

Controlled heat in the treatment of face chronoaging: evaluation of the efficacy, tolerability and safety of different treatment protocols

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Abstract

Objective: to evaluate the efficacy, safety and tolerance of different face aging treatment protocols using subcutaneous radiofrequency (RF).

Material and methods: obtaining prospective data from patients treated with subcutaneous radiofrequency: the patients with mild, moderate e severe ptosis of the middle face were divided into 2 groups, and were treated by the same surgeon, respectively, with a single subcutaneous radiofrequency session at 50° C, or 2 sessions at a distance of 45-60 days at a temperature of 45° C.

The main criterion for efficacy was the assessment of depth reduction of the naso-labial fold and the malar prominence's restoration after 1, 3 and 6 months, the evaluation of the Global Aesthetic Improvement Scale by the patients and an outside procedure surgeon was the second criteria. The safety of this procedure and the patient's tolerance were evaluated through the observed side effects.

Result: A total of 10 patients, divided into group A (3 women and 2 men), and group B (4 women and 1 men), underwent a subcutaneous radiofrequency procedure with different protocols. In both groups there was a clear improvement in facial laxity with the repositioning of the malar prominence and reduction of the nasal grooves, but what distinguished the two cohorts, was fundamentally the treatment without the need for anesthesia and the intermediate improvement period to a stabilized result, which showed a Global Aesthetic Improvement Scale -GAIS- of 2.8 two months after the first session in the group of patients undergoing two sessions, and a GAIS of 3.4 in the group that performed a single treatment session. This value then became uniform in the following checks in the two cohorts in the following months. Transitory adverse effects, more common for cosmetic procedures such as for erythema and edema, were not observed. One patient had a post procedure hematoma. No serious adverse effects such as burning or scars were reported.

Conclusion: This prospective pilot data confirmed that subcutaneous radiofrequency is safe and effective in improving skin laxity. The patients' satisfaction was high. We believe that both protocols lead to a notable improvement result, but the two-session treatment is experienced by patients in a positive way as they see the results earlier and are psychologically more comforted.

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Introduction

Aging is a natural process, which is especially visible in the face.

The association between the gradual loss of tissue integrity and the force of gravity determines a complex condition.

In 2002, the American FDA approved the treatment of the periorbitary wrinkles by monopolar radio frequency (thermage) and in 2004, its extension to the whole face. The effectiveness of the method is due to the production of heat as the radio frequency waves pass through the tissues (diathermy). The heat induces an immediate effect through the denaturation of the collagen, and a late effect by stimulating the fibroblasts to produce neo-collagen and elastin and by increasing vascularization. The results depend on the distribution, the temperature reached in the target tissue, and the timing¹⁻⁶.

Several studies support the effectiveness of the radiofrequency technology in aesthetic medicine. In the transcutaneous treatment, the limit is represented by the need to avoid causing any damage to the skin, hence by limiting the temperature that can be reached in the subcutis⁷⁻¹⁴.

Therefore, a constant scientific development has made it possible to obtain a new radiofrequency generation that allows the heat produced to reach the subcutaneous tissue in a constant and very precise manner, avoiding the increase in skin temperature.

Subdermal induced heat (S.I.H.) technology[®] is a latest generation radiofrequency with a continuous or pulsed emission of energy and opens the way to the innovation of endodermal radiofrequency, which allows for an alteration of the dermis of the treated tissue with remarkable precision.

The ability to deliver energy and reach preset temperatures at the target tissue level with extreme precision allows for multiple results. Temperatures between 45° and 50° C cause the protein denaturation of collagen fibers with a lifting effect, and secondly a fibroblastic stimulation with the production of neocollagen. A thermal imaging camera monitors the treatment area.

In just a few years, subcutaneous radiofrequency (RF) has established itself as one of the most important innovations in the world of aesthetic medicine, so much so as to require the study of treatment protocols that would optimize the patient's satisfaction.

Materials and methods

After five years of experience, and based on the excellent results obtained¹⁵, a question arose about the optimization of said treatment protocols.

Therefore, we carried out a prospective study on 2 cohorts of subjects with facial chrono ageing.

10 patients with mild, moderate, and severe ptosis of the middle face were included, after obtaining their informed consent. Patients with an ongoing anticoagulant treatment, implanted pacemakers or defibrillator were not included, since this is an absolute contraindication for RF therapy.

Patients with any presence of acute systemic infections and local infections such as herpes simplex or impetigo and those with open wounds in the area of the treatment were excluded. Patients with genetic disorders of the connective tissue, like cutis laxa, were excluded from this trial.

