

REGULATING RATE OF EATING IN PATIENTS WITH
DYSPHAGIA: THE EFFECTIVNESS OF SMARTFORKS

by

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Swallowing impairments, or dysphagia, can have a dramatic impact on physical and psychological well-being. While a variety of compensatory strategies exist that attempt to target increased safety, they often do so at the expense of decreased quality of life. More naturalistic therapy techniques, such as using an external cueing aid for decreased eating rate, may simultaneously target increased safety and increased autonomy, offering a more appropriate treatment alternative to current options. The purpose of this study was to examine the impact of a smartfork on eating rate and quality of meals in stroke survivors with dysphagia. Three individuals participated in the study. The research was conducted at Oregon Rehabilitation Center over the course of two meals: one meal was eaten without the use of the smartfork's feedback and the second meal was eaten with the vibrotactile and visual feedback turned on. Results indicated that the fork was effective for two out of the three participants. Specifically, for those two participants, their rate of eating decreased and the percentage of bite intervals when the target rate of eating was met increased with the use of the smartfork feedback. The visual feedback provided by the fork was more effective than the vibrotactile feedback.

All participants felt the fork maintained or improved the quality of their meal. These results suggest that a smartfork is potentially a helpful device to make eating a safer and more enjoyable experience for people with dysphagia.

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INTRODUCTION

Definition of Clinical Problem

Most broadly, dysphagia is any difficulty with swallowing. Dysphagia can result from a variety of underlying etiologies, including stroke, head and neck cancer, traumatic brain injury, and dementia (Daniels & Huckabee, 2014; Logemann, 1999). Choking and aspirating food or drink into the lungs are two potentially serious health-related consequences of dysphagia (Perry & Love, 2001; Samuels & Chadwick, 2006). Aspiration and choking can be life threatening as they can lead to aspiration pneumonia or choking to death if not monitored closely. Many people with dysphagia who are at risk for choking while eating have to be closely monitored while they eat or be fed entirely by someone else in order to prevent choking from occurring. One primary goal of speech-language pathologists (SLPs) working with individuals with dysphagia is to reduce the risk of aspiration and choking. Unfortunately, many current options are undesirable to patients, decrease patient autonomy, and/or are burdensome to caregivers. This section will first briefly introduce normal swallowing function, rate of eating, dysphagia (including dysphagia in the stroke population), and strategies currently used by SLPs to aid individuals with dysphagia to swallow in a safer way. It will then introduce a novel potential tool to target eating safety and discuss the potential effectiveness of this method.

Normal Eating and Swallowing Function

Normal swallowing. Typical swallowing function and its variations are important to understand prior to studying populations with dysphagia, or swallowing

impairments. There are four stages of swallowing. During the first stage, the oral preparatory stage (see Figure 1, panel A), the food enters the mouth and chewing, if needed, is initiated. The food mixes with saliva and is formed into a cohesive bolus that is then positioned in the middle of the tongue (the large mass that takes up most of the space in the oral cavity as seen in Figure 1) (Daniels et al., 2014). A bolus is a small mass of chewed food or liquid that is prepared to be swallowed.

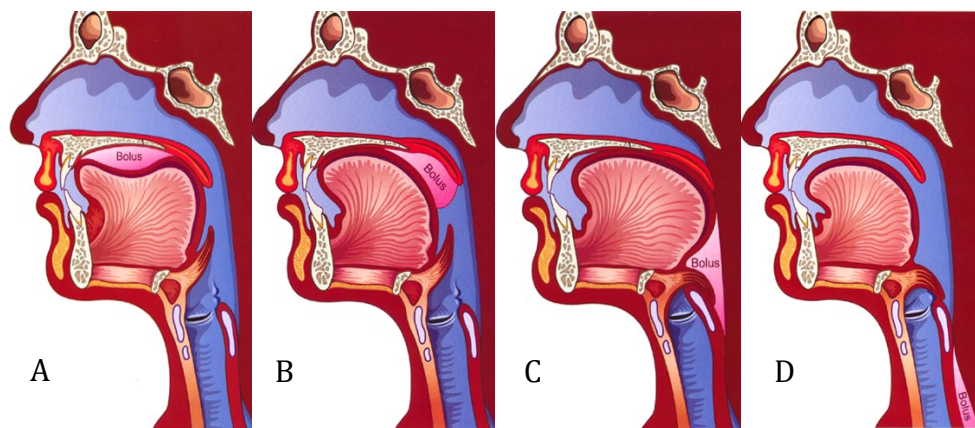


Figure 1. An illustration of the four stages of swallowing: oral preparatory (A), oral transit (B), pharyngeal (C), and esophageal (D). (Adapted from Hixon & Hoit, 2014).

During the oral transit stage (see Figure 1, panel B), the bolus is pushed from the middle of the tongue to the very back of the tongue. As the bolus moves further back, the pharyngeal swallow is triggered (Logemann, 1999). During the pharyngeal stage (see Figure 1, panel C), the swallow itself is initiated. Important events that occur in conjunction with this pharyngeal stage are the approximation of the vocal folds and arytenoid cartilages (when the vocal folds close to protect the airway from the bolus entering into the respiratory system) and the resulting period of apnea (when the breathing temporarily ceases due to the airway being blocked to allow the food to pass into the esophagus rather than the airway) (Daniels et al., 2014). The epiglottis (dark red

structure below the base of the tongue in Figure 1) flips over to completely cover the vocal folds and passageway to the lungs as an additional airway protection mechanism, while the velum (bright red structure above the tongue in Figure 1) raises to block the entrance of the nasal cavity to prevent food and drink from traveling up the nose. The muscles of the pharynx then contract and propels the bolus down toward the esophagus (Logemann, 1999). During the final stage, the esophageal stage (see Figure 1, panel D), contraction of the esophageal muscles moves the bolus down the esophagus and toward the stomach. This motion of the bolus is called peristalsis (Logemann, 1999).

As individuals age, the anatomical structures involved in swallowing and the physiologic patterns of these structures change; this has been termed presbyphagia (Ney, Weiss, Kind, & Robbins, 2009; Robbins, Hamilton, Lof, & Kempster, 1992). It is important to note that presbyphagia defines an aged, but otherwise healthy (i.e., non-disordered) swallow. It is only when flexibility and range of motion is dramatically decreased, or a disease or insult occurs that negatively interacts with the presbyphagic changes, that a person may develop a swallowing problem (Logemann, 1999). These age-related changes are seen across the swallowing process. Younger adults have a degree of functional reserve in swallowing (Logemann, 1999). In other words, young, healthy individuals demonstrate more flexibility and movement in their structures and during swallowing than is strictly needed. With time, this flexibility and movement is reduced, and in normal, healthy older individuals, swallowing function is often still fully functional, yet there is no longer as much reserve (Logemann, 1999).

A variety of other swallow-related changes occur with age. The muscles of mastication show a decrease in strength as well as bite force (McComas, 1998;

Monemi, Eriksson, Eriksson, & Thornell, 1998; Newton & Yemm, 1990). Older adults have less salivary reserve, resulting in dryness in the mouth, which can hinder swallow function (Ney et al., 2009). The larynx lowers in the neck and arthritic changes occur in the cervical vertebrae, which decreases flexibility. As aging occurs, there is a weaker pharyngeal contraction that can result in residual material (from the bolus) remaining in the mouth or throat after a swallow and an increase in the risk for this residue to move towards the airway (e.g., penetration) rather than towards the esophagus. More residual material in the mouth and throat and in the regions of the airway is not, however, linked to increased rates of aspiration (Logemann, 1999). It can lead to the need for individuals to do a second swallow to clear the larynx. There is sometimes also a slight delay in triggering the pharyngeal swallow in older adults that makes the oropharyngeal stage slightly longer than in younger adults (Logemann, 1999; Logemann et al., 2000; Mendell & Logemann, 2007; Robbins et al., 1992).

Rate of eating. Eating rate, or specifically fast eating, can negatively impact swallowing safety and lead to an increased risk of choking (Fioritti, Giaccotto, & Melega, 1997; Samuels & Chadwick, 2006). Thus, it is important in discussing typical swallowing function to also review typical eating rates. Rate of eating is different for everyone; some people like to eat quickly, while others like to eat slowly. One study that was conducted on a university campus reported that mean bite rate was 3.79 bites per minute ($SD = 0.94$) among individuals ages 18 to 35 ($SD = 3.50$) (Scisco, Muth, Dong, & Hoover, 2011). However, there was substantial variability in eating rate as the individual means for each participant in the study ranged from 2.33 to 6.73 bites per minute. Eating rate can be influenced by a plethora of factors. Firstly, rate depends on

the quantity of food being consumed, indicating that eating rate can fluctuate (generally decrease) as one consumes more (Thomas et al., 2017). Secondly, hunger levels also have an effect; when an individual begins to feel satiated during a meal, eating rate usually begins to slow down (Hill & McCutcheon, 1984; Thomas et al., 2017). Other individual-level factors that influence eating rate include body size, gender, and food preferences (Hill & McCutcheon, 1984). Significant to the application of decreasing rate for increased eating/swallowing safety and for weight loss, purposefully reducing eating rate can decrease the overall amount of food consumed by an individual without leaving the individual feeling less satiated or getting less nutrition from their food (Robinson et al., 2014).

