The Effect of Early Treatment by Low-Level Laser Therapy on the Healing of Surgically Corrected Congenital Lip Deformity Scar

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Abstract:

Background: Cleft lip is a common congenital craniofacial anomaly. The report states that the worldwide incidence of cleft lip and palate is 1 in 800 live births. We aimed to study the acceleration of low-level laser therapy on the healing of wounds after surgical correction of unilateral cleft lip. We conducted the study in a university-based tertiary hospital that recruited early wound healers of unilateral cleft lip correction. Sixty patients were divided into two groups: In the study's group, patients underwent laser bio-modulation irradiation (n = 10); in the control group, patients were followed up without intervention (n =10). In the study's group, patients underwent a low-power diode Laser with a wavelength of 810 nm and power of 100 mw. The change in the scar of cleft lip patients was assessed by ultrasound. **Results:** The results of this study revealed a reduction in the thickness of the scar on the 14th day of laser sessions and an improvement in the scar appearance on the 7th day of session in the irradiated group as compared to the control group. The thickness of treated scars was reduced as measured by ultrasonography. **Conclusion:** low-level laser therapy demonstrates a potential acceleration in the healing of hypertrophic scars after surgical repair of unilateral cleft lip deformity.

Keywords *Low-Level Laser therapy; Cleft lip; Scar healing; Craniofacial*

DOI: 10.48047/ecb/2023.12.Si8.602

INTRODUCTION

Cleft lip and palate is one of most common congenital craniofacial deformities (1) and continues to be a significant public health problem. The impact of facial disfigurement on the face has a traumatic effect on the mind of the beholder. The report worldwide incidence of cleft lip and palate is 1 in 800 live births (2).

The most common presentation is cleft lip and palate (approximately 45%) followed by cleft palate alone (approximately 35%) and cleft lip alone (approximately 20%). The unilateral cleft lip is nine times more common than the bilateral cleft and occurs twice as frequently on the left side than on the right. (3,4)

The surgical repair is the most challenging procedure encountered by surgeons. The specific goals in primary unilateral cleft lip surgery are to recreate normal lip architecture, which is esthetic and symmetrical to the normal side, normalize speech, language and hearing. (5,6,7)

Cleft lip repair should include the creation of an intact upper lip with appropriate vertical length and symmetry to compensate for the loss of philtral height, repair of underlying muscular structures producing normal function, and primary treatment of the associated nasal deformity. (8,9,10)

Hypertrophic scar formation is a postoperative complication of cleft lip repair and may require surgical revision and scarring generally occurs within 3-6 months following initial injury which leads to esthetic problem. Some of the methods for subjective and objective assessment of the repaired cleft are direct surface assessment (11,12,13), two dimensional photographs, (14,15) three–dimensional imaging (16,17) or a combination. Objective scar width measurements were performed using ultrasonography. (18)

Healing is a complex process that involves a series of events, including clotting, inflammation, granulation tissue formation, epithelization, collagen synthesis, and tissue remodeling. (19)

The use of low – power lasers is becoming increasingly popular in the treatment of a variety of medical conditions, including wound hearting. (20) Low Level Laser Irradiation (LLLI) which commonly known as Low level laser therapy (LLLT) is a form of phototherapy which involves the application of low power monochromatic and coherent light to tissue injuries and lesions to stimulate healing. LLLI has been shown to improve microcirculation by including vasodilatation, angiogenesis, and proliferation. (21)

The effect of laser on enhancing tissue metabolism and stimulating the processes of regeneration and epithelialization, and increase collagen deposition and protein synthesis, and improves the tensile strength of tissues. (22,23)

Surgical skin scars are a type of scar that can benefit from laser therapy (24). LLLT was most effective in the early stages of the healing process and acted as a biostimulating co-adjuvant by reducing inflammation and increase collagen deposition. (25)

METHODS

The study protocol gained the approval of the local ethics and research committee of a tertiary care university-based hospital. Written informed consents were obtained from eligible patients before the beginning of the study.

Study Design and Patients

We conducted a comparative, open-label, study that recruited patients who were scheduled to undergo unilateral cleft lip correction at our center between January 2018 and January 2019. After obtaining their written consent, patients underwent LLLI for 10 sessions and the follow-up period was eight months.

