INDEXED IN INDEX MEDICUS (MEDLINE) SCIENCE CITATION INDEX EXPANDED (ISI)

ITALIAN JOURNAL OF

DERMATOLOGY *and* VENEREOLOGY

OFFICIAL JOURNAL OF THE SOCIETÀ ITALIANA DI DERMATOLOGIA MEDICA, CHIRURGICA, ESTETICA E DI MALATTIE SESSUALMENTE TRASMESSE (SIDeMaST)

CLINICAL OUTCOMES AND PATIENT SATISFACTION AFTER S.I.H TECHNOLOGY®: FOLLOW-UP OF 258 PATIENTS

Benedetta FANELLI, Nicolò SCUDERI

SIDeMaST
1885
Società Italiana di Dermatologia
e Malattie Sessualmente Trasmesse

VOLUME 158 - 2023

EDIZIONI MINERVA MEDICA

PUBBLICAZIONE PERIODICA BIMESTRALE - POSTE ITALIANE S.P.A. - SPED IN A.P. D.L. 353/2003 (CONV. IN L. 27/02/2004 N° 46) ART. 1, COMMA 1, DCB/CN - ISSN 2784-8671 TAXE PERÇUE

Online version at https://www.minervamedica.it

Italian Journal of Dermatology and Venereology 2023;158
DOI: 10.23736/S2784-8671.23.07492-3

ORIGINAL ARTICLE

Clinical outcomes and patient satisfaction after S.I.H technology®: follow-up of 258 patients

Benedetta FANELLI [1] *, Nicolò SCUDERI [2]

[1]Plastic and Reconstructive Unit/Breast Unit, AUSL Latina, Sapienza University, Latina, Italy; [2]Plastic and Reconstructive Surgery Unit, Sapienza University, Rome, Italy

*Corresponding author: Benedetta Fanelli, Plastic and Reconstructive Unit/Breast Unit, AUSL Latina, Sapienza University, Polo Pontino, Viale Pier Luigi Nervi, Latina, Italy. E-mail: benedetta_fanelli@libero.it

ABSTRACT

BACKGROUND: Aging is a natural process. The association between the gradual loss of tissue integrity and the force of gravity determines a condition from which it is complex to go back. The approval by the American FDA of the monopolar radiofrequency (Thermage®) dates back to 2002. Since then, innovation has made great strides up to the development of endodermal technology in recent years which allows subcutaneous probes to act with precision and under careful control on the treated areas.
METHODS: We retrospectively reported our experience in rejuvenation treatments of the face and of different areas of the body using the Subdermal Induced Heat (S.I.H.) technology®, featuring a population of 258 patients who received 502 treatments between 2018 and 2022. Clinical outcomes and patient satisfaction were assessed, respectively by analyzing adverse events and complications at 7 days from treatment, and patient-reported outcome at 3, 6 and 12 months using a 5-point Likert Scale.
RESULTS: Only 25 complications were reported, of which 68% consisted in bruising, 24% in hematomas and 8% in edema. Most patient were reportedly satisfied with overall treatment, with 55% of them being "very satisfied" with the results at 6 months from initial procedure.
CONCLUSIONS: We highlight the manageability of the S.I.H. technology which has been proven to be safe and effective in achieving satisfying results for skin rejuvenation, with a reduced number of sessions required and good maintenance of the results obtained.

(*Cite this article as:* Fanelli B, Scuderi N. Clinical outcomes and patient satisfaction after S.I.H technology®: follow-up of 258 patients. Ital J Dermatol Venereol 2023;158. DOI: 10.23736/S2784-8671.23.07492-3)

KEY WORDS: Aging; Radiofrequency therapy; Rejuvenation.

