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DISPOSITIVE PHOTOBIOMODULADOR FOR TREATMENT OF NIPPLE TRAUMA

Suellen Fonsêca Santos
Universidade Federal de Minas Gerais, Belo Horizonte, Brazil
(suellen.lapan@gmail.com)

Angélica Rodrigues Araújo
Pontifícia Universidade Católica de Minas Gerais, Belo Horizonte, Brazil
(angelica_araujo@pucminas.br)

Maria Emília Abreu Chaves
Universidade Federal de Minas Gerais, Belo Horizonte, Brazil
(mariaemilia.ufmg@gmail.com)

Marcos Pinotti
Universidade Federal de Minas Gerais, Belo Horizonte, Brazil
(pinotti@ufmg.br)

Abstract. *Phototherapy with LED stands as a biostimulator method for promoting accelerated wound healing and pain control. Recently, the pursuit of strategies that would be able to optimize the healing of a specific type of lesion motivated the development of a photobiomodulation dispositive which uses light emitting diodes (LED) with a wavelength in the near infrared spectral range, specific for the treatment of nipple trauma. These lesions, mainly due to pain and discomfort generated for women during the act of breastfeeding may promote early weaning, bringing losses for both the child and to the mother. The aim of this study was to determine the effectiveness of a photobiomodulation dispositive consisting of LEDs with a wavelength in the near infrared spectral range in the treatment of nipple trauma. This is a longitudinal study of the clinical trial placebo-controlled, randomized, double-blind trial in Sofia Feldman Maternity. Seventeen participants with 33 nipple wounds (cracks, fissures and abrasions) were divided into two groups: experimental and control. The experimental group was submitted to standard care (guidance on correct breastfeeding technique and nipple care) and applications of the photobiomodulation dispositive, while the control group received standard treatment and applications of the placebo dispositive. Participants were treated once a day during the period of hospitalization and were subjected to 1, 2 or 3 sessions. The following parameters were used: wavelength of 860 nm, pulsatile emission mode, frequency of 100 Hz, fluency rate of 50 mWcm-2 and fluency of 4 Jcm-2 for 79 seconds. The area of the nipple injury was evaluated, measured by an image analysis software, along with pain intensity, measured by the Visual Numeric Scale. In addition, subjects were monitored for 4 weeks. The analysis showed statistically significant reduction of the area of the nipple trauma in the experimental group compared with the control (p = 0.011). There was a decrease in pain intensity in both groups with increasing sessions, but was statistically significant only in the experimental group (p = 0.004). Furthermore, the results of the follow up showed that the experimental group had, over the weeks, accelerated healing (p = 0.002) and reduction in pain (p = 0.000) when compared to the control group. The results of this study indicate that the device constituted of LEDs photobiomodulator was an effective tool in the treatment of nipple trauma.*

Keywords: *phototherapy, led, nipple trauma, pain*

1. INTRODUCTION

At the beginning of breastfeeding, most women feel a mild pain or discomfort during feedings, which can be considered normal. However, exacerbation of pain symptoms associated with the onset of sores on the nipples, although common, are not normal and can be a gateway for bacteria that lead to the development of infections such as mastitis and puerperal breast abscess (Thomassen *et al.,* 1998). Such consequences have motivated research on the effectiveness of LED phototherapy in the treatment of nipple trauma (Araújo *et al., and* Chaves *et al., 2012;* Araújo *et al., 2013).*

The association between cracked nipples and early cessation of breastfeeding has been observed in some countries like Brazil, Australia and Italy, making it necessary to identify the causes of this complication for possible intervention and prevention of early weaning (Cooke *et al.,* 2003 and MS, 2009*).* However, the efficacy of therapies commonly used in the management of the cracks and nipple cracks, as application of medications and use of physical modalities (hot or cold compresses and ultrasound) is still controversial in literature (Giugliani, 2003). Thus, determine

and validate alternative for the treatment of these injuries is therefore very important for the welfare of women and baby's health.

