Development and Evaluation of a Mobile Health Solution for Patients with Dysphagia

by

Gabriela Constantinescu

A thesis submitted in partial fulfillment of the requirements for the degree of

Doctor of Philosophy

in

Rehabilitation Science

Faculty of Rehabilitation Medicine

University of Alberta

ABSTRACT

Mobile health (mHealth) systems (e.g., apps and hardware for mobile technologies) hold potential to address long-standing gaps in access to healthcare. However, the design and usability of mHealth technologies are central to ensuring uptake and adherence for patients. The work in this dissertation constitutes a systematic and documented approach to the design and development of an mHealth system for patients in need of swallowing therapy.

In the first study, we compared the signal to noise ratio (SNR) from two surface sensors, surface electromyography (sEMG) and mechanomyography, in healthy participants and in patients with a history of head and neck cancer, to determine which sensor would be used in the mHealth device. Following this study, sEMG sensors were recommended for the device as they yielded better SNR and test-retest reliability.

In the second study, patients were interviewed to identify themes on facilitators and barriers to home-based rehabilitation therapy without a device. Then, through a second set of interviews, preferences for design concepts of biofeedback visuals in the application (app) were also sought. Simple, straightforward visuals were recommended to represent swallowing biofeedback during exercise trials.

Next, an automated swallow-detection algorithm was developed by the development team, using signals collected from healthy participants. This algorithm was central to the app as it ensures that signals arising from swallow or swallow-like exercises are reinforced for patients, while non-swallow movements are ignored. In the third study, we evaluated this automated swallow-detection algorithm in healthy and head and neck

cancer participants. The performance of the algorithm was robust even with head and neck cancer patients and hence no modifications to it were recommended before incorporating it in the app. In the final research paper we tested the usability of the mHealth system with head and neck cancer patients. This work identified additional information and development needs to be addressed before sending patients home with the system.

The dissertation concludes with a viewpoint paper that offers perspectives on the development of mobile health technologies within an academic context. In this dissertation we have developed and evaluated this mHealth system and readied it for validation on patients. We hope that the studies herein serve as examples to other researchers, clinicians, and industry wishing to develop mHealth solutions for their patients.

PREFACE

Some of the research conducted for this thesis forms part of a research collaboration, led by Professor Jana Rieger at the University of Alberta. The mobile health device developed and evaluated, Mobili-T^{TM}, was created by Professor Jana Rieger's team, of which I also was a member. Chapters 2, 3, 4, and 5 are published articles. My contribution to these manuscripts is outlined in Appendix A. The research projects, of which this thesis is a part, received research ethics approvals from the University of Alberta Research Ethics Board (Chapters 2, 3, and 4), and from the Health Research Ethics Board of Alberta (Chapter 5). These approvals are outlined in Appendix A. Associated site approvals also were obtained.

ACKNOWLEDGEMENTS

I would like to begin by thanking my two primary supervisors, Dr. Jana Rieger and Dr. William Hodgetts, who have truly mentored me with flow and perseverance in mind. I feel profoundly grateful to have found myself under their guidance over the years and I know that I will continue to learn from them. I also would like to thank my Committee members, Dr. Kerry Mummery and Dr. Sid Fels for their perspectives in the theoretical and practical aspects that shaped this dissertation, as well as my external reviewers, Drs. Martin Ferguson-Pell, Plinio Morita, and Pierre Boulanger for their time and feedback.

I am extremely grateful and indebted to all participants and patients for their time, input, and supportive feedback in this research. Without them, there would be no Mobili-T.

I also would like to thank my wonderful friends for being such a strong and effective cheerleading squad. Special mention goes to my closest team members, Kristina Kuffel and Dylan Scott, for their friendship and unrelenting support. A big thank you also goes to Matthew Yarmon for his patience and kindness and to my parents for giving me the courage to be myself no matter what pressures I may face.

Thank you to all the funders for their generous support of this work: Alberta Cancer Foundation, Alberta Innovates Health Solutions, the Covenant Health Education Fund, the Mickleborough family, the Canadian Federation of University Women, the Alberta College of Speech Language-Pathologists and Audiologists, the University of Alberta Graduate Research Association, the Faculty of Graduate Studies and Research and the Faculty of Rehabilitation Medicine.

Thank you also to the Institute for Reconstructive Medicine and my friends and colleagues there for their assistance with recruitment and for being such great promoters of this work.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABBREVIATIONS

ADC	Analog to Digital Converters
AHRQ	Agency for Healthcare Research and Quality
ASQ	After-Scenario Questionnaire
FOIS	Functional Oral Intake Scale
HNC	Head and Neck Cancer
HPV	Human Papilloma Virus
iRSM	Institute for Reconstructive Sciences in Medicine
MBS	Modified Barium Swallow
mCSES	Modified Computer Self-Efficacy Scale
mHealth	Mobile Health
MMG	Mechanomyography
PCB	Printed Circuit Board
PSSUQ	Post-Study System Usability Questionnaire
RMS	Root Mean Square
sEMG	Surface Electromyography
SNR	Signal to Noise Ratio
UES	Upper Esophageal Sphincter
WHO	World Health Organization

GLOSSARY OF TERMS

Dry swallow	Saliva swallow
Dysphagia	Difficulty swallowing
Effortful maneuver swallow	Swallow-specific behavioural exercise, where an individual is asked to swallow with maximal effort
Gamification	Use of game elements and game design techniques in a non-game context
Mendelsohn maneuver swallow	Swallow-specific behavioural exercise, where an individual is asked to swallow and prolong laryngeal elevation for three to five seconds
Mobile health	Medical and public health practice supported by mobile devices and can include mobile phones, patient monitoring devices, personal digital assistants and other wireless devices
Positive Predictive Value	(True Positives)/ (True Positives + False Positives)
Sensitivity	(True Positives)/ (True Positives + False Negatives)
Thin liquid	Liquid consistencies such as water, coffee, tea; un-thickened consistency

CHAPTER 1: INTRODUCTION

Mobile technologies have profoundly changed the world in the past few decades, allowing users to access information quickly, perform tasks remotely, and track data for self-improvement. More recently, and with increased momentum in the last decade, mobile technologies are addressing existing gaps and challenges in healthcare. These developments, however, have focused on prominent clinical populations such as diabetes and cardiovascular disease, and less so on disorders with relatively low public awareness such as dysphagia, a problem that manifests in unsafe swallowing, malnutrition, dehydration, and social isolation.

Dysphagia of varying degrees of severity affects 20% of all adults over 50 and over two thirds of head and neck cancer patients. Access to one-on-one effective swallowing treatment is restricted by a lack in resources and proximity to a clinic. Mobile technologies provide the opportunity to assist some of these patients in completing swallowing therapy in their own homes, while still under remote clinical supervision. These devices also can track adherence to home-based therapies, offering a way for treatment outcomes to be studied in relationship to treatment dose.

Our team set out to create a mobile health device with an initial focus on patients with head and neck cancer. Creating a mobile device, however, will not suffice in improving access to care; one must also consider uptake and adherence to swallowing therapy with the device. Therefore the development of this mobile technology also involved feedback from patients in conjunction with treatment goals.

The following chapter offers readers general background on the patient population and mobile health, followed by the objectives of this dissertation. Each subsequent chapter also includes more detailed background specific to the study.

Head and Neck Cancer

Head and Neck Cancer (HNC) is the sixth most common malignancy worldwide and one with the most complex care in patient survivorship (WHO, 2014). HNC refers to different subgroups of malignancies that can occur in the oral cavity, pharynx, larynx, as well as the lips, paranasal sinuses, and nasopharynx. It was estimated that 529,000 new cases of HNC occurred in 2012 worldwide. In the United States, this number was estimated at 42,440 in 2014, adding to the 281,591 people there already living with this disease (Siegel, Ma, Zou, & Jemal, 2014). In Canada, 4,300 new HNC cases were estimated for the same year (Statistics, 2014).

Alcohol consumption, smoking, poor oral hygiene and genetic features are key risk factors to the development of HNC. In addition, in the last decade it has become clear that a sub-set of HNC covering approximately 25% of the worldwide cases is associated with certain human papilloma virus (HPV) types, referred to as high-risk HPV (Kreimer, Clifford, Boyle, & Franceschi, 2005).

The prevalence of HNC is not equal between sexes, with men being affected almost twice as often as women (WHO, 2014). Most often, HNC patients are over the age of 50, with a median age of 62 at diagnosis. The survivorship is only 66% at five years, but this outcome has been steadily improving over the last three decades. These trends are shifting to an increase in HNC patients living with post-treatment effects. On top of that, the incidence is rapidly rising due to an increase in HPV-related cases (Forte, Niu, Lockwood, & Bryant, 2012; Hwang, Hsiao, Tsai, & Chang, 2015; Ryerson et al., 2008).

HNC can be addressed with surgery, radiation therapy, chemotherapy, or a combination of these. Advancements in each of these techniques have resulted in improvement of disease-specific survival (Cosmidis et al., 2004; Mendenhall et al., 2006); however, these treatments continue to impact swallowing function because of the structures involved. To understand why this happens, the physiology of a normal swallow will be described next.

Swallowing Physiology in Healthy Adults

A healthy swallow allows for the safe passage of food from the oral cavity to the stomach, while protecting the airway. A typical adult will swallow approximately 500 times a day (Shaw & Martino, 2013; Vaiman, Eviatar, & Segal, 2004), and the pharyngeal response is quick, occurring in less than a second (Matsuo & Palmer, 2008). However, swallowing is complex, requiring structural integrity of the upper aerodigestive tract and the precise coordination of more than 25 muscles and six cranial nerves (Crary & Groher, 2003; Dysphagia Section et al., 2012; Shaw & Martino, 2013). Swallowing has been described as a programmed response to sensory stimuli (Crary & Groher, 2003), as the physiology can adapt to different bolus volumes and textures (Butler, Stuart, Castell, et al., 2009). The pharynx, a key structure of the aerodigestive tract due to its connection to both the respiratory and digestive systems, is made up of three main regions: the nasopharynx, located between the skull base and the superior surface of the soft palate; the oropharynx, demarcated by the oral cavity anteriorly, the uvula superiorly and the superior aspect of the epiglottis (or hyoid bone) inferiorly; and the hypopharynx, located between the epiglottis and the esophagus.

Stages of the swallow. Swallowing is commonly described as having four interdependent and overlapping stages: oral/preparatory, oral, pharyngeal, and esophageal, where the first two stages are thought to be primarily under voluntary control (Crary & Groher, 2003; Martin-Harris et al., 2008; Shaw & Martino, 2013). The first stage is marked by the preparation of food, which is contained from spilling into the airway and processed through mastication and salivation. Three major pairs of salivary glands are responsible for the production of 95% of saliva: parotid, sublingual, and submandibular (Shaw & Martino, 2013). The posterior oral tongue elevates and soft palate drops to create a seal and cup the bolus; the soft palate elevates and posterior tongue drops.

The next stage of the swallow, the oral stage, starts as the posterior oral tongue and the velum (palatopharyngeal muscle and levator muscle of velum palatinum) elevate to create a seal between the oropharynx and the nasopharynx. Extrinsic tongue muscles propel the food posteriorly, from the oral cavity into the oropharynx.

The most complex phase of the swallow is the pharyngeal stage, where the food passes through the pharynx and upper esophageal sphincter (UES). During this stage, the suprahyoid muscles (mylohyoid, stylohyoid, geniohyoid, and anterior and posterior bellies of digastric) contract, directing the hyoid bone superiorly and anteriorly (Pearson, Langmore, Yu, & Zumwalt, 2012). This hyoid movement is important for a number of reasons. First, it helps pull the larynx under the tongue base and invert the epiglottis. Second, it aids in the elevation of the larynx and hypopharynx, which creates a negative pressure on the bolus and helps drive it inferiorly. Third, this elevation results in a biomechanical force that pulls the cricoid cartilage up and away from the posterior pharyngeal wall, subsequently opening the cricopharyngeal muscle and the UES (Matsuo & Palmer, 2008). The UES, sometimes referred to as the pharyngoesophageal segment (PES), is a functional unit made up of the circular and longitudinal musculature of the upper third of the esophagus. Closed at rest, the UES opens via two mechanisms in addition to the contraction of the suprahyoid and thyrohyoid musculature: the cricopharyngeus muscle relaxes and the pressure of the food expands this sphincter (Matsuo & Palmer, 2008). The food is propelled along by the palatopharyngeal muscle, the stylopharyngeus muscles as well as the superior, medial, and inferior constrictor muscles.

Lastly, the esophageal stage describes the transport of food from the cervical to the distal segments of the esophagus, before it finally empties in the stomach. Although these stages are commonly used when referencing swallowing, oral and pharyngeal components can overlap and are interdependent (Martin-Harris, Michel, & Castell, 2005).

Airway protection. Airway protection, a critical element of a normal swallow, is achieved through several mechanisms, such as airway closure via the adduction of the true and false vocal folds during the swallow, base of tongue retraction, epiglottic inversion, and the sensory information from the abundant mechanical, chemical and water-respondent receptors in this area. If material touches these receptors, a cough reflex is triggered to help clear it. However, when food is misdirected toward the airway, penetration or aspiration occurs: penetration describes material that has entered the airway above the level of the vocal folds, while aspiration describes food or saliva that has passed beyond this landmark. When aspiration occurs in the absence of any clinical sign, such as coughing, it is called 'silent' aspiration. Swallowing is an intricate process and an insult to the structures involved, such as that received during treatment for HNC, can result in swallowing impairments. Dysphagia is defined as difficulty with swallowing (Crary & Groher, 2003), although this definition may need to include additional descriptors such as amount and frequency of aspiration, as both penetration and aspiration can occur in healthy older adults (Butler, Stuart, Markley, & Rees, 2009).

Swallowing After Treatment for HNC

HNC is one of the most common etiologies of dysphagia (Bhattacharyya, 2014). Surgery or radiation in this area can damage the muscles and the nerves innervating them. Furthermore, radiation to this area can result in fibrosis, atrophy, and loss of muscle fibers (Dysphagia Section et al., 2012). These treatments can compound one another, as is the case of adjuvant radiation therapy received following surgical resection.

Dysphagia following treatment for HNC has been described as including a reduction in the efficiency of the swallow due to reduced movement of the swallowing mechanism, odynophagia (painful swallowing), and xerostomia (dry mouth). The sequelae of HNC treatment may lead to longer durations for various aspects of the swallow, reduced laryngeal excursion, poor clearance of ingested food, and poor airway protection (Arrese & Lazarus, 2013; Frowen & Perry, 2006; Hutcheson & Lewin, 2013; Pauloski, 2008). Aspiration can occur before and during the swallow as well. In fact, aspiration in this population has a high incidence ranging from 50% to 77% and is most often silent, meaning without a cough reflex (Frowen & Perry, 2006).

Managing dysphagia is crucial because swallowing impairments can have serious consequences on health, including aspiration pneumonia, airway obstruction, dehydration, and cachexia, as well as associated psychosocial costs, such as social isolation and depression (Couch et al., 2015; Dysphagia Section et al., 2012).

Dysphagia Management

Dysphagia can be managed in a number of ways, depending on the severity, etiology, and prognosis. For example, treatment of swallowing impairments can involve the use of compensatory techniques (e.g., modified viscosities, positioning techniques), stimulatory approaches (e.g., thermo-tactile, chemo-gustatory, electrical, vibratory) or rehabilitative exercises to improve range of motion, strength, coordination, and endurance of swallowing muscles.

An important aspect of rehabilitative exercises is to overload the system because this forces activation of residual muscles beyond their level of typical activity and results in adaptation (Burkhead, Sapienza, & Rosenbek, 2007). There are different ways to challenge the system. For example, strength-training focuses on force exertion and uses high loads with low repetitions; endurance training on the other hand, focuses on repeated contractions and uses low loads with high repetitions. Two rehabilitative exercises that overload the system are the effortful swallow and the Mendelsohn maneuver swallow. These also are the most widely documented exercises that are swallowing-specific (Wheeler-Hegland, Rosenbeck, & Sapienza, 2008).

Both the Mendelsohn maneuver and effortful swallows rely on principles of experience-dependent neuroplasticity, meaning that they involve swallow-like tasks

(Robbins et al., 2008). The Mendelsohn maneuver has been associated with longer and stronger pharyngeal contraction (Boden, Hallgren, & Witt Hedstrom, 2006) as well as changes in UES pressure before and after closure and increased nadir (lowest point) UES pressure (Hoffman et al., 2012). This maneuver involves prolonged hyolaryngeal elevation at the height of the swallow for a few seconds (Kahrilas, Logemann, Krugler, & Flanagan, 1991; Mendelsohn & McConnel, 1987). The effortful swallow has been shown to improve base of tongue to posterior pharyngeal wall retraction (Lazarus, Logemann, Song, Rademaker, & Kahrilas, 2002), oral pressure (Fukuoka et al., 2013), and higher UES relaxation duration (Hiss & Huckabee, 2005). Although evidence for the effortful swallow exists mainly in the context of a compensatory maneuver (Hind, Nicosia, Roecker, Carnes, & Robbins, 2001; Hiss & Huckabee, 2005; Wheeler-Hegland et al., 2008), clinicians also use it as a rehabilitative exercise (Arrese & Lazarus, 2013). Huckabee et al. found that the effortful swallow results in greater benefits when the instructions emphasize creating a pressure between the tongue and the palate, rather than in the pharynx (Huckabee & Steele, 2006). Biofeedback using surface electromyography (sEMG) is a useful tool to monitor the activation of submental muscles during these exercises (Wheeler-Hegland et al., 2008).

Visual Biofeedback in Rehabilitation

Biofeedback, a concept dating back to 1969 (Miller, 1989), has been defined as the use of technology to increase awareness of covert physiological processes by providing real-time, precise representations of the activity (Chen et al., 2006). Biofeedback has two broad advantages when coupled with regular therapy: (1) it recognizes and rewards small changes that will eventually lead to meaningful functional improvements; and (2) it increases self-efficacy in patients by drawing attention to these small signs of progress (Miller, 1989).

sEMG feedback, a type of visual biofeedback, has been used extensively in rehabilitation medicine by physiotherapists, occupational therapists, and speech-language pathologists because of the advantages this technology holds over intramuscular EMG. sEMG sensors are non-invasive, easy to apply, and require minimal training, allowing even relatively naïve consumers to benefit from visual biofeedback. The signal detected at the surface of the skin comes from the action potentials of motor units, where muscles closer to the skin generate a signal with a larger amplitude and higher frequency than those of muscles further away from the surface (Stepp, 2012).

When sEMG is used as an adjuvant to swallowing therapy, the activity of submental muscles (mylohyoid, geniohyoid, and anterior belly of digastric) is monitored. Specifications for electrode diameters and inter-electrode distances were created by SENIAM, a European network that generates recommendations for EMG. These specifications depend on the size of the muscle observed. The placement of the sensors also plays an important role: the ground electrode should be placed on a fixed surface, such as the body of the mandible; the remaining two electrodes should align parallel to the muscle fibers as this results in stronger signals (Vigreux, Cnockaert, & Pertuzon, 1979). Minimizing noise while maximizing desired signal is important for obtaining waveforms with good signal to noise ratio (SNR) for subsequent analysis. A high SNR can contribute to easier identification of swallowing exercise trials and muscle activation relative to a set target.

Existing Challenges to Swallowing Therapy

Although effective therapies exist (Burkhead et al., 2007; Carnaby-Mann & Crary, 2010), current service delivery models are not ideal. First of all, access to intensive therapies such as the ones studied in controlled research studies is limited. The use of visual biofeedback with these therapies also is restricted to patients who can travel to a clinic during the day, several times in a week. Furthermore, not all clinics can afford the technologies and the clinical time to provide therapy in this way. In reality, there is no gold standard, based on evidence and there is no consensus, for how to best address dysphagia in patients with head and neck cancer (Carnaby & Harenberg, 2013; Krisciunas, Sokoloff, Stepas, & Langmore, 2012). Moreover, patient compliance to home-based therapies is not adequately captured, making it difficult to draw conclusions on the number of trials and effort expended. Shinn and colleagues reported that as little as 13% of patients fully adhered to the treatment recommendations and 58% of participants did not attempt a single exercise (Shinn et al., 2013), although these numbers can vary based on whom you ask (patients or clinicians) and how adherence is measured (Hutcheson & Lewin, 2013; Krisciunas et al., 2012). From a clinical perspective, the provision of swallowing therapy can be improved in several domains: by providing timely access to intensive therapy programs, by striving to incorporate visual biofeedback, and by capturing adherence accurately. From a research perspective, a better understanding of treatment adherence and treatment dose is required (Burkhead et al., 2007; Krisciunas et al., 2012).

Mobile Health Solutions

In addition to the clinical challenges outlined above, there is a strong push for standardizing practice. As early as 2001, the Agency for Healthcare Research and Quality (AHRQ) in the United States published on translating research into practice and called for improvements to address accountability and standardized reporting as well as to reduce disparities in healthcare delivery (AHRQ, 2001). Providing standardized care that can reach all those who need it will become an even greater concern due to a growing senior population and an ageing health workforce. In 2013, the World Health Organization (WHO) published a news release stating that the world would be short of 12.9 million healthcare workers by 2035 (WHO, 2013). These existing clinical challenges coupled with recent technological advancements in mobile technologies create an opportunity for transforming the way in which healthcare is delivered. However, despite the potential for these technological solutions, the adoption of mobile health (mHealth) remains low.

mHealth is defined as medical and public health practice supported by mobile devices and can include mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices (WHO, 2011). Patient monitoring technologies use remote sensors that connect with mobile phones or tablets to facilitate data transmission to remotely manage, monitor, and treat a patient's illness, thereby reducing the number of hospital visits (WHO, 2011). One such example is the AliveECG App (AliveCor Inc., USA), a mobile ECG tracking device that provides comparable recordings to standard ECG machines and allows users to share their data with their physician (Saxon, 2013).

One of the greatest documented barriers to widespread implementation of mHealth is competing health system priorities such as addressing staff shortages and budget reductions (WHO, 2011). For mHealth to be considered, the technology requires evaluation so that high-level evidence for better outcomes and access can guide decision-making among policy-makers and administrators (Labrique, Vasudevan, Kochi, Fabricant, & Mehl, 2013; WHO, 2011). It is recognized that clinical validation is required. However, successful uptake of mHealth has been linked to end-user engagement, where design and development should focus on the health and patient needs rather than the technology (Labrique et al., 2013). Few teams fully document their development process, from the research and ideation stages to usability and feasibility testing.

Developing a mobile health technology that can be used to deliver swallowing therapy and track daily exercise completion can address several challenges in dysphagia management. A mobile device can improve patient access to intensive, quality care. Furthermore, a technology that accurately tracks adherence can be used to research appropriate exercise intensity. Until now, treatment dose has been difficult to measure because adherence to home-based therapy is a complex construct and existing measures of self-reported adherence lack psychometric validation (Bollen, Dean, Siegert, Howe, & Goodwin, 2014). However, the development of this mobile device also needs to tackle known barriers to mHealth uptake by incorporating end-user input, instrumental validation, as well as usability and feasibility testing of the device.

Dissertation Objectives

The research outlined in this dissertation contributed to the development and evaluation of a mobile health solution for swallowing therapy, Mobili-T, short for Mobile Therapy. To assist the reader in appreciating the scope of this project, a few points will be mentioned on the larger team and its aims. The development team included biomedical engineers, industrial designers, software developers, patients, and clinicians. First, the team was responsible for project-management related details, such as documentation, as well as applications for a patent and approval from Health Canada. Second, the team developed the mobile health technology that includes: (A) a patient user system, (B) a data storage system, and (C) a clinician portal (Figure 1). The goals of this team included collaborative design, bench-top testing, and internal usability testing. This author was involved in many of these phases, offering expertise and clinician perspectives; however, four formal studies were carried out and included in this dissertation. All studies involved the patient user system (A).

Figure 1. Context of Study.

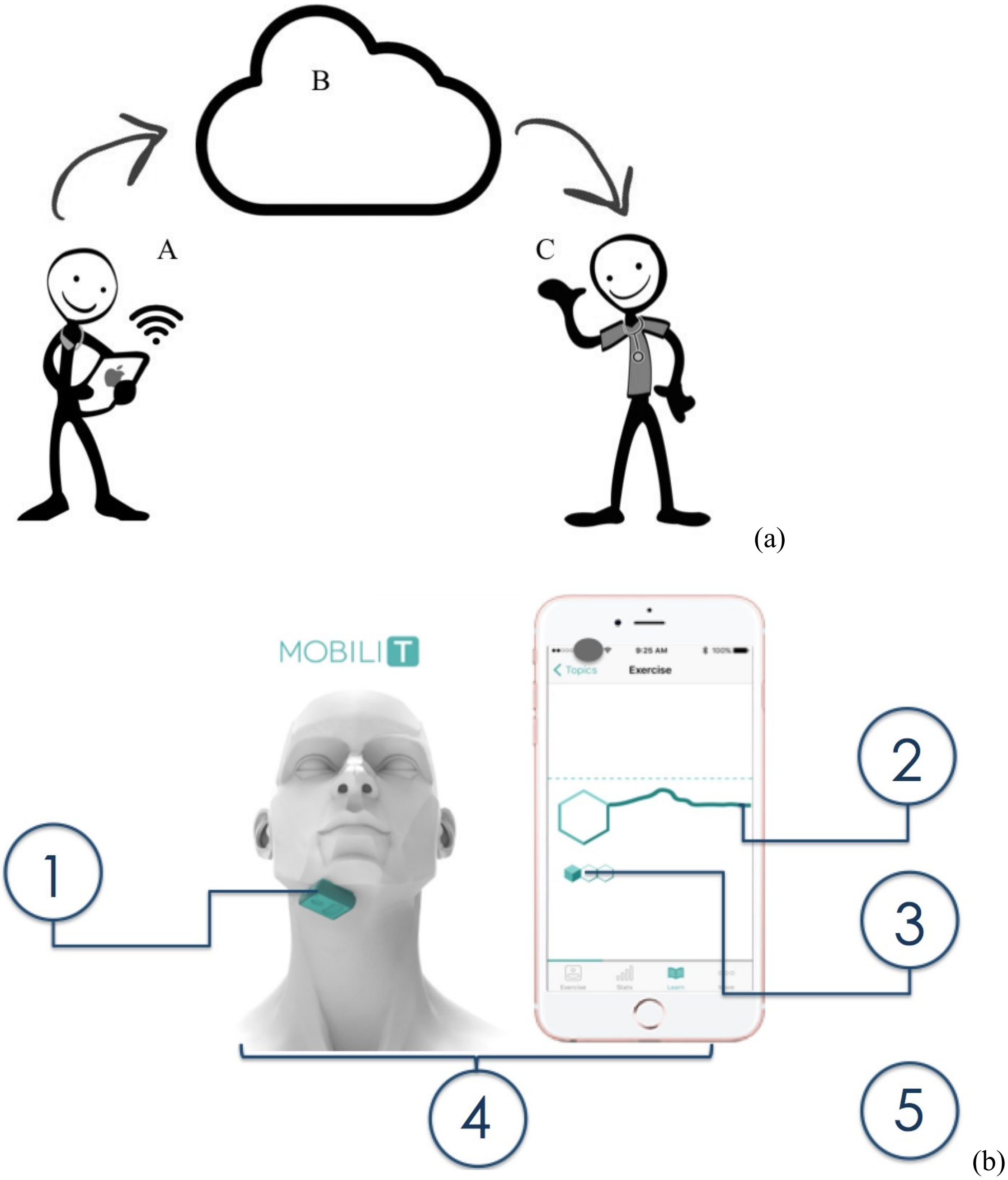


Figure 1. (a) Scope of larger Mobili-T$^{\text{TM}}$ project: (A) patient system comprised of hardware and smartphone application; (B) data storage system; (C) clinician portal. (b) A diagram of how each chapter relates to different aspects of the mobile health system: study 1 (chapter 2) relates to the hardware; study 2 (chapter 3) relates to the visual biofeedback in the application; study 3 (chapter 4) relates to the back-end

algorithm; study 4 (chapter 5) relates to the usability of the entire system; and study 5 (chapter 6) is an opinion paper on the development of mobile health technologies in the academic setting.

Study 1: Selecting the appropriate surface sensors. Our goal was to recommend to the development team one of two surface sensor technologies to be used with Mobili-T. The two surface sensor technologies selected for comparison were sEMG and MMG. sEMG was selected as it was the gold standard sensor used in clinic at the time this research was conducted. MMG was selected for a few reasons related to development: the hardware would be less complex if MMG were to be used; MMG sensors would not require electrode gel; and MMG sensors do not have the inherent 50 Hz noise. Muscle contraction occurs over several steps from action potentials arriving from motor units all the way to muscle shortening; because these sEMG and MMG sensors have different detection periods, they also are susceptible to different sources of noise. This study compared the signal to noise ratio (SNR) from sEMG and MMG in healthy participants and in patients with a history of HNC.

Study 2: Using patient input to inform software design. In this study we wished to inform the visual biofeedback design as we hypothesized this would be the most critical aspect of this mobile health system. Above all, patients need to perform the swallowing exercises correctly and stay engaged with the application long enough to see the therapeutic benefit from the exercise. In this study, patients were interviewed to identify themes on facilitators and barriers to home-based rehabilitation therapy without a device.

Preferences for design concepts of biofeedback visuals in the app also were sought. The information gained from this study was used to inform the design of the mHealth app.

Study 3: Evaluation of an automated swallow-detection algorithm. The intent is for the mobile health system to be used independently by patients, at home. Therefore, the system needs to be able to recognize whether the signal detected was generated by a swallow or by movement. To achieve this, an automated swallow-detection algorithm was developed by the team, using signals collected from healthy participants. This algorithm will be used by the app to ensure signals arising from swallow or swallow-like exercises are reinforced, while non-swallow movements are ignored. Study 3 evaluated the automated swallow-detection algorithm to determine if it required modification before use with HNC patients.

Study 4: Usability testing. Once an iteration of the app was deemed sufficiently functional and useable by the development team, usability testing with HNC patients was conducted. Systematic usability testing is important as it can validate initial designs and provide insight into the user's behaviour. The primary objective of this work was to identify any issues that needed to be addressed before sending patients home with the system.

The following chapters comprise the main body of the thesis, one for each study described above. Chapters 2 to 5 are full excerpts from journal articles, obtained with permission. Chapter 6 discusses mHealth design and development in the academic setting. The final chapter, Chapter 7, is a summary of contributions made by this dissertation.

References

AHRQ. (2001). *Translating Research Into Practice (TRIP)-II*. (Pub. No. 01-P017). Rockville, MD: Agency for Healthcare Research and Quality Retrieved from http://www.ahrq.gov/.

Arrese, L. C., & Lazarus, C. L. (2013). Special groups: head and neck cancer. *Otolaryngologic Clinics in North America, 46*(6), 1123-1136. doi:10.1016/j.otc.2013.08.009

Bhattacharyya, N. (2014). The prevalence of dysphagia among adults in the United States. *Otolaryngology-Head and Neck Surgery, 151*(5), 765-769. doi:10.1177/0194599814549156

Boden, K., Hallgren, A., & Witt Hedstrom, H. (2006). Effects of three different swallow maneuvers analyzed by videomanometry. *Acta Radiologica, 47*(7), 628-633. doi:10.1080/02841850600774043

Bollen, J. C., Dean, S. G., Siegert, R. J., Howe, T. E., & Goodwin, V. A. (2014). A systematic review of measures of self-reported adherence to unsupervised home-based rehabilitation exercise programmes, and their psychometric properties. *BMJ Open, 4*(6), e005044. doi:10.1136/bmjopen-2014-005044

Burkhead, L. M., Sapienza, C. M., & Rosenbek, J. C. (2007). Strength-training exercise in dysphagia rehabilitation: principles, procedures, and directions for future research. *Dysphagia, 22*(3), 251-265. doi:10.1007/s00455-006-9074-z

Butler, S. G., Stuart, A., Castell, D., Russell, G. B., Koch, K., & Kemp, S. (2009). Effects of Age, Gender, Bolus Condition, Viscosity, and Volume on Pharyngeal and

Upper Esophageal Sphincter Pressure and Temporal Measurements. *Journal of Speech, Language, and Hearing Research, 52*, 240-253.

Butler, S. G., Stuart, A., Markley, L., & Rees, C. (2009). Penetration and Aspiration in Healthy Older Adults as Assessed During Endoscopic Evaluation of Swallowing. *Annals of Otology, Rhinology & Laryngology, 118*(3), 190-198.

Canadian Cancer Statistics. (Producer). (2014). Canadian Cancer Statistics 2014.

Carnaby, G. D., & Harenberg, L. (2013). What is "usual care" in dysphagia rehabilitation: a survey of USA dysphagia practice patterns. *Dysphagia, 28*(4), 567-574. doi:10.1007/s00455-013-9467-8

Carnaby-Mann, G. D., & Crary, M. A. (2010). McNeill dysphagia therapy program: a case-control study. *Archives of Physical Medicine and Rehabilitation, 91*(5), 743-749. doi:10.1016/j.apmr.2010.01.013

Chen, Y., Huang, H., Xu, W., Wallis, R. I., Sundaram, H., Rikakis, T., . . . He, J. (2006). The Design of a Real-Time, Multimodal Biofeedback System for Stroke Patient Rehabilitation. *Proceedings of the 14th annual ACM international conference on Multimedia*, 763-772 doi:10.1145/1180639.1180804

Cosmidis, A., Rame, J. P., Dassonville, O., Temam, S., Massip, F., Poissonnet, G., . . . Groupement d'Etudes des Tumeurs de la Tete et du, C. (2004). T1-T2 NO oropharyngeal cancers treated with surgery alone. A GETTEC study. *European Archives of Oto-Rhino-Laryngology, 261*(5), 276-281. doi:10.1007/s00405-003-0694-8

Couch, M. E., Dittus, K., Toth, M. J., Willis, M. S., Guttridge, D. C., George, J. R., . . . Der-Torossian, H. (2015). Cancer cachexia update in head and neck cancer:

Definitions and diagnostic features. *Head & Neck, 37*(4), 594-604. doi:10.1002/hed.23599

Crary, M. A., & Groher, M. E. (2003). *Introduction to Adult Swallowing Disorders*. Missouri, USA: Butterworth Heinemann.

Dysphagia Section, Oral Care Study Group Multinational Association of Supportive Care in Cancer International Society of Oral Oncology, Raber-Durlacher, J. E., Brennan, M. T., Verdonck-de Leeuw, I. M., Gibson, R. J., Eilers, J. G., . . . Spijkervet, F. K. (2012). Swallowing dysfunction in cancer patients. *Support Care Cancer, 20*(3), 433-443. doi:10.1007/s00520-011-1342-2

Forte, T., Niu, J., Lockwood, G. A., & Bryant, H. E. (2012). Incidence trends in head and neck cancers and human papillomavirus (HPV)-associated oropharyngeal cancer in Canada, 1992-2009. *Cancer Causes & Control, 23*(8), 1343-1348. doi:10.1007/s10552-012-0013-z

Frowen, J. J., & Perry, A. R. (2006). Swallowing Outcomes After Radiotherapy for Head and Neck Cancer: A Systematic Review. *Head & Neck, 28*, 932-944. doi:10.1002/hed.2043810.1002/hed

Fukuoka, T., Ono, T., Hori, K., Tamine, K., Nozaki, S., Shimada, K., . . . Domen, K. (2013). Effect of the effortful swallow and the Mendelsohn maneuver on tongue pressure production against the hard palate. *Dysphagia, 28*(4), 539-547. doi:10.1007/s00455-013-9464-y

Hind, J. A., Nicosia, M. A., Roecker, E. B., Carnes, M. L., & Robbins, J. (2001). Comparison of effortful and noneffortful swallows in healthy middle-aged and older adults. *Archives of Physical Medicine and Rehabilitation, 82*(12), 1661-1665. doi:10.1053/apmr.2001.28006

Hiss, S. G., & Huckabee, M. L. (2005). Timing of pharyngeal and upper esophageal sphincter pressures as a function of normal and effortful swallowing in young healthy adults. *Dysphagia, 20*(2), 149-156. doi:10.1007/s00455-005-0008-y

Hoffman, M. R., Mielens, J. D., Ciucci, M. R., Jones, C. A., Jiang, J. J., & McCulloch, T. M. (2012). High-resolution manometry of pharyngeal swallow pressure events associated with effortful swallow and the Mendelsohn maneuver. *Dysphagia, 27*(3), 418-426. doi:10.1007/s00455-011-9385-6

Huckabee, M. L., & Steele, C. M. (2006). An analysis of lingual contribution to submental surface electromyographic measures and pharyngeal pressure during effortful swallow. *Archives of Physical Medicine and Rehabilitation, 87*(8), 1067-1072. doi:10.1016/j.apmr.2006.04.019

Hutcheson, K. A., & Lewin, J. S. (2013). Functional Assessment and Rehabilitation: How to Maximize Outcomes. *Otolaryngologic Clinics of North America, 46*, 657-670. doi:10.1016/j.otc.2013.04.006

Hwang, T. Z., Hsiao, J. R., Tsai, C. R., & Chang, J. S. (2015). Incidence trends of human papillomavirus-related head and neck cancer in Taiwan, 1995-2009. *International Journal of Cancer, 137*(2), 395-408. doi:10.1002/ijc.29330

Kahrilas, P. J., Logemann, J. A., Krugler, C., & Flanagan, E. (1991). Volitional augmentation of upper esophageal sphincter opening during swallowing. *American Journal of Physiology (Gastrointestinal and Liver Physiology), 260*(3 part 1), G450-G456.

Kreimer, A. R., Clifford, G. M., Boyle, B., & Franceschi, S. (2005). Human Papillomavirus Types in Head and Neck Squamous Cell Carcinomas Worldwide: A Systematic Review. *Cancer Epidemiology, Biomarkers & Prevention, 14*(2), 467-475.

Krisciunas, G. P., Sokoloff, W., Stepas, K., & Langmore, S. E. (2012). Survey of usual practice: dysphagia therapy in head and neck cancer patients. *Dysphagia, 27*(4), 538-549. doi:10.1007/s00455-012-9404-2

Labrique, A. B., Vasudevan, L., Kochi, E., Fabricant, R., & Mehl, G. (2013). mHealth innovations as health system strengthening tools: 12 common applications and a visual framework. *Global Health: Science and Practice, 1*(2), 160-171.

Lazarus, C., Logemann, J. A., Song, C. W., Rademaker, A. W., & Kahrilas, P. J. (2002). Effects of voluntary maneuvers on tongue base function for swallowing. *Folia Phoniatrica et Logopaedica, 54*(4), 171-176.

Martin-Harris, B., Brodsky, M. B., Michel, Y., Castell, D. O., Schleicher, M., Sandidge, J., . . . Blair, J. (2008). MBS measurement tool for swallow impairment--MBSImp: establishing a standard. *Dysphagia, 23*(4), 392-405. doi:10.1007/s00455-008-9185-9

Martin-Harris, B., Michel, Y., & Castell, D. O. (2005). Physiologic model of oropharyngeal swallowing revisited. *Otolaryngology-Head and Neck Surgery, 133*(2), 234-240. doi:10.1016/j.otohns.2005.03.059

Matsuo, K., & Palmer, J. B. (2008). Anatomy and Physiology of Feeding and Swallowing - Normal and Abnormal. *Physical Medicine & Rehabilitation Clinics of North America, 19*(4), 691-707. doi:10.1016/j.pmr.2008.06.001

Mendelsohn, M., & McConnel, F. M. S. (1987). Function in the Pharyngoesophageal Segment. *Laryngoscope, 97*, 483-489.

Mendenhall, W. M., Morris, C. G., Amdur, R. J., Hinerman, R. W., Malyapa, R. S., Werning, J. W., . . . Villaret, D. B. (2006). Definitive radiotherapy for tonsillar squamous cell carcinoma. *American Journal of Clinical Oncology, 29*(3), 290-297. doi:10.1097/01.coc.0000209510.19360.f9

Miller, N. E. (1989). Biomedical Foundations for Biofeedback as a Part of Behavioural Medicine. In J. V. Basmajian (Ed.), *Biofeedback: Principles and Practice for Clinicians* (pp. 5-15). Baltimore, Maryland: Williams & Wilkins.

Pauloski, B. R. (2008). Rehabilitation of dysphagia following head and neck cancer. *Physical Medicine & Rehabilitation Clinics of North America, 19*(4), 889-928, x. doi:10.1016/j.pmr.2008.05.010

Pearson, W. G., Jr., Langmore, S. E., Yu, L. B., & Zumwalt, A. C. (2012). Structural analysis of muscles elevating the hyolaryngeal complex. *Dysphagia, 27*(4), 445-451. doi:10.1007/s00455-011-9392-7

Robbins, J., Butler, S. G., Daniels, S. K., Gross, R. D., Langmore, S., Lazarus, C. L., . . . Rosenbek, J. C. (2008). Swallowing and Dysphagia Rehabilitation: Translating Principles of Neural Plasticity Into Clinically Oriented Evidence. *Journal of Speech, Language, and Hearing Research, 51*, S276-S300.

Ryerson, A. B., Peters, E. S., Coughlin, S. S., Chen, V. W., Gillison, M. L., Reichman, M. E., . . . Kawaoka, K. (2008). Burden of potentially human papillomavirus-associated cancers of the oropharynx and oral cavity in the US, 1998-2003. *Cancer, 113*(10 Suppl), 2901-2909. doi:10.1002/cncr.23745

Saxon, L. A. (2013). Ubiquitous wireless ECG recording: a powerful tool physicians should embrace. *Journal of Cardiovascular Electrophysiology, 24*(4), 480-483. doi:10.1111/jce.12097

Shaw, S. M., & Martino, R. (2013). The normal swallow: muscular and neurophysiological control. *Otolaryngologic Clinics of North America, 46*(6), 937-956. doi:10.1016/j.otc.2013.09.006

Shinn, E. H., Basen-Engquist, K., Baum, G., Steen, S., Bauman, R. F., Morrison, W., . . . Lewin, J. S. (2013). Adherence to preventive exercises and self-reported swallowing outcomes in post-radiation head and neck cancer patients. *Head & Neck, 35*(12), 1707-1712. doi:10.1002/hed.23255

Siegel, R., Ma, J., Zou, Z., & Jemal, A. (2014). Cancer statistics, 2014. *CA Cancer Journal for Clinicians, 64*(1), 9-29. doi:10.3322/caac.21208

Stepp, C. E. (2012). Surface Electromyography for Speech and Swallowing Systems: Measurement, Analysis, and Interpretation. *Journal of Speech, Language, and Hearing Research, 55*, 1232-1246. doi:10.1044/1092-4388(2011/11-0214

Vaiman, M., Eviatar, E., & Segal, S. (2004). Surface electromyographic studies of swallowing in normal subjects: a review of 440 adults. Report 1. Quantitative data: timing measures. *Otolaryngology-Head and Neck Surgery, 131*(4), 548-555. doi:10.1016/j.otohns.2004.03.013

Vigreux, B., Cnockaert, J. C., & Pertuzon, E. (1979). Factors influencing quantified sEMGs. *European Journal of Applied Physiology, 41*, 119-129.

Wheeler-Hegland, K. M., Rosenbeck, J. C., & Sapienza, C. M. (2008). Submental sEMG and Hyoid Movement During Mendelsohn Maneuver, Effortful Swallow, and

Expiratory Muscle Strength Training. *Journal of Speech, Language, and Hearing Research, 51*, 1072-1087.

WHO. (2011). *mHealth: New horizons for health through mobile technologies*. Geneva, Switzerland: World Health Organization.

WHO. (2013). Global health workforce shortage to reach 12.9 million in coming decades. Retrieved from http://www.who.int/mediacentre/news/releases/2013/health-workforce-shortage/en/

WHO. (2014). Head and Neck Cancer: Union for International Cancer Control 2014 Review of Cancer Medicines of the WHO List of Essential Medicines. *2014 Review of Cancer Medicines of the WHO List of Essential Medicines.* Retrieved from http://www.who.int/selection_medicines/committees/expert/20/applications/cancer/en/

CHAPTER 2: SELECTING THE APPROPRIATE TECHNOLOGY

Springer Dysphagia, Electromyography and Mechanomyography Signals During Swallowing in Healthy Adults and Head and Neck Cancer Survivors, 32, 2017, 90-103, Constantinescu, G., Hodgetts, W., Scott, D., Kuffel, K., King, B., Brodt, C., & Rieger, J.

