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Non-Surgical Kinetic Facial Lifting Using Pneumatic Administration of Hyaluronic Acid: Protocol Enhancement

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Abstract

Background: In recent decades, several minimally invasive methods provided by EBDs and injectables have emerged as an attractive alternative to surgical facelifts. An innovative approach to SMAS lifting has been demonstrated by a pneumatic needle-free device. **Aims:** This study aimed to enhance the facelift protocol by increasing pressure in the temporal area and using crosslinked and non-crosslinked HA. **Methods:** Nine subjects with moderate to severe skin aging and laxity were randomized into three groups: 1) 1CG—current EnerJet protocol with non-crosslinked HA; 2) 2NCLH—elevated pressure with non-crosslinked HA; and 3) 3CLH—elevated pressure with crosslinked HA. The treatment's safety was evaluated by reports of adverse reactions and pain levels through the NPRS Scale. The clinical effect was evaluated one-month post-treatment by two investigators using the GAIS Scale via four aesthetic categories: 1) reduction of fine lines and wrinkles, 2) skin's firmness, 3) eyelid lift; and iv) overall skin change. Patients were asked to answer a satisfaction questionnaire on treatment effects and experience. **Results:** All treatments were well-tolerated, with an average pain score of 2.8 ± 1.9 (out of 10). No known or new adverse reactions were documented. 2NCLH and 3CLH groups demonstrated better results than 1CG in most aesthetic features. The patient's satisfaction rate of 2NCLH and 3CLH was also higher than that of 1CG for most aesthetic features. **Conclusion:** This small group study has shown enhanced efficacy of the kinetic facelift protocol when higher pressure was applied in the temporal area, without compromising the treatment's safety profile.

Keywords

Pneumatic Needle-Free Injector, Non-Surgical Kinetic Facelift, Rhytidosis,

Skin Laxity, Hyaluronic Acid, Wrinkles

1. Introduction

Photoaging and chronological aging cause aesthetic visual effects such as wrinkles, dryness, laxity, thinning, and loss of elasticity of the skin [1]. Traditional facelift procedures typically focus on surgical methods to reposition superficial facial fat and lift excess skin. These include approaches such as short and long skin flaps, superficial musculoaponeurotic system (SMAS) flaps, and deep-plane facelifts [2]. Imbrication and plication of the SMAS referred to as "SMAS lifts" or "classical facelifts" are the most frequently used techniques [3] [4], as they are effective in restoring skin elasticity in the SMAS membrane by tightening muscles and removing excess skin and fat.

In recent decades, other non-invasive or minimally invasive methods based on energy-based devices (EBDs) (e.g., laser, radiofrequency, ultrasound) [5]-[7] and injectable materials (e.g., dermal fillers such as hyaluronic acid (HA) [8]-[10] or biodegradable materials such as botulinum toxin) have emerged as an attractive alternative to a surgical facelift [5] [11] [12]. Non-invasive EBD devices achieve SMAS-based facelift by causing SMAS tissue thermal contraction, affecting the muscles, ligaments, and subcutaneous fat packets. The success of such treatments lies in low risks of scarring, infection, and nerve damage (risks associated with anesthesia), limited-to-no recovery time, and lower cost [1] [12].

SMAS lifting can also be produced by a non-thermal medical device procedure. The innovative pneumatic needle-free device EnerJet (Viora Ltd. by Sinclair, UK) has been successfully used for skin remodeling, facial rejuvenation, and facelift [1] [13]-[17] by performing Jet Volumetric Remodeling (JVR) [18]. In this technique, a controlled injection pressure directly determines the depth of penetration [1] [19] [20] in the targeted facial anatomical structures affecting not only the superficial dermis [13] [15] [17] but also the deep reticular dermis, subcutaneous layer, and SMAS [19]. The device employs kinetic energy from a pneumatically accelerated liquid jet that penetrates the epidermis through a small entry point, volumetrically dispersing particles of the injected therapeutic material in the tissue. This produces a dual effect: 1) the effect of the therapeutic material and 2) mechanical stimulation due to the microtrauma generated by the material dispersion [21].

