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Methodology of sequential classification of non-invasive multichannel biosignals, oriented to automatic diagnosis of dysphagia.

A master's thesis presented by :

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Metodología de clasificación secuencial de bioseñales no invasivas multicanal, orientada al diagnóstico automático de la disfagia

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Abstract

Swallowing is a complex process that involves sequential voluntary and involuntary muscle contractions. Malfunction of swallowing related muscles could lead to dysphagia. The Videofluoroscopic Swallowing Study is the current gold standard in dysphagia assessment, but is related to high cost, long wait times, and harmful radiation risk. There is a lack of standardized and non-invasive methods that help to improve the diagnosis and ambulatory care. The visual inspection is a widely used method for evaluating the surface electromyography signal (sEMG) during swallowing, a process highly dependent of the examiners expertise. It is desirable to have a less subjective technique for the automatic detection of normal and abnormal neuromuscular patterns produced during the swallowing process. The current master's thesis proposes a methodology of classification that allows to detect normal and abnormal muscular sequences related to swallowing using machine learning algorithms. Thus, 22 healthy subjects and 22 patients with dysphagia were recruited to assess neuromuscular activity during the execution of swallowing tasks. A total of 15 features in time, frequency and time-frequency domains were extracted from seven sEMG channel using the sliding window method. Four statistical moments were computed over the estimated EMG features of each channel in order to characterize the neuromuscular sequences executed by the control and dysphagic groups. The optimal combination of sEMG features was computed according to the F1 score. Furthermore, different combinations of channels were assessed. A support vector machine was used as classifier. Its hyperparameters were optimized with the subset of features, and it achieved a F1 score close to 90%. The proposed scheme is the first machine learning approximation for the automatic detection of dysphagia using multichannel sEMG signals.

Keywords: Electromyography (EMG), swallowing, dysphagia, feature extraction, feature selection, pattern recognition, machine learning.

Contents

1. Introduction

1.1. Justification

Swallowing is the human act by which food is prepared and transported from the mouth to the stomach. Alteration in swallowing process is a symptom known as dysphagia, which is generated as a consequence of vascular or neurological lesions, traumas, congenital alterations, infections, prolonged intubation, among others [1, 2, 3].
Among these situations, neurogenic and neuromuscular alterations are identified as the main causes of dysphagia. For instances, it is estimated that 300 out of every 100,000 inhabitants could suffer a traumatic brain injury (TBI) as a consequence of adverse events such as falls, aggressions, wars, traffic and labor accidents [4]. The patients with TBI often demonstrate problems related to the swallowing process, regardless of the TBI severity level [5]. The stroke is the second most common cause of death in the world, causing 5.7 millions of deaths in 2004 [6, 7]. Between 27 % and 50 % of all patients with stroke have dysphagia [8]. Patients with stroke and dysphagia have a higher risk of serious disability or death [9]. Patients with Parkinson Disease (PD) have a high risk of aspiration. Evident aspiration occurs in 15% to 56% of patients, and silent aspiration in 15% to 33% [10]. When the Videofluoroscopic Swallowing Study (VFSS) is used for the evaluation of the swallowing process of patients with PD, abnormalities in the oropharyngeal phase are reported in 75% to 97% of patients [10].
The prevalence of oropharyngeal dysphagia in the general population varies between 2.3% and 16% [11]. In elderly population, it is estimated a prevalence of 10%, although in care home residents it could increase to 50% [12]. Several studies have shown that patients with neurological disorders and dysphagia stay hospitalized a longer time than those neurological patients without dysphagia [13]. In United States, patients with dysphagia represented an additional cost for the health system of 16.8 billion dollars in comparison with patients without dysphagia diagnosis between 2009 and 2013. It is important to note that this estimation did not include the daily costs such as nursing care, special nutrition, home care services, among others [14].
Dysphagia is associated with a high rate of respiratory complications such as aspiration pneumonia, dehydration and malnutrition, which generates a significant impact on the quality of life of patients [15, 16]. Another complication related to dysphagia is the difficulty to administer medicine orally, which affects the accuracy of the dose and the patient independence [17].

Clinical evidence and research suggest that a significant reduction of dysphagia symptoms can be achieved when well established an organized plans of care are implemented, that includes detection, diagnosis and treatment [18]. However, the clinical procedures in Colombia and around the world are not standardized, these are based on subjective clinical evaluations and the use of invasive diagnostic tools such as VFSS and Fiberoptic Endoscopic Evaluation of Swallowing (FEES). The main disadvantage of the VFSS is the exposure to radiation, so its reproducibility is limited: exposition to high radiation doses increases the risk of suffering cancer and genetic mutations [19]. In the FEES, the main drawback is the invasiveness, which causes discomfort, pain and infection risk. Moreover, the aforementioned techniques are useful as visual support for dysphagia assessment but they do not provide quantitative information about the neuromuscular activity of the patients. This implies that the assessment of swallowing disorders depends on the expertise of the examiner.
In recent years, surface electromyography (sEMG) signals have been investigated as a promising diagnostic tool to evaluate the physiological behavior of the swallowing process, because the use of sEMG eliminates risks of radiation, infection, and pain, in comparison with conventional diagnostic methods [20]. Furthermore, it is promising in order to extract quantitative information about the swallowing process in a electrophysiological way. For this reason, this non-invasive biosignal represents an important source of information for the dysphagia diagnosis. In this way, the current work proposes a methodology of classification that allows obtaining quantitative neuromuscular information during swallowing tasks in healthy subjects and patients with dysphagia.

1.2. Swallowing and Dysphagia

1.2.1. Anatomy and physiology of swallowing

The swallowing process involves a complex sequential activation of 25 pairs of muscles located at the mouth, pharynx, larynx, and esophagus [21]. The oral cavity or mouth contains teeth and tongue, which have functions such as chewing, saliva production, swallowing, and phonation (see Figure **1-1**). The oral cavity limits downwards with the floor of the mouth and upwards with the roof of the mouth, which comprises the hard palate (constituted by bone structure) and the soft palate (constituted by muscle), both covered by mucosa. The pharynx is divided into three parts: The nasopharynx, oropharynx and laryngopharynx (also known as hypopharynx). The larynx is composed of the epiglottis, the hyoid bone, and thyroid, cricoid and arytenoid cartilages. During swallowing its main function is to prevent the passage of the food to the airway. The esophagus has the function of being the way of the food towards the stomach. It has the upper and lower sphincters, which prevents the passage of food and acidic secretions in the opposite direction to the flow of the digestive tract [2].
Normal swallowing is based on the following three phases:

1. Oral phase: In this phase, the facial muscles, tongue and teeth allow to chew and process the food in order to obtain an adequate consistency to swallow safely. In this stage the saliva production is initialized, which is very important because it helps to lubricate and transport the bolus through the pharynx and larynx [22]. During this phase the tongue propels the bolus from the oral cavity to the pharynx. The orbicularis oris and buccinator muscles prevent the bolus to scape outside of the mouth. The hyoid bone is elevated in preparation of the pharyngeal phase by the contraction of the mylohyoid muscle [23].

2. Pharyngeal phase: In this phase muscular activation is involuntary. When it starts the chewing stops and breathing is inhibited to prevent the bolus from passing to the larynx and trachea. The stimulation of the swallowing reflex produces the elevation and retraction of the soft palate with closure of the velopharyngeal valve in order to avoid the entry of food into the nasal cavity. This phase ends when the soft palate returns to its place and the larynx is opened to breathe [22].

3. Esophageal phase: The esophageal peristalsis leads the bolus from the cervical esophagus to the thoracic esophagus and inside the stomach. The velocity and intensity of the peristaltic wave depends on the characteristics of the bolus [2].

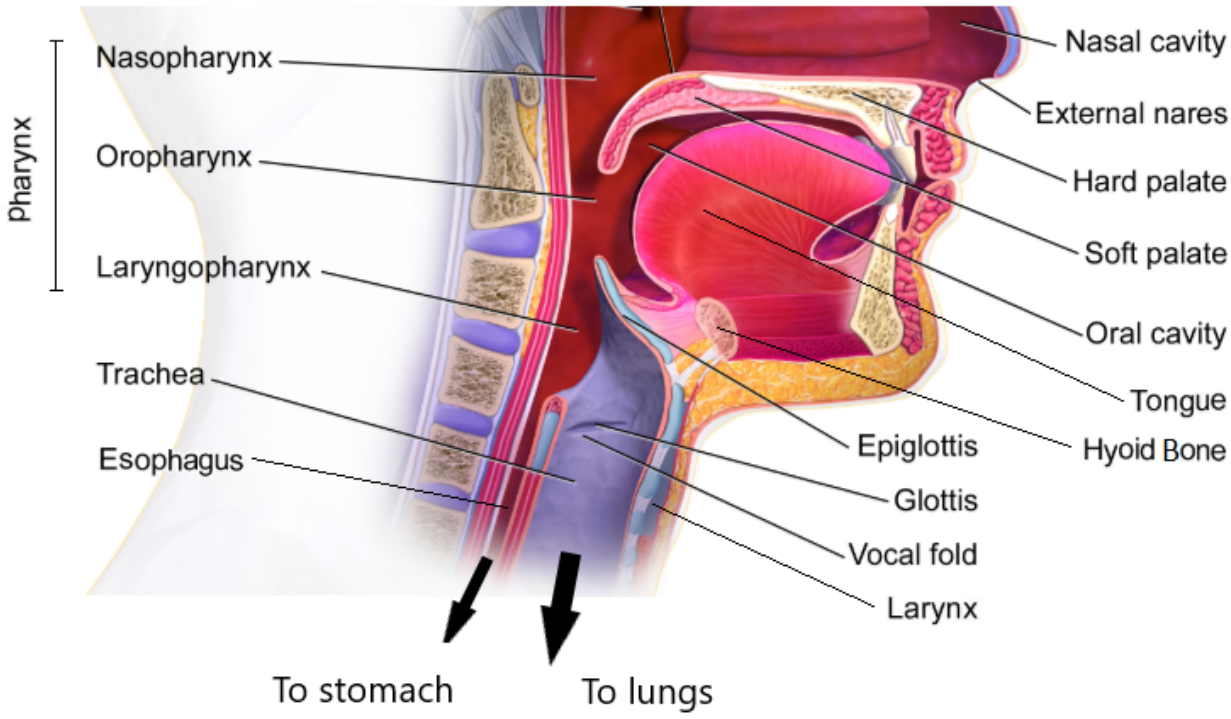

Figure 1-1.: Swallowing related anatomy. Modified from [24]

1.2.2. Dysphagia

Swallowing disorder or dysphagia difficults the oral preparation of food as well as the transport of food from the mouth to the stomach. The dysphagia can be originated from a neurogenic or mechanical alteration. Some symptoms caused by dysphagia are painful swallowing, cough, regurgitation, changes in voice quality, excessive drooling, among others[22]. The main consequences of dysphagia are malnutrition, dehydration and aspiration, which often leads to in pneumonia. These complications deteriorate the prognosis of the principal disease (i.e., Parkinson, ALS, etc). The dysphagia severity can be grouped into four categories, as follows [21]:
1. Mild: May occasionally have difficulty swallowing.
2. Moderate: Acceptable to swallow soft foods but may have difficulty with liquids and solids. It requires supervision and treatments.
3. Moderate severe: The oral swallowing is not satisfying. It requires constant supervision and assistance. Patients can only be fed with a assistance.
4. Severe: The patient's nutrition is carried out by alternative methods because he/she does not eat food by mouth.

1.2.3. Dysphagia Assessment techniques

Videofluoroscopic Swallowing Study

The Videofluoroscopic Swallowing Study (VFSS) is an image based technique used as "gold standard" to assess swallowing disorders. During this procedure, the patient is asked to swallow barium-coated boluses while X-ray video of the pharyngeal region is recorded [25]. This technique evaluates the swallowing duration and motor function during the transit of bolus by the oropharynx, hypopharynx, and cervical esophagus [26]. Although VFSS allows to recognize abnormalities in swallowing function, the final diagnosis can vary between clinicians [27], so the VFSS is a subjective evaluation technique. One important aspect to highlight is that only a restricted number of healthcare institutions can realize VFSS in the local context, causing long wait times for patients with dysphagia and increasing costs. The above mentioned together to the exposure of patients to harmful radiation [19], it reduces the reproducibility of this technique.

Fiberoptic Endoscopic Evaluation of Swallowing

The Fiberoptic Endoscopic Evaluation of Swallowing (FEES) is an invasive medical tool used to detect aspiration and to determine the safety of oral feeding in patients for whom VFSS may be difficult or contraindicated [28]. This technique allows to observe the anatomy of the digestive way through a fiberoptic endoscope, so it is possible to directly visualize the coordination of the pharyngeal phase and verify the aspiration of secretions [29]. The first step of FEES is inserting an endoscope into the nose and place it at the level of the soft

palate or below, in order to provide a downward view of the pharynx during swallowing. If the endoscope is located above the soft palate, velopharyngeal closure as well as the elevation and retraction of the soft palate can be visualized. If the endoscope is positioned behind the uvula, the pharynx can be observed before and after the pharyngeal swallow [25]. The main disadvantage of FEES is the invasiveness and the discomfort and pain caused during the process.

Cervical auscultation

Cervical auscultation (CA) involves listening of acoustic waves produced in the pharyngeal region during swallowing using a stethoscope or microphone placed on the neck [30]. The recognition of abnormal swallow sounds is the basis of this technique. The characteristics of these sounds include gurgly vocal quality, coughing, and throat clearing [31, 32]. Advantages of CA include low equipment cost, non-invasiveness, and portability. In contrast, its main disadvantage is the need for medical training in the detection of abnormal swallow sounds, what it converts to CA in a subjective evaluation.

Surface Electromyography

Surface electromyography (sEMG) uses electrodes fixed on the facial skin to detect and record the electrical potentials produced by the muscular groups during the swallowing process. This technique allows finding physiological and muscular patterns of healthy and pathological populations [33, 34]. The sEMG is a simple, non-invasive and reliable swallowing assessment method with low levels of discomfort for patients [35]. However, sEMG has been widely studied in the swallowing research field but its validation in clinical practice is quite low. Moreover, sEMG signals analysis requires medical expertise, which it indicates a subjective evaluation.

