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Evaluation of Flexibility and Thickness of Cleft Lip Scars After Treatment with Microneedling Technique: a Cohort Trial

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ABSTRACT

Introduction: The early surgical treatment of the cleft lip led to a postoperative scar formation which may affect the physiological and psychological aspects of the patient.

Objectives: Evaluating the improvement rate of thescar flexibility and thickness of the cleft lip scar after treatment with the microneedling.

Methods: Sixteen patients (12 females and 4 males), aged 16-30 years who had a cleft lip scare were included in the current study. All patients suffered from a visible defective scar in the upper cleft lip. All patients were treated with a microneedling pen device combined with topical application of oil-based hyaluronic acid. The procedure was performed in 4 sessions with 3-week intervals between sessions. The scars were assessed by the patient and an external observer using the Patient and Observer Scar Assessment Scale.

Results: Thickness of the scar was improved according to the patient and observer opinions (67.28% and 61.55% respectively). Flexibility was improved according to the patient observer opinion (65.57% and 60.25% respectively).

Conclusions: Microneedling treatment can be considered as an effective method for the treatment of the defective scars resulting from the cleft lip plastic surgery. The microneedling technique is a simple, easy, safe, non-invasive, and low-cost procedure.

Introduction

The cleft lip is a congenital development defect caused by the lack of connection of the upper lip tissues during the embryonic period [1]. The cleft lip defect has an influence on the normal facial appearance and functions such as feeding and speech, which affect the child psychosocial development negatively [2]. The surgical treatment of the cleft lip allows to secure continuity of the lip tissues. It is usually performed at the age of 2 to 6 months. There are many surgical techniques for the primary repair of cleft lip. Unfortunately, these techniques are associated with a postoperative scar formation [3].

The scar often undergoes contracture and hypertrophy, due to the repeated movements related to facial expressions and basic life activities, which adversely affect the postoperative wound healing process [4]. The scar tends to be raised above the skin surface and is hyperpigmented more than the normal skin [5]. The scar tissue leads to the creation of some secondary deformities, such as deformed philtrum, Cupid's bow asymmetry, tight upper lip, whistle deformity, and irregularities in the function of orbicularis oris muscle [6,7]. The scar of the upper lip may restrict the growth and development of the maxilla, leading to a skeletal Class III malocclusion [8].

A mature cutaneous scar usually consists of a large amount of collagen fibers (80%-90% type I, the rest type III) [9]. The collagen fibers within the scar are arranged in bundles parallel to the surface of the skin. On the other hand, the collagen fibers in the normal skin are arranged in a nonparallel "basket-weave" orientation [10]. The basement membrane of the epidermis that develops over the scar tissue is flatter than the normal skin tissue because the scar does not contain the rete pegs that penetrate the dermis [9]. In addition, the cutaneous scar does not contain dermal appendages such as hair follicles, sebaceous glands, and stem cells [5,11]. The extracellular matrix (ECM) of the scar tissue contains less elastin than normal skin, resulting in decreased elasticity in the scar [12].

Clinically and cosmetically, a favorable scar has an imperceptible fine line and is parallel to skin creases and folds, similar in color and contour to the surrounding skin, and within the level of the skin [13].

Many methods were proposed for treating the scar of cleft lip including surgery, steroids injection, botulinum toxin Type A injection, silicone gel sheeting, fractional ablative lasers, and microneedling [14,15].

The microneedling procedure is also called the Percutaneous Needle Collagen Induction Technique (PCI). The PCI was firstly introduced by Orentreich and Orentreich [16] who used the needles in order to stimulate the production of collagen in the treatment of depressed scars and wrinkles. The mechanism of action is mainly based on the rupture and removal of the damaged subepidermal collagen followed by substitution for new collagen and elastin fibers.

The microneedling treatment stimulates collagen production without removing the epidermis, and the tissue regeneration time is commonly shorter than the ablative techniques, which substantially reduces the risk of adverse effects when benchmarked. As well, the skin becomes more resistant and thicker [15].

