

Evaluation of an EMG bioimpedance measurement system for recording and analysing the pharyngeal phase of swallowing

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Abstract A neuroprosthetic device for treating swallowing disorders requires an implantable measurement system capable to analysing the timing and quality of the swallowing process in real time. A combined EMG bioimpedance (EMBI) measurement system was developed and is evaluated here. The study was planned and performed as a case–control study. The studies were approved by the Charité Berlin ethics committee in votes EA1/160/09 and EA1/161/09. Investigations were carried out on healthy volunteers in order to examine the usefulness and reproducibility of measurements, the ability to distinguish between swallowing and head movements and the effect of different food consistencies. The correlation between bioimpedance and anatomical and functional changes occurring during the pharyngeal phase of swallowing in non-healthy patients was examined using videofluoroscopy (VFSS). 31 healthy subjects (15♂, 16♀) were tested over the course of 1350 swallows and 19 (17♂, 2♀) non-healthy patients over the course of 54 swallows. The signal curves obtained from both transcutaneous and subcutaneous measurement were similar, characteristic and reproducible ($r > 0.5$) and correlated with anatomical and functional changes during the pharyngeal phase of swallowing observed using VFSS. Statistically significant differences between head movements and swallowing movements, food volumes and consistencies were found. Neither the conductivity of the food, the sex of the test subject nor the

position of the measurement electrodes exerted a statistically significant effect on the measured signal. EMBI is able to reproducibly map the pharyngeal phase of swallowing and changes associated with it both transcutaneously and subcutaneously. The procedure therefore appears to be suitable for use in performing automated evaluation of the swallowing process and for use as a component of an implant.

Keywords Dysphagia · Diagnosis · Pharyngeal phase of swallowing · Bioimpedance · EMG

Introduction

In addition to existing, conventional treatment methods, there is increasing discussion of the use of electrical stimulation and the development of neuroprosthetic devices to aid swallowing [1] as a means of treating swallowing disorders. The focus has been on the targeted stimulation of individual nerves [2] or muscles [3, 4]. Studies have shown that electrical stimulation of the thyrohyoid and mylohyoid muscles [5–7] or the submental muscle group [8] are able to prevent the aspiration of saliva or food.

Successful stimulation requires a measurement system which is able to detect and classify a swallow and to trigger stimulation at the appropriate time point. A number of published studies have investigated EMG of the muscles of the oral diaphragm. EMG does not permit noise and other movements such as speaking to be reliably distinguished. Additional examinations such as videofluoroscopy [7], heart rate and breathing [5] and piezoelectric motion sensors [6] have been used in attempts to improve this procedure, but none has been able to reliably detect and classify swallows. Impedance pharyngography (IPG) would appear to offer some promise as a measurement

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procedure. IPG measures the passage of electricity through the tissues. Using a four electrode measurement technique, Yamamoto et al. [9] were able to show that it was possible to distinguish patients with a swallowing disorder from healthy test subjects.

A combined EMG bioimpedance (EMBI) measurement system [10] which appears to be suitable as a regulatory mechanism for electrical stimulation of the muscles involved in swallowing has been developed as part of the BMBF-sponsored BigDysPro project (www.bigdyspro.de, TUB 01EZ1007A, UKB 01EZ1007B). The objective was to evaluate the EMBI system.

Materials and methods

Measurement device

The EMBI system permits independent measurement of two bioimpedance (BI) and four EMG signals. Measurements are performed using standard ECG electrodes (Ambu® Blue Sensor N REF: N-00-S/25) or needle electrodes (Ambu® Neuroline Monopolar REF: 74225-36/40) placed at the measurement points (see Fig. 1). The system uses a reference electrode, two current sources with two current electrodes and two measurement electrodes. The current electrodes apply a sinusoidal current with a frequency of 50 kHz to measure respiratory tract closure. The amplitude of the current source spans the range 3.4–137 μ A. The measurement electrodes permit the simultaneous measurement of BI and EMG.

