aesthetic medicine

Original Article

Treatment of stretch marks aged more than twenty years with the synergy of electromagnetic field and vacuum. Clinical case studies and subsequent follow-up

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Abstract

Objective: the aim of this study was to verify the efficacy of the synergy between electromagnetic field, electron flow and vacuum realized with Biodermogenesi® method. This synergy was applied on very old (more than twenty years) stretch marks (striae albae - SA) on female patients. The type of stretch marks treated were selected not by location or cause, but by the age of stretch marks. In this case, the study will allow to open a discussion on the possibility to intervene successfully also against the notoriously more difficult types of striae, analyzing the results obtained and the absence of side effects.

Method: 20 women with stretch marks aged more than twenty-years were treated with a treatment program of 9 Biodermogenesi® sessions executed weekly. The treatment was performed with Bi-one® 2.0 MD device, equipped with a generator of electric impulses, electromagnetic fields and vacuum integrated with a bio-feedback system that allows the automatic variation of frequencies and intensities of the electromagnetic field delivered. A subjective evaluation of the outcomes was asked separately to the patients and the researchers; they were asked to evaluate: the filling of the hallow area of the stretch marks, the feeling to the touch of the stretch marks, the discoloration and the eventual tanning of the stretch marks. The evaluation was carried out at T0 (before the sessions - 0%), T1 (after the ninth treatment session) and T2 (after six months from the end of the ninth session cycle). The evaluation scale is as follows:

- Level 0	No improvement	+ 0%
- Level 1	Poor improvement	from +1% to +20%
- Level 2	Minimal improvement	from +21% to +40%
- Level 3	Moderate improvement	from +41% to +60%
- Level 4	Good improvement	from +61% to +80%
- Level 5	Excellent improvement	from +81% to +100%

Results: the improvement of the SA has been evidenced with a tangible filling of those same marks, evident both to the touch and to the sight, and with the recovery of its initial color and subsequently uniform with the surrounding skin tissue. In the subsequent or simultaneous exposure to ultraviolet, we appreciated the tanning of the striae with an intensity very similar to the surrounding skin, in total absence of side effects.
There was also a general increase in the elasticity and compactness of the treatment area.

Conclusions: the synergy offered by Biodermogenesi® method has proven to regenerate even very old SA, which are the most difficult ones to treat. These imperfections were significantly reduced, and in some cases were completely eliminated their evidence to touch and sight, thanks to the newfound power to tan the striae with the exposure to ultraviolet rays. The uniformity of outcomes is appreciated, as all patients reacted positively to the therapy in the absence of side effects.

Keywords
Stretch marks, Biodermogenesi, electromagnetic field, vacuum, electroporation, capacitive radiofrequency

Abbrevations

T0	assessment made before the treatment program
T1	assessment made at the end of the treatment program
T2	follow-up made from 6 to 12 months after the end of the treatment program
PIH	post-inflammatory hyperpigmentation
SA	striae albae
SR	striae rubrae

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Introduction

Since the second half of the twentieth century, stretch marks have increased exponentially among the female gender and has gradually started to affect young boys as well, becoming probably the most widespread imperfection in the new generations.

Biodermogenesi® has shown remarkable effectiveness in the regeneration of stretch marks[1] and post-surgical scars and burns[2], favoring the production of collagen and elastic fibers. The aim of this study is to verify the outcomes of the new synergy developed by Biodermogenesi® on a group of female patients, all burdened by very old stretch marks that are white and opaque in color with a deep and rigid structure.

The new synergy, which combines electromagnetic fields with electron flow and vacuum, provides a number of sessions drastically reduced compared to the previous Bi-one® technology, to regenerate a twenty-year stria; before it required at least 20 sessions.

Stretchmarks that are more than twenty years old are more difficult to work on to obtain a significant improvement.

The existing literature has recently focused on the analysis of the results obtained with various types of lasers, facing some consolidated limits: the greater efficacy documented regarding only the red stretchmarks, and therefore newly formed stretch marks. However, we saw that at the end of laser treatment programs the results were varying from moderate to none and were not replicable on all the patients, especially on SA.

