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ORIGINAL PAPER

Flat magnetic stimulation technology: A promising therapy for erectile dysfunction management

Nicola Mondaini [1], Fabio Crocerossa [1], Andrea Abramo [1], Francesco Cantiello [1], Irene Fusco [2], Alessandra Comito [2], Tiziano Zingoni [2], Rocco Damiano [1]

[1] Department of Urology, Magna Graecia University of Catanzaro, Catanzaro, Italy;
[2] El.En. Group, Calenzano, Firenze, Italy.

Summary ***Background: The erectile dysfunction (ED), represents a very common complaint for men over forty years old.***
Aim: The purpose of the study was to evaluate if Flat Magnetic Stimulation (FMS) technology could help individuals with symptomatic erectile dysfunction.
Methods: A total of 40 patients with a mean age of 43 (± 10.4) (range 21-53) affected by erectile dysfunction, underwent eight sessions of about 30 minutes each in a twice a week frequency with the study device. During treatments, every potential side effect was monitored. The International Index Erectile Function (IIEF) and Erection Hardnes Score (EHS) (range 0-4) were selected and analysed before, at the end of the treatment, at 1 month follow up (1MFU) and at 3 months follow up (3MFU).
Results: The IIEF mean value significantly ($p < 0.001$) increased from 22.6 (± 2.4) at baseline to 26.4 (± 2.7) at 3MFU. The EHS mean score significantly ($p < 0.001$) increased from 2.7 (± 0.4) at baseline to 3.4 (± 0.6) at 1MFU and the improvement persists for up to 3MFU, thus supporting the clinical usefulness of this treatment.
Conclusions: As compared to other previously employed techniques, this technology has the potential to successfully restore erectile function. This research had limitations as the absence of a control group, a long term follow up and the lack of objective assessments of penile hemodynamics. The study findings showed that FMS represents a promising treatment option to individuals affected by symptomatic erectile dysfunction.

KEY WORDS: *Erectile dysfunction; Flat Magnetic Stimulation; Erection Hardnes Score; The International Index Erectile Function.*

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INTRODUCTION

The *erectile dysfunction* (ED), which is the inability to achieve and/or sustain a penile erection sufficient to result in a satisfying sexual performance, represents a very common complaint for men over forty years old. Important, innovative, non-invasive restorative treatments for ED include shockwave, platelet-rich plasma, and stem cell therapies. These treatments can help individuals who prefer not to undergo a more intrusive procedure. Even though these treatments have demonstrated encouraging outcomes in clinical studies, more investigation is necessary to prove that they are reliable and effective choices for treating ED (1).
It is known that some pelvic floor muscles contribute to the mechanisms of ejaculation and erectile function (2).
Among these, the use of magnetic stimulators, such as *Flat Magnetic Stimulation* (FMS) technology, has shown significant progress in the treatment of ED, as demonstrated in recent published investigations (3, 4) through the use of validated prospectively questionnaires which showed a significant improvement of *International Index of Erectile Function* (IIEF), without any significant adverse events.
Considering these evidence, the purpose of this study was to assess and confirm the effectiveness of FMS in the management individuals affect by mild erectile dysfunction.

MATERIALS AND METHODS

This prospective, non-placebo-controlled study was conducted between October 2023 and July 2024 using PelviTouch (*Dr Arnold, Deka MELA Calenzano, Italy*).
A total of 40 patients with a mean age of 43 (± 10.4) (range 21-53) affected by erectile dysfunction were enrolled. All patients underwent eight sessions lasting 30 minutes each in a twice a week frequency with the study device.
Hypotonus/Weakness 1 and Hypotonus/Weakness 2 protocols were selected. The protocol includes a cycle of 8 treatment sessions, twice a week, lasting approximately 30 minutes each.
The following FMS schedule was used: sessions 1 to 4 followed the Hypotonus/Weakness 1 protocol whereas sessions 5 to 8 followed the Hypotonus/Weakness 2 protocol. The Hypotonus/Weakness 1 protocol consists of about 30 minutes warm-up and muscle activation phase, followed by a muscle work phase focused on restoring tropism and muscle tone (20-30Hz) in a trapezoidal shape. For a total of about 30 minutes, the Hypotonus/Weakness 2 protocol consists of a warm-up and muscle activation phase, a muscle work phase targeted at increasing tropism (volume), and a muscle strength phase (40-50Hz) in a trapezoidal shape.
The IIEF and *Erection Hardness Score* (EHS) (range 0-4) were selected and analysed before, at the end of the treat-

