Introduction to High Intensity Tesla Stimulation (HITS) with StarFormer™ and Review of Electro-Magnetic Field Device clinical applications

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ABSTRACT

High Intensity Tesla Stimulation technology (HITS™) demonstrates a wide applicability in the fields of Aesthetics, Urology, Rehabilitation, Physiotherapy and Pain Management. By applying a pulsed magnetic field to a particular body area, magnetic stimulation induces a flow of electric current that can stimulate neurons. The neuronal stimulus in turn induces a corresponding body response, notably a muscle contraction. This review summarizes available studies employing magnetic stimulation in clinical applications and gives special attention to the results of existing studies using HITS™ magnetic technology.

I. INTRODUCTION

High-intensity magnetic muscle stimulation devices have recently been introduced as a means of strengthening and building up muscle mass without the need for resistance training exercises. They function by applying a pulsed magnetic field to a particular body area, which induces electrical potential inside the body tissue, thus causing an electric current to flow and excite neurons in the body. If the excited neuron is a motor neuron, a triggered nerve impulse called an action potential causes the corresponding motor units in the muscle to contract automatically. Higher the pulse repetition rate, less time is required to perform a treatment, providing that the repetition rate is below the value where muscle fatigue starts to substantially decrease the muscle response. High performance electromagnetic devices based on High Intensity Tesla Stimulation technology[1] - HITS™ such as StarFormer® can deliver repetition rates within a broad range from 1 Hz to 80 Hz where the muscle fatigue begins to decrease the muscle response.

In this review paper, we explain the basic principles of HITS™ stimulation, and give an overview of the clinical data available from existing studies using HITS™ devices in i) muscle strengthening and body firming, toning and shaping; ii) stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of male and female urinary incontinence and other pelvic floor disorders; iii) pain management; and iv) rehabilitation of motor control impairments due to disease or injury.

a) Basic principles of HITS™ stimulation

HITS™ devices such as StarFormer® (manufactured by Fotona, Ljubljana, EU) deliver repetitive magnetic pulsing with high intensity of magnetic fields, which is expressed in Tesla units (T), resulting in high intensity Tesla stimulation. The treatment is performed with an external applicator which comprises a stimulation coil located in the applicator. During treatment, an applicator is placed over the treatment area (See Fig. 1a) and an alternating electric current is sent into the stimulation coil. Alternatively, one or more applicators can be built into a treatment chair, and the patient receives the treatment while sitting in the chair (Fig. 1b). Fotona Starformer® device specially designed for pelvic floor muscle strengthening in female and male patients is called the IntimaWave®.

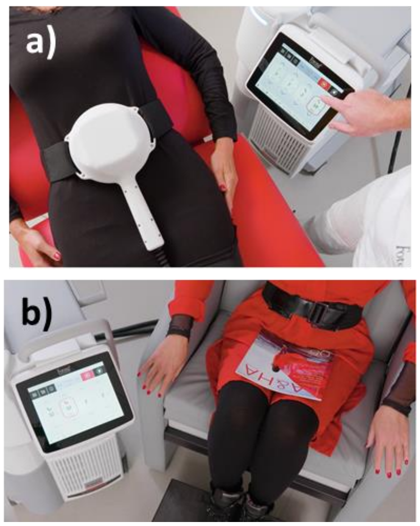

Fig. 1: During the HITS™ treatment, a) one or more applicators are placed over the patient's treatment area, or b) the patient is positioned into a chair with built-in applicator(s).

The coil builds up a magnetic field which in turn induces an electrical current[2] in the underlying tissue, which stimulates neurons. Neurons exhibit a steady charge difference across the plasma membrane known as the resting membrane potential.[5] When this voltage difference shifts by a minimum amount, known as a threshold, a nerve impulse or action potential is generated.[5] Neurons propagate the action potential using voltage-gated biochemical machinery in their membranes[1] and relay information throughout the nervous system, in turn inducing responses of the body.

