., 2010), which is comparable with the concept of functional reserve, reflecting the difference between the amount of muscle activity necessary for a given task and the maximum amount of muscle activity possible (Marcell, 2003).

Reduced functional reserve is part of normal ageing (Marcell, 2003) and has been described as increasing the risk of swallowing difficulties with age (Nicosia et al., 2000, Robbins et al., 1995). Significantly reduced maximum lingual pressure has been reported with age despite unchanging lingual pressure during swallowing, which was described as a decreased “pressure reserve” (Nicosia et al., 2000, Robbins et al., 1995). Furthermore Hind et al. (2001) found that the magnitude of difference in the oral/pharyngeal pressures generated between the normal and ES decreased with healthy ageing. Only one paper to date has investigated changes in
sEMG activity between the ES and NS with age; Yeates et al. (2010) found that a group of older healthy women (mean age 72) produced lower amplitudes during an effortful saliva swallow compared with a younger group (mean age 26), but this did not reach significance. There were limitations of Yeates et al.’s (2010) study, which may have made it difficult to produce a significant result; participants were not given an opportunity to practice the ES technique before data recording, only one ES was elicited and there was marked variation between participants, with a group SD of 74% of the mean.

Therefore further investigation of age-related changes in the ability to increase muscle activity during the ES is indicated, in which practice is provided and an adequate number of trials are elicited to ensure mastery. There is strong evidence to suggest reduced “pressure reserve” with age and therefore it is anticipated that there will also be reduced “activity reserve” i.e. the sEMG activity produced during a NS by older participants will be a greater proportion of their effortful swallowing maximum activity compared with younger participants. This would indicate that older people are working relatively harder to swallow normally due to age-related muscle weakness.

1.9.5 The effect of dysphagia on the ability to increase submental muscle activity during the effortful swallow

The ability of dysphagic patients to modify sEMG amplitude during the ES has not been examined. Loss of voluntary force following stroke is understood to result
partly from activation failure due to direct neurological effects on skeletal muscle, with impaired motor unit recruitment, and also adaptations in intrinsic muscle properties, e.g. loss of muscle mass, type II fibre atrophy and predominance of type I fibres, with reduced firing rates during contraction (Newham and Hsiao, 2001, Horstman et al., 2008). Therefore it is anticipated that an impaired ability to maximally drive the swallowing muscles following stroke, together with intrinsic muscle weakness, may affect dysphagic patients' ability to increase muscle activity for the ES. This will be demonstrated by a smaller increase in sEMG amplitudes for the ES relative to normal swallowing compared with healthy participants.

1.9.6 The effect of sEMG biofeedback on effortful swallow performance

The relationship between visual feedback and performance is complex. Evidence suggests that healthy older adults perform worse on force-control tasks with visual feedback than without, which may indicate impaired visuo-motor processing or reduced attention capacity with age (Ofori et al., 2010, Kennedy and Christou, 2011). Introducing biofeedback directs more attention to motor planning for swallowing, which could arguably improve performance on swallow tasks (Humbert and Joel, 2012) or it could serve to distract older participants as swallowing becomes less natural.

Changes in attention and visuo-motor processing with age are relevant to the stroke population as the average age for first-time stroke is 70 years (Wolfe et al., 2011).
Additionally, stroke-specific deficits in perception, information processing, language comprehension, recall and motor planning and programming may affect the ability to benefit from biofeedback. However, the ES itself is abstract, requiring alteration of habitual behaviour and it is likely that performance will be hindered in the absence of a visible target or model. Due to the anticipated benefits of biofeedback in enabling patients to be more involved in therapy, providing them with a challenge and shaping performance, it is predicted that overall participants will perform the ES better with sEMG biofeedback than “blind”, although this has not yet been investigated.

1.9.7 Acceptability of sEMG biofeedback

The National Institute for Health and Clinical Excellence (2012) guideline on patient experience in adult NHS services states that care should be individualised to the patient and should take into account their feedback and views on treatments. The Royal College of Physicians guidelines on stroke (Intercollegiate Stroke Working Party, 2012) also state that the planning process for any service development should include particular consideration of the views of patients. Furthermore, any treatment needs to be acceptable to the patient to encourage participation in therapy. Previous studies have attempted to investigate the physiological and functional benefits of sEMG biofeedback (Bryant, 1991, Crary, 1995, Huckabee and Cannito, 1999, Crary et al., 2004, Bogaardt et al., 2009), but none have examined the patients’ experience of the treatment itself. Therefore it is important to explore
participants’ own experiences of sEMG biofeedback to enable comprehensive evaluation of its role in dysphagia therapy.

1.10 Summary and Rationale for Study

Dysphagia is a common complication of stroke and leads to adverse outcome. There is an urgent need for more research to determine the best treatment for dysphagia. Physiological benefits of the ES exercise have been shown in the healthy population but outcomes of therapy in patients have not been determined. Biofeedback with sEMG may be a beneficial adjunct to dysphagia therapy, but is yet to be subjected to robust study and key methodological issues and preliminary questions need to be answered before the role of sEMG in dysphagia management can be established.

1.11 Aims of thesis

The studies in this thesis aimed to determine:

i. The practice patterns of SLTs in the UK and Ireland with respect to dysphagia therapy with stroke patients.

ii. The validity of the Digital Swallowing Workstation (KayPentax, New Jersey) for use in swallowing biofeedback and the appropriateness of its use in the subsequent studies of this thesis.

iii. The intra- and interparticipant variability of swallowing sEMG in healthy and stroke participants.

iv. The best way of normalising swallowing sEMG data.
v. If dysphagia following stroke affects the ability to increase submental muscle activity during the effortful swallow.

vi. If sEMG biofeedback improves performance of the effortful swallow exercise in healthy and stroke participants.

vii. If sEMG is an acceptable adjunct to therapy.

viii. The benefit of sEMG biofeedback for the clinician in assessing effortful swallow performance.

ix. The feasibility of a study to investigate the outcome of effortful swallow therapy with adjunctive sEMG biofeedback in acute stroke.

1.12 Structure of thesis

With the paucity of clear evidence for behavioural dysphagia therapy, clinicians are presented with a challenge in determining best practice, with a corresponding potential for variability in approaches. Practice patterns in the UK and Ireland with respect to dysphagia therapy in stroke were therefore investigated to determine common formats of therapy delivery and to inform further study design.

As many swallowing studies have used the same sEMG equipment, the Digital Swallowing Workstation (KayPENTAX) and there is no evidence regarding how the settings on the equipment were determined, the equipment was validated against a reference EMG system before it was used for further studies. The best method of normalising swallowing sEMG was investigated as well as the reliability of
swallowing sEMG measurements, to inform future studies using sEMG as a measurement tool. The effect of age on swallowing sEMG measurements as well as the ability of older adults and dysphagic acute stroke participants to modify the sEMG trace during the ES was established, together with the benefit of sEMG biofeedback on performance. Participants’ feedback on receiving sEMG biofeedback was evaluated to determine if it is an acceptable adjunct to dysphagia therapy. As current practice involves clinical evaluation of ES performance, agreement between clinicians as well as between clinicians’ assessment and sEMG measurements was determined to further investigate the benefit of sEMG in delivering accurate feedback on performance.

Finally, a pilot RCT was conducted using the information gained from the preceding studies to evaluate a protocol designed to determine if therapy with the ES exercise and adjunctive sEMG biofeedback improves swallowing safety in dysphagic acute stroke patients compared with ES therapy alone and to routine care. This pilot established the feasibility of the study protocol for further larger trials.
Chapter 2   Dysphagia therapy in stroke: a survey of speech and language therapists

A version of this study has been published and is presented in Appendix 2 (Archer et al., 2013).

2.1 Introduction

SLTs aim to reduce the risk of aspiration and improve swallowing function through their assessment and management of dysphagia (The Royal College of Speech and Language Therapists, 2005). They are increasingly recommending rehabilitative or “direct” behavioural therapy techniques, which aim to restore swallowing ability by improving muscle function or through sensory stimulation (Burkhead et al., 2007). The Royal College of Physicians (RCP) National Clinical Guideline for Stroke states that any patient unable to swallow food safely one week after stroke should be considered for an oropharyngeal swallowing rehabilitation programme designed and monitored by a dysphagia specialist (Intercollegiate Stroke Working Party, 2012). It also states that in the acute stage, patients should receive a minimum of 45 minutes of each therapy required at least five days a week. However, despite being part of routine practice, there is a paucity of evidence for dysphagia therapy and questions remain regarding the best way to prescribe exercises

Until the evidence base is established, clinicians are faced with a mix of information on which to base treatment decisions. In a survey of SLTs about dysarthria management, the most commonly reported influences on decisions to use
Oromotor exercises were evidence from own practice and discussion with colleagues (Mackenzie et al., 2010). Usual clinical practice in dysphagia is also likely to be based on an assimilation of expert or consensus opinion, clinicians’ own and colleagues’ anecdotal evidence, training they have received, studies they have read and the established approaches of their workplace. There is therefore great potential for variability in practice. Despite this, no formal process for monitoring treatment approaches exists, and studies of practice behaviour in SLT are warranted. There have been numerous surveys of SLTs’ practice patterns in dysphagia assessment with mixed patient populations (Mathers-Schmidt and Kurlinski, 2003, Bateman et al., 2007, Pettigrew and O’Toole, 2007, Martino et al., 2004, Cocks and Ferreira, 2012) which all have shown concerning variability in practice. Recent surveys of SLTs’ approaches to the treatment of dysphagia in head and neck cancer (Krisciunas et al., 2012) and Parkinson’s Disease (Miller et al., 2011) have also found limited consistency between respondents as well as poor adherence to clinical guidelines, attributed to both resource limitations and lack of evidence for existing techniques. Despite the high incidence of dysphagia in stroke and the focus on rehabilitation in the national guidelines (Intercollegiate Stroke Working Party, 2012), no studies have been found that have investigated practice patterns in the treatment of dysphagia in stroke.

2.2 Aims

The aim of this study was to determine the practice patterns of SLTs in the UK and Ireland with respect to direct dysphagia therapy with stroke patients. Consistencies
in approach to treatment determined through survey responses would then be used to inform the development of the intervention to be evaluated in the subsequent studies.

2.3 Methods

2.3.1 Study Design
A cross-sectional self-administered web-based survey was conducted, with full ethical and R&D approvals (Guy’s Hospital Research Ethics Committee, reference 10/H0804/17).

2.3.2 Participants
The survey aimed to target all SLTs working with dysphagic stroke patients in UK and Ireland. Inclusion criteria were SLTs currently working in stroke in the UK and Ireland. Exclusion criteria were SLTs working in other countries or with other clinical caseloads.

2.3.3 Questionnaire Design
No existing questionnaires were found that investigated dysphagia therapy in stroke. Therefore a new self-complete questionnaire was designed following an extensive review of the literature and adhering to accepted guidance in questionnaire design (Rattray and Jones, 2007, Dillman, 2009). It was piloted with
four SLTs working in stroke (see below) and revised following feedback. The final questionnaire consisted of 24 questions in total; these were divided into five sections: background information, factors influencing decisions to recommend therapy, content and format of therapy, therapy outcomes and biofeedback. It incorporated a combination of open and closed questions, multiple choice questions and scales, with automatic filtering/redirection where appropriate, in order to maximise the information gained from the respondents (Rattray and Jones, 2007) while reducing the effort and time required to complete the questionnaire (Taylor-Powell and Marshall, 1996). All questions required a response to continue to the next question to reduce the risk of missing data.

To determine frequency of practice approaches, respondents were asked to rate items on a five-point ordinal scale (never, rarely, half the time, frequently and always), comparable to previous published surveys of dysphagia assessment (Mathers-Schmidt and Kurlinski, 2003, Bateman et al., 2007). The questionnaire specifically asked questions about direct rehabilitative approaches to dysphagia therapy aimed at restoring swallowing function, rather than compensatory methods. Treatment approaches included in the questionnaire were determined from clinical practice, literature review and from suggestions received during the piloting stage.
2.3.4 Pilot

Four Speech and Language Therapists, with 3 - 10 years of experience of working in stroke in the UK participated in a pilot study, in which they independently completed the proposed questionnaire and then provided their comments and suggested changes and/or additions specifically relating to content (including multiple choice answer options), format and administration time. Minimal changes were suggested, including adding the item “Supervised swallow trials with a bolus” to the therapy options in question 11 and changing specific wording that was felt to be potentially ambiguous. These suggestions were incorporated into the final version of the questionnaire (2). Pilot respondents reported that the survey was clear, straight forward and unambiguous.

2.3.5 Survey Administration

The survey was administered via an online survey tool (www.surveymonkey.com) to enable ease of access and to facilitate inclusion of respondents from a wide geographical area (Wright, 2005). Participation was encouraged with an explanation of the purpose and anticipated benefits of the study, anonymity of individual responses and provision of the researcher’s contact details for queries (Dillman, 2009, Fink, 1995). An advert was placed in the Bulletin Magazine that is sent to all members of the Royal College of Speech and Language Therapists (RCSLT), the professional body for UK and Ireland SLTs. The survey was also posted on the RCSLT Facebook (Social Networking) page. An email invitation was also sent to all of the UK/Ireland Special Interest Groups (SIGS) who were listed on the RCSLT
website and had a remit to dysphagia and/or neurological disorders and those who received the email were asked to pass it onto relevant colleagues. A reminder email and Facebook message were circulated after three weeks and the survey remained open for two months from 26th May 2011.

### 2.3.6 Data Analysis

Data were entered into a Microsoft Excel database and descriptive statistics used for analysis. For the four questions requiring a response on the five-point frequency scale (proportion of dysphagic stroke patients recommended dysphagia therapy, use of instrumental assessment to inform therapy and to measure therapy outcome and frequency of recommending specific exercises), a previously described method for determining consistency was used (Mathers-Schmidt and Kurlinski, 2003). Responses were considered “highly consistent” if >75% of respondents gave the same response, “moderately consistent” if 50-75% gave the same response and “inconsistent” if <50% gave the same response. To examine if there were differences in the intensity of therapy provided and consistency of practice in specific clinical settings, the responses of the SLTs who worked exclusively in distinct settings were identified, and the settings with the greatest representation of respondents were compared.
2.4 Results

2.4.1 Response Rate

Responses were received from 138 SLTs and 101 (73.2%) completed all questions, with a gradual decrease in the number of respondents as the survey progressed. The survey was advertised to all SLTs who receive the Bulletin (approximately 15,000 SLTs and 90% of all SLTs registered with the RCSLT), and was accessible to all 3,100 RCSLT Facebook members. Fourteen SIGs were contacted from the RCSLT database that had a remit to dysphagia and/or neurological disorders and eight replied and forwarded the information, with a total membership of 393. A small proportion of RCSLT members work with stroke patients and unfortunately neither the SIGs nor the RCSLT hold information on members’ specialisms, rendering it impossible to determine the exact denominator and response rate from this method of sampling.

In order to attempt to estimate the number of SLTs working in stroke, The Department of Health for England Wales and Northern Ireland and the NHS National Services Scotland were contacted; however, no suitable data was found.

2.4.2 Results by subject

2.4.2.1 Background Information Table 2.1

Respondents represented a wide range of number of years of working as a SLT. The highest number (31.9%; n=44) reported that most of their caseload was dedicated
to stroke and several clinical settings were represented, with many respondents working in more than one setting. The largest number of respondents worked in an acute inpatient setting (58.0%, n=80). Over half (54.1%; n=72) reported that 75% of their stroke caseload consisted of the evaluation and/or management of dysphagia.

### 2.4.2.2 Factors influencing decisions to recommend therapy

The majority of respondents (93.2%; n=112) had access to instrumental swallowing assessments (Table 2.1). However, the largest number of respondents (47.6%; n=59) reported that they rarely conducted an instrumental dysphagia assessment before recommending direct dysphagia exercises for stroke patients, with 15.3% (n=19) conducting one about half the time, 18.5% (n=23) usually conducting one, 12.1% (n=15) always conducting one and 6.5% (n=8) reporting that they never do. The factors that respondents most consistently rated as essential in deciding to conduct dysphagia exercises with stroke patients (on a four-point scale from important to essential) were alertness (82.3%, n=102), cognitive status (53.2%, n=66), motivation (53.2% n=66) and medical status (49.2%, n=61). The majority of respondents (71.8%, n=89) reported that they recommend direct dysphagia exercises to some of their stroke patients and 16.1% (n=20) recommend exercises to half of their patients, with 1.6% (n=2) recommending them to all, 7.3% (n=9) recommending them to most and 3.2% (n=4) recommending exercises to none of their stroke patients.
Table 2.1: Background Information.

<table>
<thead>
<tr>
<th>Question</th>
<th>Responses</th>
<th>% of respondents</th>
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<tbody>
<tr>
<td>SLT experience (years) (n=138)</td>
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<td></td>
<td>3-5</td>
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<td>6-10</td>
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<td></td>
<td>11-20</td>
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<td></td>
<td>21+</td>
<td>15.9</td>
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<td>Clinical setting (n=138)</td>
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<td></td>
<td>Dedicated stroke unit</td>
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<td>Community</td>
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<td></td>
<td>Other</td>
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<td>Proportion of caseload adult stroke (n=138)</td>
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<td></td>
<td>Most (75%)</td>
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<td>Half (50%)</td>
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<td>Some (25%)</td>
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<td>0.0</td>
</tr>
<tr>
<td>Proportion of stroke caseload dysphagia (n=138)</td>
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<tr>
<td></td>
<td>Pharyngeal manometry/manofluorography</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>6.0</td>
</tr>
<tr>
<td></td>
<td>None</td>
<td>6.8</td>
</tr>
</tbody>
</table>

FEES = Fibreoptic Endoscopic Evaluation of Swallowing
2.4.2.3 Content and format of therapy

Figure 2.1 shows the frequency with which respondents “frequently or always” recommend different exercises. Supervised swallows with a bolus was the most commonly recommended exercise, recommended by 73% (n=90).

Figure 2.1 Percentage of respondents frequently or always recommending specific dysphagia exercises (n=122).

“Other” included chewing exercises and lip and tongue rate of movement. References for specific therapy tasks: effortful swallow (Huckabee et al., 2005), Massako (Fujiu and Logemann, 1996), Shaker exercise (Shaker et al., 2002), Falsetto voicing (Pauloski, 2008), Thermotactile Stimulation (Rosenbek et al., 1998), electrical stimulation (Clark et al., 2009).
The format of recommended dysphagia exercise programmes reported by all respondents and those from three clinical setting subgroups (those who reported that they exclusively work on a stroke unit, acute inpatient or in a community setting) is shown in Table 2.2. These subgroups were chosen as they had relatively good representation and were felt to reflect contrasting environments for therapy provision. The variation in responses to questions relating to the RCP guideline for therapy intensity (Intercollegiate Stroke Working Party, 2012) i.e. length of therapy sessions and number of sessions per week, is shown in Figure 2.2 and Figure 2.3.

Table 2.2 Format of exercise programme recommended by SLTs. Medians [IQR] shown.

<table>
<thead>
<tr>
<th></th>
<th>ALL (N=113)</th>
<th>STROKE UNIT ONLY (N=9)</th>
<th>ACUTE INPATIENT ONLY (N=11)</th>
<th>COMMUNITY ONLY (N=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of times patient seen per day by SLT</td>
<td>1 [1-1]</td>
<td>1 [1-1]</td>
<td>1 [1-1]</td>
<td>0.5 [0-1]</td>
</tr>
<tr>
<td>No. of days per week patient seen by SLT</td>
<td>3 [2-5]</td>
<td>5 [3-5]</td>
<td>3 [2.5-5]</td>
<td>1 [1-1]</td>
</tr>
<tr>
<td>No. of sessions per day patients to complete independently/with carer</td>
<td>3 [2-5]</td>
<td>3 [2-6]</td>
<td>2 [2.5-4]</td>
<td>2 [1.25-2]</td>
</tr>
<tr>
<td>No. of days per week patients to complete exercises independently/with carer</td>
<td>7 [7-7]</td>
<td>7 [7-7]</td>
<td>7 [6-7]</td>
<td>7 [7-7]</td>
</tr>
<tr>
<td>No. of repetitions of each exercise per set</td>
<td>5 [5-10]</td>
<td>5 [5-10]</td>
<td>10 [4-10]</td>
<td>5 [3.5-8.75]</td>
</tr>
<tr>
<td>No. of sets of each exercise per session</td>
<td>3 [2-5]</td>
<td>5 [1-5]</td>
<td>3 [3-5]</td>
<td>3 [1-3]</td>
</tr>
<tr>
<td>Average length of therapy programme (weeks)</td>
<td>6 [4-6]</td>
<td>4 [4-6]</td>
<td>4 [2-6]</td>
<td>6 [4.5-6.75]</td>
</tr>
</tbody>
</table>
Figure 2.2: Length of dysphagia therapy session (min) (n=113)

Figure 2.3: Number of days per week patients seen by SLT for dysphagia therapy (n=113)
Most respondents (92.9%; n=105) reported that they do not use a standard protocol for progressing dysphagia exercises i.e. not increasing load/intensity/difficulty of exercises, while 3.5% (n=4) described their protocols, two of which involved a set programme of increasing the number of repetitions of exercises completed daily over a period of weeks. About a third of respondents 34.5% (n=39) reported that they did not give their patients any specific advice about rest periods, 31.0% (n=35) reported they gave general information about avoiding fatigue, not exercising when tired or unwell and stopping when tired; 13.3% (n=15) reported they set out an individualised programme that incorporated rest periods according to the patient’s needs. Most reported adherence to dysphagia exercise programmes was “fair” (61.9%; n=70), 19.5% (n=22) reported it was “good”, 18.6% (n=21) reported it was poor and no one reported that it was excellent.

The majority of respondents (77.9%; n=95) reported their patients had not experienced any complications of dysphagia therapy. Of those who reported complications, 8.2% (n=10) reported patients finding exercises difficult to complete or adhere to due to cognitive impairment or degree of physical impairment, 4.9% (n=6) reported neck pain, dizziness, shortness of breath or PEG site complications with Shaker exercise (Shaker et al., 2002) and a further 2.5% (n=3) reported choking or aspiration of bolus trials.
2.4.2.4 Therapy Outcomes

The three most commonly reported ways of measuring outcome were advancement in the amount or consistencies of oral diet and fluids tolerated (65.1%; n=69), patient satisfaction (34.9%; n=37) and reduction in aspiration (34.0%; n=36). Half of the respondents (51.9%; n=55) reported rarely performing an instrumental assessment to determine outcome, 12.3% (n=13) reported never conducting one, 15.1% (n=16) reported using one about half the time and 20.7% (n=22) reported usually or always performing one. The majority (63%; n=67) reported using no specific formal outcome measure or rating scale to determine outcome of therapy, with the most common one used being the Rosenbek Penetration-Aspiration scale (Rosenbek et al., 1996), used by 15.1% (n=16) (Figure 2.4).

No respondent felt that all of their stroke patients improved as a result of dysphagia therapy, 33.3% (n=24) considered that half improved, 32.4% (n=33) considered that most improved, 29.4% (n=30) felt that some improved and 4.9% (n=5) reported that none improved. The most commonly reported reasons for lack of improvement with therapy were low patient motivation (47.1%; n=48), medical complications (40.2%; n=41) and dysphagia severity (31.4%; n=32).
Figure 2.4: Percentage of respondents using different specific outcome measures or rating scales to measure effect of dysphagia therapy (n=106)
Outcome measures: Rosenbek Penetration/Aspiration Scale (Rosenbek et al., 1998), TOMS= Therapy Outcome Measure (Enderby and John, 1999), Royal Brisbane Hospital Outcome Measures(Ward and Conroy, 1999), EKOS= East Kent Outcome System(Johnson and Elias, 2002), Frenchay(Enderby, 1980), Robertson (Robertson, 1982), FIM/FAM= Functional Independence Measure/Functional Assessment Measure(Hobart et al., 2001), FOIS= Functional Oral Intake Scale (Crary et al., 2005), Waxman Videofluoroscopy (Waxman et al., 1990).

2.4.2.5 Biofeedback
Most respondents (84.2%; n=101) reported not using any method of biofeedback during dysphagia therapy. Of these, 94.1% (n=80) reported limited access to necessary equipment and 75.3% (n=64) reported insufficient training or experience to use biofeedback. Others reported that there was insufficient evidence for biofeedback (7.1% n=6) or they did not have time (7.1% n=6). Of the 15.8% (n=16) who reported that they did use biofeedback, 18.8% (n=3) used sEMG, others reported using a mirror (n=3), watching videofluoroscopies with patients (n=2) and using a training stethoscope (n=1).
Of the three who reported using sEMG for biofeedback, all described using it with the ES exercise, one respondent reported using it for breath hold and one for the Mendelsohn Manoeuvre. The electrodes were placed in the submental or infrahyoid position by all three respondents. All three reported sEMG motivated patients, giving “clear targets” and enabling “measurable change” and improved coordination of swallows. The reported disadvantages were technical issues, that the measurements are non-specific and that patients need an adequate level of cognition to be able to benefit.

2.4.3 Consistency of reported practice

No question had 100% agreement and there was variation in responses for all questions, e.g. Figure 2.2 and Figure 2.3. The consistency of responses to questions requiring an answer on a five-point frequency scale is shown in Table 2.3. Only one response was highly consistent across respondents and within the specific clinical setting subgroups (>75% never use Electrical Stimulation) and most were answered inconsistently (<50% agreement between respondents). In the subgroup of respondents who reported that they exclusively work on a stroke unit (n=11), one question was answered with high consistency (use of electrical stimulation) and six items had moderately consistent responses; all other questions were answered inconsistently. Twelve respondents reported working exclusively in the community setting and eleven reported working exclusively in an acute setting and for both
subgroups, one item was answered highly consistently. There was moderate consistency for three responses by the community setting subgroup and two responses by the acute setting group; all other items were answered inconsistently.

For other questions with different response types, the most consistent responses across all respondents included the relative importance of different factors in recommending dysphagia exercise: 82% (n=102) consider alertness levels to be essential, 64% (n=79) consider that carer support is important and 62%, (n=77) consider communication ability and evidence base are important. Other responses with relatively high consistency related to format of the therapy programme, with 72% (n=81) of respondents seeing patients once a day and 74% (n=84) recommending that patients complete exercises independently seven days a week. Respondents were relatively consistent in not offering biofeedback as part of therapy (84%; n=85) and in not having a standard method for progressing patients’ exercises (92.9%; n=105). There was relatively high consistency in terms of outcome measurement, with 63.2% (n=67) not using a published outcome measure and 65.1% (n=69) assessing tolerance of oral diet and fluids to determine the outcome of therapy.
Table 2.3: Responses given with moderate or high consistency between all respondents and between those who work exclusively on a stroke unit or in a community setting. Highly consistent=>75% of respondents gave answer. Moderately consistent=50-75% of respondents gave answer.

<table>
<thead>
<tr>
<th>Consistency</th>
<th>All Respondents (N=138)</th>
<th>Stroke unit subgroup (N=11)</th>
<th>Acute inpatient subgroup (N=11)</th>
<th>Community subgroup (N=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highly consistent</td>
<td>- 98% never use electrical stimulation</td>
<td>- 100% never use electrical stimulation</td>
<td>- 81.8% never use electrical stimulation</td>
<td>- 100% never use electrical stimulation</td>
</tr>
<tr>
<td>Moderately consistent</td>
<td>- 71.8% recommend dysphagia exercises to some of their dysphagic stroke caseload</td>
<td>- 63.6% recommend dysphagia exercises to some of their dysphagic stroke caseload 72.7% usually recommend supervised swallow trials with bolus</td>
<td>- 63.6% usually recommend supervised swallow trials with bolus 50% usually conduct an instrumental assessment to determine outcome of therapy</td>
<td>- 76.9% recommend dysphagia exercises to some of their dysphagic stroke patients 58.3% recommend the Mendelsohn about half the time 50.0% recommend the effortful swallow about half the time</td>
</tr>
<tr>
<td></td>
<td>- 61.0% usually recommend supervised swallow trials with bolus</td>
<td>- 61.0% rarely recommend the Mendelsohn</td>
<td>- 61.0% rarely conduct an instrumental assessment to determine outcome of therapy</td>
<td>- 54.5% rarely recommend the effortful swallow about half the time</td>
</tr>
<tr>
<td></td>
<td>- 61.0% rarely conduct an instrumental assessment to determine outcome of therapy</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
2.5 Discussion

This is the first survey-based study of dysphagia therapy practices in stroke among SLTs in UK and Ireland, providing a valuable record against which clinicians can compare their practice. Encouragingly, the survey revealed that nearly all SLTs working in stroke have access to videofluoroscopy, which is considered the “gold standard” dysphagia assessment (Logemann, 1998). This is consistent with a previous survey by Bateman et al. (2007) in which 73% (n=217) of respondents had videofluoroscopy in their work facilities and 97% (n=288) had availability within 30 miles. In the current study, only just over a third had access to FEES, whereas Bateman et al. found 59% had access within 30 miles. The discrepancy between the studies may be due to the different target populations as Bateman and colleagues approached all SLTs working with dysphagia, not just stroke patients. However, it is surprising that FEES is not more commonly available, considering it has acknowledged benefits in clinical assessment and decision making which are complementary to videofluoroscopy (Kelly et al., 2007, Kelly et al., 2006, Langmore, 2001).

Despite having access to some form of instrumental assessment, a high proportion of respondents reported rarely or never conducting one before recommending a therapy programme or to determine outcome. An even greater number reported not using a specific outcome measure. The limitations of bedside/clinical assessments in terms of subjectivity, poor reliability and precision are well described (e.g. (Ramsey et al., 2006, McCullough et al., 2005, Leder and Espinosa,
2002) and accordingly the RCSLT Clinical Guideline advises that treatment decisions should be based on instrumental assessment (The Royal College of Speech and Language Therapists, 2005). The current findings indicate this recommendation is not being implemented in practice. This is consistent with the findings of a recent UK-based survey of SLTs working with dysphagia from mixed patient populations (n=68), which found that instrumental assessment is rarely used to make oral versus non-oral feeding decisions (Cocks and Ferreira, 2012). Since publication of this study, a survey of American SLTs has reported a similar finding, with only 29% of 254 respondents using validated dysphagia outcome measures (Carnaby and Harenberg, 2013). Additionally, a previous national survey of SLTs working with patients with Parkinson’s Disease found poor adherence to clinical guidelines, which was largely attributed to resource limitations, with insufficient numbers of SLTs working with the patient group (Miller et al., 2011). Resource limitations may be also relevant to the present findings as instrumental assessments are relatively costly in terms of time, equipment and personnel compared with clinical bedside assessments.

The therapy technique most frequently recommended was supervised bolus swallows, which is undoubtedly task specific (Robbins et al., 2008, Burkhead et al., 2007) but arguably not an exercise as it does not involve challenging the system beyond typical use (Burkhead et al., 2007). Nevertheless swallow trials comply with the principles of avoiding disuse atrophy in swallowing muscles (Burkhead et al., 2007) and the “use it or lose it” concept to avoid diminishing cortical representation.
(Kleim and Jones, 2008, Robbins et al., 2008), which is particularly relevant in patients who have less need to activate the swallowing mechanism due to non-oral feeding and reduced frequency of saliva swallows (Murray et al., 1996).

Tongue and lip strength and range of movement exercises were frequently recommended by SLTs in the survey. There is some preliminary evidence that progressive isometric tongue strengthening exercises (Robbins et al., 2007, Yeates et al., 2008) and lip force training improve swallow function (Hagg and Anniko, 2008). However, no published research has investigated the effect of range of oral movement exercises on swallowing function in dysphagic stroke patients. The common use of oromotor exercises may reflect their relative ease of completion and a carryover from SLTs’ approaches with acquired speech impairments. In a survey of SLTs in Scotland, Wales and Northern Ireland, 81% reported using oromotor exercises with dysarthric patients despite there being no robust evidence of an influence on speech outcome; furthermore 94% of those who used them for dysarthria also used them for dysphagia (Mackenzie et al., 2010).

The most frequently recommended exercise targeting both the oral and pharyngeal stages of the swallow was the ES exercise, which has been found to have physiological benefit in healthy subjects (Wheeler-Hegland et al., 2008, Takasaki et al., 2011, Peck et al., 2010). However the benefit of the ES in patients remains to be investigated.
Sensory impairment is reported as a significant feature of post-stroke dysphagia (Park et al., 2010). However, there was relatively low reported use of thermo-tactile stimulation (TTS), a traditional treatment option for sensory impairment, which may reflect the lack of evidence for this technique (Rosenbek et al., 1998). Surprisingly no other therapy technique was offered that specifically addresses sensory impairment, despite emerging evidence that stimulation with different tastes, odours, temperatures and carbonation may improve swallowing performance (Abdul Wahab et al., 2010, Michou et al., 2012a) and that different forms of heightened sensation modulate neural substrates of swallowing (Humbert and Joel, 2012). Arguably the multiple choice options provided in the survey influenced the responses received. However, the list of options was determined through consultation with experts in the pilot and respondents were encouraged to add any other treatments in the “other” section, and yet TTS was the only sensory treatment suggested. This is consistent with a more recent survey of SLTs in the USA, in which less than 4% reported using TTS with dysphagic patients, with no other sensory therapeutic methods reported (Carnaby and Harenberg, 2013). This indicates an emphasis on motor impairment in the treatment for dysphagia, which warrants further exploration.