This article can be found on the publisher's website at https://link.springer.com/article/10.1007%2Fs00455-016-9742-6.

The journal's homepage and the publisher's copyright information can be found at https://link.springer.com/journal/455

Introduction

Dysphagia affects two thirds of patients treated for head and neck cancer (HNC) (Langerman et al., 2007) and although these swallowing disorders can be characterized by several physiological impairments, a common observation is reduced hyolaryngeal movement (Hutcheson et al., 2012). Hyolaryngeal elevation occurs via the contraction of suprahyoid muscles, which include the mylohyoid, stylohyoid, digastric, and geniohyoid (Shaw & Martino, 2013). Impairment in hyolaryngeal movement results in additional complications, such as reduced inversion of the epiglottis, reduced airway protection and reduced opening of the cricopharyngeal segment.

Although dysphagia can be addressed in a number of different ways, such as diet modifications and postural adjustments, there are some rehabilitative exercises in which a patient is instructed to control the swallowing mechanism in a different way from a normal swallow, such as when performing a Mendelsohn maneuver or effortful swallow. In the Mendelsohn exercise, the patient is instructed to swallow and prolong the elevation of the larynx at its peak height for a few seconds in an effort to increase UES opening. In an effortful swallow, the patient is instructed to swallow as hard as possible so as to increase the extent of hyoid excursion (Hind, Nicosia, Roecker, Carnes, & Robbins, 2001) and prolong base of tongue to posterior pharyngeal wall contact in head and neck cancer patients (Cathy Lazarus, Logemann, Song, Rademaker, & Kahrilas, 2002). Visual biofeedback, such as surface electromyography (sEMG), can be used to bring awareness to the muscle activity used for these exercises (Bryant, 1991; Crary, Carnaby Mann, Groher, & Helseth, 2004). sEMG has been shown to be associated with kinematic data such as hyolaryngeal excursion and is sensitive to the type of swallowing task performed

(Wheeler-Hegland, Rosenbek, & Sapienza, 2008), thus making it a useful adjunct to training, provided clinicians are aware that kinematic performance cannot be confirmed with sEMG in isolation (Azola et al., 2015).

With an increased focus on the advancement of technology and its miniaturization, surface sensors that may be incorporated in future health devices should be re-evaluated. There are many factors for developers to consider when selecting a type of sensor, such as ease of application, reusability, and cost. Because biofeedback, when serving as an adjunct to swallowing therapy, is used to provide information on timing and relative amplitude related to muscle contractions, it also is important that consideration be given to the sensor with superior signal to noise ratio (SNR) in the signal collected from the submental area. Rather than selecting the most commonly used sensors (i.e., sEMG), other sensor types should be considered as technologies improve.

The quality of the biofeedback signal plays an important role in the clinical measures obtained. For example, if the signal is indiscernible from noise, identifying and reporting on the amplitude and duration of a swallowing trial may be difficult. An industry standard for assessing the overall quality of a sensor and acquisition hardware measurement setup is the SNR. The present paper examines the SNR of two types of surface sensors, electromyography (sEMG) and mechanomyography (MMG), during swallows.

sEMG sensors detect the activity, or action potentials, from motor units. The amplitude of the signal is largely dependent on the anatomy and physiology of the muscles observed (Reaz, Hussain, & Mohd-Yasin, 2006) and on how proximal those muscles are to the skin surface (Stepp, 2012). As the signal travels through the subdermal fat and other tissues between the muscles and the sensors, it will be attenuated (Stepp, 2012) while also acquiring noise. Reaz et al. categorized noise affecting sEMG signal into four different types: inherent noise in electronics equipment, ambient noise from electromagnetic radiation, motion artifacts from the electrode interface and from the electrode wires, and inherent instability of signal (Reaz et al., 2006). There are several approaches to optimize SNR in sEMG signal, such as ensuring appropriate electrode size (maximum 10 mm) and inter-electrode distance (approximately one quarter of the target muscle fiber length, or 20 mm if smaller) (Hermens, Freriks, Disselhorst-Klug, & Rau, 2000). Adequate electrode placement is another way to improve sEMG signal quality: a reference electrode should be placed on a fixed surface away from the muscle, such as the body of the mandible, while the remaining two electrodes should align parallel to the muscle fibers as this results in much stronger signals (Vigreux, Cnockaert, & Pertuzon, 1979). Finally, the signal quality also can depend on skin to sensor contact and conduction. sEMG electrodes commonly require skin preparation, such as shaving the face and cleaning the skin with a medical abrasive paste or alcohol (Hermens et al., 2000; Stepp, 2012) or the use of an electrolytic gel to reduce the electrode-skin impedance (Hermens et al., 2000). Although definitive SNR cutoffs for quality sEMG signals could not be found in the literature, Brown assigned an arbitrary minimum acceptable SNR of 10 dB in her study (Brown, 2007).

While sEMG is a well-established biofeedback method, MMG is another feasible approach to investigate muscle contractions and has been referred to as the mechanical counterpart to sEMG (Islam et al., 2014). MMG sensors detect mechanical vibrations generated by muscle activity and are susceptible to different sources of noise than sEMG.

Primarily, these vibrations can be attributed to changes in muscle shape caused by the contraction and relaxation of a muscle and result in a sharp increase in signal amplitude. Additional vibrations noted are created by oscillations in the muscle fibers at the specific resonant frequency of that muscle. These vibrations result in surface movement, which changes the pressure inside the MMG sensor chamber and is measured by the microphone (Posatskiy, 2011). Sources of noise in MMG signal when monitoring the activity of suprahyoid muscles can come from the carotid pulse, speech, and respiration (S. Silva & Chau, 2005) as well as tremor (Islam et al., 2014). The latter source of noise occurs during muscle contraction and so may contribute to the signal rather than the noise floor. Although MMG technology can use lasers, accelerometers, and microphones, the comparison in this study will focus on microphone-based MMG with a conical chamber as this design was demonstrated to have on average a 6.79 dB/Hz signal gain over cylindrical chamber designs (A. O. Posatskiy & T. Chau, 2012).

With advancements in reducing the mass and cost of MMG sensors, this approach to monitoring muscle activity has received increased attention as a potentially more advantageous alternative to sEMG. Several advantages of MMG sensors over sEMG ones are found in the literature, such as better tolerance to variations in the location of the sensor and robustness against skin impedance variations, reduction in hardware complexity and lack of need for electrode gel (Lee, Chau, & Steele, 2009; Mohamed Irfan, Sudharsan, Santhanakrishnan, & Geethanjali, 2011; Roy et al., 2007). More recently, researchers have begun to explore the potential of MMG sensors in swallowing tasks using a microphone-accelerometer sensor pair designed by Silva and Chau (Lee, Chau, et al., 2009; Lee, Steele, & Chau, 2009; J. Silva & Chau, 2003). When using this sensor design, MMG signals were not associated with significant improvements in swallow segmentation (Lee, Steele, et al., 2009). However, Posatskiy and Chau mentioned that microphone-based MMG sensors appear more robust to motion artifacts than accelerometers; improvements to MMG sensor design were made, but both models remained susceptible to this phenomenon (Posatskiy, 2011; A.O. Posatskiy & T. Chau, 2012).

Both sEMG and MMG detect muscle contractions at the surface of the skin, and therefore share some advantages associated with surface myography: surface sensors are generally easy to place, noninvasive, reliable, inexpensive, and safe. The ease of application is an important feature, particularly for patients and practitioners, who may have limited exposure to such technology. The interface with the skin is critical to both types of sensors, as uneven contact can lead to noise artifact or detection failure (Roy et al., 2007).

When using surface sensors to monitor submental muscle activity in patients with HNC, the impact of anatomical alterations secondary to surgery and radiation should be considered when interpreting the signal. Surgery can result in scarring and swelling, while radiation therapy can lead to fibrosed tissue. Increased tissue thickness can reduce the selectivity of the sEMG signal leading to attenuated waveforms (Stepp, 2012). Some patients may undergo a submandibular salivary gland transfer in the submental area (Seikaly et al., 2001) and although this gland is placed under the anterior belly of the digastric, it does increase the distance between the skin surface and the rest of the suprahyoid muscles. It also involves splitting the mylohyoid (Seikaly et al., 2001).

Anatomical changes secondary to HNC treatment will have a similar impact on MMG signals as thicker tissues attenuate the mechanical waves generated by muscles; crosstalk in MMG signal also is related to skin fold thickness (Beck et al., 2005; Jaskolska et al., 2004). The effects of scar tissue and fibrosis on muscle signal captured in the submental area remains to be explored; however, Valouchova & Lewit (2009) examined the sEMG signal captured from the rectus abdominis underneath scar tissue. The authors found that half of the participants had increased muscle activity on the side of the scar while the other half showed the same on the opposite side and speculated that increased activity under the scar tissue could be explained by muscular trigger points (Valouchova & Lewit, 2009). In addition to the signal being affected by anatomical changes, Crary and Baldwin found that sEMG waveforms can differ in timing and amplitude in participants with dysphagia (Crary & Baldwin, 1997). For example, participants with swallowing impairments secondary to brainstem stroke showed higher signal amplitudes than that in healthy controls, an observation that the authors attributed to possible increased anxiety with swallowing, increased muscle tone, and/ or a compensatory approach to swallowing.

Although MMG sensors have not been previously used to provide biofeedback during swallowing therapy, this technology has been used to monitor changes in submental muscle activity in relation to age and stimulus swallowed (Lee, Chau, et al., 2009). These authors concluded that future investigation of MMG sensors as a potential substitute for sEMG was warranted. The same group of investigators also explored the possible use of MMG in swallow segmentation (Lee, Steele, et al., 2009). In both studies, MMG sensors were used with healthy adults.

SNR from sEMG and MMG sensors have not been investigated in signals collected from suprahyoid musculature. Furthermore, to ensure that sEMG and MMG signals are robust to possible anatomical and functional changes following treatment for HNC, we examined these technologies in both healthy and HNC participants.

The purpose of this study was to compare the SNRs obtained from two surface sensors: sEMG and MMG. This study is one step in the progression of health device development. We caution readers not to project the findings herein to an assessment of swallowing kinematics. The authors set out to answer the following questions:

1) In healthy participants performing a series of swallows, do sEMG sensors and MMG sensors produce equivalent signal to noise ratios?
2) In participants with a history of HNC treatment performing a series of swallows, do sEMG sensors and MMG sensors produce equivalent signal to noise ratios?

Methods

Participants

Two groups of participants were involved in this study. In the first group, healthy adults with no history of dysphagia or treatment for HNC were recruited through advertisements and word of mouth. For the second group, participants with a history of HNC were recruited through the Cross Cancer Institute and the Institute for Reconstructive Sciences of Medicine (iRSM) in Edmonton, Alberta. All participants completed a cursory oral mechanism exam with a speech-language pathologist (GC). A chart review was completed for all patient participants, documenting the diagnosis, treatment type and dates, as well as any relevant surgical details such as defect, nerves affected and reconstruction. Reported diet and the diagnosis from the last modified barium swallow also were noted.

Instrumentation

Disk sEMG dry disposable electrodes were used in this study (7179-0020-Demo/XP, Pentax Canada Inc., Mississauga, Ontario). These are 57 mm-diameter, self-adhesive patches with three electrodes: one ground and two electrodes, in a bipolar configuration (Figure 2.1a). The electrodes all measure 12.5 mm in diameter; the center-to-center inter-electrode distance is 19.5 mm, with an edge-to-edge distance of seven mm, or slightly under one quarter of the length of the anterior belly of the digastric muscle (De-Ary-Pires, Ary-Pires, & Pires-Neto, 2003). These characteristics rendered these electrodes appropriate for collecting information in the submental area (Hermens et al., 2000; Stepp, 2012).

A sound-pressure based MMG sensor (Figure 2.1b) was assembled by a biomedical engineer (DS) according to previously published specifications (A.O. Posatskiy & T. Chau, 2012). A Knowles SiSonic™ MEMS microphone (Knowles SPU1410, Itasca, IL) was used. The acoustic chamber, created out of Delrin®, had a diameter of seven mm and a height of five mm. Aluminized mylar was used as the membrane (10 mm diameter), as recommended by Posatskiy et al. (2012). KT Tape™, an elastic sports tape, was used to secure this sensor to the submental area. The use of tape for sensor to skin adhesion has previously been shown to be effective (Lee, Steele, et al., 2009).

Figure 2.1. Surface Sensors.

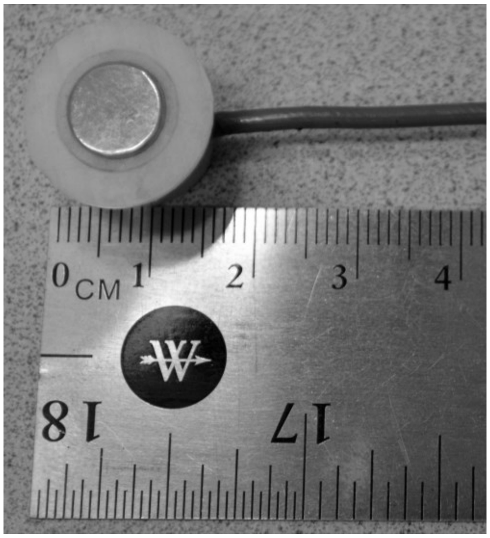
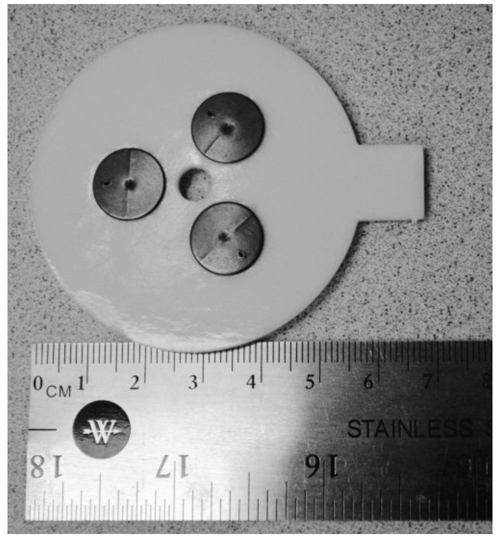

(a)

(b)

Figure 2.1. Two types of surface sensors: (a) Disk sEMG Dry Disposable electrode patch, (b) MMG sensor

A custom case for both sensors was designed (DS, BK) in Autodesk® Fusion 360 software (Autodesk® Inc., San Rafael, California) and manufactured on a CNC milling machine (Roland MDX-650A, Roland DG Corporation, Japan) (Figure 2.2). The custom case housed the mainboard and a printed circuit board (PCB) that handled the signal acquisition and conditioning prior to the signal being sampled by the analog to digital converters (ADC) of the data acquisition system (National Instruments USB-6210, National Instruments Corporation, Austin, Texas). The case was mounted to button-like snaps on the posterior side of the sEMG adhesive pad. The MMG sensor was wired to the mainboard via a shielded three-conductor cable. The case was used to capture the signal from both types of sensors for the same swallow. An LED indicator was built into the case and was used to mark the sEMG electrode designated as reference. The National Instruments Data Acquisition (NI-DAQ) was used to acquire the signals at a sampling rate of 1000 Hz, which were recorded and saved using the National Instruments™ Biomedical Workbench software suite (Version 13.0.0, Edmonton, Alberta). Data were post-processed and analyzed using custom MATLAB® (ver. R2014b, Edmonton, Alberta) scripts (DS, KK).

Figure 2.2. Complete Device.

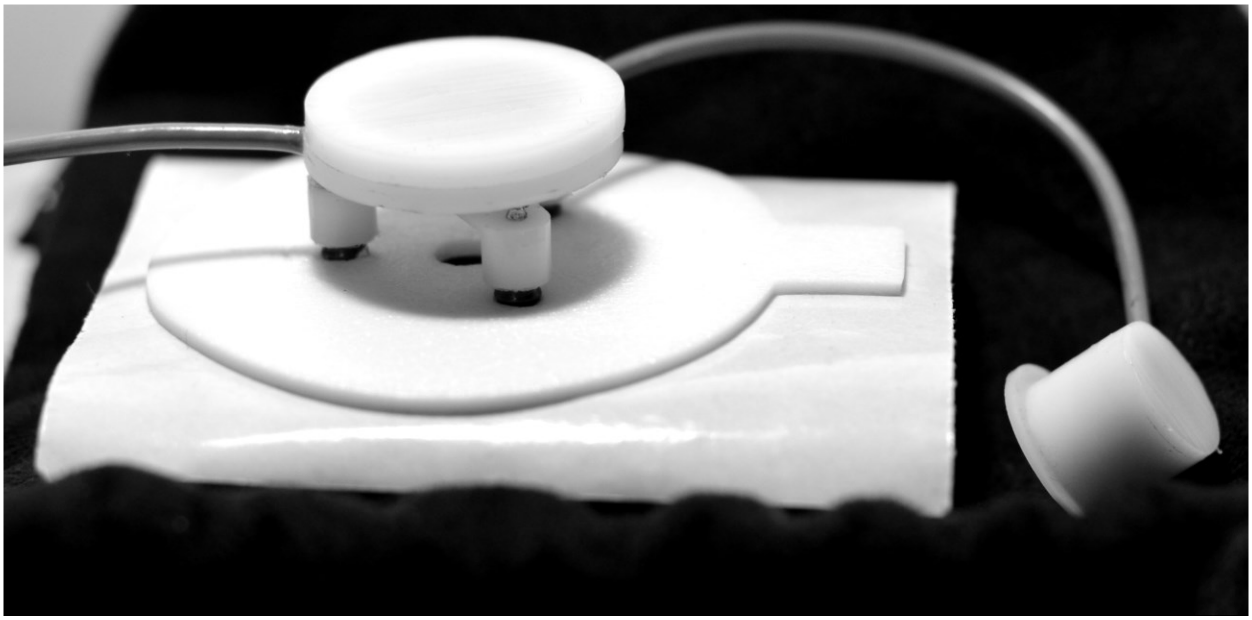


Figure 2.2. Complete signal acquisition device mounted on sEMG Dry Disposable electrode patch, collected the signal from both types of sensors

Software

Custom software was created (DS) to facilitate data collection. The user was able to select the placement (i.e., right side or left side) of the sEMG sensor as well as the task (i.e., baseline, dry swallow, thin liquid swallow, etc.). The signals from both sEMG and MMG sensors were displayed in real time. Signal acquisition began and ended by pressing the 'record' and 'stop' buttons (Figure 2.3). Each task resulted in one time-stamped recording and all data were saved to individual Excel spreadsheets.

Figure 2.3. Custom Software.

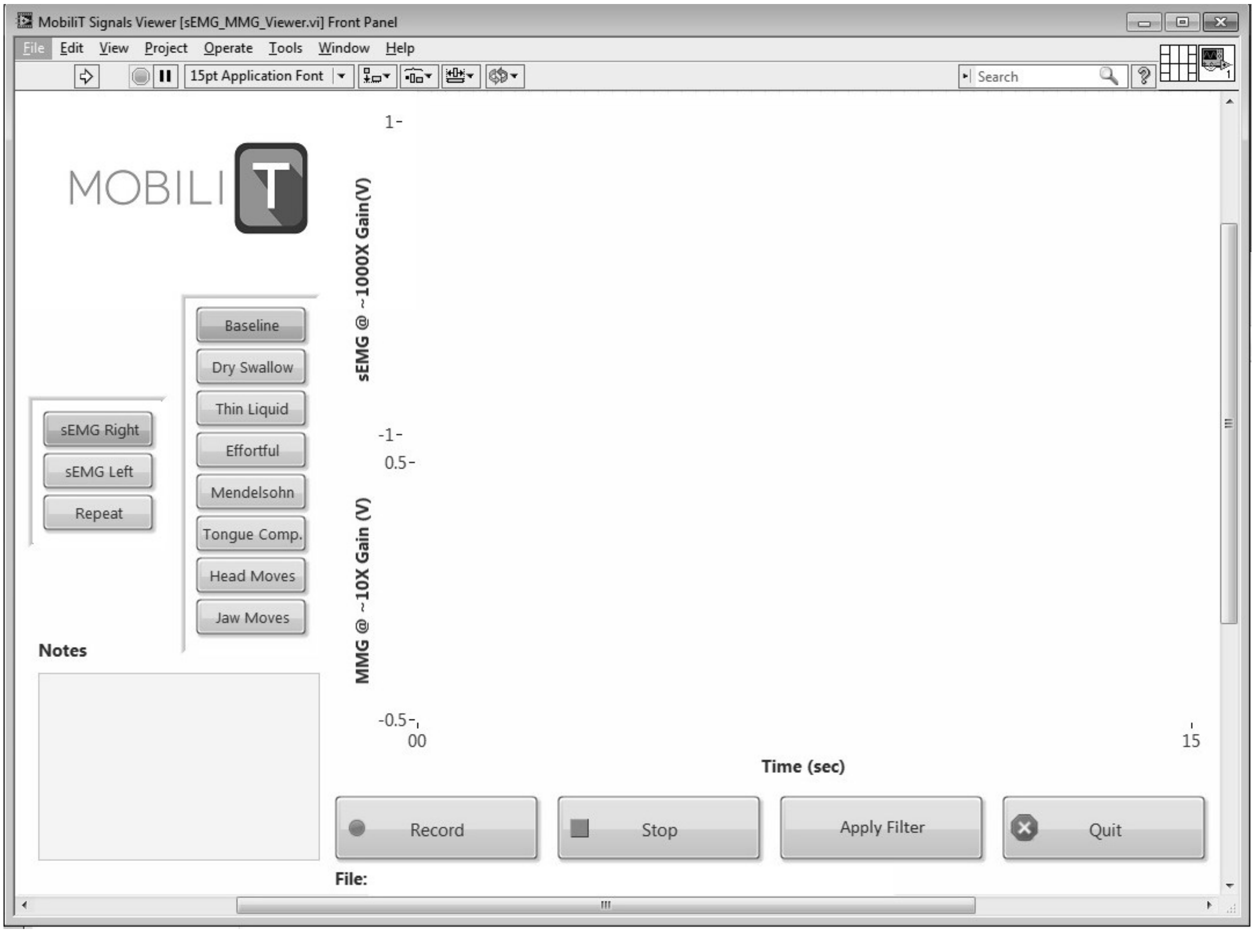


Figure 2.3. Screen shot of custom software used to collect data and save files according to placement of sensors (e.g., right, left) and task (e.g., baseline, dry swallow)

Setting

A table specific to the needs of this protocol was designed by an industrial design student using input from the clinician, industrial designer, and biomedical engineer. The table was designed using Rhinoceros 3D (McNeel & Associates, Seattle, WA, USA) and cut using a CNC router Phoenix GS510 HDR) out of 1/2” Baltic birch plywood. The aim of this design was to conceal most of the hardware from the participant and create a natural and comfortable testing environment. The hardware and most wires were secured under the tabletop. The laptop used for data acquisition was placed in the tabletop inset.

The only hardware visible to participants included the two sensors, the wire leading into the tabletop connection, and the laptop.

Data Collection

The Health Research Ethics Board at the University of Alberta, Edmonton, Alberta, Canada approved this study. Recordings took place at two locations, each with an identical set-up: iRSM and the University of Alberta in Edmonton, Canada. Consent was obtained after participants were fully informed about the study.

The skin was prepped using alcohol wipes and electrode gel (Spectra® 360, Parker Laboratories, NJ, USA) was applied to the sEMG electrodes. The sEMG adhesive pad was attached on the right side of the submental area first. The ground electrode was placed on the body of the mandible, and the two active leads over the suprahyoid muscles. The MMG sensor was placed on the opposite side using KT Tape™. A minimum of three thin strips of KT Tape™ was used, with additional strips applied as necessary. For some participants (e.g., female participants with a smaller chin), KT Tape™ also was required to secure the sEMG adhesive pad. A photo of the sensor placement was taken after ensuring that all sensors had good surface contact with the skin (Figure 2.4). This set-up allowed for the simultaneous collection of data using both sEMG and MMG devices. An engineer also was present during data acquisition to ensure that the signal looked appropriate and to troubleshoot any hardware or software malfunctions. The following tasks were recorded:

a. Baseline: Participants were asked to remain still and breathe quietly for 5-10 seconds. This recording was used as a reference for the rest of the signal.
b. Dry swallows (3 trials): Participants were asked to swallow their saliva.

c. Thin liquid swallows (3 trials): Participants were asked to swallow small sips of water.

d. Effortful dry swallows (3 trials): Participants were asked to swallow their saliva with maximum effort. This maneuver was demonstrated and practiced prior to recording.

e. Mendelsohn dry swallows (3 trials): Participants were asked to swallow their saliva, and then contract their muscles at the height of the swallow, so as to "hold" their larynx in an elevated position. The participants were asked to relax their swallowing muscles after three to five seconds. This maneuver was demonstrated and practiced prior to recording.

There was no set time duration between swallow tasks and there was no kinematic confirmation of accurate performance of tasks *d* and *e*.

Figure 2.4. Device Placement.

Figure 2.4. sEMG placement on the right side of the submental area. The MMG sensor is placed on the left side, secured with three KT Tape^{TM} strips

A button, built into the side of the tabletop, was pressed by the clinician (GC) whenever a swallow event occurred, as judged by visible elevation of the larynx. The resulting reference signal appeared as a vertical red line in the waveform tracings and was used to indicate the events of interest for analysis. Once all recordings were completed, the sensors were removed and re-attached in the opposite configuration: sEMG on the left side of the submental area and MMG on the right. This was done so that, in the HNC participants, each sensor was used to collect the signals from the less affected side. The same process was undertaken in the healthy group for consistency. Tasks *a* through *e* were repeated. To assess the test-retest reliability of each device, twenty percent of the participants (four healthy, two HNC), were randomly selected to complete all tasks one more time using the first sensor placement: sEMG on the right and MMG on the left. It should be mentioned that the sEMG pads were not reusable and lost their ability to adhere to skin once removed; therefore, new pads were used with each recording set.

Signal Acquisition

The signals captured from the sEMG and MMG sensors were amplified (981x) and filtered (high-pass filter of five Hz) by the custom-designed hardware mounted within the custom case. Hardware filtering was preferred over software filtering as it prevents aliasing (Stepp, 2012). Any electrical noise was removed using a notch filter of 58 Hz to 62 Hz. An algorithm was created (MATLAB® ver. R2014b, Edmonton, Alberta) for manual window selection of swallow events. A horizontal line delineating the noise floor was created by taking the mean of the two baseline signals, captured on the right and left side of the submental area, plus two standard deviations (Basmajian & De Luca, 1985). This resulted in two baseline marks for each participant: one for the sEMG signal and one for the MMG signal (Figure 2.5). The three trials within each task were segmented manually by visually identifying the onset and offset points near the button-press mark. A cursor was placed at the onset of the selection, which was determined as the first point where the signal was consistently above the baseline mark; the offset was determined to be the first point where the signal returned to the baseline mark. Notes regarding anomalous button marks (e.g., button was pressed accidentally) were kept during data acquisition and made available to the rater during signal segmentation. The signal was segmented separately for the two sensors as the MMG signals have been shown to lag behind those of sEMG (Petitjean, Maton, & Cnockaert, 1992). If it was difficult to discern onset and offset points in the signal from one sensor, the signal from the other device was used as a guide.

Figure 2.5. Sample Signal Display.

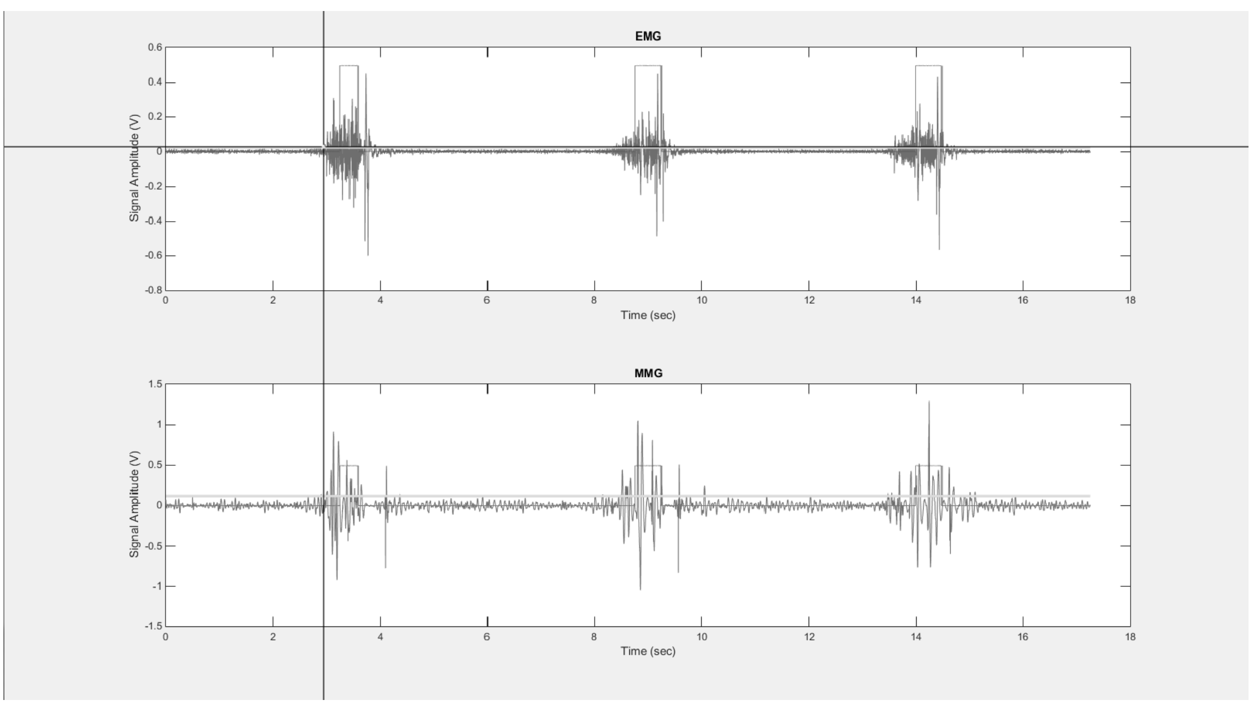


Figure 2.5. Sample signal display used in trial segmentation showing the sEMG (top) and the MMG (bottom) signals captured simultaneously. The rectangular signal was recorded

from the button-press. This example shows the onset selection in the sEMG signal: the cursor *(vertical line)* was lined up with the point in the sEMG waveform where the signal was consistently above the baseline mark (*horizontal line*), near the button press (*rectangular tracing*)

The trials within each task were used in the calculation of one SNR value (dB) per task, using the following formula:

$$\text{SNR} = 20\log_{10}\left(\frac{\overline{V_{RMS}}}{\overline{Vbaseline_{RMS}}}\right) \tag{1}$$

where V_{RMS} is the average root mean square of the voltage (V) of the trials in one task, and $Vbaseline_{RMS}$ is the average root mean square of the recorded baseline signal (V).

Statistical Analysis

All statistical analyses were performed using Version 22 IBM® SPSS® Statistics Standard. Since systematic variation between right vs. left placement is doubtful in healthy participants, the signal collected on the right side of the submental area was arbitrarily selected for data analysis. For participants who received treatment for HNC, systematic variation is more probable; the signal acquired on the side of the lesion was excluded from the analysis. For example, if the diagnosis was a carcinoma of the left tonsil, the sEMG signal acquired on the right side was compared with the MMG signal acquired on the same side. In this way, comparable analysis could be ensured.

To answer the first study question, a 2x4 repeated measures ANOVA was conducted on the signal collected from healthy participants. The first independent variable, sensor type, had two levels: sEMG and MMG; the second independent variable, task, had four levels: dry swallow, thin liquid swallow, effortful swallow and Mendelsohn maneuver swallow. Planned pairwise comparisons were conducted for each task to compare sEMG SNR to MMG SNR. A Bonferonni adjusted alpha for four comparisons was used ($\alpha = 0.0125$). The same statistical analysis was used to answer the second study question on the signal collected from participants with a history of HNC.

Test-retest reliability was assessed by using intra-class correlation (ICC) coefficient and visual inspection of graphs. Reliability measures were calculated taking into account the signal captured from both, healthy and dysphagic participants. The following agreement classes were used: very good (> 0.80), good (0.61-0.80), moderate (0.41-0.60), fair (0.20-0.40), and poor (< 0.20).

Another twenty percent of participants were randomly selected during analysis (four healthy, two HNC) and their swallows were segmented again for each task. The SNRs were re-calculated and segmentation reliability was determined through ICC coefficients between the two SNR outputs.

Results

Participants

Recruitment took place between November and December 2014. The two participant groups consisted of 22 healthy adults and 10 participants with a history of HNC (Tables 2.1 and 2.2).

Although no difference was expected between the signals collected on the right side versus the left side in healthy participants, it was anticipated that this would not be the case for participants with HNC. For this reason, data were not pooled across the two sides, nor was the signal collected using sEMG on one side compared to the MMG signal acquired simultaneously on the opposite side. Instead, the authors elected to compare all signal acquired on the right side of the submental area for healthy participants. For HNC participants, all signals collected from the side of the lesion were excluded from the analysis. Although one participant in the HNC group had an unknown primary tumour site, his treatment history revealed that the radiation was focused primarily on the left side of his neck. Therefore, the left side was selected as the affected side. The selected sEMG and MMG signals were then pooled across all tasks and used for the analysis.

Table 2.1

Participant Demographics

Participant group	Age
Healthy (N = 22)	29 (19-51)
Males (n = 11)	32 (19-51)
Females (n = 11)	25 (22-33)
HNC (N = 10)	59 (46-74)
Males (n = 5)	54 (50-57)
Females (n = 5)	64 (45-74)

Table 2.2

Head and Neck Cancer Participant Details

Subject	T-stage (site)	Side of Lesion	Surgical details[b]	Time post surgery	Adjuvant treatment[c]	Dysphagia (O; P)[d]
1	T2 (lateral tongue)	Right	Hemiglossectomy; RFFF neurotized to right lingual nerve	1.8 months	-	Minimal; minimal-mild
2	Tx (unknown primary)	(unknown) RT on left	Right SGT; neck dissection only	2.1 months	CRT	No exam on file
3	T3 (lateral tongue)	Right	½ oral tongue, FOM, ½ BOT, LPW, tonsil, retromolar trigone (all on right); right lingual and hypoglossal nerves transected and reanastomosed to flap; all right suprahyoid muscles resected except anterior belly of digastric; RFFF	8.0 years	CRT	Moderate; moderate

4	T3 (floor of mouth)	Left	Marginal mandible resection, 1/3 SP, FOM, 1/3 oral tongue, tonsil (all on left); left hypoglossal and lingual nerves affected; right SGT; RFFF	1.0 years	RT	Mild; mild
5	T1 (tonsil)	Left	Left LPW, 1 cm over the BOT at the anterior mucosa of the SP; left lingual nerve resected and reanastomosed; RFFF	11.6 years	RT	Moderate; moderate
6	T4 (tonsil)	Left	¼ BOT, ¾ SP, LPW, tonsil (all on left); left lingual nerve transected; PTFF, SPIR	5.2 months	CRT	Mild; moderate
7	T2 (lateral tongue)	Left	½ left oral tongue; RFFF	2.3 years	RT	Mild; minimal
8	T2 (tonsil)	Left	1 cm BOT, LPW, tonsillar pillar, ½ SP and uvula (all left); left hypoglossal nerve cable graft & left lingual nerve primary repair; right SGT; RFFF. Additional surgeries included a pharyngoplasty	13.7 years	RT	Marked; moderate

9	T3 (soft palate[a])	Left	1.5 cm maxilla, 1 cm BOT, total soft palate, left LPW; right SGT; RFFF	11.7 years	RT	Mild-moderate; mild-moderate
10	T4 (base of tongue and mandible)	Right	Bone from parasymphysial region on right of mandible, total oral tongue, total BOT, FOM, ½ SP, LPW (all on right); lingual and hypoglossal nerves and right inferior alveolar nerve resected; suprahyoid muscles resected except left anterior digastric and left mylohyoid; FFF and ATF	3.1 years	CRT	Moderate; moderate

[a]This participant had mucoepidermoid carcinoma; all other participants had squamous cell carcinomas.

[b]RFFF = radial forearm free flap; SGT = salivary gland transfer; FOM = floor of mouth; BOT = base of tongue; LPW = lateral pharyngeal wall; SP = soft palate; PTFF = posterior tibial free flap; SPIR = soft palate insufficiency repair; FFF = fibular free flap; ATF = anterolateral thigh flap

[c]RT = radiation therapy; CRT = chemotherapy

[d]Diagnosis retrieved from the patient's most recent Modified Barium Swallow (MBS) study at iRSM. O = oral; P = pharyngeal.

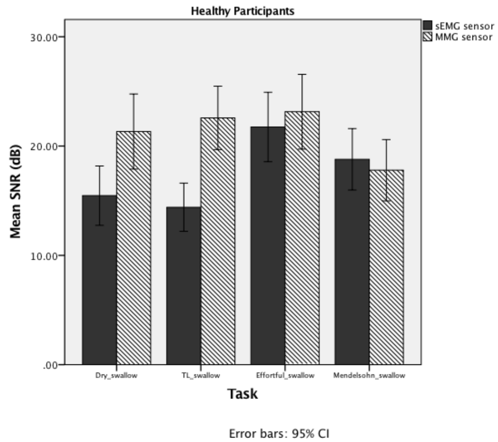
The Shapiro-Wilk test revealed normally distributed data for each task, under each sensor, for both participant groups (e.g., sEMG data collected during a dry swallow in healthy participants). The assumption of homogeneity of variance was met in all but one instance (Sensor type * task in healthy participants). For this effect, Greenhouse-Geisser statistics will be reported.

Healthy participants. The 2x4 repeated measures ANOVA revealed a statistically significant interaction for sensor type and task $F(3, 63) = 20.5$, $p < 0.001$, $\eta^2 = 0.49$. Planned pairwise comparisons between the two sensors, for each task, yielded a statistically significant difference at the specified level of $\alpha = 0.0125$ for dry swallows, $t(21) = -3.02$, $p = 0.007$, $d = -5.86$, 95% CI [-9.90, -1.82] and for thin liquid swallows, $t(21) = -4.24$, $p < 0.001$, $d = -8.17$, 95% CI [-12.18, -4.16]. In both cases, the MMG sensor had a higher SNR than the sEMG sensor (Figure 2.6a).

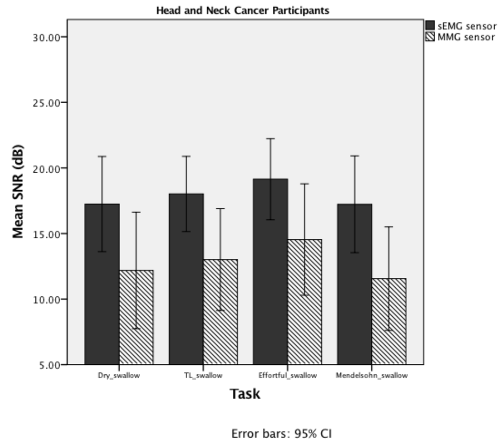
Head and neck cancer participants. The 2x4 repeated measures ANOVA revealed a statistically significant difference for sensor $F(1, 9) = 5.54$, $p = 0.043$, $\eta^2 = 0.38$ and for task $F(3, 27) = 2.98$, $p = 0.049$, $\eta^2 = 0.25$. Planned pairwise comparisons between the two sensors, for each task, showed no statistically significant differences at the specified level of $\alpha = 0.0125$. For all tasks, however, the sEMG sensor had a higher SNR than the MMG sensor (Figure 2.6b).

For ease of interpretation, mean SNR differences between the two sensors are listed in table 2.3, along with 95% confidence intervals.

Figure 2.6. Mean SNR for the Two Participant Groups.



(a)



(b)

Figure 2.6. Mean SNR in dB and 95% CI for the signal collected using sEMG (solid) and MMG sensor (hashed) are presented for each of the four tasks, for healthy participants (a) and participants with a history of HNC (b)

Table 2.3

SNR Differences Between the Two Sensors

(SNR for sEMG) – (SNR for MMG)		Mean	95% CI
Healthy	Dry	-5.86*	(-9.90 to -1.82)
	TL	-8.17*	(-12.18 to -4.16)
	Effortful	-1.40	(-5.87 to 3.08)
	Mendelsohn	1.00	(-2.59 to 4.59)
HNC	Dry	5.06	(-.22 to 10.34)
	TL	5.00	(.65 to 9.36)
	Effortful	4.60	(-1.15 to 10.35)
	Mendelsohn	5.67	(-.55 to 11.88)

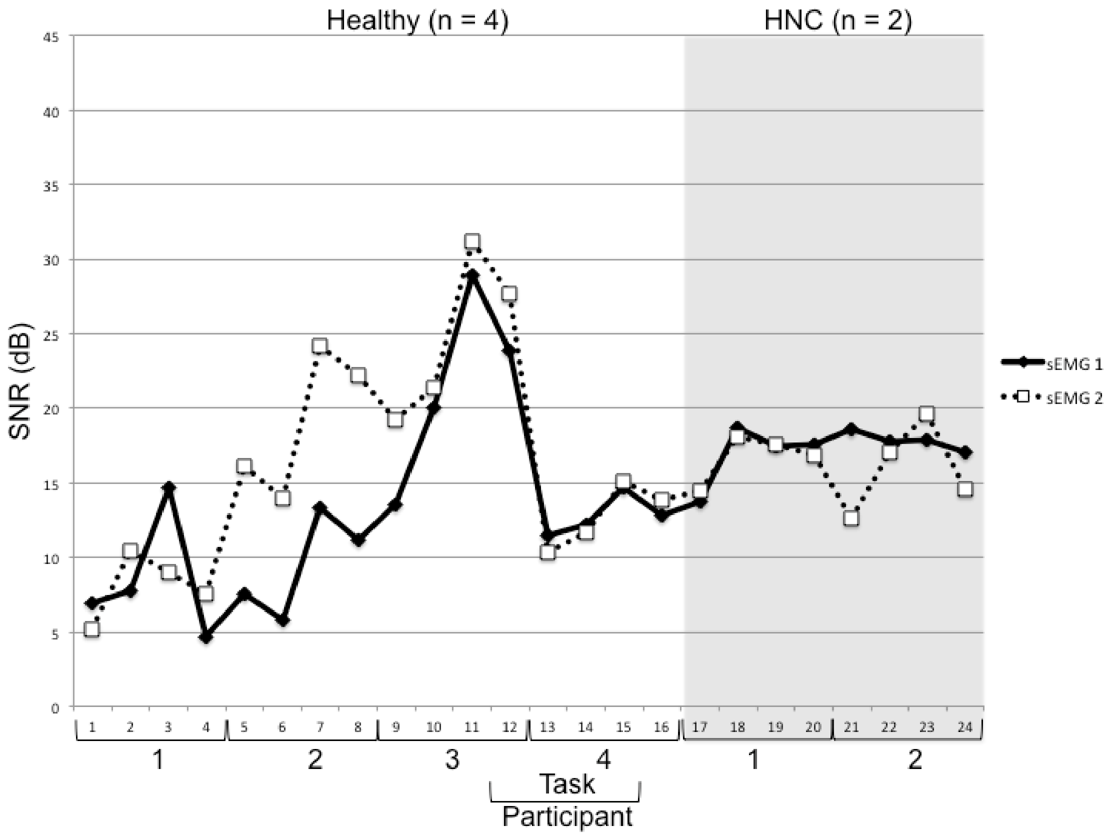
*Significant at $\alpha = 0.0125$

Test-Retest Reliability Measures

The ICC(1,k) coefficient for test-retest reliability of the sEMG sensors was 0.82, or very good. The ICC(1,k) coefficient for the MMG sensor was 0.012, in other words, poor.

