DOI: *10.4081/aiua.2025.14666*

ORIGINAL PAPER

TOP Flat Magnetic Stimulation therapy for post-prostatectomy stress urinary incontinence

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Summary

Background: *The most frequent complication in subjects of a radical prostatectomy (RP) is represented by urinary incontinence (UI), which can arise following the destruction of the pelvic floor muscles.*
Objectives: *The aim of this retrospective analysis was to assess the effect of Flat Magnetic Stimulation (FMS) in treating male stress urine incontinence (SUI) following RP.*
Materials and methods: *A total of 40 patients affected by SUI after RP, with a mean age of 56.8 (± 5.7) years old, underwent eight sessions with FMS. The Incontinence Impact Questionnaire-Short Form (IIQ-7) was administered from baseline up to 3 months of follow-up (3MFU) after the last treatment session. All possible adverse events were retrospective analysed.*
Results: *The analysis demonstrates that the scores for each individual questionnaire item decreased from baseline up to 3MFU after the last treatment session, leading to a significant ($p < 0.05$) reduction in the total IIQ-7 median score from 71.35 (66.6-76.11) at baseline to 28.54 (38.05-23.78) at 3MFU after the last treatment session. No adverse events were recorded over the whole course of treatment.*
Conclusions: *Our findings reveal that this technology may serve as a convenient and alternative treatment option for stress-caused urinary incontinence following RP.*

KEY WORDS: *Prostate cancer; Postprostatectomy; Stress urinary incontinence; Magnetic stimulation; IIQ-7 questionnaire.*

Submitted 20 November 2025; Accepted 6 December 2025

INTRODUCTION

The most common cancer in older men is prostate cancer (1), and the first-line therapy is frequently *radical prostatectomy* (RP). Standard open retropubic radical prostatectomy, robot-assisted radical prostatectomy and laparoscopic radical prostatectomy represent the most commonly performed surgical procedures for radical prostate cancer. However, the most frequent complication following a radical prostatectomy is represented by *urinary incontinence* (UI), which can arise from the destruction of the pelvic floor muscles and the nerves that supply them (2).
In actuality, many men suffer a temporary impairment of their urinary function after surgery, which gradually improves over a period of one to two years (3, 4).
Nonetheless, a portion of people with chronic incontinence continue to experience a significantly lower *quality of life* (QoL), which can lead to problems with their psychological, social, professional, and sanitary conditions. Moreover, both patients and hospitals incur high expenses resulting from UI (4). *Post-prostatectomy incontinence* (PPI) rates are still widely variable, and the pathophysiological rationale is still un-clear.
Furthermore, it will be worthwhile to explore the best therapy to use, as there is not presently a consensus on an appropriate mode of diagnostic examination and the most timely and optimal selection of the pertinent treatment.
Conventional therapies for PPI include pelvic floor muscle training (utilizing biofeedback or not), surgical treatment, electrical stimulation (perineal and anal electrical stimulation), compression penile devices, pharmacological treatment with anticholinergics, *extra-corporeal magnetic innervation* (ExMI), endoscopic treatment, artificial sphincter implantation, urethral fillers (collagen injections), and lifestyle modification (5). However, for a great number of individuals, conservative therapy may have limits (6). Anticholinergic drugs have a limited efficacy except in the case of unstable bladder demonstrated by urodynamic assessment (7).
On the contrary, duloxetine, a *selective serotonin-noradrenaline reuptake inhibitor* (SSNRI) has been used for treatment of UI because of its supposed action on the noradrenergic extrinsic sphincter. Duloxetine has demonstrated efficacy in the short-term management or improvement of PPI and shortens the time required to restore continence. Adverse effects are relatively common, and a notable proportion of men discontinue therapy due to these side effects (8).
Additionally, treating or preventing urinary incontinence through pre-operative or postoperative therapies has a considerable impact on the development of short-term problems of urine incontinence, but not long-term issues (9). While electrical nerve stimulation therapy is frequently more costly than traditional care when treating patients (10), biofeedback and professional therapist-guided treatment are equal when comparing treatment costs (11). Regular therapy and pelvic floor muscle training alone are more cost-effective than other forms of treatment, especially when urinary incontinence does not

substantially impair QoL (12). However, the effectiveness of Kegel exercises is reduced, since they are often not performed by patients in a progressive and proper manner; instead, patients should be encouraged to continue these therapies (13).