A large majority of respondents report never using electrical stimulation with their patients and this was the most consistent response within the whole questionnaire. The use of electrical stimulation in dysphagia therapy has gained much attention in the literature and there has been much debate about its efficacy, with no clear
conclusions about its benefit (Clark et al., 2009). A third of a sample of 215 SLTs in America reported using electrical stimulation as a therapeutic tool (Palmer, 2009) and it was the most commonly suggested primary intervention for a case-based example in a more recent survey of dysphagia practice in the USA (Carnaby and Harenberg, 2013). This current survey indicates that there has not been similar uptake among SLTs treating stroke in the UK and Ireland, which may relate to costs of training and delivering electrical stimulation and the lack of endorsement of the treatment by the RCSLT.

SLTs typically reported seeing their patients for dysphagia therapy once a day for 15 minutes, either three or five times a week and recommend daily independent practice. Although the data from the clinical setting subgroups should be interpreted with caution due to the small numbers in each group, the subgroup of community based therapists notably reported seeing their patients less frequently and for shorter sessions, while SLTs working exclusively on a stroke unit see patients five days per week for slightly longer sessions. The intensity of therapy required is much debated (Intercollegiate Stroke Working Party, 2012); however a “more is more” principle is accepted (Langhorne et al., 2011). Carnaby et al. (2006) found significantly more acute stroke patients returned to normal diet and recovered swallow function after an intensive (daily) dysphagia therapy programme compared with a low intensity intervention (three times a week) or “usual care”. However, the findings are confounded by the high intensity group receiving different treatment to the low intensity and control groups. Nonetheless the RCP...
recommends that acute stroke patients receive 45 minutes of therapy from SLT five days per week (Intercollegiate Stroke Working Party, 2012). There is no current recommendation for the amount of therapy provided in the community; however the RCP guidelines are arguably applicable, for at least for a proportion of patients, given the drive for early discharge from hospital (Langhorne et al., 2011). While the SLTs who responded to this survey recommended intensive independent practice, increased frequency and length of SLT-led sessions might improve outcomes.

There are currently no clinical guidelines or studies investigating the specific effect of different “dosages” of repetitions and sets of swallowing exercises within therapy sessions, which may reflect the challenges in designing such research in dysphagia. However, the average dosages reported here are consistent with accepted approaches to exercise, in which 8-12 repetitions and 2-4 sets are generally recommended to improve strength and power (Garber et al., 2011). However, the overload principle states that activity must consistently force the body beyond its usual level of activity to result in neuromuscular adaptation; therefore tasks must be progressed to maximise gains from rehabilitation and this may be more relevant than focusing on a specified number of sets and repetitions (Burkhead et al., 2007). This survey shows most respondents are not systematically implementing task progression, indicating that these principles of exercise physiology and neural plasticity, which should underpin rehabilitation, are not being translated into the clinical domain.
There was some consensus as to the parameters that SLTs look for in determining outcome, with the most common being progressing oral diet and fluids, reducing aspiration and quality of life measures. Therefore clinicians are holistic in their outcome measurement, addressing impairment, functional outcome and psychosocial issues. This is consistent with the more recent survey of SLTs in the USA, in which advanced oral diet was the most commonly reported metric of treatment success (Carnaby and Harenberg, 2013). However, without the use of specific outcome measures and instrumental examination, there is considerable potential for bias.

The respondents indicate that dysphagia exercises are generally safe as a large majority reported no complications and most reported complications related to an inability to complete the task, rather than an adverse reaction or side-effect. Motivation was the most commonly cited reason for patients not improving as a result of therapy. Effective ways of assessing and recording motivation and adherence are required and measures to increase motivation may be indicated. However, only 16% reported using biofeedback, a suggested technique for enhancing motivation (Reddy et al., 2000). More research into the application of biofeedback to improve motivation and adherence with therapy is indicated.

There was considerable variability in the responses received to each question for all respondents and for the subgroups of respondents working in distinct clinical
settings. Previous surveys of SLTs’ approaches to management of dysphagia have also found marked inconsistency between respondents (Mathers-Schmidt and Kurlinski, 2003, Bateman et al., 2007, Carnaby and Harenberg, 2013). These indicate variability in SLT practice and service delivery to patients. Such variation may relate to the overall paucity of evidence for dysphagia therapy, poor uptake of existing evidence and the requirement for ongoing professional development in SLT.

Poor uptake of clinical guidelines and evidence is commonly reported in health care, even in fields with established, robust research foundations. For example, evidence-based “bundles” of care for central line insertion and maintenance are known to prevent catheter-related infections (Pronovost et al., 2006) and yet adherence is inconsistent at ward level (Flodgren et al., 2013). (Landrigan et al., 2010) This concept has been described as “Change Implementation Failure”, where there are gaps between what is known and what is done (Rangachari et al., 2013). Barriers to uptake of evidence based practice (EBP) in SLT include time pressures related to heavy workloads, with insufficient time to read and implement new findings (O’Connor and Pettigrew, 2009, Majid et al., 2011). A culture of using traditional methods instead of evidence-based approaches has also been identified, in which clinicians will refer to their own experience or seek advice from colleagues to solve clinical queries rather than consulting the literature (O’Connor and Pettigrew, 2009). Training needs in searching for and critically analysing evidence have also been identified (Majid et al., 2011) and SLT students have been found to have low self-efficacy towards EBP, which is considered to be a significant barrier to
learning and to its use in the clinical domain (Spek et al., 2013). Methods to increase self-efficacy are therefore justified, including promotion of positive role-models and establishing a culture in which EBP is part of standard patient care, not something to be feared (Spek et al., 2013).

A Cochrane Review (Flodgren et al., 2013) found multi-faceted educational interventions that were repeatedly administered showed promise in improving adherence to guidelines for prevention of device-related infections. The review also recommended dedication of resources, with specialised personnel, positive leadership and organisational changes to promote adherence. This survey indicates that SLTs would benefit from following these principles derived from implementation research to streamline best practice. Resources should be dedicated to enable frequent training and conference attendance to encourage dissemination of information and communication between clinicians and there should be promotion of EBP role models within departments. There should also be an expectation for clinical departments to demonstrate that they are adhering to guidelines and existing evidence, while also encouraging new research locally in order to build on the evidence available. Insufficient resources to offer optimal EBP to all patients should be flagged as an urgent and unacceptable unmet need.
2.5.1 **Strengths and Limitations**

In the absence of an existing tool, a new questionnaire was developed. Face validity was determined by piloting and it was strengthened by the systematic design process, following recommended principles (Rattray and Jones, 2007, Dillman, 2009). An inherent limitation of survey research is the potential for bias; individuals who choose to respond may not be representative of the whole population and the responses obtained may not be reflective of their actual practice but be subject to inaccurate recall or instead reflect their beliefs or their desire to present themselves in the best possible light (Bowling, 2005). In this study, however, several recommended measures were implemented to minimise the risk of bias and to increase participation; a web-based survey was conducted to reduce participant burden and allow more complete population coverage for sampling, anonymity was assured, the rationale for the study was clearly described and leading questions were avoided (Bowling, 2005, Rattray and Jones, 2007). As the number of SLTs working with stroke patients is unknown and respondents were not asked to identify their location it was not possible to determine a response rate or its geographical distribution. However, we consider the sample size reasonable and there was no regional or selection bias in method of recruitment. While there was a gradual reduction in completed responses and therefore arguably potential for non-response bias from missing data, the overall completion rate was considered very good (Groves, 2006).
Most respondents reported working in more than one clinical setting, limiting the analysis of subgroups due to the small numbers in each. As such, the data for the clinical subgroups presented in this study is intended as exploratory, rather than necessarily representative of all clinicians working in these settings. An alternative approach would have been to ask respondents to answer all questions related to each different setting, but this would have made the questionnaire lengthy and increased the risk of non-response.

Bias may have been introduced by the use of a multiple choice method, as the answers obtained may have been shaped by the possible responses suggested; for example the types of therapies suggested were arguably not an exhaustive list and so frequency data was less likely to be collected on techniques not listed. However, the possible responses to multiple choice questions were carefully developed and piloted and participants were given the option to enter information in an “other” or “comment” category to reduce bias (Rattray and Jones, 2007). This survey did not set out to record practice patterns in compensatory or indirect approaches to dysphagia, which are an important part of the SLT’s toolkit and warrant further study. It was also beyond the scope of this questionnaire to analyse treatment decisions based on individual patient presentations and this topic may be of interest in future studies with more detailed clinical questions. Interestingly the use of a case-based scenario generated markedly varied responses in a recent large survey of SLTs in the USA, with 47 different treatment techniques suggested for one patient in 97 different exercise combinations. Not one exercise combination was
recommended by more than one SLT (Carnaby and Harenberg, 2013). This further highlights extreme variability in practice, which is apparently an international concern.

2.6 Conclusion

This cross-sectional survey provides a record of current SLT approaches to therapy with dysphagia in stroke in the UK and Ireland. The sample size was reasonable and the survey was widely distributed using methods to reduce selection bias to reach a broad variety of SLTs working with stroke-induced dysphagia. There is a paucity of evidence for dysphagia therapy but this study revealed that the existing evidence and guidance is not filtering into clinical practice. There was wide variability in the therapy offered, which raises concerns for equity of access to care in the UK. Further research determining the best approaches to dysphagia therapy may lead to improved patient outcomes and improved uptake and implementation of evidence by SLTs. In the meantime, methods should be developed for SLTs to discuss and disseminate existing evidence and produce a consensus to guide practice with dysphagic stroke patients.

As per the aims of the study, factors which achieved relatively high consistency in responses were used to inform the intervention package of a subsequent feasibility study of dysphagia therapy in stroke (outlined in Chapter 7). The Effortful Swallow was the most frequently used task specific dysphagia exercise so this was considered a relevant intervention to incorporate. The treatment protocol aimed to
reflect normal therapy intensity so was guided by the finding that the SLTS working on stroke units reported seeing their patients once a day, five days per week and recommending daily independent practice. Furthermore, outcomes were measured that were consistent with those most frequently assessed by clinicians, e.g. degree of aspiration and diet/fluids managed, to ensure the results were clinically meaningful. The survey indicated that sEMG biofeedback is largely not being used in the UK and Ireland but that poor patient motivation is considered the most common reason for lack of improvement with therapy. This justifies studies to examine treatments aiming to encourage motivation, such as sEMG biofeedback, and to ensure that the most appropriate methods for using this adjunctive tool are determined before it is considered for general clinical use. Specific questions relating to swallowing sEMG measurement will be addressed in the following chapters.
Chapter 3  Validation of the Digital Swallow Workstation

3.1 Introduction

Most of the studies that incorporate sEMG in the investigation and treatment of swallowing have used the same equipment: the Digital Swallowing Workstation (DSW; KayPentax, New Jersey) (Huckabee and Cannito, 1999, Steele and Huckabee, 2007, Wheeler-Hegland et al., 2008, Yeates et al., 2010, Huckabee et al., 2005, Huckabee and Steele, 2006, Crary et al., 2007, Crary et al., 2006, Crary et al., 2004, van den Engel-Hoek et al., 2012). This is an integrated system that has been specifically designed for use with swallowing. The Swallowing Signals Lab within the DSW is a data acquisition and processing system that performs “appropriate signal conditioning” of the raw EMG signal (KayPENTAX), although there is insufficient information about the processing methods used. Furthermore, the raw signal is not accessible as it is processed prior to visual display, yet inspection of the quality of the raw EMG signal and also the signal to noise ratio is considered a vital stage of the EMG procedure due to the signal’s sensitivity to external noise sources or other artifacts (Konrad, 2005).

There is limited information available on the methods of signal processing performed by the Swallow Signals Lab and none regarding how they were

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determined and validated to ensure accurate and valid measurement for swallowing. This may lead to inaccurate results, affecting both clinical decisions and also the understanding of swallowing physiology at a population level. This is particularly relevant considering the system’s application of a bandpass filter of 50-220 Hz, which is outside the recommended range of 10-20 Hz high pass and 500 – 1000 Hz low pass cut offs to preserve the important frequencies of the signal (Merletti, 1999, Hermens et al., 1999, Basmajian and De Luca, 1985). The presence of some noise in the EMG signal is unavoidable and bandpass filtering aims to remove these elements. However, there is always a compromise between reducing noise and artifact contamination to avoid misinterpretation while preserving the desired information from the EMG signal (De Luca et al., 2010).

The motor unit action potentials (MUAPs) recorded by EMG vary in amplitude, duration and frequency, dependent on the innervation ratio of the muscles and motor unit recruitment and firing patterns (Cram, 2011). It is therefore important that a bandpass filter be determined with consideration of the expected power spectrum of the muscle to be tested so that it displays the muscle activity accurately. Dominant sEMG frequencies in the range of 25-300 Hz have been reported for the infrahyoid and submental muscles during swallowing in healthy adults (Gupta et al., 1996, White et al., 2008), with a higher frequency range reported for facial muscles (Naeije and Zorn, 1981). Furthermore, with increasing force of muscle contraction, there is progressive activation of additional motor units and an increase in the firing rate of active motor units (De Luca and Contessa,
2012), and there is a shift to the lower frequencies with muscle fatigue (Kallenberg and Hermens, 2008, White et al., 2008). Therefore if the bandpass filter is too narrow, the amplitude of the EMG signal presented may be inaccurate as the contribution of motor units firing at rates outside of the cut-off values is obscured. This has possible implications for accurately analysing muscle activity during swallowing and also for using the DSW for biofeedback as it is uncertain whether increased or decreased effort and relative force of contraction can be detected with sufficient sensitivity and accuracy.

The DSW EMG signal is also smoothed prior to display by full-wave rectification and low pass filtering. This is considered a simple method of quantifying signal intensity (Bartlett, 2007, Hermens et al., 1999), and is recommended by European standards (Hermens et al., 1999). However, the low pass cut off frequency applied should be carefully determined with consideration of the type of contraction studied (Bartlett, 2007) and comparison should be possible between the raw and smoothed signal to ensure that the smoothed signal is accurate and reliable.

Therefore this study aimed to validate the sEMG measurements recorded by the DSW against a conventional EMG system in which the raw signal can be accessed and manually processed in a known manner. Measurements were compared between the two systems at different force levels, with particular attention to lower levels of force that are relevant and informative for swallowing. Due to the
inherent differences between the two systems and recording electrodes, it was not expected that the two systems would record the same absolute amplitudes of activity. However for the DSW to be considered valid, there needed to be a linear relationship between the measurements taken by the DSW and the reference system, indicating that the signal is not attenuated differently at varying levels of contraction.

3.2 Aims

1. To compare the sEMG measurements recorded with the DSW against a reference sEMG system used simultaneously on the same muscle
2. To determine if the DSW attenuates the sEMG signal differently at varying levels of muscle activity

3.3 Methods

3.3.1 Study design

A prospective experimental study was conducted with full ethical and Research and Development approvals (Guy’s Hospital Research Ethics Committee, reference 10/H0804/17). 
3.3.2 Participants

Volunteers were recruited from the academic and research staff and students at King’s College London. Inclusion criteria were healthy volunteers over the age of 18 and exclusion criteria were any self-reported musculoskeletal injury that would limit participation in the task, or a diagnosis of neurological neuromuscular disease, determined during face to face interview.

3.3.3 Procedure

It was important to compare measurements taken simultaneously from the same muscle and swallowing muscles are too small for this purpose. Therefore sEMG measurements were recorded from the right biceps brachii during graded force isometric contractions using the DSW and a reference EMG system. As opposed to the swallowing muscles e.g. the submental muscle group, the biceps brachii is larger and has parallel fibres enabling simultaneous measurement with two sets of electrodes and force output can easily be quantified.

The Delsys Bagoli-4 Desktop EMG System (Delsys Inc, Boston, MA), from here onwards referred to as “Delsys”, was used as a reference sEMG system against which to compare the DSW. The Delsys was chosen because it is a widely used and accepted EMG system (De Luca et al., 2010, Franklin et al., 2012) and it enables the user to determine the settings for signal processing. Delsys systems have built-in anti-aliasing filters with upper bandwidths of 500 Hz and are designed and configured to optimally detect the complete spectrum of the EMG signal.
3.3.3.1 Measurement of Force

Isometric elbow flexion force was measured with a dynamometer (Kin-Com, Chattanooga, TN) set in isometric mode. Participants were seated comfortably in the chair and stabilised with a waist strap (Figure 3.1a). The elbow was fixed at $90^\circ$ of flexion with the upper arm parallel to the trunk and the forearm supinated. The wrist was secured by a padded cuff attached to the load cell and the forearm was further secured to the lever arm with a bandage (Figure 3.1b). The rotational centre of the lever arm was aligned by eye with the lateral epicondyle. The knee and hip joints were at $90^\circ$ of flexion and the feet were supported by a foot rest (Figure 3.1a).

![Figure 3.1: A: Set up of Kin-Com Dynamometer. B: Arm, load cell and electrode position. The wrist was secured by a padded cuff (1) attached to the load cell (2) and the forearm was further secured to the lever arm with a bandage (3). The rotational centre of the lever arm (4) was aligned with the lateral epicondyle. DSW (5) and Delsys (6) electrodes were placed in the vertical plane along the muscle on the line between the medial acromion and the cubital fossa at one third of the distance from the cubital fossa. The Delsys reference electrode was placed on the epicondyle (7).](image-url)
The force signal was A to D converted (1401, Cambridge Electronic Design (CED), Cambridge, UK) and recorded and displayed in real time with Signal data acquisition software (Version 5, CED) on a laptop computer with force measured in Newtons (N). The force trace was displayed on a computer screen in view of the participants to provide visual feedback and verbal encouragement was given.

3.3.3.2 \textit{sEMG measurement – electrode placement}

Prior to electrode placement, the skin was prepared by light abrasion with 3M One Step Skin Prep Abrader Tape (3M Ltd) and cleaned with a Clinell chlorhexidine/alcohol wipe (NHS Supply Chain, Maidstone). Electrodes were placed on the line between the medial acromion process and the cubital fossa at one third of the distance from the fossa (Figure 3.1b), in accordance with the SENIAM Guidelines (Hermens et al., 1999). Placement on the muscle was confirmed by palpation while the participant flexed the elbow against resistance. The two sets of electrodes (Delsys and DSW) were placed in the vertical plane along the muscle with the DSW electrodes superior (Figure 3.1b).

DSW signals were recorded with the standard electrodes supplied by KayPentax for use with the DSW. These are disposable circular adhesive electrode disks (57.2 mm in diameter) with three Ag/AgCl electrodes per disk (Figure 3.2a). Each electrode has a diameter of 12mm and an inter-electrode distance of 20mm centre to centre. After application of electrode gel (Signa gel, Parker Inc, New Jersey) the two recording electrodes were placed longitudinally along the muscle with the reference
The sEMG electrode was placed on the skin adjacent to the muscle, with a small adhesive disk (Micropore, MidMeds, Waltham Abbey, UK) to secure it in place (Figure 3.1b).

![Figure 3.1: sEMG electrodes. A: DSW adhesive electrode disk. B: Delsys DE-2.1 electrodes with adhesive interface.](image)

Signals recorded with the Delsys system were captured with DE-2.1 Single Differential Electrodes (Delsys Inc., Boston, USA): a pair of parallel bar silver electrodes, 10mm long and 1mm wide, with an inter-electrode distance of 10mm and a preamplifier gain of 10 volts/volt ± 1% (Figure 3.2b). The longitudinal axis of the electrode (which passes through both detection surfaces) was aligned parallel to the muscle fibres. Adhesive skin interfaces were applied to the electrodes to secure them in position and they were further secured in place with Micropore tape (Figure 3.1b). A reference electrode was placed on the ipsilateral bony prominence of the elbow.
3.3.3.3 **sEMG signal processing**

EMG signals were sampled with the DSW at 1000 Hz and automatically processed with the in-built Swallow Signals Lab and software, i.e. filtered with a bandwidth of 50-220 Hz and a 12 dB/octave rolloff, full-wave rectified and then low passed filtered at 3 Hz. With the Delsys system, EMG signals were amplified (x 1000) and sampled at 2000 Hz with a bandwidth of 20 – 500 Hz ± 10% and a 80 dB/decade rolloff. Signals were A to D converted (1401, CED, Cambridge, U.K.) and recorded on a laptop with Signal software. No further filtering or smoothing of the Delsys signals was applied to enable comparison to the raw signal. Recording was started manually and synchronously for both sEMG systems and data was recorded for 12 seconds at a time. On completion of the tasks, the data from both systems was exported to Matlab (MathWorks Cambridge, UK) for further analysis.

3.3.3.4 **Tasks completed**

Participants were asked to perform two different tasks:

1) Maximum voluntary isometric contractions (MVC) to obtain peak force.

2) A series of targeted isometric contractions at varying percentages of the MVC.

3.3.3.5 **MVC Task**

Participants were familiarised to the task and equipment and then were asked to produce three MVCs by pulling up as hard as possible on the wrist cuff for two seconds each with a rest of two seconds between each one. Instructions for when to start and stop the MVCs were given verbally and during the task they were given verbal encouragement and visual feedback from the force trace on the computer.
screen. After this task, they were given a five minute rest. The peak force achieved was measured off-line using cursor placement.

3.3.3.6 Targeted contractions

Ten target forces were set at 5% and 10 - 90% MVC (in increments of 10%) and displayed on the computer screen. The 5% target was included to enable examination of lower levels of muscle activity, which would be more relevant to swallowing. Initially, participants were asked to relax their arm altogether for 4 seconds. Then on the command “pull” they were asked to perform a 4-second contraction by pulling up on the wrist cuff and to match the target force which was displayed visually to them with a horizontal cursor on the computer screen. Participants were given up to three opportunities to perform each trial if required. Each contraction was followed by a rest period of 3 minutes. The order of the trials was randomised (www.randomizer.org) in order to minimise the effects of fatigue and learning.

3.3.4 Data Analysis

For visual qualitative inspection, the force trace and sEMG data were imported into LabChart 7 (AD Instruments Ltd, Bella Vista, Australia) and the Delsys data was then processed in accordance with the known settings on the DSW Swallow Signal Lab (band pass filter of 50 to 220 Hz, full wave rectification and then low pass filtered at 3 Hz).
For quantitative analysis, a customised programme was written in MatLab to simultaneously display the force data and the DSW and rectified Delsys sEMG data for each subject and each task. To ensure a direct comparison of the two systems, the sEMG traces from the two systems were manually superimposed to ensure that the periods of activity corresponded. In order to accurately line up the activity, the rectified Delsys signal was low pass filtered at 3 Hz and a vertical cursor was placed across both sets of EMG data at the point which corresponded with a plateau at the target force (Figure 3.3). The amplitude of EMG activity at that time point on the DSW and the rectified unsmoothed Delsys traces was recorded. This process was repeated for the MVC task and the 10 target force tasks for each participant.

Figure 3.3. MatLab display of the data from one representative contraction. Vertical cursor (*) is positioned at point where target force was maintained and the EMG amplitude was measured from both EMG systems. A=Force trace, B=Full-wave rectified Delsys sEMG trace with smoothed signal superimposed (red line), C=DSW trace (blue) with smoothed Delsys signal (red) superimposed.
The sEMG data recorded by each system for each trial were normalised to the MVC. In order to compare the amplitude at the different levels of force, the data was presented graphically with the normalised Delsys data on the X axis and the corresponding normalised DSW data on the Y axis. As the normalised MVC sEMG amplitude was always 100, this data was excluded from analysis to avoid biasing the level of agreement between the two systems. A Bland-Altman plot of the normalised DSW and Delsys data was conducted (Bland and Altman, 1986). The relationship between the normalised DSW amplitude and the normalised Delsys amplitude was further explored using linear and non-linear regression. To compare the linear and non-linear models fitted to the same data an F test was used where F is given by the equation below in which the SS terms are the sums of squares for the two models and the DF terms are the corresponding degrees of freedom (Bieles et al., 2012): \[ F = \frac{(SS_1 - SS_2)/(DF_1 - DF_2))/(SS_2/DF_2) \].

### 3.4 Results

Seventeen healthy volunteers were recruited but two were excluded because their muscle activity was in excess of the recording range of the DSW (i.e. >1000 μV) during an MVC. The demographics of the 15 participants are shown in Table 3.1.

<table>
<thead>
<tr>
<th>Table 3.1. Demographics of Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age (SD)</td>
</tr>
<tr>
<td>---------------</td>
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<tr>
<td>34.78 (10.37)</td>
</tr>
</tbody>
</table>
Figure 3.4 shows the data from one representative contraction. By processing the Delsys signal according to the settings used by the DSW, the smoothed signals were similar in shape. However, the processed Delsys EMG was smoother than the DSW. A consistent finding with the DSW data was a baseline of zero (Figure 3.4D), which was not indicative of the actual absolute value recorded by the Delsys system (Figure 3.4C). On occasions there was activity in the Delsys trace (Figure 3.4B and Figure 3.4C) not recorded in the corresponding DSW trace (Figure 3.4D).

Figure 3.4. Representative sEMG data from one contraction by one participant. A: Force trace, B: raw Delsys sEMG trace, C: Delsys trace processed with known settings from DSW (Band pass filtered 50 Hz high pass and 220Hz low pass, then low pass filtered at 3 Hz), D: DSW trace. Circled area: activity in Delsys trace not evident in corresponding DSW trace.

The relationship between the two systems was linear (Figure 3.5) as confirmed by a second order polynomial curve not fitting the data significantly better than a first order (linear) relation (F ratio test, F=0.2, p=0.699).
Figure 3.5 Linear regression of normalised DSW amplitude against normalised Delsys amplitude (units are volts as a percentage of the sEMG amplitude (in volts) recorded at the maximum voluntary contraction). Red line = line of equality, black line = regression line, blue dashed line = 95% confidence interval for regression line. $r^2 = 0.847$ (Standard Error of estimate 11.031), p=<0.001.

There was generally good agreement between systems. The mean difference between the two methods (the bias) was -0.025 % MVC (SD 11.08) with limits of agreement -21.75 - 21.70. The Bland-Altman plot indicates greater variability, i.e. increased scatter around the bias line, as amplitude increases. The graph indicates greater variability i.e. increased scatter around the bias line, as the mean amplitude increases (Figure 3.6). To examine this, two further Bland-Altman plots were conducted with the data divided into lower and higher levels of force of contraction, one at 5-40% of MVC (Figure 3.7A) and one at 50-90% MVC (Figure 3.7B). For the lower range, the bias was -2.85 (SD 5.92), limits of agreement
-14.45 to 8.74 and for the higher range the bias was 2.80 (SD 14.01), limits of agreement -24.65 to 30.26.

Figure 3.6. Bland-Altman plot of corresponding Delsys and DSW measurements for all target force levels (5-90% MVC) with mean and 95% Confidence Intervals indicating the limits of agreement. Units are a percentage of the sEMG amplitude (in volts) recorded at the maximum voluntary contraction.
Figure 3.7: Bland-Altman Plot of corresponding Delsys and DSW measurements at (A) lower levels of force (5-40% MVC) and (B) higher levels of force (50-90% MVC). The mean difference is shown with 95% Confidence Intervals indicating the limits of agreement.
3.5 Discussion

The Kay Digital Swallow Workstation is a commonly used system for sEMG assessment and treatment of swallowing for both research and clinical purposes. However, the sEMG system is a “black box” in which the user is unable to access the raw sEMG signal or adjust the signal processing settings. No information regarding the justification and or evaluation of the automated settings, some of which lie outside of recommended standards for sEMG signal processing, is provided. Using a poorly evaluated and understood instrument may lead to inaccurate results, therefore affecting both clinical decisions at the patient level but also the understanding of swallowing at a population level. This study aimed to validate the DSW against a conventional sEMG system with known processing settings.

The mean difference between measurements made by the DSW and a reference sEMG system was small and indicated no systematic bias, with neither method consistently producing higher or lower results. The linear relationship between the two sets of measurements also confirms this finding and addresses the aim of the study, determining that the DSW does not attenuate the signal differently at varying levels of muscle activity. This indicates that the sEMG signal processing applied by the Swallow Signals Lab on the DSW is appropriate and enables accurate measurement of muscle activity.
Increased variability around the mean occurred at higher force contractions and this was confirmed by analysing data from lower and higher force contractions. This is acceptable and not surprising considering the DSW is designed for use with swallowing, which contrary to the capacity of the biceps, involves much lower levels of force from much smaller muscles. The narrow band pass filter of the DSW may have more effect on the signal at the very high force contractions due to anticipated shifts in the frequency spectrum with increasing force (Kaplanis et al., 2009, De Luca and Contessa, 2012).

Visual inspection of the sEMG signal from both systems (Figure 3.3 and Figure 3.4) shows that similarity in shape of the linear envelope was obtained by filtering and smoothing the Delsys signal at the known settings of the DSW. However, the DSW consistently produced data with a baseline of zero Volts, whereas the Delsys consistently had evidence of some noise or offset, as would be expected. While reduced noise could be accounted for by better electrode-skin contact with the DSW system, the consistently absolute flat zero baselines indicates that the DSW is performing some signal processing which essentially removes all baseline noise. It was not possible to replicate this process by following the filtering and smoothing specifications provided by the manufacturer (Figure 3.4). Noise in the sEMG signal is endemic and unavoidable and its removal makes the sEMG signal more practically useful and easier to interpret (De Luca et al., 2010). However, in the example presented, sEMG activity is shown in the Delsys trace (Figure 3.4B and Figure 3.4C) at 2 seconds (circled) which is not evident in the corresponding DSW trace (Figure
3.4D). This may indicate that the process performed to remove the baseline noise by the DSW has in fact removed some of the actual sEMG activity from the signal. This reinforces the importance of knowing exactly how the signal is being processed to be able to ensure important information is preserved.

### 3.5.1 Strengths and Limitations

As the DSW is designed for assessment and treatment of swallowing, a possible limitation of this study was the use of a non-swallowing muscle to validate the measurements. However, it was important to compare measurements taken simultaneously from the same muscle and so it was necessary to use a muscle large enough on which to place two sets of recording electrodes. As opposed to the swallowing muscles e.g. the submental muscle group, the biceps brachii is large and has parallel fibres enabling simultaneous measurement with the two EMG systems. By using isometric contractions of the biceps, it was also possible to measure and target the force of contraction, which would have been impossible in muscles of the throat. Furthermore, lower force bicep contractions were elicited as they have frequency distributions comparable to swallowing muscles (Bilodeau et al., 1992, White et al., 2008).

The sEMG data for the target force contractions were normalised to a percentage of the amplitude recorded at the MVC and therefore it was surprising that three sEMG measurements for submaximal target contractions were greater than 100% MVC.
(Figure 3.5 and Figure 3.6). This occurred in three participants as they produced a contraction at 90% of MVC and may be due to the difficulties in making small variations in muscle activity at high levels of force and the increased variability in sEMG with increased target force (Salomoni and Graven-Nielsen, 2012). Moreover, the influence of these data on the overall results is subtle; if those three sets of data are removed from the analysis there is a marginally stronger linear relationship between the two sets of measurements, but the difference is negligible ($r^2 = 0.86$, standard error of the estimate 10.10).

This study was not designed to examine fatigue and did not include patient populations. Therefore it was not possible to examine effects on the sEMG amplitude measured by the DSW from shifts in the frequency spectrum specifically due to fatigue or weakness. As different muscles have different rates and responses to fatigue (Stock et al., 2012), these factors would need to be examined in the swallowing muscles themselves in order to be informative and relevant. Access would therefore be required to the raw sEMG signal captured by the DSW, with the same signal split and processed simultaneously by the DSW and a conventional sEMG system. However, KayPentax have thus far not been able to facilitate access to the raw signal.
3.6 Conclusion

This study demonstrates an acceptable level of agreement between the measurements from the DSW and a reference sEMG system, indicating adequate information for clinical purposes and research with a strong clinical focus. Users can be confident that when a patient increases their muscle activity to produce a stronger contraction, there will be a corresponding increase of sEMG activity displayed. However, the effects of fatigue and weakness on the DSW sEMG signal have not been tested. Furthermore, the automatic processing of the sEMG signal, preventing access to the raw trace and precluding analysis of the power density spectrum, limit the application of the DSW for the in-depth scientific analysis of muscle activity during swallowing.