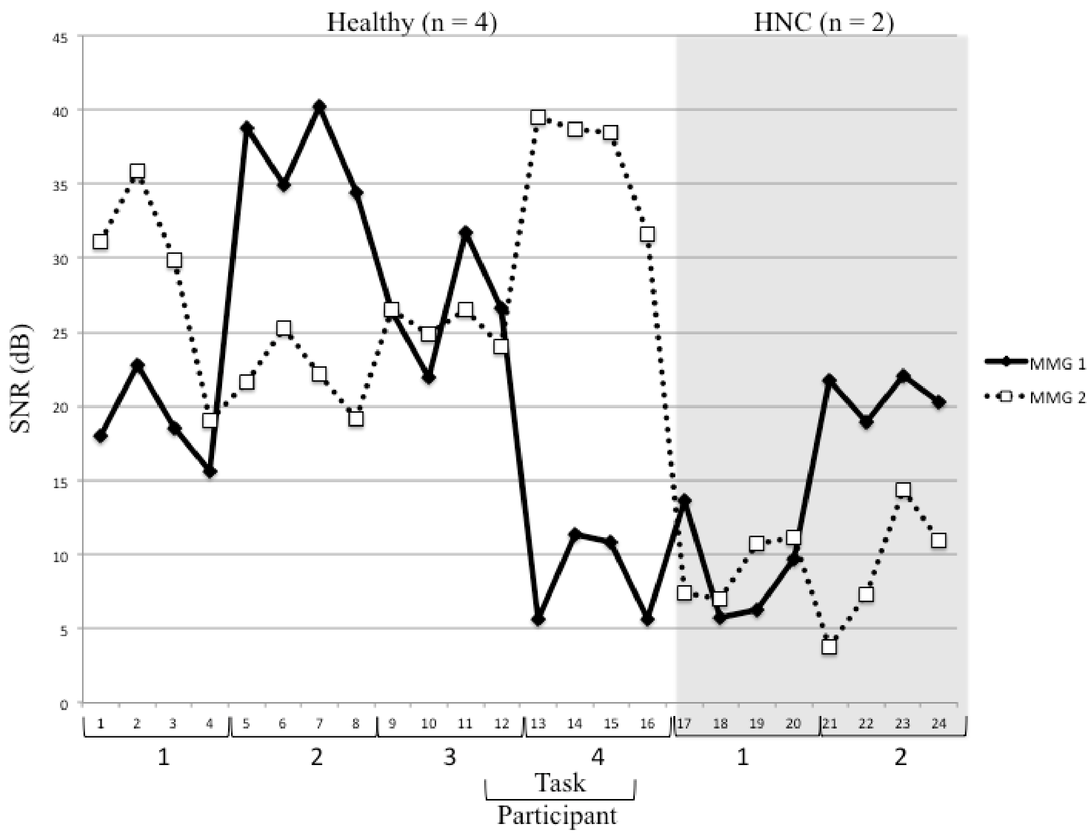
Figures 2.7a and 2.7b show the difference between test and retest measurements for each randomly selected participant (four healthy and two HNC), for each of the four tasks. These graphs illustrate the variation between the two SNR measures within each participant. Visual inspection of the sEMG test-retest measurements shows that the SNR obtained from these waveforms were fairly similar with the exception of participant 2. Visual inspection of the MMG test-retest measurements shows that the SNR varies considerably between the two measurements. Furthermore, this figure also shows that if the SNR for MMG 1 was noticeably lower or higher than MMG 2 in one participant, this observation was consistent for all four tasks for that participant. This trend would suggest that the test-retest differences in SNR observed with the MMG sensor were likely due to placement differences. The only instances where this observation does not hold true are for healthy participant 2 and HNC participant 1, where the SNR scores from MMG 1 and MMG 2 are visibly close.

Figure 2.7. Test-retest SNR for the Two Participant Groups.



(a)

Figure 2.7. (a) SNR obtained from test (sEMG 1) and retest (sEMG 2) signal for each of the 20% randomly selected participants. Each participant completed all four tasks in the same sequence: dry, thin liquid, effortful and Mendelsohn maneuver swallow. For example, point 1 represents the test and retest measure for the first randomly selected healthy participant performing a dry swallow. Point 24 represents the test and retest measure for the second randomly selected HNC participant performing a Mendelsohn maneuver swallow



(b)

(b) SNR obtained from test (MMG 1) and retest (MMG 2) signal for each of the 20% randomly selected participants. Each participant completed all four tasks in the same sequence: dry, thin liquid, effortful and Mendelsohn maneuver swallow. For example, point 1 represents the test and retest measure for the first randomly selected healthy participant performing a dry swallow. Point 24 represents the test and retest measure for the second randomly selected HNC participant performing a Mendelsohn maneuver swallow

Segmentation Reliability

The ICC(3,1) coefficients for intra-rater reliability of individual swallow segmentation were very good: 0.98 for the sEMG signal and 0.97 for the MMG signal.

Discussion

The present study compared the SNR captured from sEMG and MMG sensors in the signal collected from submental muscles during swallowing and swallow-like tasks. We expected that the MMG SNR would be higher than that of sEMG, as MMG has been said to be more robust than sEMG to variations in placement and skin impedance. Noting a trend in the opposite direction for signal collected in HNC participants was an informative discovery and has implications for which sensor should be used with this population.

In healthy participants, the MMG sensor yielded higher SNR than the sEMG sensor for dry and thin liquid swallows only, or said differently, in the two tasks that required less effort from participants. This observation was not made for the other two, more effortful tasks: effortful swallows and the Mendelsohn maneuver swallows. Standard deviations in task comparison pairs were similar (SD range = 4.96 to 7.75) and therefore, this observation cannot be attributed to a large within-subject variability in performance for these tasks. A more plausible explanation for the lack of difference between the sensors in the effortful tasks is the presence of exertion. The increased effort required by the effortful and the Mendelsohn swallows over typical saliva or water swallows may have resulted in muscle tremor. This added vibration is important because MMG signal analysis in the time domain is sensitive to muscle tremor and deformation (Ibitoye, Hamzaid, Zuniga, Hasnan, & Wahab, 2014).

In participants with a history of HNC, the lack of statistically significant difference noted between the two sensors assessed at each task level could be attributed to a smaller sample size, as this participant group was approximately half of the healthy population in this study. The unexpected trend, however, was that for all four tasks, the sEMG SNR appeared to be higher than that of the MMG sensor. This trend is the reverse of the one noted in healthy participants. A few possible explanations for this observation exist.

First, if this trend were true, it may be attributed to differences in the submental tissue between the two populations. It is possible that a reduction in tissue elasticity and thickness characteristic of scarring and fibrosis as well as fluid from edema influenced the way that contractions were detected by the MMG sensor. This hypothesis was previously suggested when attempting to explain reductions in the MMG signal amplitude noted with increased workload (Al-Mulla, Sepulveda, & Colley, 2011), and therefore warrants further testing. Furthermore, radiation-induced fibrosis is characterized by increased collagen tissue and high levels of muscle stiffness have been shown to suppress MMG amplitude (Nonaka, Mita, Akataki, Watakabe, & Itoh, 2006).

A second possible explanation is again, a difference in effort expended for these exercises between the two participants groups. In patients with a history of head and neck cancer, fibrosis has been shown to result in reduced lingual strength, poor base of tongue to posterior wall movement, reduced pharyngeal contraction, and diminished hypo-laryngeal movement (C. Lazarus, 2013). As a result, participants with HNC may exert themselves more to achieve a swallow, resulting in tremor that subsequently affects the MMG signal (Ibitoye et al., 2014). In addition, McCabe et al. suggested that fibrosed tissue might fatigue more quickly (McCabe et al., 2009), as radiation-induced damage to arteries and fine capillaries results in reduced blood supply to these muscles. Although this hypothesis remains to be tested in humans, animal studies have shown a significant reduction in tongue force production and speed of contraction with radiation, an observation further exacerbated by age (Russell & Connor, 2014). These anatomical changes may result in differences in how muscle contractions are detected by the two sensors, as well as variances in swallow performance leading to increased effort and fatigue.

Third, motion artifacts may explain why MMG SNR declined in participants with HNC. Motion artifact is significant and may be due to the skin-to-membrane contact in this sensor (A.O. Posatskiy & T. Chau, 2012). While Posatskiy and Chau found that microphone-based MMG sensors were more robust to the effects of motion artifact than accelerometer-based MMG sensors, they warned that this phenomenon is more complex when naturally occurring (A.O. Posatskiy & T. Chau, 2012), such as in the swallowing tasks included the present study. Given the complexity of the tissue in patients with HNC (i.e., scarring, fibrosis, muscle atrophy), it is likely that the MMG sensor was more sensitive to motion artifact in this particular participant group.

It was expected that the SNR of the signal collected from HNC participants would be lower than that in the signal from healthy participants because a direct relationship exists between the motor unit yield and sEMG SNR (Zaheer, Roy, & De Luca, 2012) and because HNC patients have an overall weaker swallow. The magnitude of the MMG signal also is linearly related to muscle strength in non-fatiguing contractions. Although this was not the case for sEMG, this observation was made for the MMG sensor. This may be due to differences in how the two sensors detect muscle contractions. For example, MMG sensors are able to detect muscle activity deeper than sEMG and the complex vibration of muscles may change with different motor unit recruitment patterns

(Posatskiy, 2011).

The signal collected in the present study from the sEMG sensors yielded SNR ranging from 5.17 dB to 29.12 dB. No previous reports of sEMG SNR from the signal acquired in the submental area during swallowing could be found for comparison, however, synthetic sEMG with SNR as low as 10 dB still had 100% accuracy in the detection of complete motor unit activity (Holobar & Zazula, 2004). In another study involving lower and upper limb muscles, a minimum SNR of three was needed in sEMG sensors for the motor unit yield to be reliable (Zaheer et al., 2012). The MMG sensor yielded SNR ranging from 3.58 dB to 22.99 dB. Again, no report of MMG SNR from the signal collected in the submental area during swallowing could be found for comparison.

Test-retest Measures

An interesting finding of the present study was the poor test-retest reliability observed with the MMG sensor. This was unexpected as previous ICC reports are high, albeit on the MMG signal amplitude rather than SNR and in the signal collected from limb muscles (Cramer et al., 2000; Evetovich et al., 1997; Herda et al., 2008; Smith et al., 1997). This difference in signal acquisition sites could explain the dissimilar ICCs between this study and those previously reported. The muscles investigated in the submental area are smaller and therefore, the conclusions with respect to test-retest cannot be generalized from larger limb muscles to those in the submental area.

The poor test-retest reliability observed with MMG in the present work also could be explained by the adhesion of the sensor to the skin: the MMG sensor had a smaller surface area and larger height (5mm) relative to the sEMG sensor adhesive pad. As a result, the KT™ tape may have created torque on the sensor during movement resulting in reduced contact with the skin. Furthermore, the weight of the MMG sensor may have further compounded the sensor-to-skin contact. Adhesion is important in the submental area as the sensor hangs against gravity and contact variations may result in poor signal detection or movement artefacts. In a study where activity from leg muscles was recorded, the MMG sensors were placed using a calf brace made of Polymide and Elastane, providing sufficient elasticity and adherence (Woodward, Shefelbine, & Vaidyanathan, 2014). This method of attachment was not suitable for the detection area in this study, as an elastic brace around the head could have hampered the naturalness of the swallow. This is an important finding and suggests that a more practical and reliable method for applying MMG sensors under the chin, or any areas where the sensor hangs against gravity, should be explored further. The results of the test-retest measures revealed that the type of surface sensor should be selected with consideration of the population at hand.

Although the sample size was too small to calculate test-retest reliability for each population type separately, it is not unreasonable to expect that these values would be smaller in HNC participants than in healthy participants due to the higher variance in the former population. However, the fact that very good test-retest overall reliability could be achieved with sEMG, but not MMG, suggests that the former sensor is a more robust technology when used in the submental area.

Limitations

The reader is cautioned that our primary aim was to describe a step in device development. Our findings cannot be used to draw conclusions on which sensor type is superior for investigating swallow kinematics.

Although the design was balanced for possible sex differences, the demographics for age were not balanced for the two participant groups. The mean age for healthy participants was 30 years lower than that of HNC participants. This discrepancy resulted from the nature of recruitment: the majority of healthy participants were University students. On the other hand, HNC diagnosis occurs predominantly at or after 65 years making this participant group older. Age differences, however, should not affect sEMG measurements. Although swallow function does change gradually with age, no significant differences were found in the amplitude of muscle activity collected from submental muscles in healthy adults under the age of 70 (Vaiman, Eviatar, & Segal, 2004). On the other hand, the MMG signal may be affected by age (Posatskiy, 2011) and therefore the results in this study should be carefully interpreted in light of this understanding.

Future work should focus on replicating these findings in a larger HNC participant group as well as comparing sEMG and MMG in other clinical populations (e.g., patients with dysphagia secondary to stroke). In this study, inter-swallow variability was addressed by collecting three trials of each task from all participants. However, this potential source of error could be reduced further by designing a dual sensor unit, one where the MMG sensor is placed between the two active electrodes of the sEMG sensor. In this way, the signal may be simultaneously collected with the two sensor types, from the same side of the submental area. Finally, future studies should compare other aspects of the signal between the two sensors, such as median frequency (e.g., consistency of the median frequency), to determine if trends observed with SNR outcomes are consistent across different parameters.

Conclusion

Several important discoveries were made as a result of this work. First of all, despite advancements in MMG technology, it is recommended that biofeedback devices applied in the submental area of HNC patients continue to use the more established and reliable sEMG sensors at least until the MMG sensors can yield comparable or better results in this detection area. A second important finding is that advantages held by one sensor over another cannot be generalized from healthy populations to disordered ones. Therefore, sensors should be selected based on the population and task studied.

References

Al-Mulla, M. R., Sepulveda, F., & Colley, M. (2011). A review of non-invasive techniques to detect and predict localised muscle fatigue. *Sensors (Basel), 11*(4), 3545-3594. doi:10.3390/s110403545

Azola, A. M., Greene, L. R., Taylor-Kamara, I., Macrae, P., Anderson, C., & Humbert, I. A. (2015). The Relationship Between Submental Surface Electromyography and Hyo-Laryngeal Kinematic Measures of Mendelsohn Maneuver Duration. *Journal of Speech, Language, and Hearing Research, 58*(6), 1627-1636. doi:10.1044/2015_JSLHR-S-14-0203

Basmajian, J. V., & De Luca, C. J. (1985). *Muscles Alive: Their Functions Revealed by Electromyography* (2nd ed.). Baltimore: Williams & Wilkins.

Beck, T. W., Housh, T. J., Cramer, J. T., Weir, J. P., Johnson, G. O., Coburn, J. W., . . . Mielke, M. (2005). Mechanomyographic amplitude and frequency responses during dynamic muscle actions: a comprehensive review. *BioMedical Engineering OnLine, 4*, 67. doi:10.1186/1475-925X-4-67

Brown, C. C. (2007). *Reliability of Electromyography Detection Systems for the Pelvic Floor Muscles.* (Master's of Science in Rehabilitation Science), Queen's University, Kingston, Ontario.

Bryant, M. (1991). Biofeedback in the Treatment of a Selected Dysphagic Patient. *Dysphagia, 6*, 140-144.

Cramer, J. T., Housh, T. J., Johnson, G. O., Ebersole, K. T., Perry, S. R., & Bull, A. J. (2000). Mechanomyographic and electromyographic responses of the superficial muscles of the quadriceps femoris during maximal, concentric isokinetic muscle actions. *Isokinetics and Exercise Science, 8*, 109-117.

Crary, M. A., & Baldwin, B. O. (1997). Surface Electromyographic Characteristics of Swallowing in Dysphagia Secondary to Brainstem Stroke. *Dysphagia, 12*, 180-187.

Crary, M. A., Carnaby Mann, G. D., Groher, M. E., & Helseth, E. (2004). Functional benefits of dysphagia therapy using adjunctive sEMG biofeedback. *Dysphagia, 19*(3), 160-164. doi:10.1007/s00455-004-0003-8

De-Ary-Pires, B., Ary-Pires, R., & Pires-Neto, M. A. (2003). The human digastric muscle: Patterns and variations with clinical and surgical correlations. *Annals of Anatomy, 185*, 471-479.

Evetovich, T. K., Housh, T. J., Stout, J. R., Johnson, G. O., Smith, D. R., & Ebersole, K. T. (1997). Mechanomyographic responses to concentric isokinetic muscle contractions. *European Journal of Applied Physiology, 75*, 166-169.

Herda, T. J., Ryan, E. D., Beck, T. W., Costa, P. B., DeFreitas, J. M., Stout, J. R., & Cramer, J. T. (2008). Reliability of mechanomyographic amplitude and mean power frequency during isometric step and ramp muscle actions. *Journal of Neuroscience Methods, 171*(1), 104-109. doi:10.1016/j.jneumeth.2008.02.017

Hermens, H. J., Freriks, B., Disselhorst-Klug, C., & Rau, G. (2000). Development of recommendations for SEMG sensors and sensor placement procedures. *Journal of Electromyography and Kinesiology, 10*, 361-374.

Hind, J. A., Nicosia, M. A., Roecker, E. B., Carnes, M. L., & Robbins, J. (2001). Comparison of effortful and noneffortful swallows in healthy middle-aged and older adults. *Archives of Physical Medicine and Rehabilitation, 82*(12), 1661-1665. doi:10.1053/apmr.2001.28006

Holobar, A., & Zazula, D. (2004). Correlation-based decomposition of surface electromyopgrams at low contraction forces. *Medical & Biological Engineering & Computing, 42*, 487-495.

Hutcheson, K. A., Lewin, J. S., Barringer, D. A., Lisec, A., Gunn, G. B., Moore, M. W., & Holsinger, F. C. (2012). Late dysphagia after radiotherapy-based treatment of head and neck cancer. *Cancer, 118*(23), 5793-5799. doi:10.1002/cncr.27631

Ibitoye, M. O., Hamzaid, N. A., Zuniga, J. M., Hasnan, N., & Wahab, A. K. (2014). Mechanomyographic parameter extraction methods: an appraisal for clinical applications. *Sensors (Basel), 14*(12), 22940-22970. doi:10.3390/s141222940

Islam, M. A., Sundaraj, K., Ahmad, R. B., Sundaraj, S., Ahamed, N. U., & Ali, M. A. (2014). Cross-talk in mechanomyographic signals from the forearm muscles during sub-maximal to maximal isometric grip force. *PLoS One, 9*(5), e96628. doi:10.1371/journal.pone.0096628

Jaskolska, A., Brzenczek, W., Kisiel-Sajewicz, K., Kawczynski, A., Marusiak, J., & Jaskolski, A. (2004). The effect of skinfold on frequency of human muscle mechanomyogram. *Journal of Electromyography Kinesiology, 14*(2), 217-225. doi:10.1016/j.jelekin.2003.08.001

Langerman, A., MacCracken, E., Kasza, K., Haraf, D. J., Vokes, E. E., & Stenson, K. M. (2007). Aspiration in CRT patients with HNC. *Archives of Otolaryngology—Head & Neck Surgery, 133*(12), 1289-1295.

Lazarus, C. (2013). Dysphagia Secondary to the Effects of Chemotherapy and Radiotherapy. In R. Shaker, P. C. Belafsky, G. N. Postma, & C. Easterling (Eds.), *Principles of Deglutition: A Multidisciplinary Text for Swallowing and its Disorders* (pp. 431-443). New York: Springer Science+Business Media.

Lazarus, C., Logemann, J. A., Song, C. W., Rademaker, A. W., & Kahrilas, P. J. (2002). Effects of Voluntary Maneuvers on Tongue Base Function for Swallowing. *Folia Phoniatrica et Logopaedica, 54*(4), 171-176. doi:10.1159/000063192

Lee, J., Chau, T., & Steele, C. M. (2009). Effects of age and stimulus on submental mechanomyography signals during swallowing. *Dysphagia, 24*(3), 265-273. doi:10.1007/s00455-008-9200-1

Lee, J., Steele, C. M., & Chau, T. (2009). Swallow segmentation with artificial neural networks and multi-sensor fusion. *Medical Engineering & Physics, 31*(9), 1049-1055. doi:10.1016/j.medengphy.2009.07.001

McCabe, D., Ashford, J., Wheeler-Hegland, K., Frymark, T., Mullen, R., Musson, N., . . . Schooling, T. (2009). Evidence-based systematic review: Oropharyngeal dysphagia behavioral treatments. Part IV—Impact of dysphagia treatment on individuals' postcancer treatments. *The Journal of Rehabilitation Research and Development, 46*(2), 205. doi:10.1682/jrrd.2008.08.0092

Mohamed Irfan, M. R., Sudharsan, N., Santhanakrishnan, S., & Geethanjali, B. (2011). A Comparative Study of EMG and MMG Signals for Practical Applications. *International Conference on Signal, Image Processing and Applications With workshop of ICEEA 2011, 21*.

Nonaka, H., Mita, K., Akataki, K., Watakabe, M., & Itoh, Y. (2006). Sex differences in mechanomyographic responses to voluntary isometric contractions. *Medicine and Science in Sports and Exercise, 38*(7), 1311-1316. doi:10.1249/01.mss.0000227317.31470.16

Petitjean, M., Maton, B., & Cnockaert, J.-C. (1992). Evaluation of human dynamic contraction by phonomyography. *The American Physiological Society, 73*(6), 2567-2573.

Posatskiy, A. O. (2011). *Design and evaluation of pressure-based sensors for mechanomyography: an investigation of chamber geometry and motion artefact.* (Master of Applied Science), University of Toronto.

Posatskiy, A. O., & Chau, T. (2012). Design and evaluation of a novel microphone-based mechanomyography sensor with cylindrical and conical acoustic chambers. *Medical Engineering & Physics, 34*(8), 1184-1190. doi:10.1016/j.medengphy.2011.12.007

Posatskiy, A. O., & Chau, T. (2012). The effects of motion artifact on mechanomyography: A comparative study of microphones and accelerometers. *Journal of Electromyography and Kinesiology, 22*(2), 320-324. doi:10.1016/j.jelekin.2011.09.004

Reaz, M. B., Hussain, M. S., & Mohd-Yasin, F. (2006). Techniques of EMG signal analysis: detection, processing, classification and applications. *Biological Procedures Online, 8*, 11-35. doi:10.1251/bpo115

Roy, S. H., De Luca, G., Cheng, M. S., Johansson, A., Gilmore, L. D., & De Luca, C. J. (2007). Electro-mechanical stability of surface EMG sensors. *Medical & Biologial Engineering & Computing, 45*, 447-457.

Russell, J. A., & Connor, N. P. (2014). Effects of age and radiation treatment on function of extrinsic tongue muscles. *Radiotherapy and Oncology, 9*(254), 1-15.

Seikaly, H., Jha, N., McGaw, T., Coulter, L., Liu, R., & Oldring, D. (2001). Submandibular Gland Transfer: A New Method of Preventing Radiation-Induced Xerostomia. *Laryngoscope, 111*, 347-352.

Shaw, S. M., & Martino, R. (2013). The normal swallow: muscular and neurophysiological control. *Otolaryngologic Clinics of North America, 46*(6), 937-956. doi:10.1016/j.otc.2013.09.006

Silva, J., & Chau, T. (2003). Coupled microphone-accelerometer sensor pair for dynamic noise reduction in MMG signal recording. *Electronics Letters, 39*(21), 1496. doi:10.1049/el:20031003

Silva, S., & Chau, T. (2005). A Mathematical Model for Source Separation of MMG Signals Recorded With a Coupled Microphone-Accelerometer Sensor Pair. *IEEE Transactions on Biomedical Engineering, 52*(9), 1943-1501.

Smith, D. B., Housh, T. J., Stout, J. R., Johnson, G. O., Evetovich, T. K., & Ebersole, K. T. (1997). Mechanomyographic responses to maximal eccentric isokinetic muscle actions. *The American Physiological Society* (Special Communication), 1003-1007.

Stepp, C. E. (2012). Tutorial: Surface Electromyography for Speech and Swallowing Systems: Measurement, Analysis, and Interpretation. *Journal of Speech,* *Language, and Hearing Research, 55*, 1232-1246. doi:10.1044/1092-4388(2011/11-0214

Vaiman, M., Eviatar, E., & Segal, S. (2004). Evaluation of Normal Deglutition with the Help of Rectified Surface Electromyography Records. *Dysphagia, 19*(2). doi:10.1007/s00455-003-0504-x

Valouchova, P., & Lewit, K. (2009). Surface electromyography of abdominal and back muscles in patients with active scars. *Journal of Bodywork and Movement Therapies, 13*(3), 262-267. doi:10.1016/j.jbmt.2008.04.033

Vigreux, B., Cnockaert, J. C., & Pertuzon, E. (1979). Factors Influencing Quantified Surface EMGs. *European Journal of Applied Physiology, 41*, 119-129.

Wheeler-Hegland, K., Rosenbek, J. C., & Sapienza, C. M. (2008). Submental sEMG and Hyoid Movement During Mendelsohn Maneuver, Effortful Swallow, and Expiratory Muscle Strength Training. *Journal of Speech, Language, and Hearing Research, 51*(5), 1072-1087.

Woodward, R., Shefelbine, S., & Vaidyanathan, R. (2014, 27-29 May 2014). *Pervasive Motion Tracking and Muscle Activity Monitor.* Paper presented at the Computer-Based Medical Systems (CBMS), 2014 IEEE 27th International Symposium on.

Zaheer, F., Roy, S. H., & De Luca, C. J. (2012). Preferred sensor sites for surface EMG signal decomposition. *Physiological Measurement, 33*(2), 195-206. doi:10.1088/0967-3334/33/2/195

CHAPTER 3: USING PATIENT INPUT TO GUIDE DESIGN

This chapter was published in its entirety: Constantinescu G, Loewen I, King B, Brodt C, Hodgetts W, Rieger J. Designing a Mobile Health App for Patients With Dysphagia Following Head and Neck Cancer: A Qualitative Study. JMIR Rehabil Assist Technol 2017;4(1):e3

Introduction

Background

More than half of the patients treated for head and neck cancer (HNC) will experience swallowing difficulties also known as dysphagia (Arrese & Lazarus, 2013; Dysphagia Section et al., 2012; Langerman et al., 2007; Szczesniak, Maclean, Zhang, Graham, & Cook, 2014). The inability to swallow safely can have serious consequences on the health and psychosocial well-being of these patients, such as malnourishment, dehydration, aspiration pneumonia, and depression. Although research has shown that individualized, intensive therapy achieves lasting changes to swallowing anatomy and physiology (Burkhead, Sapienza, & Rosenbek, 2007), limited clinical resources result in the majority of swallowing therapy prescribed as home programs. Home programs have been reported to have low adherence rates (Shinn et al., 2013) and require clinicians to rely on patient report to measure effectiveness. These limitations render existing approaches to dysphagia treatment inadequate. Technological advancements such as mobile health (mHealth) devices, can be combined with existing effective therapies to help address this clinical gap and remotely monitor adherence to treatment regimens.

mHealth and Swallowing Exercises

The purpose of this study was to obtain patient opinions to inform the design of an mHealth app for swallowing therapy. This app is used together with a wireless mobile device and uses surface electromyography (sEMG) sensors to provide patients with real-time feedback during the exercise. Although it has been recognized that patients prefer more appealing and intuitive displays over signal tracings, the process and research used to select visuals for mHealth apps is rarely reported.

Before this study, six design concepts for sEMG biofeedback were generated by considering a typical saliva swallow as well as the technique and clinical goals (e.g., peak amplitude and duration of contraction) for the two swallowing exercises targeted by the app: the effortful swallow and the Mendelsohn maneuver. Two elements were varied in these six designs: (1) the level of visual complexity (simple, complex, abstract) and (2) the presence of a character (e.g., coach or third person game) (Figure 3.1).

Figure 3.1. Design Concepts for Visual Biofeedback

Figure 3.1. The design concepts for visual biofeedback can be distinguished across two features: the type of visuals, and the presence or absence of a character. An example for each of the swallow exercises was created for all six categories and explained to patients in a video.

Smeddinck et al. (2013) identified visual complexity as an important element to consider in the design of games for health. They surmised from previous work and anecdotal evidence that whereas complex graphics can increase a sense of immersion and motivation in the user, they also can distract patients from their own movements resulting in injury or overexertion (Smeddinck, Gerling, & Tiemkeo, 2013). In their study, Smeddinck et al. systematically manipulated visual complexity using a taxonomy for common levels of computer graphics ranging from simplified to realistic. The authors found that although visual complexity had no influence on player experience, the older adults perceived greater exertion when realistic visuals were used (Smeddinck et al., 2013). The presence of a character (i.e., third person games) or a coach is another important element to present to patients as a visual option. The presence of a coach may help patients transition from one-on-one therapy with a clinician to home-based sessions and has been used with other health apps such as My Fitness Coach from Wii. Third person games offer a familiar and predictable game setting and have been successfully used with games for health with pediatric and young adult cancer patients (Kato, Cole, Bradlyn, & Pollock, 2008).

This study had two primary goals, both aimed at contributing to the development of a swallowing therapy app that is engaging to patients with HNC. The first part of patient interviews focused on identifying the determinants of successful adherence to home-based swallowing therapy, information that will be used to select app features (e.g., reminders). The second part of the interview focused on obtaining reactions to designs for the visual biofeedback. This aspect of the app was selected because the real-time biofeedback is what participants will rely on as an indicator of correct exercise completion, in the absence of a clinician.

Objectives

The following are our study objectives:

1. What are self-reported determinants for adherence to conventional home therapy (i.e., without a mobile device) in patients with dysphagia following treatment for HNC?
2. When shown concepts of visual biofeedback for swallowing therapy exercises that could be used with a mobile device, what are some key design elements that patients with dysphagia feel are important?

Interviewing techniques were selected based on the aim of each objective. Therefore, although each participant took part in a single interview, two distinct methods were employed in succession.

Methods

Participants

The Health Research Ethics Board at the University of Alberta, Edmonton, Alberta, Canada approved this study. Patients with a history of HNC were recruited through tertiary care centers in Edmonton. Participants were included in the study if they reported difficulties with swallowing of any kind and if they had experience with home-based, unsupervised therapy following cancer treatment. This experience was not limited to swallowing exercises as it is possible that not all participants received home programs for swallowing therapy, but may have had other rehabilitation exercises, such as physiotherapy, prescribed.

Procedures

Participants were approached either in person or by phone once consent to be contacted by the research team was provided. Participants were booked for an individual appointment, which was split up into two parts and video recorded. Part 1 used a semi-structured approach to explore the facilitators and barriers of adherence to conventional home therapy, without a mobile device. This style of interview allowed for the flexibility to understand individual and unanticipated ideas, but still retained the structure needed for interparticipant comparison (Braun & Clarke, 2006). Part 2 of the appointment determined patient preference for visual biofeedback using a convergent interviewing approach. Convergent interviewing is a structured process for explorative research in an emerging field (Jepsen & Rodwell, 2008; Williams & Lewis, 2005). This process has two distinguishing features: (1) participants are systematically selected to reflect a wide range of opinions and (2) the process is progressive whereby the initial interview questions, at first unstructured, are used to identify key issues; these findings help focus the questions for subsequent sets of interviews. In this way, converging key issues can be identified (Jepsen & Rodwell, 2008; Rao & Perry, 2003; Williams & Lewis, 2005). Convergent interviews were analyzed in sets of three; the first three interviews (i.e., first set) were analyzed for uniting themes, which were then used to guide the interview questions for the subsequent set of three appointments. Given that 10 participants were recruited, the first set of convergent interviews comprised four participants. An effort was made to ensure that each set of three interviews contained participants of different ages and sex. Demographic and past swallowing therapy information was collected at the beginning of the appointment. HNC treatment variables were collected from a chart review. All the participants who were contacted for the study participated.

Interviews were conducted by the first author, a speech-language pathologist with clinical expertise in interviewing this population. As these were her first interviews conducted for research purposes, several pilots were conducted. Recordings took place at two locations, each with an identical setup. All participants were told that this study was part of a larger research goal to develop an mHealth device for swallowing therapy with sEMG sensor technology.

Semi-structured interviews (part 1). Participants were comfortably seated in a room with the interviewer. To explore patient perceived barriers and facilitators to completing conventional swallowing exercises at home, an open-ended question was asked to all participants: "Throughout your cancer treatment, you may have been given some exercises by your speech therapist or your physical therapist. What is your honest opinion about having to do these exercises?" Questions that followed were composed using the Rogers et al. theoretical framework for physical activity behaviour in patients with HNC (Rogers et al., 2008) as a guide (Appendix B). During the interviews, follow-up questions were used to obtain more in-depth information from participants; as such, no two interviews were identical.

The interviews were transcribed verbatim, and identifiers such as names of family, friends or clinicians were removed (Braun & Clarke, 2006; Cobley, Fisher, Chouliara, Kerr, & Walker, 2013). Thematic analysis was data-driven and semantic themes (i.e., using the surface meaning of data) were sought (Braun & Clarke, 2006). Two investigators (GC, IL) coded the transcripts independently, using NVivo for Mac, version 11.1.1 (QSR International Pty Ltd). Lab notes were kept in NVivo and the study binder. Once consensus was reached, transcripts were re-coded using the mutually agreed upon set of codes. Codes were grouped into themes and subthemes (Guba, 1978) using Coggle (coggle.it, Cambridge, England).

Convergent interviews (part 2). During this part of the interview, a second interviewer was called in the room to participate with the first three participants. This was done to ensure that questions specific to design were addressed and that design ideas for biofeedback were interpreted correctly for participants (e.g., what will happen if the exercise target is unmet in a given design concept). Once the clinician felt comfortable addressing all topics independently, the second interviewer no longer took part. Each participant was introduced to, and asked to try the effortful and the Mendelsohn maneuver swallowing exercises to gain a sense of the effort and focus required to complete them. Next, they were introduced to visual biofeedback and its potential to aid in completing the demonstrated exercises. Participants were presented a short video displaying the six distinct visual biofeedback concepts. Patients were then asked a series of questions (Appendix B) to identify distinct visual biofeedback elements of importance to them with respect to swallowing exercises. This approach, like the first part, required broad and open initial questions to encourage interviewees to share as much information as possible without biasing prompts (Jepsen & Rodwell, 2008). On occasion, questions were posed again to allow participants to reflect on what had already been shared.

Three groupings of participant appointments were booked. Interviews in the first set were transcribed and analyzed to determine key design themes. These were defined as a topic or element that was brought up by at least two participants in a set of interviews. It did not matter if participants in the set agreed or disagreed on the theme. When an issue was brought up by only one interviewee, it was noted, but not regarded as key (Jepsen & Rodwell, 2008). Two researchers (GC, CB) independently analyzed the transcripts and identified key design themes through consensus.

In subsequent sets of interviews, the interviewer sought to expand on and to clarify these key design topics. Once new interview questions were generated, the industrial designers and a second clinician vetted them before the start of a new set of interviews. Rao et al. (2003) point out that as interview data are collected new insights may emerge, prompting reexamination of the literature and reshaping ideas for subsequent interviews. If a participant in the second or third group of interviews raised a new topic, it was noted, but not further probed in subsequent discussions unless at least one other interviewee in that set also brought up that topic (Figure 3.2). Following analysis of all convergent interviews, themes were once again analysed to determine if they were suitably categorized.

Figure 3.2. Sample of On-going Analysis of Issues in Convergent Interviews

Round	**1**				**2**			**3**		
Participant	1	2	3	4	5	6	7	8	9	10
A. Biofeedback function										
1. Feedback should only show amount of effort (not too much information)	✓	-	-	✗	D	D	-	A	✓	✓
2. Feedback should be immediate	✓	-	-	✓	-	A	-	A	A	A
3. Feedback should mimic what muscles are doing (e.g., lift).	✓	-	-	-	•	•	•	•	•	•
4. Feedback should be contingent on effort, but also show patient progress relative to a goal	✓	-	-	✗	A	A	-	D	A	✓
5. Feedback should only tell patients if they met a target or not	-	-	-	✓	•	•	•	•	•	•
6. Feedback should be simple and straightforward	✓	-	-	✓	✓	✓	-	A	A	A
7. 3rd person player feedback is not a good measure of what is happening	✓	-	-	✗	✓	A	-	A	D	✓
8. 3rd person player feedback does not make it obvious if the patients completed the exercise correctly	✓	-	-	✗	✓	D	-	U	A	A
9. sEMG biofeedback at the time of swallowing therapy was not helpful	-	-	-	-	-	-	A	•	✗	•
10. If patients do not understand biofeedback, they may end up doing whatever	-	-	-	-	-	-	-	-	✓	-
11. Immediate feedback can help when trying different things until patients can find success with the exercise	-	-	-	-	-	-	-	-	-	✓
B. Having choice is important (e.g., game, how much information to display, sound)	✓	-	-	-	•	•	•	•	✓	•
C. Patient education										
12. Coach may help with long term adherence	✓	-	-	-	•	•	•	•	•	•

Figure 3.2. Fragment of convergent interview analysis: (✓) participant agreed with issue; (✗) participant disagreed with issue; (-) participant did not raise this issue, or issue was not probed by clinician; (A) issue actively probed for by interviewer in subsequent set and participant agreed; (D) issue actively probed for by interviewer in subsequent set and participant disagreed; (U) issue actively probed for by interviewer in subsequent set and

participant undecided or gave contradicting statements throughout the interview; (□) not a converging theme from previous set and not specifically probed for by interviewer.

Results

Demographics

The study sample comprised a convenience sample of patients visiting the center for various reasons. Descriptive statistics are summarized in Table 3.1. Although nine patients complained of dysphagia, only seven reported having been prescribed swallowing exercises to do at home. One participant reflected mostly on his shoulder rehabilitation exercises, whereas another on his voice therapy. One participant had just begun his radiation therapy at the time of the interview and reported reduced taste sensation. Although this participant had experienced mild pain with swallowing at the time of recruitment, this had resolved. Six participants had prior experience with sEMG as an adjuvant to swallowing therapy in the clinic.

Table 3.1.

Participant Information

Sex	Age	T-stage	Education	Annual household income (CAD)	Dysphagia history	Past Swallowing Therapy
Female	45	T2	University	> 80,000	8 months	Yes
Male	64	T1	High school	< 20,000	7 years	No
Male	57	Tx	College	(left blank)	6 months	Yes

Male	66	T1	College	> 80,000	NA	Yes
Female	61	T2	High school	60,000 – 79,999	5 years	Yes
Female	60	T2	University	> 80,000	8 years	Yes
Male	70	T3	University	(left blank)	5 years	Yes
Female	68	T4	(left blank)	(left blank)	1 years 2 months	Yes
Male	60	T3	High school	< 20,000	16 years 3 months	Yes
Male	50	T2	College	> 80,000	7 years 10 months	Yes

Semi-structured interviews were on average 41 minutes in length (range 19 to 67 minutes), whereas convergent interviews lasted on average 40 minutes (range 27 to 57 minutes). As these two interviews addressed different objectives, they will be reported on separately.

Semi-Structured Interviews (Part 1)

A total of 74 mutually agreed upon set of codes were identified; five of these codes were used to mark important information, but were not relevant to the research question (e.g., frequency and format of home exercises). Codes were organized into six distinct themes: (1) perceptions on outcomes and progress, (2) role of clinical appointments, (3) cancer treatment, (4) rehabilitation program, (5) personal factors, and

(6) connection. Facilitators and barriers of adherence to unsupervised home therapy, as explained by these themes, are summarized in Appendix C.

The first theme, perceptions on outcomes and progress, revealed a potential link in adherence to the gap perceived by patients between their current function and their goal, or their progress toward that goal. Both facilitators and barriers to adherence were evident in this theme. The second theme, role of clinical appointments, included comments on how clinical appointments and clinicians serve to promote adherence. Clinical appointments provided a place for patients to receive education on the anatomy and physiology of a swallow and on how prescribed exercises could improve current function. The use of technology such as biofeedback and modified barium swallow videos facilitated education. These appointments also served as an opportunity to build confidence; patients welcomed reassurance from clinicians if they felt guilty about not completing the full treatment regimen and if they second-guessed their exercise performance. Patients also appreciated clinical appointments as they provided an opportunity to have exercise prescriptions tailored to their needs and abilities. Finally, appointments provided reminders and accountability for doing the exercises. Only facilitators were identified in this theme, although two participants brought up a wish for better access.

The third theme, cancer treatment, described various barriers to adherence that relate to surgery, radiation therapy or chemotherapy. Patients mentioned difficulties with memory and focus as well as being overwhelmed with information and recommendations. Another perceived barrier was lack of energy or weakness, expressed as either general exhaustion or as rapid muscle fatigue when completing the exercises.

Various other side effects mentioned included pain, discomfort, swelling, fibrosis, scarring, postradiation hypothyroidism, and depression. The fourth theme, rehabilitation program, revealed that although there were some facilitators and barriers general to the way the rehabilitation regimen had been set up, some factors also depended on the exercises themselves (e.g., novelty, complexity) and some were patient-dependent (e.g., time of day when exercises would be completed). Some patients preferred to continue to try new types of exercises and asked peers on social media to share their recommendations, whereas one patient reported wanting to wait until a technological solution (i.e., prosthetic throat) would exist.

The fifth theme, personal factors, revealed that patients were, at least in this context, generally positive and grateful to be alive. They revealed coping skills through their self-talk and self-compassion, respect for the extent of efforts made by their health care workers, and a wish to help others. Only facilitators to adherence were identified in this theme. The last theme, connection, explained the impact made by a patient's social context (i.e., other patients, friends, family) on adherence and on perceptions of current function. On one hand, interactions with other HNC patients provided support; however, it also facilitated peer comparison of function, a code found in nine out of the 10 participants in this study. If a patient found his or her function to be better than that of other HNC patients, this made that patient feel good. Although this comparison was not explicitly stated as a facilitator of adherence to home-based treatment, it did influence how patients perceived their current function. This shift in perception may be considered an indirect facilitator or barrier of adherence.

In addition to these themes, it became apparent during the interviews that patient perspectives varied on what home-based swallowing therapy was. When answering interview questions, participants referred to a number of different activities, such as stretches (e.g., neck, jaw), maneuvers (e.g., head tilt, head turn), and rehabilitation exercises (e.g., Mendelsohn maneuver, effortful swallow). Two participants considered swallowing in general as the exercise, making questions on adherence difficult to analyze because these patients felt that they were constantly exercising.

Convergent Interviews (Part 2)

A total of 84 issues and 11 preliminary themes were found across all 10 interviews. Of these, 21 were found to be convergent (Appendix D). These topics were first explored for level of agreement. All participants who had an opportunity to discuss the following issues agreed that biofeedback should be immediate, simple and straightforward; noting improvement over time is important and builds confidence; competition with oneself is preferred over competition with peers. Most participants (5 or more) agreed that: feedback should be contingent on effort, but also show user progress relative to a goal; having a third person character is not a good measure of what is happening during the swallow exercise; education is important for uptake and adherence; tracking progress over time is important; and visuals where structures are built over time are engaging. Most participants (5 or more) disagreed with issues raised by some of the participants in the first set of interviews, namely that: visuals with a medical look, such as raw signal, are unappealing; progress graphs are difficult to interpret; completing all assigned swallow trials is important; and that they felt concern for a third person character in the game (i.e., did not want character to get hurt if the swallow exercise was not completed well). A split in opinion was noted for the following issues: feedback should only show amount of effort (i.e., not overwhelm the user with too much information), that the third person character feedback does not make it obvious if the exercise was completed correctly, that the third person player game is engaging, that more complex visuals are better than simplistic ones, that built-in reminders are beneficial, and finally that failure motivates one to keep trying.

Discussion

Principal Findings

This study obtained detailed patient feedback on past experiences with home programs and on preferences for app visuals, findings that may generalize to other apps for HNC patients, and apps that use visual biofeedback. The study also offers a detailed documentation of our approach to designing a mobile swallowing therapy app, a methodology that may be applied when developing for other patient groups.

The exploration of determinants for adherence to home therapy revealed a number of elements that could be incorporated in future mHealth apps for swallowing therapy. First, aside from an objective approach to documenting adherence, mHealth apps would provide an opportunity for clinician remote monitoring. Fluctuations in adherence or nonadherence could alert clinicians so that they may target those patients who struggle most. Adjustments to the therapy regimen could be made remotely or in conversation with the patient, retaining an individualized quality to the therapy. For example, this is an existing feature of SwallowSTRONG, an mHealth device and app for tongue strengthening exercises (Swallow Solutions, LLC, Madison, WI). Finally, remote monitoring also provides an avenue for accountability to a clinician.

