DEVELOPMENT OF A LED CLUSTER DEVICE ABLE TO TREAT MAMMILA INJURY EMITTING IN THE INFRARED WAVELENGTH

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Abstract. *The benefits of breast-feeding are well established. Mammila traumas are one of the main limitations to this practice. Even though prevention is recognized to be useful to avoid mammila injury, it is not rare cases of complications, leading to mastitis. The aim of this paper was to develop and evaluate the effectiveness of a LED cluster which was used to emit light in the infrared wavelength in order to treat mammila injuries. The device was designed to follow the morphology and anatomy of the nipples. Four puerperal women were randomly allocated in two groups: control (n=4) and experimental (n=4). The experimental group received photon therapy applications through the prototype making use of wavelength from 880 to 904 nm and a mean dose of 400 J/mm^2 during 6 weeks. Mammila lesion measurement and numeric pain visual scale were used to evaluate the lesion's progress. The prototype developed demonstrated itself as an effective tool to treat mammila lesion in this study.*

Keywords*: Photonbiomodulation, mammila traumas, device*

1. INTRODUCTION

During the pregnancy and puerperal period, the woman faces physiological adaptations that, occasionally, can predispose to some hindrance. Literature advocates that mammary alterations are common, such as engorgement, mammila traumas (fissure and cracks) and mastitis (Giugliani, 2004).

Mammila trauma is pointed as one of the main causes of mammila pain and limitation to breast-feeding practice (Biancuzzo, 2000). These injuries tend to appear between the second and the third weeks after the child birth (Naldoni *et al.*, 2004) and it is observed breast hyper queratinezation areas, where the thick and dries epidermis lost part of its elasticity. They are characterized as being a linear continuity solution of the epidermis and superior part of dermis, establishing a line separation that enters parts of the nipples (Freitas *et al.*, 1997) and they are highly correlated to the breast dermis inflammation (Rezende, 2002).

The mammila injuries, such as fissure or cracks, can be circular or longitudinal and of different sizes. Generally, the circular injuries are displaced in the nipple base, while the longitudinal ones can be situated in any place of the nipple, breaking it into two portions in either vertical or horizontal lines (Freitas *et al.*, 1997). Both can be caused by the wrong position of the child in relation to the breast, for the number of inadequate suck and mainly, for the incorrect suction technique (Campstrini, 1991; Naldoni *et al.*, 2004).

The mammila injury treatment has its main focus in prevention, which orientation and instructions on breast-feeding and breast care are its basic tools (Linhares, 1974; Naldoni, 2004). These, however, may not be enough for nipples cracks and fissure remission and may lead to breast complications such as mastitis (Riordan; Auerbach, 1993; Fetherston, 1997; Leang; Sauve, 2005).

Indeed its negative impacts in mother health (Laurence, 1996; Hospido; Sonesson, 2003) and on baby development (Campstrini, 1991) make the treatment of mammila lesions takes distinguishes importance. Some works suggest the use of acupuncture (Kvist, *et al.*, 2004) and physical resources, such as ultrasound (Mc Lachlan *et al.*, 1991) in order to control pain and to favour the inflammatory process advances of cracks and fissures of mammila. However, there is no common sense of the real effectiveness of those methods.

A potential promising alternative in the treatment of mammila injuries is the use of low power photon therapy. This resource uses electromagnetic waves in the spectral band from the red to the near infra-red ray, which is applied in tissues by using light source devices such as the ones based on LASER (Light Amplification by Stimulated of Radiation) and LED (Light Emitting Diode) sources. In this way, many works demonstrated the effectiveness of this resource in the improvement of wounds cicatrisation (Tsuchida *et al.*, 1991; Bjerring *et al.*, 2001; Franek; Krol; Kucharzewski, 2002; SAY *et al.*, 2003; Siqueira *et al.*, 2004; Weiss *et al.*, 2005) and in the pain control (Ortiz *et al.*, 2001; Brosseau, 2000). However, the electromagnetic application spectrum effects in mammila traumas cicatrisation has been hardly investigated (Alekseenko *et al.*, 1987; Kovale, 1990).

The main objective of this study was to evaluate the clinical effectiveness of an emitting electromagnetic wave prototype using light from near infra-red wavelength, developed specifically for the treatment of non-infected mammila injuries (fissure and cracks).