The findings of this study support the use of the DSW in the subsequent studies of this thesis and in addressing outstanding questions in swallowing sEMG measurement, such as its reliability. This will be examined in the next chapter.
Chapter 4  Feasibility of sEMG as a biofeedback tool in dysphagia therapy: reliability, normalisation techniques and the effect of age

4.1 Introduction

sEMG is being used increasingly in both the studies and clinical management of swallowing disorders. However, several questions remain to be answered before swallowing sEMG data can be interpreted accurately and the extent of its role in dysphagia management can be established. The best method of normalising swallowing sEMG has not been established, with the majority of studies not normalising their data, despite this confounding comparisons within and between individuals. The reliability of swallowing sEMG measurements has not been investigated, which is a necessary precursor to using this technique as a performance or outcome measure. The effect of age on swallowing sEMG measurements and the ability to modify the sEMG trace during the ES exercise requires more attention due to the known deterioration of swallowing and specifically the reduction in functional reserve in healthy ageing.

4.2 Aims

This study sought to determine the following:

1. The intra-and inter-participant variability of submental swallowing sEMG in healthy and dysphagic acute stroke participants within and across sessions to
inform the potential application of sEMG as an assessment and outcome tool in swallowing.

2. The best way of normalising submental swallowing sEMG from dynamic measurements.

3. If swallowing sEMG amplitudes become more variable with age.

4. If age affects the ability to increase submental muscle activity during the ES relative to normal swallowing.

4.3 Hypotheses

It was hypothesised that:

1. Normalising measurements to the mean NS amplitude would lead to the greatest reduction in intra- and inter-participant variability (see section 1.9.1).

2. There would be an increase in the variability of submental sEMG amplitude with age (see section 1.9.3).

3. The relative increase in sEMG amplitude for the ES compared to the NS would become less with age (see section 1.9.3).

4.4 Methods

4.4.1 Study Design

A phase I observational study was conducted with full ethical and R&D approvals (Guy’s Hospital Research Ethics Committee, reference 10/H0804/17). Informed written consent was gained from all participants.
4.4.2 Participants

4.4.2.1 Healthy participants

Healthy volunteers in four age groups (18-30, 31-50, 51-70 and 71+ years) were recruited from staff and students at King’s College London and Guy’s and St Thomas’ NHS Trust, hospital volunteers and friends and relatives of patients. These groups were decided on to recruit a spread of adults across different ages, with representation of participants aged over 50, when sarcopenia is known to be increasingly prevalent (Messier et al., 2011), and changes in swallowing are reported (Butler et al., 2011a). The oldest group enabled comparison with patients as the average age of first stroke is 70 years (Wolfe et al., 2011). Participants responded to an email circular or to posters displayed in the hospital. Inclusion criteria were age >18 years and eating and drinking a normal diet and fluids with no difficulty determined by Sydney Swallow Questionnaire (Wallace et al., 2000). Exclusion criteria were any history of dysphagia, stroke or other neurological or neuromuscular illness or head and neck cancer or surgery (determined by face-to-face interview). The first participants recruited into the oldest age group were also allocated to form the healthy control group against which to compare to the stroke participants. Allocation into the healthy control group ended when the last stroke participant was recruited.

4.4.2.2 Stroke participants

Fifteen consecutive dysphagic acute stroke participants were recruited from the Stroke Unit at St Thomas’ Hospital. This sample size was decided a priori in order for this phase I study to gain adequate data to inform future studies. All acute
stroke patients referred to Speech and Language Therapy (SLT) for swallowing assessment were approached. Inclusion criteria were being within three months of first stroke, referral to Speech and Language Therapy (SLT) for assessment and management of dysphagia, presence of dysphagia on Fibreoptic Endoscopic Evaluation of Swallowing (FEES), Functional Oral Intake Scale (FOIS) score <6 and ability to give informed consent with supported/total communication if necessary (as determined by medical consultant and in discussion with SLT). Exclusion criteria were FOIS score ≥6, any previous history of dysphagia, stroke, neurological illness, head and neck cancer or surgery. The FOIS is a validated tool designed to document functional oral intake of food and liquid (Crary et al., 2005). The different scores are:

1. Nothing by mouth (NBM)
2. Tube dependent with minimal attempts of food or liquid
3. Tube dependent with consistent intake of liquid or food
4. Total oral diet of a single consistency
5. Total oral diet with multiple consistencies but requiring special preparation or compensations
6. Total oral diet with multiple consistencies without special food preparation, but with specific food limitations
7. Total oral diet with no restrictions

4.4.2.3 Steps taken to enable participation of participants with cognitive/linguistic impairment

As participants were not excluded from the study if they had communication and/or cognitive impairment, provided they were able to provide informed consent, it was necessary to ensure that communication was adequately facilitated throughout to enable fair and optimum participation. Key measures taken:
- The researcher was provided with information about participants’ communication/cognitive impairment from their managing SLT, including the most appropriate individualised strategies to facilitate communication throughout the study.

- To ensure participants had adequate information about the study, accessible information sheets and consent forms were developed (Appendix 6 and 7) with an aphasiology colleague following Stroke Association guidelines (Stroke Association, 2012). Documents were reviewed and approved for acceptability and ease of understanding by the King’s College London Stroke Users Group. The information sheets were given to participants and the study was also explained using total communication and support from an aphasiology colleague, where necessary.

- Consent was sought with a witness present on a subsequent day to the information-giving meeting, when it was checked that participants’ were able to recall the information provided previously.

- Throughout the protocol, instructions were provided simply and clearly using total communication, including pictures and contextual object props, to ensure participants understood what was expected of them.

### 4.4.3 Procedure

On recruitment to the study, stroke participants were assessed with Fibreoptic Endoscopic Evaluation of Swallowing (FEES) to enable detailed evaluation of their swallow function. A FEES protocol was followed (Appendix 3) and the examination
was evaluated offline by the Trust lead SLT for FEES. Presence/absence of aspiration and pharyngeal residue were determined with the Penetration Aspiration Scale (Rosenbek et al., 1996) and the Residue Rating Scale (Kelly et al., 2006). Healthy volunteers filled in the Sydney Swallow Questionnaire (Wallace et al., 2000) to identify any symptoms of dysphagia, which would lead to exclusion from testing. All participants completed the Mini-Mental State Examination (MMSE) (Folstein and Folstein, 2010) and the Barthel Index (Collin et al., 1988) was recorded for stroke participants from their medical notes.

4.4.3.1 Electrode placement
Prior to electrode placement, the skin was prepared by light abrasion with 3M One Step Skin Prep Abrader Tape (3M Ltd) and cleaned with a Clinell chlorhexidine/alcohol wipe (NHS Supply Chain, Maidstone). DSW signals were recorded with the standard electrodes supplied by KayPentax as described on page 98 and in Figure 3.2. After application of electrode gel (Signa gel, Parker Inc, New Jersey) the two recording electrodes were placed longitudinally on the anterior neck, midway between the mental spine of the mandible and the hyoid bone, with the reference electrode to the side (Figure 4.1). This electrode configuration has been used in previous studies (Huckabee and Steele, 2006) to detect collective muscle activity from bilateral submental muscles (mylohyoid, geniohyoid and anterior belly of the digastrics). The disks were taped in place (Micropore, MidMeds, Waltham Abbey, UK). Care was taken to ensure consistent positioning of electrodes between sessions and between individuals.
4.4.3.2 sEMG Signal Processing

EMG signals were sampled with the DSW at 1000 Hz and automatically processed with the in-built SSL and software, i.e. filtered with a bandwidth of 50-220 Hz and a 12 dB/octave rolloff, full-wave rectified and then low passed filtered at 3 Hz.

4.4.3.3 Swallow tasks

All participants were taught the ES and were given the instruction “swallow hard, squeezing all of your throat muscles and pushing hard with your tongue on the roof of your mouth”, which is similar to instructions given in previous studies (Witte et al., 2008, Huckabee and Steele, 2006). Prior to sEMG recording, the researcher observed participants practicing the ES and palpated their laryngeal movement until she felt they had mastered it. Participants were randomised to complete the tasks with or without biofeedback first and repeated a series of swallow tasks in each condition in the following order:

- Three normal swallows
- Six effortful swallows
For each swallow, participants were fed 5 ml boluses of water via a teaspoon and were asked to hold the water in the mouth until given the instruction to swallow. Participants considered at high risk of aspiration on teaspoons of water as per FEES assessment, were given a teaspoon of their safest consistency or moistened mouth care swabs if they were nil by mouth. For each NS, participants were asked to “swallow this in your normal way”. For each ES the instruction above explaining swallowing “hard” was repeated.

There was a 30-second rest between each bolus and the sequence was repeated after a 5-minute rest so that each participant completed the series both with and without biofeedback.

4.4.3.4 Biofeedback condition
Biofeedback involved the participant facing the DSW screen while participants completing the tasks (Figure 4.2). They were orientated to the information on the screen and it was explained that the “blue line” was showing their level of muscle activity. They were encouraged to watch the screen during the swallow tasks. For the NS, no additional sEMG-specific instructions were given. For the ES, a horizontal cursor was placed on the peak amplitude for their normal swallows and they were asked to “beat” that target and make “the blue activity line” go above the cursor (Figure 4.3). If they managed to beat this target, the horizontal cursor was then repositioned to the new maximum amplitude and so on for each trial (Figure 4.4). Verbal encouragement was also given based on the live sEMG recordings e.g. “try to
swallow even harder than last time and see if you can double your normal swallow activity”.

Figure 4.2: Participant completing swallow tasks with sEMG biofeedback

4.4.3.1 “No biofeedback” condition

In the “no biofeedback” condition, participants completed the tasks with the DSW screen turned away from them. General verbal encouragement was also given but without reference to the sEMG recordings, e.g. “try to swallow even harder than last time”. The researcher looked at the screen to check recording quality but did not use the images to frame any feedback to the participant.
4.4.3.2 Second session

All participants were then invited to return for a second identical session in which the protocol was repeated. Sessions were scheduled >24 hours apart but within one week of each other to minimise the degree of change in swallowing status in participants with stroke recovery.
4.4.3.3 Data processing

On completion of the tasks, the sEMG data was exported from the DSW to Matlab (MathWorks Cambridge, UK) and a customised programme was used to identify and record the peak amplitude for each swallow.

4.4.4 Data analysis

Data was summarised with means (SD) or medians (IQR) depending on its distribution. NS data from the no biofeedback condition was used to examine reliability and methods of normalisation in order to analyse swallows most representative of normal behaviour. To examine the intra-participant reliability between swallows, Bland-Altman plots were created between data for each NS and between the mean NS data for both sessions. The relationship between the standard deviation and the mean was explored with linear regression. Data were examined for normality with histograms and the Kolmogorov-Smirnov test. sEMG data that was found to be non-normally distributed was log-transformed (natural log) and then normality was reassessed. This data was then used for all subsequent statistical analyses.

The coefficient of variation (CV) gives a measure of variability and within-and between-participant CVs have been used to determine the effect of different normalisation techniques on the variability of EMG measurements in limb muscles.
CVs were calculated by the following equations for normally distributed data (a) and for Log-normal data (b):

a.  \( \frac{SD}{mean} \times 100 \)

b.  \( \sqrt{\exp(\sigma^2) - 1} \times 100 \), in which \( \sigma \) is the SD of the natural logs

These were calculated to examine within- and between- participant variability for non-normalised data and data normalised to each reference measure by using individual and group SDs, respectively. Accepted cut-offs for between-session reliability of sEMG in dynamic tasks were used: “acceptable” reliability was defined as a CV of <12%, “poor” was a CV of >16% and “unacceptable” was determined as a CV of >20% (Albertus-Kajee et al., 2010, Buckthorpe et al., 2012). Intra-participant CVs were compared between groups with independent t-tests for unequal variance and within groups with repeated measures ANOVA, correcting for violations in sphericity with the Greenhouse-Geisser estimates of sphericity. Post hoc pair-wise comparisons were made with correction for multiple testing with the Bonferroni criterion.

The method of normalisation providing the data with the best inter-participant reliability, i.e. lowest CV, was determined and then swallowing sEMG data was normalised by this method for all further analyses. The effect of age on the ability to modify the sEMG amplitude in the ES condition was examined with linear regression, with normalised ES amplitude plotted against age. The relationship
between swallow variability and age was explored with linear regression, with intra-participant CV plotted against age.

### 4.5 Results

#### 4.5.1 Participants

All 15 consecutive acute stroke patients who were approached consented to participate and were recruited to the study. Technical difficulties arose during the sEMG recording for one participant who was transferred to a different hospital before a second session could be conducted. Two further participants declined to have FEES. Therefore the results are based on 14 stroke participants, with baseline PAS scores available for 12 (Table 4.1). One stroke participant who was randomised to receive FB first was too fatigued to complete the session protocol and therefore did not repeat the tasks without FB; therefore his data could not be included in the comparison of different normalisation techniques. Seventeen healthy participants were recruited as the control group (Table 4.1). There were no significant differences between the healthy control group and dysphagic stroke participants for age, BMI or number of days between sessions (p>0.05). The stroke group had significantly lower FOIS, MMSE and Barthel scores (p<0.001, Table 4.1). Due to the severity of the stroke participants’ dysphagia, only three could tolerate teaspoons of water, therefore the others were given their safest consistency; five participants had moistened oral care sponges, four had teaspoons of syrup, and two had teaspoons of yoghurt.
For the study of age-related changes, 85 healthy participants were recruited but 2 did not attend the second session so between-session reliability analyses are based on 83 (Table 4.2). Group 3 had a significantly higher BMI than Group 1 (p=0.006) but there were no other significant differences between age groups.
Table 4.1: Participant demographics for stroke participants and age-sex matched healthy controls. Medians and Inter-quartile ranges shown.

<table>
<thead>
<tr>
<th>Group (n)</th>
<th>Stroke (14)</th>
<th>Healthy (17)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>74.50 (61.25 – 83.25)</td>
<td>76.00 (74.5 – 81.5)</td>
</tr>
<tr>
<td>Sex</td>
<td>Male 9</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Female 5</td>
<td>7</td>
</tr>
<tr>
<td>BMI (Kg/m)</td>
<td>25.25 (22.5 – 33.78)</td>
<td>24.8 (21.95-28.25)</td>
</tr>
<tr>
<td>MMSE</td>
<td>22.5*** (18.00-25.00)</td>
<td>30.00 (30.00-30.00)</td>
</tr>
<tr>
<td>Communication impairment</td>
<td>– Severe rec/exp aphasia (1)</td>
<td>– Moderate rec/exp aphasia (2)</td>
</tr>
<tr>
<td></td>
<td>– Mild rec/exp aphasia (1)</td>
<td>– Moderate cognitive-communication impairment (3)</td>
</tr>
<tr>
<td></td>
<td>– No impairment (7)</td>
<td>n/a</td>
</tr>
<tr>
<td>Barthel</td>
<td>4.00 *** (0.00 – 10.75)</td>
<td>20.00 (20.00-20.00)</td>
</tr>
<tr>
<td>Stroke Type</td>
<td>– R MCA infarct (5)</td>
<td>n/a</td>
</tr>
<tr>
<td></td>
<td>– L MCA infarct (3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– L PICA infarct (1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– L pontine infarct (1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– R thalamic haemorrhage (1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– R parietal haemorrhage (1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– Multiple posterior circulatory infarcts (1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– Multiple scattered lacunar infarcts (1)</td>
<td></td>
</tr>
<tr>
<td>Days from stroke to session 1</td>
<td>16.5 (7.00 – 41.25)</td>
<td>n/a</td>
</tr>
<tr>
<td>PAS on FEES</td>
<td>7.5 (5.25 – 8.00)</td>
<td>n/a</td>
</tr>
<tr>
<td>FOIS</td>
<td>4.00*** (1.00-5.00)</td>
<td>7.00 (7.00-7.00)</td>
</tr>
<tr>
<td>Days between sessions</td>
<td>3.00 (1.00-4.00)</td>
<td>5.00 (1.50 – 7.00)</td>
</tr>
</tbody>
</table>

Significant differences between groups are indicated by *** (p=<0.001) on Mann Whitney U Test for independent samples. BMI = Body mass index, MMSE = Mini-mental state examination, PAS = Penetration Aspiration Scale, FOIS = Functional Oral Intake Scale, rec/exp = receptive/expressive.
<table>
<thead>
<tr>
<th>Group</th>
<th>All</th>
<th>Group 1 (18-30 yrs) n=22</th>
<th>Group 2 (31-50 yrs) n=21</th>
<th>Group 3 (51-70 yrs) n=20</th>
<th>Group 4 (71+ yrs) n=22</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>49.00 (29.00–70.00)</td>
<td>25.00 (22.00–28.00)</td>
<td>35.5 (32.00 – 40.50)</td>
<td>62.00 (59.50 – 65.50)</td>
<td>75.50 (73.25–81.00)</td>
</tr>
<tr>
<td>Sex</td>
<td>Male 42</td>
<td>10</td>
<td>11</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>Female 43</td>
<td>12</td>
<td>10</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>BMI (Kg/m²)</td>
<td>23.30 (21.60–25.60)</td>
<td>22.75Ɨ**(21.00–4.23)</td>
<td>23.20 (22.23 – 24.00)</td>
<td>25.60 (23.05 – 27.70)</td>
<td>23.00 (21.18 – 26.98)</td>
</tr>
<tr>
<td>FOIS</td>
<td>7.00 (7.00-7.00)</td>
<td>7.00 (7.00-7.00)</td>
<td>7.00 (7.00-7.00)</td>
<td>7.00 (7.00-7.00)</td>
<td>7.00 (7.00-7.00)</td>
</tr>
<tr>
<td>SSQ (%)</td>
<td>1.18 (0.00 – 1.62)</td>
<td>0.08 (0.00 – 1.28)</td>
<td>0.00 (0.00-1.54)</td>
<td>1.18 (0.09 – 2.26)</td>
<td>1.18 (0.50 – 2.44)</td>
</tr>
<tr>
<td>Days between sessions</td>
<td>6.00 (4.00 – 7.00)</td>
<td>6.00 (4.00 – 7.00)</td>
<td>6.00 (4.00 – 7.00)</td>
<td>5.00 (2.00 – 7.00)</td>
<td>5.00 (2.00 – 7.00)</td>
</tr>
</tbody>
</table>

Significant differences between groups 1 and 3 are indicated by Ɨ** (p=<0.01) on Mann Whitney U Test for Independent samples, adjusting for multiple testing with the Bonferroni correction. BMI = Body mass index, FOIS = Functional Oral Intake Scale.
The sEMG amplitudes for all participant groups were not normally distributed for session 1, 2 or both sessions combined (≤0.001, confirmed by examining histograms), justifying log transformation (ln) for statistical analysis. There was a significant positive relationship between the mean and SD for healthy participants ($R^2=0.4588$, $p<0.001$) and a non-significant positive relationship for the stroke group ($r^2=0.260$, $p=0.063$). These findings support the use of the CV to measure reliability.

### 4.5.2 Intra-participant variability within and across sessions

#### 4.5.2.1 Healthy participants, Figure 4.5
There was one clear outlier among the healthy participants and this individual (participant 17) was excluded from further analyses. They were very distracted and tense during data collection and appeared to perform an ES for all swallows (mean amplitude 200 $\mu$V). For the remaining 84 healthy participants, the mean difference (bias) between swallows (within session) was near zero, with no evidence of an increase or decrease in sEMG amplitude on sequential swallows (Figure 4.5) (Bland-Altman plots are shown for session 1, which was representative of session 2). The maximum limits of agreement were between -21.16 and 22.64 $\mu$V (for swallow 3 – swallow 1. For between-session intra-participant variability (n=82), the mean difference was also small (-2.70 $\mu$V) and the limits of agreement were between -32.67 to 27.26 $\mu$V (Figure 4.5). These results are within the context of an amplitude range of 2.30 - 152.57 $\mu$V for all NSs by all healthy participants across sessions.
The intra-participant CV (SD) for all healthy participants was 15.14 (10.42) for session one, 15.66 (11.54) for session two and 22.79 (12.74) across sessions one and two.

Figure 4.5: Bland-Altman plots for all healthy participants (participant 17 removed). A: Session 1, swallow 1 and 2; bias=0.01 (SD 7.575), limits of agreement (LOA)= -14.83 -14.86. B: Session 1, swallow 2 and 3; bias= 0.73 (10.49) LOA: -19.83 - 21.29. C: Session 1, swallow 1 and 3; bias =0.74 (11.17), LOA -21.16 to 22.64. D: session 1 vs session 2, bias = -2.70 (15.29), LOA: -32.67 – 27.26.
4.5.2.2 Stroke participants

The mean difference in amplitude between different swallows was small, with a maximum bias of 1.963 μV and a maximum limits of agreement of -11.5689 - 15.4940 μV between swallows one and two, with no evidence of progressive change in amplitude (Figure 4.6A-C). The limits of agreement for between-session stroke participant data (Figure 4.6D) were very similar to the other participant groups, marginally narrower than for all healthy participants (Figure 4.5D), but marginally wider than for the healthy control group (Figure 4.6E). The overall range in amplitude for all NSs across sessions was 5.87 – 74.40 μV.

For non-normalised data there was no difference in intra-participant variability (CV (SD)) for session 1 between stroke 15.69 (7.45) and healthy 14.50 (5.12) participants p=0.63, but stroke participants were significantly more variable for session 2, 20.63 (10.81) vs 12.66 (9.20), t(25.69) = -2.182, p=0.038. Stroke participants had higher intra-participant variability across the two sessions 28.40 (14.34) vs 20.01(8.37), but this did not reach significance t(20.04)= -1.93,p=0.067.
4.5.3 Determining the best way of normalising swallowing sEMG

4.5.3.1 Effect of normalisation on intra-participant variability

In healthy participants, there was a significant effect of type of normalisation on intra-participant variability across sessions 1 and 2, $F(2.65, 219.99)=11.36, p<0.001$ (Figure 4.7). Normalising to the mean swallow produced significantly less variable data than absolute values, mean difference (SE) = 6.69 (1.59), $p=0.001$) and all other methods of normalisation: normalised to mean ES with FB: 6.16 (1.46), $p=0.001$, normalised to mean ES without FB: 6.06 (1.50), $p=0.001$) and normalised to maximum ES amplitude, 6.70 (1.39) $p<0.001$). There was no significant difference in intra-participant variability for the different methods of normalisation in stroke participants $F(1.81, 23.46)=2.71, p=0.092$ or in the healthy control group $F(1.92, 30.71)=1.17, p=0.323$. For data normalised to the mean NS, there was no significant difference in intra-participant variability across sessions between stroke, mean CV (SD) =17.24 (5.92), and healthy controls 15.79 (12.29), $t(28)=-0.39, p=0.70$ (Figure 4.7).
Figure 4.7: Intra-participant variability across sessions 1 and 2 for all healthy participants (n=82), healthy age/sex matched control participants (n=17) and stroke participants (n=13). FB=feedback, ES=effortful swallow, CI=Confidence Interval.
4.5.3.2 Effect of normalisation on inter-participant reliability

The inter-participant variability was high for the non-normalised data and for three out of four of the methods of normalisation for both healthy and stroke participants (Figure 4.8).

Figure 4.8: Inter-participant variability for all healthy (A) and stroke (B) participants of non-normalised data and of data normalised to four different reference measures. S1= session 1, S2=session 2, FB=feedback, ES=effortful swallow, Max=maximum.
Inter-participant variability was higher for both sessions in stroke participants than for healthy controls for non-normalised data, but there was minimal variability in both groups for data normalised to the mean swallow (Figure 4.9).

![Graph showing inter-participant variability for stroke participants and healthy controls of non-normalised data and of data normalised to mean normal swallow. S1 = session 1, S2 = session 2.](image)

**Figure 4.9:** Inter-participant variability for stroke participants and healthy controls of non-normalised data and of data normalised to mean normal swallow. S1 = session 1, S2 = session 2.

### 4.5.4 The effect of age on swallowing sEMG

#### 4.5.4.1 Variability and age

There was no change in within- or across-session intra-participant variability with age for non-normalised data ($r^2 = 0.015$, $p>0.05$) or data normalised to the mean NS ($r^2 = 0.013$, $p>0.05$) (Figure 4.10).
4.5.4.2 The ability to increase submental muscle activity during the ES relative to normal swallowing with increased age

For all analyses of ES, data is normalised to the mean NS for that session. There were no significant differences in amplitude in healthy participants between sessions 1 and 2 for ES with or without FB. Therefore the mean amplitude across the two sessions was used for further analyses of healthy data. There was no change in amplitude for the ES with or without FB with age (r=0.178, F(1)=2.61, p=0.110, and r=0.178, F(1)=2.62, p=0.110, respectively) (Figure 4.11). One participant produced markedly increased amplitude for the ES without FB than the ES with FB and compared with all others (participant 28). This participant also reported that he felt the electrode and tape were “restrictive” on his swallow (see questionnaire data, 5.5.2). It may be that the equipment was secured too tightly, which then led to electrode movement with hyo-laryngeal excursion and poor electrode contact contaminated the data. This participant’s data was removed.
from further analysis as it was a clear outlier. Three further participants’ data are marked on Figure 4.11 as they were not able to increase their sEMG amplitude above the baseline NS level for both ES conditions.

Figure 4.11: Relationship between age and mean normalised sEMG amplitude for the ES exercise in healthy participants across sessions 1&2. Dotted line at 100 %NS represents baseline, i.e. mean normalised normal swallow amplitude (n=83). ES = effortful swallow, FB=feedback. Numbers and lines indicate specific participants’ data points, with the number indicating the participant’s code.
4.6 Discussion

4.6.1 Intra- and inter-participant reliability of submental swallowing sEMG

In healthy participants within a session, it is normal for non-normalised swallow amplitudes to differ by up to $\pm 44 \, \mu V$. Between sessions, this rises by up to $\pm 60 \, \mu V$. This is within the context of an overall amplitude range for normal swallowing of $2.30 - 152.57 \, \mu V$. While the sample size was small, making it difficult to generalise, the results indicate that stroke participants fall within these same limits between swallows. Therefore variability in amplitude between swallows (in a task involving three sequential swallows) is not a distinguishing feature of dysphagia in stroke. This is surprising considering these participants had had a recent stroke affecting their swallowing and therefore instability in swallowing motor control might have been expected. The within-session CVs for healthy and stroke participants are less than CVs of sEMG measurements taken from other dynamic activities in healthy participants, for example from leg muscles during gentle walking ($31 - 52\%$; (Winter and Yack, 1987) and comparable with those taken during maximal and explosive knee extension (16-17%) (Buckthorpe et al., 2012). The within-session data was collected with no change in conditions or electrode placement and therefore gives a good indication of the reliability of muscle activity for sequential swallowing, while controlling for other influences on the signal. While the data fall outside the “acceptable” range of reliability ($<12\%$ CV (Buckthorpe et al., 2012, Albertus-Kajee et al., 2010), it achieves the aim of the study in providing a reference for the level of variability in swallowing, against which to compare future data.
Data collection adhered to a strictly controlled study protocol conducted by one individual in one setting, which may not be representative of a usual clinical setting, in which variability might be increased. Despite this, between-participant variability for non-normalised data was very high for all groups (up to 77%). This is comparable to Yeates et al. (2010) who describe SD of 74% of the mean between healthy participants. This degree of inter-participant variability is surprising in healthy participants, who have no pathology affecting their swallowing and who all swallowed the same volume and same consistency of fluid. The sample of stroke participants in this study was heterogeneous with respect to stroke type but this did not increase the inter-participant variability above the level of the healthy sample. This variability may be a reflection of the complexity of swallowing, involving several muscle groups and also the influence of varying amounts of subcutaneous tissue attenuating the signal. Promisingly the variability was markedly reduced by normalising to the mean swallow. This gives a strong message for the need to normalise data before any inferences can be made about between participant or group differences. It also throws into doubt published studies of swallowing that have not considered reliability and have made comparisons on non-normalised data (Vaiman, 2007, O’Kane et al., 2010, Coriolano et al., 2012, Crary and Baldwin, 1997, Wheeler et al., 2007, Leow et al., 2007, Vaiman et al., 2004b, Huckabee et al., 2005, Yoshida et al., 2007, Park et al., 2009, Miyaoka et al., 2010).
4.6.2 The best way of normalising swallowing sEMG

The aim of normalising sEMG data is to improve reliability and give a valid representation of muscle activity and therefore it is important to use a reliable reference for normalisation (Burden et al., 2003). Consistent with the a priori hypothesis, the best reference measure was the mean of the NS. Normalising swallow data to this measure was the only method examined that both markedly reduced the inter-participant variability and significantly improved the intra-participant reliability from the “unacceptable” to the “poor” range of reliability (CV < 16% (Albertus-Kajee et al., 2010). Other methods that have been used previously in swallow research, e.g. normalising to the maximum ES (Ding et al., 2002), produced data that was no more reliable than non-normalised data, and in stroke participants appeared to increase the intra-participant variability across sessions. This has considerable implications for the interpretation of studies using these methods. Furthermore it is consistent with findings from dynamic studies of limb muscles that have found the greatest variability in data normalised to the MVC and least variability in data normalised to sub-maximal activities (Albertus-Kajee et al., 2010), which is likely to be due to the instability of the EMG signal at maximal levels (De Luca, 1997). Asking participants to produce maximum effort for a relatively unfamiliar task (the ES) may lead to variability in technique and performance between trials and sessions and thus alter the contributions of different muscle groups to the signal, thereby producing an unstable reference measure for normalisation. Conversely, in normalising to the mean swallow amplitude, a reference measure is used that has an established movement pattern, making it a more standardised anchor.
Normalising to the NS mean achieves two of the aims of normalisation: it reduces inter-and intra-participant variability (Albertus-Kajee et al., 2010), thus increasing the power of statistical comparisons between groups (Burden, 2010). However, it also has a limitation as it removes genuine physiological differences that exist within and between participants as a result of natural variation, disease or change in swallowing ability. As it cancels out the variability in the normal swallow, this technique precludes examination of the degree of muscle activity required during a normal swallow. Only normalising to methods that elicit a maximum possible contraction would provide this information and this is inherently difficult in a patient population (Cholewicki et al., 2011). Furthermore, the variability in performance of the ES for this purpose precludes its use.

A limitation of this study was that the methods of normalisation examined were arguably not exhaustive and were derived from methods used in other swallowing studies. Task-specific, dynamic measurements were used that are inherently difficult to standardise and it was not possible to simultaneously measure force. Other authors found excellent reliability when normalising EMG of the neck muscles to MVCs elicited with dynamometry (Netto and Burnett, 2006). However, the anterior electrode placement measured activity from the platysma muscle, which is inactive in normal swallowing and the requirement of the specialised equipment including a head cuff, strain gauge and dynamometer may not be feasible in an acute clinical setting. Subcutaneous tissue is known to attenuate the EMG signal (Nordander et al., 2003) and may have influenced the inter-participant variability in
the current study. It would therefore be useful to establish ways of measuring and controlling for this in swallowing sEMG studies to allow fairer comparison between individuals.

The across-session variability was high (>20% CV) for non-normalised normal swallows across groups; however no improvement was seen in the other normalisation methods examined. Therefore in the absence of other methods, examination of within-participant changes in normal swallow sEMG can only be carried out on non-normalised data. Care must be taken to ensure identical conditions between sessions in terms of reducing noise in the signal, skin preparation and electrode placement. Attention should also be paid to the normal levels of variation between swallows and sessions presented here. However, due to the extremely high inter-participant variability, there is no justification for comparing non-normalised data between individuals.

This study has shown that normalising other swallowing activities, e.g. the ES, to the mean normal swallow will enable comparison between and across sessions, individuals and groups and provide valuable information regarding the degree of muscle activity elicited above normal, while controlling for other intrinsic and extrinsic influences on the signal.
Contrary to the original hypothesis, this study found no evidence of a change in swallowing sEMG with age, which supports and extends previous findings from a younger age range (van den Engel-Hoek et al., 2012, Ding et al., 2003). There was also no evidence of increased variability with age, which is contrary to the a priori hypothesis and to studies of ageing and hand function (Tracy et al., 2005, Jordan et al., 2012) or walking (Kang and Dingwell, 2009). This suggests that the variability in motor unit discharge and force fluctuations seen in other muscle groups with age does not affect swallowing muscles, which may relate to the consolidated pattern of motor activity for swallowing.

There was no change in the ability to modify the trace for the ES with age, indicating a preservation of “muscle activity reserve” for swallowing. Conversely, Yeates et al. (2010) found a non-significant reduction in ES amplitude with age but notably only one ES was elicited and there was no practice/training period. In the present study, the mean of six trials was taken after a practice period. Variability in the performance of the ES by all participants in both the present study and that by Yeates (2010) supports the need for adequate practice to master the novel ES task (Frost et al., 2012).

