생리통 완화를 위한 저주파 치료기(TENS) 내장 스마트 의복 개발 연구

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R & D of Smartwear Built-In TENS Device for Relief of Dysmenorrhea

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Abstract

This research attempts to develop a method to relieve dysmenorrhea, which is an obstacle to many women's social activities, by designing a smartwear with built-in thermotherapy and TENS device. TENS therapy has the advantages of being controlled by patients and not depending on the use of drugs. The TENS device is designed as a stomach band so as to be unnoticeable to others when outer clothes are worn; the size was minimized and attached to underwear to facilitate use everywhere at any time. A current problem is the limitation of minimizing, but as battery technology is further developed, we can anticipate much smaller devices. The development of aforementioned smartwear function will increase women's choices in occupations and general improvement in quality of life.

Key words: dysmenorrhea(월경통), TENS(Transcutaneous Electrical Nerve Stimulator: 경피신경 전기자국), thermotherapy(온영치료), smaller devices(최소형 고안품), smart wear(스마트 의류).

I. Introduction

As industry focus changed from manufacturing applicable hardware to creating more efficient software, the materialism that once dominated industrial society has faded to be replaced by an emphasis on ecological concerns. Consequently, human beings are now at the center of every design. Interest is now focused on the well-being of people and the importance of humanistic thinking. This interest is directed not only at the health

and safety of humans themselves, but at the surrounding natural environment in which humans live. Following this trend, the development of wearable smartwear has become more popular.

This study proposes a smartwear design that can serve as a healthcare device while maintaining the functionality and styles of garments. We expect that this study will become a cornerstone for further domestic research in smartwear, developing a homegrown industry that will end the previous trend of merely reviewing foreign studies. The first design specifically is a

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garment that has the form of smartwear with built-in TENS that relieves dysmenorrheas.

According to research conducted on a sample of Korean women, more than 70% of the respondents complained of dysmenortheas. Among them, 47% replied they experience dysmenorrhea every month, 53.2% of which were high severity cases. Among women who work in the manufacturing industry, 46% replied that dysmenortheas restricted their activities¹⁾. The occurrence rate of dysmenorrheas is also high in foreign countries with about 60% on average, while 42% of foreign respondents reported severe dysmenorrhea23. Although dysmenorrhea has a high frequency rate and is the cause of immense hindrances to women's social life in terms of absences, it is typically regarded as women's inevitable destiny, and is not carefully studied or treated seriously by the medical establishment. Both domestic and international surveys of methods used to assuage dysmenorrheas show that most patients randomly take painkillers or just bear the pain, without attempts to soothe the pain⁷. Therefore, in order to improve every individual female's life and the general economy of society, devising effective countermeasures for dysmenorrhea is necessary.

This research is dedicated to offering relief for dysmenorrhea, which is an obstacle to women's activities, without the use of drugs, through the development of an underwear-type smartwear with built-in thermotherapy and TENS function. The developed underwear-type smartwear has the form of a belt and it plays the role of relieving menstrual pains by providing physiotherapy on the lower belly.

The specific purpose of this study is as follows: first, we objectively reviewed the previous literature on the effectiveness of heat and TENS on dysmenorrhea. Second, we conducted a demand analysis with a sample of real end users, i.e., women in their twentics, and confirmed the presence of negative perceptions on the use of pain killers among them. Third, we developed a wearable device that applies heat and TENS with the purpose of ameliorating dysmenorthea, in a smartwear design underwear.

II. Research Method and Procedure

Review on Literature Regarding the Effectiveness of Topical Thermotherapy and TENS in Treating Dysmenoryhea.

