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

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ABSTRACT

Background:
Stress urinary incontinence (SUI) is a prevalent condition among women and negatively affects their quality of life (QoL). The aim of the study was to assess the effect of High-Intensity Focused Electromagnetic (HIFEM) technology in the treatment of SUI.

Study Design/Materials and Method:
30 women from two clinics (United States, Bulgaria) with SUI were delivered a treatment course with HIFEM technology. Patients attended 6 therapies scheduled 2x a week. QoL was assessed through King's Health Questionnaire (KHQ). Data was collected pre-, post-treatment, at 3- and 6-month follow-up visits. All patients reported the number of used hygienic pads. Scores of questionnaires were calculated and statistically evaluated through t-test ($p<0.001$). Number of used hygienic pads was calculated as average.

Results:
Course of the treatment with the HIFEM technology significantly improved QoL of all women. This was demonstrated as 77% level of improvement in incontinence impact according to the KHQ scores during 6-month follow-up. 95% of patients decreased the use of hygienic pads to 2.0 pads per day and night post-treatment. 71% of patients significantly decreased the use of hygienic pads to 1.33 pad per day and night during 6-month follow-up.

Conclusion:
Results suggest that HIFEM technology is an efficacious therapy for treatment of SUI.

1. INTRODUCTION

1.1. Medical background of stress urinary incontinence

Urinary incontinence (UI) is a prevalent condition manifested as involuntary urine leakage and represents a hygienic and a social problem. UI may be classified as stress, urge or mixed type. The stress urinary incontinence (SUI) is usually caused by stress applied over the pelvic floor muscles and bladder, where in the common case this stress is led by coughing, sneezing, laughing or physical activities. In women, the reasons for SUI include events such as condition after childbirth, hormonal changes in menopause, physical inactivity, obesity, aging or pelvic organ prolapse (cystocele, rectocele, uterine prolapse). Further concomitant effects in sexually active women, such as decreased gratification during intercourse and other related dysfunctions, could also be present. In the majority of the cases, patients with SUI, evaluate their QoL as affected in a negative manner due to their condition.

1.2. Current treatment methods for SUI

Therapeutic approaches for SUI depend on the underlying causes of the problem and involve medications, pelvic floor muscles exercising and re-education or surgical interventions.

1.2.1. Drug treatment

The most used drugs for SUI are Alpha-adrenergic agonists, anticholinergic and antispasmodic agents. However, their effectiveness is not always certain and wide range of side-effects are present.

1.2.2. Pelvic floor muscles exercising

The Agency for Healthcare Research and Quality suggests rehabilitation techniques such as vaginal weight training or Kegel exercises with a biofeedback. Vaginal weight training involves intravaginal approach pertruding patient's privacy and comfort. On the other hand, non-invasive Kegel exercises are hard to perform in patients with SUI, because of the decreased level of the pelvic floor muscle awareness and inability to contract these muscles selectively. The conventional muscle strengthening and re-education include intravaginal electrostimulation, which is discomfortable for the patient and risk of tissue burn is still present.

1.2.3. Pelvic floor surgery

The surgical intervention involves procedure that increases urethral outlet resistance – Transobturator Vaginal Tape (TVT). TVT are in the common case carried out only after all other approaches took place.

1.2.4. Behavioral changes

Benefits for improving the condition, to some extent, may be provided by behavior changes such as quitting smoking, avoiding alcohol, losing excess weight, avoiding physical activities (e.g. jumping, running etc.).

As discussed, the SUI condition is prevalent and finding more effective and non-invasive method addressing SUI appears essential for the female intimate health.

2. HIFEM technology

2.1. Mechanism of action

HIFEM technology uses high-intensity focused electromagnetic fields, which are generated by a coil positioned inside a chair applicator. High-intensity focused electromagnetic fields interact and depolarize the pelvic floor motoneurons. Fields deliver focused electromagnetic energy into whole pelvic floor area, which results in selective and supramaximal pelvic floor muscles contractions.

2.2. Supramaximal pelvic floor muscles contractions

For its myostimulative effect, the method is used in pelvic floor muscles strengthening in order to adress the SUI. The patient affected by the SUI is not able to contract pelvic floor muscles selectively, therefore HIFEM represents targeted pelvic floor muscles strengthening and re-education. As the electromagnetic field passes through human body non-invasively, therapy is delivered to the patients whilst they remain fully clothed throughout the whole therapy.

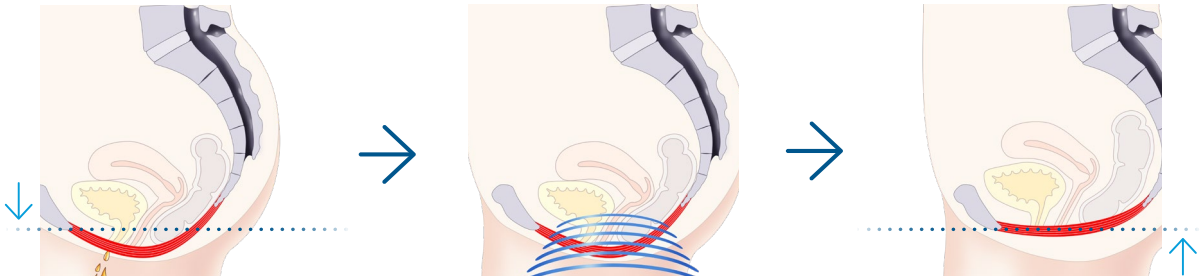

Figure 1: HIFEM technology mechanism of action

3. MATERIALS AND METHODS

3.1. Aim

The aim of the study was to assess the effect of HIFEM technology in treatment of SUI.

3.2 Subjects

30 women with SUI (classified as SUI type 0-2a), aged between 38-75 years (Mean±SD= 57.99±10.36) were voluntarily comprised in this study.

3.3. Inclusion and exclusion criteria

Women with diagnosed SUI were the main inclusion criterium. Women with pacemakers, metal implants, blood circulation disorders, tumors, fever, menstruation and pregnant women were excluded from the study.

3.4. BTL EMSELLA™ device
FDA approved device for female urinary incontinence treatment BTL EMSELLA (BTL EMSELLA, BTL Industries Inc.) was used in the course of treatments.

3.5. Used methods
The effect of the course of treatments with the HIFEM technology was assessed through the King's Health Questionnaire (KHQ). The questionnaire detects the general health condition and incontinence impact in day-to-day life. Additionally, patients were asked to report the number of used hygienic pads.

4. DATA COLLECTION

4.1. Data collection
Data was collected pre- and post-treatment. The long-term effect was evaluated during 3- and 6-month follow-ups.

4.2 Therapy protocol
All patients were delivered the course of treatments consisted of 6 therapies scheduled 2x a week. Patients sat on the BTL EMSELLA chair, feet on the ground, hips, knees and ankles were perpendicularly flexed. Throughout the procedure all patients remain fully clothed. Therapy duration was set to 28 minutes; frequency range between 20-30 Hz with trapezoid intensity modulation were used to achieve gradual motor unit recruitment. Intensity (in %) was set according to patients' feedback and comfort to trigger supramaximal pelvic floor muscle contractions.

4.3. Statistical evaluation
Data of 30 patients was collected and statistically evaluated. During the course of treatment no adverse events occured and therapy was well-tolerated by all patients. KHQ scores were calculated through Student's t-test ($p<0.001$). Results were compared between pre- and post-treatment, pre-treatment and 3- and 6-month follow-ups data. Patients' reports about the use of hygienic pads were calculated as average pre-, post-treatment, and 3- and 6-month follow-ups.

5. RESULTS

5.1. The KHQ results
The results are discussed in the text below (See Figure 2).

5.1.1. KHQ Part 1 results
Pre-treatment average score of the KHQ-Part 1 was 97.78±34.67 points. Post-treatment average score of the KHQ-Part 1 decreased to 65.83±29.31 points. During 3-month follow-up average score further decreased to 59.72±30.25 points, and to 55.00±35.12 points during 6-month follow-up. These scores are calculated as 28%, 34% and 39% levels of improvement of general health perception ($p<0.001$).

5.1.2. KHQ Part 2 results
Pre-treatment average score of the KHQ-Part 2 was 284.91±147.08 points. Post-treatment average score of the KHQ-Part 1 decreased to 110.19±115.66 points. During 3-month follow-up the score further decreased to 85.00±119.72 points. During 6-month follow-up the score decreased to 71.02±122.34 points. These scores are calculated as 61%, 70% and 77% levels of improvement of decreased negative incontinence impact ($p<0.001$).

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%**

Figure 2: Results of the KHQ score
Legend: SD = standard deviation; KHQ = King's Health Questionnaire

5.2. Hygienic pads results

Pre-treatment, patients used on average 2.43 hygienic pads per day and night. Post-treatment, all patients decreased the use to 2 pads per day and night. All patients completed 3- and 6-month follow-up. During 3-month follow-up patients used 1.4 pad per day and night. During 6-month follow-up patients used 1.33 pad per day and night (See Figure 3).