2. METHODOLOGY

Four puerperal women residents in Belo Horizonte region were investigated and followed during the months of May and August of 2006. All participants presented medical diagnosis of mammila injuries, characterized as lesions and/or cracks.

In order to be included in the study, the woman must exhibit non-infected mammila injury, have age between 18 to 35 years and sign the Free and Clarified Assent Term, agreeing to participate with the research. As exclusion criteria was considered: previous cancer history; use of other therapeutic modalities that could intervene in the injuries cicatrisation; presence of infected lesions; history of light photon sensibility; cognitive deficit that harmed the understanding and the accomplishment of breast care orientation.

The study participants were randomized in two groups: experimental and control. The control group (n = 4 breasts) only received breast care orientation and adequate techniques to breast-feeding, while the experimental one (n = 4 breasts) was submitted, additionally, to photon therapy applications by the developed photon biomodulator developed to the study.

All the participants had undergone an initial assessment, carried through by a blinded professional, that did not know to each group the woman were randomized, in order to characterize: 1- the puerperal (age, colour, number of children, scholar degree, childbirth type, previous experience with breast-feeding, time of puerperal period) and 2 - the breast and nipple (colour, size and type: protrusion, semi protrusion, inversion, pseudo inversion or hypertrophy).

Additionally to the initial assessment, in the 3rd and 6th weeks study, puerperal had been interviewed about the adhesion to breast care orientations and to breast-feeding techniques (sun exposition, bath, breasts alternation during the breast feeding and adequate catch during the breast feeding) and to probable occurrence or not of intercurrences (necessity of milks manual after the suck one, engorgement, presence of blood in milk). The mammila lesions were classified in accordance to Shimo proposal (43), in which nipples are considered complete (complete anatomical structure) with small lesion (small or equal to 3 mm); with average lesion (small or equal to 6 mm); and with great lesion (bigger than 6 mm). A 150 mm calliper (Black Bull) was used to measure mammila dimensions injuries in the initial assessment and weekly, per six consecutive weeks.

Weekly breast and nipple photographic images were made since the initial assessment. The images were used as a way to quantify lesion's evolution. Such images had been taken by the same researcher, using a photographic camera Digimax model the 402 - Samsung. The pictures were made in panoramic vision, frontal and lateral, with the camera placed at 50 mm from the nipple. The absence or presence of pain associated with mammila injuries was evaluated weekly during all the experimental period. The pain intensity was correlated with a Numerical Visual Scale to pain evaluation (NVE), where zero represents absence of pain and 10 is the higher level.

The research protocol was submitted to ethical analysis by the Ethics and Research Committee of Pontifice Catholic University of Minas Gerais that were in agreement to the research accomplishment.

2.1 Treatment Protocol

The photonbiostimulator device, showed in "FIG. 1", was developed using four light infra-red ray emitter (commercial LED), connected to an electronic unit which adapted to a positioning unit anatomically adjusted to human being breast format. The main application parameters were: total emission area, A_t, of 144 mm²; power, P, of 10 mW; infra-red wavelength (880 – 904 nm); dose, d, of 400 J/mm² and time of application, t, of 10 min, in a continuous emission mode. The application occurred three times per week, in alternated days, during consecutive six weeks.

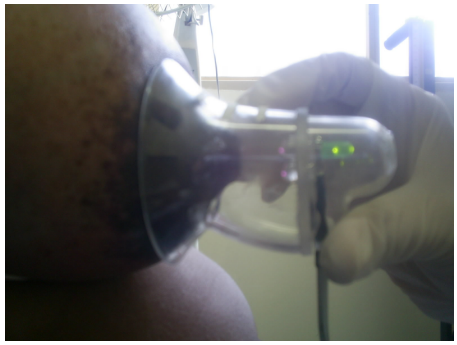

Figure 1 - Breast photonbiomodulator application to mammila lesions treatment.

The positioning unit was designed in order to perform the radiation perpendicularly to the lesion during the applications. Mechanical barriers as creams, oils, sun block were previously removed before the applications. To prevent direct eyes exposition, protection eyeglasses were used by the therapist and by the puerperal during all the application period.

2.2 Data analysis

The acquired data were processed by mathematical software and analyzed in a quantitative form. The mean and the standard deviation of pain intensity and the relative (%) and absolute (mm) dimensions of the lesions were considered for analyses. The percentage of weekly reduction lesions sizes in relation to the initial size from the same ones were compared between the groups and the differences were analyzed using the *Wilcoxon Signed Ranks Test*. The level of statistics significance was defined as $p < 0,05$.

