

Radiofrequency Waves with Filling and Peeling Substances: an Innovative Minimally Invasive Technique for Facial Rejuvenation

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ABSTRACT

Introduction: This study describes a pivotal clinical trial of a new minimally invasive cosmetic procedure for facial rejuvenation and for the treatment of scars and wrinkles. **Methods:** The procedure consisted of a combination of techniques such as fillers, biorevitalization, peeling, and intradermal radiofrequency, emitted from a new device denominated by Spherofill Medical Plus (SMP; Spherofill MD, PromoItalia Group S.p.A., Pozzuoli, Italy), for treating cutaneous regeneration, depressions, and striae. One hundred and twelve patients, divided into five groups, were treated. **Results:** The results produced were statistically analyzed and resulted in significant and long-lasting effects for facial rejuvenation. Indeed, the analysis of the Global Aesthetic Improvement Scale (GAIS) scores in the five groups demonstrated statistically significant results between 3 and 9 months after the

treatments. **Conclusion:** Evaluating the patients included in the study, it is possible to conclude that the treatment with SMP represents a safe and efficient solution for the treatment of wrinkles, acne lesions, striae, and of degenerated tissues caused by aging.

Keywords: biorevitalization; facial rejuvenation; fillers; peeling; radiofrequency; soft-tissue augmentation

INTRODUCTION

The basics of facial beauty are symmetry, balance, and proportion.¹ Beginning in a person's mid to late thirties, changes caused by aging become apparent through the face. Indeed, aging is a complex process involving two important factors: volume loss throughout the face, and repetitive muscle movements that cause wrinkles and folds.¹ Traditionally, facial rejuvenation has focussed on skin tightening through surgical resection and superficial skin resurfacing. In recent years, there has been an increasing emphasis on minimally invasive cosmetic procedures, causing a rapid increase in the number of these procedures taking place.^{2,3} In addition to botulinum toxin and laser treatments,

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the injection of dermal fillers is becoming one of the most relevant minimally invasive procedures for facial rejuvenation.⁴ Dermal fillers can be used for a multitude of indications: wrinkles, lip augmentation, facial deformities, and so on. There are currently 160 dermal fillers on the market. They differ greatly in terms of origin, duration of the effect and breakdown properties, injection depth, and risk profile.⁵ Using these products in combination allows advantage to be taken of their hydrophobic and hydrophilic properties, and can provide better and longer-lasting results. The addition of botulinum toxin can further extend the effectiveness of the results by reducing the mimetic stress that can break down the polymers.⁶

Restoration of volume using dermal fillers can rebalance facial proportions, increase symmetry, and reduce wrinkles.¹ All these effects produce a younger appearance, through a nonaggressive treatment. Therefore, fillers represent a faster, less painful, and less costly alternative to surgical procedures; moreover, they can be used preventively in younger patients, or as a test to define the changes that can be made more permanent with surgery.⁷ Nevertheless, dermatologists are also using chemical peels to rejuvenate photo-aged skin, and among peeling agents, there are alpha-hydroxy-acids, trichloroacetic acid, Jessner's solution, salicylic acid, pyruvic acid, and phenol-based formulas.³ Finally, a new technique to combat aging is called biorevitalization. Biorevitalization is a treatment that integrates those substances in the dermis that our organism may not produce anymore in an adequate form (hyaluronic acid, vitamins, coenzymes, and minerals, etc.) and stimulates the microcirculation to favor cellular turn-over. The material is rapidly absorbed by the skin, causing restoration of moisture and elasticity. Injections can be carried out not only on the face, but also on any other part of the body with skin.^{3,6}

We describe here the pivotal clinical trial of a new minimally invasive cosmetic procedure for facial rejuvenation and for the treatment of scars, stretch marks, and wrinkles. This procedure consists of a combination of techniques such as fillers, biorevitalizers, peeling, and intradermal radiofrequency, emitted from a new device denominated by Spherofill Medical Plus (SMP; Spherofill MD, PromoItalia Group S.p.A., Pozzuoli, Italy), for treating cutaneous regeneration, depressions, and stretch marks.

