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Effect of Bioptron in Treating Cracked Nipples in Breast Feeding Women: A Randomized Controlled Trial

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Abstract: The aim of this study was to evaluate the effect of polarized polychromatic non- coherent light therapy in treatment of cracked nipples in breast feeding women. Thirty primipara breast feeding women, suffered from bilateral cracked nipples were selected for this study. They were randomly allocated into two equal groups (A & B). The participants in group (A) (control group) received purelan 100 cream only once daily at night, while group (B) (study group) received bioptron light therapy (10 minutes' irradiation for each affected side) for 10 sessions (5 sessions / week) for 2 weeks in addition to purelan 100 cream once daily at night. Assessment of all subjects in both groups (A & B) was carried out before and after the treatment program through assessing the pain intensity and quality, by VAS score and McGill pain questionnaire (MPQ) and wound healing using Storr scale after photographing cracked nipples. Comparing both groups post-treatment revealed that there was a statistically highly significant decrease in MPQ and VAS ($P < 0.05$) and significant improvement of Storr scale ($P < 0.05$) in favor of the group B in compared to group A. Treatment of cracked nipples with polarized polychromatic non-coherent light (Bioptron light) therapy and purelan 100 cream is an effective and safe way to alleviate pain and enhance healing of cracked nipple in breast feeding women.

Key words: Cracked nipples · Bioptron light · Pain · Wound healing

INTRODUCTION

Cracked nipples is a condition that can occur in breast feeding women as a result of a number of causes as poor latch, breast engorgement and using of breast pumps [1]. Cracked nipples appear three to seven days after the birth, as small lacerations or breaks in the skin of the nipples [1]. Traumatized nipples can readily become superinfected with bacteria which can delay healing [2]. Developing a cracked nipple can result in soreness, dryness or bleeding, leading to severe nipple pain when the baby is nursing [1]. Nipple pain is a well-known cause of early cessation of breastfeeding [3]. It is also implicated in depression and mastitis [4].

For infants, not being breastfed, there is increased risk of infectious morbidity, type 1 and 2 diabetes and sudden infant death syndrome and, for mothers, failure to breastfeed is associated with increased incidence of pre-menopausal breast cancer and myocardial infarction [5]. The bioptron light therapy system is a medical device with an optimal unit emitting that is similar to a part of the electromagnetic spectrum produced by the sun but with no ultraviolet radiation [6]. It can act in a natural way by supporting the regenerative and rebalancing capacities of the body and therefore help it release its own healing potential [7].

Bioptron light has biostimulative effect, when applied to the skin; it stimulates light sensitive intracellular biomolecules. This initiate cellular chain reactions and also trigger secondary response not limited to treated area, but involves the entire body [8].

Bioptron light therapy can be used as mono therapy or as complementary therapy for wound healing and treating pain, such in cracked nipples. Also, it can improve microcirculation, harmonize metabolic processes, reinforce the human defense system, stimulate regenerative processes of the entire organism, promote wound healing and relieve pain [9].

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The purpose of this study is to investigate the clinical effectiveness of bioptron light therapy in relieving pain and enhancing healing of cracked nipples in breastfeeding females, thus reducing side effect that may result from cessation of breastfeeding for both mother and her baby in addition to the economic benefits, by saving family money spent on formula feeding.

MATERIALS AND METHODS

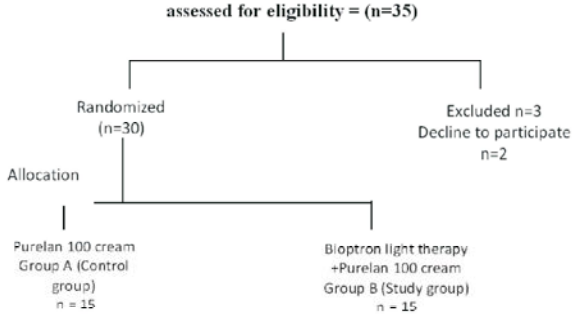
Participants: This study was a randomized, controlled trail. The treatment was offered to thirty five women, after taking clinical history and applying physical examination, 3 women did not meet the inclusion criteria and 2 refused the treatment modality due to difficulties to attend sessions for two weeks. All participants signed a term of informed consent. The age of the participants were ranged from 20 to 40 years, they were all primipara breast feeding women. Recruited from breast feeding unit –Heliopolis Cairo, after approval of the ethics committee of the faculty of physical therapy. Participants demographic data are summarized in Table (1).