ment, *1 month follow up* (1MFU) after the last treatment session and at *3 months follow up* (3MFU) after the last treatment session.

The IIEF includes a score ranging from 5 to 30, and ED severity was labeled and classified into the following five categories: severe (EF score 6 to 10), moderate (EF score 11 to 16), mild to moderate (EF score 17 to 21), mild (EF score 22 to 25), and no ED (EF score 26 to 30) (5). The EHS measures erection hardness on a 4-point scale: 0 (no enlargement), 1 (enlarged but not hard), 2 (hard but not for penetration), 3 (hard enough for penetration but not fully rigid), and 4 (fully rigid) (6).

Inclusion criteria included: patient's age between 18 and 65 years, diagnosis of erectile dysfunction via IIEF (5 items erectile function, in the range 17-21) corresponding to mild erectile dysfunction, patients who have EHS score of 2-3, the absence of neurological, in progress or previous oncological pathologies, pacemakers, metal implants, obesity, suspension of oral therapy for ED for at least 3 months. IIEF was administered in its full form of 15 questions but only items related to erectile function (Q 1-2-3-4-5 and 15) were inclusive.

Patients with IIEF score greater than or equal to 26 (items 1-2-3-4-5, 15) and with EHS score of 4 were considered as responders to treatment. All participants had to have a stable relationship for at least 6 months.

Every possible adverse effect, such as tendon soreness, local erythema, skin redness, temporary muscle spasms and pain, was tracked during treatments.

Results

The IIEF (items 1-2-3-4-5,15) mean value significantly ($p < 0.001$) increased from 22.6 (± 2.4) at baseline to 26.7 (± 3.2) at the end of the treatment, to 26.7 (± 3.2) at 1 MFU after the last treatment session and to 26.4 (± 2.7) at 3MFU after the last treatment session. At 3MFU 72.5% of patients (29 patients) were considered to be responding to treatment and showing stable results (Figure 1).

As showed in Figure 2, the mean score of IIEF items relating to sexual satisfaction (items 6-7-8) significantly ($p < 0.001$) increased from 5.0 (± 1.7) at baseline, to 12.9 (± 1.9) at the end of the treatment, to 13.0 (± 1.8) at 1 MFU after the last treatment session and to 12.9 (± 1.9) at 3MFU after the last treatment session. The mean score of Orgasmic function (items 9-10) significantly ($p < 0.001$) increased from 7.2 (± 1.1) at baseline, to 7.8 (± 0.8) at the end of the treatment, to 8.1 (± 0.6) at 1 MFU after the last treatment session and to 8.3 (± 0.5) at 3MFU after the last treatment session. The mean score of Sexual desire (items 11, 12) significantly ($p < 0.001$) increased from 6.0 (± 1.1) at baseline to 8.5 (± 1.3) at the end of the treatment, to 9.1 (± 1.2) at 1 MFU after the last treatment session and to 9.0 (± 1.2) at 3MFU after the last treatment session. The mean score of total satisfaction (items 13, 14) significantly ($p < 0.001$) increased from 6.0 ± (1.6) at baseline to 8.0 (± 1.9) at the end of the treatment, to 8.0 (± 1.9) at 1 MFU after the last treatment session and to 7.9 (± 1.9) at 3MFU after the last treatment session.

Finally, the EHS mean score significantly ($p < 0.001$) increased from 2.7 (± 0.4) at baseline to 3.4 (± 0.6) at 1MFU after the last treatment session and the improvement persists for up to 3MFU after the last treatment session, thus supporting the clinical usefulness of this treatment, as reported in Figure 3.

