



Effects of Performing Low-Level Laser on Cesarean Section Scar

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Abstract

Objectives: Evaluating the effects of low-level laser (LLL) application on pain relief and abdominal scar formation in cesarean section (C-section) incision.

Materials and Methods: The present prospective trial included 65 patients who referred to Amiralmomenin hospital of Semnan University of Medical Sciences for their first C-section. They were divided into intervention and control groups and LLL therapy was used in the intervention group after the randomization process. Then, scar formation and the level of pain in the incision site were evaluated after LLL imitation on 1, 3, 5, and 7 days of the post-partum period. As regards the scoring of the scar appearance and pain, 2 scoring methods were utilized, including Vancouver scar scale and visual analog scale.

Results: A statistically significant difference was found between intervention and control groups in terms of pain score on days 5th and 10th of the post-partum period ($P=0.000$) and patients in the intervention group had a lower complaint of pain. However, no significant difference was detected between the 2 groups regarding Vancouver scar scale score which was used for scar formation in C-section incision.

Conclusions: Overall, although pain relief is one of the most important complaints which patients suffer during the post-surgery period, other issues should be taken into account as well. By using this protocol, our study failed to prove the prophylactic role of LLL intervention in abdominal scar growth which is considered as another important point cosmetically. Accordingly, future studies might confirm the best protocol respecting preventing the scare formation with higher scale scores and reducing the pain.

Keywords: Low-level laser, Abdominal scar, Pain

Introduction

Cesarean delivery is known as one of the most common types of surgery worldwide, especially in our country although its prevalence varies in different parts of the world. In general, it is estimated that one cesarean section (C-section) is performed every 24 minutes (1,2). In recent years, the prevalence of cesarean deliveries has raised in Iran as compared to the other areas in Asia, leading to a higher rate of surgical complications (3,4). For instance, complications related to surgical wounds with an incidence of 2.5%-34% include part of these problems (5). In addition, the scar of cesarean surgery is an inevitable complication that millions of women are afflicted with annually. These scars have different severities and are due to an abnormal and, sometimes, hyper-reaction phenomena in the wound healing process (6,7). Further, post-cesarean scars are not only considered as an unimportant aspect of the surgical procedure but also they are accepted to be a

cost to wound healing. Similarly, the anatomical site of the cesarean scare is covered by the cloths thus surgeons pay no considerable attention to it. However, these scares can cause pain, itching, and skin contracture. Furthermore, cesarean scars reduce beauty due to skin deformity and thus increase the level of stress, especially in young mothers (8). In general, such scars could negatively change the quality of life, leading to anxiety and reducing the self-esteem (9,10). There are few ways to improve and optimize the scare formation such as cryotherapy, corticosteroid focal site injection, and radiation which are all related to a higher recurrence rate (11). Given the recent scientific advances, a hypertrophic scar remains a problem and prevention is regarded as the best strategy for its solving. Both wound and surgical technique factors are effective in scare formation. Generally, all the wound-associated factors, which prolong the healing time, can cause a situation of hypertrophic scar formation (12,13).

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Therefore, finding the factors regarding shortening the healing time can result in reducing the hypertrophic scar formation. The Food and Drug Administration (FDA) has confirmed the safety of low-level laser (LLL) method (14). Recent trials have discovered that the application of the LLL influences the biological behavior of inflammatory cells in animals. For example, this method can increase the lymphocyte activation, the macrophage phagocytosis, and fibroblast growth factor secretion while decreasing the inflammatory mediators and granulation tissue formation (15-17). Likewise, some studies applied LLL to treat musculoskeletal injuries and arthritis and considered it as an analgesic method (18,19). Moreover, the implementation of LLL method on the skin accelerates the neovascularization, collagenization, along with fibroblast aggregation, leading to the progression of wound healing (20). Additionally, some human studies have approved the dramatically useful effect of LLL application on diabetic foot ulcers (21,22). Similarly, other studies showed the positive effect of this method on other scars such as inguinal hernia and burnt ulcers (23-25). To the best of our knowledge, no study has yet examined the impact of LLL method on C-section abdominal scar. Accordingly, a prospective randomized trial was conducted to investigate the role of this specific method in cesarean scar formation and to evaluate the outcomes of using LLL on pain relief and scar formation in C-section incision.

Materials and Methods

This research was a randomized clinical trial and the method of sampling was based on the permuted block randomization method including four blocks. The protocol of Carvalho et al study was employed to estimate the sample size as well (26).