3. RESULTS

The general characteristics of the studied group are summarized in "Tab. 1". The mean women age was of 28 years, the nipple type presented was predominantly of protrusion type and the majority of puerperal have presented previous breast-feeding experience.

Table 1 - General characteristics of the studied group.

Characteristics	**Control group**		**Experimental group**	
	Puerperal A	**Puerperal B**	**Puerperal C**	**Puerperal D**
Age	18 years	33 years	35 years	26 years
Colour	White	White	Brown	Brown
Scholar Degree	8ª grade	Incomplete Superior	4ªgrade	8ª grade
Time of Puerperal Period	9 days	1 month and 25 days	17 days	3 months
Type / Nipple Colour	Protrusion/white brown	Protrusion/white brown	Protrusion/dark brown	Protrusion/dark brown
Previously Breast-feeding Experience	No	Yes	Yes	Yes

Mean mammila injuries had been classified as small and medium and were initially homogenously distributed between the groups. The mean initial lesions size in the control group was of 3,6 ± 2,6 mm and in the experimental group was of 3,8 ± 1,7 mm. In the control group, 50% of the injuries progressed to complete cure. The others injuries had size reduction, and in the end of the treatment was all classified as small. On the other hand, in the experimental group the cure percentage was of 100%. The mammila lesion crack sizes results during the study period for each groups are represented in "Tab. 2".

Table 2- Mean and standard deviation of the mammila injuries sizes during the six weeks treatment.

Group	Weeks						
	0	**1**	**2**	**3**	**4**	**5**	**6**
Control	3,6 ± 2,6 mm	2,8 ± 3,4 mm	3,5 ± 4,0 mm	3,0 ± 3,6 mm	2,3 ± 2,6 mm	2,0 ± 2,3 mm	1,5 ± 1,7 mm
Experimental	3,8 ± 1,7 mm	2,3 ± 1,7 mm	0,9 ± 0,6 mm	1,5 ± 1,3 mm	1,3 ± 1,5 mm	0,3 ± 0,5 mm	0,0 ±0,0 mm

The percentage of weekly reduction in the mammila injuries size in relation to the initial size of the same ones was 54,5% in the control group and 74,1% in the experimental group (*Wilcoxon's Test:* $p = 0,036$). The reduction percentage for week and the total in each group can be visualized in "Fig. 2".

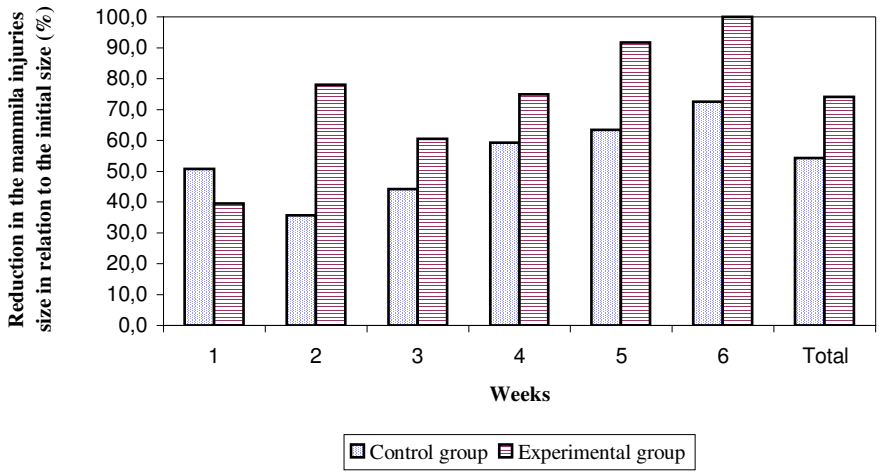

Figure 2 - Total mean and weekly reduction (%) of mammila injuries size in relation to the initial size.

The pain intensity, evaluated through NVE, reduced satisfactorily in the control and experimental groups. The mean reduction in the control group was of 73,6% and in the experimental 81,5% (*Wilcoxon's Test*: $p = 0{,}116$). The initial and final values of pain in both groups are represented in "Tab. 3".

Table 3- Mean and standard deviation values for the pain intensity during the six weeks study.

