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## Urinary incontinence and BTL EMSELLA™

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### Нетримання сечі та BTL EMSELLA™

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### Недержание мочи и BTL EMSELLA™

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### Introduction

#### Urinary incontinence

Urinary incontinence is currently defined as involuntary leakage of urine. Such an image assigns urinary incontinence to the lower urinary tract dysfunction group. Dysfunctions cause a wide range of lower urinary tract symptoms and therefore ICS indicates a classification of urinary incontinence by subjective manifestations, objective symptoms and diagnostic conditions. According to Marenčák, (2011) [4] urinary incontinence (UI – urinary incontinence) is a spontaneous, involuntary leakage of urine. AI adversely affects quality of life and is associated with a significant psychosexual and financial burden (Babecka, Gulasova, 2020) [1].

#### Kegel exercises muscle and urinary incontinence

"Kegel's muscles" are called various: pelvic muscles, pubic-coccyx muscles, but it is still the same set of muscles and tissues that sustain the organs of the abdominal cavity. In females, they are spaced between the pubo and coccyx bone, surrounding the estuary of the urethra, vagina and rectum. It is important to remember that the problem of weakened "Kegel muscles" is not only a problem in women, despite all beliefs. Men should also make sure that this group of muscles also works properly in them. In men, it is the muscles stored around the pubital bone and prostate. In European culture, the American gynecologist Dr. Arnold Kegel, who developed a series of exercises in pelvic floor muscles (Ďurišová, 2019) [2], first discovered the importance of pelvic floor muscle activity. Exercises of this group of muscles should be carried out by all women and men regardless of age. Because the effect of active exercises on the body is part of the treatment process and contributes to the improvement of the overall health of the individual (Popovicova, 2019) [5].

#### Urinary incontinence and BTL EMSELLA™

EMSELLA uses high performance fossilized electromagnetic field (HIFEM) technology to stimulate deep pelvic floor muscles and restore neuromuscular control.

It is intended for non-invasive treatment: strengthening the muscles of the pelvic floor, shaping the muscles of the seat,

treating urinary leakage. The key to efficiency is the focus of electromagnetic energy, the depth of penetration and stimulation of the entire pelvic floor. During a single EMSELLA therapy, there are thousands of supramaximal contractions of pelvic floor muscles, including urethra and rectum sphincters, which is extremely important in muscle re-education in incontinent patients with urinary incontinence and stool incontinence. During treatment, you will experience contractions of the muscles of the pelvic floor, which leads to their strengthening and improved effectiveness in the control against leakage of urine and stools. After EMSELLA therapy, there is an increase in strength and coordination of the muscles of the pelvic floor. This effect is also used in therapies of the hyperactive (irritating bladder), chronic pelvic pain in the hypotonia of the muscles of the pelvic floor, and in the dyscoordination of pelvic floor muscles after strokes or other nerve diseases such as multiple sclerosis, myasthenia gravis, conditions after spinal injury. Improvement can be observed even after one treatment. The results typically improve within 4-6 weeks. The standard treatment includes 6 sessions, which is convenient to time 1-2 times a week.

The pelvic floor muscles support the pelvic floor organs and control continence. However, natural body aging, childbirth and menopause can cause this group of muscles to decondition resulting in continence problems such as leaking urine when coughing or sneezing.

The BTL EMSELLA treatment uses High Intensity Focused ElectroMagnetic Energy (HIFEM) to stimulate and strengthen all the pelvic floor muscles, not just the subset that can be exercised with voluntary contractions (Kegel exercises). These stronger pelvic floor muscles restore continence and the confidence to enjoy normal daily activities without fear of losing bladder control.

During each 28-minute session you sit comfortably on the Emsella chair while it generates thousands of supramaximal pelvic floor muscle contractions. Each session is equivalent to doing 11000 pelvic floor exercises but without the hard work.

The procedure is non-invasive, and you remain fully clothed throughout. No drugs are required and the most you will feel is a slight tingling during the treatment. With no

recovery time needed you can leave immediately after each session and resume normal daily activity.

The majority of people need a course of six sessions over a period of three weeks to see optimum results, with most

people seeing and feeling results after just two or three treatment sessions.