1.3. State of the Art

Several non-invasive biosignals have been used to quantify the relationship between their characteristics and the swallowing function. These are acquired via EMG [33], CA [36], pulse oximetry (SpO2) [37], respiratory rate measurement (RR) [38], nasal flow measurement [39], accelerometry (ACC) [40], mechanomyography (MMG) [41], among others. One of the most widely used source of information for the classification of neuromuscular events oriented to medical diagnosis is sEMG [42]. In the swallowing case, sEMG signals have low signal noise ratio (SNR) because the muscles involved in the process have small size and suffer of cross-talk due to the platysma muscle [43].
A wide variety of studies has been reported using machine learning techniques in conjunction with non-invasive biosignals for the development of classifiers that allow the automatic detection of normal and pathological neuromuscular events [44]. However, the study of machine

learning techniques applied to the automatic diagnosis of dysphagia has been few explored, and the analysis of such biosignals has been mainly visual or statistical [45]. This limits its application in the field of dysphagia diagnosis, due to the lack of reproducibility.
Multiple linear and non-linear features in the time domain, frequency and time-frequency, have served to analyze the biosignals behavior during the execution of neuromuscular activities [46]. However, most of works have estimated these features for the discrimination of static events, such as flexion or extension of a limb during a period of time, control of a mobile device, among others [47]. Table **1-1** summarizes the most used features in neuromuscular pattern recognition activities.

Table 1-1.: Features used for pattern recognition of neuromuscular activities.

Domain		Name	Abreviation	References
Time	**Energy and complexity**	EMG Integrated	IEMG	[48]
		Mean Absolute Value	MAV	[49]
		Simple Square Integral	SSI	[50]
		Root Mean Square	RMS	[51]
		Variance	VAR	[52]
		LOG Detector	LOG	[53]
		Teager-Kaiser Energy Operator	TKEO	[54]
		Waveform Length	WL	[49]
		Average Amplitude Change	AAC	[51]
		Difference of Absolute Standard Deviation	DASDV	[51]
	Frequency	Zero Crossing	ZC	[49]
		Myopulse	MYOP	[55]
		Willison Amplitude	WAMP	[52]
	Predictive model	Autoregressive Coefficients	AR	[52]
		Cepstral Coefficients	CC	[56]
	Time dependent	Histogram	HIST	[53]
		Multiple Hamming Windows	MHW	[50]
		Multiple Trapezoidal Windows	MTW	[50]
Frequency		Mean Power	MNP	[46]
		Median Frequency	MDF	[57]
		Mean Frequency	MNF	[58]
		Peak Frequency	PKF	[46]
		Variance of Central Frequency	VCF	[50]
		Frequency Ratio	FR	[59]
		Total Power	TP	[46]
Time - Frequency		Wavelet Energy Coefficients	EnWC	[60]
		Wavelet Coefficients Zero Crossing	ZCWC	[60]
		Wavelet Packet Energy Packets	EnWP	[60]
		Wavelet Coefficients MAV	MAVWC	[60]

Feature selection is one of the most crucial stages in the design of pattern recognition systems since it helps to reduce the feature space, redundancy and model complexity [42]. Search strategies used to find the feature space that maximizes the separation between classes can be designated as filtering, wrapping, embedding, heuristic and hybrid [61, 62]. These techniques

differ in their advantages and disadvantages. For example, although the filtering techniques require lower computational cost, it does not evaluate the feature space using a classification model as the wrapping techniques [63].
Supervised [51] and unsupervised [64] algorithms have been implemented for detection of dynamic neuromuscular events using non-invasive biosignals. Supervised parametric techniques have shown promising results in the classification of multichannel sequential patterns during the execution of human tasks such as speech production [65], gait [66] and facial emotions recognition [67].
Spadotto et al. recorded the swallowing activity of 20 healthy subjects and 20 patients with dysphagia using a microphone. They used the Wavelet transform to decompose the acoustic signals into 9 frequency bands and estimate their corresponding energy. The Optimum Path and SVM classifiers were used to detect oropharyngeal dysphagia, which achieved a precision of 85% and 76.3% , respectively [68].
Sasaki et al. developed a training system based on sEMG signals of suprahyoid muscles for tongue movement in patients with dysphagia. RMS value and cepstral coefficients were extracted as features to detect the lingual movements. They obtained a classification rate of 93.5% using an artificial neural network. Although this system was oriented to rehabilitation, it showed that the muscles associated with the swallowing can be characterized to identify events of interest [69].
Lee et al. used information acquired from three sensors: biaxial accelerometer, submental mechanomyography (MMG) and nasal cannula, in order to detect the signals or the combination of signals that gives the large amount of information in order to classify swallow segments. They achieved an accuracy of 88% using an artificial neural network. In this study, frequency and time-frequency features were not used [41].
Hsu et al. designed an automatic discrimination system based on fuzzy logic for patients with myasthenia gravis using submental sEMG and audio signals. They extracted the following features: duration of contraction, intensity, entropy and fractal dimension. They achieved an accuracy of 82.6%, superior to the algorithms k-NN (69.56%), ID3 (63.04%), and ANN (71.73%) [70].
Lazareck et al., recorded swallowing and respiratory sounds using an accelerometer to discriminate between normal and abnormal swallowing behaviors. In this study participated 15 healthy subjects and 11 patients with dysphagia. A total of 350 signals were acquired during the swallowing of three boluses of different consistency. They estimated 24 features above signals (e.g. the swallow sound duration, rectified average value and the average, median and peak frequencies). A linear discriminant classifier was used to recognize between healthy and dysphagic patients and it obtained an accuracy of 77.9%, 100% and 90% for semi-solid, thick liquid and clear liquid boluses, respectively [71]. In this research, it was only analyzed the pharyngeal phase.
A biological phenomenon similar to swallowing is the speech because it must generates a sequential muscular contractions in order to produce voice. Chan et al., acquired facial

sEMG signals from 2 healthy subjects to classify the pronunciation of numbers from 0 to 9 using Hidden Markov Models(HMM). The first two auto-regressive coefficients (AR2) and integrated absolute value were extracted. A classification error of 2.70% y 3.57% were obtained for subjects 1 and 2, respectively [72]. One important aspect to highlight is that the model development was estimated using neuromuscular information from 2 healthy subject, so this study had a low statistical significance.
Lee et al., developed an automatic recognition system of Korean words using sequences of sEMG signals acquired from three facial muscles of 8 healthy subjects. The Mel filter bank (order 5) outputs and its first derivated were used as feature vector to train a HMM. This proposed model could to recognize each isolated word with a maximum accuracy of 87.07% [73]. In this study a relationship between the features and channels to discriminate each word was not established and the number of subject was low.
The gait is another physiological process that requires muscle sequential contractions to execute a daily life activity. Kuntze et al. used SVM to identify changes in muscular patterns from patients undergoing total knee arthroplasty. They decompose the signals into 10 frequency bands using a wavelet filter bank and calculate its power. The total sum of all the powers of each muscle was used as feature vector in the training stage. The results of this study indicated altered muscle activations in the vastus medialis and femoral biceps muscles, which obtained a recognition rate of 68.4% and 73.7%, respectively [74]. On the other hand, Meng et al., used HMM for the recognition of the gait phases using sEMG signals. The combination of the features average absolute value and WL, achieved the best classification performance (91.46%) [75].

1.4. Problem Statement

The health staff responsible for the diagnosis of dysphagia do not have a non-invasive medical tool that allows identifying swallowing disorders objectively. Several biosignals have been studied in order to evaluate the neuromuscular behavior of the swallowing process in an objective way. However, the lack of characterization of these biosignals in swallowing has not allowed to find muscular patterns that could be used as input for a diagnostic system.
Although the estimation of features in sEMG signals has shown good results in the detection of healthy and pathological neuromuscular events, these studies have been done over large muscles with high SNR during static tasks e.g. upper and lower limbs movements[53, 76, 55]. Thus, these results cannot be extrapolated to the swallowing related sEMG signals, since they have low SNR as well as an involuntary component (for instance supra- and infrahyoid muscles during the end of the oral phase and the pharyngeal one). Furthermore, the contractions associated to the swallowing process are dynamic.
Classification models reported in the literature applied to swallowing and dysphagia have been focused on the detection of neuromuscular patterns in the pharyngeal phase [70, 41]. This does not allow to analyze the whole swallowing, disregarding the sequentiality nature of

the physiological process. In this way, the information from facial muscles such as masseter and orbicularis oris must be also analyzed in order to obtain a better understanding of normal and abnormal process.
In order to study the neuromuscular patterns produced during the swallowing, a multichannel sEMG system must be used. This represents to analyze a high number of features, channels, and experiments. Therefore, to determinate which channels and features to contribute to the detection of abnormal muscular behavior is a complex task, because the swallowing EMG patterns varying according to variables such as bolus size and consistency. The choice of a classification model with good performance it could give useful information to health professionals for diagnosis, follow-up, and rehabilitation of dysphagia.
For this reason, it is necessary to establish a methodology which overcome the aforementioned limitations, seeking for the automatic and objective detection of normal and pathological patterns in swallowing.

1.5. Objectives

1.5.1. General objective

To design a methodology for classification of multichannel biosignals, based on sequential learning techniques oriented to the automatic diagnosis of dysphagia.

1.5.2. Specific objectives

1. To characterize non-invasive biosignals acquired during the swallowing process, in healthy and pathological subjects by analysis in time, frequency and time-frequency domains.

2. To select the combination of features and acquisition channels that maximizes separability between classes in swallowing events, using a non-parametric and parametric classifier.

3. To develop a dysphagia detection scheme based on swallowing related sequence, using supervised sequential learning techniques.

4. To assess the scheme of automatic diagnosis of dysphagia in a multichannel signals database acquired from healthy and pathological subjects.

2. Materials and methods

This chapter presents the methodology used in the present master's thesis for the automatic detection of the dysphagia. This is divided into the following five stages: sEMG data acquisition, feature extraction, feature selection, sEMG channel evaluation, and classification. Each stage of the proposed methodology is described in more detail below.

2.1. Subjects

A total of 22 healthy subjects (mean age: 32,45 ± 12,95) and 22 patients with dysphagia (mean age: 58,32 ± 15,35) were recruited. The healthy subjects were selected using the following criteria:

Inclusion criteria:

(a) Age above 18 years old, male or female, healthy.

(b) Without diagnosed dysphagia.

(c) Not taking medications that modify the texture of saliva or oral secretions.

(d) Without central or peripheral neuropathy, or neuromuscular pathology.

(e) Absence of head and neck cancer, or chronic obstructive pulmonary disease.

(f) Absence of surgical procedures on the lower 2/3 of the face or neck.

(g) sEMG swallowing record with three food consistencies.

Exclusion criteria:

(a) Presence of congenital malformations in the mouth.

(b) Presence of dental pathology.

(c) To have active inflammatory processes.

(d) To have strange elements in the mouth such as piercing, retainers, braces, or dental prosthesis.

(e) To have diagnosed cognitive impairment.

(f) To have cardiorespiratory impairment.

(g) To have chronic obstructive pulmonary disease.

(h) To have head or neck cancer antecedents.

(i) To have facial aesthetic surgery.

(j) To have a diagnosis or history of Sjogren's syndrome.

On the other hand, patients with dysphagia were selected using the following criteria:

Inclusion criteria:

(a) Age above 18 years old, male or female

(b) Presence of oral or oropharyngeal dysphagia.

(c) Confirmed diagnosis of neuromuscular etiology responsible for oral or pharyngeal dysphagia.

(d) Causes of dysphagia: ischemic or haemorrhagic stroke, multiple sclerosis, motor neuronal disease (including amyotrophic lateral sclerosis), dementia (including Alzheimer's, Vascular, Mixed and Parkinson's), cerebral palsy, neuromyelitis (myelitis with dysphagia) and head trauma. Inflammatory myopathies, muscular dystrophy, myasthenia gravis and neuropathies (including Guillain Barré).

Exclusion criteria:

(a) Patient with esophageal dysphagia.

(b) Patient with mechanical dysphagia.

(c) Patient with active treatment for cancer in facial or cervical regions (contraindication for electrodes placement).

(d) Patient with orofacial or cervical edema or hematoma.

(e) Patient with recent surgical dissection in face or neck (last three months).

(f) Patient with severe hypoxemia (oxygen saturation below 80%).

(g) Patient with deep brain stimulation device

All the males were well-shaved in both groups. Prior to the experimental procedures, the volunteers provided their written informed consent, which was approved by the Research Ethics Board at Universidad Pontificia Bolivariana.

2.2. Multichannel sEMG signals acquisition

Seven acquisition channels were assessed through the placement of surface electrodes located at the following muscular groups: bilateral masseters, suprahyoid and infrahyoid muscles, as well as orbicularis oris in the right commissure of the lips. These muscular groups were assessed with non-polarizable, bipolar, disposable and pre-gelled Ag/AgCl electrodes (Ref. 2228, 3M - 30 mm x 35 mm, 15 mm diameter in gel area, and interelectrode distance of 25 mm). Figure **2-1** shows the location of the bipolar sEMG electrodes.

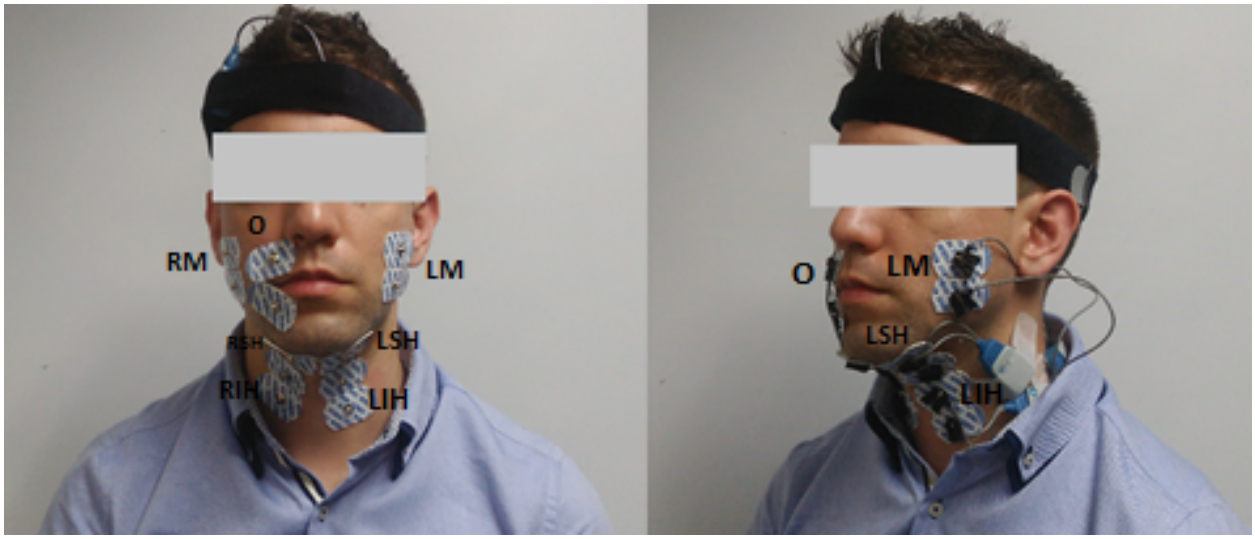

Figure 2-1.: Electrode configuration. RM and LM, right and left masseters; O indicates *orbicularis oris*; RSH and LSH, right and left suprahyoid muscles; RIH and LIH, right and left infrahyoid muscles.

