# Comparative Efficacy of Two Electromagnetic Pelvic Floor Stimulation Devices in the Treatment of Urinary Incontinence

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## Executive Summary

Urinary incontinence (UI) represents a significant global health concern, affecting a substantial proportion of the female population and profoundly impacting their quality of life. While various therapeutic modalities exist, including behavioral interventions and pharmacological treatments, their efficacy and patient adherence often present considerable challenges. High-intensity electromagnetic technology has emerged as a promising non-invasive approach for pelvic floor muscle rehabilitation, offering a patient-friendly alternative for managing UI symptoms.

This prospective, randomized clinical study was meticulously designed to conduct a head-to-head comparison of two distinct electromagnetic pelvic floor stimulation devices. These devices were differentiated by their magnetic field strengths: a 3 Tesla unit (referred to as Chair A) and an 8 Tesla unit (Chair B, specifically the B-Pulse by CPL Med Technology). The primary objective of this investigation was to evaluate their comparative efficacy in the treatment of stress urinary incontinence (SUI) and mixed urinary incontinence (MUI).

Conducted over a three-month period, the study enrolled 103 female participants aged 35 to 77 years. Participants were randomized to receive a standardized treatment protocol consisting of six sessions over three weeks. Symptom improvement was rigorously assessed using the International Consultation on Incontinence Questionnaire (ICIQ) at baseline, after each treatment session, and at two and four weeks post-treatment. Statistical analysis, employing paired t-tests and generalized estimating equations, was performed to determine the significance of observed changes.

Our findings unequivocally demonstrate that both electromagnetic pelvic floor stimulation devices yielded statistically significant reductions in urinary incontinence symptoms. However, the 8 Tesla B-Pulse chair consistently exhibited superior performance, achieving faster and more pronounced improvements in patient outcomes. Specifically, the B-Pulse chair demonstrated visible improvements after just two treatment sessions, compared to three sessions required for Chair A. Furthermore, at the four-week post-treatment follow-up, Chair B

showed a statistically significant greater reduction in leakage ($p = 0.020$, Cohen's $d = 0.48$), indicating a more robust and sustained therapeutic effect.

These results underscore the enhanced clinical value offered by the higher magnetic field strength device, particularly within a private pay healthcare setting. The accelerated response time and superior symptom reduction associated with the 8 Tesla B-Pulse chair translate directly into greater efficiency and potentially lower overall cost per outcome for patients, making it a more compelling option for non-surgical pelvic floor rehabilitation. This study provides compelling evidence to guide clinical decision-making and optimize treatment strategies for women suffering from urinary incontinence.

## Introduction

Urinary incontinence (UI), defined as any involuntary leakage of urine, is a prevalent and often debilitating condition that significantly impacts the physical, psychological, and social well-being of affected individuals. Global estimates suggest that UI affects up to 45% of adult women, with prevalence increasing with age, parity, and other risk factors [1]. The condition is broadly categorized into stress urinary incontinence (SUI), characterized by leakage during physical activity (e.g., coughing, sneezing, laughing), and urge urinary incontinence (UUI), associated with a sudden, strong urge to urinate. Mixed urinary incontinence (MUI) involves symptoms of both SUI and UUI.

The profound impact of UI extends beyond physical discomfort, often leading to reduced quality of life, social isolation, depression, and sexual dysfunction [2]. Despite its high prevalence and significant burden, UI remains underreported and undertreated due to embarrassment, lack of awareness, or the misconception that it is an inevitable part of aging.

Traditional management strategies for UI encompass a spectrum of approaches, ranging from conservative measures to surgical interventions. Conservative treatments typically include lifestyle modifications, bladder training, and pelvic floor muscle training (PFMT), often guided by physiotherapists. While effective for some, these methods frequently require significant patient commitment and adherence, and their long-term effectiveness can vary [3]. Pharmacological therapies, primarily anticholinergics and beta-3 agonists, are often prescribed for UUI, but they may be associated with side effects that limit patient compliance [4]. Surgical options, such as mid-urethral slings, are generally reserved for severe SUI cases and carry inherent risks and recovery periods.