The lack of change with age was surprising considering the evidence of increased swallowing difficulties (Butler et al., 2009), pharyngeal wall atrophy (Aminpour et
al., 2011) and reduced pharyngeal pressure generation (Hind et al., 2001, Butler et al., 2011b) with healthy ageing. However, a recent study exploring tongue function found that normalising swallowing tongue pressures to the maximum tongue pressure negated previously reported age-related differences in functional reserve, and posited that apparent deterioration in functional reserve is actually an artifact attributable to normal variation in tongue strength between individuals that is independent of age (Steele, 2013). Otherwise these differences may reflect the non-specific nature of sEMG measurement, with the resultant signal representing the composite activity of a range of muscles, including the tongue (Huckabee and Steele, 2006), which may allow for compensation of individual muscle weakness. Therefore sEMG may not be sufficiently specific and therefore sensitive to detect subtle changes in swallowing with age. Of note, the three participants who were not able to modify the trace for the ES (Figure 4.11) were in the oldest age group. While it is not possible to draw conclusions from individual data, this may indicate that they were not able to compensate for age-related changes in their swallow physiology.

4.6.4 **Strengths and Limitations**

A limitation of this study was the small sample size of stroke participants and as such the variability in the results increases the risk of a type II statistical error. However, this study was the first of its kind and was necessarily exploratory in nature. The results provide a basis for further swallowing sEMG studies.
Arguably a larger sample size of older healthy participants would have added to the robustness of the study of age-related changes, but the age range was wide and there was no trend emerging in the data, which strengthens the interpretations drawn.

While all stroke participants had no history of previous stroke/neurological impairment, the sample was varied in terms of type and location of stroke, which may have influenced the variability in results. However, participants were intentionally not included/excluded according to stroke type to make the results clinically informative; the purpose of this study was to collect data from a “normal” inpatient acute stroke population who would receive dysphagia therapy in a standard clinical setting. As such the inclusion criteria were relatively broad, enabling recruitment of patients with a range of degrees of swallowing impairment and concomitant communication and cognitive difficulties. All patients who met the inclusion criteria were recruited, which reduces the risk of bias and the sample was considered adequately representative of a dysphagic acute stroke caseload.

Due to risks of aspiration in the stroke group, only three participants were able to swallow teaspoons of water and so the other participants were given other (safe) consistencies. This may have had an effect on the amount of muscle activity required to swallow. Data collection commenced with an established protocol with healthy participants prior to recruiting the first stroke participant and the degree of
impairment of the stroke participants was not foreseen. However, the protocol was aimed to elicit the most natural swallowing possible, which justified participants having their safest consistency. Furthermore, normalising the data should have controlled for differences based on consistency and interestingly the inter-participant variability of the non-normalised data was as high for the healthy participants (who all had thin fluids) as for the stroke group.

Participants were given time to practice the ES but all were introduced to the exercise on the first day of testing and were learning a new skill. Arguably an extended training period may have improved the reliability of the technique, which may have improved its application as a reference measure for normalisation. However, there was no difference in performance between sessions 1 and 2 when participants were more familiar with the task. Training in eliciting MVCs has also been shown not to improve reliability of muscle activation for the purposes of EMG normalisation (Frost et al., 2012).

Arguably asking participants to swallow more boluses and larger volumes would have extended the information on swallowing reliability. However, this study was designed to minimise the effects of fatigue and to control for bolus volume. Furthermore, there was no trend for increased or decreased variability across the swallows, justifying limiting the number to three.
4.7 Conclusion

This study concludes that intra-participant variability of normal swallowing sEMG is high but within the same range as sEMG data from other muscles and this information can be used as a reference against which to compare clinical data. The inter-participant variability is very high for both healthy and stroke participants and confirms the need for normalised data to enable comparison between individuals and groups. The complexities of how to normalise swallowing data have been highlighted; normalising swallow exercise data, e.g. the ES, to the normal swallow is the most appropriate method to reduce intra- and inter-participant variability. However, it is not appropriate to normalise the normal swallow to this measure due to the loss of relevant biological information. Further studies are indicated to examine in detail the influences on the sEMG signal and how to control for them in order to establish methods to analyse normal swallow data. There was no effect of age on either the variability of sEMG or the ability to modify the trace in the exercise conditions, indicating that consistency of motor unit discharge is preserved for swallowing and there is unchanged “activity reserve” in the submental muscles with age.

Having determined the most appropriate method of normalising swallowing sEMG data to enable robust analysis, the next study will investigate the effect of dysphagia, the effortful swallow and biofeedback on normalised submental muscle activity.
Chapter 5  Feasibility of sEMG as a biofeedback tool in dysphagia therapy: the effect of the effortful swallow and sEMG biofeedback

5.1 Introduction

Biofeedback with sEMG has already been described as a useful adjunct to dysphagia therapy (Carnaby-Mann and Crary, 2010, Crary et al., 2004, Bogaardt et al., 2009, Huckabee and Cannito, 1999). However, the ability of patients with dysphagia to modify the sEMG trace with the ES exercise has not been investigated and therefore it is not known if the application of sEMG provides patients with meaningful biofeedback. Additionally, it is not known if patients are able to use the feedback to improve their performance of the exercise and also whether they find the technique acceptable. These fundamental questions need to be addressed before sEMG biofeedback can be recommended for dysphagia therapy.

5.2 Aims

This study sought to determine the following:

1. If post-stroke dysphagia affects the ability to increase submental muscle activity during the ES relative to normal swallowing.
2. If sEMG biofeedback improves the performance of the ES by healthy participants and if increased age reduces the benefit from biofeedback.
3. If sEMG biofeedback improves the performance of the ES by dysphagic stroke participants.
4. If participants find sEMG comfortable and helpful and whether they consider it would be an acceptable part of regular therapy.

5.3 Hypotheses

It was hypothesised that:

1. Healthy controls would produce significantly increased muscle activity for the ES relative to the NS than dysphagic stroke participants (see section 1.9.5).

2. Significantly increased submental muscle activity would be elicited for ESs with sEMG biofeedback than for ESs without (see section 1.9.6).

5.4 Methods

The study design, recruitment, participants, sEMG protocol and swallow tasks were the same as used in the preceding study and details can be found in Chapter 4.

5.4.1 Questionnaire

At the end of the second session of data collection, participants completed a questionnaire in which they were asked questions about their impression of completing the ES with and without sEMG feedback and their comfort during the tasks. The questionnaire (Appendix 4) was designed to be accessible to participants with aphasia (developed in collaboration with a senior specialist SLT in stroke) and was reviewed and approved for acceptability and ease of understanding by the King’s College London Stroke Users Group, of which several members have aphasia. The
researcher facilitated completion of the questionnaire face-to-face at the end of the
second session so as to ensure all participants fully understood each question.

5.4.2 Data analysis

Data is presented with means (SD) or medians (IQR) depending on its distribution and
type. sEMG data that was found to be non-normally distributed with Kolmogorov-
Smirnov test (and confirmed by examining histograms) was log-transformed (natural
log) and then normality was reassessed. This data was then used for all subsequent
statistical analyses. The ES amplitudes were normalised to the mean NS amplitude
recorded within the same session as this method provided the best inter-participant
reliability in the previous study (Chapter 4):

- ES amplitude/mean NS amplitude*100

Ability to modify the trace for the ES compared with the normal swallow and the
effects of biofeedback, session and participant group on ES performance were
examined with two-way repeated measures analysis of variance (RM ANOVA) with
the within subject factors “task” (i.e. normal swallow, ES with feedback and ES
without FB) and “session” and the between subject factor “group” (i.e. healthy
control vs. stroke). Violations in sphericity were corrected with the Greenhouse-
Geisser estimates of sphericity and post hoc pairwise comparisons were adjusted for
multiple testing with the Bonferroni correction. The relationship between age and
ability to benefit from biofeedback in healthy participants was examined with linear
regression, with normalised FB ES amplitude as a percentage of ES without FB amplitude plotted against age.

For questionnaire data, within-group differences between questions were examined with the Wilcoxon Signed Rank Test. Differences between groups on questions were examined with the Kruskal-Wallis and the Mann-Whitney Test with adjustment for multiple testing with the Bonferroni correction.

5.5 Results

5.5.1 Participants

The participants for this study were the same as those recruited for the study in Chapter 4 and their demographics are shown in Table 4.1 and Table 4.2. Questionnaire data was collected from all who completed the second session: 83 healthy and 14 stroke participants. The sEMG amplitudes for both healthy and stroke participants were not normally distributed for session 1, 2 or both sessions combined (≤0.001 for all three analyses, confirmed by examining histograms), but normality was achieved with log transformation (ln).

5.5.2 The effect of post-stroke dysphagia on the ability to increase submental muscle activity during the ES relative to normal swallowing.

While it appeared that healthy controls produced greater ES amplitudes than stroke participants (Figure 5.1), there was no significant main effect of participant group
There was a significant main effect of swallowing task $F(1.157, 32.385)=43.202, p<0.001$. On post hoc tests, ES tasks resulted in significantly higher amplitudes than the normal swallow; for ES with FB the In mean difference was 18.233 (SE 2.709, $p<0.001$) and for ES without FB the In mean difference was 13.964 (SE 2.064, $p<0.001$). This indicates that both stroke participants and healthy controls were able to modify the sEMG trace above their normal level of swallowing activity for the ES exercise (Figure 5.1).

5.5.1 The effect of sEMG biofeedback on the performance of the ES by healthy and dysphagic participants.

For all healthy participants (n=82), there was again a significant main effect of swallowing task on amplitude ($F(1.032,83.599)=46.674, p<0.001$, Figure 5.2) with no effect of session. Post hoc tests revealed that ES amplitudes were significantly larger with FB than without: In mean difference 3.538 (SE 0.518, $p<0.001$). The median for the ES with FB was 266.74 %NS and for the ES without FB was 235.17 %NS. For stroke participants and healthy controls there was no effect of participant group or session but ES amplitudes were significantly increased with FB; In mean difference 4.324 (SE 1.042, $p=0.001$, Figure 5.1). There was no difference with age on the effect of biofeedback on ES amplitude ($r^2=0.001, p=0.93$).
Figure 5.1: Effortful swallows (ES) with Feedback (FB) and without FB by stroke participants 'S' (n=13) and healthy controls 'HC' (n=17) for session 1 (S1) and 2 (S2) and for both combined (S1&2). Medians and IQR shown. Data is normalised to the normal swallow baseline (BL dotted line, i.e. 100 %NS). There was a significant effect of FB with no effect of session. Asterisks on BL = significant difference between ES and normal swallow ***=p<0.001.

Figure 5.2: Healthy participants effortful swallow (ES) amplitude (n=82). Medians and inter-quartile ranges shown. Dotted line at 100 %NS and BL=mean normalised normal swallow baseline. Asterisks on BL=significant difference between ES and normal swallow. There was a significant effect of FB (***p<0.001) and no effect of session.
5.5.2 Participant feedback about sEMG; acceptability, comfort and helpfulness - Questionnaire data Table 5.1

The majority of healthy (83.13%, n=69) and stroke (85.71%, n=12) participants reported that sEMG feedback helped them to complete the exercises and that they would be happy to use it regularly (98.79% n=82 and 100% n=14, respectively). Participants were asked what was good about sEMG feedback and frequent responses related to having visual feedback on performance and progress, having a target to aim for and it being interesting and enjoyable. No participants entered “nothing” in response to this question. The most frequent response to the question about what was bad about sEMG was “nothing”, by 46.99% (n=39) of healthy and 78.60% (n=11) of stroke participants. Other responses were that the electrode placement felt odd and that the process was distracting (Table 5.1).
Table 5.1: Responses to the questionnaire about sEMG biofeedback by healthy (n=83) and stroke (n=14) participants.

<table>
<thead>
<tr>
<th>Group</th>
<th>What was good about using sEMG?</th>
<th>% (n)</th>
<th>What was bad about using sEMG?</th>
<th>% (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy</td>
<td>Visual feedback about performance and progress/re-enforcing correct technique</td>
<td>38.55 (32)</td>
<td>Nothing</td>
<td>46.99 (39)</td>
</tr>
<tr>
<td>(n=83)</td>
<td>Could see what I was trying to achieve and aim for/gave me a target/personal best</td>
<td>21.67 (18)</td>
<td>Feels odd/unnatural/“stiffening”/felt like the restriction of the pad may have changed swallow</td>
<td>8.43 (7)</td>
</tr>
<tr>
<td></td>
<td>Interesting/fascinating</td>
<td>18.07 (15)</td>
<td>Distracting</td>
<td>6.02 (5)</td>
</tr>
<tr>
<td></td>
<td>Made it fun/enjoyable</td>
<td>10.84 (9)</td>
<td>Abrasive skin preparation</td>
<td>3.61 (3)</td>
</tr>
<tr>
<td></td>
<td>Helped me to understand the exercise/swallowing</td>
<td>7.23 (6)</td>
<td>Taking off the electrodes</td>
<td>2.41 (2)</td>
</tr>
<tr>
<td></td>
<td>Non invasive</td>
<td>4.82 (4)</td>
<td>Confusing</td>
<td>2.41 (2)</td>
</tr>
<tr>
<td></td>
<td>Quick and easy to set up</td>
<td>3.61 (3)</td>
<td>Fatigue</td>
<td>1.20 (1)</td>
</tr>
<tr>
<td></td>
<td>Helped motivate/encourage me</td>
<td>3.61 (3)</td>
<td>Made me cough</td>
<td>1.20 (1)</td>
</tr>
<tr>
<td></td>
<td>Easy to understand</td>
<td>3.61 (3)</td>
<td>Used other muscles to complete task</td>
<td>1.20 (1)</td>
</tr>
<tr>
<td></td>
<td>Comfortable</td>
<td>3.61 (3)</td>
<td>It is quite hard to swallow normally when you know you are being tested</td>
<td>1.20 (1)</td>
</tr>
<tr>
<td></td>
<td>Being able to see the muscles working</td>
<td>2.41 (2)</td>
<td>Felt under pressure to meet target</td>
<td>1.20 (1)</td>
</tr>
<tr>
<td></td>
<td>Screen clear/easy to see</td>
<td>2.41 (2)</td>
<td>Position of the screen above my head, would have been better at eye-level</td>
<td>1.20 (1)</td>
</tr>
<tr>
<td></td>
<td>No comment</td>
<td>6.02 (5)</td>
<td>Large equipment, small, portable version would be nicer</td>
<td>1.20 (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Coordinating EMG, spoon and swallow together was hard at first</td>
<td>1.20 (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No comment</td>
<td>4.82 (4)</td>
</tr>
<tr>
<td>Stroke</td>
<td>I could see how I was doing which was helpful</td>
<td>35.71 (5)</td>
<td>Nothing</td>
<td>78.57 (11)</td>
</tr>
<tr>
<td>(n=14)</td>
<td>Made it a challenge/gives you a target</td>
<td>14.29 (2)</td>
<td>Didn’t like smell of alcohol wipe</td>
<td>7.14 (1)</td>
</tr>
<tr>
<td></td>
<td>Helps you know how to practise.</td>
<td>7.14 (1)</td>
<td>Didn’t like electrodes stuck</td>
<td>7.14 (1)</td>
</tr>
<tr>
<td></td>
<td>You know what you have to do after the session.</td>
<td>7.14 (1)</td>
<td>My feedback loop is not strong enough. Not clear what to do to improve things</td>
<td>7.14 (1)</td>
</tr>
<tr>
<td></td>
<td>Very happy with the system</td>
<td>7.14 (1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Motivating</td>
<td>7.14 (1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Measurement of muscles</td>
<td>7.14 (1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>You (SLT) can see how I am doing</td>
<td>7.14 (1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>No comment</td>
<td>21.43 (3)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
There was a significant difference between age groups in healthy participants for the questions “How easy was the effortful swallow exercise without sEMG?” (p=0.009, Figure 5.3) and “How comfortable did you find sEMG?” (p=0.029). On post-hoc analysis, participants aged 31-50 scored significantly higher than those >71 years for the question “How easy was the effortful swallow exercise without sEMG?” (z=2.88, p=0.024), i.e. the younger group reported they found the exercise more difficult. No other age group differences were significant.

Participants in groups one to three (i.e. aged 18 – 70) reported finding the exercises significantly easier with the feedback (group 1: z=2.54, p=0.011, group 2: z=2.75, p=0.006, group 3: z=2.13, p=0.033). This pattern was also seen for group four (age >71 years), but it did not reach significance (z=1.89, p=0.059) (Figure 5.3 and Figure 5.4). The large majority of all age groups (60-90%) reported it was “very easy” to understand the information on the screen, with none reporting it was difficult. All participants of all ages reported that sEMG was “very” or “quite comfortable”. Overall, 83.13% (n=70) of healthy participants said they felt sEMG helped them with the exercise, with no statistical differences in this response according to age group (95% in group 1, 80% in group 2, 76% in group 3 and 80% in group 4). All healthy participants across age groups stated that they would be happy to use sEMG regularly apart from one participant in age group 1 (18-30 years) who also reported the electrode placement was “restrictive” (Table 5.1) and was excluded from previous analyses due to outlying amplitude data (section 4.5.4.2, page 137).
Figure 5.3: Responses to the question "How easy was the ES exercise without sEMG feedback?" across different ages of healthy participants (n=83)

Figure 5.4: Responses to the question "How easy was the ES exercise with sEMG feedback?" across different ages of healthy participants (n=83)

The presence of some age related differences in responses justified comparing stroke participants' data to their age-matched controls instead of the larger sample.
of healthy participants. The most frequent response to the question “How easy was the effortful swallow exercise without biofeedback?” was “very easy” for healthy controls (58.82%; n=10) and “quite easy” for stroke participant (42.86%; n=6), but responses were spread across the possible range for stroke participants, with 14.29% (n=2) reporting that it was “quite” or “very difficult” (Figure 5.5). Stroke participants scored significantly higher than controls for this question (i.e. reported they found the exercise more difficult than controls) (z=2.69, p=0.007, Figure 5.5).

The responses to the question “How easy was the effortful swallow exercise with sEMG biofeedback” were more positive, with the most frequent response being “very easy” for both groups (82.35% of healthy and 42.86% of stroke participants) and no participants reporting it was difficult. Again, stroke participants responses indicated they found the exercise significantly more difficult than controls (z=2.22, p=0.026, Figure 5.6).

Both healthy and stroke participants reported finding the exercises significantly easier with the sEMG biofeedback than without (z=2.24, p=0.025 and z=2.64, p=0.008, respectively) (Figure 5.5 and Figure 5.6). There were no other statistically significant differences between the groups on the other questionnaire items and both groups indicated that they largely found the procedure comfortable and easy to understand (Figure 5.7 and Figure 5.8). The majority (85.71%, n=12) of stroke participants and all healthy controls reported that sEMG helped them with the
exercise. All stroke participants and age/sex matched controls stated that they would be happy to use sEMG regularly if appropriate.

Figure 5.5: Responses to the question "How easy was the effortful swallow exercise without sEMG biofeedback" for stroke participants and healthy controls. The spread of responses was significantly different between the participant groups (p=0.007).

Figure 5.6: Responses to the question "How easy was the effortful swallow exercise with sEMG feedback?" for stroke participants and healthy controls. The spread of responses was significantly different between the participant groups (p=0.026).
Figure 5.7: Responses to the question "How easy was it to understand the information on the screen?" for stroke participants and healthy controls. The spread of responses was not significantly different between the participant groups (p=>0.05).

Figure 5.8: Responses to the question "How comfortable did you find the sEMG?" for stroke participants and healthy controls. The spread of responses was not significantly different between the participant groups (p=>0.05).
5.6 Discussion

5.6.1 The effect of post-stroke dysphagia on the ability to increase submental swallowing activity during the ES compared with normal swallowing

All groups produced significantly greater amplitudes for the ES than NS, indicating that dysphagic acute stroke, as well as healthy participants, can modify muscle activity during the ES exercise. While there was a trend for healthy controls to produce higher ES amplitudes than stroke participants, this was not significant and therefore the study hypothesis was not supported. This may be due to the small sample size and wide variability in the measurements obtained. Promisingly, stroke participants’ ability to modify their activity indicates they have some preserved functional reserve despite this being a group with relatively severe dysphagia (median PAS 7.5/8) in the acute stage of recovery. This supports the use of the ES in dysphagia rehabilitation as a task-specific exercise that challenges the system beyond normal levels of activity (Burkhead et al., 2007). The normalised amplitudes achieved by the healthy participants in this study could serve as targets for therapy programmes for dysphagic patients.

The variability in the ability to perform the ES in both healthy and stroke participants should be considered in clinical assessments. These data were based on two sessions in which the ES was presented as a novel exercise, which is likely to influence the variability in performance. It remains to be seen if a period of
training, for example through a dysphagia therapy programme, would reduce variability and improve performance of the ES.

5.6.2 The effect of sEMG biofeedback on the performance of the ES by healthy and dysphagic participants

All groups produced significantly greater sEMG amplitude for the ES with FB than without. This supports the original hypothesis and provides strong evidence for using sEMG biofeedback as an adjunct in dysphagia therapy as it facilitates an increase in muscle activity above the level achieved with the “standard” ES approach, further achieving the “overload” principle of rehabilitation (Burkhead et al., 2007). Feedback is essential for motor learning (Shumway-Cook, 2001) and yet informative and meaningful feedback is very difficult to deliver in dysphagia therapy as swallowing is a largely hidden activity. In assessing the ES, clinicians are restricted to laryngeal palpation and feedback consists of subjectively describing how they feel the patient performed, which has questionable accuracy and meaning for the patient. With sEMG feedback, both participants and clinicians are presented with objective, quantifiable data against which targets can be set and progress monitored and this could facilitate both motivation and performance.

While FB was helpful in all groups overall, not all participants increased their sEMG activity with FB. This was not influenced by age in the healthy participants as predicted a priori. On further examination, all of the stroke participants who did not increase their activity with FB had been randomised to receive FB second i.e.
after completing the task without FB first. This may indicate that fatigue affected their ability to modify their activity further. However, those healthy participants who did not perform better with FB were balanced as to whether they received FB or no FB first. It is possible that there was a “ceiling effect” in performance or that there are individual differences that affect whether FB further enhances performance. It would be interesting to see if ES training would enable participants to benefit further from feedback as the task became more familiar.

5.6.3 Participant feedback

The evaluation of patient experience has gained increased attention among healthcare providers, with an understanding that outcomes of care are improved if the patient experience is positive (Manary et al., 2013) and patient feedback can contribute significantly to treatment enhancement (Moore and Jull, 2013). sEMG biofeedback is not routinely offered in the UK or Ireland by SLTs working in stroke (Archer et al., 2013) and evaluating participants’ perceptions of this technique from the outset is indicated to establish acceptable and realistic treatment protocols.

The feedback from both stroke and healthy participants was very positive about sEMG biofeedback. The large majority of both groups reported that it helped them to complete the ES exercise and almost all reported that they would be happy to use it regularly, indicating that it is an acceptable technique and achieving one of
the aims of the study (see section 5.2). Feedback also indicated that participants largely found it easy to follow and comfortable.

Participants were asked to list both positives and negatives of the technique and there were many more positive comments than negatives, with the largest proportion of respondents reporting there was nothing bad about sEMG. A frequent response was that the technique gave them helpful visual feedback on performance and progress, reinforcing their technique and that they benefitted from having a target to aim for. As described above, successful achievement of the ES is difficult to measure and may be imperceptible to the participant, rendering target setting impossible. These results indicate that participants were aware of the benefit of the feedback that sEMG gave them and that having a visual target was a positive adjunct and so it follows that sEMG biofeedback could enhance motor learning. Respondents also reported that receiving sEMG biofeedback was fun and enjoyable. Biofeedback has been described as enabling participants to be more actively involved in therapy, providing them with the motivation to improve and thereby improving outcome (Reddy et al., 2000). The results of the present study support this theory from the perspectives of the participants themselves.

The negative comments made about sEMG biofeedback are helpful for reflecting on ways to improve treatment protocols. A small group of healthy participants reported that the presence of the electrode felt ‘odd’ and they were unsure about whether it restricted or affected their swallow. It may be that on occasions the
adhesive tape was applied too tightly, although it seems very unlikely that hyo-laryngeal movement was restricted with this technique. It is more likely that some participants were very aware of the sensation of hyo-laryngeal movement across the electrode area. Although participant comfort was always checked at the beginning of the session, establishing ongoing feedback during the exercises would have enabled re-evaluation and reassurance about electrode placement as reinforced with the examination of outlying data as discussed previously.

A small group of healthy participants reported that sEMG biofeedback was distracting and two reported that it was confusing. As these comments were made by a group with no cognitive impairment, clinicians should be mindful of the potential negative impact of sEMG biofeedback in diverting attention away from the sensation of the swallow itself. These comments were made by a small number of participants, but this feedback highlights the need to evaluate the benefits/disadvantages of biofeedback on an individual basis.

### 5.6.4 Strengths and Limitations

The strengths and limitations of this study with regard to the sample size, participants, sEMG protocol and swallow tasks are discussed in Chapter 4. A possible limitation of the questionnaire was that it was completed after just two short sessions of sEMG biofeedback and therefore participants were not given much experience of the technique before completing it. By specifically asking participants to respond to the questions “what was good” and “what was bad”
about the technique, they were arguably forced to think of an answer when they might have responded differently with a more open question. However, this approach to questioning was felt to enrich the number of responses obtained.

There was a risk of response bias with the participants potentially responding positively to please the researcher, especially as she facilitated completion face-to-face. However, this method of completion ensured that participants understood the questions adequately and there was 100% completion rate. Participants were told at the beginning of their involvement in the study that the purpose was to evaluate a new technique in which the researcher had no vested interest, to see if it was worth recommending to clinicians in the future. They were also reassured that questionnaire forms were not identifiable to them and were analysed together at a later date. Therefore the risk of response bias was minimised. As there was no existing questionnaire, it was necessary to great a new tool, which had not been previously validated. However, by developing it in consultation with experts and receiving feedback on it from the stroke users group, its face validity was determined prior to its use. Furthermore it was designed to be accessible to participants with cognitive/communication impairment, enriching the information gained.

A strength of this study was including physiological information about the effects of the ES exercise with feedback from participants. As discussed in Chapter 2,
clinicians cite low motivation as the most common reason they feel patients do not improve as a result of therapy (Archer et al., 2013). This study therefore sought to determine whether the ES with sEMG feedback was acceptable to participants. The positive feedback from participants, together with the encouraging physiological effects, strengthen the evidence for this technique in the therapist’s toolkit.

5.7 Conclusion

This study has demonstrated dysphagic stroke participants’ ability to modify the sEMG trace during the ES and this justifies using the ES in therapy as it complies with the “overload” and “use it or lose it” principles of rehabilitation (Burkhead et al., 2007, Kleim and Jones, 2008). Furthermore, both healthy and stroke participants produced higher sEMG amplitudes with feedback, indicating that sEMG biofeedback is a valuable adjunct to ES training. The results of the participant questionnaire are encouraging in terms of the acceptability of sEMG biofeedback to patients. Participants were positive in their comments and expressed the perceived benefits of the technique in terms of feedback, monitoring and target setting. These support the use of sEMG biofeedback as a useful adjunct in dysphagia therapy, which may both improve patient enjoyment and motivation as well as enhancing outcome.
Having considered the benefit of adjunctive sEMG biofeedback for patients, the following chapter outlines a study designed to investigate its potential advantages from the perspective of the clinician.
Chapter 6  Bedside assessment of the effortful swallow by SLTs – inter-rater reliability and comparison to sEMG data

6.1 Introduction

As part of therapy with the ES, SLTs provide patients with ongoing monitoring and feedback about how they complete the technique. However there is no evidence about the reliability and accuracy of SLTs’ bedside evaluation of the ES. Poor inter-rater reliability and validity of bedside swallow assessments is well known (McCullough et al., 2005, McCullough et al., 2000) and therefore treatment decisions should be based on instrumental assessment (The Royal College of Speech and Language Therapists, 2005). Even when the initial recommendation for an exercise is based on robust assessment, the within-and between-session monitoring of patients’ performance during treatment remains largely dependent on clinical evaluation. Therefore if the evaluation is not reliable or accurate, it may detrimentally affect management decisions.

Effective therapy involves reinforcement of optimal movements or strategies with feedback (Shumway-Cook, 2001, Bastian, 2008, Izawa et al., 2008). Therefore quality feedback is essential. Due to the difficulties of directly visualising the swallow, it is challenging for the patient to monitor and modify their own performance of the ES exercise, and so they are dependent on information provided by clinicians. Without instrumental techniques, SLTs routinely palpate the sub-
mandibular anterior neck using the “four-finger” method to examine the extent of hyo-laryngeal movement during the swallow (McCullough et al., 1999, Logemann, 1998). The ES significantly increases superior hyoid movement (Hind et al., 2001, Wheeler-Hegland et al., 2008) and enhances tongue activity (Huckabee and Steele, 2006). Therefore standard palpation, that detects tongue and hyo-laryngeal movement (Logemann, 1998), is arguably an appropriate technique for assessing ES achievement. However, while the assessment of the ES has not yet been examined, inter-rater reliability for laryngeal movement during normal swallowing has been described as “sporadic”, with agreement ranging from “chance” to “very good” (McCullough et al., 2000). Previous studies of bedside swallow evaluations have not explored the accuracy of clinicians’ ability to assess hyo-laryngeal excursion (Daniels et al., 2012) and the sensitivity of laryngeal palpation in accurately detecting ES accomplishment is not known.

It has been established that there is an increase in submental muscle activity with the ES, measurable with sEMG (Yeates et al., 2010, Wheeler-Hegland et al., 2008) and this was also shown in dysphagic patients in Chapter 5. If SLTs are able to accurately identify if and how well an ES has been achieved, their assessment should correlate with this increase in muscle activity.
6.2 Aims

This study sought to determine:

1. The inter-rater reliability in assessing the ES among experienced SLTs
2. The relationship between SLTs’ ratings of the ES and sEMG measurements

6.3 Methods

6.3.1 Study design

A phase I observational study was conducted with full ethical and R&D approvals (Guy’s Hospital Research Ethics Committee, reference 10/H0804/17). Informed written consent was gained from all participants.

6.3.2 Participants

6.3.2.1 SLTs

Four SLTs from Guy’s and St Thomas’ NHS Foundation Trust participated in the study. Inclusion criteria were being highly experienced (Band 7 or above) in acute adult SLT with a remit for delivering dysphagia therapy. Exclusion criteria were SLTs specialising in head and neck cancer.

6.3.2.2 Patients

Ten consecutive acute adult in-patients were approached who were recommended the ES exercise for their dysphagia following instrumental assessment by their managing SLT. Inclusion criteria were aged >18 years, referral to SLT for assessment and management of dysphagia, presence of dysphagia on Fibreoptic Endoscopic
Evaluation of Swallowing (FEES) or Videofluoroscopy (VFS), recommendation of the ES exercise as part of their dysphagia treatment and ability to give informed consent with supported communication if necessary, as determined by their managing consultant in consultation with SLT. Exclusion criteria were any history of head and neck cancer or surgery.

6.3.3 Procedure

Each participant took part in two sessions, in which sEMG measurements were taken while they performed both normal and effortful swallows. All swallows were palpated and rated by pairs of SLTs (one pair per session). The pairings of SLTs were randomly allocated with the aim that each SLT was paired with the other three SLTs with the same frequency, with all SLTs completing the same number of observations. The SLTs were introduced to the participant by name but no further clinical information was provided. On occasions, SLTs rated patients with whom they were working clinically, which was an unavoidable limitation due to the numbers of patients and SLTs available. This detail was noted on the data collection form. Neither the dysphagic participant nor the SLTs were able to see the screen showing the sEMG during or after data collection and the researcher did not communicate the measurements to them.

6.3.3.1 Electrode placement and sEMG Signal Processing

The same protocol for electrode placement and sEMG signal processing was followed as for Chapters 4 and 5.
6.3.3.2 Swallowing Tasks

All participants were already practising the ES as part of their dysphagia treatment by their managing SLT. To ensure consistency, all participants were given the same instruction at the beginning of each session (as per the instruction given in Chapters 4 and 5): “swallow hard, squeezing all of your throat muscles and pushing hard with your tongue on the roof of your mouth”. The pairs of SLTs were then asked to stand either side of the participant and to concurrently palpate the participants’ swallow from either side of the neck using the “four-finger technique” while also observing them as per clinical practice (Logemann, 1998). This involves placing the one hand on the throat, with one finger under the mandible (palpating the submental area) one on the hyoid and one on the top and bottom of the thyroid cartilage (Figure 6.1 and Figure 6.2). With the SLTs palpating, the dysphagic participants were asked to complete a series of swallow tasks in the following order:

- Three normal swallows
- Three effortful swallows
Figure 6.1: The four-finger palpation technique (Logemann 1998). The index finger is positioned behind the mandible anteriorly, the middle finger at the hyoid bone, the third finger at the top of the thyroid cartilage and the fourth finger at the bottom of the thyroid cartilage.

