The Effect Of Adjunctive Use Of Low Level Laser (LLL) After Surgical Correction Of Isolated Cleft Palate Versus Surgical Correction Without LLL In Healing Process Randomized Control Trial

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Abstract:

Introduction: Cleft palate is the 3rd most frequent congenital malformation, and oronasal fistula is among the most prevalent postoperative complications. Aim of study: the current study evaluated the effect of adjunctive use of low level laser LLL after surgical correction of cleft palate in improving healing and decreasing incidence of oronasal fistula occurrence. Methods; This study was randomized clinical trial enrolled 34 pediatrics with isolated cleft palate treated by von Langenbeck technique and they randomly distributed into two group; case group treated postoperative with Adjunctive LLL and control group without Adjunctive use of LLL postoperative. Results; The mean age for case group was 9.6±1.5 months and 8.7±2.2 months in control group, with no statistically significant difference, better results were found in laser group as; the pain decreased in laser group at 58.8% in 1st day and 41.2% in 3rd day on other hand in control group 41.2%, 47.1% and 11.8% in 1st, 3rd and 5th day respectively. Edema disappeared at day 3 and 5 of follow up between cases (76.5% and 23.5% respectively) and controls (47.1%, 52.9% respectively) with statistically insignificant difference. Hyperemia disappeared with statistically higher participants at 3rd day follow up in cases (64.7%), in comparison to controls (23.5%). The fistula incidence in current study was (5.9%) 2 cases one in each group. Conclusion; Adjuvant use of Low level laser had a good effect on isolated cleft palate postoperative healing regarding pain and edema with significant effect of hyperemia with no added effect in oronasal fistula occurrence.

Keyword: Cleft palate, oronasal fistula, healing, low level laser LLL
Introduction:

The incidence of the orofacial cleft is estimated at one per seven hundred live births, with isolated palate clefts occurring at a rate of 0.5% per 1,000 live births (1). The most common complication after cleft palate repair is oronasal fistula. In large universities, oronasal fistula rates have been reported to be as low as 2.5 percent and in people treated on humanitarian missions, up to 35.4 percent, these points are an important topic for the cleft palate and the defect in associated (2).

The most pressing goal in reconstruction is to recreate form and function. Wound healing in the oral cavity is characterized by the healing of the palate and gingival tissue in the presence of healthful underlying bones without the scar tissue formation. (3) This is due to an earlier onset of the inflammatory phase, lower levels of immune mediators, fewer blood vessels, more bone marrow cells, rapid re-epithelialization, and rapid fibroblast proliferation. In the absence of healthy underlying bone, wound healing in the palate is more difficult. In those kind of cases, healing may be accompanied by nose and antrum perforation, and also significant scarring. (4)

Low-level laser therapy (LLLT) has been used for more than 25 years in clinical practice and is known to modulate various biological processes (5). The mean number of the inflammatory cells of the wound in the mice treated with a LLL was significantly decreased and the number of the fibroblasts significantly increased (5). Reducing inflammation components may have a positive effect on wound healing and gene upregulation, resulting in increased cell proliferation (fibroblasts) and inhibition of apoptosis. (6)

Aim of study

The aim of the study was to evaluate the effect of adjunctive use of LLL after surgical correction of cleft palate in improving healing and decreasing incidence of oronasal fistula occurrence.

Patients and methods

This study was a randomized controlled trial, participants collected from Oral Surgery clinic, faculty of dentistry, Cairo University and enrolled 34 children with isolated cleft palate who fulfilled the following criteria: age:
between 6 to 18 months of age, and we excluded those with Systemic disease or hematological disorder. Two groups of patients were assigned to this trial: case group: used LLL after surgical correction of the cleft palate at the day of surgery, 1st day and 3rd day and Control group: Surgical correction of cleft palate without Adjunctive use of LLL.

Before starting the operation the patients were reviewed for anesthesia, hemoglobin, body weight, urine albumin, and sugar, advised to use of peri-operative antibiotics Haemostatic Infiltration with Epinephrine (Adrenaline) saline solution in dilution of 1:200,000 was used for infiltration in palate 5-7 min before the surgery. Lignocaine 0.5 mgm/ml added to this solution enhances vasoconstriction and hemostasis. The use of a smaller syringe makes the infiltration and hydro dissection easier in the hard palate region.