Dysphagia

There are a variety of definitions for dysphagia. Jeri Logemann, a pioneer in the field of dysphagia, defined it as “difficulty moving food from mouth to stomach ... [including] all of the behavioral, sensory, and preliminary motor acts in preparation for the swallow, including cognitive awareness of the upcoming eating situation, visual recognition of food, and all of the physiologic responses to the smell and presence of food such as increased salivation” (Logemann, 1999, p.1). The current paper will be using this definition. Most simply put, dysphagia is difficulty swallowing. There is a plethora of signs that could lead a clinician or physician to suspect a patient has dysphagia. These signs include coughing throughout meals, coughing during any stage of swallowing, recurrent pneumonia, and difficulty or inability to control food or saliva in the mouth (Logemann, 1999). When a medical professional sees these signs or others that are suggestive of dysphagia, a speech-language pathologist (SLP) or member of the

nursing staff will usually do a preliminary screening to see if the patient is at risk. If found to be at risk, the patient will then go through a more thorough diagnostic test done by an SLP to determine pathophysiology, severity, and risk of choking and aspiration (Daniels et al., 2014).

Unfortunately, dysphagia is associated with numerous negative consequences. Health risks often include malnutrition, decreased eating, weight loss, aspiration pneumonia, and choking, all of which are associated with decreased survival (Daniels et al., 2014; Foley, Martin, Salter, & Teaseel, 2009; Groher et al., 2016; Leow, Huckabee, Anderson, & Beckert, 2010; Logemann, 1999). Dysphagia is very impactful on patients' lives and can also lead to decreased quality of life (Ekberg, Hamdy, Woisard, Wuttge-Hannig, & Ortega, 2002). Individuals with dysphagia have reported that it is difficult to find food that they can safely eat and that they enjoy eating, which inhibits socialization during meals; that meal durations may be longer, further inhibiting socialization; and that dysphagia significantly impacts their mental health (Leow et al., 2010). Having swallowing problems decreases an individual's desire to eat, which has negative effects on overall nutrition and health (Ekberg et al., 2002; Leow et al., 2010). Dysphagia has also been linked to depression (Ekberg et al., 2002; Eslick & Talley, 2008; Leow et al., 2010), anxiety (Ekberg et al., 2002; Eslick et al., 2008), feelings of isolation (Ekberg et al., 2002), and decreased autonomy (Shune & Foster, 2017).

Dysphagia after stroke. Stroke affects approximately 700,000 people in the United States annually and 2,000 out of every one million people worldwide (Daniels et al., 2014). Stroke can be secondary to ischemia (accounting for 80% of strokes) or can be caused by hemorrhages (accounting for 10% of strokes) (Daniels et al., 2014). In an

ischemic stroke, there is reduced blood flow to the brain caused by a blockage, often resulting from buildup of plaque along the lining of an artery (Daniels et al., 2014). The plaque may dislodge, causing an embolism to travel in the bloodstream that can become relogged and disrupt blood flow. Hemorrhagic stroke, on the other hand, results from weakened blood vessels due to hypertension, a ruptured aneurysm, or bleeding from an arteriovenous malformation (Daniels et al., 2014).

The prevalence of dysphagia after stroke is difficult to measure and is estimated to range from 25% to 80%, with up to 50% of individuals who have dysphagia in the acute recovery stage still having dysphagia at 6 months (Daniels et al., 2014; Mann, Hankey, & Cameron, 1999; Mann, Hankey, & Cameron, 2000). It is postulated that many cases of dysphagia in this population go undetected because only patients with overt signs of dysphagia, such as aspiration and coughing, are referred to an SLP (Daniels et al., 2014). The site of the stroke has some influence on the likelihood of developing dysphagia; strokes in the brainstem, premotor cortex, primary motor cortex, insula, and periventricular white matter often indicate a higher likelihood of dysphagia post stroke. However, individuals with stroke in any area of the brain or nervous system can develop dysphagia (Daniels et al., 2014).

Compensatory strategies for swallowing and eating. Behavioral management for dysphagia often involves the use of compensatory strategies to aid in improving swallowing safety for patients with dysphagia (Daniels et al., 2014; Groher, 2010; Logemann 1999). These strategies are not intended to improve the impaired swallow mechanism or produce long-term changes. Rather, they are frequently used to facilitate improved swallow function during the acute stages of recovery and can be done either

with more rehabilitative treatments or alone when rehabilitation is not appropriate. Interestingly, rates of dysphagia and risk for aspiration are particularly high for stroke survivors immediately after stroke, suggesting the benefit of early intervention and a likelihood of spontaneous recovery for many of these patients (Crary, Humphrey, Carnaby-Mann, Sambandam, Miller, & Silliman, 2013) Thus, compensatory strategies during the acute recovery stage might be particularly valuable for this population.

Postural changes, such as the chin tuck or head turn postures, have been shown to effectively eliminate aspiration of liquids for 75% to 80% of patients (Logemann, 1999). For the chin tuck posture, patients touch their chin to their chest prior to and during the swallow (Daniels et al., 2014; Groher et al., 2010; Logemann, 1999). This results in improved airway protection by narrowing the entrance of the airway and moving the laryngeal surface of the epiglottis closer to the posterior pharyngeal wall (Daniels et al., 2014). In other words, a chin tuck would result in a more secure closure at the top of the airway, which would better prevent food or liquid from entering the lungs. A head turn postural change is when patients turn their head to one side, usually the weaker side, before and during the swallow (Daniels et al., 2014; Groher, 2010; Logemann, 1999). The result of this posture change is an improvement in bolus flow as the bolus is directed toward the stronger side of the pharynx and can result in decreased residue left after swallowing (Daniels et al., 2014). Although these strategies can be very effective, they do not always work for every individual with a swallowing disorder (Ashford et al., 2009). Patients who are cognitively impaired may be unable to adequately follow instructions on how to do the postural change and patients with physical disabilities may not be physically able to do a postural change (Groher et al.,

2010; Logemann, 1999). Further, the evidence base supporting the effectiveness of these strategies is limited (Ashford et al., 2009).

Modified textures, such as thickened liquids or pureed foods, is another compensatory strategy frequently used by clinicians to aid in swallowing and decrease the likelihood of aspiration or choking (Daniels et al., 2014; Groher et al., 2010; Logemann, 1999). For example, thickened liquids have been found to reduce rates of aspiration as compared to thin liquids (Logemann et al., 2008; Kuhlemeier, Palmer, & Rosenberg, 2001). One benefit of thickened liquids or pureed foods is that even individuals with cognitive or physical impairments, who are unable to do postural changes, can consume modified food textures (Logemann, 1999). Unfortunately, there are numerous disadvantages and questions related to the use of modified diets. First, historically there has been no international standard for thickened liquids, and therefore little regulation on how thick to make liquids (Cichero et al., 2017). There are several different thickener ingredients and brands that can be used, all of which act differently and thicken to different amounts (e.g., some continue to thicken if not immediately consumed, making thickness standardization difficult). This can lead to a large discrepancy in thickness of liquids, making it very difficult to know, particularly for caregivers, if the liquid is at the right thickness for a patient. It can be dangerous to give a patient a liquid that is either too thick or not thick enough. In response, the International Dysphagia Diet Standardization Initiative (IDDSI) recently published a diet framework for modified textures (food and liquids) (Cichero et al., 2017; International Dysphagia Diet Standardization Initiative, 2017). The standardizations that were created are based on survey responses from professionals, people with dysphagia,

and caregivers. The IDDSI framework is in the process of becoming the international standard for dysphagia diets, which would greatly help to regulate thickened liquids and modified foods (Cichero et al., 2017; International Dysphagia Diet Standardization Initiative, 2017).

Another main disadvantage of thickening liquids or pureeing food is that patients are generally very dissatisfied with them (Daniels et al., 2014). Patients do not feel hydrated when drinking thickened liquids and do not like the taste of thickened liquids leading to them refusing to drink, which increases risk for dehydration (Garcia, Chambers, & Molander, 2005; Leibovitz, Baumoechl, Lubart, Yaina, Platinovitz, & Segel, 2007). Patients often feel undignified eating pureed food and feel embarrassed eating it in front of other people (Daniels et al., 2014). These patients have also been found to have lower nutritional intake and increased risk of dehydration than patients eating a normal diet (Crary et al., 2013; Wright, Cotter, Hickson, & Frost, 2005). Given these disadvantages, and in light of unclear long-term clinical benefits, thickened liquids and pureed foods should only be implemented when other compensatory strategies or therapies are not possible (e.g., the patient has a movement disorder, whose posture is inconsistent, or who is unable to follow instructions for postural swallowing changes) (Logemann, 1999). However, thickened liquids and pureed foods are very frequently ordered for patients and are used very often.

Another strategy employed to reduce aspiration or choking is the use of a feeding tube. While feeding tubes are sometimes necessary, there is research showing that there is a higher risk of aspiration of saliva due to a suppressed cough when using a feeding tube, which can also lead to aspiration pneumonia (Daniels et al., 2014) and

feeding tubes have not been found to reduce aspiration risk (of tube feedings) in certain populations (Finucane & Bynum, 1996; Langmore, Skarupski, Park, & Fries, 2002). Even healthy individuals can microaspirate when using feeding tubes, and the likelihood and amount of aspiration increases in dysphagic individuals (Langmore Terpenning, Schork, Chen, Murray, Lopatin, & Loesche, 1998). Further, the act of eating during mealtimes plays an important role in daily life related to socialization, enjoyment, and dignity (Milte, Shulver, Killington, Bradley, Miller, & Crotty, 2017). The use of a feeding tube negatively interferes with a patient's ability, or willingness, to participate in the mealtime process. Finally, the placement of a feeding tube requires a surgical procedure. Therefore, feeding tubes should generally only be used in a worst-case scenario, due to their unpleasantness for patients and because of the dangers associated with them (Daniels et al., 2014).

