STUDY BOOK
BTL EMSELLA®

BTL Medizintechnik GmbH
Im Starkfeld 57/2, 89231 Neu-Ulm
Rgr. Ulm, HRB 727 731, USt-Idnr. DE281148860
Tel.: 0731-550-19-18-0
Fax: 0731-550-19-18-15
www.emsculpt.com I www.btlmed.de
info@btlmed.de

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

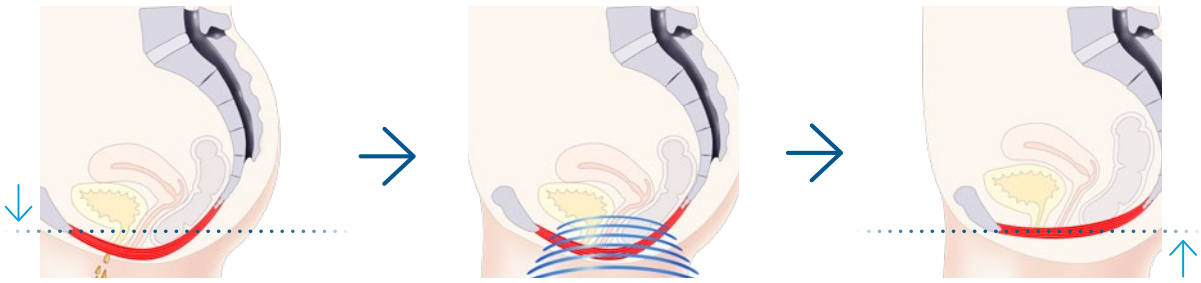


Figure 1: HIFEM™ technology

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

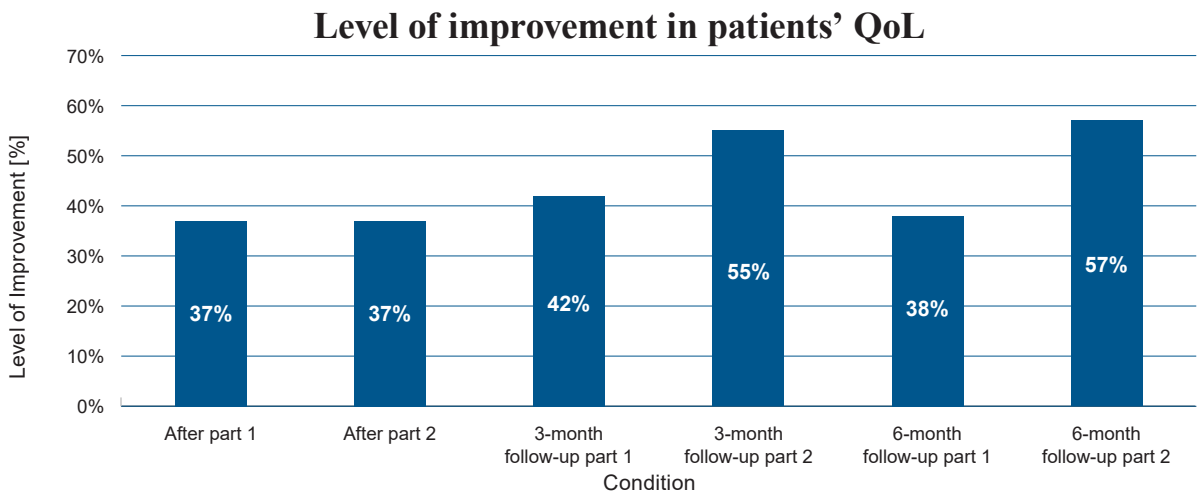


Figure 3: Level of improvement in the patients´ QoL according to the KHQ scores

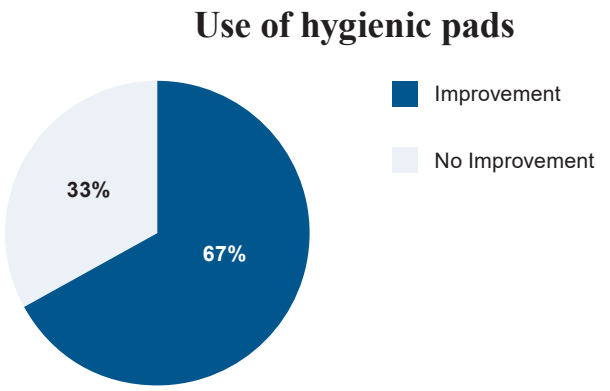


Figure 4: Use of hygienic pads

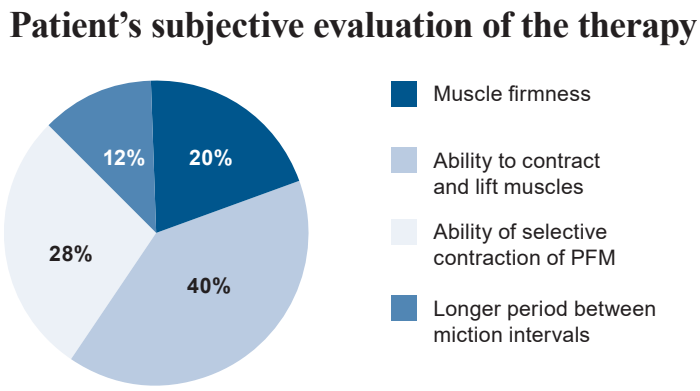


Figure 5: Patients subjective evaluation of the therapy

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.

9. REFERENCES:

Abrams P, Blaivas JG, Stanton SL, Andersen JT. The Standardisation of Terminology of Lower Urinary Tract Function. The International Continence Society Committee on Standartisation of Terminology. Scand d Suppl 1998; 114:5-19

Abulhasan, J., Rumble, Y., Morgan, E., Slatter, W. and Grey, M. (2016). Peripheral Electrical and Magnetic Stimulation to Augment Resistance Training. Journal of Functional Morphology and Kinesiology, 1(3), pp.328-342

Almeida FG, Bruschini H, Srougi M.: Urodynamic and clinical evaluation of 91 female patients with urinary incontinence treated with perineal magnetic stimulation: 1-year follow-up. J Urol. 2004 Apr; 171(4), pages 1571-4

Bickford, R., Guidi, M., Fortesque, P. and Swenson, M. (1987). Magnetic stimulation of human peripheral nerve and brain. Neurosurgery, 20(1), pp.110-116.

Bustamante, V., de Santa María, E., Gorostiza, A., Jiménez, U. and Gáldiz, J. (2010). Muscle training with repetitive magnetic stimulation of the quadriceps in severe COPD patients. Respiratory Medicine, 104(2), pp.237-245.

Coletti, D., Teodori, L., Albertini, M., Rocchi, M., Pristerà, A., Fini, M., Molinaro, M. and Adamo, S. (2007). Static magnetic fields enhance skeletal muscle differentiation in vitro by improving myoblast alignment. Cytometry Part A, 71A(10), pp.846-856.

Feldman M., Magnetic Stimulation for the Treatment of Urinary Incontinence in Women, California Technology Assessment Forum, San Francisco, CA, October 20, 2004

Han T.R., Shin H.I., Kim I.S. Magnetic stimulation of the quadriceps femoris muscle: comparison of pain with electrical stimulation. Am J Phys Med Rehabil 2006; 85(7):593-599.

Ishikawa N., Suda S., Sasaki T. et al., Development of a non-invasive treatment system for urinary incontinence using a functional continuous magnetic stimulator (FCMS) , Medical & Biological Engineering & Computing, 1998, 36, 704-710

Man, W. (2004). Magnetic stimulation for the measurement of respiratory and skeletal muscle function. European Respiratory Journal, 24(5), pp.846-860.

National Association for Incontinence (NAFC), www.nafc.org

Ostrovidov, S., Hosseini, V., Ahadian, S., Fujie, T., Parthiban, S., Ramalingam, M., Bae, H., Kaji, H. and Khademhosseini, A. (2014). Skeletal Muscle Tissue Engineering: Methods to Form Skeletal Myotubes and Their Applications. Tissue Engineering Part B: Reviews, 20(5), pp.403-436.

Sand PK, Richardson DA, Staskin DR. Pelvic floor electrical stimulation in the treatment of genuine stress incontinence: a multicenter, placebo-controlled trial. Am. J. Obstet. Gynecol. 1995; 173, pages 72–9

StÖlting, M., Arnold, A., Haralampieva, D., Handschin, C., Sulser, T. and Eberli, D. (2016). Magnetic stimulation supports muscle and nerve regeneration after trauma in mice. Muscle & Nerve, 53(4), pp.598-607.

Truijen G, Wyndaele JJ, Weyler J.: Conservative treatment of stress urinary incontinence in women: Who will benefit? Int Urogynecol J Pelvic Floor Dysfunct. 2001; 12(6), pages 386-90

Wallis, M., Davies, E., Thalib, L. and Griffiths, S. (2011). Pelvic Static Magnetic Stimulation to Control Urinary Incontinence in Older Women: A Randomized Controlled Trial. Clinical Medicine & Research, 10(1), pp.7-14.

Yamanishi T, Yasuda K, Suda S et al. Effect of functional continuous magnetic stimulation for urinary incontinence. J. Urol. 2000; 163, pages 456–9

Yamanishi T, Yasuda K, Sakakibara R et al. Pelvic floor electrical stimulation in the treatment of stress incontinence: an investigational study and a placebo controlled double- blind trial. J. Urol. 1997; 158, pages 2127–31

Yang, S., Jee, S., Hwang, S. and Sohn, M. (2017). Strengthening of Quadriceps by Neuromuscular Magnetic Stimulation in Healthy Subjects. PM&R.

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 38th American Society for Laser Medicine and Surgery Annual Conference on "Energy-based Medicine and Science", April 11-15, 2018

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.

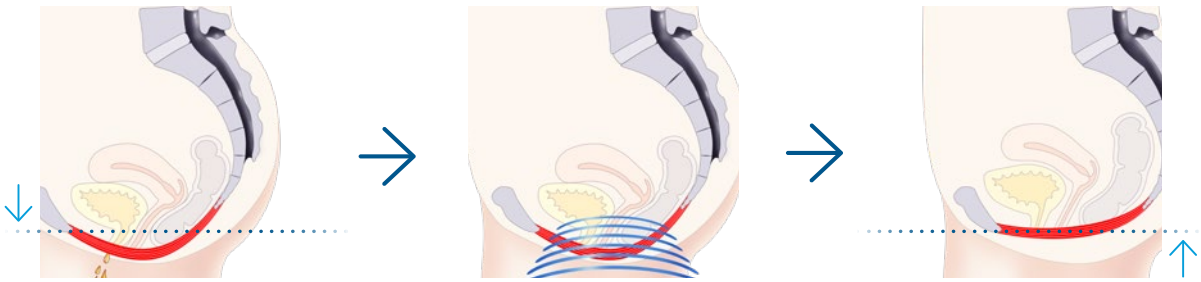


Figure 1: HIFEM technology mechanism of action

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).

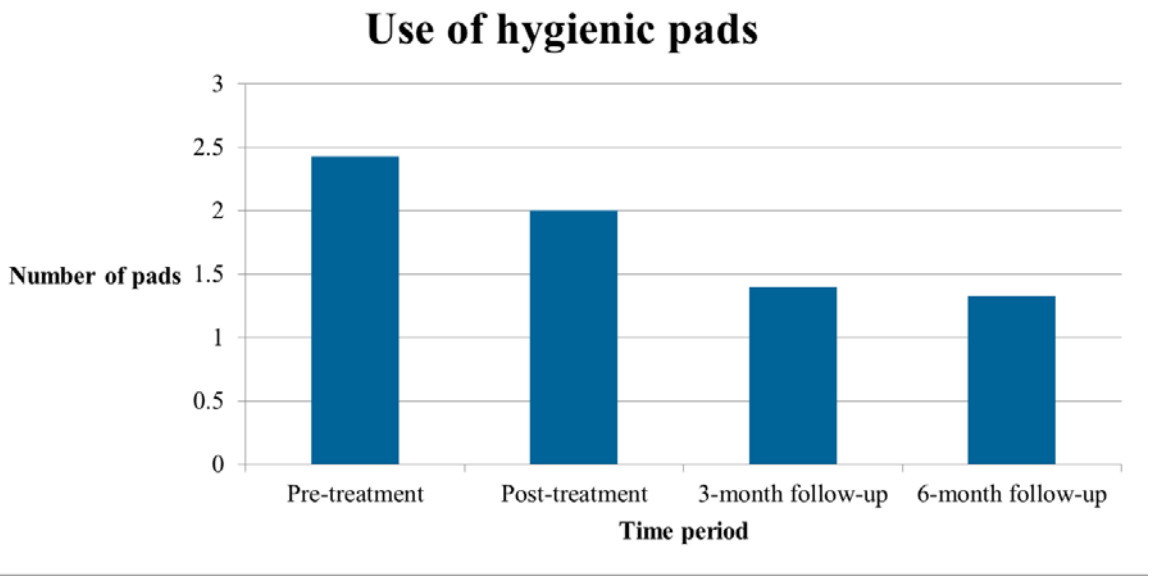


Figure 3: Use of hygienic pads

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.

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.

8. CONFLICT OF INTEREST

Authors declare that no conflict of interest exists.

9. REFERENCES

1. Cervigni M, Gambacciani M, a Department of Women's Health and New Life, Catholic University, Rome, Italy
2. National Institute of Diabetes and Digestive and Kidney Diseases. Available from: https://www.niddk.nih.gov/health-information/health-topics/urologic-disease/urinary-incontinence-women/Pages/facts.aspx 1
3. Erdem N, Chu FM. Management of overactive bladder and urge urinary incontinence in the elderly patient. Am J Med. 2006 Mar. 119(3 Suppl 1):29-36.
4. Abrams PH, Blaivis JG, Stanton SL, Anderson JT. Standardization of terminology of the lower urinary tract function. Neurourol Urodyn. 1988;7:403–427
5. Cummings JM, Rodning CB. Urinary stress incontinence among obese women: review of pathophysiology therapy. Int Urogynecol J Pelvic Floor Dysfunct. 2000. 11(1):41-4.
6. Sustersic O, Kralj B. The influence of obesity, constitution and physical work on the phenomenon of urinary incontinence in women. Int Urogynecol J Pelvic Floor Dysfunct. 1998. 9(3):140-4.
7. Patel AK, Chapple CR. Urodynamics in the management of female stress incontinence--which test and when?. Curr Opin Urol. 2008 Jul. 18(4):359-64.
8. Wilson MM. Urinary incontinence: selected current concepts. Med Clin North Am. 2006 Sep. 90(5):825-36.
9. Chutka DS, Fleming KC, Evans MP, Evans JM, Andrews KL. Urinary incontinence in the elderly population. Mayo Clin Proc. 1996 Jan. 71(1):93-101.
10. Nazir T, Khan Z, Barber HR. Urinary incontinence. Clin Obstet Gynecol. 1996 Dec. 39(4):906-11.
11. Howard D, Delancey JO, Tunn R, Ashton-Miller JA. Racial differences in the structure and function of the stress urinary continence mechanism. Obstet Gynecol. 2000 May. 95(5):713-7.
12. Linde JM, Nijman RJ, Trzpis M, Broens PM. Urinary incontinence in the Netherlands: Prevalence and associated risk factors in adults. Neurourol Urodyn. 2016 Oct 4.
13. Chaikin DC, Groutz A, Blaivas JG. Predicting the need for anti-incontinence surgery in continent women undergoing repair of severe urogenital prolapse. J Urol. 2000 Feb. 163(2):531-4.
14. Gibbs CF, Johnson TM 2nd, Ouslander JG. Office management of geriatric urinary incontinence. Am J Med. 2007 Mar. 120(3):211-20.
15. Rogers RG. Clinical practice. Urinary stress incontinence in women. N Engl J Med. 2008 Mar 6. 358(10):1029-36.
16. American College of Obstetricians and Gynecologists. Practice Bulletin No. 155: Urinary Incontinence in Women. Obstet Gynecol. 2016 May. 127 (5):e66-81.
17. DeLancey JOL. Stress urinary incontinence: where are we now, where should we go? Am J Obste Gynecol. 1996;175:311-19.
18. Handa VL, Harris TA, Ostergard DR. Protecting the pelvic floor: obstetric management to prevent incontinence and pelvic organ prolapse. Obstet Gynecol. 1996;88:470-78.
19. U.S. National Library of Medicine. Available from: https://medlineplus.gov/ency/article/000891.htm
20. Roth, E. Medically Reviewed by Graham Rogers, MD. Stress Incontinence. Available from: http://www.healthline.com/health/stress-incontinence#Overview1
21. Serati M, Braga A, Cattoni E et al. Transobturator vaginal tape for the treatment of stress urinary incontinence in elderly women without concomitant pelvic organ prolapse: is it effective and safe?. Eur J Obstet Gynecol Reprod Biol. 2013 Jan. 166(1):107-10.
22. Hay-Smith, EJC; Dumoulin, C, Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women (Cochrane Review). Review Group: Cochrane Incontinence Group; Cochrane Database of Systematic Reviews; Substantively amended: 15 November 2005;
23. American Physical Therapy Association (APTA), Available from: http://www.womenshealthapta.org/wp-content/uploads/2013/12/pelvicfloordysfunctionfaq-10-19-11.pdf
24. Peter K. Sand, MD, David A. Richardson, MD, David R. Staskin, MD, et al. Pelvic floor electrical stimulation in the treatment of genuine stress incontinence: A multicenter, placebo-controlled trial. American Journal of Obstetrics and Gynecology Volume 173, Issue 1, July 1995, Pages 72-79
25. Tomonori Y, Kosaku Y, Ryuuji S, Takamichi H, Haruo I, Shino M. Pelvic Floor Electrical Stimulation In The Treatment Of Stress Incontinence: An Investigational Study And A Placebo Controlled Double-Blind Trial, The Journal of Urology, Volume 158, Issue 6, 1997 Dec, Pp 2127–2131
26. Wang A, Wang Y, Chen M. Single-blind, randomized trial of pelvic floor muscle training, biofeedback-assisted pelvic floor muscle training, and electrical stimulation in the management of overactive bladder. Urology. Volume 63, Issue 1. 2004 Jan. pp 61-66
27. Rodrigo A. Castro, Raquel M. Arruda, Miriam R. D. Zanettiet al. Urogynecology and Vaginal Surgery Section of the Department of Gynecology, Universidade Federal de São Paulo – São Paulo/SP, Brazil. Single-blind, randomized, controlled trial of pelvic floor muscle training, electrical stimulation, vaginal cones, and no active treatment in the management of stress urinary incontinence. Clinics vol.63 no.4 São Paulo 2008
28. Hebbar S, Pandey H, Chawla A. Understanding King's Health Questionnaire (KHQ) in assessment of female urinary incontinence. Int J Res Med Sci 2015;3:531-8.
29. Espuña Pons M, Castro Díaz D, Carbonell C, Dilla T. Comparison between the "ICIQ-UI Short Form" Questionnaire and the "King's Health Questionnaire" as assessment tools of urinary incontinence among women. Actas Urol Esp. 2007;31(5):502–510. doi: 10.1016/S0210-4806(07)73674-4.

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 38th American Society for Laser Medicine and Surgery Annual Conference on "Energy-based Medicine and Science", April 11-15, 2018

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

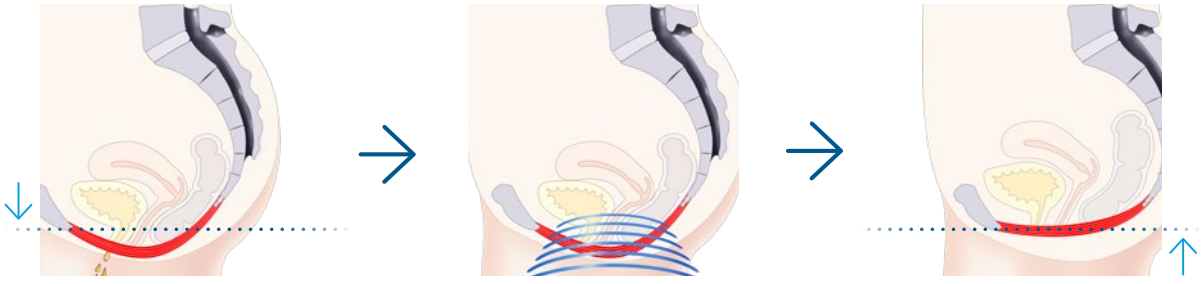


Figure 1: HIFEM technology mechanism of action

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).