In the last decades, the use of radiofrequency (RF) in aesthetic medicine has found its way from initial approval to widespread adoption and implementation in routine practice. In 2002, ThermaCool became the first RF device approved for cosmetic use (periocular rhytids) and, in 2004, it received approval for treatment of facial wrinkles and rhytids. In 2006, off-face use was approved. Dozens of RF devices have been approved in the meantime for esthetic applications with various methods used to deliver energy to the dermis and fibroseptal network in the subcutaneous fat.[1] First RF devices used monopolar technology. However, the depth of heating and the involuntary accumulation of heat in the deep layers have been blamed for the destruction of fat.[2] There is also the need to keep the temperature of the epidermis below 44 °C, the threshold for burning the dermis, to avoid complications such as hyperpigmentation, blisters and skin burns. It has been noted that keeping the skin surface at temperatures below 42 °C is essential for safe RF treatments. Therefore, various methods have been adopted to avoid heat build-up such as the rapid movement of the handpiece or the use of cooling devices.[3] Transepidermal RF tissue tightening treatments have an inherent limitation because energy is delivered through the skin surface and the threshold to prevent epidermal burns is significantly lower than the optimal temperature for neocollagenesis. While there are mild benefits to heating the dermis at 45 °C to 60 °C to get partial collagen denaturation, optimal results can be achieved only when dermal temperatures reach 65 °C to 70 °C, when coagulation and collagen denaturing occurs, leading to collagen removal

and replacement.[4, 5] Biopsies have shown no increase in fibroblast numbers with lower energy levels and only collagen thickening/contraction. Conversely, higher-energy levels have shown to achieve a hyperplastic response and increases in cellularity during the wound healing response, which continued for 10 weeks or longer.[6]

In the 1990's and 2000's, ablative and non-ablative lasers as well as fractional technologies were applied in facial rejuvenation with high complication rates (persistent erythema, hypopigmentation, infection, and scarring) and limitations.[7-9] In recent years, transdermal radiofrequency has become a viable option for skin rejuvenation and tightening. To improve the dermal heating and to ensure it spreading evenly and precisely, delivery of heat energy has been implemented through needle cannulas. The Subdermal Induced Heat (S.I.H.) technology® is one of such examples which delivers the desired energy through a millimeter-screened cannula that penetrates the skin going directly into the target tissue to deliver the RF. In this way, an inverse thermal gradient is created, with the highest temperatures in the deepest levels, counteracting the heating of the skin, responsible for the complications. We present our five-year experience with this technology, in the form of a retrospective chart, to establish the safety of SIH technology and patient satisfaction.

Materials and methods

In this study we retrospectively assessed 258 patients treated from 2018 to date. We performed a total of 502 procedures: overall, 398 face V-SHAPE treatments, 48 neck laxity treatments, 12 palpebro-malar bag treatments, 40 body treatments including laxity and adipocytolysis, four scarring fibrolysis treatments.

Patients with implanted pacemakers or defibrillator were not included, since this is an absolute contraindication for RF therapy. Patients with presence of acute systemic infections and local infections such as herpes simplex or impetigo and those with open wounds in the area of treatment were also excluded. Patients with genetic disorders of connective tissue were excluded as well.

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

A first consultation was scheduled in order to provide the patient with all the information concerning the procedure, obtain the signed consent, and to check that there were no contraindications. During this consultation, photos were taken for reference.[10]

Face and neck procedures were conducted under local anesthesia at the cannula entry point and all treatments provided retracting movement. Facial, including the palpebral region, and neck skin laxity were treated using preset, controlled, temperature ranges of 45-48 °C. In the face and neck treatment, 10-cm cannulas were used, instead for the palpebro-malar region 5-cm ones were used. Treatment vectors are schematically shown in Figure 1.

Procedures on the body were performed using tumescent anesthesia with modified Klein solution (1 cc of adrenaline in 500 cc of saline solution, with 20 cc of 2% mepivacaine and 10 cc of 7.5 mg/mL ropivacaine). The treatment program used was "skin laxity" associated in same case with "adipocytolysis." The temperature reached

