BTL EMSELLA® PATIENT FACT SHEET

SAY NO TO INCONTINENCE

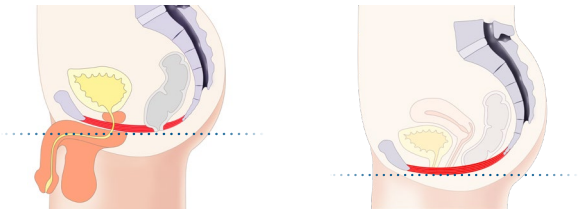
ABOUT URINARY INCONTINENCE:

Urinary incontinence is defined as the involuntary leakage of urine. This might be a result of weak pelvic floor muscles since pelvic floor muscles play an important role in supporting pelvic organs and controlling continence.

There are three different types of urinary incontinence:

- **Stress incontinence:** is when there is exerted pressure on the bladder causing leakage. This can be caused by coughing, laughing, sneezing, or exercising.
- **Urge:** is the sudden, intense urge to urinate frequently.
- **Mixed incontinence:** is a combination of both stress and urge incontinence.

Physiological changes can contribute to the development of urinary incontinence; changes such as vaginal delivery, menopause, and aging can decondition pelvic floor muscles. In order to improve symptoms, it is important to strengthen these muscles. Possible ways to improve your condition may include lifestyle changes and Kegel exercises.



The diagram below shows the pelvic organs and pelvic floor muscles in men (left) and women (right).

MECHANISM OF ACTION:

BTL EMSELLA is the HIFEM® procedure, that utilizes electromagnetic energy, at a high frequency, to cause pelvic floor muscle stimulation completely non-invasively. Similar to the contractions you perform when doing a Kegel exercise. What makes this treatment effective is the in-depth penetration and stimulation of the entire pelvic floor area. A single session brings you thousands of intense contractions that you would not be able to do on your own. These contractions are very helpful when it comes to muscle strengthening and re-education.

WHAT TO EXPECT DURING THE TREATMENT?

During BTL EMSELLA treatment you will be completely clothed yet, we recommended loosely fitted clothing to help achieve best positioning during treatment. When the treatment starts you will feel slight tingling and vibrations in your pelvic floor muscles that will then turn into full contractions. This will be completely comfortable and tolerable. If not, please let your healthcare provider know and they will adjust accordingly. Take this 28-minute session to relax, read a magazine, or watch television. You will be able to return to normal activities after the treatment.

LEARN THE TERMS

- **Pelvic floor**: The bowl-shaped muscles in the pevlic area that support pelvic organs, including the uterus, bladder and rectum.
- **Pelvic floor muscle exercises (Kegels)**: Exercises that strengthen the pelvic floor. Regular excercising of the pelvic floor muscles can improve or prevent urinary leakage.
- **Bladder training**: Behavior therapy that helps you wait longer between bathroom trips so that you can go to the bathroom when it is convenient for you rather than the sudden urge.

BTL EMSELLA IS NOT FOR YOU IF:

METAL IMPLANTS

PREGNANCY

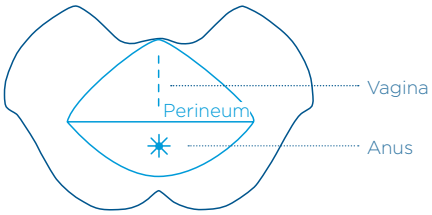
TUMOR

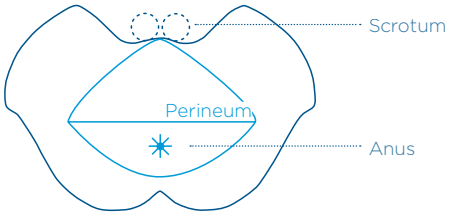
HEART DISORDERS

For the full range of contraindications, warnings and cautions, refer to your healthcare provider.

BTL EMSELLA® PATIENT POSITIONING

1. Sit comfortably at the center of the chair.
2. To achieve correct treatment position height of the chair can be set. Your health care provider will help you with this.
3. Your feet should be flat on the floor, shoulder width apart (which varies patient to patient).
4. Place your knees just above your feet at a 90-degree angle with slight outward rotation.
5. Angle your pelvic area closest to the center of the chair, you may have to tilt forward or backward to get the right angle.
6. Keep your spine straight and relax your hands on your thighs.
7. The first minute of therapy is there to help you gauge positioning. The tapping should be over the perineum (see figure below). Either adjust forward, back, or towards either side to find the target area.





ADDITIONAL PATIENT FACTS:

- Do not lean back on the chair.
- Do not hunch your back.
- Keep feet flat on the ground.
- Do not keep your legs together, crossed, or too spread out.
- Jewelry, belts, cards, coins, wallet, and watches should be removed before treatment. Also keep phones and other electronics away from the device. Wear comfortable clothing, nothing too tight that will prevent correct positioning.

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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.

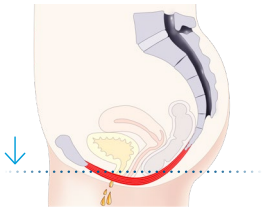

Figure 1: Cause and consequence of urinary incontinence.

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.

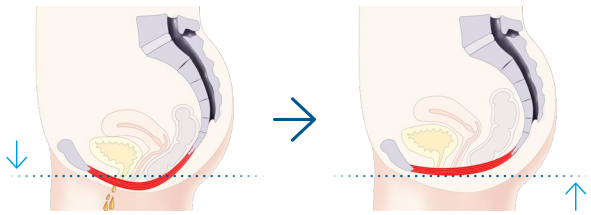

Figure 2: Comparison of patients´ condition before and after pelvic floor muscle stimulation using HIFEM technology.

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

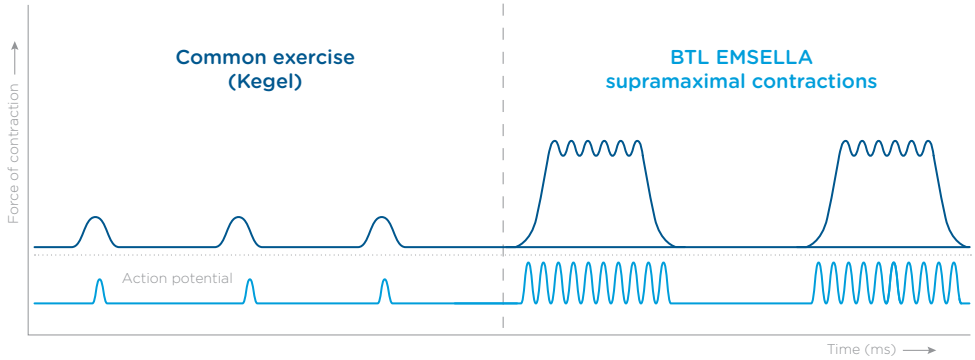

Figure 3: PFM activation using HIFEM technology compared to common exercise (e.g. Kegel).