All surgical techniques have disadvantages, including chronic pelvic pain, visceral damage, and hyperactive bladder symptoms/voiding dysfunctions (14). Also, pharmaceutical treatments for SUI are limited. Serotonin and norepinephrine reuptake inhibitors are the only pharmacological treatments available. Numerous clinical studies have documented the common side effects of these medications, which include constipation, dry mouth, vomiting, fatigue, migraine, insomnia, and digestive tract problems (15).

Furthermore, the implantation of an *artificial urethral sphincter* (AUS) shows potential hazards, including prolonged leakage, the failure of mechanical components, deterioration, and infection. Likewise, irradiated patients can potentially be more vulnerable to difficulties following the implantation of an AUS (16).

It has also been shown that the use of slings in men with severe SUI has poor efficacy in this subgroup of patients (17).

When using adjustable balloons, the most frequent intraoperative complication is urethral or bladder perforation, and early complication rates are typically greater than with other anti-incontinence procedures (18).

Magnetic stimulation (MS) has been shown in numerous trials to be effective in treating SUI/UUI disorders (19, 20) and in treating patients with *mixed urine incontinence* (MUI) (21). In contrast to ES, MS requires less current to be generated on the surface of the body. Therefore, MS can activate deep brain regions by generating electric currents without giving the patient any pain or discomfort. Furthermore, due to the deep penetration of the electromagnetic field in the pelvic area, the *pelvic floor muscles'* (PFMs') muscular force is activated more effectively in this way than with electro-stimulators, where the majority of the energy emitted is scattered on the surface. MS therapy leads to an improvement in patients' UI symptoms and QoL, with no documented negative effects. Long-term trials, on the other hand, must determine treatment outcomes over time (22).

Recent developments in technology have enhanced magnetic stimulator devices. Among these, *Flat Magnetic Stimulation* (FMS) has recently been established. FMS is defined by a homogeneous electromagnetic profile which can cover the whole pelvic area. This new magnetic field produces intense stimulation that is equally distributed, permitting a high level of muscle fiber activation without causing zones of irregular or inadequate fiber recruitment (23).

Recently published studies have already demonstrated the efficacy of FMS in the management of different types of UI and pelvic floor dysfunctions/pain in female subjects of various ethnicities (24-26), erectile dysfunction (27), male chronic pelvic pain (28) and male UI after radical prostatectomy, with good and promising results (29).

In light of the existing scientific literature, the present manuscript aims to conduct a retrospective analysis of the effects of FMS technology in the management of male SUI after RP.

Materials and methods

Study device and protocols

A non-invasive electromagnetic therapeutic device (*PelviTouch treatment by DR ARNOLD, DEKA M.E.L.A. Calenzano, Italy*) was employed for this investigation. The study device is equipped with a chair applicator that has a coil in the center of the seat in order to targeting the deep pelvic floor area. To obtain the greatest possible outcome, a urologist positions the patient prior to each session. Keeping the thighs parallel to the floor and the feet flat, the patient's legs are positioned up perpendicularly. It is advised that patients bend their knees to at least a 90-degree angle. This optimizes the local stimulation of the pelvic floor and sphincter muscles by placing the patient's perineum in respect to the center of the seat. The device is able to produce a uniform and homogenous profile (*TOP Flat Magnetic Stimulation*), that permits a deep, symmetrical, and uniform distribution of electromagnetic radiation, which, instead of spreading superficially, penetrates deep into the neuronal centers inside the pelvis.

For this treatment, the two FMS protocols Hypotonus/Weakness 1 (muscular protocol intended to restore muscle tone and trophism) and Hypotonus/Weakness 2 (muscle protocol designed to develop muscle strength and trophism (volume)) were selected.

Patient population

In this retrospective analysis, a total of 40 patients affected by SUI after RP, with a mean age of 56.8 (± 5.7) years old, were treated from May 2023 to August 2024. The demographic characteristics of the patients are reported in Table 1.