The surgical technique:

The patient was placed supine with neck extended either by keeping a pillow or a rolled towel under the shoulder or by inflating a travel pillow already placed under the child.

Von Langenbeck technique by using mucoperiosteal flaps for the repair of the hard palate region, Maintained the anterior attachment of the mucoperiosteal flap to the alveolar margin to make it a bipedicle flap. then the cleft edges were incised, a lateral incision was made, the flap was elevated from the hard palate, the palatine musculature was divided and finally, the sutures were applied. The muscle dissection and muscle suturing were done as additional procedures to create a muscle sling.  

For case group: This group was subjected to postoperative low level laser therapy LLLT by low level laser device (SIRO laser Blue)\(^1\) with wavelength (\(\lambda\)) of (600 nm to 700nm), The laser was held 1 cm away from the surface of the target tissue, the irradiated area is 0,5 cm\(^2\).The area of impact was the surgical wound zone and the neighboring 0,5-1,0 cm of the adjacent oral mucosa for 1min and 22sec, at day of surgery, 1st day and 3rd day.\(^8\)

Postoperative Management:

Arm restraints were routinely placed immediately after surgery, and it was encouraged that they are left in place for 1 to 2 weeks. ’ Postoperative
feeding; Postoperative oral fluid was given as soon as the child regained full consciousness. Early oral feeding pacified the child, who then slept well. Nonsteroidal anti-inflammatory drug, diclofenac, in the form of rectal suppository for effective analgesia were prescribed. paracetamol suppository and oral suspension also used in some cases.

**Postoperative antibiotic:** Oral amoxicillin (50 mg/kg/d, maximum dose of 1.5 g/d, and divided into 3 doses) for 5 days. Oral metronidazole (30 mg/kg/day po dose divided q6hr; not to exceed 4 g/day) for 5 days.

**Follow up:**

Both control and case groups were subjected to the same follow-up regimen;

The assessment of the healing process included the following criteria: pain by asking parents for unusual crying, edema, hyperemia by clinical evaluation, time for wound closure (count days), postoperative complications by clinical observation: inspection, clinical signs: regurgitation of food or drink. These indices were evaluated on the 1st, 3rd, and the 5th day after the operation. In the 2nd week, After month postoperative, After 3 months postoperative.

These visits follow up the healing process and detect the occurrence of complications mainly oronasal fistula.

**Statistical Methods**

Analysis of data was performed using software MedCalc v. 19.

Description of variables was presented as follows:

- Description of quantitative variables was in the form of mean, standard deviation (SD), minimum and maximum.
- Description of qualitative variables was in the form of numbers (No.) and percents (%).

Data were explored for normality using Kolmogorov-Smirnov test of normality. The results of Kolmogorov-Smirnov test indicated that most of data were normally distributed (parametric data) so parametric tests were used for most of the comparisons.
• Comparison between quantitative variables was carried out by One-way analysis of variance (ANOVA) which was used to test the difference between the means of several subgroups of a variable.

• Comparison between qualitative variables was carried out by Chi-square test, which was used to test the statistical significance of differences in a classification system (one-way classification) or the relationship between two classification systems (two-way classification).

• The significance of the results was assessed in the form of P-value that was differentiated into:
  • Non-significant when P-value > 0.05
  • Significant when P-value ≤ 0.05
  • Highly significant when P-value ≤ 0.01

RESULTS

This is a Randomized Control Trial study of 34 pediatric patients who were admitted to the Oral Surgery clinic, faculty of dentistry, Cairo University, to evaluate the effect of adjunctive use of low-level laser (LLL) after surgical correction of cleft palate in improving healing and decreasing incidence of oronasal fistula. The case group was classified into cases group, 17 patients, who used adjunctive LLL after surgical correction of cleft palate and control group, 17 patients, who done surgical correction without LLL in the healing process.

Age ranged from 7 to 12 months, with mean 9.6±1.5 months in case group, and 6 to 13 months with mean 8.7±2.2 months in control group. Case group consist of 10 females (58.5%) and 7 males (41.2%), while control group consists of 11 females (64.7%) and 6 males (35.3%), with no significant difference between both groups as shown in table 1.