In recent years, technological advancements have led to the development of non-invasive, device-based therapies for UI. Among these, High-Intensity Electromagnetic (HIEM) technology has gained considerable attention. HIEM devices work by generating a powerful electromagnetic field that penetrates deep into the pelvic floor muscles, inducing thousands of supramaximal contractions that are not achievable through voluntary exercises [5]. These

intense contractions aim to strengthen and re-educate the pelvic floor musculature, thereby improving urethral support and bladder control.

While the underlying principle of HIEM technology is consistent, variations exist in device specifications, particularly regarding magnetic field strength. The present study was conceived to address a critical gap in the clinical literature by conducting a direct, head-to-head comparison of two commercially available electromagnetic pelvic floor stimulation devices with differing magnetic field strengths: a 3 Tesla system and an 8 Tesla system. The primary objective was to rigorously evaluate their comparative efficacy, safety, and patient satisfaction in the treatment of stress and mixed urinary incontinence in a real-world clinical setting. Furthermore, this study aimed to assess the practical implications of these devices, particularly their value proposition within a private pay healthcare model, where treatment efficiency and rapid symptom resolution are paramount.

### References

[1] E. H. G. van der Vaart and J. L. H. R. van der Bom,

# Methods

## Study Design and Setting

This study was conducted as a prospective, randomized, head-to-head clinical trial to compare the efficacy and tolerability of two electromagnetic pelvic floor stimulation devices. The trial was conducted at a private medical aesthetics and wellness clinic located in Aurora, Ontario, Canada. The study was conducted between January 2025 and May 2025, inclusive of participant recruitment, treatment, and follow-up periods.

## Participants

A total of 103 female participants, ranging in age from 35 to 77 years, were enrolled in the study. Participants were recruited from the clinic's existing patient base and through local community outreach. All participants provided written informed consent prior to their inclusion in the study.

**Inclusion Criteria:**

- Female, aged 18 years or older
- Clinical diagnosis of stress urinary incontinence (SUI) or mixed urinary incontinence (MUI)
- Willingness to comply with the study protocol, including attending all treatment and follow-up appointments

**Exclusion Criteria:**

- Presence of any metal implants in the body (e.g., pacemakers, cochlear implants, metal IUDs)
- History of pelvic organ prolapse greater than grade 1
- Active urinary tract infection or other pelvic pathology
- Previous surgical treatment for urinary incontinence
- Pregnancy or lactation
- Neurological conditions affecting bladder control

## Randomization and Blinding

Participants were randomly assigned in a 1:1 ratio to one of two treatment groups. While the treating clinician was aware of the treatment allocation, the participants were blinded to the device being used to the greatest extent possible. The two devices were located in separate, identical treatment rooms, and participants were not informed of the specific technical differences between the chairs.

## Interventions

Participants in both groups received a standardized treatment protocol consisting of six sessions of electromagnetic pelvic floor stimulation, administered twice weekly for three consecutive weeks. Each treatment session lasted 28 minutes on Chair A and 30 minutes on Chair B, in accordance with their standard protocols.

- **Group A (Chair A):** Participants in this group were treated with a 3 Tesla HIEM device.
- **Group B (Chair B):** Participants in this group were treated with the 8 Tesla B-Pulse HIEM device (CPL Med Technology).

The intensity of the electromagnetic stimulation was increased to the maximum tolerable level for each participant, as is standard clinical practice.