Patient prognosis was assessed by histopathological evaluation. In line with the *World Health Organization* (WHO) classification of tumors of the prostate and bladder, 27.5% of patients were categorized with stage T2a, 37.5% of patients were categorized with stage T2b, 17.5% of patients were categorized with stage T2c, 15% of patients were categorized with stage T3a and 2.5% of patients were categorized with stage T3.

Criteria for exclusion included having severe neurological illnesses, obesity, malignant tumors in progress, metal implants or pacemakers.

All the subjects involved in the study gave their written informed consent, which was archived.

Table 1.
Patients' baseline characteristics.

Patient's baseline characteristics	
Sample size (n)	40
Mean age (years-old)	56.8 (± 5.7)
BMI (Mean ± SD)	27.8 ± 1.3
Comorbidities	9/40 with arterial hypertension 3/40 with cardiovascular pathology 4/40 with diabetes 3/40 with arterial hypertension and diabetes

Study design
All the patients included in this analysis underwent 8 sessions (4 sessions with hypotonus 1 and 4 sessions with hypotonus 2) with the study device for a treatment duration of 28 minutes. The first treatment was performed one month after surgery.

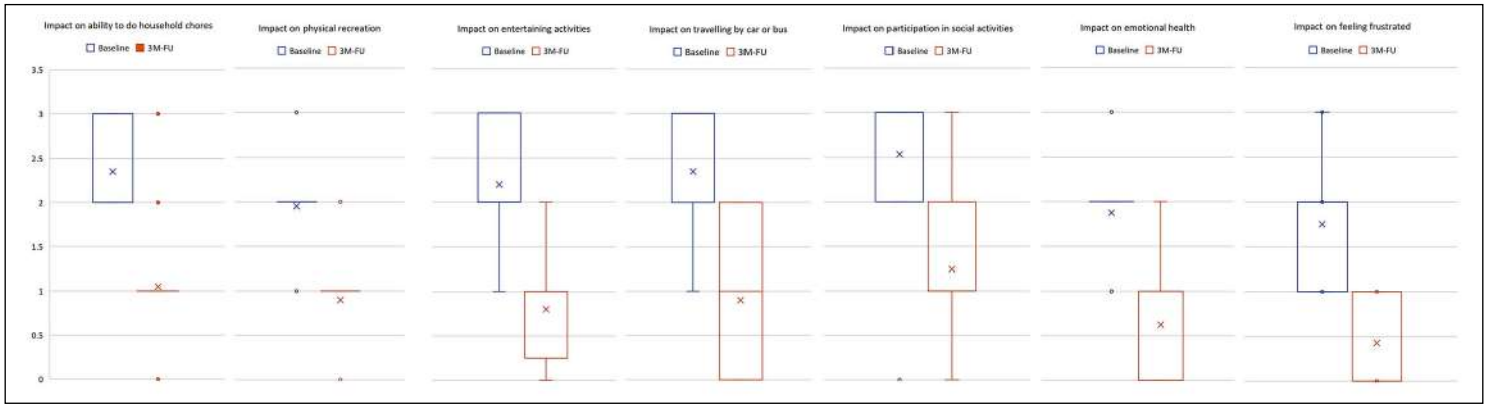
Study outcomes
The primary evaluation of the therapy was judged with the use of the Incontinence Impact Questionnaire-Short Form (IIQ-7) (30), which was a standard questionnaire useful in investigating and assessing the efficacy of this kind of treatment from baseline up to 3 *months of follow-up* (3MFU) after the last treatment session.
The secondary evaluation was represented by the analysis of the correlation between the patient's age and IIQ-7 item scores.

Side effects
All possible adverse events such as tendon/muscular pain, temporary muscle spasm, local erythema or skin redness were analysed.

Statistical analysis
Statistical examination was carried out by Wilcoxon Signed Rank Test [median and *interquartile range* (IQR)], $p < 0.05$ for significance) using SPSS (*IBMCorp., New York, USA*).

