



Assessing Discomfort Levels During Facial Neuromuscular Electrical Stimulation Using Discomfort Level Scale: A Preliminary Study

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Abstract The primary aim of the current study was to evaluate discomfort levels of facial NMES in healthy volunteers. Eight participants completed the Discomfort Level Scale (DLS) following each motor level facial neuromuscular electrical stimulation (NMES) session. Each participant completed 12 sessions of facial NMES for a total of 96 NMES treatments. Pearson product-moment correlation coefficient demonstrated a significant correlation between the facial NMES intensity level and DLS ($p < 0.001$). This study demonstrated that the DLS is a useful tool to check for discomfort levels in patients who receive facial NMES. Further, this study provides strong support for the tolerability of facial NMES.

Keywords Facial · Surface neuromuscular electrical stimulation · Discomfort scale · Percutaneous electrical stimulation · Labial NMES

Introduction

Facial and submental neuromuscular electrical stimulation (NMES) has been utilized clinically to improve various conditions such as facial palsy, sleep apnea, dysphagia and orofacial weakness. Yet, no published studies have been found to date that investigated the level of discomfort in individuals who receive facial NMES. Perhaps, it's scientifically, important to collect objective information about the discomfort level perceived by individuals who receive

treatment using this modality to objectively evaluate the advantages and adverse effects of such modality as a whole.

Neuromuscular electrical stimulation is a treatment that uses small electrical current to activate nerves innervating muscles affected by paralysis resulting from spinal cord injury, head injury, stroke and other neurological disorders [1]. NMES is delivered to muscles as a waveform of electrical current via electrodes. The application of NMES causes muscles to contract as if they were exercising. Current clinical application of NMES is limited to neurologic impairments that involve the upper and lower motor neurons that might be affected due to spinal cord injury, stroke, brain injury, multiple sclerosis, cerebral palsy [1] that resulting in muscle paresis (weakness) or paralysis and dysphagia.

The effect of NMES as a modality has been investigated in (a) patients with obstructive sleep apnea [2–7]; (b) within the facial palsy population [8]; (c) facial cosmetics [8], (d) in muscles that are involved in speech articulation [9, 10] and (e) swallowing [9–13].

To date, no published studies were found that examined the discomfort level not only in patients who undergo NMES treatments in general, but also those who receive facial NMES. Perhaps the face has significantly more sensory receptors than any other area in the body that receives surface NMES. Kawakami et al. [14] reported that research has shown that there are over 17,000 corpuscles in the human face. The face, also, presents with the highest distribution density of nerve endings [14, 15]. Sensory response to stimulation varies in the face and correlates with innervations density—upper and lower labial areas being the most sensitive to pain stimuli while submental areas are slightly less sensitive [16]. The main factors are

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epidermal thickness and composition as well as the receptors' depth.

Since no specific tools have been found in the literature to evaluate discomfort levels during NMES treatment, the logical step is to develop or, perhaps, adapt a tool that allows for objective measurement of discomfort levels in individuals that receive surface NMES. Since discomfort sensation is a light form of pain, it is logical to adopt a reliable and valid pain measurement tool to measure discomfort level. The following pain measurement tools are the most commonly used measures of pain intensity [17]: (1) The Visual Analogue Scale (VAS), (2) Numerical Rating Scale (NRS), 3. Verbal Rating Scale (VRS), and 4. Faces Pain Scale-Revised (FPS-R). Evidence presented supports the reliability and validity of each of these measures across many populations, yet none of them is considered as the “gold standard” [17]. However, according to Ferreira-Valente et al. [18] there is strong evidence in the research demonstrating that VASs present more ratio scale qualities than other pain intensity scales.

Kliger [17] Noted that the most commonly used tool for measuring pain intensity is the VAS which is a continuous scale comprised of a 100 mm horizontal or vertical line whose extremes are labeled as “no pain” and “worst imaginable pain.” Patients are, then, requested to mark their pain intensity on that line. Multiple studies investigated the advantages of the VAS [17, 19–21]. These advantages include high sensitivity [20]; low possibility for misinterpretation relative to others [19]; reducing the difficulty of balancing the intervals on a fixed interval scale [19], and being versatile enough to be employed in a variety of settings [21].

While the most commonly listed weakness using the VAS is its need for clear vision, dexterity, pen and paper or an electronic display [17], the VAS requires the ability to convert pain intensity to an abstract scale that requires more cognitive demands leading to a higher percentage of failure when used with mentally challenged people, young children, and elderly patients [18].