Furthermore the laser procedure caused the constant presence of edema and PIH and a recurrent pain detected by patients.

Briefly analyzing the existing literature in support of laser therapy, we note various evaluations of the results obtained. The results obtained with a non-ablative fractional laser in the experience of Katz et al.[3], limited to only two young patients (12 and 13 years) with striae dated 3 and 10 months, appear positive.

Other experiences speak instead of appreciable results on a part of the patients treated, compared to others whose outcomes have been minimal or none. In this sense, we recall the experiences of Bach and his colleagues[4]: "six of the 22 patients (27%) showed good to excellent clinical improvement from baseline, whereas the other 16 (63%) showed various degrees of improvement".

This is confirmed also by Stotland and his colleagues[5] who confirm that: "photographs of 8 randomly selected patients showed an overall improvement of 26% to 50% in 63% (5 of 8 patients)". Even the experience of Tretti Clementoni has obtained greater uniformity of results[6], he confirms that some patients treated with non-ablative fractional laser do not show significant outcomes: "the volume of SD depressions improved by more than 50% (mean improvement 58%) in the majority of patients (11 of 12 patients) and the color of the lesions improved by more than 50% (mean improvement 54%) in 83,33% of patients (10/12)".

Apart from Katz's experience[3], the other researchers[4,5,6] do not mention the visual appearance of stretch marks (white or red) and their dating.

The experience of De Angelis et al.[21] is based on 51 patients treated with 1540-nm fractional nonablative Er: Glass laser and the evaluation was done both by researchers and blinded, always with positive outcomes, noting a reduction in striae generally greater than 50%.

With the same technology, Farhad Malekzad and coll.[22] evaluated the efficacy on patients with skin phototype between II and V burdened by SA with different outcomes. We note that after 3 sessions, 2 out of 10 patients left the study, 3 out of 10 patients declared no results (no improvement) and 5 poor results (poor); the same patients, after a follow-up of three months, 2 out of 10 declared no results and 6 out of 10 little result.

In addition to the controversial outcomes found by the authors, the non-ablative fractional laser is characterized by moderate pain during therapy[4,6], micro-crusting[6], recurrent edema and hyperpigmentation[4,6] generally reabsorbed in the course of 5/10 days.

De Angelis and coll.[21] recommend to patients a prophylaxis in the month before the treatments and in the following six months.

Particular attention of the present study is reserved to the hypochromia of the dated striae and to the possibility to recover the faculty of tanning by the same ones. This aspect has already been studied in the past, with a therapy based on excimer lasers. Goldberg[22] treated 75 patients with 8/9 sessions per patient, with an attenuation in 60 cases, while in 15 there was no improvement. Alexiades-Armenakas et al.[23] have always performed 9 sessions per patient and have documented a 68% improvement in hypopigmentation but only stable between 1 and 6 months. At the end of the 6 months no residual outcome was found.

The practically zero stabilization of the improvements obtained has limited the spread of this therapy, leaving the problem of hypopigmentation unresolved.

Materials and methods

We analyzed a group of 20 patients aged between 34 and 66 years, all with SA aged between 20 and 35 years, and treated them with a cycle of 9 sessions of Biodermogenesi® on a weekly basis.

The patients were all healthy and did not have any preconditions for being excluded from the trial.

The exclusion criteria are as follows: Pace-Maker users; cancer therapy in progress or during the last 5 years; epilepsy; vascular alterations such as varices, phlebitis and thrombophlebitis; pregnancy or breastfeeding; alterations and hormonal therapies manifested during

the last 6 months; anti-coagulant therapy; phenomena of anorexia or bulimia during the last 2 years.
Biodermogenesi® treatment was performed with an electro-medical device called Bi-one® 2.0 MD, combined with three synergistic active ingredients.
Treated stretch marks were present on the breasts, arms, abdomen, hips, buttocks, thighs, calves; for the cases in question we treated a single area on each patient, as required by the official protocols.

