

FEASIBILITY STUDY FOR THE USE OF ELECTROMAGNETIC AND NEUROMUSCULAR MUSCLE STIMULATION AS A COMBINATION THERAPY FOR BODY CONTOURING, WITH WONDER DEVICES.

María A. Barajas, MD. Santander University Hospital, Colombia.

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BACKGROUND: Electromagnetic and Neuromuscular muscle stimulation are treatments currently used separately by different disciplines such as neurology, physiotherapy and sports medicine.

OBJECTIVE: To establish the efficacy and safety of the joint use of electrical and electromagnetic muscle neurostimulation for noninvasive contouring of the abdomen, hips, and legs.

METHODOLOGY: This was a non-randomized, prospective, open and multi-centered feasibility study, in which 12 patients from Madrid, Spain were chosen to undergo a working protocol of 16 sessions of the Wonder Prestige device in a period of 8 weeks and its effect on three body parts- abdomen, buttocks and thighs.

RESULTS: A significant reduction in the measurements of the body parts worked and a weight loss between 5-15% from the initial weight was obtained in all participants. Sex and age were not determining factors. Among the adverse effects reported, localized redness and minor pain

with spontaneous resolution, that was already foreseen, were found. It should be noted that patients reported a noticeable improvement in the definition and appearance in their body shape.

CONCLUSIONS: This feasibility study is the first to satisfactorily establish the efficacy and safety of electromagnetic and neuromuscular muscle stimulation treatment as a joint therapy in Wonder Prestige brand aesthetic medical equipment, as a non-invasive procedure for body contouring.

Key words: Aesthetic Equipment, Electric Stimulation, Magnetic Field Therapy.

I. INTRODUCTION

At present, appearance and beauty, as physical qualities are part of the 8 dimensions that make up a human being, which also comprise the integral concept of what health is, understanding this not only as the absence of disease, but as a full state of physical, mental and social well-being.

This desire for beauty dates back to ancient Egypt, as the cradle of the first aesthetic treatment and the origin of aesthetic medicine with the famous Ebers Papyrus, one of the oldest known medical treatise in which cosmetic formulas are described and sketches are presented along with other medical specialties such as ophthalmology, gynecology, plastic surgery, among others.

Subsequently, during the first half of the 20th century, with the increase in life expectancy and the purchasing power of the population, the demand for aesthetic treatments increased and with it, the development of techniques to restore and maintain beauty and health. Aesthetic medicine as we know it today, seeks to use effective, safe and least invasive procedures.

This is how new procedures are constantly being developed to improve the appearance of skin, reduce wrinkles and expression lines, tone and sculpt the body silhouette, and even treatments from other areas of knowledge have been taken for aesthetic purposes. This is the case of Neuromuscular Electrical Stimulation (NMES), which was introduced for the first time in sports training in Russia around 1970, establishing the bases for subsequent research applied not only to the field of sport, but also in the field of clinical, aesthetic and therapeutic fields, being used, for example, as a treatment for facial paralysis or for the rehabilitation of the musculoskeletal apparatus after injuries.

To understand how it works, one must keep in mind the physiology of muscle contraction: the muscle fiber is the functional unit of the muscle, and within its component parts, there are 2 contractile protein - actin and myosin, responsible for the activation of motor and/or sensory nerves. Every motor nerve can innervate one or several thousand muscle fibers, and as a whole is called a motor unit. Thus, before the voluntary intention of movement, the central nervous system (CNS) interprets and sends this signal in the form of an electrical impulse towards the periphery, which reaches the myofibrils of the muscle by depolarization of its external membrane, achieving its activation.

In this process, the release of acetylcholine and calcium ions is achieved at the intracellular level, which promotes the formation of the troponin-tropomyosin complex and finally the formation of bridges between actin and myosin, generating muscle contraction. On the other hand, in electrostimulation, the necessary signal to activate the muscles is created artificially and is produced directly on the motor nerve; however, it manages to reproduce the physiological conditions of voluntary movement, allowing muscle contraction with even greater intensity and strength, useful in rehabilitation processes and as an aid to tone and strengthen the areas of the muscle groups worked.

In the same way, we find another type of treatment such as High Frequency Electrotherapy, designed to perform treatments on biological systems through the application of Pulsed Electromagnetic Therapy. The radiation used by this equipment is within the spectrum of non-ionizing radiation, those whose energy is so small that it cannot cause a molecule to break.

The ability of the human body to absorb electromagnetic energy depends mainly on the frequency and strength of the electromagnetic field, and on the configuration and composition of the tissues. For this reason, different therapeutic results can be obtained when applying it on different patients, for example, subcutaneous fat hinders the absorption of radiation, as opposed to the response of water-soluble tissues.