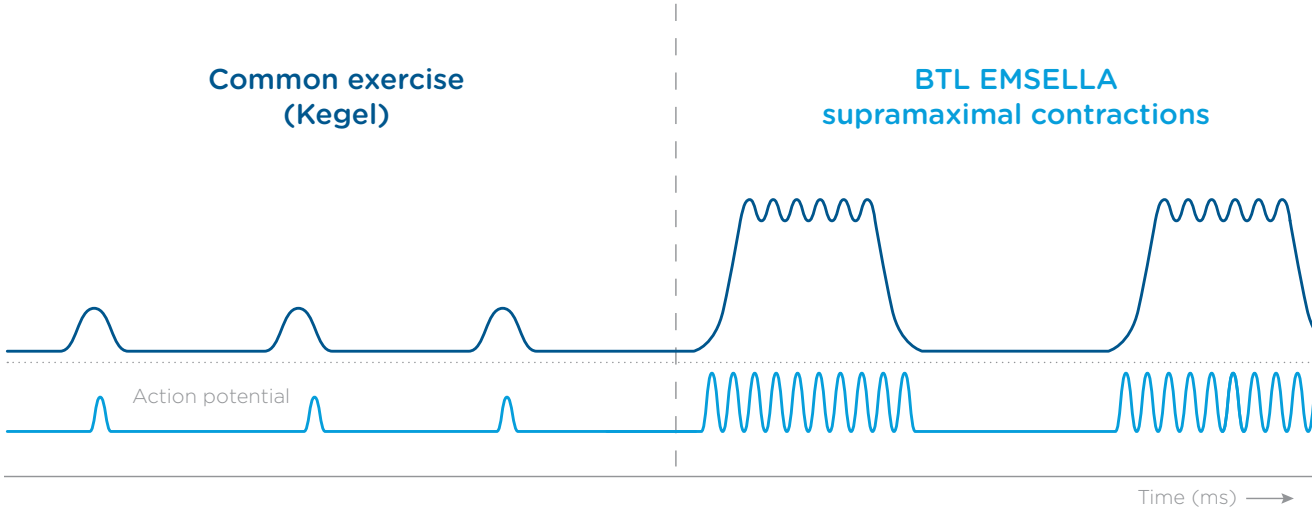


Figure 2: Supramaximal contractions caused by BTL EMSELLA device

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

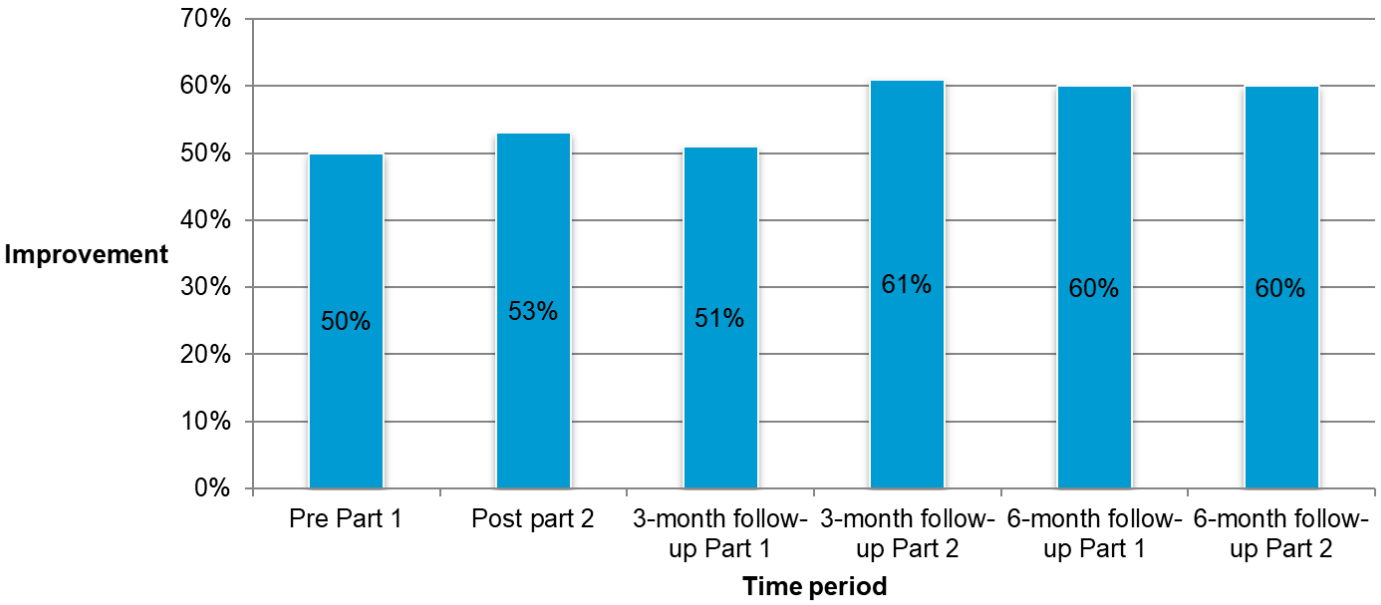


Figure 4: Level of improvement in the patients' QoL according to the KHQ scores

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

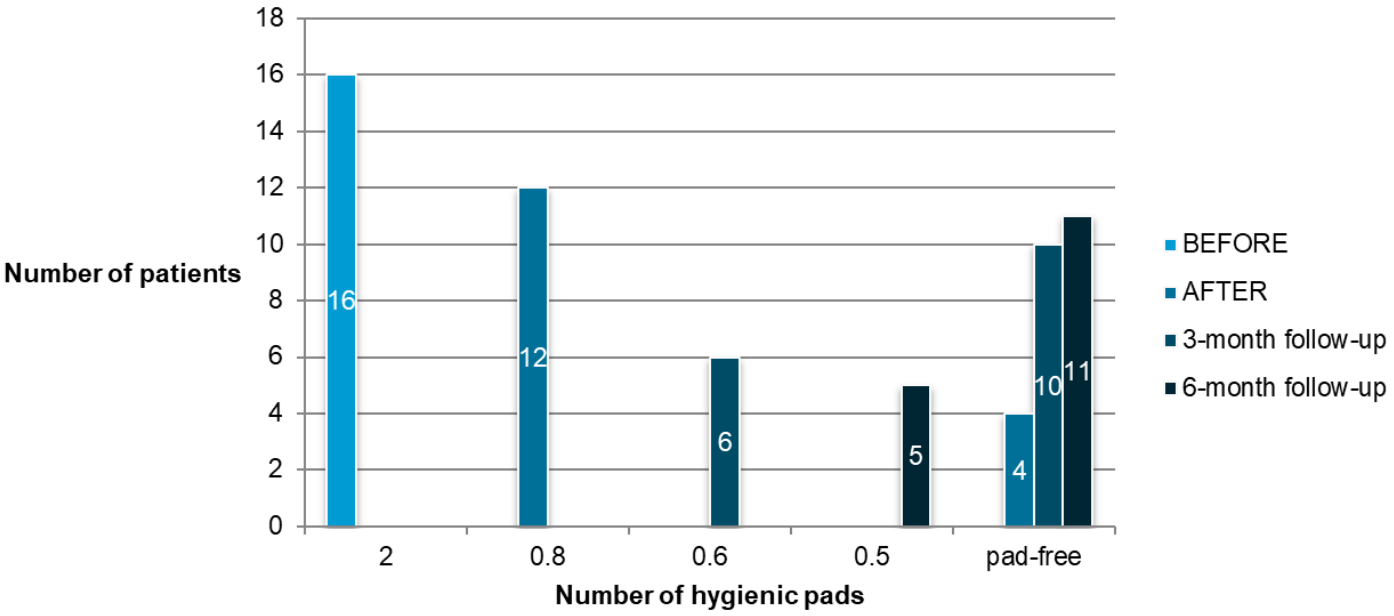


Figure 6: Use of hygienic pads

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.

10. REFERENCES

1. Abrams P, Blaivas JG, Stanton SL, Andersen JT. The Standardisation of Terminology of Lower Urinary Tract Function. The International Continence Society Committee on Standartisation of Terminology. Scand d Suppl 1998; 114:5-19
2. Abulhasan, J., Rumble, Y., Morgan, E., Slatter, W. and Grey, M. (2016). Peripheral Electrical and Magnetic Stimulation to Augment Resistance Training. Journal of Functional Morphology and Kinesiology, 1(3), pp.328-342
3. Almeida FG, Bruschini H, Srougi M.: Urodynamic and clinical evaluation of 91 female patients with urinary incontinence treated with perineal magnetic stimulation: 1-year follow-up. J Urol. 2004 Apr; 171(4), pages 1571-4
4. Bickford, R., Guidi, M., Fortesque, P. and Swenson, M. (1987). Magnetic stimulation of human peripheral nerve and brain. Neurosurgery, 20(1), pp.110-116.
5. Bustamante, V., de Santa María, E., Gorostiza, A., Jiménez, U. and Gáldiz, J. (2010). Muscle training with repetitive magnetic stimulation of the quadriceps in severe COPD patients. Respiratory Medicine, 104(2), pp.237-245.
6. Coletti, D., Teodori, L., Albertini, M., Rocchi, M., Pristerà, A., Fini, M., Molinaro, M. and Adamo, S. (2007). Static magnetic fields enhance skeletal muscle differentiation in vitro by improving myoblast alignment. Cytometry Part A, 71A(10), pp.846-856.
7. Feldman M., Magnetic Stimulation for the Treatment of Urinary Incontinence in Women, California Technology Assessment Forum, San Francisco, CA, October 20, 2004
8. Han T.R., Shin H.I., Kim I.S. Magnetic stimulation of the quadriceps femoris muscle: comparison of pain with electrical stimulation. Am J Phys Med Rehabil 2006; 85(7):593-599.
9. Ishikawa N., Suda S., Sasaki T. et al., Development of a non-invasive treatment system for urinary incontinence using a functional continuous magnetic stimulator (FCMS) , Medical & Biological Engineering & Computing, 1998, 36, 704-710
10. Man, W. (2004). Magnetic stimulation for the measurement of respiratory and skeletal muscle function. European Respiratory Journal, 24(5), pp.846-860.
11. National Association for Incontinence (NAFC), www.nafc.org
12. Ostrovidov, S., Hosseini, V., Ahadian, S., Fujie, T., Parthiban, S., Ramalingam, M., Bae, H., Kaji, H. and Khademhosseini, A. (2014). Skeletal Muscle Tissue Engineering: Methods to Form Skeletal Myotubes and Their Applications. Tissue Engineering Part B: Reviews, 20(5), pp.403-436.
13. Sand PK, Richardson DA, Staskin DR. Pelvic floor electrical stimulation in the treatment of genuine stress incontinence: a multicenter, placebo-controlled trial. Am. J. Obstet. Gynecol. 1995; 173, pages 72–9
14. StÖlting, M., Arnold, A., Haralampieva, D., Handschin, C., Sulser, T. and Eberli, D. (2016). Magnetic stimulation supports muscle and nerve regeneration after trauma in mice. Muscle & Nerve, 53(4), pp.598-607.
15. Truijen G, Wyndaele JJ, Weyler J.: Conservative treatment of stress urinary incontinence in women: Who will benefit? Int Urogynecol J Pelvic Floor Dysfunct. 2001; 12(6), pages 386-90
16. Wallis, M., Davies, E., Thalib, L. and Griffiths, S. (2011). Pelvic Static Magnetic Stimulation to Control Urinary Incontinence in Older Women: A Randomized Controlled Trial. Clinical Medicine & Research, 10(1), pp.7-14.
17. Yamanishi T, Yasuda K, Suda S et al. Effect of functional continuous magnetic stimulation for urinary incontinence. J. Urol. 2000; 163, pages 456–9
18. Yamanishi T, Yasuda K, Sakakibara R et al. Pelvic floor electrical stimulation in the treatment of stress incontinence: an investigational study and a placebo controlled double-blind trial. J. Urol. 1997; 158, pages 2127–31
19. Yang, S., Jee, S., Hwang, S. and Sohn, M. (2017). Strengthening of Quadriceps by Neuromuscular Magnetic Stimulation in Healthy Subjects. PM&R.

Journal of Women's Health Care

Hlavinka et al., J Women's Health Care 2019, 8:1
DOI: 10.4172/2167-0420.1000455

Research Article Open Access

The Use of HIFEM Technology in the Treatment of Pelvic Floor Muscles as a Cause of Female Sexual Dysfunction: A Multi-Center Pilot Study

Hlavinka TC[1], **Turčan P**[2*] **and Bader A**[3]

[1]*The Urology Place, InVita Clinics, San Antonio, USA*

[2]*Center Mediol, Olomouc, Czech Republic*

[3]*Bader Medical Institute of London, European Society of Aesthetic Gynecology ESAG, UK*

[*]**Corresponding author:** Pavel Turcan, Center Mediol, Olomouc, Czech Republic, Tel: 0256660255; E-mail: centrummediol@seznam.cz

Received date: November 14, 2018; **Accepted date:** March 2, 2019; **Published date:** March 11, 2019

Abstract

Introduction: Pelvic Floor Muscles (PFM) supports the pelvic floor organs, control continence and is crucial for adequate genital arousal and attainment of an orgasm. Due to the aging process, post-delivery condition or menopause, the PFM weaken. Therefore, they do not provide sufficient support to pelvic organs, bladder control, and they may negatively affect intimate satisfaction.

Aim: We aimed to investigate the High-Intensity Focused Electromagnetic (HIFEM) technology for strengthening of PFM in women with impeded sexual functioning.

Methods: 30 women (average age 36.41 ± 5.62) with limited arousal, ability to achieve orgasm and painful intercourse participated in the study. Patients underwent 6 treatments (28 minutes each) scheduled twice a week. Standardized Female Sexual Function Index (FSFI) questionnaire was used pre-, post-treatment, and at the 3-month follow-up visit. FSFI scores were statistically evaluated through student´s t-test (α=0.05). Subsequently, Pearson correlation coefficient was calculated for sections arousal/lubrication, lubrication/orgasm, orgasm/satisfaction, and pain/desire.

Results: The average total FSFI score significantly ($p<0.001$) increased from 20.06 ± 6.55 to 30.69 ± 7.55 post-treatment and to 30.29 ± 7.37 during the 3-month follow-up. A significant improvement was observed in all FSFI sections. The most significant change at the 3-month follow-up was observed in desire (76%), satisfaction (76%) and orgasm (60%) items. The overall FSFI score was improved in 93% (n=28) of patients post-treatment. All patients (n=30; 100%) showed improvement during the 3-month follow-up.

Conclusion: Our initial experience shows that HIFEM technology is a promising method in addressing women's decreased sexual satisfaction through the strengthening of PFM.

Keywords: HIFEM; FSFI; Sexual dysfunction; Pelvic floor muscles; Myostimulation

Introduction

Healthy sexual function is an essential component of life. Sexual dysfunction can, therefore, have a negative impact on female well-being [1]. Female Sexual Dysfunction (FSD) is age-dependent and highly prevalent in premenopausal and menopausal women. Available studies report on the prevalence of sexual dysfunction in the female population to be ranging between 25% and 63% [2-9]. The incidence in women younger than 25 years was found to be approximately 20% while in women aged 55-74 years the incidence was up to 80% [7].

Pelvic floor and its functioning are closely linked to a healthy female sexual cycle. It is formed by several pelvic muscles which support the pelvic organs and maintain their normal function by keeping these organs in their anatomical position. Pelvic Floor Muscles (PFM) also play an important role in pregnancy parturition, attainment of orgasm [10-12] and are responsible for adequate genital arousal [13,14]. Firmer muscle tone adds intensity to the muscle contractions during orgasm and enables a woman to identify, isolate, and command PFM [14].

Any insult to the pelvic floor can potentially lead to denervation of the female erectile tissues followed with sexual dysfunction [10,15,16]. The main cause for the development of Pelvic Floor Disorder (PFD) occurs when the PFM and connective tissue weaken. Weak or deconditioned muscles may provide insufficient activity necessary for vaginal friction or blood flow, and thus inhibit orgasmic potential [13,14]. Therefore the initial approach for the treatment of PFD and FSD is to start with the strengthening of PFM [11,12,17].

Non-invasive addressing of PFM should be the first treatment option prior to any surgical intervention. A novel approach for non-invasive targeting of PFM is a treatment based on High-Intensity Focused Electromagnetic (HIFEM) technology. The HIFEM technology triggers intense PFM contractions by depolarizing motoneurons and inducing electric currents in the pelvic floor area. The focused electromagnetic energy penetrates into the depth of up to 10 cm into the pelvic floor area where it induces supramaximal and brain-independent contractions at high repetition rates [18,19].

Due to the intense repetitive muscle stimulation combined with the vasodilating effect of electromagnetic fields and restoration of the muscle tonus, we assume that HIFEM may positively affect female intimate health and sexual functions. The subject of the study is a device based on HIFEM technology (BTL EMSELLA, BTL Industries Inc., Boston MA), which is FDA cleared for strengthening of pelvic floor muscles in the treatment of female urinary incontinence (UI).

Previous studies [18,19] investigating the HIFEM technology for UI proved that female patients reported a significant decrease in incontinence symptoms as well as a reduction in usage of incontinence pads. As the HIFEM technology impacts the PFM due to its myostimulatory effect, it could be beneficial not only in bladder control, but also in improvement of intimate life and sexual functions.

We aimed to investigate the myostimulatory effect of a High-Intensity Focused Electromagnetic (HIFEM) technology on PFM in women who reported impeded sexual functioning. We hypothesized that HIFEM can strengthen PFM and as a consequence will improve the quality of intimate life.

Method

Study design

This was a retrospective single-arm study of the patients who had been admitted to our department between 2017-2018. A total of 30 female patients (average age 36.41 ± 5.62) were enrolled. The inclusion criteria included initial impeded sexual functioning through limited arousal, impaired ability to achieve orgasm and increased intercourse pain.

Patients with pregnancy, metal implants, tumor, blood coagulation disorder, and vaginal infectious disease were excluded from the study. Before the treatments, all subjects received informed consent about the treatment procedure and signed written consent.

The patients received a treatment procedure applied to the PFM using the BTL EMSELLA device (BTL Industries Inc., Boston MA) based on HIFEM technology. The device consists of a control unit and a cable connecting the unit to a chair with an in-built circular coil. During the treatment, the device generates a focused electromagnetic field with intensities of up to 2.5 T and penetrating into depths of up to 10 cm.

The treatment protocol consisted of six treatments scheduled twice a week with a single treatment lasting for 28 minutes. The treatment protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki adopted by the General Assembly of the World Medical Association (1997-2000) and by Convention on Human Rights and Biomedicine of Council of Europe (1997).

During the treatment, patients were seated on the chair and remained fully clothed. Prior to the therapy, each of the patients received verbal instructions about the course of the therapy and about the principles of supramaximal PFM contractions. Contractions are supposed to help them to identify, isolate and command their PFM.

After the instructions, the patients were positioned on the chair and the optimal position for inducing muscle contractions was identified. Then, the therapy was initiated with low intensity which was continuously adjusted during the treatment in accordance with patient tolerance threshold [18,19].

Data collection

As a standard part of the treatment procedure, all of the 30 enrolled subjects reported patient's feedback in the form of the standardized Female Sexual Function Index (FSFI) questionnaire pre- and post-treatment, and during the 3-month follow-up visit [20]. Obtained feedback was statistically analyzed by comparing the pre- and post-intervention patients' condition.

A normal data distribution has been assumed (0.05 significance level), therefore the parametric Student t-test was used to calculate the significance of FSFI full-scale scores and individual FSFI sections. Furthermore, Pearson correlation coefficient was calculated for paired items Arousal/Lubrication, Lubrication/Orgasm, Orgasm/Satisfaction, and Pain/Desire. Bonferroni correction was applied according to the number of the carried tests. Finally, the percentage of improved patients was calculated according to the FSFI full-scale score.

Results

The analysis of the pre-treatment FSFI questionnaires showed an average full-scale score of 20.06 ± 6.55, which according to the predefined cut-point of 26.5 indicates sexual dysfunction. The post-treatment average full-scale score significantly increased to 30.69 ± 7.55 and was maintained during 3-month follow-up at the level of 30.29 ± 7.37 ($p<0.001$). The total FSFI scores are shown in Figure 1.

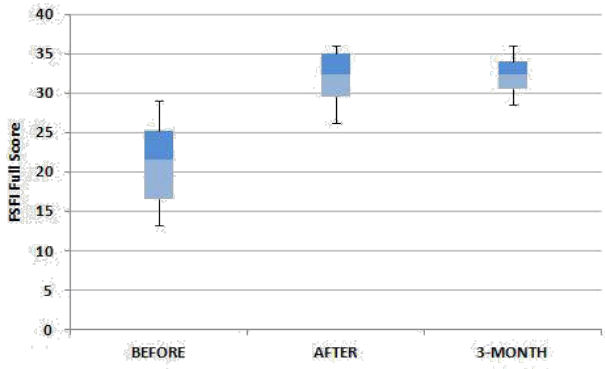


Figure 1: Changes in FSFI full score in treated patients. Data are visualized in box plots; blue rectangles contain 50% of data (interquartile range). Whiskers indicate the variability of the results.

The spread of whiskers and Interquartile Range (IQR) in the Figure 1 indicate the variability of the results obtained at the baseline. Before the treatments, there were patients with substantially lower FSFI score indicating moderate sexual function issues.

After the procedure consisting of 6 treatments the score significantly increased and also the variability of the data was reduced. At the 3-month follow-up, these results sustained showing no shift in the average, while the patient's scores were spread closely around the median.

The level of average improvement in the FSFI score, expressed in percentage, was on average 53% after the last treatment and was maintained at 51% ($p<0.001$) during the 3-month follow-up. Immediately after the 6th treatment, an improvement in FSFI score was

observed in 28 (93%) subjects. During the follow-up appointment, all of the patients (n=30, 100%) reached a certain degree of improvement.

The improvement was observed in all individual sections of the FSFI questionnaire, while the most prominent average improvement was seen in sexual satisfaction (+76%), in sexual desire (+76%) and in orgasm (+60%). The scores of individual sections can be seen in Table 1.

Timing	FSFI Score Mean ± SD (Median)					
	Desire	Arousal	Lubrication	Orgasm	Satisfaction	Pain
Before	2.79 ± 0.63 (3.00)	3.41 ± 1.2 0 (3.30)	3.42 ± 1.89 (1.60)	3.20 ± 1.33 (3.20)	3.01 ± 1.05 (2.80)	4.24 ± 1.72 (4.80)
After	4.91 ± 0.93 (5.40)	5.24 ± 1.4 3 (5.70)	4.92 ± 1.7 3 (6.00)	5.13 ± 1.50 (6.00)	5.29 ± 1.25 (5.60)	5.20 ± 1.46 (5.60)
3-Month follow-up	4.87 ± 0.82 (4.80)	5.24 ± 1.4 2 (5.40)	4.68 ± 1.5 7 (4.80)	5.06 ± 1.46 (5.60)	5.20 ± 1.38 (5.60)	5.25 ± 1.48 (6.00)

Table 1: A detailed description of FSFI items scores.

The analysis of relationships between the changes in different sections was performed to assess potential correlations. A highly significant correlation was observed in the case of before-after and before-follow-up for pairs Lubrication/Orgasm and Orgasm/Satisfaction (Table 2). The strong correlation ranged between 0.65-0.71 and was statistically significant. The correlation between the differences in Arousal and Lubrication score showed to be insignificant with weak correlation coefficients. No correlation was found between the pair Pain/Desire. Calculated correlations for investigated pairs can be found in Table 2.

Correlations				
Timeline	**Arousal and Lubrication**	**Lubrication and Orgasm**	**Orgasm and Satisfaction**	**Pain and Desire**
Difference before-after	r=0.34	r=0.65*	r=0.68*	r=0.13
Difference before-follow-up	r=0.15	r=0.66*	r=0.71*	r=0.03

Table 2: Statistically significant (Bonferroni correction, alpha less than 0.006) correlations are marked with an asterisk symbol (*).

