

The synergy between vacuum and electromagnetic fields in the treatment of striae distensae: retrospective study on 917 patients with clinical and histological case records

A possible treatment for striae distensae

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Abstract

Striae distensae (SD) are dermal lesions that cause evident and unwanted imperfections. They may occur on arms, shoulders, breasts, abdomen, gluteus and legs, usually during puberty and pregnancy. At an early stage they feature a reddish-purple colour (striae rubrae) with an inflamed appearance; at the second stage, which is defined as the chronic stage, they are also marked by hypopigmentation and dermo-epidermal atrophy. During the past twenty years, various technologies have been put forth in the treatment of striae, which have shown encouraging outcomes in some cases. This retrospective study has been conducted on 917 patients that presented stretch marks on their body. Patients underwent a treatment based on the synergy between electromagnetic fields and vacuum; 6 to 9 sessions of treatment were performed for each patient once or twice a week. Clinical evaluation was carried out at the end of the treatment cycle; patients and doctors each rated their level of satisfaction on a scale from 0 to 100%. The outcome was documented through biopsies taken on 20 patients. All patients demonstrated an improvement of their stretch marks and 83% of the patients declared being very/extremely satisfied with the result. The results of the biopsies demonstrated a reorganization of the skin layers and a qualitative and quantitative increase of collagen and elastic fibres and all patients declared a total absence of side effects. The uniformity of the results, patient compliance and lack of adverse reactions proved that the synergy between electromagnetic fields and vacuum is an effective and safe treatment for stretch marks.

Introduction

During the first half of the XXI century stretch marks proved to be the most widespread aesthetic pathology in the world, affecting males and females indifferently from puberty. To date, according to the existing literature, there is no therapy that can be considered totally satisfactory and safe.

Dermabrasion provides a moderate improvement of red striae (1, 2). The percutaneous collagen induction therapy for treating red striae seems to be more effective (1, 3). Manuskiatti et al. (4) reported improvements on stretch marks treated with non-invasive resistive radiofrequency, whilst Dong-Hye Suh et al. (5) had minor results combining resistive radiofrequency with PDL (Pulsed Dye Laser). Shokeir et al. (6) compared IPL (Intense Pulsed Light) with PDL, which

turned out to be more effective, obtaining good results only on red striae. Lee et al. (7) noted an improvement on each patient treated with 10,600-nm CO₂ (carbon dioxide) fractional laser, while Khater et al. (8) claimed to not have observed any improvement in 50% of the cases. According to Yang et al. (9) 41.67% of the patients were unsatisfied with the results, while Tehranchinia et al. (10) achieved unsatisfying results on SD on high phototypes. In a preliminary study on 4 patients, Nouri et al. (11) had no improvement and nullified the research.

Wanitphakdeedecha et al. (12) had good results on almost all patients with Er:YAG fractional laser, on the other hand, Gungor et al. (13) claimed that "We observed no satisfactory clinical improvement in striae distensae alba

lesions although histopathological changes were seen". With 858 nm. Pulsed Dye Laser (PDL) Jiménez et al. (14) had modest results on 20 patients, while Nouri et al. (11) did not achieve any improvement.

Applying 1.064-nm Nd:YAG laser, Goldman et al. (15) reported positive results on early-stage red stretch marks. Elsaie et al. (16) documented a reduction from 5.73% to 13.47% in width of the stretch marks, although the biopsies demonstrated that "clinical improvement on striae are not relevant". Lastly, Gungor et al. (13) did not recommend it for striae alba.

Positive outcomes were consistently reported

by De Angelis et al. (17) using a non-ablative fractional laser on 51 patients; Tretti Clementoni et al. (18) documented that the area of stretch marks showed filling in more than 50% of the cases. According to Guertler et al. (19), initially the reduction in depth of the furrow is equal to 32.07%, which lowers to 28.77% after six months. Contradictory outcomes were demonstrated by Yang et al. (9), a study conducted on 24 Asian patients. Stotland et al. (20) presented the blind evaluation of the results obtained on 8 patients, all of whom declared to have an improvement. Malekzad et al. (21) confirmed a lower performance of treatment on high phototypes.

Materials and methods

This retrospective study involved 917 healthy patients with intact skin burdened by stretch marks that were treated with a synergy between electromagnetic fields and vacuum in 2018-2019. The treatments were carried out in medical practices in Italy, Spain, United Kingdom and Turkey; each doctor documented the results observed on at least twenty patients.

For this study, patients between 15 and 60 years of age were selected, that presented stretch marks of any sort, location and cause, with no limitation of skin phototype.

