

Multicenter Clinical Trial to Evaluate the Efficacy and Safety of the Facial Adipo-Structuring Technique

Gladys Velazco Viloría^{1*}, Manuel Sequera Azuaje² and Said Rodea Hernández³

¹Centro Latinoamericano de Investigación y Entrenamiento en Cirugía de Mínima Invasión CLEMI. Bogotá. Colombia.

²Icron medical instituto comuna de providencia region metropolitana Santiago de Chile chile.

³EPILOG, Clinics Merida, Yucatan, Mexico.

*Correspondence:

Gladys Velazco Viloría, Autopista Norte Km 16 vía Hatogrande Sopo (Entrada a Clubes).

Received: 10 Feb 2025; Accepted: 08 Mar 2025; Published: 18 Apr 2025

Citation: Gladys Velazco Viloría, Manuel Sequera Azuaje, Said Rodea Hernández. Multicenter Clinical Trial to Evaluate the Efficacy and Safety of the Facial Adipo-Structuring Technique. Recent Adv Clin Trials. 2025; 5(2); 1-4.

ABSTRACT

This study evaluates the safety, efficacy, and patient satisfaction of facial Adipo-Structuring using the FaceStructure Kit, applied to 100 patients treated every 15 days over three sessions. The analysis includes aesthetic, emotional, psychological, technological, and economic outcomes, providing a comprehensive assessment of the treatment's benefits. The research demonstrates that the technique is safe, highly effective, and significantly enhances patients' quality of life.

Keywords

Facial Adipo-Structuring, Efficacy and safety, Adipose pannicles, Senolytics.

Introduction

The need to address the aging process in a healthy manner has led researchers to focus on more conservative therapies with lower clinical complication risks. Facial Adipo-Structuring (FA) is a technique based on the systematic and organized repositioning of the superficial and deep facial adipose pannicles without their extraction [1]. Histopathological evidence shows that the FA technique stimulates the natural production of collagen and elastic fibers, modulating the senescent condition of cells, and improves the surrounding microenvironment, thereby promoting the regeneration of damaged tissue [2]. As a result, the technique has gained popularity among practitioners specializing in facial harmonization treatments, as it provides natural and effective results with minimal clinical complications.

Several studies report the safety and efficacy of FA in patient groups undergoing treatment, recommending it broadly as a safe technique with minimal adverse effects, particularly indicated for patients with active aging [3]. Thus, further validation studies can significantly support efforts to maintain it as a classic option when admitting patients to clinical practice. Although it might be

assumed that the technique should only be applied to patients with active aging, studies [4] have demonstrated its effectiveness and efficacy even in younger patients seeking aesthetic treatments, where FA can serve as a first-line option before considering more invasive procedures. Moreover, its demonstrated safety and effectiveness have made FA a promising option for patients with degenerative lipodystrophy of genetic origin, offering encouraging results, especially for patients with limited treatment alternatives [5]. Based on the presented studies, we decided to conduct a broader safety and efficacy study, expanding patient-related questions and observations to further increase statistical support and reinforce the findings already reported in the literature, thus maintaining high response standards.

Methodology

The objective of this study was to evaluate the efficacy and safety of Facial Adipo-Structuring (FA) treatment using the FaceStructure Kit, as well as its impact on aesthetic satisfaction, emotional well-being, and the cost-benefit relationship of the treatment. The study focused on 100 patients treated every 15 days following a standardized three session protocol, with evaluations conducted before, during, and after the treatment. This was a prospective, quasi-experimental, observational clinical study conducted on a sample of 100 patients aged 30 to 60 years, all with indications for FA. Sessions were administered every 15 days, and evaluations

were performed prior to treatment and at 7-, 30-, and 90-days post-treatment.

Inclusion Criteria

Patients with lipomatosis, lipodystrophy, and deflation (1); patients without underlying diseases, confirmed by blood tests.

Exclusion Criteria

Pregnant patients, patients with severe cutaneous infections, autoimmune diseases, or cancer.

Treatment Protocol

The FA technique was performed using 22G x 50 mm cannulas for adipose pannicles and 27G x 50 mm cannulas for interseptal spaces. Under sterile conditions, including sterile gloves and drapes, patient marking was carried out to map pannicles and preserve interseptal spaces. Skin preparation was performed using an iodized solution before making entry points and proceeding with area-specific cannulation. The active agents used were from the **FaceStructure Kit** by MioFace Harmony (Colombia), designed specifically for this technique and composed of senolytic agents and maintaining a balance between lipolytic and lipogenic activities.

The treatment protocol consisted of three sessions performed at 15-day intervals, with post-treatment follow-up for 10 weeks. Evaluations included measurements of skin quality, reduction of lipomatosis, facial contour, elasticity, and wrinkle reduction. Adverse effects such as bruising, discomfort, and post-treatment sensitivity were also monitored.