Discussion

The results suggest that the treatment procedure with HIFEM technology leads to significant improvement of the intimate life in female patients with FSD. The improvement was observed in all sections of the FSFI questionnaire in both short- and long-term results.

We contribute this improvement to well-structured intense pelvic floor workout delivered through HIFEM, induced supramaximal PFM contractions consequently accompanied with increased blood flow [21]. The correlation analysis showed a positive strong relationship between lubrication and orgasm, indicating that the treatments improved the vaginal lubrication of the patients which then was reflected in the increased ability to achieve orgasm.

Similarly, strong correlation was found between the orgasm and satisfaction. This indicates that the patients were able to reach orgasm easily which was logically reflected in their sexual satisfaction. On contrary, no correlation was found between the pain and the desire even though it could be assumed that reduced pain would lead to increased sexual desire [22,23].

The importance of PFM strength during intercourse was described by the previous authors [10-17,24-28] whose results correlate with our findings. Piassarolli et al. concluded that increased EMG activity of PFM muscles was associated with the improvement in all FSFI items [25]. Kanter et al. found that among sexually active women (n=370), a strong pelvic floor was associated with higher scores in the FSFI orgasm domain [11].

The results of our study correlate with this research as the most significant improvement was observed in sexual satisfaction, desire, and orgasm domain. Similar results were reported by Martinez et al. where women with stronger PFM scored higher in the domains: desire, excitement, orgasm and also reported higher levels of FSFI score [26]. Authors also reported a moderate correlation between PFM strength and sexual satisfaction as well as between lubrication and PFM strength. This was also supported by findings from Lowenstein et al. stating that women with strong or moderately strong PFM scored significantly higher on the FSFI orgasmic and arousal domains than women with weak PFM [27].

The duration of PFM contraction was correlated with FSFI orgasmic domain and sexual arousal. Their finding suggests that both the orgasm and arousal function are related to better PFM function. Furthermore, Aydın et al. reported that Vaginal Electrostimulation (VES) treatment leads to improvement of total FSFI score, particularly in arousal, desire, orgasm, and satisfaction sections [29]. They observed no significant changes in pain or lubrication domains. Comparing to our study, pain was the part where we observed the lowest level of improvement. However, we would like to highlight that the VES includes an intravaginal probe which is not comfortable for the patient, while the BTL Emsella procedure is performed fully clothed and without a need of intravaginal probe.

The results show the importance of PFM in female intimate life and the fact, that they can be addressed in a non-invasive way. Both sexual dysfunctions and incontinence are strongly affected by the actual condition of PFM and as such, these two indications frequently accompany each other. The treatments are ideal for improving both aspects in patients with weak pelvic muscles and are thus an alternative not only to women who experience leakage issues but also to those who feel their sexual satisfaction is impeded and could be improved.

Conclusion

The obtained FSFI data showed a significant improvement in female sexual function through the strengthening of PFM. The data suggest BTL EMSELLA as an effective tool for improving patient's sexual life satisfaction and as such, it is a promising alternative to existing treatment options and deserves further investigation.

References

1. Stephenson KR, Meston CM (2015) Why is impaired sexual function distressing to women? The primacy of pleasure in female sexual dysfunction. J Sex Med 12:728-737.
2. First MB, Wakefield JC (2013) Diagnostic criteria as dysfunction indicators: bridging the chasm between the definition of mental disorder and diagnostic criteria for specific disorders. Can J Psychiatry 58: 663-669.
3. Billups KL (2002) The role of mechanical devices in treating female sexual dysfunction and enhancing the female sexual response. World J Urol 20:137-141.
4. Burri A, Spector T (2011) Recent and lifelong sexual dysfunction in a female UK population sample: prevalence and risk factors. J Sex Med 8:2420-2430.
5. Fugl-Meyer KS (2000) Sexual disabilities and sexual problems. In: Fugl-Meyer KS, editors. Sex in Sweden. Stockholm: Swedish National Institute of Health 199.
6. Hayes RD, Bennett CM, Fairley CK, Dennerstein L (2006) What can prevalence studies tell us about female sexual difficulty and dysfunction? J Sex Med 3:589-595.
7. Kontula O, Haavio-Mannila E (1916) Sexual pleasures-Enhancement of sex life in Finland 1971-1992. Acta Sociol 39: 335-337.
8. Laumann EO, Paik A, Rosen RC (1999) Sexual dysfunction in the United States: prevalence and predictors. JAMA 281: 537-544.
9. McCabe MP, Sharlip ID, Atalla E, Balon R, Fisher AD, et al. (2016) Definitions of Sexual Dysfunctions in Women and Men: A Consensus Statement From the Fourth International Consultation on Sexual Medicine 2015. J Sex Med 13:135-143.
10. Graber B, Kline-Graber G (1979) Female orgasm: role of pubococcygeus muscle. J Clin Psychiatry 40: 348-351.
11. Kanter G, Rogers RG, Pauls RN, Kammerer-Doak D, Thakar R (2015) A strong pelvic floor is associated with higher rates of sexual activity in women with pelvic floor disorders. Int Urogynecol J 26: 991-996.
12. Kao A, Binik YM, Kapuscinski A, Khalife S (2008) Dyspareunia in postmenopausal women: a critical review. Pain Res Manag 13: 243-254.
13. Ma Y, Qin H (2009) Pelvic floor muscle exercises may improve female sexual function. Med Hypotheses 72: 223.
14. Reider B (2016) Role of pelvic floor muscles in female orgasmic response. J Womens Health Issues Care 5.
15. Shafik A (1995) Vagino-levator reflex: description of a reflex and its role in sexual performance. Eur J Obstet Gynecol Reprod Biol 60:161-164.
16. Shafik A (2000) The role of the levator ani muscle in evacuation, sexual performance and pelvic floor disorders. Int Urogynecol J Pelvic Floor Dysfunct 11:361-376.
17. Kegel AH (1952) Sexual functions of the pubococcygeus muscle. West J Surg Obstet Gynecol 60: 521-524.
18. Alinsod R, Vasilev V, Yanev K, Buzhov B, Stoilov M, et al. (2018) HIFEM technology a new perspective in treatment of stress urinary incontinence. Lasers Surg Med 50: S4-S56.
19. Samuels J, Guerette N (2018) HIFEM technology the non-invasive treatment of urinary incontinence. Lasers Surg Med 50: S4-S56.
20. Giraldi A, Rellini A, Pfaus JG, Bitzer J, Laan E, et al. (2011) Questionnaires for assessment of female sexual dysfunction: a review and proposal for a standardized screener. J Sex Med 8: 2681-2706.
21. Marques A, Stothers L, Macnab A (2010) The status of pelvic floor muscle training for women. Can Urol Assoc J 4: 419-424.
22. Brækken IH, Majida M, Ellström Engh M, Bø K (2015) Can pelvic floor muscle training improve sexual function in women with pelvic organ prolapse? A Randomized Controlled Trial. J Sex Med 12: 470-480.
23. Santos AM, Santos FC dos, Cendoroglo MS (2015) Sexuality and chronic pain in long-lived females: description of interferential factors. Rev Dor 16: 48-52.
24. Rogers RG (2013) Sexual function in women with pelvic floor disorders. Can Urol Assoc J 7: 199-201.
25. Piassarolli VP, Hardy E, Andrade NF de, Ferreira N de O, Osis MJD (2010) Pelvic floor muscle training in female sexual dysfunctions. Rev Bras Ginecol Obstet 32: 234-240.
26. Martinez CS, Ferreira FV, Castro AAM, Gomide LB (2014) Women with greater pelvic floor muscle strength have better sexual function. Acta Obstet Gynecol Scand 93: 497-502.
27. Lowenstein L, Gruenwald I, Gartman I, Vardi Y (2010) Can stronger pelvic muscle floor improve sexual function? Int Urogynecol J 21: 553-556.
28. Zahariou AG, Karamouti MV, Papaioannou PD (2008) Pelvic floor muscle training improves sexual function of women with stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 19: 401-406.
29. Aydın S, Arıoğlu Aydın Ç, Batmaz G, Dansuk R (2015) Effect of vaginal electrical stimulation on female sexual functions: a randomized study. J Sex Med 12: 463-469.

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.

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

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

Accepted 6 May 2019
Published online in Wiley Online Library (wileyonlinelibrary.com).
DOI 10.1002/lsm.23106

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.

REFERENCES

1. Abrams P, Cardozo L, Fall M, et al. The standardisation of terminology of lower urinary tract function: Report from the Standardisation Sub-committee of the International Continence Society. Neurourol Urodyn 2002;21(2):167–178.
2. Parsons M, Cardozo L. The classification of urinary incontinence. Rev Gynaecol Pract 2003;3(2):57–64. https://doi.org/10.1016/S1471-7697(03)00051-0
3. Ghaderi F, Oskouei AE. Physiotherapy for women with stress urinary incontinence: A review article. J Phys Ther Sci 2014;26(9):1493–1499. https://doi.org/10.1589/jpts.26.1493
4. Hannestad YS, Rortveit G, Sandvik H, Hunskaar S. Norwegian EPINCONT study. Epidemiology of Incontinence in the County of Nord-Trøndelag. A community-based epidemiological survey of female urinary incontinence: The Norwegian EPINCONT study. Epidemiology of Incontinence in the County of Nord-Trøndelag. J Clin Epidemiol 2000;53(11):1150–1157.
5. Melville JL, Katon W, Delaney K, Newton K. Urinary incontinence in US Women: A population-based study. Arch Intern Med 2005;165(5):537–542. https://doi.org/10.1001/archinte.165.5.537
6. Swithinbank LV, Donovan JL, du Heaume JC, et al. Urinary symptoms and incontinence in women: Relationships between occurrence, age, and perceived impact. Br J Gen Pract 1999;49(448):897–900.
7. Khullar V, Sexton CC, Thompson CL, Milsom I, Bitoun CE, Coyne KS. The relationship between BMI and urinary incontinence subgroups: Results from EpiLUTS. Neurourol Urodyn 2014;33(4):392–399. https://doi.org/10.1002/nau.22428
8. Saadia Z. Effect of age, educational status, parity and BMI on development of urinary incontinence—A cross sectional study in Saudi Population. Mater Sociomed 2015;27(4):251–254. https://doi.org/10.5455/msm.2015.27.251-254
9. Tannenbaum C, Gray M, Hoffstetter S, Cardozo L. Comorbidities associated with bladder dysfunction: Perspective. Int J Clin Pract 2013;67(2):105–113. https://doi.org/10.1111/ijcp.12085
10. Wei JT, De Lancey JOL. Functional anatomy of the pelvic floor and lower urinary tract. Clin Obstet Gynecol 2004;47(1):3–17.
11. McLean L, Varette K, Gentilcore-Saulnier E, Harvey M-A, Baker K, Sauerbrei E. Pelvic floor muscle training in women with stress urinary incontinence causes hypertrophy of the urethral sphincters and reduces bladder neck mobility during coughing. Neurourol Urodyn 2013;32(8):1096–1102. https://doi.org/10.1002/nau.22343
12. Coyne KS, Kvasz M, Ireland AM, Milsom I, Kopp ZS, Chapple CR. Urinary incontinence and its relationship to mental health and health-related quality of life in men and women in Sweden, the United Kingdom, and the United States. Eur Urol 2012;61(1):88–95. https://doi.org/10.1016/j.eururo.2011.07.049
13. Sexton CC, Coyne KS, Vats V, Kopp ZS, Irwin DE, Wagner TH. Impact of overactive bladder on work productivity in the United States: Results from EpiLUTS. Am J Manag Care 2009;15(4 Suppl):S98–S107.
14. Tang DH, Colayco DC, Khalaf KM, et al. Impact of urinary incontinence on healthcare resource utilization, health-related quality of life and productivity in patients with overactive bladder. BJU Int 2014;113(3):484–491. https://doi.org/10.1111/bju.12505
15. Coyne KS, Sexton CC, Thompson C, Kopp ZS, Milsom I, Kaplan SA. The impact of OAB on sexual health in men and women: results from EpiLUTS. J Sex Med 2011;8(6):1603–1615. https://doi.org/10.1111/j.1743-6109.2011.02250.x
16. Coyne KS, Sexton CC, Irwin DE, Kopp ZS, Kelleher CJ, Milsom I. The impact of overactive bladder, incontinence and other lower urinary tract symptoms on quality of life, work productivity, sexuality and emotional well-being in men and women: Results from the EPIC study. BJU Int 2008;101(11):1388–1395. https://doi.org/10.1111/j.1464-410X.2008.07601.x
17. Sugama J, Sanada H, Shigeta Y, Nakagami G, Konya C. Efficacy of an improved absorbent pad on incontinence-associated dermatitis in older women: Cluster randomized controlled trial. BMC Geriatr 2012;12:22. https://doi.org/10.1186/1471-2318-12-22
18. Park S-H, Kang C-B. Effect of Kegel exercises on the management of female stress urinary incontinence: A systematic review of randomized controlled trials. Adv Nurs 2014;2014:1–10. https://doi.org/10.1155/2014/640262
19. Capelini MV, Riccetto CL, Dambros M, Tamanini JT, Herrmann V, Muller V. Pelvic floor exercises with biofeedback for stress urinary incontinence. Int Braz J Urol 2006;32(4):462–468.
20. Correia GN, Pereira VS, Hirakawa HS, Driusso P. Effects of surface and intravaginal electrical stimulation in the treatment of women with stress urinary incontinence: Randomized controlled trial. Eur J Obstet Gynecol Reprod Biol 2014;173:113–118. https://doi.org/10.1016/j.ejogrb.2013.11.023
21. Haddad JM, Ribeiro RM, Bernardo WM, Abrão MS, Baracat EC. Vaginal cone use in passive and active phases in patients with stress urinary incontinence. Clinics (Sao Paulo) 2011;66(5):785–791. https://doi.org/10.1590/S1807-59322011000500013
22. Golmakani N, Zare Z, Khadem N, Shareh H, Shakeri MT. The effect of pelvic floor muscle exercises program on sexual self-efficacy in primiparous women after delivery. Iran J Nurs Midwifery Res 2015;20(3):347–353.
23. Bø K. Pelvic floor muscle strength and response to pelvic floor muscle training for stress urinary incontinence. Neurourol Urodyn 2003;22(7):654–658. https://doi.org/10.1002/nau.10153
24. Pardo JI, Solà VR, Morales AA. Treatment of female stress urinary incontinence with Erbium-YAG laser in non-ablative mode. Eur J Obstet Gynecol Reprod Biol 2016;204:1–4. https://doi.org/10.1016/j.ejogrb.2016.06.031
25. Fistonić N, Fistonić I, Guštek ŠF, et al. Minimally invasive, non-ablative Er:YAG laser treatment of stress urinary incontinence in women—A pilot study. Lasers Med Sci 2016;31:635–643. https://doi.org/10.1007/s10103-016-1884-0
26. Fistonić I, Fistonić N. Baseline ICIQ-UI score, body mass index, age, average birth weight, and perineometry duration as promising predictors of the short-term efficacy of Er:YAG laser treatment in stress urinary incontinent women: A prospective cohort study. Lasers Surg Med 2018;50(6):636–643. https://doi.org/10.1002/lsm.22789
27. Tien Y-W, Hsiao S-M, Lee C-N, Lin H-H. Effects of laser procedure for female urodynamic stress incontinence on pad weight, urodynamics, and sexual function. Int Urogynecology J 2017;28(3):469–476. https://doi.org/10.1007/s00192-016-3129-y
28. Ogrinc UB, Senčar S, Lenasi H. Novel minimally invasive laser treatment of urinary incontinence in women: Laser treatment of urinary incontinence. Lasers Surg Med 2015;47(9):689–697. https://doi.org/10.1002/lsm.22416
29. Lim R, Liong ML, Leong WS, Khan NAK, Yuen KH. Magnetic stimulation for stress urinary incontinence: study protocol for a randomized controlled trial. Trials 2015;16, https://doi.org/10.1186/s13063-015-0803-1

30. Voorham-Van Der Zalm PJ, Pelger RCM, Stiggelbout AM, Elzevier HW, Lycklama A, Nijeholt GAB. Effects of magnetic stimulation in the treatment of pelvic floor dysfunction. BJU Int 2006;97(5):1035–1038. https://doi.org/10.1111/j.1464-410X.2006.06131.x
31. Kinney BM, Lozanova P. High intensity focused electromagnetic therapy evaluated by magnetic resonance imaging: Safety and efficacy study of a dual tissue effect based non-invasive abdominal body shaping: MRI evaluation of electromagnetic therapy. Lasers Surg Med 2018;51:40–46. https://doi.org/10.1002/lsm.23024
32. Alinsod R, Vasilev V. HIFEM technology—A new perspective in treatment of stress urinary incontinence. American Society for Laser Medicine and Surgery Abstracts. Lasers Surg Med 2018;50(S29):S4–S56. https://doi.org/10.1002/lsm.22799
33. Samuels J. HIFEM technology—The non-invasive treatment of urinary incontinence. American Society for Laser Medicine and Surgery Abstracts. Lasers Surg Med 2018;50(S29): S4–S56. https://doi.org/10.1002/lsm.22799
34. Felicíssimo MF, Carneiro MM, Saleme CS, Pinto RZ, da Fonseca AMRM, da Silva-Filho AL. Intensive supervised versus unsupervised pelvic floor muscle training for the treatment of stress urinary incontinence: A randomized comparative trial. Int Urogynecol J 2010;21(7):835–840. https://doi.org/10.1007/s00192-010-1125-1
35. Sherburn M, Bird M, Carey M, Bø K, Galea MP. Incontinence improves in older women after intensive pelvic floor muscle training: An assessor-blinded randomized controlled trial. Neurourol Urodyn 2011;30(3):317–324. https://doi.org/10.1002/nau.20968
36. Yokoyama T, Fujita O, Nishiguchi J, et al. Extracorporeal magnetic innervation treatment for urinary incontinence. Int J Urol 2004;11(8):602–606. https://doi.org/10.1111/j.1442-2042.2004.00857.x
37. Bø K. Pelvic floor muscle training is effective in treatment of female stress urinary incontinence, but how does it work? Int Urogynecol J Pelvic Floor Dysfunct 2004;15(2):76–84. https://doi.org/10.1007/s00192-004-1125-0
38. Dumoulin C, Glazener C, Jenkinson D. Determining the optimal pelvic floor muscle training regimen for women with stress urinary incontinence. Neurourol Urodyn 2011;30(5): 746–753. https://doi.org/10.1002/nau.21104
39. Hung H-C, Hsiao S-M, Chih S-Y, Lin H-H, Tsauo J-Y. An alternative intervention for urinary incontinence: Retraining diaphragmatic, deep abdominal and pelvic floor muscle coordinated function. Man Ther 2010;15(3):273–279. https://doi.org/10.1016/j.math.2010.01.008
40. Radzimińska A, Strączyńska A, Weber-Rajek M, Styczyńska H, Strojek K, Piekorz Z. The impact of pelvic floor muscle training on the quality of life of women with urinary incontinence: A systematic literature review. Clin Interv Aging 2018;13: 957–965. https://doi.org/10.2147/CIA.S160057
41. Lim R, Liong ML, Leong WS, Karim Khan NA, Yuen KH. Pulsed magnetic stimulation for stress urinary incontinence: 1-Year followup results. J Urol 2017;197(5):1302–1308. https://doi.org/10.1016/j.juro.2016.11.091
42. Bakar Y, Cinar Özdemir Ö, Özengin N, Duran B. The use of extracorporeal magnetic innervation for the treatment of stress urinary incontinence in older women: a pilot study. Arch Gynecol Obstet 2011;284(5):1163–1168. https://doi.org/10.1007/s00404-010-1814-5
43. Galloway NT, El-Galley RE, Sand PK, Appell RA, Russell HW, Carlin SJ. Update on extracorporeal magnetic innervation (EXMI) therapy for stress urinary incontinence. Urology 2000;56(6 Suppl 1):82–86.
44. Barroso JCV, Ramos JGL, Martins-Costa S, Sanches PRS, Muller AF. Transvaginal electrical stimulation in the treatment of urinary incontinence. BJU Int 2004;93(3):319–323.
45. Lee J-Y, Chancellor MB. Using electrical stimulation for urinary incontinence. Rev Urol 2002;4(1):49–50.
46. Schreiner L, Santos TG, dos, Souza ABA, de, Nygaard CC, Filho IG, da S. Electrical stimulation for urinary incontinence in women: A systematic review. Int Braz J Urol 2013;39(4):454–464. https://doi.org/10.1590/S1677-5538.IBJU.2013.04.02
47. Bø K, Talseth T, Holme I. Single blind, randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women. BMJ 1999;318(7182):487–493.
48. Lim R, Liong ML, Lau YK, Leong WS, Khan NAK, Yuen KH. Effect of pulsed magnetic stimulation on sexual function in couples with female stress urinary incontinence partners. J Sex Marital Ther 2018;44(3):260–268. https://doi.org/10.1080/0092623X.2017.1348417

ISSN: 2577 - 8005

Research Article

Medical & Clinical Research

Safety And Preliminary Efficacy of Magnetic Stimulation of Pelvic Floor with Hifem Technology in Urinary Incontinence

Delgado Cidranes E[1]* and Estrada Blanco[2]

[1]*Anesthesiologist, CEO and Founder Advanced Pain Management Center Madrid.*

[2]*Urogynecologist, CEO and Founder CIMEG MADRID Research Center Madrid*

***Corresponding author**
Delgado Cidranes E MD, PhD, Anesthesiologist, CEO and Founder Advanced Pain Management Center Madrid, Spin. E-mail: hospitalspain@gmail.com

Submitted: 01 May 2018; **Accepted**: 10 May 2018; **Published**: 07 June 2018

Abstract

Introduction: *BTL EMSELLA™ utilizes High-Intensity Focused Electromagnetic technology (HIFEM) to cause deep pelvic floor muscles 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 BTL EMSELLA™ session brings thousands of supramaximal pelvic floor muscle contractions, which are extremely important in muscle re-education of incontinent patients.*

Objective: *Prospective study to evaluate the safety and preliminary effectiveness of the use of BTL EMSELLA magnetic stimulation in urinary incontinence.*

Method: *Thirty-two patients with light and moderate urinary incontinence were recruited to perform 6 sessions of BTL EMSELLA during three weeks of initial treatment. Follow-up after three months. The patients received sessions lasting 28 minutes, completing the different treatment protocols. Initially the patients underwent a quality of life test before and after treatment, evaluation with advanced ultrasound using elastography to measure the initial tissue's elasticity and be able to compare after treatment, clinical functional evaluation and urodynamic test.*

Results: *No adverse reactions were observed. All the patients finished the treatment sessions. Two patients reported increased pain after treatment in the first session corresponding to a VAS scale greater than 5 with duration greater than three hours. The treatment was highly satisfactory in 84,4% of the patients. After the first three months the improvement was maintained in 77% of the patients. No muscle injuries were observed. Elastographic changes and improvement of muscle tone were detected by advanced ultrasound (elastography) in 100% of patients.*

Conclusions: *BTL EMSELLA is safe, well tolerated and effective for the treatment of mild and moderate urinary incontinence. The observed elastographic changes demonstrate the improvement of pelvic floor muscle tone after treatment. A reduction in the symptoms of urinary incontinence was demonstrated.*

Recommendations: *Continue increasing the number of cases for research and increase the variables that we have decided to incorporate in the next research section such as MRI and pressure calculation.*

Introduction

Urinary incontinence (UI) is a health problem that affects the quality of life of patients who suffer from it and the impact is different depending on the severity, the type of UTI and the woman's experience of this problem. The diagnosis and treatment and treatment of UI in women is presented in the form of algorithms with accompanying notes that incorporate existing evidence and assigned a level of evidence (NE) and a grade of recommendation (GR) [1].

