Research Article

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Supraperiosteal Filling Technique for Full Face Rejuvenation

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ABSTRACT

Modern theories of facial aging are based on the concept that bone structures play an important role in inducing the typical aged face. This study evaluated the efficacy and tolerance of a new gel, which was injected over the periosteum in a standardized pattern in order to reduce the typical aging defects due to absorption and distortion of the bony facial tissue, replacing the deep support of the overlying soft tissue. The study was a multicentric, non-controlled clinical trial. Patients were treated in a single session with a standardized infiltrative technique where small boluses was released over the periosteum in 6 specific sites of each half-face. One hundred-78 subjects completed the study. The mean total amount injected was 5.4 mL (3.6 - 6.8 mL) per face per session. Treatment was judged by the subjects as well tolerated and not very painful. Recovery time was immediate, with a minimum disconfort during the first 24 hours (edema, pain, numbness) and it did not limit social life or other activities. Rare adverse events described in literature did not occur. The study demonstrated therapeutic success in 98.32% (evaluated by subjects) and 99.44% (evaluated by doctors) of the patients demonstrating the effectiveness of injection therapy. The medical device, employed with our specific standardized technique and with our range of dosage, was proved to be valid and safe.

Background

Modern theories of facial aging are based on the concept that all layers, both superficial and deeper, are involved. Of course superficial layers such as epidermis and dermis are those where is easier to detect the signs of aging (i.e. stains, wrinkles, elastosis...), but also bone structures play an important role in inducing the typical aging face [1-3]. In fact, absorption and distortion, the two main processes that affect the bone during aging [4-6], create disproportion and alter the position of ligaments, thereby aggravating the ptosis of the soft tissues already induced by the force of gravity and by their deflation [7-12]. Nowadays there are numerous procedures aimed at improving the harmony of the face. Each of them presents specific targets and defines specific objectives. Among most used alternatives we find the filler, a minimally invasive technique, relatively safe, rapidly implemented and well tolerated by the patient, with predictable, modulable and reversible results. The infiltration of the gel into a specific tissue determines an increasing volumetric variation with consequent achievement of the objective ranging from the reduction of a wrinkle or furrow to the volumetric restoration of a specific anatomical area. From the initial targets such as nasolabial folds, marionette lines, lips, chin and cheekbones [13-15], further targets have been added in recent years. Today using ad hoc techniques it is possible to treat difficult areas such as tear trough, nasal pyramid, upper eyelid, temples and jaw line [16,17].

The aim of this study is to evaluate the efficacy and tolerance of a new gel, containing hyaluronic acid, amino acids and peptides, inject-

ed over the periosteum in a standardized pattern in order to reduce the typical aging defects due to absorption and distortion of the bony facial tissue, replacing the deep support of the overlying soft tissue.

Materials and Methods

The study was a multicentric, non-controlled clinical trial (national), carried out in accordance with the Standards of Good Clinical Practice of the European Union and the ethical principles expressed in the Declaration of Helsinki. The study began on 1st February 2021 and lasted until 31st January 2022. Patients were recruited from 1st December 2020 to 31st January 2021. The recruitment of candidates involved an initial interview in which the doctor evaluated the whole face in terms of disproportion between different areas and volumes lost. An evaluation for facial aging was done to candidates on areas where injection should be done (Figure 1). In case of interested candidates, the doctor moved on giving the information regarding the adverse events, filling in the forms (information sheet, informed consent, personal data management sheet) and explaining the active role of the candidate in the study (filling in the evaluation survey, adverse event reporting). At the end of the initial interview, in case of participation to the study, the recruitable subject picked up the forms, to read them carefully at home and if necessary, request additional information. After an interval of at least 14 days, the adequately informed consenting subject returned the forms completed with all requested data, signed and dated. From that moment on, the subject is assigned an alphanumeric identification code and was considered effectively recruited in the study.