Second, apps may address any existing or anticipated gaps in access to swallowing therapy or educational information. A mobile device also provides an opportunity for HNC patients to complete exercises during high-energy periods in the day or to customize exercise programs according to medication schedule, rather than to clinician availability.

Third, mHealth devices and apps for swallowing therapy can furthermore address adherence by providing education, instructions and biofeedback. The app could include educational screens highlighting the importance of regular exercise, and the expected impact that specific exercises are expected to have on swallow physiology. Education on how progress may change throughout the course of cancer treatment also may be important, as some patients reported neglecting their exercises when function appeared to improve. Information that can be accessed multiple times, at the user's convenience, should address concerns raised around the shame of asking for help. The app could track progress over time and use that information to demonstrate incremental improvements.

Two additional important elements that should be considered in a swallowing therapy mHealth app relate to biofeedback and social engagement. First, the biofeedback should be accurate and precise enough so that appropriate techniques are reinforced and frustration is minimized. Second, although leaderboards and status shares are important elements in many other health apps, our findings suggest that these are not recommended for swallowing therapy in HNC patients. Peer-to-peer comparison of performance may result in poor self-efficacy and lead to depression; however, social engagement in the app may take on other forms such as an anonymous patient-to-patient exchange of motivational messages.

Finally, some aspects of adherence appeared to be best mediated during clinical appointments. These included forming realistic expectations, building hope, and managing treatment side effects such as pain.

With respect to the development of our app, the following design recommendations were made once converging themes were synthesized. Visual biofeedback should be immediate and relative to the level of muscle activity detected. It should be represented simply so that it is easily understood. Since mixed opinions occurred with respect to displaying a reference target during each trial, perhaps this visual can be set to on or off based on user preferences.

With respect to visuals in the app, there was no real or perceived aversion to the raw signal. Whereas the participants agreed that it looked medical, most preferred it because they found it easy to interpret. An interesting finding was that typical game-play (i.e., third person character jumping or ducking over obstacles) was not meaningful to the patients in this study and should be avoided for swallowing therapy apps. However, the act of constructing something over time was deemed engaging and even more entertaining than simpler visuals. When biofeedback was represented through expanding shapes and colours, participants felt that the visuals were too soft and uninteresting. Furthermore, irrespective of the visual theme, failure should be presented in a sensitive way. Whereas a few participants felt that failure in the app would be a strong motivator (e.g., character falls down a cliff if target is not met), the majority of participants shared that failing in the game would be upsetting: "I would feel defeated. Like oh yeah, don't even know how to do this." Finally, tracking improvements over time within the game have the potential to build confidence with the user's swallowing ability outside of the app.

With respect to app features, participants agreed that education was important, particularly to build an understanding on the importance of completing all trials with maximum effort. Connecting with other HNC patients in the app for the purpose of competition should be avoided. Built-in reminders may help some users, but could be postponed to later app versions as some participants stated that they would not use this feature.

Limitations

This study consisted of a convenience sample of 10 participants recruited over a period of six months. Since these interviews were conducted to inform the design of an app, it is possible that data saturation was not achieved. A time frame of six months was deemed a reasonable delay in the development of our mHealth app in order to engage end-users early. Furthermore, although the sample size was small, it was heterogeneous enough (e.g., in duration of dysphagia, length of time from cancer treatment and level of adherence to swallowing exercises) to represent most types of patients using the future mHealth app. In addition, three of the 10 participants reported no prior experience with home-based swallowing therapy and had to reflect on other types of rehabilitation exercises. Therefore, the reader is cautioned when interpreting these findings, as the themes identified here may not generalize to all HNC patients or swallowing apps.

Additional limitations include self-selection and recall bias. Two participants were noted to wear a FitBit and one participant wore a smartwatch; participants varied in their experience with dysphagia (6 months to 16 years). In addition, we were unable to quantify the strength of a participant's opinion. For example, how does one distinguish between a participant who has a preference, but not a strong one, and someone who may not complete the exercise program at all if a particular design were selected?

Additional details on the study were compiled with the assistance of the Consolidated criteria for Reporting Qualitative Research COREQ checklist (Tong, Sainsbury, & Craig, 2007) and are summarized here to assist readers in assessing the level of bias present in this work. The interviewer (GC) and the second coder in part 1 (IL) are female, both with clinical experience in HNC; the industrial designers who assisted with part 2 (BK and CB) are both male. Although the interviewer had prior expertise conducting clinical interviews, this was her first time doing so in a research study. The researchers could not approach patients directly for study recruitment until consent to be contacted by the research team was provided. Therefore, it is unknown how many patients were approached, but declined to be contacted. A prior relationship existed with some patients as the primary interviewer also worked as a clinician. Furthermore, participants did not provide feedback on the transcript accuracy or findings.

Conclusions

The collection of patient perspectives is an important step in the development of mHealth technologies for a patient population that has not been extensively targeted by this industry. Although a laborious process, the themes identified in this study informed how mHealth apps could be used as an adjuvant to home rehabilitation following treatment for head and neck cancer. This approach also revealed that visuals that appeal to the development team, such a complex graphics with game elements, might not necessarily be intuitive to users.

Acknowledgements

This work was supported by Alberta Cancer Foundation Transformative Program Grant; Alberta Innovate (AI) Clinician Fellowship; Natural Sciences and Engineering Research Council (NSERC) and industrial and government partners, through the Healthcare Support through Information Technology Enhancements (hSITE) Strategic Research Network. The authors also would like to thank all patient participants for generously volunteering their time in this study.

References

Arrese, L. C., & Lazarus, C. L. (2013). Special groups: head and neck cancer. *Otolaryngologic Clinics of North America, 46*(6), 1123-1136. doi:10.1016/j.otc.2013.08.009

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology, 3*(2), 77-101. doi:10.1191/1478088706qp063oa

Burkhead, L. M., Sapienza, C. M., & Rosenbek, J. C. (2007). Strength-training exercise in dysphagia rehabilitation: principles, procedures, and directions for future research. *Dysphagia, 22*(3), 251-265. doi:10.1007/s00455-006-9074-z

Cobley, C. S., Fisher, R. J., Chouliara, N., Kerr, M., & Walker, M. F. (2013). A qualitative study exploring patients' and carers' experiences of Early Supported Discharge services after stroke. *Clinical Rehabilitation, 27*(8), 750-757. doi:10.1177/0269215512474030

Dysphagia Section, O. C. S. G. M. A. o. S. C. i. C. I. S. o. O. O., Raber-Durlacher, J. E., Brennan, M. T., Verdonck-de Leeuw, I. M., Gibson, R. J., Eilers, J. G., . . . Spijkervet, F. K. (2012). Swallowing dysfunction in cancer patients. *Support Care Cancer, 20*(3), 433-443. doi:10.1007/s00520-011-1342-2

Guba, E. G. (1978). *Toward a Methodology of Naturalistic Inquiry in Educational Evaluation.* Los Angeles: University of California.

Jepsen, D. M., & Rodwell, J. J. (2008). Convergent interviewing: a qualitative diagnostic technique for researchers. *Management Research News, 31*(9), 650-658. doi:10.1108/01409170810898545

Kato, P. M., Cole, S. W., Bradlyn, A. S., & Pollock, B. H. (2008). A video game improves behavioral outcomes in adolescents and young adults with cancer: a randomized trial. *Pediatrics, 122*(2), e305-317. doi:10.1542/peds.2007-3134

Langerman, A., MacCracken, E., Kasza, K., Haraf, D. J., Vokes, E. E., & Stenson, K. M. (2007). Aspiration in CRT patients with HNC. *Archives of Otolaryngology--Head & Neck Surgery, 133*(12), 1289-1295.

Rao, S., & Perry, C. (2003). Convergent interviewing to build a theory in under‐researched areas: principles and an example investigation of Internet usage in inter‐firm relationships. *Qualitative Market Research: An International Journal, 6*(4), 236-247. doi:10.1108/13522750310495328

Rogers, L. Q., Courneya, K. S., Robbins, K. T., Malone, J., Seiz, A., Koch, L., & Rao, K. (2008). Physical activity correlates and barriers in head and neck cancer patients. *Support Care Cancer, 16*(1), 19-27. doi:10.1007/s00520-007-0293-0

Shinn, E. H., Basen-Engquist, K., Baum, G., Steen, S., Bauman, R. F., Morrison, W., . . . Lewin, J. S. (2013). Adherence to preventive exercises and self-reported swallowing outcomes in post-radiation head and neck cancer patients. *Head & Neck*, 1707-1712. doi:10.1002/hed.2325510.1002/HED

Smeddinck, J., Gerling, K. M., & Tiemkeo, S. (2013). Visual Complexity, Player Experience, Performance and Physical Exertion in Motion-Based Games for Older Adults. *15th International ACM SIGACCESS Conference on Computers and Accessibility*.

Szczesniak, M. M., Maclean, J., Zhang, T., Graham, P. H., & Cook, I. J. (2014). Persistent Dysphagia after Head and Neck Radiotherapy: A Common and Under-reported Complication with Significant Effect on Non-cancer-related Mortality. *Clinical Oncology (R Coll Radiol), 26*(11), 697-703. doi:10.1016/j.clon.2014.08.009

Tong, A., Sainsbury, P., & Craig, J. (2007). Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care., 19*(6), 349 – 357.

Williams, W., & Lewis, D. (2005). Convergent interviewing: a tool for strategic investigation. *Strategic Change, 14*(4), 219-229. doi:10.1002/jsc.719

CHAPTER 4: VALIDATING THE MOBILI-T ALGORITHM FOR SWALLOW DETECTION

Springer Dysphagia, Evaluation of an Automated Swallow-Detection Algorithm Using Visual Biofeedback in Healthy Adults and Head and Neck Cancer Survivors, on-line, 2017, 90-103, Constantinescu, G., Kuffel, K., Aalto, D., Hodgetts, W., & Rieger, J.

This article can be found on the publisher's website at

https://link.springer.com/article/10.1007%2Fs00455-017-9859-2

The journal's homepage and the publisher's copyright information can be found at

https://link.springer.com/journal/455

Introduction

Half a million new cases of head and neck cancer (HNC) are diagnosed each year worldwide (Dwivedi, Chisholm, Kanwar, Komorowski, & Kazi, 2012; Warnakulasuriya, 2009) and approximately two thirds of these patients can develop dysphagia (Platteaux, Dirix, Dejaeger, & Nuyts, 2010). Individuals with swallowing difficulties can benefit from rehabilitation exercises (Robbins et al., 2008; Wheeler-Hegland et al., 2009), but treatment must be consistent and intensive for improvements in function to be maintained (Burkhead, Sapienza, & Rosenbek, 2007). The advent of technology miniaturization, smartphone prevalence, and healthcare innovation has led to the rapidly growing market of mobile health (mHealth). mHealth is defined as medical and public health practice supported by mobile devices and can include mobile phones, patient monitoring devices, personal digital assistants and other wireless devices (WHO, 2011). The advantage of mHealth technologies is their potential to provide more consistent, motivating and accessible therapy outside of the clinic, thereby reducing the burden of care on patients who are required to travel to appointments, as well as on the healthcare system. For example, individuals with dysphagia may benefit from an mHealth application (app) that encourages them to complete exercises more consistently, without the need for regular in-clinic appointments.

Mobili-T™ is an mHealth system (hardware and smartphone app) for swallowing therapy developed in Edmonton, Canada and its first iteration has been adapted for patients with a history of HNC (Constantinescu et al., 2017). The Mobili-T hardware adheres to the submental area and uses surface electromyography (sEMG) electrodes to capture signal from the activity of these muscles. With each new session, users are guided by the app through a series of calibration steps: a baseline signal and five regular swallows (Steele, 2004). The Mobili-T app relies on an automated swallow-detection algorithm that uses user-specific information (collected during a period of calibration) and group-specific information (a statistical model developed using pilot data from healthy adult swallows). The clinical goal of this algorithm is to provide patient users with appropriate biofeedback during swallowing therapy exercises. At home, the Mobili-T system should be able to track and reward sEMG signal resulting from patient swallows and swallowing exercises, while ignoring signal noise or signal from other muscle movements. Therefore, it follows that the performance of this algorithm is central to the uptake of and adherence to swallowing therapy with this particular mHealth system.

During in-clinic swallowing therapy, the clinician relies on visual cues (e.g., laryngeal elevation, facial grimaces accompanying exertion during an exercise) and the sEMG signal correlates (e.g., sEMG signal peaks) to confirm the presence of a swallow or swallowing exercise. The clinician also may verify with the patient to ensure the correct signal segment is evaluated. However, when it comes to a mobile swallowing therapy device for home use, the practitioner is not present to observe and consult with the patient in this way. Therefore, it is important that the swallow detection algorithm can accomplish this task even in the presence of confounding muscle contractions that occur during preparatory swallow movements and saliva collection.

Evaluating Algorithms for Detection of Biosignals

When evaluating biosensors and their algorithms, the ability to detect biosignals is typically reported in terms of the device's specificity, sensitivity, and accuracy (Davis &

Goadrich, 2006; Eklund et al., 2014; S.-Y. Lee et al., 2015; Wang, Eklund, & McGregor, 2014). For example, Wang et al. (2014) reported the sensitivity, specificity, and accuracy of an algorithm for apnea detection after comparing its performance to annotations from an apnea expert. In the context of swallow detection, sensitivity represents how well the algorithm can detect a true swallow (i.e., proportion of true positives that are correctly identified by the algorithm). On the other hand, specificity refers to how effective the algorithm is at ignoring the signal generated by non-swallow events (i.e., proportion of the true negatives that were correctly identified as such by the algorithm) (Zhu, Zeng, & Wang, 2010). In fact, there are many ways to compare the results of classifier tests; specificity, sensitivity, and accuracy are commonly used in epidemiological contexts.

Sensitivity (also known as recall) represents the proportion of true swallows correctly identified by the algorithm, whereas positive predictive value (PPV, also known as precision) is the proportion of swallows detected by the algorithm that were in fact true swallows. Sensitivity and PPV were selected as outcome measures because they have been recommended when using unequal data sets (Davis & Goadrich, 2006) and because the present study evaluated a biofeedback tool, rather than a diagnostic one. The formulas for determining these measures are presented below:

$$Sensitivity = \frac{true\ positives}{true\ positives\ +\ false\ negatives}$$

$$PPV = \frac{true\ positives}{true\ positives\ +\ false\ positives}$$

With respect to the algorithm in a clinical context, sensitivity is important to ensure that the correct user behaviour is rewarded, whereas PPV is an important test to ensure that the incorrect behaviour is not rewarded.

Swallow-detection has been the focus of previous studies (Crary, Sura, & Carnaby, 2013; J. Lee, Steele, & Chau, 2009; Schultheiss, Schauer, Nahrstaedt, & Seidl, 2013). In 2009, Lee at al. evaluated a swallow segmentation algorithm with inputs from multiple sensors: superior-inferior accelerometer, anterior-posterior accelerometer, mechanomyography sensor, and nasal airflow. The authors found that a combination of all signals resulted in the most accurate identification of swallows, although a substantial advantage of using four sensors over two, or one, was not evident (J. Lee et al., 2009). Schultheiss et al. evaluated a swallow-detection system comprised of EMG and bioimpedance signals in healthy participants and participants with pharyngeal dysphagia due to several etiologies. The authors reported statistically significant differences between swallows and other movements in the head and neck region, in seven of the nine signal characteristics evaluated (Schultheiss et al., 2013). In the same year, Crary et al. validated a multichannel recording technique with inputs from sEMG, nasal airflow, and auscultation and reported a sensitivity of 94% and a specificity of 99% for this particular system (Crary et al., 2013).

It is important to note some differences between previous studies using swallow-detection algorithms and the present algorithm and protocol. For example, in the aforementioned studies, swallows were selected for subsequent analysis (i.e., swallow, non-swallow) either by raters (Crary et al., 2013; J. Lee et al., 2009) or by the participants themselves (Schultheiss et al., 2013). Schultheiss also compared the outcomes of their system with hyoid and laryngeal movement (Schultheiss et al., 2013). Furthermore, in previous studies, signal confounders (i.e., non-swallow events) were either not deliberately included (J. Lee et al., 2009) or purposely selected to represent common activities from head and neck muscles in different proportions (Crary et al., 2013; Schultheiss et al., 2013). Whereas Schultheiss et al. included a 4.2:1 ratio of signal from swallows to that from other movements, Crary et al. conducted a particularly rigorous evaluation of their multichannel system with a 1:4 ratio of true swallow events to signal confounders. The inclusion of more non-swallow events in a testing protocol leads to a more rigorous test of a swallow-detection algorithm. Non-swallow tasks explored by Schultheiss and Crary included speaking, humming, nodding, chewing, tongue movements, throat clearing, coughing, sniffing and yawning (Crary et al., 2013; Schultheiss et al., 2013).

When selecting non-swallow movements to evaluate the Mobili-T system, in-app user prompts (e.g., press start only when ready to swallow, press stop when you have completed the swallow) were considered in conjunction with pre-swallow movements noted in patients with HNC. Since the user is prompted to press start when ready to swallow, it was reasoned that certain non-swallow behaviours could be excluded (e.g., speaking, humming). Video recordings of HNC patients swallowing from a previous study (Constantinescu et al., 2017) were reviewed and notes were made on common behaviours performed before and during a swallow (e.g., lip pursing, head movements). These behaviours observed in HNC patients created the basis for our selection of non-swallow tasks in this study.

Although algorithm development is not the focus of the present study and will not be described here, some details are provided as context for readers. During algorithm development, sEMG signal from six healthy participants was collected during swallows, swallowing exercises (effortful and Mendelsohn), and other non-swallow oral and head movements to develop and adjust the Mobili-T swallow-detection algorithm. The four parameters found most important in distinguishing swallows from non-swallow events were: duration, peak amplitude ratio, 50th percentile (median frequency), and 15th percentile of the power spectrum density. The algorithm remains to be tested on a new sample of healthy participants (i.e., one that was not used in algorithm development), as well as HNC patients.

The algorithm has two stages: segmentation and classification. In the first stage, the algorithm checks for periods of sEMG signal that is sustained above a certain amplitude threshold; the algorithm segments these periods to create saved events. These events are later classified as either swallows or non-swallows. The next step in the development of the Mobili-T algorithm is to evaluate it with a new set of healthy participants as well as with the intended end-users: patients with a history of HNC.

Evaluating the Algorithm in Two Populations

Several anatomical and physiological differences exist between healthy participants and HNC patients that may result in differences in sEMG signal characteristics and subsequently in the performance of the swallow-detection algorithm. The most apparent changes resulting from HNC treatment are anatomical differences in the chin and submental area. Patients may experience submental muscle resections, bulky reconstructions, scarring, and swelling as a result of surgery. Radiation may lead to fibrosed tissue in the head and neck area, atrophy, and loss of muscle fibers (Dysphagia Section et al., 2012). In addition, certain surgical techniques, such as the submandibular salivary gland transfer to the submental area, may further increase the distance between the sEMG sensor and target muscles (Seikaly et al., 2003).

These changes in the anatomy and physiology of HNC patients may result in attenuated sEMG signal, prolonged signal activity during swallows, multiple swallows, associated head movements, and other compensatory movements completed in conjunction with swallows. In addition, fatigue, and shifts in muscle fiber composition also may result in variations in the frequency domain characteristics between healthy and HNC participants, such as differences in signal power at the high and low frequencies (Phinyomark, Thongpanja, Hu, Phukpattaranont, & Limsakul, 2012).

An mHealth device and app that can reliably detect swallows from the sEMG signal and provide user-feedback accordingly may reduce user frustration, improve adherence to home-based rehabilitative regimens, and provide a tool for clinicians to remotely monitor therapy sessions. The present study aimed to evaluate the performance of an existing algorithm using a new set of healthy participants (i.e., participants that were not used in the development stage) and on patients with a history of HNC.

Objective

The objective of this study was to evaluate the Mobili-T algorithm for swallow detection (V03.23.2017) using sEMG signal from muscle activity in the submental area. The authors set out to answer the following questions:

1. What is the algorithm's sensitivity and PPV in healthy participants?
2. What is the algorithm's sensitivity and PPV in patients with a history of head and neck cancer?

In the event that sensitivity and PPV are high in healthy participants, but low in HNC patients, the authors were interested in comparing temporal and spectral signal parameters between the two populations. The outcome of this objective was particularly relevant to the optimization of the algorithm for HNC users.

3. Is there a difference between sEMG signal collected from saliva swallows from the control population and those from the HNC population, in the four parameters used in the algorithm development?

Since the algorithm was developed using data from healthy participants, the authors anticipated higher sensitivity and PPV in this population than in HNC patients. It also was expected that sEMG signal collected during regular (dry) swallows from HNC patients would have a peak amplitude ratio different from one (due to more swallow-to-swallow variability); a longer duration (due to more difficulty with swallowing); and more signal energy in the lower frequencies (due to more associated movement during a swallow).

Methods

Participants

The swallow-detection algorithm was evaluated with two different populations. For the first group, healthy adult participants between the ages of 41 and 70 with no history of HNC or swallowing difficulties were recruited through advertisements and word of mouth. This age group was selected based on a previous study (Vaiman, Eviatar, & Segal, 2004). Recruitment was balanced for sex.

For the second group, ten participants 18 years or older, with a history of HNC, were enrolled from a tertiary care center in Edmonton, Alberta. The study was advertised during regularly scheduled appointments for patients at different stages in their cancer treatment or jaw reconstruction. An attempt was made to include any type of patient participant that would be a candidate for the mobile swallowing therapy device in the future. Patients were included if they had a diagnosis of oral and/ or oropharyngeal cancer, had received treatment of any kind (i.e., surgery, radiation therapy, chemotherapy), had completed at least one treatment modality, and had a history of dysphagia. Patients were excluded if they had a documented history of neurologic impairment.

Once five patient participants were recruited, their demographics were reviewed to ensure that the sample was sufficiently diverse. A diverse sample was defined in this study as having at least one participant representing each sex, different dysphagia severities, and different cancer treatment modalities. The intent was to use heterogeneous purposive sampling for the remaining five participants if demographics were found to be similar (e.g., all females with mild oral dysphagia). Participants were asked to come to the session clean-shaven (males) and with no make-up on the chin.

Instrumentation and Software

Off-the-shelf disk sEMG dry disposable electrodes were used (7179-0020-Demo/XP, Pentax Canada Inc., Mississauga, Ontario). A detailed description of these adhesive pads can be found elsewhere (Constantinescu et al., 2017). Data collection was completed using a custom device (Mobili-T, revision R1.7, produced August 3rd, 2015) at a sampling frequency of 1000Hz. Raw sEMG (from the electrodes) was high-pass filtered at 1Hz. Some signal processing takes place at the level of the hardware. This includes: signal low pass filtering at 500Hz (anti-alias filter), amplification by 981x, and signal biasing to 1.5VDC. Custom software for data collection also was created, allowing the researcher to input task-type and placement of the device (left or right), view the sEMG signal in real-time, and tag events of interest. The custom software down-sampled the signal using a discrete moving average window of 100 ms.

Data Collection

This study was approved by the Health Research Ethics Board at the University of Alberta, Edmonton, Alberta, Canada. The purpose of the study was explained to participants and age and body mass index (BMI) were recorded. BMI was calculated using the BMI Calculator iOS application (version 1.4, Data Supply, Netherlands). The skin under the chin was prepped using alcohol wipes. Electrode gel (Spectra® 360, Parker Laboratories, NJ, USA) was applied to the sEMG electrodes and participants were fitted with the Mobili-T sensor in the submental area. The ground electrode was placed on the body of the mandible, and the two active leads over the suprahyoid muscles, as was completed in previous development testing (Constantinescu et al., 2017).

Every attempt was made to place the device on the same side of the submental area for all participants. Unilateral asymmetries have been documented in the anterior belly of the digastric muscles even in individuals with no history of HNC (Aktekin, Kurtoglu, & Ozturk, 2003; Mangalagiri & Razvi, 2009), therefore the right side of the submental area was arbitrarily selected for device placement for healthy participants. Similarly, for HNC participants, the automated swallow-recognition algorithm would be expected to function well using signal collected on either side. However, an attempt was made to remain consistent with right-side placement. Left-side placement was permitted only in instances when signal could not be collected on the right side after multiple attempts or when the hardware could not be fitted due to anatomical alterations.

Data collection occurred in the presence of a biomedical engineer (KK) and a speech-language pathologist (GC). The engineer saved the sEMG signal and tagged each event as it occurred. Tagging created a reference signal (i.e., vertical red line) in the waveform tracings, which was later used to identify the event. She also ensured that high quality signal was collected. This was achieved in two ways. Each time the hardware was placed on a participant, the signal from a test regular swallow was collected and analyzed using fast Fourier transform (FFT) to ensure it was free from noise resembling hardware malfunction or too much movement (i.e., a high peak in the low frequency range). Second, this type of signal check was completed periodically throughout data collection. If low frequency noise was detected, the device was secured with KT Tape™ to improve electrode-to-skin contact and the task was repeated. The speech-language pathologist provided instruction, demonstrated all tasks, and also noted how the tasks were performed. For example, if a participant swallowed, but also turned his/ her head (i.e., contamination from head turn signal), the file was discarded and the task was repeated.

The protocol consisted of three types of swallow and swallowing exercises (regular dry swallows, effortful dry swallows, and Mendelsohn dry swallows), and three types of non-swallow tasks (lip presses, tongue movements, and head movements). For swallow tasks, participants were informed of the importance of capturing signal from the swallow and to complete all pre-swallow preparation prior to data acquisition. The sequence of events is shown in Figure 4.1. This was demonstrated and practiced with participants before data collection. For non-swallow tasks, the same procedure was followed; however, patients were instructed not to swallow during data acquisition. Participants were allowed breaks and sips of water in between trials, as needed.

sEMG was collected during the following events:

a. Swallow check (as many trials as required): The participant was asked to swallow saliva as he/ she typically does. The signal from this task was analyzed before continuation of the protocol to ensure signal quality.
b. Baseline (1 trial): The participant was asked to look straight-ahead, breathe quietly and naturally with his/ her mouth closed on his/ her resting occlusion. Signal acquisition lasted for fifteen seconds.
c. Regular (dry) swallows (10 trials): The participant was asked to look straight ahead and swallow his/ her resting saliva once. The speech-language pathologist watched for thyroid movement for clinical confirmation of a swallow and for lack of extraneous movements. Half of these trials were used for calibration and half for evaluation.
d. Effortful swallows (5 trials): This task was similar to task (c), but the participant was asked to swallow with effort. Additional instructions included, "I want you to pretend you are swallowing a big bite of food. If you can, push hard with your tongue against the roof of your mouth." This task was practiced with the participant before data collection, until the participant felt comfortable with the task.
e. Mendelsohn maneuver swallows (5 trials): This task was similar to task (c), but the participant was asked to swallow and hold at the height of the swallow for two to five seconds. First, the participant was made aware of the movement of the thyroid during the swallow. Then the participant was asked to "swallow as you normally would and once your Adam's apple is up, squeeze your throat muscles and hold." For most participants, verbal cues were given during the exercise, "Hold, hold, hold… and

relax." This task was practiced prior to data collection, until the participant felt comfortable with the task. The clinician used her fingers to feel the thyroid remain elevated and return to resting position with the cue to relax. During data collection, the clinician used either visual assessment or tactile confirmation of thyroid sustained elevation.

f. Lip press (5 trials): The participant was asked to press his/ her lips together, "as if you have just put on some lip balm". The participant was instructed not to swallow during data acquisition.
g. Tongue movement (5 trials): The participant was instructed to move his/ her tongue around the mouth to collect saliva. The participant was instructed not to swallow during data acquisition, but was allowed to swallow between trials.
h. Head movements (5 sequences of four trials each): The participant was asked to turn his/ her head to the right, then to center. This constituted one trial (trial h1). A head turn to the left and back to center (trial h2), up and back to center (trial h3), down and back to center (trial h4) were completed. Again, the participant was instructed not to swallow during data acquisition.

Figure 4.1. Sequence of Events

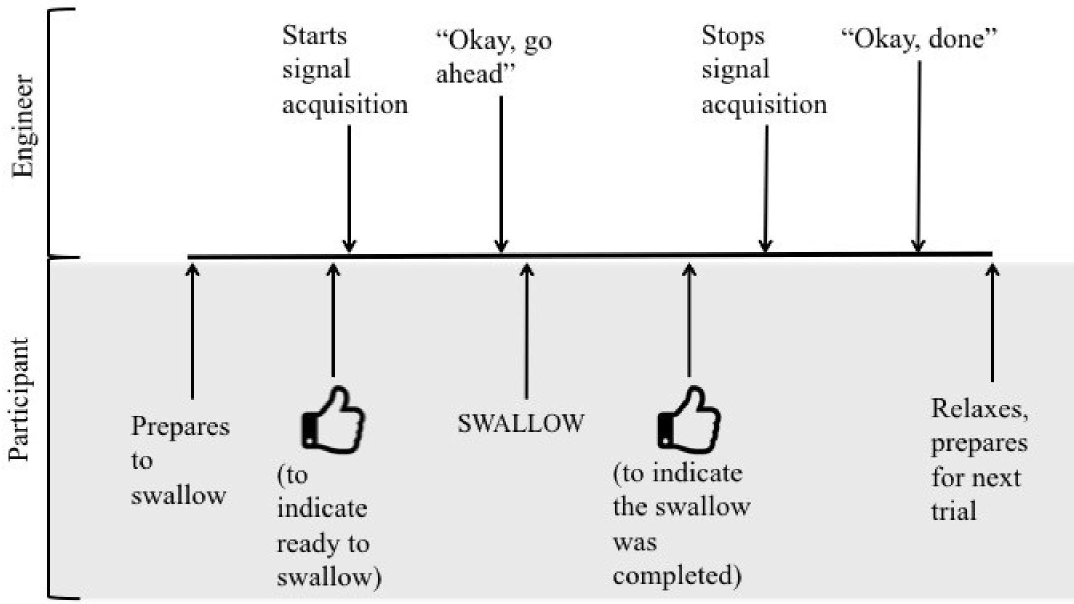


Figure 4.1. Sequence of events in signal acquisition for swallow tasks and swallowing exercises.

The device and adhesive pad were removed. The chin was cleaned with an alcohol pad and prepped again. The device was reattached with a new adhesive pad on the same side of the chin and the protocol was repeated (Trial 2).

Analysis

Data were post-processed and analyzed using custom MATLAB® (ver. R2016a, Edmonton, Alberta) scripts (KK). A distinction must first be clarified between recorded events and algorithm-identified events to help explain how signal was classified. Each recorded event (Figure 4.1) was called a recorded event (RE). In some cases, the algorithm detected more than one event in a RE; these will be referred to as algorithm-detected events (ADE). If at least one or more ADE in a RE was classified as a swallow, the entire RE was labeled a swallow (Figure 4.2). The total number of REs recorded was used to evaluate the algorithm, not the total number of ADEs. This is because the intent is for this algorithm to be used with a mobile health device where the outcome of interest is whether or not a swallow occurred within a trial recorded by the user.

Figure 4.2. Signal Detection and Classification

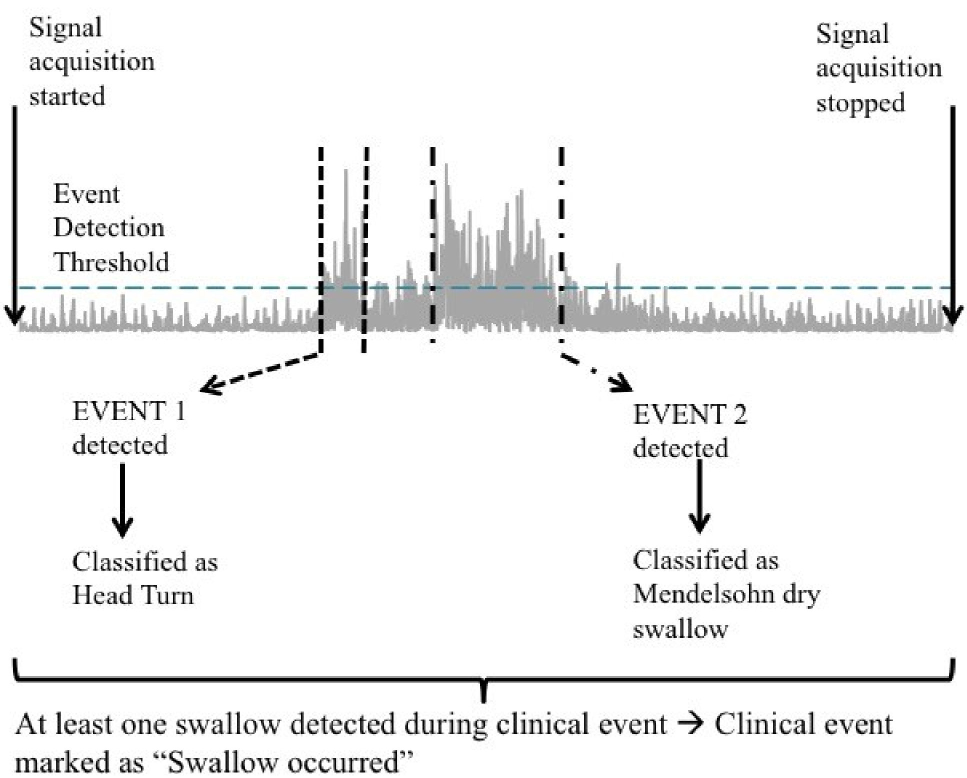


Figure 4.2. A trial is demarcated by the user starting and stopping the signal acquisition: recorded event. Within this RE, the algorithm detected two events (ADEs), one of which was classified as a head turn and the other as a Mendelsohn swallow. Since at least one ADE is a swallow, the entire RE is classified as a swallow. This is then labeled a true positive.

Tagged signal sections in dry, effortful, and Mendelsohn maneuver swallows, that the algorithm segmented and correctly classified as swallows, were coded as True Positives (TP). Tagged swallow events that were not detected by the algorithm constituted False Negatives (FN). Signal generated during lip presses, head and tongue movements incorrectly detected as swallows were False Positives (FP). True Negatives (TN) were signals generated during non-swallows that were correctly identified as such. All possible detection scenarios for the Mobili-T algorithm are categorized in Table 4.1. Overall sensitivity and PPV were calculated separately for healthy and HNC participant groups. Sensitivity is obtained by dividing the number of actual swallows correctly identified by the number of total actual swallows; PPV is the number of true swallows correctly identified divided by the number of swallow detections made by the algorithm.

Table 4.1

Swallow Detection Matrix for Mobili-T Algorithm

	Outcome of algorithm detection	
Condition, as determined by tag	Swallow not detected	Swallow detected
Non-swallow tasks	True Negative (TN)	False Positive (FP)
(tasks: f, g, h1, h2, h3, h4)*	Correct	Error
Number of tasks (trial 1) = 30		
Number of tasks (trial 2) = 30		
Swallow and swallowing	False Negative (FN)	True Positive (TP)
exercises	Error	Correct
(tasks: c, d, e)*		
Number of tasks (trial 1) = 15		

Number of tasks (trial 2) = 15

---

* (c) – regular swallows; (d) – effortful swallows; (e) – Mendelsohn maneuver swallows; (f) – lip press; (g) – tongue movement; (h) – head movements. Tasks (a) and (b), as described earlier, were used to check signal quality and calibrate.

First, sensitivity and PPV was calculated for each individual participant, for each trial, then averaged across participant group. Pooled data from both trials were used to report overall sensitivity and PPV. Trial 1 and 2 data were used to determine how consistent the algorithm was at detecting swallows for each participant. Test-retest reliability was assessed by using two-way random intra-class correlation (ICC) coefficient and visual inspection of graphs. Sensitivity and PPV reliability measures were calculated for each population. The following agreement classes were used: very good (> 0.81), good (0.61 - 0.80), moderate (0.41 - 0.60), and poor (< 0.40) (Altman, 1991).

In the event that the algorithm's sensitivity or PPV were lower in HNC participants, additional analysis was planned on signal characteristics used by the algorithm to classify segmented events: event duration (ms), event peak amplitude ratio, event median frequency (Hz), and 15th percentile of power spectrum density (Hz). This analysis was completed only for ADEs that were true positives, from regular swallows. The rectified and smoothed sEMG signal was used to determine event duration. The period of sustained amplitude over the baseline threshold (calculated during calibration) was used to determine the onset and offset of the signal. The difference between these two points resulted in the event duration. The rectified raw signal was then used to calculate all other parameters. The peak amplitude ratio was calculated by taking the highest amplitude in the event signal over the average peak amplitude obtained from calibration regular swallows. Median frequency was determined by using FFT and obtaining the frequency where 50% of the frequencies lie on one side and 50% on the other. The 15th percentile of the power spectrum density was obtained in a similar fashion, where 15% of frequencies in the event FFT were found on one side and 85% on the other. Fifteenth percentile was preferred over peak frequency as it is not as sensitive to movement artifact; it also appeared to show the largest difference between swallow and non-swallow events in healthy participants when the algorithm was developed. Since the peak amplitude recorded during trial regular swallows is divided by that obtained during calibration regular swallows, we expected this variable to be close to one in healthy participants, but further away from one in HNC patients. From a clinical perspective specific to HNC, we expected longer event durations and lower median frequencies when compared to healthy participants due to extraneous movements associated with impaired swallows, particularly in patients with dry mouth and to fatigue.

Four independent t-tests were used to determine if a significant difference exists between these parameters in true swallows completed by healthy participants and by those with a history of HNC. A Bonferonni adjusted alpha for four comparisons was used ($\boldsymbol{\alpha} = 0.0125$).

Results

Participants

Recruitment was completed in 2016, over a period of six months. The demographics of the two participant groups are summarized in Table 4.2.

Table 4.2

Participant Demographics

Participant group	Mean Age (Range)	Mean BMI (Range)
- HNC (N = 10)	53.7 (41 – 65)	26.9 (20.0 – 38.7)
Males (n = 5)	55.2 (45 – 65)	28.2 (23 – 38.7)
Females (n = 5)	52.2 (41 – 61)	25.6 (20 to 34.9)
+ HNC (N = 10)	62 (33 – 81)	26.4 (19.5 – 38.5)
Males (n = 9)	61 (33 – 81)	27.2 (20.9 – 38.5)
Females (n = 1)	72	19.5

A total of 12 participants with a history of HNC were enrolled. One participant was excluded following chart review, which revealed that she had suffered a stroke. A second participant could not be included in the study because a reliable signal could not be obtained despite several attempts. The resection for this particular participant included the mandible from the parasymphysial region on the right, total oral tongue, total base of tongue, total floor of mouth, half of the soft palate, and right lateral pharyngeal wall. His lingual and hypoglossal nerves were resected bilaterally, as well as his right inferior alveolar nerve. The suprahyoid muscles also were resected except for the left anterior digastric and left mylohyoid. The defect was reconstructed with a fibular free flap and anterolateral thigh flap. The reconstruction created a very small submental area, resulting in a bending of the sEMG adhesive pad. However, because the adhesive pad was coupled to the rigid body of the Mobili-T device, lifting of one of the electrodes or movement in the connection between the sensor clasp and the Mobili-T device may have caused large signal spikes, atypical of muscle contractions. This could not be remedied even after using KT Tape™ (Figure 4.3).

Figure 4.3. Device Placement on Patient with Small Submental Area

Figure 4.3. Mobili-T™ placement on a small submental area on participant excluded from the study. The wireless device is seen (black and white box) secured under the chin with adhesive (thin white strip between hardware and chin). The adhesive contains three sEMG sensors facing the skin and three corresponding button snaps that interface with the hardware. KT Tape™ (black strips) can be seen securing the hardware to the participant's chin.

Treatment details for patient participants are outlined in Table 4.3. sEMG signal was collected on the right side for all participants except HNC participant 1. In summary, of the patients who had sufficient diagnostic details, four had tumours on the left side and four on the right side. Two patients did not have left or right details in their diagnoses.

Table 4.3

Treatment Details for HNC Participants

Subject	Diagnosis[a]	Surgical details[b]	Time since surgery (years)	Adjuvant treatment[d]	Dysphagia diagnosis[e] (MBS date)
1	T4N1M0 SCC R oropharynx, R BOT	75% BOT, 25% SP, R tonsil; lingual nerve transected and cable grafted; L RFFF Beavertail for reconstruction	6.33	RT	Marked pharyngeal (Dec-2011)
2	T3N2C SCC L BOT p16+	NA	.76[c]	CRT	Mild oral, mild pharyngeal (Jul-2016)
3	T2N1M0 SCC R tonsil, p16+	50% R SP, R LPW; L SGT; L RFFF for reconstruction	.61	CRT	Mild oral, mild pharyngeal (Jun-2016)
4	T4N0M0 SCC R maxilla	Bilateral inferior maxillectomy; R FFF for reconstruction	7.77	RT	Mild oral (Nov-2009)
5	T4N0M0 SCC R BOT to	R mandible; 100% BOT, 100% oral tongue, 50% R SP, R FOM, R LPW	4.72	CRT	Moderate oral, moderate pharyngeal

	mandible	down to pyriform sinuses; lingual and hypoglossal nerves resected, R inferior alveolar nerve resected; all suprahyoid muscles removed except L anterior digastricus and mylohyoid; L FFF for reconstruction			(Nov-2012)
6	T4N0M0 adenoidcystic carcinoma of L lacrimal sac	L total maxillectomy, lateral rhynotomy, L orbital floor; L infraorbital and L lateral zygomatic nerves sacrificed; L SMG excision, L subtotal interfascial parotidectomy; R FFF for reconstruction	1.02	RT	Minimal oral (Feb-2016)
7	T2N2aM0 SCC L lateral tongue	1 cm L BOT, 1 cm L SP, 50% L oral tongue; lingual nerve anastomosed to flap; L SMG excision; L RFFF	2.98	RT	Mild oral, mild pharyngeal (Aug-2014)

		Beavertail for reconstruction			
8	Myxoma of right maxilla	Premaxilla from the lateral incisors on the left side to maxilla and premaxilla on the right and left side, coronoid process; small portion of gingiva; palatal island flap used	.10	No	None available. Reports being able to eat anything.
9	T4 SCC gingivobuccal sulcus	L retromolar trigone, segmental mandibulectomy; R RFFF for reconstruction	16.84	RT	Mild oral, minimal pharyngeal (Nov-2015)
10	T4N2cM0 SCC upper alveolus and maxilla	100% maxilla; nasal cavity, 50% upper lip, columella and a portion of the lobules bilaterally; interior orbital nerves resected bilaterally; L FFF and L RFFF for reconstruction of maxillary and nasal cavity defect, abbe	8.55	RT	Mild-moderate oral, moderate pharyngeal (Jan-2014)

	flap for upper lip; debridement and additional surgeries in 2013

[a]Diagnosis as found in operative report. TNM = tumour, node, metastasis; SCC = squamous cell carcinoma; R = right; L = left; BOT = base of tongue

[b]As presented in operative report. L = left; R = right; BOT = base of tongue; SP = soft palate; RFFF = radial forearm free flap; LPW = lateral pharyngeal wall; SGT = salivary gland transfer; FFF = fibular free flap; FOM = floor of mouth; SMG = submandibular gland excision

[c]Radiation therapy end-date was used instead of surgical date

[d]RT = radiation therapy; CRT = chemotherapy

[e]Diagnosis retrieved from the patient's most recent Modified Barium Swallow (MBS) study at iRSM

Sensitivity and PPV

Across the healthy participant group, 66.7% to 100% of all true swallows were correctly detected (i.e., sensitivity) (*M* = 92.3, *SD* = 10.4). Of the events classified as swallows by the algorithm, 48.0% to 100% were true swallows (i.e., PPV) (*M* = 83.9, *SD* = 12.9). In HNC participants, 73.3% to 100% of all true swallows were correctly detected (*M* = 92.7, *SD* = 9.15). Of the events classified as swallows by the algorithm, 39.4% to 100% were true swallows (*M* = 72.2, *SD* = 16.8). Figures 4.4 and 5 illustrate the intra-participant robustness of these values for both populations. The ICC(2,2) coefficient for test-retest reliability of sensitivity was .606 in healthy participants and .764 in HNC. These ICC values indicated good sensitivity reliability for both participant groups. The ICC(2,2) coefficient for PPV of the algorithm was .377 in healthy participants (poor) and .636 in HNC (good). Individual values for REs and ADEs are summarized for the patient population in Table 4.4.