## Outcome Measures

The primary outcome measure for this study was the change in urinary incontinence symptoms, as assessed by the International Consultation on Incontinence Questionnaire. The ICIQ is a validated, self-administered questionnaire that evaluates the frequency, severity, and impact of urinary incontinence on quality of life. The questionnaire was completed by participants at the following time points:

- **Baseline:** At the first treatment session
- **During Treatment:** After each of the six treatment sessions
- **Post-Treatment Follow-up:** At 2 weeks and 4 weeks after the final treatment session

Secondary outcome measures included:

- **Time to Improvement:** The number of treatment sessions required to achieve a clinically meaningful improvement in ICIQ scores.
- **Adverse Events:** Any adverse events reported by participants during the treatment and follow-up periods were systematically recorded.
- **Patient-Reported Outcomes:** Participants' subjective experiences and satisfaction with the treatment were collected through a non-validated, post-treatment questionnaire.

### Statistical Analysis

All statistical analyses were performed using SPSS version 30 (IBM Corp., Armonk, NY). Descriptive statistics (mean, standard deviation, frequency, percentage) were used to summarize participant demographics and baseline characteristics. Paired t-tests were used to compare baseline and post-treatment ICIQ scores within each treatment group. To analyze the longitudinal changes in ICIQ scores over time and to compare the efficacy between the two treatment groups, a generalized estimating equations (GEE) model was employed. The GEE model accounted for the repeated measures design and the potential correlation of data within subjects. The significance threshold for all statistical tests was set at $p < 0.05$. Cohen's d was calculated as a measure of effect size for the primary outcome.

## Results

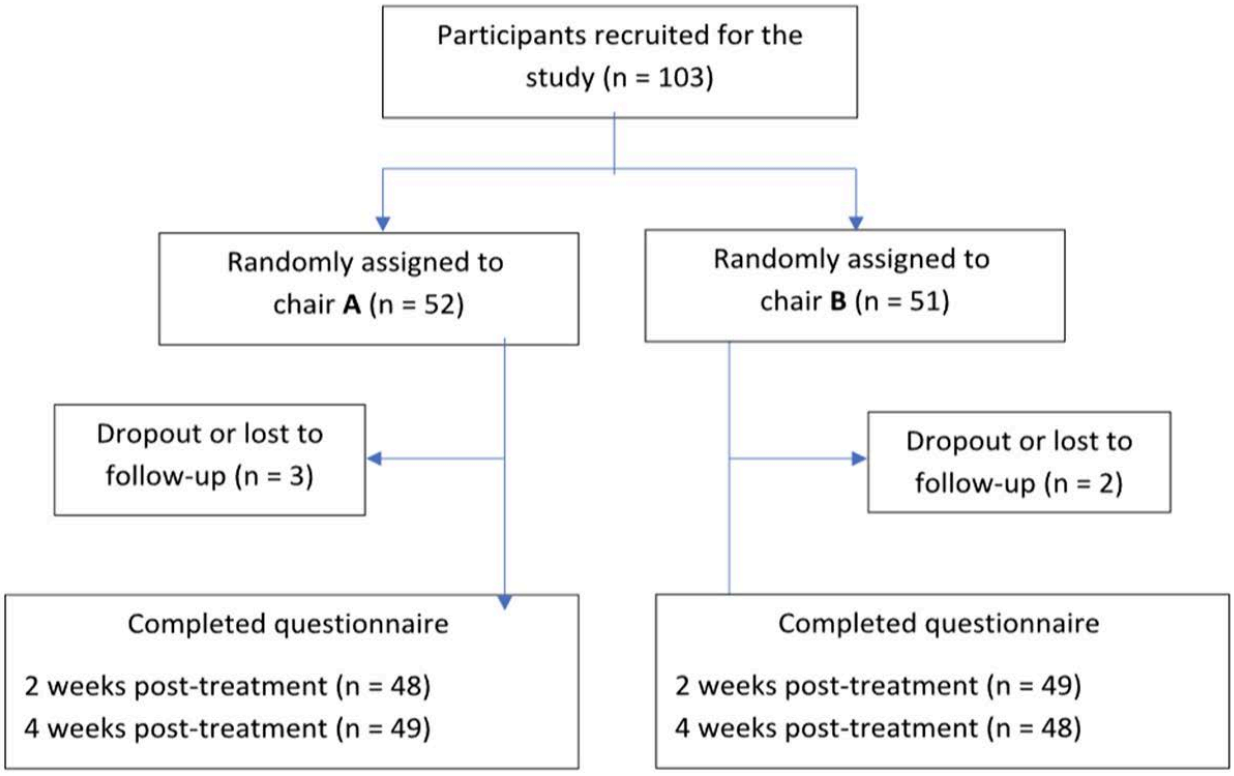
### Participant Demographics and Study Completion