We used the Subdermal induced heat (S.I.H.) technology[®], device for capacitive and resistive diathermy, in monopolar mode, using a partially shielded 15cm cannula needle and a probe transmitting the set energy in the sub-dermal tissue. Monopolar systems deliver the current through a single contact point with an assisting grounding pad, that serves as a low resistance path for the current's flow to complete the electrical circuit.

The procedure was carried out with the patient laying down, on an outpatient basis, using troncular anesthesia for group A patients and local anesthesia at the cannula entry point for group B patients.

Patients have been treated by the same surgeon, respectively, with a single endodermal radiofrequency session at 50° C (group A) or 2 sessions at a distance of 45-60 days at a temperature of 45° C (group B).

The principal efficacy criterion was the assessment of depth reduction of the naso-labial fold and the restoration of the malar's prominence after 1, 3 and 6 months, and the other criteria was the evaluation of the Global Aesthetic Improvement Scale by the patients and an outside procedure surgeon.

Safety and tolerance were evaluated through any observed side effects.

Results

The results of the study are very interesting. In both groups there was a clear improvement in facial laxity with the repositioning of the malar prominence and a reduction of the nasolabial furrows, but what basically distinguished the two cohorts was the treatment without the need for anesthesia, and the intermediate improvement period to the stabilized result, which showed a Global Aesthetic Improvement Scale -GAIS- of 2.8 two months after the first session in the group of patients undergoing two sessions and a GAIS of 3.4 in the group that performed a single treatment session. These values became uniform in the following checks in the two cohorts in the following months (*Table 1, Figure 1*). Histological studies conducted in parallel demonstrate the mechanisms leading to these results.

The images with 3D reconstruction of the face of the patients of both cohorts confirm the lifting effect, but above all the restoration of volumes (*Figures 2-3-4*).

The volumetric increase of the malar-zigomatic region and the reduction of the naso-labial fold demonstrate the lifting effect for both the patients' cohort (*Table 2*). Furthermore, we believe that both protocols lead to a notable improvement in the final result, but the two-session treatment is experienced by patients in a positive way as they see the results earlier.

ENROLLMENT OF 10 VOLUNTARY PATIENTS				
	Group A: 5 patients (3 women and 2 men)		Group A: 5 patients (3 women and 2 men)	
Iconography through QuantifiCare	3D at each follow-up visit		3D at each follow-up visit	
Treatment protocol	Only 50 ° C treatment with troncular anesthesia		Only 50 ° C treatment with troncular anesthesia	
Global Aesthetic Improvement Scale -GAIS- (Values from 1-excellent result to 4- no result) 1 month, 2 months 3 months, 6 months-	1 month	3	1 month	3,2
	2 months	3,4	2 months	2,8
	3 months	2,6	3 months	2,8
	6 months	2,6	6 months	2,6

Table 1 - Study protocol.