Table 4.4

Swallow-Detection Outcomes for HNC Participants[a]

Participant _Trial#	TP	TN	FP	FN	Sensitivity	PPV	REs	REs not detected[b]
1_1	14	13	11	1	93.3	56.0	45	6
1_2	14	18	10	1	93.3	58.3	45	2
2_1	15	24	5	0	100.0	75.0	45	1
2_2	13	30	0	2	86.7	100.0	45	0
3_1	15	5	8	0	100.0	65.2	45	17
3_2	15	8	3	0	100.0	83.3	45	19

4_1	15	12	2	0	100.0	88.2	45	16
4_2	14	18	1	1	93.3	93.3	45	11
5_1	15	7	10	0	100.0	60.0	45	13
5_2	15	17	9	0	100.0	62.5	45	4
6_1	15	20	2	0	100.0	88.2	45	8
6_2	15	18	7	0	100.0	68.2	45	5
7_1	11	6	11	4	73.3	50.0	45	13
7_2	13	10	20	2	86.7	39.4	45	0
8_1	12	9	4	3	80.0	75.0	45	17
8_2	13	23	2	2	86.7	86.7	45	5
9_1	11	20	6	4	73.3	64.7	45	4
9_2	13	12	7	2	86.7	65.0	45	11
10_1	15	25	0	0	100.0	100.0	45	5
10_2	15	16	8	0	100.0	65.2	45	6

[a]TP = True Positives; TN = True Negatives; FP = False Positives; FN = False Negatives; RE = Recorded Events (i.e., those that the patient completed).

[b]In this sample, all non-detected REs were non-swallow events (i.e., lip press, tongue movements, or head movements). This refers to events that did not pass the segmentation stage of the algorithm. TP+TN+FP+FN+(REs not detected) = 45 or Total REs

The average signal to noise ratio was calculated in the same way as previous work (Constantinescu et al., 2017). For signal acquired in regular swallows of healthy participants was 10.9 dB (*SD* = 5.42); for HNC patients, average SNR was 17.5 dB (*SD* = 5.53).

Since the PPV of the algorithm was lower in HNC participants than in healthy ones, pairwise comparisons were conducted on the four parameters. This only was completed for regular swallows. Pooled data from both trials were used in this analysis.

Mann-Whitney tests were completed to compare duration, peak amplitude ratio, and median frequency, as these data were not normally distributed for either one population or both (Shapiro-Wilk at $\alpha = 0.05$). There was no statistically significant difference in peak amplitude ratio between the two populations. A Mann-Whitney test indicated that duration was shorter for healthy participants (*Mdn* = 1001.0) than for HNC (*Mdn* = 1851.0), $U = 1925.0$, $p < .001$. Median frequency was higher for healthy participants (*Mdn* = 122.1) than for HNC (*Mdn* = 102.4), $U = 2674.0$, $p < .001$.

An independent t-test showed a significant difference between scores for 15^{th} percentile of power spectrum density in healthy participants ($M = 57.6$, $SD = 14.2$) and those in HNC ($M = 49.9$, $SD = 9.88$), $t(176.9) = 2.07$, $p < .001$, $d = 7.74$, 95% CI [4.33, 11.1]. Levene's test indicated unequal variances ($F = 12.8$, $p < .001$), so degrees of freedom were adjusted from 198 to 176.9.

Discussion

This study evaluated the performance of an automated swallow-detection algorithm that will eventually be used in an mHealth app for home-based swallowing therapy. The app will be used together with a sEMG wireless device and, in addition to providing real-time biofeedback, it will track the number of swallow exercises completed. Therefore, it is essential the algorithm detect swallows and swallowing exercises in patients following HNC treatment. In healthy participants, the algorithm's mean sensitivity (92.3%) and PPV (83.9%) were high. This was an expected finding since the algorithm's statistical model was created using signal from healthy swallows. Another expected finding was that the PPV was lower than the sensitivity, as the algorithm was designed to maximize sensitivity. This decision was made to minimize user frustration. For example, it was hypothesized that users may feel defeated if they performed a swallow that was not recognized or rewarded by the algorithm more so than if they received credit for a non-swallow activity.

The algorithm also was robust in HNC participants with a sensitivity and PPV of 92.7% and 72.2%, respectively. The high sensitivity in HNC patients was a welcomed finding, especially because this population presents with atypical anatomy and physiology. PPV was lower than sensitivity, which was expected; it also was lower than PPV in healthy participants. The range in the sensitivity was higher in healthy participants (33.3%) than HNC patients (26.7%). This was unexpected given the heterogeneous nature of HNC patients. The range in PPV value was smaller in healthy participants (52.0%) than that in HNC participants (60.6%).

Test-retest reliabilities between the two trials were good with the exception of PPV in healthy participants, which was poor. One possible explanation for this could be that healthy participants were not as familiar with the swallowing exercise tasks (i.e., effortful and Mendelsohn maneuver swallows) as some of the HNC patients were resulting in variability between the two trials. Figure 4.4 indicates that participant 6 in the healthy group had lower sensitivity in the first trial than the rest of participants. Figure 4.5 shows that participant 7 in the healthy group had poor PPV in the second trial, whereas participant 7 in the patient group had the worst scores for PPV. When consulting lab notes for these participants, no anomalous associated movements or technical difficulties were noted for the two healthy participants (#6 and #7). For the HNC participant (#7), frequencies associated with hardware movement were noted with both trials.

Figure 4.4. Sensitivity for Trial 1 and Trial 2

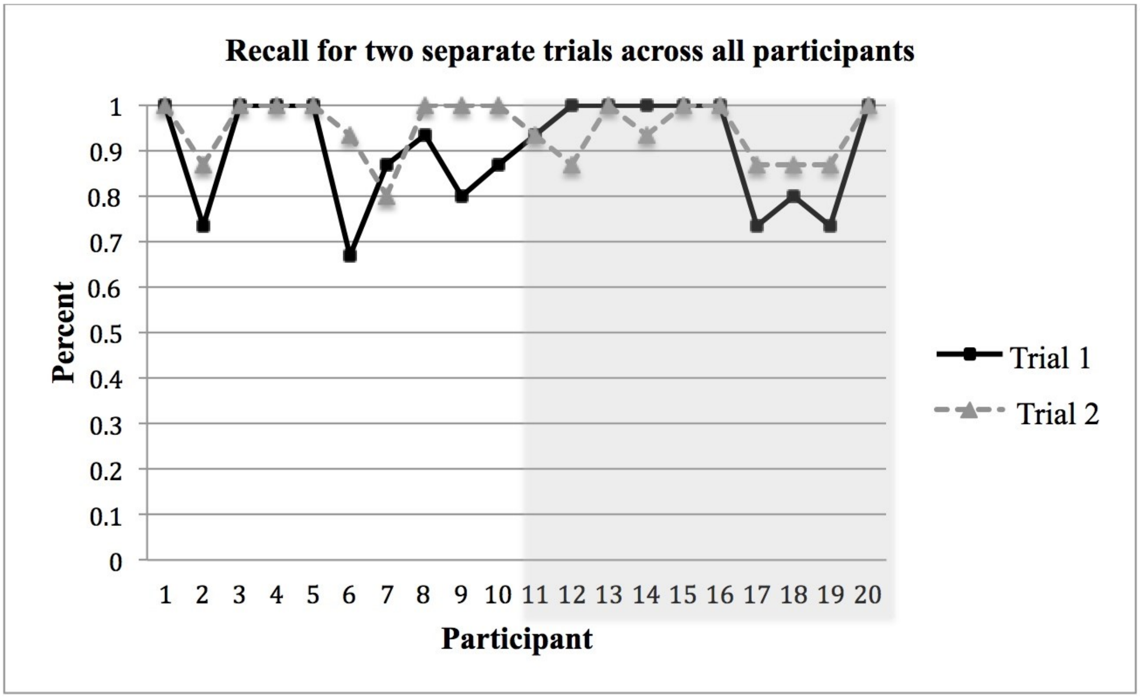


Figure 4.4. Percent of true swallows detected by the algorithm in trial 1 and trial 2, for each participant: white box (healthy) and grey box (HNC).

Figure 4.5. PPV for Trial 1 and Trial 2

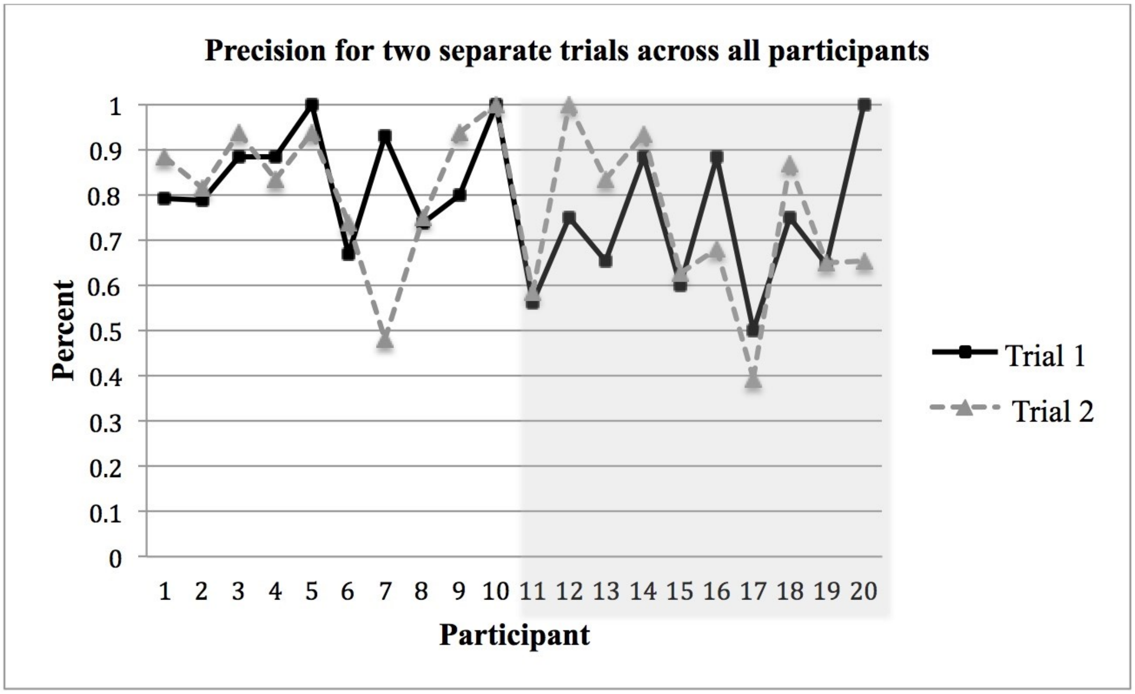


Figure 4.5. Percent of swallows detected by the algorithm that were true swallows in trial 1 and trial 2, for each participant: white box (healthy) and grey box (HNC).

Of note are instances where the examiner expected poor sensitivity and PPV and the results did not support that expectation. For example, HNC participant 6 indicated that she could not initiate a swallow without a small sip of water and all swallows appeared laborious to the attending clinician. This meant that there was a high potential for movement artifact contamination in the signal. The sensitivity for this participant was 100% and PPV was 88.2%. On the other hand, it was found that the current iteration of the Mobili-T system may not be suitable for all HNC patients, such as in the case of the patient in figure 4.3.

When comparing this swallow-detection algorithm with others reported in the literature (Table 4.5), Crary et. al's study design appears to be the closest to the one presented here, and therefore their results are most comparable to ours. Their system had a sensitivity of 94% when using a ratio of 1:4 swallow to non-swallow events, in healthy participants (Crary et al., 2013). Our algorithm was able to maintain a high sensitivity in healthy participants (92.3%) with just sEMG input, albeit at a ratio of 1:2 swallow to non-swallow events (see Table 4.1). Although these ratios do not directly impact sensitivity, they may impact PPV and should be carefully considered and reported. Furthermore, the present study included swallows as well as swallowing exercises (i.e., effortful swallow and Mendelsohn swallow), which may further explain the reduced sensitivity. However, in this study, the RE was determined to have a swallow if at least one ADE in this signal was classified as a swallow (as shown in Figure 4.2). Therefore, care should be exercised when interpreting our findings and when comparing them to others in the literature.

Table 4.5

Swallow-Detection in Previous Studies

Study	Input	Identification	Sensitivity (population)	Swallow: non-swallow ratio (swallow type)
Present	sEMG only	Algorithm based on statistical model	92.3% (healthy) 92.7% (HNC)	1:2 (saliva swallows and saliva swallow exercises)
Crary et al. (2013)	Three inputs: sEMG, nasal	Judges (graduate	94% (healthy)	1:4 (saliva and thin

	airflow, stethoscope	students)		liquid)
Lee et al. (2009)	Four inputs: S-I accelerometer, A-P accelerometer, mechanomyography; Nasal airflow	Artificial neural network	91.0 ± 5.4 (healthy)	All swallows (various consistencies)
Schultheiss et al. (2013)	Two inputs: sEMG and bioimpedance	Statistical model	96.1% (healthy and pharyngeal dysphagia)	4.2:1 (saliva and various consistencies)

The SNR reported in the present study was within the same range as the sEMG reported in a previous study using sEMG sensors (Constantinescu et al., 2017). A similar set-up was used in this study; however, the data acquisition device used in the present study was a wireless mHealth device.

The present study also compared four parameters used by the swallow-detection algorithm, between the two groups, to understand why PPV was lower in HNC participants. These parameters were event duration, peak amplitude ratio, median frequency, and 15th percentile of the power spectrum density. First, there was no difference in amplitude ratio between healthy and HNC participants. This is noteworthy because we expected patients to have smaller signal amplitude. However, it is possible that this difference was removed with the use of amplitude ratio (amplitude ratio takes into account calibration regular swallows). Previous work has compared sEMG signal amplitude between participants with a history of stroke and healthy controls (Crary & Baldwin, 1997; Kim et al., 2015), but no studies reporting on amplitude ratio could be found.

Second, sEMG regular swallows signal was characterized by longer event duration in the HNC group. This finding was expected based on clinical observations of this patient group. In another study, swallowing duration was shorter in patients with middle cerebral artery infarction when compared to healthy volunteers, an observation that the authors attributed to a lack of muscle coordination during the swallow (Kim et al., 2015). As different etiologies can result in different mechanisms of dysphagia, it follows that sEMG parameters also may differ between stroke and HNC patient groups. Finally, smaller median frequency, and smaller 15th percentile of the power spectrum density were noted for the HNC group. This observation may be attributed to an increase in associated movements and/ or fatigue with an atypical swallow, resulting in lower frequencies. Of the four parameters studied, the following would be of interest should the algorithm be optimized for HNC patients: duration, median frequency, and 15th percentile of the power spectrum density.

The question remains of whether or not adjustments should be made to the swallow-detection algorithm to increase its PPV in HNC patients. In fact, it may be undesirable to do so. For example, an algorithm adjusted to accept sEMG swallow signal of longer duration and with lower frequencies in the power spectrum density may reward compensatory or atypical swallow behaviour. To our knowledge, no studies exist that determined the clinical cut-off for acceptable PPV in a swallow-detection algorithm, one where patients do not experience frustration at the discordance between behaviour and feedback from technology. The second consideration that must be made when answering this question is what should happen when swallows change over time, as a result of swallow therapy, to approximate normal swallows. Ideally, the algorithm should detect swallows at the beginning of therapy as well as throughout therapy, as swallowing function presumably improves.

The present study provides promising preliminary information on this version of the swallow-detection algorithm. Some limitations should be considered when interpreting findings. First, like many studies involving HNC patients, our sample was small and heterogeneous, limiting the generalizability of these findings. Although heterogeneity was retained in part to ensure that the algorithm would work for all potential HNC users, future studies could include a stratification by level of dysphagia and use a standardized dysphagia rating, such as the Modified Barium Swallow Impairment Profile (Martin-Harris et al., 2008). Additional limitations include the relative lack of women participants in the HNC group (which also resulted in unmatched HNC and control groups by sex), and the possibility of practice effects with each trial.

Furthermore, in future studies, the algorithm’s performance could be evaluated with different boluses (e.g., thin liquids, thickened liquids). This study also should be replicated using the app and mobile device, to assess the feasibility of the swallow-detection algorithm in real time as well as the cut-offs for sensitivity and PPV before user frustration is triggered. Finally, this study evaluated the algorithm’s performance in providing users with adequate biofeedback when completing swallows or swallowing exercises. Future work should evaluate the algorithm's performance where all ADEs are evaluated in the context of what was recorded clinically.

Conclusion

In this study we have provided preliminary data to support that a swallow-detection algorithm can be developed that is based on a relatively simple statistical model (i.e., not machine-learning) and that can remain robust, on average, even in a patient population with altered anatomy and physiology. Validation of this algorithm for automated swallow-detection is an important prerequisite to its implementation in a mobile swallowing therapy device for HNC patients.

References

Aktekin, M., Kurtoglu, Z., & Ozturk, A. H. (2003). A Bilateral and Symmetrical Variation of the Anterior Belly of the Digastric Muscle. *Acta Medica. Okayama, 57*(4), 205-207.

Altman, D. G. (1991). *Some common problems in medical research. Practical statistics for medical research* (Vol. 1). London: Chapman & Hall.

Burkhead, L. M., Sapienza, C. M., & Rosenbek, J. C. (2007). Strength-training exercise in dysphagia rehabilitation: principles, procedures, and directions for future research. *Dysphagia, 22*(3), 251-265. doi:10.1007/s00455-006-9074-z

Constantinescu, G., Hodgetts, W., Scott, D., Kuffel, K., King, B., Brodt, C., & Rieger, J. (2017). Electromyography and Mechanomyography Signals During Swallowing in Healthy Adults and Head and Neck Cancer Survivors. *Dysphagia, 32*(1), 90-103. doi:10.1007/s00455-016-9742-6

Crary, M. A., & Baldwin, B. O. (1997). Surface electromyohgraphic characteristics of swallowing in dysphagia secondary to brainstem stroke. *Dysphagia, 12*, 180-187.

Crary, M. A., Sura, L., & Carnaby, G. D. (2013). Validation and Demonstration of an Isolated Acoustic Recording Technique to Estimate Spontaneous Swallow Frequency. *Dysphagia, 28*, 86-94. doi:10.1007/s00455-012-9416-y

Davis, J., & Goadrich, M. (2006). The Relationship Between Precision-Recall and ROC Curves. *Proceedings of the 23rd International Conference on Machine Learning*.

Dwivedi, R. C., Chisholm, E., Kanwar, N., Komorowski, A., & Kazi, R. (2012). Epidemiology, Aetiology and Natural History of Head and Neck Cancer. In A. Staffieri, P. Sebastian, M. Kapre, R. Kazi, & B. T. Varghese (Eds.), *Essentials of Head and Neck Cancer*. Delhi, India: Byword Books Private Limited.

Dysphagia Section, O. C. S. G. M. A. o. S. C. i. C. I. S. o. O. O., Raber-Durlacher, J. E., Brennan, M. T., Verdonck-de Leeuw, I. M., Gibson, R. J., Eilers, J. G., . . . Spijkervet, F. K. (2012). Swallowing dysfunction in cancer patients. *Support Care Cancer, 20*(3), 433-443. doi:10.1007/s00520-011-1342-2

Eklund, J. M., Fontana, N., Pugh, E., McGregor, C., Yielder, P., James, A., . . . McNamara, P. (2014). *Automated Sleep-Wake Detection in Neonates from Cerebral Function Monitor Signals*. Paper presented at the IEEE 27th International Symposium on Computer-Based Medical Systems, New York, USA.

Kim, H. R., Lee, S. A., Kim, K., Leigh, J. H., Han, T. R., & Oh, B. M. (2015). Submental Muscle Activity is Delayed and Shortened During Swallowing Following Stroke. *American Academy of Physical Medicine and Rehabilitation, 7*(9), 938-945. doi:10.1016/j.pmrj.2015.05.018

Lee, J., Steele, C. M., & Chau, T. (2009). Swallow segmentation with artificial neural networks and multi-sensor fusion. *Medical Engineering & Physics, 31*(9), 1049-1055. doi:10.1016/j.medengphy.2009.07.001

Lee, S.-Y., Hong, J.-H., Hsieh, C.-H., Liang, M.-C., Chien, S.-Y. C., & Lin, K.-H. (2015). Low-Power Wireless ECG Acquisition and Classification System for Body Sensor Networks. *IEEE Journal of Biomedical and Health Informatics, 19*(1), 236-246.

Mangalagiri, A. S., & Razvi, M. R. A. (2009). Variations in the Anterior Belly of Diagastric. *International Journal of Health Sciences, 3*(2), 257-262.

Martin-Harris, B., Brodsky, M. B., Michel, Y., Castell, D. O., Schleicher, M., Sandidge, J., . . . Blair, J. (2008). MBS measurement tool for swallow impairment--MBSImp: establishing a standard. *Dysphagia, 23*(4), 392-405. doi:10.1007/s00455-008-9185-9

Phinyomark, A., Thongpanja, S., Hu, H., Phukpattaranont, P., & Limsakul, C. (2012). The Usefulness of Mean and Median Frequencies in Electromyography Analysis. *Journal of Computing, 1*(1), 71-80. doi:10.5772/50639

Platteaux, N., Dirix, P., Dejaeger, E., & Nuyts, S. (2010). Dysphagia in head and neck cancer patients treated with chemoradiotherapy. *Dysphagia, 25*(2), 139-152. doi:10.1007/s00455-009-9247-7

Robbins, J., Butler, S. G., Daniels, S. K., Gross, R. D., Langmore, S., Lazarus, C. L., . . . Rosenbek, J. C. (2008). Swallowing and Dysphagia Rehabilitation: Translating Principles of Neural Plasticity Into Clinically Oriented Evidence. *Journal of Speech, Language, and Hearing Research, 51*, S276-S300.

Schultheiss, C., Schauer, T., Nahrstaedt, H., & Seidl, R. O. (2013). Evaluation of an EMG bioimpedance measurement system for recording and analysing the pharyngeal phase of swallowing. *European Archives of Otorhinolaryngology, 270*(2149-2156). doi:10.1007/s00405-013-2406-3

Seikaly, H., Rieger, J., Wolfaardt, J., Moysa, G., Harris, J., & Jha, N. (2003). Functional Outcomes After Primary Oropharyngeal Cancer Resection and

Reconstruction With the Radial Forearm Free Flap. *The Laryngoscope, 113*(5), 897-904.

Steele, C. (2004). Treating Dysphagia With sEMG Biofeedback. . *The ASHA Leader*.

Vaiman, M., Eviatar, E., & Segal, S. (2004). Evaluation of Normal Deglutition with the Help of Rectified Surface Electromyography Records. *Dysphagia, 19*(2). doi:10.1007/s00455-003-0504-x

Wang, X. L., Eklund, J. M., & McGregor, C. (2014). *Parametric Power Spectrum Analysis of ECG Signals for Obstructive Sleep Apnoea Classification*. Paper presented at the IEEE 27th International Symposium on Computer-Based Medical Systems, New York, USA.

Warnakulasuriya, S. (2009). Global epidemiology of oral and oropharyngeal cancer. *Oral Oncology, 45*(4-5), 309-316. doi:10.1016/j.oraloncology.2008.06.002

Wheeler-Hegland, K., Ashford, J., Frymark, T., McCabe, D., Mullen, R., Musson, N., . . . Schooling, T. (2009). Evidence-based systematic review: Oropharyngeal dysphagia behavioral treatments. Part II—Impact of dysphagia treatment on normal swallow function. *The Journal of Rehabilitation Research and Development, 46*(2), 185. doi:10.1682/jrrd.2008.08.0094

WHO. (2011). *mHealth: New horizons for health through mobile technologies*. Geneva, Switzerland: World Health Organization.

Zhu, W., Zeng, N., & Wang, N. (2010). Sensitivity, Specificity, Accuracy, Associated Confidence Interval and ROC Analysis with Practical SAS® Implementations. *NESUG proceedings: Health Care and Life Sciences*.

CHAPTER 5: USABILITY TESTING

The final, definitive version of this paper has been published in Health Informatics Journal, Online, April/2018 published by SAGE Publishing,

Constantinescu, G., Kuffel, K., King, B., Hodgetts, W., Rieger, J. (2018). Usability testing of an mHealth device for swallowing therapy in head and neck cancer. Health Informatics Journal.

Article first published online: April 4, 2018 https://doi.org/10.1177/1460458218766574

Introduction

Mobile health (mHealth) devices and applications (apps) have become increasingly prevalent, particularly for the management of chronic conditions (Fiordelli, Diviani, & Schulz, 2013); however, only a small proportion of studies report user assessment of technology (Reynoldson et al., 2014). Furthermore, few developers share whether or not their apps involved end-user feedback (O'Malley, Dowdall, Burls, Perry, & Curran, 2014). Usability testing of mHealth systems can influence patient engagement (Lyles, Sarkar, & Osborn, 2014), validate initial design, and shed light on user behaviour, all elements that hold great potential for increasing the adoption of the technology.

Usability testing is the systematic observation of typical stakeholders under controlled conditions to determine how well people can operate the product (Corry, Frick, & Hansen, 1997; Lyles et al., 2014). Quantitative approaches to assess usability include system usage data automatically captured by the technology (e.g., screens viewed by the user) and questionnaires. Additional information can be found using qualitative approaches involving focus groups, interviews and think-aloud interviews (user inspects the technology while verbalizing his/ her thought process). A literature review of web and mobile systems for diabetes found that qualitative methods reveal more usability problems than questionnaires alone; however, almost half of the studies used a mix of the two approaches (Lyles et al., 2014).

Some researchers have used standardized methods to assess aspects of usability recommended by ISO 9241-11 (Georgsson & Staggers, 2016; "International Organization for Standardization. Ergonomic requirements for office work with visual display terminals (VDTs) Part 11 Guidance on usability.," 1998; O'Malley et al., 2014). This framework includes the effectiveness of a system (user ability to complete assigned tasks); efficiency (resources required to complete assigned tasks, such as time); and satisfaction (user feedback). Understanding these aspects of usability is important when determining if changes should be made in subsequent device iterations.

mHealth System Evaluated

Mobili-T^{TM}, short for mobile therapy, is an mHealth system developed to address limited access to swallowing therapy for patients. The system consists of a wireless data acquisition device and an app for Apple Inc. operating system, iOS. Initial development has been for, and with the input of, head and neck cancer (HNC) patients (Constantinescu et al., 2016; Constantinescu et al., 2017). The hardware includes three surface electromyography sensors (sEMG), two active and one ground, that measure the activity of muscles under the chin (submental) during swallows and swallow-like exercises. This information is transmitted via Bluetooth to the smartphone app and presented as visual biofeedback to the user. The hardware it attached to the skin via a single-use adhesive patch.

The Mobili-T app consists of two main modes: Learn Mode and Exercise Mode. The first time the app is opened, the user is guided through a tutorial (Learn Mode) that describes the hardware and charging dock, attachment of the adhesive, placement of the device under the chin, calibration, exercises, and progress interpretation from the summary screens (Figure 5.1). Completion of this tutorial is required before the first use. Subsequent launching of the app begins directly in Exercise Mode; however, tutorial topics are still available via a Learn Mode icon located on the app tab bar. Exercise Mode guides patients through prescribed sets of different swallowing exercises and displays biofeedback relative to a target line. The target line is a goal set by the system and is based on user performance during calibration swallows. Progress is tracked for performance (i.e., number of swallows where the target was achieved, number of swallows where the target was not achieved, number of trials attempted where the system did not register a swallow, and number of trials remaining to be completed from the prescription), compliance with the prescription over time, and a cumulative number of swallows completed overall.

Figure 5.1. Sample Screens From App Tutorial

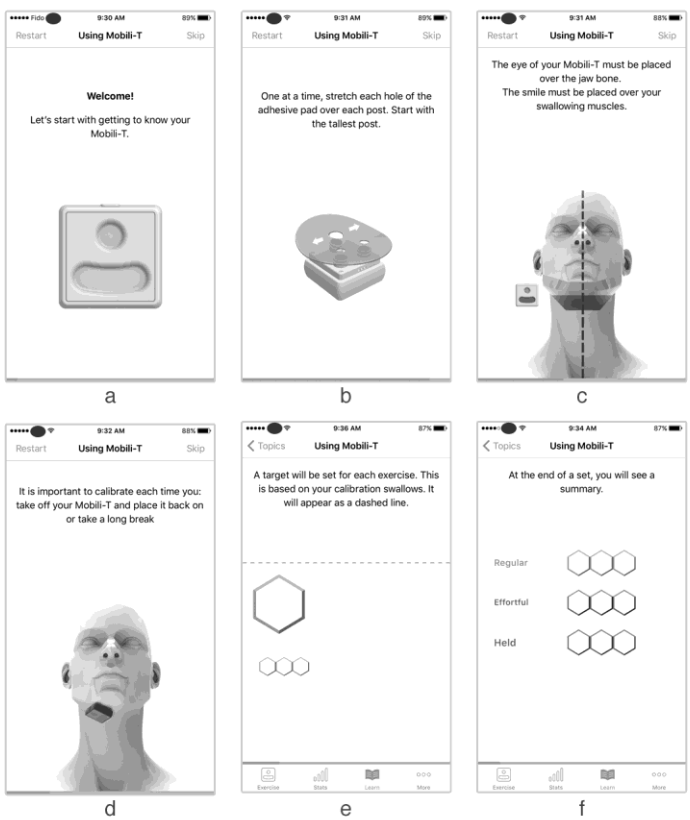


Figure 5.1 Sample screens from tutorial topics, describing (a) hardware features, (b) adhesive placement, (c) device placement, (d) calibration, (e) completion of exercises, and (f) progress interpretation from summary screens.

The design of the app was influenced by patient feedback from the inception of the project and uses game elements and remote clinician supervision to objectively track and influence adherence to home exercise. Throughout development the team iteratively assessed the usability of the Mobili-T system internally; however, the evaluation of a fully functioning app had not been completed with patients. In this study, we conducted the first usability testing with HNC patients to identify issues critical to implementation, as well as any additional features that could be improved. Quantitative and qualitative methods were used to evaluate the effectiveness, efficiency, and satisfaction of patients using Mobili-T.

Materials and Methods

This study was approved by the Health Research Ethics Board of Alberta Cancer Committee, Canada. Five adults with a history of HNC were recruited from a tertiary referral center. Virzi has shown that, regardless of participant expertise, 80% of usability problems are uncovered by the first five participants and little new information is gained from additional subjects (Virzi, 1992). Patients were excluded if they had a history of stroke, traumatic brain injury, or cognitive impairment.

Participants were booked for one-on-one sessions with a speech-language pathologist where they were introduced to the context of the study and encouraged to provide honest and detailed feedback. The clinician presented the system, demonstrated pairing the device to the app, and navigated through the tutorial. Following this introduction, participants were asked to complete five tasks, presented one at a time. Written instructions were left with the patient as reminders and the clinician stepped outside the room. Participants were encouraged to verbally describe their thought process (think-aloud) to troubleshoot any issues, and to only call the clinician back in the room if the task was completed or if assistance was needed. To eliminate confounds resulting from individual performance differences, biofeedback signals were presented using pre-corded swallowing sEMG data. Participants were aware of this.

The Self-Reported Health Literacy and the modified Computer Self-Efficacy Scale (mCSES) were administered at the beginning of the appointment (Laver, George, Ratcliffe, & Crotty, 2012; Sarkar, Schillinger, Lopez, & Sudore, 2011). The Self-Reported Health Literacy scale is made up of three questions (e.g., How confident are you filling out medical forms?) and uses a 5-point Likert scale. The mCSES contains 10 questions and a 10-point Likert scale. The questions are based on a short scenario where the participant is asked to imagine that they received a new technology. The mCSES asks questions to determine how confident the participant thinks he/ she would feel in using this new technology if, for example, there was no one to help. The same iOS device (iPhone 5s, Apple Inc., CA), iOS software [iOS 10.3(14E277)], and app [Mobili-T™ version 0.0.1(146)] were used with all participants. ScreenFlow for Mac (version 6.2, Telestream, LLC, CA) was used to simultaneously capture: screens from the iOS device, video from the FaceTime HD Camera, and audio. An additional camera (Nikon D5100) was tripod-mounted and used to record hand gestures. The two videos were later synced in iMovie (version 10.1.1, Apple Inc., CA) (Figure 5.2). Following each task, the After-Scenario Questionnaire (ASQ) was administered (three questions using a 7-point Likert scale) (Lewis, 1995).

Figure 5.2 Data Collection Set-Up

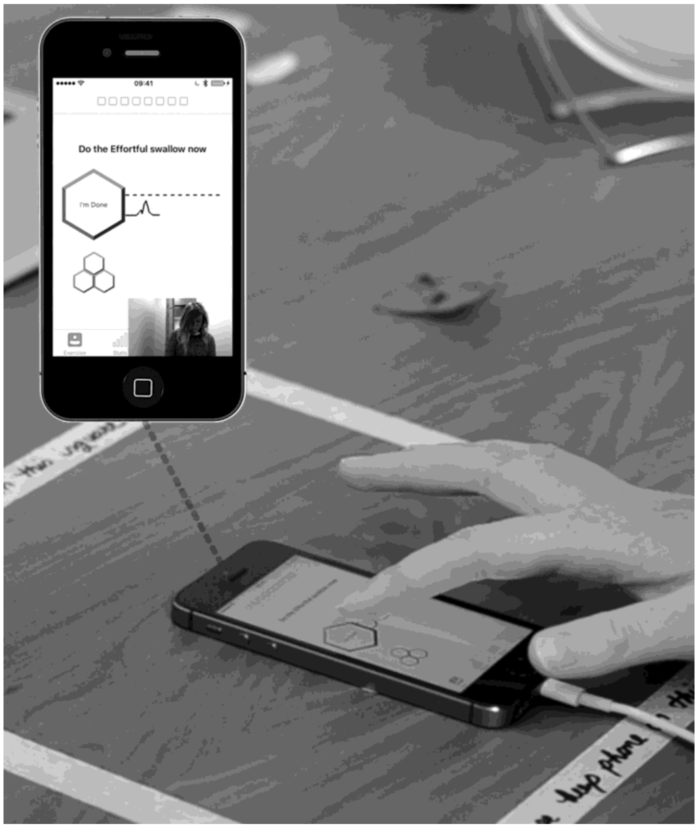


Figure 5.2 Sample screen from data collection set-up.

Tasks

A set of representative tasks was selected for testing (Georgsson & Staggers, 2016). Participants were reminded that they could revisit tutorial screens by going to the Learn section. Task one asked patients to turn on the device and Bluetooth pair it with the phone. Task two instructed patients to attach the adhesive pad to the device and place the device under their chins using a mirror if necessary. Task three asked patients to start an exercise session, follow the prompts, and complete calibration plus a full set of exercises (three exercise types with three trials each). Task four asked patients to navigate to the screen that shows their progress and state out loud how they interpret the information shown in the daily, weekly, and overall summaries. Finally, task five required participants to remove and charge the device, as well as exit the app.

Analysis

System effectiveness

To determine how effective the system is, the clinician recorded the number of times she provided assistance. This support was either requested by the participant (by calling her back in the room) or provided if the patient gave up during the task without requesting feedback or assistance.

System efficiency

To assess the efficiency of task completion, the following outcomes were captured: range and average time-on-task (O'Malley et al., 2014); and average number of gestures made by participants to complete each task (Kaufman & Starren, 2006). The start of each task was defined by the phrase “Go ahead”; the end was determined when the participant called the clinician back in the room. For each task, all gestures were recorded, including ones that did not result in display changes. For scrolling motions, a single gesture was counted from the moment the finger touched the screen and left the screen (i.e., participant scrolling up and down without lifting finger from the screen was one gesture).

User satisfaction

Although the ASQ can be condensed into a single scale, in this study, each question was reported separately to understand satisfaction with ease, time, and support. Any comments, verbal or written in the questionnaires, were compiled.

Tasks that could not be completed independently by one or more participants were considered needing critical changes. Non-critical items were those not seen as essential to the successful function of the system, but that may improve user engagement or reduce patient-training time in the initial appointment. O'Malley et al. used a similar approach, where authors categorized errors resulting in incorrect or incomplete tasks as critical; non-critical errors occurred when tasks were completed less efficiently (O'Malley et al., 2014).

Results

Participants

Four males and one female evaluated the usability of this mobile health system (Table 5.1). Median health literacy was 8 and median mCSES was 90. One participant mentioned he was a Samsung user, whereas another was noted to own a flip phone. The remaining three patients were iPhone users.

Table 5.1 Participant demographics

Participant	Sex	Age	Diagnosis[a]	Health Literacy (3 to 15)[b]	mCSES (100 to 10)[b]
1	M	34	Myxoma R maxilla	8	82
2	F	47	T2N0M0 SCC R lateral tongue	5	90
3	M	74	T2N0M0	8	90

			SCC R soft palate		
4	M	55	T3N1M0	9	91
			SCC R tongue		
5	M	62	T3/4N1M0	8	85
			SCC L tongue		

[a] R = right; L = left; SCC = squamous cell carcinoma

[b] best to worst score

System Effectiveness

Task one required five instances of assistance across three participants. Tasks two and four required assistance once. Support with task four was the only time help was provided without request from the user. Some participants were eager to use the system and progressed ahead of the assigned task, occasionally completing two tasks together (Table 5.2).

System Efficiency

Table 5.2 summarizes the resources needed to complete each task. For some participants, additional time and gestures may have been required in the first task (Bluetooth pair the device) to become familiar with the smartphone. Some participants forgot to pair the device completely and just opened the app. One participant was unfamiliar with the term “pair”. In the Bluetooth section of Settings, some participants focused on the “Devices” heading, rather than “My Devices”. Here, seeing the pinwheel turn led users to believe the iPhone was still searching for the Mobili-T device.

Table 5.2 Time and number of gestures per participant, per task

Task/ Participant		Task 1 Pair	Task 2 Placement	Task 3 Exercise	Task 4 Progress	Task 5 Close	Comments
1	Time (s)	48	130	115	71	29	
	Gestures	18	11	27	28	6	
2	Time (s)	329		360	233	49	Completed Tasks 1 and 2 together
	Gestures	68		39	15	6	
3	Time (s)	450	852		410	68	Completed Tasks 2 and 3 together
	Gestures	47	45		9	4	
4	Time (s)	33	88	358	202	51	
	Gestures	6	0	82	19	7	
5	Time (s)	260	382	557	343	53	
	Gestures	33	84	86	20	4	

The second task involved attaching the adhesive on the device and placing it under the chin. Some participants had difficulty with the adhesive: one participant pulled it off the device when trying to peel off the backing; another used a pen to stretch the adhesive holes over the sEMG sensors. During placement, two participants pushed on the device rather than press the sides of the adhesive to the skin. Notable comments made by patients during this task included: "Because of weak upper body, it took some effort to pull the adhesive patch over the [sEMG] posts" and "I think for the first time I was unsure which side to use for the adhesive; I would get better each time I used it." With respect to app navigation for this task, one participant attempted to find adhesive information in the “Placement” section of the tutorial; however, this material was located with information on hardware features. Furthermore, users continued to swipe to advance even when on the last screen of a topic, indicating that the progress bar at the bottom of the screen was either not visible or not informative.

The third task (complete a set of exercises) revealed a bug that caused the app to quit unexpectedly for two participants. These patients restarted the app and completed the task a second time. The first participant was forced by the app directly into Exercise Mode; he shared that a link to calibration would have been helpful.

The fourth task (interpret progress screens) presented the most difficulty of the five. Within separate progress meters, each of the three swallowing exercises was represented by a different colour (e.g., effortful swallows were red), and levels of success in completing each exercise by a different gradient of that colour. This visual language was present throughout the app within the Learn and Exercise modes. One participant indicated that he would like to see a number alongside these progress meters. Some participant comments signified confusion (e.g., "Daily is today?", "I need more clarification here") or a vague understanding of what was being represented (e.g., “It didn’t catch”). Furthermore, it was evident that the white section of the bar, used to represent both incomplete swallows and trials that were not detected by the app, was confusing.

The fifth task (close the app, remove and charge the device) did not present any difficulties.

Satisfaction

Figure 5.3 summarizes the ratings assigned for each of the three ASQ questions, per task, per participant. The best rating possible in the ASQ is a score of one or "Strongly Agree". Visual inspection of this figure shows that, in general, participants scored the app favorably for ease of completing a task, the time it took to do so, and the support information provided. A single average score of four was given for "Time" for the task requiring interpretation of progress screens. This user encountered significant difficulty; he was unable to interpret the progress bar length ("But how far should it be?") and colour ("Why is this darker than this?"). Participant one rated the third task (Exercise) poorly for "Ease" because he was unable to find a link to return to the calibration section.

Figure 5.3. Questionnaire Results

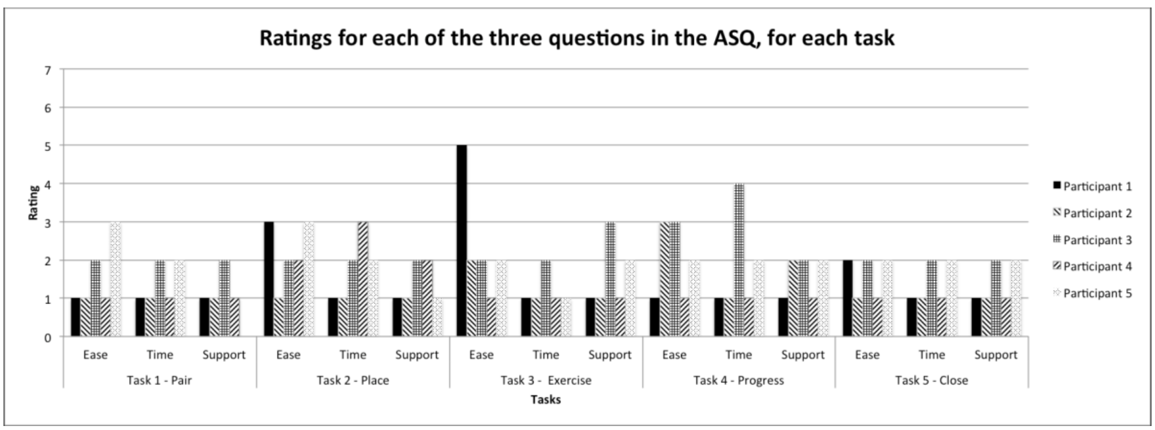


Figure 5.3 ASQ ratings for all three questions, per task, per participant. 1=Strongly Agree; 7=Strongly Disagree. Participant 5 wrote "NA" for the question on support following the first task.

Discussion

This study evaluated the usability of an mHealth system for swallowing therapy with HNC patients by employing ISO usability standards. Our aim was not to compare usability between different types of users or patients. Although the number of times assistance was requested (effectiveness) allowed the development team to prioritize recommendations, the length of time and number of gestures (efficiency) was less meaningful. Watching videos of participants interact with the system and attempt to troubleshoot was the method that provided the most valuable information and revealed usability solutions that were either more intuitive for users (based on observed behaviour) or specific to common issues. For example, whereas participants verbally shared that they were unable to pair the device, the video showed which displays in Settings were troublesome and why. This led to tailored explanations regarding pairing (e.g., “If a loading symbol appears beside ‘Other devices’, it can be ignored; Lost? Accidentally selecting the □□icon will bring you to your device’s information page. Navigate back to the ‘Bluetooth’ menu by selecting the back arrow at the top of the screen”). Finally, satisfaction questionnaires facilitated discussion following each task and could be used to evaluate modifications to future iterations; however, most scores clustered at the positive end.