MATERIAL AND METHODS

Apparatus

SMP is a bipolar electric wave generator, denominated promoitalia-radiofrequency radio (P-RFR), emitting at two different frequencies: 1134 KHz and 1769 KHz, included in the range of the AM broadcasting radio waves (525 KHz-1775 KHz). The SMP is also equipped with a frequency wave of 2000 KHz, denominated peeling wave, necessary for obtaining an electrical and mechanical peeling. SMP has a maximum nominal output power equal to 6.3 w. The emission of bipolar radiofrequency occurs through a needle-electrode for the 1134 KHz waves and 1769 KHz waves and through an electrode named "eagle probe," for peeling waves (2000 KHz). The apparatus determines a high concentration of energetic transport with microheating without thermal damage, on a microarea, creating a very intense reactive process which generates a dermal thickening, allowing the re-absorption of the filler to slow down; fibroblast reduplication enhancing biorevitalization action. The possibility to realize an electric peeling with this equipment is the rationale behind its use with chemical peels, in this manner obtaining a synergic and enhanced effect.

Patients

One hundred and twelve healthy patients, aged between 25 and 71 years of both genders, participated in the study and were divided into five groups: Group A: $n=10$, patients of both genders with mild periorcular wrinkles, only treated with radiofrequency; Group B: $n=12$, patients of both genders with striae on the abdomen and hips, treated with radiofrequency and peeling for greater lesions; Group C: $n=20$, female patients with acne scars, treated with radiofrequency, followed by the intradermal injection of revitalizers containing DNA nucleotides; Group D: $n=50$, patients with glabellar wrinkles, nasolabial folds, peri-ocular wrinkles, marionette lines, frontal wrinkles, wrinkles on the neck and décolleté, and lip contour wrinkles (these patients were treated with radiofrequency followed by the injection of a filler containing hyaluronic acid. Fillers containing "cross-linked" hyaluronic acid of third generation were used at a low, medium, and high viscosity); Group E: $n=20$, patients in which thinning of the dermis was caused by physiological aging or by sun exposure or photoexposure. In these patients, radiofrequency was combined to revitalizing mixtures of different compositions (nucleotides, vitamins, antioxidants, hyaluronic acid, amino acids).

The exclusion criteria for the study was as follows: any patients that had undergone other medical-aesthetical treatments (botulinic toxin, laser for skin resurfacing, intradermic radiofrequency), and pregnant or breastfeeding women. The inclusion criteria was as follows: patients in good health, nonsmokers, patients that do not practice any other treatments, and patients that present a severe to moderate photoaging (this last criteria is adopted only for patients in Groups D and E). The wide range of age is justified by the differences in the group

of patients treated: younger subjects (Groups B and C) that present scars from acne and stretch marks, and older patients (Groups A, D, and E) that present a severe to moderate photoaging.

No patient modified his/her lifestyle and they all consented to the protocol proposed. All patients undertook a preventive check-up, including a complete anamnesis, and an ultrasound and photographic evaluation.

Treatment and Evaluation Protocol

Each treatment was carried out according to a default protocol, which is briefly described here. Group A patients undertook 3 sessions, one every 15 days and a last session after 3 months. Group B patients undertook 8 sessions, one every 7 days and a last session after 5 months. Group C patients undertook 6 sessions, one every 7 days and a last session after 1 month. Group D patients undertook only 1 session. Group E patients undertook 4 sessions, one every 15 days and a last session after 1 month. The injection of fillers and radiofrequency were contextual in all the patients. Patients were only treated once at the first session. No touch-ups were performed.

The objective examination was carried out through the interpretation of the result compared with the score of the Global Aesthetic Improvement Scale (GAIS) used as a reference parameter (Table 1); a summary of the patients' characteristics and of the GAIS scores obtained is depicted in Table 2.

Follow-up timings anticipated an objective evaluation of the result at 48 hours, 6 months, and 9 months. The photographic evaluation was performed at each of the abovementioned timings. The ultrasound evaluation was carried out with the aim of interpreting the structural modifications that the underlying skin is subjected to, under the action of P-RFR waves or

Table 1. Global Aesthetic Improvement Scale (GAIS).