The algorithms are divided into two parts: algorithms for the initial treatment and algorithms for specialized treatment referring to diagnostic techniques and treatments that should only be used by specialists with specific training to establish personalized treatment behavior.

According to the National Observatory of Incontinence (ONI) it is estimated that in Spain could be affected by urinary incontinence about six million people [2].

In the studies carried out on women in Spain, although there are regional variations, the estimated average prevalence for women is

24%, increasing to 30-40% in middle-aged women and up to 50% in elderly women [2,3].

Types of Incontinence

1. Stress incontinence Supposedly due to urethral hypermobility and / or intrinsic Urethral Dysfunction.
2. Mixed incontinence
3. Hyperactive bladder with or without Urinary Incontinence supposedly due to detrusor overactivity

Initial Clinical Evaluation

The most important aspect in the diagnosis in the initial clinical evaluation. The most important variables are: Evaluation of the general condition, assessment of urinary symptoms (including voiding diary and validated questionnaires), impact of UI on quality of life, desire of the patient to receive treatment, urinalysis with or without culture, measurement of residual volume (Table 1).

N 32	First Visit					
	+++	++	+	no	% Positive	% Negative
	King's -	Health -	Questionnaire			
Pain	1	4	2	25	21,8 %	75,2 %
Nocturia	2	4	3	23	28,1 %	71,9 %
Infections	1	2	1	28	12,5 %	87,5 %
Urgency	2	5	6	19	40,6 %	59,4 %
Sexual problem	1	1	6	24	25,0 %	75,0 %
Stress incontinence	2	11	6	13	59,3 %	40,7 %
Physical and social limitations	1	9	14	8	75,0 %	25,0 %

Degree of affectation: --no, + mild, ++ moderade, +++ server (Cidranes & Estrada 2018 CIMEG MADRID)

Pelvic and Perineal Examination

It is one of the most important parts to define diagnosis and behavior. The advanced examination of pelvic floor should serve to rule out associations to prolapses of pelvic organs. The evaluation of the pelvic floor musculature is essential as well as the evaluation of vulvovaginal disorders due to urigenital atrophy. In complex cases and with recurrent UTI, interdisciplinary evaluation will be useful and necessary [4].

HIFEM Technology (The BLUE CHAIR EMSELLA)

EMSELLA™ utilizes High-Intensity Focused Electromagnetic technology (HIFEM) to cause deep pelvic floor muscles 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 BTL EMSELLA™ session brings thousands of supramaximal pelvic floor muscle contractions, which are extremely important in muscle reeducation of incontinent patients [5-7].

Material and Method

Thirty-two patients with light and moderate urinary incontinence were recruited to perform 6 sessions of BTL EMSELLA during three weeks of initial treatment. Follow-up after three months. (Figure 1) The first session lasted 7 minutes, (Figure 2) the second session 14 minutes to achieve a dose of priming and adequate muscle adjustment assessed in real time by elastography of muscles and fascias. (Figure 3) The patients received four sessions lasting 28 minutes, completing the different treatment protocols. Initially the patients underwent to quality of life test before and after treatment, evaluation with advanced ultrasound using elastography to measure the initial tissue's elasticity and be able to compare after treatment, clinical functional evaluation and urodynamic test.

Figure 1: Emsella CIMEG MADRID / Key Points

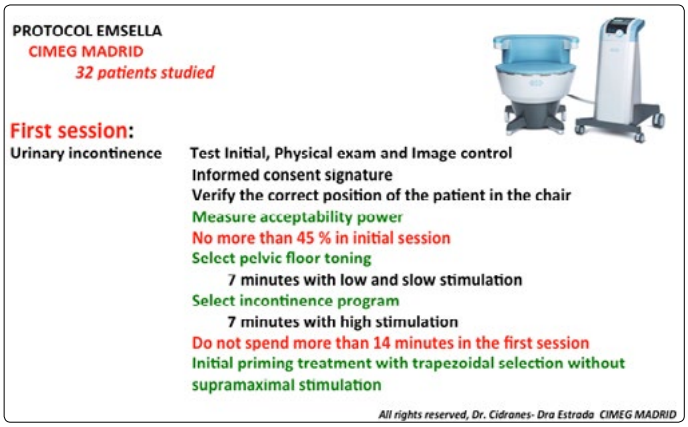


Figure 2: Emsella Protocol Cimeg Madrid First Session

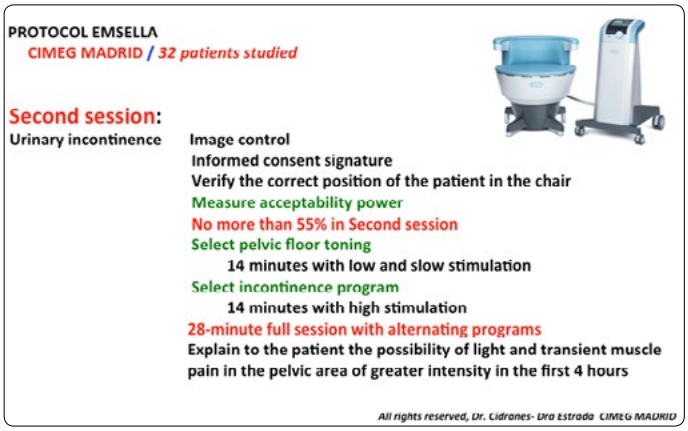


Figure 3: Emsella Protocol Cimeg Madrid , Second Session, Urinary Incontinence

Data Collection

The impact of HIFEM Emsella in our patients has been evaluated through the Spanish version of King's Health Questionnaire 1993

obtaining demographic, subjective, objective variables as well as quality of life. (Table 1) The urinary incontinence questionnaire ICIQ-SF (International Consultation of Incontinence Questionnaire) was carried out. (Table 2) We value in all patients the degree of tissue elasticity through advanced ultrasound and elastography using ESAOTE technology.

ICISF / n 32	0	1-3	4-6	7-10	Total % Positive
Frequency of urine loss	0	19	11	2	100 %
Amount of urine lost according to patient	0	22	8	2	100 %
Escaping urine and affecting daily life	2	19	7	4	93,75 %
When do you lose urine? Small activities to big activities	2	10	13	7	93,75 %

Degree of affectation: 0 no, 1-3 mild, 4-6 moderade, 7-10 server ICIQ-SF Positive greater than 1
(Cidranes & Estrada 2018 CIMEG MADRID)

Results

No adverse reactions were observed. All the patients finished the treatment sessions. Two patients reported increased pain after treatment in the first session corresponding to a VAS scale greater than 5 with duration greater than three hours. The degree of improvement after three months was already remarkable and maintained. (Table 3). The treatment was highly satisfactory in 84,4% of the patients. (Figure 4) After the first five months the improvement was maintained in 75% of the patients. No muscle injuries were observed. Elastographic changes and improvement of muscle tone were detected by advanced ultrasound (elastography) in 94 % of patients. (Table 4). After 5 months the degree of satisfaction of patients reaches 84.4% and 75% have solved the problem that generated their urinary incontinence.

N 32	After three months					
	+++	++	+	no	% positive	% Negative
	King's -	Health -	Questionnaire			
Pain	0	2	1	29	09,3 %	90,7 %
Nocturia	1	3	1	27	15,6 %	84,4 %
Infections	0	0	0	32	0,00 %	100 %
Urgency	1	3	3	26	21,8 %	79,2 %
Sexual problem	0	0	4	28	12,5 %	87,5 %
Stress incontinence	0	2	2	28	12,5 %	87,5 %
Physical and social limitations	0	2	4	28	18,7 %	81,5 %

Degree of affectation: --no, + mild, ++ moderade, +++ server (Cidranes & Estrada 2018 CIMEG MADRID)

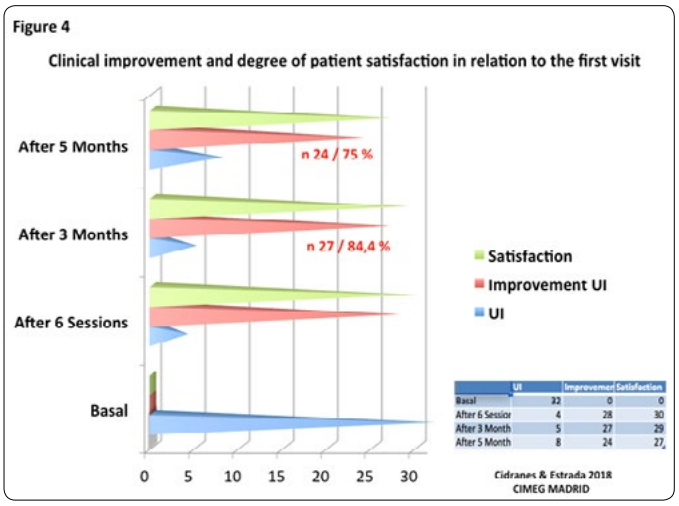


Figure 4: Clinical improvement and degree of patient satisfaction in relation to the first visit

N 32	First Visit		After three months		After five months	
	Positive	Negative	Positive	Negative	% Positive	% Negative
Elastography	30	2	7	25	3 / 09,3 %	29 / 90,6 %
Strain Rate	30	2	9	23	7 / 21,8 %	25 / 78,2 %
Urogynecological ultrasound Findings	14	18	12	16	3 / 09,3 %	29 / 90,6 %
MRI	9	23	5	27	2 / 09,3 %	30 / 93,7 %
Uroflowmetry	17	15	2	30	2 / 0,9,3 %	30 / 93,7 %
Urethrocytoscopy	4	28	4	28	4 / 12,5 %	28 / 87,5 %
Clinical Improvement	-	-	27 84,4 %		24 75 %	-

Positive: Pathological findings, Negative Non Pathological (Cidranes & Estrada 2018 CIMEG MADRID)

Conclusion

BTL EMSELLA is safe, well tolerated and effective for the treatment of mild and moderate urinary incontinence. The observed elastographic changes demonstrate the improvement of pelvic floor muscle tone after treatment. A reduction in the symptoms of urinary incontinence was demonstrated.

Recommendations

Continue increasing the number of cases for research and increase the variables that we have decided to incorporate in the next research section such as Fusion Image and pressure calculation.

References

1. Abrams P, Blaivas JG, Stanton SL, Andersen JT (1998) The Standardisation of Terminology of Lower Urinary Tract Function. The International Continence Society Committee on Standartisation of Terminology. Scand d Suppl 114: 5-19
2. F Hunskaar S, Burgio K, Diokno AC, Herzog AR, Hjalmas K, et al. (2002) Epidemiology and Natural History of Urinary Incontinence (UI). En: Incontinence 2nd Edition. Abrams P, Cardozo L, ry S, Wein A (Eds). Chp 3, Plym- bridge Distributors Ltd., United KingKhoudom 165-202.
3. Botlero R, Urquhart DM, Davis SR, Bell RJ (2008) Prevalence and incidence of urinary incontinence in women: review of the literature and investigation of methodological issues. Int J Urol 15: 230-234.
4. Almeida FG, Bruschini H, Srougi M (2004) Urodynamic and clinical evaluation of 91 female patients with urinary incontinence treated with perineal magnetic stimulation: 1-year follow-up. J Urol. 2004 Apr; 171: 1571-1574.
5. Bickford R, Guidi M, Fortesque P, Swenson M (1987) Magnetic stimulation of human peripheral nerve and brain. Neurosurgery 20: 110-116.
6. Bustamante V, de Santa María E, Gorostiza A, Jiménez U, Gáldiz J (2010) Muscle training with repetitive magnetic stimulation of the quadriceps in severe COPD patients. Respiratory Medicine 104: 37-245.
7. Berenholz J, Sims T, Botros G (2017) HIFEM Technology Can I mprove Quality of Life of I ncontinent Patients.

OPEN

A Comparative Study on the Effects of High-Intensity Focused Electromagnetic Technology and Electrostimulation for the Treatment of Pelvic Floor Muscles and Urinary Incontinence in Parous Women: Analysis of Posttreatment Data

Elena Silantyeva, MD, PhD, Dragana Zarkovic, MSc,† Evgeniia Astafeva, MD,* Ramina Soldatskaia, MD,* Mekan Orazov, MD, PhD,‡ Marina Belkovskaya, MD, PhD,* Mark Kurtser, MD, PhD,* and Academician of the Russian Academy of Sciences*

Objectives: Pelvic floor muscles (PFMs) weakening and urinary incontinence (UI) represent health issues that have a negative impact on daily life. This study compares the immediate efficiency of high-intensity focused electromagnetic (HIFEM) therapy and electrostimulation for the treatment of weakened PFMs, accompanied by the UI.

Methods: Ninety-five parous women were considered for the study. Symptomatic patients received either HIFEM or electrostimulation treatment. Treated patients completed 10 therapies scheduled 2 to 3 times per week (HIFEM) or every other day (electrostimulation). Patients underwent examination by 3-dimensional transperienal ultrasound at the baseline and posttreatments. Levator-urethra gap, anteroposterior diameter, laterolateral diameter of levator hiatus, and hiatal area were measured. In addition, Pelvic Floor Disability Index 20 questionnaire and subjective evaluation of patient's intimate health were assessed.

Results: Enrolled patients were divided into group I (n = 50, HIFEM), group II (n = 25, electrostimulation), and group III (n = 20, control) according the indication and treatment modality. Three-dimensional ultrasounds showed positive changes in dynamics of the pelvic floor posttreatment (decreased anteroposterior diameter, laterolateral diameter, and hiatal area). However, the significant ($P < 0.05$) changes of pelvic floor integrity were observed only in group I. In addition, group I achieved greater level of improvement in Pelvic Floor Disability Index 20 questionnaire compared with group II (52% and 18% respectively; $P < 0.001$). Substantially fewer patients in group I reported urine leakage after treatments.

Conclusions: Posttreatment results suggest that HIFEM technology is suitable for treatment of PFMs weakening and showed to be more effective when compared with electrostimulation in short-term. Therefore, we recommend HIFEM as treatment option for weakened PFMs and UI.

Key Words: pelvic floor, ultrasonography, urinary incontinence

(*Female Pelvic Med Reconstr Surg* 2019;00: 00–00)

The pelvic floor is highly complex, consisting of skeletal and striated muscles. It plays an important role in the maintenance of continence mechanism. For its proper functioning, strong and well-conditioned pelvic floor muscles (PFMs) are required,[1] ensuring the pelvic viscera's integrity.[2] Weakening of the PFMs may promote a wide range of health issues, such as pelvic organ prolapse or bladder dysfunction manifested as urinary incontinence (UI). Symptoms associated with UI directly affect the patient's quality of life.[3]

Between 4% and 8% of the human population suffer from UI as implied by the data released by Global Forum of Incontinence.[4] Prevalence of UI tends to increase with age[5] and can be triggered by risk factors such as surgical intervention or childbirth (especially vaginal delivery).[6,7] These may have a negative impact on the pelvic floor muscle's activity and morphology.[8] The deconditioning of PFMs accompanied with UI often influences the patient's mental and physical health. Fortunately, there are both surgical and nonsurgical methods of treatment available for such conditions. However, the nonsurgical approach should be always recommended as first-line therapy.[9]

Pelvic floor muscles can be treated with either monotherapy or combination therapy, which includes a combination of available treatment modalities to enhance treatment outcomes.[10–12] In general, nonsurgical approaches for the correction of pelvic muscle dysfunction include biofeedback therapy,[12] Kegel exercises (and its modifications),[13] magnetic stimulation,[14,15] and a wide range of electrostimulation methods.[16] Lately, a novel noninvasive technology utilizing the high-intensity focused electromagnetic (HIFEM) field was introduced for treating PFMs.[17,18] The HIFEM field depolarizes membranes of peripheral motoneurons and initiates muscle contraction.[19] High repetition rate of stimulation ensures that pelvic muscles reach nonvoluntary contractions of great intensities, referred to as "supramaximal" contractions. Although the effectiveness of HIFEM therapy was described earlier,[17,18] comparative assessment with other treatment modalities is still lacking.

The changes of the function of PFMs with regards to the UI are often assessed by the subjective standardized questionnaires, in particular with Pelvic Floor Impact Questionnaire or Pelvic Floor Disability Index (PFDI).[20] These are designed to allow patients comprehensively describe their perception of their pelvic area. This serves as a powerful tool for the practitioners when used in combination with some objective evaluation (magnetic resonance, ultrasound imaging, or electromyography).[21,22] Especially, the 3-dimensional (3D) transperineal ultrasonography of the pelvic floor has become widely used due to its ability to promptly assess essential parameters of pelvic floor integrity.[23,24]

The goal of this pilot study is to investigate and compare the immediate efficiency of HIFEM technology and electrical stimulation, for the treatment of weakened PFMs accompanied by UI.

MATERIALS AND METHODS

Inclusion Criteria and Ethical Principles

Between the 2018 and early 2019, 95 postpartum women in reproductive age referred to the Hospital Lapino (MD Medical

From the *Hospital Lapino MD Medical Group, Moscow, Russia; †Charles University, Faculty of Physical Education and Sport, Department of Anatomy and Biomechanics, Prague, Czech Republic; and ‡RUDN University, Medical Faculty, Moscow, Russia.

Correspondence: Elena Silantyeva, MD, PhD, Hospital Lapino MD Medical Group, 111, Lapino village, Odintsovo district, 143081, Moscow, Russia. E-mail: essdoktor@yandex.ru.

The authors have declared they have no conflicts of interest.

DOI: 10.1097/SPV.0000000000000807

Group) were considered for the study. The present study is a retrospective analysis of all the short-term data, which were gathered during their pretreatment and posttreatment examination.

The inclusion criteria were age 18 to 45 years and history of vaginal childbirth (not earlier than 6 months ago). The exclusion criteria included the following: pelvic organ prolapse; pregnancy at the time of therapy initiation (urinary pregnancy test was done in both groups at the baseline); the presence of metal implants in the area of lumbosacral spine, pelvis, or hip joints or intrauterine device, which includes any metal components, cardiac pacemaker, or other inner electronic devices; and general contraindications for physiotherapy. All the patients signed a voluntary informed consent.

Treatment Protocol

Patients who showed PFMs weakness and continence issues received either therapy with the BTL EMSELLA (BTL Industries Inc, Boston, MA) or BioBravo (MTR+ Vertriebs GmbH, Germany) device. BTL EMSELLA uses HIFEM technology for PFM strengthening and reduction of UI. The device is consisted of a power generator and a circular coil mounted in the seat of the chair. During the treatment, the patient is fully clothed and seated on the center of the chair while the alternating magnetic fields with intensities of up to 2.5 T have been penetrating the pelvic area. In total, 10 HIFEM treatments (for 28 minutes each) with frequency 2 to 3 sessions per week were delivered to match the electrostimulation protocol.

BioBravo portable low-frequency stimulator is used for self-administered PFMs stimulation to treat urinary/fecal incontinence symptoms (approved by European Union conformity mark, not Food and Drug Administration cleared or approved). Patients performed a course of 10 procedures at home (every other day or, at least, 3 times a week) with BioBravo device, after they passed preliminary training. Time of each BioBravo session was set to 28 minutes to mirror the duration of Emsella's treatment.

Evaluation of Study Outcomes

Various methods for documentation of treatment outcomes were used. The first (baseline) visit consisted of medical anamnesis, gynecological examination, and 3D transperineal ultrasound of the pelvic floor area by Voluson E10 device (RIC6-12-D transducer). During the examination, patients were placed in the dorsal lithotomy position with both hips symmetrically flexed, legs abducted, and knees flexed. The transducer was located on the perineum between the mons pubis and the anal margin. In particular, measured biometric indices of pelvic floor integrity included anteroposterior diameter (LH-AD) and laterolateral diameter (LH-LD) of levator hiatus and hiatal area (HA). In addition, levator-urethra gap (LUG) was studied before the first treatment (pelvic prolapse detection due to the levator ani avulsion). The ultrasound examination was repeated after the prescribed course of treatments.

Treated women were also asked to complete PFDI-20 standardized questionnaire to assess the degree of PFM functioning and continence issues. These patients also evaluated their intimate health on bimodal basis (yes/no), according to following questions: Q1 — Are you experiencing vaginal laxity during intimacy? Q2 — Are you experiencing changes of vaginal topography? Q3 — Does the water or air enter the vagina during swimming and exercise? Q4 — Are you experiencing stress UI symptoms (eg, involuntary urine leakage during physical activity, when coughing or sneezing or before you can visit the toilet)? After the successful completion of all treatments, the patients reevaluated their continence and PFM functioning.