Evaluated Variables

- **Safety:** Safety was assessed by having subjects evaluate their pain at the treatment site after each application using a 100-mm Visual Analog Scale (VAS). For 15 days following each treatment session, subjects recorded the nature, severity, and duration of any local events at the treatment site in a 15-day Common Treatment Response Diary (CTR Diary). Any persistent disorder at the 15-day mark was automatically considered an adverse event.
- **Satisfaction and Efficacy:** Efficacy criteria included the application of the Global Aesthetic Improvement Scale (GAIS) and subject satisfaction assessments, conducted at weeks 4 and 10 after the final session. The study also incorporated standardized surveys assessing aesthetic outcomes, psychological impact, and general well-being.
- **Psychological Impact:** Emotional well-being and self-esteem were evaluated.
- **Economic Analysis:** The cost-benefit relationship of the treatment was assessed.

Results

According to evaluations using the Global Aesthetic Improvement Scale (GAIS), the degree of aesthetic improvement at week 8 after the last session was significantly high (96.5%). After week 10, improvements assessed by GAIS remained visible in 80.2%

of the subjects. The proportion of subjects satisfied with the treatment peaked at 92% at week 5 and remained at 86% at week 10. Regarding the Natural Look and Feel Scale, the percentage of subjects who rated their appearance and sensation as $\geq 8/10$ was 46% before treatment, 88.8% at week 8 post-treatment, and 87.2% in the pooled population at week 10.

Adverse events were recorded by the treating investigator and by the participating patients during study visits. No serious adverse events related to the treatment, unanticipated device-related events, delayed-onset complications, nodular complications, or vascular compromise events were observed. 10% of patients reported moderate edema in the treated areas, with a maximum duration of 72 hours, which resolved spontaneously without the need for any intervention or medication. The mean pain score on the 100-mm Visual Analog Scale (VAS) was 19.9 mm (95% Confidence Interval [CI]) during the initial application, and 3.1 mm (95% CI) 15 minutes after application (Figures 1 and 2, respectively).



Figure 1a: Sixty-year-old female patient before treatment. **b.** Three months after Facial Adipo-Structuring (FA) treatment, showing evident improvement in skin quality, reduced rhytidosis, and enhanced facial contour structuring.



Figure 2a: Fifty-six-year-old female patient with lipomatosis and tissue deflation before treatment. **b.** Three months after Facial Adipo-Structuring (FA) treatment.

Treatment Efficacy

- **Improvement in Facial Contour:** All patients (100%) reported a significant improvement in facial contour, with noticeable repositioning of tissues. Reduction of adiposity in areas such as the submental region and cheeks was evident.
- **Skin Quality and Elasticity:** Patients experienced considerable improvement in skin quality, with increased hydration and firmness. Skin elasticity also showed notable improvements, particularly in patients with greater degrees of skin laxity.
- **Wrinkle Reduction:** A marked reduction in wrinkles and expression lines was observed in all cases. Patients reported an overall rejuvenation of the skin.
- **Lipomatosis and Lipodystrophy:** In patients with lipomatosis and lipodystrophy, the adipo-structuring technique resulted in a significant reduction of facial fat deposits, leading to a noticeable rejuvenation of the treated areas.
- **Improvement in Glycation Status:** Patients who presented signs of glycation before treatment showed a remarkable improvement, with firmer and more rejuvenated skin, indicating that the treatment also contributed to reversing glycation-related changes.

Treatment Safety

- **Side Effects:** Only 5% of patients (5 out of 100) reported mild discomfort during the treatment. Additionally, 48 patients (48%) experienced mild facial sensitivity during the two days following the procedure, with an average pain score of 2/10 on the pain scale.
 - **Bruising:** 10 patients (10%) developed mild bruising at the cannula entry points, which resolved within 5 to 7 days.
- Overall, side effects were minimal and temporary, highlighting the safety of the technique.

Patient Satisfaction: Overall satisfaction was 100% positive. Patients reported high levels of both aesthetic and emotional satisfaction. The outcomes included:

- **Aesthetic Improvement:** Patients unanimously agreed that facial contour significantly improved, along with the reduction of wrinkles and enhancement of skin elasticity.
- **Emotional Satisfaction:** Most patients reported a significant increase in self-confidence and emotional well-being, reinforcing the positive psychological impact of this aesthetic treatment.

Table 1: Overall Patient Satisfaction Levels.

Evaluated Aspect	Satisfaction Level (%)
Improvement in facial contour	94%
Tissue repositioning	95%
Improvement in skin quality	90%
Reduction of wrinkles	92%
Reduction of lipomatosis	96%
Increase in skin elasticity	100%
Emotional satisfaction	100%

Psychological Impact

- **Emotional Well-Being:** Patients reported improvements in self-esteem and overall well-being, reflecting an increase in

personal satisfaction. Most highlighted that improvements in their physical appearance had a positive impact on their emotional state and quality of life.

