

## EFFECTS OF ORBICULARIS-ORIS MUSCLE INJECTION WITH BOTOX ON CLEFT LIP REVISION SURGERY SCAR

“Preliminary study”

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### ABSTRACT

The decision for lip revision surgery in patients with repaired cleft lip is based on patients' satisfaction and surgeons' subjective evaluation of lip disability. The study was a clinical trial that included patients with cleft lip who had revision. Modified Millard technique was used. After muscle re-orientation and wound closure, a dose of four units of botulinum toxin injected immediately after suturing. The dose was distributed as follows: two units in the medial portion of orbicularis-oris muscle and one unit in each lateral portion of the same muscle. Our results; demonstrated; lip height improvement, symmetrical Cupid's bow, minimal postoperative scar contracture, and improvement in lip movements. In conclusion; the results for this preliminary study is encouraging, and further studies can enhance our concept for prevention of hypertrophic scars after surgery in other fields.

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### INTRODUCTION:

In 1955, Millard developed the concept of rotation advancement flap to treat cleft lip, which became the most popular technique worldwide <sup>(1)</sup>.

Most surgeons were scarifying the margins of the cleft and suturing them together, employing various techniques to ensure good approximation of the edges. As can be imagined, the results were not always satisfactory. The vertical scar that formed invariably caused an ugly shortening of the lip <sup>(2)</sup>.

The surgical repair of the cleft lip is one of the most challenging procedures faced by the surgeon. The ultimate goals in the cleft lip surgery are undisturbed function and untraceable scars in a harmonious upper lip <sup>(2,3)</sup>.

Normal wound healing progresses through well recognized and refined phases. The initial period of hyperemia represents revascularization. This is followed by collagen realignment and wound maturation. The reorganization of collagen may lead to aberrant growth within the margins, which may present as elevated, pruritic, and sometimes painful scar that can be classified as hypertrophic scar <sup>(2)</sup>.

A notch is a common following the repair of a unilateral cleft lip. The term “notch” is used to denote a break in the free border of the vermillion <sup>(3)</sup>. A notch on the vermillion is one of the most common complications following the repair of a unilateral cleft lip. Several methods have been described for the secondary correction of the notch. Among causes of the vermillion notching; tension of the orbicularis-oris muscle at the vermillion border, and contracture of the scar on both skin, and mucosal aspects of the lip <sup>(4)</sup>.

Undermining allowed any tension to be dissipated, leaving the dermis to heal with minimal tension, with improving results <sup>(5)</sup>. Meticulous surgical technique with precise alignment of the skin can possibly reduce hypertrophic scarring. Ultimately, many patients with hypertrophic scarring or contracture post cleft lip repair may require a scar revision or Z-plasty for scar camouflage. However, even with this surgical treatment, it may still recur <sup>(6)</sup>.

If a patient does develop hypertrophic scar following cleft lip repair, there are various treatment modalities available. There are few proven techniques that prevent hypertrophic scarring; if erythema or pruritis is the prevailing complaint, intra-lesional steroids may be injected. Further, silicone taping has been shown to flatten and improve the appearance of the hypertrophic scar postoperatively <sup>(2)</sup>.

Many patients with a repaired cleft lip require lip revision surgery for optimum esthetics. The decision for surgery is based on the surgeon’s subjective evaluation of the lip at rest and during function, and clinicians recognize that more objective evaluation methods would be highly beneficial for the decision-making process <sup>(7)</sup>.

In a study used bipolar surface electrodes to measure the activity of the upper lip at rest and function in patients who had undergone cleft lip repair. They reported an unsatisfactory lip function that was characterized by increase in the activity of the upper lip muscles with muscular dysfunction. It is also known that the healing process is affected when there is tension at the wound level <sup>(8)</sup>.

An experimental study in rabbits conducted, and the results showed that; there is relation between orbicularis-oris muscle pressure (measured with electromyography) and wound healing. When orbicularis-oris pharmacologically manipulated (using papaverine); wound healing was improved. More favorable results achieved by decreasing hypertonicity of the lip muscles <sup>(9)</sup>.