These muscular groups were selected because they are involved in the swallowing process [77, 78]. Based on previous works [79, 54], an acquisition protocol was designed in order to capture the most important information of the aforementioned muscles. In this study, the muscular activity from orbicularis oris was acquired using one electrode. Esophageal phase was not studied in the present master's thesis.

The neuromuscular activity was recorded with the electromyograph Noraxon $Ultium^{TM}$ EMG (Noraxon USA). It has a common-mode rejection ratio CMMR $>$ 100 dB, 16 bits A/D converter resolution and selectable high and low pass cutoff frequencies.

Noraxon $Ultium^{TM}$ allows to synchronize video and sEMG signals. Therefore, a camera was positioned diagonal to each participant and every task was video-recorded frame by frame with the sEMG recordings.

2.3. Acquisition protocol

Healthy subjects were asked to swallow eight boluses of different consistencies and volumes. These boluses have been used by other authors to assess penetration/aspiration in dysphagia [80]. The boluses were delivered in the following order:

- Yogurt 5 mL

  Pause

- Yogurt 10 mL

  Pause

- Yogurt 20 mL

  Pause

- Saliva

  Pause

- Water 5 mL

  Pause

- Water 10 mL

  Pause

- Water 20 mL

  Pause

- 3g of cracker, approximately.

Water and yogurt were delivered to the oral cavity via a 1.5 oz cup. sEMG signals acquisition starts when the examiner delivers each consistency. The sEMG recording is paused 5 seconds after each swallowing completion. This process is repeated until to complete the whole acquisition protocol. A total of 176 swallowing tasks were executed by healthy subjects. On the other hand, the acquisition protocol with dysphagic patients was more flexible for safety purposes. A total of 153 swallowing tasks were executed by patients. Thus, 329 swallowing tasks were executed by the healthy subjects and patients with dysphagia.

2.4. Signal pre-processing

sEMG signals were acquired with a sampling rate $F_s = 2$ kHz. Pre-processing, storage and visualization of the raw signals were carried out with the MR3 software (Noraxon USA). The Figure **2-2** shows the multichannel acquisition of sEMG signals during a swallowing task. The MR3 software allows to apply a primary bandpass filter (BPF) with cutoff frequencies between 10 and 500 Hz for visualization purposes, according to the standard of the International Society of Electrophysiology and Kinesiology [81].

Offline analysis was performed using custom scripts and open-source functions in Python 3.6. According to previous work realized by the dysphagia research staff [82], sEMG signals were filtered with a 10th order BPF Butterworth filter (between 90 and 250 Hz) in order to improve the burst detection.

Figure 2-2.: Seven sEMG channels visualization in the MR3 software (Noraxon USA) during the swallowing of 10 mL yogurt bolus. RM and LM, right and left masseters; OC indicates *orbicularis oris*; RSH and LSH, right and left suprahyoid muscles; RIH and LIH, right and left infrahyoid muscles. The three signals showed at the bottom right of the figure are 3-axis accelerometry signals, which were not analyzed in the present master's thesis.

2.5. Feature extraction

2.5.1. Characterization of muscular sequences using sliding window method

Table 2-1.: Mathematical formulations of the evaluated features, taken from [83]. Abbreviations: s_i: i-th sample of sEMG signal; N: number of samples; $\phi(\bullet)$: thresholding function; M: length of the power spectral density; P_j: power spectral density evaluated at j-th frequency f_j; c_i: i-th coefficient of a sEMG signal in an orthonormal basis [84].

Domain	Feature	Equation	Domain	Feature	Equation
Time	VAR	$\frac{1}{N-1}\sum_{i=1}^{N} s_i^2$	Time	ZC	$\sum_{i=1}^{N-1}[\phi(s_i \times s_{i+1}) \cap \lvert s_i - s_{i+1}\rvert \geq TH]$
	RMS	$\sqrt{\frac{1}{N}\sum_{i=1}^{N} s_i^2}$		MYOP	$\frac{1}{N}\sum_{i=1}^{N} \phi(s_i)$
	MAV	$\frac{1}{N}\sum_{i=1}^{N} \lvert s_i\rvert$	Frequency	MNP	$\sum_{j=1}^{M} P_j \Big/ M$
	LOG	$exp\left(\frac{1}{N}\sum_{i=1}^{N} log(\lvert s_i\rvert)\right)$		TP	$\sum_{j=1}^{M} P_j$
	WL	$\sum_{i=1}^{N-1} \lvert s_{i+1} - s_i\rvert$		MDF	$\sum_{j=1}^{MDF} P_j = \frac{1}{2}\sum_{j=1}^{M} P_j$
	ACC	$\frac{1}{N}\sum_{i=1}^{N-1} \lvert s_{i+1} - s_i\rvert$		PKF	$\max(P_j), \quad j = 1, \ldots, M$
	DASDV	$\sqrt{\frac{1}{N-1}\sum_{i=1}^{N-1}(s_{i+1} - s_i)^2}$	Time - Frequency	WENT	$E(c) = -\sum_i c_i^2 \log(c_i^2)$
	WAMP	$\sum_{i=1}^{N-1} \phi(\lvert s_i - s_{i+1}\rvert)$			

A total of 15 features in time, frequency and time-frequency domains were extracted from each sEMG channel using sliding window method. The table **2-1** shows the mathematical formulations of the estimated features in this study. The time domain features were estimated directly from the raw sEMG signals without any transformation, so its implementation was simple and did not demand high computational cost. The time-domain (TD) features evaluated in the present master's thesis were categorized into two groups according to the muscular information assessed (see Table **1-1**)[46]. The first group composed of the features RMS, LOG, MAV, DASDV, WL, VAR provided energy and complexity information of the sEMG signals. In this group, RMS and MAV features were used as a muscular contraction detection index, whilst VAR and LOG features measured signal power and muscular contraction force, respectively. WL and DASDV estimated the complexity of the sEMG signals.

On the other hand, the second group composed of the features WAMP, ZC, and MYOP provided frequency information in the time domain of the sEMG signals. The ZC feature measured the number of times that amplitude values of the sEMG signal cross zero amplitude level. MYOP measured the number of times that absolute values of the sEMG signal exceeds a pre-defined threshold value. WAMP estimated the number of times that adjoining segments of a sEMG signal exceeds a pre-defined threshold [46]. The definition of the threshold used in the present work can be represented with the following function:

$$\phi(x) = \begin{cases} 1 & \text{if } x \geq TH \\ 0 & \text{otherwise} \end{cases} \tag{2-1}$$

where the threshold is given by $TH = mean + h \times std$, with $mean = 0$ (detrended signal) and $h = 3$, according to [85].

The frequency domain features are used to study muscular fatigue and Motor Unit recruitment analysis [46]. They are usually statistical properties of the power spectral density. The computed frequency domain (FD) features were: MDF, TP, PKF and MNP.

The time-frequency domain features (TFD) are based on Fast Discrete Wavelet Transform (DWT) and consider both temporal and spectral information, which allows revealing aspects such as trends, breakpoints, discontinuities in high derivations and self-similarity. These aspects can not be detected by the time and frequency features separately. DWT applies two sets of functions called scaling functions and wavelet functions, which are associated to low-pass and high-pass filters, respectively [86]. When DWT is applied over a sEMG signal $s[n]$, it returns the downsampled detail coefficients $cD_1[n]$ and the approximation coefficients $cA_1[n]$. The coefficients $cA_1[n]$ are then filtered and downsampled again at the next decomposition level, generating another detail $cD_2[n]$ and approximation coefficient $cA_2[n]$. This processing is repeated until the preset decomposition level (N) is reached [54].

According to previous work developed as a product of the current master's thesis [54], the Wavelet function Daubechies of four order (db4) and a decomposition level of $N = 3$ were the Wavelet parameters that achieved the highest performance for burst detection in infrahyoid muscles. Therefore, these Wavelet parameters were used for sEMG signals decomposition. Finally, Shannon entropy was computed over the Wavelet coefficients obtained from each sEMG channel. It is known as Wavelet entropy (WENT), which measures the degree of order/disorder of the sEMG signals, so it provides information about the underlying dynamical process associated with the sEMG signals [87].
The aforementioned EMG features were extracted from each sEMG channel using a 256 ms sliding window with 50% overlap and fixed-step of 50 ms (see Figure **2-3A**). The Figure **2-3B** shows an example of the estimation of RMS feature over a sEMG channel using sliding window method.

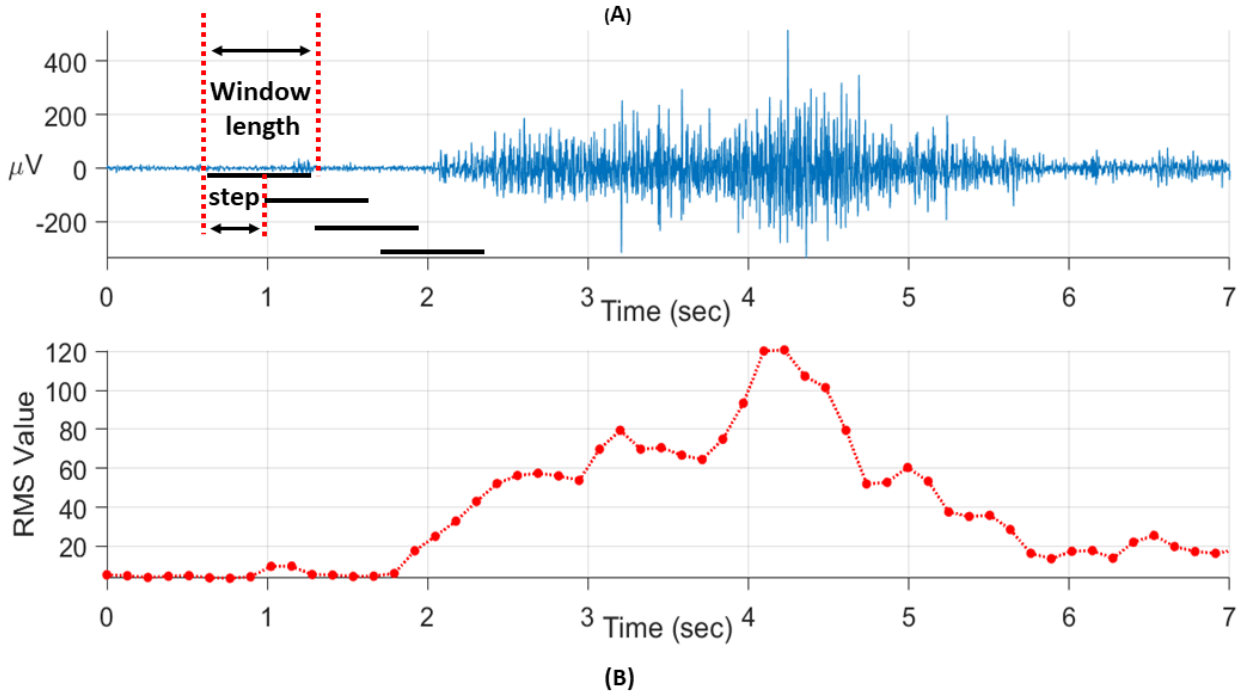

Figure 2-3.: A. Estimation of EMG features by fixed-step of 50 ms with sliding window of 250 ms. The step is defined as the distance between windows. B. Example of the estimation of RMS value over a EMG signal.

Figure **2-4** summarizes the feature extraction process used in the present master's thesis.

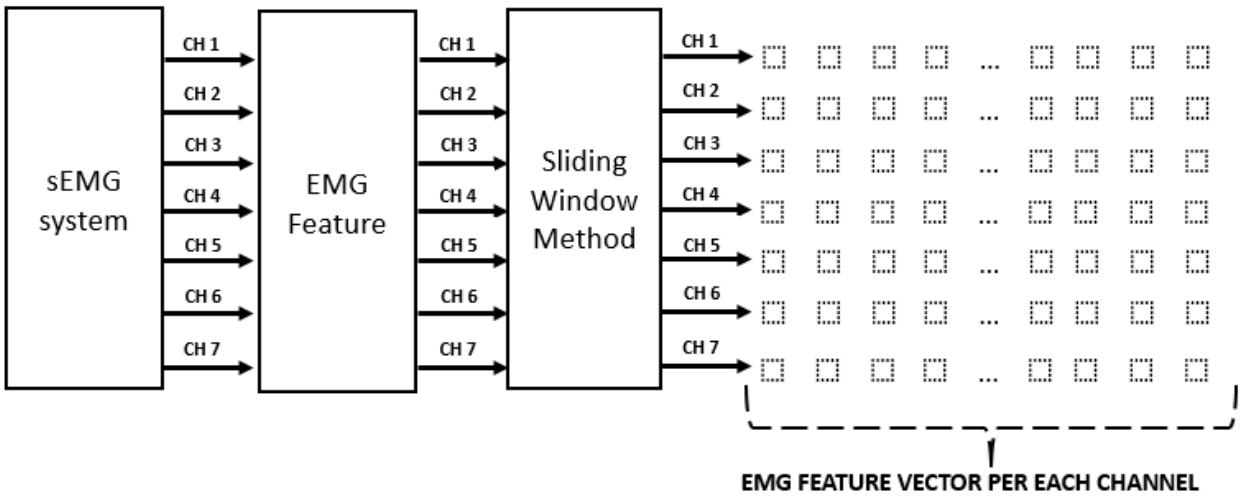

Figure 2-4.: The feature extraction process used for sEMG signals characterization.

2.5.2. Feature space generation

The estimation of each EMG feature produces a feature vector per each acquisition channel. The Figure **2-5A** shows the feature vector (red line) obtained by the estimation of RMS value over the seven sEMG channels. In this stage, the four statistical moments (mean, standard deviation, skewness and kurtosis) were computed over the feature vectors obtained from each sEMG channel (see Figure **2-5B**). Then, the four statistical moments computed were concatenated to produce a final feature vector of 1 x 28 i.e., 7 channels x 4 statistical moments (see Figure **2-5C**). Therefore, per each estimated EMG feature (see Table **2-1**) a 28-dimensional feature space was obtained (i.e. a matrix of dimension 329 x 28).