Results
The results demonstrate that mean score of each questionnaire's item significantly ($p < 0.05$) decreased from baseline (one month after surgery) up to 3MFU after the last treatment session, as is graphically represented in Figures 1 and 2.
Figure 1 indicates that the impact on the ability to perform household chores significantly ($p < 0.05$) declined from 2(2-3) at baseline to 1(1) at 3MFU after the last treatment session; similarly impact on physical recreation significantly ($p < 0.05$) declined from 2(2) at baseline to 1(1) at 3MFU; impact on entertaining activities significantly ($p < 0.05$) declined from 2(2-3) at baseline to 1(0.25-1) at 3MFU; impact on traveling by car or bus significantly ($p < 0.05$) declined from 3(2-3) at baseline to 1(0-2) at 3MFU; impact on participation in social activities significantly ($p < 0.05$) declined from 3(2-3) at base-line to 1(1-2) at 3MFU; impact on emotional health significantly ($p < 0.05$) declined from 2(2) at baseline to 1(0-1) at 3MFU, and impact on feeling frustrated significantly ($p < 0.05$) declined from 2(1-2) at baseline to 0(0-1) at 3MFU.
Finally, as shown in Figure 2, a significant ($p < 0.05$) reduction in the total IIQ-7 median score from 71.35

Figure 1.
Box plots representing partial IIQ-7 mean scores at baseline and up to 3MFU after the last treatment session.



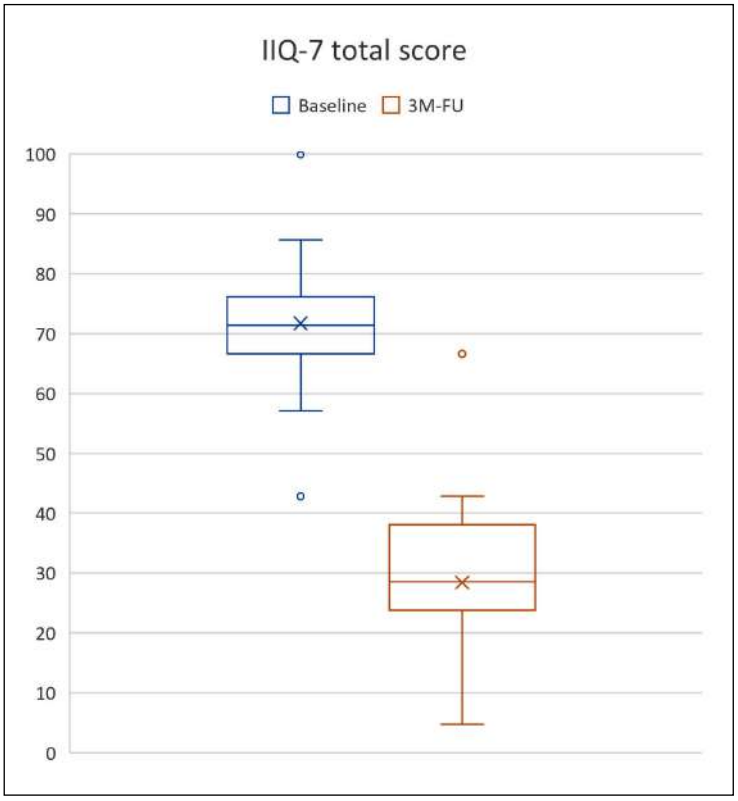


Figure 2.
Box plot for score at baseline and at 3MFU for total IIQ-7 questionnaire.

