

ORIGINAL PAPER

Novel emerging therapy for erectile dysfunction: Efficacy and safety of flat magnetic stimulation

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Summary

Background: 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. The aim of the study was to evaluate if Flat Magnetic Stimulation (FMS) technology could help individuals with symptomatic erectile dysfunction.

Methods: Twenty patients with 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 assessed. The International Index of Erectile Function (IIEF) was compiled by all patients at the beginning, after the eighth treatment and at 1 month from the end of the last treatment. The questionnaire scores were presented as median values along with the interquartile range (IQR) and we set the significance threshold at 0.01.

Results: After the treatment and at 1-month follow-up, the increase in questionnaire scores was statistically significant compared to the baseline, thus supporting the clinical usefulness of this treatment. In particular, the result of the study indicates a statistically significant difference between IIEF score before treatment (Median = 34) and IIEF score after the end of treatment (Median = 45) and between IIEF score before treatment and IIEF score at 1-month follow-up (Median = 54).

Conclusions: The study findings showed that FMS represents a promising treatment option to individuals affected by symptomatic erectile dysfunction.

KEY WORDS: Symptomatic erectile dysfunction; Flat magnetic stimulation; Emerging therapy.

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INTRODUCTION

The inability to achieve and/or sustain a penile erection sufficient to result in a satisfying sexual performance is known as *erectile dysfunction* (ED) (1). ED can have a substantial negative effect on physical and mental health of patients as well as the quality of life for their partners (2). Men who have ED are frequently feeling guilty about their condition and avoid seeking professional help (3). ED can be effectively treated with available therapies. However, it cannot be cured, except for psychogenic ED, post-traumatic arteriogenic ED in younger patients, and hormonal causes (1).

While oral *Phosphodiesterase type 5 inhibitors* (PDE5Is) have long been recommended as the initial treatment option, some patients did not respond well to this therapy. As a result, non-surgical treatment alternatives like vasodilating agents, intraurethral alprostadil, *vacuum erection devices* (VEDs) and *intracavernosal injections* (ICIs) are available (4). Nevertheless, those therapeutic approaches are not able to change the underlying pathophysiology of the erectile mechanism and have several serious drawbacks (5). Nowadays, it is established that specific pelvic floor muscles play a part in the ejaculatory and erectile mechanisms (6). As previously shown in the literature, pelvic floor electromagnetic/magnetic therapy can be a non-invasive option for men with the syndrome of *chronic prostatitis/chronic pelvic pain syndrome* (CP/CPPS) (7). Relevant advances in magnetic stimulation technology have been made recently, including *Flat Magnetic Stimulation* (FMS) (8).

Even before FMS, the goal of *pelvic floor muscle training* (PFMT) was to restore the pelvic floor muscles by enhancing proprioception, relaxation, and muscle tone. Exercises targeting the pelvic floor muscles have been shown to enhance erection, particularly in post-prostatectomy ED patients (9). Mondaini *et al.* have recently demonstrated that FMS improved CP/CPPS symptoms (pelvic/genital pain, ejaculatory pain, and urinary symptoms) (10). In light of these evidence, our goal was to investigate if FMS could help individuals with symptomatic erectile dysfunction.

MATERIALS AND METHODS

A prospective single-group study was carried out from February to November 2023, in a private medical centre, in Argentina, using *Dr Arnold* (DEKA M.E.L.A., Calenzano, Italy) device that includes a chair applicator and a main unit. An electromagnetic field with a homogenous profile produces the stimulation. Greater muscle fibre recruitment is made possible by the uniformity of the magnetic field distribution, which prevents any region of unequal stimulation intensity.

Twenty patients with erectile dysfunction in total, were enrolled in this study. Their mean (\pm SD) age was 56.89 (\pm 6.63) years, ranging from 46 to 66 years. Patients with severe neurological diseases, malignant tumours, obesity, pacemakers, or metal implants were included among the

exclusion criteria. Before beginning the treatment, PDE5I users had to endure a three-week wash-out period. For the duration of the treatment session, all patients agreed to abstain from using PDE5I or any other ED therapies. Patients underwent eight sessions of about 30 minutes each in a twice a week frequency. 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. During treatments, every potential side effect was assessed, including skin redness, local erythema, tendon pain, muscle pain, and transient muscle spasms.

