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ORIGINAL ARTICLE

V-EMF therapy: A new painless and completely non-invasive treatment for striae gravidarum

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Abstract

Background: The appearance of striae gravidarum (SG) during pregnancy is a common problem. The most common SG are abdominal striae, which can cause the greatest sequelae after pregnancy, and in the long term. There are several solutions to prevent and treat these striae, but not all are completely effective, and not without side effects.

Aims: The aim of this study was to evaluate the effectiveness of a treatment that applies an electromagnetic field under vacuum (V-EMF therapy) on the abdominal SG.

Methods: A retrospective analysis was conducted on the medical records of 26 women affected by abdominal SG and treated with V-EMF therapy. The results were evaluated using two different 5-point Likert Scales: one administered to the treated subjects to evaluate their satisfaction, and one to the doctors who performed the treatment, to evaluate the improvement of the striae. The presence of side effects, and the effects of sun exposure after treatment were also considered.

Results: Only two treated subjects rated their level of satisfaction with a Score III on the Liker Scale. Everyone else expressed higher levels of satisfaction. Only one doctor rated the improvement of the striae with a Liker scale score of III. All the others reported greater improvements. No discomfort or side effects were noted either during the individual treatment sessions, or at the end of the treatment. The striae showed a newfound ability to tan.

Conclusions: V-EMF therapy proves to be a valid, safe, and effective treatment modality for SG.

KEYWORDS
connective, elastic fibers, electromagnetic field, striae gravidarum, V-EMF therapy

1 | INTRODUCTION

A recent study defines striae gravidarum (SG) as a common skin condition during pregnancy.[1] This is not a new concept. By performing a bibliographic search on the PubMed database, using the term "striae gravidarum," 122 articles were identified. By adding the term "common" in the search filters, only 30 of the 122 articles remain (<25%).

Although not explicitly defined as "common," their presence is documented with very high prevalence rates. Already in 1949, in one of the first studies to talk about them, Aagaard reported a prevalence of 80%–90%.[2] In the literature, many extremely variable rates have been identified (range 25%–88%), probably depending in some cases on the definition of the studies. Of the 36 studies identified in PubMed that reported prevalence data, 26 had rates between 52% and 80%.

There do not appear to be large differences in percentages related to ethnicity and skin color. Incidences higher than 70% have been reported in Caucasian,[3,4] Asian,[5–9] and Middle Eastern populations.[10–13] There are no data on African populations, and therefore on dark skin, but in his study, Chang reported a higher incidence of striae in non-white women compared to white women (77.8% in non-whites vs. 45.2% in whites).[14] This demonstrated that SG is indeed a common and widespread problem.

As regards the risk factors most linked to their appearance, there are young age at pregnancy,[1,9,10,15–24] the fact that it is the first pregnancy,[21,25] a large abdominal circumference before pregnancy,[13,17,19] high body mass index both before pregnancy,[4,9,10,13,16,18,20,21,23,24,26] and during pregnancy,[1,9,13,18–21,27,28] previous presence of other striae,[14,16,17,20,25] excessive weight gain during pregnancy,[1,15,17–19,21–23] weight of the newborn,[1,4,9,13,15,18,20–24] and family history.[1,4,9,10,13–22,27,29]

It should be specified that the term "striae gravidarum" refers to a set of striae that develop in different anatomical locations: lower anterior abdominal wall, lower quadrants of the breast, hips, thighs, and buttocks.[1,2,21,30–37] The greatest incidence is in the abdomen, where larger striae develop. Abdominal SGs are those for which there is the greatest number of reports in the literature, perhaps because they are also those that produce the greatest sequelae after pregnancy, and in the long term. They undoubtedly have a negative impact on the women both psychologically and on the quality of life.[3,16,38,39] Furthermore, the presence of striae seems to be a predictive marker of the risk of intraperitoneal adhesions in the event of repeated caesarean sections,[40–46] perineal trauma during childbirth,[47–49] and pelvic organ prolapse.[50] There also appears to be a correlation between the presence and severity of striae and the presence and severity of stress urinary incontinence,[51] pelvic floor pain,[52] low back pain,[53] and obstetric anal sphincter injury during childbirth.[54]

Considering the frequency with which SGs develop, and their possible sequelae, the need to prevent their formation or to treat them in case of onset is evident. As regards prevention, topical treatments are mainly used, with contrasting results, sometimes apparently effective,[55–60] sometimes ineffective,[61] and sometimes with worse final incidences compared to untreated subjects studied as controls.[62–64] As regards the treatment, in addition to the use of the same topical agents, there are various methods currently in use, but none of them is always effective in all women considered.[15,20,36]

The aim of this study is to present the results obtained on SGs with the application of a therapy, recently introduced for the treatment of non-pregnant stretch marks (SMs).