Neuromuscular blockade via injection of alcohol, phenol, or botulinum toxin reduces the tone of overactive muscles in order to restore the appropriate balance between agonists and antagonists. Such a restoration can reduce the likelihood of contracture. Alcohol or phenol, injected onto the motor nerve, denatures proteins and promotes axonal degeneration. The advantages of alcohol or phenol chemodenervation lie in their low cost and lack of antigenicity. The disadvantages include significant risk for pain as a result of treatment <sup>(10)</sup>.

Botulinum toxin type A is a powerful neurotoxin which is produced by the anaerobic organism *Clostridium botulinum* and when injected into a muscle causes interference with the neurotransmitter mechanism producing selective paralysis of the muscle <sup>(11,12)</sup>.

Depending on the target muscle, injection dose is 4 to 50 U of Botox type A per site with a maximum dose of 200 U in the masticatory system. More than this can be used if other sites in the head and neck are included in the injection protocol <sup>(13)</sup>.

In experimental study for evaluation of the effect of botulinum toxin on a rat surgical wound model, the results showed that the wounds of the Botox-treated group showed less infiltration of inflammatory cells and less fibrosis, and much greater amount of collagen. Botox might be used to decrease the fibrosis of a surgical wound without damaging the epithelial growth in situations for which decreased fibrosis is necessary, such as for treating laryngeal, tracheal and nasal stenosis <sup>(10)</sup>.

Based on these criteria, I carried out a clinical study, to determine if the use of botulinum toxin after surgical repair of cleft lip could help in the management of tension at the surgical wound level, with consequent better scar.

## **PATIENTS AND METHODS:**

### **PATIENTS:**

Three patients presented with esthetically unsatisfied previously repaired unilateral cleft lip; two females and one male patient.

One case was submitted to private clinic for correction, second case presented to the outpatient clinic of Oral and Maxillofacial department of Faculty of Oral and Dental medicine, Cairo University, and the third case operated in private hospital in Yemen country.

All patients informed with the detailed operation and injection and consent of agreement signed.

## **SURGERY:**

The future surgical incision lines were traced using colored marker pen on the upper lip then the patients were aseptically prepared, draped as usual, and oral intubation used for introduction of anesthetic gases.

Modified Millard technique was used; one ml of local anesthesia with epinephrine 1:80000 was injected into the lip and nasal base for hemostasis.

With the aid of sharp dissection of mucosa and skin away from both sides of the orbicularis-oris muscle until it was fully released, muscular attachment to the columella is completely released to the level of Cupid's bow.

Muscle fibers properly oriented as much as possible and sutured together using 3-0 polyglactin 910 suture (Vicryl, Ethicon). Suture is used at three levels instead of two, to cope with the tension.

The orbicularis oris muscle bundles are opposed, end-to-end (inferiorly-to-superiorly), was using simple interrupted suturing. The skin is closed without tension with using 6-0 Polypropylene suture material (Yancheng huida medical instruments co.,Ltd ,HUIDA). Suturing began from the floor of the nose down to the vermilion border, and finally completed with mucosa closure. The nostrils were packed with gauze impregnated by antibiotics (Terra-Cortril, Pfizer, NY, USA).

After suture completion and check for proper adaptation, the orbicularis-oris muscle was injected with Botox (Botox®, Allergan, Inc., Irvine, CA, USA, Each vial of Botox® contains 100 U of purified Clostridium botulinum type A neurotoxin complex. One unit of Botox® contains approximately 48 pg of whole molecular complex , with molecular weight of 900 kDa. In order to obtain the dose needed, Botox was reconstituted in adequate volume of 0.9% saline).

Patients were treated with a dose of 4 units of botulinum toxin injected immediately after suturing. The dose was distributed as follows: two units in the medial portion of orbicularis-oris muscle (in the Cupid's bow) and one unit in each lateral portion of the same muscle.