The *International Index of Erectile Function* (IIEF) is a psychometrically and cross-culturally valid tool to identify treatment-related alterations in erectile dysfunction patients which showed high sensitivity and specificity. It comprises 15 items and 5 domains and is an accurate and valid psychometric tool for assessing efficacy of ED treatment. The IIEF has a possible score range from 5 to 25, and ED is classified into five categories based on the scores: severe (5-7), moderate (8-11), mild to moderate (12-16), mild (17-21), and no ED

(22-25). In the IIEF there are six items in the *erectile function* domain (EF-score), two items in the *orgasmic function* domain (OF-score), two items in the *sexual desire* domain (SD-score), three items in the *intercourse satisfaction* domain (IS-score), and two items in the overall *sexual satisfaction* domain (OS-score) (11).

An higher post-test IIEF score compared with the pre-test score was considered an improvement in ED.

The IIEF was compiled by all patients at the beginning, after the eighth treatment and at 1 month from the end of the last treatment (1MFU).

The questionnaire scores were presented as median values along with the *interquartile range* (IQR). Significance threshold was set at 0.01.

Student's t-test, SPSS (*IBM Corp., New York, NY, USA*) and R 4.1 (the *R Core Team, Vienna, Austria, 2021*) were used to perform statistical analysis.

The article is in accordance with the Declaration of Helsinki on Ethical Principles for Medical Research involv-

Table 1.

Median values and interquartile range at baseline, at the end of the treatment sessions (after the eighth treatment), and at 1-month follow-up, related to international index of erectile function (IIEF), erectile function (EF) score, orgasmic function (OF) score, sexual desire (SD) score, intercourse satisfaction (IS) score and overall satisfaction (OS) score.

	Baseline Median (IQR)	End of treatment Median (IQR)	1MFU Median (IQR)	p-value (Baseline vs end of treatment)	p-value (Baseline vs 1MFU)
IIEF score	34 (32-38)	45 (43-46)	54 (51-57)	< 0.001	< 0.001
EF score	13 (10.75-16)	18 (16.75-19)	21.5 (20.75-23.25)	< 0.01	< 0.001
OF score	5 (4-5)	6 (6-7)	7 (7-8)	< 0.01	< 0.001
SD score	5 (5-6)	7 (6-7)	7 (7-8)	< 0.001	< 0.001
IS score	6 (5-7)	8 (7-9)	9 (9-11)	< 0.01	< 0.001
OS score	4 (4-6)	6 (6-7)	8 (8-8)	< 0.01	< 0.001