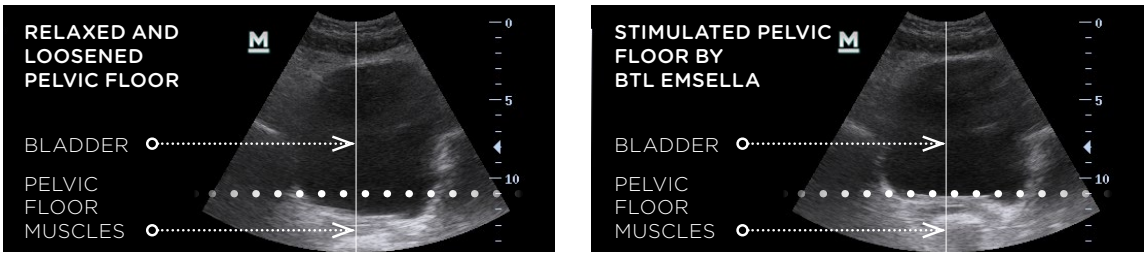

Figure 4: A frontal view of the pelvic floor muscles and bladder using medical ultrasound. Relaxed and loosened pelvic floor muscles and bladder (left). Stimulated and lifted pelvic floor muscles and bladder using HIFEM technology (right).

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BTL EMSELLA®

BTL Emsella (AKA The Kegel Throne) is a new non-invasive FDA approved therapy to condition the pelvic floor muscles in patients.

- Emsella decreases the impact of stress/urge/mixed incontinence, overactive bladder, and nocturia on quality of life.
- Studies show strengthened pelvic floor muscles have sexual benefits for men and women.
- Emsella re-establishes effective neural control of the pelvic floor muscles, educating patients on how to selectively contract these muscles so they can maintain muscle tone and function long term.
- Emsella is FDA and Health Canada cleared for the treatment of stress, urge and mixed incontinence in both women and men. FDA also lists secondary sexual benefits for women and men.
- Imagine 11,800 kegel exercises in only 28 minutes while relaxing on a chair.

How does BTL Emsella differ from intra-vaginal lasers or RF claiming to improve incontinence?

- Emsella targets and strengthens the pelvic floor **muscles** much like kegel exercises but with higher intensity.
- Vaginal laser/RF only stimulate collagen and elastin production in the vaginal walls. Emsella strengthens the pelvic floor **muscles** which has been established as the first line of treatment for incontinent patients.
- The FDA does not approve any intra-vaginal lasers/RF for the treatment of incontinence.

How does BTL Emsella work?

- The device is a chair containing a very powerful magnet (2.5 Tesla, similar strength to MRI). The energy is focalized to the depths and location of the pelvic floor muscles using *High Intensity Focused Electromagnetic Energy (HIFEM).*
- HIFEM Technology triggers intense pelvic floor muscle contractions by targeting neuromuscular tissue and depolarizing motor neurons to create 11,800 kegel like contractions per 28 minute treatment.

How does Emsella fit into traditional patient care?

- First course of treatments for a patient suffering from incontinence typically involves expensive pharmaceutical drugs and/or pelvic floor physiotherapy.
- Manual kegel exercise programs are a challenge for patients due to poor compliance and improper technique.
- Due to high rates of complications with surgery, many patients have accepted incontinence as a part of life and as a result they end up living with leakage pads (the average patient spends > $1000 per year).
- BTL Emsella is utilized as a course of 6 x 28 minute treatments spaced about 3 days apart, to provide increased control and strength of pelvic floor muscles.
- Multiple studies have been published in peer-reviewed journals showing up to 95% satisfaction rate.

The Opportunity:

- A leading drug store in Canada has shown that urinary leakage pads are the highest revenue generating product on their shelves.
- Most women with incontinence suffer silently, many without seeking help. Up to 50% of the adult female population suffers from incontinence to a certain extent.
- Emsella offers an easy, non-threatening and effective treatment that will change your patients lives.
- For medical aesthetic clincs, the majority of the demographics fall into the same category as those suffering from incontinence.

MULTICENTRIC STUDY: IMPROVEMENT IN URINARY INCONTIENCE AND QUALITY OF LIFE

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

Julene B. Samuels, MD,[1] Andrea Pezzella, MD,[2] Joseph Berenholz, MD,[3] and Red Alinsod, MD[4]

1. Julene B. Samuels, MD, FACS, Louisville, KY
2. Southern Urogynecology: Center for Female Pelvic Medicine and Reconstructive Surgery, West Columbia, SC
3. The Laser Vaginal Rejuvenation Institute Of Michigan Farmington Hills, MI
4. South Coast Urogynecology, Laguna Beach, CA

Published in Lasers in Surgery and Medicine, 2019

HIGHLIGHTS

- Patients reached on **average 64.42% improvement in ICIQ-UI score and 53.68% decrease in absorbent pad usage**.
- **21 (34.43%) subjects were cured** (zero score in ICIQ-UI and free from UI symptoms at follow-up).
- **64.29% fewer patients experienced leakage while sleeping.**
- **19 patients (44.19%)** reported they were **not using pads anymore.**

Parameter	ICIQ-SF	Absorbsent Pads
Number of evaluated subjects	61	43
Baseline	10.57±4.22	2.47±2.25
After 6th Treatment	5.33±3.97	1.35±1.74
Difference Before & Follow-up	5.25±4.02	1.12±1.80
Average Improvement	49.93%	43.80%
3-month Follow-Up	4.16±4.04	1.19±1.91
Difference Before & Follow-up	6.41±3.75	1.28±1.83
Average Improvement	64.42%	53.68%

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

Stephanie Molden, MD[1]

1. The Female Pelvic Health Center, Newtown, PA, USA

Abstract accepted for oral presentation at ASLMS 2020

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 **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 PFM muscles.
- HIFEM procedure was found to be more comfortable.