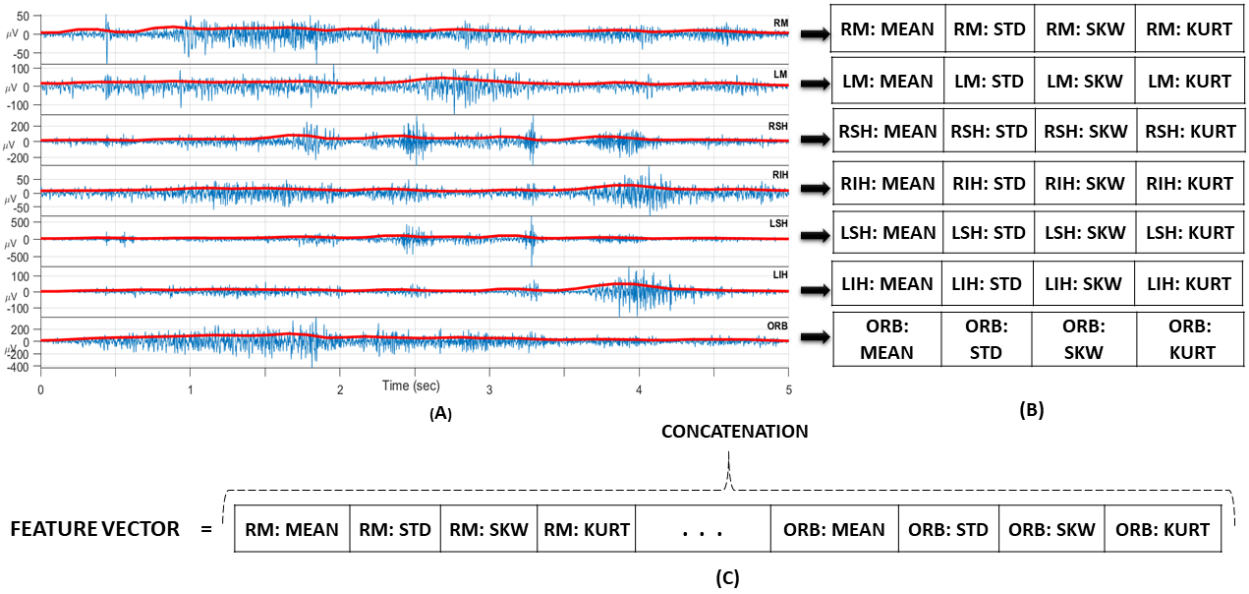

Figure 2-5.: A. Example of the estimation of RMS value (red line) over the seven sEMG channels using the sliding window method. B. Estimation of the statistical moments: mean, standard deviation (STD), skewness (SKW) and kurtosis (KURT) over the RMS values obtained for each channel. C. Concatenation of all statistical moments of all channels to create a one feature vector per swallowing task of size 1 x 28.

2.5.3. Z-score Normalization

Z-score normalization is a strategy of normalizing data to transform the features on the same scale. It calculates the arithmetic mean and the standard deviation of the given features. Each feature matrix obtained in the section 2.5.2 was z-score scaled as follows:

$$x_j^{(i)} := \frac{x_j^{(i)} - \mu_{x_j}}{\sigma_{x_j}} \tag{2-2}$$

where $x_j^{(i)}$ is the j-th variable of the i-th training sample, and μ_{x_j} and σ_{x_j} are the mean and standard deviation of the j-th variable, respectively. Here, variables correspond to the statistical moments of the estimated EMG features over the sEMG channels.

2.6. Statistical analysis

The main idea behind this study was to choose the variables (or statistical moments) from each feature matrix estimated in section 2.5.2, whose data distributions were not entirely overlapped i.e., there is a significant statistical difference between the medians of a specific variable for healthy and dysphagic groups. The Figure **2-6** illustrates the scheme used to analyze the feature matrices and to select the variables. A D'Agostino- Pearson normality test was carried-out [88]. If data comes from a normal distribution the null hypothesis of normality was rejected with specific significance level α (i.e., $p - value < \alpha$) and the Mann-Whitney U test was carried out. In contrast, if the data had a normal distribution and the two samples had homoscedasticity according to the F test, a t-test was applied. Finally, whether any of the aforementioned statistical tests were not used, Welch's t-test was applied [88]. Two values for α were established, one for normality and F tests ($\alpha = 0.001$), and another for comparison between the control and dysphagic groups ($\alpha = 0.05$), according to [89]. Finally, n-dimensional features spaces were estimated per each EMG feature, where n is the number of selected variables by statistical analysis.

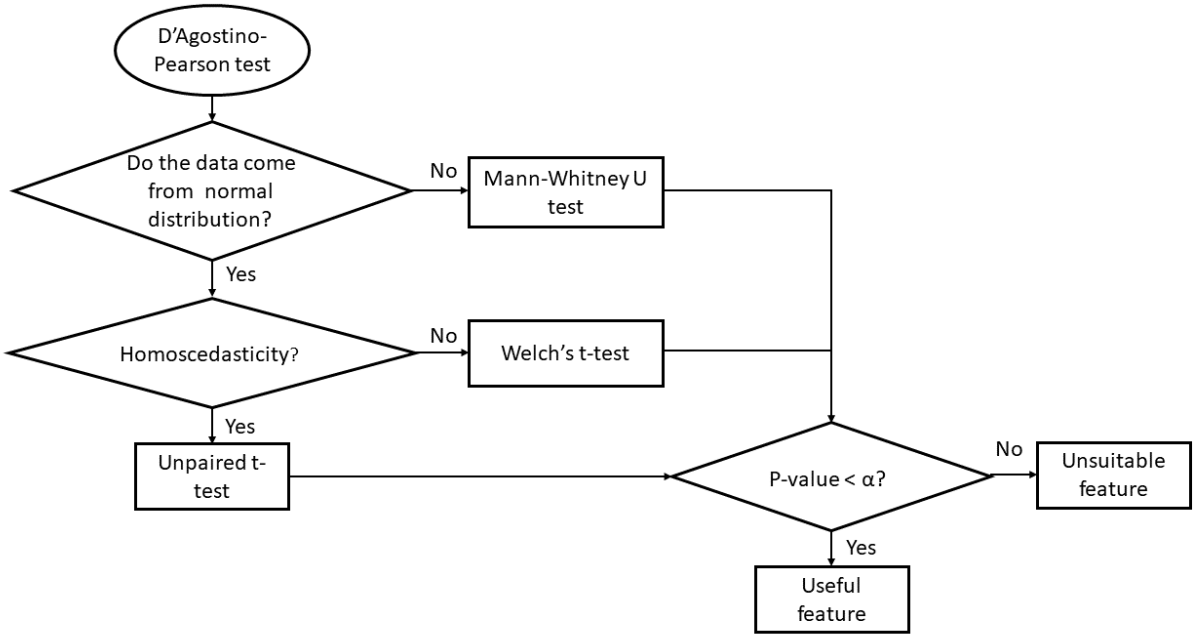

Figure 2-6.: Scheme to determine whether one feature is or not suitable to discriminate between healthy and dysphagic groups.

2.7. Feature selection

Two strategies were explored in order to select the feature space that generates the highest classification performance. First, each 28-dimensional EMG feature space obtained in the section 2.5.2 was evaluated individually using four classification algorithms (see section 2.8). The second strategy was to apply a sequential feature groups selection, where combinations of 28-dimensional EMG features spaces were evaluated using classification algorithms. The aforementioned strategies were also evaluated with the n-dimensional EMG features spaces obtained by statistical analysis in the section 2.6.

2.8. Classification models

For all the experiments presented in the present master's thesis, a 5-fold cross validation with non-overlapping groups was applied in order to guarantee that information from one patient or control subject will not appear simultaneously in the training and validation sets. Also, a grid search was performed to determine the hyper-parameters values that produce the highest F1-score value from the following classifiers: logistic regression, support vector machines, linear discriminant analysis and multilayer perceptron.

2.8.1. Logistic Regression

Let consider a supervised learning problem where a set $S = \left\{\left(x^{(i)}, y^{(i)}\right)\right\}_{i=1}^{m}$ of m training examples is given. Logistic regression (LR) models the probability distribution of the class y given a feature vector x as follows [90]:

$$p(y = 1|x; \theta) = \frac{1}{1 + \exp\left(-\theta^T x\right)} \tag{2-3}$$

where $\theta \in \mathbb{R}^n$ are the parameters of the model.
In order to find the θ parameters of the LR model, the following optimization problem is presented

$$\arg\max_{\theta} \sum_{i=1}^{m} \log p\left(y^{(i)}|x^{(i)}; \theta\right) - \alpha R(\theta) \tag{2-4}$$

where $R(\theta)$ is a regularization term used to penalize large parameters values.
If $R(\theta) \equiv 0$, the model is unregularized and its parameters are fitted using the maximum likelihood criteria. If $R(\theta) = \|\theta\|_1 = \sum_{i=1}^{n} |\theta_i|$ the model is L_1 regularized. In contrast, if $R(\theta) = \|\theta\|_2^2 = \sum_{i=1}^{n} \theta_i^2$ the model is L_2 regularized. Finally, the parameter $\alpha \geq 0$ controls a tradeoff between the goodness of fit from data and well-regularized/small parameters.

2.8.2. Linear Discriminant Analysis

Linear Discriminant Analysis (LDA) classifier can be represented as a probabilistic model, so the k classes are modeled as a multivariate Gaussian distribution such as follows [91]

$$f_k(x) = \frac{1}{(2\pi)^{p/2} \left|\mathbf{\Sigma}_k\right|^{1/2}} e^{-\frac{1}{2}(x-\mu_k)^T \mathbf{\Sigma}_k^{-1}(x-\mu_k)} \tag{2-5}$$

Where p is the number of features, μ_k is the mean of the inputs for class k and $\mathbf{\Sigma}_k$ is the covariance matrix of each class. LDA assumes that the classes have common covariance matrix $\mathbf{\Sigma}_k = \mathbf{\Sigma} \forall k$.
The log-ratio is used to compare two classes k and ℓ.

$$\begin{aligned} \log \frac{\Pr(y=k|X=x)}{\Pr(y=\ell|X=x)} &= \log \frac{f_k(x)}{f_\ell(x)} + \log \frac{\pi_k}{\pi_\ell} \\ &= \log \frac{\pi_k}{\pi_\ell} - \frac{1}{2}\left(\mu_k + \mu_\ell\right)^T \mathbf{\Sigma}^{-1} \left(\mu_k - \mu_\ell\right) \\ &\quad + x^T \mathbf{\Sigma}^{-1} \left(\mu_k - \mu_\ell\right) \end{aligned} \tag{2-6}$$

Where π_k and π_ℓ are the prior probabilities of each class. According to the equation 2-6, linear discriminant functions can be established as follows:

$$\delta_k(x) = x^T \mathbf{\Sigma}^{-1} \mu_k - \frac{1}{2} \mu_k^T \mathbf{\Sigma}^{-1} \mu_k + \log \pi_k \tag{2-7}$$

Finally, given an input x, LDA classifier predicts the response with the highest δ_k.

2.8.3. Support Vector Machines (SVM)

The following mathematical formulation of the SVM models was extracted from one of the papers published in the development of this thesis [79]. The goal of SVMs is to define a hyperplane that divide a set of examples into two classes labeled by $y_i \in \{-1, 1\}$, so that points with the same label are on the same side of such hyperplane, given by [92]:

$$y_i(\mathbf{w} \cdot \mathbf{x_i} + b) \geq 1 \quad i = 1, \cdots, N \tag{2-8}$$

where N is the number of data; $(\mathbf{x_i}, y_i)$, the set of training segments, $\mathbf{x_i} \in \mathbb{R}^d$; d, the dimension of the feature space; and $\mathbf{w}$ and b, parameters that satisfy equation (2-8). When the data are not linearly separable, equation (2-8) becomes

$$y_i(\mathbf{w} \cdot \mathbf{x_i} + b) \geq 1 - \xi_i \quad i = 1, \cdots, N \tag{2-9}$$

where $\xi_i \geq 0$ is a variable that allows missclassified points. The general optimization problem can be written as follows [92]:

$$\min_{\mathbf{w},b} \frac{1}{2} \mathbf{w} \cdot \mathbf{w} + C \sum_{i=1}^{N} \xi_i \tag{2-10}$$

Although SVMs are primary intended for bi-class classification problems, a large number of problems imply $K > 2$ classes [93]. The one-vs.-all method was used to train the SVM model. There are different ways to define the hyperplane decision function. Since the radial basis function (RBF) kernel function offers better accuracy [94], it was used for the SVM model, i.e., the decision function is expressed as

$$f(\mathbf{x}) = sgn\left[\sum_{i=1}^{l} w_i \exp\left(-\frac{||\mathbf{x} - \mathbf{x_i}||^2}{2\sigma^2}\right)\right] \tag{2-11}$$

An heuristic variation of the penalty parameter C and the kernel width σ (hyperparameters) was conducted to improve the performance of the classifier. In order to prevent under–or overfitting, the heuristic search avoided the following criteria [95]:

- Underfitting: fixed σ^2 with $C \to \infty$; small and fixed C with $\sigma^2 \to 0$; fixed C with $\sigma^2 \to \infty$.

- Overfitting: large and fixed C with $\sigma^2 \to 0$.

Furthermore, hyperparameters should change in exponentially growing sequences [96]. Thus, both of them varied between 10^{-3} and 10^3.

2.8.4. Multilayer Perceptron (MLP)

MLP is an ANN-based classification model, which is inspired in the central nervous system. It comprises many artificial neurons that are connected to each other according to the established network architecture. Figure **2-7** shows an MLP example with five inputs, one hidden layer (3 neurons) and a scalar output.

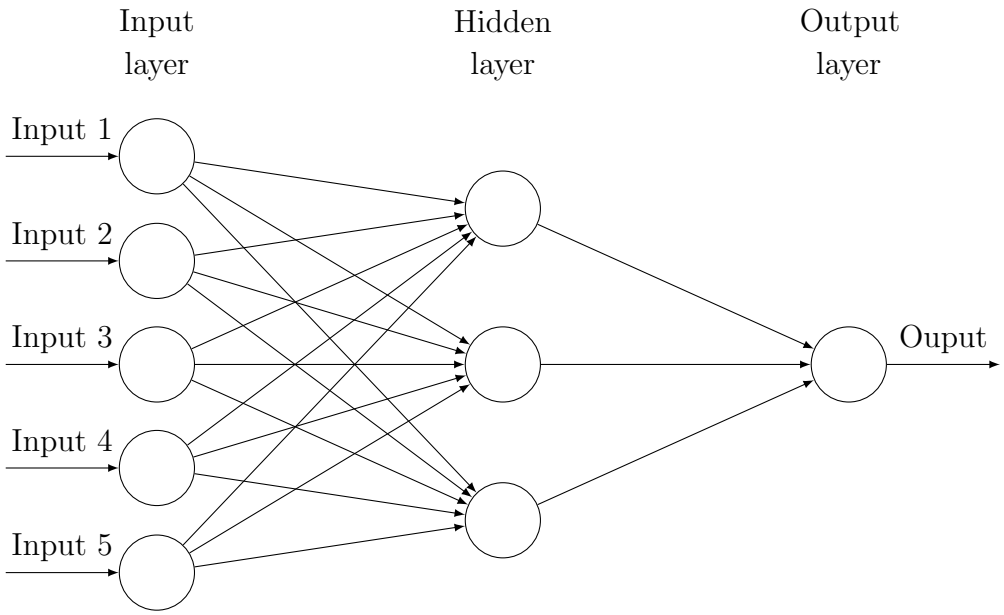

Figure 2-7.: Example of an MLP with one hidden layer and a scalar output.