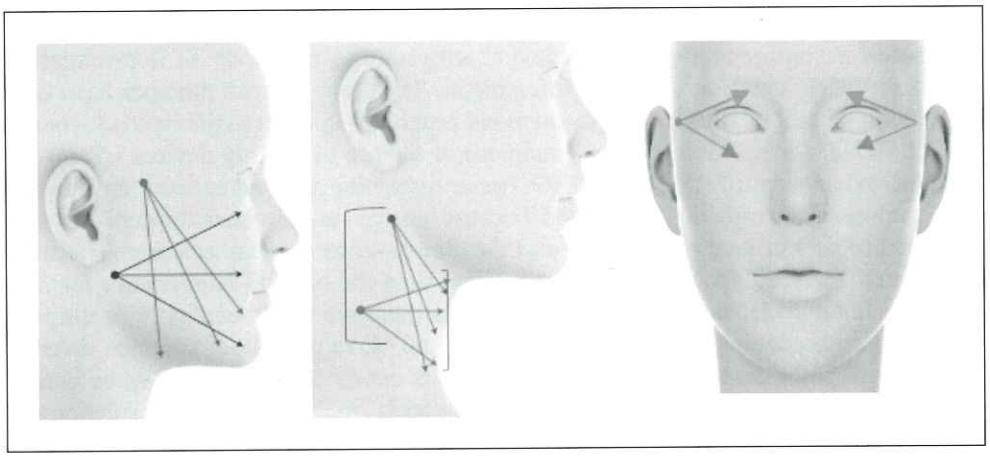

Figure 1.—V-shape vectors, neck laxity vectors, palpebral-malar bag vectors.

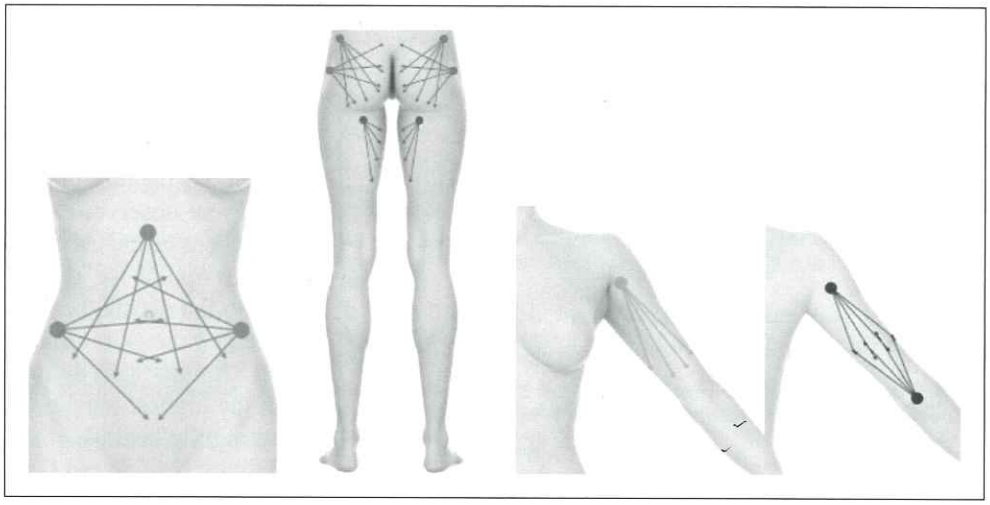

Figure 2.—Body procedures vectors.

Enter your degree of satisfaction with S.I.H. technology treatment here (1 very satisfied, 2 satisfied, 3 uncertain, 4 dissatisfied, 5 very dissatisfied).

1 2 3 4 5

Figure 3.—Five-point Likert-style scale.

for skin tightening was 62-65° C and 70° for adipocytolysis. Larger 20-cm cannulas were used to treat the abdomen, buttocks, lower and upper limbs. Treatment vectors are schematically shown in Figure 2.

Subjects were given a post-treatment questionnaire to assess their comfort and degree of satisfaction. Answers were recorded on a five-point Likert-style scale Figure 3, entered into a database and were analyzed. A follow-up consultation was planned 1 week later to evaluate side effects, 3 and 6 mouth later, and a final control visit look place 12 mouth after the procedure to assess patient treatment outcome recording a five-point Likert-style scale.

Results

This retrospective study included 258 patients with an average age of 46 years. All patients were Caucasians with Fitzpatrick skin phototype I to III.