Women excluded from participation if they had breast mass or implants or women with infants suffering from tongue disorders.

Randomization: The participants were randomly assigned to group (A) (Purelan 100 cream only) (n=15) or group (B) (Bioptron light therapy + Purelan 100 cream) (n=15) by an independent person who did the selection blindly from sealed envelopes containing numbers created by a random numbering generator. The randomization was restricted to permuted blocks to ensure that equal numbers were allocated to each group. The sequences assigned to the participants were placed in envelopes containing the allocation to each group.

Consort Diagram

Enrollment



Outcome Measures: Severity and quality of pain (the primary outcome) was measured before and after conducting the study by using visual analogue scale (VAS) and McGill pain questionnaire (MPQ), while healing of nipple fissure (Secondary outcome) was assessed by storr scale, after photographing the cracked nipple before and after 2 weeks of treatment.

Visual Analogue Scale: (VAS) is a valid scale in which women mark the relative severity of pain on a 10cm scaled tape. The zero point represented no pain and the 10 point represented the maximal pain severity. Pain severity was determined by calculating the distance between the zero point and the marked point [10].

McGill Pain Questionnaire (MPQ): To measure quality of pain, through rating each participant to her pain ranks and a numerical score called pain rating called pain rating scale index was assigned. The pain rating index was scored by the number of words chosen by each participant. The higher the total score on the MPQ, the more the pain experienced [11].

Canon Camera was used to photograph the cracked nipple to assess the improvement, before and after 2 weeks of treatment in both groups (A&B).

Storr Scale: Was used to assess healing of nipple fissure. Degrees of this scale is from 0 to 4 as follows: A painless nippleswith normal colour = 0, slightly reddened nipple with pain at the beginning of breast feeding (the first 5 to 10 seconds) = 1, a reddened nipple with pain at the beginning of and in the intervals between breast feeding times = 2. A nipple beginning to develop fissure with pain at the beginning of and in the intervals between breast feeding times = 3 and nipple fissure with pain at the beginning of and in the intervals between breast feeding times = 4 [12].

Procedures

Bioptron Light Therapy for Group (B) (Study Group)

Bioptron Compact III: PAG-860 was used to deliver the bioptron light with the following output characteristics: light wave length 480-3400 nm, degree of polarization <95%, power density 40 mw/cm^2 and light energy per minute 2.4j/cm^2, applied at a distance of 10cms from the skin surface.

Each participant in the study group (B) was instructed to lie in a relaxed confortable position and to remove clothes and any topical medications over the area

to be treated. The affected breast was cleaned using alcohol and the bioptron light probe was held perpendicular, 10 cms above the cleaned bare skin of the affected side to achieve maximal penetration of light irradiation of the bioptron. Each treatment session was 10 minutes irradiation for each affected side, carried out for 10 sessions (5 sessions /week) for 2 weeks. Participants in both groups (A & B) were given advice about right way of nursing their babies.

Statistical Analysis: Results are expressed as mean ± standard deviation or median (interquartile range (IQR). Comparison between mean values of variables in the two groups (A and B) were performed using unpaired t-test, while Paired t-test comparison (pre-treatment versus post-treatment) within the same group was performed. Comparison between median values of the two groups (A and B) was performed using Mann-Whitney U test, while pair-wise comparison (pre-treatment versus post-treatment) within the same group was performed using Wilcoxon Signed Ranks test. Statistical Package for Social Sciences (SPSS) computer program (version 23 windows) was used for data analysis. P value ≤ 0.05 was considered significant.