Measured signal

Bioimpedance can be described as the ratio of voltage to current arising across a biological tissue. The movement of

R = reference electrode, M = voltage measurement electrodes, C = current source electrodes

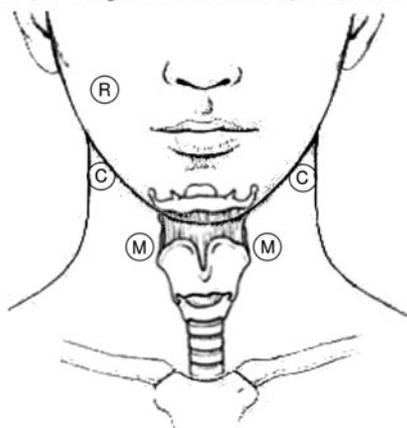


Fig. 1 Electrode positioning. R reference electrode, M voltage measurement electrodes, C current source electrodes

the larynx and the closure of the pharynx gives rise to a characteristic EMG–BI curve, characterised by a fall in bioimpedance during laryngeal elevation (see Fig. 2). EMG activity begins prior to the fall in the bioimpedance signal and mirrors the muscle activity ($A(EMG_{diff})$) involved in laryngeal elevation. EMG activity reaches its high point during laryngeal elevation (EMG_{max}). The downward movement of the larynx back to its initial position (BI_{end}) is the result of infrahyoid muscle activity which is not captured by this system.

Points BI_{start} and BI_{end} mark the swallow and the pause in breathing associated with it. The slope between BI_{start} and BI_{min} represents the speed of laryngeal elevation in ohms/s ($S(BI_I)$). The area between BI_{start} and BI_{min} marks the extent of pharyngeal closure ($A(BI_I)$). The duration of the swallow in seconds is measured between the BI_{start} and BI_{end} values. The swallow is followed by a breath (see Fig. 3).

The following analysis looks at nine swallow-specific characteristics of BI and EMG: duration of swallow, duration of laryngeal elevation, duration of preparation for swallowing and bolus formation, extent of laryngeal closure, maximum laryngeal elevation, speed of laryngeal

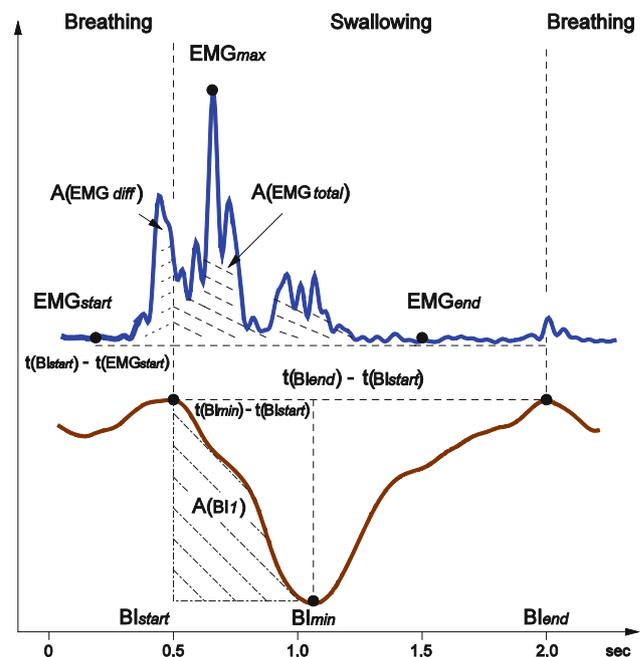


Fig. 2 Bioimpedance and EMG. BI_{start} start of laryngeal elevation, BI_{min} maximum laryngeal elevation, BI_{end} end of laryngeal elevation, $A(BI_I)$ extent of laryngeal closure, $t(BI_{min}) - t(BI_{start})$ duration of laryngeal elevation, $t(BI_{end}) - t(BI_{start})$ duration of swallow, EMG_{start} start of muscle activity, EMG_{max} maximum muscle activity during laryngeal elevation, EMG_{end} end of muscle activity, $A(EMG_{diff})$ preparation for swallowing, bolus formation and start of laryngeal elevation, $A(EMG_{total})$ EMG activity over the whole swallow, $t(BI_{start}) - t(EMG_{start})$ duration of preparation for swallowing and bolus formation