Technology
The treatment was performed with a non-invasive electro-medical device "Bi-one® 2.0 MD" and protected by some international patents (Expo Italia S.r.l., via Segantini, 34, Firenze, Italy). The apparatus was equipped with a generator of electromagnetic fields, an electron flow generator, a pair of vacuum pumps and a series of handpieces.
The generator of electromagnetic fields emits a capacitive shielded signal at a variable frequency, ranging from 0.5 to 1 MHz ± 10%, and variable intensity up to a maximum value of 6W on a 500 Ohm resistance. The device is equipped with a bio-feedback system that allows to change independently the intensity and frequency of the signal delivered according to the different biological characteristics of each individual patient, increasing the temperature of the treated area between 39° C and 40° C.
The electron flow generator emits a 5 Hz square wave signal with a maximum intensity of 0.36 mA on a 500 Ohm load. Generators of the electromagnetic field and of the electron flow are separated mechanically and galvanically from each other and towards the network plant. The brushless vacuum pumps allow delivering negative pressure with absolute precision and stability, with a maximum value of - 0.35 atmospheres.

Procedures
The treatment procedure was divided into two distinct phases, during which several forms of energies are present for different biological actions.
The first phase was about a light mechanical peeling. For this phase, we used a single-use abrasive pad placed inside the PEELING handpiece.
PEELING handpiece works with a gentle vacuum action, designed to lift the tissue with the stretchmarks, bringing the hollow area of the imperfection outwards. The complete deconstruction of the elastic fibers that characterizes very old striae[1,7] allows the striae to extend outwards, bringing the dense and compact corneous layer in relief, favoring a selective reduction.
The second phase, called ACTIVE PLUS, provides the synergistic action of vacuum and biocompatible electromagnetic field generated thanks to a capacitive radiofrequency with variable frequency and intensity. The combination of these forms of energy activates a greater action by the arterial capillaries, it increases the caliber and brings to the matrix oxygen and nutritional elements, stimulates the lymphatic microcirculation, and helps to drain part of the toxins present[11]. The simultaneous flow of electrons, object of the new technology, allows a reduction to the electrical resistance of the skin tissue, effectively amplifying the yield of the electromagnetic field.
As the effectiveness and the useful dose of the applied electromagnetic field is inversely proportional to the electrical resistance; the flow of electrons reduces this value and consequently increases the regenerative efficacy of the electromagnetic field.
At the same time we observe a strong pumping of the Na + / K +, able to increase the fibroblast activity, leading to the synthesis of collagen and elastic fibers[1,7] and favoring a tissue repair [11, 12, 13].
The technology adopted for the present study provides a platform developed by NXP, a company owned by Philips, able to compare the acceleration obtained with sodium and potassium through the cellular barriers:

Previous Bi-one® technology from 300 to 450 mV
New Bi-one® 2.0 MD technology from 750 to 850 mV

Documenting an effectiveness on average by double with respect to the previous technology.
The full treatment session takes about 25 minutes in total. The protocol provides a preliminary evaluation system of stretch marks that determines the level of difficulty and therefore anticipates the patient what the result will be, how many sessions will be needed to obtain this result and how long the treatment cycle will take to be completed. All the patients examined, respected the indications provided by the protocol.

Evaluation
The evaluation of the results of the treatment of stretch marks was carried out by using the VAS (Visual Analogue Scale) scales of the patient and the doctor.
Assessments were made before the start of treatment, during the preliminary visit (T0), after the last treatment (T1) and after a period between 6 and 12 months from the end of the sessions (T2).
The VAS scale asks the patient to make the most of the following parameters:
- Improvement of the stretch marks to the touch (depth and fibrosis)
- Improvement of the visual stretch marks (color and opacity)
- Increase in the faculty of the stretch mark to get a tan

The values are expressed from 0 = 0% (no improvement), from 1 = 1% to 20% (poor improvement), from 2 = 21% to 40% (minimal improvement), from 3 = 41% to 60% (moderate improvement), from 4 = 61% to 80% (good improvement), from 5 = 81% to 100% (excellent improvement).