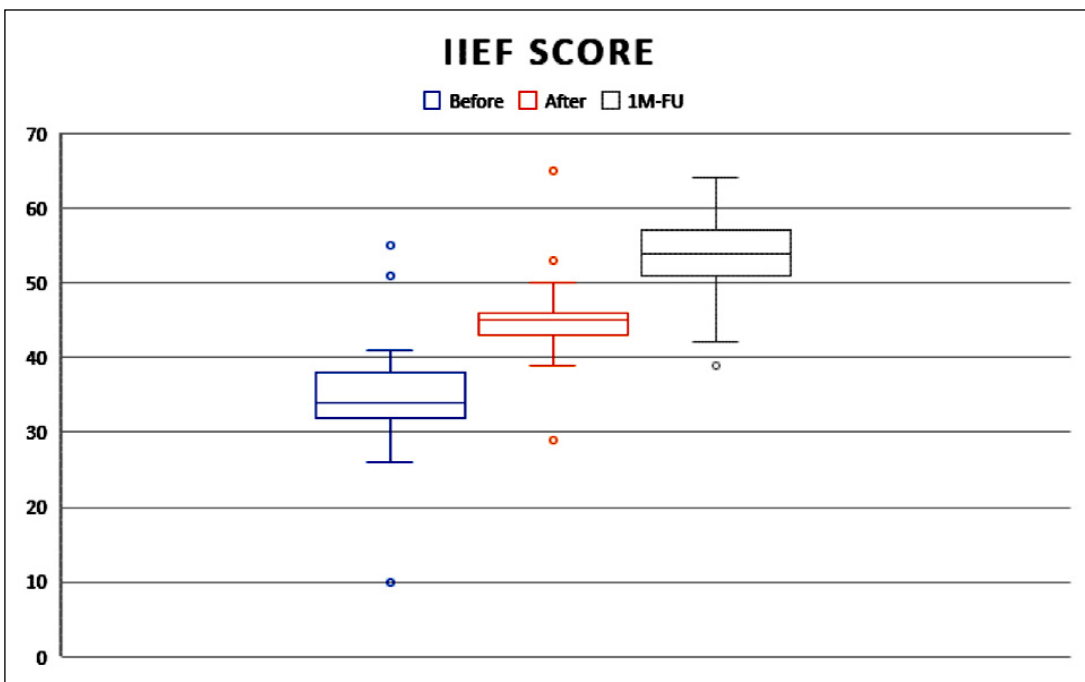
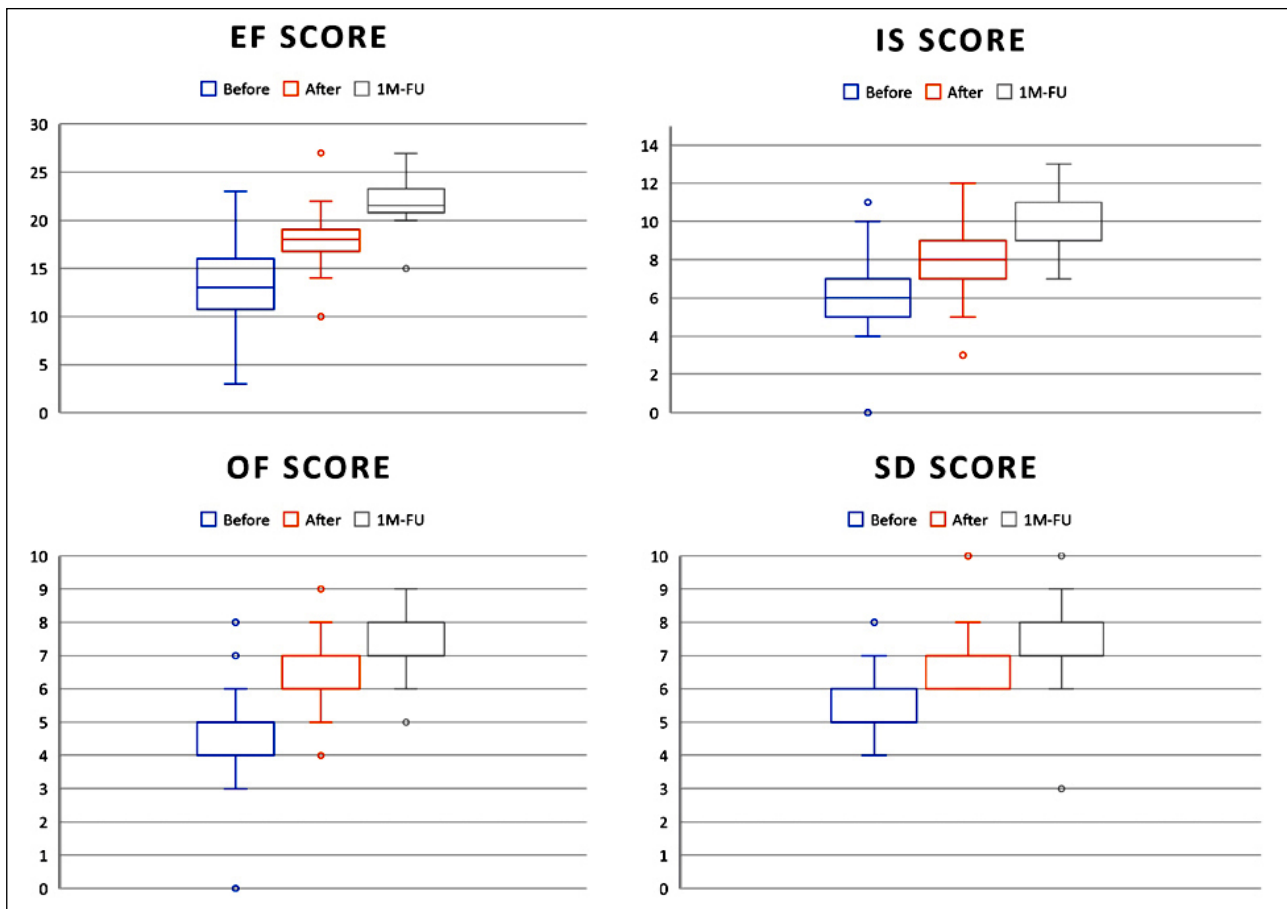