7. CONCLUSION

The results obtained from this study suggest the HIFEM technology is promising approach for pelvic floor muscles stimulation that further improves the quality of life among SUI patients.

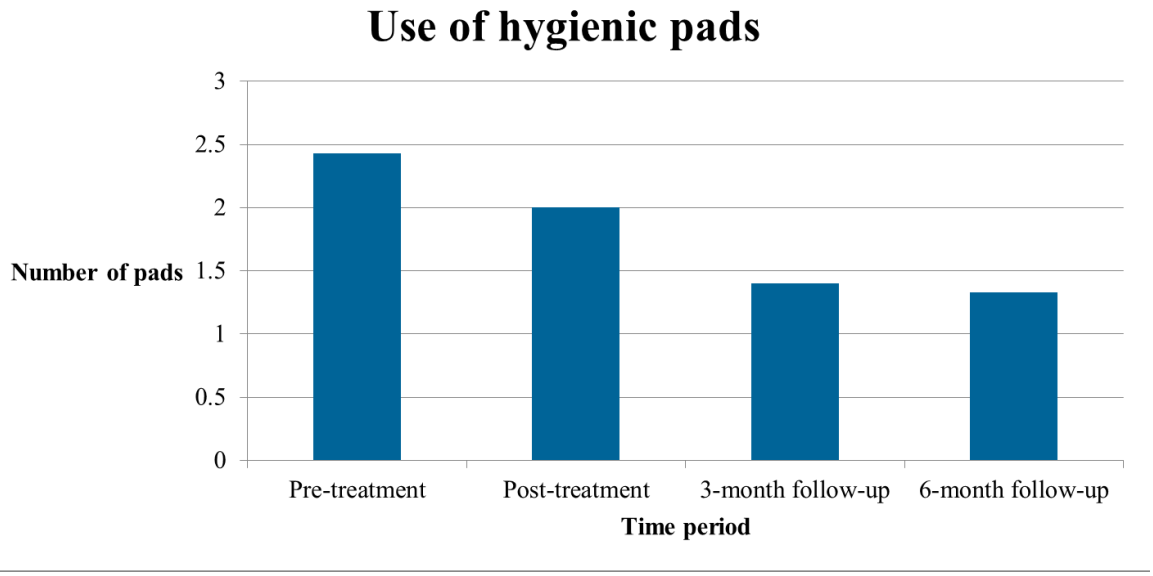

Figure 3: Use of hygienic pads

6. DISCUSSION

Prior to undergoing the treatment, the majority of patients described, according to the answers in the KHQ, that their overall health condition is affected and role, social and emotional limitations are present, which signifies affected QoL. Improvement in patients' QoL was observed in short- and long-term period according to the results of KHQ and decreased use of hygienic pads. Evidence for effectiveness of this method in addressing SUI is available from previous research. These results are explained through intense stimulative effect of the entire pelvic floor area by using high-intensity focused electromagnetic fields.

8. CONFLICT OF INTEREST

Authors declare that no conflict of interest exists.

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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

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Background:
Urinary incontinence (UI) has a prevalence of 30-40% in post-partum and menopausal women. Women may be reluctant to discuss UI with their healthcare providers as well as the degree to which it may negatively impact their quality of life (QoL) for numerous reasons including embarrassment and fear associated with treatment options. Women consistently express the preferred desire to address UI in a non-surgical and discreet manner. This study sought to report on results of a novel non-surgical treatment that may provide an affordable and discrete solution to this common problem.

Study Design/Materials and Method:
This is a retrospective two-site study investigating the effectiveness of the treatment using quantified data, as well as the impact on QoL of incontinent women using a High-Intensity Focused Electromagnetic Technology (HIFEM) device.
20 women, 45 to 77 years (58.63±SD=9.86) who presented with urinary incontinence including stress, urge and mixed UI, were included in a pilot study. All patients completed a total of 6 treatments performed twice weekly for 3 consecutive weeks. Twenty patients completed King's Health Questionnaire (KHQ) pre- and post-treatment. The same data was collected during 3 and 6-month follow-up as well. Additionally, patients reported the frequency of urinary leakage episodes and pad usage. Scores of the KHQ were calculated and statistically evaluated through t-test ($p<0.05$). The frequency of urinary leakage episodes and number of used hygienic pads were calculated through frequency of occurrence.

Results:
Treatment with the HIFEM technology significantly improved QoL scores in all patients. There was a 60% improvement in both parts of the KHQ which were maintained through the 6-month follow-up ($p<0.05$). Nearly 75% of patients significantly decreased urinary leakage or achieved total dryness and maintained these results through follow-up. Pre-treatment, 16 patients used on average 2 hygienic pads per 24 hour period. During 3-month follow-up, 6 patients used 0.6 pads, 10 patients were completely dry. Twenty patients completed the 6-month follow-up, with eleven patients completely dry and 5 patients used 0.5 pads per 24 hour period. The vast majority of the patients decreased usage of hygienic pads to a minimum or totally eliminated usage.

Conclusion:
Results suggest that HIFEM technology significantly improves the QoL and reduces UI in post-partum and menopausal female patients who present with all types of UI. This study confirms that further investigation is warranted.

1. INTRODUCTION

1.1. Prevalence of urinary incontinence

Urinary incontinence (UI) is defined as an involuntary loss of urine affecting mainly the female population. It is estimated that prevalence in young women is 20-30%, in mid-aged women 30-40%, whereas in elderly women prevalence rises to 50%.

1.2. Cause and consequence of urinary incontinence

The pelvic floor muscles (PFM) support pelvic organs and help control continence. Due to physiological changes such as body aging, childbirth or hormonal changes, PFM decondition and do not provide sufficient support for pelvic organs and continence control. This leads to PFM dysfunction with direct consequence toward incontinence.

1.3. Types of urinary incontinence and treatment options

There are 3 types of UI comprising stress urinary incontinence (SUI), urge incontinence and mixed urinary incontinence (MUI).

1.3.1. Stress urinary incontinence

Clinical symptoms of SUI are associated with involuntary urinary leakage during increased intra-abdominal pressure (e.g. coughing, sneezing, laughing, lifting etc.). The cause of the SUI is discoordination among weakened PFM and increased abdominal pressure. SUI is often associated with vaginal delivery, studies have shown 78.5 % of women were unable to contract pelvic floor muscles properly 1 year after delivery. SUI occurs as well in the post-menopausal period. Weakening of the pelvic floor muscles is caused by reduced estrogen level. In the case of SUI, treatment options range from PFM exercising (e.g. Kegel), intravaginal electrotherapy, hormone therapy, in addition to surgical intervention. Surgical intervention is recommended usually only in severe cases of SUI and a vast majority of female patients are reluctant to undergo surgical intervention, especially due to adverse events such as bleeding, development of urge incontinence due to inability to empty the bladder fully, and decreased sexual satisfaction.

1.3.2. Urge urinary incontinence

Urge incontinence is associated with an intense desire to void, during which the bladder pathologically contracts without cause. It is a neuromuscular dysfunction, typically representing a symptom of an underlying disease (e.g. diabetes mellitus). Traditional treatment of urge incontinence usually involves drug treatment.

1.3.3. Mixed urinary incontinence

A third type – mixed urinary incontinence (MUI) usually includes combination of stress and urge incontinence symptoms. MUI treatments usually involve a combination of PFM exercises and drug therapies. (1, 2)

1.4. Disadvantages of current treatment options

There are disadvantages to current treatment methods. In the case of SUI, one of the main problems in the case of pelvic floor exercising is the patients' inability to selectively contract their pelvic floor muscles and to maintain an exercise routine. Kegel exercises are the most common form of PFM excercise, yet lack proof of efficiency as an effective solution. Another available treatment is intravaginal electrotherapy and biofeedback. A common concern of intravaginal electrostimulation is the electrode placements, which can cause patient's discomfort. Adverse events can include bleeding, localized pain or irritation of the tissue under the patch electrodes. Surgical interventions are invasive and can also include adverse events. Pharmacotherapy is non-targeted, and side-effects such as dry mouth, bowel constipation and indigestion can occur. Today, both physicians and their patients seek a solution that meets the criteria of providing an effective clinical outcome via a non-invasive modality.

2. HIFEM technology

2.1. HIFEM technology Mechanism of Action

High-intensity Focused Electromagnetic technology (HIFEM) uses focused electromagnetic field with its intensity measured in Tesla. Such an intense electromagnetic field passes non-invasively through the pelvic floor area, interacts with PFM motoneurons and subsequently triggers supramaximal PFM contractions due to the action potential.