Degree	Description
1	Exceptional improvement
2	Very improved patient
3	Improved patient
4	Unaltered patient
5	Worsened patient

of eventual filling material (fillers or revitalizers). The ultrasound evaluation was conducted only after 48 hours and at the end of the follow-up in order to identify the structural modifications that the skin has been subjected to.

Histology

A woman aged 51 needed surgical abdominoplasty. After giving her informed consent, she agreed to have the skin on her abdomen treated with SMP once before surgery. The surgery was carried out 5 days after the treatment and under lumbar anesthesia, and two representative full-thickness skin samples were taken at the same time, one at the site of the

SMP application and one at the contra-lateral, symmetric, untreated side to be examined by means of histopathology. Excised tissue samples were transferred in 4% (m/v) paraformaldehyde solution and were paraffin embedded. Sections of 5 microns were stained with hematoxylin-eosine, hematoxylin-van Gieson, and PAS-Alcian blue hematoxylin (Carlo Erba, Milan, Italy).

Statistical Analysis

Descriptive analysis was created using median values and 95% confidence intervals (CI). The differences in the GAIS scores in the different time-points of each group was found using the Wilcoxon's test for nonparametric dependent

Table 2. Patient characteristics and Global Aesthetic Improvement Scale (GAIS) score obtained.

Patients	Groups	Age, years	Sex	GAIS T		GAIS T		GAIS T		GAIS T	
				0 months	3 months	6 months	9 months	6 months	9 months		
10	A	46.3	7 F/3 M	8 p=3, 2 p=4	5 p=3, 5 p=4	7 p=3, 3 p=4	10 p=4				
12	B	39.8	7 F/5 M	2 p=3, 10 p=4	5 p=3, 7 p=4	8 p=3, 2 p=4	4 p=3, 1 p=4,	2 p=2	7 p=2		
20	C	30.0	10 F/10 M	6 p=3, 14 p=4	13 p=3, 4 p=4,	10 p=3, 1 p=4	5 p=3, 15 p=2	3 p=2	9 p=2		
50	D	46,8	39 F/11 M	45 p=4, 5 p=2	45 p=1, 5 p=2	23 p=1, 6 p=3	17 p=4, 19 p=3,	21 p=2	14 p=2		
20	E	58.3	15 F/5 M	12 p=4, 8 p=3	5 p=4, 15 p=3	5 p=1, 5 p=3,	12 p=4, 8 p=3	9 p=2, 1 p=4			

Group A: $P=0.008$ at 3 months. Group B: $P=0.005$ at 9 months. Group C: $P=0.0001$ at 9 months. Group D: $P=0.0001$ at 9 months. Group E: $P=0.0001$ at 6 months. F=female; M=male; p=patients.

continuous variables. SPSS software (version 17.00, SPSS, Chicago, USA) was used for the statistical analysis. A *P* (two tailed) value of <0.05 was considered to indicate statistical significance.

RESULTS

The treatment caused minimum discomfort, without any post-treatment pain. All patients returned to their everyday activities immediately after the treatment. In a small number of patients ($n=10$) hematomas were found, and areas of hyperemia secondary to the traumatic action of the needle and to the radiofrequency microheating; these resolved in a few days, following the application of antiedemigen creams. Concerning substances with filling characteristics, in a small percentage of patients (10%), inflammatory reactions (edema, redness, herpes) were found, and were sometimes associated with itchiness or pain due to pressure after the injection. Ecchymosis or petechial reactions were found in subjects undergoing therapy with anticoagulants or salicylates. Concerning such complications, we think that they are not only correlated to the therapy with anticoagulants or salicylates, but also to radiofrequency treatment, since we are dealing with intradermal radiofrequency and the heat induced by the electrode needle may break some small vessels of the dermis. Peels induced a very intense erythematous reaction, accentuated by the reaction of heat induced by the P-RFR wave.

The use of the SMP apparatus in the patients in Group A determined an excellent therapeutic success 3 months after treatment with a statistically significant difference in the GAIS scores ($P=0.008$). In panel A of Figure 1 an exemplificative case is shown. To note, this optimal cosmetic effect was almost completely lost at 9 months after the treatment.