2 | MATERIALS AND METHODS

2.1 | Study population

We performed a retrospective chart review of patients scheduled for treatment of abdominal SGs, in 2022. The study was conducted in full compliance with the ethical norms and standards of the Helsinki Declaration of 1975, as revised in 1983. An informed written consent statement for data use, and publication was obtained from all subjects.

The criteria for excluding patients from accessing treatment were: presence of pacemaker, epilepsy, open unhealed wounds, history of oncological surgery or therapy in the previous 5 years, history of anorexia or bulimia in the previous 2 years. The inclusion criterion in the study was: patients must not have undergone previous instrumental treatments for striae.

2.2 | Treatment

The treatment was delivered with the subject lying supine on a table. Before starting each session of treatment, a neutral non-alcoholic cleanser was used on the skin. The treatment consisted of nine weekly sessions of vacuum and electromagnetic field (V-EMF) therapy performed with the Bi-one® Life Touch Therapy device (Expo Italia Srl, Florence, Italy), each lasting 25 min. The treatment was delivered via the external probe of the Bi-One device, slid over the area affected by the SGs, that is, in a completely non-invasive way. The probe operates in a vacuum regime (100–150 mb) and, at the same time, delivers an EMF with a frequency range varying between 0.5 and 2 MHz, and an average power between 4 and 6 W. This variability depends on a biofeedback system of the device, which controls the amount of energy absorbed by the skin, in relation to the thickness of the skin itself, and automatically regulates the current emitted, avoiding pain, and burns.

Patients were asked not to use topical SM products during the entire treatment course. At the end of all treatment sessions, patients were asked to expose themselves to the sun at least once, for 2–3 h at the hottest time of the day, to detect any skin reaction at the SGs level. In fact, it is known that striae do not tan, being an atrophic tissue.

2.3 | Data collection and evaluation

Patients were asked to report any sensation of discomfort or pain felt both during the sessions, between one session and another, and at the end of the entire treatment. They were also asked to report

any side effects, both at the level of the treated area (such as redness, hyperemia, and lesions) and general (e.g., appearance of fever).

After each single session, the patient's report of discomfort or pain was noted in the medical record. Before each session, following the first, the report of the appearance of discomfort, pain, or side effects resulting from the treatment was also noted in the medical record.

If a patient complained of discomforts, pain, or side effects, the doctor had to evaluate the severity (mild, medium, or severe), and the extent (SGs only, localized to the treated area, extended beyond the treated area), and report them in the medical record. He/she had to evaluate and justify any decision to temporarily or permanently suspend the therapies. In case of side effects, he/she also had to indicate the duration of the effects (<8, 8–60, >61 days), and any treatments prescribed.

To evaluate the aesthetic results, two different 5-point Likert Scales were used, one for the treated subjects, and one for the doctors who performed the treatments. Assessments were performed at 1-month follow-up, using a VAS scale.

To test the level of satisfaction of the treated subjects, relating to the aesthetic results obtained, a scale was used, called Scale A, whose levels were: I—dissatisfied; II—moderately satisfied; III—satisfied; IV—very satisfied; V—extremely satisfied.

To test the level of satisfaction of the doctors who had performed the treatments, a level relating to the aesthetic improvements of the individual patients, a second scale was used, called Scale B, whose levels were: I—worsening or no outcome; II—improvement between 1% and 25%; III—improvement between 26% and 50%; IV—improvement between 51% and 75%; V—improvement between 76% and 100%.

To evaluate the improvement of the striae, the doctor noted in the medical record the level of depression and the size of the striae before treatment and 1 month after the end of treatment. He/she also tested skin firmness and tone using the pinch test.

