

LONG-TERM EFFICACY OF HIFEM[®] PROCEDURE FOR TREATMENT OF URINARY INCONTINENCE

NON-INVASIVE HIFEM PROCEDURE FOR TREATMENT OF URINARY INCONTINENCE: 6-MONTH AND 1-YEAR FOLLOW-UP DATA

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HIGHLIGHTS

- **ICIQ-SF** questionnaire showed **continuous improvement** in urinary incontinence up to **6-month**, while slightly receding at 1-year follow-up.
- Subjects reported **substantially decreased** usage of **absorbent pads** at all follow-ups.
- The results imply that the **improvement in UI outcomes may persist for as long as the 12-month** study period.
- The data suggests that a **maintenance treatment might be indicated in selected patients**, since **at the 1-year follow-up** an individual decline of results was observed.

DESIGN AND METHODOLOGY

- **Eleven subjects** (60.91±10.35 years, 2.27±1.62 deliveries), who participated in a previously published **multi-center study¹**, were followed up to **1 year** after the completion of **six HIFEM procedures** applied on pelvic floor.
- Subjects suffered from various types of **incontinence** including **stress, urge and mixed**.
- Subjects' QOL were evaluated by **ICIQ-SF and pad-usage questionnaires** at the baseline, after last treatment, at 3-month, 6-month and 1-year follow-up.
- Wilcoxon signed-rank test ($\alpha=0.05$) was used for **statistical analysis**.

¹Samuels JB, Pezzella A, Berenholz J, et al. Safety and efficacy of a noninvasive high-intensity focused electromagnetic field (HIFEM) device for treatment of urinary incontinence and enhancement of quality of life. Lasers Surg Med 2019;51(9):760-766.

RESULTS

- ICIQ-SF questionnaire showed **significant (P<0.01) reduction** of UI:
 - The baseline score of 11.09±4.37 points declined by **51.91%** (5.33±2.94 points) at **6 months** and by 36.89% (7.00±3.92 points) at 1-year follow-up.
 - **Frequency of leakage** occurrences were found to **consistently decrease** up to 6 months.
 - **One subject** reported complete loss of treatment outcomes at 1 year.
- **The HIFEM procedure considerably helped to reduce** usage of **absorbent pads** from 3.0 pads/24 hours at the baseline to 1.4 pads/24 hours at 1-year follow-up.
- **The interference of urine leakage** with the patients' everyday life **improved** from "moderate" to "mild" throughout the whole study.
- The patients' **subjective feedback** at 1-year follow-up **coincided with the observed results**.

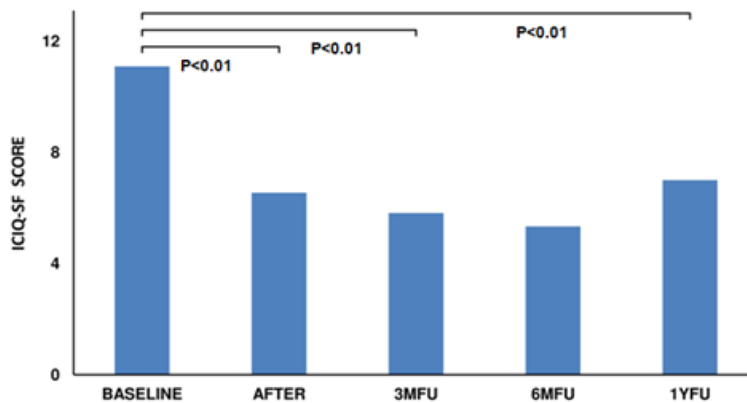


Figure 1: ICIQ-SF score throughout the whole study. Patients were constantly improving up to 6 months. There is seen a rise of ICIQ score at 1-year follow-up.

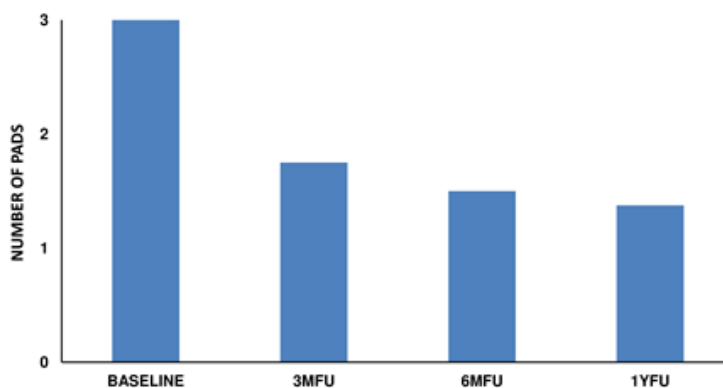


Figure 2: Pad usage documented in study subjects. Reduced usage of absorbent pads was seen in four out of five patients who were using pads at the baseline. The achieved improvement was sustained at the 1 year when patients used only 1.4 pads in 24 hours.