Among its benefits are:

- Muscle relaxation on the striated muscle fiber.
- Antispasmodic effect on smooth muscle fiber.
- Hyperthermia secondary to local vasodilatation, with anti-inflammatory effect and regulation of circulation.
- Increase in the partial pressure of oxygen in the tissues with a trophic effect.
- Effect on the metabolism of calcium in bone and on collagen, stimulating ossification and wound healing.
- Analgesic effect.

The existing literature supports the separate use of neuromuscular electrical stimulation and electromagnetic muscle stimulation for aesthetic purposes, associated with muscle strengthening, skin toning and firming, fat loss and volume in areas located contouring the silhouette, as well as the drainage and elimination of waste by stimulation of the circulatory system, among others. Therefore, the objective of this study is to establish the efficacy and safety of the joint use of neuromuscular electrical stimulation and electromagnetic muscle stimulation, found as combined therapy in a single aesthetic medical device - Wonder Prestige brand - for the improvement of body contour, in terms of reducing body fat mass, and both toning and firming of the abdominal area, buttocks and thighs.

II. METHODS

This was a nonrandomized, prospective, open-label, multicenter feasibility study. Eligible subjects were men and women from Madrid between 30 and 50 years of age, with a desire to reduce subcutaneous fat, as well as toning and/or firming of the abdominal area, buttocks, and legs. The inclusion and exclusion criteria of the sample are presented below:

A. Inclusion criteria:

- Subjects with a BMI ≤ 30 kg/m².
- Subjects who wish and can refrain from participating in any other aesthetic treatment.
- Subjects willing and able to maintain their diet and regular physical exercise, without making significant changes in any direction.

B. Exclusion criteria:

- Subjects with any electronic or metallic implants, catheters, insulin pumps, skin patches and any other whose location interferes with the placement of the equipment.
- Subjects with cardiac and/or pulmonary diseases.
- Subjects with arterial or venous thromboembolic disease requiring anticoagulant drug therapy.
- Subjects with epileptic syndromes or pathologies that debut with convulsive crises.

- Subjects with hematological disorders.
- Subjects with malignant tumor pathology.
- Subjects with anatomical malformations of the abdominal wall.
- Subjects with sensory nerve disorders.
- Subjects with the presence of scars, lesions or open wounds on the abdomen, buttocks and/or thighs.
- Subjects with a history of surgery in the last year.
- Pregnancy
- Breastfeeding

In this way, a total sample of 12 subjects were obtained: 6 men and 6 women, on whom the combined therapy of the Wonder Prestige brand aesthetic medical equipment was applied, in 3 areas of the body: abdomen, buttocks and thighs.

The intervention was administered to each participant in 2 weekly sessions for 8 weeks, complying with the following therapeutic scheme:

C. Protocol:

- Session duration: 25 minutes.
- Posture: prone position in accordance with the "Wondergym" exercise guide
- Sequence of programs used: 20 minutes on "Muscular/Hypertrophy", followed by 5 minutes on "Cellulite".
- Muscle groups treated: rectus abdominis and obliques, quadriceps and hamstrings, and gluteus maximus and medius.
- Total number of sessions: 16.

The participants attended a specialized aesthetic medical center, where specialists trained in the management and use of the Wonder brand device, were in charge of both administering the therapies and recording the body perimeters of the areas to be treated and total body weight, at the beginning and at the end of the treatment. A conventional meter was used to measure the perimeters and an appropriately calibrated electronic scale was used to quantify the weight.

The subjects were correctly informed and they were provided with an informed consent document that they signed. The information record was entered into a Microsoft Office Excel database. It is noted that all the participating women were still of childbearing age, therefore the respective follow-up for birth control was guaranteed during the duration of the study, and the non-application of the therapy on the menstrual uterus was taken as a precaution.

Additionally, the subjects maintained a balanced diet, low in sugars and saturated fats, with abundant consumption of water and restriction of alcohol intake, together with performing aerobic physical exercise three times a week. In accordance with the objective of the study, the efficacy was evaluated by measuring the perimeters of the body areas to be worked on: abdomen, hips and thighs, as well as weight control.

In turn, safety was determined by the incidence of adverse effects reported by the patients during the study period other than those expected, consisting of heat, flushing and localized pain in the worked areas, or systemic such as nausea and dizziness, which were resolved spontaneously in the following 48 to 72 hours.