Overall, 244 patients underwent two treatment sessions, distanced by 45 days from each other. All procedures were performed by the same physician. From the starting population, seven patients dropped out after the first treatment and seven patients performed only one treatment. Each treatment took 40 minutes. In 458 procedures, anesthesia only at the cannula entry point was sufficient, while 44 required tumescent anesthesia with modified Klein solution. Adverse events reported at 7 days from the treatment, are shown in Table I, and feature only 25 reports, of which most cases (68%) were bruising, followed by hematoma (24%) and edema (8%). Patient satisfaction at 3 months, 6 months and 12 months follow-up, assessed by recording the five-point Likert-style scale, is reported in Table II. Graphical representation of clinical outcomes and patient satisfaction are reported in Figure 4 and Figure 5.

TABLE I.—*Adverse events.*

Adverse events on 502 treatments	N.	%
Bruising	17	3.38%
Hematoma	6 (4 in cases of tumescent anesthesia)	1.2%
Edema	2 (palpebral-malar area)	0.39% tot. – 16.6% (palpebral-malar area)
Persistent erythema	0	0%
Burn	0	0%
Pain after treatment	0	0%
Paresthesias	0	0%
Hyperpigmentation	0	0%

TABLE II.—*Patient satisfaction.*

Parameters	Satisfaction rate	N. patients
Patients who have dropped out (dissatisfied - other causes)	2.7%	7
Patient satisfaction 3 months after the course of 2 treatments	50% very satisfied	129
	40% satisfied	103
	10% uncertain	26
Patient satisfaction 6 months after the course of 2 treatments	55% very satisfied	141
	42% satisfied	108
	3% uncertain	9

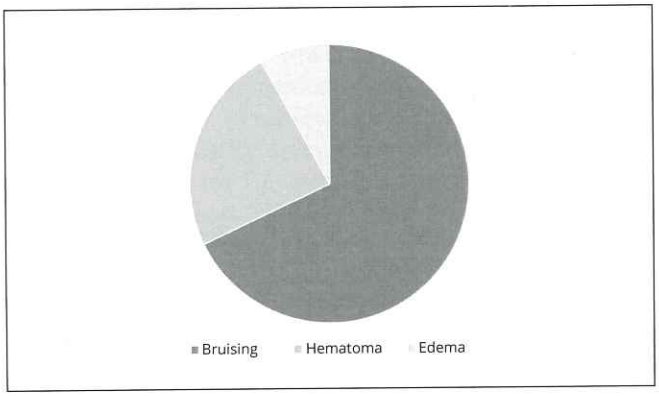

Figure 4.—Distribution of complications following S.I.H. treatment at day 7.

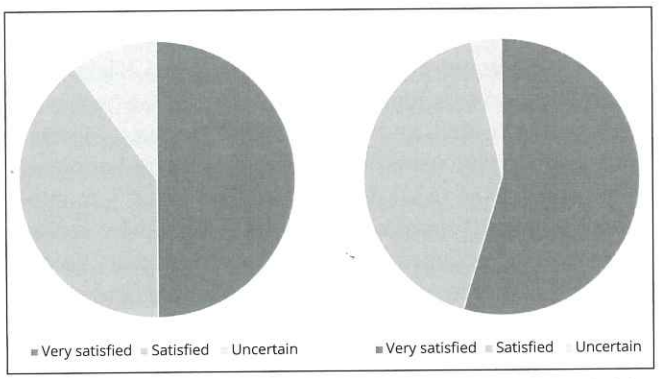

Figure 5.—Patient satisfaction at 3 months (left) and 6 months (right).

Discussion

Over the past decade, the increasing demand for antiaging treatments caused a proliferation of systems such as laser, light-based and RF systems. Non-ablative technology has been steadily replacing traditional ablative systems (long considered the gold standards for skin resurfacing) because of the ability of these non-ablative systems to induce dermal neo-collagenesis without epidermal disruption, thus limiting adverse effects and reducing social recovery.[11-27] Doshi and Alster demonstrated that dual-mode Polaris WR RF/diode laser system for wrinkle reduction and skin laxity showed no significant adverse effects, and 80% of patients reported only mild treatment-associated discomfort.[28] Because of an only "modest" level of success, RF devices were introduced to address these shortcomings and to provide the added benefit of tissue tightening.

