

## EFFICACY OF A LIGHT EMITTING DIODE PROTOTYPE ON THE REPAIR PROCESS OF NIPPLE TRAUMA

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**Abstract.** Breastfeeding provides the optimum feed for the growth of a child. However, there are factors which limit the breastfeeding practice. Nipple trauma are one of the most common reasons for early weaning. The therapeutic approach includes orientation, dry treatment and wet treatment. However, none of these interventions provides satisfactory results. The aim of this study was to verify the efficacy of a prototype for phototherapy consisting of LEDs in the near infrared spectral range for the treatment of nipple trauma. Ten participants with nipple lesions (abrasions, cracks and fissures) were randomly in two groups: control (n=5) and experimental (n=5). The two groups received nipple care orientation and adequate techniques to breastfeeding, but the control received, additionally, placebo phototherapy, while the experimental was submitted to phototherapy applications by LED prototype developed for this study. The parameters of the irradiation were wavelength of 860 nm, fluency of 4 J/cm<sup>2</sup>, fluency rate of 50 mW/cm<sup>2</sup> and time of application of 79 seconds, in a pulsed emission mode. The application occurred two times per week, in alternated days, during consecutive four weeks. The nipple lesion area was measured by an image analysis software, and the pain intensity was measured by the Numeric Visual Scale. The analysis showed a statistically significant reduction in the area of the nipple lesions of both experimental and control groups (p=0.00) and, also, a significant difference between them (p=0.00). In the first sessions of the intervention, there was an acceleration of the healing process of the nipple lesions in the experimental group when compared to the control group. Pain intensity decreased in both groups with the increase in the number of sessions, but was statistically significant only for the experimental group (p=0.00). Moreover, a significant difference between groups (p=0.03) was observed for pain reduction. The results of this study showed that the prototype for phototherapy with LEDs in the near infrared spectral range was an effective tool in treatment of nipple trauma.

**Keywords:** LED, prototype, phototherapy, nipple trauma

### 1. INTRODUCTION

Breastfeeding is an irreplaceable way of providing optimum food for the healthy growth and development of children. However, there are complications that hinder the success of the breastfeeding practice, including nipple trauma (Lamounier et al., 2004).

Nipple trauma is characterized by rupture of the skin that covers the nipple, with lesions such as cracks, fissures and abrasions which are usually accompanied by local pain (Pereira et al., 1998; Biancuzzo, 2000). They constitute a major cause of early weaning and, if not treated, can eventually lead to mastitis (Smith and Tully, 2001; Coca, 2005).

The main cause of nipple trauma is inadequate positioning and latch-on of the child during breastfeeding (WHO, 1998; Prachniak, 2002). The usual therapeutic approaches for nipple trauma include orientation on correct technique of breastfeeding and nipple care (Weigert, 2004; Fraser and Cullen, 2006). However, these are more preventive approaches than curative and in most cases, may not be enough for the healing of nipple trauma.

Other alternatives are recommended for the treatment of nipple trauma such as application of sunlight, warm water compress, teabag compress, lanolin and freshly extracted breast milk (MS, 2003; Zorzi and Bonilha, 2006; Coca and Abrão, 2008). However, the efficacy of these treatments has not been adequately assessed and, consequently, they are not based in scientific evidence (Giugliani, 2003).

The low intensity phototherapy with LED (light emitting diode) may be a promising alternative for the treatment of nipple trauma, which promotes a process termed photobiomodulation. It consists of electromagnetic waves in the spectral range from red to near infrared that stimulate cellular functions by promoting beneficial clinical effects (Desmet et al., 2006).

Many studies demonstrate the efficacy of LED phototherapy in wound healing and pain control (Vinck et al., 2003; Vinck et al., 2006; Corazza et al., 2007; Barolet, 2008). However, its effect on the repair process of nipple trauma has been poorly investigated (Araújo et al., 2007). The aim of this study was to verify the efficacy of a prototype for phototherapy consisting of LEDs in the near infrared spectral range for the treatment of nipple trauma.

## 2. METHODOLOGY

Participants were recruited between August and October 2010 at the Hospital das Clínicas in Belo Horizonte. The study was approved by the Research Ethics Committee of the Universidade Federal de Minas Gerais (protocol No. ETIC 205/07, August 30, 2007).

Inclusion criteria were the following: presence of nipple trauma (crack, fissure or abrasion), up to 5 months postpartum and ages between 18 and 40 years. The exclusion criteria were: nipple trauma with clinical signs of infection (mastitis), presence of any form of cancer, photosensitivity or any adverse reactions to exposure to sunlight, pregnancy, use of other forms of treatment for nipple trauma and cognitive impairment.

Ten participants with nipple trauma were included in this study. All participants were informed about the objective of the study and signed a consent form after agreeing. Then they were randomized to one of two treatment groups: experimental and control. The experimental group received standard treatment and application of active phototherapy, while the control group received standard treatment and placebo phototherapy.