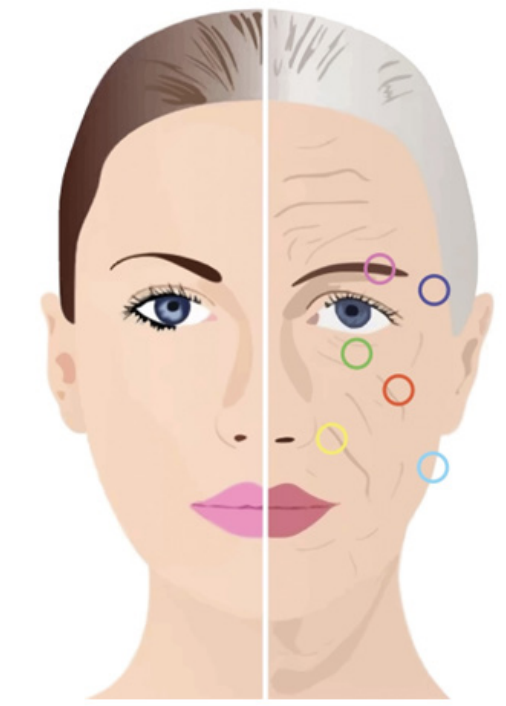


Figure 1: Drawn image of a youthful (A) and an aged face (B). Different colored circles show areas where supraperiosteal implants was performed. Dark blue circle: concavity of temple area was evaluated. Pink circle: lateral superior orbital ridge prominence was evaluated. Green circle: palpebral-malar groove was evaluated. Red circle: retrusion of malar bone was evaluated. Yellow circle: naso-labial fold was evaluated. Light blue: gonion prominence was evaluated.

Study Inclusion Criteria

Subjects with disharmonious face and typical aging loss of volume.

Study Exclusion Criteria

Psychological problems (indecisive or immature personalities, anxious, dysmorphophobic, with factitious disorders or with family disapproval), minors, pregnancy or breastfeeding, known allergies to one or more of the active ingredients, severe or skin-related autoimmune diseases, current acute infections, immunosuppression, haemorrhagic diathesis, oral anticoagulant therapy, platelet disorders, hormonal, metabolic and organ diseases in acute phase or with functional deficiency, patients who tend to develop hypertrophic scars, keloids or skin inflammation. The contraindications relating to the area to be treated are represented by acute pathologies in progress (inflammations, burns, continuous solutions, acute dermatological lesions), infections (including herpetic reactivations), skin cancers, foreign bodies or permanent fillers in the involved area.

Medical device used in the study was Neofound STRUCT LIDO (LOVE COSMEDICAL srls - Via Toniolo 9, 57022 Castagneto Carducci, ITALY) containing Sodium Hyaluronate/Hyaluronic Acid HIGH molecular weight (1.500<HA<2.000 KDA) 24%, Sodium Hyaluronate/ Hyaluronic Acid LOW molecular weight (155<HA<230 KDA) 9%, Niacinamide, Glycine, Proline, Arginine, Acetyl hexapeptide-8, DNA/ RNA complex, Tripeptide 29, BDDE, Lidocaine chlorhydrate 3%. This gel is an injectable implant indicated to correct various blemishes of the face and body due to to its temporary filling action. Owing to the highly hygroscopic property of hyaluronic acid, the gel integrates into the extracellular matrix, restoring lost volumes by attracting large quantities of water. This capacity increases over time thanks to the cross-linking process which delays its reabsorption by enzymatic way and by the antioxidant system which reduces its degradation by oxidative way. The volumetric effect is also supported by amino acids, peptides and polynucleotides which together stimulate neocollagenogenesis and, more generally, the synthesis of new extracellular matrix. Owing its rheological characteristics it is particularly indicated for the treatment of aging signs due to bony absorption and/or distortion and deep volume loss. Patients were treated in a single session by the authors through the modality and in accordance with the following protocol and technique. Before carrying out the treatment, the skin of the area to be treated was carefully cleaned and any make-up was removed.