III. RESULTS

The 12 participants completed the entire study, complying with the work protocol established for the 8 weeks, in addition to following the recommendations for diet and physical exercise. Additionally, none of the women reported pregnancy and there was no difficulty at the time of data collection.

The recording of the body perimeters used to establish the effectiveness of the Wonder Prestige equipment is shown in Table 1. It can be seen that the loss of predominantly fatty tissue at the minimum abdominal level was 7 cm with a maximum of 15.5 cm, for a mean of 10.3 cm, without significant changes between both sexes. Additionally, in Graph 1, the trend of the reduction of the abdominal perimeter is observed, which was symmetrical and proportional among all the individuals.

In the buttock region, the reduction was a minimum of 3 cm and a maximum of 11 cm, for an average of 7 cm in the study group, with no significant differences between both sexes. The reduction in measurements in relation to the thighs was a maximum of 9 cm and a minimum of 0, presented in subject number 9. The average was 4.5 cm, with a slightly greater loss of fatty tissue in women compared to the group male.

Table 1. Body perimeters: waist, gluteal and thighs

INDIVIDUAL	AGE	GENDER	INITIAL (cm)			DELTA (cm)		
			WAIST	GLUTEAL	THIGHS	WAIST	GLUTEAL	THIGHS
1	32	FEMALE	102	92	65,5	10	11	5,5
2	30		123	94	70	15,5	3	6,5
3	46		130	113	61	11	8	6
4	36		102	86	60	10	8	4
5	36		109	94	60	7	7	9
6	35		102	90	60	7	8	6
7	49	MALE	114	111	56	11	11	3
8	33		135	118	75	11	3	9
9	38		120	110	59	10	5	0
10	33		113	112	55	9	7	2
11	32		111	109	54	15	8	2
12	30		118	115	62	8	6	2

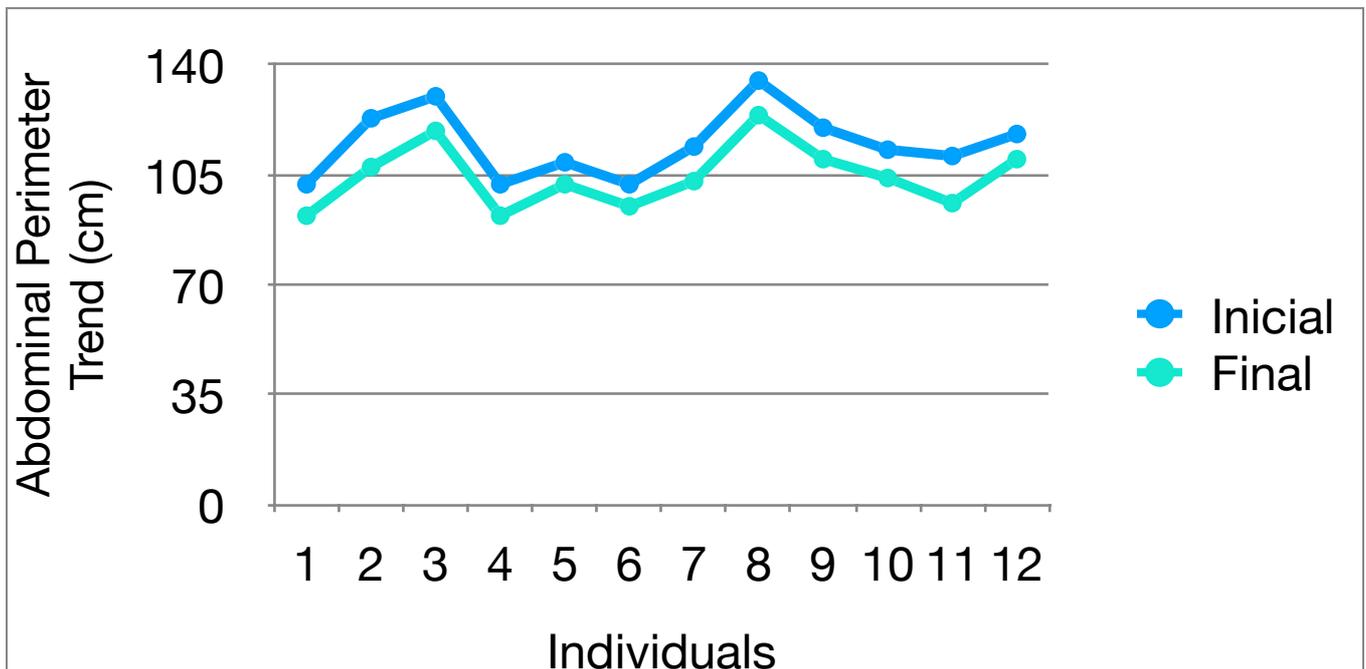
*DELTA: Value corresponding to the difference in perimeters by body areas, at the beginning and at the end of the study.