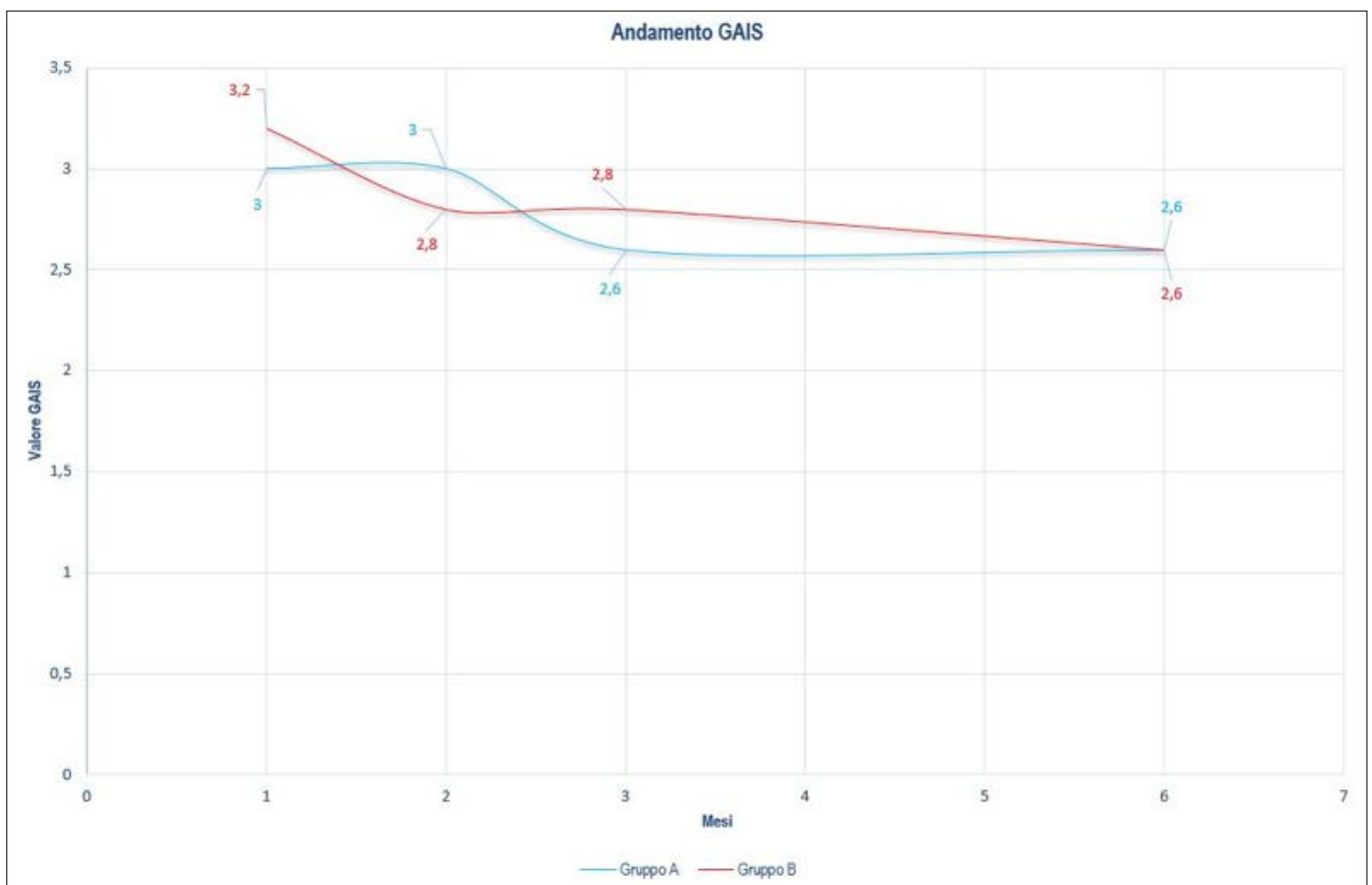


Figure 1 - GAIS trend over time.



Figure 2 - Patient Group B 3D pre-treatment evaluation (SX) after 3 months (DX).