Safety and comfort of the patients were monitored (any possible adverse effects or adverse events, for example, pain, muscle fatigue, or bruising induced by therapies). Patients who performed treatments at home were instructed to record any inconveniences caused by electrotherapy.

There was a large number of patients to provide sufficient sample for statistical analysis, further verified by G-power 3.1.9.2 software.[25] Gathered results were statistically analyzed using Statistica version 6 software (StatSoft Inc, Tulsa, OK) using the paired t test and 2-way analysis of variance followed by least significant difference post hoc test. Level of significance α was set to 5%. Assumption of normality was tested by Kolmogorov-Smirnov and Lilliefors tests.

RESULTS

All 95 patients were recruited. In total, 75 women reported PFMs weakness and incontinence issues. Symptomatic patients were divided into 2 groups. Group I (n = 50, mean ± SD age of 31.1 ± 5.4 years) received therapy with the EMSELLA device. Group II (n = 25, mean ± SD age of 32.0 ± 7.7 years) was treated with BioBravo stimulator. The remaining patients marked as a group III (n = 20, mean age of 27.2 ± 4.3 years) were classified as healthy participants and were used only as control for 3D ultrasound measurements.

Each patient from groups I and II finished the prescribed course of treatments. No adverse events or pain were reported. None of the patients experienced prolapse of pelvic floor, which can be seen in Table 1. Thickness of LUG on both sides of the pelvis did not exceed the cutoff value of 25 mm as stated in literature,[26] and thus, both treated groups met the inclusion criteria. The minor differences in LUG thickness within the groups were insignificant.

3D Ultrasounds of Pelvic Floor

The rest of the parameters obtained by 3D ultrasounds are documented in Table 2. Before the treatment, significantly higher values were documented in all studied indices against the control group. After the last therapy, the initially high values of LH-AD, LH-LD, and HA were significantly reduced only in group I ($P < 0.05$), approaching the averages of group III. Results of group II showed similar yet insignificant trend ($P > 0.05$). Such difference indicates the significant effect only in patients treated by HIFEM technology.

The examples of 3D ultrasounds obtained before and after HIFEM treatments are visualized on the Figure 1. There is visible improvement in LH-AD and HA parameters. Thickness of LH--AD was decreased by 2.6 mm, which is comparable with mean difference of whole group I (−3.12 mm on average). In addition, HA showed more profound reduction of 1.83 cm^2 that exceeds the group I average difference (−1.38 cm^2) of almost 0.5 cm^2.

TABLE 1. Examination of LUG Thickness for Determination of Levator Ani Avulsion as Sign of Pelvic Organ Prolapse

Levator Avulsion	LUG Right Side, Mean (SD), mm	LUG Left Side, Mean (SD), mm
Group I	20.94 (3.22)	21.76 (3.14)
Group II	20.96 (2.49)	21.48 (2.68)
Group III	20.70 (2.68)	20.85 (2.94)

Data are expressed as mean with SD.

TABLE 2. Three-dimensional Ultrasound Examination of Intervention (I and II) and Control (III) Groups

	LH-AD, Mean (SD), mm		LH-LD, Mean (SD), mm		HA, Mean (SD), cm^2	
PFM Integrity	**Before**	**After**	**Before**	**After**	**Before**	**After**
Group I	51.10 (6.80)†	47.98 (6.25)*	41.44 (6.43)†	38.40 (6.03)*	14.47 (1.72)†	13.09 (1.78)*
Group II	52.52 (5.75)†	51.36 (5.36)†	46.60 (6.70)†	45.56 (6.41)†	14.77 (1.82)†	14.69 (1.79)†
Group III	46.60 (2.30)	N/A	35.40 (2.50)	N/A	11.59 (0.35)	N/A

Data are expressed as mean with SD. Group III was measured only at the baseline as a reference, therefore values after treatment are not available.

*Statistically significant differences against baseline ($P < 0.05$).

†Statistically significant differences against control.

N/A, not available.

PFDI-20 Standardized Questionnaire

No difference in the baseline PFDI-20 score was found. Although the baseline score was slightly higher in group II, this tendency showed to be insignificant ($P = 0.45$). The more profound change has been achieved by group I. After the HIFEM treatments, patients improved by 31.45 points (52%, $P < 0.001$). On the contrary, group II showed lesser yet significant mean difference of 11.70 points (18%, $P < 0.001$). The comparison of results obtained after the last treatments revealed also significant difference between the group I and II mean scores ($P < 0.001$; Table 3).

Patient's Self-Evaluation

Results of the patient's subjective bimodal evaluation are summarized in Table 4. The percentages describe a portion of patients who answered questions Q1 to Q4 positively (yes). After the treatments, the percentage of answers regressed in both groups; however, group I showed substantially greater differences in comparison with group II. On average, the subjective assessment revealed that patient self-reported 2 times greater results after HIFEM treatment. Especially remarkable improvement was observed in questions Q1 (laxity) and Q4 (incontinence). In group I, the differences reached up to 30% (Q1) and 44% (Q4), respectively, whereas group II reported much lower change of 16%.

Sample Size and Verification of Power

Using G-power software, we calculated the minimal sample size to reveal statistical significance in gathered data as 16 patients for both 2-tailed t test ($\alpha = 0.05$; power, 0.95; effect size, 1) and analysis of variance ($\alpha = 0.05$; power, 0.95; 3 groups; effect

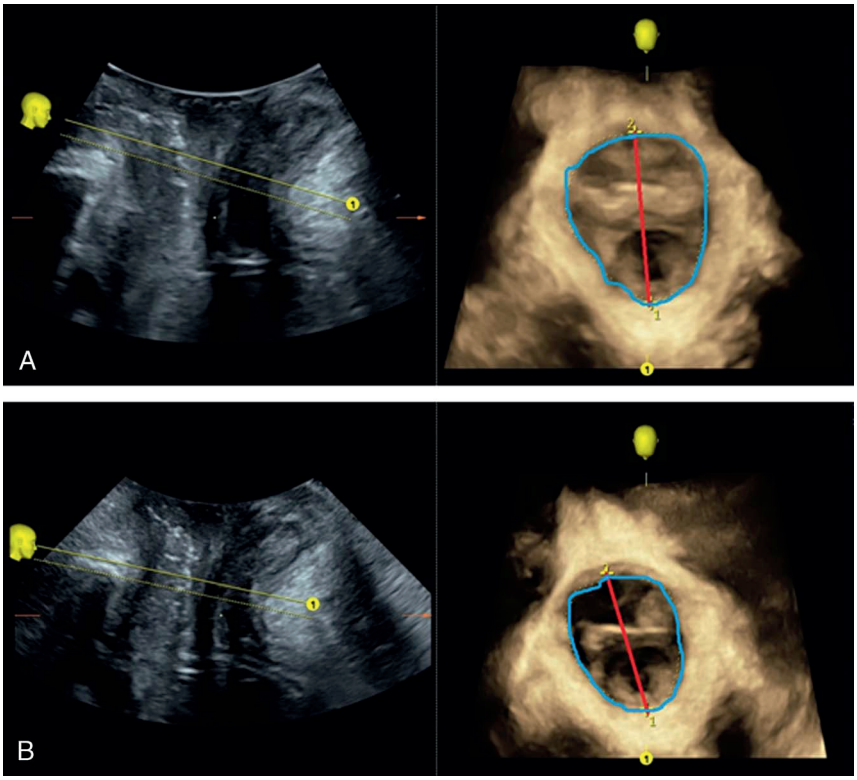


FIGURE 1. A 39-year-old patient, 1 childbirth. Visualization of ultrasound measurements (Voluson E10, equipped with RIC6-12-D transducer) before (A) and after (B) HIFEM treatments. Midsagittal plane on the left, axial rendered volume on the right. Red line indicates LH-AD dimensions. Area of HA is bordered by blue line. Direction of view in 3D is indicated by yellow lines and ❶ mark.

TABLE 3. Mean Scores of the Standardized PFDI-20 Questionnaire Including the 95% CIs

PFDI-20	Baseline Score (CI)	After Tx Score (CI)	*P*
Group I	60.22 (50.62–69.82)	28.77 (20.74–36.81)	<0.001
Group II	66.21 (54.08–78.34)	54.51 (43.92–65.11)	<0.001
P value	0.45	<0.001	

Data were gathered at baseline and after treatments (After Tx).
CI, confidence interval;Tx, treatment.

size, 1). In addition, the power of conduced statistical analysis was verified post hoc and showed to be equal to 0.99.

DISCUSSION

According to the documented results, we suggest that HIFEM therapy was more effective method for treatment of weakened pelvic floor than electrostimulation in short-term. Apparently, based on the evaluation by both subjective (questionnaires) and objective (3D transperineal ultrasound) methods, HIFEM therapy produces more profound improvement in PFMs and UI posttreatment.

Besides the magnetic resonance, one of the most reliable methods for examination of pelvic area is diagnostic ultrasound. Because of the complex manner of structures forming the pelvic floor, 2-dimensional image may not always provide proper visualization. Hence, the examination should be combined with 3D analysis.[23] The use of such technology in routine practice may help to reveal pelvic floor muscles weakening even if the patient does not have any subjective complaints. Early diagnosis helps start timely treatment, as the 3D reconstruction of pelvic floor allows to obtain specific parameters of its integrity (LUG, LH-AD, LH-LD, and HA).

Recent research demonstrated that LUG is strongly associated with puborectalis avulsion, and the cutoff threshold for its diagnosis appears to be 25 to 27.5 mm.[23,26] Our initial gynecological examination showed no levator avulsion, which would exclude patients from the study. Levator-urethra gap ranged from 20.70 to 21.76 mm (Table 1), and thus, no pelvic organ prolapse was diagnosed because measured values showed to be substantially lower than cut-off threshold.

The biometric indices of control group are comparable with the results reported in literature for nuliparous women at rest.[27] It was found that LH-AD in healthy patients ranges from 45.2 to 48.4 mm, LH-LD from 32.8 to 37.5, and HA from 11.3 to 12.0 cm^2, which corresponds to our observations in healthy parous women (group III). However, both treated groups at the baseline showed significantly higher LH-AD, LH-LD, and HA in comparison with the group III. As a result of the treatments, these indices decreased toward the control values. Nonetheless, significant changes of the pelvic floor anatomy were demonstrated only in patients treated by HIFEM technology (Table 2; Fig. 1).

The presented data showed an enhanced functioning of PFMs with reduction of UI severity and impact on the quality of life has been achieved (Tables 3 and 4). Differences in PFDI-20 mean scores were found to be highly statistically significant. Both treatment modalities proved to be effective in treating PFMs weakness accompanied with UI. However, our observations indicate significantly more profound efficiency of the HIFEM technology in comparison with the electrostimulation after a course of 10 treatment sessions. Based on the questionnaire data, it was proved ($P < 0.001$) that group I reached a higher level of improvement (2.68 times) after a series of 10 treatments. Patients treated by HIFEM technology showed mean difference in PFDI of over 50%. On the contrary, group II was only able to reach an average improvement of 18%.

The patient's subjective bimodal assessment revealed greater results in group I, which reported reduced incontinence symptoms after the treatments, when compared with group II. In addition, those who received HIFEM therapy noticed a substantial reduction in vaginal laxity symptoms. Modest improvement of incontinence and laxity issues was seen in group II, probably attributed to the less recognizable improvement of PFM functioning. Conversely, the greater results observed in patients from group I correlate to their significant change in pelvic floor integrity and PFDI-20 score.

For PFM strengthening, the strong contractions with interposed rest periods should be involved to deliver sufficient load.[28] If the muscles are properly stimulated, both endurance and strength are regained.[29] Superior results after HIFEM therapy in our study may be explained by the deep penetration of high-intensity electromagnetic field into the pelvic area, resulting in uniform activation of PFMs. On the contrary, electrical devices may not be able to involve whole pelvic floor with sufficient intensity of the stimuli. Because of its superficial application, the electrostimulators lost the largest portion of emitted energy on the surface, and only its fraction reaches deep-lying tissues.[30] Although some positive effects of electrostimulation on PFM strengthening was documented in the past, there is still not sufficient evidence to determine whether it is more effective than traditional exercise.[20,31,32]

In this study, the treated postpartum patient groups were consisted of relatively young women of average age 31.1 ± 5.4 years and 32.0 ± 7.7 years. However, we assume that our findings are applicable also in the older postmenopausal patients who would probably show symptoms of greater severity because of the estrogen deficiency. Samuels et al,[33] for instance, was able to reach similar degree of immediate posttreatment improvement after the series of 6 HIFEM treatments in patient group aged 55.5 ± 12.8 years. Almost identically aged group (55.2 ± 12.8 years) was established also by Castro et al[34] who described significant and continuous results of electrostimulation therapy.

TABLE 4. Subjective Examination of Patient's Intimate Health Obtained at the Baseline and After Treatments (After Tx)

	Group I			Group II		
Question	Baseline	After Tx	Difference	Baseline	After Tx	Difference
Q1	48%	18%	−30%	44%	28%	−16%
Q2	36%	12%	−24%	36%	24%	−12%
Q3	34%	16%	−18%	48%	36%	−12%
Q4	74%	30%	−44%	72%	56%	−16%

The percentages express the portion of patients who answered *yes*.
Tx, treatment.

Continuity of results after noninvasive pelvic floor stimulation is still being investigated in the literature. Based on the long-term observation of treatment outcomes after magnetic and electrical stimulation, it is assumed that beneficial effect of induced PFM strengthening may be sustained up to 1 year.[14,35] However, after this period of time, the relapse may occur and maintenance session should be considered in some patients.

Although the presented data are based on the short-term observation of patient cohort, the discovered findings showed to be sufficient to identify contrast in efficacy between the HIFEM technology and electrostimulation. Future research should verify the persistence of herein published results and further tendencies in patient's PFMs and UI management as well as retreatment period. Treatment groups of at least 16 patients should be established when the great effect of intervention is observed. Otherwise, the higher number of patients might be required.

It was demonstrated that HIFEM technology was able to significantly improve biometric indices of pelvic floor integrity and UI symptoms. Therefore, we recommend HIFEM for a widespread uses in practice as the treatment of weakened pelvic muscles and continence issues.

REFERENCES

1. Jundt K, Peschers U, Kentenich H. The investigation and treatment of female pelvic floor dysfunction. *Dtsch Ärztebl Int* 2015;112(33–34):564–574.
2. Elneil S. Complex pelvic floor failure and associated problems. *Best Pract Res Clin Gastroenterol* 2009;23(4):555–573.
3. Zargham M, Alizadeh F, Moayednia A, et al. The role of pelvic organs prolapse in the etiology of urinary incontinence in women. *Adv Biomed Res* 2013;2:22.
4. Incontinence — Global Forum on Incontinence — GFI. Available at: http://www.gfiforum.com/incontinence. Accessed January 30, 2019.
5. Gomelsky A, Dmochowski RR. Urinary incontinence in the aging female: etiology, pathophysiology and treatment options. *Aging Health* 2011;7(1):79–88.
6. Wang X, Shi JX, Zhai GR, et al. Postpartum stress urinary incontinence and associated obstetric factors. *Zhonghua Fu Chan Ke Za Zhi* 2010;45(2):104–108.
7. Luber KM. The definition, prevalence, and risk factors for stress urinary incontinence. *Rev Urol* 2004;6(Suppl 3):S3–S9.
8. Aoki Y, Brown HW, Brubaker L, et al. Urinary incontinence in women. *Nat Rev Dis Primer* 2017;3:17042.
9. Radzimińska A, Strączyńska A, Weber-Rajek M, et al. The impact of pelvic floor muscle training on the quality of life of women with urinary incontinence: a systematic literature review. *Clin Interv Aging* 2018;13:957–965.
10. Siff LN, Hill AJ, Walters SJ, et al. The effect of commonly performed exercises on the levator hiatus area and the length and strength of pelvic floor muscles in postpartum women. *Female Pelvic Med Reconstr Surg* 2018.
11. Yang S, Sang W, Feng J, et al. The effect of rehabilitation exercises combined with direct vagina low voltage low frequency electric stimulation on pelvic nerve electrophysiology and tissue function in primiparous women: a randomised controlled trial. *J Clin Nurs* 2017;26(23–24):4537–4547.
12. Newman DK. Pelvic floor muscle rehabilitation using biofeedback. *Urol Nurs* 2014;34(4):193–202.
13. Kegel AH. Physiologic therapy for urinary stress incontinence. *JAMA* 1951;146(10):915.
14. Lim R, Liong ML, Leong WS, et al. Pulsed magnetic stimulation for stress urinary incontinence: 1-year followup results. *J Urol* 2017;197(5):1302–1308.
15. Yokoyama T, Fujita O, Nishiguchi J, et al. Extracorporeal magnetic innervation treatment for urinary incontinence. *Int J Urol* 2004;11(8):602–606.
16. Martellucci J, ed. *Electrical Stimulation for Pelvic Floor Disorders*. New York, NY: Springer International Publishing; 2015. Available at: https://www.springer.com/gp/book/9783319069463. Accessed March 26, 2019.
17. Samuels J, Guerette NL. HIFEM technology the non-invasive treatment of urinary incontinence. *Lasers Surg Med* 2018;50(S29):S4–S56.
18. Alinsod R, Vasilev V, Yanev K, et al. HIFEM technology a new perspective in treatment of stress urinary incontinence. *Lasers Surg Med* 2018;50(S29):S4–S56.
19. Voorham-Van Der Zalm PJ, Pelger RC, Stiggelbout AM, et al. Effects of magnetic stimulation in the treatment of pelvic floor dysfunction. *BJU Int* 2006;97(5):1035–1038.
20. Bø K, Berghmans B, Mørkved S, et al. *Evidence-Based Physical Therapy for the Pelvic Floor: Bridging Science and Clinical Practice. Edinburgh, Scotland: Churchill Livingstone;* 2015.
21. Zuchelo LTS, Bezerra IMP, Da Silva ATM, et al. Questionnaires to evaluate pelvic floor dysfunction in the postpartum period: a systematic review. *Int J Womens Health* 2018;10:409–424.
22. Glazer HI, Romanzi L, Polaneczky M. Pelvic floor muscle surface electromyography. Reliability and clinical predictive validity. *J Reprod Med* 1999;44(9):779–782.
23. Yan Y, Dou C, Wang X, et al. Combination of tomographic ultrasound imaging and three-dimensional magnetic resonance imaging-based model to diagnose postpartum levator avulsion. *Sci Rep* 2017;7(1):11235.
24. Dietz HP. Pelvic floor ultrasound: a review. *Am J Obstet Gynecol* 2010;202(4):321–334.
25. Faul F, Erdfelder E, Lang A-G, et al. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behav Res Methods* 2007;39(2):175–191.
26. Dietz HP, Abbu A, Shek KL. The levator-urethra gap measurement: a more objective means of determining levator avulsion? *Ultrasound Obstet Gynecol Off J Int Soc Ultrasound Obstet Gynecol* 2008;32(7):941–945.
27. Gaspari AL, Sileri P. *Pelvic Floor Disorders: Surgical Approach*. Milan, Italy: Springer-Verlag Mailand; 2014.
28. Nyland J, ed. *Clinical Decisions in Therapeutic Exercise: Planning and Implementation*. Upper Saddle River, NJ: Pearson Education; 2006.
29. Fowler CJ, Panicker JN, Emmanuel A. *Pelvic Organ Dysfunction in Neurological Disease: Clinical Management and Rehabilitation*. Cambridge, England: Cambridge University Press; 2010.
30. Prodanovic M, Malešević J, Filipovic M, et al. Numerical simulation of the energy distribution in biological tissues during electrical stimulation. *Serbian J Electr Eng* 2013;10:165–173.
31. Amaro JL, Gameiro MO, Kawano PR, et al. Intravaginal electrical stimulation: a randomized, double-blind study on the treatment of mixed urinary incontinence. *Acta Obstet Gynecol Scand* 2006;85(5):619–622.
32. Bø K, Talseth T, Holme I. Single blind, randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women. *BMJ* 1999;318(7182):487–493.
33. Samuels JB, Pezzella A, Berenholz J, et al. 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. *Lasers Surg Med* 2019;51(9):760–766.
34. Castro RA, Arruda RM, Zanetti MRD, et al. Single-blind, randomized, controlled trial of pelvic floor muscle training, electrical stimulation, vaginal cones, and no active treatment in the management of stress urinary incontinence. *Clinics* 2008;63(4):465–472.
35. Fürst MC, Mendonça RR, Rodrigues AO, et al. Long-term results of a clinical trial comparing isolated vaginal stimulation with combined treatment for women with stress incontinence. *Einstein (Sao Paulo)* 2014;12(2):168–174.

SEXUAL MEDICINE ORIGINAL RESEARCH

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,[1] Zarkovic Dragana, MSc,[2] Soldatskaia Ramina, MD,[1] Astafeva Evgeniia, MD,[1] and Mekan Orazov, MD, PhD[3]

ABSTRACT

Introduction: Impaired coordination, relaxation, and atrophy of pelvic floor muscles (PFMs) may cause various health issues referred to as pelvic floor dysfunction (PFD). In recent years, electromagnetic noninvasive stimulation of the pelvic floor was successfully used to treat PFD symptoms.

Aim: This study aims to compare the effectiveness of electrical and magnetic noninvasive stimulation for the treatment of PFD in postpartum women.

Methods: 2 intervention groups treated with high-intensity focused electromagnetic ([HIFEM]; G1) procedure and electrical stimulation (G2) were established along with the control group (G3). Patients received 10 therapies delivered at the hospital (G1; 2−3 times per week) or self-administered at home (G2; every other day) after initial training. The protocol was identical for both modalities. Functionality of the PFM was examined by surface electromyography measurements (maximal voluntary contraction [MVC]; mean MVC; muscle activity at rest; endurance of contraction) while patient's subjective perception of pelvic floor functionality was assessed by Pelvic Floor Impact Questionnaire−Short Form 7 (PFIQ-7) standardized questionnaire. Changes in electromyography values and PFIQ-7 scores were statistically evaluated from baseline to after all treatments.

Main Outcome Measure: The main outcome measure was enhancement of PFM activity.