Results
The results obtained are summarized in the following *Tables 1, 2* (patient's VAS scale) and *Table 3* (doctor's VAS scale). The scales measure the perceived improvement on the treated stretch marks.

VAS Scale - Patient
At the end of the treatment program (T1), 11 patients (55%) found an improvement between 41% and 60%, while 9 patients (45%) found an improvement between 61% and 80%. The perception of the improvement obtained was increased when the follow-up (T2) was performed

Patient	Patient's Age	The presence of stretch marks in years	Area	Patient T1	Patient T2	Doctor T1	Doctor T2
RK	34	> 20	Buttocks	4	5	4	5
CS	52	25	Abdomen	3	5	4	4
GF	43	20	Thighs	3	4	4	4
MR	38	20	Abdomen	3	5	5	5
ML	39	20	Breasts	3	5	4	5
SA	42	22	Abdomen	3	5	4	5
VA	43	20	Abdomen	4	5	3	4
ST	53	30	Abdomen	3	5	4	4
GA	42	20	Thighs	3	3	2	3
IR	66	> 30	Thighs	3	5	4	4
CN	35	22	Breasts	3	4	4	5
LM	58	> 30	Arms	3	4	4	5
SL	43	20	Abdomen	4	5	5	5
SM	41	25	Flanks	4	5	4	4
FM	38	21	Abdomen	4	5	5	5
LA	42	25	Inner Thighs	4	4	4	4
VD	40	24	Flanks	3	4	4	4
LB	48	33	Buttocks	4	4	4	5
HR	36	21	Thighs	4	5	4	5
PMG	34	21	Buttocks	4	5	4	5

Table 1 - VAS scale of the doctor and the patient.

