MEDINFO 2017: Precision Healthcare through Informatics
A.V. Gundlapalli et al. (Eds.)
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## Design and Evaluation on the Mobile Application of Transcutaneous Electrical Nerve Stimulation (TENS)

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#### Abstract

This study aims to design a transcutaneous electrical nerve stimulation Application (TENS App) according to the suggestions from potential users. To the best of our knowledge, this is the first App including meridian and acupoints for TENS. After its development, there are eight participants recruited for evaluating the usability. Despite two out of eight users reporting that the typical TENS system requires lower cost and has better functionality than TENS App, the results show that almost seventy percent of participants have a better perception of TENS App on price, functionality, convenience, operational ability, and quality. However, participants still reported concerns about the safety issue of adopting TENS App. Therefore, for people who are the first time or unfamiliar with TENS App, instructions from occupational or physical therapists are recommended. We conclude that by using TENS App, users can not only use the portable electrotherapy devices at anyplace, but also reduce their outpatient visits.

#### Keywords:

Electric Stimulation Therapy; Smartphone; Mobile Applications

#### Introduction

Pain is the unpleasant feeling induced by illness, physical impairments, or harmful outer stimuli. The two major causes of pain include the activation of stimuli to nociceptor and impairment of human nervous system. Nociceptor receives chemical, thermal, or forceful stimuli which damage human tissues and transmits painful sensation to the nervous system. And if the nervous system is impaired due to injury or illness, it will induce neurological pain or neuropathy.

Past related studies found evidence to support short-term physical therapy intervention to be effective in relieving knee joint pain or joint arthritis pain. It is also recommended to provide intensive treatment program using transcutaneous electrical nerve stimulation (TENS) with pulse rate setting between 1Hz to 150 Hz, a minimum of 20 minutes as treatment duration each session, for a minimum of 5 sessions, in a period of two to four weeks[1-3].

Clinical physical therapy relieves pain based on the Gate Control Theory (Figure 1). Based on this theory, TENS device utilizes subtle low-frequency electronic current to stimulate epidermal nerves [4]. The signals from the device are transmitted faster than pain signals, which arrive at the "gate" first and block the pain signals from passing through, thus reduce the pain perceived by the brain. TENS has been extensively used by physicians and therapists in physical medicine and rehabilitation (PM&R), and most of the TENS devices apply electrical stimulation to skin tissues, using lowfrequency pulse rate changes to induce the release of pain relief substances from central nervous system.

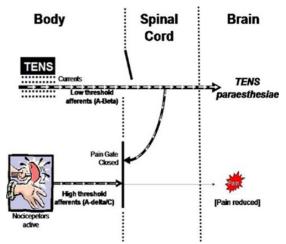


Figure 1 - Gate Control Theory.

TENS for pain relief requires customization according to the characteristics of pain, and it requires regular intervention. Physical therapy intervention with TENS devices involves with a professional assessment and adjustment protocols. Patients usually can only receive the services in clinics or hospitals. Despite its effectiveness to relieve pain, the accessibility of TENS is insufficient. Therefore, some companies such as Panasonic, Koka, Tatung, and Omron have been selling similar products for patients to use at home. Most of the devices can be operated through the equipment interfaces but few devices can be handled or configured by App, such as iTENS [5]. Moreover, these few Apps do not show the meridian and acupoints to precisely guide users in the use of pain patches. Also, there was a noticeable absence of rsearch projects dealing with the usability of Apps for TENS.

Moreover, the portable electrotherapy pain relief patches using the latest technology have appeared on the market. The new product applies professional TENS technology to a thin pad design. It is compact in size and reusable with power saving technology, providing users more convenience and reducing waste from traditional disposable pain patches. This also presents an opportunity to design a new health information technology with portable TENS. This study aims to design a TENS App including meridian and acupoints information and then to assess its usability in five dimensions (price, functionality, convenience, operational ability, and quality) and do the comparison between the typical TENS device and our TENS App with summarizing their advantages and disadvantages.

