# The use of Botulinum Toxin A in the surgical treatment of secondary cleft lip (secondary cheiloplasty): An objective and subjective evaluation of esthetic outcomes

**Shreyas Orvakonde[1*], Bidyalaxmi Mutum[2]**

[1]Resident, [2]Private Practitioner, Dept. of Dentistry (Oral and Maxillofacial Surgery), Chamarajanagar Institute of Medical Sciences, Chamarajanagar, Karnataka, India

***Corresponding Author: Shreyas Orvakonde**
Email: drshre890@gmail.com

## Abstract
The surgical correction of the cleft lip is a challenging one and obtaining consistently good esthetic outcomes sometimes can be elusive. Primary correction of cleft lip often results in secondary deformities requiring re intervention. Chemoimmobilsation with Botulinum Toxin A post-secondary cheiloplasty can help obtain favourable esthetic results.

**Aims:** To evaluate the esthetic value of Botulinum Toxin A injection in secondary cleft lip surgeries and to assess the role of Botulinum toxin A in secondary cleft lip scars.

**Materials and Methods:** 30 systemically healthy unilateral cleft lip patients reporting for secondary cheiloplasty procedure were taken up for the study.

10-12 units of Botulinum Toxin A was injected along pre-determined points on the lip. Objective (Photographic evaluation) and subjective (Patient questionnaire method) evaluation was carried out after one year post injection of Botulinum Toxin A.

**Results:** Photographic evaluation revealed that the outcomes were mostly excellent or good. Subjective evaluation conducted showed that majority of patients were either happy or very happy with the esthetic results.

**Keywords:** Botulinum Toxin A, cheiloplasty scars, esthetic evaluation, secondary cheiloplasty, secondary cleft lip, subjective evaluation, unilateral cleft lip.

## Introduction
Primary correction of cleft lip provides the surgeon with the best opportunity to obtain favorable esthetic outcomes. Meticulous surgical technique coupled with good post-operative wound care can help obtain pleasing results. In spite of employing precise methods during primary cheiloplasty various esthetic shortcomings persist, presenting a tough challenge to the surgeon. Optimum surgical results are often compromised due to post-operative scar contracture[1] which results in notching and lip asymmetry. The surgeon has control over certain factors such as obtaining adequate rotation of the medial element, augmenting the cleft side by borrowing muscle from the unaffected side, tension free approximation of the wound edges and adequate release of the underlying aberrant musculature. The surgeon has no control over the dynamic process of wound healing and the subsequent scar contracture.

The orbicularis oris is a dynamic sphincter which after reconstitution transfers repetitive tensile forces to the healing scar prompting increased fibroblastic response and thus forming a less than ideal scar which is often raised, thick and visually quiet apparent. Injection of Botulinum Toxin A provides a focal area of temporary paralysis thus providing an environment free of these distracting forces.

Muscles of facial expression are present superficially devoid of bony attachments and create facial expressions by altering the tension of the adjacent skin[2]. Therefore negating facial muscular activity temporarily results in decreased skin tension during healing and thus enabling the formation of a scar with good characteristics. A study by Gassner highlighted the utility of Botulinum Toxin A in optimising facial scars.[3] This hypothesis laid the basis of our study to utilize Botulinum Toxin A in improving the esthetic outcomes of secondary cheiloplasty.

## Material and Methods
30 healthy unilateral cleft lip and palate patients reporting for cleft procedure were taken up for the study. (Ethical clearance obtained from the Institutional review board of the institution.)

**Inclusion criteria**
1. Systemically healthy unilateral cleft lip patients wanting secondary correction of deformities, between the ages of 10 to 40 years of age.

**Exclusion criteria**
1. Patients having co morbidities such as diabetes mellitus, thyroid disorders and individuals on medications that interferes with wound healing including anticoagulants.
2. Patients allergic to Botulinum Toxin A.

The surgical techniques that are used secondarily to correct abnormal defects in the cleft lip patient depend on the defect that is present. The technique varies from patient to patient and cannot rely totally on any set approach. The various problems addressed through lip revision are, 1) Lip scars, lip defects-discrepancies pertaining to lip height, projection, and lip thickness(fullness of the lip), 2) Lip architectural defects-Gross asymmetry, mismatch of the vermillion border, notching, peaking, tubercle asymmetry, philtral ridge distortion. Thus our technique of lip revision is aimed at dealing with specific problems existing in the patient, resulting from muscle tension. The below description

will provide a brief overview of the surgical technique carried out, with minor modifications being incorporated as and when deemed necessary in order to optimize and target existent discrepancies. Surgical markings are made. Local anaesthesia infiltrated (Lignocaine + Adrenaline 1:100000).

