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Research Article

CO_2 Fractional LASER versus Botulinum Toxin Injection in Aesthetic Outcome of Post Cleft Lip Repair Scar

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Abstract

Background: A hypertrophic scar is a serious side effect of cleft lip repair that impairs a patient's function, appearance, and mental health. Numerous methods, including BTA injection, laser therapy, and steroids, have been recommended to improve lip scars. **Purpose:** The aim of this study was to compare the aesthetic outcome of Co_2 fractional laser and Botulinum toxin injection on post-surgical cleft lip scar utilizing the Patient and Observer Scar Assessment Scale (POSAS) to measure scar subjectively. **Methods**: This was a prospective ,comparative, randomized clinical study, The study had been performed at the Plastic Surgery Department- Minia University Hospital on twenty patients with recent cleft lip scar, Patients were divided into two groups, each with 10 patients;Group (A): 10 cases have recieved CO_2 fractional laser immediately post operative, for 4 sessions with 2 weeks apart and Group (B): 10 cases have received intraoperative botulinum toxin. **Results**: The study showed that there was a significant difference between the two studied groups regarding Vascularity, pigmentation, thickness and relief, better in laser group compared to botox group, but no-significant difference was found regarding pliability. **Conclusions**: CO_2 fractional laser usage is safe and linked to high patient satisfaction, also BTA is a safe and useful supplement to enhance the appearance of scars after cleft lip repair. This study demonstrated a difference in scar outcomes in laser group compared to Botox group. Better results were observed in laser group.

Keywords: cleft lip scar, fractional CO_2 laser, Botulinum toxin A.

Introduction

A cleft lip (CL) is a congenital developmental problem that frequently describes failure of fusion of the upper lip tissues during the embryonic stage of development. It is possible to identify this abnormality bilaterally or unilaterally. In the event of an incomplete cleft, the physical separation of the upper lip's two sides takes the form of a narrow opening or fissure that is located in the inferior part of the lip at the level of the skin, muscle, and mucosa; the superior part of the lip is attenuated. It doesn't split apart, though. When there is a complete cleft, the entire height of the top lip that extends above the nose base is affected by the three-layer abnormality [1]

The child's psychosocial development is adversely impacted by the cleft defect, which interferes with normal face appearance and functions including speaking and ingestion.[2]

The only form of treatment that ensures tissue continuity for cleft lip patients is surgery. Between the ages of two and six months, it is typically done. Primary cleft lip repair involves a variety of surgical approaches. However, every one of them is linked to the unavoidable production of scars following surgery. The process of surgical wound healing is negatively impacted by the recurrent motions of the central area of the face during facial expressions and

daily activities, resulting in contracture and hypertrophy of the ensuing scar [3]

A cleft lip scar must be properly cared for and corrected in order to prevent or reduce the unfavorable consequences of scar tissue's appearance, given the complications that might arise from the emergence of hypertrophic scars[4]

Various techniques were suggested to repair the scar created by cleft lip, such as microneedling, fractional ablative lasers, silicone gel sheeting, corticosteroid injections, and injections of botulinum toxin Type A.[5]

Despite wide variations in techniques of repair and management of post cleft lip scar , optimal results are not reached till now.[6]

Patient and Methods

1- Study design:

This is a prospective, comparative, randomized clinical study

2- Study setting:

The study had been performed at the Plastic Surgery Department, Minia University Hospital on twenty patients with recent cleft lip scar from march 2024 to December 2024

3- Target population and criteria for inclusion:

Patients:

- This study had been conducted on 20 cleft lip patients.
- An informed consent has been obtained from all patients following the guidelines established by the Ethical Medical Committee. (4 / 2024.1134)
- Patients were divided in 2 groups, each with 10 patients;

Group (A): 10 cases have recieved CO_2 fractional laser immediately postoperative, for 4 sessions with 2 weeks apart.

Group (B): 10 cases have received intra-operative botulinum toxin injection at dose of 10 units; two units of the dose in the lateral part of the orbicularis muscle and three units in the medial part of the same muscle.