The most evident body response is contraction of muscles, which is responsible for the muscle strengthening behind the HITS™ magnetic stimulation. However, magnetic stimulation acts on both the motor (efferent) and sensory (afferent) component of the nervous system. The motor component carries information from the central nervous system (CNS) to the muscles, inducing muscle contractions and other effector responses. The sensory component is responsible for conveying information to the CNS from the body itself (proprioception and interoreception) and from the environment (exteroreception), inducing perceptions and sensations.

At the peripheral level, the motor system is composed of a nerve fiber, one highly efficient synapse per muscle fiber, and a set of muscle fibers (motor unit) that connects to tendon and bone. Due to the highly efficient nerve-muscle synapse, a single evoked propagating action potential will result in a measurable muscle force when the motor axon is excited.[3] When a motor neuron fires, all the muscle fibers in its motor unit contract briefly. When stimulated by a single action potential, a muscle contracts and then relaxes. The time between the stimulus and the initiation of contraction is termed the latent period, which is followed by the contraction period. This response is a muscle twitch. If a new nerve impulse arrives before a twitch ends, the muscle twitches again. Repeated twitch contractions, where the previous twitch has not relaxed completely, are called a summation. If the frequency of these contractions increases to the point where maximum tension is generated and no relaxation is observed then the contraction is termed tetanus. Muscles normally contract in this way, which generates three or four times the force of a single twitch. Muscle contraction by magnetic stimulation results from depolarization of terminal motor nerve branches by the induced current and not by direct muscle activation, as evidenced by lack of response from curarized muscle.[4]

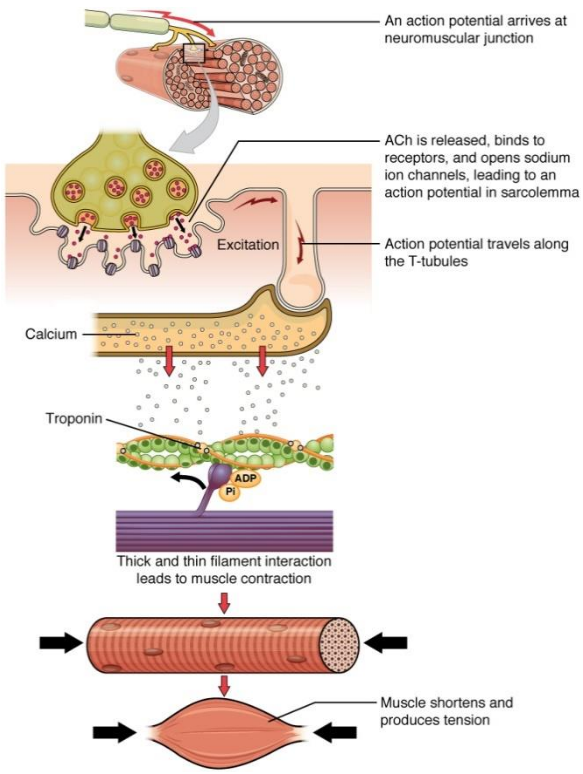

Fig. 2: Excitation of a motor neuron triggering a muscle contraction
Source: https://cnx.org/contents/FPtK1zmh@8.25:fEI3C8Ot@10/Preface
An action potential travels along the nerve to the neuromuscular junction where a chemical message (neurotransmitter called acetylcholine - ACh) is released by the motor neuron. The chemical message binds to receptors on the outside of the muscle fiber, setting off a chemical reaction within the muscle. Membrane channels open and allow an influx of sodium ions into the cytoplasm of the muscle fiber. The sodium influx triggers a release of stored calcium ions. The calcium ions diffuse into the muscle fiber and bind to Troponin C on the protein (actin) filament, enabling the interaction between filaments and the consequent contraction of a muscle fiber.

Unlike the motor systems, the sensory systems usually involve multiple synapses between the activated nerves and numerous involved regions of the CNS, and the behavioral response (perception or a feeling) is not as easily measured.[3] Magnetic stimulation of peripheral sensory fibers potentially affects cerebral activation and neuroplasticity[5] in the brain. It triggers a flow of proprioceptive afferents, either through direct activation of sensorimotor nerve fibers or an indirect activation of mechanoreceptors in the muscle fibres.[5] This mode of action is employed in rehabilitation and pain management of the neuromuscular system.