The standard treatment was adequate techniques of breastfeeding and nipple care orientation. These informations were verbally given to the participant by a professional, blinded in regard to the group the participant belonged to, during the initial evaluation. In addition, the orientations were reinforced by an educational brochure given to each participant.

The phototherapy consisted of application of the LED prototype (Fig. 1) which was developed by the company Bios Serviços e Comércio Ltda in partnership with the Bioengineering Laboratory (Labbio). The photobiomodulation prototype consists of three parts: applicator, software and control circuit. The applicator consists of a base structure and a spindle. The base structure was designed according to the anatomy of the breast, it comes into contact with the breast of the participant during the application of the LED prototype. The spindle contains five LEDs and plays the role to emit the radiation. It fits into in the base structure by means of a threaded. The applicator is mounted on a brassiere that holds it in place during the application of the phototherapy. The software is responsible for prototype user interface. Through this, the user can configure the parameters as fluence, duty cycle and fluence rate. The application time is calculated automatically depending on the desired fluence. The control circuit includes the electronics of the LED prototype and it is connected to AC power (127 V) to the computer via USB. The control circuit is responsible for activate the applicator from the parameters sent by the software (Chaves, 2011).



Figure 1. LED prototype

For the double-blind study, two prototypes were assembled. They presented identical external conformation, with one of them being active and the other inactive. The active prototype, herein denominated A, emitted radiation and was applied to the participants in the experimental group. The placebo prototype, herein denominated B, did not emit radiation and was applied to the participants in the control group. Both the applicant professional and the participants were blinded in regard to the prototype being used during the treatment sessions. They had no contact with the manufacturer of the prototypes during the study.

The parameters used for the phototherapy were wavelength of 860 nm; frequency of 100 Hz; pulsed emission mode with 50% duty cycle; fluency of 4 J/cm<sup>2</sup>, fluency rate of 50 mW/cm<sup>2</sup> and time of application of 79 seconds. The LED prototype consists of electromagnetic waves in the near infrared spectral range that activates cellular functions by promoting stimulation of ATP synthesis, increase in proliferation of fibroblasts and production of collagen, and stimulation of angiogenesis.

The professional sterilized the participant's nipple with a 0.9% physiologic solution and a brassiere with the LED prototype mounted on it was carefully adjusted to the participant's breast (Fig. 2), with prototype A and B being used for participants of the experimental and control group, respectively. During the phototherapy, the eyes of each participant and of the professional were covered with protective goggles. The application of the LED phototherapy to the participants in both groups was performed twice a week for a period of four weeks.



Figure 2. The prototype application

The nipple lesions area was measured by an image software. Photographs of each nipple lesion were obtained before application of the LED prototype in all sessions during the 4 weeks of treatment. The photographs were always taken by the same professional, blinded to which group the participant belonged. An EOS Rebel XS camera (Canon, USA), 10.1-megapixel lens 18 x 55 mm, was used. The photographs were 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, and were taken in frontal view. The temperature and relative humidity inside the room were monitored through an analog thermo-hygrometer (Incoterm). The digital images obtained were analyzed by the image software Quantikov, version 8.12 (Pinto, 2010), to quantify the total area of nipple lesions. Through a software tool the margins of each lesion were defined and their total area was calculated automatically.

Pain intensity was measured by Visual Numerical Scale (VNS) and it was applied to all participants in the therapeutic sessions, before and after the application of the LED prototype. The VNS was always applied by the same

professional who did not know the group that participant belonged. The VNS is a subjective measure of pain and is usually represented by a line scored from 0 to 10, where zero represents no pain and ten the highest pain level. The participant should circle the score number that best describes the intensity of pain to be evaluated.

The variables nipple lesions area and pain intensity were analyzed by the Anderson-Darling test and did not have a normal distribution. Thus, we used the median, an appropriate measure for asymmetric distributions and nonparametric tests: Wilcoxon test and Spearman correlation for intra-group analysis and Mann-Whitney test for inter-group analysis. The Wilcoxon test compares the medians between the beginning and end of treatment for each participant 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 the treatments (Soares and Siqueira, 2002). The level of significance in all tests was  $p < 0.05$  and the programs used were SPSS 12.0 and MINITAB 14.

### 3. RESULTS

There was reduction in area of nipple lesions in both the experimental and control groups with the increase in the number of therapeutic sessions. This finding is confirmed by intra-group analysis showed a significant reduction in area in the experimental group and in the control group (Spearman correlation:  $p = 0.00$ ).

The nipple lesions resulted in complete healing in both groups by the end of intervention (8 sessions). However, the nipple lesions in the experimental group healed faster than the lesions in the control group (Fig. 3). The inter-group analysis showed a significant difference (Mann-Whitney test:  $p = 0.00$ ).

