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Evaluation of the Effect of Pretreatment with "Electronic Cryotheronic Pad"^{P} On Acute Pain Caused by Laser Hair Removal

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Abstract: Background: Despite the use of active cooling leading to reduced pain along with thermal damage reduction, laser hair removal is still a painful process. According to the cold's numbing effect on nerve endings, the present study aimed at evaluating the effect of pretreatment with controlled cryotherapy on this acute pain. **Methods:** This clinical trial study was performed on 45 female volunteers, aged 20-49 years, with unwanted hair growth on their faces. After marking two completely symmetrical mirror-image areas, low temperature (4°C) was applied for 2 min to one side (test side) by "Electronic Cryotherapeutic Pad" and the other side was served as control. Then, laser hair removal was introduced on both sides and pain was evaluated on a 0-10 VAS. The effects of treatment were evaluated 1 day and 2 months following the treatment. Finally, the obtained data were analyzed statistically at $p<0.05$. **Results:** All the 45 subjects significantly expressed less pain on the test side ($p\leq0.05$). The mean pain intensities were 3.6 and 7.1 for the test and control sides, respectively. The mean pain difference between these two sides were 3.9, 3.1, and 2.8 for chin, cheek, and behind lip, respectively and the differences were significant ($p\leq0.05$); however, the differences between different age groups were not significant($p>0.05$); furthermore, no significant difference was detected in short- and long-term effects and side-effects in both sides. **Conclusions:** In spite of active cooling, all the subjects expressed reduction of acute pain on test side. Treatment area proved the positive effect of cold with the highest and lowest effects on chin and behind-lip, respectively; however, aging cannot be considered to change the effect of pretreatment with cooling. The results indicated that pretreatment with controlled cold temperature, induced with "Electronic Cryotheraputic Pad"^{p}, led up to a noticeable reduction of acute pain caused by laser hair removal without any side-effects.

Key words: pretreatment, cryotherapy, acute pain, laser hair removal

INTRODUCTION

Among currently available methods for permanent hair removal, use of lasers has been considered the most efficient method and has found its place as a widely-requested cosmetic procedure in the world. In this procedure, which is based on the selective photothermolysis, laser light is absorbed by the melanin found in the hair shaft in form of chromophore and consequently, follicular epithelium is subjected to thermal damage (Ibrahimi *et al*. 2011; Liew 1999). This is normally associated with immediate acute pain and long-term milder post-treatment discomforts, such as pain and erythema. (Lask *et al*. 2006)

Caused by stimulation of sensory nerves located near follicles in the basal layer of the epidermis, the immediate acute pain is felt during each treatment pulse and may, after a few shots, accumulate to an extent which brings about an intolerable sensation. This pain may necessitate some pain reduction methods such as topical analgesic creams and/or applying less efficient low-energy densities so as to slow down the process (Lask *et al*. 2006); however, such methods might suffer from some limitations. In their study on 3 types of hair removal lasers, Nanni *et al*. (1999) reported the mean pain to be %81.

As the main challenge of laser hair removal is delivering the highest tolerable influence to the hair follicles with the least side effects of thermal damage on the epidermis (Nahm *et al*. 2002), different studies have recommended use of active cooling which cools the area before each shot for a short time. So, a longer pulse can be used to burn the hair follicles more effectively with minimized epidermal damage when the effect of epidermal cooling is exerted at its peak (Sadighha *et al*. 2009; Nelson *et al*. 2000). In addition, because

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treatment of darker skin phototypes is particularly more problematic due to their excessive melanin, use of an effective approach for cooling epidermis is emphasized to reduce such adverse reactions (e.g. pain and erythema) among dark-skinned persons (Sadighha *et al*. 2009; Eliot *et al*. 2004). The main mechanism, in fact, to reduce laser's subsequent pain and side effects is to reduce thermal damage to surrounding tissues; nevertheless, a proper cooling approach may also activate pain-reducing mechanisms.

Cryotherapy is defined as the use of low temperature to treat injuries; it has the effects of considerable pain relief in addition to reduction of swelling, bruising and bleeding after acute injury or surgical procedures. Low temperature can provide temporary relief along with a numbing effect on nerve endings and decreasing the impulses to brain perceived as pain. Thus, it may be effective to soothe the pain caused by laser hair removal (Kinoshita *et al*. 2010). Different studies have accredited the pain reduction effect of cold pretreatment for different purposes (Saeki 2002; Hasanpour *et al*. 2006; Kinoshita *et al*. 2010; Bechara *et al*. 2007; Skiveren *et al*. 2008; Taghizadeh *et al*. 2011; Nestor *et al*. 2010).