Figure 6.2: Two SLTs both palpating the same swallow using the four-finger technique

For each swallow, participants’ mouths were moistened with oral care sponges dipped in water and they were asked to hold the water in the mouth until given the instruction to swallow. For each NS, participants were asked to “swallow this in your normal way”. For each ES, the instruction above explaining swallowing “hard” was repeated. There was a 30 second rest between each swallow.

6.3.3.3 Ratings

A rating form was specially designed to collect rating data in consultation with the SLTs in the study to ensure there was nothing ambiguous or unclear in the scoring system (Appendix 5). At the start of each session, the form was shown to the SLTs and they were reminded of the rating scale. For each swallow, the SLTs were asked two questions, whether they thought the ES had been achieved (yes/no) and to grade how well it had been completed on a five-point Likert-style scale from not achieved at all to excellent achievement. The NSs were not scored but the SLTs
were asked to use these as the baseline against which to rate the subsequent ES. Ratings were completed on individual forms immediately after each ES attempt and the form was kept out of view of the other rating SLT. As they were palpating jointly rather than individually, which is normal practice, SLTs were also asked whether they were confident about how well they had been able to complete each assessment. They were asked not to confer about their observations or ratings during or after the assessment.

6.3.4 Data Analysis
For the inter-rater reliability analysis, each observer was not individually identified but was coded as either observer 1 or observer 2 for that session. Agreement between observers for whether the ES was achieved across all sessions was assessed with Kappa and for how well it was completed with the linear weighted Kappa. For the weighted Kappa, a weighting of 0.5 was given for a disagreement of one point on the five point Likert scale but disagreement of two or more points was classed as complete disagreement and not weighted. Altman’s (1991) categories were used to interpret the Cohen’s Kappa (<0.20 = poor agreement, 0.21 – 0.40 = fair agreement, 0.41 – 0.60 = moderate agreement, 0.61-0.80 = good agreement and >0.81 = very good agreement).

Peak ES sEMG amplitudes were normalised to the NS mean from the same session (as determined in Chapter 4). Distribution was assessed with the Kolmogorov-
Smirnov test and confirmed by examining histograms. The relationship between normalised ES sEMG amplitudes and the swallow ratings were examined with Spearman’s rank correlation coefficient with each individual observer’s score and the corresponding sEMG measurement included in the analysis. This meant that for each session there were six ratings of ES attempts by two observers. Differences in the mean normalised amplitudes between the ES attempts rated as “achieved” and “not achieved” were analysed with an unpaired t-test. To examine any differences between observers in the relationship between ES sEMG amplitude and ratings, each individual SLT’s ratings were examined separately with the Spearman’s rank correlation coefficient. As it was expected that some participants would be known to one of the SLTs, the swallow ratings where the participant was known to the observer were also examined separately. This was in case there was a difference in results due to the SLT having more information about the participant’s swallowing ability from previous assessments and ES trials.

6.4 Results

All four SLTs working with acute adult inpatients at St Thomas’ Hospital who were band 7 or above agreed to participate in the study. The four who participated were three Band 7s (in stroke, critical care and respiratory medicine, and cardiothoracics and respiratory medicine) and one Band 8 in stroke. All 10 consecutive dysphagic patients consented to participate and they had a range of medical diagnoses (Table 6.1). The median (IQR) age was 66 (57.25-77.75 years), Penetration Aspiration Scale (PAS) (Rosenbek et al., 1996) was 8.00 (6.75-8.00) and FOIS (Crary et al., 2005) was
1.00 (1.00-3.00). Several participants had previously required Intensive Care Unit (ICU) treatment during their admission but all were recruited after transfer to the general medical, surgical or stroke wards.

One SLT was not available for one of the scheduled rating sessions and so one of the sessions was completed by a single SLT. All other SLTs completed the same number of ratings; therefore there were 57 paired ratings and 117 individual ratings of ES attempts available for analysis. Unfortunately the random allocation of pairings of SLTs was unsuccessful due to time commitments of those participating. This meant while all SLTs performed at least one rating with all other colleagues, observers 1 and 4 completed eight together and observers 2 and 3 completed six together (out of the nineteen paired ratings). The SLTs who participated more frequently together worked in more similar clinical settings i.e. both in stroke or both with a partial remit for respiratory medicine. All reported being confident about the quality of each assessment they performed.
Table 6.1: Demographics of dysphagic participants (n=10).

<table>
<thead>
<tr>
<th>Participant</th>
<th>Diagnosis</th>
<th>Age</th>
<th>Sex</th>
<th>BMI (Kg/m²)</th>
<th>MMSE</th>
<th>Barthel</th>
<th>PAS</th>
<th>FOIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Aortic Valve Replacement, infective endocarditis and chest sepsis, requiring ICU care</td>
<td>66</td>
<td>M</td>
<td>19</td>
<td>30</td>
<td>0</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>Myoclonic epilepsy with ragged red fibres, peripheral neuropathy, requiring ICU care</td>
<td>19</td>
<td>F</td>
<td>21.1</td>
<td>25</td>
<td>2</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>Faecal peritonitis secondary to perforated diverticular disease, requiring ICU care</td>
<td>63</td>
<td>M</td>
<td>22.0</td>
<td>28</td>
<td>4</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>Diabetic ketoacidosis, requiring ICU care</td>
<td>67</td>
<td>M</td>
<td>24</td>
<td>26</td>
<td>0</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>L PICA infarct</td>
<td>64</td>
<td>M</td>
<td>20.1</td>
<td>28</td>
<td>13</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>R MCA infarct</td>
<td>84</td>
<td>M</td>
<td>25</td>
<td>30</td>
<td>0</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>7</td>
<td>Spinal abscess with cord compression T9/T10, acute kidney injury requiring ICU care</td>
<td>76</td>
<td>M</td>
<td>35.7</td>
<td>24</td>
<td>0</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>8</td>
<td>Multiple scattered lacunar infarcts following chest sepsis, requiring ICU care</td>
<td>40</td>
<td>M</td>
<td>34</td>
<td>28</td>
<td>2</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>9</td>
<td>R MCA infarct</td>
<td>83</td>
<td>F</td>
<td>21</td>
<td>24</td>
<td>0</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>10</td>
<td>Out of hospital arrest requiring ICU care. New swallowing problems on waking, neurological testing inconclusive.</td>
<td>66</td>
<td>F</td>
<td>18</td>
<td>30</td>
<td>20</td>
<td>8</td>
<td>1</td>
</tr>
</tbody>
</table>

BMI = Body mass index, MMSE = Mini mental state examination, PAS = penetration aspiration score, FOIS = functional oral intake scale.
### 6.4.1 Inter-rater agreement

For paired ratings of ES attempts, there was fair agreement between SLTs on whether the participants had achieved an ES or not ($\kappa=0.389$, $p=0.003$). There was also fair agreement on the grading of how well the participant had achieved the ES ($\kappa=0.221$, $p=0.17$).

### 6.4.2 Relationship between SLT ratings of ES and sEMG measurements

There was no significant difference in mean sEMG amplitude between ES attempts rated as achieved and those rated as not achieved (mean 153.69 %NS (SD 61.89) and 138.90 %NS (SD 51.53), respectively) $t(115) = 1.36$, $p=0.177$ (Figure 6.3). There was also no relationship between ES sEMG amplitude and SLTs’ grading of how well participants had completed the ES on the 117 ratings (Spearman’s rho =0.151, $p=0.105$) (Figure 6.4).

No individual SLT produced ES ratings that were significantly correlated with sEMG amplitude (Figure 6.5). In five of the paired ratings, one of the SLTs was also managing the participant’s dysphagia care and therefore had more background knowledge of them and their swallowing ability. However, there remained no significant correlation with the sEMG data over the 15 swallows assessed by these SLTs (Spearman’s rho=0.161, $p=0.566$) (Figure 6.6).
Figure 6.3: ES sEMG amplitude against whether SLTs rated the ES as "achieved" or "not achieved" (117 ratings). Horizontal cursor (100 %NS) indicates mean normalised NS amplitude.

Figure 6.4: ES sEMG amplitude against ratings by SLTs on how well participants had completed the ES (117 ratings). 1 = not achieved at all (no different to a normal swallow), 2 = poor achievement, 3 = fair achievement, 4 = good achievement and 5 = excellent achievement. Horizontal cursor (100 %NS indicates mean normalised NS amplitude.
Figure 6.5: Relationship between sEMG amplitude and ratings by individual SLT observers on how well participants had completed the ES. 1 = not achieved at all (no different to a NS), 2 = poor achievement, 3 = fair achievement, 4 = good achievement and 5 = excellent achievement. Horizontal cursors (100 %NS) indicate mean normalised NS baseline.

Figure 6.6: ES sEMG amplitude against ratings by SLTs managing the participants’ dysphagia care (n=5, 15 ES attempts). 1 = not achieved at all (no different to a NS), 2 = poor achievement, 3 = fair achievement, 4 = good achievement and 5 = excellent achievement. Horizontal cursor (100 %NS) indicates mean normalised NS baseline.
### 6.5 Discussion

This is the first study to examine the inter-rater reliability of SLTs in the clinical assessment of the commonly prescribed ES exercise and to compare this assessment to objective measurement. Among four experienced SLTs there was only fair agreement about whether dysphagic participants had achieved the ES and also for grading how well it was achieved. This is disconcertingly low and could have an impact on patient care. Patients could be given very different feedback about their performance dependent on the clinician managing them, which is important as knowledge of performance helps an individual to know how to perform the task better in the next trial (Shumway-Cook, 2001, Bastian, 2008, Izawa et al., 2008). Additionally, contrasting decisions could be made by different SLTs about whether to abandon or continue with ES therapy for a particular patient due to different interpretations of their progress.

There was no relationship between sEMG amplitudes and the observer ratings, either for whether the participant had achieved the ES at all or for how well they had achieved it. This suggests that the observers were not accurate in their assessment of ES performance, which again has considerable implications for the appropriateness of the feedback and “results” given to patients and also for management decisions. In Chapter 5 it was found that participants produced greater muscle activity during the ES when presented with sEMG biofeedback. This current study further indicates that a specific benefit of sEMG in training is the accuracy of the feedback presented to the patient. Performance is shaped by
feedback and behaviours that are rewarded are more likely to be repeated at the
cost of those that are not (Shumway-Cook, 2001, Izawa et al., 2008). Therefore
inaccurate clinician-to-patient feedback is likely to impact on ES technique and
potentially therapy outcome. This study indicates that sEMG measurements during
ES therapy could greatly enhance the information available to clinicians to give
them better knowledge of performance and results, facilitate consistency and help
them plan ongoing therapy.

6.5.1 Strengths and limitations
Variable inter-rater reliability has been found previously between SLTs using the
four-finger technique to identify whether laryngeal movement was reduced as
patients swallowed normally, with kappa scores ranging from “chance” to “very
good” (McCullough et al., 2000). However a limitation of that study was that
observers assessed different swallows, which meant that variability in scores may
have been accounted for by variability in swallowing. A strength of the current
study was that SLTs rated the same swallow and were also given a “baseline” i.e.
the participant’s NS, against which to compare the ES. This should have increased
consistency as SLTs were performing a direct comparison, rather than a comparison
to their own concept of “normal”. As participants were practising the ES as part of
therapy, there was a chance that they were habitually altering their NS with
increased effort, which may have blurred the distinction between the ES and the
NS. However, the ES data was normalised to the NS data for that session and most
ESs amplitudes were above those for the NSs, indicating that participants
intentionally distinguished between the two swallow tasks. It is not usual practice
to have two clinicians examining the same swallow and it could be argued that their assessments were affected by palpating together. However, the relevant structures can all be comfortably palpated by two observers and all SLTs confirmed that they were confident with the standard of each assessment they carried out.

A limitation of this study is that it did not assess how the participants were attempting the ES, i.e. to what extent they achieved an increase in hyolaryngeal movement and/or tongue and pharyngeal pressure, and what contributed to an increase (or no increase) in muscle activity. Therefore it is difficult to determine why the SLTs’ assessments did not relate to the sEMG measurements. Some participants may have performed extra facial, oral or head movement in the ES attempt, which would have appeared “effortful” and yet not increased submental muscle activity during the swallow. Alternatively, the degree of increased tongue and/or hyo-laryngeal movement achieved may not actually be perceptible from palpation alone. No previous study has compared palpation with objective assessment of tongue and laryngeal movement. Therefore comparison of observer ratings, sEMG measures and another simultaneous instrumental swallowing assessment e.g. videofluoroscopy, would provide further detail on the elements of the ES that were or were not detected by the clinicians. The majority of participants achieved normalised ES amplitudes of >100, i.e. they were able to increase muscle activity for the ES, which is encouraging as they were completing the ES as part of their dysphagia therapy programme. This study indicates that these increases in
muscle activity during the ES are not accurately detected or graded by laryngeal palpation alone.

A strength of the study was including SLTs of similarly high levels of experience. This reduced the risk of accuracy being affected by expertise and poor agreement being due to comparison of junior and senior clinicians. Due to the nature of the swallow palpation technique, it is not possible to examine intra-rater agreement or the agreement of more than two observers at a time. There is an inherent limitation in using multiple observers and by “collapsing” four observers into two categories for comparison (observer 1 and observer 2) as there are two sources of variation: systematic variation between observers and heterogeneity (observer and participant interaction) (Altman, 1991). By randomising the pairings, an attempt was made to balance these factors, but this was not effective. Despite more paired ratings being conducted by clinicians from similar clinical backgrounds and all SLTs being from the same Trust, agreement remained only “fair”. Arguably agreement may have been worse if the planned random pairings been achieved or clinicians were from more varied settings.

The sample size of both participants and SLTs was small, which would increase the risk of type II error. However, multiple swallow ratings per participant were used, which increased the amount of data available and yet no trends emerged. With the small sample size, it is difficult to be certain of how representative the findings are;
however participants were not selected based on diagnostic group with the aim that they would reflect a “normal” acute hospital caseload.

The findings of this study are not surprising considering the variably poor validity of clinical swallow assessments (Daniels et al., 2012, McCullough et al., 2005). While it paints a seemingly negative picture of SLT assessment, this study did not examine SLTs’ ability to assimilate the wide range of clinical information normally available to them when making treatment decisions, instead it only examined palpation. Furthermore, there is evidence to suggest that incorporating several items in a clinical swallow assessment improves validity (Daniels et al., 2012, Smithard et al., 1998). By asking SLTs to rate the ES with no further clinical information, the assessment was arguably not representative of a normal evaluation, in which they would have access to a case history and spend time evaluating oro-motor function and the swallow (Logemann, 1998). However, the purpose of this study was to examine assessment of ES achievement alone, not overall swallow safety, and this approach enabled evaluation without bias by expectations. Unavoidably five of the participants were known to one of the SLTs; however interestingly this did not appear to improve the relationship of their observations with sEMG measurements, although it is acknowledged that this was a very small sample.
6.6 Conclusion

This study has demonstrated that SLTs are unable to accurately assess achievement of the ES, as determined by increased muscle activity, by standard laryngeal palpation. Furthermore, agreement in assessment between experienced SLTs is sufficiently low to raise concerns about consistency of care and management decisions. These findings indicate that feedback provided by clinicians at the bedside about ES performance may be unhelpful or even misleading in guiding therapy. Measurements taken with sEMG during therapy can provide patients with objective feedback on performance and provide the clinician with useful information to enable optimum treatment monitoring and progression.

This study and those in the proceeding chapters support further investigation of the benefit of sEMG on patient outcome and this will be discussed in the next chapter.
Chapter 7  Effects of the Effortful Swallow Exercise with Surface Electromyographic Biofeedback on Aspiration and Functional Swallowing Status in Acute Stroke – A Feasibility Study

7.1 Introduction

The previous studies (Chapters 4-6) have shown the potential benefit of sEMG in helping both healthy and stroke participants complete the ES and suggested it might enhance the quality of the feedback provided by the clinician. Earlier studies by other authors have incorporated sEMG biofeedback in dysphagia treatment and concluded that it improves outcome (Huckabee and Cannito, 1999, Crary et al., 2004, Bogaardt et al., 2009). However none have involved a control group and all have been retrospective in design, potentially biasing the findings. Therefore it remains to be tested whether incorporating sEMG biofeedback in dysphagia therapy improves swallowing in patients with dysphagia.

A recent Cochrane review concluded that more research is needed to determine the effect of behavioural dysphagia therapy and specifically which components of the therapy are beneficial, through studies using valid outcome measures (Geeganage et al., 2012). These conclusions relate to the paucity of robust research in this field, the range of non-validated outcome measures used (Foley et al., 2008) and the mixed treatment approaches adopted (Carnaby et al., 2006). The ES has been
shown to increase submental muscle activity, oral and pharyngeal pressure generation, pharyngeal clearance, airway protection and cortical activity (Huckabee et al., 2005, Steele and Huckabee, 2007, Hind et al., 2001, Peck et al., 2010). However, its ability to improve swallow function in dysphagic patients has not been established. Studies are indicated that incorporate sound research methods, such as randomisation, controls and blinding, to investigate specific exercises, such as the ES, to inform the clinician of their worth. The survey of SLTs working in stroke in the UK and Ireland (Archer et al., 2013) showed marked variability in practice and also that accepted principles of exercise physiology and neural plasticity (Burkhead et al., 2007, Kleim and Jones, 2008) are not underpinning adopted approaches. Most SLTs reported not incorporating any method of biofeedback during swallowing therapy. This further justifies more research to inform clinical practice, which may facilitate improved consistency between clinicians.

Previous studies have highlighted the complexities of trials designed to investigate behavioural swallowing treatments (Brandt et al., 2006). Before setting up a large scale comprehensive study of a particular therapy, pilot studies are indicated to ensure feasibility of the research design (Thabane et al., 2010, Arain et al., 2010, Lancaster et al., 2004). Information gained can then be used to refine or modify the protocol to ensure that subsequent studies are optimally robust and provide results that inform patient care. (Thabane et al., 2010)
7.2 Aims

This study sought to evaluate the feasibility of a study protocol which was designed to determine:

1. Whether an ES exercise programme improves airway protection in dysphagic acute stroke patients. Whether sEMG biofeedback is a beneficial adjunct to an ES exercise programme in improving airway protection in dysphagic acute stroke patients.

2. Patient satisfaction with the intervention.

7.3 Specific feasibility objectives

Following recommended principles of testing feasibility (Thabane et al., 2010, Arain et al., 2010, Lancaster et al., 2004), this study aimed to evaluate:

1. The feasibility of the study protocol within available resources.

2. Recruitment, consent and retention rates

3. The effectiveness of randomisation and blinding procedures

4. The acceptability of the intervention.

5. The appropriateness of outcome measures including reliability of outcome and feasibility of measurement.
7.4 Methods

7.4.1 Study Design
A single-centre pilot randomised control trial was conducted with ethical and R&D approvals (Guy’s Hospital Research Ethics Committee, reference 10/H0804/17). Informed written consent was gained from all participants.

7.4.2 Participants
Recruitment was conducted for 12 months from 25th February 2012. All adult stroke patients admitted to St Thomas’ Hospital, London who were referred to SLT for dysphagia assessment were considered for the study. Inclusion and exclusion criteria are shown in Table 7.1.

7.4.2.1 Consent procedure
Steps were taken to support the inclusion of participants with cognitive and/or language difficulties and these are described in full in section 4.4.2.3. Information sheets and consent forms (Appendix 6 and 7) were accessible to participants with aphasia and were developed with an aphasiology colleague following Stroke Association guidelines (Stroke Association, 2012). Documents were reviewed and approved for acceptability and ease of understanding by the King’s College London Stroke Users Group, in which several members have aphasia.
<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Aged &gt;18 years</td>
<td>• Unable to give informed consent due to cognitive and/or profound communication impairment.</td>
</tr>
<tr>
<td>• Within one month of first stroke</td>
<td>• History of:</td>
</tr>
<tr>
<td>• Referred to SLT for swallow assessment due to evidence of dysphagia</td>
<td>- previous stroke</td>
</tr>
<tr>
<td>• Able to give informed consent (with supported/total communication from SLT if necessary)</td>
<td>- other neurological or neuromuscular disease</td>
</tr>
<tr>
<td>• Evidence of dysphagia on clinical swallow assessment by managing SLT</td>
<td>- head and neck cancer/ surgery</td>
</tr>
<tr>
<td>• Presence of pharyngeal dysphagia on baseline FEES assessment with evidence of aspiration and/or pharyngeal residue post swallow</td>
<td>- previous dysphagia</td>
</tr>
<tr>
<td>• Functional Oral Intake Scale ≤5 (Crary et al., 2005)</td>
<td>• Receiving palliative care due to poor medical prognosis</td>
</tr>
<tr>
<td>• Sufficient cognitive and communication skills to participate in dysphagia therapy, as determined by managing SLT</td>
<td>• Absence of pharyngeal dysphagia on baseline FEES</td>
</tr>
</tbody>
</table>

**7.4.3 Sample size**

This study sought to recruit 30 participants (10 randomised to each group), giving 80% power to detect a two unit difference in the mean PAS scale score (primary outcome measure, see below), using a two-sided t-test at the 5% level of significance and allowing for a 25% drop out. This was based on the previous Phase I studies in which there was a standard deviation of 1.31 on the PAS from the 12 FEES assessments conducted with dysphagic acute stroke patients (Chapters 4 and 5). At the time of study design, approximately two patients were referred weekly.
from the stroke ward for swallowing assessment and therefore it was anticipated that the recruitment target was feasible.

7.4.4 Protocol (Figure 7.1)

7.4.4.1 Baseline Measures

The following baseline data were collected from all participants:

1. Type of stroke from CT scan.
2. Barthel Index (Collin et al., 1988), Mini Mental State Examination (MMSE) (Folstein and Folstein, 2010) and body mass index (BMI) from medical notes.
3. Presence and severity of language impairment, as determined by ward SLTs, following clinical assessment.
4. Functional swallowing abilities measured with the validated Functional Oral Intake Scale (FOIS) (Crary et al., 2005) from the initial assessment by the ward SLT.
5. A Fibreoptic Endoscopic Evaluation of Swallowing (FEES) was conducted to enable baseline measurement of a range of factors following an established protocol (Appendix 3). The occurrence, depth, participant response to and clearance of material entering the airway was assessed by the validated PAS (Rosenbek et al., 1996). Level of pharyngeal secretions was measured using an established four-point severity scale (Murray et al., 1996). Pharyngeal clearance was also rated using a five-point pharyngeal residue severity scale that has good reliability (Kelly et al., 2006) and an overall dysphagia severity rating was determined based on interpretation of the whole FEES assessment (Appendix 8).
6. Following an explanation of dysphagia and the purpose of therapy, participants’ self-determined motivation with swallow therapy was recorded, determined by their response to the question “How keen are you to do your swallow exercises?” on a visual analogue scale from 0-100%, with anchors every 10%. No published validated scales exist that were appropriate for measuring motivation, hence this scale was devised following principles of exercise self-efficacy (Hanley, 2003).

7.4.5 Randomisation
A block randomisation technique was used to ensure similar numbers in each group. There were six treatment allocations per block, determined by the Research Randomiser programme (www.randomizer.org) and inserted into sequentially numbered sealed envelopes.

7.4.6 Treatment groups – for details of interventions, see 7.4.7
- Group 1: ES exercise programme with adjunctive sEMG biofeedback and routine dysphagia care
- Group 2: ES exercise programme and routine dysphagia care
- Group 3: sham dysphagia exercise programme and routine dysphagia care.
Acute stroke patient is referred to SLT for swallow assessment

Participant information given to patient by SLT and permission gained to meet with researcher

Fulfils inclusion and exclusion criteria

Informed consent gained

Baseline assessment- FEES, FOIS, Motivation scale. Confirmation of fulfilment of Inclusion/exclusion criteria

Participant randomisation

Group 1  Group 2  Group 3

End of treatment outcome measurement
Reassessed as at baseline

Three month follow up assessment
Reassessed as at baseline

Figure 7.1: Flow of participants through study
7.4.7 Treatment

Intensity of treatment was informed by the results of the survey of SLTs working in stroke (Archer et al., 2013) and further guided by national guidelines (Intercollegiate Stroke Working Party, 2012). All treatments were conducted by the researcher. The researcher met with the ward SLTs daily and recorded any changes in the participants’ status, but did not share any details of the participants’ progress with treatment.

7.4.7.1 Effortful swallow exercise programme

Participants were given five therapy sessions per week of up to 45 minutes in length. The participants were taught the ES and were initially asked to complete five sets of five repetitions of the exercise, with rest periods of 1 minute between sets. If this was accomplished with no signs of fatigue, the number of repetitions was gradually increased to 10 per set and then the number of sets was increased. In order to complete the exercises, participants were asked to swallow individual 5 ml boluses of water unless they were considered at risk of aspiration on water on their baseline FEES, in which case their safest type of oral intake, e.g. thickened fluid or moistened mouth-care sponges, was used. During the exercises, the researcher palpated participants’ submental and laryngeal movement as per normal practice (McCullough et al., 1999) and they were given verbal encouragement and feedback during the session based on her clinical evaluation. Participants were also asked to complete three further sessions per day, seven days per week independently or with a carer. They/their carers were asked to complete a log of the exercises they completed outside of sessions with the researcher and to document the reasons if
they were not completed (Appendix 10). The log was adapted from a similar form used within the clinical SLT department at the hospital, which was designed to be easy for patients to understand and complete. The researcher reviewed the log and also discussed any independent practice from the preceding 24 hours with each participant at the start of each session, in case the log was incomplete.

7.4.7.2 Effortful swallow exercise programme with adjunctive sEMG biofeedback

The ES programme was conducted as outlined above. Additionally, at the start of each session sEMG electrodes were placed in the submental position following the protocol for electrode placement outlined in Chapter 4. The same format was followed as for the biofeedback condition in Chapter 4.3.3.4, in which participants were asked to observe the sEMG trace on the screen while they completed the ES exercise and to “beat” the horizontal cursor placed on the previous ES elicited. They were also given verbal encouragement and feedback during the session. They were also asked to complete independent sessions without the sEMG feedback as for the ES programme, above.

7.4.7.3 Sham swallow exercises

Participants were seen with the same frequency and duration as for the ES treatment programmes. A buccal extension manoeuvre, “the valchuff” (Carnaby-Mann et al., 2012) was completed with the same pattern of repetitions and sets as the ES programme. The manoeuvre involves asking participants to gently close their lips and then puff air out of their mouths and has been used previously as a sham dysphagia treatment (Carnaby-Mann et al., 2012).
7.4.7.4  **Routine dysphagia care**

All participants received routine dysphagia care by ward SLTs, including regular swallowing assessments and recommendations for safe oral/non-oral nutrition and hydration. The ward SLTs had access to all participants’ baseline FEES to inform recommendations for thickened fluids, compensatory strategies and safe swallow advice, as appropriate, and according to normal clinical practice. No direct dysphagia exercises were recommended or carried out as part of routine dysphagia care.

7.4.8  **Treatment duration**

The programme consisted of 20 treatment sessions, following which ongoing SLT management was continued by the ward SLTs. If the ward SLT assessed a participant’s swallow before 20 sessions had been completed and concluded that their dysphagia had clinically resolved (i.e. rated as “unlikely” on Mann Assessment of Swallowing Ability (MASA) groupings (Mann, 2002) and scoring 7 on the FOIS (Crary et al., 2005), treatment was stopped and outcome measures were taken. If participants were discharged from hospital prior to completion of the treatment programme, outcomes were measured on the day of transfer.

7.4.9  **Outcome Measures**

Measurements were taken before, immediately after treatment and at three months follow up.
7.4.9.1 Primary Outcome Measure

- The degree of aspiration and/or penetration from FEES assessment using the PAS scale (Rosenbek et al., 1996).

7.4.9.2 Secondary Outcome Measures

- Degree of pharyngeal residue noted on FEES assessment using the five point pharyngeal residue severity scale (Kelly et al., 2006).
- Secretion management noted on FEES assessment using the four point secretion severity scale (Murray et al., 1996).
- Change in functional swallowing abilities measured with the FOIS (Crary et al., 2005), completed by the ward SLTs managing the participants’ dysphagia care.
- Patient satisfaction with treatment for their dysphagia, measured with the validated self-completion Client Satisfaction Questionnaire (CSQ) at the end of treatment (Larsen, 1979) (Appendix 12).
- Time to swallow recovery and return to pre-stroke diet, indicated by time taken to obtain “Nil abnormality detected” score on MASA and FOIS 7.
- Patient adherence with treatment, indicated by number of sessions refused, number of independent session completed and drop-out rate, determined by the treatment logs (Appendix 10 and 11). Treatment records (Appendix 11) were completed by the researcher during each session and practice logs (Appendix 10) were completed by participants. If the participant had not completed the log by the next session, the researcher would ask them about any independent practice completed in the preceding day and fill in the log on their behalf.
- Incidence of chest infections, diagnosed by the stroke consultant from chest x-ray and clinical presentation and documented in the medical notes.
- Motivation with swallowing therapy, determined by the motivation scale (Appendix 9).

### 7.4.10 Three month follow up

Participants were invited to return to the hospital for a repeat of outcome measurements three months after completing treatment. Their carers and current managing SLT were also contacted (if appropriate) to gain further information about the level of input they had received since finishing the study intervention. The three month outcome period was selected as there is evidence that outcomes following stroke remain relatively constant from this time (Wolfe et al., 2011).

### 7.4.11 Standardisation of Baseline and Outcome Assessments

To ensure consistency in examination, the FEES assessment followed a strict protocol (Appendix 3). All were conducted by the researcher and the lead SLT for the FEES service at Guy’s and St Thomas’ NHS Foundation Trust (SLT1), who both have over five years experience of conducting and reporting on FEES at least weekly. Secretions were rated before any food/fluids were introduced and then all participants were given three teaspoons then three sips of thin and syrup consistency fluids followed by three teaspoons of puree. The worst score attained on each measure for each consistency was recorded. If a large amount was aspirated and the participant was unable to clear their airway or was considered to
be at significant risk of airway occlusion prior to introduction of all boluses, the assessment was terminated and the worst scores were entered for any consistencies not trialled. The FEES recordings were analysed offline by SLT1. A random sample of 40% of the examinations were subsequently rated in a random order by the lead SLT for FEES from another NHS Foundation Trust (SLT2) for inter-rater reliability.

### 7.4.12 Blinding

The SLTs who rated the FEES examinations were blind to participant group. All ward SLTs who delivered the routine dysphagia care and carried out the FOIS and MASA assessments were blind to participant group, as were the nursing and medical staff looking after the participants and this was aided by use of a private treatment room rather than conducting sessions at the bedside where they could be overheard. Success of blinding was assessed informally by asking staff if they could identify participants’ group allocation. It was not possible to blind participants to their treatment but they were all asked whether they thought they were receiving active treatment for their dysphagia at the end of the programme to examine their understanding of their group allocation.

### 7.4.13 Data Analysis

Due to the small numbers recruited, there was insufficient participant outcome data to analyse. To examine the appropriateness of the primary and secondary outcome measures determined from FEES, inter-rater reliability was assessed with
the linear weighted Kappa. A weighting of 0.5 was given for a disagreement of one point on each scale but disagreement of ≥ two points was classed as complete disagreement and not weighted. Altman’s (1991) categories were used to interpret the Cohen’s Kappa (<0.20 = poor agreement, 0.21 – 0.40 = fair agreement, 0.41 – 0.60= moderate agreement, 0.61-0.80 = good agreement and >0.81 = very good agreement).

7.5 Results

The results are presented to reflect the aim of assessing the feasibility of the protocol. Due to the small numbers recruited, participant outcome data is not presented to avoid misinterpretation.

7.5.1 Feasibility of study protocol within resources available

The target sample size was not achieved within the resources available (further detail follows in 7.5.2). Throughout the data collection period, the researcher’s time was dedicated to the study on a full time basis, which was necessary due to the intensity of the treatment programme. In order to fulfill the study protocol adequately, she was able to manage three participants on the study at any one time (as she was responsible for recruitment, consent procedures, treatment delivery and collecting baseline and outcome data). Due to the paucity of available patients, this capacity was not stretched. Daily discussions with the ward SLTs to identify participants and access updates on participants’ swallowing took less than 20 minutes. Considerable time commitment was required from SLT1 in conducting and
analysing FEES as each participant had up to three examinations (up to 1.5 hours per examination). The study had sole access to a Digital Swallowing Workstation (DSW, KayPentaz, New Jersey) and this was necessary in preventing any delay in offering sEMG and FEES due to lack of equipment.