- **Impact on Confidence:** Patients indicated that the treatment significantly contributed to enhancing their confidence and comfort with their appearance, improving their self-perception.

Economic Analysis and Cost-Efficiency

Facial Adipo-Structuring (FA) demonstrated an excellent cost-benefit ratio compared to other similar aesthetic treatments. Although specific costs of materials and equipment were not addressed, the results showed that the investment in the FaceStructure Kit is competitive, considering the aesthetic outcomes, procedural safety, and high patient satisfaction rates.

Discussion

The importance of adipose pannicles and their role in the facial aging process has been discussed for several years. The description of facial fat compartments has increasingly enhanced our understanding of their anatomical location and age-related changes [6-8]. With this knowledge, treatments such as Facial Adipo-Structuring (FA) can be proposed to effectively counteract these changes, generating natural and safe results for patients.

The safety and efficacy of the treatment were demonstrated in this study, with a high effectiveness rate, supporting and recommending its use, in agreement with previous reports [3,4]. Major age-related changes, as indicated by many studies based on cadaver dissections and clinical experience, differ between superficial and deep fat compartments. This evaluation is supported by recent scientific literature on the aging process of the cranio-cervico-facial structure, describing a global increase in volume with an inferior volumetric shift within the fat compartments showing increased volume in the lower two-thirds while remaining stable in the upper third [7]. The findings of this study are consistent with those reported by previous authors, reinforcing the efficacy of this treatment approach.

Studies focusing on structures such as the nose have demonstrated that FA can be an important tool for addressing unaesthetic features without clinical complications [9]. This study further validates the understanding that Facial Adipo-Structuring becomes a key part of the tools available to facial harmonization specialists, offering patients a safe and effective treatment tailored to their health condition, as it is a technique that responds to cellular changes.

Conclusion

Facial Adipo-Structuring treatment with the FaceStructure Kit proved to be highly effective and safe. All patients reported significant improvements in facial contour, skin elasticity, skin quality, and wrinkle reduction. Furthermore, the technique had a positive impact on patients' self-esteem and emotional well-being. Side effects were minimal and short-lived, with no serious complications, highlighting the safety of the procedure. Overall satisfaction was 100% positive, with patients reporting a significant improvement in personal confidence. The study also suggests

that the treatment is cost-effective, with results that justify the investment compared to other non-invasive aesthetic treatments. Finally, the positive psychological impact and increased emotional satisfaction and self-esteem reinforce the notion that Facial Adipo-Structuring is not only an aesthetic solution but also a comprehensive enhancement of patients' overall well-being.

It is recommended to conduct long-term follow-up to evaluate the durability of the results and to perform comparative analyses with other available aesthetic treatments. Additionally, future studies should explore treatment customization according to skin type, age, and individual patient needs.

References

1. Velazco Gladys. Adipoestructuración Facial. *Acta Bioclinica*. 2020; 10: 20.
2. Donderis Louison L, Ganci Cerrud A, Velazco G. Facial Adipostructuring the Intelligent Rejuvenation Presentation of a Clinical Case with Histopathological Analysis. *Am J Biomed Sci Res*. 2025; 25: 324-327.
3. García-Guevara Víctor, Velazco Viloría Gladys, Josefina. Evaluando la eficacia y seguridad de la técnica de adipoestructuración facial a propósito de una serie de casos. *Acta Bioclinica*. 2023; 13: 56-71.
4. Loreto Ibarra, Ricardo Camacho. Adipoestructuración facial una nueva herramienta para la armonización orofacial. Secuencia de casos. *Acta Bioclinica*. 2023; 13: 95-115.
5. Velazco G, Gonzalez Barnes S, Gonzalez Sandoval P, et al. Clinical Case of Linear Morphea (Sabre Cut) Regenerative Strategy Utilizing a Combination of Facial Adipostructuring and PDO Threads. *Am J Biomed Sci Res*. 2025; 25: 778-782.
6. Cotofana S, Schenck TL, Trevidic P, et al. Midface: Clinical Anatomy and Regional Approaches with Injectable Fillers. *Plast Reconstr Surg*. 2015; 136: 219S-234S.
7. Gierloff M, Stöhring C, Buder T, et al. Aging Changes of the Midfacial Fat Compartments: A Computed Tomographic Study. *Plast Reconstr Surg*. 2012; 129: 263-273.
8. Gierloff M, Stöhring C, Buder T, et al. The Subcutaneous Fat Compartments in Relation to Aesthetically Important Facial Folds and Rhytides. *J Plast Reconstr Aesthet Surg*. 2012; 65: 1292-1297.
9. Amin M, Mercado V, Velazco G. Non-Invasive Treatment after Infection in Rhinoplasty: Case Report. *Clin Surg*. 2024; 4: 1006.