Patients with dysphagia may also require a family or staff member to feed them or provide verbal cues for increased safety, which can lead to feeding dependency. There are many negative consequences associated with feeding dependency. These include malnutrition (Chavarro-Carvajal, Reyes-Ortiz, Samper-Ternent, Arciniegas, & Gutierrez, 2015) and increased aspiration pneumonia risk (Langmore et al., 1998; Langmore et al., 2002). Verbal cueing from staff members has not been found to increase fluid or food intake or increase body weight (Beattie, Algase, & Song, 2004; Cleary, Hopper, & Van Soest, 2012; Van Ort & Phillips, 1995). Also, cueing and assisted feeding both necessitate a lower patient to staff ratio, which can be difficult to achieve and is time consuming for staff (McGrail & Kelchner, 2015; Simmons, Osterweil, & Schnelle, 2001). Cueing can also result in an interruption to the flow of

conversation in order to provide the verbal cue, potentially resulting in decreased socialization during mealtime. Having a family or staff member cue a patient can reduce a patient's feelings of autonomy during mealtimes (Goldsmith, Lindholm, & Bute, 2006; Shune & Foster, 2017).

Clinicians often use a combination of these strategies when managing dysphagia. However, of the many compensatory strategies that can improve eating safety for individuals with dysphagia, they may also negatively impact various aspects of quality of life.

Smartforks and Decreasing Eating Rate

A slower rate of eating and taking smaller bites of food is a simple strategy that can eliminate the risk of aspiration (Daniels et al., 2014; Groher et al., 2016; Logemann, 1999). Unfortunately, as described above, cueing may not be the most effective or beneficial way to get a patient to reduce eating rate. While primarily intended to promote weight loss, smartforks have recently appeared on the market and in research as a strategy for reducing eating rate (Hermans, Hermsen, Robingson, Higgs, Mars, & Frost, 2017; Hermsen, Frost, Robinson, Higgs, Mars, & Hermans, 2016). Smartforks use a combination of vibrotactile feedback and visual colored lights that indicate eating speed to aid in slowing the rate of eating. These forks allow the user to set a target interval for eating rate (e.g., ranging from a bite every 6 seconds to a bite every 2 minutes). If the fork senses that a bite has been taken too soon, it will vibrate and light up to alert the user. Specifically, for the purpose of weight loss, research has found that smart forks that provide vibrotactile feedback during mealtimes can be very effective in reducing rate of eating (Hermans et al., 2017; Hermsen et al., 2016). Previous research

has explored how individuals with normal swallowing and eating function perceive using the fork to eat regular meals. It is important to note that this fork was originally designed to aid with weight loss and was not originally meant to be used clinically with patients with dysphagia (Hermans et al., 2017). The results of the preliminary testing of this fork in individuals without dysphagia found that participants who used it felt the size and shape was perfectly acceptable and, though the vibrotactile feedback was strong enough to be effective, the feedback was not so disrupting that it alarmed anyone while they ate. They also found that these otherwise healthy participants were very aware of their eating rate and therefore ate slower with the use of the fork. Importantly, none of the participants felt embarrassed when eating with the fork around company. Rather, they expressed that it was a topic of conversation and sparked further conversation about healthy eating and eating rates (Hermsen et al., 2016). This suggests that the fork may have clinical utility in aiding individuals with swallowing disorders eat in a healthier way, with a rate that may reduce the risk of choking or aspiration.

PURPOSE OF CURRENT STUDY

Problem

Dysphagia is associated with overall decreased safety and decreased quality of life. Patients with dysphagia are at a tremendously high risk of choking and aspirating while eating and drinking. Individuals with dysphagia also have very high rates of depression and anxiety, specifically surrounding food and mealtime. Being unable to participate or feeling embarrassed participating in social mealtimes greatly decreases quality of life. While a variety of compensatory strategies exist that attempt to target increased safety, they often do so at the expense of decreased quality of life. The use of a more naturalistic, external cueing aid for decreased eating rate (i.e., a smartfork) may simultaneously target increased safety and increased autonomy, offering a more appropriate treatment alternative to current options.

Research Questions and Hypotheses

The current study addresses the following questions:

1) Can a smartfork that uses vibrotactile and visual feedback reduce the rate of eating for people with dysphagia? If it does, it could be an alternative tool to ensure that individuals with dysphagia who need to eat at a slower rate for safety reasons are indeed eating slower. There are several methods to reduce rate of eating (e.g., verbal cueing, reminders), but a smartfork has the potential to reduce rate of eating without involving another person and therefore increasing patient autonomy and safety simultaneously. In the current study, it was expected that the use of a smartfork would be just as effective,

if not more effective, than the baseline condition (eating under “typical conditions” with the feedback turned off).

2) When using a smartfork to control rate of eating, do participants find it to be helpful and do they enjoy using the fork? It is important to gather information about individuals’ perceptions regarding fork use because if individuals with dysphagia dislike using the fork, or do not find it helpful, it will not be a successful method to reduce rate of eating. Liking, or at least not disliking, the smartfork is imperative to the effectiveness of the fork. It was expected that the participants would find the fork to be unobtrusive and helpful when eating.

METHODS AND PROCEDURE

Participants

Inclusion criteria. The participants were patients in the inpatient rehabilitation center at PeaceHealth Sacred Heart Medical Center University District (Oregon Rehabilitation Center). All participants were receiving rehabilitation services following a stroke and had dysphagia as determined by the facility's speech-language pathologists. Additional inclusion criteria were moderately broad and included: adults (ages 18-100), adequate cognition for providing informed consent (see appendix A – informed consent document) and for being able to understand the meaning of the fork's vibrations, be able to self-feed, and have a therapy recommendation for decreased eating rate. Involvement in this project was open to both sexes and in no case was sex used as an inclusion/exclusion criterion. Additionally, in no case was minority status used as an inclusion/exclusion criterion. All participants met the above criteria.

Recruitment and informed consent. All procedures were approved by the University of Oregon's Institutional Review Board prior to study commencement. Speech-language pathologists at ORC, Lisa Newman and Kersten Carr, assisted with recruitment. When they had a patient that met the above inclusion criteria, they provided them with a recruitment flyer that contained information on how to contact the research team (see appendix B – recruitment flyer). They in no way made the patients feel obligated to participate and the flyers clearly indicated that the research study was through the University of Oregon (not ORC) in order to further emphasize that the decision to participate or not would in no way influence the therapy services a patient was receiving. Participants were offered a \$10 Target gift card as compensation for their

time and as an incentive for participants to enroll in the study. Participants were asked screening questions by the researcher (see appendix C – screening questions) to determine eligibility to participate in the study prior to beginning the study.

After completing the informed consent process, the participants were asked if they would be willing to sign a release of medical information form. This allowed the research staff to gather medically relevant and demographic information about the participants (including date of stroke, type of stroke, location of stroke, dysphagia severity and characteristics – see Table 1). It was made clear to the participants that they would still be able to participate in the study if they chose not to release this information. Having access to this information aided in informing which demographics the fork might be most effective for based on specific patient profiles. All participants agreed to the release of information.

Participant characteristics. This study had three participants in total. All met the inclusion criteria. Table 1 below presents participant demographics information.

Equipment

The HAPIfork (hapi.com) was the smartfork used in this study. It is the only smartfork commercially available for purchase. Figure 2 below shows the components of a generic smartfork, which is similar in make to the HAPIfork.

HAPIfork specifications. The HAPIfork contains an electronic key with a circuit that links the fork tines with the handle. When the fork enters the mouth, the circuit closes. The device is able to count the number of fork servings during a meal (i.e., from one bite to the next bite) because it interacts solely with the mouth and hand (hapi.com).

Variable	Participant Code		
	A	B	C
Age (in years)	71	77	58
Gender	Female	Female	Male
Etiology (type of stroke)	Right frontal hemorrhagic stroke	Left basal ganglion stroke	Right middle cerebral artery stroke and uncontrolled hypertension
Toime (post stroke onset*)	14 days	100 days	18 days
Handedness	Right	Right	Right
Concomitant medical condtions	Decreased functional mobility, ADL capacity, cognition, and swallowing secondary to stroke	Hemiparesis affecting right side, right hemiplegia, and deficits in functional mobility, delayed swallow, and decreased vision	Decreased functional mobility, ADL capacities, cognition, and swallow, uncontrolled hypertension, vision problems
Preexisting conditions	COPD, hyperlipidemia, moderate OSA, depression, chronic back pain/sciatica, osteoporosis, hiatal hernia, anemia, osteoarthritis, and prediabetes	CVA occurring 20 years ago due to embolism of cerebral artery, essential hypertension, history of left breast cancer, neuropathy, lobar emphysema, peripheral vascular disease, recurrent major depressive order, restless leg syndrome, seizure disorder, acquired hypothyroidism, chronic GERD, history of left carotid artery stenosis, diabetes mellitus, chronic UTI, panlobular emphysema, dysarthria of speech	Hypertension, anxiety disorder, possible OSA
MMSE (out of 30)	29	27	23
Swallowing status/diets recommendations	Dysphagia. Modified diet: pureed food, thin liquids. Aspiration recommendations: cued eating, small bites, complete swallow before next bite, check oral clearance	Dysphagia. Modified diet: nectar thick liquids with chin tuck and head turning. Pneumonia risk, fluid balance and nutritional intake risk, do diet level available	Dysphagia. Modified diet: mechanical soft with thin liquids. Has left neglect, with attention and memory problems – requires supervision during meals
Other	Former smoker (smoked at least 100 cigarettes in lifetime) chronic back pain treated with opioid use, does not consume alcohol, or use recreational drugs	Former smoker (2 packs a day for 40 years, quit 1992), does not consume alcohol or recreational drugs	Smoker (has smoked at least 100 cigarettes in lifetime – is currently down to 6-9 a day, wants to fully quit), does not consume alcohol or use recreational drugs

Table 1. Relevant participant demographic information. *Time between stroke onset and first day of study. Note: ADL = activities of daily living; COPD = chronic obstructive pulmonary disease; CVA = stroke or cerebrovascular accident; GERD = gastroesophageal reflux disease (acid reflux); MMSE = Mini Mental State Examination; OSA = obstructive sleep apnea; UTI = urinary tract infection.