## Literature Review

This study reviews articles regarding the medical concepts behind TENS, myofascial pain, and related physical therapy intervention, as well as the clinical application of TENS systems. It aims to summarize the studies and understanding on TENS systems.

### Medical Concepts behind TENS

TENS product has been widely used for palliative care in developed countries, including the non-noxious or acute pain from malignant neoplasms or related medical treatments. The product is safe, low in cost, and free from serious side effects. Under the directions of a physical therapist, people with muscular pain or patient with needs could operate the product at home and receive short-term pain relief effects. Therefore patients could apply two self-adhesive patches on their skin, and use the low-frequency electrical stimulation with control of set protocol safely [1].

Literature reviews found that the first records of using electrical stimulation to relieve pain date back to a Roman physician [2]. In 1786, the Roman physician experimented on the frog leg and proved electrical stimulation can relieve pain and reduce muscle tension. The observation along with the progress of power generation further urges the use of electrical stimulation to treat various diseases and relieve pain. In 1965, Doctor Ronald Melzack from Monterey, Canada and Doctor Patrick Wall from England published the focus treatment mechanism in University of London. Their mechanism is that the central neuron system modifies the quality and quantity of neuron signal from the peripheral neuron system to the brain[3]. Based on the Gate Control Theory, they proposed that by selectively utilizing low-frequency electrical stimulation to large diameter nerve through skin tissues, transmission of pain signals could be inhibited and thus reduce pain perception.

TENS devices are usually made of a single line (two electrodes) or two lines (four electrodes). There are potentiometer or regulator on the devices for the users to adjust the stimulation intensity. The stimulation variables include wave formation, frequency, and intensity. In sum, when utilizing TENS devices, chronic patients can choose protocols with low frequency and high-intensity stimulation, while acute patients are recommended to use protocols with high frequency and highintensity stimulation.

# Common myofascial pain and related physical therapy intervention

Myofascial Pain Syndrome is not a specific disease. Instead, it is a syndrome caused by extensive muscle tension. If the muscle is under tension status for a long period, it will impede peripheral blood flow and thus impedes the circulation system to take away waste productions from metabolism mechanism such as lactic acid. The accumulation of lactic acid in specific parts would then induce soreness and discomfort. Therefore, Myofascial Pain Syndrome is one of the common causes of low back pain.

If human body keeps in the same position for a long period, there must be a group of muscles stay in tension status for a long time. As time goes by, Myofascial Pain Syndrome occurs with muscle soreness and fatigues. Different from medical diagnosis by physicians, physical therapist evaluates and assesses patients using structure diagnosis, providing a diagnosis of somatic dysfunction and setting intervention plans accordingly. In general, physical therapist diagnoses patients under the three principles A-R-T:

- Asymmetry (A): Physical Therapist assesses patient's symmetry on the musculoskeletal system through palpation and observation.
- The Range of Motion (R): The assessment focuses on the range of the movement and its movement quality of a single or multiple joints, such as hyper- or hypomobility. The patient follows directions to check the active and passive range of motion at different joints.
- Soft Tissue (T): Physical Therapist evaluates abnormal soft tissue textures, including skin, muscle, fascia, tendon, etc.

## **Clinical Application of TENS System**

The clinical experiments had proved a regulation rule for pain treatment. The Randomized Controlled Trials (RCTs) in the early period indicated that many patients used TENS to treat focal pain and acute pain. Carroll found that TENS did not relieve pain after surgery because no significant difference was found between the experiment group and control group on pain relief [4]. Researchers suggested that TENS could relieve chronic pain. Although this was a commonly accepted concept, current studies on TENS are not extensively enough to provide sufficient evidence on its effectiveness for rheumatoid arthritis, neck disorders, or chronic low back pain [6]. On contrast, several RCTs have provided evidence for TENS on treating pain symptoms for knee joint arthritis [7] and chronic skeletal muscle pain [8]. Some researchers report that TENS can improve pain symptoms for some patients with chronic disorders including focal muscle pain, postherpetic neuralgia, trigeminal neuralgia, phantom limb pain and diabetic neuropathy. Therefore, applying TENS to muscle inflammation on ipsilateral or contralateral parts is likely to reduce the chronic pain response over bilateral limbs caused by unilateral inflammation [9].