The inclusion criteria included early wound healers of unilateral cleft lip correction. Only patients who underwent correction using Modified Millard rotation advancement technique by the same surgeon were included. We excluded syndromic patient and patients with secondary lip pathology.

Sample size calculation was done using the comparison of scar width in patients with surgically corrected unilateral cleft lip treated with low power diode laser (LLL) and non-treated matched patients. According to a previous publication reporting the raw data (26), the calculated mean ± SD of scar width in LLL group was approximately 3.8 ± 0.89 cm, while in control group it was approximately 5.0 ± 0.93 cm. Accordingly, we calculated that the minimum proper sample size was 10 participants in each group to be able to reject the null hypothesis with 80% power at $\alpha = 0.05$ level using Student's t test for independent samples. Sample size calculation was done using PS Power and Sample Size Calculations Software, version 3.1.2 for MS Windows (William D. Dupont and Walton D., Vanderbilt University, Nashville, Tennessee, USA).

Postoperatively, all patients received our doses of ampicillin/sulbactam as a prophylactic antibiotic. Then, 20 patients were divided randomly into two groups: In study's group, patients undergo LLLI (n =10); in the control group, patients were followed-up without intervention (n =10).

Data Collection, Laser Parameters, and detailed history were taken from all patients, followed by clinical examination. Investigatory work up was done including routine laboratory tests. In the study's group, patients underwent low-level Diode Laser with wavelength of 806 nm and power of 100 mw. Patients underwent twelve sessions (each 15 min); the first session started immediately after removal of stitches at 1st week, then the sessions were done three times per week.

Each session consisted of five minutes on skin above the scar, five minutes on vermillion border, and five minutes inside the lip on the mucosa. Following each session, an ice pack was applied for 3–5 min on the targeted area.

The assessment was done at the time of suture removal, then after six months, of a post-operative. All assessments were done by a single, independent, investigator.

Study Outcomes

The primary outcome of this study was the change in the scar of cleft lip patients, which was assessed by ultrasound. The scar thickness measurements were performed using ultrasonography. A commercial 12-MHz ultrasound transducer (Model T3000, Terason; settings: depth of penetration 20 mm; capacity of ultrasound imager 0.1 mm) and imager were also used to quantify scar width. The transducer was placed with its upper border touching the columella-philtral junction and upper lip imaging was obtained, and the scar width was measured at the skin surface.

Statistical analysis:

Data were statistically described in terms of mean ± standard deviation (± SD) and compared using Student t test for independent samples. Two-sided p values less than 0.05 was considered statistically significant. IBM SPSS (Statistical Package for the Social Science; IBM Corp, Armonk, NY, USA) release 22 for Microsoft Windows was used for statistical analysis.

RESULTS

A total of 20 cases divided in 2 groups. Study group (n = 10) and Control group (n= 10) were included. The results of this study revealed reduction in thickness of the scar on the 14th day of laser sessions and improvement in the scar appearance on the 7th day session in the study group as compared to the control group.

In the study group, 8 patients (80%) showed marked improvement in which the average thickness before therapy was 44 mm (**SD 1.2**), after 1 month the average thickness was 29 mm (**SD 1**) and after 6 months almost it reached 25 mm. Two patients (20 %) showed delayed improvement.

In the control group, the average thickness was 45 mm (**SD 1.3**), after 1 month it reached 44 mm (**SD 1.1**), after 6 months it was about 33 mm.

The thickness of treated scars was reduced as measured by ultrasonography and it was statistically significant with ***P-value 0.003***. There was no significant difference in the scar width between both groups. We also observed change in skin texture and color in the 7th laser session with softening and flattening of the scar.

Signs of acute inflammation were less intense and subsided earlier in the treated group, while in control group the healing process was slow and delayed. ***(Fig 1, 2)***

No significant complications occurred during the study. All patients maintained clinical improvement at the end of follow up examination.