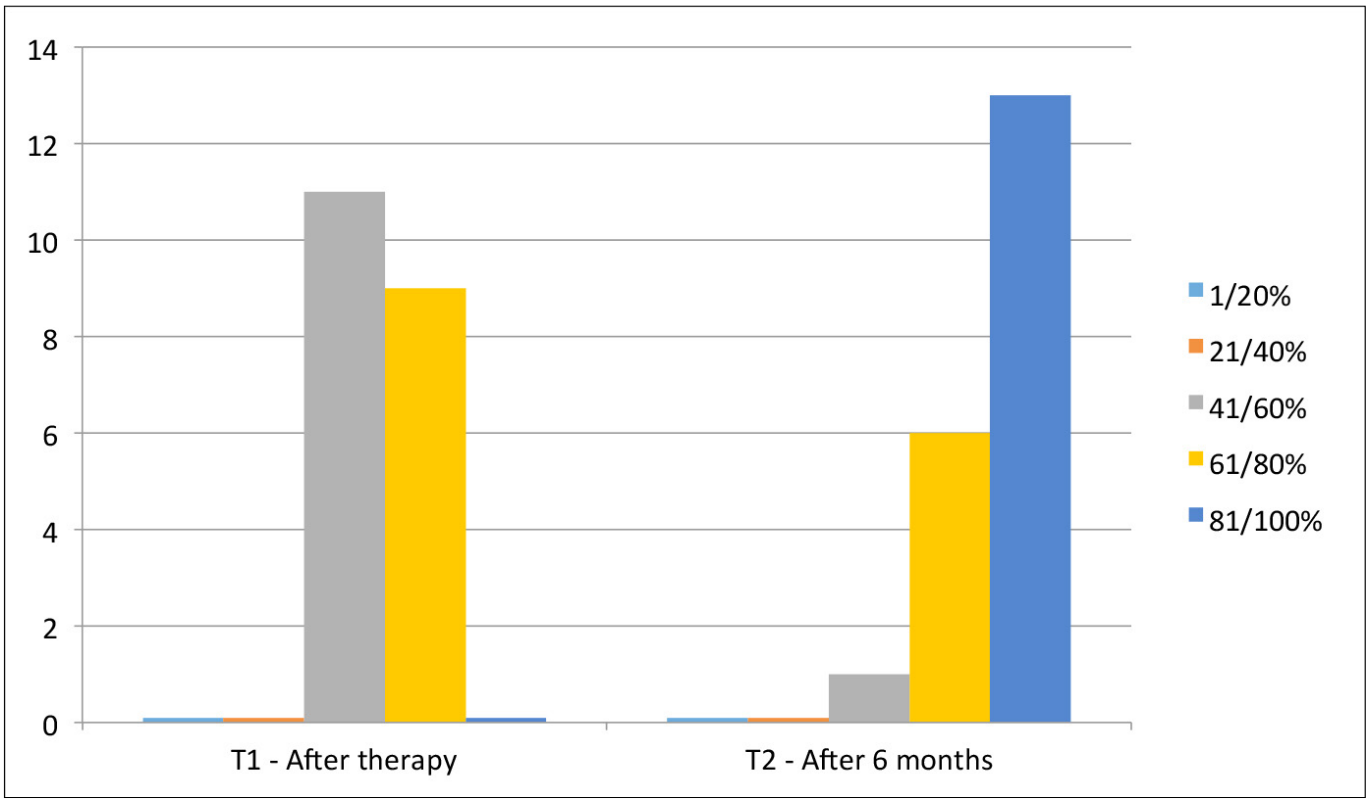

Table 2 - Patient's VAS scale.