Inclusion Criteria:

- Patients from 3 months to 3 years
- Both sexes
- Non syndromic cases
- Patients operated upon by millard technique
- Unilateral or bilateral cleft lip scar.
- Recent scars with maximum 2 weeks postoperatively

Exclusion Criteria;

- Uncooperative parents.
- Infected wounds
- Cases operated by other techniques rather than millard
- Syndromic cases

4- Procedure

➢ **Surgical phase**

Cleft lip repair was done via millard technique. Under general anesthesia. The incisions, dissection and suturing were done in a three-layer fashion: mucosal, muscle, and skin.

➢ **For group A**

Patients began treatment 10 days after surgery and were followed for 4 months after the final treatment session

➢ **For group B**

Botulinum toxin A was diluted with saline in a ratio of 25U/ml 0.9% saline, During the procedure, ten units of botulinum toxin were administered to the children as part of their treatment. Each cleft lip received two units of the dose in the lateral part of the orbicularis muscle and three units in the medial part of the same muscle. A Millard-type cheiloplasty was performed.

5- Tratment outcome Evaluation:

Clinical evaluation by Patient And Observer Scar Assessment Scale (POSAS),Both the patient and the clinician evaluated the quality of scars using the POSAS, Two scales make up the Patient and Observer Scar Assessment Scale; the patient Scale, which has six items, and the Observer Scale, which has five items, Every item on the two scales has a numerical score, The observer rated scar vascularization, pigmentation, pliability, thickness and relief whereas the patient rated scar color, pliability, thickness, relief, itching and pain

Every item has a 10step score, with 10 representing the worst scar or experience that might exist.

The observer's scale overall score is calculated by summing the scores for each of the five items, which range from 5 to 50. The sum of the scores for each of the six components (which

range from 6 to 60) makes up the patient's scale overall score.

In the current study all patients age ranged between 3 months to 3 years. So, in the assessment for patient scar scale, their mothers were included

Results

Table (1) Shows comparative study between the two groups regarding baseline data.

Comparative study between the two groups utilizing Observer scar assessment scale (OSAS) showed statistically significant difference as regard Vascularity, pigmentation, thickness and relief (p value <0.05) as mean scores of these items were significantly lower

in group I who underwent scar management by laser than group II who underwent scar management by Botox. On the other hand, no-significant difference was found regarding pliability (p value >0.05), however, the mean score was slightly lower among cases of group I than group II as shown in Table (2) Fig. (1)

Table (1): Shows comparative study between the two groups regarding baseline data.

Baseline data	Group I (scar management by laser) (N=10)	Group II (scar management by botox) (N=10)	P value
Age			
Mean ±SD	3.5±0.5	4.9±4.6	0.85
Range	3-4	3-18	
Median	3.5(3-4)	3.5 (3-4)	
Sex			
Male	5(50%)	6 (60%)	0.65
Female	5(50%)	4 (40%)	
Side			
Unilateral	3(30%)	5 (50%)	0.33
Bilateral	2(20%)	1 (10%)	
Microform	5(50%)	4 (40%)	

Table (2): Shows comparative study between the two groups utilizing Observer scar assessment scale

Observer scr assessment scale	Group 1 (scar management by laser)	Group 1 (scar management by botox)	P value
Vascularity			
Mean ±SD	3.2 ±0.42	4.8 ±0.42	**<0.001***
Range	3-4	4-5	
Median (IQR)	3(3-3.25)	5(4.75-5)	
Pigmentation			
Mean ±SD	3.3 ±0.48	4.4 ±0.84	**0.009***
Range	3-4	3-5	
Median (IQR)	3(3-4)	5(3.7-5)	
Thickness			
Mean ±SD	3.3 ±0.48	4.4 ±0.51	**0.001***
Range	3-4	4-5	
Median (IQR)	3(3-4)	4(4-5)	
Relief			
Mean ±SD	3.3 ±0.48	4.2 ±0.78	**0.01***
Range	3-4	3-5	
Median (IQR)	3(3-4)	4(3.75-5)	
Pliability			
Mean ±SD	3.5 ±0.5	3.8 ±0.42	**0.28**
Range	3-4	3-4	
Median (IQR)	3.5(3-4)	4(3.75-4)	