2.2. Supramaximal pelvic floor muscle contractions

Maximal voluntary contraction (MVC) is the greatest

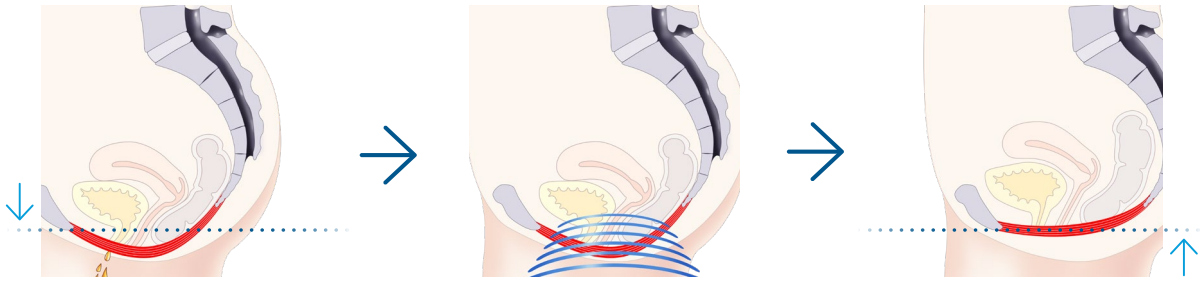

Figure 1: HIFEM technology mechanism of action

amount of tension that could be developed and held physiologically by the PFM for a few seconds. Contractions with a tension higher than MVC are defined as supramaximal. HIFEM triggers supramaximal PFM contractions and holds them for multiple seconds (see Figure 2). Supramaximal contractions are independent of brain function and target directly the motoneurons in the pelvic floor area. This phenomenon cannot normally be achieved by voluntary muscle action (e.g. Kegel exercise).

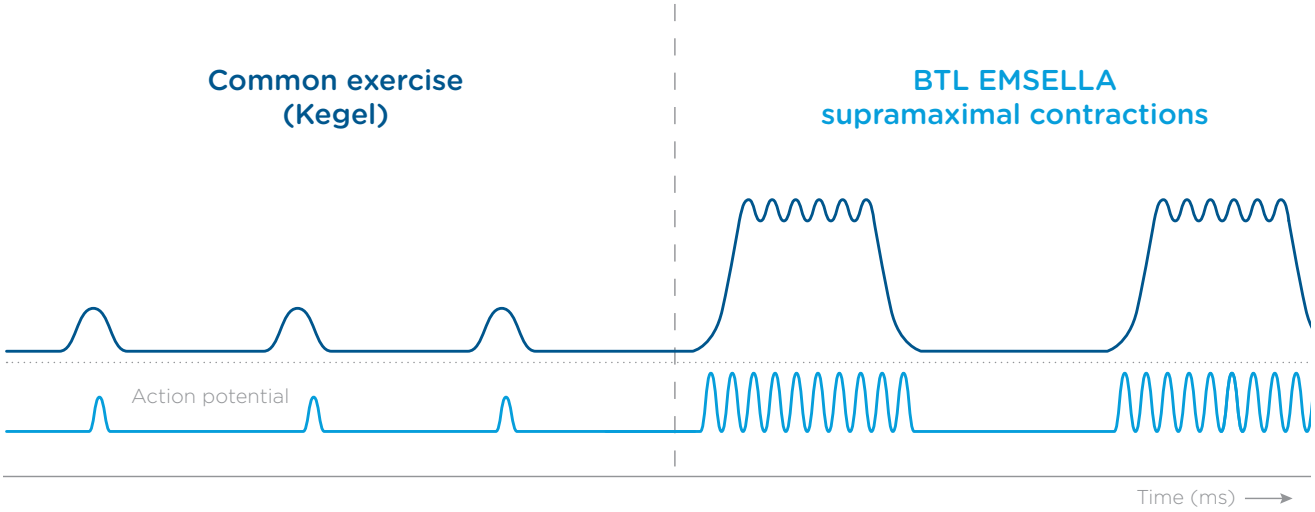

Figure 2: Supramaximal contractions caused by BTL EMSELLA device

2.3. HIFEM muscle re-education

During a normal treatment session, thousands of PFM supramaximal contractions are performed. This is extremely important to PFM re-education, as the patients are typically not able to perform these high-repetition rate contractions due to PFM weakness.

3. MATERIALS AND METHODS

3.1. Aim

We aimed to investigate the impact of the course of treatment on QoL of incontinent patients through a device based on HIFEM technology.

3.2. Hypotheses

We hypothesized as follows:

H0: Course of treatments with the HIFEM technology will not improve the QoL of incontinent patients.

H1: Course of treatments with the HIFEM technology will significantly improve the QoL of incontinent patients.

H2: Course of treatments with the HIFEM technology will reduce the frequency of urine leakage episodes and number of used hygienic pads.

3.3. Subjects

Subjects were enrolled after their voluntary agreement and signed written informed consent. 20 women, 45 to 77 years (58.63±SD=9.86) with SUI, urge incontinence and MUI were included in the pilot study. According to the patients' history, UI was a consequence of vaginal delivery, sudden weight change, obesity or post-menopausal status.

3.4. BTL EMSELLA device

FDA cleared device for female urinary incontinence treatment. BTL EMSELLA (BTL Industries, Marlborough, MA) was used in the course of treatments.

3.5. Inclusion and exclusion criteria

The main inclusion criteria were female patients with diagnosed stress, urge or mixed UI. Women with pacemakers, metal implants, blood circulation disorders, tumors, fever, menstruation and pregnant women were excluded from the study.

3.6. Used methods

The effect of the course of treatments with the HIFEM technology on the QoL of incontinent patients was assessed through the King's Health Questionnaire (KHQ). KHQ helps to observe the general health condition and incontinence

impact on day-to-day life. Additional questions inquired regarding the number of used hygienic pads and frequency of urinary leakage.

4. DATA COLLECTION

4.1. Data collection

Data was collected pre- and post-treatment. The long-term effect was tested during 3- and 6-month follow-ups.

4.2. Therapy protocol

All patients completed 6 therapy sessions, 2 times per week. Patients were instructed by medical personnel to sit on the BTL EMSELLA chair with their spine straight, feet on the ground, hips, knees and ankles perpendicularly flexed. Throughout the procedure patients remained fully clothed. Therapy duration was set at 28 minutes; frequency range between 20-30 Hz with trapezoid intensity modulation were used to achieve gradual motor unit recruitment. Intensity (in %) was set according to patients' feedback and comfort to achieve supramaximal PFM contractions.

4.3. Statistical evaluation

Data from the 20 patients were collected and statistically evaluated. During the course of treatment, no adverse events were recorded, and therapy was well-tolerated by all patients. KHQ scores were calculated ($p<0.05$). Results were compared between pre- and post-treatment, pre-treatment and 3- and 6-month follow-up data. Patients reported frequency of the urinary leakage episodes and use of hygienic pads, this data was then calculated as frequency of occurrence between pre- and post-treatment, as well as between pre-treatment and 3- and 6-month follow-ups.

5. RESULTS

5.1. The KHQ results

The results and hypotheses are discussed in the text below.

- H0: *Course of treatments with the HIFEM technology will not improve the QoL of incontinent patients.*

H0 hypothesis disproved. All patients (n=20) experienced improved QoL after course of treatment with the HIFEM technology, which was further proved by H1.

- H1: *Course of treatments with the HIFEM technology will improve the QoL of incontinent patients.*

H1 hypothesis proven.

5.1.1. KHQ Part 1 results

Pre-treatment average score of the KHQ-Part 1 was 92.22 points. Post-treatment average score of the KHQ-Part 1 decreased to 66.94 points. During 3-month follow-up, average score further decreased to 60.56 points, and to 37.04 points during 6-month follow-up, respectively. These scores are demonstrated as 50%, 51% and 60% levels of improvement in general health perception ($p<0.05$).

5.1.2. KHQ Part 2 results

Pre-treatment average score of the KHQ-Part 2 was 194.63 points. Post-treatment average score of the KHQ-Part 1 decreased to 154.44 points and was maintained during 3-month follow-up. During 6-month follow-up the score decreased to 90.59 points. These scores are demonstrated as 53%, 61% and 60% levels of improvement ($p<0.05$).

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%**

Figure 3: Results of the KHQ score
Legend: SD = standard deviation; KHQ = King's Health Questionnaire