The EnerJet-based proprietary kinetic facelift outcome was previously supported by clinical and histological evidence for SMAS lifting [19] [20] [22]. The first in-house case report by Levenberg *et al.* [22] used injection of non-cross-linked HA with 30% - 50% maximum pressure to the patient's scalp over the hairline (see **Figure 1**, Blue vector (1)). Levenberg *et al.* study established the "Kinetic Facelift" treatment guidelines, outlining specific substances and parameters for optimal results. However, since the desired clinical effect is based on targeting the SMAS layer, and the device's premise is based on penetration depth influenced by

applied pressure, it was hypothesized that clinical outcomes could be further enhanced by applying higher pressure during treatment. The following studies indicated that higher pressure may be more effective for SMAS-lift, especially in the temporal area. Mashiko *et al.* [19] demonstrated effective kinetic facelift outcomes using 85% jet pressure and a mixed solution of non-cross-linked HA and 20% glucose solution. A recent cadaver study conducted by Sandhofer *et al.* [20] showed that higher pressure values allowed material penetration to the SMAS and fascia layers. In this study, elevating the pressure up to 100% resulted in significant penetration into the periosteal structures, cheek fat, and structurally binding in the retinacula, especially the temporal fascia.

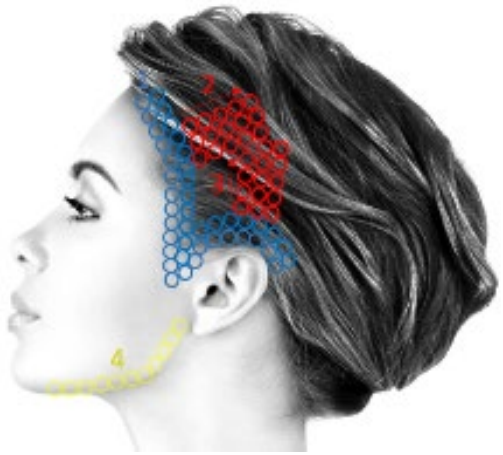

Figure 1. EnerJet kinetic facelift protocol: anatomical vectors.

This study aimed to evaluate, for the first time, the effectiveness of enhancement of EnerJet proprietary kinetic facelift by increasing the pressure values in the temporal area (one of the most contributing vector lines for facial lifting [23]). The study compared the use of non-crosslinked HA and crosslinked HA, ensuring that the safety of the treatment was not compromised.

2. Materials and Methods

The study employed a structured approach to investigate the efficacy of the EnerJet kinetic facelift protocol using different injection pressures and types of hyaluronic acid formulations (**Figure 2**). The participants' ages ranged from 37 to 65 years old, with moderate to severe skin aging and laxity. The research adhered to the ethical guidelines of the 1975 Declaration of Helsinki.

The participant screening and selection process included signing an informed consent form, completing a detailed health history questionnaire, and ensuring they were fully aware of the treatment methods and potential side effects. The participants presented moderate to severe skin aging and laxity and were excluded from a comprehensive range of medical and cosmetic considerations to ensure safety and study integrity. These exclusions included patients with inflammatory or infectious cutaneous diseases in the treatment area, chronic or active autoim-

mune skin disorders, genetic predisposition to keloid development, a history of collagen vascular diseases, uncontrolled diabetes, those on chronic anticoagulant medications, and individuals who had undergone plastic surgery in the treatment area within the previous 12 months. Additional exclusion criteria included unhealed scars (less than 6 months post-injury or surgery), recent childbirth (within 6 months), ongoing breastfeeding (within 3 months), recent use of Isotretinoin (within 6 months), recent deep chemical or laser peels (within 6 months), facial abrasion procedures (within 3 months), and recent cosmetic interventions such as natural fillers, hyaluronic acid injections, collagen or fat injections (within 3 months), as well as recent Botulinum Toxin treatments (within 3 - 7 days) or meso-threads (within 1 - 2 months). Nine participants were enrolled and randomly divided into three groups, each comprising three individuals with specific treatment protocols.