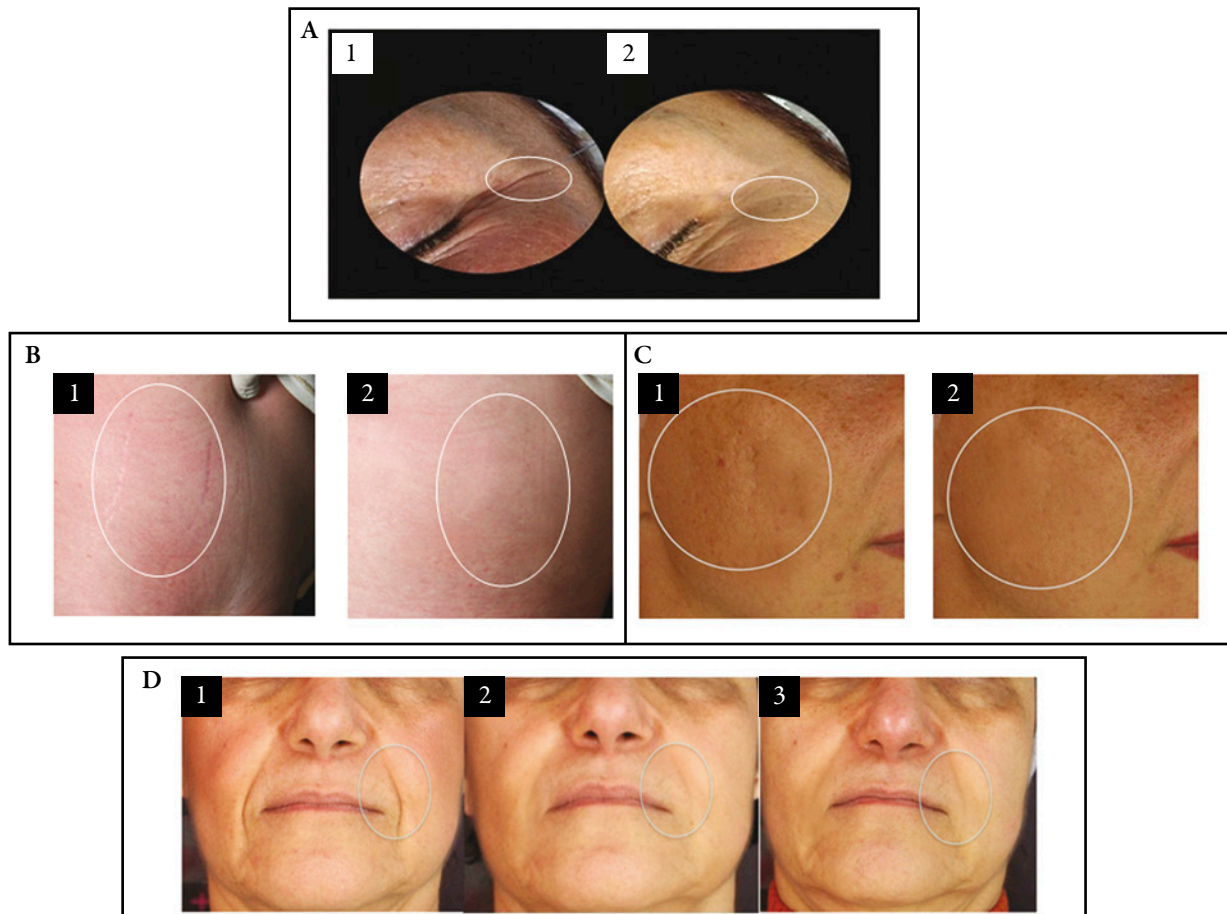
The synergic use of the P-RFR wave with peels in the patients in Group B for treating striae determined an improvement in the epidermal texture and an increase of elasticity, through a thermographic and dermoscopic evaluation, and through photographic documentation. This optimal cosmetic effect was statistically significant 9 months after the treatment ($P=0.005$). In panel B of Figure 1 an exemplificative case is shown.

The use of SMP with revitalizers containing nucleotides for scarring forms of acne, of slight and average gravity (Group C patients), gave good results. An improvement of the skins elasticity and a flattening of the scarring results were appreciable by gently tapping the skin. The cosmetic effect was statistically significant 9 months after the treatment ($P=0.0001$). In panel C of Figure 1 an exemplificative case is shown.