7.5.2 Recruitment, consent and retention

During the recruitment period, 62 stroke patients were referred to the SLT department at St Thomas’ Hospital. Of these, 11 met the inclusion criteria, 1 declined to participate and 10 were recruited (Figure 7.2). The process of identifying potential participants with input from the clinical SLT team was effective and efficient although there was often a gap between stroke onset and recruitment (Table 7.2) due to transfer from another hospital, poor medical status and/or the time taken for assessments to determine that they met the inclusion/exclusion criteria. The consent procedure was smooth but extra time was required for information giving meetings and consent interviews when participants had language or cognitive impairment (up to 45 minutes per meeting).

Baseline characteristics for all participants are shown in Table 7.2. All were fully independent pre-admission. Five participants completed all 20 sessions and the overall range was 11-20 sessions. No participants dropped out and early treatment termination was due to discharge from hospital (n=2) or clinical swallow recovery (n=3) (Figure 7.2).
The mean length of session received was 39.73 (8.20) min and was very similar across the groups. The number of daily independent practice sessions by Groups 1 and 2 was also very similar (Figure 7.2). Treatment sessions were sometimes shorter than the planned 45 minutes (range 10–45 minutes). This was due to participant tiredness, fatigue or coughing during the exercises (recorded on treatment logs, Appendix 11). Otherwise treatment was well tolerated. Participants were seen for 4.34 (0.44) sessions per week, with a similar frequency between groups (Figure 7.2).

One participant (2B in Group 2) refused sessions (n=4), although she did complete 20 sessions over a longer period (mean 3.78 sessions per week). She had a history of refusing all interventions, for which she had been referred for psychological assessment. It was sometimes not possible to deliver treatment daily due to planned medical interventions (e.g. PEG insertions) or poor medical status. All participants were seen twice a week by one of two stroke specialist SLTs for their routine dysphagia care.

Two participants returned for the three month follow up assessment, a further four declined but were interviewed by phone, with additional information gained from carers and community SLTs. One participant was not contactable and three participants had died (Figure 7.2).
62 stroke patients referred to SLT for swallowing assessment

52 excluded:
- 21 due to inability to consent (12 cognitive impairment and 9 profound aphasia)
- 11 as not dysphagic on initial assessment
- 9 due to palliative care status
- 5 due to previous stroke
- 5 due to history of dementia
- 1 due to history of head & neck cancer and surgery

10 participants consented and randomised

Group 1
n=3

Group 2
n=3

Group 3
n=4

Sessions completed:
- 15 - as discharged (pt 3B)
- 16 - as dysphagia clinically resolved (pt 4B)
- 19 - as discharged pt (7B)

Mean (SD) sessions x week:
3.90 (0.30)
Mean (SD) session length:
38.33 (7.49) min
Mean (SD) independent sessions x day:
1.31 (0.41)

3 month follow up:
- 2 attended (pt 3B and 7B)
- 1 phone consultation (pt 4b)

Sessions completed:
- 20 (2B)
- 20 (8B)
- 10 - as dysphagia clinically resolved (5B)

Mean (SD) sessions x week:
4.68 (0.32)
Mean (SD) session length:
41.18 (3.22) min
Mean (SD) independent sessions x day:
1.31 (0.41)

3 month follow up:
- 0 attended
- 2 phone consultations (pts 2B and 5B)
- 1 had died (8B)

Sessions completed:
- 20 (1B)
- 20 (9B)
- 20 (10B)
- 11 - as dysphagia clinically resolved (6B)

Mean (SD) sessions x week:
4.68 (0.32)
Mean (SD) session length:
41.18 (3.22) min
Mean (SD) independent sessions x day:
1.31 (0.41)

3 month follow up:
- 0 attended
- 1 phone consultation (pt 9B)
- 1 lost to follow up
- 2 had died (1B and 10B)

Figure 7.2: Recruitment Pathway
Table 7.2: Baseline demographics and measures for participants.

<table>
<thead>
<tr>
<th>Group</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Age</td>
<td>Sex</td>
<td>Stroke type</td>
<td>Days since stroke</td>
<td>Barthel</td>
<td>MMSE</td>
<td>BMI</td>
<td>Language/speech</td>
<td>Worst PAS</td>
<td>Dysphagia Severity</td>
</tr>
<tr>
<td>Participant</td>
<td>3B</td>
<td>4B</td>
<td>7B</td>
<td>2B</td>
<td>5B</td>
<td>8B</td>
<td>1B</td>
<td>6B</td>
<td>9B</td>
<td>10B</td>
</tr>
<tr>
<td>Age</td>
<td>83</td>
<td>79</td>
<td>64</td>
<td>56</td>
<td>59</td>
<td>84</td>
<td>87</td>
<td>56</td>
<td>40</td>
<td>83</td>
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<td>Sex</td>
<td>F</td>
<td>F</td>
<td>M</td>
<td>F</td>
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<td>F</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>F</td>
</tr>
<tr>
<td>Stroke type</td>
<td>L MCA infarct, R inattention</td>
<td>L MCA infarct</td>
<td>L PICA infarct</td>
<td>R Basal Ganglia haem</td>
<td>L basal ganglia haem, bilat cortical &amp; sub-cortical microbleeds</td>
<td>R MCA infarct, L inattention</td>
<td>Bilateral Thalamic haem</td>
<td>L caudate nucleus infarct</td>
<td>Multiple scattered lacunar infarcts following chest sepsis</td>
<td>R MCA infarct with haemorrhagic transformation</td>
</tr>
<tr>
<td>Days since stroke</td>
<td>9</td>
<td>8</td>
<td>9</td>
<td>2</td>
<td>19</td>
<td>7</td>
<td>12</td>
<td>10</td>
<td>≤28 days</td>
<td>8</td>
</tr>
<tr>
<td>Barthel</td>
<td>0</td>
<td>5</td>
<td>13</td>
<td>2</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>11</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>MMSE</td>
<td>14</td>
<td>18</td>
<td>28</td>
<td>21</td>
<td>16</td>
<td>30</td>
<td>20</td>
<td>29</td>
<td>28</td>
<td>24</td>
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<tr>
<td>BMI</td>
<td>14</td>
<td>17.5</td>
<td>20.7</td>
<td>28.1</td>
<td>26.9</td>
<td>25</td>
<td>16.5</td>
<td>20.3</td>
<td>34</td>
<td>21</td>
</tr>
<tr>
<td>Language/speech</td>
<td>Severe exp &amp; rec aphasia, mild oral apraxia &amp; dysarthria</td>
<td>Mild dysarthria, Language WNL</td>
<td>WNL</td>
<td>Language WNL Mild dysarthria</td>
<td>Severe receptive &amp; expressive aphasia.</td>
<td>WNL</td>
<td>WNL</td>
<td>WNL</td>
<td>WNL</td>
<td>WNL</td>
</tr>
<tr>
<td>Worst PAS</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Dysphagia Severity</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Profound</td>
<td>Severe</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Severe</td>
<td>Mild</td>
<td>Moderate</td>
<td>Mod-severe</td>
</tr>
<tr>
<td>FOIS</td>
<td>5</td>
<td>5</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>5</td>
<td>3</td>
<td>2</td>
</tr>
</tbody>
</table>

L=left, R=right, MCA=middle cerebral artery, PICA=posterior inferior cerebellar artery, BMI=Body mass index, MMSE=Mini Mental State Examination, PAS=Penetration Aspiration Scale, FOIS=Functional Oral Intake Scale, WNL=within normal limits, Exp=expressive, Rec=receptive, Haem=haemorrhage
7.5.3 Effectiveness of Randomisation and Blinding

All participants were willing to be randomised into treatment groups but there were too few participants to assess whether the three groups were equivalent in terms of baseline characteristics (Table 7.2). From informal assessment, blinding of health care professionals (including ward SLTs) to participant group allocation was effective. More than half (6/10) of participants correctly identified which treatment group they were in, although all in Group 3 thought they were in Group 2 (i.e. receiving direct dysphagia therapy) (Table 3).

7.5.4 Acceptability of Intervention

All participants reported high levels of satisfaction with treatment (Table 7.3).

Table 7.3: Participant Satisfaction with treatment and understanding of group allocation at end of programme

<table>
<thead>
<tr>
<th>Group</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant</td>
<td>3B</td>
<td>4B</td>
<td>7B</td>
</tr>
<tr>
<td>CSQ (%)</td>
<td>100</td>
<td>94.75</td>
<td>100</td>
</tr>
<tr>
<td>Participant’s understanding of group allocation</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
| CSQ = Client Satisfaction Questionnaire

7.5.5 Selection of outcome measurement, including reliability of tools and feasibility of measurement

The second FEES expert (SLT2) independently blind rated nine (40%) of the FEES examinations completed. Agreement ranged from good to very good, depending
on the measure (Table 7.4). It was possible to conduct FEES on all participants at baseline and end of treatment but it was not possible to carry out the examination at three month follow up on 6/8 of the surviving participants (see section 7.5.2). FOIS assessment was possible at all scheduled measurement points for all surviving participants apart from the one individual lost to follow up. Where necessary information was used from phone consultations (Figure 7.2). On occasions, participants required assistance to complete the CSQ, the motivation scale and variably the treatment logs.

Table 7.4: Inter-rater reliability for the primary outcome measure (Penetration Aspiration Scale - PAS) and for the residue, secretions and overall severity scales for the nine examinations that were analysed independently by SLT 1 and SLT 2.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Weighted Kappa</th>
<th>Level of agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAS</td>
<td>0.649</td>
<td>Good</td>
</tr>
<tr>
<td>Residue</td>
<td>0.870</td>
<td>Very good</td>
</tr>
<tr>
<td>Secretions</td>
<td>0.802</td>
<td>Good</td>
</tr>
<tr>
<td>Overall severity</td>
<td>0.930</td>
<td>Very good</td>
</tr>
</tbody>
</table>

7.6 Discussion

This study has provided useful information on the feasibility of a protocol designed to inform the clinical management of dysphagic stroke patients. No previous study has evaluated the ES in patients or compared dysphagia treatment with and without biofeedback, but several have suggested it improves outcome (Huckabee and Cannito, 1999, Crary et al., 2004, Bogaardt et al., 2009). This study is the first to use randomisation, blinding, validated outcome measures and controls to
investigate these interventions and the results can be used to support further trials that will in turn inform clinical practice.

Recruitment rates compromised the feasibility of this study as it was not possible to recruit the target sample size (30) of acute stroke participants in the designated 12 month period. The recruitment rate was unexpectedly low, with only 10 participants recruited. Following the National Sentinel Stroke Audit in 2008 (Royal College of Physicians Intercollegiate Stroke Working Party, 2008), the London Stroke Model was established with the aim of improving acute stroke care (Healthcare for London, 2008). In this model, patients in London are now initially taken to one of eight Hyper Acute Stroke Units (HASUs) for immediate assessment, treatment and stabilisation before being transferred to their local Stroke Unit (SU). When this study was designed, St Thomas’ Hospital had a designated HASU and SU with 28 beds. However, by the time recruitment commenced, hyper acute care had been transferred to neighbouring Trusts and St Thomas’ had reduced its capacity to just a 19 SU bed unit. This affected the referral rate to SLT and was felt by the ward SLTs to account for the considerable number of patients who were referred for swallowing assessment but were not dysphagic on SLT assessment as there was time for spontaneous recovery before assessment at St Thomas’. In addition, a proportion of patients with less severe impairments are discharged straight home from the HASU, leading to the SUs receiving patients who are more severely affected. This may have increased the proportion of potential participants who did not meet the inclusion criteria due to previous strokes, dementia, palliative care
status and inability to consent due to cognitive or profound language impairment. Extending the recruitment period and/or introducing other sites including a HASU would have improved the chances of meeting the recruitment target but this was not possible within the resource limitations of this study. Brandt et al. (2006) describe a process of needing to continually involve new research sites in order to recruit sufficient participants to their study of compensatory dysphagia treatments and this had significant financial implications. Methods to promote recruitment would need to be considered carefully in future study planning.

The largest proportion of patients who were referred to SLT for swallowing assessment but did not meet the inclusion criteria for the study were those who had significant cognitive or communication impairment that precluded gaining informed consent. This was not felt to lead to selection bias as these patients were also too impaired to participate in direct dysphagia therapy. All participants had relatively severe strokes, with Barthel Indices of ≤13 (Wolfe et al., 2011) and all had significant dysphagia at the start of treatment (PAS of 8). The study was strengthened by not excluding patients with aphasia and not using an arbitrary cut-off on the MMSE, as has been used previously (Crary et al., 2012), provided patients could communicate adequately to give informed consent, using supported/total communication with an SLT, if necessary. This meant that the sample was more representative of those who would be offered therapy in a normal clinical setting. Patients were excluded, however, who had preexisting stroke or conditions that
would affect their ability to benefit from therapy due to altered capacity for retention or neuroplasticity (Hamdy, 2003).

In the development of the protocol, the consent process was given particular consideration to ensure it was possible to access participants with cognitive and language impairments without coercion. Any future study targeting this vulnerable population should follow similar steps and factor in the time required for a fair consent procedure. Promisingly, no participants dropped out of the study and only one declined to take part, therefore the study was not subject to attrition bias and this indicates that the intervention and protocol were acceptable. Two of the participants were discharged home before completing the 20 treatment sessions. Future studies should consider ensuring there are resources to enable continuation of treatment in participants’ homes, especially with the drive for early hospital discharge (Langhorne et al., 2011).

Adherence to the treatment protocol was very good but it was not always possible to deliver therapy sessions five days per week and for 45 minutes each time and participants tended not to achieve three practice sessions per day (Figure 7.2 and section 7.5.2). This reflects the challenges of delivering intensive therapy in an acute hospital environment and with an acute caseload. “More is more” is an accepted principle in therapy provision (Langhorne et al., 2011) but there is a limit to how much patients can be expected to complete.
It was felt that the choice of outcome measures was sufficiently broad to reflect the impairment and functional implications of dysphagia, while also assessing participant adherence and satisfaction. Detection bias was reduced by successfully blinding the primary outcome measurement, which has rarely been attempted in previous dysphagia trials (Speyer et al., 2010, Foley et al., 2008) and by using validated, standardised outcome measures. Furthermore, the inter-rater reliability of the primary and secondary outcome measures determined on FEES was examined. Despite using a conservative measure of agreement (the kappa assumes any observed agreement could have occurred by chance and adjusts for this), the agreement was good for the primary outcome measure (the PAS), in agreement with previous studies (Kelly et al., 2007, Rosenbek et al., 1996, Colodny, 2002). Agreement was very good for the residue rating and better than reported previously (Kelly et al., 2006). Reliability has not previously been examined for either the secretion rating scale or the overall severity scale, but was found to be good and very good, respectively. Therefore there can be increased confidence in the validity of the findings of future studies employing these outcome measures.

Having dedicated equipment and two fully trained FEES practitioners available enabled participants to have timely baseline and outcome assessments. Unfortunately it was largely not possible to conduct instrumental assessments at three months. Participants declined to attend the follow up appointment because the effort of travelling to the hospital outweighed the perceived benefit as they were no longer concerned about their eating and drinking. Future studies should
consider ways of incentivising return appointments and/or coordinating follow up with other clinic appointments to reduce burden. Using a range of outcome measures including the FOIS made it possible to collect some data through phone calls with participants, even if they were not able to attend for a FEES assessment. Allowing for visits to participants’ homes would further facilitate data collection.

Where possible participants were asked to complete the CSQ, motivation scale and treatment logs independently or with the help of a carer but there were occasions when the researcher needed to assist. This was a potential source of bias as participants may have altered their responses in order to please her. By collecting this data from participant-completed treatment logs, there is also a potential for recall bias. Future studies would be strengthened by employing an independent person to assist in the completion of these questionnaires, who would be blind to participant group.

7.6.1 **Strengths and limitations**

A limitation of this study was the small sample size, precluding analysis of patient outcomes. However, useful information has been gained about the feasibility of the protocol. Further measures and resource allocation are justified to increase recruitment, for example identification and enrollment of other research sites and extended recruitment periods.
A strength of this study was the successful randomisation of treatment allocation to reduce systematic bias and also the inclusion of three groups, including a control. As the benefit of the ES exercise in stroke patients has not yet been adequately tested, this design is necessary so that the specific and individual effects of the ES and sEMG biofeedback can be examined. A previous RCT indicated that behavioural swallowing therapy was of benefit (Carnaby et al., 2006); however individual exercises were not studied separately and therefore it was not clear which part of the treatment was effective. Furthermore there was a significant difference in the number of sessions and their duration between the treatment groups in the Carnaby (2006) study, whereas the current study ensured that participants in the three groups were treated with the same intensity, removing the impact of dose on outcomes.

All participants received ongoing dysphagia input from the ward SLTs during the study to ensure they received assessment and advice to manage their nutrition and hydration safely. To control for differences in care between participants, the SLTs were blinded to treatment group and were asked to see patients twice a week and not to provide direct dysphagia therapy. There were only two SLTs involved which increased the consistency in care provided to all participants.

To determine treatment length, the protocol was designed with reference to normal practice as SLTs working on a stroke unit reported that the average length of
treatment was four weeks (Archer et al., 2013) and 77% of stroke patients are discharged from hospital within 28 days of their stroke (Intercollegiate Stroke Working Party, 2010). The length of treatment was also comparable to or longer than other dysphagia intervention studies (Carnaby et al., 2006, Crary et al., 2012). However, future studies should explore ways in which to deliver the intervention for longer periods as it is clear that recovery continues beyond the acute hospital stay.

Previous studies have not investigated the optimum “dosage” of exercises to drive swallowing improvement and so the current protocol was informed by the survey of practicing SLTs working in stroke (Archer et al., 2013) and the national guidelines (Intercollegiate Stroke Working Party, 2012). Future research may indicate more advantageous treatment protocols. However, the format of repetitions and sets of the exercise was consistent with current recommendations for exercise prescription (Garber et al., 2011). Furthermore, this study incorporated task progression, in terms of increasing the number of repetitions and/or sets of the ES and in the biofeedback group challenging participants to beat their own peak sEMG amplitude. This follows the overload principle of exercise physiology and neural plasticity, which should underpin rehabilitation (Burkhead et al., 2007, Kleim and Jones, 2008) but is not currently adopted in routine practice by SLTs (Archer et al., 2013).
It was not possible to blind the participants to their treatment group due to the nature of the intervention. However, all participants in the control group (routine care) thought they were receiving direct dysphagia therapy, reducing the risk of performance bias. The researcher delivered all three interventions, which was a potential source of bias as her approaches with the different groups could have been influenced by her interest in the study hypotheses. However, the risk of this was minimised by following a strict study protocol. If future studies recruit more centres, there will be a need to recruit more members to the study team and this will lead to considerable training needs to ensure that sEMG and FEES are available and that there is equity in treatment between sites.

This study did not select participants by type of stroke and this led to participants with both ischaemic and haemorrhagic strokes in a range of locations, which will have affected the course of recovery (Paolucci et al., 2003). Furthermore, participants had different impairments such as neglect and language impairment that may have influenced their ability to benefit from therapy (Gillen et al., 2005). A strength of the study was that it was designed to represent patients who would be offered dysphagia therapy in a normal clinical setting and so a mixed population of stroke patients was unavoidable. By randomising participants into the treatment groups, the aim was to ensure an even-spread of stroke-related impairments across the groups. However, the small numbers recruited limited the effect of this strategy.
SLTs offer a range of dysphagia therapy techniques but the only intervention offered here was the ES. It could be argued that this may have been the wrong exercise for some participants or that SLTs would have offered the ES in combination with another exercise in clinical practice. However, the inclusion criteria stated that participants had to have evidence of pharyngeal residue and/or reduced airway protection on FEES, both of which would indicate the ES as an appropriate exercise (Steele and Huckabee, 2007, Hind et al., 2001). The aim of this study protocol was to ascertain the effect of a single exercise +/- biofeedback and therefore it was necessary to only prescribe the ES.

### 7.7 Conclusion

This study has shown that recruitment rates are a genuine concern in conducting an investigation of behavioural swallowing treatments in acute stroke as the target sample size was not reached in the time available. However, one of the key objectives of a feasibility study is to determine if all components of the methodology run smoothly (Arain et al., 2010) and this study has successfully tested the protocol with promising results. It indicated that patients who met the inclusion criteria tended to consent to participate and adhere to the programme. Furthermore the intervention was well-tolerated and led to high levels of patient satisfaction. The methods used to minimise bias were successful and outcome measures were reliable. It is suggested that the design of this study could be used to inform future trials. Further resource allocation is needed to optimise recruitment and to continue the intervention on discharge from hospital.
Chapter 8 Summary and Conclusions

8.1 Introduction

Dysphagia is common after stroke and leads to worse outcome. According to national guidelines, any patient with dysphagia one week after stroke should be considered for a swallowing rehabilitation programme (Intercollegiate Stroke Working Party, 2012). However, there is a paucity of evidence for behavioural dysphagia therapy and the best approaches to treatment are not known (Geeganage et al., 2012). Recovery of swallowing after stroke is associated with cortical reorganisation and it is accepted that exercises that attempt to drive neuroplasticity will optimise improvements. The ES follows many of the principles of both neuroplasticity and exercise physiology and has been shown to lead to physiological improvements in the swallow in healthy participants. However, its effect in dysphagic patients has not been evaluated.

Swallowing typically occurs without conscious attention or manipulation and there are few visible indicators of performance, increasing the challenge of swallowing rehabilitation. sEMG biofeedback therefore may be a beneficial adjunct to ES therapy as it can provide an objective measure of an otherwise hidden activity. However, the reliability of sEMG and the most appropriate way of normalising the data to enable comparison of performance have not been studied. Furthermore
there is a lack of understanding of the effect of healthy ageing on the muscle activity for swallowing and for completing the ES. It is not known if dysphagic stroke patients are able to increase their muscle activity during the ES, if sEMG biofeedback improves performance or is an acceptable technique. Therefore it is unclear whether sEMG is an appropriate addition to the clinician’s toolkit. Furthermore, the benefit of the ES with and without sEMG biofeedback in dysphagic acute stroke patients remains to be tested in a robustly designed study with appropriate controls for spontaneous recovery and measures to reduce bias. This thesis sought to address these issues to determine the role of sEMG biofeedback in ES dysphagia therapy in acute stroke.

8.2 Summary of findings

8.2.1 Practice patterns in dysphagia therapy in stroke in the UK and Ireland

Chapter 2 presented the findings of a nationwide survey of SLTs working in stroke. There was variability in the responses to all questions, which is unsurprising considering there is insufficient evidence to guide clinicians with respect to individual therapies (Geeganage et al., 2012). Further research investigating specific treatments and the best way to prescribe them should inform and streamline practice. However, it was also shown that existing national guidelines are not routinely being adhered to, such as the need to perform instrumental assessments to guide treatment (The Royal College of Speech and Language Therapists, 2005) and the intensity of treatment sessions delivered (Intercollegiate
Furthermore, instrumental assessments and standardised measures are not typically used to assess outcome and core principles of exercise physiology and neuroplasticity, for example “use it and improve it” and task progression, are not being translated into the design of treatment packages, which may limit their effectiveness. These findings are consistent with studies of SLT practice patterns in other areas, which all show concerning variability in practice and poor adherence to clinical guidelines (Carnaby and Harenberg, 2013, Krisciunas et al., 2012, Miller et al., 2011).

SLTs’ current approaches to dysphagia treatment are therefore not routinely incorporating the evidence that does exist. In relation to clinical practice development, the RCSLT website states:

‘It remains the responsibility of individual clinicians to seek out relevant national and local policy documents and position papers and to critically appraise the evidence base for their clinical area.’ (Royal College of Speech and Language Therapists, 2013a).

However, the findings of the current survey suggest a need to introduce new measures, in addition to the development of the evidence base, to promote the adoption of guidelines and research to improve and unify practice. Targeted
methods to draw together existing and emerging evidence and to enhance communication among clinicians, with the support of strong leadership, potentially through the RCSLT professional body may be most effective in driving improvements.

The survey showed that the ES is a relatively commonly exercise in stroke-related dysphagia (Archer et al., 2013), justifying the need to establish its benefit for patients. Low patient motivation was cited as the most common reason for patients not improving with direct therapy, which supports the exploration of methods to motivate patients during rehabilitation. Biofeedback is suggested to improve motivation (Reddy et al., 2000) but the survey indicated that it is currently rarely used by SLTs in the UK and Ireland.

SLTs tend to recommend intensive independent practice of dysphagia exercises but themselves see patients no more than once a day and for arguably short treatment sessions, on average three times a week (Archer et al., 2013). In the pilot RCT in Chapter 7 it was found that patients achieved one session of independent practice per day, despite being advised to complete three. This indicates that recommending concentrated independent practice does not necessarily translate into the intensity envisaged by the prescribing SLT. In the absence of trials examining different doses of dysphagia exercises, it is difficult to evaluate the appropriateness of the typical treatment schedule indicated in the survey.
However, it is suggested that more intensive therapy is more effective (Langhorne et al., 2011, Carnaby et al., 2006), and this principle has been adopted in the national stroke guidelines (Intercollegiate Stroke Working Party, 2012). Further studies are required that examine different intensities of various treatments in order to direct resources most efficiently and effectively.

### 8.2.2 Validation of the Digital Swallow Workstation

sEMG systems have been developed with integrated automatic software for measurement and analysis and in using them, clinicians and researchers are distanced from viewing the raw unprocessed signals and also the methods used for signal processing. These are important determinants of the validity and accuracy of measurements and therefore it is important that these systems capture and process the data in a known and appropriate way. The DSW is commonly used in sEMG swallowing studies but no data are available on the validity of its automatic signal processing settings, which lie outside international guidelines (Hermens et al., 1999, Merletti, 1999). The study presented in Chapter 3 validated the equipment against a reference system and found that it enables accurate measurement of amplitude of muscle activity. This means that a clinician or researcher can be confident that a patient’s increased effort for swallowing will be reflected in an increase in muscle activity recorded by the DSW, supporting its use for biofeedback and justifying its use in the subsequent studies in this thesis. Notwithstanding, the inaccessibility of the raw signal limits the application of the DSW for in-depth analysis of the power
spectrum and the company have been asked to consider adapting future systems accordingly.

8.2.3 Normalisation and reliability of swallow sEMG

The study presented in Chapter 4 investigated for the first time the reliability of swallowing sEMG and also the best way to normalise the data. The inter- and intra-participant reliability of non-normalised “absolute” swallowing sEMG falls outside the range of acceptable reliability for physiological measures (Buckthorpe et al., 2012). However, reliability is comparable or better than for sEMG measurements in other dynamic activities (Winter and Yack, 1987, Buckthorpe et al., 2012) and the variability presented here can be used as a reference for future studies.

The very high inter-participant variability even for healthy participants confirms the need to normalise data to enable fair comparison between sessions and individuals. This finding sheds doubt over conclusions made in previous studies comparing groups with absolute sEMG measurements (Vaiman, 2006, Vaiman and Eviatar, 2009, Vaiman and Nahlieli, 2009, Coriolano et al., 2012, O’Kane et al., 2010). Normalising submental swallowing sEMG to the mean NS was plainly the best method for reducing variability in sEMG measurements and it is recommended that future studies adopt this method for comparing exercise performance.

However, normalising to the mean NS removes physiological variation in NS amplitudes, which has implications for examining changes in the normal swallow
with time or treatment. Future studies should explore factors that can be controlled for, e.g., amount of subcutaneous tissue, and identify alternative standardisable tasks that can be used as a reference measure for normalisation. Although this is challenging in an activity as complex as swallowing and in populations with dysphagia, who may find novel tasks difficult.

Even when data is normalised to the measure that was found to optimally reduce variability, the levels of intra-participant reliability of swallowing sEMG across sessions remain poor. Therefore the use of sEMG as an outcome measure in swallowing rehabilitation is questionable as it is likely to lack the capacity to reveal small treatment effects due to its variability. This study therefore supports the use of sEMG as a biofeedback tool, in which data is normalised to the NS to reveal relative gains in muscle activity above normal, but more research is needed to determine whether it is sensitive to treatment effects.

8.2.4 The effect of age on swallow sEMG

There was no change in intra-participant variability of muscle activity for normal swallowing with age, indicating that the patterned motor response is preserved in an undemanding water swallowing task. There was also no change in the ability to increase muscle activity for the ES, suggesting preservation of muscle activity reserve for swallowing. This is consistent with emerging evidence of stability in tongue pressure with age when measurements have been normalised to control for
age-independent variation in tongue strength (Steele, 2013). It is acknowledged that sEMG is non-specific and therefore the lack of change with age may reflect the ability to compensate for age-related weakness by working harder with other muscles. Conversely, dysphagic patients may lack this reserve to compensate for weakness. Therefore this has provided useful insights to enable the differentiation of changes in swallowing that are due to pathology and age to inform the diagnosis and appropriate treatment of dysphagia.

8.2.5 The ability of dysphagic acute stroke patients to increase submental activity during the ES and the benefit of sEMG biofeedback on performance

Previous research in healthy participants has demonstrated the physiological benefit of the ES e.g. (Hind et al., 2001, Huckabee et al., 2005, Yeates et al., 2010, Wheeler-Hegland et al., 2008). However, the ability of dysphagic patients to increase submental activity during the exercise cannot be assumed due to the effects of weakness, impaired motor planning, cognitive deficit and fatigue. The study presented in Chapter 5 showed for the first time that dysphagic stroke patients were able to significantly increase their muscle activity for the ES exercise, although unsurprisingly healthy controls produced greater amplitudes than the dysphagic group. This shows that despite having severe dysphagia these patients retained some functional reserve for swallowing, and supports the ES as an exercise incorporating “overload”, challenging the motor system beyond its normal level of activity (Burkhead et al., 2007). Incorporating sEMG biofeedback led to significantly
increased sEMG amplitudes, supporting the theory that it helps to challenge and improve performance (Reddy et al., 2000).

The questionnaire outlined in Chapter 5 clearly indicated that participants perceived a benefit of incorporating sEMG biofeedback with the ES exercise. They reported that they found the exercise significantly easier with the feedback than without and comments indicated that both healthy and dysphagic participants had insight into specific advantages of the technique, including having a target to aim for. Previous studies of dysphagia therapy have not included patient feedback on techniques, although it is understood that outcomes of care are improved if patient experience is positive (Manary et al., 2013). The physiological benefits of sEMG biofeedback shown in this study and others are more valuable because patients view it as an acceptable technique in which they are therefore more likely to participate.

8.2.6 The benefit of sEMG for accuracy of therapy feedback

Experienced SLTs were found to have limited inter-rater agreement in the assessment of ES performance in the study outlined in Chapter 6. Furthermore, there was no relationship between sEMG amplitudes and rated performance for the exercise. This is consistent with studies that have found poor validity of clinical swallowing examinations (McCullough et al., 2005, McCullough et al., 2000). This highlights a further benefit of incorporating sEMG into treatment sessions as it can enhance the accuracy of the information available to the clinicians in monitoring exercise performance. In adaptive motor learning, accurate feedback is essential to
beneficially shape behaviour (Bastian, 2008, Shumway-Cook, 2001). By providing accurate feedback, sEMG could assist in shaping motor learning for swallowing post stroke, positively reinforcing helpful motor programmes to compensate for or overcome the impairment. This could also help clinicians to redirect their treatment if there are cases where patients are unable to elicit an ES even with training.

8.2.7 The feasibility of a RCT examining the benefit of the ES with adjunctive sEMG biofeedback in acute stroke

An original aim of this thesis was to include a fully powered RCT designed to determine whether the ES with sEMG led to significant improvements in airway protection compared with the ES alone and to sham. However, the low recruitment rate meant the study outlined in Chapter 7 was underpowered to achieve this aim. However, this study has provided valuable information regarding the feasibility of the protocol (Thabane et al., 2010). While the recruitment targets were not possible within the context and resources available, retention rates were 100%, methods of blinding and randomisation were successful and outcome measurements were sound. Patient feedback about the treatment was also very positive, a factor not previously addressed in other dysphagia trials (Carnaby et al., 2006, Park et al., 2012).

The protocol was not set out to study different intensities/doses of treatment, but instead based the treatment protocol on national guidelines (Intercollegiate Stroke
Working Party, 2012), with further information from the survey outlined in Chapter 2 (Archer et al., 2013) and from principles of exercise physiology and neuroplasticity (Burkhead et al., 2007, Kleim and Jones, 2008). Interestingly, despite the protocol aiming to deliver 45 minutes of therapy five days per week and there being dedicated resources to achieve this aim, the mean length of therapy session was 40 minutes, with 4.34 sessions per week. Also patients were asked to complete three independent sessions per day but on average completed one. Reasons for not completing therapy were related to fatigue, medical status and other interventions.