Objectives

The current study aimed to evaluate the efficacy of microneedling in improving the flexibility and thickness of the cleft lip scar as one of the conservative techniques in the management of postoperative scars.

Methods

Trial Design

This study was a cohort study. The current trial was achieved at the Department of Maxillofacial Surgery at the Faculty of Dentistry, Damascus university, Syria between August 2019 and September 2021. Ethical approval was obtained from the Local Ethics Research Committee at the University of Damascus, Dental School (Reference Number: 25223102017-DEN).

Participants and Eligibility Criteria

The sample consisted of 18 scars in 16 patients (14 unilateral clefts, 2 bilateral clefts). The distribution was as following: 2 males (3 scars) and 14 females (15 scars) of cleft lip and palate patients who completed their lip repair surgeries. The age of patients ranged from 16-35 years. All patients had a visible defective scar and the desire to perform cosmetic procedures in order to improve the general appearance of the lip. All individuals were able to follow the stages of treatment.

Microneedling Intervention

The automated microneedling tchnique was performed using an automated micro needling Dermapen (Beijing HYE Technology Co) which is considered an advanced technology for vertical pricking of the skin through several needles that puncture the skin with an automatic percussion function. The device consists of a handpiece, equipped with an electric motor and a head consisting of 12 needles, 33 gauges are attached to a disposable rod (Figure 1).

The needles move up and down from 0.25 mm to 2.5 mm entering depth. The speed of movements ranges from 1 to 7 pricks per second. The entry depth and speed are adjusted depending on the scare area via private keys.

The treatment was divided into 4 sessions with an interval of 3 weeks. The surface of scar was cleaned well with 0.10 ml Hexamidine solution, then a local anesthetic cream (EMLA) was applied for 20 minutes. After that an oil-based hyaluronic substance with a concentration of 3.5% and formulated from a mixture of hyaluronic acid of non-cross-linked biotechnological origin was applied to the skin surface. The dermapen was applied to the scar with a prick depth of 2-2.5 mm and speed of 5 pricks per second, depending on the device instructions for the treatment of scars. Finally, the surface of the scar was cleaned with a piece of sterilized gauze soaked in saline solution and a steri-strip bandage was applied (Figures 2 and 3). Additional images for clinical cases were treated in the current study have been included in Figures 4 and 5.

Figure 1. The automated microneedling Dermapen.

All patients were informed that a redness can be seen after treatment and may last for 2-3 days after the procedure. All of them were also asked to apply a cold compress to the workplace for the first couple of hours.

Outcome Assessment

The thickness and flexibility of the cleft scar were assessed before treatment and one month after the last treatment session by both the patient and three external observers from the Oral and Maxillofacial Surgery Residents using the Patient and Observer Scar Assessment Scale (POSAS) [17]. Comparisons have been made between the baseline data (before treatment) and after one month of treatment.

Thickness: the distance between the surface of the scar and the adjacent skin surface.

Flexibility: It is measured by the flexibility of the scar between the index finger and thumb.

The evaluated items consist of a 10-point scale where 1 indicates the best scar that matches the adjacent healthy skin and the number increases as the scar worsens as 10 indicates the worst scar.