DESIGN AND METHODOLOGY

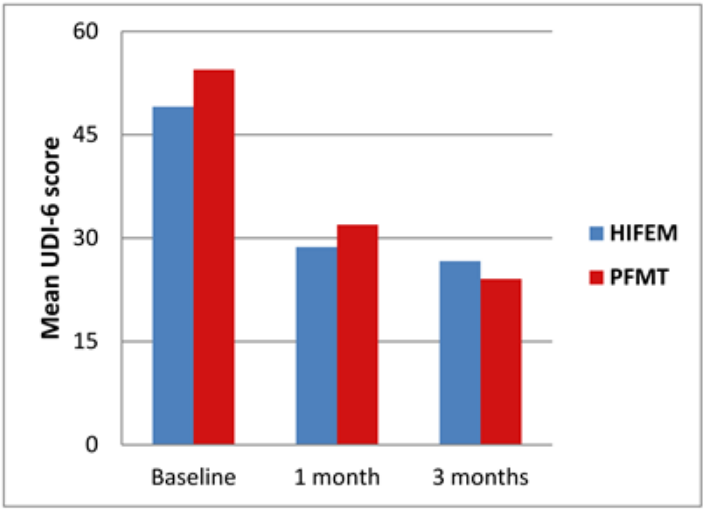
- **Fifteen subjects** with various UI symptoms were recruited and **randomly divided** into the **HIFEM** (N=8, 57.4±5.9 years) and **PFMT** (N=7, 51.9±12.7 years) groups.
- All subjects **completed six** HIFEM **treatments** or PFMT **sessions** performed **twice a week** for **three weeks**.
- The **same evaluation methodology** was used in both groups in regards to **comparison** of achieved **results**.
- **Subject's 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	8	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 followups.
- Subjects found the **HIFEM procedure to be more comfortable** then 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.



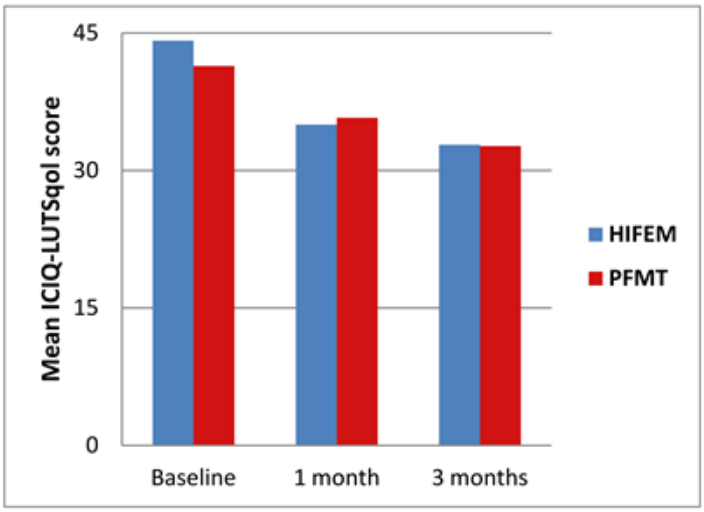


Figure: ICIQ-LUTSqol and UDI-6 scores were continuously decreasing in both groups and exceeded minimally clinically important difference of 4 points or 11 points respectively.

FEMALE URINARY INCONTINENCE AND SEXUAL FUNCTION AFTER THE **HIFEM®** PROCEDURE

EFFICACY OF HIFEM PROCEDURE FOR IMPROVEMENT OF URINARY INCONTINENCE AND FEMALE SEXUAL FUNCTION: EVALUATION OF 3 MONTHS PRELIMINARY DATA

Kimberly Evans, MD, FACOG[1]; Julene B. Samuels, MD, FACS[2]

1. Sugar Land Medical Spa, Sugar Land, TX, USA
2. Julene B. Samuels MD, Prospect, KY, USA

Abstract accepted for oral presentation at ASLMS 2020

HIGHLIGHTS

- Subjects' **continence and sexual function** have been **significantly improved**.
- Interim results showed that the **HIFEM** procedure is an **effective** non-invasive solution for enhancement of **female sexual function**, accompanied with **urinary incontinence**.
- Besides **reduction of incontinence**, patients benefit most from **reduced pain** during intercourse, **increased lubrication**, and **arousal**, and they were also **more satisfied** with **orgasm intensity**.

DESIGN AND METHODOLOGY

- **Twenty-two subjects** (48.1±10.6 years), demonstrating incontinence-related problems in sexual life, were assessed in this prospective one-arm study.
- All subjects received **six HIFEM treatments**, with a frequency of **two sessions per week for three weeks**, focused on pelvic floor.
- **UI and sexual function** attributes were evaluated using **ICIQ-SF**, **FSFI** and **PISQ-12** standardized questionnaires.
- Follow-up visits were scheduled at the **baseline**, after the last treatment, 1 month and **3 months** post-treatment.
- Questionnaires' post-treatment scores were statistically analyzed using two-tailed t-test (α=5%).
- **Therapy comfort** was assessed after the last treatment session.

RESULTS

- Subjects reported **significant improvement (P<0.05)** in **all questionnaires** compared to baseline, with the greatest change at 3-month follow-up:
    - **ICIQ-SF** overall score decreased on average by **66.7%** (-8.0 points).
    - **FSFI** overall score showed significant increase by **42.7%** (+9.2 points).
    - **PISQ-12** score increased significantly by **29.4%** (+9.4 points).
- Considerable improvement in the **control of leakage** during **coughing**, **sneezing** and while performing **physical activity**, was observed in treated subjects.
- FSFI questionnaire revealed a substantial **improvement in lubrication**, **arousal**, and **greater satisfaction** with **orgasm intensity**.
- PISQ-12 questionnaire showed **high level of improvement** in **emotive** and **physical domains**, referring to overall comfort and satisfaction during the intercourse.
- More data with longer follow-up is needed to corroborate the interim results.

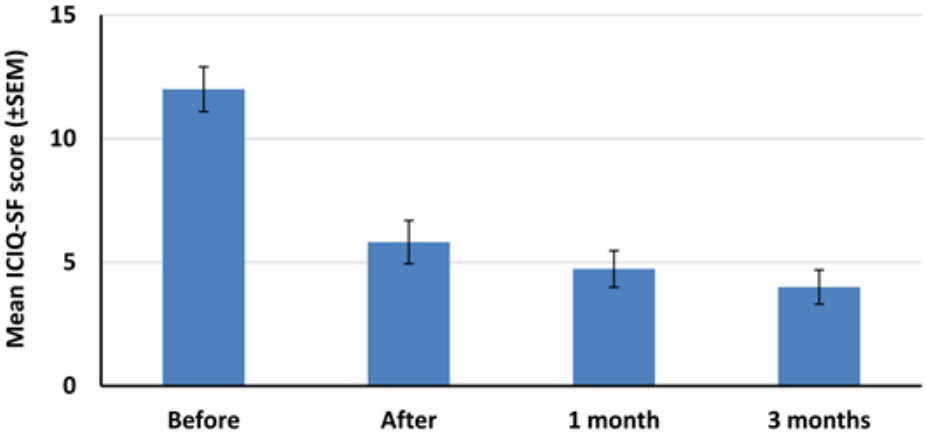


Figure 1: The mean of ICIQ-SF score before the treatment and at 1, and 3-month follow-up. The score significantly (P<0.05) decreased after the HIFEM treatment.