Definition of Dysmenorrhea and Its Treatment Method

Dysmenorrhea, one of the most common gynecological diseases, refers to pain that accompanies menstruation. Dysmenorrhea occurs when blood flow to the uterine tissues is hindered by a contraction of uterine muscles, which suppresses oxygen supply and eventually stimulates the end plate. Common features among young women that suffer from dysmenorrhea are that they have unstable personality and feel conflict in sex roles. Moreover, dysmenorrhea is more frequently observed among women who had received trauma or mental shock during menarche due to lack of previous knowledge about menstruation. Moreover, most dysmenorrheal cases occur during ovulation, and began to show about 6~12 months after menarche⁴⁹.

The symptoms of dysmenorrhea are most severe right before menstruation begins or right after when the amount of bleeding is highest. The pain is similar to the feeling of being squeezed by the lower belly with hard pressure inside the pelvis. Patients usually

¹⁾ Inn Sook Lee and Hye Sook Choi, "Effect of Self Moxibustion on Dysmenorrhea and Activities of Daily Living in Female College Students," Koran J. Women Health Nurs. Vol. 11 No. 1 (2005), p. 1.

Mi Young Ham, Kyoung Soon Han, Soo Ok You and Kyung Sook Park, "A Phenomenological Study on Dysmenorrhe a Experience of Women," Koran J. Women Health Nurs. Vol. 5 No. 2 (1999), pp. 245-254.

³⁾ Inn Sook Lee and Hye Sook Choi, Op. cit., (2005), pp. 77-82.

⁴⁾ Mi Young Ham, Kyoung Soon Han, Soo Ok You and Kyung Sook Park (1999), Op. cit., pp. 245-254.

cope with this pain through the use of pain killers such as ibuprofen, taking a hot bath, or placing a hot pack on the belly. Although taking painkillers is helpful to temporarily alleviate pain, repeated use reduces medicine's effectiveness, thus doses must be increased and taken repeatedly. This can result in adverse reactions and unnecessary expense for medical treatments. Hence, a need for non-medicinal treatments clearly exists.

2) The Effect of Topical Thermotherapy and TENS

The effectiveness of topical heat in treating dysmenorrhea has been proven in a number of studies and books, and the application of TENS to dysmenorrhea cases has also proven to have effective results in several overseas studies. Even though it is not commonly used in Korea, TENS has been commercialized widely in foreign countries, and the effectiveness in treating dysmenorrhea, post-partum complications, and post-surgery cases has been proven. A review of this literature regarding the safe and efficient method of topical heat and TENS, focusing on the relief of dysmenorrheal, shall now be undertaken.

Alleviating dysmenorthea through application of topical heat is one of the most commonly used and most efficient non-drug treatment methods. Chun(2003)⁵³, examines how women deal with dysmenorthea through a research project consisting of 202 female students. 87 of the respondents(43.1%) replied that they mostly used a hot pack on the lower belly and lower back, among which 96% replied that it was effective in relieving pain. Kang and Cho(2001)⁶³ conducted an

experiment to examine the effectiveness of heat therapy on relieving dysmenorrhoea with a sample of 40 high school female students. The sample was divided into two groups: an experimental group who received a hot water pack on the pain area for 30 minutes, and a control group who rested on a bed for 30 minutes without any treatment. As for the measurement of pain, the visual analogue scale(VAS) was used. Results showed that 52% of students in the experimental group reported a decrease in pain, while only 30% of the control group reported relief. Meanwhile, Cathy R. Kessenich(2001)⁷⁾ argues that topical heat is as effective as the pain killer ibuprofen in treating dysmenorrhea.

TENS has also been effectively used for treating dysmenorrhoea for decades, also proven in a number of research papers. A physiotherapy book "Treatment of pain: cases using TENS'81 offers a number of research projects proving the effectiveness of TENS on treating dysmenorrhea. Mannheimer and Lampe (1984) conducted an experiment with a sample of 27 women who did not use birth control pills but had a history of dysmenorrhea. The experiment's volunteers were randomly allocated into two groups, a highfrequency TENS group and a control group. The former reported a 72% decrease of pain on average, while the latter reported an average of only 26%. Moreover, 70% of the participants wanted to keep using the method of high-frequency TENS. Heltzel et al.(1987)91 conducted an experiment that examined the effectiveness of TENS using a sample of 14 women with severe dysmenorrhea. All 14 patients reported a clear

E. M. Jun, "A Study on Menstrual Symptoms, Coping and Relief of Symptoms in Female College Students," Koran J. Women Health Nurs. Vol. 9 No. 2 (2003), pp. 161-169.