The area to be treated has been thoroughly disinfected with chlorhexidine. Needle used was 27 gauge per 18 mm length. A standardized amount was injected with bolus technique over the periosteum of those specific sites:

- 0,5 mL to 1,0 mL was injected in each side on the temple area, just below the point of maximum concavity;
- 0,1 mL to 0,2 mL was injected in each side on supero-lateral bony orbital rim, just below the transition between the body and tail of the eyebrow;
- 0,3 mL to 0,5 mL was injected in each side on the suture between zygomatic process of maxilla and zygomatic bone;
- 0,3 mL to 0,5 mL was injected in each side on pyriform fossa;
- 0,5 mL to 1,0 mL was injected in each side 5 mm up and 5 mm medially to the gonion;
- 0,1 mL to 0,2 mL was injected on the orbital rim just on the emipupillary vertical line.

Needle was inserted just directly over the site at an angle of 90° from the skin surface. Fingers of free hand were very helpful in giving a good orientation, avoiding an incorrect positioning of the needle and protecting during the injection migration of the gel on the surround areas. Injection was performed slowly only after doing aspiration test in order to avoid intravascular complications. After injection mild compression was done for 30 seconds in order to limit possible bruising, applying a massage, if necessary, to remould the shape of the bolus.

Subjects were asked to avoid strenuous physical activities, prolonged exposure to sunlight and tanning beds or extreme weather conditions for 24 hours after the treatment in order to reduce redness, edema and irritation. Recruited subjects were evaluated before, immediately after, 2 and 7 months after the treatment. The inclusion and exclusion criteria, the protocol and the method of use have minimized the factors that could have compromised the results. In particular:

- Concomitant aesthetic therapies: recruited subjects who during the whole period of the study performed medical aesthetic treatments (e.g. fillers, botulinum toxin, biostimulation, RF, laser) or facial surgery procedures (including dental and oral cavity procedures) were excluded from the study;
- Acute diseases: recruited subjects who during the whole period of the study had an acute disease affecting the face (e.g. infections, traumas, dermatological and periodontal pathologies) where excluded from the study.
- Recruited subjects who interrupted the study have not been replaced.

The clinical evaluation aimed to detect the efficacy and tolerance of the solution and its protocol. The efficacy was evaluated:

- By 2 doctors who had not performed the treatment and whom had not been provided with any additional information regarding the individual treated with photographic comparison before and after treatment. The two doctors have evaluated the improvement of facial proportion and volume loss expressing an improvement value according to the Global Aesthetic Improvement Scale (GAIS) [18] ranking between 1 and 5 (Table 1) and to fill out the effectiveness evaluation form for the doctor.
- By the treated patient through an anonymous self-evaluation test for results and their level of satisfaction given in the waiting room and collected completely anonymously by non-medical personnel. They were also asked to express an improvement value according to the GAIS ranking between 1 and 5 (Table 2) and to fill out the effectiveness evaluation form for the patient.
- The data deriving from the two different categories (doctors and treated individuals) were then collected and statistically evaluated in order to obtain the percentages of each of the 5 GAIS classes (1 optimal improvement, 2 good improvement, 3 moderate improvement, 4 no improvement, 5 worsening). Safety was evaluated using an adverse event onset form.

Table 1: Global Aesthetic Improvement Scale (GAIS).

Degree of Improvement	Description
1 Excellent	Excellent result
2 Good	Marked improvement of the appearance, but not completely optimal
3 Sufficient	Improvement in the appearance, better compared to the initial condition
4 No improvement	The appearance remains substantially unvaried compared to the original condition
5 Worsening	The appearance has worsened compared to the original condition

Results

The study recruited 184 subjects, across three different centers, among these 178 completed the study. Four subjects did not complete the whole follow-up, two were excluded because of aesthetic treatments during the follow-up. The subjects that completed the study were 156 women and 22 men, with an average age of 63 (43-78 years old), representing all classes of phototype. The mean total amount injected was 5.4 mL (3.6 - 6.8 mL) per face per session. Treatments and were evaluated both from efficacy and tolerance point of view. Tolerance. Treatment was judged by the subjects as well tolerated, not very painful. Recovery time was immediate, with a minimum disconfort during the first 24 hours (edema, pain, numbness). They declared themselves willing to carry it out again. Adverse events occurred during the study was:

24 (13.48%) bruising,

16 (8.99%) prolonged pain lasting more 72 hours,

15 (8.43%) numbness more 72 hours,

7 (3.93%) bumps/lumps, contour irregularities or asymmetries,

6 (3.37%) pain that required pain killer for the first 72 hours after,

5 (2.81%) oedema lasting more 72 hours,

2 (1.12%) hypersensitivity or itching.

Those adverse events did not limited social life or other activities.

Rare adverse events described in literature after filler treatments, such as seroma, organized hematoma, migration of filler, fibrosis, stains, infections, allergic reactions, impaired muscle function, inflammatory reactions, nodules/abscess, granulomas, dysesthesia/paresthesia/anesthesia, persistent scarring, tissue necrosis and embolism did not occur. Bruising was small and not very visible thanks to bolus supraperiosteal technique that provides single injections with 27 gauge needle adherent to periosteum in a slow manner. Prolonged pain lasted more than 72 hour (9 x 4 days, 2 x 5 days, 3 x 6 days, 2 x 7 days with an average of 4,875 days) was well tolerated and required no therapy. Numbness was mild and self resolved in maximum 4 days. Bumps/lumps self resolved in maximum 7 days and appeared only in very thin subjects. Asymmetries, contour irregularities were minimal, probably due to technical mistakes occurring during the procedure. Effectiveness. T The 178 patients who completed the study gave to the results an improvement value (according to the GAIS score) of 2.04±0.44. The percentage of therapeutic failure, judged with a score equal to or greater than 4 or 5, was 1.68 %. The average best score (1.96±0,43) occurred in subjects with BMI< 20 (Table 3). The medical evaluation reported an average score of 2.04±0.47. The percentage of therapeutic failure was 0.56%. As for patients evaluation, the average best score was found in subjects with BMI< 20 (1.94±0.33) (Table 2). Patients and physicians evaluations did not show significant differences in male and female subjects (Table 4 & Graphic 1).

Table 2: Medical evaluation on the efficacy of the treatment at 2 months.

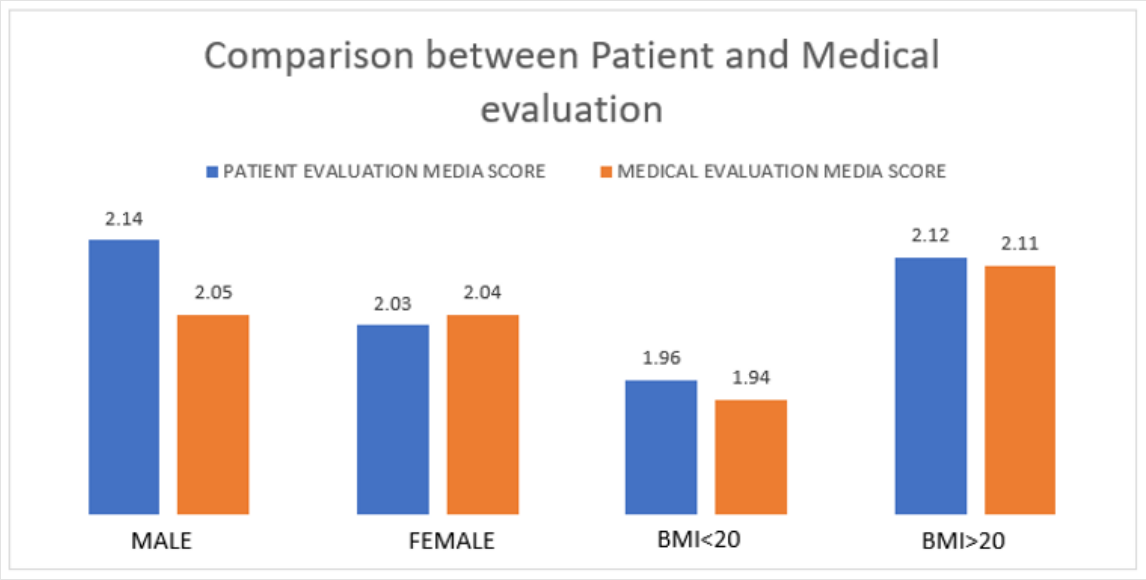
Degree of improvement GAIS	Number of subjects	Male	Female	BMI < 20	BMI > 20
Total	178	22	156	83	95
1 Excellent	12 (6.74%)	3 (13.64%)	9 (5.77%)	7 (8.43%)	4 (4.21%)
2 Good	148 (83.15%)	16 (72.73%)	131 (83.97%)	74 (89.16%)	78 (82.11%)
3 Sufficient	17 (9.55%)	2 (9.09%)	16 (10.26%)	2 (2.41%)	12 (12.63%)
4 None	1 (0.56%)	1 (4.54%)	0	0	1 (1.05%)
5 Worsening	0	0	0	0	0
Average Score	2,04±0.47	2.05±0.65	2.04±0.38	1.94±0.33	2.11±0.45