An MLP model is typically defined by three types of parameters: (a) the interconnection configuration between the different layers of neurons, (b) the learning process to update the weights of the interconnections and (c) the activation function that generates the hypothesis (h_θ(z)) of each neuron and its corresponding output activation. The activation functions explored in the present master's thesis were:

Sigmoid or Logistic Activation Function

$$h_\theta(z) = \frac{1}{1 + e^{-z}} \tag{2-12}$$

$$z = \theta^T x = \sum_{j=0}^{n} \theta_j x_j \tag{2-13}$$

where,

θ are the parameters associated to each neuron, x are the inputs of each neuron and n is the total number of inputs.

Tanh or Hyperbolic Tangent Activation Function

$$h_\theta(z) = \frac{2}{1 + e^{-2z}} - 1 \tag{2-14}$$

Rectified Linear Unit (ReLU) Activation Function

$$h_\theta(z) = \begin{cases} 0 & \text{for} \quad z < 0 \\ z & \text{for} \quad z \geq 0 \end{cases} \tag{2-15}$$

The cost function of an MLP is described in the Equation 2-16.

$$J(\theta) = -\frac{1}{m}\left[\sum_{i=1}^{m}\sum_{k=1}^{k} y_k^{(i)} \ln\left(h_\theta\left(x^{(i)}\right)_k\right) + \left(1 - y_k^{(i)}\right) \ln\left(1 - h_\theta\left(x^{(i)}\right)_k\right)\right] + \frac{\lambda}{2m}\sum_{i=1}^{sl}\sum_{i=1}^{sl}\sum_{i=1}^{sl+1}\left(\theta_{ji}^{(l)}\right)^2 \tag{2-16}$$

Where, λ is the parameter of regularization or learning rate, L is the number of layers of the neural network and sl the number of neurons of the l-th layer. $h_\theta\left(x^{(i)}\right)$ is the model built from the training data, θ_j are the model parameters, and $x^{(i)}, y^{(i)}$ are the input and output data of the i-th training example.
Several MLP were trained using adam optimizer with the following network architectures: one hidden layer (10, 50 and 100 neurons), two hidden layers ([10, 10], [50, 50], [100, 100]) and three hidden layers([10, 10, 10],[50, 50, 50], [100, 100, 100]).

2.9. sEMG channel evaluation

The muscles involved in the swallowing process have a bilateral muscular behavior, except for orbicularis oris muscle. Therefore, to analyze the contribution of each muscular groups in the detection of dysphagia and guarantee the bilateral neuromuscular information, the elimination of the sEMG channels or muscular groups was always carried out as follows:

- Right and left masseters (RM - LM).
- Right and left suprahyoid (RSH - LSH).
- Right and left infrahyoid (RIH - LIH).
- Orbicularis oris (ORB).

2.10. Assessment of the dysphagia detection scheme

A true positive (TP) is achieved whether the classifier is able to identify correctly a patient with dysphagia. If the real case is patient with dysphagia and the classifier predicts it as healthy subject, a false positive (FP) occurs. If the algorithm classifies correctly a healthy subject, it will be a true negative (TN), otherwise it will be a false negative (FN) [97]. The confusion matrix is a technique used to assess the performance of a classifier (see Figure

2-8). The diagonal of this matrix indicates the number of samples classified by the algorithm correctly. The confusion matrix was normalized in order to have a straightforward interpretation because it is given in relative terms instead of absolute values.

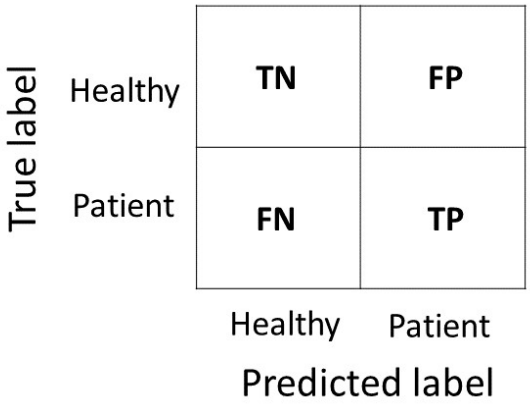

Figure 2-8.: Representation of a binary confusion matrix.

Precision (also known as predictive positive value), recall (also known as true positive rate) and F_1 score were estimated using the results obtained from the confusion matrix in order to prevent overfitting inter-subject misclassification, a characteristic problem in sEMG signals [98].

$$Precision = \frac{TP}{TP + FP} \tag{2-17}$$

$$Recall = \frac{TP}{TP + FN} \tag{2-18}$$

$$F_1 score = 2\frac{Precision \times Recall}{Precision + Recall} \tag{2-19}$$

The above-mentioned metrics were used to find the best hyperparameters of the classification models in study.

Finally, receiver operating characteristic (ROC) curve was used in order to get a graphical representation of the true positive rate versus false positive rate. The area under the curve (AUC) is a measure estimated from the ROC curve used to select the optimum classification model. An AUC value near to 1 means a good discriminatory model. Figure **2-9** summarizes the methodology used in the present master's thesis.

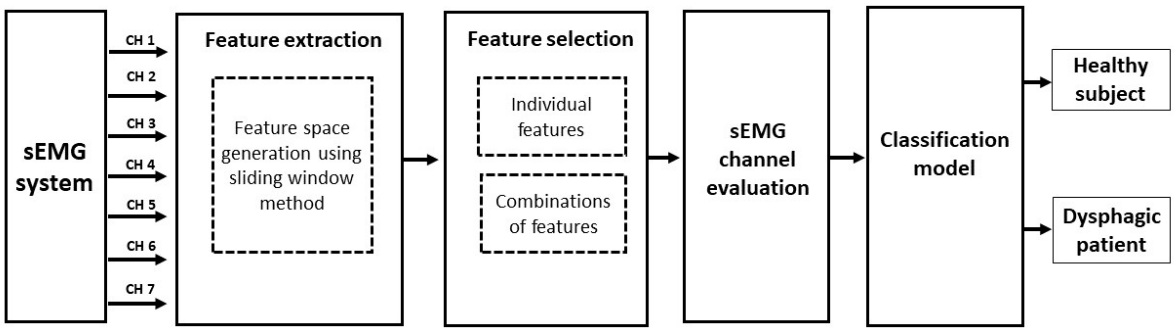

Figure 2-9.: Methodology used for the development of the automatic detection dysphagia scheme.

3. Results and discussion

3.1. Feature space evaluation

Two feature selection strategies were implemented to find the classification scheme that detects dysphagia more accurately. The first strategy was to assess the performance of the classifiers using each 28-dimensional EMG feature space separately. Table **3-1** shows the F1-score values achieved by the optimized classifiers using the features spaces obtained for each EMG feature. In this experiment, the hyper-parameters with the best performance were: SVM ($C = 100$, $\sigma = 0.1$), MLP (one hidden layer with 100 neurons and activation function Relu), LR ($C = 1$). The DASDV feature space obtained the highest F1 score value

Table 3-1.: Mean and standard deviation of the F1-score values (%) obtained for each classifier using 28-dimensional EMG feature spaces separately.

Feature	SVM		MLP		LR		LDA	
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
VAR	71,63	15,04	71,82	16,25	49,37	11,02	64,74	6,84
RMS	76,20	16,29	72,09	10,67	69,13	6,67	67,96	8,89
MAV	76,35	14,16	70,95	8,13	69,89	9,30	67,75	10,61
LOG	69,39	10,76	69,05	9,04	69,17	8,55	67,75	10,61
WL	77,06	15,92	72,97	12,48	63,02	9,44	**73,56**	**10,45**
ACC	78,01	14,16	71,91	10,39	70,10	10,83	68,91	10,21
DASDV	**79,76**	**14,48**	**75,44**	**9,22**	69,90	10,38	68,91	10,21
ZC	67,68	13,80	71,32	12,35	68,13	7,81	65,63	11,03
WAMP	68,67	5,86	71,53	8,41	69,19	11,74	70,16	8,67
MYOP	64,53	4,52	66,57	5,40	**74,15**	**7,99**	**73,12**	**8,87**
MNP	71,63	15,04	71,80	15,63	58,67	9,51	71,87	12,78
TP	71,63	15,04	72,63	16,04	49,37	11,02	64,74	6,84
MDF	70,96	7,48	70,05	10,81	49,37	11,02	35,42	2,59
PKF	67,39	6,14	58,75	4,18	68,74	13,46	**73,20**	**7,31**
WENT	70,15	9,63	58,75	4,18	53,42	10,29	63,04	5,09

(79,76 ± 14,48%) using SVM classifier.

The use of features spaces separately achieved low classification performance, so all possible combinations of 2,3,4 and 5 feature spaces were evaluated in order to improve the dysphagia detection. In this experiment, the hyper-parameters with the best performance were: SVM ($C = 100$, $\sigma = 1$), MLP (one hidden layer with 100 neurons and activation function Relu), LR ($C = 1$). Table **3-2** summarizes the results for the best combinations of 28-dimensional feature spaces in terms of F1-score. For the SVM classifier, the combination of DASDV + ZC achieved the highest F1-score value (85,41 ± 9,95%) but it was similar to DASDV + ZC + LOG (85,10 ± 11,74%). In this exploratory analysis, the combinations with more than five feature spaces did not achieve a performance higher than 85%.

Table 3-2.: Mean and standard deviation of F1-score value (%) obtained for each classifier using the combination of 28-dimensional EMG feature spaces. Lines separate the combinations of two, three, four and five feature spaces.

Features								SVM		MLP		LR		LDA	
RMS	MAV	LOG	ACC	DASDV	ZC	MYOP	MDF	Mean	SD	Mean	SD	Mean	SD	Mean	SD
x					x			81,67	13,30	74,38	14,36	75,87	9,73	70,05	10,18
	x				x			81,86	12,29	76,15	9,28	**76,29**	**11,37**	68,92	14,15
			x		x			83,09	12,14	38,23	8,07	72,85	9,81	69,11	12,41
				x	x			**85,41**	**9,95**	**77,64**	**14,43**	74,13	9,56	70,42	9,35
x		x			x			82,72	12,03	73,79	12,64	74,42	11,43	73,50	13,90
	x			x	x			83,69	11,56	67,59	20,09	75,76	10,39	67,55	8,35
	x				x	x		82,32	11,64	69,98	13,73	74,81	10,73	75,23	11,04
		x		x	x			**85,10**	**11,74**	68,68	19,87	73,93	10,67	73,97	11,27
				x	x	x		83,63	9,82	74,51	9,37	71,81	13,08	71,61	10,91
x	x	x					x	81,86	12,18	76,87	17,20	75,11	8,54	**77,83**	**12,46**
x	x		x				x	82,57	11,52	75,88	15,38	75,73	8,09	73,71	11,94
	x	x		x	x			83,13	13,65	73,78	14,81	74,36	12,22	75,41	13,05
		x	x	x	x			83,45	14,86	74,05	12,79	74,90	9,79	73,95	15,27
x			x	x	x		x	82,24	12,24	69,39	18,93	74,55	12,33	73,34	8,70
	x		x	x	x		x	82,08	12,20	75,88	11,35	49,62	10,85	72,44	9,62
		x	x	x	x		x	82,89	9,89	55,88	26,98	74,15	13,49	72,08	14,65

3.2. Statistical analysis

Statistical analysis was carried out to select from each feature space, those variables that presented significant statistical differences to discriminate between healthy and patient with dysphagia. Table **3-3** shows the number of selected variables from each EMG feature space and the F1-score values achieved by the optimized classifiers. In this stage, the hyper-parameters with best performance were: SVM ($C = 100$, $\sigma = 1$), MLP (one hidden layer with 100 neurons and activation function Relu), LR ($C = 1$). The application of the statistical analysis over DASDV feature allowed to reduce dimensional space from 28 to 22, which increased the F_1 score value from 79,76% to 82,55% using the SVM classifier.

Table 3-3.: Mean and standard deviation of the F1-score values (%) obtained for each classifier using n-dimensional feature spaces separately. n indicates the number of selected variables by statistical analysis.

Feature	Dimensions of feature space ($\mathbb{R}^n$)	SVM		MLP		LR		LDA	
		Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
VAR	20	65,83	15,54	70,48	13,22	47,16	7,88	63,78	5,93
RMS	22	79,56	18,47	**75,46**	**9,98**	66,58	6,75	63,27	6,57
MAV	21	75,62	11,59	73,64	8,70	68,08	10,08	65,43	13,27
LOG	19	70,44	10,16	70,63	13,50	70,18	12,13	72,24	11,19
WL	22	77,81	13,28	74,82	12,03	67,67	8,38	65,01	9,84
ACC	22	79,27	11,81	71,86	10,11	66,82	8,11	65,01	9,84
DASDV	22	**82,55**	**15,47**	74,75	7,28	65,50	4,57	62,68	7,81
ZC	25	62,22	4,99	60,71	6,74	59,45	7,61	64,31	8,81
WAMP	26	69,29	6,65	74,19	7,00	**73,87**	**8,15**	**73,36**	**7,92**
MYOP	17	65,09	3,34	64,14	3,50	59,77	10,67	72,66	9,41
MNP	20	65,83	15,54	69,32	12,13	47,16	7,88	63,78	5,93
TP	20	65,83	15,54	71,54	8,68	47,16	7,88	63,78	5,93
MDF	17	69,32	7,46	58,17	10,98	68,93	9,64	69,81	7,66
PKF	12	61,06	11,29	63,10	17,08	56,30	7,93	57,17	6,38
WENT	10	68,76	9,45	70,13	11,03	65,41	8,45	69,32	5,47

Table **3-4** summarizes the results for the best combinations of reduced features spaces. For SVM classifier, the combination of MAV + LOG + DASDV + ZC achieved a F1-score value of 83,67 ± 9,72% . In the case of LDA classifier, the unique feature combination that generated acceptable perfomance was RMS + MAV + LOG + MDF (82,23 ± 8,93%).