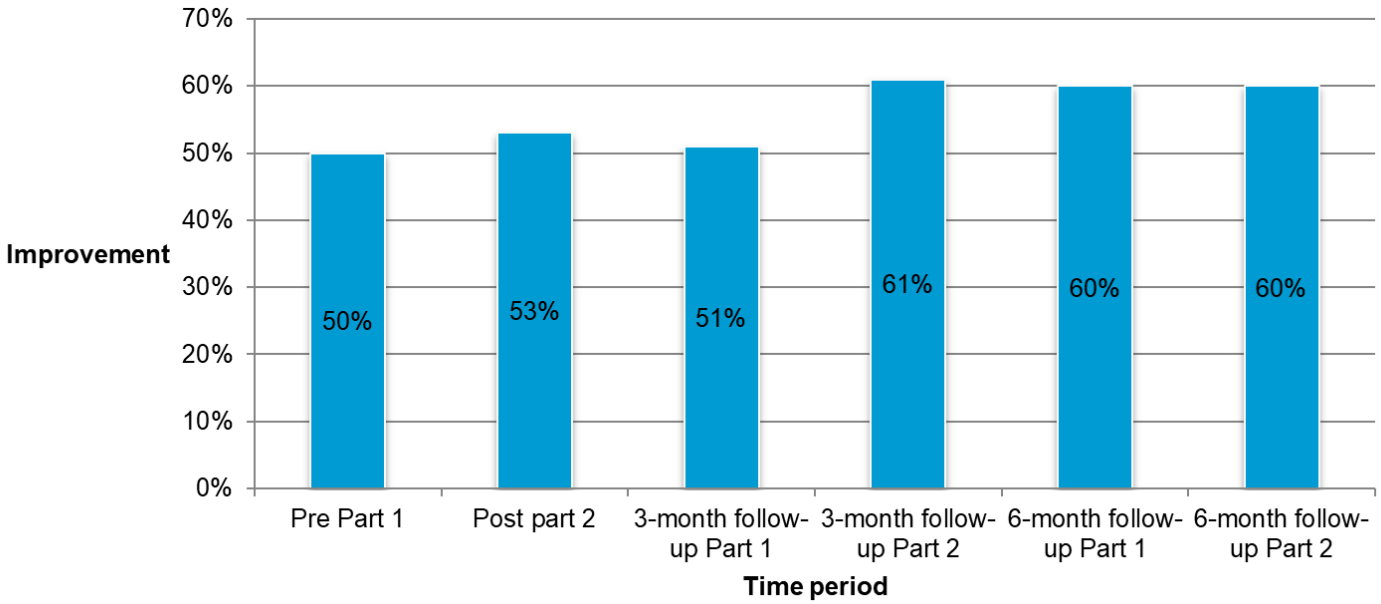

Figure 4: Level of improvement in the patients' QoL according to the KHQ scores

5.2. The urinary leakage episodes and use of hygienic pads

- *H2: Course of treatments with the HIFEM technology will reduce the frequency of urine leakage episodes and number of used hygienic pads.*

H2 hypothesis proven.

5.2.1. Urinary leakage episodes

Pre-treatment, all patients reported urine leakage in different severity (See Figure 6). Post-treatment, in 7 patients urine leakage episodes decreased to 1-3x a day, whereas 4 patients were completely dry. During 3-month follow-up, 7 patients decreased episodes to 1-3x a day, and another 11 patients to 1-3x a week, while 5 patients were completely dry. 20 patients completed the 6-month follow-up. 3 patients decreased episodes to 1x a day, whereas 12 decreased episodes to 1-3x a week, while 5 patients were completely dry.

5.2.2. Use of hygienic pads

Pre-treatment, 16 patients used on average 2 hygienic pads per 24 hour period. Post-treatment, 12 patients decreased use to 0.8 pad per 24 hour period, whereas 4 patients were completely dry. During 3-month follow-up, 6 patients were using 0.5-0.6 pad per 24 hour period, whereas 10 patients remained completely dry. At the 6-month follow-up, 5 patients were using 0.5-0.6 pad per 24 hour period, whereas 11 patients remained completely dry (See Figure 6).

Frequency/number of patients	5x a day	3x a day	2x a day	1x a day	3x a week	2x a week	1x a week	Never
Pre-treatment	3	3	2	4	2	2	4	0
Post-treatment	2	2	2	3	3	3	1	4
3-month follow-up	0	0	2	2	2	5	4	5
6-month follow-up	0	0	0	3	2	4	6	5

Figure 5: Frequency of leakage episodes

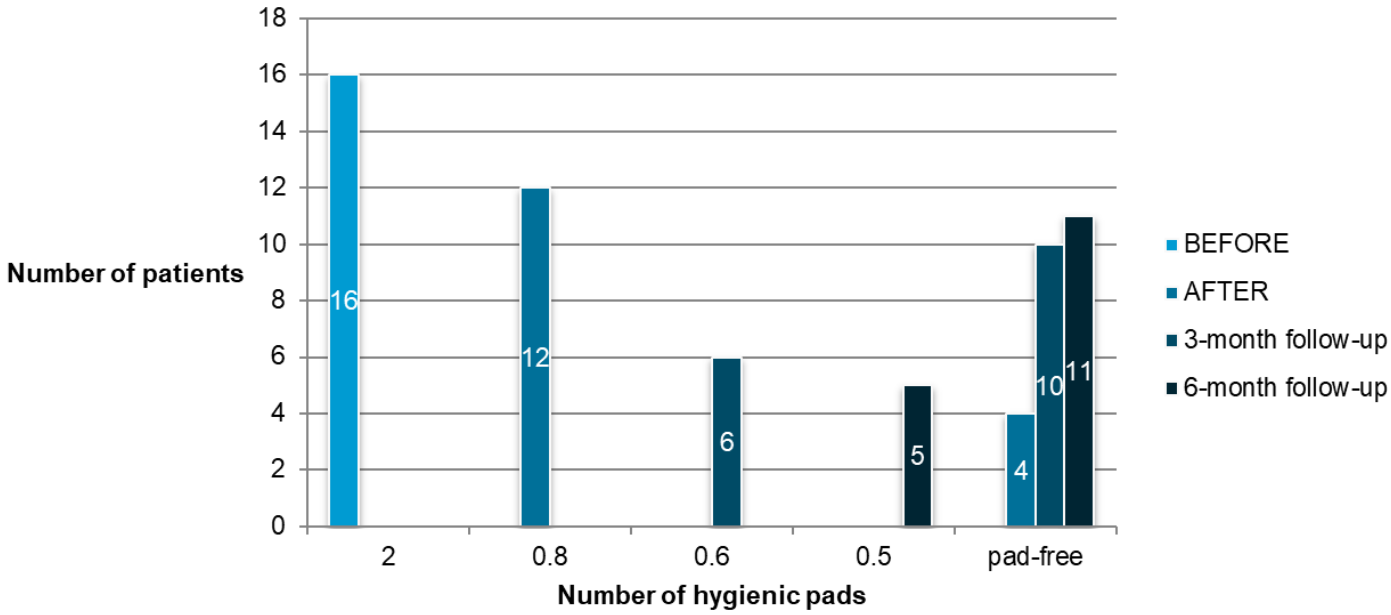

Figure 6: Use of hygienic pads

6. DISCUSSION

The results suggest that the treatment with HIFEM technology significantly decreases the negative impact incontinence has in patients' day-to-day life. This improvement was observed in both short- and long-term results by KHQ, decreased frequency of urine leakage episodes, and decreased use of hygienic pads. The results are explained through myostimulation of the pelvic floor area by using high-intensity focused electromagnetic fields therapy, which trigger supramaximal PFM contractions. A single session brings thousands of PFM contractions. This is extremely important in PFM re-education helping the patients to regain PFM strength and bladder control.

7. CONCLUSION

UI represents an important healthcare problem with high prevalence and negative impact on patients' QoL. As most of the patients are not suitable for current treatment methods, this study as well as previous research, suggest that UI can be treated non-invasively through HIFEM technology.

8. LIMITATIONS

The limitations of this study were the small number of patients and absence of a control group, such that a control randomized study with larger number of patients should take place in further research.

9. CONFLICT OF INTEREST

Authors declare that no conflict of interest exists.

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HIFEM™ TECHNOLOGY CAN IMPROVE QUALITY OF LIFE OF INCONTINENT PATIENTS

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

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

Background:
Urinary incontinence (UI) represents one of the most prevalent female intimate health issues negatively affecting a patients' quality of life (QoL). Current treatment options require a combination of pelvic floor muscles exercising and intravaginal electrostimulation or drug treatment with side effects. Women seek non-invasive and efficacious solutions for UI.

Aim:
The aim was to investigate the effect of High-Intensity Focused Electromagnetic technology (HIFEM) on QoL of incontinent patients.

Methods:
30 women (mean age 53.05 years) with stress, urge and mixed type of UI took part in the pilot study. They attended 6 therapies scheduled 2x a week. QoL was assessed through King's Health Questionnaire (KHQ). The number of used hygienic pads and patients' subjective feedback were recorded. Data was collected pre-, post-treatment, during 3- and 6-month follow-ups. KHQ scores were statistically evaluated through t-test ($p<0.05$). Number of used hygienic pads and patients' subjective feedback were evaluated through frequency of occurence.

Results:
After 6 treatments, 95 % of treated patients improved their QoL according to the scores of the KHQ. These results were maintained during the 3- and 6-month follow-ups. 67 % of the treated patients reduced or totally eliminated the use of hygienic pads in day-to-day life. 100 % of patients reported better awareness of the pelvic floor muscles.

Conclusion:
Results suggest that the tested device significantly improves the QoL of incontinent patients.