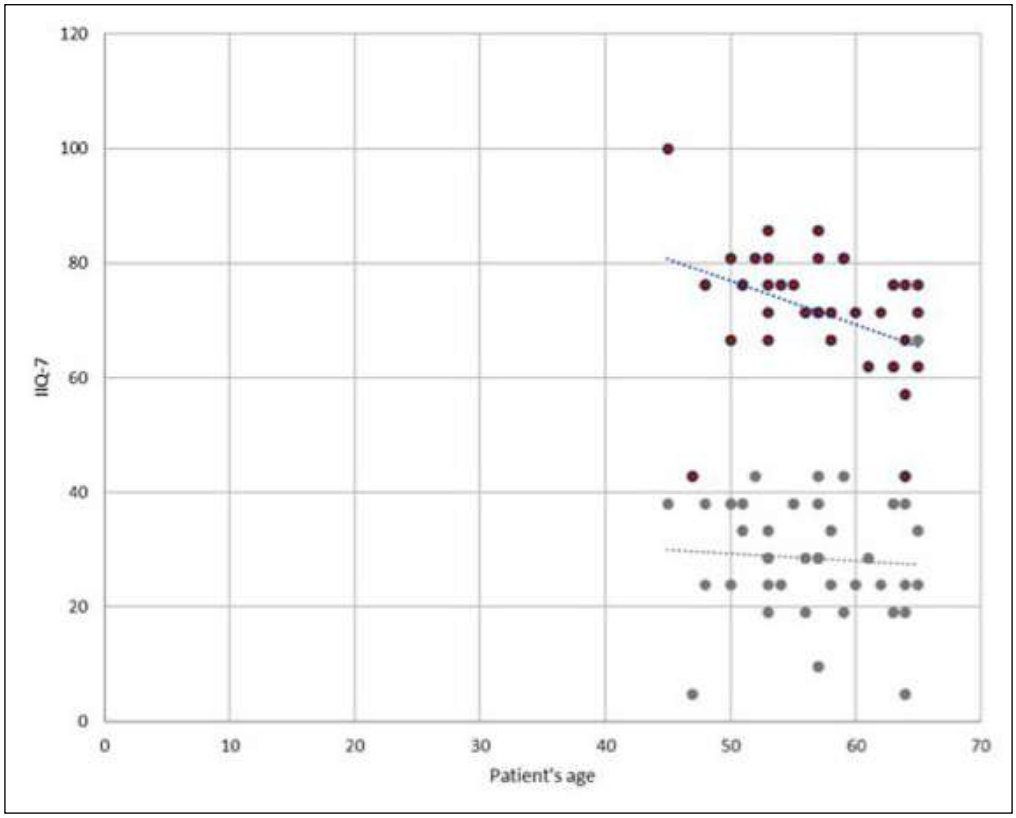


Figure 3.
Graphical representation of the correlation between the patient's age and IIQ-7 item scores (red dots at baseline; gray dots at 3 months of follow-up).

(66.6-76.11) at baseline to 28.54 (38.05-23.78) at 3MFU after the last treatment session was observed.
Patient age showed significant negative correlations with IIQ-7 score at baseline ($r = -0.385$, $p = 0.014162$). On the contrary, a non-significant correlation between age and the values of the questionnaire was identified at 3 months of follow-up ($r = -0.059$, $p = 0.717627$) (Figure 3).
All patients reported improvements and increased participation in social activities, and throughout the entire duration of treatment, no adverse events were noted.

Discussion

The patient's biological and surgical conditions influence post-prostatectomy UI, which requires an accurate evaluation. According to the questionnaire's results, our data clearly show the benefits of performing FMS therapy for post-prostatectomy SUI conditions in all patients enrolled, indicating an improvement in SUI symptoms from baseline to 3MFU after the last treatment session, confirmed by the significant reduction in IIQ-7 median scores observed in all treated subjects. Indeed, the mean of each IIQ-7 item (impact on ability to do household chores, impact on physical recreation, impact on entertaining activities, impact on traveling by car or bus, impact on participation in social activities, impact on emotional health and impact on feeling frustrated) significantly ($p < 0.05$) declined from baseline to 3MFU after the last treatment session. In addition, this marked reduction in SUI symptoms' severity has been shown to have a positive impact on patient's QoL.
According to the qualitative evaluation, patients also reported improved sexual satisfaction and better urine control. The study results were validated by the use of IIQ-7, which is an easy questionnaire of high psychometric quality that can be used in clinical settings to assess treatment effectiveness and characterize the severity of incontinence (30). The validity and reliability of the IIQ-7 was tested in the study of *Moore et al.* (31), in which fifty-eight men with incontinence after radical prostatectomy were enrolled.
Gonzalez et al. (29) also employed the IIQ-7 to explore and assess the efficacy of the research device in resolving UI symptoms in a 70-year-old man with a history of laparoscopic RP. These clinical data demonstrate that after treatment with the study technology, all individual questionnaire scores decreased from baseline to *2 month follow up* (2MFU), resulting in a reduction in the total IIQ-7 mean score from baseline to 2MFU.
The patient was very satisfied and reported QoL improvement and more involvement in social activities, while no adverse events were recorded for the entire treatment period.
Our study expands on the research of *Gonzalez et al.* (29), including a great-er number of patients and extending the follow-up to 3 months, demonstrating also in this case a significant improvement in the patient's urinary symptoms after treatment, which resulted in improved urine control and enhanced sexual satisfaction. The published scientific research indicates that magnetic stimulation is more effective than electrical stimulation in improving patients' QoL and UI symptoms after RP (32).
Furthermore, the evidence of the efficacy of magnetic stimulation in the treatment of chronic male pelvic pain