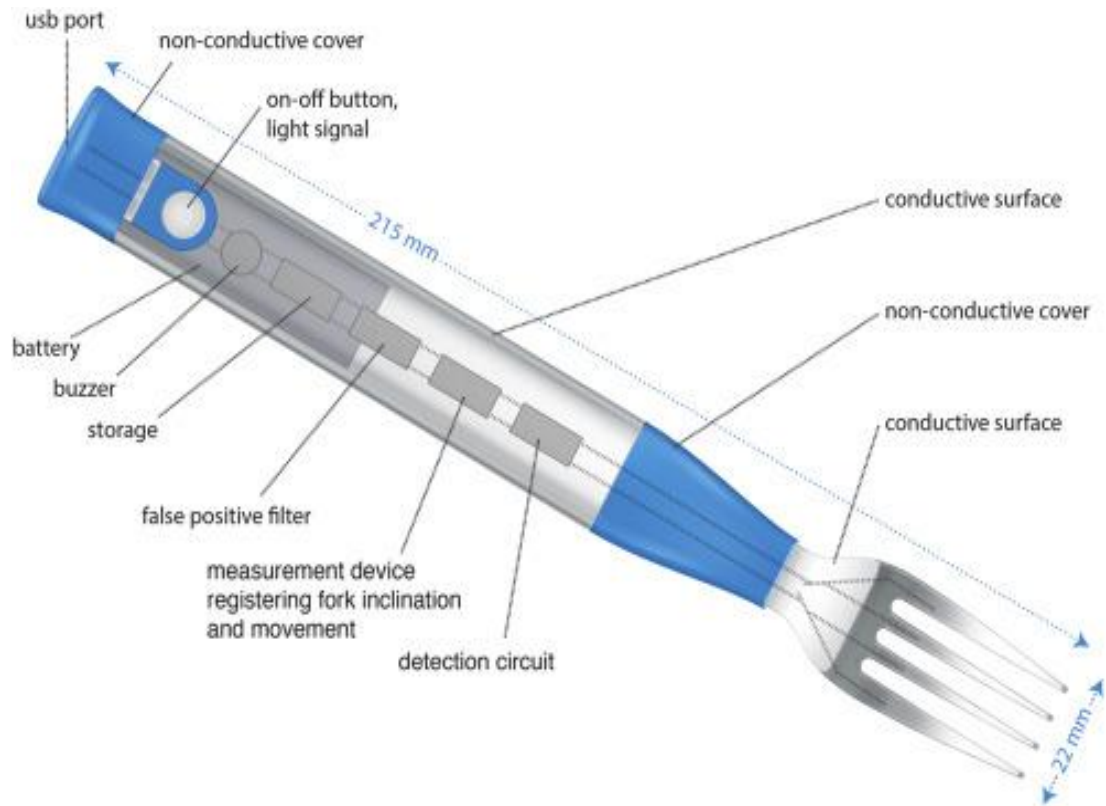


Figure 2. An illustration of a smartfork
(Hermsen et al., 2016).

The HAPIfork is light, durable and easily transportable; it even comes with a carrying case. The fork's dimensions are:

Length: 7.87 inches - 200 mm

Width: 1 inch - 24.5 mm

Height: 0.66 inch - 15.70 mm

Weight: 0.14 pound - 65 grams

The target time interval between bites can be set to be between 6 and 15 seconds, 20, 25, 30, 60, 90, or 120 seconds. There are several different modes that can be used with

the HAPIfork. The fork can be muted (does not give any vibrotactile feedback or visual cueing), the alarm can be turned on (the default setting where only vibrotactile feedback is turned on and will vibrate when the user takes a bite too quickly) or the fork can be in coaching mode (both vibrotactile and visual feedback is turned on). The intensity of vibrations can also be adjusted to gentle, medium, or strong. For this study, the fork's vibrations were set to medium. The vibrotactile feedback is perceived as a slight vibration in the hand; on the medium setting, it is strong enough to be noticeable, but not strong enough to cause the user to drop their food. The user only feels the vibration when they are eating at a rate that is faster than the target interval; in other words, if the fork senses that the user has taken a bite before the target interval has passed, it will vibrate. The visual feedback comes from a small red or green light on the handle of the fork. The light coincides with the target interval; if the light is green, it means that the allotted interval has passed since the previous bite, if the light is red, it means that the allotted time has not passed. If the fork is set on alarm only (vibrotactile feedback when rate is too fast only), and the user takes a bite prior to the allotted time passing, the light will flash red, but there will be no green light to indicate when the allotted time has passed. There are three fork settings to optimize the fork's data collection dependent on an individual's typical eating pattern (e.g., scooping food with the fork, stabbing the food, and mixed). For the purpose of this study, the fork was on the default "data lover" mode which is conducive for any method of eating (mix of scooping and stabbing).

Data syncing. After downloading the connecting software to a computer, the HAPIfork can be attached to the computer via a USB cable and the data can be synced from the fork to the computer for analysis. After initially syncing the data with a

computer, the fork can be synced with a smartphone or tablet via Bluetooth. This function makes accessing data very easy and simple, and also allows for control of the fork from a smartphone or tablet (hapi.com).

Procedure

Data was collected over the course of two days from participants in the dining room of ORC when eating “typically” (day one) and when using the smartfork (day two). After providing informed consent, participants were asked to eat with the smartfork for 1 minute while the researcher counted how many bites they took to establish a baseline eating rate. The researcher then decreased the baseline rate of eating by 20% to be the target eating rate for each participant during the study. This was done by dividing the number of bites taken during the baseline period by 60, then multiplying it by 1.2 $[(X/60) * 1.2 = \text{the target eating rate, where } X \text{ was the number of bites during the baseline period}]$. The resulting number was rounded up to be the next closest whole number. Because the smartfork does not offer every possible number for target rate, if the target rate of eating was unavailable, it was rounded up to the nearest interval available. Each participant’s target rate of eating was therefore set at 20% of their baseline or slower.

After completing the baseline rate of eating assessment on the first day, participants were then asked to eat their meal (breakfast or lunch) with the smartfork. The fork was muted or turned entirely off so for the duration of their meal participants did not receive any feedback (vibrotactile or visual) on their rate of eating. All participants ate in the dining room with other patients, family members and staff available to talk with as is typical. The researcher remained in the dining room and

acted as any other staff member (e.g., brought patients milk when requested, answered questions about the fork during the meal). Participants chose if they wanted to talk with other patients or staff members – this mimicked a normal eating environment for each individual. After finishing their meal, participants were asked to fill out a survey with questions about their experience with the smartfork (see appendix D – surveys). They were given the opportunity to elaborate on the survey if they wished. Trial one was video recorded for later data analysis.

The second trial occurred no more than 2 days after trial one and was done at the same time of day (i.e., at breakfast for both trial one and two or at lunch for both). During trial two, the participants were asked to eat a meal using the same smartfork as the previous trial, however, this time the fork was turned on to coaching mode. Coaching mode provides vibrotactile as well as visual feedback on the participant's rate of eating. Prior to beginning the meal, the researcher explained that the fork would provide vibrotactile feedback if the participant's rate of eating was faster than the target rate. The research also explained that a green light indicated that the target time before another bite had passed, while a red light indicated that the target time had not yet passed and another bite should not yet be taken. The participants were again in the dining room with other patients, family members and staff. The researcher remained in the room just as in trial one. The participant was then asked to eat their meal and try to adhere to the feedback from the fork – if they felt the fork vibrate because they were eating too quickly, they should attempt to slow their rate of eating to match the target rate, or if they saw that the red light was showing, they should wait until it turned green to continuing eating. After the participants had finished their meal, they were asked

again to fill out a survey regarding how they felt about using the fork. They were given the opportunity to elaborate on the survey verbally if they wished. Trial two was video recorded for later data analysis. Participants ate different foods during their meals for trial one and two depending on what was being served in the dining room, however the meals were similar in that participants' dietary modifications were the same for both meals and the meals were at the same time of the day for each trial.

Data Analysis

After collecting data, results were compared between the two trials for each participant individually. The independent variable was the trial (using the fork on coaching mode versus muted or turned off) and the dependent variables included: 1) the participant's rate of eating, 2) outward signs of aspiration, including choking or coughing, and 3) opinions about the fork used. The dependent variables are further defined below. The first two dependent variables were coded from the video recordings and the third variable was taken from the survey results. Additional qualitative data were collected on what the participant ate or drank during each trial, including which meal was consumed. As the food and drink was different between trial one and two, it could affect the results of the study and are considered in the results. Descriptive statistics were used to describe the differences between the conditions for each participant.

Definition of dependent variables. Participant's rate of eating refers to how many bites were taken every one minute and the length of time between bites. These data were calculated as number of bites per minute and number of seconds between bites. Rate of eating was calculated for all bites and sips (i.e., combination of bites taken

with the smartfork, bites taken with any other utensil or using the hands, and sips taken) and rate of eating was also calculated for bites taken with the smartfork only. In order to calculate rate of eating for all bites and sips, the number of seconds between all bites and sips was calculated and divided by number of bites and sips. To calculate the rate of eating for smartfork bites only, the researchers calculated the total time between all successive smartfork bites (i.e., when there were two or more smartfork bites in a row), and then divided that time by total number of successive smartfork bites. In other words, for a smartfork bite to be included in the data for the second calculation, two (or more) fork bites had to occur in a row. This criterion was set by the researcher as a way to separate out bites taken with the smartfork from bites taken with other utensils.