Exclusion criteria were epilepsy, pacemakers, oncologic therapy undergone in the last 5 years, pregnancy and breast-feeding, open wounds, severe skin inflammation, varicose veins, phlebitis or thrombophlebitis in the area to be treated. All the patients signed the informed consent and agreed to share their personal data for this study. The total of 917 patients showed

Fitzpatrick skin type between I and VI (Table I) with different dating of the striae (Table II), located in different body areas (Table III). Some of them underwent stretch mark treatments on multiple parts of the body, therefore on these 917 patients the results that were documented were obtained on 1.256 different body districts with on average 7.9 sessions per treated part for a total of 9.784 treatments delivered. The causes of the onset of the striae were detected (Table IV, V) and a total of 172 patients with striae rubrae and 745 patients with striae alba were treated. The patients declared to not have undergone other stretch mark treatments in the previous three months and that they would not wear any cosmetic products in the 24 hours preceding each treatment session. The treatments were performed by Bi-one® 2.0 MD and Bi-one® LifeTouchTherapy devices (Expo Italia Srl, Florence, Italy).

Table I. *Patients phototype*

Phototype	I	II	III	IV	V	VI
Patients	22	325	348	105	73	44

Table II. *The age of striae (of the 1.256 treated areas).*

Less than 2 years	2-5 years old	6-10 years old	11-20 years old	Over 20 years old
263	165	278	372	178

Table III. *The body parts with stretch marks (of the 1.256 treated areas).*

Arm	Breast	Abdomen	Kidney area	Gluteus	Thigh	Calf	Shoulder
90	146	322	63	346	215	42	32

Table IV. *Patient age and sex.*

	Women	Men
15-20 years old	92	18
21- 30 years old	309	34
31- 40 years old	291	11
41- 50 years old	99	4
41- 50 years old	65	0

Table V. *The suspected cause.*

Pregnancy	Puberty	Weightlifting	Hormone therapy	Other	No idea
407	221	9	85	64	131

These appliances function thanks to the synergy between electromagnetic fields and low-suction vacuum, usually between 10 and 15 hundredths of bar and with only 3-millimetre

skin dilatation, where the mechanotransduction activates (22). Mechanotransduction converts mechanical information into biochemical signs, increasing cellular conversation and activity; this determines a synergy with the electromagnetic fields also known as “shielded electrode” and affects epidermis and dermis, in fact, a relevant interaction between sodium (Na⁺) and potassium (K⁺) ions - noted for their cell membrane permeability - is appreciated (25). When the shielded electrode is positively charged, it pulls sodium and potassium ions, which are also positive, across the cell membranes through intrinsic proteins (26), consequently enhancing the supply of oxygen and nourishment. A negative phase follows the early positive one of the same duration and intensity. During this phase, sodium and potassium are attracted towards the outside of the cell membrane and become available for a new pumping action.

This technology uses a frequency ranging from 0.5 to 2 MHz and a 4-to-6 W mean power automatically set by the device's bio-feed-back system capable of reading the amount of the energy absorbed by the skin in real time, thus guaranteeing the maximum yield of the treatment and preventing overdose-related risks (27).

The synergy between the electromagnetic fields and the vacuum used is called Biodermogenesi®. A neutral non-alcoholic-based detergent was used to clean the skin before starting the treatment. On wide and sunken striae, a mechanical peeling was performed with a handpiece equipped with an interchangeable abrasive head, made of ISO 5832 standards-compliant non-cytotoxic steel, provided with the device. Afterwards, treatment was carried out by following the operating

protocols to guarantee performance uniformity. The treatment lasted 25 minutes, during which a stimulation of the striae and of the surrounding tissue was provided by the movement of the handpiece along set paths, allowing to combine stretch marks regeneration and skin reshaping, and reduce the effects of gravity.

To corroborate Alberti and Laura's experience (28), who witnessed how stretch marks on 20 patients treated with the technologies that are subject of this study got tanned in total absence of side effects, the patients were invited to expose skin to the sun during the period of treatment.

During the first session, the patients with white stretch marks, excluding stretch marks on the inner thighs, were asked to expose to the sun and check whether the striae were able to positively react to ultraviolet rays and reactivate their tanning ability. Two-hundred-and-ninety-seven patients out of 312, exposed themselves to the sun regularly, encouraged by the fact that the treatment period coincided with Summer. The doctors compared the pictures taken of these patients before and after the treatment cycle and evaluated whether the pearly-white colour of the striae changed after exposure to sun and tanning. Seven days after the last session, the doctors who performed the treatments evaluated the outcome achieved, identifying 5 levels of result using an evaluation form based on the Likert Scale (I - none; II - mild improvement 1-25%; III - moderate improvement 26-50%; IV- good improvement 51-75%; V - excellent improvement 76-100%); in addition, the patient satisfaction score was rated using the following scale: 0 = not satisfied, 1 = slightly satisfied, 2 = satisfied, 3 = very satisfied, 4 = extremely satisfied.