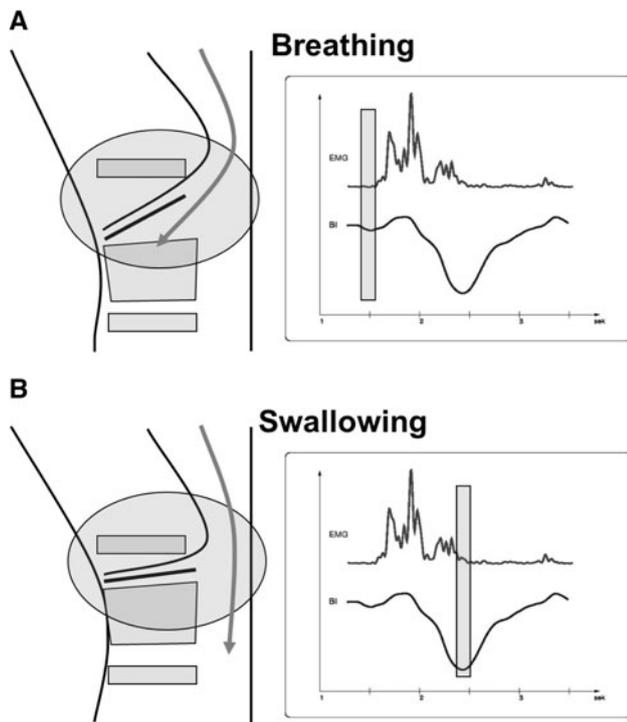


Fig. 3 Schematic of bioimpedance measurement. **a.** During breathing the pharynx is filled with air and tissue resistance is consequently high. **b.** On swallowing, the pharynx is closed through muscle action and resistance is reduced

elevation, maximum EMG activity, extent of EMG activity over the entire swallow and extent of preparation for swallowing and bolus formation.

Test subjects

Healthy subjects with no swallowing disorders, aged from 18.0 to 51.0 and of both sexes, were recruited for both the comparative investigations and the investigations on reproducibility. Exclusion criteria were pregnancy, a cardiac pacemaker, defibrillator, stent or central venous catheter. To study the correlation between visible anatomical changes in VFSS and EMBI during the swallowing process, patients requiring a radiological examination to clarify a swallowing disorder were recruited. All patients were given an explanation of the procedure and agreed to sign a consent form. The study was approved by the Charité Berlin ethics committee in votes EA1/160/09 and EA1/161/09.

Conducting the comparative investigation

The investigations were performed on alert patients seated in an upright position. After applying the electrodes, the

test subjects were given a hand switch with which they were asked to delineate head movements (lowering, turning, speaking) and swallowing. Food was divided into appropriate portions. The test subjects then placed it in their mouths and chewed and swallowed it without further prompting. Reproducibility was tested using 100 g yoghurt in 5 g portions, 200 ml liquid in 20 ml portions and 5 g bread, the effect of volume using 5, 10, 20 and 30 ml of liquid, of consistency using 20 ml liquid, 5 g yoghurt and 5 g bread and of conductivity using 20 ml liquid. Where possible, subjects were asked to keep their head in a neutral position during swallowing. The investigations took an average of 30 min.

Videofluoroscopy

To examine the significance of the information provided by the bioimpedance signal, comparison measurements were made using BI and VFSS. Hyoid and laryngeal skeleton movement visible in lateral VFSS correlated with BI. The investigations were conducted on alert patients seated in an upright position who needed to undergo VFSS as a result of a swallowing disorder. Exclusion criteria were pregnancy, a cardiac pacemaker, defibrillator, stent or central venous catheter. The patients were requested to drink 10 ml of gastrografin, which they placed in their mouths themselves. Movement of the hyoid and larynx was recorded by manually controlling a semi-automatic tracking program (Kinovea, www.kinovea.org) at a frame rate of 15 frames/second (Pulsera, Phillips). The data were then exported. To calculate the extent of any movement, the most anterior and inferior points of the hyoid and larynx and the second (C2) and fourth (C4) cervical vertebrae were marked on the x-ray image as reference points. The standard C2/C4 plane was used for orientation. Starting from C2 to C4, the movements of the hyoid and larynx in the superior (*y*-axis) and anterior (*x*-axis) directions were measured in pixels (see Fig. 4).

