

HIFEM[®] PROCEDURE AND PELVIC FLOOR EXERCISE FOR URINARY INCONTINENCE

RANDOMIZED MULTI-CENTER TRIAL OF HIFEM PELVIC FLOOR STIMULATION DEVICE COMPARED WITH PELVIC FLOOR EXERCISES FOR TREATMENT OF URINARY INCONTINENCE: EVALUATION OF INITIAL SINGLE-CENTER DATA

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HIGHLIGHTS

- **Initial** short-term data demonstrated that **patients might benefit** either from **HIFEM** or pelvic floor muscle training (**PFMT**) procedures for **urinary incontinence (UI)**.
- **Preliminary** evaluation suggests **higher** level of **improvement** after the **HIFEM procedure**.
- **HIFEM** procedure resulted in considerable **reduction of incontinence pads** usage.
- Subjects reported **positive changes** in their **quality of life** resulting from reduction of UI symptoms and regained control over the pelvic floor muscles (PFM).
- HIFEM procedure was found to be more comfortable.

DESIGN AND METHODOLOGY

- **Fifteen subjects** with various UI symptoms were recruited and **randomly divided** into the **HIFEM** (N=8, 57.4±5.9 years) and **PFMT** (N=7, 51.9±12.7 years) groups.
- All subjects **completed six** HIFEM treatments or PFMT sessions performed **twice a week** for **three weeks**.
- The **same evaluation methodology** was used in both groups in regards to **comparison of achieved results**.
- **Subjects' evaluation** included **various methods**: UDI-6, ICIQ-LUTSqol, 3-day ICIQ-BD, Pad Usage, maximal voluntary contraction measurement using biofeedback and digital palpation, therapy comfort and subject satisfaction questionnaire.
- **Safety** of the HIFEM procedure and pelvic floor exercise **was documented**.

Table: Number of participants at the baseline, after 6th treatment (Tx) and follow-up visits.

Group	Baseline (N)	After 6th (N)	1-month FU (N)	3-month FU (N)
HIFEM	8	6	6	5
PFMT	7	6	4	3

RESULTS

- Assessment of pelvic floor contractions revealed **muscle strength enhancement** in both groups which led to **improvement of subjects' continence**.
- The HIFEM procedure **tended to have a higher impact** on subjects by the means of **objective and subjective** examination.
- **The 3-day bladder diary in HIFEM group** revealed considerable **decrease of pad usage** by -1.2 pads/24 hours, reported at 3 months.
- At 3-month follow-up, the average **bladder sensation decreased by 38.9%** (-0.82 points on 0-4 scale) **after HIFEM procedure** while PFMT group score returned to its baseline values.
- UDI-6 and ICIQ-LUTSqol questionnaires in both groups indicated **clinically significant improvement** of subject's **quality of life** after the treatment and at both completed follow-ups.
- Subjects found the **HIFEM procedure to be more comfortable** than exercise.
- **Both** treatment modalities showed to be **safe**, as **no adverse events** were observed.
- **More data** with longer follow-up is needed to corroborate the interim results.

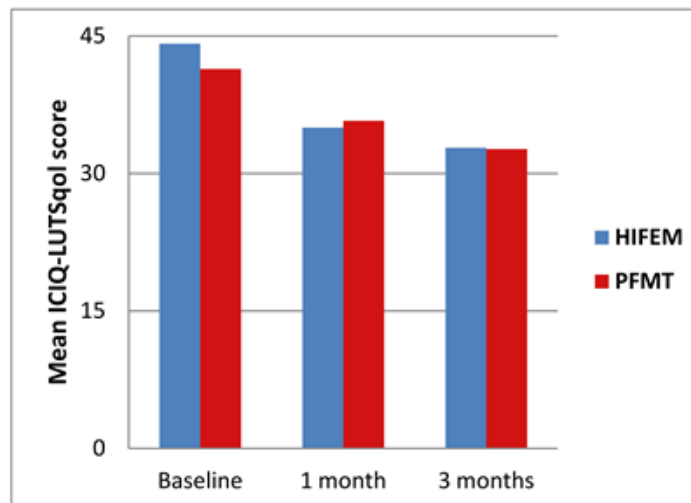
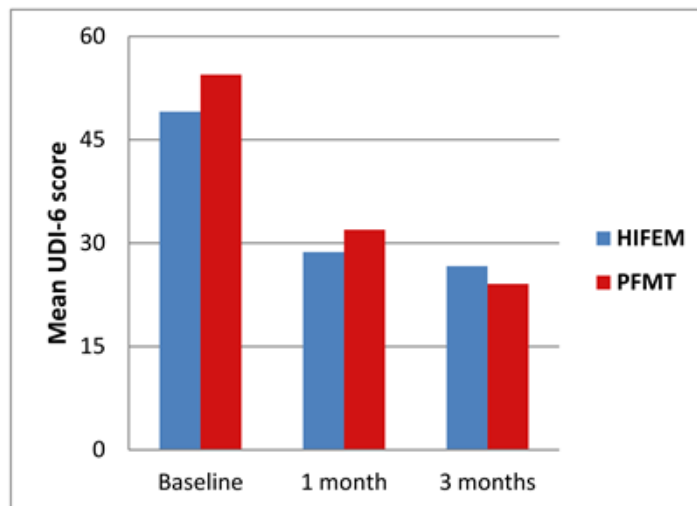


Figure: ICIQ-LUTSqol and UDI-6 scores were continuously decreasing in both groups and exceeded minimally clinically important difference of 4 points or 11 points respectively.