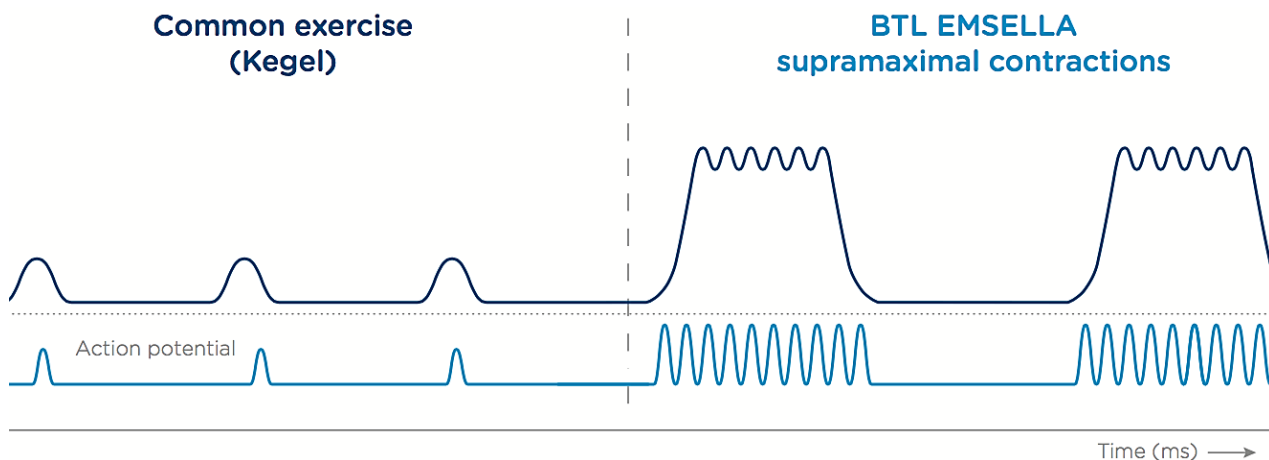


Fig. 1. Kegel vs. BTL EMSELLA™ (Source: <https://www.theurologyplace.com/emsella-for-incontinence>)



Fig. 2. BTL Emsella™  
(Source: <https://www.mirellemedispa.com/contents/body-treatments/body-sculpting-lifting/btl-emsella>)

### Materials and methods

The study followed an institutional review board approved protocol. A total of 20 women (54.40±11.70 years, 1.75±1.38 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, 18 out of 20 patients (80.34%) reported significant reduction of their symptoms. The average improvement of 48.90% in ICIQ-SF score was observed after the sixth treatment, which further increased to 63.40% at the follow-up (both  $P<0.001$ ). Individually, the highest level of improvement was reached in patients suffering from mixed urinary incontinence (68.95%). The reduction of absorbent pads averaged 45.85% after the sixth treatment and 54.78% at 3 months (both  $P<0.001$ ), while almost 75% of patients (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.

### Discussion

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. 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. 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. 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) 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, 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. Our results also correspond to observations from other modalities such as exercising or electrical stimulation 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.

### 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.

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In the article, the author analyzes urinary incontinence, the influence of kegel exercises and high-performance fossilized electromagnetic field technology to stimulate deep pelvic floor muscles and restore neuromuscular control using the BTL EMSELLA™ device for urinary incontinence. EMSELLA uses high performance fossilized electromagnetic field (HIFEM) technology to stimulate deep pelvic floor muscles and restore neuromuscular control.

It is designed for strengthening the muscles of the pelvic floor, shaping the muscles of the seat and treating urine leakage.

**Materials and methods.** The study followed an institutional review board approved protocol. A total of 20 women (54.40 ± 11.70 years, 1.75 ± 1.38 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 statistical analysis was conducted by paired T-test and Pearson correlation coefficient ( $\alpha=0.05$ ).

**Results.** After the sixth session, 18 out of 20 patients (80.34%) reported significant reduction of their symptoms. The average improvement of 48.90% in ICIQ-SF score was observed after the sixth treatment, which further increased to 63.40% at the follow-up (both  $P < 0.001$ ). Individually, the highest level of improvement was reached in patients suffering from mixed urinary incontinence (68.95%). The reduction of absorbent pads averaged 45.85% after the sixth treatment and 54.78% at 3 months (both  $P < 0.001$ ), while almost 75% of patients (reported decreased number of used pads).

**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.

**Key words:** urinary incontinence, Kegel exercises, BTL EMSELLA™, lower urinary tract.

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У статті автор аналізує нетримання сечі, вплив вправ Кегеля та високоефективної технології електромагнітного поля для стимуляції глибоких м'язів тазового дна та відновлення нервово-м'язового контролю за допомогою пристрою BTL EMSELLA™ для нетримання сечі. EMSELLA використовує високоефективну технологію електромагнітного поля (HIFEM) для стимуляції глибоких м'язів тазового дна та відновлення нервово-м'язового контролю. Він призначений для зміцнення м'язів тазового дна, формування м'язів сідниць та лікування підтікання сечі.