_* significant at p value <0.05

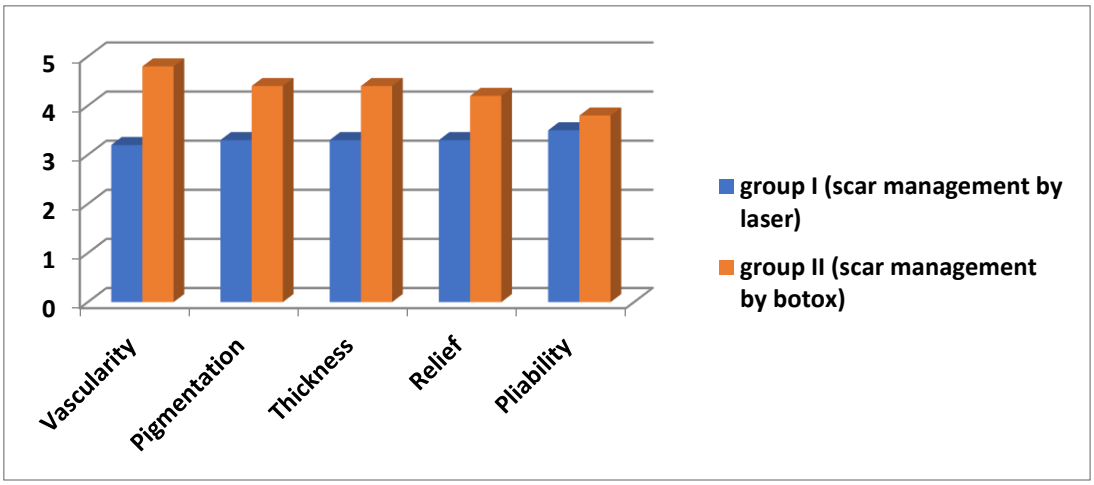

Fig. (1): Bar chart represents comparative study between the two groups regarding OSAS.

Fig. (2): (a) 4 months female patient with Lt sided microform cleft lip (b) 2 months after laser therapy (c) 4 months after laser therapy

Fig. (3): (a) 4 months female patient with Lt sided microform cleft lip (b) 2 months after botox injection (c) 4 months after botox injection

Discussion

Significant advancements have been made in the management of scars following cleft lip surgery thus far. All of these approaches, though, have drawbacks.

Currently, silicone-based products, botulinum toxin type A injections, laser therapy and subsequent surgery are used to improve surgical scars. To get rid of scars, new approaches and strategies that are less intrusive or more effective are still required [6].

The main method of treating face scars has been CO_2 laser resurfacing technology, Numerous clinical research on the use of CO_2 lasers to repair postoperative scars on cleft lips have been published since 2018. The majority of these studies conclude that the procedure is safe, effective, and results in high patient satisfaction. In particular, the increase in flexibility is more noticeable[7].

The lip scar is stretched because a functional orbicularis oris muscle beneath it maintains a zone of dynamic tension. It is possible to temporarily paralyze the orbicularis muscle during the healing process by using botulinum toxin type A (BTA). After a cleft lip repair, this can result in better scar formation [8].

Injections of botulinum toxin have been used during surgical repair of CL/P to help improve the scar tissue outcome. The size, length, and width of scars have decreased due to the paralyzing effect of the poison [9].

The aim of this study was to compare the aesthetic outcome of CO_2 fractional laser and Botulinum toxin injection in post-surgical cleft lip scar using subjective evaluation of scar by Patient and Observer Scar Assessment Scale (POSAS).

In the present study, total number of studied cases were 20 cases, ten cases underwent scar management by laser with median age of 3.5 months, ten cases underwent scar management by Botox with median age of 3.5 months and non-significant difference was found between studied groups regarding age.

Also, it was found that, there was non-significant difference regarding gender and side as 50% of cases in group I were males compared to 60% of group II, and 30% had unilateral scar in group I compared to 60% in group II, while microform scar was found among 50% and 40% of group I and II respectively.

