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

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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

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

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

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

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

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

MATERIALS AND METHODS

Subjects and Ethics

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

Investigational Device

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

TABLE 1. Demographic Data of Enrolled Subjects

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

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

TABLE 2. Number of Deliveries

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

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

Treatment Protocol

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

Outcomes and Evaluation

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

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

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

Statistical Analysis

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

RESULTS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DISCUSSION

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

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

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

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

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

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

CONCLUSION

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

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