Statistical analysis

Statistical analysis was carried out using SPSS 20. Statistical comparison between swallowing and head movements was performed using the non-parametric Mann *U* test. At a significance level of $p \leq 0.05$, there was adequate evidence for the assumption that swallowing movements can be distinguished with high statistical significance from head movements. The reproducibility of the bioimpedance signal was calculated from the correlation between two or four measurements. A correlation coefficient of $r > 0.5$ provides adequate evidence for the assumption that the measured bioimpedance signal is reproducible. Calculation of the correlation was preceded by a calculation of the mean

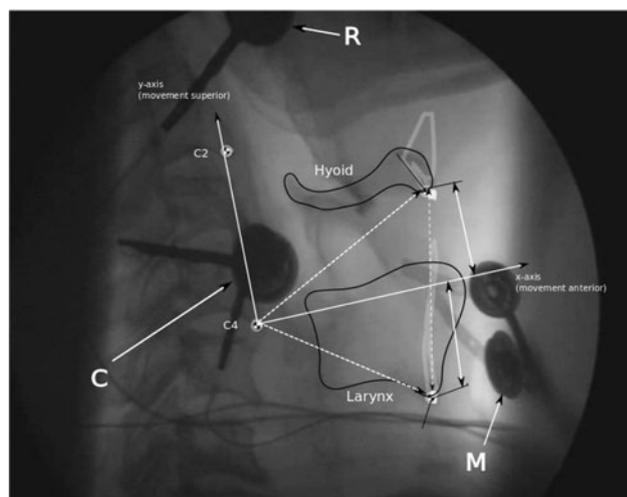


Fig. 4 Calculating laryngeal movement. C2 2nd cervical vertebra, C4 4th Cervical vertebra, R reference electrode, C current source electrodes, M voltage measurement electrodes

value curves for both swallowing and head movements. The means of the correlation coefficients were calculated using Fisher's z transformation. Inter-rater reliability was calculated from the intraclass correlation (ICC). VFSS results were analysed using regression analysis. Means for VFSS analysis were calculated using a meta-analysis, i.e. the means of the correlation coefficients were data point weighted [11].

Results

Test subjects

31 test subjects (mean age = 32.5 ± 7.8 , 15 ♂, 16 ♀) were studied. 20 test subjects were investigated for the comparison between swallowing and head movements and for testing influencing factors. The reproducibility of the measurement signal was tested in 15 test subjects. Inter-rater comparison was conducted on nine test subjects by four different investigators.

The VFSS were carried out with 19 patients (mean age = 65.6 ± 10.4 , 17 male, 2 female). All patients had ENT-specific disorders which results in pharyngeal dysphagia. No side-effects or unpleasant sensations were experienced during testing, as the electric current applied was below the threshold of perception.

Reproducibility

Reproducibility of transcutaneous EMBI was performed using four repeat measurements with a liquid consistency on a total of 15 test subjects (11 male, 4 female, 698

swallows). Calculation of the correlation between individual measurements yielded means of correlation coefficients of $\bar{r} = 0.878\text{--}0.992$. The correlation values indicate high BI reproducibility ($r \geq 0.8$) (see Table 1).

Inter-rater reliability

To examine investigator influence on electrode positioning, transcutaneous measurements were performed on nine test subjects (mean age = 38.6 ± 9.4) by four investigators (119 swallows, liquid consistency). The mean ICC value was $\overline{ICC} = 0.846$, giving adequate to very good correlation (see Table 2).

Swallowing movements versus head movements

In addition to laryngeal movements during swallowing, EMBI also records other movements (e.g. speaking, nodding, chewing). We therefore tested whether EMBI possesses characteristics which permit a reliable distinction to be made between these movements. These characteristics were identified by segmenting the measurement curves on the basis of anatomical and functional changes during swallowing. Cutaneous measurements for swallowing and head movements and for influencing factors were performed on 20 test subjects (mean age = 30.5 ± 7.7 , 328 swallows, 78 head movements). The comparison revealed a statistically significant difference between the mean values for seven of the nine characteristics (see Table 3).

Influencing factors

Electrode comparison

Parallel transcutaneous (self-adhesive electrode) and subcutaneous (needle electrode) measurements (205 swallows, saliva, $N = 49$; liquid, $N = 68$; semisolid, $N = 76$ and solid, $N = 12$) were performed to test whether the measured signal was altered by measuring through the skin. A very high correlation for the two measurement procedures was found ($r = 0.997^{**}$, $p = 0.000$).