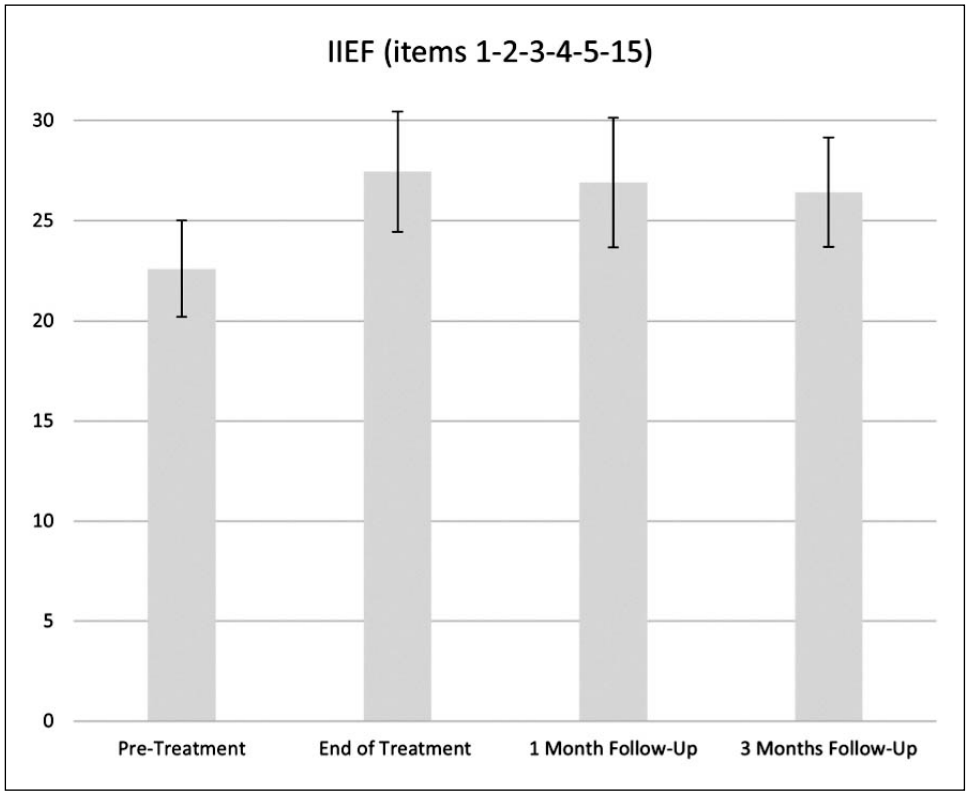

Figure 1.
Histogram representation of mean values of IIEF related to the items 1-2-3-4-5,15, measured at baseline, at the end of the treatment, at 1 month follow up after the last treatment session and at 3 months follow up after the last treatment session.