Results: In total, 95 patients (G1 = 50; G2 = 25; G3 = 20) participated in the study. The MVC, mean MVC, and endurance were lowered in symptomatic patients. After the treatments, these parameters significantly increased ($P < .001$) and moved toward the values of healthy population. Electrogenesis at relaxation revealed divergent tendencies in the G1 and G2 groups. PFIQ-7 scores significantly improved in treated patients ($P < .001$). In general, superior results were documented in the HIFEM group as it reached improvement of electromyography parameters from 48% to 59% (electrical stimulation from 7% to 36%) and similarly the improvement of PFIQ-7 score by 57% (electrical stimulation by 32%).

Conclusion: This study documented that the HIFEM procedure was significantly more effective than electrical stimulation in treatment of PFD in postpartum women. Both the objective and subjective evaluation indicates more profound effects of magnetic stimulation. **Elena S, Dragana Z, Ramina S, et al. Electromyographic Evaluation of the Pelvic Muscles Activity After High-Intensity Focused Electromagnetic Procedure and Electrical Stimulation in Women With Pelvic Floor Dysfunction. Sex Med 2020;XX:XXX−XXX.**

Key Words: Electrical Stimulation; Electromyography; HIFEM Procedure; Pelvic Floor Dysfunction; Pelvic Floor Muscles

Received September 7, 2019. Accepted January 10, 2020.

[1]Hospital Lapino (MD Medical Group), Moscow, Russia;

[2]Faculty of Physical Education and Sport, Department of Anatomy and Biomechanics, Charles University, Prague, Czech Republic;

[3]Medical Faculty, Department of Obstetrics and Gynecology, RUDN University, Moscow, Russia

https://doi.org/10.1016/j.esxm.2020.01.004

INTRODUCTION

Electromyography (EMG) is a method frequently used for examination of electrical activity of muscle tissue. Although this technology is relatively new, it is assumed to be reliable and objective, while causing minimal or no discomfort to patients. Essentially, EMG uses the surface or intramuscular electrodes to record the intensity of signals which propagate in the muscle

fibers during the contraction because muscle tissue conducts electrical potentials similar to the nerves. Results of the measurements are expressed as a function of voltage over the time. Except single-fiber EMG,[1] measured values represent a sum of all signals originated from the muscle tissue of certain body area.[2–4]

Besides ultrasound,[5,6] magnetic resonance,[7] manometers,[8] dynamometers,[9] or simple palpation combined with observation,[10] surface EMG (sEMG) is one of the possible objective methods for monitoring resting level, strength, and endurance of the pelvic floor muscles (PFMs). The pelvic floor consists of 3 main compartments—anterior (bladder and urethra), middle (vagina and uterus), and posterior (rectum). Furthermore, there are morphologically complex multilayers of anatomical structures such as pelvic diaphragm (composed of levator ani and coccygeus muscles), urogenital diaphragm (composed of connective tissue, perineum, bulbospongiosus, and ischiocavernosus muscles), and urethral/anal sphincters. All of these tissues are arranged in the pelvic area and have multiple attachments to the surrounding structures.[11] Under normal circumstances, the PFM prevents multiple disorders such as incontinence (urinary/fecal), sexual dysfunction, or pelvic organ prolapse accompanied with pain and discomfort. However, the atrophy and relaxation of PFMs may promote manifestation of these heath issues, collectively referred as pelvic floor dysfunction (PFD),[10–12] occurring naturally with aging or as a consequence of childbirth.

Recording of sEMG in women who showed certain symptoms of PFD was reported previously by multiple authors. It has been found that EMG is a suitable method for investigation of PFM functioning among healthy subjects and women with signs of urinary incontinence or PFM weakness.[13–21] Despite the various protocols and electrode configurations used, in general, there is a clear relationship between the characteristics of the EMG signal and PFD. In comparison with the healthy and asymptomatic subjects, postmenopausal and even premenopausal women affected by some form of PFM impairment, show distinctively lower EMG values. The intensity of maximum voluntary contraction (MVC) is reduced because the PFMs are weakened and endurance of contraction and muscle activity during rest are affected as well.[13,14,18–20] Aside from sEMG, various subjective questionnaires (Pelvic Floor Disability Index, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, Pelvic Floor Impact Questionnaire, International Consultation on Incontinence Questionnaire - Vaginal Symptoms or Pelvic Floor Bother Questionnaire) were also used to document strengthening and reeducation of the PFM which helped patients to improve their symptoms.[22,23]

Besides the regular exercise,[24] the function of the weakened PFM can be enhanced by noninvasive PFM stimulation. Along with well-established electrical stimulation,[25,26] high-intensity focused electromagnetic (HIFEM) technology is being more frequently used in recent years.[27–29] Both technologies deliver electric currents into the pelvic floor to depolarize membranes of motoneurons to elicit action potential and achieve brain-independent muscle contractions when the action potential of sufficient strength reaches the neuromuscular junction.[30] However, despite the direct flow of electric charge through electrode-tissue surface, the HIFEM induces electrical currents selectively in the PFM by mechanism of electromagnetic induction.[31] As magnetic field passes any medium without attenuation of the energy, the induced contractions may be achieved at greater depths and intensities[32] to possibly provide better outcomes.

Based on the rationale mentioned previously, the aim of this study is to investigate and compare treatment outcomes of the HIFEM procedure and electrical stimulation in women suffering from PFD. The expected changes in PFM activity would be examined by subjective (questionnaire) and objective (sEMG) methods. The measured values will be compared with asymptomatic subjects.

MATERIALS AND METHODS

Patient's Recruitment Criteria

The inclusion criteria were specified as follows: women of age 18–45 years, who had vaginal delivery, and who already stopped lactation. There were 3 patient groups. The symptomatic patients who reported PFD symptoms related to weakened PFM as lower urinary tract or bowel symptoms (incontinence) and/or sexual dysfunction (dyspareunia, vaginal laxity, decreased sensitivity during intimacy, inability to achieve orgasm—anorgasmia), were randomly (2:1) divided into the G1 group treated by HIFEM and G2 group which received electrical stimulation. The third group G3 consisted of healthy postpartum patients, to obtain sEMG values of normal population. Exclusion criteria were presence of any metal implants or devices which include metal components, pregnancy, malignant tumor, history of surgical procedure in the pelvic region, presence of pelvic organ prolapse of stage II-IV as per the Pelvic Organ Prolapse Quantification classification, and all general contraindications for physiotherapy. Patients were asked to perform pregnancy test before the first treatment and then retest on a regular basis.

Ethical Considerations

This study was approved by the local ethics committee of Hospital Lapino (MD medical group). It complied with ethical principles stated in the Declaration of Helsinki, Convention on Human Rights and Biomedicine, and International Ethical Guidelines for Health-related Research Involving Humans, and it completely excludes impairment of patients' interests and damage to health. All of the subjects were informed about the potential risks and possible benefits of the study, and all participants provided written informed consent.

Treatment Protocol

Both intervention groups received 10 treatments in total addressing the stimulation of PFM. The G1 group was treated using a BTL EMSELLA (BTL Industries Inc, Boston, MA) device, which uses HIFEM technology for noninvasive PFM

stimulation and reeducation based on the principle of electromagnetic induction. The device consists of a generator connected to the chair where the stimulation coil is located. The coil emits focused magnetic field of intensities up to 2.5 Tesla, responsible for induction of muscle contraction up to depths of 10 cm. Each therapy with the BTL EMSELLA device lasted 28 minutes, and it was administered under the supervision of a skilled physician at the Lapino Hospital. Patients were seated in a chair, and the intensity of the stimulus was modulated on the scale of 0−100% (0−2.5 Tesla) in accordance with their feedback up to maximum tolerable threshold, when patients felt a strong muscle contraction but without pain or discomfort. All patients have achieved 100% intensity during the first or second procedure. Treatments with HIFEM were addressed 2−3 times per week for a duration of 4 weeks. The sessions were planned to suffice this interval as per the patient/device availability. 2 consecutive treatments were spaced at least 48 hours apart to prevent muscle fatigue.

The G2 group performed home-based and self-administered procedures with a BioBravo (MTR+ Vertriebs, GMBH, Germany) electrical stimulation device. First, the patients were comprehensively trained how to safely and effectively use a BioBravo stimulator. Then, they were instructed to finish treatments at home by repeating therapy every other day. The protocol of stimulation was identical for both groups because the settings of the BioBravo device have been adjusted to reflect those used by the BTL EMSELLA device. Finally, group G3 did not receive any treatment.

sEMG Measurements

The primary outcome of the study was to perform sEMG measurements to determine activation of the PFM in symptomatic and asymptomatic patients and to document the hypothesized changes caused by muscle strengthening. At first, by using a Myomed 632 myofeedback device (Enraf-Nonius B.V., Netherlands), the patients were instructed how to correctly perform contractions of the PFM without (voluntary) involving the muscles of the anterior abdominal wall and gluteal or hip region. When performing contractions, patients were lying in the supine position. During the examination, they were requested to repeat 3 specified PFM activations which consisted of the following: 5 short (quick flick) contractions at maximum intensity with an interval of 10 seconds, followed by sustained contraction and relaxation (both 10 seconds long, 5 repetitions) and finally the sustained contraction held as long as possible to determine PFM endurance.[33]

The sEMG recordings were performed by the Myomed 632 device at the baseline (all groups) and after the patient's last treatment (only G1 and G2). To isolate the signal originated in the PFM, 2 types of superficial electrodes were used: first was applied on the anterior abdominal area (served as reference), and the second (vaginal) electrode was mounted on the intravaginal probe. Neutral gel was always applied on the sensor introduced into the vagina. An experienced physiotherapist confirmed the correct placement of intravaginal probe and PFM contractions. Concurrent registration of muscular electric potential by using the vaginal and skin electrodes allowed differentiating PFM contractions. During the sEMG examination, myofeedback (in a form of graph) was displayed on the device's monitor and the external monitor unit which was additionally connected to the device to enlarge the graphic output. The sEMG measurements were performed automatically by the Myomed device, following the pattern of PFM activations described higher. These parameters were acquired for each patient during each visit: MVC, mean MVC, mean activity at rest/resting level (all in μV), and endurance of contraction (in seconds).

Standardized Questionnaire

The secondary outcome was to assess subjective changes in perception of PFD by the PFIQ-7. This standardized questionnaire was used to determine the impact of PFD on the patient's quality of life as it showed to be psychometrically valid and reliable in previous research.[34] Patients from groups G1 and G2 were given the PFIQ-7 at baseline and after the last treatment. Based on their answers, the PFIQ mean scores (on a scale from 0 = no distress to 300 = maximal distress) were calculated and compared against baseline and between the both groups.

Safety

The safety of treatments and sEMG measurements and possible adverse events (AEs) were monitored. Patients were also asked to report any signs of discomfort or pain during the therapies or caused by the positioning of the intravaginal electrode.

Statistical Analysis

All variables were checked for normality by the Kolmogorov-Smirnov test. Descriptive statistics were estimated by the sample mean with 95% confidence interval. The differences between groups were tested using analysis of variance test followed by Least Significant Difference post hoc tests. Levene's test of homogeneity of variance was run before analysis of variance to verify the equal variances in groups. Paired variables were tested by a student's t-test. All statistical tests were 2-tailed. Whole statistical analysis was conducted with Statistica v.6 (StatSoft Inc, Tulsa, OK), and the significance level was set as default to 0.05 (5%). Initially, the minimum sample size was verified by using Statistica software. At least 19 subjects must have been included in each of the 3 tested groups, to achieve a power of 80% with $\alpha = 5\%$.

RESULTS

Patient Group Characteristics

In total, 95 patients were recruited during 2018 and early 2019 in accordance with the specified criteria and current state of patients in the clinic: G1 (n = 50), G2 (n = 25), and G3 (n = 20). See Table 1 for detailed characteristics of patient groups. All of the recruited patients from the G1 and G2 groups finished a prescribed

Table 1. Characteristics of patient groups at the time of recruitment (mean followed by 95% confidence interval)

Group	Age (years)	BMI ($kg \cdot m^{-2}$)	Vaginal deliveries	PFD symptoms (% of patients)
G1 (n = 50)	31.12 (1.52)	23.27 (0.76)	1.76 (0.22)	Urinary incontinence (74%); decreased sexual desire (36%); decreased sensitivity during intimacy (70%); dyspareunia (26%); hypo/anorgasmia (52%)
G2 (n = 25)	31.96 (3.20)	24.32 (3.70)	1.56 (0.27)	Urinary incontinence (72%); decreased sexual desire (44%); decreased sensitivity during intimacy (44%); dyspareunia (24%); hypo/anorgasmia (40%)
G3 (n = 20)	27.20 (2.02)	22.40 (1.27)	1.25 (0.21)	-

BMI = body mass index; PFD = pelvic floor dysfunction.

number of treatment sessions. 8 patients who reported zero PFIQ-7 score at the baseline (G1 = 5, G2 = 3) were excluded from the questionnaire evaluation. No AEs were observed in regard to the delivered treatments or sEMG measurements. Subjects seldom reported only mild discomfort when recording sEMG using an intravaginal electrode.

Quantification of the EMG Signal

The results of sEMG measurements are summarized in Table 2. In general, there are significant differences between the symptomatic groups in comparison with healthy patients. On the other hand, the changes in the measured values after the HIFEM or electrical stimulation were highly statistically significant ($P < .001$) in comparison with the baseline, showing that stimulation of the PFM modifies the muscle (electrical) activity.

At baseline, measured peak intensity of the MVC signal was significantly higher in healthy patients by approximately 22 μV on average, when compared with that in the G1 or G2 group. At the same time, there was no change between the intervention groups. At the end of study, the G1 group showed significantly higher EMG values than the G2 group ($P < .001$), reaching an average change of 10.58 μV (57.29%) and 1.44 μV (7.34%), respectively. Although the HIFEM treatment considerably increased the PFM activity, the G1 group still showed lower values than control.

Similar findings were observed in case of average MVC. As expected, the average MVC magnitudes are lower in each group. The more profound increment was also observed in the G1 group (6.65 μV, 58.69%) compared with the modest increase of the G2 group (0.91 μV, 6.81%). There were also significant differences between G1 and G2 groups after treatments ($P < .05$). Despite the observed improvement, asymptomatic subjects still showed greater EMG values.

Interestingly, the examination of muscle activity at rest revealed divergent tendencies. Initially, only the G1 group showed significantly different (higher) values from control ($P < .05$) while after the last therapy, the G1 average resting level decreased at the level of G3 (2.08 μV and 1.90 μV, respectively). Conversely, the average resting level of the G2 group had risen from 2.42 μV to 3.94 μV. In conclusion, the G2 subjects manifested significantly higher EMG values than the control and G1 group at the end of study ($P < .001$).

In terms of endurance, there were observed significant differences between both the symptomatic groups and either control group at the baseline and after the treatments (see Table 2). The measurement of the G3 group showed that healthy patients were able to hold contraction of the PFM on average for 62.25 s. Furthermore, we observed a significant increase in endurance of PFM contraction by 48.24% in the G1 group because the patients have been able to hold a contraction by 13.44 s longer after their treatments, reaching 41.30 s in total. The G2 group improved by 36.26%, and PFM contraction was prolonged on average by 6.60 s.

Pelvic Floor Impact Questionnaire—Short Form 7

Patient's subjective evaluation is summarized in Table 3 and Figure 1. The minimal variation in the baseline score of both symptomatic groups was insignificant. Nonetheless, after the last treatment, there was an observed significant difference in the PFIQ score between the G1 and G2 group ($P = .01$). Although both treatment modalities resulted in highly significant subjective improvement, the patients treated with HIFEM experienced greater outcomes. In addition, 16 patients (35.56%) from the G1 group reached a score of zero after the HIFEM treatments (meaning 100% improvement against the baseline). Contrary to this, only 3 patients (12.00%) from the G2 group, who underwent electrical stimulation, reported zero score at their last visit.

The shift in PFIQ scores is visualized in Figure 1. As can be seen, the relative frequency of scores was remarkably changed in the G1 group while almost 90% of patients fall into the low-score categories (0—10 or 10—20) after the treatments. In addition, the scores more than 50 were entirely eliminated from patient's responses. The G2 group showed only minimal changes in distribution of patient's PFIQ scores, corresponding to a moderate average improvement of 5.15 points (see Table 3).

DISCUSSION

Our examination of PFM electrogenesis in patients, who showed signs of PFD, revealed a significant reduction of the

Table 2. Results of the sEMG measurements at the baseline and after the last therapy for both treated groups (G1 and G2) and control subjects (G3) presented as mean followed by 95% confidence interval in brackets

Group	Peak MVC (μV)		Average MVC (μV)		Resting level (μV)		Endurance (s)	
	Baseline	After	Baseline	After	Baseline	After	Baseline	After
G1 (n = 50)	19.49† (2.31)	30.06†,*** (3.75)	11.33† (1.54)	17.99†,* (2.50)	3.83†,* (0.82)	2.08 (0.38)	27.86†,** (4.17)	41.30†,*** (5.21)
G2 (n = 25)	19.56† (2.93)	21.00† (2.82)	13.39† (2.46)	14.30† (2.42)	2.42 (0.45)	3.94†,*** (0.60)	18.20† (2.85)	24.80† (3.12)
G3 (n = 20)	41.96 (2.51)	-	32.69 (1.88)	-	1.90 (0.63)	-	62.25 (3.68)	-

EMG = electromyography; MVC = maximal voluntary contraction; sEMG = surface electromyography.
Significantly different results ($P \leq .002$) against control are depicted by† and * denotes significantly higher EMG values for comparison of G1 and G2.
*$P < .05$, **$P < .01$, ***$P < .001$.

generated EMG signal in comparison with the asymptomatic patients at baseline (MVC, mean MVC, and endurance). The results of intervention groups G1 and G2 denote that noninvasive PFM strengthening is able to positively influence the activity of the PFM. As seen in Table 2, the sEMG measurements obtained after therapies with the BTL EMSELLA device or electrical stimulation showed increased values of maximum possible voluntary contraction and endurance. It suggested that at the end of study, patients were capable of stronger and more complex PFM contractions resulting in reduction of PFD symptoms (whether incontinence or sexual based), demonstrated also by significant decrease in the PFIQ-7 score.

In contrast to sEMG measurements, which demonstrated considerable PFM weakening in the G1 and G2 group at baseline, the PFIQ resulted in relatively low scores in both groups. We attribute this to perhaps a less specific grading system of the PFIQ, when evaluating patients who showed a various range of PFD-related symptoms of different severity. In future studies, it might be beneficial to focus on the evaluation of particular patient's symptoms by using condition-specific questions evaluated by a visual analogue scale or 5- to 7-point Likert scale for instance to enhance grading possibilities.

Comparison of the Magnetic and Electrical Stimulation

Significantly, greater improvement in EMG values was observed in the G1 group, treated by HIFEM technology. In comparison with electrical stimulation, the BTL EMSELLA device showed to be substantially more effective in restoration of muscle strength as the MVC, mean MVC, and endurance parameters uniformly increased ranging from 48 to 59% after HIFEM treatments. On contrary, electrical stimulation induced only mild changes in MVC (7.34%) or mean MVC (6.81%) while reaching mild to moderate improvement (36.26%) of endurance.

The sEMG measurements coincide with the results of the PFIQ. Patient's subjective evaluation showed more pronounced improvement in the G1 group (57.16%) than in the G2 group (32.18%), which corresponds to the improvement rate in EMG values. The HIFEM procedure also resulted in substantial reduction of high PFIQ scores after the last therapy session (see Figure 1).

PFM Electrical Activity and sEMG Measurements

Given the specific patient group and scarce evidence in literature, control group G3 was established to obtain normative EMG values, valid for the studied sample. In general, herein presented results coincide with the previously published findings. It has been documented by numerous authors[13–15,17,18,20] that women who are suffering from PFD show lower MVC and endurance values because of the impairment of the PFM. By the proper stimulation of the PFM, patients are able to produce

Table 3. Results of the PFIQ-7 for the both treated groups (G1 and G2) presented as mean followed by 95% confidence interval in brackets

	PFIQ-7 average score		Improvement		
Group	Baseline	After	Absolute	Relative	*P*-value
G1 (n = 45)	24.68 (6.81)	9.67 (3.38)	15.01	57.16%	<.001
G2 (n = 22)	26.04 (8.69)	20.89 (8.04)	5.15	32.18%	<.001
P-value	.81	.01	-	-	-

Absolute and relative differences against baseline were calculated.

greater voluntary contractions for longer durations. In addition, the muscle activity at rest is influenced by the PFD as the PFMs are less electrically active. However, the evaluation of the PFM resting level revealed significant differences between both modalities in our study. Although the G1 group after treatments reached similar EMG values as healthy population, patients from group G2 showed altered muscle activation with relatively high electromyogenesis at rest (3.94 μV on average, see Table 2). This indicates that G2 patients cannot properly relax their PFM after treatments because they are not able to isolate and control the appropriate muscle activation patterns, which was then reflected by the lower MVC amplitudes. The correct activation pattern during PFM contraction is associated with increased activation of the PFM and lower transverse abdominal wall with markedly less activation of the upper abdominal and chest wall. The inappropriate activation refers to an increased level of abdominal and chest wall activation while PFM activation decrease,[16] resulting in lessened strength (MVC amplitude) of contraction.