Keywords:
urinary incontinence, hygienic pads, King's Health Questionnaire, Quality of Life, HIFEM technology, FDA

1. INTRODUCTION

1.1. Definition of the problem

Urinary incontinence (UI) is involuntary loss of urine, which objectively and subjectively represents a social, psychological and hygienic problem. It is estimated that 1 in every 4 women aged between 30 and 59 years has experienced a problem with urinary leakage. Estimation of worldwide UI prevalence is around 40 % of the female population. However, a vast majority of the patients is reluctant to discuss this intimate issue with their medical doctors. National Association for Incontinence (NAFC) reports that 4.5 out of 10 patients do not seek help. (1, 11)

1.2. Types of urinary incontinence

UI can be divided into 3 types according to its' etiology. Clinical symptoms of stress urinary incontinence (SUI) usually involve involuntary leakage of urine when events with increased intra-abdominal pressure are performed (e.g. coughing, sneezing, laughing and lifting). The cause of SUI is due to a loss of support of urethra and deconditioned pelvic floor musculature (PFM), which is usually a consequence of damage to the pelvic support structures. SUI is strongly associated with vaginal childbirth and menopausal hormonal changes (1). The second UI 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 commonly treated with pharmacotherapy. Urge incontinence is usually a symptom of an underlying problem (e.g. diabetes mellitus). The third UI type is mixed urinary incontinence (MUI) and involves a combination of the SUI and urge incontinence symptoms (1).

1.3 Treatment options for urinary incontinence

The choice of treatment for UI depends on its' type and severity. In the case of SUI, treatment options range from pelvic floor muscle exercising, intravaginal electrotherapy up to surgical intervention. Surgical intervention is recommended usually only in severe cases of SUI, whereas drug treatment of urge incontinence is common. A vast majority of patients use hygienic pads and their quantity depends on the severity of UI and leakage episodes (13, 15).

2. HIFEM technology

2.1. Mechanism of Action

High-intensity Focused Electromagnetic technology (HIFEM) triggers intense pelvic floor muscles contractions by targeting neuromuscular tissue and inducing electric currents. Electric currents depolarize neurons resulting in concentric contractions and lift up of all pelvic floor muscles. Key effectiveness is based on focused electromagnetic energy, in-depth penetration, and stimulation of the entire pelvic floor area. The HIFEM technology brings deep PFM stimulation and restoration of the neuromuscular control. The HIFEM passes non-invasively through pelvic floor area. Therefore, it represents a non-invasive solution for incontinent patients, who remain fully clothed during the therapy (2-10, 12, 14-19).

- *H0: Course of treatments with the HIFEM technology will not lead to any improvement of QoL of incontinent patients.*
- *H1: Course of treatments with the HIFEM technology will lead to significant improvement of QoL of incontinent patients.*
- *H2: Course of treatments with the HIFEM technology will reduce the use of hygienic pads.*

3.2. Patients

All patients were enrolled in the pilot study after their voluntarily agreement and signed written informed consent. 30 women aged 36-76 years (mean age 53.05±11.74) with SUI, urge and MUI were included in the pilot study. UI resulted out as a consequence of vaginal childbirth, hormonal changes (menopause) or through obesity.

3.3. Exclusion criteria

Women with pacemakers, metal implants, blood coagulation disorders, tumors, fever, menstruation and pregnant women were not included in this study.

3.4. HIFEM technology tested device

In this pilot study, FDA approved device for female urinary incontinence treatment BTL EMSELLA (BTL EMSELLA, BTL Industries Inc.) was used.

3.5. Methods

The effect of HIFEM technology on QoL of incontinent

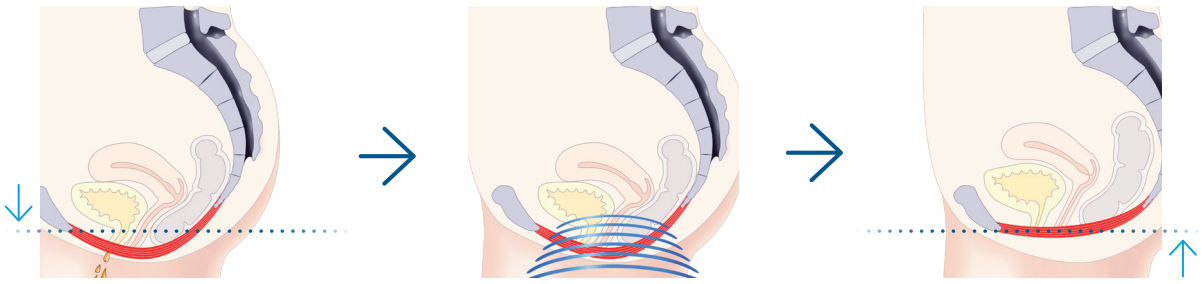

Figure 1: HIFEM™ technology

3. MATERIALS AND METHODS

3.1. Aim

The aim was to investigate the effect of HIFEM technology on QoL of incontinent patients. For such purpose 3 hypotheses were created:

patients was assessed through the King's Health Questionnaire (KHQ). The KHQ detects incontinence impact in patients' socio-emotional life and activities of daily living (ADL) (13). Additionally, number of used hygienic pads and patients' subjective feedback were recorded.

4. COLLECTING THE DATA

4.1. Data collection
Data was collected pre-, post-treatment and during 3- and 6-month follow-ups.

4.2. BTL EMSELLA therapy protocol
All women absolved 6 therapies scheduled 2x a week. Therapy was performed by medical personnel, who positioned the patient into a comfortable sitting position, feet on the floor, hip, knee and ankle joints perpendicularly flexed. 30-minute duration for each treatment session.

4.3. Therapy parameters
Frequency range 20-30 Hz with trapezoid intensity modulation was used to achieve gradual motor unit recruitment. Relative intensity (in %) was gradually increased from patients' motor up to above the motor threshold.

4.4. Statistics
Data of 30 patients was collected and statistically evaluated. During the course of treatment no adverse events occurred and therapy was well tolerated. KHQ scores were calculated and tested for statistical significance by means of Student's t-test at statistical significance level $p<0.05$. Improvements were compared as follows: between pre-treatment and post-treatment data, between pre-treatment and 3- and 6-month follow-ups data. Patients' reports of the number of used hygienic pads were calculated as statistical frequency of occurrence between pre-treatment and post-treatment data, between pre-treatment and 3- and 6-month follow-ups data. Additionally, subjective feedback was collected from all patients. The frequency of answer occurrence was calculated.

5. RESULTS

5.1 The King's Health Questionnaire results
The KHQ has two parts – Part 1 reports about the general health perception; Part 2 reports about the incontinence impact on the patient's life. The scores are calculated separately. The research results proved/disproved following hypotheses and are discussed in the text below:

- *H0: Course of treatments with the HIFEM technology will not lead to any improvement of QoL of incontinent patients.*

H0 hypothesis disproved. All patients (n=30) have improved their QoL after a course of treatment with the HIFEM technology, which was proved by H1.

- *H1: Course of treatments with the HIFEM technology will lead to significant improvement of QoL of incontinent patients.*

H1 hypothesis proved. After the course of treatment with the HIFEM technology, 95 % of treated patients reported improvement in the QoL according to the scores of the KHQ. Before the therapy, the average score of the KHQ-Part 1 was 82.08 points. After course of treatment with the HIFEM technology, the average score of the KHQ-Part 1 was 51.67 points, which decreased to 45.42 points during 3 months and to 48.33 points during 6 months, respectively. These improvements are demonstrated as 37%, 42% and 38% levels of improvement in general health perception ($p<0.05$).

Before the therapy, the average score of the KHQ-Part 2 was 187.50 points. After a course of treatment with the HIFEM technology the average score of the KHQ-Part 1 was 103.75 points, which decreased to 81.11 points during 3 months and further to 74.44 points during 6 months, respectively. These improvements are demonstrated as 37%, 55% and 57% levels of improvement ($p<0.05$).

5.2 The results of use of hygienic pads

- *H2: Course of treatments with the HIFEM technology will reduce the use of hygienic pads.*

H2 hypothesis proved. In this study, 12 patients wore hygienic pads during the day and night. Before the therapy, average number of used hygienic pads was 1.1 pad per day and night. After a course of treatment, 67 % (n=9) of treated patients totally eliminated or decreased the average number of used hygienic pads decreased to 0.45 pad per day and night. The results were maintained during the 3- and 6-month follow-ups.

5.3. The patients' subjective evaluation of the therapy
Additionally, patients answered the question *'What is the major difference you noticed after the BTL EMSELLA therapies?'*

40 % of patients reported that they are able to perform proper contraction of the PFM; 28 % of patients were able to contract PFM selectively; 20 % of patients reported better muscle firmness and 12 % of patients reported that the period between micturition is longer. Additionally, all patients (n=30; 100 %) reported better awareness of pelvic floor muscles.