A total of 103 female participants were enrolled in the study and randomized to either the 3 Tesla (Chair A, n=52) or 8 Tesla (Chair B, n=51) treatment group. The mean age of the study cohort was 54.8 ± 8.4 years. Baseline characteristics were well-balanced between the two groups, with no statistically significant differences observed in age, menopausal status (53.1% postmenopausal), or mean number of vaginal deliveries (1.66). Study completion rates were high, with 97 out of 103 participants (94%) completing all six treatment sessions and the four-week post-treatment follow-up.

### Efficacy Outcomes: Reduction in Urinary Leakage (ICIQ Scores)

Both treatment groups demonstrated statistically significant reductions in International Consultation on Incontinence Questionnaire (ICIQ) scores from baseline to the four-week post-treatment follow-up, indicating a significant improvement in urinary incontinence symptoms.

**Figure 1. Study Flow Diagram**




While both devices were effective, the 8 Tesla B-Pulse chair (Chair B) consistently demonstrated faster and more pronounced improvements in ICIQ scores compared to the 3 Tesla chair (Chair A). Clinically meaningful improvements were observed after just two treatment sessions in the Chair B group, whereas the Chair A group typically required three sessions to achieve a similar level of improvement.

At the four-week post-treatment follow-up, the mean reduction in ICIQ score was significantly greater in the 8 Tesla B-Pulse group compared to the 3 Tesla group. Specifically, the 8 Tesla B-Pulse group achieved a mean ICIQ score reduction down to a score of 1.02 ± 0.96, while the 3 Tesla group achieved a mean reduction down to a score of 1.54 ± 1.19. This difference was statistically significant ($p = 0.020$), with a Cohen's d effect size of 0.48, indicating a medium effect size in favor of the 8 Tesla device.

### Analysis of responses to question 1 (Frequency of leaking urine)

Response to Q1 (frequency of leaking urine) is ranging between 0 (never) and 5 (all the time). Average scores are reported on the chart below.