Showing high test-retest reliability,[13,14] the sEMG measurement is a useful tool for detection of PFM activity. For recording of PFM electrical activity, we used an intravaginal electrode with a large surface to obtain EMG signals of sufficient amplitude with high sensitivity.[2,3] Fortunately, the PFM encompasses only a partial amount of subcutaneous tissue which may possibly further attenuate the amplitude of EMG.[35] To prevent any systematic error during measurements, insertion and the position of the measuring electrode was supervised by the skilled physiotherapist. The normalization of data was not considered necessary as we assessed the same muscle group during one measurement session without removal of the active electrode.[3]

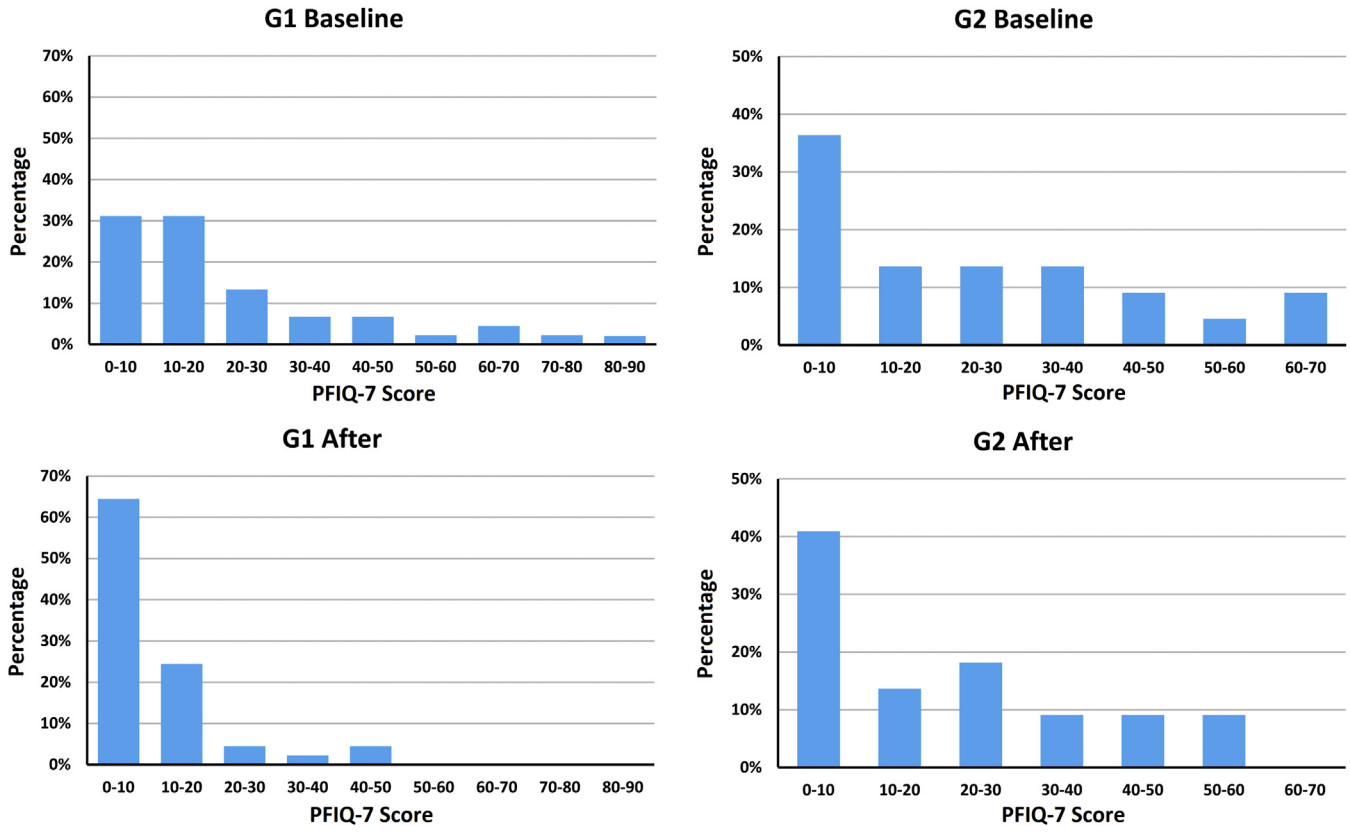


Figure 1. The comparison of PFIQ-7 scores per group and appointment. The relative frequencies of scores reported by the patients of group 1 (G1) and group 2 (G2) are plotted in the graphs. There is a substantial shift toward the lower PFIQ-7 scores in the G1 group after the treatments.

The selectivity of measured values was accomplished by the reference electrode, placed on the abdomen. The signal obtained by the abdominal electrode was subtracted from the recording site to eliminate common components, and received EMG values thus represented summation activity of the whole PFM. To achieve an even greater degree of selectivity, the specific design of the vaginal electrode is required. For instance, Voorham-van et al[14] have been able to successfully measure and compare the activity of selected pelvic muscles (pubococcygeus, puborectalis, bulbospongiosus and ischiocavernosus) by using experimental intravaginal probe with a matrix of 24 electrodes.

Study Limitations

Still, a sEMG measurement faces various challenges. The nature of the recorded electrical signal (amplitude, frequency or noise) is influenced by several factors, such as composition of measured muscle along with structure and position, or placement of electrodes.[35] The core and skin temperature[36] or different humidity of measured environments may also influence the signal parameters. Because of the moisture and temperature within the vaginal lumen, it is difficult to ensure identical conditions at each visit during the intravaginal measurements. Especially, the moisture between the electrode and tissue may lead to decreased EMG amplitude. Furthermore, the electrode positioning is crucial for reliability of sEMG measurement. Therefore, the operator must insert the intravaginal probe consistently with respect to the measured muscles as the power of the signal is affected by the electrode orientation.[37] In addition, the intravaginal probes should be designed in such a way to minimize any impact on the PFM by its insertion to avoid cross talk and motion artifacts.[14]

Indisputably, the appropriate planning of treatments is essential to achieve desired results. Unlike the electrical stimulation, HIFEM is relatively new technology which is still being investigated to some extent. In our study, the HIFEM treatments were administered at least 48 hours apart (2−3 per week) to maximize treatment outcomes but also to avoid muscle fatigue, caused by overtreatment of the PFM, as the therapy with maximum settings produces intense muscle contractions. Presumably, the results would differ because of changes of the treatment frequency; however, this should be verified by future studies.

CONCLUSION

Electromyographic measurement of PFM activity proved to be a valid method for examination of patients with PFD (suffering from urinary incontinence and/or accompanied with sexual dysfunction) treated with HIFEM and electrical stimulation. Surface EMG of the PFMs showed more profound muscle activation after HIFEM treatments along with improved relaxation and enhanced endurance. As well, the PFIQ indicates greater effect of HIFEM procedure based on the significant change of score reported by patients. Documented outcomes imply that the HIFEM procedure is substantially more effective in restoration of PFM strength and treatment of PFD when compared with the electrical stimulation, applied correspondingly in postpartum women.

Corresponding Author: Silantyeva Elena, MD, Hospital Lapino MD Medical Group, 111, Lapino village, Odintsovo District 143081, Moscow Region, Russia. Tel: +7-916-060-20-00; Fax: +7-495-433-73-79; E-mail: essdoktor@yandex.ru

Conflict of interest: None.

Funding: None.

STATEMENT OF AUTHORSHIP

Category 1

(a) Conception and Design
Silantyeva Elena

(b) Acquisition of Data
Silantyeva Elena; Zarkovic Dragana; Soldatskaia Ramina; Astafeva Evgeniia

(c) Analysis and Interpretation of Data
Silantyeva Elena; Astafeva Evgeniia; Mekan Orazov; Soldatskaia Ramina

Category 2

(a) Drafting the Article
Soldatskaia Ramina; Astafeva Evgeniia

(b) Revising It for Intellectual Content
Silantyeva Elena; Zarkovic Dragana; Mekan Orazov

Category 3

(a) Final Approval of the Completed Article
Silantyeva Elena

REFERENCES

1. Selvan VA. Single-fiber EMG: a review. **Ann Indian Acad Neurol 2011;14:64-67.**
2. Bø K, Sherburn M. Evaluation of female pelvic-floor muscle function and strength. **Phys Ther 2005;85:269-282.**
3. Ribeiro AM, Mateus-Vasconcelos ECL, Silva TD da, et al. Functional assessment of the pelvic floor muscles by electromyography: is there a normalization in data analysis? A systematic review. **Fisioter e Pesqui 2018;25:88-99.**
4. Raez MBI, Hussain MS, Mohd-Yasin F. Techniques of EMG signal analysis: detection, processing, classification and applications. **Biol Proced Online 2006;8:11-35.**
5. Salsi G, Cataneo I, Dodaro MG, et al. Three-dimensional/four-dimensional transperineal ultrasound: clinical utility and future prospects. **Int J Womens Health 2017;9:643-656.**
6. Braekken IH, Majida M, Engh ME, et al. Test-retest reliability of pelvic floor muscle contraction measured by 4D ultrasound. **Neurourol Urodyn 2009;28:68-73.**

7. García del Salto L, de Miguel Criado J, Aguilera del Hoyo LF, et al. MR imaging—based assessment of the female pelvic floor. **RadioGraphics 2014;34:1417-1439.**
8. Angelo PH, Varella LRD, de Oliveira MCE, et al. A manometry classification to assess pelvic floor muscle function in women. **PLoS One 2017;12.**
9. Chamochumbi CCM, Nunes FR, Guirro RRJ, et al. Comparison of active and passive forces of the pelvic floor muscles in women with and without stress urinary incontinence. **Braz J Phys Ther 2012;16:314-319.**
10. Faubion SS, Shuster LT, Bharucha AE. Recognition and management of nonrelaxing pelvic floor dysfunction. **Mayo Clin Proc 2012;87:187-193.**
11. Strohbehn K. Normal pelvic floor anatomy. **Obstet Gynecol Clin North Am 1998;25:683-705.**
12. Pemberton J, Swash M, Henry MM, eds. The pelvic floor: its function and disorders. London: Saunders; 2002.
13. Koenig I, Luginbuehl H, Radlinger L. Reliability of pelvic floor muscle electromyography tested on healthy women and women with pelvic floor muscle dysfunction. **Ann Phys Rehabil Med 2017;60:382-386.**
14. Voorham-van der Zalm PJ, Voorham JC, van den Bos TWL, et al. Reliability and differentiation of pelvic floor muscle electromyography measurements in healthy volunteers using a new device: the multiple array probe leiden (MAPLe). **Neurourol Urodyn 2013;32:341-348.**
15. Zhang Q, Wang L, Zheng W. Surface electromyography of pelvic floor muscles in stress urinary incontinence. **Int J Gynecol Obstet 2006;95:177-178.**
16. Thompson JA, O'Sullivan PB, Briffa NK, et al. Altered muscle activation patterns in symptomatic women during pelvic floor muscle contraction and Valsalva manouevre: altered Muscle Activation Patterns. **Neurourol Urodyn 2006;25:268-276.**
17. Smith MD, Coppieters MW, Hodges PW. Postural response of the pelvic floor and abdominal muscles in women with and without incontinence. **Neurourol Urodyn 2007;26:377-385.**
18. Sapsford RR, Richardson CA, Maher CF, et al. Pelvic floor muscle activity in different sitting postures in continent and incontinent women. **Arch Phys Med Rehabil 2008;89:1741-1747.**
19. Pereira LC, Botelho S, Marques J, et al. Are transversus abdominis/oblique internal and pelvic floor muscles coactivated during pregnancy and postpartum? **Neurourol Urodyn 2013;32:416-419.**
20. Lauper M, Kuhn A, Gerber R, et al. Pelvic floor stimulation: what are the good vibrations? **Neurourol Urodyn 2009;28:405-410.**
21. Junginger B, Baessler K, Sapsford R, et al. Effect of abdominal and pelvic floor tasks on muscle activity, abdominal pressure and bladder neck. **Int Urogynecol J 2010;21:69-77.**
22. Gagnon L-H, Boucher J, Robert M. Impact of pelvic floor muscle training in the postpartum period. **Int Urogynecol J 2015;27:255-260.**
23. Zuchelo LTS, Bezerra IMP, Da Silva ATM, et al. Questionnaires to evaluate pelvic floor dysfunction in the postpartum period: a systematic review. **Int J Womens Health 2018;10:409-424.**
24. Radzimińska A, Strączyńska A, Weber-Rajek M, et al. The impact of pelvic floor muscle training on the quality of life of women with urinary incontinence: a systematic literature review. **Clin Interv Aging 2018;13:957-965.**
25. Correia GN, Pereira VS, Hirakawa HS, et al. Effects of surface and intravaginal electrical stimulation in the treatment of women with stress urinary incontinence: randomized controlled trial. **Eur J Obstet Gynecol Reprod Biol 2014;173:113-118.**
26. Schreiner L, Santos TG dos, Souza ABA de, et al. Electrical stimulation for urinary incontinence in women: a systematic review. **Int Braz J Urol 2013;39:454-464.**
27. Samuels JB, Pezzella A, Berenholz J, et al. 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. **Lasers Surg Med 2019;51:760-766.**
28. Hlavinka T, Turcan P, Bader A. The use of HIFEM technology in the treatment of pelvic floor muscles as a cause of female sexual dysfunction: a multi-center pilot study. **J Womens Health Care 2019;08.**
29. Alinsod R, Vasilev V, Yanev K, et al. Hifem technology a new perspective in treatment of stress urinary incontinence. **Lasers Surg Med 2018;50:S4-S56.**
30. Omar A, Marwaha K, Bollu PC. Physiology, neuromuscular junction. In: StatPearls. Treasure Island, FL: StatPearls Publishing; 2019; Available at: http://www.ncbi.nlm.nih.gov/books/NBK470413/. Accessed December 5, 2019.
31. Faraday MV. Experimental researches in electricity. **Philos Trans R Soc Lond 1832;122:125-162.**
32. Kanjanapanang N, Chang K-V. Peripheral magnetic stimulation (transcutaneous magnetic stimulation). In: StatPearls. Treasure Island, FL: StatPearls Publishing; 2019; Available at: http://www.ncbi.nlm.nih.gov/books/NBK526087/. Accessed May 29, 2019.
33. Mehler B, Larsson KM. Electromyographic (EMG) biofeedback in the treatment of pelvic floor disorders. In: Mostofsky DI, ed. The handbook of behavioral medicine. Oxford, UK: John Wiley & Sons, Ltd; 2014. p. 313-338.
34. Barber MD, Kuchibhatla MN, Pieper CF, et al. Psychometric evaluation of 2 comprehensive condition-specific quality of life instruments for women with pelvic floor disorders. **Am J Obstet Gynecol 2001;185:1388-1395.**
35. De Luca CJ. The use of surface electromyography in biomechanics. **J Appl Biomech 1997;13:135-163.**
36. Coletta NA, Mallette MM, Gabriel DA, et al. Core and skin temperature influences on the surface electromyographic responses to an isometric force and position task. **PLoS One 2018;13:e0195219.**
37. Basmajian JV, Luca CJD. Muscles alive: their functions revealed by electromyography. Subsequent edition. Baltimore: Williams & Wilkins; 1985.

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

ABSTRACT

Background: Post-prostatectomy incontinence (PPI) is a common and bothersome side effect of the surgery which may be persistent. Aim of this pilot study is to document the change in quality of life (QoL) of subjects with PPI treated by High-Intensity Focused Electromagnetic (HIFEM) procedure.

Materials and methods: Ten male subjects (72.90±3.90 years) with history of prostatectomy accompanied by persistent PPI were recruited. They received six 28-minute HIFEM treatments spaced two treatments per week. Change in subject's QoL was monitored by using standardized King's Health Questionnaire (KHQ) at the baseline, after the last therapy, at 1 month, and 3 months. The usage of absorbent pads was assessed by 24-hour Pad Usage questionnaire. Data was statistically analyzed and tested for normality (α=5%).

Results: All patients showed improvement of QoL after HIFEM treatments. KHQ score decreased significantly in both parts of questionnaire (30.8 points in Part I, P=0.002; 107.5 points in Part II, P=0.001) revealing that subjects improved most in the domains: incontinence impact (23.3 points; P=0.01), social limitations (21.1 points; P=0.01), emotions (18.9 points; P<0.001), role limitations (18.3 points; P=0.03), and sleep/energy (13.3 points; P=0.04). All of the differences in domain scores exceeded the minimally clinically important difference of 5 points. The 1-month and 3-month data showed further improvement in subject's QoL. All ten subjects were using absorbent pads at the baseline. Post-treatment, they reported average reduction of 1.0 absorbent pad per day. Also, two subjects were pad free after the last therapy. HIFEM procedure was safe and no adverse event was found.

Conclusion: The first use of HIFEM procedure for the treatment of PPI in men showed that HIFEM can significantly improve QoL immediately after the last treatment and this improvement may be sustained. In future research, it is necessary to identify longevity of achieved outcomes.

INTRODUCTION

Surgical removal of prostate referred as radical prostatectomy is one of the most common therapeutic options for patients with localized prostate cancer[1–3]. Despite the latest advancements in surgical techniques and therapeutic approaches, still post-prostatectomy incontinence (PPI) is a commonly reported side effect of the operation with prevalence reaching up to 60%[2]. Although patients may recover from PPI in one year post surgery, as much as 65% of them continue to experience incontinence symptoms beyond 12 months[4,5].

During surgery the prostatic segment of urethra is being removed with occasional intraoperative damage to intrinsic and striated urethral sphincters along with impairment of detrusor contractility, triggering the PPI[1,6,7]. Urodynamic examination revealed that vast majority of incontinent men after prostatectomy tend to describe symptoms consistent with stress urinary incontinence (SUI)[8]. There are also several risk factors which increase the subjects predisposition to develop PPI, including pre-existing abnormalities of bladder function, high body mass index, and advancing age[2,9].

PPI is a clinically significant and distressing condition. It has a high impact on quality of patient's life (QoL)[3], negatively affects mental health and subsequently leads to social isolation[10]. Nevertheless, due to the similar etiology of PPI and SUI, the non-surgical strengthening of pelvic floor muscles (PFM) may be effectively used to recover subject's continence and self-esteem.

Continence in men depends on the contribution of urethral constriction by striated muscles which maintains its activation during urine storage and prevents urine leakage when intra-abdominal pressure is suddenly raised during physical activities[6]. To enhance muscular control of urinary incontinence (UI), patients are recommended to perform pelvic floor muscle training (PFMT) by teaching an accurate voluntary PFM contractions timed against increases in intra-abdominal pressure[2]. However, the conventional PFMT faces the difficulty to selectively engage the PFM and patients may not be able to sustain the intensity of contractions.

We hypothesized that High-Intensity Focused Electromagnetic (HIFEM) procedure may be a promising alternative for a non-invasive PPI treatment. It utilizes time-varying magnetic fields of great intensities which selectively targets neuromuscular tissue to induce supramaximal PFM contractions. In contrast to voluntary contractions, the supramaximal contractions are of higher tension and they can be easily sustained, therefore the muscles are encouraged to improve its strength and function. The efficacy of HIFEM procedure for UI treatment and QoL changes in women has been established by the recent research[11–14], nonetheless its effectiveness in men is not clear yet.

The aim of this pilot study is to document changes in quality of life following HIFEM procedure in male population suffering from persistent PPI.

MATERIALS AND METHODS

Ten elderly men with average age of 72.90±3.90 years were recruited. All of them had a history of radical prostatectomy (2014-2017) accompanied with continuous PPI symptoms. At the time of enrollment, they were examined for medical history and eligibility with inclusion/exclusion criteria listed in the manual of investigated device. The study was carried out with respect to generally accepted ethical standards stated in Declaration of Helsinki and all subjects signed informed consent prior to the treatments.

In the course of three weeks the subjects were required to undergo six 28-minute HIFEM procedures (2 sessions per week). Treatments were performed over the pelvic area by utilizing EMSELLA device (BTL Industries Inc., Boston, MA; see Figure 1), capable of inducing supramaximal PFM contractions. EMSELLA uses flat spiral coil to generate HIFEM fields which may be modulated according to the patient's tolerability on the scale from 0-100% (2.5 Tesla). As the proper positioning is necessary to maximize therapy outcomes, subject's posture was supervised by the therapist and verified by using device's positioning system to achieve optimal PFM contractions.

Figure 1: Subject device. The spiral coil is embedded in the center of the therapeutic chair and connected to the main unit which supplies the whole system with power and allows operator to adjust therapy settings.

The evaluation of change in subject's QoL was assessed by the standardized King's Health questionnaire (KHQ, Part I and Part II) and 24-hour Pad Usage questionnaire at baseline and after completion of the treatments. The 1-month and 3-month follow-up visits have been scheduled as optional. Subjects were monitored throughout the whole study for occurrence of any adverse events.

Obtained results were compared to baseline and statistically analyzed by two-tailed paired t-test with level of significance set as 5%. Normality of data was verified by the Shapiro-Wilks test for normality.

RESULTS

All subjects successfully finished the treatments while three subjects completed also the 1-month and 3-month non-mandatory visits. The KHQ showed significant improvement in QoL of all treated patients. The total baseline KHQ score was significantly reduced from 426.9±117.5 to 288.6±133.4 points. The improvement was seen in both parts of questionnaire. Score of Part 1 (general health perception and incontinence impact) decreased on average from 114.2±24.2 to 83.3±26.4 points (-27.0%; P=0.002) post treatment, whereas Part II (role limitations, physical limitations, personal relationships, emotions and sleep/energy, severity measures) showed even more pronounced improvement from 312.8±98.1 to 205.3±93.9 points (-34.4% P=0.001).

The change in score divided according the particular KHQ domains is shown in Figure 2. Detailed analysis revealed that subjects improved most in sleep/energy domain (-13.3 points, 53.3%; P=0.04), emotions (-18.9 points, 42.5%; P<0.001) and social limitations domain (-21.1 points, 42.2%; P=0.01) which indicated a significant shift in subject's QoL. The greatest absolute improvement in score was observed in the incontinence impact domain, as subjects reported reduction of 23.3 points (-30.4%; P=0.01). Also, the role limitations domain, which refers to limitations of daily activities, showed substantial improvement of 18.3 points (31.4%; P=0.03). In general, all of the differences in domain scores exceeded the minimal clinically important difference (MCID) of 5 points, suggested by Kelleher et al[15].