The weight record can be evidenced in Table 2, where it is notable that all the subjects had a weight loss corresponding mainly to subcutaneous fat, with a minimum weight loss of 5.2 kg and a maximum loss of 14.7 kg, with an average of 9.5 kg in the group. Thus, there was a loss of 5-10% of the initial weight in 60% of the participants, and a loss of 10-15% of the initial weight in the remaining 40%. Furthermore, weight loss was found to be slightly higher in the female participants. In Graph 2, the weight loss in each individual can be evidenced in a comparative way.

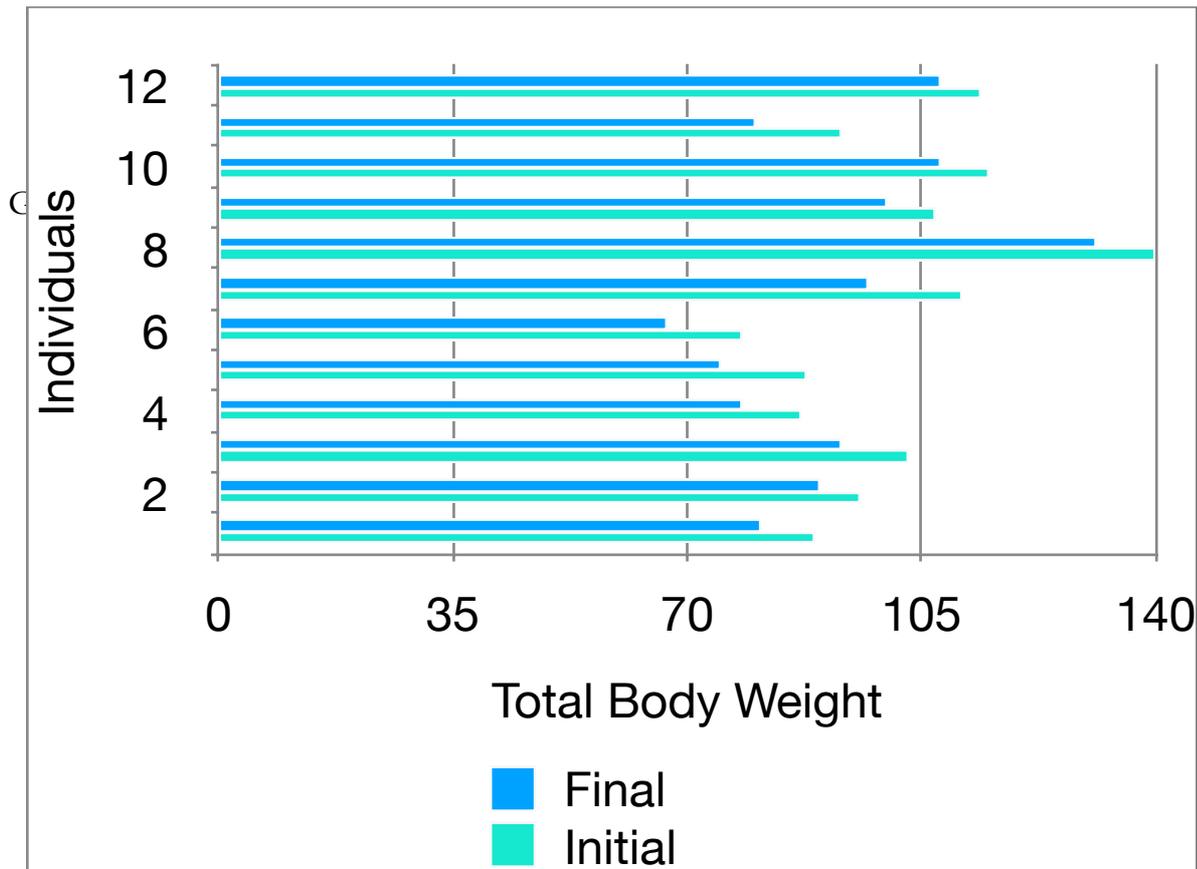
Table 2. Total body weight.

INDIVIDUAL	AGE	GENDER	INITIAL (cm)		
			INITIAL WEIGHT	FINAL WEIGHT	WEIGHT LOSS
1	32	FEMALE	102	92	65,5
2	30		123	94	70
3	46		130	113	61
4	36		102	86	60
5	36		109	94	60
6	35		102	90	60
7	49	MALE	114	111	56
8	33		135	118	75
9	38		120	110	59
10	33		113	112	55
11	32		111	109	54
12	30		118	115	62

Graph 1. Trend of the reduction of the abdominal perimeter



Graph 2. Trend of the reduction of total weight.