The implementation of the statistical analysis and the combination of the features spaces RMS + MAV + LOG + MDF helped to increase the F1-score value of the LDA classifier from 77,83% to 82,23%. However, it did not achieve overcome the F1-score value obtained by the SVM classifier, when it was trained with the combination of 28-dimensional feature spaces (see Table **3-2**.)

Although the statistical analysis eliminated the variables from each feature space that did not present significant statistical difference, this did not have in consideration that these variables combined with others could increase the separability between classes. Therefore, the use of 28-dimensional feature spaces allowed to improve the discrimination between healthy subjects and patients with dysphagia.

In general, the SVM classifier outperforms MLP, LDA and LR classifiers. It could be because the feature space generated by the kernel function allowed to find a hyperplane and margin through C parameter tuning that separates the classes more accurately. The F1-score values obtained from the MLP and LR classifiers were lesser than 78%. Moreover, the threshold-based features WAMP, ZC and MYOP (see the equation 2-1) produced F1-score values below to 69%. However, when they were combined with other features such as DASDV

Table 3-4.: Mean and standard deviation of F1-score value (%) obtained for each classifier using the combination of n-dimensional feature spaces. n indicates the number of selected variables by statistical analysis. Lines separate the combinations from two, three, four and five feature spaces.

Features								SVM		MLP		LR		LDA	
RMS	MAV	LOG	ACC	DASDV	ZC	MYOP	MDF	Mean	SD	Mean	SD	Mean	SD	Mean	SD
x					x			76,92	12,44	76,34	13,09	69,55	10,95	67,37	12,53
	x				x			82,07	8,26	72,28	9,52	76,29	10,12	71,40	11,55
			x		x			76,30	14,21	56,59	16,58	71,13	15,12	69,27	12,48
				x	x			79,61	10,37	72,00	17,42	70,33	13,89	67,91	12,37
x		x			x			79,32	13,61	76,09	9,96	71,77	7,13	79,65	6,96
	x			x	x			81,34	12,25	76,22	11,65	74,04	3,65	64,57	7,33
	x				x	x		77,38	15,81	68,65	15,12	75,80	11,25	66,54	12,13
		x		x	x			82,47	9,77	63,13	23,62	72,28	10,59	69,82	7,94
				x	x	x		80,79	12,52	73,06	11,82	73,64	12,11	72,81	15,74
x	x	x					x	80,14	13,42	76,90	15,37	**77,21**	**11,31**	**82,23**	**8,93**
x	x		x				x	81,63	12,92	**77,52**	**15,47**	76,27	10,88	71,24	10,99
	x	x		x	x			**83,67**	**9,72**	75,92	10,86	74,92	12,27	77,40	10,09
		x	x	x	x			82,22	14,20	72,21	13,80	76,09	12,14	71,10	11,61
x			x	x	x		x	**83,49**	**11,84**	62,43	22,27	**77,21**	**11,31**	69,93	10,01
	x		x	x	x		x	**83,19**	**6,36**	68,37	19,06	76,27	10,88	71,57	12,95
		x	x	x	x		x	82,05	7,76	65,91	19,10	74,92	12,27	76,91	11,18

and LOG, helped to increase F1-score value until 85% (see Table **3-2**). The behavior of these features was very similar to the results of a previous work, where the use of threshold-based features separately also produced a poor performance to identify swallowing events in healthy subjects, but the combination of these features with the features DASDV and LOG contributed to discriminate healthy swallowing phases more accurately [79].

3.3. sEMG channel evaluation

The elimination of sEMG channels were carried out in order to analyze the contribution of each sEMG channel in the detection of dysphagia. Table **3-5** shows the F1-score values achieved by the optimized SVM classifier ($C = 10$, $\sigma = 1$) when it was trained only with sEMG information (DASDV + ZC) of one, two, three and four muscular groups. In general, the channels RSH and LSH were the sEMG channels with major contribution in the detection of patients with dysphagia. For instance, the optimized SVM classifier achieved an acceptable F1-score value (82,43 ± 15,42%) when it was only trained with information of the RSH and LSH channels. Moreover, when the information of the RSH and LSH channels was not considered the F1-score value was below to 75%.
On the other hand, the optimized SVM classifier achieved the highest F1-score value (89,21 ± 10,51%) when it was trained without information of infrahyoid muscles (i.e., RIH and LIH channels). However, the present sEMG channels analysis must be validated when more neuromuscular information will be recorded.

Table 3-5.: Mean and standard deviation of F1-score value (%) obtained for SVM classifier using as input the features DASDV + ZC of one, two, three and four muscular groups. Horizontal lines separate the number of muscular groups used for classification. The sEMG channels marked with "X" were used for SVM model training.

Number of groups assessed	sEMG Channels							Mean (%)	SD (%)
	RM	LM	RSH	LSH	RIH	LIH	ORB		
1	X	X						64,48	9,37
			X	X				82,43	15,42
					X	X		69,66	11,25
							X	67,69	12,44
2	X	X	X	X				80,81	13,09
	X	X			X	X		67,97	10,00
	X	X					X	74,41	7,11
			X	X	X	X		84,28	13,50
			X	X			X	83,75	17,52
					X	X	X	69,01	14,93
3	X	X	X	X	X	X		83,43	9,67
	X	X	X	X			X	**89,21**	**10,51**
	X	X			X	X	X	72,39	7,24
			X	X	X	X	X	81,30	19,15
4	X	X	X	X	X	X	X	85,41	9,95

3.4. Performance measures of the dysphagia detection scheme

According to Table **3-5**, the optimized SVM classifier achieved the highest F1-score value when it was trained with the features DASDV + ZC of the sEMG channels RM, LM, RSH, RIH and ORB (i.e., 40-dimensional feature space). Figure **3-1** shows the ROC curve of the proposed classification scheme and how its AUC value varies when the training set is splited into five folds. The mean AUC value obtained was of 92,40 ± 9,77%.

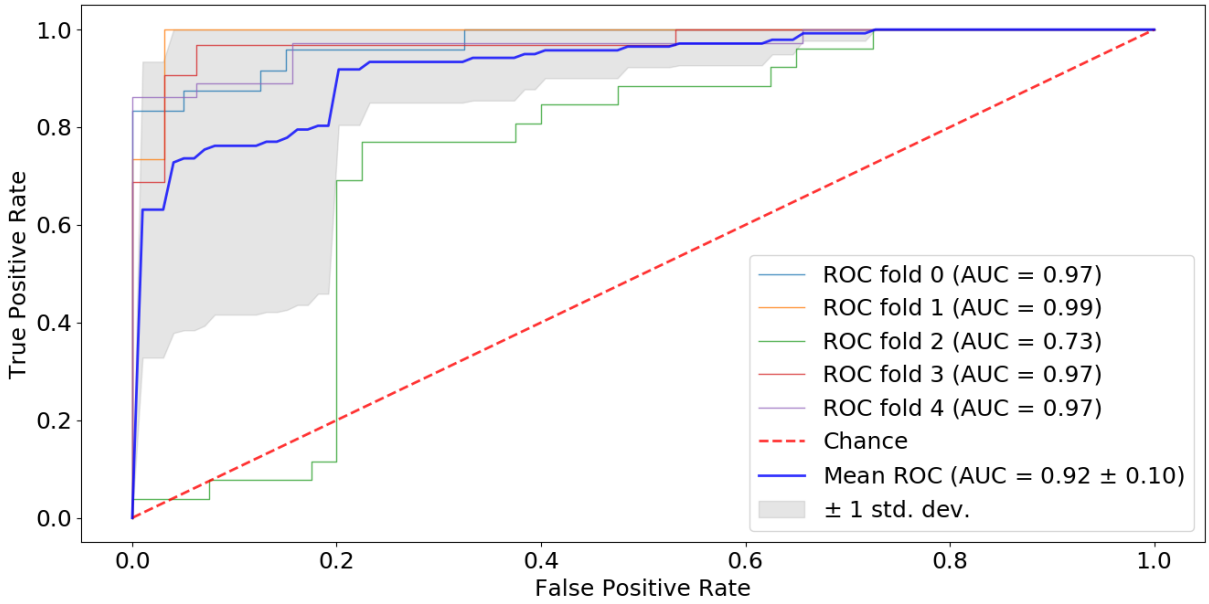

Figure 3-1.: ROC curve obtained by the optimized SVM classifier when it was trained with the sEMG features DASDV + ZC of the channels RM, LM, RSH, RIH and ORB.

In ROC analysis, the sEMG signals used to validate the training of the third partition were examined, in order to understand why the AUC value of this partition was much lower than the rest of them (see Figure **3-1**). Although the presence of artifacts was discarded, the muscular behavior of one patient looks similar to a healthy subject in terms of amplitude and synchronization of muscular activations during swallowing. It could be explained by the low severity of the symptom of mentioned patient.

From 153 samples of patients with dysphagia, 129 were classified correctly, whilst from 176 samples of control subjects 12 were misclassified. Figure **3-2** shows the normalized confusion matrix in order to evaluate the quality of the proposed dysphagia detection scheme.

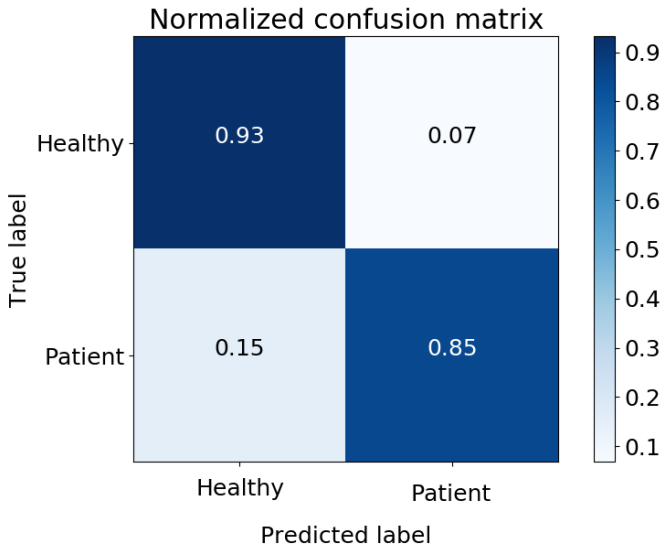

Figure 3-2.: Normalized confusion matrix obtained by the optimized SVM classifier when it was trained with the sEMG features DASDV + ZC of the channels RM, LM, RSH, RIH and ORB.

Table 3.4 presents the performance measures per class obtained by the proposed dysphagia detection's scheme. The F1-score values for the control and dysphagic groups were 90,36% and 88,05%, respectively.

	Precision (%)	**Recall (%)**	**F1-score (%)**
Control	87,70	93,18	90,36
Patient	91,49	84,87	88,05
Average	89,59	89,03	89,21

Table 3-6.: Performance measures obtained by the optimized SVM classifier when it was trained with the sEMG features DASDV + ZC of the channels RM, LM, RSH, RIH and ORB.

Some methodologies have reported similar results for the detection of dysphagia using non-invasive biosignals. For instance, Schultheiss et al. used bioimpedance and EMG measurements to compare between healthy subjects and patients with swallowing disorders using statistical tests. The proposed classification scheme achieved a recall of 84.1% and specificity 84.7% [99]. Similarly, Hsu et al. designed a dysphagia discrimination system for patients with myasthenia gravis based on sound and sEMG signals, which achieved an accuracy of 82.6% [70].

The main limitation of the present thesis was the reduced number of patients with dysphagia. It did not allow to analyze the effect of variables such as age, gender, dysphagia state, bolus consistency, and bolus volume over the classification performance. The study of these variables could contribute to have a better understanding of the swallowing disorders.
Therefore, it is necessary to increase the acquisition of muscular information from patients with different dysphagia levels in order to convert the proposed classification scheme in a multiclass problem. It could contribute to reduce inter-patient variability. Moreover, it would help to determine dysphagia state and its evolution during the rehabilitation process.
Another limitation of the proposed scheme for dysphagia detection is that the sEMG signals are an indirect measure of the swallowing process due to their no-invasive nature. Therefore, these sEMG recordings must be acquired in conjunction with the current dysphagia screening methods such as VFSS and FEES, in order to correlate the physiological patterns generated in both methodologies and improve dysphagia diagnosis and treatments. After validation, these findings should be used as a non-invasive, objective and complementary tool for dysphagia detection and follow-up.
Future works should also include information acquired from other sensors such as accelerometer and microphone. These have demonstrated give valuable information about the swallowing process. The combination of acoustic and accelerometry signals with sEMG signals could improve the identification of swallowing disorders. For instance, Lee et al showed how the classification performance of an ANN increased, while more information sources were used for the segmentation of swallowing events [100].

4. Conclusions and contributions

The development of an automatic dysphagia detection scheme based on multichannel sEMG signals was exposed in the present master's thesis. The SVM classifier outperforms MLP, LDA and LR classifiers. It could be because the feature space generated by the kernel function contributed to find the decision function that better discriminates between healthy and pathological classes. Therefore, SVM demonstrated to be a promissory classification algorithm for the identification of normal and abnormal muscular sequences related to swallowing. The proposed classification scheme achieved a mean AUC value of 92,40 ± 9,77%. The combination of the DASDV + ZC was the feature space that achieved the highest F1-score value (89,21 ± 10,51%). Although these features belong to the time domain, these provide complementary data about muscular behavior i.e., DASDV gives energy and complexity information, whilst ZC provides frequency information in the time domain. The combination of these two types of information contributed to improving the detection of swallowing disorders.

RSH and LSH groups were the sEMG channels with the major contribution in the detection of dysphagic patients, since the classification performance decreases when such muscles are not analyzed. It could be because suprahyoid muscles are involved in both the oral and pharyngeal phases due to their muscular contribution to propels the bolus from the oral cavity to pharynx. However, results obtained by the sEMG channels evaluation must be validated in further studies, where other variables such as the bolus consistency and severity grade will be considered.

During the development of the current thesis, a first approximation based on machine learning algorithms were proposed to discriminate between healthy subjects and patients with dysphagia, using multichannel sEMG signals.

In future works, it is necessary to collect more neuromuscular information from patients with different grades of dysphagia severity in order to use the proposed scheme not only for discrimination but also to follow-up purposes. Moreover, further efforts must be done in order to adapt the designed protocol to acquire sEMG signal synchronously with VFSS or FEES. It will allow to correlate well known physiological findings of the gold standard methods with the electrophysiological patterns recorded with sEMG. It could contribute to validate the sEMG based method as well as to have a better understanding of the swallowing disorders.

This master thesis the following several contributions in the fields of biomedical signal processing and machine learning applied to swallowing related problems:

1. One paper entitled: "Improving surface EMG burst detection in infrahyoid muscles during swallowing using digital filters and discrete wavelet analysis"[54]. In this study, the performance of burst detection in infrahyoid muscles was increased, despite of their intrinsic difficulty to assess them non-invasively. This was achieved by the application of BPF, with cutoff frequencies between 130 and 180 Hz; and DWT, using db4 and third decomposition level (i.e., a frequency band between 125 and 250 Hz aproximately).