**Матеріали та методи.** Дослідження проводилося відповідно до затвердженого протоколу. Загалом було включено 20 жінок ( $54,40 \pm 11,70$  років,  $1,75 \pm 1,38$  пологів), у яких були симптоми стресового, імперативного або змішаного нетримання сечі. Вони отримали шість процедур HIFEM (2 на тиждень) тривалістю 28 хвилин. Результати оцінювали після шостого сеансу лікування та через 3 місяці спостереження. Статистичний аналіз проводили за парним Т-критерієм та коефіцієнтом кореляції Пірсона ( $\alpha = 0,05$ ).

**Результати.** Після шостого сеансу 18 з 20 пацієнтів (80,34%) повідомили про значне зменшення симптомів. Середнє покращення показника ICIQ-SF на 48,90% спостерігалось після шостого сеансу лікування, яке в подальшому зросло до 63,40% під час подальшого спостереження (обидва  $P < 0,001$ ). Індивідуально найвищого рівня поліпшення досягнуто у пацієнтів, які страждають на змішане нетримання сечі (68,95%). Зменшення використання абсорбуючих прокладок становило в середньому 45,85% після шостої процедури і 54,78% через 3 місяці (обидва  $P < 0,001$ ), тоді як майже 75% пацієнтів повідомили про зменшення кількості використаних прокладок.

**Висновки.** Це дослідження продемонструвало, що технологія HIFEM здатна безпечно та ефективно лікувати широкий спектр пацієнтів, які страждають від нетримання сечі. Після шести процедур спостерігалось покращення показника ICIQ-SF та зменшення використання абсорбуючих прокладок. За суб'єктивною оцінкою ці зміни позитивно вплинули на якість життя.

**Ключові слова:** нетримання сечі, вправи Кегеля, BTL EMSELLA™, нижні сечовивідні шляхи.

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В статье автор анализирует недержание мочи, влияние упражнений Кегеля и высокоэффективной технологии электромагнитного поля для стимуляции глубоких мышц тазового дна и восстановления нервно-мышечного контроля с помощью BTL EMSELLA™ для недерхания мочи. EMSELLA использует высокоэффективную технологию электромагнитного поля (HIFEM) для стимуляции глубоких мышц тазового дна и восстановления нервно-мышечного контроля. Он предназначен для укрепления мышц тазового дна, формирования мышц ягодиц и лечения подтекания мочи.

**Материалы и методы.** Исследование проводилось в соответствии с утвержденным протоколом. В общей сложности было включено 20 женщин ( $54,40 \pm 11,70$  лет,  $1,75 \pm 1,38$  родов), у которых были симптомы стрессового, императивного или смешанного недерхания мочи. Они получили шесть процедур HIFEM (2 в неделю) продолжительностью 28 минут. Результаты оценивали после шестого сеанса лечения и через 3 месяца наблюдения. Статистический анализ проводили по парному Т-критерию и коэффициенту корреляции Пирсона ( $\alpha = 0,05$ ).

**Результаты.** После шестого сеанса 18 из 20 пациентов (80,34%) сообщили о значительном уменьшении симптомов. Среднее улучшение показателя ICIQ-SF на 48,90% наблюдалось после шестого сеанса лечения, которое в дальнейшем выросло до 63,40% во время дальнейшего наблюдения (оба  $P < 0,001$ ). Индивидуально высокий уровень улучшения достигнут у пациентов, страдающих смешанным недерханием мочи (68,95%). Уменьшение использования абсорбирующих прокладок составило в среднем 45,85% после шестой процедуры и 54,78% через 3 месяца (оба  $P < 0,001$ ), тогда как почти 75% пациентов сообщили об уменьшении количества использованных прокладок.

**Выводы.** Это исследование продемонстрировало, что технология HIFEM способна безопасно и эффективно лечить широкий спектр пациентов, страдающих недерханием мочи. После шести процедур наблюдалось улучшение показателя ICIQ-SF и уменьшение использования абсорбирующих прокладок. По субъективной оценке, эти изменения положительно повлияли на качество жизни.

**Ключевые слова:** недержание мочи, упражнения Кегеля, BTL EMSELLA™, нижние мочевыводящие пути.

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