It is also noteworthy that cryotherapy must be performed in a correct manner. Adoption of too long and/or too low temperature may cause tissue injuries (Ross *et al*. 1999). Therefore, controlling time and temperature of cooling plays an important role to achieve the optimum outcome.

"Electronic Cryotheraputic Pad"[p] made on the basis of thermoelectric systems can induce the required cryotherapy temperature in a short time; the device is also able to keep a given temperature stable in a predefined time temperature leading to prevention from potential side effects of cryotherapy (Jaberansari *et al*. 2012). The present study, therefore, aimed at evaluation of the effect of pretreatment with "Electronic Cryotheraputic Pad"[p] on acute pain caused by laser hair removal.

MATERIALS AND METHODS

This clinical trial study was performed on 45 female volunteers aged from 20 to 49 years (30± 6.1 years) with II-IV Fitzpatrick skin type; the subjects suffered from unwanted dark hair growth on their faces. Having at least two symmetrical regions (mirror-image areas with midline demarcation) on face with quite similar unwanted hair condition was regarded as the main criterion. Pregnant, skin-impaired, cold-sensitive, and light-sensitive subjects along with those subjected to tanning before 6 weeks from onset of the study were excluded.

Initially, two completely symmetrical mirror-image areas (4×4 cm) were marked on both sides of subjects' faces. After shaving these areas, low temperature (4°C) was applied on test side for 2 min by "Electronic Cryotherapeutic Pad"[p] while the other side was left as control.

Laser hair removal was unhesitatingly introduced on test side and then on the Control side by use of SmoothCool laser (Jeisys Medical Inc, Seoul, Korea) with active cooling at -1°C. Depending on patients' need, wavelength was adjusted to 770±50 nm. Afterwards, the subjects were asked to announce the amount of pain at each side based on Visual Analog Scale ranging between 0 and 10 with 10 representing the worst possible pain and 0 representing no pain.

The patients were subjected to a visit one day after exposure to the treatment in order to determine possible side-effects. Another visit was introduced to the patients 2 months following the treatment where hair count on both sides were obtained so as to evaluate possible effect the proposed laser hair removal method may exert on efficacy of the treatment.

Then, obtained data were analyzed by covariance analysis, T-test, Pierson correlation coefficient, and ANOVA using SPSS software (Version 20). Statistical significance was considered at $p<0.05$.

Results:

All the 45 subjects significantly expressed less pain on the test side in comparison with control side ($p\leq0.05$). Average pain intensities were 3.6±1.6 and 7.1±1.8 for test and control sides, respectively. The participants expressed 0-8 levels of pain intensities on the test side where the level 3 witnessed the highest number of reports (24.4%). However, the subjects expressed 3-10 levels of pain intensities on control side where the level 8 witnessed the highest number of reports (33.3%) (Figure 1).

Both age groups 20-29 and 30-39 were comprised of 21 members while 40-49 consisted of 3. According to covariance analysis, the mean pain difference between test and control sides were 4.1, 3.3, and 2.8 for 30-39, 20-29, and 40-49; the differences were not significant between different age groups ($p>0.05$) (Table 1).

27, 15 and 3 of treatment cases were introduced on chin, cheek and behind lip, among other areas, respectively. According to Covariance analysis, the mean pain differences between test and control sides were 3.9, 3.1, and 2.8 for chin, cheek, and behind lip, respectively and there were significant differences between these three areas. ($p\leq0.05$)(Table 2)

In the visit performed a day after the treatment, only one of the patients, among others, reported to feel pain and discomfort in test side. In addition, one of the subjects experienced inflammation and burn in both sides and another had this experience only on test side. However, there was no significant difference in terms of treatment side effects on both sides. (Table 3)