Parameter	KHQ Part 1	KHQ part 2
KHQ score pre-treatment (Mean±SD)	**82.08±29.53**	**187.50±119.24**
KHQ score post-treatment (Mean±SD)	**51.67±33.62**	**103.75±83.07**
KHQ score, 3-month follow-up, (Mean±SD)	**45.42±26.83**	**81.11±64.94**
KHQ score, 6-month follow-up, (Mean±SD)	**48.33±23.66**	**74.44±58.03**
Level of improvement, Pre/Post-treatment	**37%**	**37%**
Level of improvement, Pre-treatment/3-month follow up	**42%**	**55%**
Level of improvement, Pre-treatment/6-month follow- up	**38%**	**57%**

Figure 2: Results of the KHQ score
SD = standard deviation

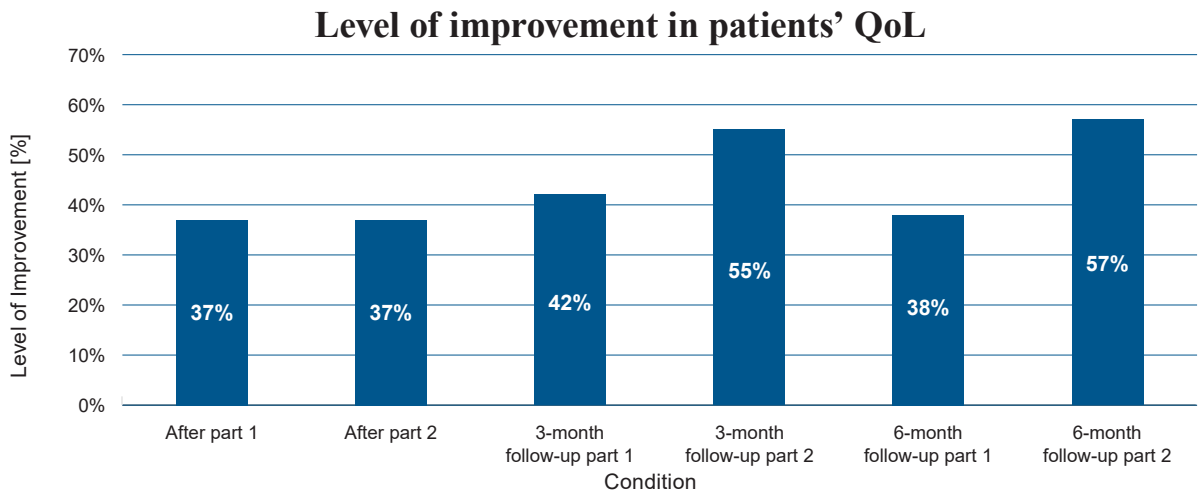

Figure 3: Level of improvement in the patients´ QoL according to the KHQ scores

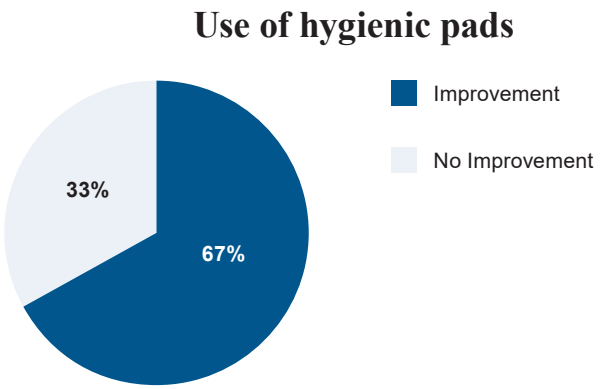

Figure 4: Use of hygienic pads

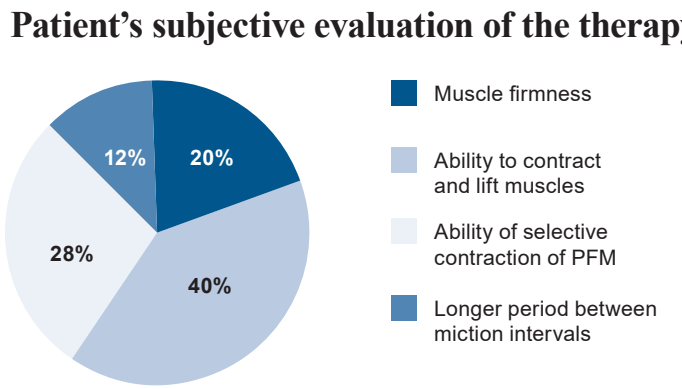

Figure 5: Patients subjective evaluation of the therapy

6. DISCUSSION

To regain continence, regular pelvic floor muscles exercising is required. Normally, 300-500 contractions of the pelvic floor muscles should be performed to begin to develop a new motor pattern, whereas 3,000-5,000 contractions are required to erase and correct poor motor pattern. During 1 session using HIFEM technology, thousands PFM 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 and an inability to consistently contract this muscle group. After 6 therapeutic sessions with HIFEM therapy, patients developed the new motor pattern needed to better control pelvic floor muscles and also regained muscle strength and continence control (3-9, 12-16).

7. CONCLUSION

UI represents a significant psycho-socio-economical healthcare problem that has a major negative impact on today's modern lifestyles. The majority of patients are not satisfied with the current treatment methods offered, which include surgical intervention, drug therapy, pelvic floor muscles exercising (Kegel) or minimally invasive intravaginal procedures. This latest research, as well as, previous studies suggest that HIFEM technology leads to significant improvement in QoL of incontinent patients, maintains a patient's privacy all while avoiding more invasive approaches.

8. CONFLICT OF INTEREST

Authors declare that no conflict of interest exists.

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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]*FACS, Louisville, MD9419 Norton Commons Blvd Suite 101, River Bluff, KY, 40059*
[2]*Southern Urogynecology: Center for Female Pelvic Medicine and Reconstructive Surgery, 115 Midlands Ct, West Columbia, SC, 29169*
[3]*The Laser Vaginal Rejuvenation Institute of Michigan, 30445 Northwestern Hwy Suite 100, Farmington Hills, MI, 48334*
[4]*South Coast Urogynecology, 31852 Coast Hwy #203, Laguna Beach, CA, 92651*

Background and Objectives: Urinary incontinence is a common and distressing condition which interferes with everyday life. Patients frequently experience discomfort related to urine leakage and the subsequent need to use absorbent pads. Since the continence mechanism is primarily maintained by a proper function of pelvic floor muscles (PFM), many treatment methods focused on strengthening of the PFM have been introduced in the past. The aim of this study was to evaluate the safety and efficacy of a high-intensity focused electromagnetic technology (HIFEM) for treatment of urinary incontinence with emphasis on effects on prospective patients' quality of life.

Study Design/Materials and Methods: The study followed an institutional review board approved protocol. A total of 75 women (55.45 ± 12.80 years, 1.85 ± 1.28 deliveries) who showed symptoms of stress, urge, or mixed urinary incontinence were enrolled. They received six HIFEM treatments (2 per week) in duration of 28 minutes. Outcomes were evaluated after the sixth treatment and at the 3-month follow-up. The primary outcome was to assess changes in urinary incontinence by the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) and changes in the number of absorbent pads used per day. The secondary outcome was subjective evaluation of the therapy and self-reported changes in quality of life. The statistical analysis was conducted by paired *T-test* and Pearson correlation coefficient ($\alpha = 0.05$).

Results: After the sixth session, 61 out of 75 patients (81.33%) reported significant reduction of their symptoms. The average improvement of 49.93% in ICIQ-SF score was observed after the sixth treatment, which further increased to 64.42% at the follow-up (both $P < 0.001$). Individually, the highest level of improvement was reached in patients suffering from mixed urinary incontinence (69.90%). The reduction of absorbent pads averaged 43.80% after the sixth treatment and 53.68% at 3 months (both $P < 0.001$), while almost 70% of patients (30 out of 43) reported decreased number of used pads. At the follow-up, a highly significant medium correlation ($r = 0.53$, $P < 0.001$) was found between the ICIQ-SF score improvement and the reduction in pad usage. A substantial decrease in the frequency of urine leakage triggers was documented. Patients reported no pain, downtime or adverse events, and also reported additional beneficial effects of the therapy such as increased sexual desire and better urination control.

Conclusions: This study demonstrated that HIFEM technology is able to safely and effectively treat a wide range of patients suffering from urinary incontinence. After six treatments, an improvement in ICIQ-SF score and reduction in absorbent pads usage was observed. Based on subjective evaluation, these changes positively influenced quality of life. Lasers Surg. Med.
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Key words: HIFEM; pelvic floor muscles; urinary incontinence

INTRODUCTION

Urinary incontinence (UI), defined as involuntary loss of urine [1], is a chronic condition which may negatively affect quality of life (QOL). On the basis of its etiology and

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Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

*Correspondence to: Julene B. Samuels, MD, FACS, Louisville, MD9419 Norton Commons Blvd Suite 101, River Bluff, KY 40059. E-mail: jbsamuelsmd1@gmail.com

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pathophysiology it is classified as stress (SUI), urge (UUI), or mixed UI (MUI) [2,3]. According to clinical research performed on large population samples, its prevalence was reported to range between 25 and 45% [4,5] with the maximum prevalence quoted as high as 69% [6]. These studies revealed that severity of UI symptoms increases predominantly with age. In addition, it was found that factors such as higher body mass index [7,8], parity [8], or certain medical comorbidities [9] are also associated with development of UI. In general, the continence mechanism is mainly associated with the pelvic floor muscles (PFM). The pelvic skeletal muscles support the urinary bladder, the urethra and other pelvic organs, and thus maintain the optimal urethral closure pressure that prevents involuntary urine leakage. In the case of PFM weakening, the pressure balance is disrupted, which results in UI [10,11].