The primary aim of the current study was to evaluate discomfort levels of facial NMES in healthy volunteers. Thus, adopting a discomfort level scale was needed to provide a tool to answer the following research questions:

1. Is there any correlation between (stimulation intensity level) and (discomfort level as reported by participants)?
2. What is the overall tolerance level of facial NMES of all the sessions when a motor level stimulation is reached?

Methods

Approval of the Howard University Institutional Review Board was obtained for this study.

Participants

Eight volunteers participated in the study. Table 1 presents the demographics of the participants. All participants completed and signed a written consent form as well as a medical screening form prior to participating in the study. All participants met the eligibility criteria that included the absence of neurological, phonological, psychiatric, speech, or swallowing disorders. Individuals who also had cardiac irregularities or a history of rheumatic fever were excluded from participating in this study.

Procedure

Neuromuscular Electrical Stimulation: NMES Device and Electrodes

The AMPCARE ES (AMPCARE ES, Restorative Medical Inc., Brandenburg, KY) neuromuscular electrical stimulation unit was used for surface NMES application. The electrical stimulation unit provided two channels of bipolar electrical stimulation. The following fixed waveform specifications were used in the study: a symmetrical biphasic waveform, 50 μ sec phase duration, frequency of 30 Hz.

For submental electrical stimulation, AMPCARE E series surface re-usable electrodes (AMPCARE, Restorative Medical Inc., Brandenburg, KY) were used. Columbia 600 Electrodes were used for the application of electrical stimulation to the patients' lips. New electrodes were provided for each subject. A self-adherent bandaging tape (3 M vetrap bandaging tape, 3 M, St. Paul, MN) was fitted over the electrodes to maintain good skin contact.

The skin in the submental and labial regions was cleaned with alcohol and rubbed with a TENS Clean-Cote Skin Wipe to increase adherence of the electrodes to the skin (Tyco Uni-Patch Model UP220). All male participants were also clean-shaven to allow optimum electrode adherence. Each participant was familiarized with the sensations to expect from the electrodes to prepare them for the actual electrical stimulation. Then, each electrode pair was placed on the skin, and the electrical stimulation was presented with the stimulation intensity gradually increasing until the participant felt a tingling sensation. To achieve motor level stimulation, the intensity level was increased gradually until the participants indicated that the sensation level was becoming uncomfortable. Next, the stimulation

Table 1 Demographics of the participants

<i>N</i>	8
Mean age	36.24 SD = 5.75
Gender	7 Male 1 Female

N number of participants; *SD* standard deviation

intensity was increased until the participant reported it was at the maximum tolerance level. The stimulation was set at the participant’s maximum stimulation tolerance level for each placement. After 5 min of stimulation, the participants were asked if they felt any pain or if they could tolerate further stimulation. The intensity of stimulation was adjusted according to their responses. This maximum tolerance level in each session was recorded for the two electrode placements. Each session lasted 30 min with a duty cycle of 5:25 (5 s on and 25 s off).

Electrode Placement

Since this study was part of a larger study that investigated the effect of surface NMES on labial and lingual muscles, the placement of the electrodes was predetermined by the study. Two electrodes were placed submentally between the hyoid bone and the chin. Another pair of electrodes was placed at the superior lateral corner and the inferior lateral position of the lips.

Discomfort Level Scale (DLS)

The DLS consists of a horizontal line 100 mm in length, with the end points indicating “Not bad at all” and “The most intense bad feeling possible” at each end of the line. Respondents are asked to make a mark on the line that best represented the level of discomfort for the intensity that they were experiencing (Fig. 1).

Data Analysis

The intensity level number that was shown on the NMES device was recorded for each placement every session. These numbers were converted to mA using the following formula provided by the manufacturer per device manual (Device Intensity Level multiplied by 4.9). The Mean Facial Intensity Level was calculated by combining the mean of intensity measurements of the two placements (submental and labial placements) for all the sessions for each participant. The mean DLS was calculated for all sessions for each participant.

Statistical Analysis

To measure the linear correlation between the intensity level and DLS, a Pearson correlation coefficient was calculated along with the probability (*p*) level for the relationship.

Results

All the participants were able to tolerate the NMES for all 12 sessions for a total of 96 NMES treatments. Table 2 shows mean maximum tolerated intensity level of stimulation for lingual and submental stimulation. Table 3 shows the mean level of facial intensity and DLS of all sessions for each participant when a motor level stimulation was reached. The results show that the acceptable tolerable stimulation level for participants to achieve motor level stimulation was 60.7355 mA.