3 | RESULTS

A total of 26 patients were considered in the study. Six were treated at the Medical Centre for Vascular Diseases and Aesthetic Pathologies, in Arezzo, Italy, and 20 at the Universidad Autónoma de Barcelona, Spain. In Italy the treatments were performed by a single highly experienced aesthetic surgeons. In Spain the treatments were performed by three highly experienced aesthetic surgeons.

Subjects ranged in age from 28 to 65 years (mean 48 years), with skin tones II–IV according to the Fitzpatrick classification. The striae were dated from 6 to 38 years (mean 25 years) after onset. Therefore, they were striae distensae, atrophic, white, and opaque in appearance.

All subjects completed the entire treatment within the expected time and manner. No subject reported any sensations of discomfort or pain during individual sessions or between sessions. No side effects occurred either during or at the end of the entire treatment.

The results of the subjects' satisfaction ratings are shown in Table 1.

Based on the doctors' assessments, all treated subjects had an improvement in the appearance of their striae, which were less depressed and smaller in size. The skin was more compact and toned (Figure 1).

The results of their assessments with respect to the percentage of improvement detected are shown in Table 2.

All patients had also exposed the treated areas to the sun, following the instructions received, and using the sunscreen usually used. After exposition, the skin appeared red, indicating reactivation of melanin (Figure 2).

4 | DISCUSSION

The discussion about what striae are, and how they should be treated has been going on for a long time. Already in 1982, for instance, Pieraggi et al.[65] defined them as dermal lesions with specific alterations of both fibroblasts and connective tissue, alterations completely different from those observed in scars and wrinkles. They recognized them as belonging to the group of connective tissue dystrophies. Almost simultaneously, in 1985, Zheng et al.[66] called them scars. Both of these studies used ultrastructural analysis to draw their conclusions.

Numerous other studies have investigated the anatomo-morphological, physical, and mechanical characteristics of striae.[67–74] Of particular interest are the studies by Borrelli et al.,[67] and Ud-Din et al.,[68] who reconstructed the pathological, and histological path of striae formation. In the first phase of the striae rubrae, they observed the triggering of a process characterized by the activation of macrophages, by a characteristic neo-angiogenesis, and by a gradual but clear differentiation of the structure of the ECM, both at the level of

TABLE 1 Levels of patient satisfaction with the appearance of striae 1 month after the end of treatment.

Patients' satisfaction		
Likert Scale A Levels	**Number of subjects**	**Percentage of subjects (%)**
I	0	0
II	0	0
III	2	7.7%
IV	13	50%
V	11	42.3%

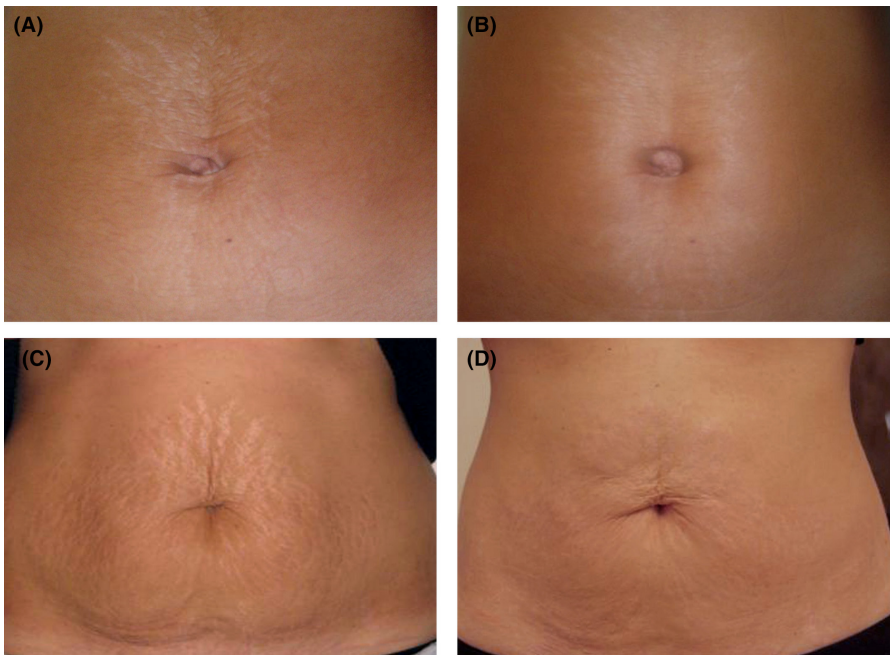

FIGURE 1 Effects of treatment at 1-month follow-up. (A) Radius striae around the umbilicus before treatment in Subject 1. (B) Striae after treatment in Subject 1. The reduction in the number of striae is evident. Residual striae are no longer depressed. Skin tone looks better overall. (C) Radius striae around the umbilicus before treatment in Subject 2. (D) Striae after treatment in Subject 2. In addition to the marked reduction of striae, complete restructuring of the entire abdominal wall is evident.