Punch biopsy samples were taken from the most atrophic site of the stretch marks on 18 volunteers with over 20-year-old striae 3mm, before the first treatment and one week after the last one. On 2 volunteers, the second biopsy was taken after 2 sessions done 2 days apart. The sections of the excised skin were stained with haematoxylin and eosin and Masson trichrome stains; a

dermatologist and an anatomopathologist evaluated the histological samples.

The doctor's evaluations and the patients' satisfaction were assessed using the Wilcoxon Signed Rank test to compare the final data and the starting point; P less than 0.05 was considered significant.

Results

The outcomes of the treatments were documented with VAS scale according to participants and doctors (Table VI). No patient declared to be unsatisfied, 2.47% of the patients declared slight

satisfaction of the results (31 body areas), 14.57% declared to be satisfied (183 body areas), 41.64% declared to be very satisfied (523 body areas) and 41.32% extremely satisfied (519 body areas).

Table VI. VAS scale according to the participating patients and doctors.

	VAS doctor	VAS patient	
No improvement	0 (0%)	0 (0%)	Unsatisfied
1-25% of improvement	24 (1.91%)	31 (2.47%)	Slightly satisfied
26-50% of improvement	184 (14.65%)	183 (14.57%)	Satisfied
51-75% of improvement	485 (38.61%)	523 (41.64%)	Very satisfied
76-100% of improvement	563 (44.83%)	519 (41.32%)	Extremely satisfied

The evaluation of the doctors basically confirmed what had been declared by the patients: no improvement on 0 body areas (0%), mild improvement between 1-25% on 24 body areas (1.91%), moderate improvement between 26-

50% on 184 body areas (14.65%), good between 51-75% on 485 body parts (38.61%) and excellent improvement between 76-100% on 563 body areas (44.83%). The renewed ability of stretch marks to gradually tan has been particularly

appreciated by the patients.

One week after the end of the treatment cycle, the doctors examined the 297 patients that exposed themselves to the sun; the pigmentation of the striae was evident in all of them. Stretch marks were darker in colour, more similar to the surrounding skin tissue and in some cases perfectly uniform and becoming invisible.

Upon first sun exposure which took place after 3/4 treatment sessions, the striae almost reached erythema and started to gain colour progressively, sometimes with less intensity than the surrounding tissue. In contrast to reports regarding other types of technologies, the vacuum

stimulates skin remodelling, as documented by Moortgat et al. (23) while the electromagnetic field enables cellular and molecular multiplication (24) and skin reparative actions.

The electromagnetic field is generated through a high-frequency electrical signal directed to a specific handpiece with an electro-conductor inside. The external part is covered with a dielectric to prevent the signal from being discharged on the patient. The dielectric, relevant and uniform outcomes have been achieved on patients with phototypes V and VI as well as tanning of the striae.



Fig. 1. A young man with striae rubrae probably due to heavy weightlifting workout. After a treatment cycle the stretch marks are less evident and now tanned in a similar way to the surrounding skin tissue. Courtesy P.A. Bacci, Arezzo – Italy.

The treatment was found to be safe, in fact only two patients out of 9.784 total sessions

monitored by us had adverse reactions limited to mild skin erythema that dissipated on its

own within a week. A few minutes after the therapeutic treatment the patient felt a pleasant warmth, which lasted at least a few hours after the treatment terminated. Once the session was completed, the skin appeared blood-bedewed but not reddened. Since the treatment does not have any downtime, the patients can return to their normal daily routine without any limitation.

The biopsies taken on the 20-year-old white stretch marks confirmed the doctor's evaluation. Before starting the treatment session, all patients presented loss of volume of stretch mark epidermis and dermis, flattening of basement membrane, and collagen fibres destructured and parallel to the stratum corneum. In the bioptic

analysis conducted at the end of the treatment cycle, an overall restructuring of the skin layers was noticeable: the epidermis was well-structured; the basement membrane has recovered its correct sinusoidal shape, a fundamental element to melanocytes, which, founding their correct position, enable stretch marks to tan when exposed to the sun; and the dermis has gained volume and new collagen fibres, being no longer parallel to the stratum corneum as in the case of the skin tissue featuring stretch marks.