Volumes and consistencies

To test the influence of food consistency, 210 swallows of foods of differing consistencies (saliva, $N = 27$; liquid, $N = 106$; semisolid, $N = 53$ and solid, $N = 24$) were compared. The Mann U test identified differences between individual characteristics for the comparison between saliva and other consistencies (duration of laryngeal elevation with liquid, $p = 0.002^{**}$, with semisolid food, $p = 0.007^{**}$; speed of laryngeal elevation with liquid, $p = 0.040^*$, with semisolid food, $p = 0.002^{**}$, with solid

Table 1 Repeat measurement

Subject (code)	Liquid						Mean correlation
	M1/M2	M1/M3	M1/M4	M2/M3	M2/M4	M3/M4	
1 (<i>N</i> = 75)	0.984**	0.904**	0.895**	0.848**	0.836**	0.978**	0.929
3 (<i>N</i> = 33)	0.998**	0.991**	0.963**	0.994**	0.966**	0.983**	0.992
4 (<i>N</i> = 80)	0.993**	0.952**	0.930**	0.923**	0.958**	0.788**	0.963
5 (<i>N</i> = 59)	0.995**	0.993**	0.958**	0.996**	0.971**	0.976**	0.991
6 (<i>N</i> = 49)	0.996**	0.975**	0.973**	0.973**	0.970**	0.999**	0.984
7 (<i>N</i> = 42)	0.867**	0.930**	0.937**	0.967**	0.945**	0.993**	0.933
8 (<i>N</i> = 48)	0.668**	0.686**	0.763**	0.993**	0.977**	0.981**	0.878
9 (<i>N</i> = 42)	0.973**	0.987**	0.994**	0.963**	0.981**	0.988**	0.983
10(<i>N</i> = 43)	0.942**	0.956**	0.988**	0.966**	0.956**	0.958**	0.968
11(<i>N</i> = 50)	0.981**	0.973**	0.959**	0.997**	0.987**	0.987**	0.984
13(<i>N</i> = 39)	0.947**	0.833**	0.934**	0.951**	0.982**	0.929**	0.926
14(<i>N</i> = 35)	0.926**	0.961**	0.983**	0.822**	0.949**	0.950**	0.945
17(<i>N</i> = 28)	0.860**	0.924**	0.921**	0.853**	0.944**	0.965**	0.894
24(<i>N</i> = 38)	0.951**	0.948**	0.893**	0.987**	0.931**	0.953**	0.956
27(<i>N</i> = 37)	0.992**	0.970**	0.866**	0.985**	0.902**	0.929**	0.973

Pearson's correlation

** Correlation is statistically significant at a level $p = 0.01$ (two-sided)

Table 2 Comparative investigations

Subject	I1 vs. I2	I1 vs. I3	I1 vs. I4	I2 vs. I3	I2 vs. I4	I3 vs. I4
1	0.880	0.931	0.922	0.941	0.892	0.987
2	0.874	0.959	0.970	0.959	0.903	0.962
3	0.906	0.402	0.542	0.346	0.469	0.914
4	0.624	0.480		0.774		
5	0.846	0.234	0.440	0.578	0.710	0.858
6	0.938	0.789		0.863		
7	0.964	0.903	0.877	0.949	0.891	0.746
8	0.958	0.951	0.940	0.923	0.929	0.919
9	0.649	0.966	0.973	0.712	0.705	0.977

Intraclass correlation (ICC)

≥ 0.75 very good, 0.6–0.74 good, 0.40–0.59 adequate, <0.40 poor, I investigator

food, $p = 0.038^*$) and EMG activity over the whole swallow (liquid, $p = 0.004^{**}$, semisolid, $p = 0.027^*$).

Comparison between liquids and other consistencies revealed statistically significant differences for duration of preparation for swallowing and bolus formation (semisolid, $p = 0.032^*$), maximum laryngeal elevation (solid, $p = 0.040^*$) and maximum EMG activity during the swallow (solid, $p = 0.004^{**}$). A statistically significant difference in the extent of laryngeal closure was found between semisolid and liquid consistencies ($p = 0.039^*$).