The first task required the most support and was deemed critical to address before sending patients home with Mobili-T. Although participants were shown how to pair the device to the app in the same session, no in-app tutorial existed on this topic. Some level of support on pairing should be provided. The second critical issue was with placement. Although the development team anticipated that positioning of the device under the chin could be a challenge, the main issue was not this, but rather working with the adhesive. The following recommendations were put forward: move the adhesive tutorial to the Placement section (where users expected to find it), and include an extra screen instructing patients to push down on the edges of the adhesive. The final critical issue occurred with the fourth task, where patients were asked to interpret progress visuals. Here, it was recommended that percentages be added to the meters and that a new colour gradient be introduced to distinguish swallow trials that were not completed from those that were attempted, but not registered by the device.

Finally, recommendations were made to improve the usability of the system. These included attaching a tag on the adhesive backing to facilitate peeling, adding a message informing users they reached the end of a tutorial topic, fixing app bugs, and providing users with a “Calibrate now” link, visible in Exercise Mode.

Future usability testing of Mobili-T should include an opportunity to engage with the system over longer time periods as this may identify different issues and reveal whether or not current issues were resolved. In this study, some participants interacted with the system beyond the assigned task, unwittingly completing two tasks together. This may be due to trait differences associated with a willingness to try out new technologies (Greenhalgh, Robert, MacFarlane, Bate, & Kyriakidou, 2004). Whereas the mCSES was used to determine the level of self-efficacy with new technology, all participants self-rated high on this scale. In fact, the patient with a flip-phone self-rated the highest, indicating that self-efficacy and early adoption may be unrelated. Although systematic usability testing can result in a comprehensive set of variables (Georgsson & Staggers, 2016), it is possible that a more organic interaction with the system would yield additional information on how users expect the app to work and how to troubleshoot problems. For example, Georgsson and colleagues used a multi-method approach to evaluate an mHealth system for diabetes and found that usability testing alone only detected half of the issues experienced by patients, while post-testing interviews revealed close to another third.

Although there are likely additional issues that remain to be uncovered during long-term home-use of the Mobili-T system, the nature of the issues identified by patients, but not the development team, rendered usability testing at this stage a critical step before any additional clinical trials.

Conclusion

The aim of this study was to conduct usability testing with HNC patients and identify any issues that needed to be addressed before sending patients home with the system. The version of the Mobili-T system used was an iteration deemed sufficiently functional and usable by the development team. Critical and non-critical issues were found with a sample of five participants. This work also revealed that, for the purposes of identifying and understanding issues related to usability, qualitative methods were better suited than quantitative ones. This first patient usability testing of the Mobili-T set an example for testing during the development of a mobile health device for swallowing therapy in patients with head and neck cancer.

Acknowledgements

The team would like to thank all patient participants for their time. We also would like to thank Mr. Fraaz Kamal, Mr. Kent McPhee, and Webzao for their assistance in developing the Mobili-T app; and Mr. Dylan Scott for his work on the Mobili-T hardware and charging dock.

Funding

This work was supported by Alberta Cancer Foundation Transformative Program Grant (26355) and Alberta Innovates (AI) Clinician Fellowship (201400350).

Declaration of Conflicting Interest

Authors Constantinescu, King, and Rieger are inventors listed on a patent for the mobile swallowing therapy device. The patent application was made through TEC Edmonton Office, University of Alberta (file number: 2014015. No commercial interest has been shown at this stage).

References

Constantinescu, G., King, B., McMahon, M., Brodt, C., Hodgetts, B., & Rieger, J. (2016). Designing for patients: Using a cultural probe in the development of a mobile health device and application for swallowing therapy in head and neck cancer patients. *University of Alberta Health Sciences Journal, 12*(1), 5-10.

Constantinescu, G., Loewen, I., King, B., Brodt, C., Hodgetts, W., & Rieger, J. (2017). Designing a Mobile Health App for Patients With Dysphagia Following Head and Neck Cancer: A Qualitative Study. *Journal of Medical Internet Research: Rehabilitation and Assistive Technologies, 4*(1), e3. doi:10.2196/rehab.6319

Corry, M. D., Frick, T. W., & Hansen, L. (1997). User-centered design and usability testing of a web site: An illustrative case study. *Educational Technology Research and Development, 45*(4), 65-76.

Fiordelli, M., Diviani, N., & Schulz, P. J. (2013). Mapping mHealth Research: A Decade of Evolution. *Journal of Medical Internet Research, 15*(5), e95. doi:10.2196/jmir.2430

Georgsson, M., & Staggers, N. (2016). Quantifying usability: an evaluation of a diabetes mHealth system on effectiveness, efficiency, and satisfaction metrics with associated user characteristics. *Journal of the American Medical Informatics Association, 23*(1), 5-11. doi:10.1093/jamia/ocv099

Greenhalgh, T., Robert, G., MacFarlane, F., Bate, P., & Kyriakidou, O. (2004). Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations. *The Milbank Quarterly, 82*(4), 581-629.

International Organization for Standardization. Ergonomic requirements for office work with visual display terminals (VDTs) Part 11 Guidance on usability. (1998). *International standard, 9241-11*. Geneve: ISO.

Kaufman, D. R., & Starren, J. B. (2006). A Methodological Framework for Evaluating Mobile Health Devices. *American Medical Informatics Association Symposium*, 978.

Laver, K., George, S., Ratcliffe, J., & Crotty, M. (2012). Measuring technology self efficacy: reliability and construct validity of a modified computer self efficacy scale in a clinical rehabilitation setting. *Disabil Rehabil, 34*(3), 220-227. doi:10.3109/09638288.2011.593682

Lewis, J. R. (1995). IBM computer usability satisfaction questionnaires: Psychometric evaluation and instructions for use. *International Journal of Human-Computer Interaction, 7*(1), 57-78. doi:10.1080/10447319509526110

Lyles, C. R., Sarkar, U., & Osborn, C. Y. (2014). Getting a Technology-Based Diabetes Intervention Ready for Prime Time: a Review of Usability Testing Studies. *Current Diabetes Reports, 15*(534), 1-12. doi:10.1007/s11892-014-0534-9

O'Malley, G., Dowdall, G., Burls, A., Perry, I. J., & Curran, N. (2014). Exploring the Usability of a Mobile App for Adolescent Obesity Management. *Journal of Medical Internet Research: mHealth uHealth, 2*(2), e29. doi:10.2196/mhealth.3262

Reynoldson, C., Stones, C., Allsop, M., Gardner, P., Bennett, M. I., Closs, S. J., . . . Knapp, P. (2014). Assessing the Quality and Usability of Smartphone Apps for Pain Self-Management. *Pain Medicine, 15*, 898-909.

Sarkar, U., Schillinger, D., Lopez, A., & Sudore, R. (2011). Validation of self-reported health literacy questions among diverse English and Spanish-speaking populations. *J Gen Intern Med, 26*(3), 265-271. doi:10.1007/s11606-010-1552-1

Virzi, R. A. (1992). Refining the Test Phase of Usability Evaluation: How Many Subjects is Enough? *Human Factors, 34*(4), 457-468.

CHAPTER 6: mHEALTH DESIGN AND DEVELOPMENT IN THE ACADEMIC SETTING

Gabriela Constantinescu[1,2], Jana Rieger[1,2], William Hodgetts[1,2]

[1] Department of Communication Sciences and Disorders, Faculty of Rehabilitation Medicine, University of Alberta, 8205 114St 2-70 Corbett Hall, Edmonton, Alberta, Canada

[2] Institute for Reconstructive Sciences in Medicine (iRSM), 1W-02, 16940-87 Avenue Misericordia Community Hospital, Edmonton, Alberta, Canada

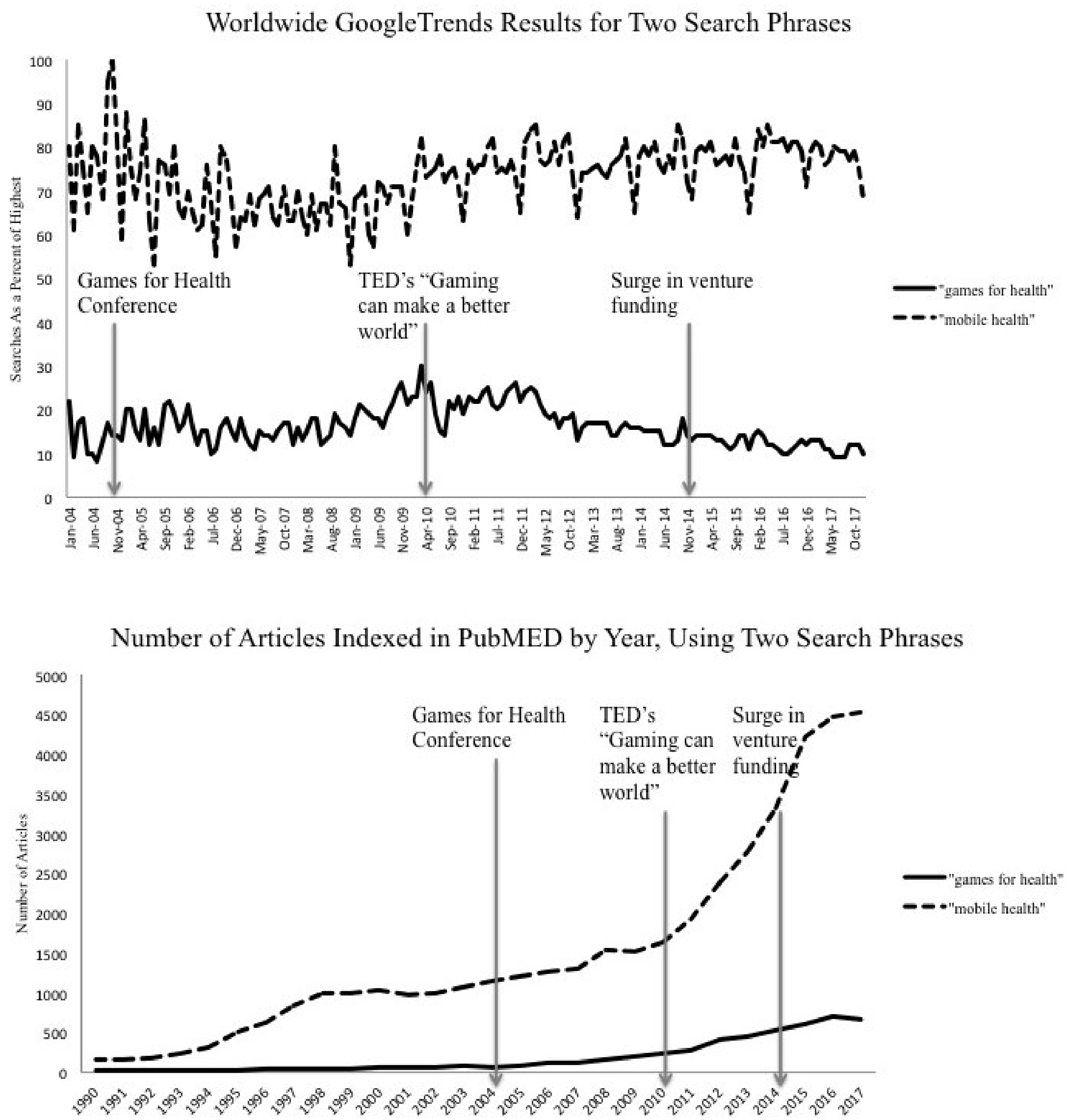
Corresponding author: William Hodgetts, PhD, Associate Professor, Department of Communication Sciences and Disorders, 2-70 Corbett Hall, University of Alberta, Edmonton, Alberta T6R 3T5, Canada. Email: bill.hodgetts@ualberta.ca Tel: 780.492.4992 Fax: 780.492.9333

Keywords: design; development; mHealth; mobile apps; rehabilitation; uptake

Introduction

In the last two decades, considerable focus has been given to the topics of mobile health (mHealth) and gamified mHealth apps, with many believing that these technologies are one-stop solutions to long-standing healthcare problems; however, the prevailing question is who should be the driver of development in this healthcare sector. The answer to this question is important as it could influence the success of these apps. The rise in the popularity of mHealth, the use of mobile and wireless devices to support medical and public health (WHO, 2011), could be linked to an increase in micromanufacturing and the pervasiveness of smartphones. The engineering of small devices and systems has provided the means for easy and convenient patient monitoring outside the hospital setting. As the popularity of small personal trackers has grown, so has the need to keep users engaged with them, creating a fertile ground for innovation in the field of gamification.

Gamified mHealth apps or "games for health" are apps in which classic game elements are applied to health management (Deterding, Dixon, Khaled, & Nacke, 2011). The interest in games for health grew steadily with the increased popularity of video games (Kato, 2010). In 2010, TED, a conference aimed at spreading ideas in science, business, and global issues, released a speech by Professor Jane McGonigal titled, "Gaming can make a better world". In her talk, and later in her book, *Reality is Broken*, McGonigal proposed that people should strive to make reality more like a video game, one in which our experience is optimized (McGonigal, 2011). 2010 also became the year when the Games for Health Europe conference was founded, a non-profit organization aimed at spreading ideas on the topic. Two years later, the Games for Health Journal was launched by Mary Ann Liebert Inc. publishers, now in its sixth volume. Interest in both, mHealth and games for health has grown rapidly in the past decade and a half (Figure 6.1) also accumulating interest from investors.



a

b

Figure 6.1. Public interest (a) and research interest (b) for the search phrases "games for health" and "mobile health".

Venture interest soared in apps that promised to improve public health. In 2014, funding for startup companies working on health apps rose to $4.3 billion, double what was cited in the previous year. This surge in investment leveled off at $4.5 billion in the following year; however, digital health continued to account for 7% of all venture funding (Rock_Health, 2015). As interest and development grew, Apple Inc. released CareKit on March 21st, 2016, an open source framework that gave developers a means to rapidly create health apps compatible with iOS. Although public interest in mobile health and games for health appears to have plateaued following 2010 (Figure 6.1a), academic activity in mobile health and games for health continued to rise (Figure 6.2b). Furthermore, the development of new mHealth apps continues to grow. In 2017, out of the 325,000 health apps available, 78,000 or 24% were newly released that year (Research2Guidance, 2018). Yet despite this recognizable growth, only a small fraction of mHealth apps are downloaded and used consistently (Informatics, 2015; Research2Guidance, 2018). The reason why some apps are successfully adopted whereas others are not is unknown, although surveys of healthcare providers and patients conducted by Vodafone (2011) listed cost, lack of evidence, lack of user-engagement, design, and support with the technology as potential barriers to mHealth uptake. Even in light of these perceived barriers, it remains unknown which sector, academia or industry, should be the driver for mHealth development.

One perspective is that each sector holds the advantage at different stages in development. For example, it has been suggested that academia is driven by innovation and less so by scalable or reimbursable projects (Schwartz & Macomber, 2017). Industry on the other hand often has more experience with product manufacturing, regulatory processes, and commercialization, all of which are valuable in the later stages of mHealth development. In this chapter, we discuss three key reasons why early development stages may be better suited for the academic environment:

1. Academia is set up to systematically research health concerns, gaps in care, specific therapies, and strategies to encourage adherence to those therapies.
2. Academics already have close collaborations with patients and clinicians, allowing for the incorporation of end-user feedback early and even co-generation of solutions, and
3. The peer-review process and transfer of knowledge essential to academia can build early awareness of the mHealth technology being developed.

Additionally, designs driven by clinical practice, early patient engagement, and gradual promotion of the technology are factors that may contribute to the uptake and sustained use of mHealth technologies.

We recognize that, even in light of these advantages, development of mHealth in academia presents with drawbacks as well. In this chapter, we will expand on the aforementioned three benefits and hope to persuade the reader that early development of mHealth technologies is best suited for the academic setting despite the challenges that parallel it.

Addressing Specific Clinical Concerns

Perhaps the most obvious advantage of early development in academia is that this sector is well set up for systematic and thorough research in the health concerns it aims to address. Rather than approaching mHealth as a universal solution, researchers may explore how this technology could be leveraged to answer existing questions and gaps in the field.

Ultimately, mHealth is a tool that has the potential to make therapy easier and more accessible; it is not a solution by itself. Every patient population will have different needs and different therapies. Therefore, mHealth development should be driven by a clinical problem, one that is well understood. Academics, and the healthcare teams with whom they are involved, have the advantage of conducting methodical, organized, hypothesis-driven research to better understand their patient populations, the therapies given, and how to best engage patients in their own healthcare.

This advantage could be perceived as a criticism as well, as academic institutions can be seen as too protocol-bound and slow moving. mHealth development by industry may be faster, and therefore in the hands of patients sooner and able to incorporate new technology quicker. However, a consumer report from the IMS Institute for Healthcare Informatics on the adoption of mobile health revealed that only 12% of the 6,998 apps in this report were responsible for more than 90% of all downloads (Informatics, 2015). Also only 5% of mHealth apps have 100,000 or more monthly active (i.e., consistent) users (Research2Guidance, 2018). The authors of these reports cited lack of scientific evidence behind most mHealth apps and called for further research into the efficacy, accuracy, and appropriateness of available apps, as well as additional sub-population and long-term follow-up. For these reasons, the academic setting may still be the place to begin mHealth development.

One way in which researchers can provide value to persuasive design is to systematically investigate patient-specific behaviour change techniques needed to be addressed through the mHealth apps. Persuasive design, or changing behaviour by influencing motivation and beliefs (Fogg, 2002), plays an important role in engaging patients to adhere to a given health activity. Behaviour Change Techniques (BCTs) are defined as the smallest observable and replicable components aimed to modify behaviour and are used to promote a common language regarding approaches to intervention (S. Michie et al., 2015). Examples of BCTs include goal setting, feedback on behaviour, and social supports. BCTs are typically incorporated in gamified mHealth apps (Cugelman, 2013; Susan Michie, Atkins, & West, 2014), albeit not always with purposive intent. The selection of BCTs to be leveraged by apps should be informed by evidence and/or clinical practice. For example, patients who already understand the benefits of a particular activity (e.g., smoking cessation) may benefit more from apps that focus on teaching and goal setting BCTs rather than those that focus on information about health consequences (Susan Michie et al., 2014).

Academia provides the setting and process to systematically investigate BCTs specific to a sub-population (e.g., patients with head and neck cancer) or behaviour (e.g., swallowing rehabilitation). Swallowing therapy researchers are already starting to look at the BCTs most commonly used in clinic to promote adherence to therapy (Govender, Smith, Taylor, Barratt, & Gardner, 2017). This type of research may be extremely useful to mHealth development because BCTs already used in clinic can be leveraged by gamified mHealth apps. This sequence of steps is an example of design driven by clinical practice. Starting with sub-population specific BCTs, then leveraging mHealth technologies to address them also has been suggested by Qasim and colleagues in their systematic process for designing persuasive technologies (Qasim, Ahmad, Omar, Zulkifli, & Bakar, 2017). Motivating a healthy individual to exercise may require different BCTs, and therefore a different type of gamified app, than motivating a patient with head and neck cancer to complete exercises despite pain and discomfort. Therefore, behaviours that should be targeted by persuasive design should be specific to the patient population and rehabilitation targeted, and therefore, well studied.

Industry typically targets large consumer markets. Therefore, mHealth apps developed for this purpose may focus on disease states or needs that affect large proportions of the population. Examples include apps that assist with monitoring blood pressure, medication, apps that help manage personal health records, and apps that promote mental health and fitness. Industry may partner with researchers in the latter stages of development, such as usability, feasibility, and effectiveness testing. However, engaging patients this late in development may result in mixed findings during validation testing (e.g., the technology works for some patients, but not others) and a lack of clarity as to why something worked or did not. In contrast, mHealth apps driven by clinician scientists may focus on smaller sub-populations, such as sedentary seniors with cardiovascular disease.

Although targeting wider proportions of the population may have a financial advantage for industry, patient populations with unique and complex needs may not benefit from these mainstream mHealth apps. Researchers and clinician scientists typically have content expertise with a given clinical population and are acutely aware of the gaps that can be addressed using these technologies. This knowledge is a key first step in proposed frameworks for mHealth development (Matthew-Maich et al., 2016; Qasim et al., 2017). Furthermore, early engagement of patients in early development stages can highlight aspects of mHealth design important only to those living with the particular condition.

Engaging Patients in Design and Development

Design thinking combines empathy for the context of the problem with the creativity to generate viable solutions (Brown, 2008). Engaging patients as early as possible is critical to the design process. Whereas industry also includes patients in their design and development teams, clinician scientists typically enroll patients consecutively and therefore may be exposed to a wider range of perspectives that includes early as well as late-adopters of technology.

Researchers can leverage their pre-existing partnerships with front-line clinicians and patients, allowing for a natural engagement of end-users in early stages of mHealth design. Furthermore, academics are well practiced in active questioning and scientific inquiry (Vale, 2013), making it easier for this group to formulate research studies regarding app design and development, not just app effectiveness. In this section, we present a brief review of the literature related to mHealth design to determine if indeed rehabilitation researchers engaged patients and clients in mHealth app development. The search was conducted using Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present (Table 6.1). The search yielded a total of 37 articles.

Table 6.1

Details of Search

Search	Results

1. ("mobile app*" OR mHealth).mp.	6209
2. (mobile adj3 app*).mp.	6495
3. 1 OR 2	7983
4. (rehabilitation OR "speech therapy" OR "occupational therapy" OR "physical therapy").af.	457488
5. (design AND development).af.	174137
6. 3 AND 5	542
7. 4 AND 6	37

Following review of abstracts and, in some cases, the introduction and methods, nine articles were excluded: five were not related to mHealth, one was a review of existing apps, one was related to Telehealth, one was an assessment of need, and one discussed a framework for mHealth app development. This resulted in a final total of 28 articles (Appendix E).

When summarizing this literature, the following definitions were used: “Design & Development” stage was used to refer to engagement of patients or clients in research, ideation, or prototyping phases of development. Usability or feasibility testing, pilot testing, and randomized controlled trials were deemed to be part of the “Validation” stage. In some cases, it is possible that patients or clients were informally involved in the design and development stages. For this reason, we reviewed articles for details of app development and noted instances where authors referenced the inclusion or engagement of patients or clients at any point in the design and development stages. Seeking the opinion of other professionals (e.g., clinician expert opinion) was noted, but not counted.

Of the 28 articles included in this brief review, 14 (50%) were found to engage patients or clients in the Design & Development stages. These findings should be interpreted with caution, as this was not an exhaustive review of the literature and focused on mHealth in rehabilitation setting only.

One evident argument against seeking input from patients in the early stages of mHealth development, particularly in a rigorous manner such as that demanded by research, is the resources required to do so. Carrying out formal studies necessitates devising well-articulated questions, selecting the appropriate methodology, obtaining ethics and operational approvals, and making an effort to remain unbiased to the outcome. These steps take time, which is at odds with the fast pace of technological advancements. For example, in the past few decades, several technologies have been developed and rendered obsolete including DVD and BluRay players, various media storage devices, and point-and-shoot cameras. In other words, if we take the time to be thorough in our investigation of patient wants and needs, we may be putting technological development at risk because platforms such as smartphones may become obsolete by the time well-researched mHealth apps become widely available.

Although it may follow that including patients along the continuum of mHealth design would result in better uptake and retention of these technologies (Birnbaum, Lewis, Rosen, & Ranney, 2015), doing so may delay development and ultimately, getting the technology in the hands of patients. When developing mHealth in the academic setting, one must strike a balance between rigorous methods and timely development. To do this, researchers may wish to use approaches that are methodologically sound, but still efficient, such as convergent interviewing. Another important advantage to engaging patients in development early is the contribution their involvement has on knowledge translation.

Knowledge Translation and Uptake

Knowledge translation (KT) is a term used to describe the exchange between knowledge creators and users (Grimshaw, Eccles, Lavis, Hill, & Squires, 2012). Whereas mHealth technologies developed by industry may be publicized only once they are production-ready, the academic setting facilitates early awareness and engagement with end-users as described in the previous section. The latter may be important in preparing patients and clinicians for an upcoming technological solution. The development of health apps in the academic setting is well positioned for this activity given the ongoing dissemination of knowledge through publications and presentations. Furthermore, the peer-review aspect of KT may also foster greater transparency and trust with early adopters and champions of these technologies.

In their scoping review, Matthew-Maich and colleagues (2016) found that one important theme pertaining to the implementation of mHealth technologies is the readiness of organizational systems to adopt them. mHealth technologies developed and led by a clinician scientist may hold an advantage in this respect. Clinician scientists influence their respective fields of research; they have credibility with other researchers and practitioners and are local opinion leaders at their respective centers. Local opinion leaders are informally recognized as such by their peers and hold “unique and influential positions in the system’s communication structure” (p.7 Grimshaw et al., 2012). KT through these individuals has been shown to have the largest impact on clinician practice across studies (Grimshaw et al., 2012).

Furthermore, Matthew-Maich and colleagues (2016) called for an mHealth evaluation framework that supports an iterative process and knowledge transfer between developing teams, clinicians, and patients. Development of mHealth in the academic setting has already established this sequence by virtue of the nature of research. Partnerships with clinicians that may have formed during the design, development, and validation stages of research also may assist with the dissemination of findings and introduction of the device in healthcare settings (Barwick, 2008, 2013). These clinicians may act as champions of the technology, identifying potential barriers and facilitators for its uptake, and act as connections to decision makers from the community, such as Community of Practice Leads.

Partnerships between developers and end-users can also form in industry. The CEO of Procter and Gamble Companies advocates for asking consumers directly, rather than assuming, what works and what does not about a given product (Jain, 2015). An example from swallowing rehabilitation is Swallow Solutions LLC who developed the mHealth system SwallowSTRONG. This company partnered with local researchers to test their technology in clinic and disseminate findings at the Dysphagia Research Society conference and in publications (Rogus-Pulia et al., 2016). However, even when industry partners with clinician scientists in this way, technology can still see poor adoption. Cohn (2009) and colleagues recommended that clinicians become leaders who will champion the technology with their local administration. Cohn et al. highlighted the importance of early involvement of clinicians in a shared vision for change in healthcare in order to facilitate their adoption of new technology, especially in the case of disruptive innovations. Not doing so may result in clinicians becoming fearful of new technology and perceiving its introduction as a loss of autonomy (Cohn et al., 2009).

Knowledge Translation between developers and front-line clinicians can take place with both academic developers and industry. This involvement is essential because buy-in from clinicians is critical to mHealth uptake. However, the academic setting is once again well established for knowledge translation. The field does not just encourage it, but expects it; researchers are asked to consider KT from the early stage of grant applications and partner with patients and clinicians in the co-creation of research questions and clinical solutions.

Conclusion

Development of mHealth apps can be led by both academia and industry. In this paper we discussed the advantages of developing within an academic setting. It is possible that mHealth can see successful uptake when these technological solutions are driven by a focused and well-understood clinical need, when patient engagement occurs in the earliest stages of design, and when knowledge transfer provides evidence of rigour and transparency. However, even when mHealth is led by academia, industry still plays a crucial role in scaling up the technology. For example, some academic research teams have developed innovations and invited investors and strategic companies as late stage stakeholders to commercialize their medical devices (Vagelos, 2007). To achieve success with this type of approach, academics need to be mindful of intellectual property, creation of reimbursement schedules, and documentation of existing competitors (Schwartz & Macomber, 2017).

mHealth holds great potential for better understanding and improving both population based health considerations (e.g., activity monitoring) and individual patient/client outcomes (e.g., swallowing therapy for head and neck cancer survivors). However, as with any new technology or idea, its potential should be defined by a well understood processes of discovery, innovation, and validation. In this paper we have argued that mHealth development in academia offers a setting that is well established for systematic clinical research, that already works closely with mHealth end-users, and that thrives on regular knowledge transfer.

References

Barelli, R. G., Aquino Junior, P. T., & Ferrari de Castro, M. C. (2016). Mobile interface for neuroprosthesis control aiming tetraplegic users. *Conference proceedings : ... Annual International Conference of the IEEE Engineering in Medicine and Biology Society. IEEE Engineering in Medicine and Biology Society. Annual Conference, 2016*, 2618-2621. doi:https://dx.doi.org/10.1109/EMBC.2016.7591267

Barwick, M. (2008, 2013). Knowledge Translation Planning Template. Ontario: The Hospital for Sick Children.

Ben-Zeev, D., Kaiser, S. M., Brenner, C. J., Begale, M., Duffecy, J., & Mohr, D. C. (2013). Development and usability testing of FOCUS: a smartphone system for self-management of schizophrenia. *Psychiatric rehabilitation journal, 36*(4), 289-296. doi:https://dx.doi.org/10.1037/prj0000019

Bendixen, R. M., Fairman, A. D., Karavolis, M., Sullivan, C., & Parmanto, B. (2017). A User-Centered Approach: Understanding Client and Caregiver Needs and Preferences in the Development of mHealth Apps for Self-Management. *JMIR mHealth and uHealth, 5*(9), e141. doi:https://dx.doi.org/10.2196/mhealth.7136

Birnbaum, F., Lewis, D., Rosen, R. K., & Ranney, M. L. (2015). Patient engagement and the design of digital health. *Academic Emergency Medicine, 22*(6), 754-756. doi:10.1111/acem.12692

Brown, T. (2008). Design Thinking. *Harvard Business Review.* Retrieved from https://hbr.org/2008/06/design-thinking

Cohn, K. H., Berman, J., Chaiken, B., Green, D., Green, M., Morrison, D., & Scherger, J. E. (2009). Engaging Physicians to Adopt Healthcare Information Technology. *Journal of Healthcare Management, 54*(5), 292-300.

Constantinescu, G., Loewen, I., King, B., Brodt, C., Hodgetts, W., & Rieger, J. (2017). Designing a Mobile Health App for Patients With Dysphagia Following Head and Neck Cancer: A Qualitative Study. *JMIR rehabilitation and assistive technologies, 4*(1), e3. doi:https://dx.doi.org/10.2196/rehab.6319

Crook, A., Kenny, J., Johnson, H., & Davidson, B. (2017). Perspectives of a mobile application for people with communication disabilities in the community. *Disability and rehabilitation. Assistive technology, 12*(2), 184-196.

Cugelman, B. (2013). Gamification: what it is and why it matters to digital health behavior change developers. *JMIR Serious Games, 1*(1), e3. doi:10.2196/games.3139

Danilovich, M. K., Diaz, L., Saberbein, G., Healey, W. E., Huber, G., & Corcos, D. M. (2017). Design and development of a mobile exercise application for home care aides and older adult medicaid home and community-based clients. *Home health care services quarterly, 36*(3-4), 196-210. doi:https://dx.doi.org/10.1080/01621424.2017.1381869

Darcy, S., Green, J., & Maxwell, H. (2017). I've got a mobile phone too! Hard and soft assistive technology customization and supportive call centres for people with disability. *Disability and rehabilitation. Assistive technology, 12*(4), 341-351. doi:https://dx.doi.org/10.3109/17483107.2016.1167260

Deterding, S., Dixon, D., Khaled, R., & Nacke, L. (2011). From game design elements to gamefulness: defining "gamification". *MindTrek '11 Proceedings of the 15th International Academic MindTrek Conference: Envisioning Future Media Environments*, 9-15. doi:10.1145/2181037.2181040

Dithmer, M., Rasmussen, J. O., Gronvall, E., Spindler, H., Hansen, J., Nielsen, G., . . . Dinesen, B. (2016). "The Heart Game": Using Gamification as Part of a Telerehabilitation Program for Heart Patients. *Games for health journal, 5*(1), 27-33. doi:https://dx.doi.org/10.1089/g4h.2015.0001

Fairman, A. D., Yih, E. T., McCoy, D. F., Lopresti, E. F., McCue, M. P., Parmanto, B., & Dicianno, B. E. (2016). Iterative Design and Usability Testing of the Imhere System for Managing Chronic Conditions and Disability. *International journal of telerehabilitation, 8*(1), 11-20. doi:https://dx.doi.org/10.5195/ijt.2016.6194

Fledderus, M., Schreurs, K. M., Bohlmeijer, E. T., & Vollenbroek-Hutten, M. M. (2015). Development and Pilot Evaluation of an Online Relapse-Prevention Program Based on Acceptance and Commitment Therapy for Chronic Pain Patients. *JMIR human factors, 2*(1), e1. doi:https://dx.doi.org/10.2196/humanfactors.3302

Fogg, B. J. (2002). *Persuasive Technology: Using Computers to Change What We Think and Do*: Morgan Kaufmann Publishers Inc.

Frederix, I., Sankaran, S., Coninx, K., & Dendale, P. (2016). MobileHeart, a mobile smartphone-based application that supports and monitors coronary artery disease patients during rehabilitation. *Conference proceedings : ... Annual International Conference of the IEEE Engineering in Medicine and Biology Society. IEEE*

Engineering in Medicine and Biology Society. Annual Conference, 2016, 513-516. doi:https://dx.doi.org/10.1109/EMBC.2016.7590752

Giesbrecht, E. M., Miller, W. C., Jin, B. T., Mitchell, I. M., & Eng, J. J. (2015). Rehab on Wheels: A Pilot Study of Tablet-Based Wheelchair Training for Older Adults. *JMIR rehabilitation and assistive technologies, 2*(1), e3. doi:https://dx.doi.org/10.2196/rehab.4274

Goldberg, M., Karimi, H., & Pearlman, J. L. (2016). Interactive, mobile, AGIle and novel education (IMAGINE): a conceptual framework to support students with mobility challenges in higher education. *Disability and rehabilitation. Assistive technology, 11*(1), 50-60. doi:https://dx.doi.org/10.3109/17483107.2014.959074

Govender, R., Smith, C. H., Taylor, S. A., Barratt, H., & Gardner, B. (2017). Swallowing interventions for the treatment of dysphagia after head and neck cancer: a systematic review of behavioural strategies used to promote patient adherence to swallowing exercises. *BMC Cancer, 17*(1), 43. doi:10.1186/s12885-016-2990-x

Grimshaw, J. M., Eccles, M. P., Lavis, J. N., Hill, S. J., & Squires, J. E. (2012). Knowledge translation of research findings. *Implement Sci, 7*, 50. doi:10.1186/1748-5908-7-50

Gyori, M., Stefanik, K., & Kanizsai-Nagy, I. (2015). Evidence-based development and evaluation of mobile cognitive support apps for people on the autism spectrum: methodological conclusions from two R+D projects. *Studies in health technology and informatics, 217*, 55-62.

Hidalgo-Mazzei, D., Mateu, A., Reinares, M., Undurraga, J., Bonnin, C. d. M., Sanchez-Moreno, J., . . . Colom, F. (2015). Self-monitoring and psychoeducation in bipolar patients with a smart-phone application (SIMPLe) project: design, development and studies protocols. *BMC psychiatry, 15*, 52. doi:https://dx.doi.org/10.1186/s12888-015-0437-6

Informatics, I. I. f. H. (2015). *Patient Adoption of mHealth: Use, Evidence and Remaining Barriers to Mainstream Acceptance*. Retrieved from Parsippany, NJ:

Jain, S., H. (2015). What Procter & Gamble Can Teach The Healthcare Industry: Assume Nothing About Patients. *Pharma & Healthcare.* Retrieved from https://www.forbes.com/sites/sachinjain/2015/11/09/incorporating-the-patient-voice-into-health-care-moving-beyond-our-assumptions/2/ - 4acaf7b27fa6

Kato, P. M. (2010). Video games in health care: Closing the gap. *Review of General Psychology, 14*(2), 113-121. doi:10.1037/a0019441

Krumsvik, O. A., & Babic, A. (2017). Designing an E-Learning Platform for Postoperative Arthroplasty Adverse Events. *Studies in health technology and informatics, 235*, 348-352.

Larrosa, F., Rama-Lopez, J., Benitez, J., Morales, J. M., Martinez, A., Alanon, M. A., . . . Rey-Martinez, J. (2015). Development and evaluation of an audiology app for iPhone/iPad mobile devices. *Acta oto-laryngologica, 135*(11), 1119-1127. doi:https://dx.doi.org/10.3109/00016489.2015.1063786

Matthew-Maich, N., Harris, L., Ploeg, J., Markle-Reid, M., Valaitis, R., Ibrahim, S., . . . Isaacs, S. (2016). Designing, Implementing, and Evaluating Mobile Health Technologies for Managing Chronic Conditions in Older Adults: A Scoping Review. *JMIR Mhealth Uhealth, 4*(2), e29. doi:10.2196/mhealth.5127

McGonigal, J. (2011). *Reality is Broken: Why Games Make Us Better and How They Can Change the World*. New York: Penguin Press.

Michie, S., Atkins, L., & West, R. (2014). *The Behaviour Change Wheel - A Guide to Designing Interventions*. UK: Silverback Publishing.

Michie, S., Wood, C. E., Johnston, M., Abraham, C., Francis, J. J., & Hardeman, W. (2015). Behaviour change techniques: the development and evaluation of a taxonomic method for reporting and describing behaviour change interventions (a suite of five studies involving consensus methods, randomised controlled trials and analysis of qualitative data). *Health Technology Assessment, 19*(99), 1-188. doi:10.3310/hta19990

Murphy, K., & Darrah, M. (2015). Haptics-Based Apps for Middle School Students with Visual Impairments. *IEEE transactions on haptics, 8*(3), 318-326. doi:https://dx.doi.org/10.1109/TOH.2015.2401832

Nahar, L., Jaafar, A., Ahamed, E., & Kaish, A. B. M. A. (2015). Design of a Braille Learning Application for Visually Impaired Students in Bangladesh. *Assistive technology : the official journal of RESNA, 27*(3), 172-182. doi:https://dx.doi.org/10.1080/10400435.2015.1011758

Nicholson, J., Carpenter-Song, E. A., MacPherson, L. H., Tauscher, J. S., Burns, T. C., & Lord, S. E. (2017). Developing the WorkingWell mobile app to promote job tenure for individuals with serious mental illnesses. *Psychiatric rehabilitation journal, 40*(3), 276-282. doi:https://dx.doi.org/10.1037/prj0000201

Parmanto, B., Pramana, G., Yu, D. X., Fairman, A. D., Dicianno, B. E., & McCue, M. P. (2013). iMHere: A Novel mHealth System for Supporting Self-Care in

Management of Complex and Chronic Conditions. *JMIR mHealth and uHealth, 1*(2), e10. doi:https://dx.doi.org/10.2196/mhealth.2391

Pfaeffli, L., Maddison, R., Whittaker, R., Stewart, R., Kerr, A., Jiang, Y., . . . Dalleck, L. (2012). A mHealth cardiac rehabilitation exercise intervention: findings from content development studies. *BMC cardiovascular disorders, 12*, 36. doi:https://dx.doi.org/10.1186/1471-2261-12-36

Powell, L. E., Wild, M. R., Glang, A., Ibarra, S., Gau, J. M., Perez, A., . . . Slocumb, J. (2017). The development and evaluation of a web-based programme to support problem-solving skills following brain injury. *Disability and rehabilitation. Assistive technology*, 1-12. doi:https://dx.doi.org/10.1080/17483107.2017.1389999

Qasim, M. M., Ahmad, M., Omar, M., Zulkifli, A. N., & Bakar, J. A. A. (2017). A systematic process for persuasive mobile healthcare applications. *AIP Conference Proceedings, 1891*, 020115. doi:10.1063/1.5005448

Radhakrishnan, K., Toprac, P., O'Hair, M., Bias, R., Kim, M. T., Bradley, P., & Mackert, M. (2016). Interactive Digital e-Health Game for Heart Failure Self-Management: A Feasibility Study. *Games for health journal, 5*(6), 366-374.

Rawstorn, J. C., Gant, N., Meads, A., Warren, I., & Maddison, R. (2016). Remotely Delivered Exercise-Based Cardiac Rehabilitation: Design and Content Development of a Novel mHealth Platform. *JMIR mHealth and uHealth, 4*(2), e57. doi:https://dx.doi.org/10.2196/mhealth.5501

Research2Guidance. (2018). *mHealth App Economics: Current Status and Future Trends in Mobile Health*. Retrieved from http://www.research2guidance.com

Rock_Health. (2015). Digital Health Funding: 2015 Year in Review. Retrieved from https://rockhealth.com/reports/digital-health-funding-2015-year-in-review/

Rogus-Pulia, N., Rusche, N., Hind, J. A., Zielinski, J., Gangnon, R., Safdar, N., & Robbins, J. (2016). Effects of Device-Facilitated Isometric Progressive Resistance Oropharyngeal Therapy on Swallowing and Health-Related Outcomes in Older Adults with Dysphagia. *Journal of the American Geriatrics Society, 64*(2), 417-424. doi:10.1111/jgs.13933

Schwartz, J., & Macomber, C. (2017). So, You Think You Have an Idea: A Practical Risk Reduction-Conceptual Model for Academic Translational Research. *Bioengineering (Basel), 4*(2). doi:10.3390/bioengineering4020029

Svarre, T., Lunn, T. B. K., & Helle, T. (2017). Transforming paper-based assessment forms to a digital format: Exemplified by the Housing Enabler prototype app. *Scandinavian journal of occupational therapy, 24*(6), 438-447. doi:https://dx.doi.org/10.1080/11038128.2016.1255774

Tabak, M., Vollenbroek-Hutten, M. M., van der Valk, P. D., van der Palen, J., & Hermens, H. J. (2014). A telerehabilitation intervention for patients with Chronic Obstructive Pulmonary Disease: a randomized controlled pilot trial. *Clinical rehabilitation, 28*(6), 582-591. doi:https://dx.doi.org/10.1177/0269215513512495

Vagelos, P. R. (2007). Innovation and industry-academia interactions: Where conflicts arise and measures to avoid them. *Cleveland Clinic Journal of Medicine, 74*(Supplement 2), S12-S13.

Vale, R. D. (2013). The value of asking questions. *Molecular Biology of the Cell, 24*(6), 680-682. doi:10.1091/mbc.E12-09-0660

Vodafone Group. (2011). *Evaluating mHealth Adoption Barriers: Human Behaviour - Insights Guide*. Retrieved from Newbury, Berkshire: mhealth.vodafone.com

Vorrink, S. N., Kort, H. S., Troosters, T., & Lammers, J.-W. J. (2016). A Mobile Phone App to Stimulate Daily Physical Activity in Patients with Chronic Obstructive Pulmonary Disease: Development, Feasibility, and Pilot Studies. *JMIR mHealth and uHealth, 4*(1), e11. doi:https://dx.doi.org/10.2196/mhealth.4741

WHO. (2011). *mHealth: New horizons for health through mobile technologies*. Geneva, Switzerland: World Health Organization.

CHAPTER 7: CONCLUSION

Summary of Contributions

In my PhD dissertation, I set out to collaborate with engineers, software developers, designers, patients, and clinicians to develop and evaluate a mobile health (mHealth) system for swallowing therapy for patients with head and neck cancer (HNC). We called this system Mobili-T^{TM}, short for Mobile Therapy. Several studies were carried out that have made substantial contributions to the field of mHealth technologies for home-based therapies and swallowing research. These contributions are listed below:

1) The studies in this dissertation constitute one of the few documented approaches to the design and development of such a device using stakeholder involvement from research and ideation design stages. The idea for this mHealth technology was co-conceived by clinicians and biomedical engineers. Since then, the design and development of this technology has involved an ongoing interdisciplinary collaboration and iterative cycles of team meetings, research, knowledge transfer, and implementation of findings.
2) With respect to surface sensors, my research on signal to noise ration (SNR) revealed that sensors may perform differently with distinct populations (e.g., healthy vs. HNC) and even tasks (e.g., regular swallows vs. Mendelsohn swallows). This finding has important implications for clinicians and mHealth developers. Although sEMG sensors currently are considered the clinical gold standard for swallowing therapy with biofeedback, clinical use does not go beyond simple, smoothed and rectified waveform displays. In our development,

we expected to expand on this basic use by incorporating analysis of the signal collected (e.g., did the signal come from a swallow event or not). Therefore, ensuring we had the best starting SNR was a critical step in development.

3) Among other factors, patient perception of outcomes following HNC treatment and perceived progress may play a role in adherence to home-based rehabilitation. We also identified that patients preferred simple, intuitive biofeedback displays, even if these have a medical versus game-like appearance. Visual biofeedback displays are important to consider as some may elicit unnecessary anxiety (e.g., patients do not want the third person character to lose a life in the game) or may be too monotonous when paired with an exercise that requires exertion and attention.
4) When we evaluated an automated swallow-detection algorithm developed by our biomedical engineers, we found that the algorithm performed well with healthy participants and retained a high performance with HNC patients even in the presence of deliberately inputted noise signals. The performance of our algorithm was comparable to that of existing algorithms/procedures reported in the literature, but it required fewer input modalities and relied on a simple statistical model.
5) Finally, observing patients use the app and troubleshoot independently offered important usability information that was not readily apparent to the development team. This usability testing resulted in critical changes recommended to the next iteration of Mobili-T.