To explore the relation between stimulation intensity level and discomfort level, a Pearson product-moment correlation coefficient was computed (Table 4 shows the results). There was a negative correlation between the two variables, $r = - 0.471$, $n = 96$, $p < 0.001$. There was also a negative correlation between discomfort level and labial and submental placements. The correlation (*r*) values were $- 0.82$ and $- 0.65$ respectively.

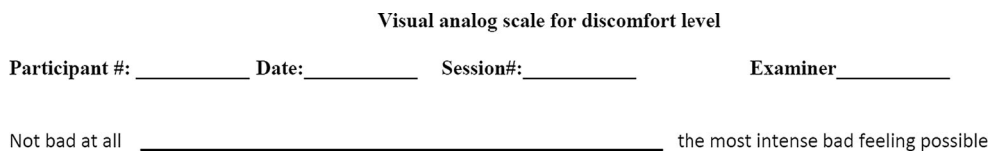


Fig. 1 Visual analog scale for discomfort level

Table 2 Maximum tolerated intensity stimulation for lingual and submental stimulation for all sessions

Participant #	Mean labial intensity level all sessions (mA)	Mean submental intensity level all sessions (mA)
1	46.96	47.37
2	45.33	42.88
3	61.66	45.73
4	60.84	49.41
5	70.64	71.05
6	84.12	66.15
7	82.48	72.28
8	75.95	47.78

mA milliamperes

Table 3 Mean facial intensity levels and discomfort scale

Participant #	Mean facial intensity level all sessions (mA)	Mean DLS all sessions (cm) ^a
1	47.63	7.02
2	43.90	6.21
3	53.31	5.72
4	55.08	3.73
5	70.76	3.68
6	75.26	3.89
7	77.62	3.93
8	62.33	4.02
Mean	60.74	4.78

DLS discomfort level scale; *mA* milliamperes; *cm* centimeter

^aNumber represents the discomfort level on a 10 cm scale

Table 4 Pearson product-moment correlation coefficient

	Facial intensity level	DLS
Facial intensity level	1	– .471**
Pearson correlation		
Sig. (2-tailed)		.000
N	96	96
DLS	– .471**	1
Pearson correlation		
Sig. (2-tailed)	.000	
N	96	96

DLS discomfort level scale; *Sig* significance; *N* total number of sessions

**Correlation is significant below the 0.01 level (2-tailed)

Discussion

Results of this study provide strong support for the tolerability of facial NMES. Since the face has a significant number of sensory receptors as well as high distribution density of nerve endings, it might be argued that motor level NMES might be intolerable by patients who have some sort of facial and labial weakness. However, this study demonstrated that healthy participants were able to tolerate motor level facial NMES with an acceptable amount of discomfort.

Further, this study demonstrated that the DLS is a useful tool to check for discomfort levels in patients who receive motor level NMES. Additionally, this tool may be useful in comparing the tolerability levels in patients who receive NMES, hence, predicting if a motor level stimulation can be achieved or not. Indeed, the statistical analysis demonstrated significant correlations between DLS and NMES intensity levels.

Review of the literature revealed no prior studies that addresses assessing discomfort levels when NMES is used. Hence, the results of this study cannot be compared to other studies. However, this study is consistent with studies that investigated pain measures in healthy participants [17, 19–22].

The Pearson Product Moment Correlations revealed a negative value. This negative factor indicates that as the stimulation increased in intensity, the comfort level judgement for participants decreased over time. This is surprising that an increase in electrical stimulation over multiple sessions would lead to a person identifying that the comfort of the treatment was reduced.

One significant limitation of the present study is that it was performed on healthy participants. Participants in experimental studies can be assured that there will be no harm, whereas patients in clinical settings cannot always be so sure of this factor. Thus, in clinic, discomfort level may be associated with emotional and psychological implications that can influence one's perception of discomfort. Therefore, the findings from this study do not necessarily generalize to patients in the clinic. It would be useful to examine DLS findings in response to treatment procedures known to evoke clinical discomfort to determine generalizability of the scale.

Another limitation is that this study did not address the effect of gender on discomfort levels. Previous studies that investigated pain measurements showed that there is gender effect, with females reporting higher pain tolerance [23].

Nevertheless, this study provided a stepping-stone to develop a tool to measure discomfort levels in procedures that evoke discomfort such as NMES. Additionally, such a scale is can be useful in research to demonstrate the safety of a procedure but also in clinical sittings to compare the tolerance level of our patients in comparison with the general population. Thus, further research is needed to compare this measure in clinical settings to confirm the generalizability of the current findings to clinical populations.

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Data Availability The data that support the findings of this study are available on request from the corresponding author, [MS].

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