RESULTS

As shown in Table (1) statistically there was no significant difference between both groups regarding age, weight, height and BMI.

VAS: The mean ± SD values of VAS in the "pre" and "post" tests are presented in Table (2) for both groups. "Paired t test" revealed that there was a significant reduction of VAS ($p<0.05$) at post treatment in compared to pre treatment for both groups. Considering the effect of the tested group (first independent variable) on VAS, "unpaired t test" revealed that the mean values of the "pre" test between both groups showed there was no significant differences ($p>0.05$). But, the mean values of the "post" test between both groups showed there was significant differences ($p<0.05$) and this significant reduction in favor of group B.

MPQ Pre and Post-Treatment for Both Groups A and B: In group A, there appeared to be a statistically significant decline in the value of MPQ measured after treatment when compared with its corresponding value measured before treatment. While in group B,

Table 1: General characteristics of patients.

General characteristics	Group A Mean ±SD	Group B Mean ±SD	t-value	P-value
Age (yrs)	26.3±3.93	26.6±3.29	- 0.26	0.795
Weight (kg)	71.7±9.1	73.1±8.86	- 0.493	0.625
Height(cm)	164.1±5	165.7±5.1	- 0.976	0.335
BMI (kg/m2)	26.6±2.99	26.8±2.8	- 0.018	0.986

SD: standard deviation, P: probability, Significance Level (P<0.05)

Table 2: Mean ±SD, t and P values of VAS pre and post treatment at both groups

	Means ± SD	Means ± SD			
VAS	Pre test	Post test	% of improvement	t-value	P- value
Group A	7.6±1.93	4.9±1.86	35.5	7.285	0.0001*
Group B	8.55±1.63	1.25±1.68	85.38	15.327	0.0001*
t-value	-1.678	6.507			
P- value	0.101	0.0001*			

*Significant level is set at alpha level <0.05.

Table 3: Inter and intra-group comparison between values of MPQ in the two studied groups measured before and after treatment

	Group A	Group B	$Z^{\#}$ value	P-value
Before treatment	26 (4)	26 (5.5)	-1.284	0.211 (NS)
After treatment	19 (6)	1 (3)	-4.75	0.0001 (S)
$Z^{\#\#}$ value	-3.924	-3.926		
p-value	0.0001 (S)	0.0001 (S)		

Data are expressed as median (IQR interquartile range). NS = p > 0.05 = not significant.

S = p < 0.05 = significant. $Z^{\#}$ value = Mann–Whitney test.

$Z^{\#\#}$ value = Wilcoxon signed ranks test.

Table 4: Frequency distribution of the Storr scale in pre and post treatment for both groups

Hot flushes dairy card	Group A					Group B				
Frequency distribution	Normal colour	Slightly reddened	Reddened nipple	Beginning develop fissure	Nipple fissure	Normal colour	Slightly reddened	Reddened nipple	Beginning develop fissure	Nipple fissure
Pre treatment	0(0%)	0(0%)	4(20%)	8(40%)	8(40%)	0(0%)	0(0%)	0(0%)	9(45%)	11(55%)
Post treatment	0(0%)	9(45%)	7(35%)	4(20%)	0(0%)	8(40%)	10(50%)	2(10%)	0(0%)	0(0%)
					Within groups					
Pre Vs.Post			Z-value					p-value		
Group A			-4.042					0.0001*		
Group B			-4.027					0.0001*		
					Between groups					
Group A Vs. Group B			Z-value					p-value		
Pre treatment			-1.438					-3.764		
Post treatment			0.201					0.0001*		

*significant ($p<0.05$)

a statistically significant decrease appeared in the median value of MPQ measured after treatment when compared with its corresponding value measured before treatment. Between the groups, no statistically significant difference was noted between the median value of MPQ in group A and their corresponding value in group B and after treatment, there was a statistically significant decrease in the value of MPQ in group B in comparison to its corresponding value in group A as shown in Table 3.