The effect of food volume on the measured signal was tested by comparing a saliva swallow ($N = 27$) with a liquid swallow for volumes of 5 ml ($N = 27$), 10 ml

($N = 27$), 20 ml ($N = 26$) and 30 ml ($N = 26$). The Mann *U* test for the comparison between saliva and varying volumes of liquid food showed statistically significant differences for the following characteristics: duration of laryngeal elevation (5 ml, $p = 0.030^*$; 10 ml, $p = 0.026^*$; 20 ml, $p = 0.029^*$; 30 ml, $p = 0.001^{**}$), duration of swallowing (30 ml, $p = 0.027^*$), speed of laryngeal elevation (5 ml, $p = 0.010^{**}$; 10 ml, $p = 0.024^*$) and EMG activity over the whole swallow (10 ml, $p = 0.014^*$; 20 ml, $p = 0.003^{**}$; 30 ml, $p = 0.016^*$). These differences suggest that food volume and consistency do affect BI characteristics.

Conductivity

The study also examined the effect of the conductivity of the swallowed liquids (isotonic saline, distilled water, a 1:1 mixture of saline and distilled water and mineral water; 104 swallows) in the pharynx on the measured signal. The mean correlation between the above liquids \bar{r} was 0.986 and comparisons between saliva and liquid, semisolid and solid consistencies found correlation coefficients r of between 0.852 and 0.998. Conductivity was not found to have an effect on the measured signal (see Table 4).

Sex

188 swallows and 46 head movements in male subjects and 140 swallows and 32 head movements in female subjects were compared. Calculation of the correlation yielded a

Table 3 Swallowing movements versus head movements

Characteristic	Swallowing movement		Head movement		Mann <i>U</i> test (two-sided)
	Mean	SD	Mean	SD	
$t(BI_{min})-t(BI_{start})$	0.394	0.140	0.505	0.407	0.628
$t(BI_{end})-t(BI_{start})$	0.768	0.204	1.069	0.795	0.303
$t(BI_{start})-t(EMG_{start})$	-0.373	0.389	0.049	1.035	0.000**
$A(BI_I)$	-0.795	0.126	-0.858	0.138	0.000**
BI_{min}	-1.522	0.564	-0.783	0.569	0.000**
$S(BI_I)$	-6.430	2.569	-3.431	2.623	0.000**
EMG_{max}	0.050	0.022	0.015	0.016	0.000**
$A(EMG_{ges})$	0.296	0.345	0.236	0.356	0.000**
$A(EMG_{diff})$	0.088	0.195	0.054	0.129	0.000**

Mann *U* test

** Significance level $p = 0.01$ (two-sided), *MW* mean, *SD* standard deviation, BI_{min} maximum laryngeal elevation, $A(BI_I)$ extent of laryngeal closure, $S(BI_I)$ speed of laryngeal elevation, $t(BI_{min})-t(BI_{start})$ duration of laryngeal elevation, $t(BI_{end})-t(BI_{start})$ duration of swallow, EMG_{max} maximum muscle activity during laryngeal elevation, $A(EMG_{diff})$ preparation for swallowing and bolus formation, $A(EMG_{ges})$ EMG activity over the entire swallow, $t(BI_{start})-t(EMG_{start})$ duration of preparation for swallowing and bolus formation

correlation coefficient r of 0.998, and therefore showed no statistically significant difference.

Videofluoroscopy

VFSS was used to test the hypothesis that EMBI is able to provide information on closure of the pharynx during swallowing. The extent and speed of laryngeal movement are the key factors in determining whether a swallow is adequate. Investigations were carried out on 19 patients (55 swallows). Bioimpedance was compared to the movement of the hyoid and larynx towards the C2/C4 plane. The mean correlation coefficient \bar{r} was 0.813. The hypothesis that BI provides information on the extent and speed of laryngeal movement and of pharyngeal closure during swallowing was therefore confirmed.

Discussion

An implantable stimulation system for treating swallowing disorders requires a measurement system which is able to

reliably evaluate a swallow and to trigger stimulation at the appropriate time point. In this study we evaluate a novel EMG bioimpedance measurement technique [10]. EMBI correlates with pharyngeal closure during the swallowing process and thus provides information on the quality of a swallow. The measured signal proves to have good reproducibility, which is investigator independent. By segmenting the measurement curve, it proved possible to reliably distinguish between swallowing and movements such as speaking and head movements and between different food consistencies.