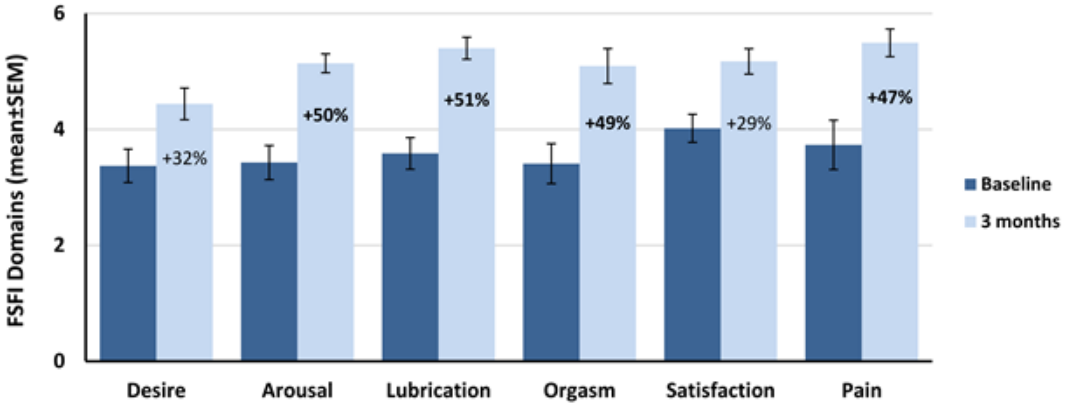


Figure 2: FSFI scoring for each domain. Comparison of FSFI Score and its domains at baseline and 3-month follow-up visit.

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

Julene B. Samuels, MD, FACS[1]

1. Julene B. Samuels, Prospect, KY, USA

Abstract accepted for oral presentation at ASLMS 2020

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 study**[1], 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 (α=0.05) was used for **statistical analysis**.

[1]Samuels 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**.

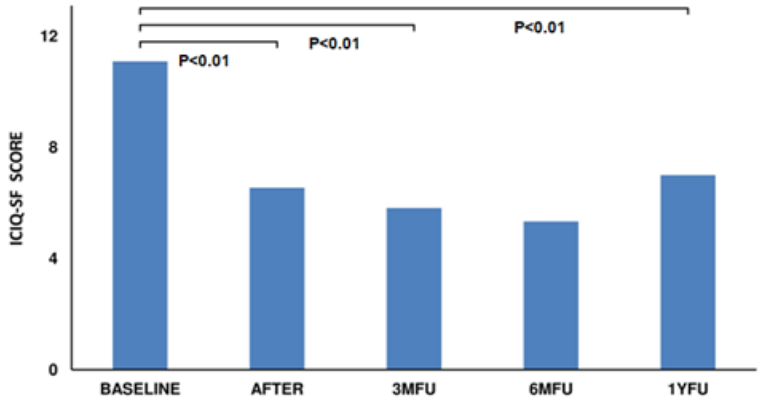


Figure 1: ICIQ-SF score throughout the whole study. Patients were constantly improving up to 6 months. There is seen a rise of ICIQ score at 1-year follow-up.

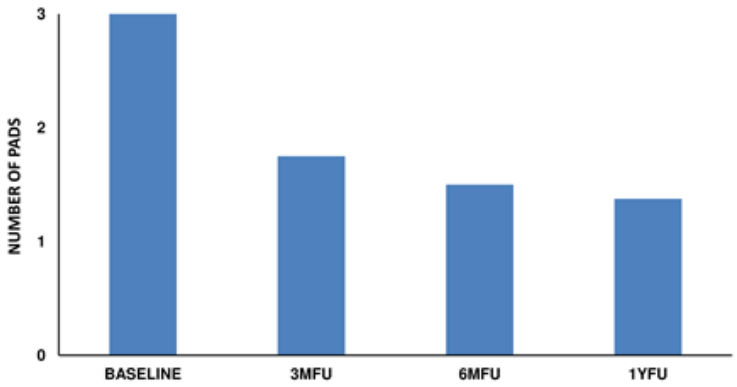


Figure 2: Pad usage documented in study subjects. Reduced usage of absorbent pads was seen in four out of five patients who were using pads at the baseline. The achieved improvement was sustained at the 1 year when patients used only 1.4 pads in 24 hours.

HIFEM® PROCEDURE AND ELECTROSTIMULATION FOR TREATMENT OF PELVIC FLOOR MUSCLE WEAKNESS AND URINARY INCONTINENCE

A COMPARATIVE STUDY ON THE EFFECTS OF HIFEM TECHNOLOGY AND ELECTROSTIMULATION FOR THE TREATMENT OF PELVIC FLOOR MUSCLES AND URINARY INCONTINENCE IN PAROUS WOMEN: ANALYSIS OF POSTTREATMENT DATA

Elena Silantyeva, MD, PhD[1], Dragana Zarkovic, MSc[2], Evgeniia Astafeva, MD[1], Ramina Soldatskaia, MD[1], Mekan Orazov, MD, PhD[3], Marina Belkovskaya, MD, PhD[1], Mark Kurtser, MD, PhD[1].

1. Hospital Lapino MD Medical Group, Moscow, Russia
2. Charles University, Faculty of Physical Education and Sport, Department of Anatomy and Biomechanics, Prague, Czech Republic
3. RUDN University, Medical Faculty, Moscow, Russia

Published in Female Pelvic Medicine & Reconstructive Surgery journal: December 19, 2019