Figure 1. Box plot for score at baseline, at the end of the treatment sessions (after the eighth treatment), and 1-month follow-up for international index of erectile function (IIEF).

Figure 2.

Box plots at baseline, at the end of the treatment sessions (after the eighth treatment), and 1-month follow-up related to erectile function (EF) score, orgasmic function (OF) score, sexual desire (SD) score, and intercourse satisfaction (IS) score.



ing human subjects. Ethical approval is not necessary as the study device is already CE marked since 2020. Written informed consent has been obtained from the patients to publish this paper.

RESULTS

Outcome measures of questionnaire score at the baseline, end of treatment, and 1-month follow-up are summarized in Table 1, Figure 1 and Figure 2. After the treatment and at 1-month follow-up, the increase in scores was statistically significant compared to the baseline, thus supporting the clinical usefulness of this treatment. In particular, the test result indicates a statistically significant difference between IIEF score before treatment (Median = 34) and IIEF score after the end of treatment (Median = 45) and between IIEF score before treatment and IIEF score at 1-month follow-up (Median = 54).

The improvement was confirmed in all IIEF domains (see Table 1). Although the erectile function domain showed the largest change, significant modifications were noted in all the domains in the patients after treatment.

The ED severity is shown in Figure 3 and Table 2. Among the 20 participants of this study during the pre-test, we found that 20% of patients had severe ED (score range 6-

10), 70% moderate ED (score range 11-16), 5% mild-moderate ED (score range 17-21), and 5% mild ED (score range 22-25). None of them was found without dysfunction (score range 26-30).

After the treatment, 5% of participants were found to have severe ED, 20% had moderate ED, 65% had mild-moderate ED, 5% mild ED (score range 22-25), and lastly, 5% were found without dysfunction (score range 26-30).

During the post-test (after one month of the last treatment session), no participant was found to have severe ED. Few (10%) had moderate ED, the majority (45% and 40%) had mild-moderate ED and mild ED respectively, while 5% were found without dysfunction (see Table 2).

Table 2.

% of patients divided into 5 categories of ED classification.

ED classification	Before	End of treatment	1MFU
Severe (range score: 6-10)	4/20 (20%)	1/20 (5%)	0/20 (0%)
Moderate (range score: 11-16)	14/20 (70%)	4/20 (20%)	2/20 (10%)
Mild to moderate (range score: 17-21)	1/20 (5%)	13/20 (65%)	9/20 (45%)
Mild (range score: 22-25)	1/5 (5%)	1/20 (5%)	8/20 (40%)
No ED (range score: 26-30)	0/20 (0%)	1/20 (5%)	1/20 (5%)