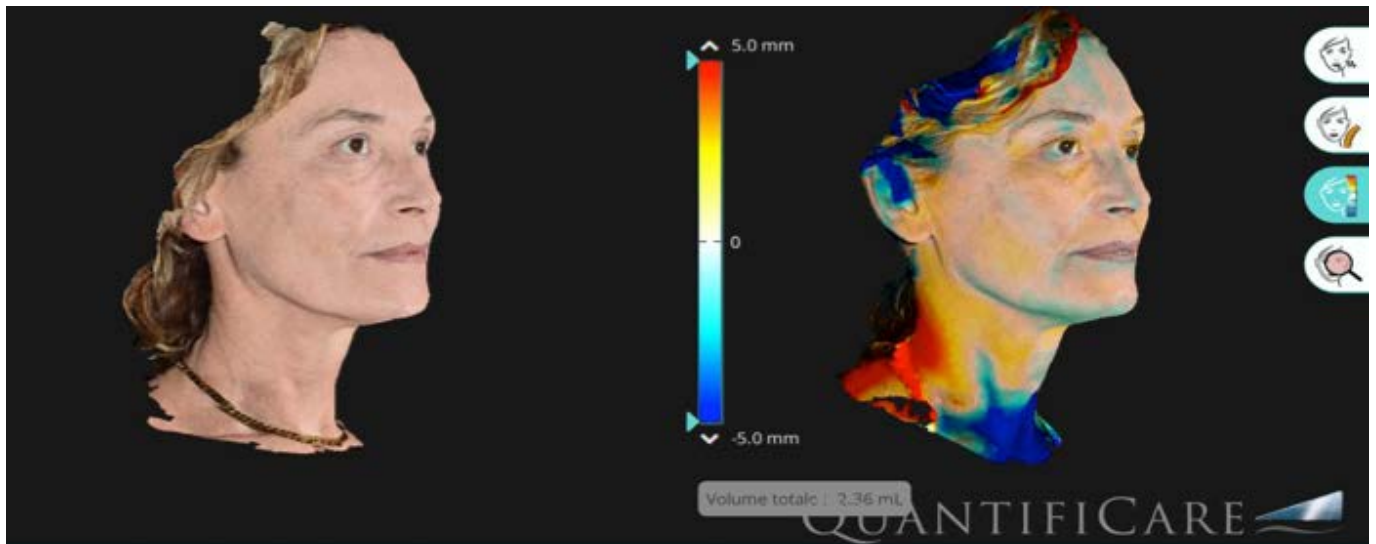


Figure 3 - Patient Group B 3D pre-treatment evaluation (SX) after 3 months (DX): a color scale demonstrates the face volume repositioning.

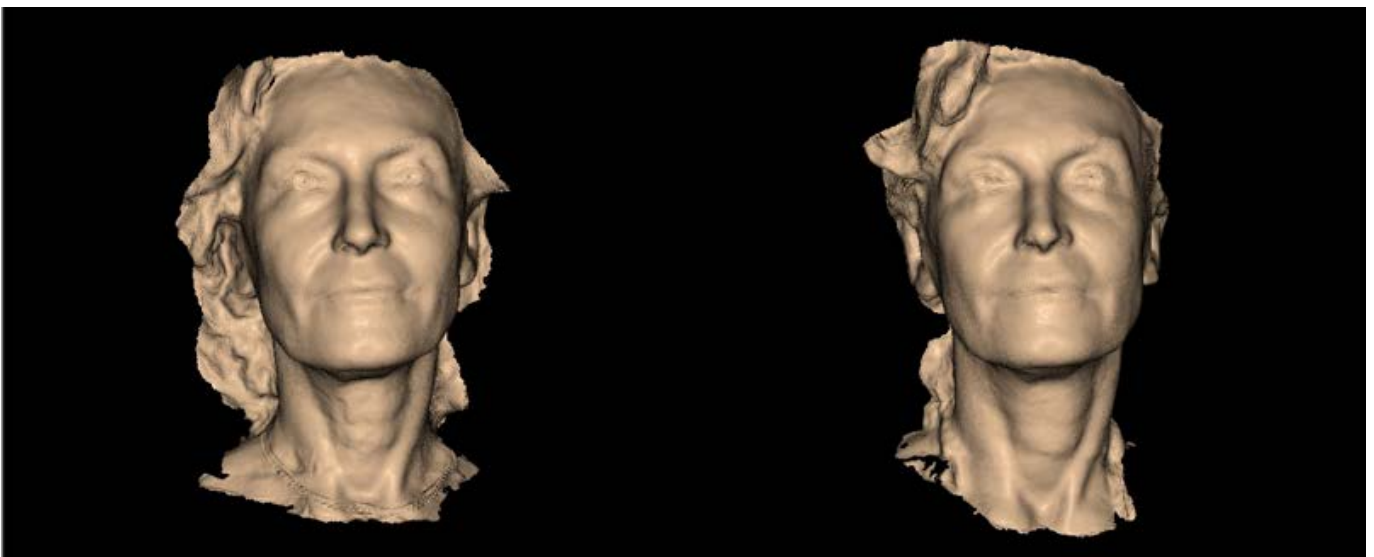


Figure 4 - Patient Group B 3D evaluation of the pretreatment surface (SX) after 3 months (DX).

	Mean volume increase of the malar prominence	Decrease of naso-labial wrinkle
A cohort	2,3 ml	-0,9
B cohort	2,2 ml	-1,1

Table 2 - The volumetric increase of the malar-zigomatic region and the reduction of the naso-labial fold demonstrate lifting effect for both patients cohort.

Discussion

Numerous clinical studies support the efficacy of RF therapy for aesthetic skin tightening of the face and body. The goal of RF therapy is not to replace excisional procedures when indicated, but rather to achieve skin tightening in the “treatment gap” population, broadening the plastic surgeon’s armamentarium.

Seo et al compared facial soft tissue laxity improvements with RF vs a surgical facelift, employing a blinded grading of the photographs. They demonstrated a 49% improvement in the skin’s laxity relative to the baseline for a surgical facelift, compared with 16% for fractional RF. Furthermore, the mean laxity improvement from a single fractional RF treatment was 37% of the surgical facelift’s¹⁶.