TABLE 2 Evaluation of the doctors who had performed the treatment on the degree of visual improvement of the striae.

Doctor's evaluation		
Likert Scale B Levels	**Number of doctors**	**Percentage of doctors (%)**
I	0	0
II	0	0
III	1	3.8%
IV	13	50%
V	12	44.2%

the collagen components, and the elastic fibers. In the second phase of the striae distensae, the maturation of the striae rubrae was observed, with a reduction in vascularization, linked to the atrophic process, and the consolidation of the structural alteration of the ECM.

The structural characterizations of both elastic components and collagen have been extensively investigated by Wang et al.[69,70] and in other studies.[71–74] Collagen bundles expand, and a disorganized structure of collagen fibrils is generated.[69,71,72] Elastic fibers are broken down, and thin tropoelastin-rich fibrils are synthesized and arranged in a completely disorganized manner.[70,73–75]

Knowledge of the structure of the striae allows us to state that a treatment of the striae, to be effective, must act first of all at the level of the dermis and hypodermis, on the components of the ECM.

V-EMF therapy has recently been applied to a whole series of skin disorders in which there is a structural degeneration of the ECM, such as scarring,[76–78] aging,[79] and in SMs present on the buttocks, in correspondence of the gluteus medius and maximus muscles.[80] In all these studies, the application of EMF performed under vacuum conditions led to a normalization of the physical and mechanical properties of the skin, with an increase in skin tone linked to an elasto-collagen rebalancing. This restructuring appeared evident in the bioptic study performed by Scarano et al.,[80] who analyzed both the elastic and the collagenic components.

The results of the present study were not obvious. The abdominal SGs, although always SMs, are in fact generally wider and longer than the SMs present in other parts of the body. They also affect a large area of the body. The fact that the minimum level of satisfaction reported by the treated subjects was Level III on the Likert scale (still a level of full satisfaction), and that only 2 patients out of 26 reported it, while all the others presented greater satisfaction with what concerned the results obtained, highlights the success of the treatment. This success was also confirmed by the doctors' evaluations who, except one, reported a clinical improvements of more than 50%.

The absence of discomfort, during the sessions, or side effects, after the individual sessions, and after the entire treatment, is what is most striking, given that the women participating in the study had the opportunity to immediately return to their daily lives without the need to take precautions (e.g., use of topical products) and without having to take any type of medication (e.g., painkillers, anti-inflammatories, and antibiotics). This aspect is extremely interesting because it differentiates V-EMF therapy from all other known treatments against SMs. Laser and microneedling can be painful during application, to the point that the latter may require the use of local anesthetics.[15,20] In general, mild and transient side effects have been reported (mild erythema, edema),

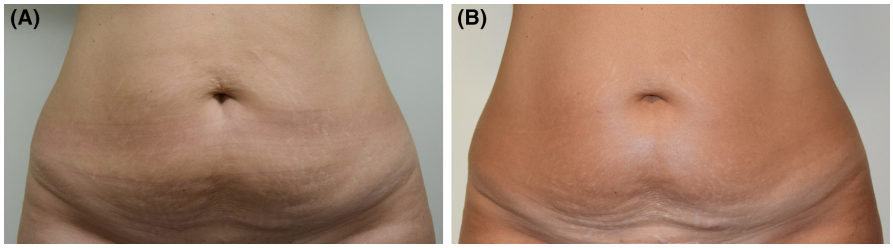

FIGURE 2 Effect of sun exposure after treatment. (A) Subject 3 before treatment, with evident concentric striae around the umbilicus and vertical striae in the sub-umbilical region. (B) Subject 3 after treatment and after sun exposure, with pinkish-looking striae.

but post-inflammatory hyperpigmentation, crusting, and bruising were documented.[15,20,36]

Another interesting result of the present study is given by the renewed ability of the skin to tan, which confirms the reactivation of melanin, already highlighted by Nicoletti et al.,[76] and by Scarano et al.[80] Although this seems to be a secondary phenomenon, it is not, both in aesthetic terms, and above all from a biological point of view, because it means a complete regeneration of the treated tissues, in all their components.