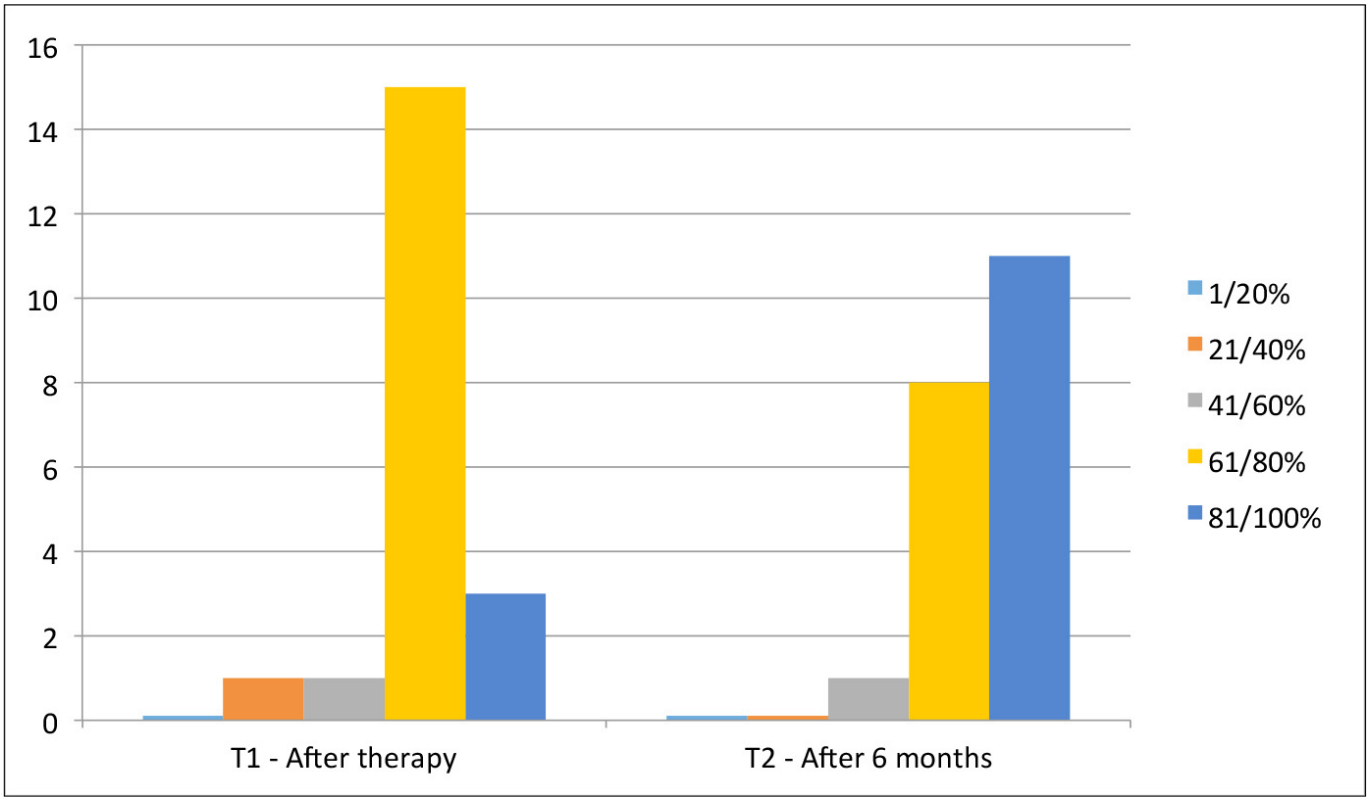

Table 3 - VAS scale of the doctor.

after more than 6 months from the end of the treatment program: 1 patient (5%) found an improvement between 41% and 60%, 6 patients (30%) found an improvement between 61% and 80%, while 13 patients (65%) found an improvement between 81% and 100%.

VAS scale - Doctors

At the end of the treatment program (T1) the doctors in one case (5%) evaluated an improvement between 21% and 40%, on another patient (5%), between 41% and 60%, on 15 patients (75%), between 61% and 80% and on 3 patients, between 81% and 100%. Also the evaluation of the improvements obtained was increased by the doctors during the follow-up (T2): in one patient (5%) they evaluated an improvement between 41% and 60%, on 8 patients (40%) between 61% and 80% and on 11 patients (55%) between 81% and 100%.

Analyzing the documented results, a noticeable overall improvement of the treated stretch marks is evident, both in the evaluation of the patients and the doctor.

In the T1 test, we notice an overall improvement of the SA, which tends to increase in the months after the treatment. The progression of the improvement is due to the activation of virtuous reactions, which we have also found with the previous version of the technology. The reactivation of the sodium and potassium pump allows restoring a better activity of the fibroblast, which physiologically manifests itself in the course of a few weeks after the treatments, during when the maximum regenerative response is obtained by the treated tissue. Another aspect that the patients have greatly appreciated is given by the newfound ability of striae to tan with the sun exposure another aspect that we had found with the previous technology. Early experiences, first of Dr. Artigiani and coll.[1] had documented a recovery of the ability to tan by the stretch marks treated with Biodermogenesi®. This aspect has allowed patients to expose themselves to ultraviolet also during the treatments, highlighting a progressive tanning of the striae. Of course, for the patients living in Sanremo and Palermo who were part of this study, it was much easier to obtain the tanning of the stria as both of the cities are known for their beach attractions.

The stabilization and progression of the outcomes, as shown by the conclusions made in T2, where the appreciation of patients and doctors is consolidated, is confirmed by Bacci[14], who performed a follow-up after more than 5 years from the end treatment with Biodermogenesi®. In his study, Bacci highlighted a general improvement of the results previously achieved, without any regression of the outcomes obtained on the patients.

Unlike what was found with other technologies, the treatment of striae with Biodermogenesi® did not cause pain, discomfort, or any side effects, even minimal, at the end of each treatment session. Patients were able to regain their lifestyle immediately without any limitation.

The choice of evaluating the results obtained with the present therapy by means of the VAS scale exposes to the risk of subjectivity that would not occur with instrumental or bioptic tests. However, we believe that the type of result obtained, which is the filling of the striae, even if they are present for more than twenty years, and their subsequent tanning makes this assessment acceptable. In fact, the filling and the rediscovered capability of tanning of the stretched skin derives exclusively from a reorganization of the epidermis

and the dermis, a restored basal membrane, a correct positioning of the melanocytes and from an adequate dermal vascularization. Basically, to completely tan the striae, it is essential to fully regenerate the skin tissue. In our opinion, the results obtained on all patients adopting t the VAS scale is certainly subjective, but in the specific case it is not questionable.