In order to verify the effectiveness of a fotobiomodulador prototype using LEDs in nipple trauma, Araújo *et al*. (2007) and Chaves *et al*. (2012) conducted studies to analyze the effects of phototherapy in the closure of lesions and pain modulation. Positive preliminary results with the possibility of it being used in the home environment, creates the need to validate the end device and determine an effective protocol because the faster occurs the closing of nipple trauma, the smaller the chances of an early weaning or complications on women's health.

Therefore the aim of this study was to evaluate the effectiveness of a fotobiomodulador device using LEDs with a wavelength in the near infrared spectral range for the treatment of nipple trauma.

2. METHODOLOGY

The study participants were recruited from December 2012 to March 2013 at the Maternity Sofia Feldman in Belo Horizonte. This study was approved by the Ethics Committee of the Federal University of Minas Gerais. Inclusion criteria were: women, nursing mothers diagnosed with nipple trauma (splitting, cracking or abrasion) in at least one of the nipples; up to 5 months postpartum; and in the age group 18-40 years. Exclusion criteria were: nipple trauma to the presence of mastitis (inflammation of the breast); age 18 years or above 40 years; history or presence of malignancies; photosensitivity or any adverse reactions to exposure to sunlight; pregnant women; in use of other forms of treatment for nipple trauma and presence of cognitive impairment.

Seventeen participants were included in this study and, after being informed about the objectives of it, signed a consent form. Soon after, they were randomized into one of two treatment groups: control and experimental. The experimental group performed the standard treatment and the application of phototherapy, the control group, however received the standard treatment and placebo phototherapy.

Standard treatment consisted of guidance on correct breastfeeding technique and care for the breasts. These guidelines were given verbally and reinforced by an explanatory brochure, delivered to all participants. The therapy consisted of the application of the device composed of LEDs as a result of a partnership of the Bioengineering Laboratory (Labbio) with the company Bios Services e Comércio Ltda. The photobiomodulation device consists of two parts: the applicator and control circuit in which the program contains.

The applicator is formed by a base and a spindle (Figure 1). The control circuit includes the electronics of the device and the program responsible for user-interface device. In it, parameters such as LED radiation dose (fluence), duty cycle and power density (fluence rate) was established. The application time is fixed (79 seconds). The electronics circuit is responsible for connecting the applicator to the mains (127V) and activate its functioning.

Figure 1. Constitution fotobiomodulador device.

For the double-blind study, 2 devices were made. They had identical design, but differed in respect with tissue radiation. The control group of the device does not emit radiation LED and was named as "A", while the experimental device emitted LED radiation and was termed as "B". This information was unknown to the professional responsible for device application and the participants, they had no contact with the manufacturer during the study.

The parameters used for device application were: wavelength of 860nm light; pulsed emission mode; frequency of 100 Hz; duty cycle 50%; fluence rate of 50 mW / cm²; fluence of 4 J / cm²; and application time of 79 seconds.

After disinfecting the nipple with a 0.9% saline, the participant wore a bra and then applied to the "A" or "B" device, according to the group to which it belonged. For the procedure, both the participant and researcher used the eyes goggles during treatment (Figure 2).

Figure 2. Clinical application of photobiomodulator device.

Photographic records were made before the device application in all sessions (1, 2 or 3 sessions). The photographs were always made by the same individual, blind with respect to which group the participant belonged and were always performed in the maternity milk collection room.

To perform the photographic records, an EOS Rebel XS (Canon, USA) 10.1 megapixels, with 18 x 55 mm lens was used. The image was standardized by positioning the participant sitting in a chair with the camera mounted on a tripod and parallel to the nipple, with a focal length of 25 cm. The photos were taken in front view, placing the caliper below the nipple injury to standardize the scale.

The analysis of digital images obtained was carried out by the program Image Analyzer Quantikov, version 8.12 (Pinto, 2010) to quantify the total area of nipple trauma. By means of a software tool were defined margins of each lesion and automatically calculated its total area in mm².

Pain intensity was measured by the Visual Numerical Scale (VNS), and applied to each treatment session before and after the application of the device in all participants. The NVS is a subjective measure of pain and a dotted line is usually from 0 to 10, where zero represents no pain and ten the highest level painful. It circulates in the line the point that best describes the intensity of pain being evaluated (Sakata *et al.*, 2003).