syndrome and associated UI complications is already well established (31). Indeed, the study of *Rowe et al.* (33) has demonstrated that the use of pelvic floor electromagnetic therapy may be a promising new non-invasive option for chronic pelvic pain syndrome in men, with positive outcomes observed up to 1 year of follow-up. Our data are in line with and confirm these positive findings.

According to the scientific literature, the research technology can be used to safely and effectively treat urge, stress, and mixed UI in a wide range of patients when combined with PFMs strengthening, leading to the patient's efficient recovery of neuromuscular control, as previously discussed in the introduction section.

The device's effectiveness in restoring male SUI is linked to its mechanism of action. Indeed, unlike surgical procedures, this technology triggers intense PFMs contractions by targeting neuromuscular tissue and inducing electric currents. Its primary effectiveness is based on the electromagnetic radiation, deep penetration, and stimulation of the entire pelvic floor area. This has a direct impact on muscle structure, causing more efficient myofibril growth (muscle fiber hypertrophy) and the formation of new protein strands and muscle fibers (muscle fiber hyperplasia).

Magnetic stimulator technology stimulates deep PFMs and restores neuromuscular control.

Maximal voluntary contraction (MVC) is the maximum amount of tension that a muscle can produce and maintain physiologically, but it normally lasts only a fraction of a second.

A contraction is considered supramaximal if its tension is greater than the MVC. With this technology, supramaximal PFMs contractions can be produced and maintained for a few seconds. These contractions directly affect the pelvic floor's peripheral nerves and are not influenced by brain activity. This process causes supramaximal contractions that it is typically not possible to achieve with natural muscle movement (for example, with the Kegel exercise).

The effectiveness of this method is contributed to by the steadily increasing intensity of the electromagnetic fields and the frequency of pulses, which result in distinctive, vigorous contractions.

The effectiveness of the treatment is linked to the ability to correctly contract the affected muscle. Since the magnetic field's intensity is not a fixed variable, the output intensity is maintained during the course of treatment by keeping it just above each patient's tolerance threshold. A fundamental aspect that distinguishes the study device from other devices is the spatial profile of the electromagnetic stimulation, which is graphically represented in Figure 4.

Since it is uniformly dispersed, electromagnetic radiation can be disseminated deeply, symmetrically, and uniformly, reaching deep neural regions within the pelvis without superficial dispersion.

Indeed, the tested device's performance is dependent on neuromuscular control rehabilitation deepening PFMs stimulation via electromagnetic radiation.

Additionally, this technology offers a number of noteworthy benefits over traditional pelvic floor restoration treatment approaches. The first benefit is related to the absence of a probe, which allows non-invasive muscle stimulation, while the patient remains comfortably dressed in an ergonomic and comfortable seat, via the consistent emission of gradually delivered energy.

During the treatment, patients perceive the relaxation of their muscles and can subsequently acquire greater self-awareness, which allows them to resume their daily activities.

Moreover, the device's capacity to operate via distinct protocols renders it efficacious in addressing various pathological disorders associated with urine incontinence. Lastly, this technology may potentially be employed in conjunction with additional physical or drug-based approaches.