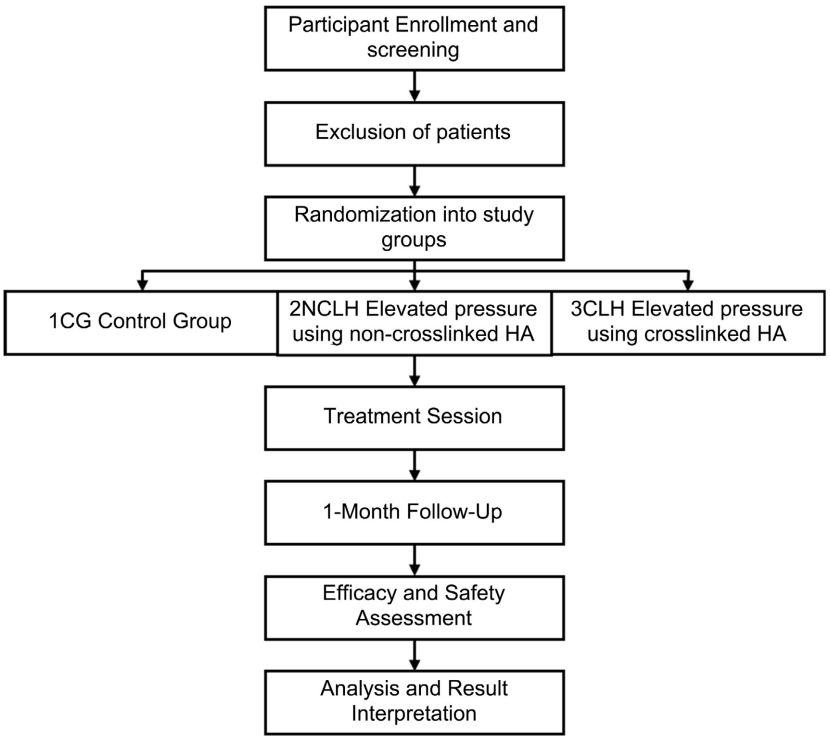

Figure 2. Schematic study method.

The first group, designated as the Control Group (1CG), received treatment using non-crosslinked hyaluronic acid with standard jet pressure applied across all areas. The second group (2NCLH) utilized non-crosslinked hyaluronic acid, applying standard pressure, with elevated pressure in the temporal area. The third group (3CLH) followed a similar approach but employed crosslinked hyaluronic acid.

The treatment protocol utilized the EnerJet device, a needle-free jet-injection system (Viora Ltd. by Sinclair, UK). The injection solution consisted of a mixture of 10 ml, combining either non-crosslinked or crosslinked hyaluronic acid with

0.9% NaCl solution. The final hyaluronic acid concentration was standardized at 2.5 mg/ml. Injection parameters were controlled, with pressure ranges between 2-6 bars and injection volumes of 0.05 - 0.15 ml, applied across a 1-cm grid pattern (presented in Figure 1 and Table 1).

Table 1. Kinetic facelift pressure parameters tested for each patient.

Study groups/ Anatomical vectors	Blue vectors (1)	Red vectors (2 & 3)	Yellow vectors (4)
1CG	30% - 50%	30% - 50%	30% - 40%
2NCLH & 3CLH		**60% - 80%**	

For all participants, the treatment course consisted of three treatment sessions at four-week intervals, followed by a one-month follow-up visit after the last treatment to assess long-term outcomes and patient responses.

Efficacy and safety were assessed through multiple methodologies. Safety was evaluated by a review of adverse reactions and side effects after each treatment session and at the one-month follow-up. Pain level reported by the patients was assessed at the end of each treatment according to the Patient Numeric Pain Rating Scale (NPRS). The efficacy assessment, evaluated by both the investigator and an external blinded evaluator, utilized the Global Aesthetic Improvement Scale (GAIS) as the primary assessment tool, examining four critical aesthetic categories: reduction of fine lines and wrinkles, skin firmness and lifting effect, eyelid lift, and overall skin change (Table 2). An additional assessment from a blinded evaluator conducted a randomized analysis of before and after images, providing an independent perspective on the treatment outcomes.

Table 2. Study investigator and blind evaluator GAIS evaluation.

Category		1CG	2NCLH	3CLH
		Avg.	Avg.	Avg.
Reduction of Fine Lines and Wrinkles	Investigator	3 ± 0.58	3 ± 0.00	3 ± 0.00
	Blinded Evaluator	3 ± 1.00	3 ± 0.00	3 ± 1.00
Skin's Firmness (Lifting Effect)	Investigator	4 ± 0.58	3 ± 0.58	3 ± 0.00
	Blinded Evaluator	4 ± 0.58	4 ± 0.58	3 ± 0.58
Eyelid Lift	Investigator	4 ± 0.48	3 ± 0.58	2 ± 0.58
	Blinded Evaluator	3 ± 1.15	3 ± 1.15	3 ± 1.00
Overall Skin Change	Investigator	4 ± 0.58	3 ± 0.00	3 ± 0.00
	Blinded Evaluator	4 ± 0.58	3 ± 0.58	3 ± 0.58

Patient satisfaction was captured through a questionnaire at the one-month follow-up visit. Participants rated their experience using a 5-point subjective satisfaction scale, evaluating aspects such as skin firmness, improvement in fine lines and wrinkles, and overall skin enhancement.

