Hyaluronic filler for lip augmentation and scar correction in cleft lip Egyptian patients

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Abstract

Objectives: The goal of the current study was to assess how hyaluronic acid dermal filler was applied and how well it worked to conceal lip abnormalities after surgery in a group of Egyptian cleft lip and palate (CLP) patients.

Methods: This research included sixteen female patients with unilateral lip scars between 15 and 20 years of age. Hyaluronic acid dermal filler (HADF) was injected with needle in upper lip at the scar site. Evaluation was done clinically and by digital photography before and after the procedure. Visual Analog Scale (VAS) from (0-10) was used as a patient satisfaction assessment survey. Follow up period was made one week and one month post injection.

Results: All these patients noted a significant improvement in their lip scars following HA filler injection with better psychological state. The VAS satisfaction rate assessment was high and ranging from 7-9 with a mean of (8.0 ± 0.9). Clinical observation showed no long-term complications, however patients complained of some discomfort due to fibrosed tight lips during the injection.

Conclusion: HADF is a safe noninvasive temporary method used for masking cleft lip scars and restoring vermilion border volume which promotes the appearance and psychological status of the CL patient.

Keywords: cleft; filler; lip; scar; hyaluronic.

INTRODUCTION

Around 1:700 child birth congenital deformity is represented by Cleft lip and palate CLP cases. [1] After 2 months of birth, primary surgical cleft lip repair typically occurs at an early stage. In the puberty period, secondary surgical repair normally takes place along with nasal deformity correction. It ends, however, with an unwanted scar for the patient, mainly females who are eager for a better appearance. [2]

In most cases, a revision operation is required to repair the current old fibrous scar, however, the timing of the scar revision is key to the final outcome. [3] Scar revision usually means waiting periods to allow full scar development before surgery. Lack of bulk or poor vermilion border alignment may cause many deformities in the lip shape. [4,5] Absence of volume is mainly caused by soft tissue deficiency, insufficient planning and inability to reconstruct the lower part of the Orbicularis Oris muscle during the initial lip repair. [6–8]

If more bulk is needed, relatively small filler grafts can be used. Subcutaneous tissue flaps and autologous fascial, fat graft or dermal fillers are also used. A cross lip flap technique can be done for more severe deficiencies of the vermilion, as defined by Kawamoto. Management of hyperplastic depressed scar with HA resorbable dermal fillers has shown promising results with high patient satisfaction and minimal risk. [9] By many approaches, atrophic scarring can be improved. This involve scar re-
excision, which has not been favored by our patients. Laser based devices such as carbon dioxide or erbium laser can also be considered, but the missing volume will not be recovered. [10]

The resulting asymmetry and low upper lip volume can be treated using less invasive approaches. To restore symmetry and volume loss, the injectable hyaluronic acid filler may be injected into the patient's upper lip.[11–13]

Hyaluronic acid (HA) is a natural glycosaminoglycan and is a main element of the adult matrix. Approximately 50% of the total body HA is contained in the dermis.[14] In 1996, Food and Drug Administration (FDA) approved Hyaluronic HA filler, as a sterile, biodegradable, viscoelastic, injectable gel material. Dermal fillers demonstrate excellent tolerability and protection of matrix and dermal cells. Indications are incompetence or lip asymmetry, scar development (accidental and postoperative).[14,15]

Therefore, the current study was designed to clinically evaluate the use of hyaluronic filler present in a group of Egyptian CLP patients as current product for aesthetic dermatological purposes in camouflage lip deformities.

**Methods**

**Study design**

The study was a prospective case series clinical study on a group of cleft lip patients who seeking care after surgical repair procedures of their cleft for their unpleasant scar and defective vermillion border.

**Study setting and population**

This research involved sixteen female patients aged 15 to 20 years with a unilateral cleft lip scar. Patients were randomly chosen between Jan 2018 and Jan 2020 from the outpatient clinic of Cairo National Research Center, Orodental Genetics Department and Al-Azhar University, Dental Medicine Faculty, Oral & Maxillofacial Surgery Department.

All patients agreed to be a part of the study by signing an informed consent forms. Patients were conscious of the importance of the injected subject. The study was accepted by the national research center's ethical committee and performed in accordance with the Statement of the Helsinki Clinical Research Guidelines.

**Inclusion and precautions**

Anticoagulants and anti-inflammatory drugs should be avoided 5 days before the injection; they are also contraindicated for pregnant or breastfeeding women, as well as anyone with skin inflammation or an allergic background, active skin infection near the site of injection, a known allergy/hypersensitivity to the material or the amide-type local anesthetics lidocaine mixed in the filler syringe and in porphyria patients.

**Technique of injection**

The Stylage Vivacy M (Vivacy Type Dermal Filler medium, France) was injected with 1 ml needle in the upper lip at the scar site without any complications. The procedure is conducted only under local anesthesia and takes two minutes on average.

Application depth: To repair medium and severe wrinkles, Stylage M should be injected between the middle and deep dermis.