⁶⁾ I. S. Kang and G. Z. Cho, "The Effect of Thermotherapy on High School Girls' Dysmenorrhea," *The Korean Community Nurses Academic Society* Vol. 12 No. 3 (2001), pp. 773-784.

Cathy R. Kessenich, "Continuous Topical Heat was as Effective as Ibuprofen for Dysmenorrhoea," Evid. Based Nurs. Vol. 4 No. 4 (2001), p. 113.

D. Ottoson and T. Lundeberg, Treatment of Pain-Cases of Treatment using TENS, (Seoul: Korea Medicine Publisher, 1991), pp. 96-97.

H. A. Schiøtz, "Treatment of Dysmenorthoea with a New TENS Device (OVA)," J. Obstet Gynaecol. Vol. 27 No. 7 (2007), pp. 726-728.

decrease in abdominal and back pain. Lindeberg et al.(1985)¹⁰¹ reported the result of using high-frequency TENS on 21 dysmenorrhea patients, among which 14 responded pain control over 50%.

Cochrane review in 2001 confirmed the effectiveness of high-frequency TENS on relieving dysmenorrhea. while reporting no promising result from low-frequency TENS. Treatment using TENS has the benefit of allowing full patient control over the amount of treatment and does not depend on the use of drugs. TENS is relatively inexpensive and is of low risk, and usually uses a high-frequency with low current. The underlying principle of using TENS is that the large diameter A-beta nerve fiber is stimulated by electronic current without the activity of A-delta C pain fiber, According to the pain gate theory, when A-delta nerve fiber is stimulated by electronic stimulus, it can prevent the pain signal from entering the spinal code. Moreover, TENS can also accelerate the secretion of beta-endorphin, which is effective in pain relief, while alleviating the ischemic pain by improving blood flow in the uterus. Such effects are clear as long as TENS is applied. 11,

As such, sufficient literature exists to confirm the effectiveness of heat and TENS on treating dysmenorrhea. This study applies these results to devising a solution which relieves menstrual pains without depending on drugs. This non-medical method to treat dysmenorrhea can be very valuable to those who suffer from side effects from drug use. In sum, we have examined the definition of dysmenorrhea, its treatment methods and their effectiveness by reviewing existing literature. Now, we expect that we can reduce the discomfort of dysmenorrhea by designing a treatment method in a smartwear design.

2. Research Subjects and Demand Analysis

1) Research Subjects

The research subjects of this study include reproductive women in their late teens to late twenties, who generally suffer high severity cases of dysmenorrhea. According to the medical text "American College of Physicians Complete Home Medical Guide¹⁽²⁾ dysmenorrhea refers to a pain in the lower belly that occurs right before or during menstruation, and is most often observed in women in their late adolescence. About three-fourths of women experience dysmenorrhea, with one-fifth being restricted in their regular daily activities due to severe pain. Generally, dysmenorrhea begins during the early teens, with pain commencing about 24 hours before menstruation begins and lasting for about one or two days. For about 1 > 2 years after menarche, the pain comes during ovulation, while the severity of pain decreases after 25 years with further decrease after the age of 30 or after giving birth. This is due to the increased amount of uterine blood flow. Types of dysmenorrhea can be largely divided into protopathic dysmenorrhea that have no particular reason and secondary dysmenorrhea that is caused by a malfunction in the reproductive system. In this paper, we focus on protopathic dysmenorrhea, regarding it as primary dysmenorrhea.