In each patient in Group D, an improvement in the appearance of wrinkles was visible immediately after treatment with a favorable cosmetic result. Patients re-evaluated at 6 months presented an almost unaltered correction situation. After 9 months of follow-up, a slight reduction of the correction of the wrinkle was seen in 70% of the patients ($P=0.0001$). In particular, an excellent result was found in patients in whom the zygomatic area had been treated. A double effect was encountered: lifting and filling (see panel D of Figure 1).

In patients in Group E, the effect of the contraction of collagen and of the production of new natural collagen was highlighted by the increase of the tone, compactness, and cutaneous brightness of the skin. Such features were appreciable by gently skimming over or touching the skin. An increase in skin brightness and an improvement in skin color was also visible. The skins compactness also became a subjective evaluation given by the patient. These

Figure 1. Exemplificative cases of facial rejuvenation in the different patient groups. Panel A: periorcular wrinkles of a patient in Group A treated with Spherofill Medical Plus (SMP) through the emission of the only promoitalia-radiofrequency radio (P-RFR) wave, before the treatment (1) and at 3 months after the treatment (2). Panel B: striae of a patient in Group B treated with SMP and peeling, immediately before the treatment (1), and at 9 months after the treatment (2). Panel C: acne scar of a patient in Group C treated with SMP and revitalizing substances containing nucleotides, immediately before the treatment (1), and at 9 months after the treatment (2). Panel D: treatment of nasolabial folds of a patient in Group D, before the treatment (1), immediately after the treatment (2), and at 9 months after the treatment (3).



optimal cosmetic effects reached their maximal value 6 months after treatment ($P=0.0001$).

The ultrasound evaluation showed a hyperechogenicity increase after the treatment, a clear sign of hyperreactivity. After 48 hours, the increase of hyperechogenicity persisted in an even more outstanding manner. After 3 months, hyperechogenicity persisted, with the presence of the hypoanaecogen filler in the ultrasound image. After 9 months, the hypoechogen areas reduced to small hyperechogen spots, which was a sign of partial reabsorption of the filler,

favoring a well-organized connective structure (see Figure 2).

To further characterize the effects of the treatment on the skin, histopathological analysis of an area of the abdomen of the patients treated with SMP was performed. Biopsies were taken 5 days after completion of the treatment, as specified in the methods section. The histological analysis, indeed, showed an early inflammatory process with neutrophil recall and an initial process of dermis thickening due to P-RFR waves (see Figure 3).

Figure 2. Ultrasound evaluation of the treated skin at different times. Panel A: the distance between the skin and the osseous layer is 6.3 mm. Panel B: an increase of the hyperechogenicity (more whitish area), a clear sign of hyper-reactivity, is already noticeable. Panel C: the increase of hyperechogenicity persists in an even more highlighted manner. The length between the skin and bone layer goes from 6.3 to 7.2 mm. Panel D: hyperechogenicity is still visible; moreover, dermal thickening with the filler anechogenic image inside is visible. Panel E: filler anechogenic image is still visible.