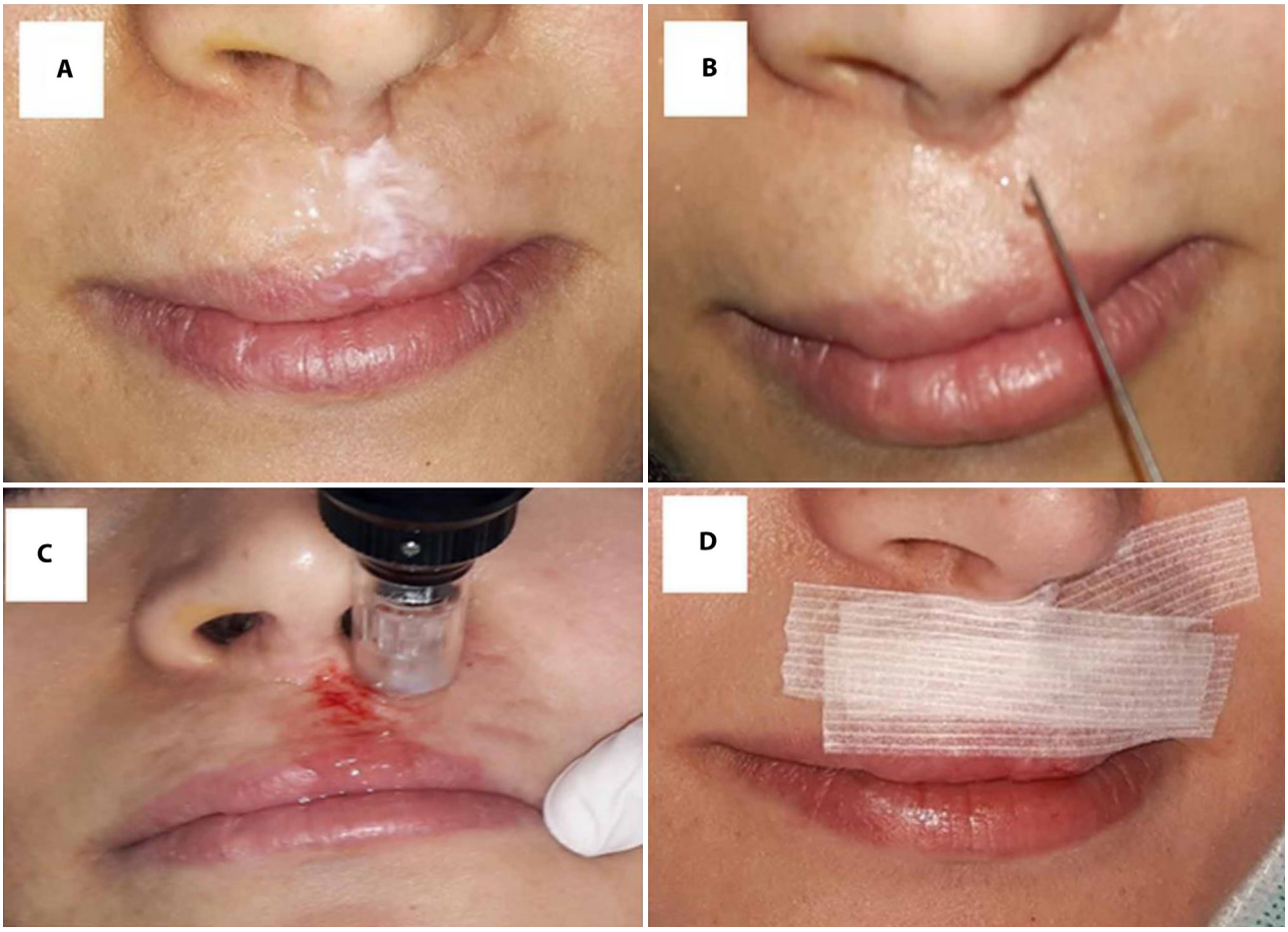

Figure 2. (A) Topical anesthesia; (B) Application of hyaluronic acid; (C) The microneedling process; (D) Steri-strip dressing.

Figure 3. Clinical case 1. (A) Before treatment; (B) Immediately after microneedling; (C) After 1 month of the final microneedling process.

Figure 4. Clinical case 2. (A) Before treatment; (B) Immediately after microneedling; (C) After 1 month of the final microneedling process.

Figure 5. Clinical case 3. (A) Before treatment; (B) Immediately after microneedling; (C) After 1 month of the final microneedling process.

Statistical Analysis

All statistical analyses were performed using SPSS software (version 20; IBM)). The paired sample t-test was applied to assess the differences in the thickness and flexibility of the cleft lip scar before and after treatment with microneedling.

Results

The percentage of improvement for both the thickness and elasticity of the scar was assessed, according to the opinions of both the patient and the observers with the POSAS, according to the following equation:

The Improvement percentage = (the amount of the improvement after treatment / pre-operative rate) * 100 (Table 1).