Peterson et al also studied objective measurements of mechanical skin properties and demonstrated a statistically significant improvement (5%-12% decrease in Young’s modulus and 10%-16% decrease in retraction time) as well as a 1.42 grade improvement on the Fitzpatrick scale for wrinkles and 0.66 on the Alexiades scale for skin laxity, increasing to an improvement of 1.57 and 0.70, respectively, at 6 months. The patient’s satisfaction was noted to be “very high” for >90% of patients¹⁷.

As demonstrated in this manuscript, our clinical experience has shown a marked improvement in skin laxity and fine wrinkling in both patient groups. Adverse effects were not noted.

Surely this study has limitations, given the small number of patients enrolled and the difficulty of having an objective measure of skin laxity. Multicenter studies and more detailed measurements of these results would be useful.

In our judgment the device is a valid tool with high levels of patient satisfaction.

Conclusion

To our knowledge both protocols lead to a notable improvement in their result, but the two-session treatment is experienced by patients in a positive way as they see the results earlier and are psychologically more comforted.

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REFERENCES

1. Sadick NS, Makino Y. Selective electro-thermolysis in aesthetic medicine: A review. *Lasers Surg Med.* 2004; 34(2):91-97.
2. Zelickson BD, Kist D, Bernstein E, et al. Histological and ultrastructural evaluation of the effects of a radiofrequency-based nonablative dermal remodeling device: a pilot study. *Arch Dermatol.* 2004; 140(2):204-209.
3. Goldman A, Shavelzon D, Blugerman G. Laser lipolysis: Liposuction using Nd:YAG laser. *Rev Soc Brasil Chir Plast.* 2002; 17:17-21.
4. Goldman A. Submental Nd:YAG laser-assisted liposuction. *Lasers Surg Med.* 2006; 38(3):181-184.
5. Arnoczky SP, Aksan A. Thermal modification of connective tissues: Basic science considerations and clinical implications. *J Am Acad Orthop Surg.* 2000; 8(5):305-313.
6. Dierickx CC. The role of deep heating for non invasive skin rejuvenation. *Laser Surg Med.* 2006; 38(9):799-807.
7. Hsu TS, Kaminer MS. The use of nonablative radiofrequency technology to tighten the lower face and neck. *Semin Cutan Med Surg.* 2003; 22(2):115-23.
8. Fitzpatrick R, Geronemus R, Goldberg D, Kaminer M, Kilmer S, Ruiz-Espara J. Multicenter study of noninvasive radiofrequency for periorbital tissue tightening. *Lasers Surg Med.* 2003; 33(4):232-342.
9. Alster TS, Tanzi E. Improvement of neck and cheek laxity with a nonablative radiofrequency device: A lifting experience. *Dermatol Surg.* 2004; 30(4 Pt 1):503-507.
10. Nahm WK, Su TT, Rotunda AM, Moy RL. Objective changes in brow position, superior palpebral crease, peak angle of the eyebrow and jowl surface area after volumetric radiofrequency treatments to half of the face. *Dermatol Surg.* 2004; 30(6):922-928.
11. Fritz M, Counters JT, Zelickson BD. Radiofrequency treatment for middle and lower face laxity. *Arch Facial Plast Surg.* 2004; 6(6):370-373.
12. Koch RJ. Radiofrequency nonablative tissue tightening. *Facial Plast Surg Clin North Am.* 2004; 12(3):339-346.
13. Weiss RA, Weiss MA, Munavalli G, Beasley KL. Monopolar radiofrequency facial tightening: A retrospective analysis of efficacy and safety in over 600 treatments. *J Drugs Dermatol.* 2006; 5(8):707-712.
14. Alexiades-Armenakas M, Rosenberg D, Renton B, Dover J, Arndt K. Blinded, randomized, quantitative grading comparison of minimally invasive, fractional radiofrequency and surgical face-lift to treat skin laxity. *Arch Dermatol.* 2010; 146(4):396-405.
15. Fanelli B, Scuderi N. Subcutaneous radiofrequency: prospective pilot study on safety and efficacy in face chrono-ageing treatment *J Dermat Cosmetol.* 2021; 5(3):57-60.
16. Seo KY, Yoon MS, Kim DH, Lee HJ. Skin rejuvenation by microneedle fractional radiofrequency treatment in Asian skin; clinical and histological analysis. *Lasers Surg Med.* 2012; 44(8):631-636.
17. Peterson JD, Palm MD, Kiripolsky MG, Guiha IC, Goldman MP. Evaluation of the effect of fractional laser with radiofrequency and fractionated radiofrequency on the improvement of acne scars. *Dermatol Surg.* 2011; 37(9):1260-1267.