The study's limitations include the lack a longer follow

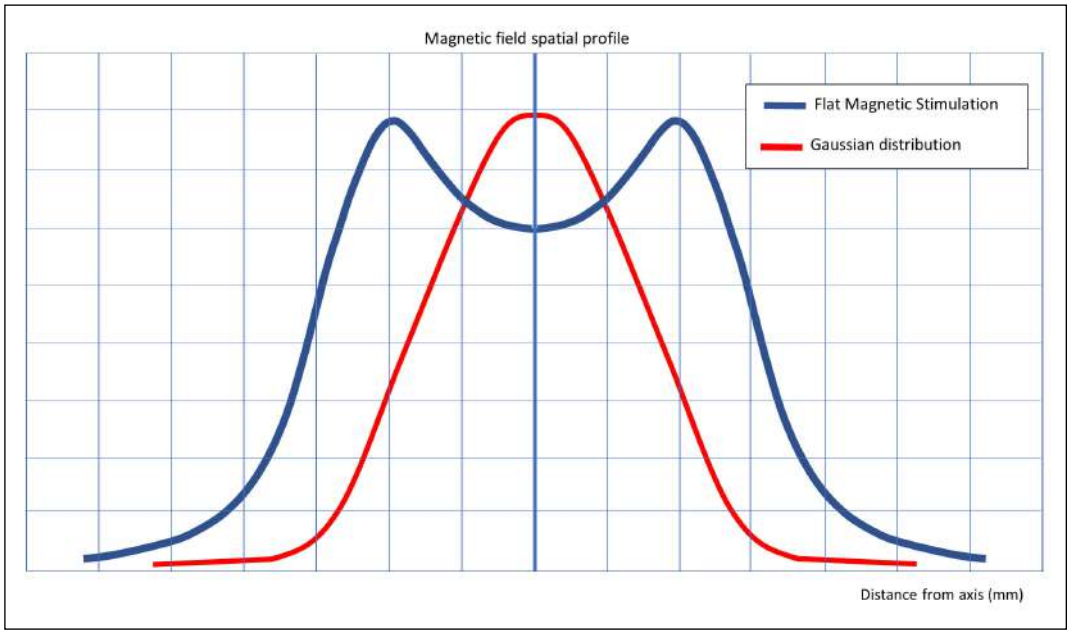


Figure 4.
The spatial profile of the magnetic field, which allows for a double-dome distribution of electromagnetic energy. Courtesy of DEKA M.E.L.A srl.

up, the lack of sample size calculation, and the lack of a comparison group.
Further investigations will be planned, including a longer follow-up period, a larger number of patients, and an analysis extension, in order to confirm the study's outcomes.

Conclusions

This retrospective analysis clearly shows the benefits of FMS therapy for post-prostatectomy SUI conditions in all patients enrolled, indicating an improvement in SUI symptoms from baseline to 3MFU after the last treatment session, suggesting that this technology offers an alternative and convenient post-prostatectomy stress urinary incontinence treatment tool. We will undertake further research on practical contexts, focusing on intervention development and new directions of scientific inquiry, examining the efficacy of this technology in improving UI conditions.

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Declarations

Institutional Review Board Statement: *The study was conducted with routine clinical activity. 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.*

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

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 other 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 received no external funding.*

Authors' contributions: *Conceptualization, NM, FC, MG, FC, and RD; methodology, NM, FC, MG, FC, and RD; validation, NM, FC, MG, FC, AC, TZ, and RD; formal analysis, NM, FC, MG, FC, AC, TZ, and RD; software, NM, FC, MG, FC, and RD; investigation, NM, FC, MG, FC, and RD; visu-alization, NM, FC, MG, FC, IF, AC, TZ, and RD; resources, NM, FC, MG, FC, and RD; data curation, NM, FC, MG, FC, IF, AC, TZ, and RD; writing—original draft preparation, IF; writing—review and editing, NM, IF, AC, and TZ; supervision, NM, FC, MG, FC, IF, AC, TZ, and RD; project admin-istration, NM and TZ. All authors have read and agreed to the published version of the manuscript.*

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