HIGHLIGHTS

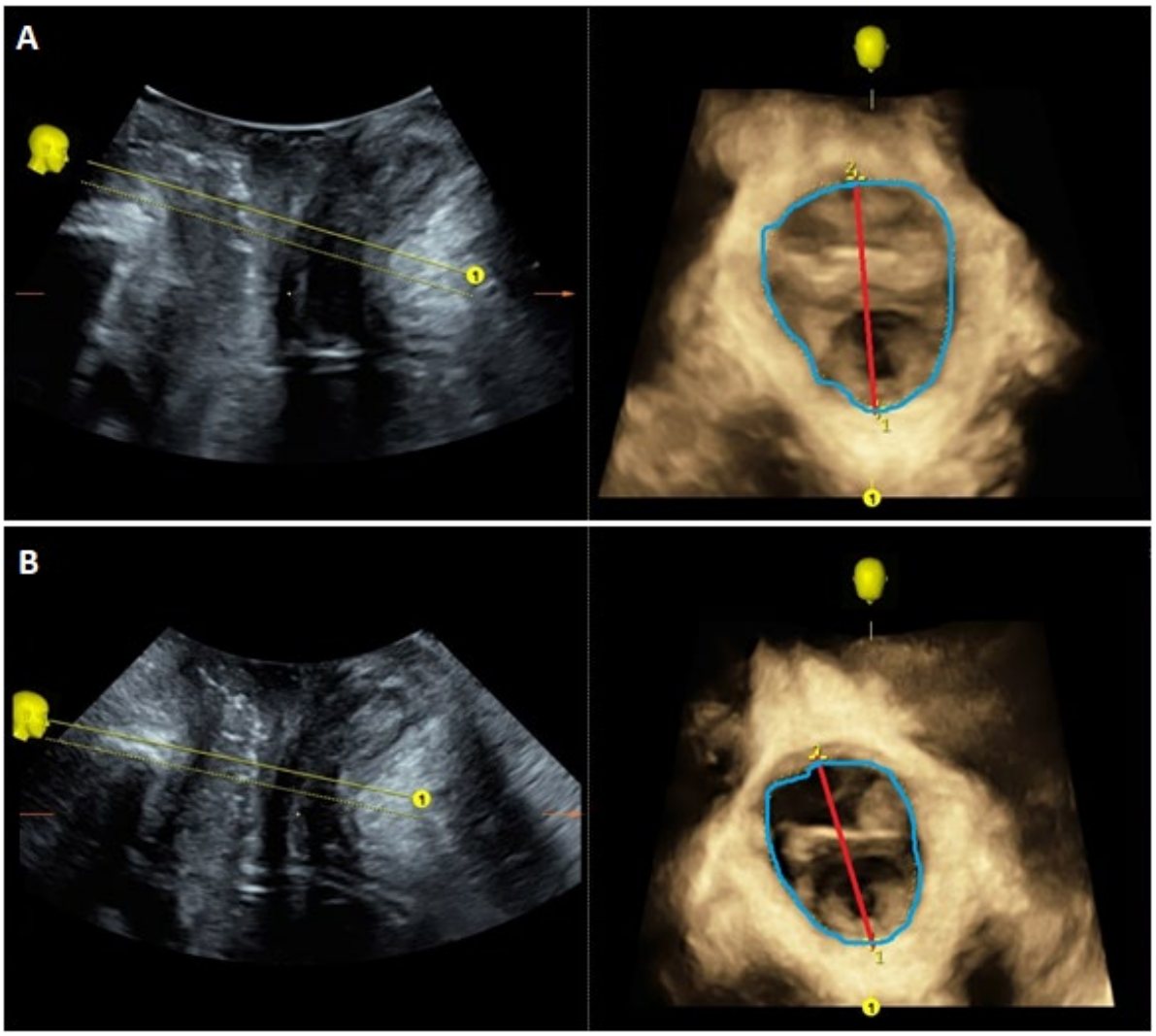
- 3D ultrasound examination revealed **significant improvement of pelvic floor integrity** after HIFEM treatment.
- Subjects treated with HIFEM achieved **a three times higher level of improvement** in PFDI-20 standardized questionnaire.
- Subjects reported two **times better results in a subjective evaluation** after HIFEM.
- All the assessment methods showed that **HIFEM procedure is more effective than electrostimulation** for treatment of weakened pelvic floor muscles.

DESIGN AND METHODOLOGY

- **Two groups** showing weakened pelvic floor muscles and urinary incontinence were treated with HIFEM (N=50, 31.1 years) and electrostimulation (N=25, 32.0 years).
- **One group** of healthy patients (N=20, 27.2 years) served as **control**.
- Treated subjects completed 10 therapies scheduled 2-3 times per week (HIFEM) or every other day (electrostimulation).
- **3D ultrasound** was used to quantify the **biometric indices of pelvic floor integrity** e.g. anteroposterior diameter (LH-AD) and laterolateral diameter (LH-LD) of levator hiatus, hiatal area (HA) and levator-urethra gap (LUG) for pelvic prolapse detection.
- **Pelvic Floor Disability Index 20** (PFDI-20) standardized questionnaire and **subjective evaluation** of subject's intimate health was assessed.
- Data was collected at the baseline and after completion of treatments.

RESULTS

- **HIFEM** procedure resulted in **significant (P<0.05) improvement** in 3D ultrasound measurements, approaching the values of control group after the treatment. Results of **electrostimulation** group showed similar yet **insignificant trend**.
- The HIFEM group showed **improvement in PFDI-20** questionnaire by **52% (31.45 points)**, whereas electrostimulation resulted in a change of only 18% (11.78 points).
- The post-treatment **difference** in PFDI-20 scores **between HIFEM and electrostimulation** was highly significant.
- Subjects treated with HIFEM reported a decreasing number of urine leakage and improvement in vaginal laxity during intimacy.
- In general, **subjective self-evaluation** showed a **two times higher level of improvement** after HIFEM when compared to electrostimulation.
- **HIFEM** procedure **improved integrity of pelvic floor** and **incontinence** while **outperforming** electrostimulation.



3D Ultrasound measurements of the pelvic floor at the baseline (A) and post-treatments (B) in patient from HIFEM group. Anteroposterior diameter of levator hiatus (red line) and hiatial area (blue line) have been considerably improved after HIFEM.

QUANTIFICATION OF HIFEM EFFECTS ON URINARY INCONTINENCE

HIFEM® TECHNOLOGY – THE NON-INVASIVE TREATMENT OF URINARY INCONTINENCE

Samuels J., MD[1] and Guerette N., MD[2]

1. Julene B. Samuels, MD, FACS, Louisville, KY
2. The Female Pelvic Medicine Institute of Virginia, Richmond, VA

Presented at the Annual Meeting of the American Society for Laser Medicine and Surgery, 2018; Dallas, TX

HIGHLIGHTS

- **Quality of life improved in all patients** using HIFEM technology, based on King's Health Questionnaire.
- **Nearly 75% of patients** significantly decreased **urinary leakage or achieved total dryness** and maintained these results through 6-month follow-up.
- Patients reached **60% of average improvement** in both parts of the King's Health Questionnaire.
- **Majority of patients decreased pad usage to a minimum or totally eliminated them.**

Parameter	KHQ Part 1	KHQ part 2
Score pre-treatment (Mean±SD)	92.22±36.09	194.63±107.34
Score post-treatment (Mean±SD)	66.94±34.91	154.44±104.23
Score 3-month follow-up (Mean±SD)	60.56±27.68	154.63±87.42
Score 6-month follow-up (Mean±SD)	37.04±34.44	90.59±90.79
Level of improvement pre- and post-treatment (%)	50%	53%
Level of improvement pre-treatment and 3-month follow-up (%)	51%	61%
Level of improvement pre-treatment and 6-month follow-up (%)	60%	60%