A total of four stratum were formed considering that there were 2 baseline variables (e.g., age and body mass index) and at least 2 levels for each of them. To achieve the study objectives, 14 samples were considered for each stratum according to the above-mentioned formula. Therefore, the total sample was required to be 56. In addition, a number of 6 individuals were added considering 10% of withdrawal to the total volume. Finally, the required sample volume for this prospective study was 62 with a total of 31 individuals in each group. Likewise, Vancouver scar scale (27) and visual analog scale (28) were employed to score the scar appearance and pain. In this system, four physical aspects of scar were examined as follows.

- *Vascularity* (0-3). Normal skin color: 0; Pink like: 1; Red like: 2; Purple like: 3;
- *Pigmentation* (0-2). Without any pigmentation: 0; Hypopigmented: 1; Hyperpigmented: 2;
- *Pliability* (0-5). Normal: 0; Supple: 1; Yielding: 2; Firm banding: 3; Contracture: 4;
- *Height* (0-3). Normal: 0; 0-2 mm: 1; 2-5 mm: 2; >5 mm: 3;

- *Visual analog scale*. Not painful: (0); Mild pain (pain exists but without any interference with daily living activities): 1-3; Moderate pain (the patient can do daily living activities but not the same as before): 4-6; Severe pain (the patient is unable to do daily living activities): 7-10.

According to the protocol of Amiralmomenin hospital, patients routinely complete the consent form at the onset of hospitalization, which allows the authorities to use the information from the files for any research in the future. Finally, 68 patients, as the candidates for cesarean section (C-section) due to obstetric reasons, were enrolled after a comprehensive discussion about the study goal and obtaining the consent forms. The inclusion criteria were as follows.

1. Being within the age range of 17-37;
2. Being in the gestational age of 37-42 weeks of gestation;
3. Experiencing the first C-section;
4. Having no history of any diseases with prolonged wound repair such as chronic disease of cardiac, renal, liver, or lung, as well as connective tissue disorder, diabetes mellitus, psychological disorder, and cancers;
5. Having no history of drug use such as anti-coagulant agents, corticosteroids, chemotherapy, radiotherapy, anti-histamines, and calcium canal blockers;
6. Having no prior supra-pubic scar;
7. Having no history of keloid formation on the body;
8. Having no obstetric complication such as preeclampsia, chorioamnionitis, placental abruption, placenta previa, and meconium amniotic fluid.

Three patients discontinued their cooperation at the beginning of the study while the remaining patients performed C-section with 10-15 cm incision with 0-0 nylon sutures subcutaneously. Then, the duration of the surgery and the probable complications were listed as well. The exclusion criteria included:

1. The duration of surgery >90 minutes;
2. Any surgery-related complications such as infection, anemia, and dehiscence;
3. Hospitalization after surgery >7 days;
4. The dissatisfaction with the continuation of the study.

As mentioned earlier, women were assigned to intervention and control groups by the permuted block randomization method after C-section.

In the intervention group, the LLL method was used by Mustang 2000 (Russian) with the wavelengths of 830 nm (4 J/cm²) for 6 days. The angle between probe and skin was 90 degrees on days 1, 3, 5, 7, 9, and 11th after C-section. In the control group with the same condition, the angle 90 degrees was used but no laser was emitted from the probe. The imitation interval was considered one day apart since the effect of laser on mitochondria and repair lasts 24 hours. Laser imitation was performed by the training operator considering the safety principles.

Body mass index on suture pulling time was recorded for every patient. Numerous photos of the incisions were vertically taken by iPhone S6 (8 megapixel camera) with a distance of 15 cm, and the same imitation condition was provided for both groups during 6 months after the surgery. Then, AutoCAD 2014 application was used for photo arrangement, followed by utilizing Vancouver visual scale for scoring, as well as measuring the height on three points, mid, and 1 cm inner of the incision on each side. The amount of pain was also estimated based on the visual analog scale on day 5th and 10th after the surgery. The patients were then questioned about the presence or absence of itching. Eventually, the ANOVA test was used and all calculated P values were two-sided and $P < 0.05$ was considered meaningful.