Statistical analysis utilized descriptive methods, calculating average values,

standard deviation, and percentage distributions. The analysis was conducted using Microsoft Office Excel.

3. Results

Patients' demographic

Nine (9) subjects were enrolled in this study. All participants (male (n = 1), female (n = 8), aged 37 - 65 years old (54 ± 10), Fitzpatrick Skin Type II-IV (III ± 1)) finalized the treatment course. After the enrollment meeting, participants were randomized into three study groups (1CG, 2NCLH, and 3CLH).

Safety

A total of 27 treatments were conducted during this study, all of which were well-tolerated by all participants. No known or new adverse reactions or systemic side effects were documented during the treatment course or at the one-month follow-up visit. Mild side effects reported during the treatment course included well-known side effects associated with the device use, such as local bleeding (33.3%), tenderness at the injection sites (7.4%), as well as mild headache (3.7%). All were transient and resolved within 24 hours.

NPRS injection pain was scored at an average of 2.8 ± 1.9 for all groups. The 1CG group scored with the highest pain grade (4.4 ± 0.9), whereas the 2NCLH and 3CLH groups scored with lower grades (1.2 ± 0.2 and 2.9 ± 1.7, respectively). Only one patient (1CG group) poorly tolerated the treatment and requested numbing cream, which was applied 30 minutes prior to the treatment (5% EMLA Cream, AstraZeneca AB, Sweden).

Efficacy

The treatment efficacy was determined by an assessment of the B&A images by the investigator and an external blinded evaluator using the GAIS scale (**Table 2**).

The external blinded evaluator correctly determined 100% of all "before" and "after" images. The evaluation of the reduction of fine lines and wrinkles scored by both investigators showed similar average grades of improvement (3-improved) in all study groups.

For skin firmness, featuring the lifting effect of the EnerJet treatment, both evaluators agreed that the 3CLH study group showed improvement (3) whereas the control group (1CG) showed no changes (4). There was disagreement, however, regarding the 2NCLH study group, where the blinded evaluator considered that there was no change (4), and the practitioner scored it as an average improvement (3).

The eyelid lift evaluation showed greater disagreements between the investigator and the blinded evaluator. The investigator considered that the 3CLH group showed superior improvement (2) in comparison with other groups. The 2NCLH was graded as improved (3) whereas the control group (1CG) was considered as no change (4). In contrast, according to the blinded evaluator, all groups showed noticeable improvement (3).

Finally, for overall skin change, both evaluators scored an average noticeable improvement (3) in both study groups (3CLH and 2NCLH), in comparison with no change (4) in the control group (1CG).

In summary, groups treated with the higher-pressure settings in the temporal area (2NCLH and 3CLH) showed better results in comparison with the control group (1CG) in most of the aesthetic features, except for the reduction of fine lines and wrinkles, in which all groups showed a similar clinical outcome.

When comparing the use of crosslinked HA versus non-crosslinked HA (3CLH and 2NCLH groups, respectively), the crosslinked group showed better results in terms of skin firmness according to the blinded evaluator and eyelid lift according to investigator, with no differences noticed in the reduction of fine lines and wrinkles or overall skin change.

In the one-month follow-up, all patients expressed satisfaction with the treatment procedure and results. All of them (100%) saw positive changes in the treated area after the treatment course. 100% of the patients in the study groups (2NCLH and 3CLH) noticed instant results after each treatment and were willing to recommend the treatment to friends and acquaintances in addition to being willing to receive an additional EnerJet treatment in the future, in comparison to 67% in the control group (1CG).

The patients' satisfaction rate for fine lines and wrinkles reduction, skin firming, and overall skin change scored an average of 3 (neutral) in the control group (1CG) and 4 (satisfied) in the 3CLH study group. The 2NCLH study group also scored an average of 4 (satisfied) for fine lines and wrinkles reduction and an average of 3 (neutral) for skin firming effect.

In summary, the patients treated with higher-pressure settings (2NCLH and 3CLH groups) reported a greater satisfaction rate than the control group (1CG), for most aesthetic features.

4. Discussion

The current study explores an innovative approach to facial rejuvenation using the EnerJet kinetic facelift protocol, specifically investigating the potential benefits of modifying injection pressure in the temporal area. Existing literature highlights the benefits of enhancing soft tissue lifting by adjusting injection parameters, particularly in challenging facial regions that demonstrate significant age-related changes [19] [20].