Outward signs of aspiration refers to if the participant was seen to cough or choke at any time during either trial. Because the researcher was relying solely on visual cues, it is possible that aspiration events were missed (i.e., silent aspiration). However, outward signs of choking/coughing are commonly used signs by nursing staff to indicate possible aspiration and/or choking risk. Opinions about the fork used refers to various questions asked about the participants' experience using the smartfork under the two conditions and their perceptions about its use and comfort.

RESULTS

Given the great variability in performance between the three participants, the results for each participant are first presented separately. The results taken from the smartfork will be presented first, followed by the survey results, and lastly observations noted during mealtimes. A brief summary of the overall results across all participants will follow.

Participant A

Results for participant A are presented in Table 2.

Variable	Trial Number	
	1	2
Food and beverage consumed	French toast, scrambled eggs, muffin, milk, and juice	Scrambled eggs, toast, and juice
Meal duration (in minutes and seconds)	11:57	39:57
Total number of bites and sips taken	19	49
Number of seconds between bites and sips	37.737	48.918
Bites and sips per minute	1.59	1.227
Smartfork bites per minute	2.167	1.883
Seconds between smartfork bites	27.692	31.857
Percent of time target rate was achieved	54%	78%
Target rate of eating (seconds between bites)	15	

Table 2. Results for participant A

The overall mealtime duration differed greatly between trial one and two for participant A; during trial one, she ate for approximately 12 minutes (11:57), while during trial two, she ate for approximately 40 minutes (39:57). Based on her baseline eating rate of 12 seconds between bites (5 bites per minute), her target eating rate was set to be 15 seconds between bites (a 20% increase of 12 is 14.4, which rounds up to 15 seconds between bites). Participant A's overall rate of eating including all bites and sips was 1.59 bites and sips per minute (37.74 seconds between bites/sips) during trial one and 1.23 bites and sips per minute (48.92 seconds between bites/sips) during trial two. Together this indicates that she had an overall slower rate of eating during trial two with an increase of approximately 11 more seconds, on average, occurring between bites/sips. When comparing only successive fork bites, participant A again demonstrated a decreased rate in the second trial: 2.17 smartfork bites/minute (27.69 seconds between bites) versus 1.88 smartfork bites/minute (31.86 seconds between bites) for trials one and two, respectively. Participant A's smartfork rate of eating slowed by approximately 4 seconds between trials one and two. Overall, participant A was more successful at achieving her target rate of eating (15 seconds) in the second trial (78% of her bite intervals) as compared to the first trial (54% of her intervals).

Survey results for participant A are presented in Table 3. All survey question ratings were from 1 to 10, with 1 being the least agreement (1 indicated that the participant did not agree at all with the statement), and 10 being the most agreement (10 indicates that the participant strongly agreed with the statement). A rating of 5 indicated neither agreeing nor disagreeing. Survey results taken after trial one indicated that participant A found her eating experience to be adequate. She rated her overall eating

experience at a 6 and rated her satiation levels at 7. She rated how easy the smartfork was to use at a 6, indicating that the fork was a comfortable size and weight, comparable to other cutlery (rating it at 9). She found the fork mostly unobtrusive while eating and felt comfortable using the fork around other people (8).

Question	Trial Number	
	1	2
How would you rate your eating experience using the HAPIfork?	6	8
How would you rate your satiation levels after this meal?	7	9
Was the fork easy to use?	6	9
Did the size and weight of the fork compare well to cutlery you usually use? Was the size and weight acceptable to you?	9	10
Was using the HAPIfork unobtrusive while eating?	8	n/a
Did you feel comfortable using the HAPIfork while eating around other people?	8	9
How much did using the HAPIfork alter your rate of eating?	n/a	5
Did you feel like you ate slower than normal while using the HAPIfork?	n/a	2
If the HAPIfork were available to use, would you use it to aid in reducing your rate of eating?	n/a	8
How intrusive were the vibrations from the fork while eating?	n/a	2

Table 3. Survey results for participant A

After trial two, she rated her overall eating experience at 8. She rated her satiation levels and ease of use for the smartfork at 9. She found the fork to be comparable to other cutlery and found the fork size and weight was excellent (10). She still felt comfortable using the fork around other people (9). She was unsure if her rate of eating was altered by the smartfork (5) and felt that it did not slow down her rate of eating (2). The vibrations were not intrusive while eating (rated at 2). Participant A rated her likelihood of using a smartfork, were it available to her, at 8.

During trial one, participant A's daughter came partway through her meal and engaged with her in conversation. This did not significantly distract Participant A from her meal and it mimicked a regular meal spent with family or friends. During trial two, she spent a significant amount of time sitting at the dining table, talking with another patient, without eating. This conversation disrupted her meal more than the conversation during trial one. She had already taken a few bites and sips before the conversation began, thus, the time she spent conversing, rather than eating, was difficult to determine out of her total meal duration time. It is evident, however, that she did take significantly more bites and sips during trial two versus trial one, which would indicate that despite her periods of not eating, her second mealtime was longer due to more bites, not just due to taking breaks from eating for conversation. Many of these bites and sips were bites of toast and sips of juice, which were not used when calculating smartfork rate of eating. During trial one, the food she ate was more conducive for eating with a fork (French toast, scrambled eggs, and a muffin), versus during trial two, she ate scrambled eggs and toast – of which, only the scrambled eggs were eating with a fork. Consequently, there is more smartfork data from trial one than from trial two.

Participant A coughed a few times during trial one following bites of solid food (e.g., eggs). She drank some juice after coughing which helped her to stop. She did not show any other signs of choking or aspirating and finished her meal without issues. She did not exhibit any coughing directly related to eating during trial two.

Participant B

Results for participant B are presented in Table 4. The overall mealtime duration varied significantly between trial one and two for participant B; during trial one, she ate

Variable	Trial Number	
	1	2
Food and beverage consumed	Salad, bread, lunchmeat, and a chocolate milkshake	Salad, spinach dish, sandwich, and a chocolate milkshake
Meal duration (in minutes and seconds)	7:55	26:07
Total number of bites and sips taken	27	79
Number of seconds between bites and sips	17.593	19.835
Bites and sips per minute	3.411	3.025
Smartfork bites per minute	4.195	2.982
Seconds between smartfork bites	14.304	20.118
Percent of time target rate was achieved	33%	44%
Target rate of eating (seconds between bites)	20	

Table 4. Results for participant B

for approximately 8 minutes (7:55), and during trial two, she ate for approximately 26 minutes (26:07). Based on her baseline eating rate of 15 seconds between bites (4 bites per minute), her target eating rate was set to be 20 seconds between bites (a 20%

increase of 15 is 18, which rounds up to 20 seconds between bites). Participant B's overall rate of eating including all bites and sips was 3.41 bites and sips per minute (17.59 seconds between bites/sips) during trial one and 3.03 bites and sips per minute (19.83 seconds between bites/sips) during trial two. Her eating rate for bites and sips slowed by a bit over 2 seconds between trial one and two. Participant B's rate of eating slowed down for successive smartfork bite rates as well: for trial one, she took 4.20 bites per minute (14.30 seconds between bites) and for trial two, she took 2.98 bites per minute (20.12 seconds between bites). This indicates a slower rate of eating by approximately 6 seconds, which is less than when all bites and sips were calculated together. Overall, she achieved her target rate of eating 33% of the time during trial one, and 44% of the time during trial two.

Survey results for participant B are presented in Table 5. After trial one, participant B rated all survey questions at 10, except for the question about how much the smartfork changed her rate of eating (rated at 1); indicating that it did not change her rate of eating when not turned on. After trial two, she rated every question at 10, except the question about how intrusive the vibrations were (rated at 1), indicating the vibrations were not intrusive. The results from both surveys indicate that she found the smartfork to be comfortable to use around other people, a nice size and weight, and helpful when eating, the vibrations to be unobtrusive, and that she would use the fork if it were available.

During trial one, participant B's husband sat with her and talked with her intermittently throughout the meal. Per participant report, her husband usually sat with her during mealtimes and reminded her to slow her rate of eating, which he

also did during trial one. During trial two, however, he sat at another table and did not talk to her during the meal, or provide feedback on her rate of eating. This better ensured that she slowed her rate of eating because of the smartfork, rather than because she listened to her husband's cues. During trial one, participant B had

Question	Trial Number	
	1	2
How would you rate your eating experience using the HAPIfork?	10	10
How would you rate your satiation levels after this meal?	10	10
Was the fork easy to use?	10	10
Did the size and weight of the fork compare well to cutlery you usually use? Was the size and weight acceptable to you?	10	10
Was using the HAPIfork unobtrusive while eating?	10	n/a
Did you feel comfortable using the HAPIfork while eating around other people?	10	10
How much did using the HAPIfork alter your rate of eating?	1	10
Did you feel like you ate slower than normal while using the HAPIfork?	n/a	10
If the HAPIfork were available to use, would you use it to aid in reducing your rate of eating?	n/a	10
How intrusive were the vibrations from the fork while eating?	n/a	1

Table 5. Survey results for participant B

a sandwich and salad. Before the trial began, her husband cut all of her food into bite size pieces so that it could all be eaten with a fork. For trial two, she had a sandwich, salad, and spinach dish. Again, her husband cut her sandwich up to make it easier to eat with a fork. Trial one had a shorter meal duration than trial two because the researcher was not present for the entirety of the meal for trial one; thus, less data was collected. On average, she did reduce her rate of eating for both trials and was within her target rate of eating both with the smartfork feedback on and with it off. However, the percent of times she was within the target rate increased from trial one to trial two, with the use of the smartfork. Participant B found the smartfork to be effective and pleasant to use and even purchased one for her own personal use following the study. It is unknown, however, the frequency with which she uses it, and how helpful she perceived it to be after longer term use. Participant B coughed minimally in trial two but recovered quickly and finished her meal.