Limitations

The work in this dissertation has a few overarching limitations worth noting. First, studies with this patient population face two major intrinsic challenges: a small number of cases and a high variability between these patients. HNC affects approximately 500 Albertans each year and roughly two thirds of them (i.e., 330) will develop dysphagia (Langerman et al., 2007). This is in contrast with other populations, such as the 2,333 cases of breast cancer a year (Surveillance & Reporting, 2015) and the 288,000 individuals living with diabetes in Alberta (Canadian Diabetes Association). In addition to this patient population being small, it also is heterogeneous. Researchers are faced with the predicament of publishing underpowered studies or reporting on heterogeneous patient groups. Both of these challenges result in a potential reduction in external validity of findings. Aside from patient demographics such as age, sex, personal characteristics and co-morbidities, patients can differ on variables such as site and size of tumor, treatment approach, surgical access, type of reconstruction technique and source of flap, nerve involvement, and presence of adjuvant therapies. Furthermore, procedures are carried out by different surgeons, each with his/her own approach to free-hand reconstruction and classification of defect size (i.e., percent of anatomy resected). Having said that, a sample size of 35 HNC patients over all studies still represents 10% of the population of interest in this province. In addition, we purposely sought out a heterogeneous sample, as Mobili-T would end up being used by all patients with HNC who suffer from dysphagia.

A second limitation is that our mHealth technology was designed for and evaluated by HNC patients. To upscale the adoption of this technology, similar evaluations should be made with other patient populations. These studies may reveal that other types of surface sensors (e.g., mechanomyography) may be better suited for different patient populations. It is possible that Mobili-T may need to become a modular device, one where the unit encasing the different sensors can be exchanged based on the target patient population. Along the same lines, different app versions may need to exist, each with visuals addressing additional challenges faced by the target patient population (e.g., larger buttons for someone with reduced manual dexterity). The swallowing-detection algorithm will need to be tested with additional patient populations.

The timing to complete a rigorous research study was at odds with the fast-turnaround required to inform the next step in development. For this reason, all studies were conducted as part of technology development while keeping in mind how the device and app would be used in clinic. For example, when interviewing patients about their experiences with unsupervised, home rehabilitation practice, it is possible that data saturation for that particular study was not achieved. In this case, a reasonable end-point was considered when themes relevant to the development of Mobili-T were found.

Finally, there are a few study-specific limitations noted below:

Study 1 (Chapter 2)

The comparison between the two sensors, sEMG and MMG, was based on the design of these two sensors and the associated design limitations (e.g., form factor), rather than the physical/ physiological principles of operation. The reader is referred to the Discussion of the aforementioned chapter for additional information. Furthermore, the results in this study reflect the quality of the sensor placement. Future development testing should include additional validation of the sEMG sensors using the new Mobili-T device, first with clinicians placing the device and second, with patients placing the device.

Study 3 (Chapter 4)

There was no gold standard against which the Mobili-T™ could be compared. With respect to signal acquisition, the KayPENTAX® was considered. The results of a pilot test on this system comparing two different signal device inputs and two different wire lengths are summarized in Appendix F. With respect to the swallowing-detection algorithm, the button press was used as the gold standard, or truth. The button was pressed whenever a swallow was observed and also confirmed by the participant.

Furthermore, it is worth noting that there were participants in this study for whom the positive predictive value (PPV) (i.e., of the number of events rewarded by the system, how many were actual swallows) was low. Ways of addressing this limitation include short-term solutions, such as screening patients during their first swallowing therapy appointment to determine whether or not they are good candidates for Mobili-T use; and long-term solutions, such as improving the PPV of the algorithm.

Study 4 (Chapter 5)

It is important to re-iterate that this particular usability testing was the first usability evaluation of a fully functional Mobili-T prototype. It does not and should not replace more extensive usability testing of this mobile health system. For instance, a usability evaluation where patients will have had an opportunity to interact with the device and app over an extended period of time is planned. Exit interviews also would be an important means of obtaining additional feedback on user experience at that time.

Future Work

The development of Mobili-T has made it possible for researchers to study functional improvements in swallowing ability related to exercise dose (i.e., how many exercise trials were actually completed). For the first time, objective measures of swallowing therapy adherence can be captured using Mobili-T. Specifically, home practice can be tracked; a clinician will be able to remotely log in to a profile and access practice data from patients under his/her care. The clinician or researcher will have access to how many trials were completed using Mobili-T per day out of the total prescribed and whether or not clinical targets were achieved. The device also provides important information related to the time of day that the exercises were completed. This achievement alone will pave the way for research on treatment dose, adherence, and factors that predict if a patient will complete therapy at home, on their own or not.

Mobili-T can also be studied with other muscle groups of the head and neck, as long as the size of the electrodes and their placement can still adhere to the Surface Electromyography for the Noninvasive Assessment of Muscles (SENIAM).

In conclusion, we hope that Mobili-T, a mobile health system designed with early input from patients, will improve access to swallowing rehabilitation and even prehabilitation (exercises prescribed during the pre-treatment phase of cancer care). This increased engagement from patients in home therapy using mHealth will have downstream implications for clinicians and researchers: it may bring us closer to understanding how home therapy is completed and how true exercise dose is related to therapeutic gains.

References

Canadian_Diabetes_Association. Diabetes in Alberta. Retrieved from https://www.diabetes.ca/getmedia/5efbfb1b-6acd-4169-938d-59f24400e2cf/alberta-election-diabetes-stats.pdf.aspx

Langerman, A., MacCracken, E., Kasza, K., Haraf, D. J., Vokes, E. E., & Stenson, K. M. (2007). Aspiration in CRT patients with HNC. *Archives of Otolaryngology–Head & Neck Surgery, 133*(12), 1289-1295.

Surveillance & Reporting: 2012 Report on Cancer Statistics in Alberta. Edmonton:

CancerControl AB, Alberta Health Services, 2015.

BIBLIOGRAPHY

AHRQ. (2001). *Translating Research Into Practice (TRIP)-II*. (Pub. No. 01-P017). Rockville, MD: Agency for Healthcare Research and Quality Retrieved from http://www.ahrq.gov/.

Al-Mulla, M. R., Sepulveda, F., & Colley, M. (2011). A review of non-invasive techniques to detect and predict localised muscle fatigue. *Sensors (Basel), 11*(4), 3545-3594. doi:10.3390/s110403545

Aktekin, M., Kurtoglu, Z., & Ozturk, A. H. (2003). A Bilateral and Symmetrical Variation of the Anterior Belly of the Digastric Muscle. *Acta Medica. Okayama, 57*(4), 205-207.

Altman, D. G. (1991). *Some common problems in medical research. Practical statistics for medical research* (Vol. 1). London: Chapman & Hall.

Arrese, L. C., & Lazarus, C. L. (2013). Special groups: head and neck cancer. *Otolaryngologic Clinics in North America, 46*(6), 1123-1136. doi:10.1016/j.otc.2013.08.009

Azola, A. M., Greene, L. R., Taylor-Kamara, I., Macrae, P., Anderson, C., & Humbert, I. A. (2015). The Relationship Between Submental Surface Electromyography and Hyo-Laryngeal Kinematic Measures of Mendelsohn Maneuver Duration. *Journal of Speech, Language, and Hearing Research, 58*(6), 1627-1636. doi:10.1044/2015_JSLHR-S-14-0203

Barelli, R. G., Aquino Junior, P. T., & Ferrari de Castro, M. C. (2016). Mobile interface for neuroprosthesis control aiming tetraplegic users. *Conference proceedings : ... Annual International Conference of the IEEE Engineering in Medicine and*

Biology Society. IEEE Engineering in Medicine and Biology Society. Annual Conference, 2016, 2618-2621. doi:https://dx.doi.org/10.1109/EMBC.2016.7591267

Barwick, M. (2008, 2013). Knowledge Translation Planning Template. Ontario: The Hospital for Sick Children.

Basmajian, J. V., & De Luca, C. J. (1985). *Muscles Alive: Their Functions Revealed by Electromyography* (2nd ed.). Baltimore: Williams & Wilkins.

Bhattacharyya, N. (2014). The prevalence of dysphagia among adults in the United States. *Otolaryngology-Head and Neck Surgery, 151*(5), 765-769. doi:10.1177/0194599814549156

Beck, T. W., Housh, T. J., Cramer, J. T., Weir, J. P., Johnson, G. O., Coburn, J. W., . . . Mielke, M. (2005). Mechanomyographic amplitude and frequency responses during dynamic muscle actions: a comprehensive review. *Biomed Eng Online, 4*, 67. doi:10.1186/1475-925X-4-67

Ben-Zeev, D., Kaiser, S. M., Brenner, C. J., Begale, M., Duffecy, J., & Mohr, D. C. (2013). Development and usability testing of FOCUS: a smartphone system for self-management of schizophrenia. *Psychiatric Rehabilitation Journal, 36*(4), 289-296. doi:https://dx.doi.org/10.1037/prj0000019

Bendixen, R. M., Fairman, A. D., Karavolis, M., Sullivan, C., & Parmanto, B. (2017). A User-Centered Approach: Understanding Client and Caregiver Needs and Preferences in the Development of mHealth Apps for Self-Management. *mHealth and uHealth, 5*(9), e141. doi:https://dx.doi.org/10.2196/mhealth.7136

Birnbaum, F., Lewis, D., Rosen, R. K., & Ranney, M. L. (2015). Patient engagement and the design of digital health. *Academic Emergency Medicine, 22*(6), 754-756. doi:10.1111/acem.12692

Boden, K., Hallgren, A., & Witt Hedstrom, H. (2006). Effects of three different swallow maneuvers analyzed by videomanometry. *Acta Radiologica, 47*(7), 628-633. doi:10.1080/02841850600774043

Bollen, J. C., Dean, S. G., Siegert, R. J., Howe, T. E., & Goodwin, V. A. (2014). A systematic review of measures of self-reported adherence to unsupervised home-based rehabilitation exercise programmes, and their psychometric properties. *BMJ Open, 4*(6), e005044. doi:10.1136/bmjopen-2014-005044

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology, 3*(2), 77-101. doi:10.1191/1478088706qp063oa

Brown, C. C. (2007). *Reliability of Electromyography Detection Systems for the Pelvic Floor Muscles.* (Master's of Science in Rehabilitation Science), Queen's University, Kingston, Ontario.

Brown, T. (2008). Design Thinking. *Harvard Business Review.* Retrieved from https://hbr.org/2008/06/design-thinking

Bryant, M. (1991). Biofeedback in the Treatment of a Selected Dysphagic Patient. *Dysphagia, 6*, 140-144.

Burkhead, L. M., Sapienza, C. M., & Rosenbek, J. C. (2007). Strength-training exercise in dysphagia rehabilitation: principles, procedures, and directions for future research. *Dysphagia, 22*(3), 251-265. doi:10.1007/s00455-006-9074-z

Butler, S. G., Stuart, A., Castell, D., Russell, G. B., Koch, K., & Kemp, S. (2009). Effects of Age, Gender, Bolus Condition, Viscosity, and Volume on Pharyngeal and Upper Esophageal Sphincter Pressure and Temporal Measurements. *Journal of Speech, Language, and Hearing Research, 52*, 240-253.

Butler, S. G., Stuart, A., Markley, L., & Rees, C. (2009). Penetration and Aspiration in Healthy Older Adults as Assessed During Endoscopic Evaluation of Swallowing. *Annals of Otology, Rhinology & Laryngology, 118*(3), 190-198.

Canadian Cancer Statistics (Producer). (2014). Canadian Cancer Statistics 2014.

Canadian Diabetes Association. (2010, May 15). *Diabetes in Alberta.* Retrieved from https://www.diabetes.ca/getmedia/5efbfb1b-6acd-4169-938d-59f24400e2cf/alberta-election-diabetes-stats.pdf.aspx

Carnaby, G. D., & Harenberg, L. (2013). What is "usual care" in dysphagia rehabilitation: a survey of USA dysphagia practice patterns. *Dysphagia, 28*(4), 567-574. doi:10.1007/s00455-013-9467-8

Carnaby-Mann, G. D., & Crary, M. A. (2010). McNeill dysphagia therapy program: a case-control study. *Archives of Physical Medicine and Rehabilitation, 91*(5), 743-749. doi:10.1016/j.apmr.2010.01.013

Chen, Y., Huang, H., Xu, W., Wallis, R. I., Sundaram, H., Rikakis, T., . . . He, J. (2006). The Design of a Real-Time, Multimodal Biofeedback System for Stroke Patient Rehabilitation. *Proceedings of the 14th annual ACM international conference on Multimedia*, 763-772 doi:10.1145/1180639.1180804

Cobley, C. S., Fisher, R. J., Chouliara, N., Kerr, M., & Walker, M. F. (2013). A qualitative study exploring patients' and carers' experiences of Early Supported Discharge services after stroke. *Clinical Rehabilitation, 27*(8), 750-757. doi:10.1177/0269215512474030

Cohn, K. H., Berman, J., Chaiken, B., Green, D., Green, M., Morrison, D., & Scherger, J. E. (2009). Engaging Physicians to Adopt Healthcare Information Technology. *Journal of Healthcare Management, 54*(5), 292-300.

Constantinescu, G., Hodgetts, W., Scott, D., Kuffel, K., King, B., Brodt, C., & Rieger, J. (2017). Electromyography and Mechanomyography Signals During Swallowing in Healthy Adults and Head and Neck Cancer Survivors. *Dysphagia, 32*(1), 90-103. doi:10.1007/s00455-016-9742-6

Constantinescu, G., King, B., McMahon, M., Brodt, C., Hodgetts, B., & Rieger, J. (2016). Designing for patients: Using a cultural probe in the development of a mobile health device and application for swallowing therapy in head and neck cancer patients. *University of Alberta Health Sciences Journal, 12*(1), 5-10.

Constantinescu, G., Loewen, I., King, B., Brodt, C., Hodgetts, W., & Rieger, J. (2017). Designing a Mobile Health App for Patients With Dysphagia Following Head and Neck Cancer: A Qualitative Study. *Journal of Medical Internet Research: Rehabilitation and Assistive Technologies, 4*(1), e3. doi:10.2196/rehab.6319

Corry, M. D., Frick, T. W., & Hansen, L. (1997). User-centered design and usability testing of a web site: An illustrative case study. *Educational Technology Research and Development, 45*(4), 65-76.

Cosmidis, A., Rame, J. P., Dassonville, O., Temam, S., Massip, F., Poissonnet, G., . . . Groupement d'Etudes des Tumeurs de la Tete et du, C. (2004). T1-T2 NO oropharyngeal cancers treated with surgery alone. A GETTEC study. *European Archives of Oto-Rhino-Laryngology, 261*(5), 276-281. doi:10.1007/s00405-003-0694-8

Couch, M. E., Dittus, K., Toth, M. J., Willis, M. S., Guttridge, D. C., George, J. R., . . . Der-Torossian, H. (2015). Cancer cachexia update in head and neck cancer: Definitions and diagnostic features. *Head & Neck, 37*(4), 594-604. doi:10.1002/hed.23599

Cramer, J. T., Housh, T. J., Johnson, G. O., Ebersole, K. T., Perry, S. R., & Bull, A. J. (2000). Mechanomyographic and electromyographic responses of the superficial muscles of the quadriceps femoris during maximal, concentric isokinetic muscle actions. *Isokinetics and Exercise Science, 8*, 109-117.

Crary, M. A., & Baldwin, B. O. (1997). Surface Electromyographic Characteristics of Swallowing in Dysphagia Secondary to Brainstem Stroke. *Dysphagia, 12*, 180-187.

Crary, M. A., & Groher, M. E. (2003). *Introduction to Adult Swallowing Disorders*. Missouri, USA: Butterworth Heinemann.

Crary, M. A., Carnaby Mann, G. D., Groher, M. E., & Helseth, E. (2004). Functional benefits of dysphagia therapy using adjunctive sEMG biofeedback. *Dysphagia, 19*(3), 160-164. doi:10.1007/s00455-004-0003-8

Crary, M. A., Sura, L., & Carnaby, G. D. (2013). Validation and Demonstration of an Isolated Acoustic Recording Technique to Estimate Spontaneous Swallow Frequency. *Dysphagia, 28*, 86-94. doi:10.1007/s00455-012-9416-y

Crook, A., Kenny, J., Johnson, H., & Davidson, B. (2017). Perspectives of a mobile application for people with communication disabilities in the community. *Disability and Rehabilitation. Assistive technology, 12*(2), 184-196.

Cugelman, B. (2013). Gamification: what it is and why it matters to digital health behavior change developers. *Journal of Medical Internet Research: Serious Games, 1*(1), e3. doi:10.2196/games.3139

Danilovich, M. K., Diaz, L., Saberbein, G., Healey, W. E., Huber, G., & Corcos, D. M. (2017). Design and development of a mobile exercise application for home care aides and older adult medicaid home and community-based clients. *Home Health Care Services Quarterly, 36*(3-4), 196-210. doi:https://dx.doi.org/10.1080/01621424.2017.1381869

Darcy, S., Green, J., & Maxwell, H. (2017). I've got a mobile phone too! Hard and soft assistive technology customization and supportive call centres for people with disability. *Disability and Rehabilitation. Assistive Technology, 12*(4), 341-351. doi:https://dx.doi.org/10.3109/17483107.2016.1167260

Davis, J., & Goadrich, M. (2006). The Relationship Between Precision-Recall and ROC Curves. *Proceedings of the 23rd International Conference on Machine Learning*.

De-Ary-Pires, B., Ary-Pires, R., & Pires-Neto, M. A. (2003). The human digastric muscle: Patterns and variations with clinical and surgical correlations. *Annals of Anatomy, 185*, 471-479.

Deterding, S., Dixon, D., Khaled, R., & Nacke, L. (2011). From game design elements to gamefulness: defining "gamification". *MindTrek '11 Proceedings of the 15th International Academic MindTrek Conference: Envisioning Future Media Environments*, 9-15. doi:10.1145/2181037.2181040

Dithmer, M., Rasmussen, J. O., Gronvall, E., Spindler, H., Hansen, J., Nielsen, G., . . . Dinesen, B. (2016). "The Heart Game": Using Gamification as Part of a Telerehabilitation Program for Heart Patients. *Games for Health Journal, 5*(1), 27-33. doi:https://dx.doi.org/10.1089/g4h.2015.0001

Dwivedi, R. C., Chisholm, E., Kanwar, N., Komorowski, A., & Kazi, R. (2012). Epidemiology, Aetiology and Natural History of Head and Neck Cancer. In A. Staffieri, P. Sebastian, M. Kapre, R. Kazi, & B. T. Varghese (Eds.), *Essentials of Head and Neck Cancer*. Delhi, India: Byword Books Private Limited.

Dysphagia Section, Oral Care Study Group Multinational Association of Supportive Care in Cancer International Society of Oral Oncology, Raber-Durlacher, J. E., Brennan, M. T., Verdonck-de Leeuw, I. M., Gibson, R. J., Eilers, J. G., . . . Spijkervet, F. K. (2012). Swallowing dysfunction in cancer patients. *Support Care Cancer, 20*(3), 433-443. doi:10.1007/s00520-011-1342-2

Eklund, J. M., Fontana, N., Pugh, E., McGregor, C., Yielder, P., James, A., . . . McNamara, P. (2014). *Automated Sleep-Wake Detection in Neonates from Cerebral Function Monitor Signals*. Paper presented at the IEEE 27th International Symposium on Computer-Based Medical Systems, New York, USA.

Evetovich, T. K., Housh, T. J., Stout, J. R., Johnson, G. O., Smith, D. R., & Ebersole, K. T. (1997). Mechanomyographic responses to concentric isokinetic muscle contractions. *European Journal of Applied Physiology, 75*, 166-169.

Fairman, A. D., Yih, E. T., McCoy, D. F., Lopresti, E. F., McCue, M. P., Parmanto, B., & Dicianno, B. E. (2016). Iterative Design and Usability Testing of the Imhere System for Managing Chronic Conditions and Disability. *International Journal of Telerehabilitation, 8*(1), 11-20. doi:https://dx.doi.org/10.5195/ijt.2016.6194

Fiordelli, M., Diviani, N., & Schulz, P. J. (2013). Mapping mHealth Research: A Decade of Evolution. *Journal of Medical Internet Research, 15*(5), e95. doi:10.2196/jmir.2430

Fledderus, M., Schreurs, K. M., Bohlmeijer, E. T., & Vollenbroek-Hutten, M. M. (2015). Development and Pilot Evaluation of an Online Relapse-Prevention Program Based on Acceptance and Commitment Therapy for Chronic Pain Patients. *Journal of Medical Internet Research: Human Factors, 2*(1), e1. doi:https://dx.doi.org/10.2196/humanfactors.3302

Fogg, B. J. (2002). *Persuasive Technology: Using Computers to Change What We Think and Do*: Morgan Kaufmann Publishers Inc.

Forte, T., Niu, J., Lockwood, G. A., & Bryant, H. E. (2012). Incidence trends in head and neck cancers and human papillomavirus (HPV)-associated oropharyngeal cancer in Canada, 1992-2009. *Cancer Causes & Control, 23*(8), 1343-1348. doi:10.1007/s10552-012-0013-z

Frederix, I., Sankaran, S., Coninx, K., & Dendale, P. (2016). MobileHeart, a mobile smartphone-based application that supports and monitors coronary artery disease patients during rehabilitation. *Conference proceedings : ... Annual International Conference of the IEEE Engineering in Medicine and Biology Society. IEEE Engineering in Medicine and Biology Society. Annual Conference, 2016*, 513-516. doi:https://dx.doi.org/10.1109/EMBC.2016.7590752

Frowen, J. J., & Perry, A. R. (2006). Swallowing Outcomes After Radiotherapy for Head and Neck Cancer: A Systematic Review. *Head & Neck, 28*, 932-944. doi:10.1002/hed.2043810.1002/hed

Fukuoka, T., Ono, T., Hori, K., Tamine, K., Nozaki, S., Shimada, K., . . . Domen, K. (2013). Effect of the effortful swallow and the Mendelsohn maneuver on tongue pressure production against the hard palate. *Dysphagia, 28*(4), 539-547. doi:10.1007/s00455-013-9464-y

Georgsson, M., & Staggers, N. (2016). Quantifying usability: an evaluation of a diabetes mHealth system on effectiveness, efficiency, and satisfaction metrics with associated user characteristics. *Journal of the American Medical Informatics Association, 23*(1), 5-11. doi:10.1093/jamia/ocv099

Giesbrecht, E. M., Miller, W. C., Jin, B. T., Mitchell, I. M., & Eng, J. J. (2015). Rehab on Wheels: A Pilot Study of Tablet-Based Wheelchair Training for Older Adults. *Journal of Medical Internet Research: Rehabilitation and Assistive Technologies, 2*(1), e3. doi:https://dx.doi.org/10.2196/rehab.4274

Goldberg, M., Karimi, H., & Pearlman, J. L. (2016). Interactive, mobile, AGIle and novel education (IMAGINE): a conceptual framework to support students with mobility challenges in higher education. *Disability and Rehabilitation. Assistive Technology, 11*(1), 50-60. doi:https://dx.doi.org/10.3109/17483107.2014.959074

Govender, R., Smith, C. H., Taylor, S. A., Barratt, H., & Gardner, B. (2017). Swallowing interventions for the treatment of dysphagia after head and neck cancer: a systematic review of behavioural strategies used to promote patient adherence to swallowing exercises. *BMC Cancer, 17*(1), 43. doi:10.1186/s12885-016-2990-x

Grimshaw, J. M., Eccles, M. P., Lavis, J. N., Hill, S. J., & Squires, J. E. (2012). Knowledge translation of research findings. *Implementation Science, 7*, 50. doi:10.1186/1748-5908-7-50

Greenhalgh, T., Robert, G., MacFarlane, F., Bate, P., & Kyriakidou, O. (2004). Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations. *The Milbank Quarterly, 82*(4), 581-629.

Guba, E. G. (1978). *Toward a Methodology of Naturalistic Inquiry in Educational Evaluation.* Los Angeles: University of California.

Gyori, M., Stefanik, K., & Kanizsai-Nagy, I. (2015). Evidence-based development and evaluation of mobile cognitive support apps for people on the autism spectrum: methodological conclusions from two R+D projects. *Studies in Health Technology and Informatics, 217*, 55-62.

Herda, T. J., Ryan, E. D., Beck, T. W., Costa, P. B., DeFreitas, J. M., Stout, J. R., & Cramer, J. T. (2008). Reliability of mechanomyographic amplitude and mean power frequency during isometric step and ramp muscle actions. *Journal of Neuroscience Methods, 171*(1), 104-109. doi:10.1016/j.jneumeth.2008.02.017

Hermens, H. J., Freriks, B., Disselhorst-Klug, C., & Rau, G. (2000). Development of recommendations for SEMG sensors and sensor placement procedures. *Journal of Electromyography and Kinesiology, 10*, 361-374.

Hidalgo-Mazzei, D., Mateu, A., Reinares, M., Undurraga, J., Bonnin, C. d. M., Sanchez-Moreno, J., . . . Colom, F. (2015). Self-monitoring and psychoeducation in bipolar patients with a smart-phone application (SIMPLe) project: design, development and studies protocols. *BMC Psychiatry, 15*, 52. doi:https://dx.doi.org/10.1186/s12888-015-0437-6

Hind, J. A., Nicosia, M. A., Roecker, E. B., Carnes, M. L., & Robbins, J. (2001). Comparison of effortful and noneffortful swallows in healthy middle-aged and older adults. *Archives Physical Medicine and Rehabilitation, 82*(12), 1661-1665. doi:10.1053/apmr.2001.28006

Hiss, S. G., & Huckabee, M. L. (2005). Timing of pharyngeal and upper esophageal sphincter pressures as a function of normal and effortful swallowing in young healthy adults. *Dysphagia, 20*(2), 149-156. doi:10.1007/s00455-005-0008-y

Hoffman, M. R., Mielens, J. D., Ciucci, M. R., Jones, C. A., Jiang, J. J., & McCulloch, T. M. (2012). High-resolution manometry of pharyngeal swallow pressure events associated with effortful swallow and the Mendelsohn maneuver. *Dysphagia, 27*(3), 418-426. doi:10.1007/s00455-011-9385-6

Holobar, A., & Zazula, D. (2004). Correlation-based decommposition of surface electromyograms at low contraction forces. *Medical & Biological Engineering & Computing, 42*, 487-495.

Huckabee, M. L., & Steele, C. M. (2006). An analysis of lingual contribution to submental surface electromyographic measures and pharyngeal pressure during effortful swallow. *Archives of Physical Medicine and Rehabilitation, 87*(8), 1067-1072. doi:10.1016/j.apmr.2006.04.019

Hutcheson, K. A., Lewin, J. S., Barringer, D. A., Lisec, A., Gunn, G. B., Moore, M. W., & Holsinger, F. C. (2012). Late dysphagia after radiotherapy-based treatment of head and neck cancer. *Cancer, 118*(23), 5793-5799. doi:10.1002/cncr.27631

Hutcheson, K. A., & Lewin, J. S. (2013). Functional Assessment and Rehabilitation: How to Maximize Outcomes. *Otolaryngologic Clinics of North America, 46*, 657-670. doi:10.1016/j.otc.2013.04.006

Hwang, T. Z., Hsiao, J. R., Tsai, C. R., & Chang, J. S. (2015). Incidence trends of human papillomavirus-related head and neck cancer in Taiwan, 1995-2009. *International Journal of Cancer, 137*(2), 395-408. doi:10.1002/ijc.29330

Ibitoye, M. O., Hamzaid, N. A., Zuniga, J. M., Hasnan, N., & Wahab, A. K. (2014). Mechanomyographic parameter extraction methods: an appraisal for clinical applications. *Sensors (Basel), 14*(12), 22940-22970. doi:10.3390/s141222940

Informatics, I. I. f. H. (2015). *Patient Adoption of mHealth: Use, Evidence and Remaining Barriers to Mainstream Acceptance*. Retrieved from Parsippany, NJ:

International Organization for Standardization. Ergonomic requirements for office work with visual display terminals (VDTs) Part 11 Guidance on usability. (1998). *International Standard, 9241-11*. Geneve: ISO.

Islam, M. A., Sundaraj, K., Ahmad, R. B., Sundaraj, S., Ahamed, N. U., & Ali, M. A. (2014). Cross-talk in mechanomyographic signals from the forearm muscles during sub-maximal to maximal isometric grip force. *PLoS One, 9*(5), e96628. doi:10.1371/journal.pone.0096628

Jain, S., H. (2015). What Procter & Gamble Can Teach The Healthcare Industry: Assume Nothing About Patients. *Pharma & Healthcare.* Retrieved from https://www.forbes.com/sites/sachinjain/2015/11/09/incorporating-the-patient-voice-into-health-care-moving-beyond-our-assumptions/2/ - 4acaf7b27fa6

Jaskolska, A., Brzenczek, W., Kisiel-Sajewicz, K., Kawczynski, A., Marusiak, J., & Jaskolski, A. (2004). The effect of skinfold on frequency of human muscle mechanomyogram. *Journal of Electromyography and Kinesiology, 14*(2), 217-225. doi:10.1016/j.jelekin.2003.08.001

Jepsen, D. M., & Rodwell, J. J. (2008). Convergent interviewing: a qualitative diagnostic technique for researchers. *Management Research News, 31*(9), 650-658. doi:10.1108/01409170810898545

Kahrilas, P. J., Logemann, J. A., Krugler, C., & Flanagan, E. (1991). Volitional augmentation of upper esophageal sphincter opening during swallowing. *American Journal of Physiology (Gastrointestinal and Liver Physiology), 260*(3 part 1), G450-G456.

Kaufman, D. R., & Starren, J. B. (2006). A Methodological Framework for Evaluating Mobile Health Devices. *American Medical Informatics Association Symposium*, 978.

Kato, P. M., Cole, S. W., Bradlyn, A. S., & Pollock, B. H. (2008). A video game improves behavioral outcomes in adolescents and young adults with cancer: a randomized trial. *Pediatrics, 122*(2), e305-317. doi:10.1542/peds.2007-3134

Kato, P. M. (2010). Video games in health care: Closing the gap. *Review of General Psychology, 14*(2), 113-121. doi:10.1037/a0019441

Kim, H. R., Lee, S. A., Kim, K., Leigh, J. H., Han, T. R., & Oh, B. M. (2015). Submental Muscle Activity is Delayed and Shortened During Swallowing Following Stroke. *American Academy of Physical Medicine and Rehabilitation, 7*(9), 938-945. doi:10.1016/j.pmrj.2015.05.018

Kreimer, A. R., Clifford, G. M., Boyle, B., & Franceschi, S. (2005). Human Papillomavirus Types in Head and Neck Squamous Cell Carcinomas Worldwide: A Systematic Review. *Cancer Epidemiology, Biomarkers & Prevention, 14*(2), 467-475.

Krisciunas, G. P., Sokoloff, W., Stepas, K., & Langmore, S. E. (2012). Survey of usual practice: dysphagia therapy in head and neck cancer patients. *Dysphagia, 27*(4), 538-549. doi:10.1007/s00455-012-9404-2

Krumsvik, O. A., & Babic, A. (2017). Designing an E-Learning Platform for Postoperative Arthroplasty Adverse Events. *Studies in Health Technology and Informatics, 235*, 348-352.

Labrique, A. B., Vasudevan, L., Kochi, E., Fabricant, R., & Mehl, G. (2013). mHealth innovations as health system strengthening tools: 12 common applications and a visual framework. *Global Health: Science and Practice, 1*(2), 160-171.

Langerman, A., MacCracken, E., Kasza, K., Haraf, D. J., Vokes, E. E., & Stenson, K. M. (2007). Aspiration in CRT patients with HNC. *Archives of Otolaryngology – Head and Neck Surgery, 133*(12), 1289-1295.

Larrosa, F., Rama-Lopez, J., Benitez, J., Morales, J. M., Martinez, A., Alanon, M. A., . . . Rey-Martinez, J. (2015). Development and evaluation of an audiology app for iPhone/iPad mobile devices. *Acta Oto-laryngologica, 135*(11), 1119-1127. doi:https://dx.doi.org/10.3109/00016489.2015.1063786

Laver, K., George, S., Ratcliffe, J., & Crotty, M. (2012). Measuring technology self efficacy: reliability and construct validity of a modified computer self efficacy scale in a clinical rehabilitation setting. *Disability and Rehabilitation, 34*(3), 220-227. doi:10.3109/09638288.2011.593682

Lazarus, C., Logemann, J. A., Song, C. W., Rademaker, A. W., & Kahrilas, P. J. (2002). Effects of Voluntary Maneuvers on Tongue Base Function for Swallowing. *Folia Phoniatrica et Logopaedica, 54*(4), 171-176. doi:10.1159/000063192

Lazarus, C. (2013). Dysphagia Secondary to the Effects of Chemotherapy and Radiotherapy. In R. Shaker, P. C. Belafsky, G. N. Postma, & C. Easterling (Eds.), *Principles of Deglutition: A Multidisciplinary Text for Swallowing and its Disorders* (pp. 431-443). New York: Springer Science+Business Media.

Lee, J., Chau, T., & Steele, C. M. (2009). Effects of age and stimulus on submental mechanomyography signals during swallowing. *Dysphagia, 24*(3), 265-273. doi:10.1007/s00455-008-9200-1

Lee, J., Steele, C. M., & Chau, T. (2009). Swallow segmentation with artificial neural networks and multi-sensor fusion. *Medical Engineering & Physics, 31*(9), 1049-1055. doi:10.1016/j.medengphy.2009.07.001

Lee, S.-Y., Hong, J.-H., Hsieh, C.-H., Liang, M.-C., Chien, S.-Y. C., & Lin, K.-H. (2015). Low-Power Wireless ECG Acquisition and Classification System for Body Sensor Networks. *IEEE Journal of Biomedical and Health Informatics, 19*(1), 236-246.

Lewis, J. R. (1995). IBM computer usability satisfaction questionnaires: Psychometric evaluation and instructions for use. *International Journal of Human-Computer Interaction, 7*(1), 57-78. doi:10.1080/10447319509526110

Lyles, C. R., Sarkar, U., & Osborn, C. Y. (2014). Getting a Technology-Based Diabetes Intervention Ready for Prime Time: a Review of Usability Testing Studies. *Current Diabetes Reports, 15*(534), 1-12. doi:10.1007/s11892-014-0534-9

Matthew-Maich, N., Harris, L., Ploeg, J., Markle-Reid, M., Valaitis, R., Ibrahim, S., . . . Isaacs, S. (2016). Designing, Implementing, and Evaluating Mobile Health Technologies for Managing Chronic Conditions in Older Adults: A Scoping Review. *Journal of Medical Internet Research: mHealth uHealth, 4*(2), e29. doi:10.2196/mhealth.5127

Mangalagiri, A. S., & Razvi, M. R. A. (2009). Variations in the Anterior Belly of Diagastric. *International Journal of Health Sciences, 3*(2), 257-262.

Martin-Harris, B., Brodsky, M. B., Michel, Y., Castell, D. O., Schleicher, M., Sandidge, J., . . . Blair, J. (2008). MBS measurement tool for swallow impairment--

MBSImp: establishing a standard. *Dysphagia, 23*(4), 392-405. doi:10.1007/s00455-008-9185-9

Martin-Harris, B., Michel, Y., & Castell, D. O. (2005). Physiologic model of oropharyngeal swallowing revisited. *Otolaryngology-Head and Neck Surgery, 133*(2), 234-240. doi:10.1016/j.otohns.2005.03.059

Matsuo, K., & Palmer, J. B. (2008). Anatomy and Physiology of Feeding and Swallowing - Normal and Abnormal. *Physical Medicine & Rehabilitation Clinics of North America, 19*(4), 691-707. doi:10.1016/j.pmr.2008.06.001

McCabe, D., Ashford, J., Wheeler-Hegland, K., Frymark, T., Mullen, R., Musson, N., . . . Schooling, T. (2009). Evidence-based systematic review: Oropharyngeal dysphagia behavioral treatments. Part IV—Impact of dysphagia treatment on individuals' postcancer treatments. *The Journal of Rehabilitation Research and Development, 46*(2), 205. doi:10.1682/jrrd.2008.08.0092

McGonigal, J. (2011). *Reality is Broken: Why Games Make Us Better and How They Can Change the World*. New York: Penguin Press.

Mendelsohn, M., & McConnel, F. M. S. (1987). Function in the Pharyngoesophageal Segment. *Laryngoscope, 97*, 483-489.

Mendenhall, W. M., Morris, C. G., Amdur, R. J., Hinerman, R. W., Malyapa, R. S., Werning, J. W., . . . Villaret, D. B. (2006). Definitive radiotherapy for tonsillar squamous cell carcinoma. *American Journal of Clinical Oncology, 29*(3), 290-297. doi:10.1097/01.coc.0000209510.19360.f9

Michie, S., Atkins, L., & West, R. (2014). *The Behaviour Change Wheel - A Guide to Designing Interventions*. UK: Silverback Publishing.

Michie, S., Wood, C. E., Johnston, M., Abraham, C., Francis, J. J., & Hardeman, W. (2015). Behaviour change techniques: the development and evaluation of a taxonomic method for reporting and describing behaviour change interventions (a suite of five studies involving consensus methods, randomised controlled trials and analysis of qualitative data). *Health Technology Assessment, 19*(99), 1-188. doi:10.3310/hta19990

Miller, N. E. (1989). Biomedical Foundations for Biofeedback as a Part of Behavioural Medicine. In J. V. Basmajian (Ed.), *Biofeedback: Principles and Practice for Clinicians* (pp. 5-15). Baltimore, Maryland: Williams & Wilkins.

Mohamed Irfan, M. R., Sudharsan, N., Santhanakrishnan, S., & Geethanjali, B. (2011). A Comparative Study of EMG and MMG Signals for Practical Applications. *International Conference on Signal, Image Processing and Applications With workshop of ICEEA 2011, 21*.

Murphy, K., & Darrah, M. (2015). Haptics-Based Apps for Middle School Students with Visual Impairments. *IEEE transactions on haptics, 8*(3), 318-326. doi:https://dx.doi.org/10.1109/TOH.2015.2401832

Nahar, L., Jaafar, A., Ahamed, E., & Kaish, A. B. M. A. (2015). Design of a Braille Learning Application for Visually Impaired Students in Bangladesh. *Assistive technology : the official journal of RESNA, 27*(3), 172-182. doi:https://dx.doi.org/10.1080/10400435.2015.1011758

Nicholson, J., Carpenter-Song, E. A., MacPherson, L. H., Tauscher, J. S., Burns, T. C., & Lord, S. E. (2017). Developing the WorkingWell mobile app to promote job tenure for individuals with serious mental illnesses. *Psychiatric Rehabilitation Journal, 40*(3), 276-282. doi:https://dx.doi.org/10.1037/prj0000201

Nonaka, H., Mita, K., Akataki, K., Watakabe, M., & Itoh, Y. (2006). Sex differences in mechanomyographic responses to voluntary isometric contractions. *Medicine & Science in Sports & Exercise, 38*(7), 1311-1316. doi:10.1249/01.mss.0000227317.31470.16

O'Malley, G., Dowdall, G., Burls, A., Perry, I. J., & Curran, N. (2014). Exploring the Usability of a Mobile App for Adolescent Obesity Management. *Journal of Medical Internet Research: mHealth uHealth, 2*(2), e29. doi:10.2196/mhealth.3262

Parmanto, B., Pramana, G., Yu, D. X., Fairman, A. D., Dicianno, B. E., & McCue, M. P. (2013). iMHere: A Novel mHealth System for Supporting Self-Care in Management of Complex and Chronic Conditions. *Journal of Medical Internet Research: mHealth and uHealth, 1*(2), e10. doi:https://dx.doi.org/10.2196/mhealth.2391

Pauloski, B. R. (2008). Rehabilitation of dysphagia following head and neck cancer. *Physical Medicine & Rehabilitation Clinics of North America, 19*(4), 889-928, x. doi:10.1016/j.pmr.2008.05.010

Pearson, W. G., Jr., Langmore, S. E., Yu, L. B., & Zumwalt, A. C. (2012). Structural analysis of muscles elevating the hyolaryngeal complex. *Dysphagia, 27*(4), 445-451. doi:10.1007/s00455-011-9392-7

Petitjean, M., Maton, B., & Cnockaert, J.-C. (1992). Evaluation of human dynamic contraction by phonomyography. *The American Physiological Society, 73*(6), 2567-2573.

Pfaeffli, L., Maddison, R., Whittaker, R., Stewart, R., Kerr, A., Jiang, Y., . . . Dalleck, L. (2012). A mHealth cardiac rehabilitation exercise intervention: findings from content development studies. *BMC Cardiovascular Disorders, 12*, 36. doi:https://dx.doi.org/10.1186/1471-2261-12-36

Phinyomark, A., Thongpanja, S., Hu, H., Phukpattaranont, P., & Limsakul, C. (2012). The Usefulness of Mean and Median Frequencies in Electromyography Analysis. *Journal of Computing, 1*(1), 71-80. doi:10.5772/50639

Platteaux, N., Dirix, P., Dejaeger, E., & Nuyts, S. (2010). Dysphagia in head and neck cancer patients treated with chemoradiotherapy. *Dysphagia, 25*(2), 139-152. doi:10.1007/s00455-009-9247-7

Posatskiy, A. O. (2011). Design and evaluation of pressure-based sensors for mechanomyography: an investigation of chamber geometry and motion artefact. (Master of Applied Science), University of Toronto.

Posatskiy, A. O., & Chau, T. (2012). Design and evaluation of a novel microphone-based mechanomyography sensor with cylindrical and conical acoustic chambers. *Medical Engineering & Physics, 34*(8), 1184-1190. doi:10.1016/j.medengphy.2011.12.007

Posatskiy, A. O., & Chau, T. (2012). The effects of motion artifact on mechanomyography: A comparative study of microphones and accelerometers.

Journal of Electromyography and Kinesiology, 22(2), 320-324. doi:10.1016/j.jelekin.2011.09.004

Powell, L. E., Wild, M. R., Glang, A., Ibarra, S., Gau, J. M., Perez, A., . . . Slocumb, J. (2017). The development and evaluation of a web-based programme to support problem-solving skills following brain injury. *Disability and Rehabilitation. Assistive Technology*, 1-12. doi:https://dx.doi.org/10.1080/17483107.2017.1389999

Qasim, M. M., Ahmad, M., Omar, M., Zulkifli, A. N., & Bakar, J. A. A. (2017). A systematic process for persuasive mobile healthcare applications. *AIP Conference Proceedings, 1891*, 020115. doi:10.1063/1.5005448

Radhakrishnan, K., Toprac, P., O'Hair, M., Bias, R., Kim, M. T., Bradley, P., & Mackert, M. (2016). Interactive Digital e-Health Game for Heart Failure Self-Management: A Feasibility Study. *Games for Health Journal, 5*(6), 366-374.

Rao, S., & Perry, C. (2003). Convergent interviewing to build a theory in under-researched areas: principles and an example investigation of Internet usage in inter-firm relationships. *Qualitative Market Research: An International Journal, 6*(4), 236-247. doi:10.1108/13522750310495328

Rawstorn, J. C., Gant, N., Meads, A., Warren, I., & Maddison, R. (2016). Remotely Delivered Exercise-Based Cardiac Rehabilitation: Design and Content Development of a Novel mHealth Platform. *Journal of Medical Internet Research: mHealth and uHealth, 4*(2), e57. doi:https://dx.doi.org/10.2196/mhealth.5501

Reaz, M. B., Hussain, M. S., & Mohd-Yasin, F. (2006). Techniques of EMG signal analysis: detection, processing, classification and applications. *Biological Procedures Online, 8*, 11-35. doi:10.1251/bpo115

Research2Guidance. (2018). *mHealth App Economics: Current Status and Future Trends in Mobile Health*. Retrieved from http://www.research2guidance.com

Reynoldson, C., Stones, C., Allsop, M., Gardner, P., Bennett, M. I., Closs, S. J., . . . Knapp, P. (2014). Assessing the Quality and Usability of Smartphone Apps for Pain Self-Management. *Pain Medicine, 15*, 898-909.