The research emerged from a critical observation in aesthetic medicine: the need for more precise, customizable non-surgical facial rejuvenation techniques. The current kinetic facelift protocol has been limited by standardized pressure settings, which may not adequately address the nuanced anatomical variations in different facial regions. Our investigation specifically targeted the temporal area, a critical zone in facial aesthetics that plays a significant role in perceived youthfulness and facial structure [23].

The most notable findings focus on the potential of increased injection pressure to improve clinical outcomes. By elevating pressure from the standard 30% - 50% to 60% - 80% in the temporal region, we observed meaningful improvements in skin firmness, eyelid lift, and overall skin appearance. This approach challenges the current treatment protocol and proposes a more nuanced method of soft tissue

manipulation.

The increased pressure did not compromise the safety profile of the kinetic facelift procedure, as the study did not reveal any change in known side effects or the appearance of new adverse reactions. This finding is particularly significant, as patient safety is the primary consideration in any aesthetic intervention. The consistent pain levels and absence of additional adverse reactions support the potential clinical applicability of the modified protocol. According to EnerJet data collected to date, the procedure's safety profile is considered very high, with limited to mild side effects [21]. Moreover, the treatment average NPRS score is comparable to previously reported pain levels [18] [19], confirming that increased pressure did not compromise safety.

An intriguing finding emerged regarding pain perception. Contrary to expectations, the higher-pressure groups reported lower pain levels compared to the control group. While this observation requires further investigation due to the small sample size, it suggests a complex physiological response to different injection pressures [24] [25].

The evaluation of clinical outcomes showed consistency between both evaluators, who reported similar improvements in fine lines and wrinkle reduction in all three groups (**Table 2**). The high-pressure settings, however, lead to greater improvements in eyelid lift (**Figures 3-5**), skin firmness (**Figure 5**, **Figure 6**) and overall skin appearance (**Figure 6**) in comparison with the control group, supporting the improved SMAS lifting hypothesis of this study.

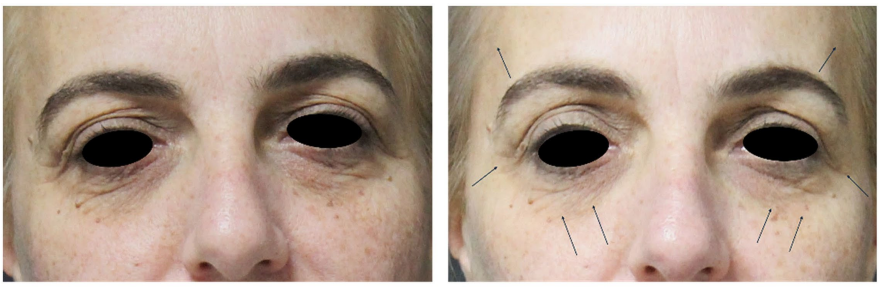

Figure 3. A 51-year-old woman before and after 3 EnerJet treatments with current pressure using non-crosslinked HA (1CG group).

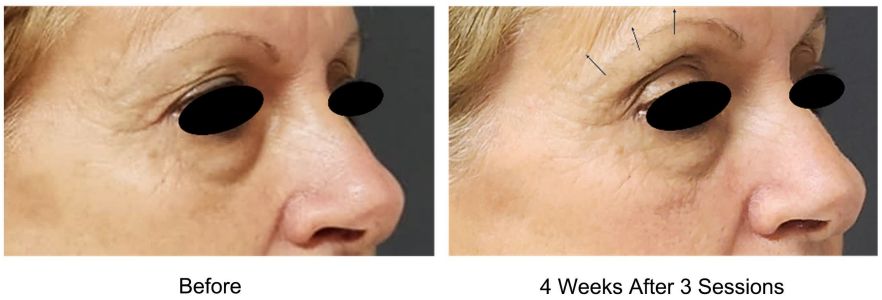

Figure 4. A 65-year-old woman before and after 3 EnerJet treatments with increased pressure using crosslinked HA (3CLH group).