Table 3: Evaluation of the patients on the efficacy of the treatment at two months.

Degree of improvement GAIS	Number of subjects	Male	Female	BMI < 20	BMI > 20
Total	178	22	156	83	95
1 Excellent	13 (7.30%)	2 (9.10%)	11 (7.05%)	8 (9.64%)	5 (5,26%)
2 Good	147 (82.58%)	16 (72.72%)	131 (83.98%)	71 (85.54%)	76 (80%)
3 Sufficient	15 (8.44%)	3 (13.63%)	12 (7.69%)	3 (3.61%)	12 (12.63%)
4 None	3 (1.68%)	1 (4.55%)	2 (1.28%)	1 (1.21%)	2 (2.11%)
5 Worsening	0	0	0	0	0
Average Score	2.04±0.44	2.14±0.64	2.03±0.45	1.96±0.43	2.12±0.50

Table 4: Evaluation on the efficacy of the treatment at 7 months.

Degree of improvement GAIS	Evaluation by patients	Medical evaluation
Total	178	178
1 Excellent	0 (0.00%)	0 (0.00%)
2 Good	10 (5.62%)	12 (6.74%)
3 Sufficient	22 (12.36%)	39 (21.91%)
4 None	145 (81.46%)	127 (71.35%)
5 Worsening	1 (0.56%)	0 (0.00%)
Average Score	3.77±0.55	3.65±0.60



Graphic 1: Mean patient (blue columns) and medical (red columns) evaluation score in male (1a) and female (1b) patients and in patients with BMI <20 (1c) and >20 (1d). Statistical analysis using Students t-test. There was no statistically significant difference between patient assessment (subjective) and medical assessment (objective) (p> 0.05). There is no statistically significant difference between males and females (p value> 0.05). The difference in efficacy between group with BMI<20 and BMI >20 was statistically significant (p value <0.05).

Discussion

This study demonstrates therapeutic success, judged as sufficient, good or excellent, in 98.32% (patients evaluation) and 99.44% (doctors evaluation) of the subjects who completed the entire protocol, confirming the effectiveness of injection therapy. The medical device used with specific standardized technique and with the suggested range of dosage in this study proved to be valid and safe. While the difference between male and female was not significant, a signifi-

cant (objective and subjective) difference according to BMI value was found. The subjects who benefited most were those with a BMI<20, showing that patients with greater adiposus tissue tend to compensate better the aging related defects of osseous structure. The study demostrated to be successful in all phototype classes (1-6 according to Fitzpatrick classification), smokers and non smokers, with different superficial features typical of dermo-epidermal layer aging (such as stains, wrinkles, elastosis) The proposed protocol, based on the technical evaluation of bone absorption and distortion processes typical of aging, proved to be valid, effective, safe and of good compliance by the patients. In fact, patients showed to be satisfied of treatment giving them a more rested, refreshed and juvenile aspect without changing own anatomical features. Moreover the deep infiltration induced minimal discomfort, without downtime, with immediate stabilization of the result.