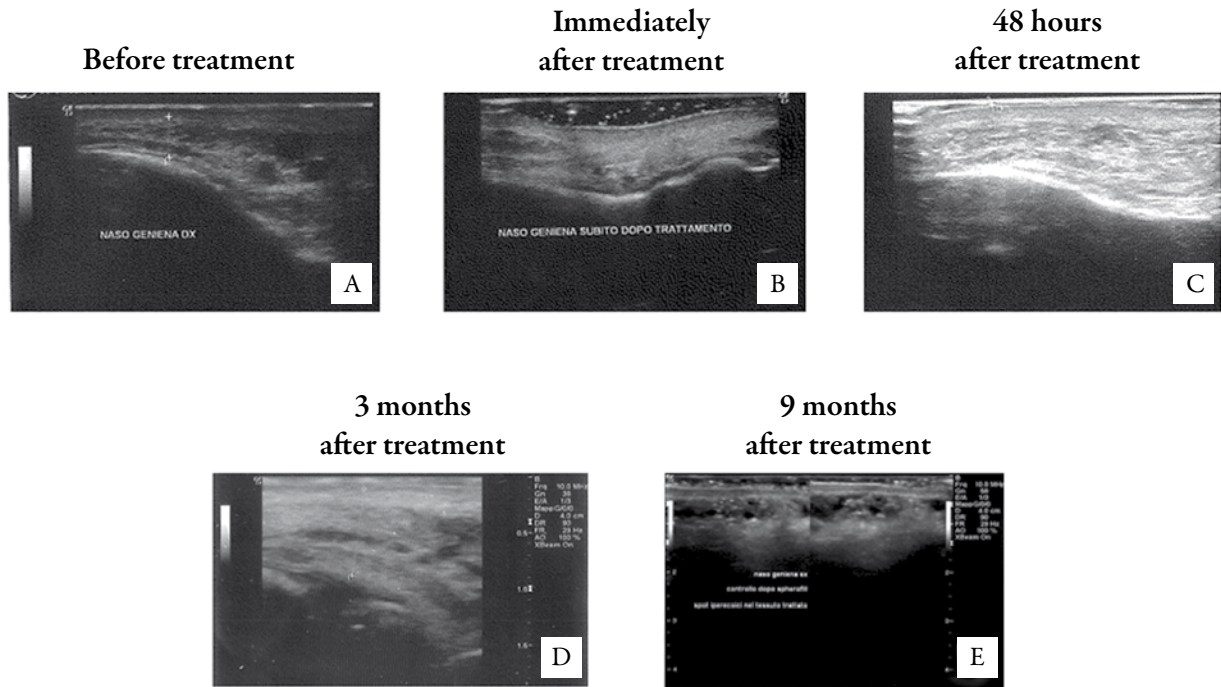
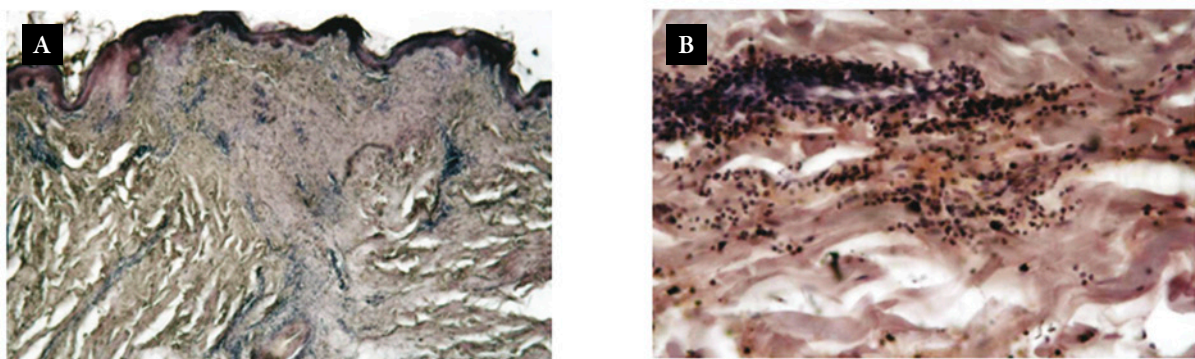


Figure 3. Histopathology of skin and of subcutaneous fat tissue, taken 5 days after the ultrasound treatment. (A) Fibroblasts producing new collagen and initial process of dermis thickening due to promoitalia-radiofrequency radio (P-RFR) waves; (hematoxylin and eosin staining, original magnification x10). (B) Early inflammatory process with neutrophils recall (hematoxylin and eosin staining, original magnification x20).



DISCUSSION

Cosmetic procedures for facial rejuvenation are rapidly increasing amongst men and women. Among nonsurgical cosmetic procedures, the

most widely adopted methods include the use of neuromuscular blocking agents and injectable fillers.⁸ Physicians who administer dermal fillers and neuromodulators must carefully select the patients and discuss with them the benefits and

limitations. Moreover, the physicians should have a thorough knowledge of the characteristics of the injectables and of the anatomy of the area to be treated.⁹ Nevertheless, many aspects of facial rejuvenation still require surgical intervention.¹⁰ However, many of the surgical procedures have significant risks. The increasing patient demand for cosmetic rejuvenation and the strong desire to attain aesthetic enhancement with minimal risk and rapid recovery has led to a great improvement in the techniques of nonsurgical skin rejuvenation. Attention is beginning to focus on the use of wavelengths that preserve the epidermis but deliver enough energy to promote rhytid improvement and skin tightening.¹¹ Currently, noninvasive, nonablative methods of rejuvenation have even surpassed ablative methods in public demand.