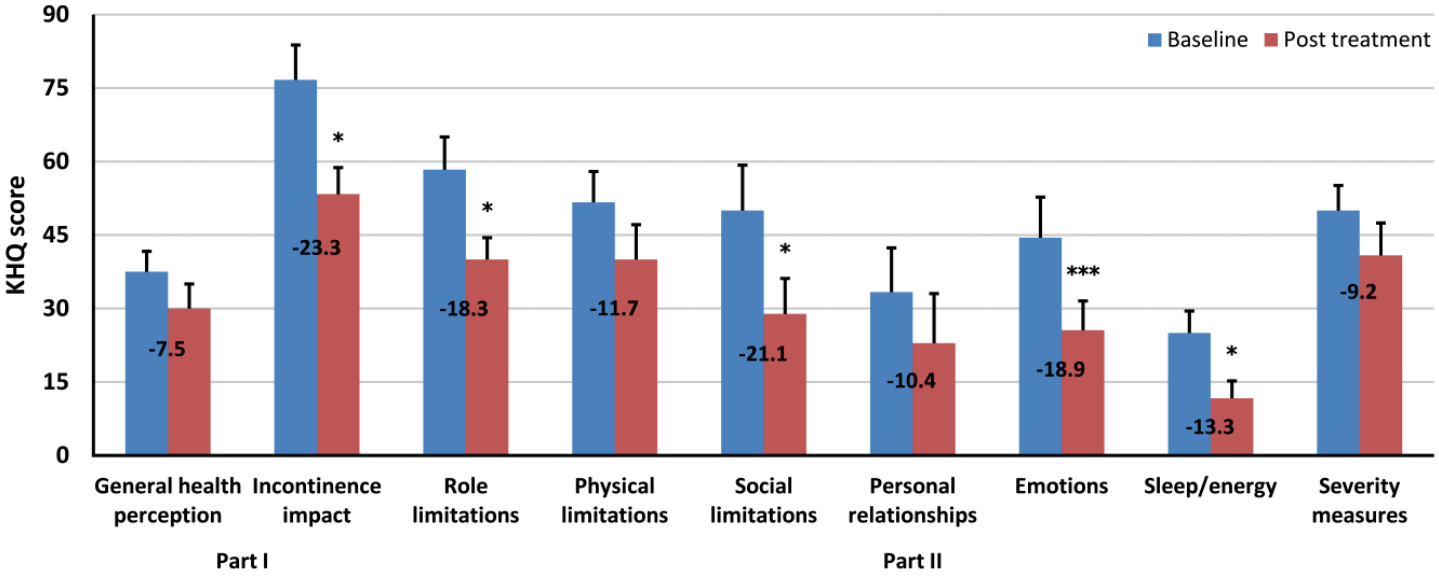


Figure 2: Difference in mean KHQ score achieved in particular KHQ domains (mean ± standard error). Maximum score of each domain is 100 points. Lower scores indicate patient wellbeing and higher scores mean that the QoL is severely affected by the PPI. The statistical significance of difference in score is highlighted by the asterisk (*P<0.05; ***P<0.001).

Further improvement was seen at 1 month in those subjects (N=3) who referred to their follow-up visits (see Table 1). Documented results suggest that effect of HIFEM procedure may improve in time as the examined patients showed a decrease in Part I and Part II scores at 1 month. Subject No. 5 even reached zero score in Part I of the KHQ, meaning that incontinence did not affect his life and he also rated his health condition as "*very good*". Results of subject No. 5 persisted up to 3 months followed with noticeable improvement in Part II of the questionnaire, leading to overall score of 16.7 points (reported in physical limitations domain). Similar tendency was observed in subject No. 8, who also showed continuous improvement of QoL at 1 month which persisted at 3 months. Nonetheless, subject No. 6 was not able to sustain treatment-induced changes at 3 months and reported slight elevation of score in both parts of KHQ, since he returned to his post-treatment values.

24-hour Pad Usage questionnaire revealed that all of the subjects were using absorbent pads at baseline with an average use of 2.5 pads per day. In addition, four subjects reported they wore pads at night due to the nocturia. After the treatments the whole patient group reduced pad usage on average by 1.0 pad (1.5 pads per day on average). Furthermore, two subjects reported to be pad free and two out of four subjects achieved complete reduction of pads used during the sleep.

DISCUSSION

Post-prostatectomy incontinence considerably compromises men's quality of life. As health-related QoL is a multidimensional construct, it involves all aspects of human wellbeing including health status in general, physical activities, psychological state and social interactions[16]. Therefore, many individuals are seeking for an effective treatment options, hoping that they no longer have to worry about the inability to control their bladder during their day-to-day activities. This study documented that HIFEM procedure may be effectively used for treatment of PPI.

The present results showed clinically significant decrease in all KHQ domains which also corresponds with reduced usage of absorbent pads. The procedure was safe and no adverse event was documented.

Previous studies have described that impact of PPI can be reduced by PFM strengthening by the means of pelvic floor muscle exercises or electromagnetic stimulation[2,5]. Majority of the papers studied the evolution of UI and QoL in the 12-month post-treatment period or evaluated effects of pre-operative PFMT on male continence as the PPI is iatrogenic, therefore predictable and perhaps preventable[17]. Although it was found that patients with stronger PFM need less time to be continent after the surgery, and at the same time they report higher QoL levels, the evidence is still limited due to the lack of randomized controlled trials[2,18,19]. Also the exercise protocols may possibly fail to properly target the muscles that control continence in men or do not target the aspect of function that needs to be trained[6].

ID	Part I score (range 0-200)				Part II score (range 0-700)			
	Baseline	Post treatment	1 month	3 months	Baseline	Post treatment	1 month	3 months
5	83.3	33.3	0.0	0.0	244.4	83.3	41.7	16.7
6	116.7	116.7	58.3	91.7	233.3	194.4	186.1	222.2
8	91.7	83.3	58.3	58.3	275.0	202.8	113.9	113.9

Table 1: KHQ score (Part I and Part II) of subjects at 1 month and 3 months.

The PPI is associated with impaired functioning of striated urethral sphincter, pubovisceralis, bulbocavernosus, and levator ani muscles which cannot fully compensate the prostate removal, thus control urethral pressure and prevent descent from excessive abdominal pressure[20,21]. Therefore, it is hypothesized that optimal treatment strategy should aim to target these particular muscles. HIFEM procedure utilizes non-invasive and painless electromagnetic stimulation of pelvic floor. It selectively activates motor neurons[22] that innervate striated muscles. The high repetition rate of stimulation forces muscles to perform intense supramaximal contractions which lead to enhanced strength, endurance[23], and re-education. Due to the great penetration, depth, and zero attenuation of magnetic field in biological tissues[24]; the HIFEM procedure is able to effectively stimulate the muscles involved in the male continence mechanism, treat incontinence and consequently improve QoL.

This study documented significant improvement in QoL after only six HIFEM treatments. Presumably, adding additional two to four treatments according to the severity of subject's symptoms may result into more noticeable improvement. At baseline subjects achieved highest KHQ score in the incontinence impact domain, followed by the role limitations, physical limitations, social limitations, emotions and severity measures domains, which in general corresponds to severe post-operative UI[19]. The greater is the urinary loss, the greater impact it has on these domains of QoL. As the severity of incontinence symptoms decreased after the treatments, patients showed uniform improvement in all KHQ domains accompanied with a reduced number of pads used. The examination showed that elderly subjects with persistent PPI appreciated that they were less limited in their social life (being able to visit relatives without being afraid of urine leakage) or when performing daily/physical activities and they also slept better. Emotions domain showed that patients did not feel depressed due to the PPI after the treatments and in general, they reported a more pro-active life style.

We see the strength of our study in detailed analysis of KHQ which is complex, highly reliable, and validated questionnaire that covers important aspects of patient's QoL. On the other hand there are several limitations in this pilot research. The sample size of ten subjects is relatively small and enables only basic statistical analysis. Furthermore, this study lacks solid follow-up data, since only three subjects referred to their 1-month and 3-month follow-ups. In future studies it would be mandatory to observe prolonged effect of HIFEM procedure on QoL similarly to Yamanishi et al[19], as the individual results of subjects 5,6, and 8 suggest that outcomes may considerably improve over time. This coincides with the findings of Frontera et al[25], who observed significant and continuous muscle changes in an elderly man in a 12-week period (approximately 3 months) after the strength training

program. Results may be also influenced due to the specific patient group consisting of elderly men (average age of almost 73 years), where muscle response is mediated through a combination of hypertrophy and neural adaptation[26], and strength gains (although substantial), may be less than in young individuals. Moreover, the male urinary incontinence is being often associated with erectile dysfunction[27]. Since sexual function is also an integral part of QoL, later studies should consider assessing its changes as well.

CONCLUSION

This pilot study documented the first use of HIFEM procedure for the treatment of persistent post-prostatectomy incontinence in men. The achieved results imply that HIFEM is able to significantly improve quality of life of incontinent elderly men, and this improvement may be sustained. Future studies should verify documented outcomes and determine the longevity of achieved changes to establish HIFEM as a convenient first-line modality for treatment of male incontinence.

CONFLICT OF INTEREST

The authors have declared they have no conflicts of interest.

REFERENCES:

1. Singla N, Singla AK. Post-prostatectomy incontinence: Etiology, evaluation, and management. *Türk Ürol DergisiTurkish J Urol*. 2014;40(1):1-8.
2. 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.
3. Cooperberg MR, Master VA, Carroll PR. Health Related Quality of Life Significance of Single Pad Urinary Incontinence Following Radical Prostatectomy. *J Urol*. 2003;170(2):512-515.
4. Flynn BJ, Webster GD. Evaluation and Surgical Management of Intrinsic Sphincter Deficiency after Radical Prostatectomy. *Rev Urol*. 2004;6(4):180-186.
5. Goode PS. Behavioral Therapy With or Without Biofeedback and Pelvic Floor Electrical Stimulation for Persistent Postprostatectomy Incontinence: A Randomized Controlled Trial. *JAMA*. 2011;305(2):151.
6. Hodges P, Stafford R, Coughlin GD, et al. Efficacy of a personalised pelvic floor muscle training programme on urinary incontinence after radical prostatectomy (MaTchUP): protocol for a randomised controlled trial. *BMJ Open*. 2019;9(5):e028288.
7. Hubner WA, Schlarp OM. Treatment of incontinence after prostatectomy using a new minimally invasive device: adjustable continence therapy. *BJU Int*. 2005;96(4):587-594.
8. Kielb SJ, Clemens JQ. Comprehensive urodynamics evaluation of 146 men with incontinence after radical prostatectomy. *Urology*. 2005;66(2):392-396.
9. Seth J, Pakzad M, Hamid R, Greenwell T, Ockrim J. The assessment and management of post-prostatectomy stress urinary incontinence. *Rev Médica Clínica Las Condes*. 2018;29(2):193-196.
10. Yuan Y, Hu Y, Cheng J-X, Ding P. Psychological nursing approach on anxiety and depression of patients with severe urinary incontinence after radical prostatectomy – a pilot study. *J Int Med Res*. 2019;47(11):5689-5701.
11. Samuels JB, Pezzella A, Berenholz J, Alinsod R. 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. *Lasers Surg Med*. Published online June 7, 2019:lsm.23106.
12. Alinsod R, Vasilev V, Yanev K, Buzhov B, Stoilov M, Georgiev M. HIFEM Technology - A New Perspective in Treatment of Stress Urinary Incontinence. *Lasers Surg Med*. 2018;50(S29):S4-S56.

13. Samuels J, Guerette N. HIFEM Technology - The Non-Invasive Treatment of Urinary Incontinence. *Lasers Surg Med*. 2018;50(S29):S4-S56.

14. Silantyeva E, Zarkovic D, Astafeva E, et al. A Comparative Study on the Effects of High-Intensity Focused Electromagnetic Technology and Electrostimulation for the Treatment of Pelvic Floor Muscles and Urinary Incontinence in Parous Women: Analysis of Posttreatment Data. *Female Pelvic Med Reconstr Surg*. Published online December 2019:1.

15. Kelleher CJ, Pleil AM, Reese PR, Burgess SM, Brodish PH. How much is enough and who says so? *BJOG Int J Obstet Gynaecol*. 2004;111(6):605-612.

16. Bernardes MFVG, Chagas S de C, Izidoro LC de R, Veloso DFM, Chianca TCM, da Mata LRFP. Impact of urinary incontinence on the quality of life of individuals undergoing radical prostatectomy *. *Rev Lat Am Enfermagem*. 2019;27.

17. Sandhu JS, Breyer B, Comiter C, et al. Incontinence after Prostate Treatment: AUA/SUFU Guideline. *J Urol*. 2019;202(2):369-378.

18. Geraerts I, Van Poppel H, Devoogdt N, et al. Influence of Preoperative and Postoperative Pelvic Floor Muscle Training (PFMT) Compared with Postoperative PFMT on Urinary Incontinence After Radical Prostatectomy: A Randomized Controlled Trial. *Eur Urol*. 2013;64(5):766-772.

19. Yamanishi T, Mizuno T, Watanabe M, Honda M, Yoshida K-I. Randomized, Placebo Controlled Study of Electrical Stimulation With Pelvic Floor Muscle Training for Severe Urinary Incontinence After Radical Prostatectomy. *J Urol*. 2010;184(5):2007-2012.

20. Roscow AS, Borello-France D. Treatment of Male Urinary Incontinence Post–Radical Prostatectomy Using Physical Therapy Interventions: *J Women's Health Phys Ther*. 2016;40(3):129-138.

21. Stafford RE, Ashton-Miller JA, Constantinou CE, Hodges PW. A New Method to Quantify Male Pelvic Floor Displacement From 2D Transperineal Ultrasound Images. *Urology*. 2013;81(3):685-689.

22. Robinson AJ, Snyder-Mackler L. *Clinical Electrophysiology: Electrotherapy and Electrophysiologic Testing*. 3rd ed. Wolters Kluwer Health/Lippincott Williams & Wilkins; 2008.

23. Elena S, Dragana Z, Ramina S, Evgeniia A, Orazov M. Electromyographic Evaluation of the Pelvic Muscles Activity After High-Intensity Focused Electromagnetic Procedure and Electrical Stimulation in Women With Pelvic Floor Dysfunction. *Sex Med*. 2020;0(0).

24. Barker AT. An Introduction to the Basic Principles of Magnetic Nerve Stimulation: *J Clin Neurophysiol*. 1991;8(1):26-37.

25. Frontera WR, Meredith CN, O'Reilly KP, Knuttgen HG, Evans WJ. Strength conditioning in older men: skeletal muscle hypertrophy and improved function. *J Appl Physiol*. 1988;64(3):1038-1044.

26. Lexell J. Strength Training and Muscle Hypertrophy in Older Men and Women. *Top Geriatr Rehabil*. 2000;15(3):41–46.

27. Fornari A, Gressler M, Neis A, Cunha I, Oliveira L, Carboni C. The Impact of Urinary Incontinence on Male Erectile Dysfunction. *J Sex Med*. 2017;14(5):e264.

HIFEM® FOR IMPROVEMENT OF SEXUAL FUNCTION

THE NON-INVASIVE HIFEM PROCEDURE FOR IMPROVEMENT OF WOMEN'S SEXUAL FUNCTION

Alexander Bader MD, FAAOCG, FAAC[1], Maria Papadopoulou MD, CCST, ABAARM, EBCCP[1]

1. Bader Medical Institute of London, Marylebone, London, United Kingdom

Presented at IMCAS annual world congress in Paris: January 30, 2020

HIGHLIGHTS

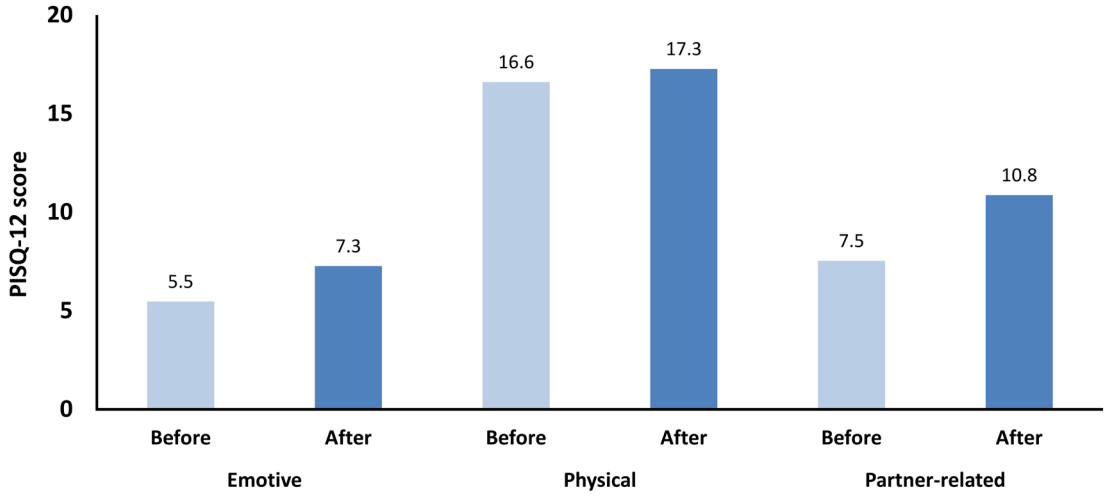
- **HIFEM** procedure **enhanced sexual function** of all treated women after the course of six treatments.
- **PISQ-12** score showed **clinically** and **statistically significant** improvement.
- Subjects reported **more intense** and **frequent orgasm** along with **greater sexual desire** and **excitement**.

DESIGN AND METHODOLOGY

- **Fifteen women** (on average 46.9±14.0 years) were recruited.
- All subjects received **six** 28-minute **HIFEM treatments** to enhance their sexual function.
- Therapies were scheduled **twice a week for three consecutive weeks**.
- **Intensity** of the treatments (0-100%) was **modulated** according to the subject's feedback.
- Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire short form **(PISQ-12)** was used for **analysis of sexual function** at baseline and at 1 month.
- **Cronbach's** coefficient **alpha** was used to verify **internal consistency** and **reliability** of the data.
- **Safety** of the procedure was **monitored**.

RESULTS

- **Each subject** showed an **improvement** in PISQ-12 total score **when compared** to baseline with minimum improvement of 3 points (range 3-14).
- The mean **score increased** by **5.8 points** (+19%; P<0.001) from 29.6±5.6 to 35.4±5.1.
- The **greatest change** was observed in **partner-related domain** (+3.3 points, P<0.001) mainly due to the **considerable improvement** in subject's **orgasm intensity**.
- Additionally, subjects reported **greater sexual desire** and **excitement**, as they were **more satisfied** with the variety in their sexual life and were more likely to **attain orgasm**.
- The subjects with **lower** PISQ **scores** at the baseline **benefited most** from the treatment, showing that **HIFEM procedure** is able to **improve sexual function** in **women** who are substantially **dissatisfied** with their sexual life.
- **Results** were found to be both **statistically and clinically significant**, since the change in score **highly exceeded** generally accepted level of **MCID** (minimal clinically important difference).
- **HIFEM** procedure was **safe** with no adverse events or side effects.



Mean PISQ-12 score before and after the treatments divided according to the domains. Improvement was found to be statistically significant in each domain (P<0.05).

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**.

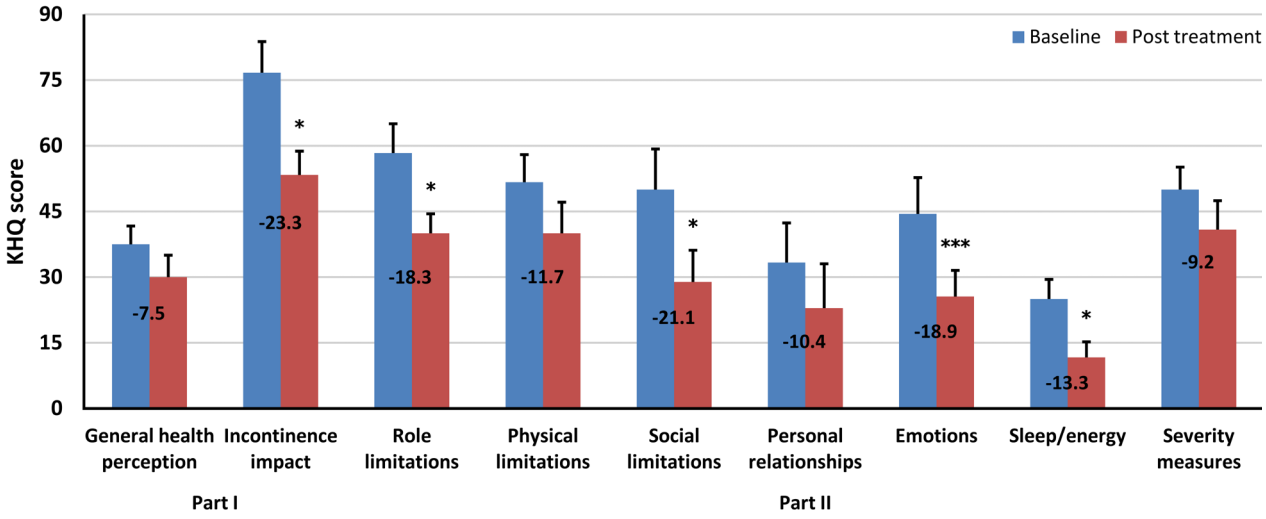
DESIGN AND METHODOLOGY

- 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

RESULTS

- **Each subject** achieved favorable **changes** in the QOL after the treatments by reason of reduction in various domain scores of KHQ.
- Baseline **KHQ score** was **significantly reduced** post-treatment.
    - o KHQ Part I from 114.2±24.2 to 83.3±26.4 points (-27%; P=0.002)
    - o KHQ Part II from 312.8±98.1 to 205.3±93.9 points (-34%; P=0.001)
- Subjects reported the highest improvement in the following **domains**: *sleep/energy* (-53.3%; P<0.001); *emotions* (-42.5%; P<0.001); *social limitations* (-42.2%; P=0.01); *role limitations* (-31.4%; P=0.03) and *incontinence impact* (-30.4%; P=0.01).
- In general, all differences in domain scores **exceeded** minimal **clinically important** difference (MCID) of 5 points.
- Individual patients' results at 1-month and 3-month follow-up visits showed **further improvement** of QOL.
- **Pad usage** decreased on average by 1.0 pad from 2.5 pads/day at baseline to 1.5 pads/day after the treatments while two subjects reported to be **pad free**.
- Two out of four subjects who wore pads at night due to **nocturia** achieved **complete reduction of pads** during the sleep.
- No adverse events were found.



Difference in mean score of KHQ domains (mean ± standard error). Maximum score of each domain is 100 points and lower scores indicate patient wellbeing. The statistical significance is highlighted by the asterisk (*P<0.05; ***P<0.001), reduction in score by 5 points indicates clinical significance.

099-74EMSSBCA4DE100
BTL_Emsella_LF_Studybook-cover_A4_DE100
06/2020