The latest Sentinel Stroke National Audit Programme (SSNAP) data indicated that the median number of minutes of SLT received by patients on stroke units was 30 (range 20 – 44), with just 27% of patients receiving the recommended 45 minutes of therapy five days per week (Intercollegiate Stroke Working Party, 2013). The current study was much closer to achieving the recommended standard and the intensity of treatment delivered was not far off the pre-planned programme. This discrepancy with clinical practice may relate to the specific therapist/researcher dedication in the study. However, this does highlight that even with adequate resources, the nature of the acute stroke caseload may preclude more intensive therapy input.

While “more is more” is the accepted principle for therapy intensity (Langhorne et al., 2011), it has been suggested that exercise adherence may decrease with
increasing intensity and therefore the effectiveness of therapy may be jeopardised by over-ambitious protocols (Easterling, 2008). The adherence to the protocol in this study supports its design, provided adequate resources are available for its delivery.

8.1 Limitations

Evidence is emerging of factors influencing recovery from stroke, including the impact of different genetic profiles on the ability of the brain to recover motor function (Takeuchi and Izumi, 2013) and this supports an individualised approach to stroke rehabilitation. The studies presented here did not select patients based on their individual characteristics, which therefore has the potential for diluting the findings as it assumed a “one size fits all” approach. However, more data is needed regarding those patients most likely to benefit from specific treatments before this can influence trial design. In addition, the present studies were designed to examine just one dysphagia exercise and therefore did not aim to directly address all features of post-stroke dysphagia, such as sensory impairment and disordered timing. However, by essentially treating swallowing with swallowing, while increasing awareness with biofeedback, it was felt that the ES was an appropriate, functional, task-specific exercise to focus on.
8.2 Implications and clinical relevance of findings

This thesis has shown that more evidence is needed to inform the treatment of dysphagia in stroke but also that SLTs as a profession need to focus on ensuring that therapy follows existing principles of best practice and to establish consistency in approaches. Emerging initiatives such as the RCSLT Regional Hubs (Royal College of Speech and Language Therapists, 2012.) and the Research Champions (Royal College of Speech and Language Therapists, 2013b) may be the best modes for driving this forward and improving the quality and consistency of care.

The studies outlined here provide good evidence of the potential benefit of sEMG biofeedback for dysphagic acute stroke patients. Incorporating this tool in therapy should encourage patients to work harder during swallow exercises, therefore enhancing the treatment delivered. Furthermore, it is a technique well tolerated by patients that should give clinicians more accurate information on performance, thus enabling them to provide better feedback, helping to shape motor learning. In order to compare sEMG amplitude data between participants and sessions, it is recommended that exercise measurements are normalised to the NS. However, the poor reliability of the technique throws doubt over its use as an outcome measure.
8.3 Future recommendations

Further studies are required to ascertain whether swallowing sEMG is sensitive to treatment effects and change over time and therefore to determine whether it has a role as an objective outcome measure in dysphagia management. The pilot RCT demonstrated a feasible protocol and the preceding studies supported the use of sEMG in therapy. A further, larger study is therefore justified, including multiple centres to promote recruitment, to examine the benefit of the ES with adjunctive biofeedback in improving outcome for dysphagic acute stroke patients.
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Appendices
### Svenssen et al. 2003

- **Sample**: N=11 healthy (5f, 6m) aged 21-29 years
- **Intervention**: Tongue protrusion task with biofeedback from a force transducer. Relax-protrude-hold-relax cycle with a constant target force and timing targets. 60 minutes per day every day for 7 days.
- **Outcome measures**: TMS and EMG used to measure MEPs and map corticomotor excitability. Measured at baseline, immediately post training and at 2 week follow up. First Dorsal Interosseos (FDI) used as comparison.
- **Results**: Significantly increased tongue corticomotor excitability at the end of training and 2 week follow up (p<0.001). Significant increase in the amplitude of MEPs in tongue musculature at end of training (p=0.005). Significant increase in the M1 tongue representation following training. Significant decrease in fatigue reports over the week (p<0.001). Significant progressive improvement in task completion (p<0.001). No effect of training on FDI measurements.
- **Strengths**: Control with FDI which did not change. Two different outcome points. Training task designed to match previous studies with primates. All subjects completed the protocol.
- **Weaknesses**: Functional relevance of task. Small healthy young sample. No blinding of outcome measurement. Did not assess if there were neuroplastic changes after individual sessions. Did not compare performance with neuroplastic changes.

### Svenssen et al. 2006

- **Sample**: N=11 healthy (5f, 6m) aged 21-29 years
- **Intervention**: Tongue protrusion task (as in Svenssen et al. 2003) 1 x 60 minute session.
- **Outcome measures**: TMS and EMG used to measure MEPs and map corticomotor excitability. Measured at baseline, 30 min post training, 1 day post training and 7 days post training.
- **Results**: Significantly increased threshold for evoking MEPs by TMS in the tongue at all time points compared to baseline (p<0.001). Tongue MEPs significantly increased amplitude at 1 day follow up and had returned to baseline at 1 week (p=0.001). Significant increase in area on corticomotor maps at 1 day follow up (p<0.001). Significant correlation between task performance and net increases in tongue MEPs at 1 day follow up (p=0.0039). No change in FDI muscle measurements.
- **Strengths**: Control with FDI which did not change. Different outcome points. Builds on finding from previous study. All completed the protocol. Links neuroplastic changes to performance.
- **Weaknesses**: As for previous study, small healthy young sample. No blinding of outcome measurement.

### Boudreau et al. 2007

- **Sample**: N=9 healthy (7m 2f) mean age 24 years.
- **Intervention**: Tongue protrusion training (as above) Two cross-over training sessions: algesic chemical capsaicin or vehicle cream applied to tongue. 1x 15 minutes training session.
- **Outcome measures**: TMS applied to M1 and MEPs recorded in the tongue musculature and the FDI muscle as a control. Measurements taken before and immediately after intervention.
- **Results**: Significantly enhanced tongue TMS-MEP stimulus response curve and reduced MEP threshold was observed after the vehicle session but not after the capsaicin session. Subjects’ overall mean performance scores were significantly higher in the vehicle session than in the capsaicin session. No change in FDI measurements.
- **Strengths**: Power calculation based on previous studies confirmed adequate sample size. Randomised order of delivery. Control with FDI which did not change.
- **Weaknesses**: Small healthy young sample. No blinding.
<table>
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<th>Authors</th>
<th>Sample Size</th>
<th>Age</th>
<th>Protocol Details</th>
<th>MRI Details</th>
<th>Findings</th>
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| Arima et al. 2011 | N=13        | 27.3 | - Tongue protrusion task (as above).  
- 1x60min session                   | - fMRI before and 1 hour, one day after and one week after training.       | - Increased activity in the precentral gyrus 1 h after training.  
- Increased activity in the precentral gyrus, SMA, putamen and cerebellum 1 day after training.  
- Increased activity in the parahippocampal gyrus one week later  
- Significant correlations between success in task and changed in the number of voxels in specific areas. | Small, young, healthy sample, ?clinical relevance of task. |
| Boudreau et al. 2013 | N=18        | 24.3 | - Tongue typing using custom-made intra-oral keypads  
- Two keypads, one bidirectional and one multidirectional.  
2x 30 min sessions on consecutive days. | - Immediately after each training session excitability of the tongue M1 assessed with TMS-MEPs | - Tongue-typing performance improved within and across training days.  
- Both tasks led to changes in tongue cortical motor map sites.  
- Multidirectional training (ie more complex task) associated with greater number of cortical map sites with increased excitability.  
- No effect of training on FDI measurements | Small, young, healthy sample, ?clinical relevance of task. |
| Kothari et al. 2013 | N=48        | 23.7 | - 1 hour of tongue training from one of three protocols:  
1. Tongue protrusion task (as studied previously),  
2. Therapeutic tongue exercises (TTE) derived from Facial Oral Tract Therapy (FOTT) principles,  
3. Tongue drive system (TDS) ie playing computer games with the tongue. | - Excitability of the tongue M1 assessed with TMS-MEPs before, immediately after and 1h after tongue training  
- FDI muscle used as control.  
- Resting motor thresholds of tongue MEPs were lowered by training with TDS and TPT (p<0.011) but not by TTE.  
- Tongue MEP amplitudes increased after training with TDS and TPT (p<0.03) but not TTE.  
- No effect of tongue training on FDI MEPs.  
- Tongue cortical motor map areas not significantly increased by training.  
- TDS rated as most motivating and fun (p<0.001). | - Emphasis on skill training.  
- With TTE used more functionally/clinically relevant intervention.  
- Randomisation between groups. | Only one session and only one outcome point.  
- ?Different intensity in different training conditions  
- TTE not routine clinical treatment and ?ceiling effect in healthy population. |
Appendix 2. Dysphagia therapy in stroke: a survey of speech and language therapists

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Abstract

Background: Dysphagia is common after stroke, leading to adverse outcome. There is a paucity of high-quality evidence for dysphagia therapy, thus making it difficult to determine the best approaches to treatment. Clinical decisions are often based on usual practice, however no formal method of monitoring practice patterns exists.

Aims: To determine speech and language therapists’ (SLTs) approaches to direct dysphagia therapy with stroke patients in the UK and Ireland.

Methods & Procedures: A 24-item questionnaire was developed, piloted and delivered in a web-based cross-sectional survey targeting all SLTs working with stroke patients in the UK and Ireland.

Outcomes & Results: A total of 138 SLTs responded from a range of clinical settings and levels of experience. There was variation in the responses to all questions. Respondents reported treating patients a median of once a day, 3 days a week for 15 min. The most commonly recommended direct exercises were supervised swallow trials (recommended ‘frequently or always’ by 73%). Despite most respondents having access to an instrumental swallowing assessment, over half reported rarely or never conducting one before recommending exercises. Most (93%) did not use a protocol for systematically progressing patients’ exercises and only 37% reported using standardized outcome measures.

Conclusions & Implications: This survey gives valuable insight into the direct dysphagia therapy practices of SLTs based in the UK and Ireland working in stroke. It highlights discrepancies between reported approaches and recommendations from existing evidence and clinical guidelines. The variation in responses indicates a need to develop a consensus statement and further research to guide practice.

Keywords: dysphagia, stroke, speech and language therapy, rehabilitation, therapy, survey.

What this paper adds

What is already known on the subject?
Dysphagia is common after stroke, leading to adverse outcome and optimum treatment is a priority. A range of exercises are used by SLTs with the aim of restoring swallowing ability by improving muscle function or through sensory stimulation. However, there is a paucity of robust evidence for many of these interventions and therefore there is limited guidance for the clinician on the best way to treat dysphagia.

What this paper adds
This survey of SLTs working with stroke patients in the UK and Ireland highlights variability in practice in dysphagia therapy and reveals discrepancies between reported approaches and recommendations from existing evidence and clinical guidelines. This indicates the need for more research on individual therapy techniques and a consensus statement to guide practice.

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Introduction

Dysphagia affects up to 50% of all stroke patients (Smithard et al. 2007). It is associated with a threefold increase in the risk of pneumonia, rising to an 11-fold increase if the patient is known to aspirate (Martino et al. 2005). Dysphagia has been identified as an independent predictor of mortality in stroke and is associated with increased institutionalization and poor outcome (Smithard et al. 2007, Martino et al. 2005).

Speech and language therapists (SLT) aim to reduce the risk of aspiration (entry of food/fluid into the airway) and improve swallowing function through their assessment and management of dysphagia (Royal College of Speech and Language Therapists (RCSLT) 2005). There has traditionally been a focus on recommending compensatory techniques, e.g. altering food/fluid consistencies and/or posture, to prevent aspiration (Bisch et al. 1994). However, SLTs are increasingly recommending rehabilitative or ‘direct’ therapy techniques, which aim to restore swallowing ability by improving muscule function or through sensory stimulation (Burkhead et al. 2007). The Royal College of Physicians’ (RCP) National Clinical Guidelines for Stroke states that any patient unable to swallow food safely 1 week after stroke should be considered for an oropharyngeal swallowing rehabilitation programme designed and monitored by a SLT (Intercollegiate Stroke Working Party 2012). It also states that in the acute stage, patients should receive a minimum of 45 min of each therapy required at least 5 days a week. However, despite being part of routine practice, there is a paucity of evidence for dysphagia therapy and questions remain regarding the best way to prescribe exercises.

A recent Cochrane Review (Geeganage et al. 2012) of dysphagia treatments post-stroke included five studies (423 patients in total) that assessed the outcome of dysphagia therapy and reported significantly reduced dysphagia (OR = 0.52; 95% CI = 0.30–0.88; p = 0.01) and a non-significant reduction in length of stay and chest infection as a result of behavioural swallowing therapy. This represents considerable progress from the previous Cochrane Review on this subject in 1999 which concluded that there was insufficient evidence to draw reliable conclusions (Bath 1999). However, the latest review by Geeganage et al. (2012) also concluded that it was unclear which components of the therapies were beneficial and therefore recommended more research to guide practice.

A recent study of 50 dysphagic patients within the first 6 months post-stroke indicated improved functional swallowing status and quality-of-life measures as a result of a mixed dysphagia exercise programme compared with ‘conventional swallowing therapy’ consisting of thermotactile stimulation (Kang et al. 2012). However, there was no random allocation into groups or blinding and therefore there is a considerable risk of confounding and bias in this study. Carnaby et al. (2006) performed a more robust randomized controlled trial of dysphagia therapy in 306 stroke patients and found a consistent trend towards more favourable outcomes, e.g. return to a normal diet and a lower incidence of swallowing-related medical complications, in patients who were assigned a programme of swallowing intervention compared with those receiving ‘usual care’ from the attending physician. The intervention package delivered was multifactorial and patient specific; however, information is not provided on the specific content, intensity or format of the sessions. Therefore, while these findings are promising with respect to the benefit of SLT, they do not provide the clinician with sufficient guidance on how to treat an individual patient.

Other studies have examined the effect of individual direct therapy approaches and promising results have been reported from a lingual exercise programme on swallowing recovery post-stroke, particularly incorporating biofeedback from oral pressure sensors (Yeates et al. 2008, Robbins et al. 2007). However, the existing evidence for this technique is from small case series without control groups or blinding. Lip strength training has been described as improving swallowing function, but this has yet to be investigated in stroke beyond a small retrospective study (Hagg and Anniko 2008). Other commonly used direct techniques, e.g. the effortful swallow, the massako or ‘tongue-hold’ and the Mendelsohn manoeuvre, have been shown to beneficially alter the biomechanics of the swallow during their execution (Huckabee et al. 2005, Wheeler-Hegland et al. 2008, Doeltgen et al. 2011) but are yet to be subject to controlled trials in which their benefit as individual rehabilitative techniques are examined. Biofeedback, e.g. by surface electromyography, has been advocated as a beneficial adjunct to dysphagia exercises such as the effortful swallow (Crary et al. 2004). However, due to the lack of existing evidence, the RCP National Clinical Guide-lines for Stroke recommends that biofeedback should not currently be used outside of the context of clinical trials (Intercollegiate Stroke Working Party 2012). Neuromuscular electrical stimulation (NMES) has received considerable attention as a treatment option for dysphagia but the evidence is unclear with respect to its efficacy (Lim et al. 2009, Bulow et al. 2008, Permsirivanich et al. 2009, Park et al. 2012). The Shaker or ‘head-lift’ exercise is a prescriptive programme incorporating both isotonic and isometric tasks and was found to lead to significantly improved swallow function and return to oral diet in a cross-over study of dysphagic patients of mixed aetiologies (Shaker et al. 2002). A subsequent multi-centre randomized control trial in dysphagic patients of mixed aetiologies indicated physiological
benefits of both the Shaker exercise and ‘traditional swallowing therapy’, consisting of a mixed programme of exercise and compensatory strategies (Logemann et al. 2009). However, this study failed to recruit sufficient numbers to draw reliable conclusions, with outcome data only available on 11 patients, despite recruiting from seven centres.

A commonly used treatment for sensory impairment in swallowing is thermotactile stimulation (Lim et al. 2009). However, the few studies that have examined its efficacy do not support its use in stroke-related dysphagia (Power et al. 2006, Rosenbek et al. 1998). Preliminary research from Michou et al. (2012) has indicated benefits of combining peripheral pharyngeal electrical stimulation with cortical stimulation on both neuro-physiological and swallowing safety measures in a small sample of stroke patients. Results of further studies of this new treatment are awaited to determine its role in clinical practice.

While existing studies indicate a benefit of direct dysphagia therapy, the complexity of swallowing and the heterogeneity of dysphagia, even within the classification of stroke, make it difficult to determine the true effect of different treatment techniques on specific impairments. Researchers face great challenges in designing and conducting studies with sufficient numbers of patients and reliable outcome measures to establish evidence for individual treatment techniques and the appropriate doses of these therapies, while controlling for spontaneous recovery. Until the evidence base is established, clinicians are faced with a mix of information on which to base treatment decisions. In reality, usual clinical practice is likely to be based on an assimilation of expert or consensus opinion, clinicians’ own anecdotal evidence, training they have received, studies they have read and the established approaches of their work-place. There is therefore great potential for variability in practice.

Despite this, no formal process for monitoring treatment approaches exists, and studies of practice behaviour in SLT are therefore warranted. There have been numerous surveys of SLTs’ practice patterns in dysphagia assessment with mixed patient populations (Mathers-Schmidt and Kurlinski 2003, Bateman et al. 2007, Pettigrew and O’Toole 2007, Martino et al. 2004, Cocks and Ferreira 2012) which all have shown concerning variability in practice. Recent surveys of SLTs’ approaches to the treatment of dysphagia in head and neck cancer (Krisciunas et al. 2012) and Parkinson’s disease (Miller et al. 2011) have also found limited consistency between respondents as well as poor adherence to clinical guidelines, attributed to both resource limitations and lack of evidence for existing techniques. Despite the high incidence of dysphagia in stroke and the focus on rehabilitation in the national guidelines (Intercollegiate Stroke Working Party 2012), no studies have been found that have investigated practice patterns in the treatment of dysphagia in stroke.

**Aim**

The aim was to determine the practice patterns of SLTs in the UK and Ireland with respect to direct dysphagia therapy with stroke patients.

**Methods**

**Study design**

A cross-sectional self-administered web-based survey was conducted that was aimed at all SLTs working with dysphagic stroke patients in UK and Ireland. Approval was obtained from Guy’s Research Ethics Committee, London (Reference No. 10/H0804/17).

**Selection of participants**

Inclusion criteria were SLTs currently working in stroke in the UK and Ireland. Exclusion criteria were SLTs working in other countries or with other clinical caseloads. An advert was placed in the magazine (Bulletin) sent to all members of the RCSLT, the professional body for UK and Ireland SLTs. The survey was also posted on the RCSLT Facebook (social networking) page and an e-mail invitation was sent to all UK and Ireland Specific Interest Groups (SIGs) listed on the RCSLT website with a remit to dysphagia and/or neurological disorders. Those who received the e-mail were asked to forward the invitation to relevant colleagues.

**Survey development, content and administration**

A self-complete questionnaire was designed by the authors following accepted guidance in questionnaire design (Rattray and Jones 2007, Dillman 2009). It was piloted with four SLTs working in stroke and revised following feedback. The final questionnaire consisted of 24 questions in five sections: Background informa-tion; Factors influencing decisions to recommend therapy; Content and format of therapy; Therapy outcomes; and Biofeedback. It incorporated open and closed ques-tions, multiple choice questions and scales, with automatic filtering/redirection and mandatory responses where appropriate, in order to maximize the informa-tion gained while reducing effort and time for completion (Rattray and Jones 2007). To determine fre-quency of practice approaches, respondents were asked to rate items on a five-point ordinal scale (never, rarely, half the time, frequently and always), comparable with
previous published surveys of dysphagia assessment (Mathers-Schmidt and Kurlinski 2003, Bateman et al. 2007). The questionnaire specifically asked questions about direct rehabilitative approaches to dysphagia therapy aimed at restoring swallowing function, rather than compensatory methods. Treatment approaches included in the questionnaire were determined from clinical practice, literature review and from suggestions received during the pilot stage.

The survey was administered via an online survey tool (http://www.surveymonkey.com) to enable ease of access. Participation was encouraged with an explanation of the purpose and anticipated benefits of the study, anonymity of individual responses and provision of the researcher’s contact details for queries (Dillman 2009). A reminder e-mail and Facebook message were circulated after 3 weeks and the survey remained open for 2 months from 26 May 2011.

**Data analysis**

Data were entered into a Microsoft Excel database and were analysed with descriptive statistics. For the four questions requiring a response on the five-point frequency scale (proportion of dysphagic stroke patients recommended dysphagia therapy, use of instrumental assessment to inform therapy and to measure therapy outcome and frequency of recommending specific exercises), a previously described method for determining consistency was used (Mathers-Schmidt and Kurlinski 2003). Responses were considered ‘highly consistent’ if more than 75% of respondents gave the same response, ‘moderately consistent’ if 50–75% gave the same response and ‘inconsistent’ if fewer than 50% gave the same response. To examine if there were differences in the intensity of therapy provided and consistency of practice in specific clinical settings, the responses of the SLTs who worked exclusively in distinct settings were identified, and the settings with the greatest representation of respondents were compared.

**Results**

Responses were received from 138 SLTs and 101 (73.2%) completed all questions. The survey was advertised to all SLTs who receive the Bulletin (approximately 15 000 SLTs and 90% of those registered with the RCSLT), and was accessible to all 3100 RCSLT Facebook members. Fourteen SIGs with a remit to dysphagia and/or neurological disorders were contacted from the RCSLT database. Eight replied and forwarded the information to their members (n = 393). A small proportion of RCSLT members work with stroke patients and neither the RCSLT nor the SIGs hold information on members’ specialisms, rendering it impossible to determine the exact denominator and response rate from this method of sampling.

**Results by subject**

**Background Information**

Respondents represented a wide range of number of years of working as a SLT and a range of clinical settings, with many respondents working in more than one setting (table 1).

**Factors influencing decisions to recommend therapy**

The majority of respondents (93.2%; n = 112) had access to instrumental swallowing assessments (table 1). However, over half (54.1%; n = 67) reported rarely or never conducting an instrumental assessment before recommending dysphagia exercises for stroke patients. The factors that respondents most consistently rated as essential in deciding to conduct dysphagia exercises with stroke patients (on a four-point scale from important to essential) were alertness (82.3%, n = 102), cognitive status (53.2%, n = 66), motivation (53.2% n = 66)

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**Table 1. Background information**

<table>
<thead>
<tr>
<th>Question</th>
<th>Responses</th>
<th>Percentage of respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>SLT experience (years) (n = 138)</td>
<td>0–2</td>
<td>15.9</td>
</tr>
<tr>
<td></td>
<td>3–5</td>
<td>28.3</td>
</tr>
<tr>
<td></td>
<td>6–10</td>
<td>21.0</td>
</tr>
<tr>
<td></td>
<td>11–20</td>
<td>18.8</td>
</tr>
<tr>
<td></td>
<td>21+</td>
<td>15.9</td>
</tr>
<tr>
<td>Clinical setting (n = 138)</td>
<td>Acute inpatients</td>
<td>58.0</td>
</tr>
<tr>
<td></td>
<td>Dedicated stroke unit</td>
<td>54.3</td>
</tr>
<tr>
<td></td>
<td>Community</td>
<td>47.1</td>
</tr>
<tr>
<td></td>
<td>Inpatient rehab</td>
<td>37.0</td>
</tr>
<tr>
<td></td>
<td>Outpatient clinic</td>
<td>34.1</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>5.1</td>
</tr>
<tr>
<td>Proportion of caseload adult stroke (n = 138)</td>
<td>All</td>
<td>16.7</td>
</tr>
<tr>
<td></td>
<td>Most (75%)</td>
<td>31.9</td>
</tr>
<tr>
<td></td>
<td>Half (50%)</td>
<td>20.3</td>
</tr>
<tr>
<td></td>
<td>Some (25%)</td>
<td>31.2</td>
</tr>
<tr>
<td></td>
<td>None (0%)</td>
<td>0.0</td>
</tr>
<tr>
<td>Proportion of stroke caseload dysphagia (n = 138)</td>
<td>All (100%)</td>
<td>6.0</td>
</tr>
<tr>
<td></td>
<td>Most (75%)</td>
<td>54.1</td>
</tr>
<tr>
<td></td>
<td>Half (50%)</td>
<td>24.1</td>
</tr>
<tr>
<td></td>
<td>Some (25%)</td>
<td>15.8</td>
</tr>
<tr>
<td></td>
<td>None (0%)</td>
<td>0.0</td>
</tr>
<tr>
<td>Instrumental swallowing assessments available (n = 120)</td>
<td>Videofluoroscopy</td>
<td>90.2</td>
</tr>
<tr>
<td></td>
<td>Fibreoptic endoscopic evaluation of swallowing (FEES)</td>
<td>35.3</td>
</tr>
<tr>
<td></td>
<td>Surface electromyography</td>
<td>2.3</td>
</tr>
<tr>
<td></td>
<td>Pharyngeal manometry/ manofluorography</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>6.0</td>
</tr>
<tr>
<td></td>
<td>None</td>
<td>6.8</td>
</tr>
</tbody>
</table>
and medical status (49.2%, \(n = 61\)). The majority of respondents (71.8%, \(n = 89\)) reported that they recommend direct dysphagia exercises to some of their stroke patients and 16.1% (\(n = 20\)) recommend exercises to half of their patients, with 1.6% (\(n = 2\)) recommending them to all, 7.3% (\(n = 9\)) recommending them to most and 3.2% (\(n = 4\)) recommending exercises to none of their stroke patients.

### Content and format of therapy

Figure 1 shows the frequency with which respondents ‘frequently or always’ recommend different exercises. Supervised swallows with a bolus was the most commonly recommended exercise, recommended by 73% (\(n = 90\)). The format of recommended dysphagia exercise programs reported by all respondents and those from three clinical setting subgroups is shown in table 2. The variation in responses to questions relating to the RCP guideline for therapy intensity (Intercollegiate Stroke Working Party 2012), i.e. length of therapy sessions and number of sessions per week, is shown in figures 2 and 3. Most respondents (92.9%; \(n = 105\)) reported not using a standard protocol for progressing exercises, i.e. not systematically increasing load/intensity/difficulty of exercises. A about one-third of respondents 34.5% (\(n = 39\)) reported that they did not give their patients any specific advice about rest periods, 31.0% (\(n = 35\)) reported they gave general information about avoiding fatigue, not exercising when tired or unwell and stopping when tired; 13.3% (\(n = 15\)) reported they set out an individualized programme that incorporated rest periods according to the patient’s needs. Most reported adherence to dysphagia exercise programmes was ‘fair’ (61.9%; \(n = 70\)), 19.5% (\(n = 22\)) reported it was ‘good’, 18.6% (\(n = 21\)) reported it was poor and no one reported that it was excellent.

### Table 2. Format of the exercise programme recommended by the SLTs

<table>
<thead>
<tr>
<th>Clinical setting where respondents work</th>
<th>All ((n = 113))</th>
<th>Stroke unit only ((n = 9))</th>
<th>Acute inpatient only ((n = 11))</th>
<th>Community only ((n = 10))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of times per day the patient was seen by the SLT</td>
<td>1.0 [1.0–1.0]</td>
<td>1.0 [1.0–1.0]</td>
<td>1.0 [1.0–1.0]</td>
<td>0.5 [0.0–1.0]</td>
</tr>
<tr>
<td>Number of days per week the patient was seen by the SLT</td>
<td>3.0 [2.0–5.0]</td>
<td>5.0 [3.0–5.0]</td>
<td>3.0 [2.5–5.0]</td>
<td>1.0 [1.0–1.0]</td>
</tr>
<tr>
<td>Number of sessions per day patients recommended to complete exercises independently/with carer</td>
<td>3.0 [2.0–5.0]</td>
<td>3.0 [2.0–6.0]</td>
<td>2.0 [2.5–4.0]</td>
<td>2.0 [1.3–2.0]</td>
</tr>
<tr>
<td>Number of days per week patients recommended to complete exercises independently/with carer</td>
<td>7.0 [7.0–7.0]</td>
<td>7.0 [7.0–7.0]</td>
<td>7.0 [6.0–7.0]</td>
<td>7.0 [7.0–7.0]</td>
</tr>
<tr>
<td>Number of repetitions of each exercise per set</td>
<td>5.0 [5.0–10.0]</td>
<td>5.0 [5.0–10.0]</td>
<td>10.0 [4.0–10.0]</td>
<td>5.0 [3.5–8.8]</td>
</tr>
<tr>
<td>Number of sets of each exercise per session</td>
<td>3.0 [2.0–5.0]</td>
<td>5.0 [1.0–5.0]</td>
<td>3.0 [3.0–5.0]</td>
<td>3.0 [1.0–3.0]</td>
</tr>
<tr>
<td>Average length of session (min)</td>
<td>15.0 [10.0–20.0]</td>
<td>20.0 [10.0–22.0]</td>
<td>20.0 [12.5–22.0]</td>
<td>15.0 [10.0–20.0]</td>
</tr>
<tr>
<td>Average length of therapy programme (weeks)</td>
<td>6.0 [4.0–6.0]</td>
<td>4.0 [4.0–6.0]</td>
<td>4.0 [2.0–6.0]</td>
<td>6.0 [4.5–6.8]</td>
</tr>
</tbody>
</table>

Note: Values are median (IQR).
The majority of respondents (77.9%; \( n = 95 \)) reported their patients had not experienced any complications of dysphagia therapy. Of those who reported complications, 8.2% (\( n = 10 \)) reported patients finding exercises difficult to complete or adhere to due to cognitive impairment or degree of physical impairment, 4.9% (\( n = 6 \)) reported neck pain, dizziness, shortness of breath or PEG site complications with Shaker exercise and a further 2.5% (\( n = 3 \)) reported choking or aspiration of bolus trials.

**Therapy outcomes**

Respondents were asked to indicate their two main ways of measuring outcome. The most frequent responses were advancement in the amount or consistencies of oral diet and fluids tolerated (65.1%; \( n = 69 \)), patient satisfaction (34.9%; \( n = 37 \)) and reduction in aspiration (34.0%; \( n = 36 \)). The majority (64.2%; \( n = 68 \)) reported rarely or never performing instrumental assessments to determine the outcomes and 63% (\( n = 67 \)) used no specific outcome measure or rating scale. The most commonly reported scale used to measure outcome was the Rosenbek Penetration–Aspiration scale, used by 15.1% (\( n = 16 \)). No respondent felt that all of their stroke patients improved as a result of dysphagia therapy, 33.3% (\( n = 24 \)) considered that half improved, 32.4% (\( n = 33 \)) considered that most improved, 29.4% (\( n = 30 \)) felt that some improved and 4.9% (\( n = 5 \)) reported that none improved. The most commonly reported reasons for lack of improvement with therapy were low patient motivation (47.1%; \( n = 48 \)), medical complications (40.2%; \( n = 41 \)) and dysphagia severity (31.4%; \( n = 32 \)).

**Biofeedback**

Most respondents (84.2%; \( n = 101 \)) reported not using any method of biofeedback during swallowing exercises. Of these, 94.1% (\( n = 80 \)) reported limited access to necessary equipment and 75.3% (\( n = 64 \)) reported insufficient training or experience to use biofeedback. Of the 15.8% (\( n = 16 \)) who reported that they did use biofeedback, 18.8% (\( n = 3 \)) used sEMG, others reported using a mirror (\( n = 3 \)), watching videofluoroscopies with patients (\( n = 2 \)) and using a training stethoscope (\( n = 1 \)).

**Consistency of reported practice**

No question had 100% agreement among respondents and there was variation in responses for all questions (e.g. figures 2 and 3). Table 3 shows the consistency of responses to questions requiring an answer on a five-point frequency scale. Only one response was highly consistent across respondents and within the specific clinical setting subgroups (more than 75% never use electrical stimulation) and most were answered inconsistently (less than 50% agreement between respondents).