The participants of this study were reported in the assessment, which would be accompanied by phone calls (follow-up) after hospital discharge. Telephone calls have been conducted once a week for 4 weeks after the beginning of treatment. Thus, monitoring the end there were five responses; the 1st day of the evaluation and the other on the 7th, 14th, 21st and 28th days after the first application.

During follow-up, the following questions were asked: "The damage (fissure, crack, excoriation) closed?" (Yes or no); "I feel pain in the nipple?" (Yes or no). "If yes to quantify 0 to 10". Data were stored for statistical analysis. The Analysis was divided in two steps; The first consisted of Applications and the Second Analysis on the follow-up analysis. Were used the nonparametric Wilcoxon testicles and Spearman correlation (for intra-group analysis) and Mann - Whitney (Analysis paragraph inter-group) (Soares and Siqueira, 2002). The Wilcoxon test comparing medians between the beginning and the end of the treatment of each member for all groups. The Spearman correlation checks for relationship between two variables and the Mann-Whitney test compares two independent groups using the medians of treatments.

For all analyzes, the level of significance was 5% and the statistical software used were MINITAB 14 and SAS Enterprise Guide 4.3.

3. RESULTS AND DISCUSSION

The study was conducted at the Maternity Sofia Feldman in Belo Horizonte, from December 2012 to April 2013. This institution is known to be a reference in carrying out normal deliveries and humanized health care. During the year 2011, 9,909 deliveries were carried out of which only 24% were caesarean section (Sofia Feldman, 2012). This is a hospital with high flow pregnant women, since patients undergoing vaginal delivery, and those who do not require specific care is discharged in 24 hours. As the period of occurrence of nipple trauma is usually the first week postpartum, emerging, on average, on the second day (Coca *et al.*, 2009), in some cases these injuries manifest themselves after the patient discharge. These facts may explain the limited sample size (n = 17) . As the hospital stay was the same variable, the number of phototherapy sessions ranged from 1, 2 or 3 applications in both groups (Figure 3).

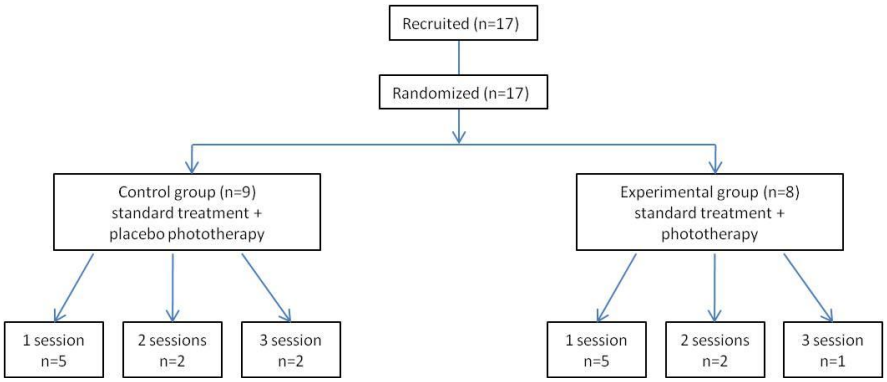

Figure 3. Flowchart randomization of participants.

One goal of this study was to evaluate the clinical efficacy of fotobiomodulador device at closing of nipple trauma . According to Figure 4, it is clear that for the control group there was a lesion area oscillation with increasing sessions. In contrast, the experimental group, with the advance of the sessions, there was a decrease in the lesion area.