The mechanism of HITS™ at the neural level is equivalent as in electrical stimulation, namely an electrical current that passes across the nerve membrane,[6] with the effect of the applied electrical field being greatest on the largest nerves.[3] However, as magnetically-induced electric field decreases less with tissue depth compared to electrical stimulation, for the same effective current at the nerves, the current at the skin is much lower with magnetic than with electrical stimulation.[7] Consequently, in contrast to the electrical stimulation, magnetic pulses can be applied painlessly to the efferent motor nerves at higher intensities, since the cutaneous receptors and their nerves are not stimulated to the same extent[8] or not at all.[9] As these are involved in the perception of pain, magnetic stimulation is associated with much less discomfort compared to electrical stimulation.

b) Intensity and Frequency of HITS™ Stimulation

Magnetic stimulation intensity is usually reported in Tesla units or in percentage of the maximal stimulator output (MSO).[9] However, the magnetic field strength at the depth of the targeted structures cannot be easily estimated because it depends on the type of coil, the depth of tissue stimulated and the geometry of the area beneath the coil.[9] Furthermore, patient/target specific variables such as thickness of nerve myelin sheet, distance of target from coil (e.g. subcutaneous fat layer thickness,[10,11] muscle mass), threshold variation through time, etc. influence the clinical response. No absolute magnetic field value can be prescribed for all patients. The motoric threshold (lowest intensity inducing visible contraction) and maximum response (involuntary contraction corresponding to maximal voluntary contraction) must be determined clinically. It is common practice to start with low field intensity and then increase up to patient tolerance. A range of 0.4 T to 0.55 T has been reported as the intensity of the motor threshold in healthy subject and subjects with increased spastic tone, respectively.[12] Moreover, involuntary muscle contraction can be achieved when the induced electrical current in the body is of high enough intensity; and the motor neuron is not in the refractory period, a time during which an action potential cannot be triggered.

Evidence from repetitive peripheral magnetic stimulation at sufficient intensity to produce muscle contractions denote that lower frequencies (< 5 Hz) and theta-burst frequency induce muscle twitching whereas higher frequencies (>10 Hz) produce sustained muscle contractions due to temporal summation of motor units recruitment.[9] When compared to sustained contraction, muscle twitching gives rise to more but weaker contractions and smaller joint movements.[9] For example, 5 Hz MS induces 5 weak contractions or small movements per second while 20 Hz induces one strong fused tetanic contraction or larger movement during the same period of stimulation.[9] Typically, fused tetanic contractions are achieved at a stimulation frequency of 20 Hz. Sustained contraction may be chosen to strengthen muscles and muscle twitching would be a better choice to improve movement control by mimicking contractions/relaxations and triggering massive proprioceptive inflow towards frontoparietal areas.[9]

Normal voluntary activity is characterized by relatively low motor neuron firing rates (10–20 Hz) that results in only partial summation of force.[9] The elicited contraction torque increases with frequency due to summation, up to a tetanic frequency where a plateau is reached. Frequencies of above 20 Hz do not produce significantly different contraction torques. Tetanic frequency may differ between individuals and between muscles. Slow and fast skeletal muscles have been shown to have firing frequencies of approximately 10 and 30 Hz, respectively, during maximal voluntary contraction.[13]

Elicited contraction torque increases with intensity, as more motor units are recruited. It would plateau if all units could be recruited, resulting in supramaximal contraction. However, practically the same contraction intensity can be achieved by various combinations of stimulation intensity and frequency. Stimulation at higher frequencies allows the intensity of the stimulator output to be reduced, reducing discomfort.[11]