The patient scale was based on six criteria: color, rigidity, thickness, itching, pain, and surface irregularity. The elements of the observer scale include vascularization, pigmentation, thickness, relief, pliability, and surface area. A 10-point rating system was used for each parameter. For all scales, the total scar score goes from 6, which is equivalent to "normal skin," to 60, which is equivalent to the "worst imaginable scar."

As regard Observer scar assessment scale (OSAS), this study showed statistically significant difference between the Laser group (Group 1) and Botox group (Group 2) regarding: Vascularity, pigmentation, thickness and relief. As mean scores of these items were significantly lower in group I than in group II.

But regarding pliability there was no significant difference between the 2 studied groups when compared to each other in this study.

The current results were in accordance with that done by Shadad et al., (2021) who reported that patients who began FCO_2 application post-operatively for 5–7 sessions had significant improvements in their lip scar's vascularity, color, pliability, and thickness following FCO_2 laser sessions..[10]

Another study was done by Buelens et al., 2017 on recent postsurgical noncleft scars showed that mean POSAS scores by the masked observer for the treated half of the scars were (34.0) before treatment and (20.4) 3 months after laser application, which indicates a significant improvement. These findings matched the results in the current study. [11]

Lee et al., (2013), also reported similar observations with the use of FCO2 to treat 16 patients with postoperative scars, satisfactory results were documented after three months, particularly in terms of pliability and thickness. They received treatment in two sessions spaced two weeks apart, beginning three weeks following surgery.[12]

Although Meynköhn et al., 2021, reported 16 Patients with facial scars who had received FCO_2 treatment between May 2019 and May 2020 in a retrospective study, revealed significant improvement in the thickness, pliability, relief, pigmentation, and surface treatment in all patients regarding POSAS, there was no significant improvement in vascularity. This disagreed with the findings in the current study. however in the previous study, mean age of patients was 43.6±16.8 years, approximately two-thirds of the patients were females, and one third were males, Patients were with four different scar origin (burn injury, tumor resection, trauma, or acne) but in the current study regarding group 1 mean age of patients was 3.5 months ,50% of patients were males and Scar origin was only cleft lip surgery.[13]

Table (3): Comparison between the present study and different results

	Present study	**Lee**	**Buelens**	**Shadad**	**Meynköhn**
Year	2024	2013	2017	2021	2021
Number of cases	20	16	9	40	16
Score used	POASA	VSS	POSAS	VSS	POASA
Difference in total VSS/POSAS	Significant except in pliability	Significant particularly in terms of pliability and thickness	significant	significant	Significant Except in vascularity
Used LASER	Fractional CO_2 LASER	Fractional CO_2 LASER	Fractional CO_2 LASER	Fractional CO_2 LASER	fractional, ultrapulsed CO_2 LASER
Sessions	3-5	2	3	5–7	1-2

Regarding botox, Ziade et al., 2013 assessed if postoperative injections of type A botulinum toxin helped the scarring of facial wounds, thirty patients, older than 18 years, with facial wounds were randomly assigned to one of two groups, either receiving a BTA injection or not, within 72 hours after surgery. BTA was injected into the face muscles either directly or indirectly involved in scar widening, at a one-year follow-up visit, patients used the Patient Scar Assessment Scale (PSAS) to measure their scars, and an independent assessor used the Observer Scar Assessment Scale (OSAS). For the PSAS and OSAS, there were no statistically significant differences between the two groups. These findings agreed with the results of the current study.[14]

However, Mustafa et al., (2024) showed that eleven patients received BTA injections in their lip muscles one week before to surgery, the research group's vascularity, pigmentation, pliability, and height were all noticeably improved six months after surgery, however in the current study BTA was injected intraoperatively at dose of 10 units in accordance to Galarraga et al., (2009) while in previous study the BTA was diluted with saline as a 25U/ml 0.9% saline ratio and administered at a dose of 1 unit / kg (9) of body weight one week before to surgery.[15]

Conclusions

- This study demonstrated a difference in scar outcomes in laser group compared to Botox group. Better results were in laser group
- Furthermore, more comparative studies with bigger sample size and longer follow up periods are required regarding combi-nation between botox and FCO2 for cleft lip scar management.

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