The thickness of the scar was improved according to the patient's and observer's opinions (67.28% and 61.55% respectively). Flexibility was improved according to the patient's and observer's opinion (65.57% and 60.25% respectively).

The thickness and flexibility were improved significantly after the PCI according to the patient and outer observer reports ($P < 0.05$) (Table 2). According to the patient opinion, the mean improvement rate was 4.899 and 5.791 for thickness and flexibility of the scare respectively. According to the observer opinion the mean improvement rate was 4.548 and 4.963 for thickness and flexibility of the scar respectively.

Conclusions

Aesthetics is a science, practice and experience. It is developing rapidly due to the entry of new technologies and devices

Table 1. The descriptive values in both the thickness and elasticity of the scar.

Studied Item	The Resident	Before	After	The amount of improvement[a]	improvement percentage
Thickness	Patient	7.281	2.382	-4.899	67.28%
	Observer	7.389	2.841	-4.548	61.55%
Flexibility	Patient	8.831	3.040	-5.791	65.57%
	Observer	8.237	3.274	-4.963	60.25%

[a] The amount of improvement = post-operative rate value – pre-operative rate value.

Table 2. Comparison of the thickness and flexibility of the lip scar before and after the microneedling operation.

Variable	Assessor	Time	N	Mean ± SD	T-test value	P value[b]
Thickness	Patient	Before	18	7.28±1.36	15.149	<0.001[a]
		After	18	2.38±1.17		
	Observer	Before	18	7.38±0.99	23.795	<0.001[a]
		After	18	2.84±0.79		
Flexibility	Patient	Before	18	8.83±1.58	5.57	<0.001[a]
		After	18	3.04±1.14		
	Observer	Before	18	8.23±0.74	30.233	<0.001[a]
		After	18	3.27±0.67		

[a] P <0.05 significant difference; [b] paired t test was applied
SD = standard deviation.

in this field. On the other hand, aesthetics has a principal role in people social and professional life.

This study was conducted to evaluate the efficacy of microneedling with hyaluronic acid therapy in the management of postoperative cleft lip scars resulting from primary and secondary repair surgeries in cleft lip patients. The elasticity and thickness of the scar were assessed according to the opinion of the patient and external observers.

In the current study, the flexibility of the scar was improved to reach as close as the surrounding natural skin with an average improvement percentage of 65.57% and 60.25% for the patient and observer respectively. The same findings were observed in the thickness of scar. The level of scare (thickness) also improved to become very similar to the surrounding natural skin with an average improvement percentage of 67.28% and 61.55% for patient and observer respectively.

These results were similar to what was reported by Lakshmi et al who evaluated the PCI efficacy in treating the scars resulting from trauma, surgery, or cleft lip. Lakshmi et al reported that the scar improvement rate after microneedling was 100% [18]. This percentage was higher than the current results. This dissimilarity may be due to the involvement of many types of scares not only the scars resulting from postoperative clef lip scars.

El-Domyati et al demonstrated that the treatment with microneedles enhances the growth of type I, III, and VII collagen and tropoelastin [19].

Lee et al found that the microneedling combined with other substances is effective in the enhancement of cleft lip scare. In the current trial, the microneedling treatment and hyaluronic acid application were combined together. Lee et al combined the microneedling treatment with a human stem cell conditioned medium [20]. The same findings were observed by Aust et al who conducted a study to evaluate the effectiveness of microneedling in improving the appearance of post-burn scars [21].

Finally, the lack of number of the patients in the current study and the short duration of the follow-up period are the main limitations of this trial.

In conclusion, the cleft lip scar management should be considered as a principal element of the treatment plan in cleft patients. In the case of patients with secondary cleft lip deformities, surgical correcting methods should be considered taking into account that any surgical intervention leads to new scars formation. Therefore, it is necessary to implement nonsurgical methods to prevent the scar hypertrophy. Microneedling therapy can be considered an effective modality for the treatment of surgical cleft lip scars in patients. Microneedling treatment is a simple and cost-effective technique in the treatment of the facial scars. Damascus Dental School (Reference Number: 25223102017-DEN).

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