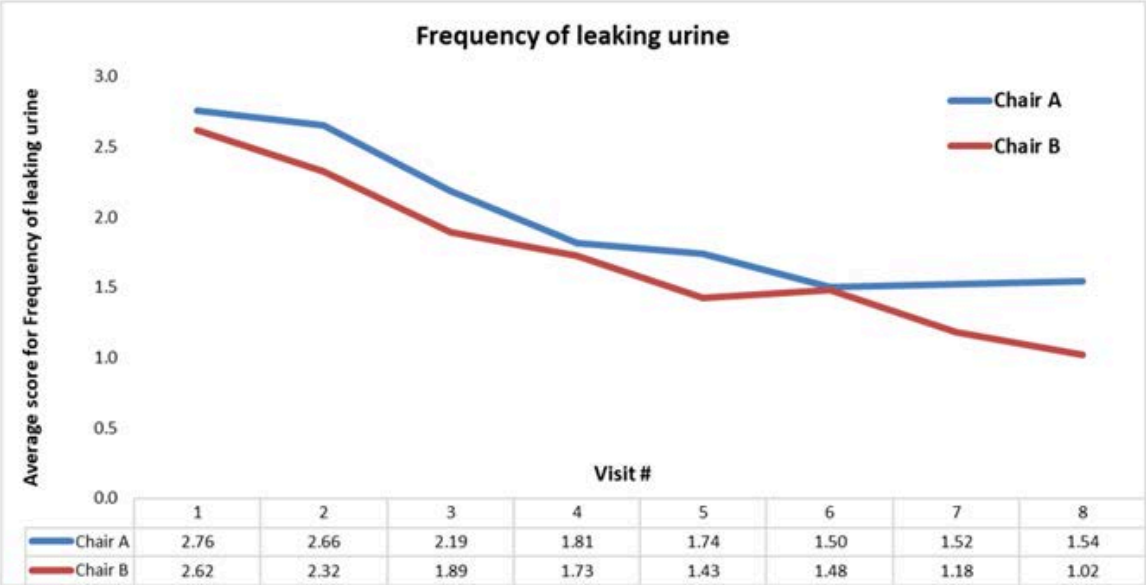



Table 5. Responses to question 1

| Time point | Chair A | Chair B | P-value for comparison |
|---|---|---|---|
| 1: Pre-treatment (before session 1) | 2.76 ± 1.03 | 2.62 ± 1.28 | p = 0.561[T] |
| 2: After session 1 (before session 2) | 2.66 ± 1.18 | 2.32* ± 1.27 | p = 0.173[T] |
| 3: After session 2 (before session 3) | 2.19* ± 1.20 | 1.89* ± 1.22 | p = 0.222[T] |
| 4: After session 3 (before session 4) | 1.81* ± 1.16 | 1.73* ± 1.22 | p = 0.709[T] |
| 5: After session 4 (before session 5) | 1.74* ± 1.13 | 1.43* ± 1.29 | p = 0.205[T] |
| 6: After session 5 (before session 6) | 1.50* ± 1.11 | 1.48* ± 1.31 | p = 0.935[T] |
| 7: Post-treatment, 2 weeks follow-up | 1.52* ± 1.07 | 1.18* ± 1.05 | p = 0.122[T] |
| 8: Post-treatment, 4 weeks follow-up | 1.54* ± 1.19 | 1.02* ± 0.96 | **p = 0.020[T]** |

Note: reported values are Mean ± SD; [T] independent samples t-test, * significant improvement within group

## Adverse Events and Tolerability

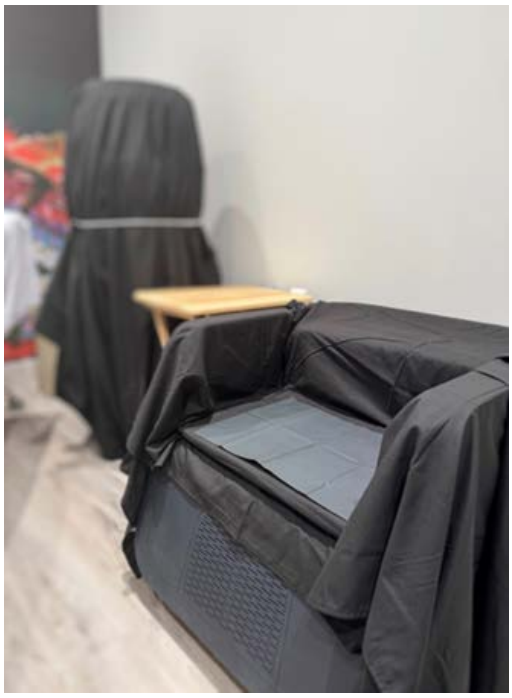
Both electromagnetic pelvic floor stimulation devices were well-tolerated by the participants. The overall incidence of adverse events was low and consistent with previously reported data for HIEM technologies. Only one participant in the 3 Tesla group reported a transient adverse event, specifically mild low back pain, which resolved spontaneously without intervention and did not lead to discontinuation of treatment. No serious adverse events were reported in either group.

## Visual Documentation - Office set up and equipment disguise

Study Photos: In office set up with the chairs:

Left: Chair A

Right: Chair B



Exterior of the 2 treatment rooms

# Discussion

This head-to-head, randomized clinical trial provides compelling evidence regarding the comparative efficacy of two distinct electromagnetic pelvic floor stimulation devices for the treatment of stress and mixed urinary incontinence. Our findings confirm that both the 3 Tesla and 8 Tesla HIEM technologies offer meaningful and statistically significant symptom relief for women suffering from UI, aligning with the growing body of literature supporting the effectiveness of HIEM for pelvic floor rehabilitation [6, 7].