Participant C

Results for participant C are presented in Table 6. The meal duration varied for participant C: during trial one, he ate for approximately 19 minutes (18:49), and for trial two, he ate for approximately 9 minutes (8:31). Based on her baseline eating rate of 20 seconds between bites (3 bites per minute), her target eating rate was set to be 25 seconds between bites (a 20% increase of 20 is 24, which rounds up to 25 seconds between bites). Participant C's overall rate of eating including all bites and sips was 1.70 bites and sips per minute (35.28 seconds between bites/sips) for trial one, and 2.23 bites and sips per minute (26.89 seconds between bites/sips) for trial two. This indicates a faster rate of eating for trial two, by approximately 9 seconds. Participant C's

Variable	Trial Number	
	1	2
Food and beverage consumed	French toast, scrambled eggs, and milk	Scrambled eggs, biscuit, banana, and milk
Meal duration (in minutes and seconds)	18:49	8:31
Total number of bites and sips taken	32	19
Number of seconds between bites and sips	35.281	26.895
Bites and sips per minute	1.7	2.231
Smartfork bites per minute	2.887	3.871
Seconds between smartfork bites	20.786	15.5
Percent of time target rate was achieved	53%	44%
Target rate of eating (seconds between bites)	24	

Table 6. Results for participant C

successive smartfork bite rate also increased between trial one and two: 2.89 smartfork bites/minute (20.79 bites per second) and 3.87 smartfork bites/minute (15.50 seconds between bites), respectively. This is an increase of approximately 5 seconds. Participant C achieved his target rate of eating 53% of the time for trial one, and 44% for trial two.

Survey results for participant C are presented in Table 7. The results for after trial one, indicated that his experience was excellent; all questions were rated at 10, except for the question about whether the smartfork altered his rate of eating (rated at 1), indicating that the smartfork did not slow him down when not turned on. After trial two, participant C found the fork to be easy to eat with, comfortable, and a pleasant size

and weight (10). He remarked on how the handle size was better than ordinary cutlery. He felt satiated (10). He marked how much his rate of eating was affected at a 5 and if he thought he ate at a slower pace at a 4. He felt comfortable using the fork around other people (10) and felt that if the smartfork were available to him, he would use it to

Question	Trial Number	
	1	2
How would you rate your eating experience using the HAPIfork?	10	10
How would you rate your satiation levels after this meal?	10	10
Was the fork easy to use?	10	10
Did the size and weight of the fork compare well to cutlery you usually use? Was the size and weight acceptable to you?	10	10
Was using the HAPIfork unobtrusive while eating?	10	n/a
Did you feel comfortable using the HAPIfork while eating around other people?	10	10
How much did using the HAPIfork alter your rate of eating?	1	5
Did you feel like you ate slower than normal while using the HAPIfork?	n/a	4
If the HAPIfork were available to use, would you use it to aid in reducing your rate of eating?	n/a	10
How intrusive were the vibrations from the fork while eating?	n/a	n/a

Table 7. Survey results for participant C

slow his rate of eating (10). The question about modified textures did not apply and the question about vibration levels did not apply because he watched the lights on the fork, and therefore ate at the target rate the entire time; thus, never felt it vibrate.

During trial one, participant C's meal was conducive to eating with a fork (French toast, and scrambled eggs) and he indicated that he enjoyed it, whereas during trial two, he did not like his breakfast and most of it was not food usually eaten with a fork (scramble eggs, biscuit and banana). He expressed displeasure at his meal and hurried through it presumably because he did not like it. He also did not eat the whole meal. The fact that he did not like his meal during trial two could be a reason for his significantly shorter mealtime, and possibly also for his faster rate of eating despite the feedback from the fork. He remarked multiple times after his meal that the fork was very comfortable and that he liked the thickness of the handle. He also mentioned that he thought the fork would be helpful for people. The data from trial two for participant C is not enough to properly calculate his smartfork rate of eating; he only took two consecutive smartfork bites, meaning that his smartfork bite rate was calculated from only two bites. He closely followed the visual feedback from the smartfork and took great care not to take fork bites before the allotted time had passed, but while he waited for the time to pass, he would take bites of his biscuit or banana which do not require a fork to eat. Participant C did not cough noticeably in either trial.

Of note, participant C had an MMSE score that was significantly lower than the other participants (23 out of 30). When administering the MMSE, it was evident that he was cognitively aware enough to understand the purpose of and participate in the study,

but that he was confused about date and time. The tasks on the MMSE that involved writing or drawing were difficult for him as well because of his visual problems.

Summary

Participants A and B slowed their rates of eating using the smartfork when including all bites and sips and when only successive smartfork bites were calculated. They also had longer meal durations during trial two. Percentage of time that participants A and B met their target rate of eating increased for trial two. Participant C had a faster rate of eating during trial one than two. He also had a shorter meal duration for trial two. Participant C met his target rate of eating a smaller percentage of the time during trial two.

All participants found the smartfork to be at least adequate in all areas, however, their perceptions of whether it slowed their rate of eating did not always match what actually occurred (e.g., in the case of participant A). Participant C especially indicated his approval of the smartfork and mentioned its usefulness during trial two.

DISCUSSION

The purpose of this study was to measure the effectiveness of smartforks in reducing rate of eating for individuals recovering from stroke who have dysphagia. It was hypothesized that the smartfork would reduce rate of eating through the use of vibrotactile and visual feedback and that the participants in the study would find the fork to be helpful and enjoy using it. Two of the three participants in this study reduced their rate of eating with the use of the smartfork. Although participant C's overall rate of eating did not decrease with the smartfork, he adhered to the visual cues provided by the fork particularly when consuming fork bites of food, indicating that the cueing from the smartfork was effective to a degree for all participants. All of the participants found the fork to be acceptable to use and indicated that they would use the fork if it were available to them; notably, one participant purchased a smartfork after study completion.

The original purpose of this study was to measure how effectively the smartfork reduced rate of eating, but what was found to be more important during the course of the study was how rate of eating was regulated. The participants frequently ate several bites of food (with or without the smartfork) in rapid succession, and then would take long breaks without eating anything for up to several minutes at a time. Although taking longer breaks is not harmful for individuals who need to reduce their eating rate, it was frequently followed or preceded by a period of rapid eating which could be dangerous or harmful (Fioritti et al., 1997; Logemann 1999; Samuels & Chadwick, 2006). Emphasizing regulating rate of eating rather than simply reducing the overall rate of eating could be a more effective strategy and could better promote a safe eating pace.

There is little to no research done on factors contributing to rate regulation and how rhythm of eating effects satiation levels, digestion, and safety for choking or aspiration risk populations. This would be an important next step for better understanding the typical eating process as well as safety in clinical populations. It is imperative that patients who need to eat with a reduced rate of eating do not have periods of rapid consumption, which would undermine the strategy recommendation (Logemann 1999). Emphasizing a regulated rate of eating by creating a more rhythmic eating pattern could be an effective way of preventing this. Given the way in which many of the participants in the current study attended to the smartfork's cues (see further details below), it is likely that the use of a smartfork could greatly assist with such regulation.

Each of the participants had one meal that was significantly longer than the other. For all of the participants, the meal that was longer in duration was also the meal in which they had a slower rate of eating. This could possibly indicate that one reason for the faster rate during the shorter meal was that they felt hurried. This seems particularly relevant for participant C, who did not like his meal, and seemed hurried to finish because of this. Because the trials took place in a rehabilitation setting, the participants often had therapy sessions scheduled after meals. If they were still eating when it was almost time for an appointment, they could have felt the need to increase their rate in order to finish sooner. In future research, a longer time allotment should be given to finish the meal to ensure that participants do not feel rushed. It should also be taken into account that in typical mealtime settings, patients with reduced rate of eating should not have hurried meals or else they may increase their rate to finish their meal, or not finish it and therefore not feel satiated.

Several questions came up out of the results of this study. The primary question is: what is a normal rate of eating, and what is a normal eating rhythm? It was difficult to find any data on normal rates of eating in healthy population and what was found had limited generalizability beyond healthy young adults (Scisco et al., 2011). There was no data on safe rates of eating for individuals with dysphagia or even an operationalized definition of “reduced rate of eating” despite it commonly being used as a therapeutic strategy. Because the scale of the current study was so small, no conclusions can be made about typical rates of eating for this population, despite all having recommendations by their speech-language pathologists to reduce their rate of eating for increased safety. It was evident, however, that none of the three participants ate with a consistent rhythm. The fact that bites either occurred within very short succession or that long periods of time elapsed between bites suggests that establishing a consistent eating rhythm may be important to establishing a safe and slower rate of eating. It would be much easier to adhere to a specified rate of eating if one is focusing on eating rhythmically and with predictable regularity as compared to when simply given the recommendation to “slow down”. Further, this inconsistent rhythm also might be the factor that prompts speech-language pathologists to recommend a slower eating rate (i.e., the therapists are attending to a rhythm problem and interpreting it as an overall rate issue).