2) Demand Analysis

With this purpose, we conducted a demand analysis. The main purpose of the survey was to explain the effect of TENS and heat on dysmenorrhea relief and to ask the respondents about their willingness of using such built-in smartwear. The questionnaires were distributed to a total of 436 women in their late teens and late twenties and collected throughout the period of April 15, 2008 to May 15, 2008.

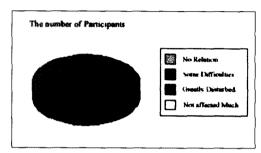
According to the demand analysis results, 239(55.4%)

T. Lundeberg and D. Ottoson, "Relief of Primary Dysmenorrhea by TENS 1," Acta. Obstet. Gynecol. Scand. Vol. 64 No. 6 (1985), pp. 491-497.

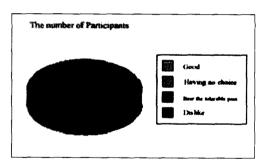
¹¹⁾ H. A. Schietz, Op. cit., (2007), pp. 726-728.

British Medical Association, American College of Physicians Complete Home Medical Guide. (London: David R. Goldmann, MD FACP Publishing, 2003).

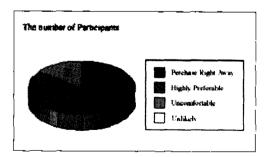
replied that their daily life activities are disturbed and 53(12%) said that the severity is high enough to make them unable to engage in daily life activities(Fig. I). This data proves the seriousness of dysmenorrhea. Moreover, according to the survey results regarding drug use, 92% expressed a negative attitude towards drug treatments for dysmenorrhea with 63% replying they refuse to take any drugs(Fig. 2). This result differs



(Fig. 1) Survey result of extent of distraction by menstrual pain.



<Fig. 2> Perception of pain killers.



<Fig. 3> Opinions about purchasing menstrual pain alleviating smartwear.

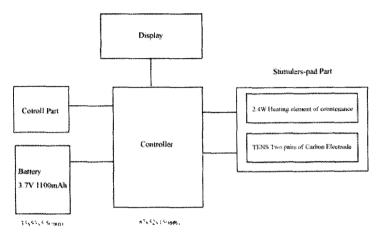
remarkably from that of foreign countries, showing that Koreans are generally very pessimistic about medical treatment of dysmenorrhea, i.e., taking painkillers. This particular result emphasizes the importance of development of non-drug treatment. When asked, 57% of the 239 respondents who stated that their daily life activities are disturbed replied positively to purchasing the item that we propose in this paper(Fig. 3).

3. Smartwear Design

Smartwear refers to new conceptual clothing that comes from combining a "function of materials" of the fabric, which detects external stimulus and reacts to it, and a "mechanical function" of device that is attached to the garment. Since the devices are built inside the clothes, the users do not have to separately carry them. It is especially attractive in that the garment itself functions effectively without additional steps once worn. In order to assess the appearance and fit of the developed garment, we organized a panel of five female students in their twenties who majored in clothing design. During the course of this research, those members discussed problems and made an evaluation sheet after experiments.

1) Composition and Materials

The overall composition of garment includes garment, stimulating pad, and a device with built-in battery and circuit. Considering that too loose underwear cannot embrace the body, and too tight can worsen dysmenorrhea, we used polyurethane materials that have high flexibility and are generally used for functional clothes. A stimulating pad is attached to the underwear-type garment playing the role of applying heat or TENS stimulus to the desired area of lower belly and lower back. Since it directly touches the skin, we chose a material of silicon that has high attachment and is harmless to body. The device is composed as follows: a controller that turns on the TENS and plate-type heater, a controller that allows a user to choose mode, a battery for portable power, and an LCD screen that



(Fig. 4) Device component map.

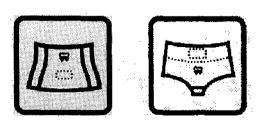
displays status. The components were designed with a focus on minimizing the size and weight of the device (Fig. 4).

