

Prospective Multi-Center Study on Long-term Effectiveness of HIFEM Procedure for Treatment for Urinary Incontinence and Female Sexual Dysfunction

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ABSTRACT

Objective: Weakening of the pelvic floor muscles (PFMs) may lead to urinary incontinence (UI) and female sexual dysfunction (FSD). This study investigated the long-term efficacy of HIFEM-induced PFMs strengthening to reduce UI and improve female sexual function.

Methods: Thirty-one females (47.9±8.6 years) showing UI and FSD symptoms underwent a total of six pelvic floor HIFEM treatments. These treatments were scheduled twice a week over three weeks with five follow-up visits at 1, 3, 6, 9, and 12 months. There were four different questionnaires administered: ICIQ-UI SF, FSFI, PISQ-12, and Therapy Comfort Questionnaire. Due to patients' drop-out, data evaluation was divided into two subgroups – patients monitored from baseline to 6 months (Group A, N=31) and from baseline to 1 year (Group B, N=18).

Results: At baseline, the ICIQ-UI SF average score showed 12.1±4.8 (A) and 12.8±4.8 points (B) referring to moderate to severe UI. The severity of UI significantly ($P<0.001$) decreased post-treatment, and subjects achieved the greatest improvement of 71% (A, -8.6 points) and 72% (B, -9.3 points) at 6-month follow-up. At 9 and 12 months, a slight but insignificant relapse was seen in ICIQ-SF scores. FSFI baseline scores of 18.4±5.8 (A) and 19.8±4.1 points (B) improved significantly ($P<0.001$) after the final treatment while maintaining the level of improvement throughout the study with a maximum improvement of +9.4 (A) and +10.0 (B) points. The most prominent changes were seen in the following subdomains: Orgasm, Lubrication, Arousal, and Satisfaction, similar to PISQ-12, where patients reported higher orgasm frequency, lubrication, and sexual desire.

Conclusion: The study documents that the HIFEM procedure significantly improves the quality of life of patients who are suffering from urinary incontinence and enhances female sexual function. Achieved results were seen to be sustained in a 1-year period. Considering the patient's needs and expectations, re-treatment may be indicated.

Keywords: FSFI, leakage, sexual disorders, pelvic floor dysfunction, sexual dysfunction, ICIQ-UI SF, orgasm, pelvic floor muscles

INTRODUCTION

Urinary incontinence (UI) is defined as any involuntary leakage of urine, and it presents a common problem among both males and females. Specific classifications include; Stress urinary incontinence

(SUI) where involuntary leakage of urine manifests during physical activity due to the sudden rise of abdominal pressure, for instance, when sneezing or coughing; Urge urinary incontinence (UUI) is involuntary urine loss associated with a sudden urge to urinate,

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