2. Another paper entitled: "Automatic detection of oral and pharyngeal phases in swallowing using classification algorithms and multichannel EMG" [79]. In this study, a new classification scheme for detection of swallowing phases based on multichannel sEMG recordings was developed. As general remarks, the time domain features: LOG detector and DASDV were the features that best described the neuromuscular behavior during the swallowing process from healthy subjects. One important aspect to highlight was that the use of threshold-based features (ZC, MYOP and WAMP) separately did not achieve acceptable classification performances. However, the combination of these with features like LOG and DASDV contributed to increasing the classification accuracy. A common finding was that TD features have better performance than their FD counterpart, behavior in agreement with [101]. The SVM and ANN obtained similar performance measures, so these were suitable for the classification of swallowing muscular events. These aforementioned studies allowed to establish the proposed classification methodology in the present master's thesis.

3. An automatic dysphagia detection scheme based on multichannel sEMG recordings was development. Several features in time, frequency and time-frequency domains were extracted from sEMG signals using the sliding window method, which have demonstrated to be a promissory technique for the characterization of muscular sequences of healthy subjects [79] and patients with dysphagia. The 28-dimensional feature space related to DASDV achieved a F1-score value of 79,76 $\pm$ 14,48% using SVM classifier. Similarly to [79], the combination of the DASDV and ZC features contributed to improve the classification performance (85,41$\pm$ 9,95%). The SVM model demonstrated to be a suitable classifier for the detection of normal and abnormal muscular sequences related to swallowing. The channels RSH and LSH were the more relevant sEMG channels in the classification of patients with dysphagia, in terms of F1-score. In contrast, when the information of infrahyoid muscles was not used the classification performance increased until 89,21%.

4. The development of the present master's thesis allowed the construction of local database with multichannel sEMG information of the swallowing process from healthy subjects and patients with dysphagia.

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A. Informed consent for healthy subjects (in spanish)

Desarrollo de un sistema de diagnóstico asistido de disfagia en pacientes con desórdenes neuromotores, basado en procesamiento de señales no invasivas.

Este documento de Consentimiento Informado tiene dos partes:

- Información (proporciona información sobre el estudio)
- Formulario de Consentimiento (para firmar si está de acuerdo en participar)

Se le dará una copia del Documento completo de Consentimiento Informado.

Parte I: información

Este documento consiste en una autorización para la realización de un procedimiento de registro y observación de algunas señales eléctricas y de sonidos emitidos en boca, rostro y cuello por parte de los músculos durante el proceso de tragar (deglución), de forma no invasiva, es decir utilizando una serie de sensores que se aplican sobre la piel. Usted puede autorizar o rechazar el procedimiento luego de conocer y comprender los beneficios y riesgos que pueda tener, y que han sido explicados por el equipo de investigación.

Justificación y objetivo de la investigación

Tragar o deglutir es un proceso natural de los seres humanos, que se produce a lo largo de toda la vida, y permite entre otras funciones, que los alimentos masticados en la boca puedan llegar de manera segura al esófago y al estómago. Este proceso cuando se daña o altera se llama disfagia o trastorno en la deglución, y pone en riesgo la capacidad de nutrición, hidratación y respiración de la persona. Debilidad en los músculos del cuello, rostro y mandíbula, alteraciones en la faringe (órgano que conecta las fosas nasales, la boca, laringe y faringe) y lesiones en los nervios y estructuras del cerebro, causan trastornos de la deglución o disfagia. Cuando los daños o alteraciones comprometen nervios, cerebro y músculos encargados del acto de tragar, se agrupan bajo el nombre de desorden neuromotor, el cual, a su vez, es el conjunto de causas más frecuentes de disfagia en los adultos (en este grupo se incluyen enfermedades como Parkinson, esclerosis lateral amiotrófica, esclerosis múltiple, trauma encéfalo

craneano y el ataque cerebrovascular). En términos generales cerca del 50 al 80% de las personas que posean un desorden neuromotor experimentan una disfagia. La disfagia es un problema frecuente que pone en peligro la vida, la nutrición y afecta la calidad de vida de los pacientes con desordenes neuromotores.

Existen profesionales de la salud especializados en diagnosticar, tratar y rehabilitar los trastornos de la deglución, que utilizan varias técnicas para poder evaluar la disfagia. Muchas de estas técnicas son costosas o de difícil realización, lo que lleva a la necesidad de ejecutar investigaciones sobre este tema para encontrar nuevas opciones de evaluación y seguimiento.

Basados en lo anterior, se conformó un equipo de investigación entre profesionales del Instituto Tecnológico Metropolitano (ITM), Organización Fonoaudiológica (OFA) y Universidad Pontificia Bolivariana (UPB-sede Robledo, Medellín), que tiene como objetivo desarrollar un sistema de diagnóstico automático de disfagia, mediante técnicas de procesamiento de señales eléctricas de los músculos del cuello, rostro y boca, reconocimiento de patrones para tragar ('?Cómo tragan las personas con desorden neuromuscular?), electromiografía de superficie (equipo tecnológico que capta señales eléctricas desde la piel) y auscultación cervical (recibir los sonidos en la garganta al tragar). En otras palabras diseñar un equipo, que tiene sensores y programas de computador, que ayude en el diagnóstico y seguimiento de las personas con disfagia al personal de la salud, que combine las activaciones de los músculos con los sonidos producidos al tragar.

Procedimiento

1. **Personas sanas**

   Si usted acepta ingresar a este estudio, y es candidato para el mismo (es mayor de edad, no tiene infecciones en los dientes, no tiene malformaciones en la boca, no tiene cuerpos extraños en la boca y comprende bien las instrucciones), los profesionales del equipo de investigación, le aplicaran sobre la piel que rodea la boca, el mentón (o parte inferior de la cara o rostro) y en el cuello una serie de sensores pequeños (electrodos), con cuatro distribuciones diferentes (es decir, los sensores tendrán cuatro formas para ubicarse en su boca, mentón y cuello, para que los investigadores puedan detectar la mejor forma de ubicarlos en las personas con disfagia). Los sensores pequeños (electrodos) únicamente registran señales emitidas de los músculos que se encuentran por debajo de la piel de boca, mentón y cuello. Los sensores se adhieren a la piel mediante una cinta (igual a la que utilizan en los hospitales y clínicas).

   Cada sensor posee una conexión mediante un cable delgado y pequeño que lo conecta a una maquina tipo computador. Fuera de los sensores, se le colocará sobre la piel del

cuello, cerca de su laringe, un pequeño micrófono que captará los sonidos producidos al tragar. Este micrófono también estará conectado por un cable delgado y pequeño a un computador.

Una vez los sensores estén aplicados sobre su piel que rodea boca, mentón y cuello, los investigadores le pedirán a usted realizar una serie de movimientos similares a los que se realizan al momento de tragar o deglutir comida, líquidos y saliva.

2. **Personas con disfagia (pacientes)**

   Si usted acepta ingresar a este estudio, y es candidato para el mismo (es mayor de edad, tiene disfagia o dificultad para tragar, y posee alguno de los siguientes diagnósticos: esclerosis lateral amiotrófica, enfermedad de Parkinson, ataque cerebro vascular o ACV, o trauma encefalocraneano), los profesionales del equipo de investigación realizaran lo siguiente:

   a) Un examen físico de su rostro, boca y cuello para saber el grado de dificultad de su trastorno deglutorio (disfagia).

   b) Clasificar el tipo de trastorno deglutorio en pre-oral, oral o faríngea (es decir, reconocer si su dificultad para tragar es más de la zona de labios, lengua o garganta).

   c) Le aplicaran sobre la piel que rodea la boca, el mentón (o parte inferior de la cara o rostro) y en el cuello una serie de sensores pequeños (electrodos), con una distribución ya probada y seleccionada en la fase inicial de esta investigación en personas sanas. Los sensores pequeños (electrodos) únicamente registran señales emitidas de los músculos que se encuentran por debajo de la piel de boca, mentón y cuello. Los sensores se adhieren a la piel mediante una cinta (igual a la que utilizan en los hospitales y clínicas).

      Cada sensor posee una conexión mediante un cable delgado y pequeño que lo conecta a una maquina tipo computador. Fuera de los sensores, se le colocará sobre la piel del cuello, cerca de su laringe, un pequeño micrófono que captará los sonidos producidos al tragar. Este micrófono también estará conectado por un cable delgado y pequeño a un computador.

      Una vez los sensores estén aplicados sobre su piel que rodea boca, mentón y cuello, los investigadores le pedirán a usted realizar una serie de movimientos para tragar o deglutir comida, líquidos y saliva.

NOTA: este procedimiento se realizará en las instalaciones de la IPS Organización Fonoaudiológica (OFA). Calle 11 A 43 D-88 Barrio Manila El Poblado, Medellín. Teléfono: 2669226

Molestias o Riesgos esperados

Los sensores pequeños (electrodos) solo registran o captan señales eléctricas emitidas por sus músculos que están en la región de la boca, mentón y cuello, por lo tanto NO son invasivos a su boca, no invaden más allá de su piel, y no producen ninguna descarga eléctrica o estimulación sobre su piel. Es decir, los sensores no producen ninguna sensación extraña, a diferencia de sentirlos ubicados alrededor de su boca, mentón y cuello.

Es posible que usted, ya sea persona sana o persona con disfagia, sienta ansiedad o temor por la presencia de los sensores alrededor de su boca, mentón o cuello. Frente a esto el personal de investigación siempre estará a su lado, explicando el procedimiento y evaluando cualquier dificultad que se pueda presentar.

En las personas con disfagia, puede haber presencia de tos o sensación de ahogo secundario a la disfagia de base o pre existente, y no por la presencia de los sensores. Si esto ocurre, el personal de salud que hace parte de la investigación lo revisara y tratara sus síntomas para dar alivio.

Beneficios

El presente estudio es el paso inicial y necesario para diseñar un nuevo equipo, de manera que beneficios inmediatos frente a problemas de salud (en este caso la disfagia por enfermedad de Parkinson, esclerosis lateral amiotrófica, ataque cerebrovascular y trauma cráneo encefálico) no existirán. El beneficio será mediano o largo plazo, a partir de los datos recogidos en la investigación, puedan utilizarse por los profesionales de salud en el diagnostico o seguimiento de la disfagia.

Procedimientos alternativos

Las personas con disfagia, previo a la realización de este estudio, ya han recibido procedimientos alternativos aprobados por el sistema de salud para diagnosticar la presencia o no de disfagia, y realizados por los profesionales de la salud tratantes. Estos procedimientos son: examen físico de la deglución, video deglución, prueba de deglución con colorante, auscultación cervical con fonendoscopio y ejercicios de rehabilitación de disfagia.

Participación Voluntaria

Su participación en esta investigación es totalmente voluntaria. Usted puede elegir participar o no hacerlo. Usted puede cambiar de idea más tarde y dejar de participar aun cuando haya aceptado antes.

Confidencialidad

Nosotros como equipo de investigación no compartiremos la identidad de aquellos que participen en el estudio. La información que sea recolectada se mantendrá confidencial. La información acerca de usted que se recogerá durante la investigación será puesta fuera de alcance de otros, y nadie sino los investigadores, tendrán acceso a verla y analizarla. Cualquier información acerca de usted tendrá un número en vez de su nombre.

Compromiso del equipo de investigación

Los profesionales del equipo de investigación, nos comprometemos a que usted reciba respuesta a cualquier pregunta y aclaración de dudas acerca de los procedimientos, riesgos, beneficios y otros asuntos relacionados con la investigación (ya sea usted como persona sana o como persona con disfagia).

De igual manera, el equipo de investigación, se compromete a proporcionarle información actualizada obtenida durante el estudio, aunque ésta pudiera afectar la voluntad suya para continuar participando. Si llega a ocurrir cualquier daño o compromiso de su estado de salud directamente causados por el procedimiento de investigación ya explicado, el equipo de investigación es responsable de brindar tratamiento médico, indemnización y cubrir gastos adicionales cubiertos por el presupuesto de la investigación.

Limitantes expresadas por el paciente:

(Hace referencia a restricciones como: Rechazo al contacto, participación del investigador en el registro o presencia en la atención, entre otras).

Parte II

CONSENTIMIENTO DEL VOLUNTARIO

He sido invitado a participar en la investigación "**Desarrollo de un sistema de diagnóstico asistido de disfagia en pacientes con desórdenes neuromotores, basado en procesamiento de señales no invasivas"**. He entendido que el estudio consiste en un registro de los músculos y sonidos emitidos al tragar o deglutir, y la no invasividad del procedimiento. Queda claro que no me aplicaran ningún medicamento, cirugía, intervención o modificaran mi forma de tragar.

Declaro que me encuentro satisfecho con la información obtenida del investigador, quien me ha dado la oportunidad de preguntar y resolver dudas que se me presentaron y todas ellas se han resuelto satisfactoriamente. A demás comprendo y acepto el alcance y los riesgos posibles que conlleva este procedimiento.

Me reservo expresamente el derecho a revocar mi consentimiento (cambiar mi decisión), en cualquier momento, antes o después de que se realice el procedimiento.

Nombre del Participante: _____ Fecha _____
Firma: _____

Nombre del testigo 1: _____ Fecha _____
Firma: _____

Nombre del testigo 2: _____ Fecha _____

Firma: _____

Nombre del investigador: _____ Fecha _____
Firma: _____

Responsables del proyecto

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Pontificia Bolivariana).Correo: juanca.suarez@upb.edu.co

REVOCATORIA AL CONSENTIMIENTO INFORMADO

Yo, _____ identificado con CC. N°_____ de_____ manifiesto que, en pleno uso de mis facultades mentales, y por mi propia voluntad, he decidido revocar el consentimiento que había otorgado previamente para la realización del procedimiento del registro de actividad electromiográfica con electrodos de superficie.

Nombre del Participante

_____
CC. _____
Fecha: _____

B. Informed consent for dysphagic patients (in spanish)

Diagnóstico y seguimiento de pacientes con disfagia neuromuscular y neurogénica mediante la integración de señales no invasivas y variables clínicas

Gracias por querer ser parte de este estudio. A continuación, se presenta información detallada para que usted comprenda de que trata y para qué sirve esta investigación y quienes realizan.

Nombre del investigador principal: Juan Camilo Suárez Escudero. Integrante de la línea de investigación en discapacidad, grupo de salud pública Escuela de Ciencias de la Salud Universidad Pontificia Bolivariana (UPB). Estudiante de doctorado en Ciencias Médicas, Universidad Pontificia Bolivariana (UPB).