Discussion

Biodermogenesi® opens up a new perspective in the treatment of SA by applying for the first time a non-invasive method that is not based on damage and subsequent repair. We know that collagen fibers change between 52° and 55° C[15] and contract at 65° C[16] and come to denature between 60° and 70° C[17].
The thermal effect induced by Biodermogenesi® stabilizes the dermis temperature between 39° and 40° C and therefore the variation of collagen and elastic fibers documented bioptically by Bacci[6] and by Artigiani et all. 1 gives us a curiosity about the induced regenerative mechanism, presumably related to the Van't Hoff law.
In the case of Biodermogenesi®, it is believed that the thermal effect is the consequence of the increased activity of Na+ / K+ across the membranes, favored by the applied electromagnetic field [18,19], it determines this reaction for mere friction.
The regenerative faculty of the tissues subject to greater activity by these carriers is amply demonstrated by the literature in sports medicine, in the field of recovery of muscle injuries [11,12,13].
However, the evident improvement of the treated striae is obtained in total absence of side effects.

Conclusions

Biodermogenesi® can be used successfully in the treatment of SA, even if they are very old (more than twenty years), favoring both an aesthetic result and an effective regeneration of dermis and epidermis, as evidently demonstrated by the renewed ability to tan by the striae as a result of correct skin reorganization. All patients treated in accordance with the protocols have noticed a significant improvement in the imperfection, also confirmed by the doctors, with no side effects and without limitations to a normal lifestyle.

Conflict of interest

The authors declare that they have no conflict of interest.

Documented cases

Case 1

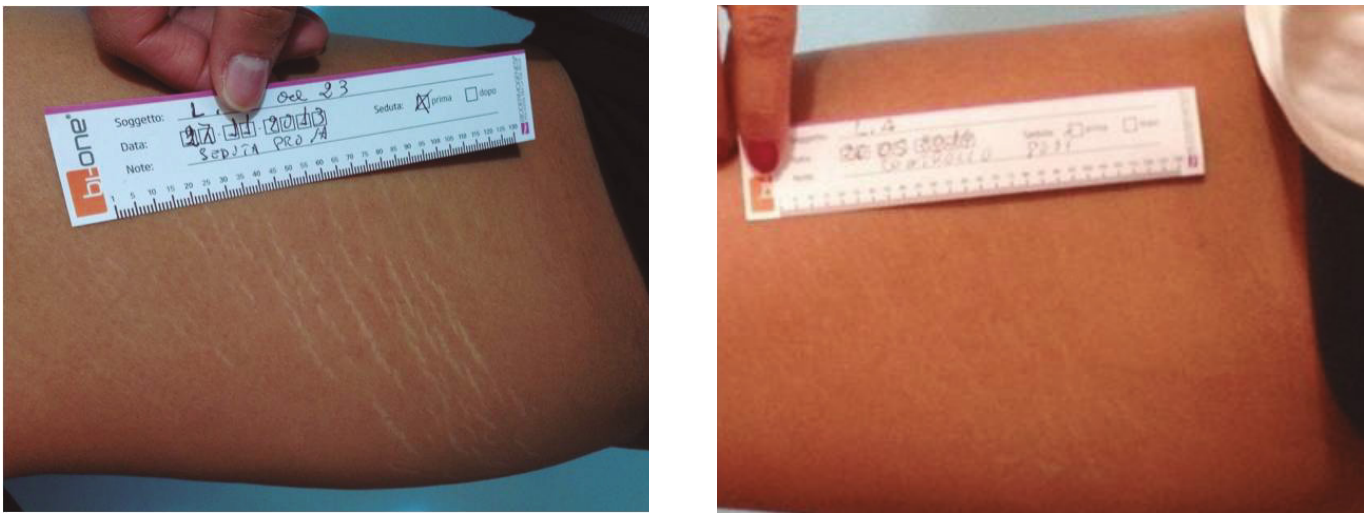

Figure 1 *- L.A., a 42-year-old patient with striae present for 25 years. Pictures taken at T0 and T1 + 6 months. Stretch marks are filled and tanned, uniform to the touch and to the sight.*