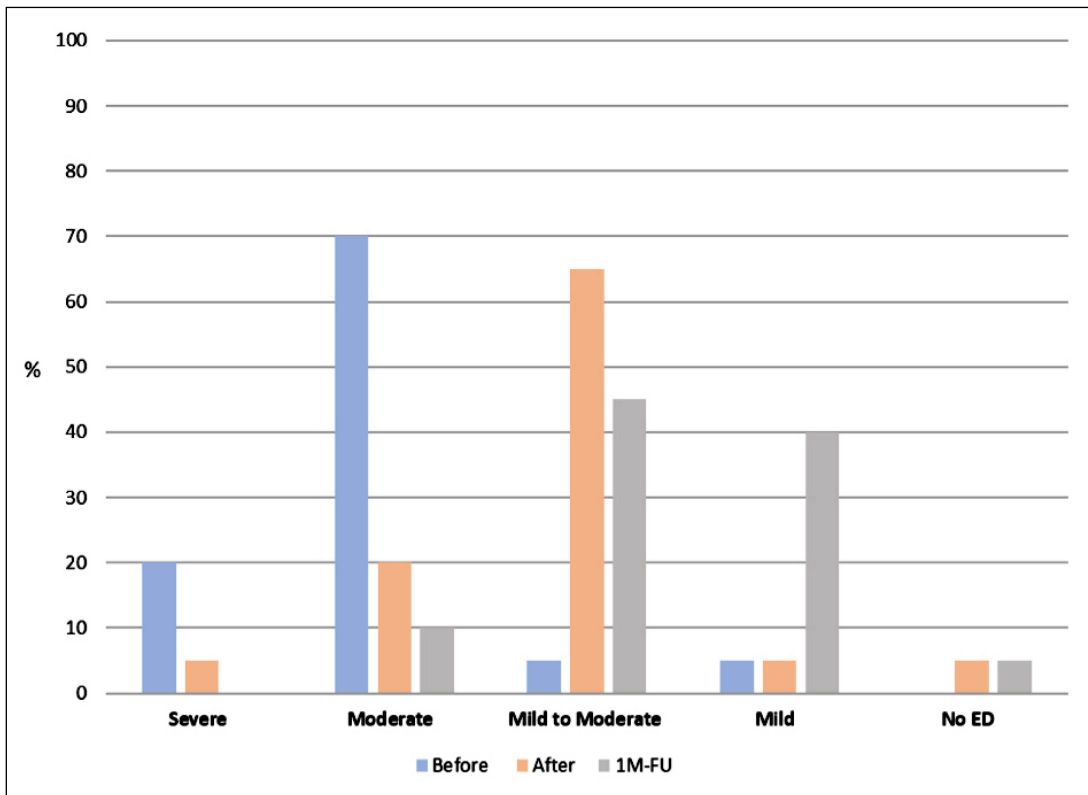


Figure 3. The percentage of patients is divided into 5 categories of ED classification. No ED (EF score 26-30), mild (EF score 22-25), mild to moderate (EF score 17-21), moderate (EF score 11-16) at baseline, at the end of the treatments and 1 month after the last session.

DISCUSSION

The current pharmacological treatment of ED and non-surgical treatment alternatives (such as vasodilating agents, intraurethral alprostadil, vacuum erection devices and intracavernosal injections) do not appear to improve endothelial dysfunction, restoring physiological erectile function, or significantly changing the underlying pathophysiology of the *erectile function* (EF) (12). These therapeutic approaches have a lot of drawbacks (side effects, low response rates) and a steady discontinuation rate of them was displayed (13). On the other hand, a penile prosthesis implant is an irreversible form of treatment and, even after the implantation, a man will never again be able to achieve a spontaneous erection.

The low-intensity extracorporeal shock wave therapy (Li-ESWT) has been proposed as a promising treatment for vasculogenic ED in recent years.

Since Vardi *et al.* (14) initially reported the use of Li-ESWT in the treatment of ED in 2010, several studies have assessed the effectiveness of Li-ESWT in various form of ED, whether they are organic (vasculogenic or neurogenic) or mixed (15). The patients included in the studies exhibit significant differences regarding cardiovascular risk factors, response to PDE5I, duration, and severity of ED. Additionally, there is a great deal of variation in the shockwave generators, the kind of shockwaves released, the parameters set, and the treatment plans employed (1). It is challenging to determine whether Li-ESWT is a practical option for the management of ED overall given the heterogeneous data. Several sexual medicine societies have cautiously accepted Li-ESWT as a treatment for men with ED in the past year. It is safe and

reasonably effective, but it should only be used in the context of clinical research (12, 16).