2) Designing

According to the demand survey, research subjects in their teens or twenties put great weight on comfortable feeling and convenience rather than on design. We applied these concerns identified in survey results to designing the smartwear.

(1) Appearance

Heat therapy and TENS are the proven non-drug methods in pain relief. However, most products on the market are not portable and patients are effectively unable to go outside while wearing them. We improved the design though a series of experiments testing wearability and comfort, and debating over a number



〈Fig. 5〉 Panty-type and belt-type.

of different underwear type garment designs. Panty-type and belt-type designs were proposed(Fig. 5), and we chose the latter considering that women will wear it only during menstruation, and that wearing it should not affect coordination with outfits. Hence, we chose a belt-style that is also easy to wear.

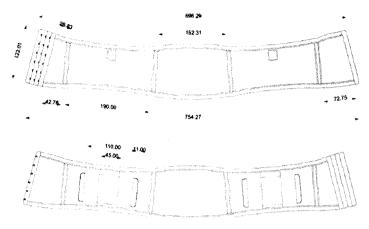
(2) Combination of Heat and TENS Device in a Garment

By minimizing the TENS and building it inside the garment, we reduced the size and improved convenience. Moreover, by making the TENS in an underwear-type garment as a separate type, rather than insertion type, we made it possible for users to detach the heat and TENS device and attach them to their own clothes.

III. Research Results and Discussions

1. Designing Underwear Belt

The smartwear has the form of a belt around the lower belly. As for materials, polyurethane was used due to its flexibility. Since it is underwear, the feeling of wearing is one of the most important factors considered. Moreover, we designed the underwear such that a stimulating pad can be built inside. Hooks were designed on the side for easy wearing, with the number



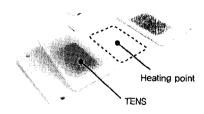
<Fig. 6> Smartwear drawing.

of hooks greatly decreased to six, compared to that of the general belt(Fig. 6).

2. Device Design

1) Composition of Stimulating Pad

The stimulating pad attached in the underwear belt provides heat and TENS stimulation on the desired area of either the lower belty or lower back. In designing the pad, the thickness and ability to keep warm was considered to be of most importance, and silicon was used for materials due to its harmlessness on the body(Fig. 7). In the stimulating pad, topical heat at 2.4W produces heat of 55~60 degrees, while providing high-frequency TENS stimulus on the pain site. The reason the stimulating pad was not fully integrated

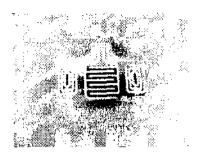


(Fig. 7) Composition of stimulating pad.

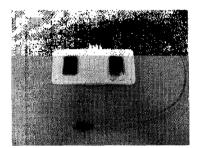
into the design was to allow the heat pack to be usable on other pain areas, in addition to the lower belly. For example, a person can first attach it to the lower back and fix it with a belt. The size of the stimulating pad is 130 cm in width, 70 cm in length, and has a thickness of 0.5cm. It includes a plate-type heater and carbon electrode pad.

2) Composition of Device

The composition of the device can be largely divided as follows: controller that turns on TENS and platetype heater, a modulator that detects switch input of strength, timing, and motion mode, a 3.7v lithium-ion battery that provides portable power, and an LCD display that shows current battery, current mode, remaining time, etc(Fig. 8, 9). The size and weight of each component has been minimized. The number of switches is 6 of the smd-type used in cellular phones, while the circuit components are also of the smd type. The switch has six choices of strong, weak, time, power, heat control, and TENS control. As for the battery, a rechargeable 3.7V 1100mAh lithium-ion battery was used. The size of the battery is 35mm in width, 55mm in length, and has a thickness of 5.5mm. A circuit of small TENS device was used, and the circuit was built based on high-frequency TENS, since it is the most effective in treating dysmenorrhea. The size



(Fig. 8) Inside of plate-type heater.