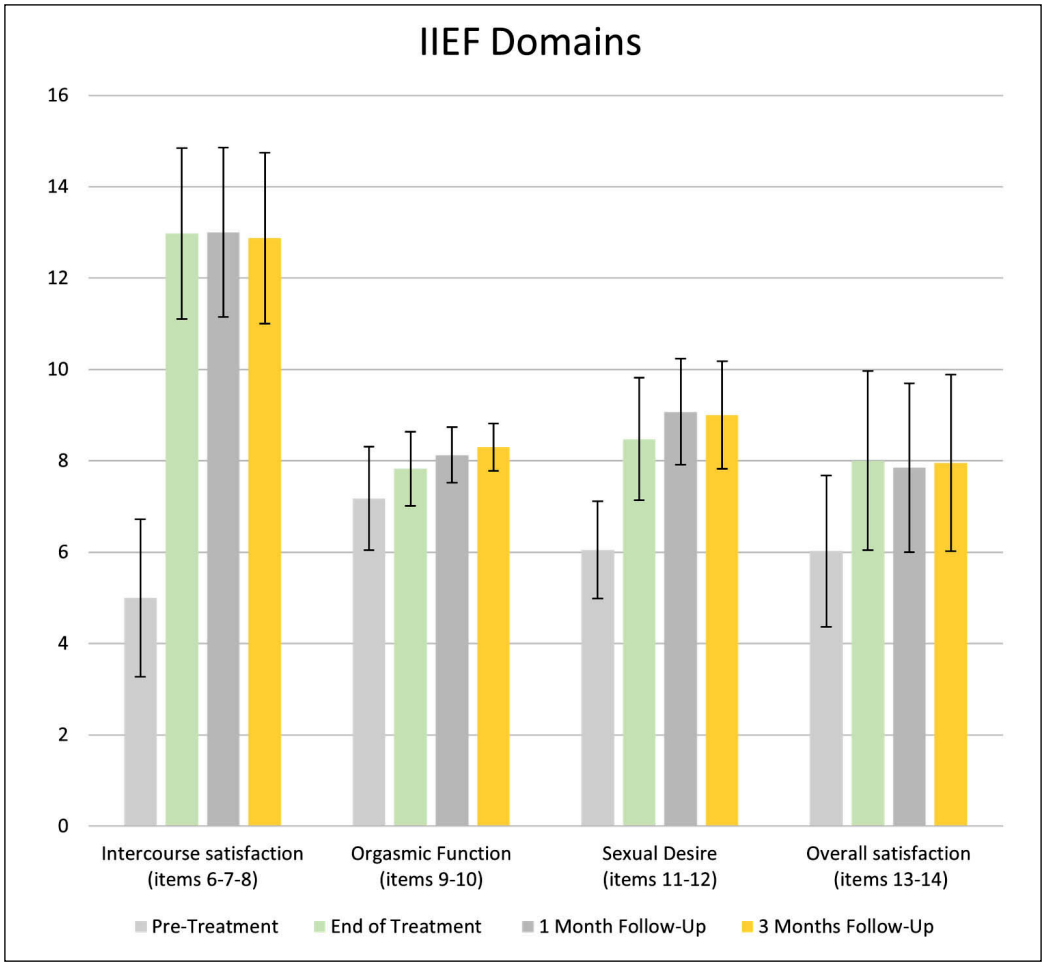

Figure 2.
Histogram representation of mean values of IIEF related to the items 6-7-8-9-10-11-12-13-14, measured at baseline, at the end of the treatment, at 1 month follow up after the last treatment session and at 3 months follow up after the last treatment session.