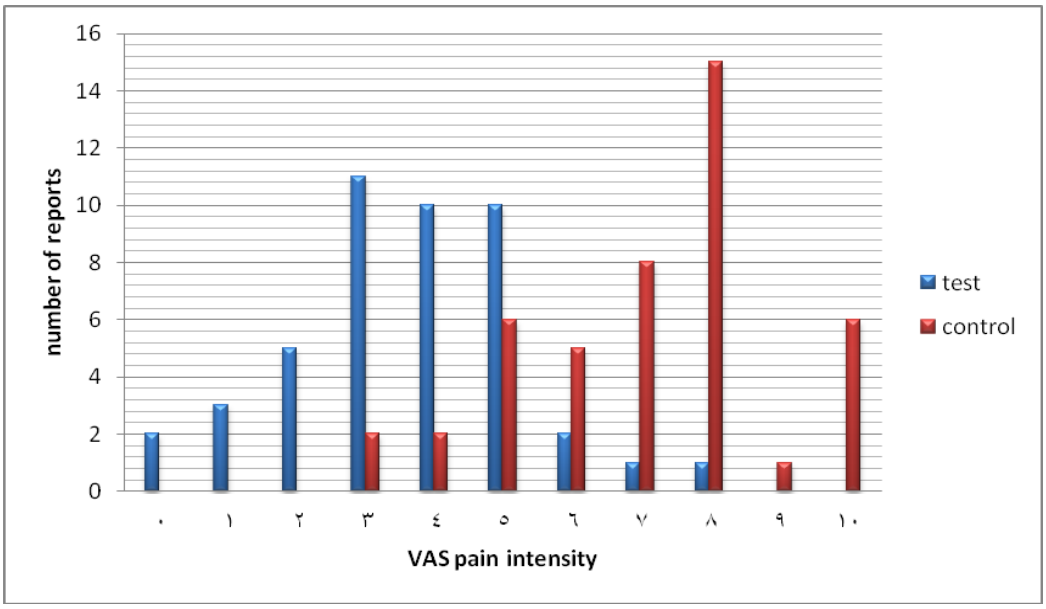

Fig. 1: Numerical descriptive pain intensity on the basis of VAS on both sides.

Table 1: Subjects' details and the mean pain differences between test and control sides in different age groups.

Age group	Number of subjects	Percentage of total	Mean pain difference between Test and Control sides	Standard deviation
20-29	21	46.67	3.9	0.257
30-39	21	46.67	3.1	0.257
40-49	3	6.66	2.8	0.682

Table 2: Subjects' details and the mean pain difference between test and control sides in different anatomical areas.

Anatomical area	Number of areas	Percentage of total	Mean pain difference between Test and Control sides	Standard deviation
chin	27	60	3.9	0.212
cheek	15	33.33	3.1	0.292
Behind lip	3	6.67	2.8	1.24

Table 3: Side effects after one day.

Side effects	Control Side	Test Side
Pain and Discomfort	0	1
Burning lesion	1	2

In the visit performed 2 months following the treatment, the mean hair counts were found to be 18.3±1.65 and 17.8±1.3 on test and control sides, respectively; however the difference was not significant. ($p \leq 0.05$)

Discussion:

Although active cooling has led us to exert damage to hair follicles' epithelium which is considered the main objective of laser hair removal to reduce resulting pain and discomfort, as it has been well documented, (Ibrahimi *et al*. 2011; Nahm *et al*. 2002; Sadighha *et al*. 2009; Nelson *et al*. 2000; Saeki 2002) the soothing effect is not efficient yet so that many patients complain about pain and discomfort during and following the treatment.

Sensory receptors of pain as free nerve endings are located on the edge of epidermis and dermis. The receptors are divided into two fast and slow groups. Fast receptors are Aδ fibers which travel through a direct route toward central nervous system and receive pain in a localized manner. The receptors remain active as stimulus exists. Slow receptors are C-type fibers which pass through several synapses toward central nervous system and receive pain indefinitely. (Guyton *et al*. 2011) In addition, pain itself is classified into two groups, i.e. acute and chronic. Acute pain is felt due to acute tissue damage, infection, or inflammation in a short term; however, chronic pain is an incomparable pain lasting for weeks, if not months or years. (Guyton *et al*. 2011) The present study aimed at evaluation of the effect of pretreatment with "Electronic Cryotheraputic Pad"[p] on acute pain caused by laser hair removal.

Despite use of CIPL laser with active cooling system on the tip its handpiece, all the subjects significantly reported reduced laser acute pain in pretreated area with cooling. Therefore, the method can be concluded to reduce pain through preventing it from thermal damage as well as adopting other pain-relieving mechanisms of cooling.