Scar exicison-Scar excised in a rhomboidal fashion and the orbicularis oris muscle is split in the midline. Intra oral horizontal incision placed to aid in mobilization of the cleft segment, and subsequent periosteal scoring done. Abnormal muscle insertions were released and tissue mismatch addressed. Muscle repair-It is done in an inverted figure of eight manner, suturing from superficial to deep and then back vice-versa using 4-0 vicryl. Muscle repair in conjugation with the above technique is carried out in a superior to inferior direction. Cupids bow was then matched using prolene 5-0 sutures. Skin closure-Final skin closure was achieved using prolene 5-0.

Timing and site of Botulinum Toxin injection-Test dose was given to all the patients prior to administration of the full dosage of Botulinum toxin. Botulinum Toxin A was injected at suture removal(7 days) into 6 predetermined points on either sides and along the cleft scar, base of the columella and alar base of the cleft side as shown in Fig. 1 Dosage-The average no of units administered was 10-12 units.

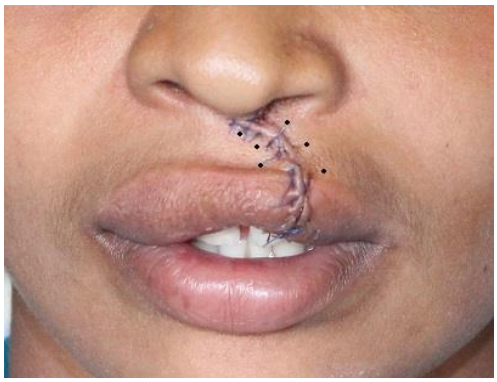

**Fig. 1:** Points of botulinum Toxin A injection

## Evaluation of outcome

Evaluated by two independent observers (professors at our unit) with a scale[3] procured from another study which was modified to suit our study. Standardization of photographic images was achieved by clicking photographs with the same DSLR camera (cannon EOS 1200D). A standard mode at a distance of 5 feet with a resolution of 800 X 600 px, was used for evaluation. The method used for grading facial appearance has been described by peerlings et al. Two views were utilised, i.e. Photograph showing the full face (Fig. 2) and a cropped version of the same photograph revealing only the nose and mouth[4,5] – Fig. 3).

**Fig. 2:** Full frontal image and cropped version utilised for photographic evaluation

Altered scale for photographic evaluation.[3]

| **Parameter** | **Score 1** | | **Score 2** | | **Score 3** | |
|---|---|---|---|---|---|---|
| White roll match | No disparity present | 1 | Disparity less than 2mm | 2 | >2mm | 3 |
| Vermillion match | No disparity | 1 | Disparity of wet and dry mucosa <2mm | 2 | >2mm | 3 |
| Sear appearance | No Hypertrophy | 1 | Hypertrophy with no disturbance of cupids bow or columella | 2 | Hypertrophy with disturbance of cupids bow or columella | 3 |
| Cupids bow form | No disparity | 1 | Distortion on cleft side <2mm | 2 | >2mm | 3 |
| Lip length | Equal length on cleft and non-cleft sides | 1 | Shortening on cleft side >2mm -5<mm | 2 | Shortening on cleft side >5mm | 3 |
| Total | 5 | | 10 | | 15 | |
| Excellent -5<br>Good- 6-10<br>Poor – 11-15 | 1St Independent observer<br>Total score-<br>Final grade- | | 2nd Independent Observer<br>Total score-<br>Final grade | | | |

Parameters such as white roll match, vermillion match, scar appearance, cupids bow form and lip length were assessed and scored. Each individual scores were totalled and the final score was graded as excellent, good or poor.

**Subjective evaluation**
Questionnaire- Christofides, A et al.[6]

**Patient ouestionnaire**
Please answer the following questions and mark the pertinent boxes below. We are assessing the scar and wish to identify what exactly bothers you the most.

| | |
|---|---|
| 1 | Very satisfied (Very Happy) |
| 2 | Doesn't bother me much (Happy) |
| 3 | Could have been better (Okay) |
| 4 | Not satisfied at all (Unhappy) |

1. Are you satisfied with the colour of the scar?

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 1 | | 2 | | 3 | | 4 | |

2. Are you satisfied with the texture (smoothness) of the scar?

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 1 | | 2 | | 3 | | 4 | |

3. Are you satisfied with the width of the scar?

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 1 | | 2 | | 3 | | 4 | |

4. Are you satisfied with the thickness (amount of budging above the skin) of the scar?

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 1 | | 2 | | 3 | | 4 | |

5. What part of the scar bothers you the most?

| | |
|---|---|
| **Upper part closer nose** | |
| **Middle part** | |
| **Lower part closer to lip** | |

Descriptive statistics was used to analyse the data.

## Results

**Photographic evaluation**
Two independent observers rated the surgical outcomes based on a scale obtained, which was altered to the needs of our study. White roll match, vermillion match, scar appearance, cupids bow form and lip length and were subsequently evaluated and scored. These individual scores for each parameter were totalled and a final grading was given.

***1st Independent observer***
After assessment, 8(26.66%) patients were deemed to have excellent esthetic outcome, 18 (60%) patients had a good outcome and the results of the remaining 4(13.33%) patients was poor.