Bioimpedance describes the resistance which can be measured when a current with a specific frequency is passed through tissues such as the human body. The measurement procedure was first described many years ago and is used in fields such as bioelectric impedance analysis (BIA), uses of which include measuring body fat [12]. Resistance depends on tissue composition and structure (e.g. tissue cavities) and alters in response to tissue movement. The pharynx is an air-filled space surrounded by muscle. On swallowing, this space is modified and compressed by the movement of the tongue and larynx towards the back of the pharynx. This phenomenon can be detected in changes to the bioimpedance curve [9].

This hypothesis was tested by comparing VFSS and EMBI. Movement of the hyoid and larynx towards the spine and the reduction in the distance between the hyoid and larynx required for closure of the larynx were used as a measure of anatomical change in the pharynx during swallowing. The results showed an excellent correlation between VFSS and EMBI. Various published papers describe measurements of laryngeal and hyoid movement as providing information on swallowing and its disorders

Table 4 Effect of liquid conductivity

	MeanNaCl	Mean1:1	MeanDH ₂ O	MeanMH ₂ O
Mean Saliva	0.852**	0.881**	0.872**	0.939**
Mean Liquid	0.964**	0.978**	0.976**	0.998**
Mean Sieved	0.955**	0.969**	0.966**	0.987**
Mean Solid	0.943**	0.963**	0.962**	0.990**

Pearson's correlation

** Correlation is statistically significant at a level of 0.01 (two-sided), meanNaCl, saline solution; mean1:1, 1:1 mixture (NaCl and distilled water); meanDH₂O, distilled water; meanMH₂O, mineral water

[13]. The correlation between these measurement techniques demonstrates the clinical significance of EMBI, which uses cutaneous measurement to provide information on the swallowing process and changes involved in swallowing.

A measurement technique for evaluating swallowing must be able to reliably distinguish swallowing from head or tongue movements. This has not been possible with previous techniques. EMG measurement permits the swallow to be described, but is not suitable for distinguishing between different head and throat movements. Our own investigations have shown that segmenting EMBI based on typical anatomical and functional changes permits a reliable distinction between swallowing and head movements to be made. In addition, EMBI proves to be highly reproducible (85 %). This contrasts with inter-rater reliability for VFSS (40–69 %, [14]) and FEES (51 %, [15]). EMBI also reliably reflects known changes in the swallowing process induced by food volume and consistency. Kendall et al. [16] were able to demonstrate an effect on oropharyngeal and hypopharyngeal transit time with increasing bolus size. Reimers-Neils et al. [17] were able to demonstrate an increase in total swallow duration from liquid, to semisolid, to solid food. Observation of individual swallow-specific characteristics shows an effect on the swallowing process, which is also found in EMBI. Duration and speed of laryngeal elevation and EMG activity all appear to be affected by food type.

Several attempts have been made to use neuroprosthetic devices to improve swallowing ability. The most intensive area of research has been on vocal cord closure to prevent aspiration during swallowing [1]. An alternative approach involves improving laryngeal elevation through carefully timed electrical stimulation of individual muscle groups during swallowing [4]. Although this procedure was successful, stimulation required the patient to be alert as it required them to operate a manual switch. None of these systems possesses the kind of robust, implantable measurement procedure—capable to identifying and evaluating a swallow and (for example) emit a carefully timed electrical impulse to assist the swallowing process—which would be required for clinical use.

Our investigations for this study show that the measuring device developed by Nahrstaedt, Schauer and Seidl [10] is able to reproducibly record swallowing and that segmenting the measured signal permits the differentiation of quality characteristics of the swallowing process. The method enables for the first time the possibility to measure the central parameters of the pharyngeal swallow with a physical method. Previously, similar parameters are collected only through complex measurements from VFSS. This leads to a simplification and standardization in the diagnostic of swallowing disorders. Is it possible to

automate the detection of these parameters, the measurement system can be used for an automated evaluation of the swallowing process. It may well be possible to distinguish these characteristics regardless of the underlying disease, but further studies involving patients with, for example, neurological disorders are required. There is now a need to develop algorithms which permit such distinctions to be made automatically such that they are able to be used to regulate a neuroprosthetic device.

Summary

We evaluated an EMG bioimpedance (EMBI) measurement system which reproducibly maps swallowing and the changes which take place during swallowing. It permits swallowing to be reliably distinguished from head movements and a distinction to be made between different foods. There is no difference between cutaneous and transcutaneous measurements, and this measurement system could therefore be integrated into an implantable neuroprosthetic device to serve as a regulatory system.

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