## Methods and Study Subjects

#### **TENS App Mechanism**

If blood flow and massage could alleviate the pain, it is seen as the effect of relaxing muscle pain. This App could transport the electric energy from the device to muscle via the audio card in the smartphone. Users could easily attach two electrode pads on their skin surface to conduct energy. The electrotherapy can alleviate the pain and relax the strained muscle through the muscle layer. Then the power improves the blood circulation to decrease pain substance in the body. Both mechanisms have the pain alleviating effect.

Different low-frequency current has a different effect on alleviating and relieving pain. The effect is caused by activating neural functionality and the power of body fluid as well as increasing blood flow in the body to gradually decrease the muscle hypertonia. TENS App provides multiple functionalities which can easily control the current mode, time duration, and intensity. Users can configure its functionalities to active the effects of rhythmic muscle contraction on unbalanced muscles.

#### **TENS App Design**

Authors make many principles for the interface design to maximize the operational efficiency. The design principles include the visualization, feedback, response, synchronizing, and responsibility. We could improve and raise convenience in the TENS equipment through replacing the traditional TENS devices by the interface on the smartphone. The study is based on the interview with a focus group [10]. After TENS App is developed. We invite those study subjects who have at least one year experience of using other TENS system to join the study. We have an interview with the study subjects for 60 to 90 minutes in a semi-constructional way. Then we can summarize the features for the prototype interface which can fulfill with designer's requirement. Furthermore, we can find out its advantages and disadvantages.

## Method and Subjects

The study subjects who finished the questionnaire were aged between 20 and 50, with myofascial pain syndrome on upper back and neck, and pain lasting for at least one week. We excluded patients have operation history on the upper back, neck or vertebra. We invited 10 subjects for the interview through purposive sampling[11; 12], eight respondents finished the interview. Participants were contacted in order to explain our research purpose. After we had their agreement, we had an interview by questionnaire with every single one to listen to their experience with using the TENS App. All participants had taken the typical TENS (X brand) therapy and TENS App selfrelax therapy for four times within two weeks. All participants were evaluated by a five-dimension questionnaire which is modified according to Liu's [13]. These five dimensions are in regard with users' opinion on the price, functionality, convenience, operational ability, and quality. We used their feedback about these two devices to evaluate their effects.

#### Results

#### **TENS App Design**

The App primary functionality includes a brief instruction film about how to use the system, a Chinese medicine acupuncture point and symptom chart, a symptom and acupuncture chart for office workers, a symptom and acupuncture point chart, formale common symptom and acupuncture point chart, female common symptom and acupuncture point chart, Chinese medicine meridian charts and reflection area lists. The homepage combines all symptoms with acupuncture points based on Chinese medicine theory. It could help users understand the relationship between the symptoms and acupuncture points (Figure 2).

We upload the instruction film on the Internet for the purpose of publicizing and advocating this product to more people and providing users an easy know-how for using this product. The built-in homepage in App also helps the first time users and individuals who are interested to know more about this App and detail (Figure 3).

The system is designed to activate the TENS operation mode automatically when the earphone connects to the smartphone. The purpose of TENS interface in this system is to provide an appropriate stimulus wave, frequency, duration and power export. Users can undergo their physical relaxing therapy at home based on their status and physiatrist or physical therapist's instructions. The duration in the system is between 10 to 60 minutes. There is a total of three different modes for users in the electrotherapy setting mode. The operation interface provides 13 levels of energy (Figure 4).