Due to the discomfort and inconvenience caused by urinary leakage, incontinent patients are usually forced to change their habits regarding their personal and professional lives, which may result in lowered self-esteem. Depression and anxiety [12], negative impact on work productivity [13,14] or diminished sexual desire and activity [15,16] are only a few of the possible negative consequences. To deal with urine leakage, patients often use absorbent pads. However, this passive solution does not improve UI symptoms, and despite the advancements in pad composition, there is still a risk of incontinence-associated dermatitis (IAD), an inflammation of the skin caused by the contact of urine with the perineal or perigenital skin [17].

To increase patient's QOL by reduction of UI severity, many treatment methods addressing the weakened PFM via its (in)voluntary stimulation were introduced in the past. These include Kegel exercise [18], PFM exercise with bio-feedback [19], surface and intravaginal electrotherapy [20] and vaginal cones [21], however all these techniques have limitations. It was estimated that 30–50% of women do not perform PFM exercises properly [22,23], and a common issue with electrical stimulation is the discomfort caused by the electrodes and the risk of vaginal infections [20]. Finally, there has been documented evidence which supports non-invasive laser therapy as an effective modality for SUI treatment by the thermal action on the vaginal mucosa, resulting in the rejuvenation processes [24–28].

Most recently, the high-intensity focused electromagnetic (HIFEM) stimulation [29] was introduced to address UI problems. HIFEM technology is known for its simulative effects. The electromagnetic field passes in a non-invasive manner through the neuromuscular tissue where induced electric currents depolarize neuronal cells and initiate action potentials [30]. The high frequency of action potentials then leads to selective and supramaximal muscle contractions. Previous research documented that HIFEM technology is able to affect abdominal [31] as well as pelvic muscles, and that it may be an effective and safe modality in treatment of UI [32,33]. However, further investigation should result in more evidence of how strengthening of PFM by HIFEM reduces UI symptoms and improves QOL.

The aim of this study was to objectively evaluate the efficacy and safety of the BTL EMSELLA device (BTL Industries Inc., Boston, MA) utilizing the HIFEM technology for treatment of UI with emphasis on QOL enhancement.

MATERIALS AND METHODS

Subjects and Ethics

This was a prospective, multi-center, open-label, single-arm study. In total, 75 adult women (mean age 55.45 ± 12.80 years, on average 1.85 ± 1.28 deliveries) who showed signs of SUI, UUI, or MUI urinary incontinence and who expressed an interest in treatment were enrolled (for detailed patient data see Tables 1 and 2). The study was conducted in accordance with ethical standards stated in the Belmont Report and followed the institutional review board approved protocol. At study initiation, patients underwent medical history examination, and a written informed consent was obtained from all participants. Enrolled subjects were required to meet the following inclusion criteria: age > 22 years, weight ≤ 300 lb, were medically stable, and reported UI symptoms. The exclusion criteria were: metal implants, a recent surgical procedure, pregnancy, any concurrent treatment of UI and any contraindication listed in the investigational device manual. Additionally, women with childbearing potential underwent a urine pregnancy test prior to their enrollment and were asked to re-test prior any subsequent exposure.

Investigational Device

BTL EMSELLA generates a rapidly changing, high-intensity focused electromagnetic field that interacts with the motor neurons and triggers stimulation and toning of PFM. The electromagnetic field is produced by a flat spiral-shaped coil which reaches intensities up to 2.5 T. The coil is situated within a seat of a uniquely designed

TABLE 1. Demographic Data of Enrolled Subjects

Data	*N* (%)
Age	
22–29	2 (2.67)
30–39	6 (8.00)
40–49	14 (18.67)
50–59	22 (29.33)
60–69	21 (28.00)
70–79	8 (10.67)
80–89	2 (2.67)
Diagnosis	
SUI	37 (49.33)
MUI	30 (40.00)
UUI	8 (10.67)
Deliveries	
Vaginal	104 (74.82)
C-section	35 (25.18)

MUI, mixed urinary incontinence; SUI, stress urinary incontinence; UUI, urge urinary incontinence.

TABLE 2. Number of Deliveries

	Patients	
Number of deliveries	*N*	%
0	13	17.33
1	13	17.33
2	31	41.33
3	12	16.00
4 or more	6	8.00

chair, externally supplied by the power from the main unit. The electromagnetic energy is directed vertically upward from the center of the seat, while the chair design ensures that the patient's perineum is centered when sitting.

Treatment Protocol

Subjects received six treatments at a frequency of two sessions per week and were required to complete the 3-month follow-up evaluation. Each therapy consisted of a 28-minute treatment session, during which the patient sits straight in the center of the chair seat. To ensure adequate PFM stimulation, the operator confirmed the patient's chair posture throughout the treatments and adjusted the intensity of stimulus as high as tolerated by patient, usually at 100%. Patients received the treatments at a discounted price to minimize dropouts.

Outcomes and Evaluation

The primary outcome was the evaluation of improvement in UI with an emphasis on QOL. To assess a patient's continence, the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) was used. The questionnaire consists of three questions designed to quantify the frequency of leakage, the amount of urine leaked, and the level of interference with daily life, with the total score ranging from 0 (no interference) to 21 (severe involuntary urination interfering with the subject's QOL). At least a 50% [34–36] overall improvement in the total score was expected. The fourth ICIQ-SF question relates to urine leakage triggers and was assessed separately. Subjects were asked to indicate the listed answers that pertained to them, and changes in their answers in time were evaluated. In regard to patient's QOL, the usage of absorbent pads (per 24-hour cycle) was monitored via a pad usage questionnaire.

The secondary outcome was a voluntary subjective evaluation of the therapy. This also served as feedback for the operator and a subjective evaluation of changes in patient's QOL. The evaluation consisted of the following questions: "What would you praise (+) or reproach (–) regarding the therapy" and "Specify if there were any other positive/negative changes in QOL after the therapy."

The primary outcome data was acquired before the first therapy, after the sixth therapy, and at the 3-month follow-up appointment. The subjective evaluation was performed only at the follow-up visit. Adverse events (AE) were monitored throughout the entire study. Only subjects who report an AE that is deemed unsafe for continued participation in the study, should be immediately excluded. The observation of side effects in the treated area included evaluation of: muscular pain, temporary muscle spasm, temporary joint or tendon pain, local erythema or skin redness.

Statistical Analysis

Results were analyzed for statistical significance. The null hypothesis was formulated as: "The treatments caused no difference in patients score." To evaluate the significance of differences caused by the treatments (alternative hypothesis) we used Student's paired t test and Wilcoxon signed-rank test for small sample sizes at the significance level $\alpha = 0.05$. The sample size of 75 subjects was considered as sufficient for purposes of this single-arm prospective study to reveal clinically relevant improvement [29,34,35]. Possible association between measured variables was verified by Pearson correlation coefficient ($\alpha = 0.05$).

RESULTS

The patient group was composed mostly of menopausal and postmenopausal women as there were approximately only 10% of subjects below the age of 40. Almost 90% of patients suffered from SUI or MUI symptoms. Medical examination revealed there were seven (9.33%) women who had undergone hysterectomy in the past, which was the most common procedure stated during the anamnesis when considering the treatment area. Some patients had received a urethral/bladder sling surgery or vaginal rejuvenation (both $N = 4$, 5.33%), hernia repair ($N = 2$, 2.67%), abdominoplasty, removal of ovaries, appendectomy, endometrial ablation, interstitial cystitis surgery, or vaginoplasty (all $N = 1$, 1.33%).

Generally speaking, after the sixth session, 61 out of 75 patients (81.33%) reported significant improvement of their symptoms. Their average ICIQ-SF score at baseline was 10.57 ± 4.22 (ranging 2–18) which declined to 5.33 ± 3.97 after six sessions, and further improved to 4.16 ± 4.04 points at the 3-month follow-up. The ICIQ-SF score improvement thus averaged 49.93% ($P < 0.001$) after six sessions, and 64.42% ($P < 0.001$) at the 3 months. At the end of the study, there were 31 (50.82%, $P = 0.028$) patients who further improved at follow-up compared to immediate post-treatment evaluation. Zero ICIQ-SF score was observed in 13 (21.31%) subjects after the sixth session and in 21 (34.43%) subjects at follow-up. Summarization of ICIQ-SF results is shown in Table 3.

When evaluating ICIQ-SF score separately according to the symptoms we found that SUI patients reached improvement of 54.64% (5.83 ± 3.62 points) after six treatments and 66.98% (6.66 ± 3.45) at 3-month follow-up. Similarly, the MUI patients showed before-after difference score of 52.00% (5.38 ± 4.34 points) which further improved to 69.90% (6.67 ± 3.66 points) at

TABLE 3. Summarization of ICIQ-SF and Pad Usage Data

Parameter	ICIQ-SF	*P* value	Absorbent pads	*P* value
Number of evaluated subjects	61		43	
Baseline	10.57 ± 4.22		2.47 ± 2.25	
After sixth Tx	5.33 ± 3.97		1.35 ± 1.74	
Difference Before & After	5.25 ± 4.02	<0.001	1.12 ± 1.80	<0.001
Average improvement	49.93%	<0.001	43.80%	<0.001
Zero score after sixth Tx (%)	13 (21.31%)		15 (34.88%)	
3 Months Follow-Up	4.16 ± 4.04		1.19 ± 1.91	
Difference Before & Follow-Up	6.41 ± 3.75	<0.001	1.28 ± 1.83	<0.001
Average improvement	64.42%	<0.001	53.68%	<0.001
Zero score after Follow-Up (%)	21 (34.43%)		19 (44.19%)	

ICIQ-SF, International Consultation on Incontinence Questionnaire-Short Form.

follow-up. Results of both SUI and MUI patient group were highly statistically significant ($P < 0.001$). The patients who experienced UUI symptoms initially do not respond to the treatments well; as they reported mild yet significant improvement of 26.54% (4.00 ± 4.74 points; $P < 0.05$) after the sixth treatment. However, at the follow-up examination, they showed a substantially greater level of improvement, reaching 54.11% (7.00 ± 5.24 points, $P < 0.05$).