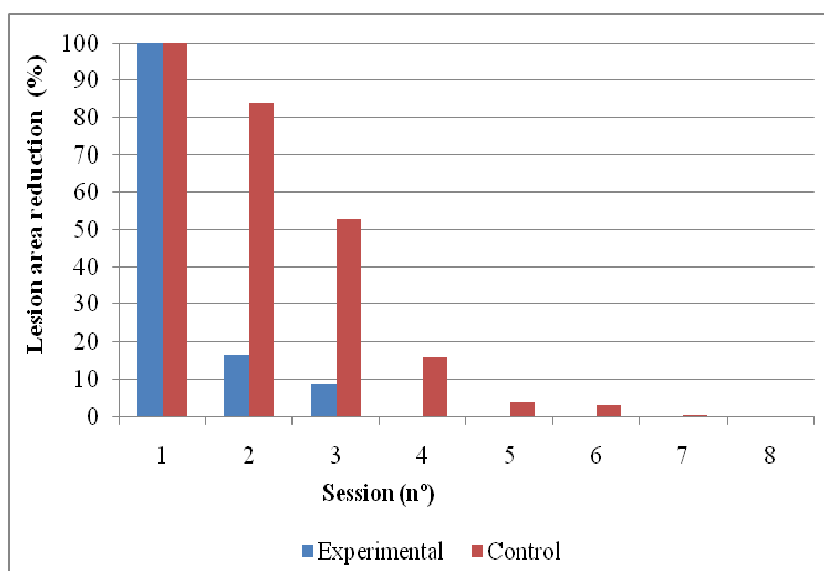


Figure 3. Percent reduction in area of the nipple lesions (median) in each group.

Table 1 shows the median pain intensity, measured by the Visual Numerical Scale (scored from 0 to 10), each treatment session. The pain intensity decreased with the increase in the number of sessions for both experimental and control groups.

Table 1. Median pain intensity during the 8 sessions.

Session	1	2	3	4	5	6	7	8
Experimental	7,5	6,0	4,0	3,5	1,5	0,0	0,0	0,0
Control	5,0	5,0	4,0	5,0	1,5	0,0	0,0	0,0

However, Wilcoxon test indicated no significant difference between the measure of pain before and after treatment session in the control group ( $p = 0.14$ ). On the other hand, this test showed a significant reduction in pain with treatment in the experimental group ( $p = 0.00$ ). The inter-group analysis showed a significant difference between them (Mann-Whitney test:  $p = 0.03$ ).

### 4. DISCUSSION

The nipple lesions together with pain interfere with continued breastfeeding during the first postnatal weeks, so a third of mothers who have these symptoms move to alternative methods of infant feeding (Tait, 2000). A number of

interventions have been referred to in the literature; however, it is still unclear whether they are effective or not (Page et al., 2003). Thus, further studies are needed in this area in order to promote a more effective therapeutic approach to the healing of nipple trauma.

In this study, we evaluated the clinical efficacy of the LED prototype in healing of nipple trauma (fissures, cracks and abrasions). The results showed significant reduction in the area of nipple lesions in the experimental group and in the control group. This finding may be explained by the fact that both groups received standard treatment, such as orientations about correct breastfeeding technique and nipple care. This practice allowed for the removal of causal factors which were basically inadequate positioning and latch-on of the child during breastfeeding (Weigert, 2004).

A complete wound healing was attained in both groups by the end of 8 sessions. However, there was a significant difference between the groups. The nipple lesions in the experimental group treated with active phototherapy healed faster than the lesions in the control group treated with placebo phototherapy. Similar results were found in other studies which demonstrate that LED phototherapy accelerates wound healing in animals (Whelan et al., 2003; Erdle et al., 2008) and humans (Caetano et al., 2009; Minatel et al., 2009). The acceleration is attributed to the physiological effects caused by LED radiation, such as stimulation of ATP synthesis, increase in proliferation of fibroblasts and production of collagen, and stimulation of angiogenesis (Karu, 2003; Corazza et al., 2007; Sousa et al., 2010).

In the present study, we analyzed the effects of the LED prototype in pain control of nipple trauma. There was a pain reduction in both experimental and control groups with the increase in the number of sessions. The decrease in pain intensity in both groups may be related to the removal of causal factors by the standard treatment, leading to the closure of nipple lesions, which indirectly reduced nociceptive levels.

However, it was a significant difference between them. These results are in accordance to the reports in the literature, which demonstrate that LED phototherapy is effective in the pain control (Eells et al., 2004; Takezaki et al., 2006; Siqueira et al., 2009). The analgesia observed may be attributed to changes in nerve conduction and in genes involved in wound healing and possibly pain modulation (Vinck et al., 2005; Desmet et al., 2006).

The LED prototype provided comfort to participants, was designed respecting the anatomic format of the breast, demonstrated to be useful on transport and handling, and ease in cleaning. Moreover, the results suggested that the LED prototype can be used as adjuvant tool in the treatment of nipple trauma, promoting healing of these lesions and pain control.

## 5. CONCLUSION

The LED prototype in the near infrared spectral range was effective in nipple trauma treatment. The prototype accelerated the nipple lesions healing and controlled the pain after treatment in experimental group compared with control group.

Since acceleration of the nipple lesions healing was observed in early sessions of treatment, this study suggests as a future work, the application of phototherapy-based LEDs with shorter treatment periods and increased frequency of sessions.

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