A study published by Alster and Tanzi, about the experience with a non-ablative RF device for neck and cheek laxity treatment reported mild post-treatment erythema in all studied patients and persisted for 2 to 12 hours (average of 2.3 hours) after the procedure. Twenty eight of 50 subjects (56%) described a sore or achy sensation in the treated areas after the RF procedure; this was controlled with oral nonsteroidal anti-inflammatory medications. Erythematous papules that resolved spontaneously within 24 hours were observed in three patients (6%).[23]

In recent years, transdermal radiofrequency has become a viable option for skin rejuvenation and tightening, improving the dermal heating a millimeter-screened cannula penetrates the skin going directly into the target tissue of the RF. In this way, an inverse thermal gradient is created, with the highest temperatures in the deepest levels, counteracting the heating of the skin, responsible for the complications. The authors in a recent study report the results of facial rejuvenation treatment by S.I.H technology® with reduction of skin laxity, excellent patient satisfaction and no significant adverse events.[29]

Conclusions

Our clinical experience confirmed lower percentages of adverse events compared to the other technologies used for rejuvenation and treatment of skin laxity, all the while reporting high degree of patient satisfaction. Surely this study has limitations, given the difficulty of having an objective measure of skin laxity. Multicenter studies and more detailed measurements of results would be useful. In our judgment, the device is a valid tool with high levels of patient satisfaction.

References

1. Weiner SF. Radiofrequency Microneedling: Overview of Technology, Advantages, Differences in Devices, Studies, and Indications. Facial Plast Surg Clin North Am 2019;27:291–303.

2. de Felipe I, Del Cueto SR, Pérez E, Redondo P. Adverse reactions after nonablative radiofrequency: follow-up of 290 patients. J Cosmet Dermatol 2007;6:163–6.

3. Alster TS, Lupton JR. Nonablative cutaneous remodeling using radiofrequency devices. Clin Dermatol 2007;25:487–91.

4. Clementoni MT, Munavalli GS. Fractional high intensity focused radiofrequency in the treatment of mild to Moderate laxity of the lower face and neck: A pilot study. Lasers Surg Med 2016;48:461–70.

5. Hayashi K, Thabit G 3rd, Massa KL, Bogdanske JJ, Cooley AJ, Orwin JF, *et al.* The effect of thermal heating on the length and histologic properties of the glenohumeral joint capsule. Am J Sports Med 1997;25:107–12.

6. Abstracts of the American Society for Laser Medicine and Surgery 30th Annual Conference. Phoenix, Arizona, USA. April 16-18, 2010. Lasers Surg Med Suppl 2010;22:1–125.

7. Bernstein LJ, Kauvar AN, Grossman MC, Geronemus RG. The short- and long-term side effects of carbon dioxide laser resurfacing. Dermatol Surg 1997;23:519–25.

8. Preissig J, Hamilton K, Markus R. Current laser re-surfacing technolgies: a review that delves beneath the surface. Semin Plast Surg 2012;26:109–16.

9. Chan HH, Manstein D, Yu CS, Shek S, Kono T, Wei WI. The prevalence and risk factors of post-inflammatory hyperpigmentation after fractional resurfacing in Asians. Lasers Surg Med 2007;39:381–5.

10. Ascher B, Coleman S, Alster T, Bauer U, Burgess C, Butterwick K, *et al.* Full scope of effect of facial lipoatrophy: a framework of disease understanding. Dermatol Surg 2006;32:1058–69.

11. Alster TS. Cutaneous resurfacing with CO2 and erbium: YAG lasers: preoperative, intraoperative, and postoperative considerations. Plast Reconstr Surg 1999;103:619–32, discussion 633–4.

12. Alster TS, Lupton JR. An overview of cutaneous laser resurfacing. Clin Plast Surg 2001;28:37–52.

13. Alster TS, Lupton JR. Prevention and treatment of side effects and complications of cutaneous laser resurfacing. Plast Reconstr Surg 2002;109:308–16, discussion 317–8.

