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Patient satisfaction and Experience with the Use of a New Stabilized Hyaluronic Acid Dermal Filler (Intraline, Canada Inc., Kelowna BC, Canada): 10 month Follow Up.

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ABSTRACT

Background: The most common request among facial rejuvenation procedures is the augmentation of the nasolabial fold. Objective: To evaluate the safety, efficacy and patient satisfaction with the use of a new cross-linked hyaluronic acid (HA) based dermal filler (Intraline 2, Canada Inc., Kelowna BC, Canada) in reducing medium to deep nasolabial folds.

Materials and Methods: This was a single center, blind evaluator, 300-day study in which 70 patients with moderate to deep, nasolabial folds were treated at their baseline visit with up to three 1mL syringes of HA. The physician and evaluator assessed patients 7 days after treatment and then every month after the initial treatment for 10 months (300 days).Moreover, patient satisfaction was measured at 1,3,6 and 10m through a self-evaluation questionnaire.

Results: Subjects experienced statistically significant improvement in nasolabial folds and maintained those results for more than 240 days. In proximity of the end of the observational period (300 days) the studied area revealed minor reabsorption of the product being at all times better than baseline. Patient satisfaction scores were rather excellent or very good for all the length of the study.

Conclusion: Injectable HA new cross-linked based dermal filler (Intraline 2, Canada Inc., Kelowna BC, Canada) was efficacious in reducing medium to deep nasolabial folds, resulting in satisfactory corrections up to 300 days and excellent patient compliance and satisfaction rate.

INTRODUCTION

Dermal fillers use has grown exponentially in the last decade. Their use extend from rejuvenating purposes, facial features enhancement, to skin scars camouflage [1]. The key features of the treatment rely on patient compliance and satisfaction rate [2-6]. Generally measured through satisfaction questionnaires [7], and safety, efficacy and lasting effect of the corrections [8].

Nasolabial folds (NLF) are natural bilateral dynamic creases that form when zygomatic muscles contract due to facial motility. NLF's extend from the side of the nose to the corner of the mouth. They tend to accentuate with aging and volume depletion, being its augmentation among the most requested procedures in aesthetic medicine [9,10]. Several dermal fillers have been used to treat this in esthetism [11], being hyaluronic acid dermal fillers among the most popular due to their good safety and efficacy profile.

The use of a new cross-linked hyaluronic acid (HA) based dermal filler (Intraline 2, Canada Inc., Kelowna BC,

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Canada), was tested for the treatment of moderate to severe NLF, regarding patient satisfaction, safety, efficacy and lasting effect.

MATERIALS AND METHODS

Eligible participants were women aged 30 and older seeking tissue augmentation treatments for the nasolabial folds. To be qualified to receive injections for those indications, participants had to have a wrinkle score between 2-4 (moderate to extreme wrinkles) on the wrinkle severity scale (WSS). The details of the scale are shown in **Table 1**. After local ethics committee approval, the procedure and study design were discussed with patients and informed consents were obtained.

Table 1. Wrinkle severity rating scale

Score	Brief Description	Full description
0	Absent	No visible fold; continuous skin line
1	Mild	Shallow but visible fold, with slight indentation, minor facial feature
2	Moderate	Moderately deep folds; clear facial feature visible at normal appearance but not when stretched
3	Severe	Very long and deep folds; prominent facial feature; less than 2 mm visible fold when stretched
4	Extreme	Extremely deep and long folds; detrimental to facial appearance; 2–4 mm V-shaped fold when stretched

Exclusion criteria included poor general health, known hypersensitivity or allergy to the treatment components, breastfeeding or pregnancy, previous permanent fillers treatments in the area, or temporal fillers in the area in the previous 10 months. Other exclusion criteria included; history of autoimmune diseases; active skin disease, irritation, or inflammation in the target areas of injection.

A new cross-linked hyaluronic acid (HA) based dermal filler (Intraline 2, Canada Inc., Kelowna BC, Canada) was used. The syringes contain 1mL of cross-linked HA the maximum volume per patient did not exceed 3ml.

Seventy evaluable patients with moderate to severe nasolabial folds who met all study inclusion and lack exclusion criteria were enrolled into this single center, evaluator-masked, study.