The results obtained can be explained by considering the characteristics and physico-chemical properties of the device and the EMF used, and by analyzing the induced biological effects.

The simultaneous application of vacuum to EMF is essential to increase the effectiveness of treatment, as demonstrated in wound healing.[81] The vacuum causes a dilation of the skin of 3 mm, activating mechano-transduction, that is, the transformation of mechanical traction in biochemical signals.[82,83] Both metabolic and catabolic reactions are therefore favored by the increase in ionic exchanges. An amplification of tissue reactions occurs, with activation of endothelial cells, fibroblasts, and myofibroblasts, and, consequently, cell replication and angiogenesis are promoted.[84,85]

The EMF is generated by a capacitive radiofrequency, in which the capacitor has for plates/armatures:

- The application electrode insulated with epoxy glass, covered with a disposable non-cytotoxic PVC cap (dielectric);
- The components of the skin tissues with insulating properties.

Between these two armatures, the EMF induces a flow of ions in the tissues, correlated to an endogenous diathermic effect (temperature increase of 1–2°C). In fact, part of the kinetic energy of the ions is transformed into heat (Joule effect).[86–88] According to Van't Hoff's law, heating the tissues favors an increase in metabolic reactions. An increase in microcirculation occurs, associated with an increase in the number of gas exchanges between blood and tissues. Consequently, there is also an increase in catabolic drainage products, and in the diapedesis of granulocytes, macrophages, and cells involved in inflammatory and reparative processes. Senescent and/or damaged cells undergo the "cell killing" effect.[89–92] Finally, the thermal increase leads to an overall analgesic effect, with muscle relaxation, and an increase in the elasticity of the connective tissue.[90,93–95] This is reflected in the sense of well-being perceived at the end of therapy.

In addition to the diathermic effect, capacitive EMF also determines a second effect, which is a magneto-mechanical effect. The latter manifests itself above all at the connective tissue level, due to the piezoelectric characteristics of this tissue. The effect consists in a structural deformation of the connective tissue, which lengthens and expands, favoring the resolution of fibrotic states, and causing a complete restructuring of the ECM.[96,97]

The main limitation of this study is that it was performed on only 26 women. Further studies with larger numbers of subjects and with additional systems for evaluating improvements are needed. However, given the dating of the striae, the results are extremely relevant and promising. The other limitation of this study is that the data in the literature on the interaction of the specific EMFs used in V-EMF therapy with tissues are few and conflicting.[98] Consequently, this interaction can only be hypothesized, but more in-depth studies are needed to understand the real responses of the different tissues that make up the skin and subcutaneous tissues. And, above all, to understand the real responses of these tissues when alterations are present, as in the case of SGs.

5 | CONCLUSIONS

This study on V-EMF therapy, combined with the previous ones present in the literature, seems to consolidate the validity and effectiveness of the action of this therapy on skin problems that affect, in particular, the structural component of the ECM. Abdominal SGs are fully included among these skin problems, and among the conditions that could benefit from the V-EMF therapy.

AUTHOR CONTRIBUTIONS

Sheila Veronese: conceptualization, data curation, formal analysis, methodology, validation, visualization, writing—original draft and review and editing; **Pier Antonio Bacci**: data curation, formal analysis, investigation, methodology, writing—review and editing; **Victor Garcia-Gimenez**: data curation, formal analysis, investigation, methodology, writing—review and editing; **Casiana Cecilia Canel Micheloud**: data curation, formal analysis, investigation, methodology, writing—review and editing; **Norma Laura Haro García**: data curation, formal analysis, investigation, methodology, writing—review and editing; **Andrea Sbarbati**: conceptualization, formal analysis, investigation, project administration, validation, writing—original draft and review and editing.

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No funding was received for this study.

CONFLICT OF INTEREST STATEMENT

None.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ETHICS STATEMENT

Authors declare human ethics approval was not needed for this study. The study was conducted in full compliance with the ethical norms and standards in the Declaration of Helsinki.

INFORMED CONSENT

All the participants gave informed consent for the publication of their data.

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