DISCUSSION

Orofacial clefts are one of the most common birth anomalies worldwide. As World Health Organization (WHO) reported that at birth the prevalence is ranging 3.4–22.9 per 10,000 births for CL/P, and 1.3–25.3 per 10,000 births, it differs among populations (18). Risk factors are still under study to be assured. Esthetic complications after surgical repair of cleft lip deformities are one of the most challenging concerns for surgeons.

Optimal management of cleft lip needs correlation of different aspects to minimize cleft lip scarring that affects child development physically and psychologically. The aim of reconstructive surgery for cleft lip is to create the normal anatomy for the lips as a bilaterally symmetrical Cupid’s bow and alar base, with symmetrical upper lip dimensions (length and height) and minimal scarring (19).

To achieve that many factors should be taken in consideration carefully (pre, intra and post-surgically) can affect the end results, as age, blood supply, infection, sun exposure, anatomical location, Fitzpatrick skin type, genetic predisposition, and incisional tension.

Scar assessment is important for evaluation success of surgical repair and monitoring healing process and comparing different interventions for scar prevention.

Modern modalities have been developed, in order to achieve the best outcome of such reconstructive surgeries. One of these modalities is using diode laser LLLT after surgical correction of the cleft lip. The diode laser (LLLT) was introduced in dentistry and oral surgery in the mid-90s (20).

This study included 20 patients who firstly had surgical correction of the complete unilateral cleft lip by Modified Millard rotation advancement technique; then divided into two groups: the 1st group (n = 10) was treated by diode LLLT with wavelength = 806nm after surgical correction of the unilateral lip, while the 2nd group (n = 10) was a control group. It was assessed using Ultrasonography for Scar thickness measurements.

The idea of scar prevention is considered challenging research in the medical field. A range of collagen-controlling techniques, such as pressure treatment, silica gel products, laser treatment, Scar massage, Tension reduction, Wound edge eversion, surgical revision, and medication (Onion extract, Vitamin E, Recombinant TGF-β3) have been used during the proliferation phase affecting growth and maturation of scar tissue (21).

Scar development is the result of a dynamic sequence of complicated molecular, cellular, and physiological healing processes, including collagen synthesis and degradation. Healing process can be classified into three overlapping stages: i) inflammation phase (day 1 - 3), ii) proliferation phase with formation of granulation tissue (day 4 -21) and iii) remodeling or maturation phase constituting remodeling (3 weeks -2 years) after wounding (22).

Various medical and conventional surgical scar repair treatments have been investigated. With various degrees of success, retinoids, corticoid injection, and cryosurgery can be utilized. Conventional surgical procedures may appear effective, but have the drawback of generating new scar tissue (23).

Scar reduction using laser therapy is supposed to be safe and effective treatment option less invasive.

Laser-Assisted Skin Healing (LASH) is a new approach based on a preventive treatment of scars was developed in 2010 using 810-nm laser diode whereas laser is applied immediately after surgery (24). Early laser intervention to reduce scar formation when introduced in inflammation, proliferation or remodeling phases of wound healing. This is one of the modern modalities for scar prevention under medical research to understand its mechanism and approve its effectiveness.

LLLT was approved by the Food and Drug Administration (FDA) as an important method for treating healing processes, after experimental in vitro and in vivo studies since the 1960s, and in the early 1990s (25,27). In the 1980's, Castro et al., (28) reported first experiments analyzing the effects of the YAG laser on human skin fibroblasts. Early studies could achieve promising results but then subsequent studies showed limited efficacy and a high incidence of side effects (29).

The principle of using low-intensity laser beam on tissues and its role in the healing process depends on that has no thermal effect. But the energy from the photons absorbed is not transformed into heat. On the molecular level, cellular impacts are caused by the absorption of light in the red or near-infrared wavelengths by mitochondrial cytochrome c oxidase (mitochondrial photoreception), which leads to energy generation via respiration, triggering a cascade of intracellular processes that cause subsequent cellular effects (30). Thus it creates photochemical, photophysical, and photobiological effects on the target tissues (31). It can stimulate cell responses and promote cell migration and proliferation by stimulating mitochondrial activity and maintaining viability without causing additional stress or damage to wounded fibroblasts, if used in the correct energy density or photon flux and number of exposures.