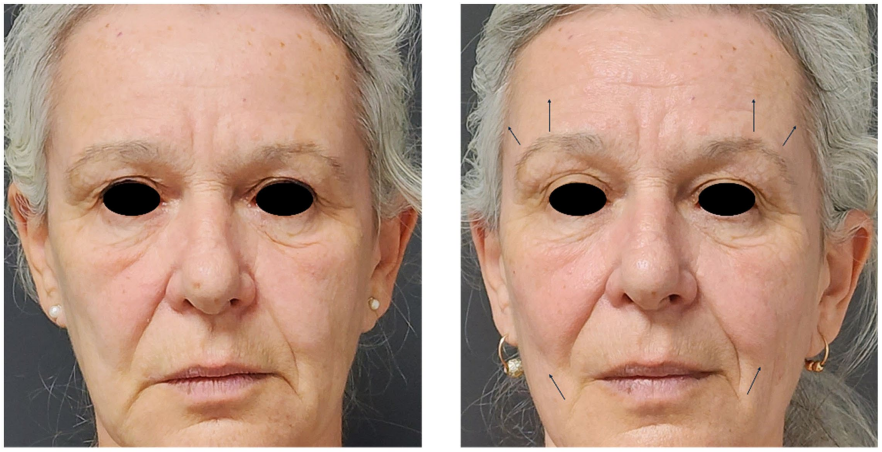

Figure 5. A 62-year-old woman before and after 3 EnerJet treatments with increased pressure using non-crosslinked HA (2NCLH group).

Figure 6. A 65-year-old man before and after 3 EnerJet treatments with increased pressure using non-crosslinked HA (2NCLH group).

The study's exploration of crosslinked versus non-crosslinked hyaluronic acid offers a novel contribution to the field. The crosslinked group exhibited higher GAIS scores, particularly in skin firmness and eyelid lift (**Figure 4**). Although minimal differences were observed in this short-term study, the potential for extended tissue presence with crosslinked HA highlights the need for further investigation. This opens new avenues for research into long-term soft tissue lifting techniques.

The patient's satisfaction in the higher-pressure groups was either equal to or greater than that in the control group, suggesting that the increased treatment pressure did not compromise patient experience but rather improved it. The lower satisfaction in the control group may also be associated with a higher reported pain sensation.

The current study acknowledges several significant methodological constraints that may interfere with the interpretation of its findings. The most prominent limitation is the small sample size, which significantly restricts the statistical power and generalizability of the research results. With only nine participants distributed across three groups, the study provides preliminary insights rather than definitive conclusions. The short follow-up period of one month further limits the understanding of long-term treatment effects and tissue response. The participant demographic was notably homogeneous, primarily comprising female subjects within a specific age range, which substantially narrows the applicability of the findings across broader population groups. This lack of diversity presents a critical constraint in understanding the potential efficacy of the treatment across different skin types, ages, and genders.

The research was confined to exploring only two types of hyaluronic acid, which provides a limited perspective on the potential variations in treatment outcomes. Furthermore, the study did not incorporate objective measurement techniques beyond visual assessment and patient-reported outcomes, which introduces potential subjective bias.

These methodological limitations do not diminish the study's value but, instead highlight the critical need for more comprehensive, longitudinal research. Future investigations should address these constraints by implementing larger sample sizes, more diverse participant groups, extended follow-up periods, and more sophisticated assessment methodologies to provide more robust and generalizable insights into the EnerJet kinetic facelift protocol.

5. Conclusions

This small-group study provides preliminary evidence for an enhanced EnerJet kinetic facelift protocol. The application of higher pressure (60% - 80%) in the temporal area showed notable improvements in clinical outcomes without compromising patient safety or comfort. Patient satisfaction was notably higher among the study groups compared with the control group, suggesting that adjusted injection settings can be safely integrated into existing treatment guidelines.

These findings represent an important step forward in non-surgical facial rejuvenation techniques, offering a more precise and targeted approach to addressing age-related skin changes. The potential to optimize injection parameters provides clinicians with a more nuanced tool for aesthetic interventions.

Author Contributions

S. R. G conducted the research and contributed to data acquisition. S.R.G, O.C.-L., and I.B. contributed to the data interpretation. I.B. served as a blind evaluator. All authors were involved in the drafting and revision of the manuscript and issued final approval for publication of the version. Each author has agreed to be responsible for all aspects of the job to ensure that issues relating to the accuracy or integrity of any part of the job are properly investigated and resolved.

Conflict of Interest Statement

O.C.-L., I.B., and G.V.M. are employed at Sinclair EBD. The authors declare that the study was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Ethics Statement

All study procedures were conducted according to the 1975 Declaration of Helsinki. The authors confirm that the ethical review committee approval is not necessary as the study device is already CE-marked device.

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