An important factor that would have ensured the collection of more consistent data and allowed for a better assessment of the success of the smartfork would have been to tell participants that they should not eat or drink anything, whether with the fork or not, while the red light was displayed on the fork. Because this was not said, all of

the participants ate or drank at some point between smartfork bites. This was an ineffective way of regulating rate of eating, and although the initial focus of the current study was on slowing overall rate, and made it harder to calculate smartfork rates of eating because there were fewer consecutive smartfork bites. Also, either ensuring that food and liquid is not consumed between smartfork bites, or providing explicit instructions to continue to monitor the smartfork signals (and make contact with the fork to reset bite time) with other foods/drinks, would make it easier to generalize the regulated rate to all items consumed during that meal. This would therefore be a more effective way of increasing eating safety for patients at risk of aspiration or choking from eating too quickly. In future research, it could be stressed that nothing should be eaten or drunk while the red light is displayed on the smartfork, including foods that do not need a fork to eat, so that rate of eating is regulated throughout the entire meal, not just with smartfork bites. It also could be beneficial to expand the smartfork technology into spoons and/or cups that could sync together. However, this technology does not yet exist. Overall, it would be far safer to regulate and reduce rate across the entire meal when a slow rate is recommended by an SLP rather than just portions of the meal (Fioritti et al., 1997; Logemann 1999; Samuels & Chadwick, 2005).

The researcher did not anticipate that the participants would take bites of food without the smartfork between smartfork bites during trial two. The fact that all three participants, at times, would alternate smartfork bites and taking bites or sips of other foods made it harder to calculate smartfork rate of eating because there were fewer consecutive smartfork bites, and could have possibly skewed the data. This is especially evident in participant C's trial two: he adhered to the smartfork feedback for fork bites,

but frequently ate/drunk between fork bites and therefore his overall rate is faster than the smartfork target rate.

The HAPIfork smartfork was created to aid in weight loss specifically through decreasing rate of eating. For the purposes of establishing a safer eating rate and rhythm for individuals with dysphagia, there are some improvements that could be made on the smartfork. If the smartfork had a wider range of options for seconds between bites, bite rate could be better customized for individual needs and rates. Perhaps the most important adjustment would be to make the smartfork vibrate when the allotted time has passed to signal that it is time for another bite, rather than only vibrating when the user is eating too quickly. The participants of this study paid significantly more attention to the visual feedback on the fork than to the vibrations; especially participants B and C, who did not cause the smartfork to vibrate at all. In order to help establish a consistent and safe eating rate, having a gentle vibration serve as a reminder that the allotted time has passed could help keep rate of eating consistent and regulated more than vibrating when the user is eating too quickly. Participants had no trouble following the red and green lights, and if the fork were to vibrate when it was time to take another bite rather than only if the rate of eating was too fast, participants would not need to pay as much attention to the smartfork itself. Receiving proprioceptive feedback from the arm and hand while eating has been shown to be important and provides different cues than visual cues. For example, proprioception has been found to be an essential cue for timing mouth opening for eating in both older and younger adults, supporting its natural role in the eating process (Shune, Moon, & Goodman, 2016). For this reason as well, having vibrotactile feedback from the fork to indicate the allotted time has passed could

be more beneficial than having the visual cue alone. Together, these cues could allow for a more natural eating experience with fewer of the negative consequences of dysphagia. The use of the smartfork could also increase autonomy and desire to eat which are a significant issue for many people with dysphagia (Ekberg et al., 2002; Shune & Foster, 2017). This could increase quality of life and could lessen some of the emotional stressors of having dysphagia, such as depression (Ekberg et al., 2002; Eslick et al., 2008; Leow et al., 2010), anxiety (Ekberg et al., 2002; Eslick et al., 2008), and feelings of isolation (Ekberg et al., 2002).

There is evidence that errorless learning is often very helpful and effective in teaching new skills because it helps with memory performance and recall (Bridger & Mecklinger, 2014), and avoids reinforcing error patterns (Manasco, 2017). When learning a new activity, in this case, learning to eat slower and with more regularity, it would be better learned through repetition of the correct pattern rather than by making errors and having the smartfork notify the user of the error (Bridger & Mecklinger, 2014; Manasco, 2017). Practicing a new skill with errors can be likened to practicing an error pattern and will increase the likelihood of future errors being made (Manasco, 2017). Making a mistake when learning a new pattern is not beneficial for learning that pattern; thus, eating too quickly and being corrected by the smartfork would not be as beneficial as being taught when to eat and then internalizing that eating rhythm and speed with repetition over time. Errorless learning, rather than the trial-and-error approach, has been found to be beneficial for individuals with cognitive impairments (such as impaired executive function and attention), including individuals following

traumatic brain injury and stroke. Thus, this is likely an appropriate strategy to use for individuals with dysphagia related to neurologic impairment.

These changes to the smartfork itself and the use of the smartfork would not only make it easier and more effective to use for individuals with dysphagia, but it would also make it easier for aides or other caregivers to feed individuals who cannot feed themselves. Many individuals are dependent for feeding (i.e., require total feeding assistance) (Milte et al., 2017; Pierson 1999). Unfortunately, many feeding assistants demonstrate difficulty attending to safety recommendations such as decreased rate (Aziz & Campbell-Taylor, 1999; Chadwick, Jolliffe, & Goldbart, 2003) as they often do not receive adequate training (Milte et al., 2017). Using smartforks to regulate rate of eating would make mealtime safer for participants who need a reduced rate and who need special eating accommodations as they would help the aide or caregiver feed patients at a regular pace that is safe and healthy for their needs.

The results of the current study are promising; when using the smartfork to reduce and regulate rate of eating, two of the three participants were successful in slowing their overall rate. Even though participant C did not slow his rate between trials one and two, he still adhered to the visual feedback provided by the fork, which shows that all participants were able to use the smartfork for its intended purpose to some degree in this study. While the smartfork was successful at reducing rate of eating, the slower rate of eating was often not generalized to other foods. With a few adjustments made to the smartfork, or even simply by rewording the instructions for use, the benefits of the smartfork could be maximized and therefore also more be more successful at ensuring safe rates and rhythms of eating.

Another interpretation of these results could be that the participants were more aware of their eating rate during trial two given the nature of the study and ate at a slower rate for that reason alone rather than due to the feedback from the smartfork. This seems unlikely because while observing the participants eating, it was clear that, for example, participant B and C would look at the fork to check for the green light before taking another bite with the smartfork. It is also impossible to rule out additional environmental factors as influencing these findings. Because the conditions for trials one and two were not identical for any of the participants (e.g., meal time started at slightly different times, meal content was different, and there were different conversation partners and staff in the dining room), such environmental factors could also have contributed to the results. Participant C's lower MMSE score could be significant as to why his rate of eating did not decrease with the use of the smartfork; it is possible that cognitive status influences the effectiveness of the smartfork as a therapeutic technique. While it was clear that the participant in the current study understood the purpose of the smartfork and how to use it, it would be beneficial to further explore the appropriateness of a smartfork in a larger sample size with a wider range of cognitive abilities (e.g., individuals with memory impairments).

Additional Limitations

The significant meal duration disparity between trials one and two for all participants resulted in a large discrepancy between how much data was collected for each trial, which could affect the results and the calculations on rates of eating. Future research should attempt to make meal environment more consistent in both trials and

serve the same meal both days to ensure that the meal is at least equally liked and contains similar types of food for each trial.

In the current study, the baseline rate of eating was calculated from only a one minute sample. This was done because of time constraints. Ideally, however, the baseline would be calculated over a much longer period of time; taking the baseline rate of eating during an entire separate trial would give a more accurate measure of the participant's rate of eating to allow for a more precise calculation of target rate and would therefore also give more accurate results on how effective the smartfork is at regulating rate of eating.

This study also had a limited number of participants. Three participants are sufficient to gather preliminary data on this topic, but further research with a larger body of participants and evidence would be needed to fully evaluate whether a smartfork is really comparable to current strategies used, and whether it does increase quality of life in individuals with swallowing disorders. Further research should also establish what a normal and healthy rate of eating is for healthy populations as well as populations with dysphagia or other eating/swallowing disorders and evaluate what effect the use of a smartfork has on aspiration and choking rates and incidences of aspiration pneumonia.

CONCLUSION AND CLINICAL IMPLICATIONS

Overall, this study suggests that a smartfork can be effective in regulating rate of eating. For two out of the three participants, the rate of eating decreased from trial one to trial two, and the percentage of times they took bites within their target bite rate increased from trial one to trial two. Because all participants expressed liking the smartfork and that it was pleasant to use, it seems that the smartfork is an appropriate way to regulate rate of eating for patients recovering from stroke with dysphagia. The use of the smartfork to help regulate rate of eating could have beneficial effects on patient's quality of life and improve attitudes towards mealtime.

The use of the fork for this population could allow for a more typical eating environment and could destigmatize the mealtime for patients with dysphagia. It could afford more autonomy to individuals with dysphagia because the fork could eliminate the need for external cueing from a caregiver. This would not only benefit the patient, who could regain some of their prior eating independence, but also help reduce caregiver burden by requiring less attention from the caregiver while still ensuring safe eating. This method of cueing is less noticeable than verbal cueing which could reduce disruption to conversation and would be less likely to be noticed, which could make people with dysphagia feel more comfortable eating in public or around friends and family. The smartfork is also easily transportable and is therefore also a method that could be used at restaurants or dinner parties in an unobtrusive way. Overall, the smartfork could ameliorate many of the detrimental outcomes of dysphagia, improving overall quality of life.

APPENDICES

Appendix A: Informed consent form



UNIVERSITY OF OREGON

ADULT INFORMED CONSENT DOCUMENT

Project Title: Measuring the effectiveness of the HAPIfork to aid in slower eating for patients with dysphagia

Primary Investigator(s): Samantha Shune, PhD, CCC-SLP
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(541) 346-7494
Communication Disorders and Sciences

Anyasha Aragon-Herbert
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This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered all your questions and you decide that you want to be a part of this study.