14. Tanzi EL, Alster TS. Side effects and complications of variable-pulsed erbium:yttrium-aluminum-garnet laser skin resurfacing: extended experience with 50 patients. Plast Reconstr Surg 2003;111:1524–9, discussion 1530–2.

15. Alster TS, Lupton JR. Are all infrared lasers equally effective in skin rejuvenation. Semin Cutan Med Surg 2002;21:274–9.

16. Tanzi EL, Alster TS. Comparison of a 1450-nm diode laser and a 1320-nm Nd:YAG laser in the treatment of atrophic facial scars: a prospective clinical and histologic study. Dermatol Surg 2004;30:152–7.

17. Alster TS, Tanzi EL. Laser and light source treatment of clinical manifestations of photodamage. In: Goldberg DB, editor. Photodamaged skin. New York: Marcel Dekker, Inc; 2004. p. 115-43.

18. Alster TS, Tanzi EL. Laser skin resurfacing: ablative and nonablative. In: Robinson J, Sengelman R, Siegal DM, Hanke CM, editors. Surgery of the skin. Philadelphia: Elsevier; 2005. p. 611-24.

19. Alster TS, Doshi S. Ablative and nonablative laser skin resurfacing. In: Burgess C, editor. Cosmetic dermatology. Heidelberg: Springer-Verlag; 2005. p. 111-26.

20. Ruiz-Esparza J, Gomez JB. The medical face lift: a noninvasive, nonsurgical approach to tissue tightening in facial skin using nonablative radiofrequency. Dermatol Surg 2003;29:325–32, discussion 332.

21. Fitzpatrick R, Geronemus R, Goldberg D, Kaminer M, Kilmer S, Ruiz-Esparza J. Multicenter study of noninvasive radiofrequency for periorbital tissue tightening. Lasers Surg Med 2003;33:232–42.

22. Hsu TS, Kaminer MS. The use of nonablative radiofrequency technology to tighten the lower face and neck. Semin Cutan Med Surg 2003;22:115–23.

23. Alster TS, Tanzi E. Improvement of neck and cheek laxity with a nonablative radiofrequency device: a lifting experience. Dermatol Surg 2004;30:503–7, discussion 507.

24. 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;30:922–8, discussion 928.

25. Fritz M, Counters JT, Zelickson BD. Radiofrequency treatment for middle and lower face laxity. Arch Facial Plast Surg 2004;6:370–3.

26. Sadick NS, Makino Y. Selective electro-thermolysis in aesthetic medicine: a review. Lasers Surg Med 2004;34:91–7.

27. Kushikata N, Negishi K, Tezuka Y, Takeuchi K, Wakamatsu S. Nonablative skin tightening with radiofrequency in Asian skin. Lasers Surg Med 2005;36:92–7.

28. Doshi SN, Alster TS. Combination radiofrequency and diode laser for treatment of facial rhytides and skin laxity. J Cosmet Laser Ther 2005;7:11–5.

29. Fanelli B, Scuderi N. Subcutaneous radiofrequency: prospective pilot study on safety and efficacy in face chrono-ageing treatment. J Dermatol Cosmetol 2021;5.

Conflicts of interest.—Both authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Authors' contributions.—Both authors read and approved the final version of the manuscript.

History.—Manuscript accepted: March 13, 2023. - Manuscript revised: March 3, 2023. - Manuscript received: October 24, 2022.

ATTIVA

SUBDERMAL INDUCED HEAT TECHNOLOGY

- FACE LIFTING
- WRINKLES
- SKIN TIGHTENING
- TABOO ZONES LIFTING
- FACE & BODY CONTOURING
- HYPER-HIDROSIS
- DOUBLE CHIN

FDA APPROVED

S.I.H. TECHNOLOGY ™

Subdermal Induced Heat Technology

FOR MEDICAL USE ONLY

TEMA MEDICINA

Tema Medicina S.r.l. | www.temamedicina.it | info@temamedicina.com | Tel +39 051 0828559