

HIFEM™ TECHNOLOGY IN TREATMENT OF URINARY INCONTINENCE

MECHANISM OF ACTION

HIFEM* TECHNOLOGY CAUSES DEEP PELVIC FLOOR MUSCLE STIMULATION AND RESTORATION OF THE NEUROMUSCULAR CONTROL.

- Key effectiveness is based on **focused electromagnetic energy, in-depth** penetration, and stimulation of the **entire pelvic floor area**.
- A single HIFEM session brings thousands **supramaximal pelvic floor muscle contractions**, which are extremely important in **muscle re-education** of incontinent patients.
- Incontinent patients are not able to perform **high-repetition rate pattern** due to pelvic floor muscles weakness.

The role of the pelvic floor muscles

Pelvic floor muscles (PFM) are the group of muscles that support the pelvic floor organs and control continence. Due to the body's normal aging, childbirth and menopause, PFM decondition and insufficiently support the pelvic floor organs. These conditions have a direct correlation to incontinence.

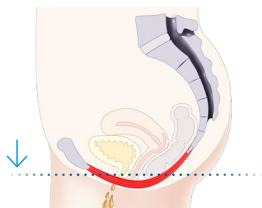


Figure 1: Cause and consequence of urinary incontinence.

Incontinence

Incontinence is defined as an involuntary loss of urine. The International Continence Society defines 3 main types of incontinence according to the etiology. Stress urinary incontinence (SUI) involves urine leakage when events with increased intra-abdominal pressure are performed (e.g. coughing, sneezing, laughing, lifting etc.). SUI is caused by a loss of support of the urethra, and deconditioned PFM as a consequence of damage to the pelvic support structures. SUI is also strongly associated with vaginal childbirth and menopause. The second type is associated with a strong desire to void and pathological contractions of the bladder, so-called urge incontinence. Urge incontinence is a neuromuscular dysfunction and usually represents as a symptom of an underlying problem (e.g. diabetes mellitus). The third type is mixed urinary incontinence (MUI) and involves a combination of both the SUI and urge incontinence symptoms. In all 3 types, patients are not able to contract the PFM properly due to the muscle weakness, as in the case of SUI,

or due to a pathological bladder over-activity, as is the case with urge UI.

HIFEM technology

HIFEM technology triggers intense PFM contractions by targeting neuromuscular tissue and inducing electric currents. Electric currents depolarize neurons resulting in concentric contractions and lift up of all PFM. Key effectiveness is based on focused electromagnetic energy, in-depth penetration, and stimulation of the entire pelvic floor area. This directly modifies the muscle structure, inducing a more efficient growth of myofibrils – muscle fiber hypertrophy, the creation of new protein strands and muscle fibers – muscle fiber hyperplasia. HIFEM technology causes deep PFM stimulation and restoration of the neuromuscular control.

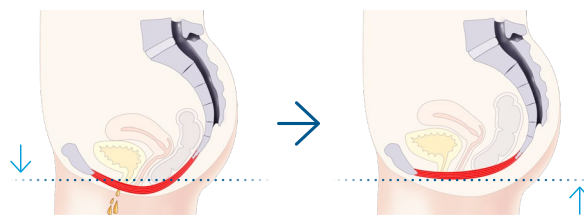


Figure 2: Comparison of patients' condition before and after pelvic floor muscle stimulation using HIFEM technology.

Supramaximal pelvic floor muscle contractions

Maximal voluntary contraction (MVC) is the greatest amount of tension that could be developed and held physiologically by the muscle, but usually only for a split second. Contractions with a tension higher than MVC are defined as supramaximal. HIFEM technology is able to create supramaximal PFM contractions and hold them for a couple of seconds (see Figure 1). These contractions are independent of brain function and target directly the peripheral nerves in the pelvic floor area. This

*High-Intensity Focused Electromagnetic Technology

phenomenon leads to supramaximal contractions which cannot normally be achieved by voluntary muscle action (e.g. Kegel exercise). The key to the effectiveness of HIFEM technology is in the gradually increasing intensity of the focused electromagnetic fields and frequency of pulses, which result in unique vigorousness of the contractions. During 1 session using HIFEM

weakness. Such effect cannot be achieved through common exercise (e.g. Kegel).

HIFEM therapy protocol

HIFEM therapy protocol takes around 30 minutes and consists of 3 different phases. These phases ensure an intense awakening of the deconditioned

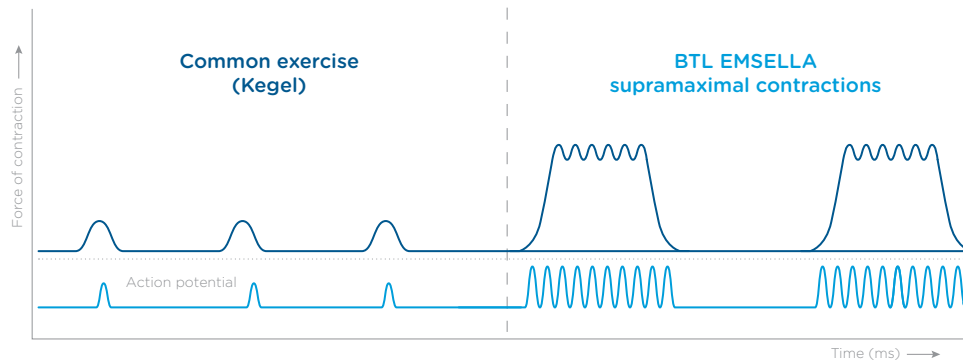


Figure 3: PFM activation using HIFEM technology compared to common exercise (e.g. Kegel).

technology, thousands PFM supramaximal contractions are performed. This method is extremely important to PFM re-education as the patients are not able to perform this high-repetition rate pattern due to PFM

PFM, stimulation, and relaxation of the PFM. Repetition of these phases and focused electromagnetic energy delivery leads to pelvic floor muscle stimulation, adaptation, and remodeling.

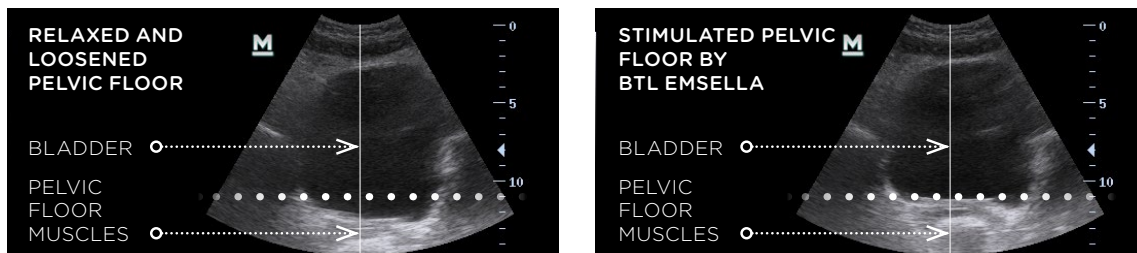


Figure 4: A frontal view of the pelvic floor muscles and bladder using medical ultrasound. Relaxed and loosened pelvic floor muscles and bladder (left). Stimulated and lifted pelvic floor muscles and bladder using HIFEM technology (right).

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