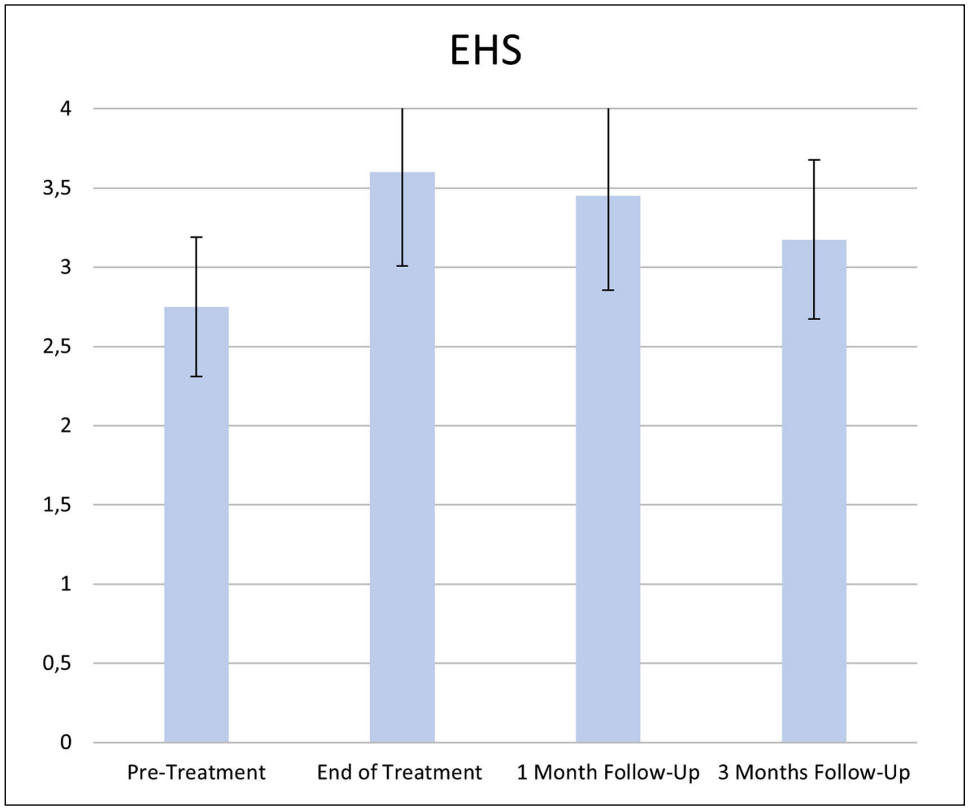

Figure 3.
Histogram representation of mean scores of EHS measured at baseline, at the end of the treatment, at 1 month follow up after the last treatment session and at 3 months follow up after the last treatment session.

Discussion

In worldwide, existing therapies can effectively treat erectile dysfunction. However, it cannot be cured, except for psychogenic ED, post-traumatic arteriogenic ED in younger patients, and hormonal causes (7).

Phosphodiesterase 5 inhibitors (PDE5is) are well-established therapeutic alternatives and utilized first-line therapeutic option for ED (8). These drugs have been extensively studied in hundreds of thousands of men, demonstrating similar efficacy across the different active ingredients and a modest, nonlinear dose-response relationship. Due to underlying comorbidities or prior surgery, a non-negligible percentage of ED patients do not respond to PDE5-Is, despite their non-invasive nature, great efficacy, and safety (9). The high rate of non-or less-responders and the unmet needs in the medicines that are currently on the market have spurred research into the creation of new treatment alternatives. Furthermore, in patients with diabetes or those who have undergone prostatectomy, erectile dysfunction is generally more severe and the response to PDE5 inhibitors is less pronounced (10, 11). The most common side effects include headache, dyspepsia, flushing, back pain, nasal congestion, myalgia, visual disturbances, and dizziness, with slight differences between the drugs. Adverse events increase with dose (8). PDE5 inhibitors should be used with caution in cases of mild to moderate hepatic or renal impairment or spinal cord injury, while they are generally not recommended in severe cases. Furthermore, many treatments failures result from incorrect use of the drug (for example, taking it after a large meal or without sexual stimulation); it is therefore essential to provide precise instructions to the patient.

Finally, the physician must balance efficacy and tolerability, adjusting the dose in collaboration with the patient and partner until the best results are achieved with minimal side effects.

As a result, patients began exploring for non-surgical therapeutic alternatives such vasodilating medicines (such as prostaglandin E1), intraurethral alprostadil, *intracavernosal injections* (ICIs) and *vacuum erection devices* (VEDs) (8).

However, such treatment methods have a number of significant disadvantages and are unable to alter the fundamental pathophysiology of the erectile mechanism (EF). Due to the fact that these patients are not regularly monitored following therapy, they include adverse effects and low response rates (12-14).

Indeed, these therapeutic methods have numerous disadvantages such as side effects and low response rates (12). For patients who fail to respond to medication therapy or who want a permanent solution for their ED, surgical implantation of a penile prosthesis might represent a viable option. However, a penile prosthesis implant is a therapy that cannot be reversed. A man will never be able to have an erection on his own again, even after the implantation. Furthermore, infection and mechanical failure are the two primary issues related to the implantation of penile prostheses (15).

Although regenerative treatments are a promising therapy option for erectile dysfunction (16) there is currently limited human data to support this assertion (17).

Magnetic stimulation can also be considered a form of regenerative therapy and it has already been employed successfully in patients with urine incontinence and pelvic floor issues (18, 19).