According to the findings, the cumulative effect of smaller dosages determines the stimulatory effect, whereas multiple exposures at larger levels results in an inhibitory effect with more harm (31). Other studies suggest that laser light causes rearrangements in the cell cyto-skeleton, thus inducing cell modulation. Medrado, A et al., stated that Laser therapy reduced the inflammatory reaction, induced increased collagen deposition and a greater proliferation of myofibroblasts in experimental cutaneous wounds (30).

It was found that LLLT at 830 nm or 635 nm+830 nm with a fluence of 60 J/cm2 might modify fibroblast proliferation and collagen production, with cells irradiated at 635 nm+830 nm perhaps performing better. However, It is hard to compare these findings to those of other research in the literature since most studies reported just one or two distinct single wavelengths, and treatment design differs depending on the study (31).

CONCLUSION

In conclusion, low-level laser therapy demonstrates a potential efficacy in managing the hypertrophic scars after surgical repair of unilateral cleft lip. Further studies are required to support the current findings and evaluate the long-term efficacy of laser therapy in such scars.

Acknowledgements: Not applicable.

Conflict of interests: The authors declare that they have no competing interests.

Funding: There are no funding sources to declare.

Authors' contributions: We confirm that all listed authors meet the authorship criteria and that all authors agree with the manuscript's content.

ABBREVIATIONS

- **LLLI:** Low-level laser irradiation.
- **LLLT:** Low-level laser therapy
- **LASH:** Laser-Assisted Skin Healing

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Figures Legends

Figure 1	Before laser application after 1 week from surgery
Figure 2	After 6 months from laser application

Figure 1

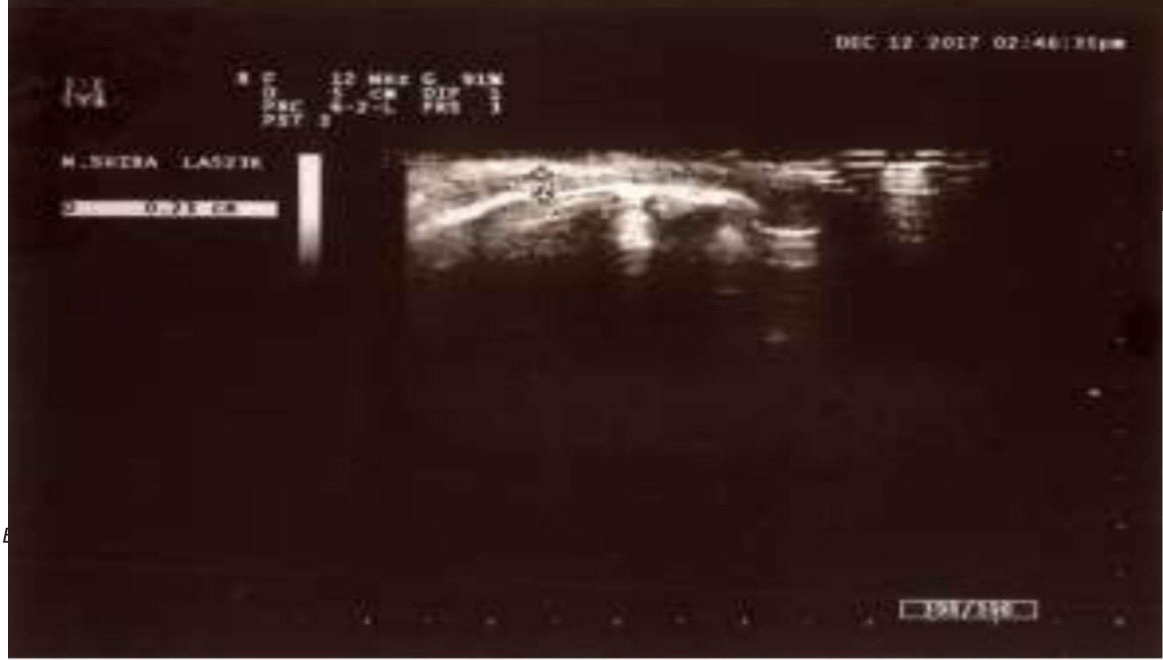

Figure 2