The biopsies taken after two sessions confirm the presence of skin regeneration and show a mild but evident increase in collagen and elastic fibres.



Fig. 2. A patient with skin phototype V and 18-year-old stretch marks. After a 6-session Biodermogenesi® treatment cycle the stretch marks are filled and have the same colouring as the surrounding skin. Courtesy M. Wade – London, UK.

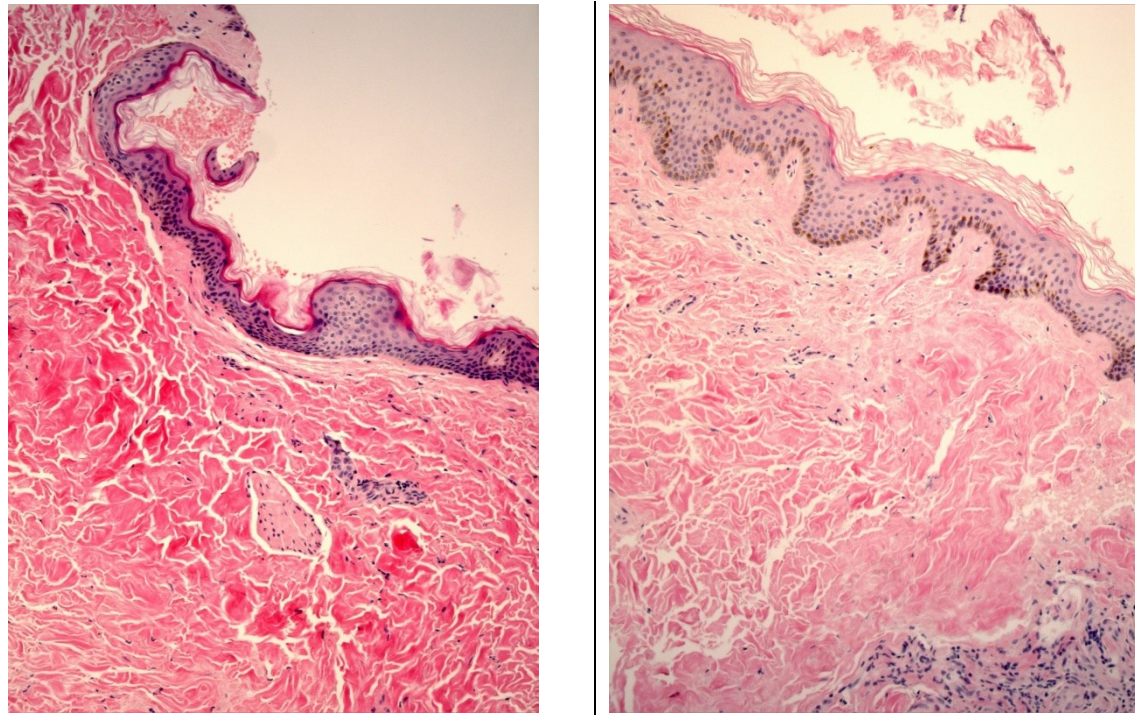


Fig. 3. The biopsies before and after a 7-session Biodermogenesi® treatment cycle on a patient with skin phototype VI and 25-year-old striae are presented above. We witness the reorganization of epidermis, basement membrane and dermis, where a qualitative and quantitative increase in collagen fibers is noticeable. Courtesy A. Artigiani, Pisa, Italy.