Results

In our study, 68 patients were enrolled of whom three dropped out due to their lack of tendency for cooperation. Therefore, 65 patients were categorized into intervention and control groups each containing 32 and 33 cases, respectively. The average age was totally 29.85 ± 2.89 years, as well as 29.25 ± 2.74 and 29.9 ± 3.04 years in intervention and control group, respectively, and there was no significant difference between the 2 groups ($P = 0.364$). The average body mass index was totally 27.67 ± 3.07 in addition to 27.40 ± 3.09 and 27.95 ± 3.08 in intervention and control groups, respectively. There was no significant difference between the 2 groups ($P = 0.472$) and they had almost identical conditions.

Regarding pain score on day 5th after the surgery, a significant difference was observed between the 2 groups ($P = 0.000$), demonstrating the scores of 4.15 ± 0.84 and 5.61 ± 1.33 for intervention and control groups, respectively (Figure 1).

There was also a significant difference between the 2 groups in terms of the pain score on day 10th after the surgery ($P = 0.000$), displaying the ranges of 1.43 ± 0.66 and 2.51 ± 1.00 for intervention and control groups respectively (Figure 2).

Likewise, the average of vascularity scar score was 0.43 ± 0.98 and 0.57 ± 1.06 in intervention and control groups, respectively, and no significant difference ($P = 0.588$) was detected between the 2 groups (Figure 3).

The pigmentation score of the abdominal incision scar was 1.18 ± 0.85 and 1.45 ± 0.79 in intervention and control groups and there was no significant difference ($P = 0.198$) between the 2 groups in this regard (Figure 4).

Similarly, the average of the pliability of the scar score (Figure 5) was 0.46 ± 1.10 in the intervention group and 0.63 ± 1.34 in control group and the difference between these 2 groups was not statistically significant ($P = 0.585$).

The average of the height of scar score (Figure 6) was equal to 0.31 ± 0.53 and 0.27 ± 0.57 in intervention and control groups, respectively. Further, no significant difference was observed between the 2 groups in this

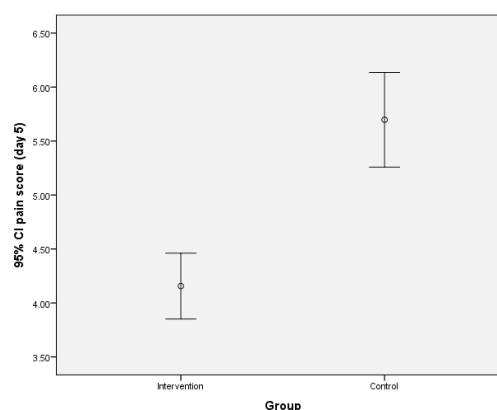


Figure 1. Pain Score on Day 5th of Surgery in Intervention and Control Groups ($P = 0.000$).

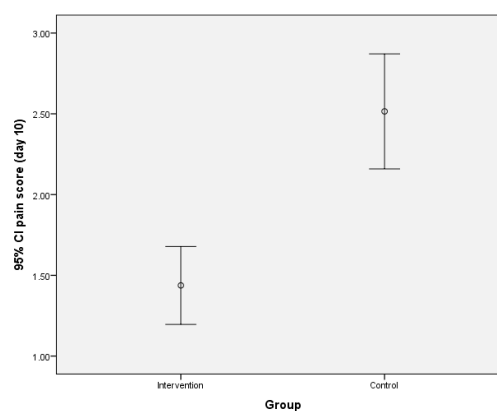


Figure 2. Pain Score on Day 10th of Surgery in Intervention and Control Groups ($P = 0.000$).

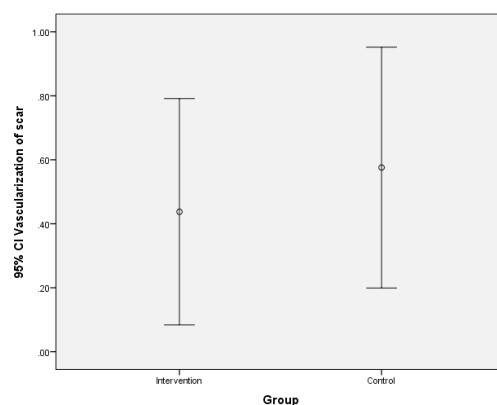


Figure 3. The Average of Scar Vascularity Score Between Intervention and Control Groups ($P = 0.588$).

respect ($P = 0.774$).

Fisher exact test was used to compare the incidence of itching rate in both groups. Although itching incidence in the intervention group was higher as compared to the group ($9\% > 0\%$), the difference was negligible ($P = 0.114$).