The supraperiosteal implant has caused a low frequency and scarcity of common adverse events such as ecchymosis, edema and pain, as well as it conferred longer duration of the treatment, as shown by a therapeutic success of seven month on 17.98% and 28.65% in patients and doctor evaluation respectively.The stability of the result is also supported by the particular gel composition, with combined "direct" filling agents (reticulated hyaluronic acid) and "indirect" filling agents, i.e. promoters of suntesis of new extracellulare matrix (free low-molecular weight hyaluronic acid, amino acid, peptide, polynucleotides). The infiltration were done in relevant focal areas where the bone aging process in particularly important [19,20]. They represent crucial points for restoring the right juvenile structure without correcting or changing the own anatomical features of the single individual (Figure 2). Volume changes in the skin and soft tissue contribute greatly to age-related facial reshaping, but a significant contribution to these volume changes is determined by the loss of craniofacial skeletal support to the overlying soft tissue. Gravity, once considered the major culprit in facial aging, is now recognized to determine the direction (rather than the extent) of soft tissue deflation. Midfacial soft tissue descent has been observed in response to decreased craniofacial support in both congenital craniofacial hypoplasia and following trauma, leading to a hypothesis that the loss of underlying bony support for any reason, leads to soft tissue descent particularly in the face.

As craniofacial support decreases, it leaves less surface area for the soft tissue envelope causing it to fold or sag. Replacing this deep support with craniofacial implants has been shown to reposition the overlying soft tissue [20].

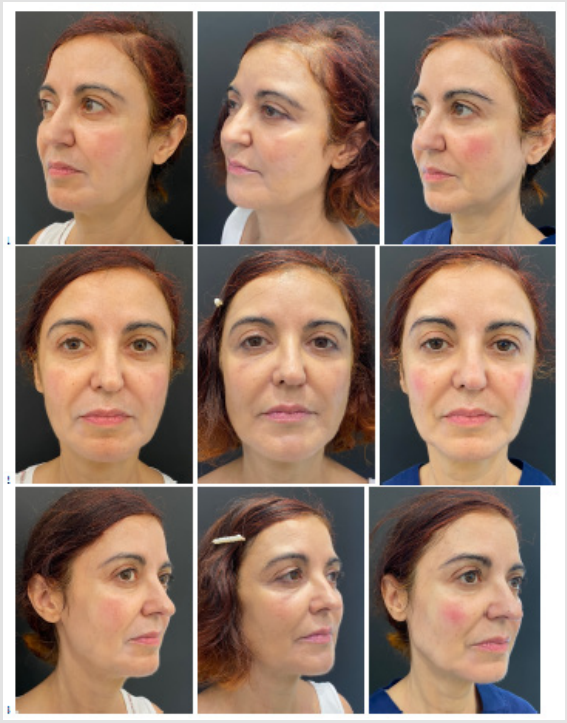


Figure 2: Pretreatment (1a, 1b, 1c), 2 months posttreatment (2a, 2b, 2c) and 7 months posttreatment photographs (3a, 3b, 3c) of female subject 64 y.o. Treatment gave her a more rested, refreshed, and juvenile aspect without changing own anatomical features. The result obtained, as evident in the two-month follow-up, progressively decreased. At seven months the beneficial effects, even if minimal, are still present.

Conclusion

The clinical data emerging from this study showed that the medical device is effective and safe to treat the typical aging defects due to absorption and distortion of the bony facial tissue. The protocol used in this study proved to be valid, effective, safe and of good compliance by patients. In future investigations it will be interesting to extend the follow up to a longer time interval and to evaluate instrumentally the durability of the implanted gel. Moreover it will be useful to study the combination of this technique with other more superficial volume restoring techniques in order to evaluate possible synergic action and corrective effect optimization.

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