**Discussion**

This is the first survey-based study of dysphagia therapy practices in stroke among SLTs in UK and Ireland,
Dysphagia therapy in stroke: a survey of SLTs

Table 3. Responses given with moderate or high consistency between all respondents and between those who work exclusively on a stroke unit, in an acute inpatient setting or in the community

<table>
<thead>
<tr>
<th>Consistency</th>
<th>All respondents (n = 138)</th>
<th>Stroke unit subgroup (n = 11)</th>
<th>Acute inpatient subgroup (n = 11)</th>
<th>Community subgroup (n = 12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highly consistent</td>
<td>98% never use ES</td>
<td>100% never use ES</td>
<td>82% never use ES</td>
<td>100% never use ES</td>
</tr>
<tr>
<td>Moderately consistent</td>
<td>71% recommend dysphagia exercises to some of their dysphagic stroke caseload</td>
<td>64% recommend dysphagia exercises to some of their dysphagic stroke caseload</td>
<td>64% usually recommend supervised swallow trials with bolus</td>
<td>77% recommend dysphagia exercises to some of their dysphagic stroke patients</td>
</tr>
<tr>
<td></td>
<td>61% usually recommend supervised swallow trials with bolus</td>
<td>73% usually recommend supervised swallow trials with bolus</td>
<td>50% usually conduct an instrumental assessment to determine the outcome of therapy</td>
<td>58% recommend the Mendelsohn manoeuvre about half the time</td>
</tr>
<tr>
<td></td>
<td>61% rarely recommend the Mendelsohn manoeuvre</td>
<td>73% rarely recommend the Mendelsohn manoeuvre</td>
<td>100% usually recommend the effortful swallow about half the time</td>
<td>50% recommend the effortful swallow about half the time</td>
</tr>
<tr>
<td></td>
<td>52% rarely conduct an instrumental assessment to determine the outcome of therapy</td>
<td>55% rarely recommend the effortful swallow about half the time</td>
<td>100% usually recommend the effortful swallow about half the time</td>
<td>50% recommend the effortful swallow about half the time</td>
</tr>
<tr>
<td></td>
<td>55% rarely recommend falsetto voicing</td>
<td>55% rarely recommend falsetto voicing</td>
<td>100% usually recommend the effortful swallow about half the time</td>
<td>50% recommend the effortful swallow about half the time</td>
</tr>
<tr>
<td></td>
<td>55% usually recommend tongue strength exercises</td>
<td>55% usually recommend tongue strength exercises</td>
<td>100% usually recommend the effortful swallow about half the time</td>
<td>50% recommend the effortful swallow about half the time</td>
</tr>
<tr>
<td></td>
<td>55% usually recommend tongue range exercises</td>
<td>55% usually recommend tongue range exercises</td>
<td>100% usually recommend the effortful swallow about half the time</td>
<td>50% recommend the effortful swallow about half the time</td>
</tr>
</tbody>
</table>

Notes: Highly consistent = more than 75% of respondents gave same answer. Moderately consistent = 50–75% of respondents gave same answer. ES = electrical stimulation.

Providing a valuable record against which clinicians can compare their practice. Encouragingly, nearly all respondents had access to instrumental swallowing assessments and to videofluoroscopy, which is considered the ‘gold standard’ dysphagia assessment (Logemann 1998). This is consistent with a previous survey by Bateman et al. (2007) where 97% (n = 288) of respondents had access to videofluoroscopy (within 30 miles). However, only just over one-third had access to FEES in the current study, which is surprising considering it has acknowledged benefits in clinical assessment and decision-making which are complementary to videofluoroscopy (Kelly et al. 2007).

Despite having access to some form of instrumental assessment, a high proportion of respondents reported rarely or never conducting an instrumental assessment before recommending a therapy programme or to determine the outcome. An even greater number reported not using a specific outcome measure. The limitations of bedside/clinical assessments in terms of subjectivity, poor reliability and precision are well described in the literature (McCullough et al. 2005) and accordingly the RCSLT Clinical Guidelines (2005) advises that treatment decisions should be based on instrumental assessment. The current findings indicate this recommendation is not being implemented in practice. This is consistent with the findings of a recent UK-based survey of SLTs working with dysphagia from mixed patient populations (n = 68) which found that instrumental assessment is rarely used to make oral versus non-or oral feeding decisions (Cocks and Ferreira 2012). Additionally, a previous national survey of SLTs working with patients with Parkinson’s disease found poor adherence to clinical guidelines, which was largely attributed to resource limitations, with insufficient numbers of SLTs working with this patient group (Miller et al. 2011). Resource limitations may be also relevant to the findings of the present study as instrumental assessments are relatively costly in terms of time, equipment and personnel compared with clinical bedside assessments.

The direct therapy technique most frequently recommended was supervised bolus swallows, which is undoubtedly task specific but arguably not an exercise as it does not involve challenging the system beyond typical use (Burkhead et al. 2007). Nevertheless, swallow trials comply with the principles of avoiding disuse atrophy in swallowing muscles and the ‘use it or lose it’ concept to avoid diminishing cortical re-presentation (Burkhead et al. 2007), which is particular in relevant in patients who have less need to act to the swallowing mechanism due to non-oral feeding and reduced frequency of saliva swallows (Murray et al. 1996). Tongue and lip range and strength exercises were frequently recommended in the survey. There is some preliminary evidence that progressive isometric tongue
strengthening exercises (Yeates et al. 2008) and lip force training improve swallow function (Hagg and Anniko 2008). However, no published research has investigated the effect of range of oral move-ment exercises on swallowing function in dysphagic stroke patients. The frequent use of oromotor ex-
ercises may reflect their relative ease of delivery and carry over from SLTs’ common approaches
with acquired motor speech impairments (Mackenzie et al. 2010).

SLTs typically reported seeing their patients for di-
rect dysphagia therapy once a day for 15 min, either three or five times a week and recommend daily inde-pendent practice. Although the data from the clinical setting
subgroups should be interpreted with caution due to the
small numbers in each group, the subgroup of community
based therapists notably reported seeing their patients less
frequently and for shorter sessions while SLTs working
exclusively on a stroke unit see pa-tients 5 days per week
for slightly longer sessions. The intensity of therapy
required is much debated (Intercol-legate Stroke
Working Party 2012); however, a ‘more is more’
principle is accepted (Langhorne et al. 2011). Carnaby et
al. (2006) reported more acute stroke pa-tients returning
to a normal diet and recovering swallow function after
intensive dysphagia therapy than low-intensity therapy or
‘usual care’ and the RCP recom-mends that acute stroke
patients receive 45 min of SLT therapy 5 days per week
(Intercollegiate Stroke Work-ing Party 2012). There is no
current recommendation for the amount of therapy
provided in the community; however, the RCP guidelines
are arguably applicable, for at least for a proportion of
patients, given the drive for early discharge from hospital
(Langhorne et al. 2011). While the SLTs who responded
to this survey recom-mended intensive independent
practice, increased fre-quency and length of SLT-led
sessions might improve outcomes.

No studies were found that investigated the specific
effect of different ‘dosages’ of repetitions and sets of
swallowing exercises within sessions, which may reflect
the challenges in designing such research in dysphagia.
However, the average dosages reported here are con-
sistent with accepted approaches to exercise, in which
eight to 12 repetitions and two to four sets are gen-erally
recommended to improve strength and power (Garber et
al. 2011). However, the overload principle states that
activity must consistently force the body be-yond its
usual level of activity to result in neuromuscular
adaptation; therefore, tasks must be progressed to max-
imize gains from rehabilitation and this may be more
relevant than focusing on a specified number of sets and
repetitions (Burkehead et al. 2007). This survey shows
most respondents are not systematically implementing
task progression, indicating that these principles of ex-
ercise physiology and neural plasticity, which
should underpin rehabilitation, are not being
translated into the clinical domain.

This survey indicates that clinicians are holistic
in their approach to determining outcome, assessing
im-pairment, functional outcome and psychosocial
issues. However, without specific outcome measures
and in-premental examination, there is considerable
potential for bias. Low motivation was the most
commonly cited reason for patients not improving
with direct therapy. This suggests that effective
ways of assessing and en-hancing motivation may
be indicated and should be investigated further.

There was considerable variability in the responses
received to each question for all respondents and for
the subgroups of respondents working in distinct clin-
cal settings. Previous surveys of SLTs’ approaches to
management of dysphagia have also found in-consistency between respondents (Mathers-Schmidt
and Kurlinski 2003, Bateman et al. 2007). These
indicate variability in SLT practice and service
delivery to patients. Such vari-ation may relate to the
overall paucity of evidence for dysphagia therapy, poor
uptake of existing evidence and the requirement for
ongoing professional development in SLT.

Critique of the method
In the absence of an existing tool, a new questionnaire
was developed. Face validity was determined by piloting
and it was strengthened by the systematic design process,
following recommended principles (Rattray and Jones
research is the potential for bias; individuals who choose
to respond may not be representative of the whole pop-
ulation and the responses obtained may not be reflective
of their actual practice but be subject to inaccurate recall
or instead reflect their beliefs or their desire to present
themselves in the best possible light (Bowling 2005). In
this study, however, several recommended measures were
implemented to minimize the risk of bias and to in-crease
participation; a web-based survey was conducted to
reduce participant burden and allow more complete
population coverage for sampling, anonymity was as-
sured, the rationale for the study was clearly described
and leading questions were avoided (Bowling 2005,
Rattray and Jones 2007). As the number of SLTs work-
ing with stroke patients is unknown and respondents were
not asked to identify their location it was not pos-sible to
determine a response rate or its geographical distribution.
However, we consider the sample size rea-sonable and
there was no regional or selection bias in method of
recruitment.

Most respondents reported working in more than
one clinical setting, limiting the analysis of subgroups
Due to the small numbers in each. As such, the data for the clinical subgroups presented in this study are intended as exploratory data, rather than necessarily representative of all clinicians working in these settings. An alternative approach would have been to ask respondents to answer all questions related to each different setting, but this would have made the questionnaire lengthy and increased the risk of non-response. Bias may have been introduced by the use of a multiple choice method, as the answers obtained may have been shaped by the possible responses suggested. For example, the types of therapies suggested were arguably not an exhaustive list and so frequency data were less likely to be collected on techniques not listed. However, the possible responses to multiple choice questions were carefully developed and piloted and participants were given the option to enter information in an ‘other’ or ‘comment’ category to reduce bias (Rattray and Jones 2007). This survey did not set out to record practice patterns in com-pensatory or indirect approaches to dysphagia, which are an important part of the SLT’s toolkit and warrant further study. It was also beyond the scope of this questionnaire to analyse treatment decisions based on individual patient presentations and this topic may be of interest in future studies with more detailed clinical questions.

Conclusions

This cross-sectional survey records current SLT approaches to direct therapy for dysphagia in stroke in the UK and Ireland. The survey was widely distributed using methods to reduce selection bias to reach a broad variety of SLTs working with stroke-induced dysphagia. There is a paucity of evidence for direct dysphagia thera-apy but this study revealed that the existing evidence and guidance is not filtering into clinical practice. There was wide variability in the therapy offered, which raises concerns for equity of access to care in the UK. Further research determining the best approaches to dysphagia therapy may lead to improved patient outcomes and improved uptake and implementation of evidence by the SLTs. In the meantime, methods should be developed for SLTs to discuss and disseminate existing evidence and produce a consensus to guide practice with dysphagia stroke patients.

Acknowledgements

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References


Questionnaire

Survey of speech and language therapists working in stroke

1. How many years have you been practising as a Speech and Language Therapist?
   0 – 2   3-5   6-10   11-20   21 +

2. How many years have you been working with an adult stroke caseload?
   0 – 2   3-5   6-10   11-20   21 +

3. Approximately what proportion of your current total caseload is spent working with adult stroke patients?
   All (100%)   Most (75%)   Half (50%)   Some (25%)   None

4. Please indicate the settings where you work (tick all that apply)
   Dedicated stroke unit   Outpatient clinic setting
   Acute inpatient setting   Community setting
   Inpatient rehabilitation setting
   Other (please specify) ____________________________

5. Within the past year, approximately what percentage of your stroke caseload consisted of the evaluation and/or management of dysphagia?
   None   25%   50%   75%   100%

6. Which instrumental dysphagia assessments are available to your patients (tick all that apply):
   Videofluoroscopy
   Fibreoptic Endoscopic Evaluation of Swallowing (FEES)
   Surface Electromyography
   Pharyngeal manometry/manofluorography
   None
   Other (please specify) ____________________________

7. With approximately what proportion of your dysphagic stroke patients do you recommend direct rehabilitative exercises for dysphagia?
   All   Most   Half   Some   None
   100%   ≈75%   ≈50%   ≈25%   0%

8. How frequently do you conduct an instrumental dysphagia examination, for example videofluoroscopy or FEES, before recommending a direct dysphagia exercise programme for stroke patients?
   Never   Rarely   About half the time   Usually   Always
9. Please rate the importance of these factors in your decision about whether to conduct direct dysphagia exercises with a stroke patient. Please add any factors that you feel are appropriate that are not listed.

<table>
<thead>
<tr>
<th>Factor</th>
<th>Not important</th>
<th>Of low importance</th>
<th>Important</th>
<th>Essential</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alertness</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cognitive status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Communication ability</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dysphagia severity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient motivation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient insight</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Speech and Language Therapy time pressures</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Availability of carer support for patient</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evidence base</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other factors you consider (please specify, including relative importance)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

10. Which direct dysphagia exercises do you recommend to your stroke patients and how frequently?

<table>
<thead>
<tr>
<th>Exercise</th>
<th>Never</th>
<th>Rarely</th>
<th>Half the time</th>
<th>Frequently</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lip range of movement</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lip strength/resistance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tongue range of movement</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tongue strength/resistance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thermotactile stimulation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Massako/tongue hold</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mendelsohn manoeuvre</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Falsetto voicing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shaker/head raise</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effortful swallow</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supervised swallow trials with bolus</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrical stimulation</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Other (please describe)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Please state any other direct exercises</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

11. Have any of your stroke patients ever experienced any complications of the exercises listed in question 10 (above)?

<table>
<thead>
<tr>
<th>Answer</th>
<th>Complication</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Please describe_____________________________</td>
<td></td>
</tr>
</tbody>
</table>

12.
12. Please indicate the most common format of any direct dysphagia exercise programmes you recommend

- Number of times you see patient per day
- Number of times you see patient per week
- Number of sessions you recommend patients to complete independently/with carers per day
- Number of days per week you recommend patients to complete exercises independently/with carers
- Number of repetitions of each exercise you recommend per set
- Number of sets of each exercise you recommend per session
- Average length of each dysphagia therapy session (in minutes)
- Average length of the total therapy programme (in weeks)
- Please add any comments

13. Do you give any advice about rest periods? Please specify

14. Do you use a standard method for progressing your direct dysphagia exercise programme with a stroke patient (i.e. increasing load/intensity/difficulty)?

- No
- Yes
- Please specify and/or comment

15. Overall, how would you rate stroke patients’ adherence with direct dysphagia exercise programmes?

- Excellent
- Good
- Fair
- Poor

16. Please indicate your two principal outcome measures for your direct dysphagia exercise programmes:

- Oral control/preparation
- Tongue base retraction
- Hyo-laryngeal movement
- Pharyngeal clearance
- Reduced aspiration
- Advanced oral diet/fluids
- Reduction in tube feeding dependency
- Respiratory status
- Medical status
- Nutritional status
- Hydration
- Patient satisfaction
- Others (please state)

17. How often do you conduct an instrumental dysphagia examination, e.g. videofluoroscopy or FEES, to measure outcome of a direct exercise programme for a stroke patient?

- Never
- Rarely
- About half the time
- Usually
- Always
18. Please describe any **specific outcome measures** or **rating scales** you use to determine outcome of dysphagia therapy

19. What proportion of your patients would you estimate improve as a result of their direct therapy programme?

<table>
<thead>
<tr>
<th></th>
<th>All</th>
<th>Most</th>
<th>Half</th>
<th>Some</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>≈75%</td>
<td>≈50%</td>
<td>≈25%</td>
<td>0%</td>
<td></td>
</tr>
</tbody>
</table>

20. What do you think are the **two** principal reasons for patients **not** improving as a result of their dysphagia therapy programme?

Severity of dysphagia
Other medical co-morbidities/complications
Poor comprehension of task
Speech and language therapy staff/resource shortages
Lack of support from carers
Ineffective therapy task
Poor patient motivation
Poor patient insight
Programme not completed due to transfer from hospital/caseload
Others (please state)

21. Do you use any method of biofeedback for your patients during their swallow exercise programme? If so, what method do you use?

No       Yes
Please specify __________________________ If “yes” skip to question 23.

22. If you answered “no” to question 21, please indicate any reasons why you are not currently using biofeedback with your stroke patients? Please tick all that apply.

- I don’t have access to necessary equipment
- I have not been trained or had sufficient experience
- I don’t have time
- I don’t think it is necessary in dysphagia therapy
- There is insufficient evidence for biofeedback in dysphagia therapy
- I have tried using biofeedback but don’t find it useful
- Biofeedback is not appropriate for my patients (please indicate why below)
- Other/comment

23. If you answered “yes” to question 21, do you use surface Electromyography (sEMG) as a biofeedback tool with your patients?

Yes       No

a. If yes, which swallowing exercises do you use sEMG with?

b. Which muscle groups do you target/where do you place the electrodes?
c. Please describe any advantages of using sEMG in your treatment for dysphagia

____________________

d. Please describe any disadvantages of using sEMG in your treatment for dysphagia

____________________

24. Do you have any further comments about using sEMG as a biofeedback tool with dysphagia exercises

____________________

Thank you very much for taking the time to complete this questionnaire.
## Appendix 3. FEES Protocol

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>Informed consent obtained</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of assessment:</td>
<td>Managing Consultant:</td>
</tr>
<tr>
<td>Medical team aware:</td>
<td>Managing therapist:</td>
</tr>
<tr>
<td>Endoscopist</td>
<td>Second Therapist:</td>
</tr>
<tr>
<td>Current method of nutrition</td>
<td></td>
</tr>
<tr>
<td>Other salient clinical information</td>
<td></td>
</tr>
<tr>
<td>Nasendoscope serial number:</td>
<td>Date and time of Decontamination:</td>
</tr>
<tr>
<td></td>
<td>Expiry time:</td>
</tr>
<tr>
<td>Nostril Used?</td>
<td>Adverse Reaction?</td>
</tr>
</tbody>
</table>

### Palatal Function at rest then ask patient to say:
1. Mmm ahhh
2. “Fifty fifty fifty”

### Laryngeal Anatomy, voice and vocal fold movement at rest then ask patient to:
1. Sniff
2. Ahhh Eeeeee
3. Glide up eeeeee
4. “Three green trees”
5. Cough
6. Hold breath

### Swallow Trials
Explain procedure to patient. Ensure attending to task.

If significant aspiration or risk of airway occlusion noted at any time, terminate assessment.

1. **Secretions**—Observe during above tasks before introduction of boluses. Rate: \(0 \quad 1 \quad 2 \quad 3\)

2. **Thin fluid – milk dyed with blue food colouring**
   - **Teaspoon 1**: Residue rating scale: 0: None 1: Coating 2: Mild 3: Moderate 4: Severe
   - Penetration/Aspiration Scale: 1 2 3 4 5 6 7 8
   - Comments
   - **Teaspoon 2**: Residue rating scale: 0: None 1: Coating 2: Mild 3: Moderate 4: Severe
   - Penetration/Aspiration Scale: 1 2 3 4 5 6 7 8
   - Comments
   - **Teaspoon 3**: Residue rating scale: 0: None 1: Coating 2: Mild 3: Moderate 4: Severe
   - Penetration/Aspiration Scale: 1 2 3 4 5 6 7 8
   - Comments

3. **Syrup consistency fluid – fortifresh dyed with blue food colouring**
   - **Teaspoon 1**: Residue rating scale: 0: None 1: Coating 2: Mild 3: Moderate 4: Severe
   - Penetration/Aspiration Scale: 1 2 3 4 5 6 7 8
   - Comments
   - **Teaspoon 2**: Residue rating scale: 0: None 1: Coating 2: Mild 3: Moderate 4: Severe
   - Penetration/Aspiration Scale: 1 2 3 4 5 6 7 8
   - Comments
   - **Teaspoon 3**: Residue rating scale: 0: None 1: Coating 2: Mild 3: Moderate 4: Severe
   - Penetration/Aspiration Scale: 1 2 3 4 5 6 7 8
   - Comments
<table>
<thead>
<tr>
<th></th>
<th>Residue rating scale: 0: None   1: Coating 2: Mild 3: Moderate 4: Severe</th>
<th>Penetration/Aspiration Scale: 1 2 3 4 5 6 7 8</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaspoon 2</strong></td>
<td>Comments</td>
<td></td>
</tr>
<tr>
<td><strong>Teaspoon 3</strong></td>
<td>Comments</td>
<td></td>
</tr>
<tr>
<td><strong>Slp 1</strong></td>
<td>Comments</td>
<td></td>
</tr>
<tr>
<td><strong>Slp 2</strong></td>
<td>Comments</td>
<td></td>
</tr>
<tr>
<td><strong>Slp 3</strong></td>
<td>Comments</td>
<td></td>
</tr>
</tbody>
</table>

4. **Puree – fortesip pudding dyed with blue food colouring**

<table>
<thead>
<tr>
<th></th>
<th>Residue rating scale: 0: None   1: Coating 2: Mild 3: Moderate 4: Severe</th>
<th>Penetration/Aspiration Scale: 1 2 3 4 5 6 7 8</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaspoon 1</strong></td>
<td>Comments</td>
<td></td>
</tr>
<tr>
<td><strong>Teaspoon 2</strong></td>
<td>Comments</td>
<td></td>
</tr>
<tr>
<td><strong>Teaspoon 3</strong></td>
<td>Comments</td>
<td></td>
</tr>
</tbody>
</table>

**Impression:**

**Overall severity:** 0 – normal 1 – mild 2 – moderate 3 – severe 4 - profound

**Recommendations:** Inform medical team, nursing staff and managing SLT and document in medical notes if any adverse incident or information gained from FEES that requires change in patient management

<table>
<thead>
<tr>
<th>Name:</th>
<th>Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature:</td>
<td>Signature:</td>
</tr>
<tr>
<td>Designation:</td>
<td>Designation:</td>
</tr>
</tbody>
</table>
1. How easy were the exercises without surface Electromyography?

Very easy | Quite easy | Neither easy nor difficult | Quite difficult | Very difficult

2. How easy was it to understand the information on the screen?

Very easy | Quite easy | Neither easy nor difficult | Quite difficult | Very difficult
3. How **easy** were the exercises **with** surface Electromyography?

<table>
<thead>
<tr>
<th>Very easy</th>
<th>Quite easy</th>
<th>Neither easy nor difficult</th>
<th>Quite difficult</th>
<th>Very difficult</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. Did surface Electromyography **help** you with the exercises?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

---
5. How **comfortable** was surface Electromyography?

<table>
<thead>
<tr>
<th>Very comfortable</th>
<th>Quite comfortable</th>
<th>Quite uncomfortable</th>
<th>Very uncomfortable</th>
</tr>
</thead>
</table>

6. What was **good** about using surface Electromyography?

7. What was **bad** about using surface Electromyography?
8. Would you be happy to use surface Electromyography regularly?

Yes ☑  No ☒

9. Any comments?

________________________

Thank you
Appendix 5. Effortful Swallow Rating Scale for Clinicians

Effortful Swallow Rating

Palpate each effortful swallow attempt and rate it below. If an effortful swallow is achieved the patient should be squeezing hard with the muscles of the throat and pushing hard with their tongue while swallowing.

ATTEMPT 1

1. Do you think the patient achieved an effortful swallow?
   YES  NO
2. How well was the effortful swallow completed?

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Not achieved at all (no different to normal swallow)</td>
<td>Poorly achieved</td>
<td>Fair achievement</td>
<td>Good achievement</td>
<td>Excellent achievement</td>
</tr>
</tbody>
</table>

ATTEMPT 2

1. Do you think the patient achieved an effortful swallow?
   YES  NO
2. How well was the effortful swallow completed?

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Not achieved at all (no different to normal swallow)</td>
<td>Poorly achieved</td>
<td>Fair achievement</td>
<td>Good achievement</td>
<td>Excellent achievement</td>
</tr>
</tbody>
</table>

ATTEMPT 3

1. Do you think the patient achieved an effortful swallow?
   YES  NO
2. How well was the effortful swallow completed?

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Not achieved at all (no different to normal swallow)</td>
<td>Poorly achieved</td>
<td>Fair achievement</td>
<td>Good achievement</td>
<td>Excellent achievement</td>
</tr>
</tbody>
</table>

Are you confident that you were able to palpate and assess the swallow adequately in this session?  YES  NO

Any comments
Appendix 6. Aphasia Friendly Information Sheet

Version 1 08/01/10 Guy’s Hospital Research Ethics Committee
Ref: 10/H0804/17

The Use of Surface Electromyography in Dysphagia Rehabilitation.

Can you help with a research project?

The research is being done on the stroke unit at St Thomas’ Hospital.

Sally Rosenvinge is the researcher working on the project.

This information book tells you about the research and how you can help.
What is the research project about?

Many people who have a stroke have difficulties swallowing (dysphagia).

We do not know the best way to treat dysphagia.

This research is looking at ways to treat dysphagia after stroke.
Our Research Questions:

Do swallowing exercises help people with dysphagia to improve?

Does Surface Electromyography help people with dysphagia to improve more than exercises alone?
Surface Electromyography

Sensors are put on the skin.

Muscle activity is measured.

Showing patients their muscle activity may help them to do swallowing exercises.
What will the researcher do?

Sally will look at your medical notes

She will assess your swallowing
The Speech and Language Therapists will see you regularly on the ward.

You will be put into a treatment group by chance.
GROUP 1

Swallowing assessment and advice.

No exercises
GROUP 2
Swallowing **assessment** and **advice**

**Swallowing exercises** 5 times each week with Sally

**Exercises 3 times each day** on your own or with a carer
GROUP 3
Swallowing assessment and advice

Swallowing exercises 5 times each week with Sally

Surface Electromyography with the exercises.

Exercises 3 times each day on your own or with a carer
You can **stop** the assessments or exercises at any time

![Stop sign]

We will **assess** you again **before** you leave hospital.

![Medical illustration]

We will invite you **back 3 months later** to assess your swallowing again.

![Calendar with dates marked]

**Appendix 6**
Your name will not be used.

Everything will be confidential.

Information will be stored securely

Why is this research important?

We hope to improve our understanding of treating swallowing problems following stroke.

We hope to improve future care for patients.
What will happen to the research?

We will send you a **summary** of the **findings**.

The **findings** will be **published** in **reports**.

The research will be used for **teaching** or at **conferences**.

The **findings** will help us to **improve** the service for people with swallowing problems after stroke.
Do you have to take part?

You are free to decide whether or not to take part in the research.

If you agree to take part you need to sign a consent form.

You are free to stop the research at anytime and you do not have to give a reason why.
Any questions?

If you have any questions talk to Sally

Sally Rosenvinge
Speech and Language Therapist & National Institute for Health Research/Biomedical Research Centre Research Fellow Centre for Human and Aerospace Physiological Sciences King's College London School of Biomedical Sciences 3.11 Shepherd's House Guy's Campus London SE1 1UL

020 7848 6679

sally.rosenvinge@kcl.ac.uk
The Use of Surface Electromyography in Dysphagia Rehabilitation.

Supporting Information for Consent Form

I have been given information about the study

Yes  No

I understand the information about the study

Yes  No
I have been able to ask questions about the study.

Yes | No

I understand that I can stop the study at any time.

I do not have to give a reason.

This will not affect my care.

Yes | No
I allow the researcher to look at my medical notes

Yes  No

I understand that my doctor will be told that I am taking part in the study

Yes  No
I understand that **information** will be **collected** from my assessments.

This information will be used in the study.

**It will be stored securely.**

This information will **not include** my **name**.

[Yes] [No]
I agree to take part in the study

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

Name | Signature | Date

My signature as witness certifies that I witnessed the “Consent Interview” for the research study named above and the participant gave verbal consent in my presence.

Name of witness | Signature | Date

Researcher | Signature | Date
Appendix 8. Baseline and Outcome Measures

BASELINE AND OUTCOME MEASURES

Functional Oral Intake Scale (FOIS) (Crary et al., 2005)
8. Nothing by mouth (NPO)
9. Tube dependent with minimal attempts of food or liquid
10. Tube dependent with consistent intake of liquid or food
11. Total oral diet of a single consistency
12. Total oral diet with multiple consistencies but requiring special preparation or compensations
13. Total oral diet with multiple consistencies without special food preparation, but with specific food limitations
14. Total oral diet with no restrictions

Secretion Scale (Murray et al., 1996)
Residue Scale (Kelly et al., 2006)
0 Normal
0 None
1 Outside laryngeal vestibule
1 Coating (trace)
2 Pooling in vestibule transiently
2 Mild
3 Pooling within vestibule consistently
3 Moderate
4
4 Severe

Penetration aspiration scale (Rosenbek et al., 1996)
1 Material does not enter airway
2 Material enters airway, remains above vocal cords and is ejected from the airway
3 Material enters airway, remains above vocal cords and is not ejected from the airway
4 Material enters the airway, contacts the vocal cords and is ejected from the airway
5 Material enters the airway, contacts the vocal cords and is not ejected from the airway
6 Material enters the airway, passes below the vocal cords and is ejected into the larynx or out of the airway
7 Material enters the airway, passes below the level of the vocal cords and is not ejected from the trachea despite effort
8 Material enters the airway, passes below the level of the vocal cords and no effort is made to eject

Overall severity rating from FEES
0 – normal
1 – mild
2 – moderate
3 – severe
4 - profound
Appendix 9. Motivation Scale

How **keen** are you to do your **swallowing exercises**?

[Diagram showing a scale from 0% to 100% with different expressions representing different levels of motivation]
Appendix 10. Practice log

Swallowing Exercise Chart

Complete your exercises **three times** a day

Tick **when** you do the exercises in the chart

If you have **not** done the exercises please say **why**

<table>
<thead>
<tr>
<th>Day</th>
<th>Time</th>
<th>Exercises done?</th>
<th>Comment?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>✅</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>❌</td>
<td></td>
</tr>
<tr>
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</tbody>
</table>
## Appendix 11: Treatment Record

<table>
<thead>
<tr>
<th>Date</th>
<th>Start time</th>
<th>End time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient number</td>
<td>Position/alertness</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Comments from SLT incl FOIS</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Details from med notes/HCP</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Consent to session?</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Bolus type</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Repetition number</th>
<th>Task</th>
<th>Comment. Note any adverse signs, comments from patient, signs of fatigue. Indicate rest period and length.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

Name_________________________Signed_________________Date________
Appendix 12: Client Satisfaction Questionnaire

CLIENT SATISFACTION QUESTIONNAIRE (Larsen 1979)

Please help us improve our program by answering some questions about the services you have received. We are interested in your honest opinions, whether they are positive or negative. Please answer all of the questions. We also welcome your comments and suggestions. Thank you very much; we really appreciate your help.

Circle your answer:

1. How would you rate the quality of service you have received?
   
<table>
<thead>
<tr>
<th>4</th>
<th>3</th>
<th>2</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent</td>
<td>Good</td>
<td>Fair</td>
<td>Poor</td>
</tr>
</tbody>
</table>

2. Did you get the kind of service you wanted?
   
<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>No, definitely</td>
<td>No, not really</td>
<td>Yes, generally</td>
<td>Yes, definitely</td>
</tr>
</tbody>
</table>

3. To what extent has our program met your needs?
   
<table>
<thead>
<tr>
<th>4</th>
<th>3</th>
<th>2</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almost all of my needs have been met</td>
<td>Most of my needs have been met</td>
<td>Only a few of my needs have been met</td>
<td>None of my needs have been met</td>
</tr>
</tbody>
</table>

4. If a friend were in need of similar help, would you recommend our program to him or her?
   
<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>No, definitely not</td>
<td>No, I don’t think so</td>
<td>Yes, I think so</td>
<td>Yes, definitely</td>
</tr>
</tbody>
</table>

5. How satisfied are you with the amount of help you have received?
   
<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quite dissatisfied</td>
<td>Indifferent or mildly dissatisfied</td>
<td>Mostly satisfied</td>
<td>Very satisfied</td>
</tr>
</tbody>
</table>

6. Have the services you received helped you to deal more effectively with your problems?
   
<table>
<thead>
<tr>
<th>4</th>
<th>3</th>
<th>2</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, they helped a great deal</td>
<td>Yes, they helped</td>
<td>No, they really didn’t help</td>
<td>No, they seemed to make things worse</td>
</tr>
</tbody>
</table>

7. In an overall, general sense, how satisfied are you with the service you have received?
   
<table>
<thead>
<tr>
<th>4</th>
<th>3</th>
<th>2</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very satisfied</td>
<td>Mostly satisfied</td>
<td>Indifferent or mildly dissatisfied</td>
<td>Quite dissatisfied</td>
</tr>
</tbody>
</table>

8. If you were to seek help again, would you come back to our program?
   
<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>No, definitely not</td>
<td>No, I don’t think so</td>
<td>Yes, I think so</td>
<td>Yes, definitely</td>
</tr>
</tbody>
</table>

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