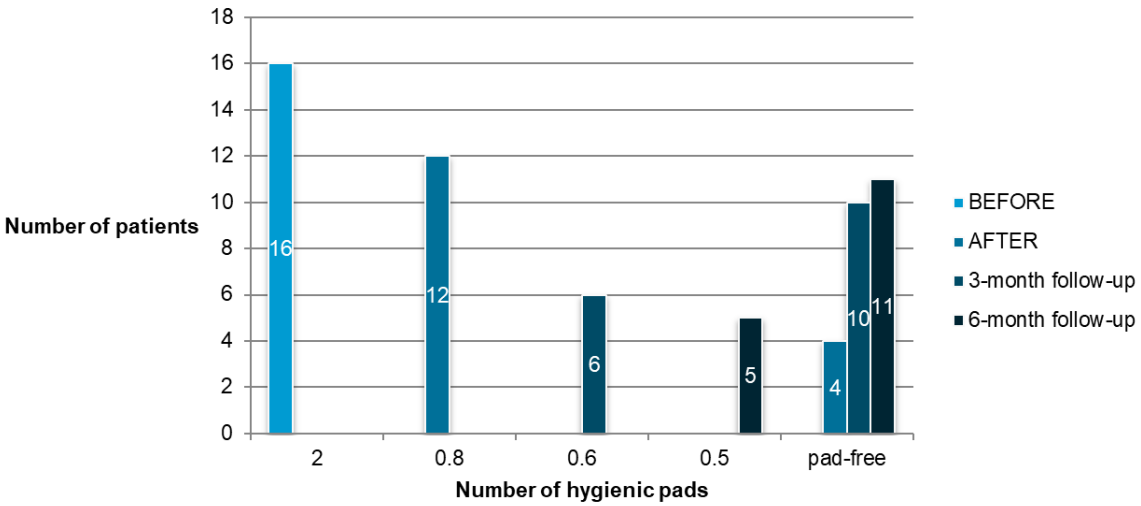
Results of the King's Health Questionnaire (KHQ) score; SD = standard deviation.

DESIGN AND METHODOLOGY

- Retrospective, two-site study investigating the effectiveness of HIFEM treatment for urinary incontinence.
- 20 women aged from 45 to 77 years with either stress, urge, or mixed urinary incontinence.
- Study aimed to quantify data as well as the impact on quality of life of incontinent women.
- All patients completed six treatments, delivered twice a week for three consecutive weeks.
- Data was collected using the King's Health Questionnaire (KHQ) pre-and post-treatment, also at 3 and 6-month follow-up.
- Additionally, patients recorded any urinary leakage episodes and pad usage.

RESULTS

- Improvement was observed in both **short- and long-term** results based on King's Health Questionnaire.
- Patients reported **decreased frequency of hygienic pad usage, and decreased frequency of urine leakage episodes.**
- The post-treatment initial improvement in KHQ averaged as 50% was maintained and further improved up to 60% at the 6-month follow-up.
- **11 patients were pad free at 3-month follow-up.**
- Results suggest that treatment with HIFEM technology **significantly decreases the negative impact of urinary incontinence** on patient's daily life.



STRESS URINARY INCONTINENCE STUDY: 6-MONTH FOLLOW-UP

HIFEM® TECHNOLOGY – A NEW PERSPECTIVE IN TREATMENT OF STRESS URINARY INCONTINENCE

Alinsod R.[1], Vasilev V.[2], Yanev K[3], Buzhov B.[2], Stoilov M.[2], Yanev K.[3], Georgiev M.[3]

1. South Coast Urogynecology, Laguna Beach, California
2. Urology Cabinet 'Dr. Vasilev', Sofia, Bulgaria
3. Department of Urology, Aleksandrovska University Hospital, Sofia, Bulgaria

Presented at the Annual Meeting of the American Society for Laser Medicine and Surgery, 2018; Dallas, TX

HIGHLIGHTS

- Quality of life **significantly improved in all women** after a course of six treatments with HIFEM technology.
- **71% of patients significantly decreased the use of hygienic pads.**
- At 6-month follow-up there was a **77% level of improvement** in incontinence according to KHQ questionnaire.

Parameter	KHQ Part 1	KHQ part 2
Score pre-treatment (Mean±SD)	97.78±34.67	284.91±147.08
Score post-treatment (Mean±SD)	65.83±29.31	110.19±115.66
Score 3-month follow-up (Mean±SD)	59.72±30.25	85.00±119.72
Score 6-month follow-up (Mean±SD)	55.00±35.12	71.02±122.34
Level of improvement pre- and post-treatment (%)	28%	61%
Level of improvement pre-treatment and 3-month follow-up (%)	34%	70%
Level of improvement pre-treatment and 6-month follow-up (%)	39%	77%

Results of the King's Health Questionnaire (KHQ) score; SD = standard deviation.

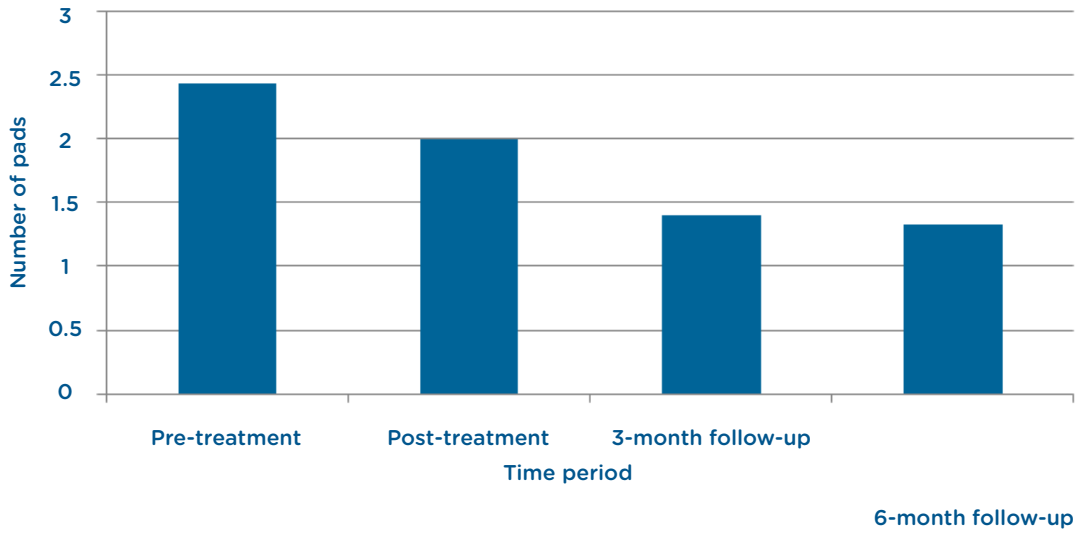
DESIGN AND METHODOLOGY

- 30 women with stress urinary incontinence (classified as SUI type 0-2a), of average age 57.99±10.36 years were enrolled.
- Patients had six therapies scheduled twice a week.
- Quality of life was assessed using King's Health Questionnaire (KHQ) investigating general health and the impact of incontinence on daily life.
- Additionally, patients were asked to report the number of used hygienic pads per day.
- Data was collected pre-treatment, post-treatment, and at both 3-month and 6-month follow-up.