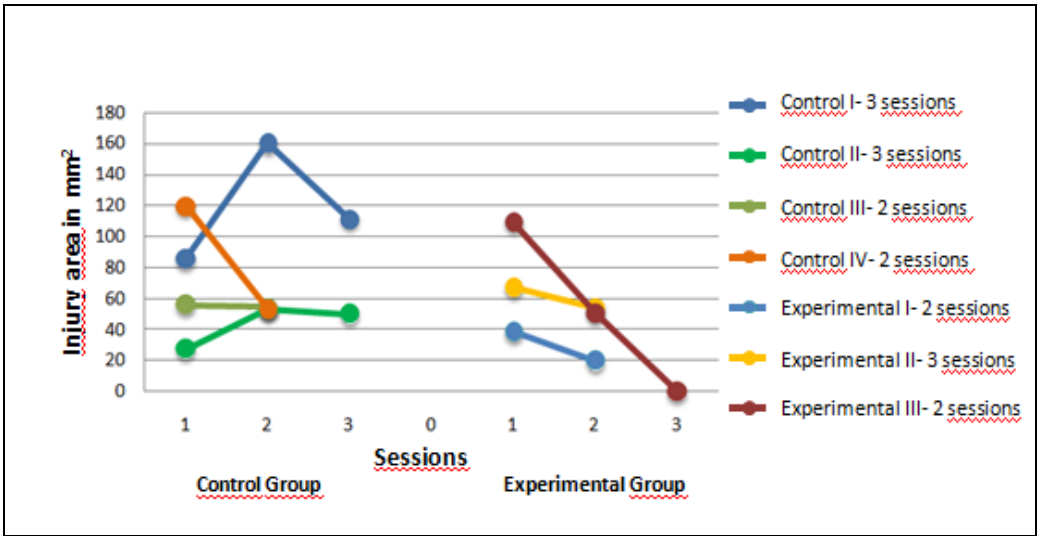

Figure 4. GRAPHIC : Area of nipple trauma of participants in both groups over 2:03 phototherapy sessions using the device with LEDs.

Statistical analysis intra group using the correlation of Spearman, pointed out that there is a relationship between the number of sessions and the area of injury only in the experimental group ($p = 0.01$). As the correlation coefficient was -0.519, the relationship is that with the advancement of applications there is a statistically significant reduction in the fissure area for the group that received phototherapy. The acceleration of the healing process observed in the experimental group, enjoys a return to breastfeeding and decreases the chance of secondary maternal complications, since these lesions are gateways to bacteria (Riordan and Nichols, 1990).

Corroborating these findings, according Trelles *et al.* (2006) LED radiation used after plastic surgery trauma, decreases the time resolution of side effects such as erythema, edema and hematomas in half the time to one third of its effective anti-inflammatory action (Trelles and Allone, 2006). This phenomenon occurs when absorption of light by chromophores called photoreceptors modulate biochemical and physiological activities of the cells in primary and secondary mechanisms (Karu, 1990). For Karu (1999), the primary mechanisms occur during irradiation acting directly on the photoreceptor molecules. However, it is known that many biochemical reactions occurring in the cell for hours or even days after irradiation, are known as secondary reactions (Karu, 1999). That would justify the monitoring of long-term results.

During the phone calls (1 per week), all mothers were asked if nipple injury had healed. The results of Tab. 1 demonstrate that while in the 1st week, no control group had a healed injury, 88% of the experimental group had healed lesions.

Table 1. Scarring of nipple trauma in the weeks in both groups.

No. weeks	Group	
	Control	Experimental
1 day	0 (0%)	0 (0%)
1 week	0 (0%)	7 (88%)
2 weeks	4 (44%)	8 (100%)
3 weeks	8 (89%)	8 (100%)
4 weeks	9 (100%)	8 (100%)

The correlation between wound healing and time is significant and positive for both groups (p = 0.00), indicating that the greater the number of weeks, the greater the number of healed lesions for both the experimental group and for the control. The above results can be justified by both groups having received as treatment basis, guidance on how to avoid and correct incorrect positioning of the child picks. This leads us to believe that the approach toward prevention of injuries, with the delivery of the folder, downplayed the effects of the main causative factor of nipple trauma.