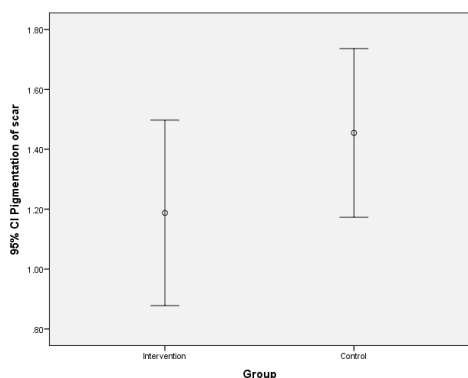


Figure 4. The Pigmentation Score of the Scar Between Intervention and Control Groups ($P=0.198$).

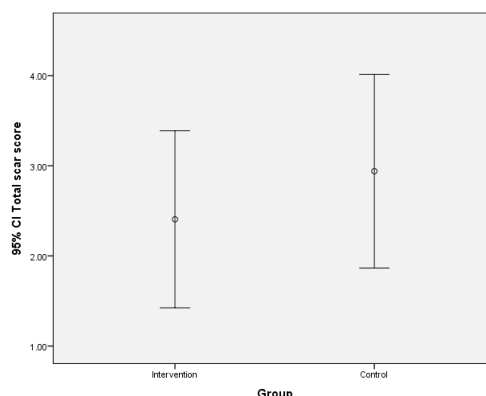


Figure 7. Total Vancouver Scar Scale Score Between Intervention and Control Groups ($P=0.459$).

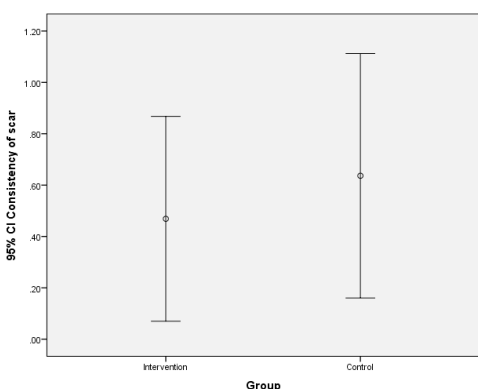


Figure 5. The Average of the Pliability of the Scar Score Between Intervention and Control Groups ($P=0.585$).

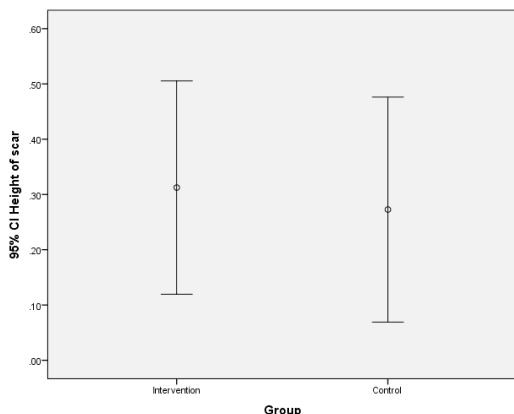


Figure 6. The Average of the Height of Scar Score ($P=0.774$).

Furthermore, the average of the total Vancouver scar scale score (Figure 7) was calculated and compared between the 2 groups, demonstrating no significant differences between the 2 groups in this regard ($P=0.459$).

Discussion

The present study was conducted on patients who referred to Amiral momenin hospital of Semnan University

of Medical Sciences due to the first cesarean section (C-section) for obstetric indications. As previously explained, the randomization process was performed correctly. As regards the effect of laser on scar formation, Vancouver scar scale was employed to score numerous items while no significant difference was found between 2 groups in this regard. Thus, it was found that using LLL method during the post-operation period had no effect on scar formation. In the case of scar formation, several studies were reviewed, including Gaida et al (24) who used LLL therapy (with a wavelength of 670 nanometers) for burn scar treatment twice a week for 8 weeks. A specified zone was considered not to imitate in each patient. Additionally, the average of Vancouver scar scale was significantly lower after LLL therapy in the intervention group and 17 out of 19 patients were cured completely (24). The above-mentioned study investigated the therapeutic effect of LLL but our study evaluated the prophylactic effect of LLL method. On the other hand, the dosage of LLL was three times more than that of our study thus these different results can be justifiable. Similarly, Carvalho et al studied the role of LLL application in patients with inguinal hernia incision. They used LLL with a wavelength of 830 nanometers on 1, 3, 5, and 7 days after the surgery and checked the outcome based on the Vancouver scar scale after six months. Based on their results, no significant differences were found in pigmentation, vascularization, and height scores between the 2 groups while the pliability score was lower in the intervention group as compared to the control group. However, there was a significant difference between the 2 groups in terms of the total of Vancouver scale score. In other words, the total of Vancouver scale score was lower in the intervention group when compared to control group. As a result, the researchers reported that LLL therapy can be helpful for scar formation (26,29). In our study, neither the single parameters nor the total scores differed in the 2 groups.