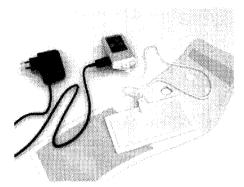


(Fig. 9> Patch-type heat stimulator.

of device is 87mm in width, 52mm in length, and has a thickness of 15mm, which is smaller than a cellular phone and hence easy to carry.

3) Development of TENS Device and Underwear Type Smartwear

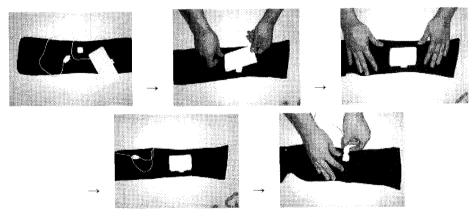
The smartwear is composed of an underwear belt, stimulating pad battery and a device with a built-in





(Fig. 11) Finished polished product.

circuit. In order to address the washing problem of smartwears, we made the underwear such that garment and device are separate, rather than integrated. Moreover, since it is an underwear-type, women can wear it with any fashion code, solving the previous problem of being unable to freely choose what to wear(Fig. 10, 11).



(Fig. 10) Combining TENS and helt.

N. Summary and Conclusions

The effect of TENS and heat on dysmenorrhea relief has been confirmed in a number of studies. This study also shows a high rate of pain relief(presented in VAS), while showing additional pain relief effectiveness among those using drug treatment. In conclusion TENS is a safe and effective non-drug method, which can effectively provide a clear non-medical treatment. Since this study solves the previous problem of low portability by developing a smartwear with a built in TENS device, it is now possible to alleviate dysmenorrhea in a non-medical way by simply wearing the smartwear as an underwear.

1. According to the objective review on the existing literature regarding the effectiveness of heat and TENS, heat and TENS are clearly effective in treating dysmenorrhea, while it was revealed that high-frequency TENS yields better results. Moreover, it is expected that combining heat and TENS will produce stronger effects. The non-drug methods further benefit when combined with additional pain-killing medicines. Since the two methods of heat and TENS are proven to be

safe and effective in a number of published studies,

we believe that the effectiveness of the smartwear that

we developed in this study is clear.

The following summarizes the result of this study.

- 2. We conducted a demand analysis with female subjects in their twenties who are the actual end users and clarified a negative perception concerning the use of pain killers among them. Additionally, according to the survey results regarding the perception of drugs, most of the respondents show negative reaction to using drug treatment(92%), while 63% said that they refuse to take any drugs. This result differs remarkably from that of foreign countries, showing that Koreans are generally very pessimistic about medical treatment of dysmenorrhea, i.e., taking pain killers. This particular result emphasizes an importance of non-drug treatment, giving sufficient ground for this study.
 - 3. We developed a wearable device that has the

function of heating and Transcutaneous Electrical Nerve Stimulator(TENS) with a purpose of relieving menstrual pain, and combined this device with smartwear underwear. The smartwear is composed of an underwear belt, stimulating pad, and device. Since the garment and the device are not integrated, there is no problem in washing the garment. Moreover, with its form as underwear, it can be worn with any fashion style, solving smartwear's problem of limiting choices in fashion codes.

There was no difficulty in developing devices. However, further research into developing a device with smaller size can be undertaken. Considering the current speed of technological development in battery and electronic component, we expect that even smaller devices will be available in the foreseeable future. The present problem is the limitation of minimizing, but considering the pace of development in battery technology, it is easy to anticipate much smaller devices. The development of aforementioned smartwear function will increase women's choices in occupations and general improvement in quality of life. We expect that smartwear with built-in heat and TENS function that was developed in this study will ameliorate symptoms of dysmenorrhea, eventually contributing to more active social activities for women and improvement of women's well-being.

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