Overall, there was an improvement in the IIEF-EF score according to the pooled data from meta-analyses, but the estimates are low (ranging from roughly 2-4 IIEF-EF points) and the heterogeneity is high (16). Most of the research that has been published only included follow-up data for two years (12) and this raises the question of whether the early improvements in EF can be maintained over the long run. The results of the long-term study by Chung and Cartmill, indicate that, 48-60 months after the end of Li-ESWT, the clinical improvement in EF that was previously seen is still declining and appears to plateau at 40% clinical efficacy (17).

The idea of "regenerative" therapies for the treatment of ED has drawn a lot of attention in recent years. This concept makes sense because ED causes the erectile tissue to undergo anatomical and functional changes that are typified by progressive cavernosal fibrosis (18). Stem cell injections, platelet-rich plasma, and *low-intensity shock-wave therapy* (Li-SWT) are examples of regenerative treatments. Angiogenesis and neurogenesis may be induced by these methods, "restoring" malfunctioning erectile tissue, according to accumulating animal data (19). Regenerative therapies are a viable treatment option for erectile dysfunction, but there is currently little human data to support this claim (20).

We can also include magnetic stimulation in the list of regenerative therapies. In patients with urinary incontinence and pelvic floor disorders, magnetic stimulation has already been used to treat the human pelvic floor with great success. There have been no negative side effects or dis-

comfort and the *pelvic floor muscle* (PFM) tone and strength have significantly improved. The demonstration was conducted both quantitatively, using ultrasound exams, and qualitatively, using validated questionnaires (21).

Magnetic stimulation is a type of passive rehabilitation where there is no need for the patient to get undressed during treatment. Patients sit in an ergonomic chair that has a height-adjustable backrest, allowing them to experience total comfort and relaxation at every session. This innovative device targets neuromuscular tissue by creating an electric current that causes PFM to contract passively and strongly.

Electric currents associated with magnetic stimulation led to neuron depolarization, which triggers concentric contractions and lifts all PFM. This results in profound stimulation and the regeneration of neuromuscular control. Indeed, the entire procedure causes the muscle structure to change because the fibres tend to become hypertrophic and hyperplastic (8, 22). In addition to having a specific protocol for muscle hypertonicity, the device used in our study was appropriate for treating pelvic floor muscle dysfunction and ED. Indeed, by using lower frequencies (about 10 Hz) in the overtone protocol for hypertonic management, the electromagnetic field is distributed uniformly and does not produce areas of varying stimulation intensity.

Frigerio and colleagues showed that FMS significantly increased the size of the urethral rhabdosphincter, leading to a 15.4% increase in muscle volume, increasing the quality of life scores related to urination (8).

It has also been demonstrated that strengthening the pelvic floor muscles greatly enhances post-prostatectomy urine continence, post-micturition dribble and erectile function (22).

FMS technology has also a comparable impact on different skeletal muscles. In a study by Leone *et al.*, the effectiveness of similar device, which uses FMS technology, was assessed on the abdomens of 15 patients (23). This study showed that one month following the last treatment, all treated areas had experienced hypertrophy in terms of the thickness of abdominal muscle tissue.

Smooth muscle tissue makes up about 45% of the cavernous volume, with collagen making up most of the non-muscle component. The most crucial component of the hemodynamic processes that underlie an erection is the smooth muscle of the penis, consequently, magnetic stimulation, may be crucial in the treatment of ED, restoring fibromuscular pathological changes within the corpus cavernosum.

In 2003, Van Kampen *et al.* carried out a literature review whose results suggested that perineal rehabilitation could be an effective treatment for erectile dysfunction (24).

In human studies, Karacan *et al.* have shown that peaks in blood flow recordings coincided with bursts in the perineal muscles' EMG activity during nocturnal penile tumescence (25).

Our findings support the notion that pelvic floor rehabilitation plays a part in erectile dysfunction and are consistent with those of Rival and Clapeau (6). Indeed the improvement in IIEF-scores after the treatment and at the one-month follow-up was statistically significant when compared to the baseline, indicating the treatment's clin-

ical utility. The mechanisms supporting the potential role of strengthening the pelvic floor in erection would be an increase in endocavernous pressure and the limitation of venous return from the penis. Awareness of the region would also allow the patient to regain control of this part of their body.