Each subject underwent one treatment with up to three 1mL syringes of HA. Each HA syringe was attached to a 0.5-inch, 30-G needle in preparation for injection. The same physician treated all patients in a similar manner. The area to be treated was properly cleansed with chlorhexidine. The HA was deposited in the superficial subcutaneous plane using a serial puncture, linear retrograde technique; directed straight along the folds. At the corner of the mouth (oral commissure) and in the paranasal area (alar base) a fanning technique was use to give extra structural support. The patients were ask to move the folds during the procedure to reveal muscular action and points of structural breakdown. Extra material was delivering perpendicular to these areas. The treatment design is shown in **Figure 1.** Any skin blebs were massaged down after administration. Total product administered varied per patient based on the severity of the folds, with most patients receiving an average of 2 mL (~2 syringes) per treatment session. Total volume at the per treatment was recorded. Patients followed up 7 days after treatment and then every 30 days after the initial treatment session for 300 days.

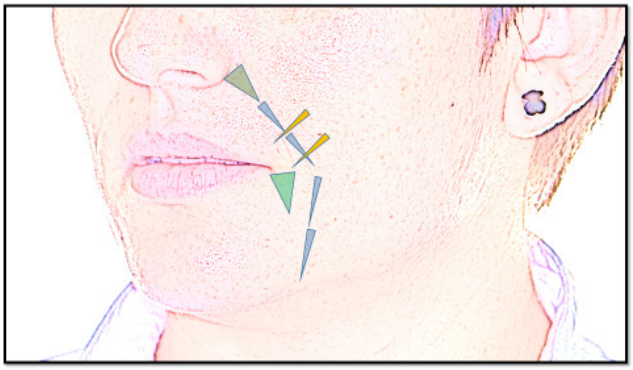


Figure 1. Treatment pattern of patients; blue triangles retrograde linear infiltration, green triangles fanning technique, orange triangles perpendicular infiltration for extra structural support.

Self-assessment questionnaire (SAQ) were applied to patients at 1, 3, 6 and 10 months to evaluate compliance and satisfaction rate. Details of SAQ are show in **Figure 2.**

Outcome and Statistical Analysis

Standardized photographs were taken from the front, left, and right sides of each participant using a Nikon Camera (D-

610, lens 24-85mm) at a given distance (2,5mts) with a standardized illumination (NikonSB-700 Flash) set at each visit. The blind observer assessed aesthetic improvement of the nasolabial folds at each visit using the WSS which was parallel with the initial value for that patient and baseline photographs as reference. According to the units displaced in the scale the outcome was informed as: +2 much worse, +1 worse, 0 identical, -1 improved, -2 much improved, -3 very much improved.

Scale: 1 scarse, 2 medium, 3 good, 4 very good, 5 excellent

1) How do I consider my improvement? 1-2-3-4-5
2) Do I consider myself satisfied with the outcome? 1-2-3-4-5
3) Is my result symmetrical? 1-2-3-4-5
4) Do I consider myself to look better in any way? 1-2-3-4-5
5) Do I look younger or refresh? 1-2-3-4-5
6) Is my result natural? 1-2-3-4-5
7) How do I rate the lasting of the product? 1-2-3-4-5
8) Have I got any defects or flaws regarding the treatment? Y/N
   If yes please rate: 0 none, 1 scarse, 2 moderate, 3 severe

- Erythema 0-1-2-3
- Edema and swelling 0-1-2-3
- Bruising 0-1-2-3
- Lumps and bumps 0-1-2-3
- Pain and tenderness 0-1-2-3
- Pruritus 0-1-2-3
- Other (specify)..... 0-1-2-3

Scores results range: Excellent (35-29), very good (28-22), good (21-15), medium (14-8), scarse (7 or less)

Figure 2. Self-assessment questionnaire (SAQ) of treatment of the Nasolabial folds.

Participants completed four satisfaction questionnaires at 1, 3, 6 and 10 months after the treatments. The former, assess overall satisfaction considering the treatment area.

The questionnaire focused on the aesthetic results after treatment and contained 7single-choice questions. For each single-choice question, a scale of 5 possible score options (scarse1, medium2, good3, very good4, excellent5), was provided, so that participants had opportunities to provide their feedback regarding treatment. The SAQ scores were arbitrarily defined according to their range in: Excellent (35-29), very good (28-22), good (21-15), medium (14-8) or scarse (7 or less).