**Methods of follow up evaluation**

The Visual Analog (0-10) Scale (VAS) form was used as a questionnaire to report the patient satisfaction level and registered in a sheet indicating (No satisfaction, mild satisfaction and great satisfaction). Before and during the treatment, the clinical assessment was digitally photographed. After one week and one month after injection, the follow-up period was carried out.
Results

Sixteen female patients aged between 15-20 years in the current study complained of cleft lip scars caused by lip surgical repair. After the HA filler injection STYLAGE M medium, all patients observed a major change in their lip scars with improved psychological status.

Clinical observation and Visual Analog Scale VAS were measured for satisfaction rates ranged from 7-9 with a mean of (8.0 ± 0.9) (Table. 1) and a set of digital images taken before and after the operation (Fig 1-3). There were no post-operative complications, but patients complained intra-operatively of some injection discomfort due to fibrous tight lips and some edema that lasted for few days post injection and resolved. All patients were happy with the outcomes and even said they would like it to last forever.

Table (1) VAS measurements after treatment

<table>
<thead>
<tr>
<th>variable</th>
<th>Mean ± SD</th>
<th>Range (min-max)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGE (Years)</td>
<td>17.8 ± 2.7</td>
<td>7 (15-20)</td>
</tr>
<tr>
<td>Visual Analogue Scale</td>
<td>8.0 ± 0.9</td>
<td>2 (7-9)</td>
</tr>
</tbody>
</table>

Discussion

The resultant distortions and poor upper lip volume in the cleft lip and palate (CLP) patients post-surgically can be managed via various invasive and non-invasive modalities. The current study was designed to evaluate the application and clinical outcomes of hyalouronic filler in camouflaging lip deformities in a group of Egyptian CLP patients.

Cleft lip surgical repair may leave an unnecessary scar for the correction of deformity and dysfunction. [16] To restore symmetry and thickness, HADF may be administered into the upper lip of the patient. Large, poorly healed upper lip scars with visible stitch marks around the scar lines are mostly caused by technical inaccuracies such as improper tissue handling, tension closure, tightly use of large sutures, and long-standing sutures.[3]

This study included sixteen female patients with unilateral cleft lip scar resulting from previous repair surgery. Patients came seeking for a treatment for their ugly scar as noted by them. Their main complaint was that the lip doesn’t look normal and its noticed by other people and that they wish to wear a lipstick and look beautiful. Most of them tried to avoid the surgical option and two of them have already tried to do fractional laser resurfacing CO2, but in addition to being painful and resulting in a brown irritating crust, it did not restore the missing lip volume.[17,18]
The effects of purified hyaluronic filler are reported to last up to a year and are generally safe, effective, and don't need a preoperative sensitivity test. Stylage is a monophasic hydrophilic cross-linked injectable filler that contains hyaluronic acid and antioxidants such mannitol or sorbitol that has been marketed since 2009 and is available from Laboratories VIVACY in France with and without lidocaine.[19] Stylage was found to be more lightweight, less dense, and to degrade more slowly than other fillers.[15,20]

Dermal fillers are commonly used to treat wrinkles, natural lip filling, hydration, chin remodeling, tear correction, neck and hand rejuvenation, and other conditions.[15] The injection of dermal fillers for tissue augmentation has increased over the past decade. Among the most commonly used materials is hyaluronic acid (HA), which is a stable, safe, biocompatible and temporary filler.[21] The injection of the HA filler was occasionally associated with minor discomfort, bruising or swelling of the lips. In addition to a strong psychological impact, the patient satisfaction rate evaluation showed great satisfaction with the results. However its effect can last only for about six months then it disintegrates and the patient needs to inject again. The challenging thing was that the lip tissue that was greatly fibrosed due to previous surgeries and the injection procedure wasn’t as easy as with normal lip tissues scars. [22] To prevent duck lips in these patients, only one syringe was used for each treatment.

The challenge was that the lip tissue that was extremely fibrous due to prior operations and injection was not as simple as normal lip tissues[8]. Due to almost no vermilion, two patients also needed a greater volume of filler injection. There have been some limits to this concise research. The lack of control population and blinding make it somehow difficult to correlate physical properties with clinical results, but the use of placebo or blinding is also not possible with many other trials testing filler therapies.[23] Nevertheless, since the purpose of the research was to test lip enhancement using a drug that is already being used clinically, this subjective evaluation was considered to be the most suitable, in particular, since the natural look of lip improvements is not measured on an objective scale.

In this study model, the aim of this study was planned to identify any possible adverse effects and the short-term benefit of the product. The lip fullness indicators also weren't assumed to be of use. However, because of the short-term effectiveness and safety of the product that has already been investigated, a relatively small follow-up period may also be considered a study limit.[24,25]

Conclusion

HA dermal filler is a safe noninvasive temporary filler method for masking cleft lip scars and restoring vermilion border volume which promotes the appearance and psychological status of the patient.

REFERENCES