

# Safety and Efficacy of a Non-Invasive High-Intensity Focused Electromagnetic Field (HIFEM) Device for Treatment of Urinary Incontinence and Enhancement of Quality of Life

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**Background and Objectives:** Urinary incontinence is a common and distressing condition which interferes with everyday life. Patients frequently experience discomfort related to urine leakage and the subsequent need to use absorbent pads. Since the continence mechanism is primarily maintained by a proper function of pelvic floor muscles (PFM), many treatment methods focused on strengthening of the PFM have been introduced in the past. The aim of this study was to evaluate the safety and efficacy of a high-intensity focused electromagnetic technology (HIFEM) for treatment of urinary incontinence with emphasis on effects on prospective patients' quality of life.

**Study Design/Materials and Methods:** The study followed an institutional review board approved protocol. A total of 75 women (55.45 ± 12.80 years, 1.85 ± 1.28 deliveries) who showed symptoms of stress, urge, or mixed urinary incontinence were enrolled. They received six HIFEM treatments (2 per week) in duration of 28 minutes. Outcomes were evaluated after the sixth treatment and at the 3-month follow-up. The primary outcome was to assess changes in urinary incontinence by the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) and changes in the number of absorbent pads used per day. The secondary outcome was subjective evaluation of the therapy and self-reported changes in quality of life. The statistical analysis was conducted by paired *T*-test and Pearson correlation coefficient ( $\alpha = 0.05$ ).

**Results:** After the sixth session, 61 out of 75 patients (81.33%) reported significant reduction of their symptoms. The average improvement of 49.93% in ICIQ-SF score was observed after the sixth treatment, which further increased to 64.42% at the follow-up (both  $P < 0.001$ ). Individually, the highest level of improvement was reached in patients suffering from mixed urinary incontinence (69.90%). The reduction of absorbent pads averaged 43.80% after the sixth treatment and 53.68% at 3 months (both  $P < 0.001$ ), while almost 70% of patients (30 out of 43) reported decreased number of used pads. At the follow-up, a highly significant

medium correlation ( $r = 0.53$ ,  $P < 0.001$ ) was found between the ICIQ-SF score improvement and the reduction in pad usage. A substantial decrease in the frequency of urine leakage triggers was documented. Patients reported no pain, downtime or adverse events, and also reported additional beneficial effects of the therapy such as increased sexual desire and better urination control.

**Conclusions:** This study demonstrated that HIFEM technology is able to safely and effectively treat a wide range of patients suffering from urinary incontinence. After six treatments, an improvement in ICIQ-SF score and reduction in absorbent pads usage was observed. Based on subjective evaluation, these changes positively influenced quality of life. *Lasers Surg. Med.*

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**Key words:** HIFEM; pelvic floor muscles; urinary incontinence

## INTRODUCTION

Urinary incontinence (UI), defined as involuntary loss of urine [1], is a chronic condition which may negatively affect quality of life (QOL). On the basis of its etiology and

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