Figure 2 – The Visulization of Symptoms And Acupuncture Points.



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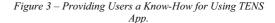




Figure 4 – Different Currency Mode, Time Duration, and Intensity Selections.

Also, the built-in main symptom and acupuncture points charts show the users where the correct points are to relieve the pain on the body (Figure 5). The terminal of this device has two electrode pads attached to the human skin to relax the pain in muscle layers by electrotherapy (Figure 6). Its convenience lies in that it can increase the patient's willingness to do the portable electrotherapy at home.



Figure 5 – Acupuncture Points Charts Show the Users where the Correct Points are to Relieve the Pain on Body.



Figure 6 – The App with Two Electrode Pads Attached to Human Skin.

#### Demographics

In total eight respondents used similar typical TENS devices and responded to the questionnaire. The basic information is presented in Table 1. There were six female and two male respondents aged between 28 and 50. Their career sectors included service, catering, public affairs, and construction industry. There were four managers and four office administrators.

Table 1 – The Basic Information About the Study Subjects.

Responden	to Ac	o Condon	Occupation	Industry
Responden		ge Gender	Occupation	· ·
А	28	Male	Office	Service
			Administrator	
В	32	Female	Secretary	Service
С	35	Female	Accountant	Service
D	44	Female	Middle-class	Public Affaiı
			Manager	
E	47	Female	General	Construction
			Administrator	
F	48	Male	Middle-class	Service
			Manager	
G	48	Female	Secretary	Carting
Н	50	Female	Senior	Carting
			Manager	-

#### Assessment

This study used the X brand a conventional TENS device on the market and TENS App (named as App) to do an assessment analysis. The study endpoints in the evaluation are in Table 2. Almost seventy percent of respondents (67.5%) have a better perception of price, function, convenience, operation, and quality in operating TENS App, even two of respondents believed that the X brand device has better price and functionality. There are some suggestions from users such as the professional assistance or instruction from the occupational therapist or physical therapist to operate TENS App for the first time user. The user should use TENS App according to their pain status to alleviate the pain correctly and safely.

Table 2 – The Summary for the Advantage and Disadvantage from Respondents.

Brand		Price		Functionality		Convenience		Operational ability		Quality	
		Х	App	Х	Арр	Х	Арр	Х	Арр	Х	App
Respondents	А		V		V		V	V	V		
	В		$\mathbf{V}$	V	V		V		$\mathbf{V}$		V
	С				V		v	$\mathbf{V}$	$\mathbf{V}$		V
	D		$\mathbf{V}$	V	V		V		$\mathbf{V}$		V
	Е		$\mathbf{V}$	v			v		$\mathbf{V}$		v
	F	$\mathbf{V}$			V		v				v
	G		$\mathbf{V}$				v			$\mathbf{V}$	v
	н		$\mathbf{V}$		V		v		V	V	v
count		1	6	3	6	0	8	2	6	2	7
bet	ter	1	6	1	4	0	8	0	4	0	5

## Discussion

We only took consideration on Asian user's experience from eight study subjects with their agreement. All potential users' feeling can not be generalized. This study could help TENS App's upgrade and development in the future. So far we could not figure out the issue about the automatic detection of human acupuncture points. We suggest that it could compare our result with the big data to understand more about the relationship between the currency frequency and time duration. That information could help users improve and relax their body even faster. Moreover, we suggest that users could play music with the therapy for relaxing and balancing their mind.

## Conclusions

Based on the comparison between the typical TENS device and TENS App, we find that participants are more focused on quality and convenience. TENS App has much better performance on these end points than the conventional ones. TENS App also has more advantages on the price than the regular ones.

To our knowledege, this is the first TENS App that was installed on a smartphone with the Chinese medicine acupuncture point charts. This helps users to find the correct position immediately that could help relax the strained muscles and relieve the pressure quickly. Furthermore, because of the high use rate of the smartphone around the world, it is possible to advocate and advertise the use of TENS App widely.

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