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Original article

Subdermal Induced Heat (S.I.H.) technology for malar bags treatment. Preliminary clinical evaluation

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Abstract. The purpose of this study is to present our experience in the treatment of laxity of the malar region using Subdermal induced heat (S.I.H.) technology, a new technology that uses cannulae to bring monopolar radiofrequency (RF) under the skin, to treat malar defects in a minimally invasive, non-surgical way and produce an aesthetic improvement. *Methods:* Ten patients with edema, malar bags and malar festoons had two treatment sessions with S.I.H. technology using a 5 cm cannula at a temperature between 45 and 50 degrees. The overall duration of the bilateral treatment was 360 seconds and the time required for each session was no longer than 20 minutes. No postoperative care was required. *Results:* All the patients in the study showed an aesthetic improvement in the malar region, in relation to the severity of the blemish, through collagen contractions and the production of neo-collagen through fibroblastic stimulation. All the patients were able to immediately return to their normal routine. Although the results were gradual, patient satisfaction was remarkable. There were no complications during the study. *Conclusion:* This new therapeutic proposal that uses S.I.H. technology, guarantees a safe, non-invasive aesthetic improvement in patients with excessive skin laxity of the malar region.

Key words: Subdermal Radiofrequency, malar bags, efficacy

Introduction

Malar bags are a chronic bulging of soft tissues in the pre-zygomatic space. They are their own distinct entity, with a specific location, etiology, and clinical characteristics for which they deserve their own appropriate treatment. In fact, when the bulging is mainly composed of swelling with fluid retention, it is defined as "malar edema". An accumulation of fat is properly referred to as "malar mounds", which may be ptotic, atrophic, or hypertrophic. Conversely, if the bulging is caused by skin relaxation and the underlying orbicularis oculi muscle, it is called "malar festoon", which consists of sagging skin and redundant muscle forming the shape of a hammock underneath the eyelid below the inferior orbital rim. Malar festoons often represent the chronic evolution of malar edema and mounds. Malar bags are commonly associated with other aesthetic defects of other surrounding areas, such as lower eyelid bags with which they are frequently mistaken. These aesthetic imperfections are noticeably more prevalent in the elderly, although they may be present themselves earlier in life, even congenitally[1,2].

There is no current consensus regarding the clinical, diagnostic, and therapeutic options used to approach malar bags.

The correction of malar bags is complex, and the treatment cannot always guarantee improvements comparable to the correction of other aesthetic defects, such as eyelid bags or facial rhytids. Especially in the

early stages characterized by recurrent edema, dermatological treatments, including topical, and systemic drugs can be useful to avoid surgery.

A direct intervention on malar bags can consist of either aesthetic medicine treatments or surgical procedures. The results from the first option are not sufficient to satisfy the requests but can represent the first-choice treatment for mild or moderate defects. They can also be implemented as a useful adjuvant strategy to complement the results obtained surgically, which may not always be sufficient in achieving complete results.

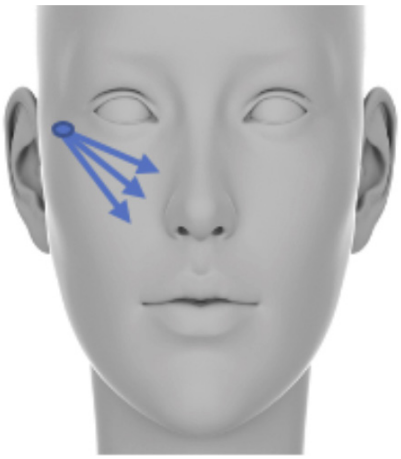

Figure 1. Treatment vectors.

Methods

This was an open trial for malar bags treated with subdermal induced heat (S.I.H.) technology.

In this prospetictive pilot study, ten patients (8 women and 2 men) with an average age of 51.8 years and with heterogeneous malar area imperfections (2 oedema, 4 bags, 4 festoons) were selected and treated. Four patients were smokers. All patients were Caucasians with photo-skin type I to III; the majority (n=8) had a skin type II. Patients with ongoing anticoagulant treatment, implanted pacemaker, or defibrillator were not included since this is an absolute contraindication for RF therapy. Patients with genetic disorders of connective tissue, like cutis laxa, were excluded from this trial.

We used S.I.H. technology, the device for capacitive and resistive diathermy, in monopolar mode, using a partially shielded 5 cm cannula needle and a probe transmitting the set energy in the sub-dermal tissue. Monopolar systems deliver current through a single contact point with an accompanying grounding pad that serves as a low-resistance path for a current flow to complete the electrical circuit.

The procedure was carried out, in a lying position, on an outpatient basis, using local anesthesia (0,2 ml of xylocaine 20 mg/ml) at the cannula entry point.

All treatments provided one entry point for the cannula with a retracting movement (Figure 1).

All patients underwent two treatment session, at a distance of 40 ± 5 days from each other, with a cutaneous lift program (180 seconds in each malar region) with a temperature ranging between 45° and 50° C performed by the same physician.

Each treatment session lasted no more than 20 minutes.

A first consultation (T_0) was scheduled immediately before the treatment in order to provide the patient with all the information concerning the procedure and to check that there were no contraindications. During this consultation, reference photos were taken (Figure 2A).