Introduction

- You are being asked to be in a research study about the effects of a smart fork on eating patterns, specifically for patients with swallowing problems (dysphagia).
- You were selected as a possible subject because you developed dysphagia following a stroke.
- We ask that you read this form and ask any questions that you may have before agreeing to be in the study.

Purpose of Study:

- The purpose of this study is to determine whether vibrotactile feedback (vibration) from a smart fork impacts eating patterns/eating rate for patients with dysphagia.
- Information gathered from this study may be used to design new therapy approaches or eating strategies for patients with dysphagia.
- It is expected that up to 20 subjects will participate in this study.

Description of the Study Procedures:

- The study will take place during two meals over the course of two to five days.
- During one of the meals, you will be provided with a specific fork to eat with (the “smart fork”). The smart fork will not be turned on and everything else about the meal will be regular. For example, if you usually eat in the dining room, you will still eat in the dining room. If you usually eat with an aide at your table, you will still have the aide at your table.



- During the other meal, you will be provided with the smart fork and the fork will be turned on. The fork will cue you to eat slower using vibration if it senses that your eating rate is too fast. Everything else about the meal will remain as typical as possible.
- Video recordings will be made during the study. The use of these recordings is a required component of the study and will allow us to thoroughly analyze all collected data. No portion of the recordings will be heard or seen outside of the research team without first obtaining your explicit, written permission.
- You will be free to stop the study at any time.
- Individual results will be confidential, but we are happy to discuss any of the study's overall findings with you. If you would like to be notified of this study's findings, please initial here and we will contact you when they are available: _____.

Risks/Discomforts of Being in the Study:

- You may experience one or more of the following risks or uncomfortable conditions during the course of this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.
- As with all daily meals, particularly for individuals with dysphagia, the consumption of foods and liquids may result in coughing or choking. Depending on your experiences, you may find it difficult to talk about your experience with dysphagia. There is also a risk of loss of confidentiality of your information. We will protect the information we collect about you as described in the "Confidentiality" section below.

Benefits of Being in the Study:

- You will not benefit from being in this study.
- We hope that, in the future, other people might benefit from this study because the results may guide the development of better treatment options for individuals with dysphagia.

Payments/Costs:

- You will receive a \$10 gift card upon completion of the study for your participation.
- There is no cost to you to participate in this research study.

Funding:

- A grant from the Robert D. Clark Honors College is funding this study. These funds are being used to support the activities that are required to conduct this study. No one on the research team will receive a direct payment or increase in salary from these funds.

Confidentiality:

- We will keep your participation in this research study confidential to the extent permitted by law. All records will be maintained for ten years for data analysis and publication purposes.
- The records of this study will be kept private. In any sort of report we may publish, we will not include any information that will make it possible to identify any subject. All records will be identified only by a code number.
 - With explicit, written permission, video recordings may be used for educational purposes (e.g., classroom teaching). Please indicate if you release your video for non-research staff viewing (circle one): Yes / No



- If “yes”, we would notify you prior to any non-research use. Please include the best way to contact you here: _____.
- All paper/hard copy records will be maintained in locked filing cabinets in an office or laboratory that is always locked unless a member of the research team is present.
- All electronic information will be coded and secured on password-protected computers.
- Access to the records will be limited to the researchers; however, please note that regulatory agencies, and the Institutional Review Board and internal University of Oregon auditors may review the research records.
- Absolute confidentiality of study participation cannot be guaranteed due to the nature of participation during typical mealtimes. For example, another patient in your rehabilitation facility could disclose information about your participation.

Voluntary Participation/Withdrawal:

- Your participation is voluntary. Your decision to participate or not participate will not affect your current therapies in your facility in any way. If you choose not to participate, it will not affect your current or future relations with the University.
- You are free to withdraw at any time, for whatever reason.
- There is no penalty or loss of benefits for not taking part or for stopping your participation. Not taking part or stopping your participation will not jeopardize present or future faculty/school/University/rehab facility relationships. If you withdraw from the study early, you will not receive compensation.

Contacts and Questions:

- We encourage you to ask questions.
- If you have any questions about the research study itself, please contact: Samantha Shunc, Communication Disorders and Sciences, 249 HEDCO, (541) 346-7494, or email sshunc@uoregon.edu.
- If you believe you may have suffered a research related injury, contact Samantha Shunc at (541) 346-7494 for further instructions.
 - You do not waive any liability rights for personal injury by signing this form. All forms of medical diagnosis and treatment, whether routine or experimental, involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the researchers will assist you in obtaining appropriate medical treatment, but PeaceHealth and the University of Oregon do not provide financial assistance for medical or other costs.
- If you have any questions about your rights as a research subject, you may contact: Research Compliance Services, University of Oregon at (541) 346-2510 or ResearchCompliance@uoregon.edu

Copy of Consent Form:

- You will be given a copy of this form to keep for your records and future reference.



Statement of Consent:

- I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent to participate in this study. I have received (or will receive) a copy of this form.

Study Participant (Print Name)

Participant or Legal Representative Signature

Date

Signature of Person who Obtained Consent

Date

Volunteers Invited

**Adults ages 18-100
are invited to participate in a research study on eating
and swallowing.**

**The study will involve two, one-hour visits. You will be asked
to a regular meal while using a smart fork to track your rate
of eating.**

Compensation will be provided.

**For more information, please contact us:
aaragon3@uoregon.edu
541-517-2681**

Communication Disorders and Sciences Program



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Appendix C: Screening questions

Screening for Fulfilling Eligibility Criteria

Question 1: Are you between the ages of 18 and 100 years old?

Question 2: Are you a patient at the Oregon Rehabilitation Center?

Question 3: Are you recovering from stroke?

Question 4: Has a speech-language pathologist diagnosed you with dysphagia?

Question 5: Are you able to self-feed?

Question 6: Does your speech therapist recommend a decreased eating rate for you?

Question 7: Do you understand that when you feel the fork vibrate, that means you are eating too quickly and should slow your eating rate?

Appendix D: Surveys

Survey 1 for after trial 1:

Please answer the following questions with the most applicable answer.

Question 1:

On a scale of 1-10 (1 being the least, 10 being the most), how would you rate your eating experience using the HAPIfork? (please circle best response)

1 2 3 4 5 6 7 8 9 10

Question 2:

On a scale of 1-10 (1 being the least, 10 being the most), how would you rate your satiation level after this meal? How full do you feel? (please circle best response)

1 2 3 4 5 6 7 8 9 10

Question 3:

On a scale of 1-10 (1 being the least, 10 being the most), was the fork easy to use? (please circle best response)

1 2 3 4 5 6 7 8 9 10

Question 4:

On a scale of 1-10 (1 being the least, 10 being the most), was the size and weight of the fork compare well to the cutlery you usually use? Was the size and weight acceptable to you? (please circle best response)

1 2 3 4 5 6 7 8 9 10

Question 5:

On a scale of 1-10 (1 being the least, 10 being the most), was using the HAPIfork unobtrusive while eating? (please circle best response)

1 2 3 4 5 6 7 8 9 10

Question 6:

On a scale of 1-10 (1 being the least, 10 being the most), did you feel comfortable using the HAPIfork while eating around other people? (please circle best response)

1 2 3 4 5 6 7 8 9 10

Question 7:

On a scale of 1-10 (1 being the least, 10 being the most), was the HAPIfork usable while eating modified textured foods (pureed or minced)? (please circle best response)

1 2 3 4 5 6 7 8 9 10

Question 8:

On a scale of 1-10 (1 being the least, 10 being the most), how much did using the HAPIfork alter your eating rate? (please circle best response)

1 2 3 4 5 6 7 8 9 10

Survey 2 for after trial 2:

Please answer the following questions with the most applicable answer.

Question 1:

On a scale of 1-10 (1 being the least, 10 being the most), how would you rate your eating experience using the HAPIfork? (please circle best response)

1 2 3 4 5 6 7 8 9 10

Question 2:

On a scale of 1-10 (1 being the least, 10 being the most), how would you rate your satiation level after this meal? How full do you feel? (please circle best response)

1 2 3 4 5 6 7 8 9 10

Question 3:

On a scale of 1-10 (1 being the least, 10 being the most), was the fork easy to use? (please circle best response)

1 2 3 4 5 6 7 8 9 10

Question 4:

On a scale of 1-10 (1 being the least, 10 being the most), was the size and weight of the fork compare well to the cutlery you usually use? Was the size and weight acceptable to you? (please circle best response)

1 2 3 4 5 6 7 8 9 10

Question 5:

On a scale of 1-10 (1 being the least, 10 being the most), how much did using the HAPIfork alter your eating rate? (please circle best response)

1 2 3 4 5 6 7 8 9 10

Question 6:

On a scale of 1-10 (1 being the least, 10 being the most), do you feel like you ate slower than normal while using the HAPIfork? (please circle best response)

1 2 3 4 5 6 7 8 9 10

Question 7:

On a scale of 1-10 (1 being the least, 10 being the most), did you feel comfortable using the HAPIfork while eating around other people? (please circle best response)

1 2 3 4 5 6 7 8 9 10

Question 8:

On a scale of 1-10 (1 being the least, 10 being the most), was the HAPIfork usable while eating modified textured foods (pureed or minced)? (please circle best response)

1 2 3 4 5 6 7 8 9 10

Question 9:

On a scale of 1-10 (1 being the least, 10 being the most), if the HAPIfork were available to use, would you use it in aid in reducing your eating rate? (please circle best response)

1 2 3 4 5 6 7 8 9 10

Question 10:

On a scale of 1-10 (1 being the least, 10 being the most), how intrusive was the vibrations from the fork while eating? (please circle best response)

1 2 3 4 5 6 7 8 9 10

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