Este consentimiento informado se dirige a los pacientes y/o acudientes/cuidadores de pacientes con disfagia atendidos en la Organización Fonoaudiológica E.U (IPS OFA).
Este documento de Consentimiento Informado tiene dos partes:

- Información (proporciona información sobre el estudio)
- Formulario de Consentimiento (para firmar si está de acuerdo en participar)

Se le dará una copia del Documento completo de Consentimiento Informado.

Parte I: información

De manera conjunta, profesores e investigadores de la Institución Educativa Instituto Tecnológico Metropolitano (ITM) y Escuela de Ciencias de la Salud de la Universidad Pontificia Bolivariana (UPB), y profesionales en fonoaudiología de la Organización Fonoaudiológica (IPS OFA), hemos conformado un equipo de investigación con el objetivo de estudiar el proceso de tragar en personas con enfermedades del cerebro, de los nervios y de los músculos, para poder entender cuáles son las características de las personas con problemas para tragar, con la finalidad de identificar a tiempo los problemas para tragar alimentos y líquidos, y como esas dificultades mejoran o empeoran en el tiempo.

Para poder cumplir lo anterior, el equipo de investigación está conformado por ingenieros electrónicos, ingenieros biomédicos, fonoaudiólogos y médicos del ITM, OFA y UPB.
Hay muchas causas que producen problemas para tragar en las personas, y en el cuidado integral de la salud, es muy importante identificar a tiempo y conocer cómo cambian las dificultades para tragar en las personas, con el fin de evitar infecciones respiratorias, desnutrición, deshidratación y complicaciones más graves cuando las personas están hospitalizadas. Las dificultades o trastornos para tragar, se conocen científicamente como disfagia. Es así, que este estudio quiere investigar la disfagia por enfermedades del cerebro, de los nervios y de los músculos a través de sensores que se ponen en la piel por parte de los ingenieros y de evaluaciones físicas de la boca, respiración y tragar por parte de fonoaudiólogos y médicos.

Usted es libre y autónomo(a), independiente de que sea atendido o no en la IPS-OFA, de decir si desea o no ser parte de la investigación que a continuación se explicará, y sobre lo que se le desea preguntar e indagar en su historia clínica y en los sensores que se pondrán en su cuerpo. Estamos en total disposición de responder a sus dudas e inquietudes sobre esta investigación.
NOTA: Si es usted es paciente de la Dra. Liliana Martínez, Dra. Claudia Liliana Bedoya o del Dr. Juan Camilo Suárez, no significa que esté obligado a participar en esta investigación y no habrá consecuencias negativas en sus servicios de salud si decide no participar.

Tipo de Investigación y protocolo

Esta es una investigación que requiere acompañarlo a usted por un tiempo de seis (6) meses, donde cada mes en uno de los consultorios de la IPS OFA, se le pegarán con una cinta que se parece a una curita en la piel de su cara y cuello 15 sensores pequeños (del tamaño de un botón), un micrófono pequeño en el cuello, dos sensores del tamaño de un sacapuntas en la parte más alta de su cabeza y en el cuello, un sensor del tamaño de un borrador en uno de los dedos de la mano y un sensor tipo correa delgada en su pecho; además su cara y cuello serán filmados con una cámara colocada al lado suyo. Cuando los sensores se coloquen en su cuerpo y la cámara de video esté preparada, se le darán tres pruebas de alimentos: agua, yogurt y galleta, y de manera separada mientras usted los mastica y traga, los sensores y cámara de video registraran la forma como usted traga, respira y habla. En cada revisión, usted será medido (para la estatura) y pesado en una balanza (para conocer su peso). Todo el proceso anterior dura una hora en la IPS-OFA. Este proceso se repetirá en usted una vez al mes durante seis meses.
En otras palabras, esta investigación trata de revisarlo a usted en siete ocasiones, a lo largo de seis meses, y en cada ocasión (revisión) se mirará como es su forma de tragar mediante unos sensores y un examen físico.
Fuera de lo anterior se solicita su permiso para revisar su historia clínica y extraer (sacar) algunos datos sobre su diagnóstico, y se le harán unas preguntas sobre cómo se siente usted

al momento de tragar y respirar.
NOTA: los sensores se pegan de manera suave en su piel. Ningún sensor se pondrá dentro de su boca o garganta. Ningún sensor será tipo aguja para chuzarlo. No se le aplicará ningún tipo de inyección, no se le dará medicamentos ni se realizarán en usted cirugías, tratamientos o técnicas de rehabilitación.
En cada sesión de revisión en IPS-OFA, estará presente un ingeniero y un profesional de la salud (fonoaudiólogo o médico).

Selección de participantes

Se invita a todos los pacientes que posean disfagia y sean atendidos en la IPS-OFA o en otros servicios o instituciones de salud.

Participación Voluntaria

Su participación en esta investigación es totalmente voluntaria. Usted puede elegir libremente participar, o no participar. Tanto si elige participar o no, continuarán todos los servicios que reciba en la IPS-OFA o en otras instituciones, y nada cambiará. Usted puede cambiar de idea más tarde y dejar de participar aun cuando haya aceptado antes, incluso si ya están los sensores instalados en su piel o se está en medio de la prueba con los tres alimentos, y usted no desea continuar, el estudio se suspende, y no habrá ninguna penalidad. Es decir, usted puede renunciar a no continuar en el estudio, así estemos en la primer, cuarta o última revisión (dentro de los seis meses que dura el estudio).

Riesgos y molestias

Todos los sensores que le serán aplicados en su cara, cuello, cabeza, pecho y manos, son considerados No invasivos, es decir, no chuzan o atraviesan la piel ni se colocaran en su boca o garganta. A continuación, se presentan los posibles riesgos y molestias del estudio, y la forma como se pueden evitar y controlar:

1. Molestias en la instalación de los sensores en su piel del rostro y del cuello. Esta molestia se evitará mediante la explicación del proceso por parte de los investigadores, y la utilización de adhesivos que no generan rasquiña, ardor ni dolor. Si usted tiene mucho vello en la piel del rostro y del cuello se le ofrecerá ser rasurado, para evitar molestias derivadas de la instalación de los sensores. El sensor tipo correa que va en su pecho se pone mediante una banda elástica tipo velcro, el cual no genera dolor, ardor ni rasquiña. El sensor que parece un borrador y que irá en uno de los dedos de la mano, se sujeta a manera de pinza, el cual no duele y presiona muy poco su dedo.

2. Sensación de intimidación “al verse lleno” de sensores en parte de su rostro y cuello,

mas filmación en video de su cara y cuello. Esto se controlará mediante una detallada explicación y acompañamiento durante todo el proceso por parte de los investigadores. Si usted lo desea estará acompañado por familiares y/o cuidador.

NOTA: Si usted se siente muy intimidado y ansioso, aún con el apoyo anterior, se procederá a retirar todo el montaje de los sensores, no se realiza la prueba, y no habrá ningún tipo de sanción o penalización para usted.

3. Presencia de tos y ahogo cuando usted este tomando el agua, el yogurt o la galleta. Este riesgo se evitará mediante una mínima cantidad de los alimentos que se ofrecerán en las pruebas. Es decir, solo se le dará en cada una de las siete revisiones un máximo de 35 ml de agua, un máximo de 35 ml de yogurt y solo 5 gramos de galleta. Esto se hace con la finalidad de evitar que usted tenga tos y se ahogue. Si con esta medida, usted tose o se ahoga, los investigadores suspenderán la prueba, y usted será evaluado, se procederá a medidas médicas como promoción de la tos, aspirar su boca con una manguera pequeña para retirar saliva y restos de alimentos, colocación de oxígeno en su nariz o boca, y en el caso más extremo asistencia médica de reanimación y traslado a un centro hospitalario.

4. La IPS OFA no tiene segundo o tercer piso, de manera que no hay que subir escalas. Todo el estudio se hará en un primer piso, esto se hace con la finalidad de evitar caídas y tropiezos. Si usted tiene silla de ruedas, puede ingresar con ella al consultorio. Además, usted estará sentado durante cada una de las siete sesiones de evaluación.

5. Todas las medidas anteriores se tomarán con el objetivo de evitar una neumonía (infección del pulmón) y broncoaspiración (presencia de saliva o comida en los conductos de aire del pulmón). Sin embargo, en caso de presentarse una broncoaspiración o neumonía, esta se debe tratar con antibióticos, a través de los médicos de su entidad promotora de salud (EPS). En este caso los investigadores darán toda la información sobre usted a los médicos para facilitar el diagnóstico y tratamiento ante una eventual broncoaspiración o neumonía.

Beneficios

Si usted participa en esta investigación a mediano y largo plazo (en cuestión de meses) gracias a su ayuda (en datos e información sobre el proceso de tragar), la ciencia podrá conocer mejor que fenómenos mecánicos, eléctricos y respiratorios que ocurren cuando el proceso de tragar no funciona bien (disfagia) con el fin de poder seleccionar mejor las terapias y tratamientos que se les ofrece a los pacientes, y conocer cuando una persona mejora o no del todo de la disfagia en el tiempo.

Incentivos

Le daremos un subsidio de transporte por valor de $30.000 (treinta mil pesos) en agradecimiento a su tiempo, paciencia y disposición de asistir a cada una de las revisiones. No se le dará ningún otro dinero o regalos por aceptar participar en esta investigación.

Confidencialidad

Nosotros no compartiremos la identidad de aquellos que participen en la investigación. La información que recojamos por este proyecto de investigación se mantendrá confidencial. La información acerca de usted que se recogerá durante la investigación será puesta fuera de alcance de personas no autorizadas, y nadie sino los investigadores (**las tres instituciones)**, tendrán acceso a verla y analizarla. Cualquier información acerca de usted tendrá un número en vez de su nombre.

Compartiendo los Resultados

El conocimiento que obtengamos por realizar esta investigación se compartirá con usted, con la comunidad, y con diferentes actores de salud, académicos, sociales y políticos que trabajan en discapacidad a nivel nacional e internacional. Pero en ningún caso, se presentará información individual de cada paciente, sino la información global y resumida de todos.
El equipo de investigación realizará en el año tres del estudio una charla educativa gratuita para usted y todos los participantes del estudio, donde se les mostrará los principales resultados del estudio, y se realizará una explicación sobre temas relacionados con la disfagia, como diagnóstico y rehabilitación.

Contacto

Si tiene cualquier pregunta puede hacerlas ahora o más tarde, incluso después de haberse iniciado el estudio. Si desea hacer preguntas más tarde, puede contactar a:

Juan Camilo Suárez Escudero
Correo: juanca.suarez@upb.edu.co
Celular: 316 328 64 22

PARTE II: Formulario de Consentimiento para el paciente

He sido invitado a participar en la investigación "**Diagnóstico y seguimiento de pacientes con disfagia neuromuscular y neurogénica mediante la integración de señales no invasivas y variables clínicas**". Entiendo que me acompañaran durante seis meses, donde se realizaran siete revisiones, de una hora cada una. En cada revisión me colocaran en mi piel sensores en rostro, cabeza, cuello, pecho y manos, me darán a comer tres tipos de alimentos, me filmaran el rostro y el cuello mientras mastico y trago, me harán algunas preguntas sobre cómo me siento al tragar y revisaran algunos datos de mi historia clínica. Queda claro que no me aplicaran ningún medicamento, cirugía, intervención o modificaran mi forma de tragar, respirar y hablar.
He leído la información proporcionada o me ha sido leída. He tenido la oportunidad de preguntar sobre ella y se me ha contestado satisfactoriamente las preguntas que he realizado. Consiento voluntariamente participar en esta investigación como participante y entiendo que tengo el derecho de retirarme de la investigación en cualquier momento sin que me afecte en ninguna manera mi cuidado médico.

Nombre del Participante: _____ Fecha: _____
Firma: _____

Nombre del testigo 1: _____ Fecha: _____
Firma: _____

Nombre del testigo 2: _____ Fecha:_____
Firma: _____

Nombre del profesional y/o investigador responsable #1 :_____
Fecha _____
Firma: _____

Nombre del profesional y/o investigador responsable #2 :_____
Fecha _____
Firma: _____

PARTE III: Formulario de Consentimiento Informado para los representantes de pacientes que no están en capacidad de asentir

Como representante del paciente, el cual ha sido invitado a participar en la investigación "**Diagnóstico y seguimiento de pacientes con disfagia neuromuscular y neurogénica mediante la integración de señales no invasivas y variables clínicas**". Entiendo que al paciente lo acompañaran durante seis meses, donde le realizaran siete revisiones, de una hora cada una. En cada revisión le colocaran en la piel sensores en su rostro, cabeza, cuello, pecho y manos, y le darán a comer tres tipos de alimentos, le filmaran el rostro y el cuello mientras mastica y traga, y le harán algunas preguntas sobre cómo se siente al tragar y le revisaran algunos datos de su historia clínica. Queda claro que no le aplicaran ningún medicamento, cirugía, intervención o modificaran su forma de tragar, respirar y hablar.
He leído la información proporcionada o me ha sido leída. He tenido la oportunidad de preguntar sobre ella y se me ha contestado satisfactoriamente las preguntas que he realizado. Consiento voluntariamente, como representante del paciente que no tiene capacidad para asentir este documento, de participar el paciente en esta investigación como participante y entiendo que él tiene derecho de retirarse, o cuando yo como representante lo considere, de la investigación en cualquier momento sin que se afecte en ninguna manera el cuidado médico del paciente.

Yo _____ con cédula No. _____ de _____, actuando en representación del paciente _____ con cédula No. _____ de _____, autorizo la participación de mi representado en esta investigación.

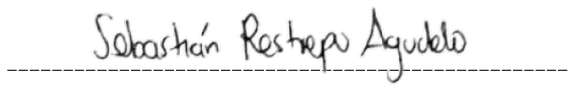
Nombre del Participante: _____Fecha:_ _____
Firma: _____

Nombre del testigo 1: _____Fecha: _____
Firma: _____

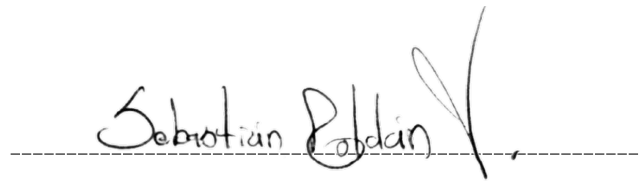
Nombre del testigo 2: _____Fecha:_____
Firma: _____

Nombre del profesional y/o investigador responsable #1 :_____
Fecha _____
Firma: _____

Nombre del profesional y/o investigador responsable #2 :_____
Fecha _____
Firma: _____



Firma del estudiante



VoBo. Sebastián Roldán Vasco, MSc.

VoBo. Andrés Felipe Orozco Duque, PhD.