Table (1): Demographic data of the participants:

<table>
<thead>
<tr>
<th>Demographic data</th>
<th>Cases (N=17)</th>
<th>Control (N=17)</th>
<th>P.value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (month)</td>
<td>Mean ± SD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>9.6±1.5</td>
<td>8.7±2.2</td>
</tr>
<tr>
<td></td>
<td>7-12</td>
<td>6-13</td>
<td>0.1382</td>
</tr>
<tr>
<td>Female</td>
<td>N (%)</td>
<td>10 (58.8%)</td>
<td>11 (64.7%)</td>
</tr>
<tr>
<td>Male</td>
<td>N (%)</td>
<td>7 (41.2%)</td>
<td>6 (35.3%)</td>
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<td></td>
<td></td>
<td></td>
<td>0.1412</td>
</tr>
</tbody>
</table>
Table 2 showing statistically insignificant difference of pain decreased at day 1, 3 and 5 of follow up between cases (58.8%, 41.2%, 0% respectively) and controls (41.2%, 47.1%, 11.8% respectively) (P > 0.05). There is statistically insignificant difference of edema disappeared at day 1, 3 and 5 of follow up between cases (0%, 76.5%, 23.5% respectively) and controls (0%, 47.1%, 52.9% respectively) (P > 0.05).

Hyperemia disappeared with statistically higher participants at day 3 follow up in cases (64.7%) , in comparison to controls (23.5%), while incidence was statistically higher at day 5 follow up in controls (76.5%) , in comparison to cases (35.3%),( P < 0.05).There is statistically no difference of incidence of wound closure at day 14 follow up between cases (100%) and control (100%). In the same line; There is statistically insignificant difference of fistula incidence between cases (5.9%) and controls (5.9%) (P = 1).

There is statistically insignificant difference of early and late complications between cases (0, 11.8% respectively) and controls (5.9%, 5.9% respectively) (P > 0.05).

**Table (2):** Comparing pain end between cases and control group by Chi square test

<table>
<thead>
<tr>
<th></th>
<th>Case</th>
<th>Control</th>
<th>Chi square</th>
<th>P.value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>Pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 1</td>
<td>10</td>
<td>58.8</td>
<td>7</td>
<td>41.2</td>
</tr>
<tr>
<td>Day 3</td>
<td>7</td>
<td>41.2</td>
<td>8</td>
<td>47.1</td>
</tr>
<tr>
<td>Day 5</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>11.8</td>
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<tr>
<td>Edema</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Day 1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Day 3</td>
<td>13</td>
<td>76.5</td>
<td>8</td>
<td>47.1</td>
</tr>
<tr>
<td>Day 5</td>
<td>4</td>
<td>23.5</td>
<td>9</td>
<td>52.9</td>
</tr>
<tr>
<td>Hyperemia</td>
<td></td>
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<td>-------------------------------------------</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Day 1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Day 3</td>
<td>11</td>
<td>64.7</td>
<td>4</td>
<td>23.5</td>
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<tr>
<td>Day 5</td>
<td>6</td>
<td>35.3</td>
<td>13</td>
<td>76.5</td>
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<table>
<thead>
<tr>
<th>Time for wound closure</th>
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<tr>
<td>Day 14</td>
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<table>
<thead>
<tr>
<th>Fistula</th>
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<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
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<table>
<thead>
<tr>
<th>Complications</th>
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<tbody>
<tr>
<td>Early</td>
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<tr>
<td>Late</td>
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</table>

* P < 0.05 is considered significant

**DISCUSSION**

Low-level laser therapy (LLLT) has recently inspired the interest of many researchers due to its numerous benefits. Anti-inflammatory activity is one of these properties. This treatment can improve revascularization and epithelialization while increasing collagen production and decreasing inflammatory exudation.\(^9\)

So in this study, we aimed to evaluate the effect of adjunctive use of LLL after surgical correction of cleft palate in improving healing among children with isolated cleft palate.

This study enrolled 34 patients had isolated cleft palate treated by von Langenbeck technique and they randomly distributed into two group; case group enrolled 17 one treated postoperative with Adjunctive low level laser (LLL) and control group without Adjunctive use of LLL postoperative.

In the current study the mean age for case group was 9.6±1.5 months and 8.7±2.2 months in control group, with no statistically significant difference. The mean ages of patients in Fakhim et al.\(^{10}\) study, who study the phenytoin in prevention of oronasal fistula occurrence post clef palate operation was 11.42 ± 1.30 and 11.08 ± 1.25 months for case and control groups respectively, and age median was 11.8 months in Leu et
al. (11) study to assess the incidence of palatal fistula after primary repair of the cleft palate. Patients underwent primary palatoplasty.