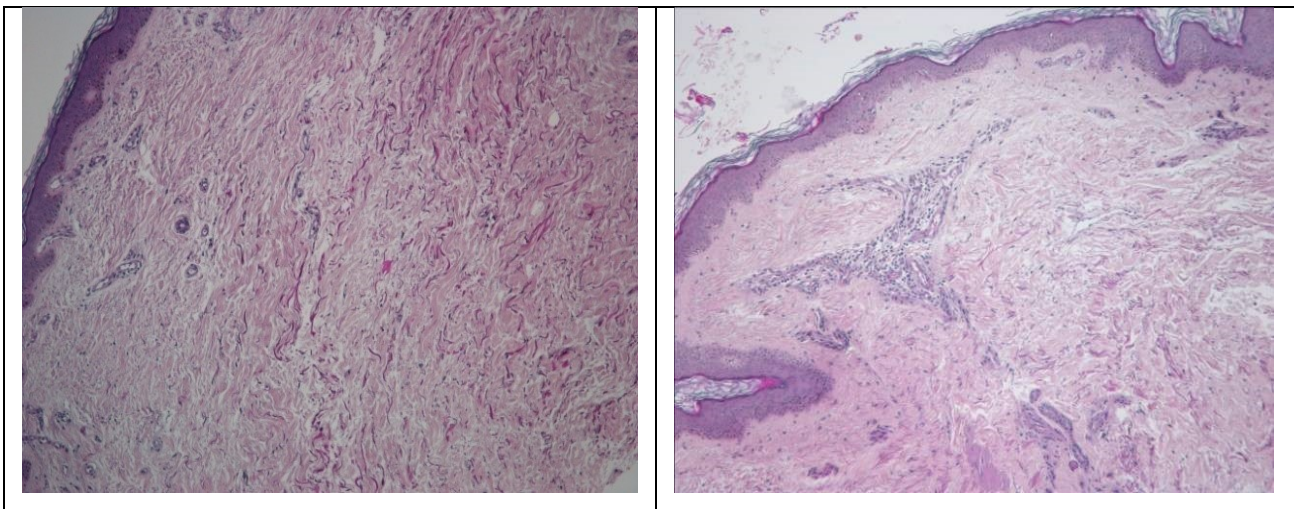


Fig. 4. The biopsies before and after two Biodermogenesi® treatment sessions, two days apart on a patient with skin phototype II and 20-year-old striae. The microscopic analysis shows a mild but evident increase in collagen fibers. Courtesy P.A. Bacci, Arezzo, Italy.

Discussion

We have to reflect on many limits of the previous studies executed on stretch marks treatments. The outcomes are generally documented on a

low number of patients, sometimes 1 or 2, mostly between 10 and 40, with only one exception of a maximum of 51 patients (17) (non-ablative

fractional laser). Another limit is the lack of objective reports on the outcomes, like biopsies; moreover, when the biopsies are present, they are usually very few, from 1 to 4, and basic factors like the age of the patient, the dating and the severity of the striae are not provided. Through the comparison of those biopsies with Hague's (29) description of red and white striae's structural alterations, much more affinities with red stretch marks are found. A further limit is the often contradictory results mentioned in the pre-existing studies, where the researchers observed different outcomes although they used the same technologies.

Our perceptions are validated by other researchers (29) who claim that "No treatment has proved to be completely effective", Elsaie et al. (30) states that "None of the existing therapeutic options offer a complete treatment", Sardana (31) argues that in literature there are no high-quality studies involving a large number of patients and objective checks to guarantee a therapeutic prospect replicable on a high number of patients. First of all, the current study differs from the others for the significant number of patients with heterogeneous features and different skin phototypes coming from various Countries, which means for the first time there is a relevant sample for purpose of replication; having 20 biopsies taken on stretch marks of which dating and patient's phototype are known, together with the amount of information provided, makes this study more reliable than the others, with the awareness of the fact that such a wide pathology is worth a more detailed and specific comparative histological investigation.

The other difference is the patients' high level

of satisfaction, with the 83% of patients rating the result as "good" or "excellent"; an additional confirmation is the assessment of the tanning, as a matter of fact stretch marks on all 297 patients who regularly exposed to the sun regained pigmentation.

All this data, together with the total absence of side effects, allows us to affirm that Biodermogenesi® is an effective and safe therapy that opens new and interesting perspectives in stretch mark treatment.

The comparison between the side effects arising from the synergy between vacuum and electromagnetic fields and other cutting-edge technologies is simple; comprehending that the contraindications of other treatment methods are mild, short-lived or statistically rare, the synergy matter of this study is preferred to the other methods for its lack of side effects, its safety and tolerability.

From 2008, P.A. Bacci conducted many studies on this technology (32), which have formed the basis for more recent developments. It is worth mentioning that, in the treatment of striae, Artigiani et al. (33) of the School of Dermatology at the University of Pisa achieved an actual regeneration of the skin tissue in total absence of side effects and histologically documented a qualitative and quantitative increase in the collagen and the elastic fibres. Alberti et al. (28) presented the restructuring of the skin featuring stretch marks by documenting its renewed ability to tan when exposed to sun and consequently the reorganization of the basement membrane and the reactivation of melanocytes.

Nicoletti et al. (34) documented the effectiveness of the treatment on post-surgical and burn scars

by underlining the reorganization of elastic fibers and collagen with no side effects. Considering the previous experiences, uniformity of the results obtained, patient compliance, the almost total absence of side effects, the downtime and the renewed ability of stretch marks to tan, it can

be asserted that Biodermogenesi® is considered the most suitable treatment for its effectiveness, safety, tolerability, and replicability on stretch marks regardless of the age of the striae and the phototype of the patient.

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