Indeed, men with the syndrome of *chronic prostatitis/chronic pelvic pain syndrome* (CP/CPPS) may benefit from non-invasive pelvic floor electromagnetic/magnetic therapy, as demonstrated in past studies (20).

In contrast to traditional magnetic stimulation therapy, the homogeneous profile of electromagnetic fields generated by FMS can be customized to target the pelvic region. The homogeneity of the magnetic field distribution allows the muscle working at the same intensity in every field, avoiding areas of different stimulation intensity (21).

Pelvic floor muscle training (PFMT), even before FMS, aims to repair pelvic floor muscles by improving proprioception, relaxation, and muscle tone. Actually, exercises targeting the pelvic floor muscles have been demonstrated to improve erections, notably in post-prostatectomy ED patients (22).

Additionally, FMS led to a 15.4% increase in muscle volume and a significant increase in the size of the urethral rhabdosphincter, which improved the quality of life scores associated with urination (23), and it alleviated CP/CPPS symptoms as recently demonstrated by *Mondaini et colleagues* (4).

The experiments to support this claim were also carried out quantitatively, using ultrasound exams, and qualitatively, using validated questionnaires (24).

A substantial improvement in erectile function was noted in the study by *Mondaini et colleagues* (4) where the total mean IIEF-5 score increased significantly ($p < 0.001$) from 21.3 (± 2.7) at baseline to 24.3 (± 0.5) at the 1-month follow-up following the last treatment session.

This data was confirmed by *Galimberti et colleagues* (3) on 20 men, where IIEF-5 mean score significantly ($p < 0.001$) increased from 34 before treatment to 54 at 1 month follow-up.

Our findings are consistent with previously published data, and they were supported by validated questionnaires that demonstrated a considerable improvement in IIEF and EHS with no notable adverse effects.

Indeed, the IIEF, that comprises 15 items and 5 domains, represents a reliable and robust psychometric instrument to evaluate the effectiveness of ED therapy. An improvement in ED was defined as a higher post-test IIEF score relative to the pre-test score.

In comparison to the previous studies, these outcomes were also analysed with the support of EHS, a simple-self-reported questionnaire that represents that a key indicator of erectile dysfunction (6). Indeed, the EHS has been shown to be a reliable, user-friendly, patient-reported, single-item outcome measure that has powerful discriminatory capacity to recognize ED, with appropriate response quality and distribution, as well as validity for recognized groups, successfully distinguishing between normal and impaired erectile function when compared to the IIEF (25, 26). It also shown moderate to strong validity convergence with the IIEF and *Quality of Erection Questionnaire* (QEQ) categories (25).

Our findings are in accordance with those of *Rival and Clapeau* (2) and provide evidence to the concept that pelvic floor rehabilitation contributes to erectile dysfunction.

The increase in endocavernous pressure and the reduction of venous return from the penis are two processes that support the potential function of pelvic floor strengthening in

erection. Perineal rehabilitation has been suggested by several authors as a first-line treatment for erectile dysfunction (27). Numerous investigations have shown that vascular damage or endothelial dysfunction is a major mechanism of ED in addition to muscle involvement (28). It has been demonstrated in animal models that magnetic stimulation can decrease the production of the pro-inflammatory cytokine TNF-alpha and increase the production of the anti-inflammatory cytokine IL-10 via altering astrocytic phenotypes (A1-A2). Angiogenesis-related factors TGF and VEGF, which can aid in angiogenesis, were also released faster in A2 astrocytes upon magnetic stimulation. Angiogenesis-related genes (VEGFA and BAI1) were discovered to be increased in rats after magnetoelectric stimulation (29).
Since the production of *nitric oxide* (NO) is necessary for a normal penile erection (30) we may hypothesize that FMS may have some NO-dependent benefits in angiogenesis in addition to its beneficial effects on muscles, which would make it beneficial for patients with vasculogenic ED who have a poor PDE5I response.
Furthermore, the smooth muscle of the penis is the most important component of the hemodynamic processes that supports an erection; thus, magnetic stimulation of the striated muscles may be crucial in the treatment of ED, by correcting the pathological fibromuscular alterations within the corpus cavernosum (31, 32).