However, when comparing the groups if there were statistically different (p = 0.00) in which the control group was lower during the healing time compared to the experimental group. In accordance with these results, several studies have found that phototherapy with LEDs accelerates the wound healing process (Whelan, 2001; Corazza *et al.*, 2007). This therapeutic effect can be explained by the physiological effects promoted by light, found in studies that histologically analyzed the irradiated tissue. The reduction of the inflammatory infiltrate, the angiogenesis stimulation, and increased fibroblast proliferation and collagen synthesis (Vinck, 2003) found by those authors, justify the clinical use of the device under consideration and suggests that radiation with LED could increase the tensile strength and toughness of the wound, reducing thereby the chance of recurrence of nipple trauma (Chaves, 2012).

Another objective of this study was to analyze the effects of the photobiomodulator device in reducing pain resulting from nipple trauma. The Mann Whitney test was performed to compare the two groups, it showed that a reduction in pain intensity at the time of application was significantly higher in the experimental group (p = 0.01). These findings suggest an analgesic response to phototherapy at the time of application, in accordance with other authors (Chaves *et al., 2012;* Araújo *et al., 2013*).

Already the anti algic action of LED phototherapy in the weeks after the intervention, can be analyzed during the post hospital discharge survey. All participants were questioned for 4 weeks, also for the presence of nipple pain. And if there were, its intensity should be measured between 0 and 10.

Figure 5 shows that for the control group the average pain starts with 5 falling to 3.4 after the second week and to 1 in the fourth week. However, the experimental group the average pain was in the first four after the first week I was 0.8, reaching zero in the third week.

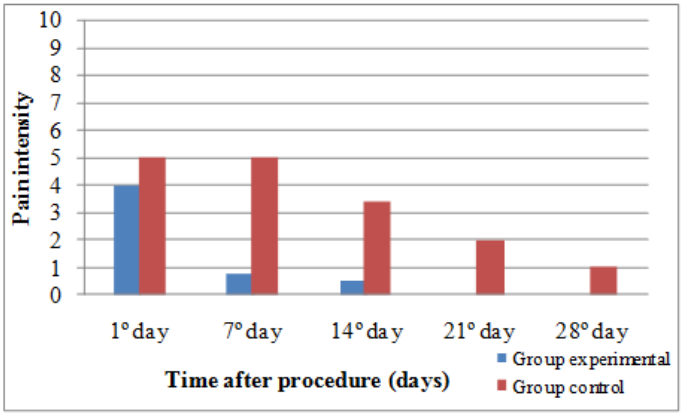

Figure 5. Pain intensity during 28 days of treatment

The relationship between evolution of weeks and pain is statistically significant in both groups (p =0.00). As the ratio is negative, the greater the number of weeks, the lower the level of pain mentioned by participants. This analgesia noted in both groups may be related to the withdrawal of the causal factors because standard treatment. Causing a favorable outcome to the closure of nipple trauma, which indirectly decreased the nociceptive levels.

To see if there was significant difference between the groups, the Mann Whitney test was performed and indicated that the level of the control group pain over the weeks is statistically greater than the experimental group (p=0.00). The physiological effects substantiating the analgesic potential promoted by light, involve changes in nerve conduction and genes involved in wound healing process (Takezaki *et al.*, 2006).

By comparing the experimental results with the follow-up, we can conclude that the objective of evaluating the clinical efficacy of the prototype in promoting the closing of the injury and the resulting pain modulation nipple injuries, have been achieved.

If the LED phototherapy depends on a protocol in which parameters such as wavelength, dose, fluency, irradiation time, emission mode and number of sessions, from the results described in this study, it can be said that the protocol favored analgesic and healing effects. Restricting treatment to the patient 's hospital stay was, for example, essential for compliance of participants with the proposed therapy .

It is believed that the search results may support the implementation of policies to the reduction of early weaning, emphasizing the promotion of exclusive breastfeeding, from the identification and treatment of nipple trauma.

4. CONCLUSION

With this study, clinical efficacy of the prototype was proven in promoting the closing of lesions and pain modulation caused by nipple injuries.

The photobiomodulator device consisting of LEDs promoted the optimization of the healing process and the reduction of the pain levels in the experimental group compared to control.

The results remained significantly positive during four weeks confirming the benefits of the proposed long-term therapy.

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6. RESPONSIBILITY NOTICE

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