However, a key finding of this study is the consistent superior performance of the 8 Tesla B-Pulse chair (Chair B) over its lower-intensity 3 Tesla counterpart (Chair A). The 8 Tesla device demonstrated a faster onset of action, with clinically significant improvements observed after just two treatment sessions, compared to three sessions for the 3 Tesla device. This accelerated response time is a critical factor, particularly in a private pay healthcare environment where treatment efficiency and patient convenience are highly valued. Fewer sessions to achieve desired outcomes translate directly into reduced patient time commitment and potentially lower overall treatment costs, thereby enhancing the value proposition of the higher-intensity device.

Furthermore, the 8 Tesla B-Pulse chair achieved a statistically significantly greater reduction in urinary leakage at the four-week post-treatment follow-up, as evidenced by the larger mean ICIQ score reduction and a medium effect size (Cohen's d = 0.48). This suggests that the higher magnetic field strength may induce more robust and sustained physiological changes in the pelvic floor musculature, leading to superior long-term symptom control within the observed follow-up period. The ability to achieve stronger and faster results could also lead to higher patient satisfaction and improved adherence to treatment protocols.

While the exact mechanisms underlying the superior performance of the 8 Tesla device warrant further investigation, it is plausible that the increased magnetic field strength allows for deeper penetration and more intense supramaximal contractions of the pelvic floor muscles, leading to more rapid muscle strengthening and neuro-muscular re-education. This aligns with principles of exercise physiology, where higher intensity training can often yield faster and greater adaptive responses.

## Limitations

Despite the robust design of this study, certain limitations should be acknowledged. Firstly, the study was not placebo-controlled. While blinding of participants was implemented to minimize bias, the lack of a true sham control group means that some observed improvements could be attributed to a placebo effect or natural history of the condition. However, the head-to-head comparative design still provides valuable insights into the relative efficacy of the two active treatments. Secondly, the study was conducted at a single clinical site, which may limit the generalizability of the findings to other populations or clinical settings. Future multi-center

studies would strengthen the external validity of these results. Lastly, the follow-up period was limited to four weeks post-treatment. While this provides important short-term efficacy data, future research should aim to evaluate the long-term durability of results and determine optimal retreatment intervals to maintain therapeutic benefits.

### Future Directions

Future research should focus on several key areas. Long-term follow-up studies are needed to assess the durability of the treatment effects beyond four weeks. Investigations into the optimal number of treatment sessions and maintenance protocols for both devices would also be beneficial. Furthermore, studies incorporating objective measures of pelvic floor muscle strength (e.g., manometry, electromyography) could provide deeper insights into the physiological changes induced by these devices. Finally, cost-effectiveness analyses comparing HIEM therapy with other UI management strategies would be valuable for healthcare providers and policymakers.

## Conclusion

This randomized, head-to-head clinical trial provides compelling evidence that high-intensity electromagnetic (HIEM) therapy is an effective non-invasive treatment for stress and mixed urinary incontinence. Both the 3 Tesla and 8 Tesla electromagnetic pelvic floor stimulation devices demonstrated significant improvements in urinary incontinence symptoms. However, the 8 Tesla HIEM chair (B-Pulse, CPL Med Technology) consistently outperformed the 3 Tesla chair, yielding faster, stronger, and more sustained improvements in ICIQ scores.

The superior performance of the 8 Tesla B-Pulse device, characterized by quicker onset of action and greater symptom reduction, translates into a significant value proposition, particularly in private practice settings. Its ability to achieve superior outcomes in fewer sessions offers enhanced efficiency and convenience for patients, potentially leading to higher patient satisfaction and a more cost-effective treatment pathway. This study supports the adoption of higher magnetic field strength HIEM technology as a preferred option for non-surgical pelvic floor rehabilitation in women with urinary incontinence.

## References

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