Declarations

Availability of data and material: *Data that support the study findings are available on reasonable request from the corresponding author.*

Competing interests: *IF, AC and TZ are employed at El. En. Group. The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.*

Funding: *This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.*

Authors' contributions: *Conceptualization: NM, FC, AA, FC, and RD; Methodology: NM, FC, AA, FC, and RD; Validation: NM, FC, AA, FC, TZ and RD; Formal analysis: NM, FC, AA, FC, AC, TZ and RD; Software: NM, FC, AA, FC, AC, TZ and RD; Investigation: NM, FC, AA, FC, TZ and RD; Visualization: NM, FC, AA, FC, IF, AC, TZ and RD; Resources: NM, FC, AA, FC and RD; Data curation: NM, FC, AA, FC, IF, AC, TZ and RD; Writing—original draft preparation: NM, IF; Writing—review and editing: NM, FC, AA, FC, IF, AC, TZ and RD; Supervision: NM, FC, AA, FC, TZ and RD; Project administration: NM, TZ; Funding acquisition: NM, TZ. All authors have read and agreed to the published version of the manuscript.*

Institutional Review Board Statement: *The study was conducted in accordance with the principles of Declaration of Helsinki. Ethical approval was not required as the study device is already CE marked since July 2020. No activity was carried out outside the scope of the device intended purpose or that no additional invasive or burdensome procedures were carried out compared to procedure performed under the normal condition of use of the device.*

Informed Consent Statement: *Informed consent was obtained from all subjects involved in the study.*

Additionally, since it has been observed that exposure of human spermatozoa to a very low frequency electromagnetic field increases their motility (33 we can speculate that FMS may have a beneficial effect on sperm motility.
Among the many noteworthy advantages of the study technology are the capacity to stimulate muscles without the use of a probe and the gradual proper emission of supplied energy, which allows patients to stay completely clothed while seated in a comfortable and ergonomic position. Lastly, as it helps the patient understand the muscles involved in the treatment and it can also be utilized in conjunction with other physical or medicinal procedures.
The physiology of erection is the basis for the necessity of an effective contraction of the ischiocavernosus, and magnetic stimulation of the muscle within the corpus cavernosum undoubtedly causes muscle hypertrophy. Indeed, the study device acts on bulbo and ischio-cavernosus muscles (BCM, ICM) which are implicated in achieving and maintaining erection and penile rigidity (34, 35).
Therefore, ED may be partly due to atrophy of the ischiocavernosus muscle and may be treated with FMS technology. The treatments have been found to be free of side effects and to be highly accepted by patients. Our clinical experience shows that FMS represents a safe and efficient therapeutic approach to treat erectile dysfunction, through its muscle effects and the potential ability to interfere with sperm motility and angiogenesis process.
More research in this field will be necessary to determine the long-term safety and effectiveness of this therapy, which is still in the experimental stage. Therefore, as compared to other previously employed techniques, this technology has the potential to successfully restore erectile function.
Finally, we stated that our research had limitations as the absence of a control group and of a long term follow up and the lack of objective assessments of penile hemodynamics.

Conclusions

FMS therapy seems to be an effective non-invasive solution for individuals affected by mild erectile dysfunction.

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Correspondence

Nicola Mondaini, MD
n.mondaini@unicz.it

Fabio Crocerossa, MD
crocerossa@unicz.it

Andrea Abramo, MD
a.abramo10@gmail.com

Francesco Cantiello, MD
cantiello@unicz.it

Rocco Damiano, MD
damiano@unicz.it

Department of Urology, Magna Graecia University of Catanzaro, Catanzaro, Italy

Irene Fusco, PhD (Corresponding Author)
i.fusco@deka.it

Alessandra Comito, Msc
a.comito@elen.it

Tiziano Zingoni, Msc
t.zingoni@elen.it

El.En. Group, 50041 Calenzano, Firenze, Italy