Group	Weeks						
	0	**1**	**2**	**3**	**4**	**5**	**6**
Control	5,7 ± 1,5	3,0 ± 1,4	2,5 ± 2,9	2,2 ± 1,9	1,0 ± 1,2	0,5 ± 0,6	0,2 ± 0,5
Experimental	7,0 ± 0,0	2,5 ± 1,7	2,0 ± 1,2	1,2 ± 1,0	1,2 ± 1,3	0,2 ± 0,5	0,5 ± 0,6

4. DISCUSSION

Mammila lesions and cracks are a common problem during the breast-feeding period (GIUGLIANI, 2004). Pains, breast-feeding difficulty (and/or interruption) and mainly increased risk for mastite development justify the necessity of a safe technique for an efficient treatment to these injuries. In this study, it was evaluated the clinical effectiveness of a photonbiomodulation device developed to treat non-infected mammila injuries. The prototype presented showed itself of simple application, anatomically adjusted to the treatment area, easy to carry and to hygienist. Moreover, the results were suggestive that the photonbiomodulator prototype can be used as coadjutant tool to the treatment of non-infected mammila lesions, improving these injuries closing.

The nipple lesions size percentage reduction was significantly higher in the experimental group, indicating that the cicatrisation process in this group seemed to be potentially increased by light application. Similar results were found by Simunovic *et al.* (2000) and Ortiz *et al.* (2001) when they irradiated skin with ulcerative injuries. According to these authors, photon therapy in infra-red wavelength was efficient in promoting increase in fibroblast tissues and in epithelial proliferation, with consequent reduction of injuries size. These findings are in accordance to the literature, which seems to be concise in relation of photon therapy benefits on cicatrisation process of animal and human coetaneous wounds. (Mester *et al.*, 1974; Tschida *et al.*, 1991; Fuirini, 1993; Simunovic; Ivankovich; Depolo, 2000; Franek; Krol; Kucharzwski, 2002; Lucas *et al.*, 2003; Say *et al.*, 2003; Siqueira *et al.*, 2004; Weiss *et al.*, 2005). A great number of mechanisms were considered to explain the effect of the photon therapy in cicatrisation process. The phenomenon known as "photonbiomodulation" involves: ATP synthesis stimulation, immune system activation, fibroblast increase proliferation, growth factors concentration and collagen production (Karu, 1987, Whela *et al.*, 1999). Other important photon therapy effect that can justify its actions on cicatrisation process is: microcirculation stimulation and neo - vascularisation. These factors contribute to a better nutritionist elements arrive that, associated with ATP production increment, provides an increase in the mitotic cells speed, facilitates cellular multiplication and tissue granulation (Harris, 1991). According to Karu (1989) and Ortiz *et al.* (2001) the new ATP's production occurs quickly after the tissue light radiation, favouring fibroblasts metabolic activity. According to Sound *et al.* (1989), Franek *et al.* (2002) and Bjerring *et al.* (2001) photon therapy induces a significant increase in type III collagen production after 72 hours of treatment and this contributes to tensile resistance increases.

This could be a reasonable justification to greater percentile reduction in mammila lesions size observed in the experimental group in the present work. Some authors have demonstrated the effectiveness of photonbiomodulation in

promotion analgesia (Brosseau, 2000; Matera *et al.*, 2003). In the present study, pain percentage reduction in experimental group (81.5%) was relatively higher than in control group (73.6%), but it was not found statistically significant difference between the groups. Pain involves physical aspects (related to the tissue injury) and psychological ones that if they are interrelated they become of a complex control. Some theories have been proposed to explain the induced effect of photonbiomodulation in pain. Amongst these, those related to increase levels of Beta-endorphin in spinal cord fluid and urinary excretion of Glico-corticoid and serotonin; the halogen substances reduction release (bradicinine, acetylcholine and prostaglandin-2) and to the electrolytic blockade of fibber nervous, that is the most argued and accepted in literature (Ortiz *et al.*, 2001). The occurrence of these phenomenons, however, is dose-dependent (Karu, 2004). Thus, the dose used in this study can not have been enough to activate satisfactorily the pain modulation mechanisms and promote statistically significant results and so it is necessary to investigate the effect of photonbiomodulation prototype with different doses from the one used in this first study.

5. CONCLUSION

The present work results proved that the infra-red spectral band electromagnetic wave emitter prototype, developed specifically for non-infected mammila lesions, was an efficient tool to clinical mammila lesions treatment for the mothers involved in this first study.

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