RESULTS

- There was a **77% level of improvement** in incontinence impact according to KHQ **at 6-month follow-up**.
- The average KHQ score (both parts) was continuously decreasing during the course of study.
- **Short and long-term** results showed **improvement in patients' quality of life.**
- Patients **significantly decreased pad usage by 71% and at 6-month follow-up** patients only used 1.33 pad per day and night after the treatments.
- The results obtained from this study suggest the HIFEM technology is a promising approach for pelvic floor muscles stimulation that further improves the quality of life among SUI patients.

Use of hygienic pads



PILOT STUDY: HIFEM TECHNOLOGY FOR THE TREATMENT OF URINARY INCONTINENCE

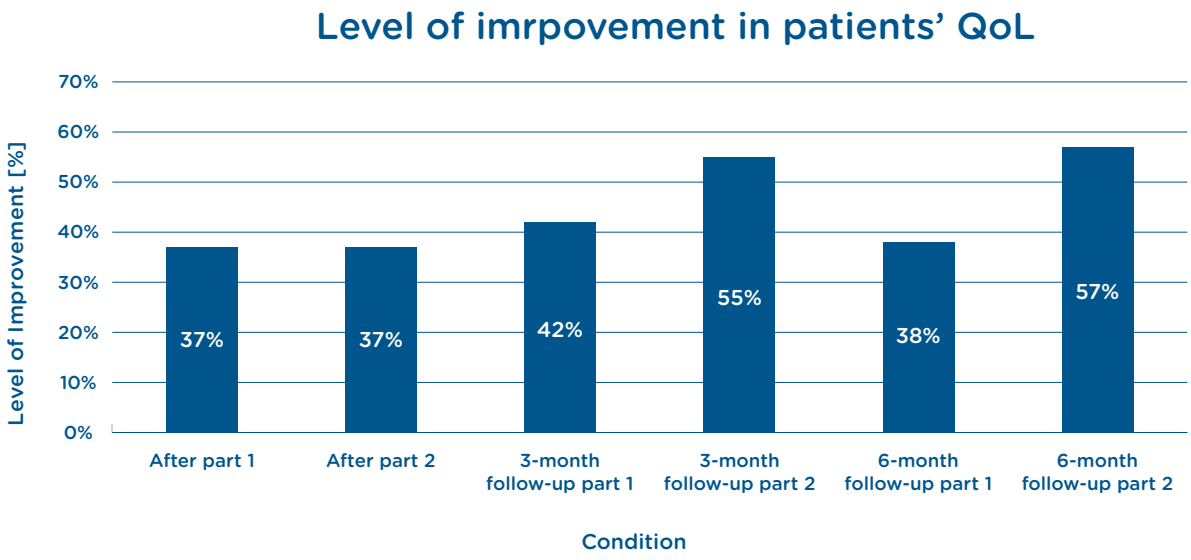
HIFEM® TECHNOLOGY CAN IMPROVE QUALITY OF LIFE OF INCONTINENT PATIENTS

Berenholz J., MD[1], Sims T., MD[2], Botros G., MD[2]

1. The Laser Vaginal Rejuvenation Institute Of Michigan Farmington Hills, MI, USA
2. The Medical Laser and Aesthetics Group, Wirral, United Kingdom

HIGHLIGHTS

- After 6 treatments, **95% of treated patients improved their quality of life** according to King's Health Questionnaire.
- **67%** of treated patients **reduced or totally eliminated day-to-day use of hygienic pads.**
- **100% of patients reported better awareness of pelvic floor muscles.**



Level of improvement in the patients' Quality of Life (QoL) according to the Part 1 and 2 of King Health Questionnaire

DESIGN AND METHODOLOGY

- 30 women (36-76 years) who showed signs of stress, urge, and mixed incontinence took a part in this study.
- Each participant had six therapy sessions total, scheduled twice a week.
- Results were assessed using the King's Health Questionnaire.
- The number of hygienic pads used and subjective patient feedback was recorded.
- Data was collected pre-, post-treatment, 3-month, and 6-month follow-up.

RESULTS

- After a course of treatment, **67% of treated patients totally eliminated or decreased the average number of hygienic pads used** to 0.45 pad per day and night.
- King's Health Questionnaire Part 2 improved from **37% post-treatment to 57% at 6-month follow-up**, showing continuous improvement.
- The results were maintained during **the 3- and 6-month follow-ups.**
- **All patients** reported better **awareness of their pelvic floor muscles.**

Patient's subjective evaluation of the therapy

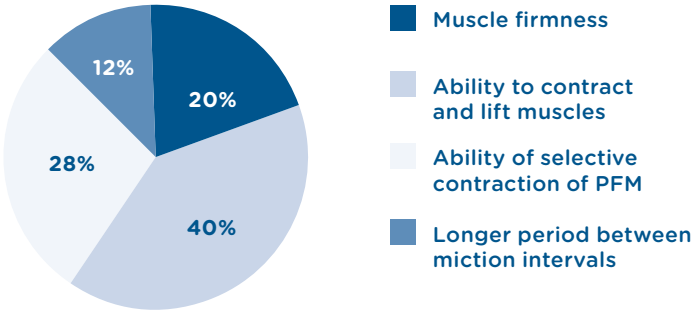


Figure 5: Patients subjective evaluation of the therapy

HIFEM® FOR MALE URINARY INCONTINENCE

HIFEM PROCEDURE ENHANCES QUALITY OF LIFE OF ELDERLY MEN WITH POST-PROSTATECTOMY INCONTINENCE

Javier Azparren MD[1], Judson Brandeis MD[2]

1. Madina and Azparren Medical Center, Donostia-San Sebastian, Spain
2. Male Sexual Medicine and Rejuvenation Center, San Ramon, CA, USA

HIGHLIGHTS

- Post-prostatectomy incontinence (PPI) is a commonly reported side effect of the radical prostatectomy with prevalence reaching up to 60%[a].
- HIFEM procedure significantly **enhanced quality of life** of men with PPI.
- **All subjects** achieved **improvement** after six HIFEM treatments.
- In general, subjects were **less limited** in their social life, daily activities, physical activities and reported improvement in sleep quality.
- Average pad usage was reduced by **1.0 pad/day**.

DESIGN AND METHODOLOGY

- Ten **elderly men** (72.9±3.9 years) with a recent history of **radical prostatectomy** accompanied with PPI were recruited.
- They underwent six HIFEM treatments scheduled twice a week for three weeks.
- Subject's **Quality of Life** (QOL) was assessed by King's Health Questionnaire (KHQ) at baseline and post-treatment; 1 and 3-month follow-up were optional.
- 24-hour **Pad Usage** questionnaire was used to identify any changes in the frequency of wearing absorbent pads.
- **Adverse events** were monitored throughout the study.