Some authors have proposed including perineal rehabilitation as a first-line treatment for erectile dysfunction (26). This approach has no side effects, is cost-controlled and it can be combined with recommended approaches in the management of erectile dysfunction.

However, we do agree that more investigation is needed to look at different pathophysiological changes associated with FMS on penile tissue, including long-term histological changes.

In addition to muscular involvement, many studies have indicated that endothelial dysfunction or vascular damage is a key mechanism of ED (27).

In animal models, it has been shown that by shifting astrocytic phenotypes (A1-A2), magnetic stimulation can reduce the production of the pro-inflammatory cytokine TNF-alpha and promote the production of the anti-inflammatory cytokine IL-10. In A2 astrocytes, magnetic stimulation also promoted the release of angiogenesis-related factors TGFβ and VEGF, which can support angiogenesis. In a prior study, angiogenesis-related genes (VEGFA and BA11) were found to be upregulated in rats following magnetic stimulation (28). Lee and colleagues, following a stroke in an animal model, argued that magnetic stimulation, on the affected hemisphere, caused modifications in the angiogenic pathways; indeed, magnetic stimulation significantly raised *endothelial nitric oxide synthase* (eNOS) phosphorylation, which enhances angiogenesis (29). Since *nitric oxide* (NO) is essential for a physiological penile erection (as well as the mechanism through which PDE5Is act), we could speculate that FMS, besides the positive muscular effects, might have some NO-dependent benefits in angiogenesis, making it advantageous for patients with vasculogenic ED and low PDE5I response.

Furthermore, sperm motility is increased when human spermatozoa are exposed to a very low-frequency electromagnetic field (30).

While it's true that a person with erectile dysfunction might not have any difficulties to procreating, there are general characteristics and shared risk factors that lead to the development of infertility and erection dysfunction, so we can also conjecture about the potential positive impact of FMS on spermatozoa motility.

Filippini's study [which showed a significant improvement in PFM tone and strength in patients with urinary incontinence and pelvic floor disorders, both qualitatively and quantitatively with ultrasound exams (21)] and Mondaini's study [which showed improved erectile functioning, with the total mean IIEF-5 score significantly increasing from 21.3 ± 2.7 at baseline to 24.3 ± 0.5 at 1 month follow up after the last treatment session, $p < 0.001$ (10)] contributed to the concept of using FMS for ED treatment.

Our preliminary clinical findings were validated using prospectively questionnaires and, the outcome measures were the significant improvement of IIEF, without any significant adverse events.

Our device offers a number of significant benefits, including the ability to stimulate muscles without the need for a probe and the ability for patients to remain fully clothed while seated in an ergonomic and comfortable position due to the gradually correct emission of supplied energy. Finally, Dr. Arnold can be defined as an "educator" system because it helps the patient perceive the muscles involved in the treatment; additionally, other pharmaceutical or physical techniques can be used in conjunction with this new technology.

We recognized that our study had several limitations, including a small sample size, the absence of a sham treatment arm, and the lack of objective measurements of penile hemodynamics like penile colour duplex ultrasonography. However, prior research (12) has shown a strong correlation between the subjective report of EF recovery and objective penile hemodynamic improvements.

In conclusion, perineal physiotherapy seems to have its place in the management of erectile dysfunction.

Furthermore, magnetic stimulation of the muscle within the corpus cavernosum certainly induces muscle hypertrophy and the physiology of erection underlies the need for effective contraction of the ischiocavernosus; the treatments turned out with no side effects and with a high degree of patient acceptance. Undoubtedly, our experience has shown that FMS is a safe and effective option for improving ED with certainly muscular effects and with a potential interference in angiogenesis and spermatozoa motility.

For most men with ED, the ideal result is a lasting solution, which is something that FMS can potentially accomplish.

The long-term safety and efficacy of this therapy, which is still in the experimental stage, require further research in this area. Therefore, from a theoretical standpoint, this method can restore erectile function when compared to other previously used treatment methods.

CONCLUSIONS

The study findings showed that FMS represents a successful treatment option to individuals affected by symptomatic erectile dysfunction.

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