SMP is a device that combines the P-RFR wave with substances such as fillers, revitalizers, and peels. The result expected from this combination is potentially a long-lasting effect of the filler and enhanced action of revitalizers and peels. Based on the well-known effects on fibroblast proliferation caused by radiofrequency, our group has created this apparatus that emits P-RFR generating a microheat, which gives origin to a dermal thickening able to extend the duration of the filler, to act synergistically with revitalizers, and to induce support to the peeling. One hundred and twelve patients, divided into five groups, were treated. The results produced were statistically analyzed, and treatment resulted in significant and long-lasting effects. Many studies exist in the literature describing the duration and the effect of the therapy using only fillers.¹⁻⁵ In several of these clinical studies (realized using only the filler, with similar inclusion criteria to this present study), the duration of the filler is 6 months at most. In our experimental conditions, the duration is up to 6 months as described by the GAIS scale. Therefore, long-

lasting effects can be claimed by this present study. Evaluating the patients included in the study, we might reach the conclusion that the treatment with SMP represents a safe and efficient solution for the treatment of wrinkles, acne lesions, striae, and of degenerated tissues caused by aging. The real innovation lies in the possibility of being able to use this device in combination with other well-known methods in the medical-aesthetic field, such as those substances with filling characteristics, both fillers as well as revitalizers and peels, clearly improving its efficiency. A filling/lifting/smoothing effect is therefore obtained, concerning the effects of aging, and a therapeutic effect occurs on acne scars and striae. This system is simple, versatile, and efficient, thanks to its transportability and by the fact that it does not require particular maintenance, besides replacing the disposable needle-electrodes.

Major limitations of the study are the heterogeneity of the patients treated and the lack of a comparable apparatus in the market. Indeed, this is a pivotal analysis and further studies in different clinical settings are required in order to confirm the validity of this system in the aesthetic-dermatological field.

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REFERENCES

1. Buck DW, Alam M, Kim JYS. Injectable fillers for facial rejuvenation: a review. *J Plast Reconstr Aesth Surg.* 2009;62:11-18.
2. De Maio M. The minimal approach: an innovation in facial cosmetic procedures. *Aesth Plast Surg.* 2004;28:295-300.
3. Ogden S, Griffiths TW. A review of minimally invasive cosmetic procedures. *Br J Dermatol.* 2008;159:1036-1050.
4. Duranti F, Salti G, Bovani B, Calandra M, Rosati ML. Injectable hyaluronic acid gel for soft tissue augmentation. A clinical and histologic study. *Dermatol Surg.* 1998;24:1317-1325.
5. Zbili M. Personal experience in the filling of wrinkles and remodelling lips with Juvéderm. *J Med Esth Chir Derm.* 2002;29:241-246.
6. Rokhsar CK, Lee S, Fitzpatrick RE. Review of photorejuvenation: devices, cosmeceuticals, or both. *Dermatol Surg.* 2005;31:1166-1178.
7. Olenius M. The first clinical study using a new biodegradable implant for the treatment of lips, wrinkles, and folds. *Aesth Plast Surg.* 1998;22:97-101.
8. Manna F, Dentini M, Desideri P. Comparative chemical evaluation of two commercially available derivatives of hyaluronic acid (Hyaloform from rooster combs and Restylane used for soft tissue augmentation). *J Eur Acad Dermatol Venereol.* 1999;13:183-192.
9. Friedman PM, Mafong EA, Kauvar ANB, Geronemus RG. Safety data of injectable non animal stabilized hyaluronic acid gel for soft tissue augmentation. *Dermatol Surg.* 2002;28:491-494.
10. Helfrich YR, Sachs DL, Voorhees JJ. Overview of skin aging and photoaging. *Dermatol Nurs.* 2008;20:177-183.
11. Goldberg DJ, Cutler KB. Nonablative treatment of rhytids with intense pulsed light. *Lasers Surg Med.* 2000;26:196-200.