Likewise, several studies addressed the effect of LLL on pain relief. For example, Alvarenga et al evaluated the

impact of LLL therapy on relieving the pain in episiotomy incision in 54 patients following 6, 24, and 48 hours and 7 days after delivery, followed by calculating Vancouver scale scar in each time. Based on their findings, LLL had no effect on decreasing the pain and there was no significant difference between the intervention and control groups (having the same Vancouver score) in this respect (30). Moreover, Santos Jde et al investigated the impact of LLL therapy on alleviating the pain in episiotomy incision immediately, 2, and 24 hours after suturing in 56 patients and found that it cannot affect the pain score (31). Aradmehr et al also examined the effect of LLL therapy on episiotomy incision. They considered three points on the incision and used 2 different sorts of LLL (i.e., infrared and red) between the 2 groups. In this study, 3 groups were compared with each other, including 2 intervention groups and 1 control group. The pain score was recorded on 3 times including before the intervention, along with immediately and 30 minutes after the intervention. The results revealed no significant differences between the interventions groups, as well as the interventions and control groups in terms of both kinds of laser (32). Similarly, Gaida et al used LLL with a wavelength of 670 nanometers to treat the burn scar (twice a week for eight weeks). The average of the pain score was significantly lower after LLL therapy in the intervention group (24). The results of our study are in line with those of the above-mentioned study since both utilized more frequent laser imitation.

Additionally, Carvalho et al studied the effect of LLL therapy on pain relief in patients with inguinal hernia incision. To this end, they used LLL with a wavelength of 830 nanometers in 1, 3, 5, and 7 days after the surgery and checked the pain score based on the visual analog score after 6 months. The pain score in the intervention group was 50% less than that of the control group but this difference was not statistically significant (26). The present study applied the same laser interval but the dose and angle of imitation differed from those of the above-mentioned study.

In another study, Nesioonpour et al evaluated the role of LLL application in pain relief in 56 subjects suffering from tibia fracture. They used LLL on the anterior, posterior, internal, and external surfaces of Tibia fracture sites just after the completion of the surgery. The control group also did the imitation with the device turned off. Then, the pain score based on visual analog score and the dose of analgesics were recorded, indicating significant differences between the 2 groups in this respect. The pain score was lower in the intervention group as compared to the control group thus the analgesic dose was lower as well (33), which is consistent with the results of our study.

Respecting the itching relief after LLL therapy in the study by Gaida et al, the findings represented that LLL therapy could significantly relieve itching in the intervention group but in our study, the rate of itching

demonstrated no difference after the intervention.

As mentioned above, there are contradictory results about the effect of LLL therapy on incision scar and pain. The positive effects of this intervention depend on numerous parameters including the wavelength, location, and the duration of laser imitation (34). Accordingly, the different results of various studies can be attributed to different protocols. The best protocol for this intervention is still unknown and thus more studies are needed in this field in order to obtain a unique and safe protocol.

In our study, although the Vancouver scale was not different between the 2 groups and LLL therapy had no effect on scar formation, it could alleviate the incision pain after C-section. Our study was a double-blind randomized clinical trial which was conducted on 65 women and the final result indicated a reduction in the pain of the site.

Conclusions

Overall, pain reduction is regarded as one of the common complaints of the patients during the post-surgery period. By using this protocol, our study could not prove the prophylactic role of LLL therapy in abdominal incision scar formation which is another cosmetically important point. Thus, further studies are suggested to show the best protocol which can prevent scar formation with higher scale scores and lead to a decrease in patients' pain.

Conflict of Interests

Authors have no conflict of interests.

Ethical Issues

This randomized controlled trial study was authorized by the Ethics Committee of the Research of Semnan University of Medical Sciences and registered in Iranian Registry of Clinical Trials (identifier: IRCT2016011926099N1, <https://www.irct.ir/trial/21724>).

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