[a]Anderson CA, Omar MI, Campbell SE, Hunter KF, Cody JD, Glazener CM. Conservative management for postprostatectomy urinary incontinence. Cochrane Incontinence Group, ed. Cochrane Database Syst Rev. Published online January 20, 2015

PELVIC **MUSCLES STRENGHTENING** BY **HIFEM®** PROCEDURE AND ELECTROSTIMULATION FOR TREATMENT OF **PELVIC FLOOR DYSFUNCTION**

ELECTROMYOGRAPHIC EVALUATION OF THE PELVIC MUSCLES ACTIVITY AFTER HIGH INTENSITY FOCUSED ELECTROMAGNETIC PROCEDURE AND ELECTRICAL STIMULATION IN WOMEN WITH PELVIC FLOOR DYSFUNCTION

Silantyeva Elena MD, PhD, Doctor of Medical Sciences[1]; Zarkovic Dragana MSc[2]; Soldatskaia Ramina MD[1]; Astafeva Evgeniia MD[1], Mekan Orazov MD, PhD[3].

1. Hospital Lapino MD Medical Group, Moscow, Russia
2. Charles University, Faculty of Physical Education and Sport, Department of Anatomy and Biomechanics, Prague, Czech Republic
3. RUDN University, Medical Faculty, Moscow, Russia

Published in Sexual Medicine journal: February, 2020

HIGHLIGHTS

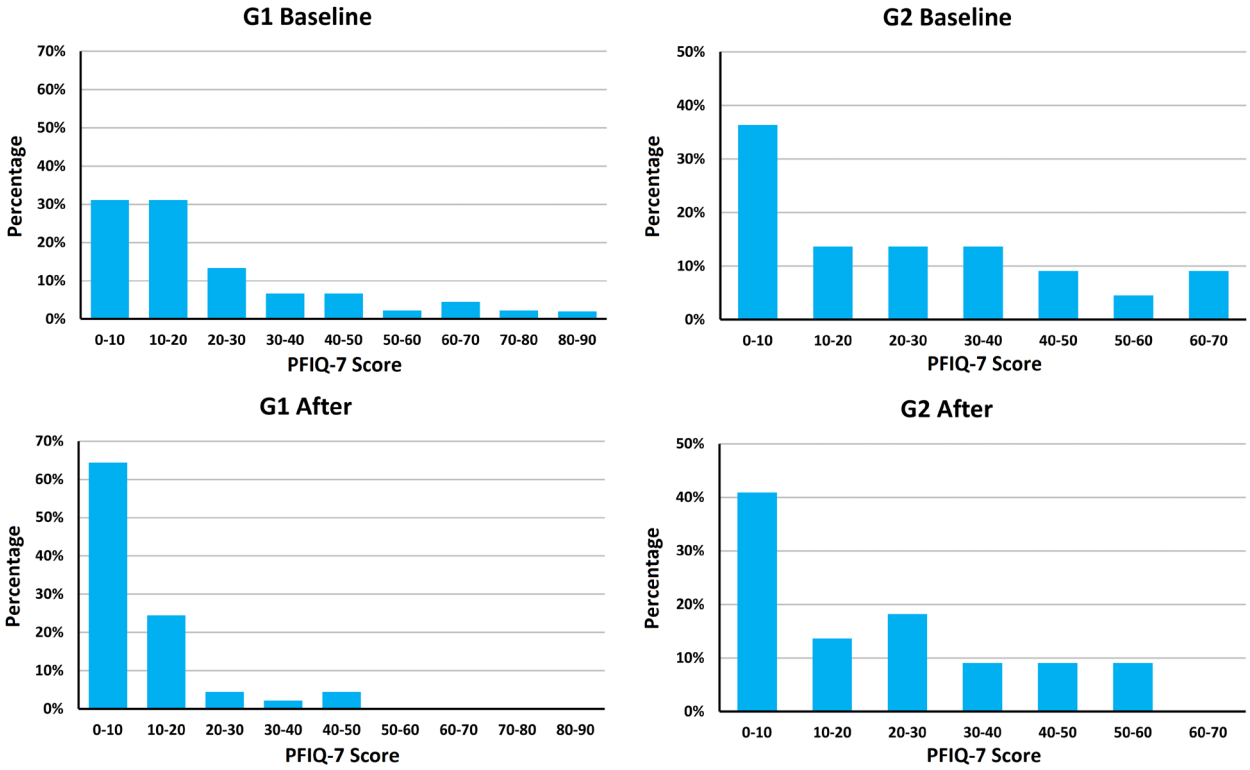
- **HIFEM procedure** considerably **enhanced pelvic** floor **muscles (PFM) activation** in subjects with **pelvic floor dysfunction** (PFD).
- Subjects were able to **produce stronger contractions** of **greater endurance** after HIFEM.
- **HIFEM procedure** resulted in far greater **improvement** in PFIQ-7 questionnaire when compared to electrostimulation.
- **36% of HIFEM patients** reported a score of 0 on PFIQ-7 after the treatments.

DESIGN AND METHODOLOGY

- **Two groups** of post partum women with various PFD symptoms were established and treated by HIFEM (N=50, 1.76 deliveries on average) or electrostimulation (N=25; 1.56 deliveries on average).
- Both treated groups completed **10 therapies** according their allocation.
- **Electromyographic** (EMG) evaluation was used to determine **activation of PFM**.
- **A control group** (N=20, 1.25 deliveries on average) was included to determine EMG normative values.
- **Pelvic Floor Impact Questionnaire 7** (PFIQ-7) was used to asses life impact of PFD.
- Data was collected at the baseline and after completion of treatments.

RESULTS

- **HIFEM significantly** (P<0.001) modified **PFM activity**, since the EMG results of HIFEM group moved towards the values of healthy population.
- The mean change of **EMG values** after HIFEM ranged **from 48% to 59%**, while electrostimulation resulted in mild-to-moderate improvement of 7-36%.
- In comparison to electrostimulation, HIFEM patients were able to generate PFM contractions of **higher intensity and endurance**.
- PFIQ-7 questionnaire showed significantly (P=0.01) more pronounced results in **HIFEM group (improved by 57.16%)**, than in electrostimulation group (improved by 32.18%)
- Additionally, **35.56% of subjects** reported **zero PFIQ score** after HIFEM and almost 90% of subjects from HIFEM group showed none or mild life impact of PFD post treatment.
- **HIFEM procedure** was **substantially more effective** in restoration of PFM strength and treatment of PFD in postpartum women when **compared** to the **electrostimulation**.



The frequency of PFIQ-7 scores documented in the HIFEM (G1) and electrostimulation (G2) groups. There is a substantial shift towards lower scores in HIFEM group after the treatment; since the scores over 50 were entirely eliminated from responses.