According to the baseline evaluation, patients most frequently reported they had been experiencing leakage about one time per day. At the 3-month follow-up, most of them mentioned that leakage occurred only about once a week or less. A similar shift was observed when evaluating interference of UI with everyday life. Patients in general improved from "moderate interference" (median score 5 out of 10) to "almost no interference" (median score 1 out of 10) at the 3-month follow-up.

Initially, there were 43 patients who had been using one or more absorbent pads per day, with the average number of used pads 2.47 ± 2.25 daily. After the sixth treatment, a significant improvement of 43.80% ($P < 0.001$) was observed as the average number of used pads decreased to 1.35 ± 1.74 per day. Similarly, to ICIQ-SF evaluation, the improvement at the follow-up was even more significant as the average pad usage further decreased to 1.19 ± 1.91 per day which resulted in an average 53.68% ($P < 0.001$) improvement (see Table 3). The therapy course also allowed some patients to completely get rid of pads. After the sixth treatment, 15 (34.88%) subjects reported they were not using pads anymore, and at the 3 months this number increased to 19 (44.19%) subjects. In total, 29 out of 43 patients (67.44%) reported a reduction in used pads after the sixth treatment, and this increased to 30 out of 43 patients (69.77%) at the follow-up.

A medium, significant and positive correlation ($r = 0.43$, $P < 0.01$) was found between the improvement in ICIQ-SF questionnaire score and the reduction in absorbent pads after the sixth treatment. At the follow-up this correlation was even more profound ($r = 0.53$, $P < 0.001$). Any other possible relations such as between age, the number of pads or ICIQ score, and the number of deliveries were found insignificant with weak correlation coefficients (<0.30).

Evaluation of urine leakage triggers revealed a gradual improvement. At the follow-up, 54.05% fewer patients reported leakage before they could reach the restroom, 64.29% fewer patients who experienced leakage while

TABLE 4. Analysis of Urinary Incontinence (UI) Causes and Frequency of Patients' Answers

Question	Baseline	After sixth Tx (impr. in %)	3 Months Follow-Up (impr. in %)
Never—urine does not leak	2	11 (550.00)	10 (500.00)
Leaks before you can go to the toilet	37	26 (29.73)	17 (54.05)
Leaks when you cough or sneeze	54	38 (29.63)	32 (40.74)
Leaks when you are asleep	14	7 (50.00)	5 (64.29)
Leaks when you are physically active/exercising	45	24 (46.67)	19 (57.78)
Leaks when you have finished urinating and are dressed	21	10 (52.38)	9 (57.14)
Leaks for no obvious reason	14	9 (35.71)	8 (42.86)
Leaks all the time	5	3 (40.00)	3 (40.00)
Total frequency of answers	192	128 (33.33)	103 (46.35)

asleep, and 57.78% fewer patients who experienced leakage during physical activity/exercise. Detailed results are shown in Table 4.

Patients were satisfied with the therapy and treatment results. We observed no AE related to the treatment and only minor side effects such as "muscle fatigue" were documented. Patients described that the therapy was easy and very tolerable as there was no pain, downtime or negative effects. In total, 43 out of 75 patients answered the voluntary section of the questionnaire focused on their subjective satisfaction with the results. They described beneficial changes in QOL as a response to the treatment mostly as: better control over urination throughout the day and night ($N = 17$) a reduced number of pads and incidents of involuntary urination ($N = 10$), a reduced number of visits to the toilet ($N = 6$), much better urine flow ($N = 4$), an improved vaginal and pelvic floor tone ($N = 3$), increased sexual desire and more intense orgasms ($N = 3$).

DISCUSSION

According to results documented in this study, the PFM training by HIFEM stimulation proved to be effective in treatment of a patient group demonstrating multiple types of UI and differing degrees of severity (ICIQ-SF scores at baseline ranging from 2 to 18). The improvement in UI severity measured by ICIQ-SF standardized questionnaire and pad usage questionnaire (showing a medium correlation) was associated with an enhanced QOL according to the patient subjective evaluation. As a result of the treatment, UI interfered less with one's everyday life and/or these symptoms completely disappeared which enabled patients to regain self-confidence. The statistically significant differences in ICIQ-SF score at the 3-month follow-up implies that results were gradually improving over time. Data describing causes of leakage are also a useful indicator of patients QOL, and as shown in Table 4, we observed a substantial suppression of the urine leakage triggers at the follow-up when patients indicated fewer responses that applied to them.

It is suggested that PFM training increases the tone of pelvic muscles and causes hypertrophy and strengthening of the muscle fibers. This should lead to elevation of the levator plate and restoration of protective continence mechanisms [37]. To effectively achieve motor and PFM re-education, hundreds of correctly performed contractions are required. Various training programs have been examined in the past to determine the most effective elements of a training regime [38]. However, when treated subjects perform the exercise, they must be individually educated on the anatomy of the pelvic floor, lower urinary tract and continence mechanism, and also supervised by a skilled physiotherapist. Furthermore, a number of additional education sessions necessitate inclusion, especially in case of individual, self-monitored exercises in the patient's home [39]. The advantage of the HIFEM technology over such traditional approach is its mechanism of a rapidly changing electromagnetic field which initializes thousands of supramaximal contractions during one therapy, something that cannot be achieved by any conventional training program. The high intensity and frequency of the stimuli ensure that PFM are targeted properly. Each contraction is then repeated identically while the outcome of regular exercise may be limited by the inability of patients to perform contractions consistently. Moreover, regular exercise is more time-consuming (multiple studies reported treatment duration of 12 weeks and longer [40]) in comparison to a 3-week duration for each patient who receives the HIFEM treatments.

Patients' overall improvement by 64.42%, as well as 34.43% of cured subjects (zero score at the follow-up) is comparable to previously published literature on the effects of electromagnetic stimulation for PFM strengthening [36,41,42], despite the fact that our patients received fewer treatment sessions than in the referenced studies. Our data showed slightly higher level of improvement in SUI ($N = 37$; 66.98%) and MUI ($N = 30$; 69.90%) patients which may be contributed to the limited size of UUI patient group ($N = 8$). Additionally, the number of subjects who improved in absorbent pads usage (70%) was similar to what was previously documented by Galloway et al [43]. Our results also correspond to observations from other modalities such as exercising [34] or electrical stimulation [44,45] where the reported improvement usually ranged between 50 and 90%. Nevertheless, exact comparison of various modalities and treatment outcomes throughout the literature is complicated due to utilization of a range of different standardized and non-standardized methods of UI evaluation, as well as patient self-evaluation or QOL assessment. Previous studies also vary in terms of methodology and composition of the patient group which could substantially influence the outcomes and conclusions. It can be assumed that these circumstances are responsible for the diversity of published results [40,46,47].

The therapy was well tolerated, and subjects provided positive feedback about the procedure, its non-invasive manner and its low-risk profile. Patients reported additional benefits of the therapy as improvement in sexual satisfaction which was also documented by other authors who investigated effects of electromagnetic stimulation [48].

A limitation of this study was the lack of any control group which received sham treatments, however we believe the statistical significance of our results is sufficient to overcome this limitation. We did not establish a sham treatment group due to the likelihood that patients would be aware they were not receiving a full electromagnetic treatment if they perceived a lowered intensity of stimulus or an otherwise adjusted treatment protocol. Another major limitation was a relatively short follow-up interval of 3 months. Documented results seem to be promising in terms of the continuing improvement over time, however it would be necessary to follow patients in a future study for 6–12 months in order to establish appropriate re-treatment intervals for maintenance of continence results. Furthermore, the subjective

evaluation of patient satisfaction should be more comprehensively designed in future studies, as the results obtained by voluntary questionnaire indicate there might be other interesting benefits associated with HIFEM therapy. It would be also beneficial to recruit a greater portion of UUI patients to provide sufficient sample for analysis of treatment outcomes.

CONCLUSION

This study demonstrated that HIFEM technology can safely and effectively treat stress, urge and mixed urinary incontinence by pelvic floor muscle strengthening in a wide demographic of patients. Subjects benefited from a decreased severity of UI symptoms and a reduced usage of absorbent pads which positively influenced their quality of life. On the basis of the subjective evaluation, patients also reported additional effects of the therapy such as a better control of urination as well as an increased sexual satisfaction.

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