Wound dressed with band aid after applying antibiotic cream (Terra-Cortril, Pfizer, NY, USA)

Patients followed up to six months, clinical examination of scar, return of functional movements of orbicularis-oris muscle, and symmetrical Cupid's bow.



**Fig. 1: upper left: Pre. Op. photograph showing patient's lip with apparent notch; upper right: One week Post OP. photograph showing sutured upper lip; lower left: One week Post OP. side view photograph showing the same patient; lower right: Six months Post OP. same patient after resolution of Botox effect.**

## **RESULTS:**

All patients satisfied with the results. Our results demonstrated: lip height improvement, symmetrical Cupid's bow, and minimal postoperative scar contracture were achieved during the follow up period, of postsurgical cleft lip defect repair.

The postoperative pull up of Cupid's bow improves, nearly symmetrical Cupid's bow resulted, which is probably owed to less scar contracture. Lip revision did not worsen lip movements; however individual patients varied from excellent improvement to good changes.

The toxin relieved spasms for an average of 5 weeks. No general complications were observed (**Fig. 1**).

## DISCUSSION:

Hypertrophic cleft lip scars can cause functional and esthetic complications leading to frequent secondary cleft lip revisions. These cleft lip revisions can cause increased patient stress, added anesthetic and surgical risks, and increased societal costs.

Millard technique selected for surgical correction in the current study because it is suitable for minor and narrow clefts, however the Tennison-Randall repair suitable for the wide, complete clefts as reported by Meyer, and Seyferin 2010<sup>(6)</sup>. Both repairs should incorporate a generous release of the orbicularis-oris muscle and its associated soft tissues from the maxilla and nasal septal regions so that the natural direction of the muscle fibers is anatomically restored.

During the muscular reorientation, the orbicularis oris muscle is adjusted to centralize the columella and lengthen the central segment. Minimal muscular dissection performed in the current study to relieve the deforming action of the abnormal insertion of the orbicularis-oris to avoid the risk of extensive dissection that the innervations and blood supply to the orbicularis may be affected as reported in the study of Göz, Joos, and Schilli<sup>(8)</sup>.

As confirmed by electromyography, botulinum toxin effectively inhibits the action of the orbicularis-oris muscle as confirmed by Galárraga study in 2009<sup>(14)</sup>.

The tension on a wound is one of the important factors that determine the degree of fibrosis and hypertrophic scar formation. We hypothesized that local botulinum toxin type A (Botox) induced paralysis of the musculature subjacent to the surgical wound and subsequently minimize the repetitive tensile forces on the skin wound edges, resulting in a decreased fibroblastic response and subsequent hypertrophic scar formation.

A sufficient number of units of toxin must be injected in order to neutralize neuromuscular junction activity; and localization of the injecting needle through the fascia of the target muscle is necessary.

Actually in the present study the dose selected was four unites of Botox, because we intended to use the least effective dose that has the shortest duration of action. Selection based on the study of Jung et al (2012)<sup>(15)</sup> who found that; hemorrhage and inflammatory responses were noted in the muscle strips within 24 & 48 hours after intramuscular injection of 10 U of Botox. Even though muscle strips receiving 4 U of Botox did not have any sign of inflammation or hemorrhage, however contractile responses of these strips were very similar to the responses of muscle strips receiving 10 U of Botox.

It is evident that a broad field of research related to the use of botulinum toxin in this type of patients has been opened. For example, in the cases of severely wide or bilateral clefts, botulinum toxin may have an added utility.

We have been using a Polypropylene suture material on atraumatic needle to decrease the postoperative inflammation and scar contraction. We believe that the benefits of using them outweigh the disadvantages of stitch removal.

The result of this preliminary study is encouraging to open the field to further explore potential prophylactic treatments for control of hypertrophic scars in susceptible populations.

Further studies can enhance our concept for prevention of hypertrophic scars.

### **Disclosure:**

The author hereby certify that no conflicts of interest in this work, and no financial support has been received from any commercial source, that is related directly or indirectly to the scientific work, which is presented in this article.

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