Storr Scale Pre and Post-Treatment for Both Groups A and B: In group A, there appeared to be a statistically significant improvement in the frequency distribution of Storr scale measured after treatment when compared with its corresponding frequency distribution measured before treatment. While in group B, a statistically significant improvement appeared in the frequency distribution of Storr scale measured after treatment when compared with its corresponding frequency distribution measured before treatment. Between the groups, no statistically significant difference was noted between the frequency distribution of Storr scale in group A and their corresponding frequency distribution in group B and after treatment, there was a statistically significant improvement in the frequency distribution of Storr scale in group B in comparison to its corresponding frequency distribution in group A as shown in Table 4.

DISCUSSION

In the present study, pain severity based on VAS score, pain quality based on MQP questionnaire as well as assessment of healing of cracked nipple using storr scale revealed significant improvement in two weeks after initiating the treatment in the study group(B) treated by Bioptron light therapy.

There is rarity of studies evaluating the effect of Bioptron light therapy on breast feeding women with cracked nipples. Bioptron is a new therapeutic modality which efficacy has been investigated for burns, carpal tunnel syndrome, lateral epicondyles [13], postsurgical healing [8] and ulcers.

There are several theories about Bioptron's mechanism of action, as it accelerates the cellular mechanisms and improves the blood supply, increase plasma level of anti-inflammatory and fibroblast growth factors [14, 15]. In line with our results, no side effects were reported for Bioptron in previous studies [16, 17]. In agreement with our results, therapeutic effect of Bioptron therapy on episiotomy in postpartum women was examined and there was a highly significant decrease in present pain intensity scale (ppi) as well as level of white blood cells, with conclusion that, it was considered as an efficient method in accelerating wound healing and pain relief after episiotomy [17].

Looking further into the effect of Bioptron light therapy Raeissadat *et al*. [18] found that using Bioptron therapy with wave length 480-3400 nm and density 40 mw/cm^2 led to significant improvement in the mean of pain severity based on (VAS) scores in patients with mild to moderate carpal tunnel syndrome after (eight sessions, for 3 weeks) of treatment [18]. Another study conducted by Dimitrios *et al*. [19] indicated that there were significant improvement in self-reported degree of pain via VAS, ankle edema and range of motion over a 5 days period of treatment by Bioptron, device, in patients suffering from acute ankle sprain [19].

The mechanism behind pain relief via usage of Bioptron light, could be explained through its phototherapy anti-inflammatory effect, as it can decrease pain via the emitted light causing warming of the skin as it contains infra-red light [20]. Furthermore, the effect of

Bioptron light therapy on wound healing was assessed by Medienica and Lens, 2003 evaluating its effectiveness in the treatment of venous leg ulcer with conclusion that there was statistical significant decrease in wound surface area and increase in healing rate [14]. The mechanism of action of photobiostimulation is the absorption of visible light by mitochondria which may cause a chain of reactions on molecular levels, leading to activation of nucleic acid synthesis which is essential for wound repair [14].

In contrary to our results Abdel Mageed *et al*. [21] reported that treatment of deep partial thickness second degree burns by Bioptron light therapy using (Bioptron compact III light therapy system) was not satisfactory and statistically non-significant [21]. The strong point of our study was that we evaluated the efficacy of Bioptron via VAS score, MQP and by photographing cracked nipple pre- and post-treatment, to assess the degree of healing.

Appling Bioptron with different therapeutic protocols, longer duration of light therapy, long term assessment and finally larger sample size are suggested to get final conclusion about the efficacy of Bioptron therapy in cracked nipple. Limitations: one of the limitations of our study is that the satisfaction of patients from the therapeutic processes had not been considered.

CONCLUSION

Treatment of cracked nipples with polarized polychromatic non-coherent light (Bioptron light) therapy and purelan 100 cream is an effective and safe way to alleviate pain and enhance healing of cracked nipple in breast feeding women.

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