Case 2

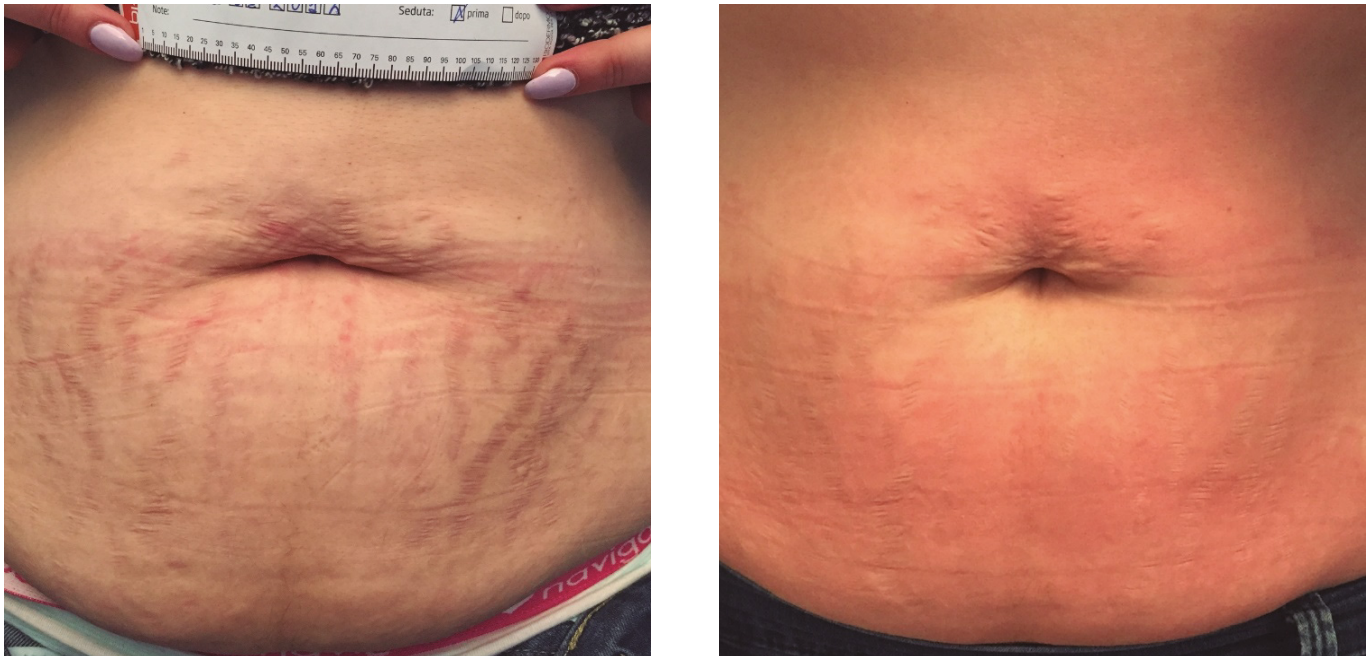

Figure 2 *- S.L., a 43-year-old patient with stretch marks present for 20 years. Pictures taken at T0 and T1 + 6 months. Stretch marks are filled and tanned and at the same time, skin tone has improved. The abdomen is more compact and firm and the navel has reopened.*

Case 3 dx

Case 3 sx

Figures 3 (A-B) *- P.G.M., a 34-year-old patient with stretch marks present for 21 years. Pictures taken at T0, T1 and T1 + 6 months. In the patient in question we appreciate the filling of stretch marks since T1, where they started to pigment due to limited sun exposure. The photo taken at T1 + 6 months highlights an excellent tanning of stretch marks thanks to subsequent sun exposure and the achievement of substantial uniformity with the surrounding tissue.*

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