Saeki has mentioned five probable mechanisms for pain-relieving effect of cooling: first, painlessness can be achieved by local use of cooling for skin; second, this can be obtained through DNIC, that is, body represses irritating stimulations through several different sensory stimulations; third, according to "input control", irritating input relayed by myelinated Aδ fibers and non-myelinated C fibers are repressed by various non-irritating stimulations transmitted by Aβ fibers. Consequently, ascending irritating stimulations along sensory nerves are reduced. On this basis, adequate cooling acts as a non-irritating stimulator and represses irritating and painful inputs induced by laser beam; fourth, cooling skin may repress pain receptors' susceptibility leading to elevated pain threshold; fifth, limited thermal variations contribute to variations in addicting activity of central nervous system. As descending pain-relieving route messenger in central nervous system has quasi-addicting peptides such as endorphin, a noted painkiller, cooling may trigger pain-relieving route. (Saeki 2000) Thus, the reduced pain as a result of cryotheraputic pretreatment observed in the present study may have been caused by such mechanisms.

Although laser studies have focused on various methods for using active cooling, (Sadighha *et al*. 2009; Nelson *et al*. 2000; Saeki 2002; Hubbard *et al*. 2004) pain-relieving effects of the cryotheraputic pretreatment have been considered in several studies. (Nahm *et al*. 2002; Sadighha *et al*. 2009; Nelson *et al*. 2000; Eliot *et al*. 2004; Saeki 2002; Hasanpour *et al*. 2006) However, detailed reports have not been made yet for a precise temperature and time to use cryotheraputic treatment in different parts and with therapeutic purposes. Hasanpour *et al*. (2006) performed their study by putting a piece of ice before penicillin injection for 30 sec. Kinoshita *et al*. (2010) adopted melting ice in goserelin acetate injection area for 30 sec. Taghizadeh *et al*. (2011) cooled injection area at -4°C for 5 sec before dermal injections. Nestor *et al*. (2010) made use of 1.6°C for 20 sec before injecting filler. In order to reduce the pain caused by Botox injection, Bechara *et al*. (2007) used two methods for cooling (i.e. ice particles and cold air), each for 1 minute, while Skiveren *et al*. (2008) utilized frozen gel bag wrapped in gas for 5 minutes. The results obtained from all the clinical studies have acknowledged pain-relieving effect of the cryotheraputic pretreatment. However, as Hubbard *et al* (2004) mentioned in their study to assess the results acquired by cryotheraputic treatment, in spite of available evidence to prove pain-relieving effect of cryotheraputic treatment, more studies are needed on statuses, duration, and intervals of cooling for better results.

Ross *et al*. mentioned freezing point of skin to be 0-5°C and too much cooling may cause irreversible dermal damage. Long-term cooling is allowable for targeted deep chromophores (e.g. hair follicles) and the temperatures higher than skin freezing point may be useful for prevention from cooling damage. (Ross *et al*. 1999) Therefore, the present study used 4°C for 2 min to be tolerable for most tissues.

Furthermore, Electronic Cryotheraputic Pad^{p} with ability to provide controlled temperature in programmed intervals protects skin from cooling damages and leads to the best result in the best time. On the other hand, the device can be comfortably used without any anxiety and intervention. (Jaberansari *et al*. 2012)

Since the subjective index VAS depends on various statuses including the patient's interference of pain, the present study was compared with herself and the pain difference reported in two parties was adopted as the main indicator in order to increase validity of the results.

According to the results obtained from the present study, pain-relieving effect of cooling was different in various parts of face. The highest effect of cryotheraputic treatment was in chin and cheek with moustache area being minimally affected. This may be due to the factors such as skin thickness, hair thickness and darkness, accumulation of cooling receptors, pain in the area, etc.

In the present study, the highest and lowest pain difference were in 30-39 and 40-49 year old subjects, respectively; however, as the difference between different age groups was not significant, aging can be considered as a factor in effectiveness of cryotheraputic treatment.

On the other hand, short- and long-term visits after the treatment showed that no significant difference was detected in short-term side effects and long-term effects caused by laser hair removal although little difference was seen on test and control sides. Therefore, on the basis of the results, use of pretreatment with controlled cold preceding laser hair removal seems not to cause any side effects.

Conclusion:

It can be concluded that pretreatment with controlled cooling by Electronic Cryotheraputic Pad^{p} results in reduced acute pain caused by laser hair removal and consequently, it is recommended before the treatment. It is noteworthy that further studies should be performed in order to find optimum temperature and time.

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