IV. PATIENT SATISFACTION AND SAFETY

The participants in the study did not report or present symptoms or signs other than those expected given the way the equipment is used and nature of the treatment. Among the expected adverse effects, the subjects only reported the presence of transient reddening of the skin in the body areas worked on and muscle pain after the sessions, which resolved spontaneously after a few minutes or within 24 hours. No local hyperthermia or systemic symptoms were reported. It should be noted that at the end of the study, the patients reported feeling in better general condition and better physical condition with respect to their initial baseline state. In addition, they subjectively felt lighter, with a positive increase in their self-esteem when they saw themselves physically with reduced measurements, a more defined silhouette and with more toned areas worked on, with an improvement in the appearance of the skin.

V. DISCUSSION

The use of the Wonder Prestige device as a combined neuromuscular and electromagnetic muscle stimulation therapy is effective for improving body contour in terms of reducing body fat mass, and both toning and firming of the abdominal area, buttocks and legs.

In the first place, a significant reduction in measurements and weight was achieved in all the participants, observing that sex and age do not interfere in obtaining results. Although it is true that the most appropriate tool to measure subcutaneous fat is the caliper, it is operator dependent and its margin of error is quite wide. Due to this, the electronic scale is used taking into account clear concepts about body compartments.

Our body is made up mostly of water and most of it is found in metabolically active tissues. Therefore, results depend on body composition and, consequently on age and sex. Within the other compartments we find the lean mass, made up of muscle, bone, nervous tissue and other substances other than adipose tissue, which constitutes fat mass.

Given that the participants were healthy subjects, who followed the nutritional recommendations given with plenty of water intake, and who were also under a therapy that evidenced muscle work and strengthening, the reduction in measurements and weight corresponds mainly to fat mass. . In addition, taking into account that the literature recommends a maximum voluntary weight loss of 3-4 kg per month, the weight loss was given under healthy and controlled conditions, progressively and over a period of 2 months.

The weight loss that occurred predominantly in the female subjects is explained by an association between lower initial weights than in the men in this study, corresponding to smaller body perimeters and a reduction in the subcutaneous fat component among them; remembering that subcutaneous fat hinders the absorption of radiation emitted by the device, and decreases the scope of treatment.

As previously mentioned, the sample was under a therapeutic scheme that has multiple advantages at the muscle level, among which stand out that it allows muscle groups to work in an isolated and selective way, prolong the contraction time forging a stimulus for muscle growth more intense, deploy a greater number of repetitions avoiding inhibition due to CNS fatigue, increase muscle oxidative capacity and avoid cardiovascular stress that regular physical exercise would entail, as well as increase muscle tension generating greater definition.

In summary, strengthening of the muscle from the electrical impulses generated by the Wonder Prestige equipment could translate into hypertrophy and increase in muscle mass, however, in the present study this parameter was not evaluated or quantified, so it would require an additional study that took its measurement into account, in order to clearly establish the efficacy of combined neuromuscular and electromagnetic muscle stimulation therapy for gaining muscle mass.

Secondly, the non-presentation of adverse effects other than those expected establishes the safety of the use of the joint treatment with Wonder Prestige aesthetic medical equipment as safe.

None of the side effects were experienced as per the available literature that mentions about that the side effects may occur when administering electric current in a controlled manner to the body were experienced during this study with Wonder prestige. The existing literature mentions about these side effects such as thermal effect, galvanic effect, excitatory effect, burns, appearance of mild erythema or localized redness, nausea , vomiting, dizziness, and others even more serious such as rhabdomyolysis

Thirdly, it is important to point out how a better definition and appearance of the body silhouette positively contributes to the general conditions and the self-esteem that each subject has of himself, giving the combined therapy of the Wonder Prestige device additional value.

VI. CONCLUSIONS

Finally, this feasibility study is the first to establish the efficacy and safety of neuromuscular and electromagnetic muscle stimulation treatment as joint therapy with Wonder Prestige aesthetic medical equipment, as a non-invasive procedure for body contouring as satisfactory.

Both treatments are currently used separately for multiple purposes in different disciplines such as neurology, cardiology, orthopedics, physiotherapy and sports medicine; and clinical studies have been published that demonstrate their safety and efficacy by themselves, however, in the present study the improvement of body contour in terms of reduction of ad tissue is also evidenced.

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