Rock Health. (2015). Digital Health Funding: 2015 Year in Review. Retrieved from https://rockhealth.com/reports/digital-health-funding-2015-year-in-review/

Rogus-Pulia, N., Rusche, N., Hind, J. A., Zielinski, J., Gangnon, R., Safdar, N., & Robbins, J. (2016). Effects of Device-Facilitated Isometric Progressive Resistance Oropharyngeal Therapy on Swallowing and Health-Related Outcomes in Older Adults with Dysphagia. *Journal of the American Geriatrics Society, 64*(2), 417-424. doi:10.1111/jgs.13933

Robbins, J., Butler, S. G., Daniels, S. K., Gross, R. D., Langmore, S., Lazarus, C. L., . . . Rosenbek, J. C. (2008). Swallowing and Dysphagia Rehabilitation: Translating Principles of Neural Plasticity Into Clinically Oriented Evidence. *Journal of Speech, Language, and Hearing Research, 51*, S276-S300.

Rogers, L. Q., Courneya, K. S., Robbins, K. T., Malone, J., Seiz, A., Koch, L., & Rao, K. (2008). Physical activity correlates and barriers in head and neck cancer patients. *Support Care Cancer, 16*(1), 19-27. doi:10.1007/s00520-007-0293-0

Roy, S. H., De Luca, G., Cheng, M. S., Johansson, A., Gilmore, L. D., & De Luca, C. J. (2007). Electro-mechanical stability of surface EMG sensors. *Medical & Biological Engineering & Computing, 45*, 447-457.

Roy, S. H., De Luca, G., Cheng, M. S., Johansson, A., Gilmore, L. D., & De Luca, C. J. (2007). Electro-mechanical stability of surface EMG sensors. *Medical & Biological Engineering & Computing, 45*, 447-457.

Russell, J. A., & Connor, N. P. (2014). Effects of age and radiation treatment on function of extrinsic tongue muscles. *Radiotherapy and Oncology, 9*(254), 1-15.

Ryerson, A. B., Peters, E. S., Coughlin, S. S., Chen, V. W., Gillison, M. L., Reichman, M. E., . . . Kawaoka, K. (2008). Burden of potentially human papillomavirus-associated cancers of the oropharynx and oral cavity in the US, 1998-2003. *Cancer, 113*(10 Suppl), 2901-2909. doi:10.1002/cncr.23745

Sarkar, U., Schillinger, D., Lopez, A., & Sudore, R. (2011). Validation of self-reported health literacy questions among diverse English and Spanish-speaking populations. *Journal of General Internal Medicine, 26*(3), 265-271. doi:10.1007/s11606-010-1552-1

Saxon, L. A. (2013). Ubiquitous wireless ECG recording: a powerful tool physicians should embrace. *Journal of Cardiovascular Electrophysiology, 24*(4), 480-483. doi:10.1111/jce.12097

Schultheiss, C., Schauer, T., Nahrstaedt, H., & Seidl, R. O. (2013). Evaluation of an EMG bioimpedance measurement system for recording and analysing the pharyngeal phase of swallowing. *European Archives of Otorhinolaryngology, 270*(2149-2156). doi:10.1007/s00405-013-2406-3

Schwartz, J., & Macomber, C. (2017). So, You Think You Have an Idea: A Practical Risk Reduction-Conceptual Model for Academic Translational Research. *Bioengineering (Basel), 4*(2). doi:10.3390/bioengineering4020029

Seikaly, H., Jha, N., McGaw, T., Coulter, L., Liu, R., & Oldring, D. (2001). Submandibular Gland Transfer: A New Method of Preventing Radiation-Induced Xerostomia. *Laryngoscope, 111*, 347-352.

Seikaly, H., Rieger, J., Wolfaardt, J., Moysa, G., Harris, J., & Jha, N. (2003). Functional Outcomes After Primary Oropharyngeal Cancer Resection and Reconstruction With the Radial Forearm Free Flap. *Laryngoscope, 113*(5), 897-904.

Shaw, S. M., & Martino, R. (2013). The normal swallow: muscular and neurophysiological control. *Otolaryngologic Clinics of North America, 46*(6), 937-956. doi:10.1016/j.otc.2013.09.006

Shinn, E. H., Basen-Engquist, K., Baum, G., Steen, S., Bauman, R. F., Morrison, W., . . . Lewin, J. S. (2013). Adherence to preventive exercises and self-reported swallowing outcomes in post-radiation head and neck cancer patients. *Head & Neck*, 1707-1712. doi:10.1002/hed.2325510.1002/HED

Siegel, R., Ma, J., Zou, Z., & Jemal, A. (2014). Cancer statistics, 2014. *CA Cancer Journal for Clinicians, 64*(1), 9-29. doi:10.3322/caac.21208

Silva, J., & Chau, T. (2003). Coupled microphone-accelerometer sensor pair for dynamic noise reduction in MMG signal recording. *Electronics Letters, 39*(21), 1496. doi:10.1049/el:20031003

Silva, S., & Chau, T. (2005). A Mathematical Model for Source Separation of MMG Signals Recorded With a Coupled Microphone-Accelerometer Sensor Pair. *IEEE Transactions on Biomedical Engineering, 52*(9), 1943-1501.

Smeddinck, J., Gerling, K. M., & Tiemkeo, S. (2013). Visual Complexity, Player Experience, Performance and Physical Exertion in Motion-Based Games for Older Adults. *15th International ACM SIGACCESS Conference on Computers and Accessibility*.

Smith, D. B., Housh, T. J., Stout, J. R., Johnson, G. O., Evetovich, T. K., & Ebersole, K. T. (1997). Mechanomyographic responses to maximal eccentric isokinetic muscle actions. *The American Physiological Society* (Special Communication), 1003-1007.

Steele, C. (2004). Treating Dysphagia With sEMG Biofeedback. *The ASHA Leader*.

Stepp, C. E. (2012). Tutorial: Surface Electromyography for Speech and Swallowing Systems: Measurement, Analysis, and Interpretation. *Journal of Speech, Language, and Hearing Research, 55*, 1232-1246. doi:10.1044/1092-4388(2011/11-0214

Surveillance & Reporting: 2012 Report on Cancer Statistics in Alberta. Edmonton: CancerControl AB, Alberta Health Services, 2015.

Szczesniak, M. M., Maclean, J., Zhang, T., Graham, P. H., & Cook, I. J. (2014). Persistent Dysphagia after Head and Neck Radiotherapy: A Common and Under-reported Complication with Significant Effect on Non-cancer-related Mortality. *Clinical Oncology (R Coll Radiol), 26*(11), 697-703. doi:10.1016/j.clon.2014.08.009

Svarre, T., Lunn, T. B. K., & Helle, T. (2017). Transforming paper-based assessment forms to a digital format: Exemplified by the Housing Enabler prototype app. *Scandinavian Journal of Occupational Therapy, 24*(6), 438-447. doi:https://dx.doi.org/10.1080/11038128.2016.1255774

Tabak, M., Vollenbroek-Hutten, M. M., van der Valk, P. D., van der Palen, J., & Hermens, H. J. (2014). A telerehabilitation intervention for patients with Chronic Obstructive Pulmonary Disease: a randomized controlled pilot trial. *Clinical Rehabilitation, 28*(6), 582-591. doi:https://dx.doi.org/10.1177/0269215513512495

Tong, A., Sainsbury, P., & Craig, J. (2007). Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care., 19*(6), 349 – 357.

Vagelos, P. R. (2007). Innovation and industry-academia interactions: Where conflicts arise and measures to avoid them. *Cleveland Clinic Journal of Medicine, 74*(Supplement 2), S12-S13.

Vaiman, M., Eviatar, E., & Segal, S. (2004). Evaluation of Normal Deglutition with the Help of Rectified Surface Electromyography Records. *Dysphagia, 19*(2). doi:10.1007/s00455-003-0504-x

Vale, R. D. (2013). The value of asking questions. *Molecular Biology of the Cell, 24*(6), 680-682. doi:10.1091/mbc.E12-09-0660

Valouchova, P., & Lewit, K. (2009). Surface electromyography of abdominal and back muscles in patients with active scars. *Journal of Bodywork and Movement Therapies, 13*(3), 262-267. doi:10.1016/j.jbmt.2008.04.033

Vigreux, B., Cnockaert, J. C., & Pertuzon, E. (1979). Factors Influencing Quantified Surface EMGs. *European Journal of Applied Physiology, 41*, 119-129.

Virzi, R. A. (1992). Refining the Test Phase of Usability Evaluation: How Many Subjects is Enough? *Human Factors, 34*(4), 457-468.

Vodafone Group. (2011). *Evaluating mHealth Adoption Barriers: Human Behaviour - Insights Guide*. Retrieved from Newbury, Berkshire: mhealth.vodafone.com

Vorrink, S. N., Kort, H. S., Troosters, T., & Lammers, J.-W. J. (2016). A Mobile Phone App to Stimulate Daily Physical Activity in Patients with Chronic Obstructive Pulmonary Disease: Development, Feasibility, and Pilot Studies. *Journal of Medical Internet Research: mHealth and uHealth, 4*(1), e11. doi:https://dx.doi.org/10.2196/mhealth.4741

Wang, X. L., Eklund, J. M., & McGregor, C. (2014). *Parametric Power Spectrum Analysis of ECG Signals for Obstructive Sleep Apnoea Classification*. Paper presented at the IEEE 27th International Symposium on Computer-Based Medical Systems, New York, USA.

Warnakulasuriya, S. (2009). Global epidemiology of oral and oropharyngeal cancer. *Oral Oncology, 45*(4-5), 309-316. doi:10.1016/j.oraloncology.2008.06.002

Wheeler-Hegland, K., Rosenbek, J. C., & Sapienza, C. M. (2008). Submental sEMG and Hyoid Movement During Mendelsohn Maneuver, Effortful Swallow, and Expiratory Muscle Strength Training. *Journal of Speech, Language, and Hearing Research, 51*(5), 1072-1087.

Wheeler-Hegland, K., Ashford, J., Frymark, T., McCabe, D., Mullen, R., Musson, N., . . . Schooling, T. (2009). Evidence-based systematic review: Oropharyngeal dysphagia behavioral treatments. Part II—Impact of dysphagia treatment on normal swallow function. *The Journal of Rehabilitation Research and Development, 46*(2), 185. doi:10.1682/jrrd.2008.08.0094

WHO. (2011). *mHealth: New horizons for health through mobile technologies*. Geneva, Switzerland: World Health Organization.

WHO. (2013). Global health workforce shortage to reach 12.9 million in coming decades. Retrieved from http://www.who.int/mediacentre/news/releases/2013/health-workforce-shortage/en/

WHO. (2014). Head and Neck Cancer: Union for International Cancer Control 2014 Review of Cancer Medicines of the WHO List of Essential Medicines. *2014 Review of Cancer Medicines of the WHO List of Essential Medicines.* Retrieved from http://www.who.int/selection_medicines/committees/expert/20/applications/cancer/en/

Williams, W., & Lewis, D. (2005). Convergent interviewing: a tool for strategic investigation. *Strategic Change, 14*(4), 219-229. doi:10.1002/jsc.719

Woodward, R., Shefelbine, S., & Vaidyanathan, R. (2014, 27-29 May 2014). *Pervasive Motion Tracking and Muscle Activity Monitor.* Paper presented at the Computer-Based Medical Systems (CBMS), 2014 IEEE 27th International Symposium on.

Zaheer, F., Roy, S. H., & De Luca, C. J. (2012). Preferred sensor sites for surface EMG signal decomposition. *Physiological Measurement, 33*(2), 195-206. doi:10.1088/0967-3334/33/2/195

Zhu, W., Zeng, N., & Wang, N. (2010). Sensitivity, Specificity, Accuracy, Associated Confidence Interval and ROC Analysis with Practical SAS® Implementations. *NESUG proceedings: Health Care and Life Sciences*.

Appendix A – Ethics and Involvement

Chapter 2

Ethics (Approval Date MM/DD/YYYY): Pro00050134 Detection of swallowing events using surface electromyography and mechanomyography (08/18/2014).

Role in project: Study design with mentorship; obtained HREBA and institutional ethics; data collection with one other co-author; results, analysis and interpretation; presented outcomes at 2015 Resident's Research Day, Edmonton, Canada & 2015 Faculty of Rehabilitation Medicine Research Day, Edmonton, Canada; prepared manuscript; oversaw submission and review process.

Chapter 3

Ethics (Approval Date MM/DD/YYYY): Pro00055975 Engaging patients in the design of a mobile swallowing therapy device (04/14/2015).

Role in project: Study design; obtained HREBA and institutional ethics; data collection; trained two co-authors in part of the data analysis; results, analysis and interpretation; presented outcomes at Games for Health Conference, Utrecht, The Netherlands & 2016 Resident's Research Day, Edmonton, Canada & 2016 Faculty of Rehabilitation Medicine Research Day, Edmonton, Canada; prepared manuscript; conducted submission and review process.

Chapter 4

Ethics (Approval Date MM/DD/YYYY): Pro00061781 Developing and validating a new algorithm for swallow detection (1/18/2016).

Role in project: Study design; obtained HREBA and institutional ethics; data collection with one other co-author; co-analysis and interpretation of results; presented pilot results at 2016 American Head and Neck Society, Seattle, USA & accepted to present full findings at the 2017 Advanced Digital Technology for Head and Neck Cancer, Amiens, France in May; prepared manuscript; conducted submission and review process.

Chapter 5

Ethics (Approval Date MM/DD/YYYY): HREBA.CC-16-0732 Usability testing of a mobile health system (3/16/2017).

Role in project: Study design; obtained HREBA and institutional ethics; data collection; analysis and interpretation of results; prepared manuscript.

Approval Form

Date:	August 14, 2014
Study ID:	Pro00050134
Principal Investigator:	Jana Rieger
Study Title:	Comparing the accuracy of swallow detection of two different muscle activity acquisition methods: surface electromyography and mechanomyography in a normal population and in patients following treatment for head and neck cancer.
Approval Expiry Date:	August 13, 2015
Sponsor/Funding Agency:	Alberta Cancer Foundation — ACF Alberta Innovates Health Solutions — AIHS — Canada

RSO-Managed Funding:

	Project ID	Project Title	Speed Code	Other Information
View	RES0021802	Portable Swallowing Therapy Unit (PSTU): Interfacing Technology and Rehabilitation Medicine to Provide Accessible Care for Patients with Chronic Swallowing Difficulties		
View	RES0021344	Portable Swallowing Therapy Unit: Using Innovative Technology to Provide Accessible Care for Head and Neck Cancer		

Thank you for submitting the above study to the Health Research Ethics Board - Health Panel. Your application, including revisions received July 23, 2014, has been reviewed and approved on behalf of the committee.

The Health Research Ethics Board assessed all matters required by section 50(1)(a) of the Health Information Act. Subject consent for access to identifiable health information is required for the research described in the ethics application, and appropriate procedures for such consent have been approved by the HREB Health Panel. In order to comply with the Health Information Act, a copy of the approval form is being sent to the Office of the Information and Privacy Commissioner.

A renewal report must be submitted next year prior to the expiry of this approval if your study still requires ethics approval. If you do not renew on or before the renewal expiry date (August 13, 2015), you will have to re-submit an ethics application.

Approval by the Health Research Ethics Board does not encompass authorization to access the patients, staff or resources of Alberta Health Services or other local health care institutions for the purposes of the research. Enquiries regarding Alberta Health approval should be directed to (780) 407-6041. Enquiries regarding Covenant Health approvals should be directed to (780) 735-2274.

Sincerely,

Anthony S. Joyce, Ph.D.
Chair, Health Research Ethics Board - Health Panel

Note: This correspondence includes an electronic signature (validation and approval via an online system).

Approval Form

Date:	April 8, 2015			
Study ID:	Pro00055975			
Principal Investigator:	Jana Rieger			
Study Title:	Determinants for adherence to home swallowing therapy in patients with dysphagia following head and neck cancer and patient preference for visual biofeedback			
Approval Expiry Date:	April-07-16			

Approved Consent Form:

Approval Date	Approved Document
04/08/2015	Consent to participate in study v2
04/08/2015	Letter of Information v2
04/08/2015	Consent to contact

Sponsor/Funding Agency:

Alberta Cancer Foundation	ACF	
Alberta Innovates Health Solutions	AIHS	Canada

RSO-Managed Funding:

	Project ID	Project Title	Speed Code	Other Information
View	RES0021344	Portable Swallowing Therapy Unit: Using Innovative Technology to Provide Accessible Care for Head and Neck Cancer		
View	RES0021802	Portable Swallowing Therapy Unit (PSTU): Interfacing Technology and Rehabilitation Medicine to Provide Accessible Care for Patients with Chronic Swallowing Difficulties		

Thank you for submitting the above study to the Health Research Ethics Board - Health Panel . Your application, including revisions received April 8, 2015, has been reviewed and approved on behalf of the committee. The following documents have also been approved:

- Questionnaire: Demographics (18/03/2015)
- Part 1: Semi-structured Interview (18/03/2015)
- Part 2: Convergent Interview (18/03/2015)

- Data Collection Form (18/03/2015)

The Health Research Ethics Board assessed all matters required by section 50(1)(a) of the Health Information Act. Subject consent for access to identifiable health information is required for the research described in the ethics application, and appropriate procedures for such consent have been approved by the HREB Health Panel. In order to comply with the Health Information Act, a copy of the approval form is being sent to the Office of the Information and Privacy Commissioner.

A renewal report must be submitted next year prior to the expiry of this approval if your study still requires ethics approval. If you do not renew on or before the renewal expiry date (April-07-16), you will have to re-submit an ethics application.

Approval by the Health Research Ethics Board does not encompass authorization to access the patients, staff or resources of Alberta Health Services or other local health care institutions for the purposes of the research. Enquiries regarding Alberta Health approval should be directed to (780) 407-6041. Enquiries regarding Covenant Health approvals should be directed to (780) 735-2274.

Sincerely,

Anthony S. Joyce, Ph.D.
Chair, Health Research Ethics Board - Health Panel

Note: This correspondence includes an electronic signature (validation and approval via an online system).

Approval Form

Date:	January 18, 2016
Study ID:	Pro00061781
Principal Investigator:	Jana Rieger
Study Title:	Developing and validating a new algorithm for swallow detection
Approval Expiry Date:	Tuesday, January 17, 2017

	Approval Date	Approved Document
Approved Consent Form:	1/18/2016	Consent Form

Sponsor/Funding Agency:	Alberta Cancer Foundation	ACF

RSO-Managed Funding:

	Project ID	Project Title	Speed Code	Other Information
View	RES0021344	Portable Swallowing Therapy Unit	ZA377	

Thank you for submitting the above study to the Health Research Ethics Board - Health Panel . Your application, including the following, has been reviewed and approved on behalf of the committee;

- Recruitment Poster (12/17/2015)
- Consent to Recruit/be Contacted (1/15/2016)
- Algorithm Information Letter (1/5/2016)
- Data Collection Form for Head and Neck Cancer Patients (12/17/2015)

The Health Research Ethics Board assessed all matters required by section 50(1)(a) of the Health Information Act. Subject consent for access to identifiable health information is required for the research described in the ethics application, and appropriate procedures for such consent have been approved by the HREB Health Panel. In order to comply with the Health Information Act, a copy of the approval form is being sent to the Office of the Information and Privacy Commissioner.

A renewal report must be submitted next year prior to the expiry of this approval if your study still requires ethics approval. If you do not renew on or before the renewal expiry date (Tuesday, January 17, 2017), you will have to re-submit an ethics application.

Approval by the Health Research Ethics Board does not encompass authorization to access the patients, staff or resources of Alberta Health Services or other local health care institutions for the purposes of the research. Enquiries regarding Alberta Health approval should be directed to (780) 407-6041. Enquiries regarding Covenant Health approvals should be directed to (780) 735-2274.

Sincerely,

Anthony S. Joyce, Ph.D.
Chair, Health Research Ethics Board - Health Panel

Note: This correspondence includes an electronic signature (validation and approval via an online system).

Health Research Ethics Board of Alberta
Cancer Committee
1500, 10104 - 103 Avenue NW
Edmonton, Alberta, T5J 4A7
Telephone: (780) 423-5727
Fax: (780) 429-3509
Email: cancer@hreba.ca

Modification of Ethics Approval

This is to acknowledge that the modification to the research indicated below has been reviewed and on behalf of the Health Research Ethics Board of Alberta (HREBA) – Cancer Committee (CC), I am pleased to advise that approval has been granted.

Ethics ID:	HREBA.CC-16-0732_MOD2
Principal Investigator:	Jana Rieger
Co-Investigator(s):	There are no items to display
Student Co-Investigator(s):	Gabriela Constantinescu
Study Title:	Usability testing of a mobile health system for swallowing therapy in patients with head and neck cancer
Sponsor (if applicable):	

Effective: 12/01/2017 **Expires:** 11/01/2018

Reviewed and approved by delegated review on 16 March 2017

The following documents have been approved:

- Recruitment Poster Clean, 2, March 10, 2017
- Informed Consent Clean Copy, 2, March 10, 2017

This Committee is constituted and operates in accordance with the Alberta Health Information Act (HIA), the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2), Good Clinical Practice (GCP) Guidelines of the International Conference on Harmonization (ICH), Health Canada's *Food and Drug Regulations* (FDR), Part C, Division 5 and is registered with the U.S. Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP), IRB # 00009687.

Members of the HREBA-CC who are named as principal investigators or co-investigators in this research do not participate in discussions related to, nor vote on, such studies when they are presented to the Committee. The membership of this Committee is listed at www.hreba.ca.

Please note that the approval of this modification does not change the effective or expiry dates of this study as indicated above.

Please accept the Committee's best wishes for success in your research.

Approved on behalf of CC by,	**Date:**
Raul Urtasun , HREBA-CC	March 16, 2017

Note: This correspondence includes an electronic signature (validation and approval via an online system).

Appendix B – Semi-Structured Interview Questions

Throughout your cancer treatment, you may have been given some exercises by your speech therapist or your physical therapist. What is your honest opinion about having to do these exercises?

Probe: How often did you complete them? What were some of the factors that led you to completing/ not completing your exercises?

Perceived facilitators and barriers

- What do you feel are some things/ factors that help you complete your exercises?
- What do you feel are some things/ factors that keep you from completing your exercises?

Enjoyment

- What types of things help you enjoy your exercises?
- What things make you not enjoy your exercises?

Social support

- What social supports (family, friends) help your complete your exercises?
- What social factors (family, friends, family dynamics) prevent you from completing your exercises?

Role models

- What are some role models (e.g., past patients, friends or family who have gone through something similar) help you complete your exercises?
- What are some things that these role models do, or any things about them, that impede you from completing your exercises?

Depression

- When you're not having the best of days, what do you do or tell yourself to get yourself to do your exercises anyway?
- In those situations, what helps the most in getting you to do the exercises?

Symptoms

12) What sort of symptoms impede your from doing your exercises?

- When you feel those symptoms, what do you do anything or tell yourself something to get you to stick to your exercises?
- In those situations, what helps the most in getting you to do the exercises?

Additional questions:

13) Do you feel that you knew how to complete the exercises correctly? (i.e., was the exercise demonstrated only once, did you have the opportunity to demonstrate your ability to do the exercise accurately before you were sent home to do them?

14) Did you perceive any change, positive or negative, as a result of the exercises?

Convergent Interview – Questions for Set 1

1) What did you think about the concepts we came up with?
2) What do you think about looking at one of those concepts while doing one of the exercises we practiced earlier?
3) What type of concept would make the exercise more exciting for you?
4) What type of concept would you find most engaging?
5) What type of concept would make it easier for you to do the exercise?
6) What would be most important to you in a feedback like that?

7) What kind of frame of mind do you prefer to be in when doing these exercises? (prompt: When you’re doing a hobby, do you prefer to do it with others, do you like to be alone, do you like to be focused, relaxed?

Appendix C – Summary of Facilitators and Barriers to Adherence Identified in Each Theme

	Factor	Sample quote
Theme 1 Perceptions on outcomes and progress		
Barriers	No swallowing problem or restored function	"I told myself, oh I'm in the clear!"
	Perceived little or no progress	"I don't see any more progress, I'm not doing this anymore."
	Unrealistic post-cancer treatment outcome expectations	"(…) you realize okay well this is gonna take time."
	Pessimistic adjustment in outcome expectations	"I just resigned myself to the fact that I don't think my situation is really gonna change."
Facilitators	Perceived regression in function or fear of poor outcomes	"I need to work harder at it. And, because, I've already been pretty sick, I don't want to get sick again."
	Perceived benefit as a result of	"I did stick with it because I went,

	the exercise	'Wow, I'd do this.' Any improvement in swallowing, being able to maybe eat a little faster cuz it's going down quicker, I want. I really want it."
Theme 2 Role of clinical appointments		
Barrier	Access	"So so if I was doing something wrong, I didn't have the feedback to tell me try this or try that. I had to wait till my next appointment."
Facilitators	Education	"Now, now I see where you-, what you're getting at, when you invent these exercises."
	Building confidence	"I was always second-guessing really my technique. So I found the technique a little bit difficult to actually maintain. Um, especially after (…) I would leave the in-house session and try to do them at home."

	Tailored prescriptions	"But she said if it's too difficult and you find an issue then just at least continue on with the other ones. Just don't stop"
	Accountability	"(…) you slide into bad habits pretty fast. If you're not constantly monitored."
Theme 3 Cancer treatment		
Barriers	Memory and focus	"I'd get home and you'd hand it to me, like do this, this and this, and I'd go, 'Well that's so simple' Good God. And I'd get home and go [face palm] 'What, what (…) oh man, I don't remember, I don't know what this means, and I'm not gonna phone because this is grade three instructions' know what I mean?"
	Sense of overwhelm with information and recommendations	"(…) this type of cancer is very complex in its requirements for support and therapy, yeah, some

	days, it's just like whoa, it's a lot to keep on track, I can't keep it all up."
Low energy and fatigue	"So sometimes all I had time for or energy in the day was a one hour visit with somebody. Maybe half an hour only. And then exercises, even eating sometimes would fall off because I wanted to go nap and sleep."
Other side effects	"You're tired. You're tired of choking. You're miserable. You're isolated. You can't communicate as it is except by writing a lot of places. Like for months. After the radiation burns your throat and that, it makes it harder to swallow, your throat's raw. For so many reasons that make it easy not to, to swallow. And to take the food, there's just an endless list of reasons why you can say, 'Well, it's too hard!'"

Theme 4 Rehabilitation program		
Barriers	General: no structure, distractions, length of time in rehabilitation program	"(…) But it's not official, it's not regimented, it's not programmed (…)"
	Exercise-specific: too complex or difficult, feeling self-conscious, misinterpreting other activities as exercise	"(…) but after a while the complex ones fell off rather quickly" "So there is an embarrassment factor that you have to get over. But I just go down into in my room in the basement and sortta, I guess isolate myself a lot to do certain exercises."
Facilitators	General: tracking progress, providing reminders, routine, setting goals	"So then I was tracking my swallow exercises at home, which, yeah, helped, I think. Helped to motivate me, to remind me that those were really critical. And helped me to also track how was how well I was doing."
	Patient-specific: adjusting the	"At first, I'd get up in the morning

	practice environment, customizing the exercise schedule	and do them, kind of when I did my meds and stuff and try and get rid of all that at the same time.”
	Exercise-specific: novel, interesting, easy, tackle multiple goals at once	“(…) but some of the ones were very unique, so there [were] more complex ones where you held […] your breath. I thought, ‘Oh, actually this is kind of cool’ So it was kind of intriguing for a while.”
Theme 5 Personal factors		
Facilitators	Positive and grateful	“But then after I started feeling better again, then I thought, ‘Well, the rest of me is getting better, this part might as well come along too’ so, I kind of got back into doing them a little more.”
	Coping, through self-talk and self-compassion	“I would think, ‘Just stop, stop whining, get get up and get better’”. “I would forgive myself that day.

		And then I would [unintelligible] tomorrow."
	Sense of personal obligation to healthcare workers involved in extended treatment	"The thing is to (…) keep it in your mind that the surgeons and the therapists and the nurses and the whoever are the ones that are the reason why you're here. And you owe it to them and to yourself to, [unintelligible] and to be strong (…)."
	Wish to become a role model or helper	I think more like, I want to be a role model for my friends. Yeah. I want to show them that if you put your mind to it, you can do it.
Theme 6		
Connection		
(Potential indirect) barrier	Patient perceives his/ her function to be worse than that of peers	"(…) and it got really depressing, because all these people they would be put on the peg, taken off the peg, off they go. New norm! (…) and they would come in and, 'Today I ate half a hamburger!' Well, I ate my first half of

		hamburger the other day. And this was within three months of their treatment (…).”
(Potential indirect) facilitator	Patient perceives his/ her function to be better than that of peers	“It’s not fair, but then there’s others where, like there’s for example the guy that can only eat cream of wheat, I’m going ‘Wow, I’m miles ahead of him!’”

Appendix D – Convergent Themes

Key issue	Agreed	Disagreed	Undecided or not addressed
Feedback should only show amount of effort (not too much information)	4	3	3
Feedback should be immediate	6	0	4
Feedback should be contingent on effort, but also show progress relative to goal	5	2	3
Feedback should be simple and straightforward	7	0	3
Third person player feedback is not a good measure of what is happening	5	2	3
Third person player feedback does not make it obvious if user completed exercise correctly	4	2	4
Education is important to get patients to do the exercises	6	1	3
Visuals that look medical do not look good (e.g., graphs)	2	5	3
Visuals that are more complex are better that those that are too simple	4	4	3
Graphs are difficult to interpret	1	5	4
Artistic creations using biofeedback were nice, but	3	0	7

too soft and boring			
Completing the number of swallow trials is important	3	5	2
Built-in reminders are beneficial; patients have a lot of time demands	2	2	6
Failure motivates users to keep trying again and work harder	4	3	3
Improvement over time is important; building confidence in swallowing ability	6	0	4
Building structures over time is engaging	5	2	3
Concern expressed for third person player in the game	1	7	2
Third person player game is engaging	3	4	3
Tracking progress over time is important	8	1	1
Tracking progress should include a baseline	3	0	7
Competition with self is better than that with others	5	0	5

Appendix E – Studies Discussing mHealth Apps in Rehabilitation

Study	Target patients or clients	Patient or client engagement in any stage prior to validation	Stages of any end-user involvement evident from article	mHealth name
(Barelli, Aquino Junior, & Ferrari de Castro, 2016)	Neuroprosthesis tetraplegics users at C5 and C6 levels	No user engagement at this stage; Human Computer Interface paradigms and usability concepts used	Not applicable	Not mentioned
(Ben-Zeev et al., 2013)	Individuals with schizophrenia	Yes	**Design & development:** users and clinician surveys regarding current use of and interest in mHealth devices and attitudes and expectations;	FOCUS

			Validation: usability testing	
(Bendixen, Fairman, Karavolis, Sullivan, & Parmanto, 2017)	Individuals with brain and spinal cord anomalies	Yes	**Design & development:** second app iteration, with focus groups	Interactive Mobile Health and Rehabilitation (iMHere 2.0)
(Constantinescu et al., 2017)	Head and neck cancer patients with dysphagia	Yes	**Design & development**: paper prototype stage with interviews	Not mentioned
(Crook, Kenny, Johnson, & Davidson, 2017)	Individuals with complex communication needs	Yes	**Design & development:** field notes, focus groups, interviews	Not mentioned

(Danilovich et al., 2017)	Older adults	Yes	**Design & development**: focus group and semi-structured interviews to investigate exercise and mobile app preferences; Client interviews to find exercise preferences, and barriers and facilitators to exercise	Not mentioned
(Darcy, Green, & Maxwell, 2017)	Individuals with disability	No	**Validation:** usability interviews before, in the middle, and at the end of a 13 week pilot project	Village Networks (pseudonym) designed
(Dithmer et al., 2016)	Patients with a history of heart failure, myocardial infarction, or angina pectoris who also were participating in	Yes	**Design & development**: qualitative interviews of patients/ nurses, participant observations (field notes), workshop, focus group; Content approved by cardiologist	The Heart Game

	a telerehabilitation program		**Validation:** usability testing	
(Fairman et al., 2016)	Young adults (ages 18-40 years) with spina bifida	No	**Validation:** usability testing	Interactive Mobile Health and Rehabilitation (iMHere)
(Fledderus, Schreurs, Bohlmeijer, & Vollenbroek-Hutten, 2015)	Chronic pain patients	Yes	**Design & development**: contextual inquiry	Not mentioned
(Frederix, Sankaran, Coninx, & Dendale, 2016)	Patients with coronary artery disease	No	**Design & development**: discussions, collaboration between technical and paramedical team **Validation:** pilot testing	MobileHeart

(Giesbrecht, Miller, Jin, Mitchell, & Eng, 2015)	Older adults using wheelchairs	No	**Validation:** usability testing	Enhancing Participation In the Community by improving Wheelchair Skills (EPIC Wheels)
(Goldberg, Karimi, & Pearlman, 2016)	Students with disabilities wishing to participate in school	No	**Validation:** pilot testing, baseline questionnaires followed by focus groups before and after use of app	Interactive, mobile, AGIle and novel education (IMAGINE)
(Gyori, Stefanik, & Kanizsai-Nagy, 2015)	Individuals with autism spectrum disorders (ASD)	No	**Design & development:** three teams of experts provided input **Validation:** randomized controlled trial; teens with ASD provided input on the first prototype	HANDS project

(Hidalgo-Mazzei et al., 2015)	Individuals with bipolar disorder	No	**Validation:** feasibility testing; randomized controlled trial Design was determined by a collaborative team of clinical experts (psychiatrists and psychologists), software engineers, and graphical designers	SIMPLe
(Krumsvik & Babic, 2017)	Physicians, medical students, and patients wishing to learn about arthroplasty	No	**Validation:** usability testing	Not mentioned
(Larrosa et al., 2015)	Audiologists	No	**Validation:** non-randomized validation study where the accuracy	AudCal

			of the app was tested AudCal application was designed and developed by one of the authors (J. R. M.).	
(Murphy & Darrah, 2015)	Students with visual impairments	Yes	**Design & development:** app review where once internal reviewers approved the app, it was sent for external review by people with visual impairments or people who work with them	Novint Falcon
(Nahar, Jaafar, Ahamed, & Kaish, 2015)	Visually impaired students	Yes	**Design & development**: school visits and opinion of teachers and several visually impaired students were gathered	mBRAILLE

(Nicholson et al., 2017)	Individuals living with serious mental illnesses	Yes	**Design & development:** focus groups	WorkingWell
(Parmanto et al., 2013)	Individuals with spina bifida	No	**Validation:** three phases of usability testing: natural environment app use, controlled environment app use, natural environment app use with a focus on app-to-portal communication	iMHere (iMobile Health and Rehabilitation)
(Pfaeffli et al., 2012)	Individuals needing cardiac rehabilitation exercise intervention	Yes	**Design & development:** expert group (cardiologists, cardiac rehabilitation nurse specialist, exercise scientists, behavioural researcher, expert in mobile phone delivered interventions, a M?ori (Indigenous) health researcher); user input obtained with	Not mentioned

			focus groups, telephone interviews. **Validation:** pilot testing	
(Powell et al., 2017)	Individuals with cognitive impairments following brain injury	Yes	**Design & development:** focus groups, interviews	Web-based programme, ProSolv
(Radhakrishnan et al., 2016)	Community-dwelling older adults' with heart failure	Yes	**Design & development:** prior research cited in which older adults were asked which types of digital games they preferred; open-ended survey for providers' (i.e. nurses) awareness of patient preferences for	Not mentioned

			electronic games **Validation:** usability testing	
(Rawstorn, Gant, Meads, Warren, & Maddison, 2016)	Individuals requiring cardiac rehabilitation exercise programs	No	**Validation:** randomized controlled trial	REMOTE-CR
(Svarre, Lunn, & Helle, 2017)	Occupational Therapists	Yes	**Design & development**: observation of use of paper version of Housing Enabler assessment; interviews, workshops **Validation:** usability testing	Housing Enabler
(Tabak, Vollenbroek-Hutten,	Individuals with Chronic Obstructive	No	**Validation:** randomized controlled pilot trial	Activity coach (3D accelerometer with

van der Valk, van der Palen, & Hermens, 2014)	Pulmonary Disease (COPD)			smartphone)
(Vorrink, Kort, Troosters, & Lammers, 2016)	Individuals with chronic obstructive pulmonary disease and reduced levels of daily physical activity	No	**Validation:** pilot testing App created by a small business enterprise, mentioning interactive team work sessions	Not mentioned

Appendix F – Pilot Testing KayPENTAX With Known Signal Input

KayPENTAX® is a company specializing in medical instruments, many related to speech and swallowing. Clinicians use the KayPENTAX® Digital Swallowing Workstation (latest model: 7200) and the Swallowing Signals Lab (latest model: 7120B) to provide sEMG biofeedback as an adjunct to swallowing therapy. When using this technology, an adhesive pad with three electrodes (the same as the one used in Chapter 2) is placed under the patient's chin. The signal can be sampled at 250 Hz, 500 Hz or 1000 Hz. The acquired signal is transmitted to the hardware, filtered using a Butterworth Bandpass with a center frequency of 105 Hz and 3 dB points at 52 Hz and 220 Hz. The filter roll off is 6 dB/octave. The signal is displayed on the workstation screen with a time delay of less than 5 ms (M. Szoke, personal communication, July 31, 2015). The KayPENTAX® software can then generate quantitative measurements related to the signal, such as maximum amplitude (μV), mean amplitude (μV) and area under the curve (μV*s).

Pilot Testing

Before this equipment could be used as a gold standard for comparison, signal differences within KayPENTAX® needed to be determined. Signal was acquired using the sEMG Channel 1 and sEMG Channel 2 of the Swallowing Signal Lab. Two wires provided by KayPENTAX®, varying in length, also were tested. The known signal was generated using a National Instruments cDAQ-9174 (Austin, United States) and was a 100 Hz sine wave of varying amplitudes: 300 μV, 600 μV, 900 μV, and 1200 μV. A baseline signal also was captured. A total of four possible combinations were tested: (1)

EMG Channel 1, long wire; (2) EMG Channel 2, long wire; (3) EMG Channel 1, short wire; (4) EMG Channel 2, short wire. Combinations (3) and (4) were repeated for test-retest analysis. A window of 5 seconds was collected using the KayPENTAX® software, set at a sampling rate of 250 Hz and a window amplitude maximum of 1000 μV. The signal was exported to a word file, where the amplitude was shown for every 4 ms interval in the 5 s sample. The amplitudes from these files were used to determine the mean and standard deviation amplitude (μV) for each signal type, under each of the 4 conditions. Whereas the length of the wire connected to the sensor appeared to result in equivalent signal captured on the KayPENTAX® software, the channel used did result in signal differences. The variability within KayPENTAX® noted in this pilot testing revealed that signal equivalency between KayPENTAX® and Mobili-T™ may be difficult to demonstrate.

Results

Wire length did not make a difference in the signal captured (figure F.1). The channel input used did make a difference in the signal captured: Channel 2 attenuated the signal more than Channel 1 (figure F.2).

Figure F.1 Signal comparison with two wire lengths.

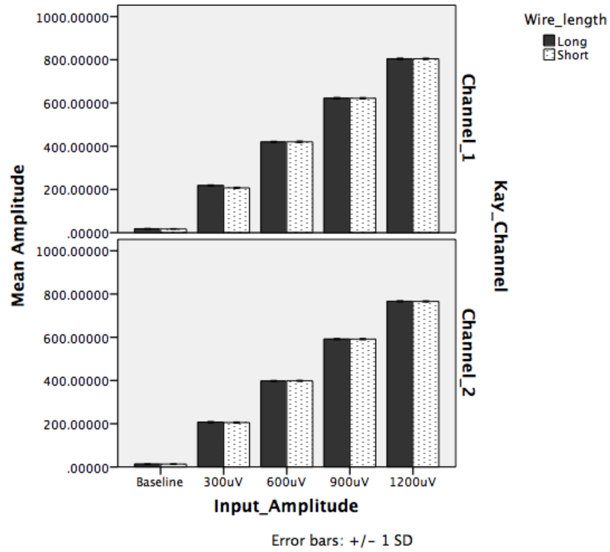


Figure F.1 Mean signal amplitude using two different wire lengths and the two input channels from the KayPENTAX® equipment.

Figure F.2 Signal comparison with two channel inputs.

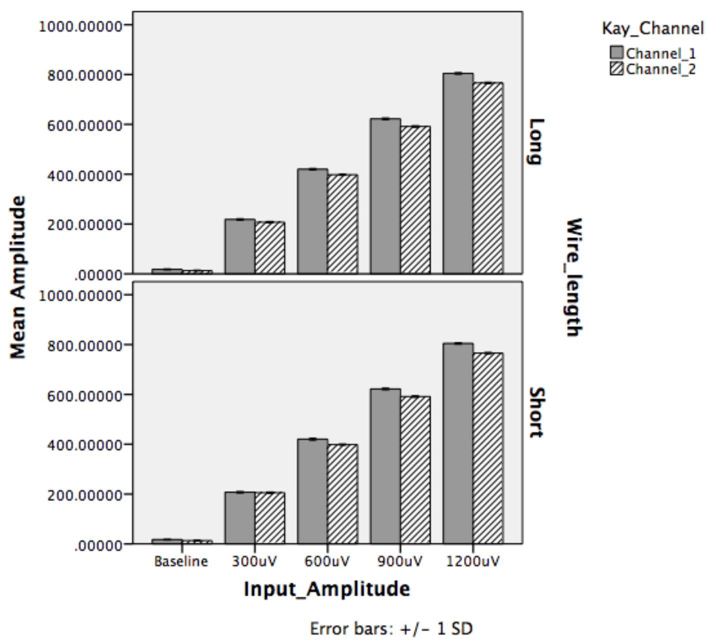


Figure F.2 Mean signal amplitude using two different input channels from the KayPENTAX® equipment and wire lengths.

Next, we calculated the difference between the amplitude recorded from the two channels and graphed this against the known amplitude inputed. A discrepancy appeared at 300 Hz (figure F.3).

Figure F.3 Difference between known signal inputted and signal acquired by KayPENTAX®.

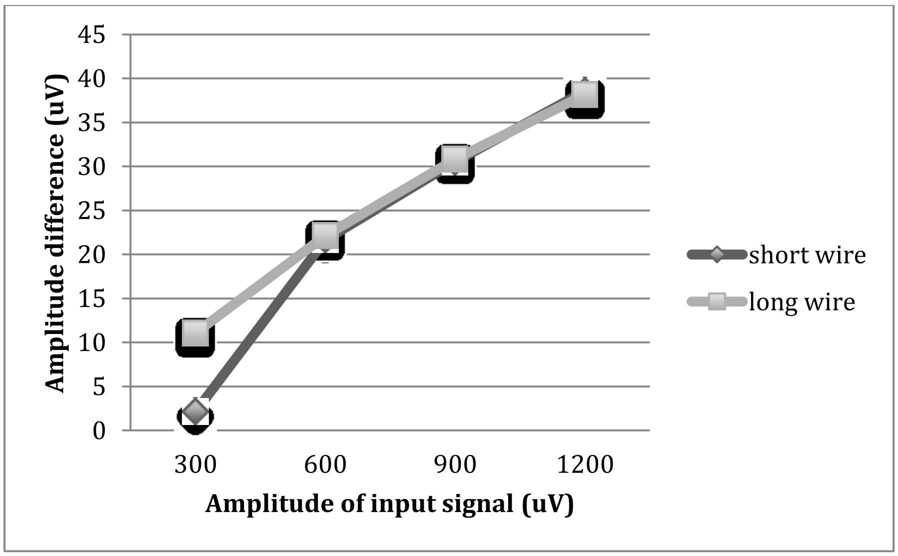


Figure F.3 Difference in amplitude between inputted known signal and recorded signal.

There were no concerns regarding test-retest with either input channel.