Adverse events (AEs) were monitored throughout the study. At each study visit, the investigators assessed erythema, edema and swelling, bruising, lumps and bumps, pain and tenderness, and pruritus on a scale of 0 (none) to 3 (severe). During the entire duration of the study patients recorded the possible adverse events and rate them using the same scale within the SAQ.

Statistical Analysis

Statistical analysis was done with excel 13 (windows 10). P .05 was considered to be statistically significant, and .001 was considered to be highly statistically significant.

RESULTS

Seventy female Caucasian patients were enrolled in the study. The mean age of the patients was 58 (range 37-68). Eight patients were lost during the length of the study, sixty two patients completed the study. The mean amount of HA injected for the NLF was 1.8 mL, with a range from 1-3mL.

Figure 3. Female 63y, Treatment of nasolabial and labiomental folds, Intraline 2, 2ml total (1ml per side). Cannula technique inferior approach from mental crease. Needle refinements for oral commissure (Monalisa Smile).

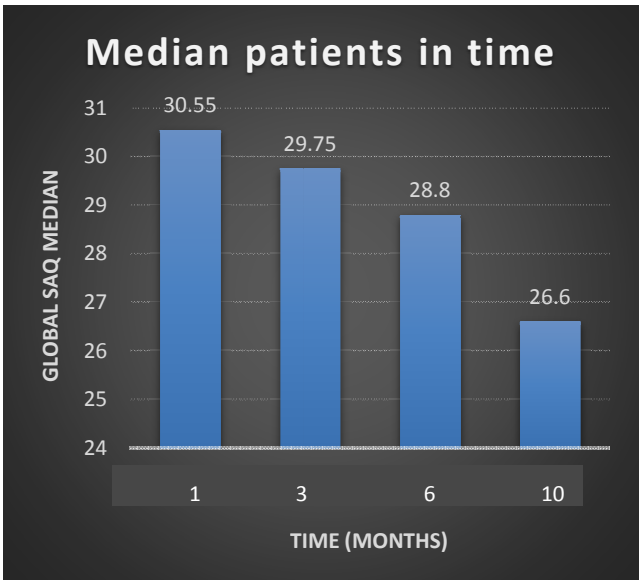
Mean baseline NLF wrinkles according to WWS was 3.3. The severity of the folds improved by 1,4 point scale by day 7 ($p < .001$) and remained statistically significantly improved by day 300 ($p = .003$), although by day 180, the level of improvement had begun to decrease.

Figure 4. Female patient, 67years, Correction of Nasolabial and labiomental folds, INTRALINE 2, 1,5ml, Needle technique.

Satisfaction questionnaires was rated as very good or excellent for the majority in the controls at 1 (median 30,55), 3 (median 29,75), 6 months (median 28,8)and at the last 10m control (median 26,6). The global median for all the study period was 28,925. Details are shown on **Table 2.**

Side effects included bruising 4% (n=6), swelling 3% (n=5), bumpiness 2% (n=3), asymmetry 1,6% (n=2), and erythema/discoloration 0,62% (n=1) that were primarily self-limiting within the first 1–2 weeks postinjection. Tyndall effect, granulomatous or nodular reactions, and focal necrosis were not registered.

Table 2. Global Self-assessment questionnaires median scores in time.



DISCUSSION AND CONCLUSIONS

A successful filler treatment is defined as a good aesthetic result, free of complications, with a good evolution in time and maximal patient compliance and satisfaction [12-15]. The former is possible with the correct selection of the patient, material and technique.

A new cross-linked HA dermal filler (Intraline 2, Canada Inc., Kelowna BC, Canada) probed to be effective in treating moderate to severe nasolabial folds with consistent results, maintained during all along study length. Patients and physician satisfaction, was very good or excellent for the majority.Particularly interesting is the fact that the severity of wrinkles improved even at day 300 and satisfaction also remained good even at 10 months. The long lasting action and patient satisfaction was probably due to the cross-linking technology of this new medical device, which is characterized by isovolumetric degradation. While hyaluronic acid reabsorbs, water molecules are able to bind the rest of the HA structure to maintain the whole structure in place, until the last of the HA molecules is reabsorbed. Moreover the filler material interacts with the recipient site cells and increases their metabolism, collagen synthesis and hydration, which may explain why the benefits of the treatment are present even after the products reabsorbs. The adverse events were few and self-limited.

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