***2nd Independent observer***
The surgical results of 10 (30%) patients were excellent, 17(56.66%) patients had a good esthetic outcome and 3(10%) patients were graded as poor.

**Table 1:** Photographic evaluation

| | | | |
|---|---|---|---|
| 1ST Independent Observer | Excellent | 8 | 26.66% |
| | Good | 18 | 60% |
| | Poor | 4 | 13.33% |
| 2ND Independent Observer | Excellent | 10 | 33.33% |
| | Good | 17 | 56.66% |
| | Poor | 3 | 10% |

**Subjective evaluation**
Colour, texture width and thickness of the scar was evaluated. Most patients were either very happy or happy with scar characteristics evaluated (Table 2).

**Table 2**

| | | Color | Texture | Width | Thickness |
|---|---|---|---|---|---|
| Subjective evaluation | Very happy | 13(43.33%) | 17(56.66%) | 14(46.66%) | 15(50%) |
| | Happy | 10(33.33%) | 9(30%) | 9(30%) | 11(36.66%) |
| | Okay | 2(6.67%) | 3(10%) | 5(16.66%) | 2(6.66 %) |
| | Unhappy | 5(16.67%) | 1(3.3%) | 2(6.66%) | 2(6.66%) |

**Fig. 3:** Pre and post op Photographs. Note the post op photo demonstrates good scar characteristics with adequate vermillion match, lip volume and the absence of peaking and notching

**Part of the scar which created maximum concern**
The lower part of the scar created most concern in 17 patients, whereas the upper area of the scar bothered 13 patients.

## Discussion

Esthetic parameters such as white roll match, vermillion match, scar appearance, cupids bow form and lip length were assessed and graded. Majority of the results were rated as excellent or good (Table 1). The above results reinforce the ability of Botulinum Toxin A to help produce imperceptible scars. Few patients rated the surgical outcome as poor. Secondary cleft deformities present to the surgeon with a multitude of issues such as lack of muscle, extensive scarring from previous surgery and also varied skin types. The patients who rated the outcome as poor were the set of patients who developed a hypertrophic scar post surgery. Although Botulinum Toxin A provides an ideal environment for seamless healing owing to its property of chemoimmobilisation, we learnt through our study that it might be of little value in changing the innate nature of healing patterns in certain individuals who are susceptible to hypertrophic scarring. Subjective evaluation was carried out. Most of the subjects were either very happy or happy with the scar characteristics (Table 2). We also noted during our study that vermillion width in most patients was almost equal on both cleft and non-cleft side.

The goal of secondary cleft lip repair is varied and tailor made to address various issues such as peaking notching scarring and lip volume defects. The effort is also towards correcting misalignment of Cupid's bow and reconstruction of the philtral column.[8] In general RSTL lie perpendicular to the tension vector of the underlying muscular contraction. Scars aligned with the RSTL heal well, whereas scar oriented against RSTL, are subjected to repeated tension and result in scar hypertrophy. Similarly such a scenario exists in cleft lip repair whereby the cleft lip closure results in a scar oriented against the RSTL.

Favorable outcomes are often elusive due to post-surgical scar contracture, resulting in poor esthetic. Despite meticulous surgical techniques, scar contracture remains a predominant feature in few patients owing to the organic nature of wound healing. Even moderate control over this dynamic process helps in obtaining good esthetic results. It is in such a context that Botulinum toxin A with its feature of temporary chemoimmobilisation prevents distracting tensile forces on the scar which is present superficially.This feature of Botulinum toxin A was further supported by Iván Marcelo Cueva Galárraga, by electromyographic testing.[7] Clinical observations indicate that Botulinum toxin A can improve the appearance of hypertrophic scar and inhibit its growth. Evidence supporting this potential use arises from Botulinum toxin's ability to prevent excessive muscle contraction and its influence on cellular proliferation and cellular apoptosis.

Various modalities such as application of silicone gels/sheets, ointments are used to decrease post-operative scarring and wound contracture. These methods are employed after wound healing has been completed. Altering wound healing during the healing phase offers more value and predictable results. In such a context Botulinum Toxin A provides an ideal environment for seamless healing thus optimising the surgical results.

## Conclusion

A scar is an end product of dermal fibrous replacement tissue culminating from a process that has healed by resolution. The overlying skin present on the upper lip is at constant risk of hypertrophic and unsightly scars due to the presence of constant forces of the dynamic oral and peri oral musculature. These forces are amplified during routine activities such as speech, eating, and facial expressions. Botulinum Toxin A negates the effect of such forces owing to its property of temporary muscular paralysis.

The current study investigated the role Botulinum Toxin A and its effect on secondary cheiloplasty scars. The results of our study demonstrate the clinical value of Botulinium Toxin A in improving secondary cheiloplasty scars.

## Source of Funding

None.

## Conflict of Interest

None.

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