As previously stated, number of studies have demonstrated that palate rebuild before the age of 18 months is required for better speech outcomes. Good speech requires an intact palate and adequate musculature at the time of speech development. Following early surgery, it was also reported to have a lower incidence of otitis media. (12)

The use of LLL to control inflammatory reactions and pain is controversial. The literature presents divergent opinions on the efficacy of this therapy in clinical practice (13). However, LLL was found more encouraging outcomes with the use of laser therapy for reduction of pain (14, 15) and edema (16).

In the current study; we used LLL with wavelength (λ) of (600 nm to 700 nm) postoperative and found insignificant difference between both groups. However, better results were found in laser group. LLL was used to heal wounds in Alipanah et al. (17) study, and the results showed that: Less inflammation was observed on days 3 and 7 in the treatment group (p < 0.05). On day 14, the inflammation rate on both sides was the same (p > 0.05). They came to the conclusion that using the right parameters for LLLT can speed up full thickness wound healing.

According to the Asnaashari et al. (18) study, LLL was used to reduce pain after a single dental session treatment, and the results showed that: With a significant pain reduction in the LLLT group at 4, 8, 12, and 48 hours after endodontic treatment, LLLT appears to be an effective and non-pharmacological approach for reducing post-endodontic treatment pain. Garcia et al. (19) underwent LLLT after rapid maxillary expansion and used CBCT to assess the recovery of the midpalatal suture. They discovered that LLLT significantly accelerated the bone recovery process. Abd-Elaal et al. (20) used LLLT after mandibular distraction osteogenesis and used ultrasonography and digital panoramic radiography to assess new bone formation. As a result, they illustrated that LLLT improved bone healing significantly.

Metin et al. (21) concluded in a recent study that LLLT advanced soft and hard tissue healing after endodontic surgery and had a positive effect on pain and life quality of patients, particularly in the early stages of healing.
LLL reduces pain by changing the redox system of the cell, whereas laser changes anaerobic metabolism to aerobic. Anaerobic metabolism significantly contributes to the creation of pain and inflammation, and the slowing of the healing process via waste product formation and PH reduction. As a result, laser has a beneficial effect on metabolism, causing it to shift from anaerobic to aerobic. Laser energy's anti-oedematous effect is based on the dilation of lymphatic vessels and the reduction of blood vessel permeability. Laser energy has a regenerative effect on lymphatic vessels, just as it does in veins.(22)

Incidence of palatal fistula in literature ranges from 0 to 35% with overall incidence of 8.6% as reported by a meta-analysis of studies in Europe, America, Asia and Africa (23) The fistula incidence in current study was(5.9%) 2 cases one in each group, lower incidence presented in Mahoney et al. (24) study as fistula occurred in (0.8 %), but higher values found in a 2019 systematic review examining multiple studies from around the world determined a mean fistula percentage of 9.94%. (25) Moreover, a fistula occurred in 27% of two-stage repairs versus 14% of one-stage repairs (26)

The current study results showed no statistically significant difference between laser group and control group regarding fistula occurrence, but our incidence was lower than many studies as mentioned before,

Regarding to complication in the present study, Laceration in check and repeated cough with drinking in case group and difficulty in feeding in control group were the recorded complications and each of them was represented in one patient. In differ with other studies as early and late postoperative infection was a common complication in Katusabe et al. (27), study and was associated with palatal fistula formation. Postoperative infection is one of the likely reasons for fistula formation but is unlikely in babies unless compromised immunologically or nutritionally.(12)

The surgical repair of an extensive palatal defect can be challenging but, when successful may amount to a transformational intervention for the patient. Postoperative fistula formation is an impediment to achieving optimal surgical results and often merits revision palate surgery.

**Conclusion**
We concluded that; Adjuvant use of Low level laser had a good performance on isolated cleft palate postoperative healing regarding pain and edema with significant effect of hyperemia with no added effect in oronasal fistula occurrence.

**Recommendation**

We recommend using adjuvant Low level laser post isolated cleft palate surgery to improve the healing process.

We also recommend to do further related studies on the effect of LLL as adjuvant therapy post-operative isolated cleft palate in multiple centers with higher number of cases.

**References**


27. Katusabe JL, Hodges A, Galiwango GW, Mulogo EM. Challenges to achieving low palatal fistula rates following primary cleft