Two follow-up consultations and pictures were planned 1 week after each treatment to evaluate side

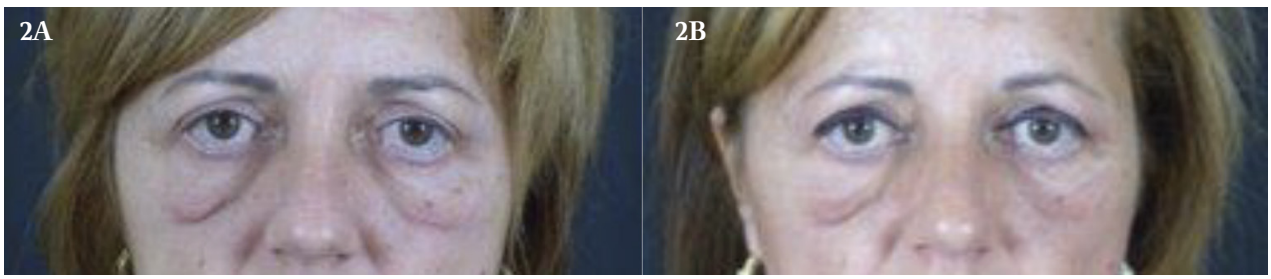

Figure 2. A) Photos pre-treatment; B) 12 months after the procedure.

Rating		Description
1	Very much improved	Optimal cosmetic result in this subject
2	Much improved	Marked improvement in appearance form the initial condition, but not completely optimal for this subject
3	Improved	Obvious improvement in appearance from initial condition, but a re-treatment is indicated
4	No change	The appearance is essentially the same as the original condition
5	Worse	The appearance is worse than the original condition

Figure 3. Global Aesthetic Improvement Scale.

effects (T_1, T_{1bis}), 3 months later (T_2), 6 months later (T_3), and a final control visit took place 12 months after the procedure to assess the treatment outcome (T_4) (Figure 2B).

The global efficacy was assessed by the patient's satisfaction after 3, 6, and 12 months using the Global Aesthetic Improvement Scale (Figure 3).

A blinded score of the photos (T_0,T_3,T_4) was performed by a doctor who was not involved in the treatment. Scoring was carried out by the evaluation of the Global Aesthetic Improvement Scale.

Results

All the patients showed a malar region aesthetic improvement immediately after treatment, in relation to the severity of the blemish, through collagen contraction and the production of neo-collagen through fibroblastic stimulation.

We did not see any serious adverse effects, such as burning, ecchymosis, or pigmentary changes after treatment (T1, T1bis). Two patients reported post-treatment edemas lasting 2-3 days.

Table 1 is a summary of the improvement in the overall appearance of the malar region of the patients

Table 1. Patients Global Aesthetic Improvement Scale.

Patient	Inesthetism	T_2 GAIS	T_3 GAIS	T_4 GAIS
1	oedema	4	4	x
2	bags	1	1	1
3	bags	1	2	2
4	bags	2	2	2
5	festoons	3	3	3
6	festoons	2	3	x
7	oedema	2	3	3
8	festoons	2	2	2
9	festoons	1	1	1
10	bags	1	2	2
Average		1,9	2,3	2,0

Table 2. Blinded Global Aesthetic Improvement Scale.

Patient	Inesthetism	T_3 GAIS	T_4 GAIS
1	oedema	4	x
2	bags	1	1
3	bags	2	2
4	bags	2	2
5	festoons	3	3
6	festoons	3	x
7	oedema	3	3
8	festoons	2	2
9	festoons	1	1
10	bags	2	3
Average		2,3	2,1

using a Global Aesthetic Improvement Scale from 1 to 5 (very much improved, much improved, improved, no change, worsening).

The blinded assessment of the photographs using GAIS is shown in Table 2.

Two patients were lost in the12-month follow-up (20%).

All patients were able to immediately return to their normal routine.

Lasting results were observed, and patient satisfaction was remarkable.

Discussion

In this study, we used S.I.H. in different malar conditions: edema, bags, and festoons being aware that minimally invasive procedures may not be sufficient to eliminate the defect and that surgical solutions, which remain the gold standard, are not always sufficient to ensure a perfect solution and weighed down by a higher number of complications[1].

The use of S.I.H. technology in aesthetic medicine is well established. This technology is effective in correcting facial laxity and repositioning convexities[3,4].

RF treatments allow immediate and delayed results. The immediate result consists of a tissue contraction due to the direct effect of the heat, which translates into soft tissues with a tone increase and a lifting effect. After a few months, the stimulation of the fibroblasts allows an increase in their number and in their collagen, elastin, and hyaluronic acid synthesis activity and an increase in skin firmness[5].

The treatment temperature ranged between 45-50°C which was sufficient to determine the contraction of the collagen without inducing necrosis and to determine tissue regeneration in the medium term in the treatment of light-moderate bags, especially where the skin laxity component is prevalent[1,6].

The possibility of carrying out the treatment through a cannula that acts directly on the target tissue allows to avoid the skin overheating, typical of exodermal RF, in a delicate area such as that of the prezygomatic space in which the skin has transition characteristics between very thin skin of the eyelid and thicker than the malar area.

Conclusion

S.I.H. technology acts on all the etiopathogenetic factors that cause malar bags: relaxation of the skin, relaxation of the orbicularis retentive ligament, of the zygomatic-cutaneous ligament and of the malar septum, excess/ptosis of the adipose tissue and oedematous component, and is applicable to any patient with imperfections in the malar area. The results were excellent in younger people for an active response by a more

biologically subcutaneous response.

RF cannot be considered a substitute for a surgical treatment but can postpone it or allow for a less aggressive intervention[7].

Surely this study has limitations, given the small number of patients enrolled and the difficulty of having an objective measure of the aesthetic improvements in the malar region.

Multicenter studies and more detailed measurements of these results would be useful.

Having considered this, the device appears to be a valid tool with high levels of patient satisfaction.

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