After prolonged stimulation (i.e., 15 minutes or more) at frequencies of 50 Hz or higher, muscle fatigue becomes a factor and the muscle response decreases. It has been reported that in involuntary muscle contraction lower frequencies are less fatiguing on the muscle than higher frequencies. [14] Moreover, frequencies below 40–50 Hz recruit more slow-twitch muscle fibers, that are more fatigue-resistant, while higher frequencies recruit more fast-twitch, that fatigue more easily.[15] Over a range of frequencies from 50 to 200 Hz, muscle response is still present after 15 minutes of stimulation.[16] After a 30-minute stimulation period at the maximal frequencies available by a HITS devices there will still be considerable muscle response, based on extrapolation of the plotted response data from the study (see Figure 2). A medium level frequency of 56 Hz will enable the triggering of 50,000 contractions in 30 minutes, with a 50% duty cycle (active time and a pause time both of 1 s). This delivers a trigger pulse every 18 millisecond, which is more than the muscle refractory period. Therefore, each trigger pulse will excite at least one muscle unit contraction. At the highest frequency of 80 Hz available with HITS™ devices, 72,000 contractions can be achieved.

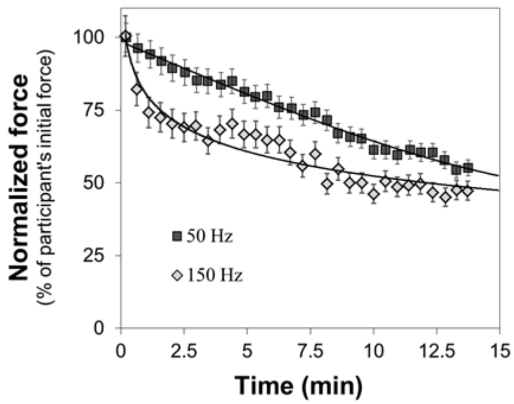

Fig. 2: Curve fitting pattern of normalized stimulated force values obtained during a 15-minute fatigue test under all stimulation conditions. Data are presented as mean. Error bars represent standard error of mean. Adapted from Kuwabara et al. [16]

HITS™ devices can produce high intensity magnetic field pulsed at a range of low to high frequencies, therefore allowing for versatile treatments that can activate both slow- and fast- twitch muscle fibers, which is very difficult to achieve with exercise alone.

II. MATERIALS AND METHODS

a) Review method

This survey article provides an overview of the available studies reporting on the clinical use of Electro-Magnetic Field Devices. A literature search was conducted on PubMed, Scopus and Google Scholar up to 15.2.2021. Records were screened for duplicates, excluding records of wrong devices and indications. Remaining records were assessed for eligibility in full text. Criteria for eligibility were the following: clinically and technically equivalent device, appropriate device application, appropriate patient group and acceptable report/data collation. If all criteria were met, the studies were included in the review. For the search term and results refer to Table 1. Some studies using HITS technology supplied by the authors were not retrieved with web searches.

b) Review outcomes

The outcomes for this review were available data about the following indications of Electro-Magnetic Field Devices: a) muscle strengthening and body firming, toning and shaping; b) stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of male and female urinary incontinence and other pelvic floor disorders; c) pain management; and d) rehabilitation of motor control impairments due to disease or injury. The most frequently reported study metrics for each indication were documented. Selected parameters used in magnetic stimulation protocols (see Table 2) were compared among indications. If possible, a median value was computed, which represents the value of a selected parameter most frequently used for treatment of a specific indication and is not intended to serve as guidance for treatment protocols.

Additionally, in case of available data (at least 2 studies reporting on the same indication performed on an equivalent patient group) a comparison of magnetic stimulation treatment with other treatment modalities was made.

Special attention was given to the results of available published HITS™ magnetic technology studies, which are presented in more detail. Nevertheless, the outcomes of this review are based on all studies included in the review, representing clinically equivalent Electro-Magnetic Field Devices

Table 1) Search terms used for each indication

Clinical application/ indication	Web search terms	Web search results	Studies not retrieved from web search	Full texts assessed for eligibility	Studies included in the review
Muscle strengthening, body firming/toning/ shaping	electromagnet* OR magnet* AND stimulat* "body shaping" "body contouring" "buttock augmentation" "muscle stimulation" "muscle strengthening" "increase muscle strength" "muscle toning" NOT brain NOT transcranial NOT resonance	PUBMED 48 citations SCOPUS 56 citations Google Scholar 4 citations	2	25	17
Stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and male and female urinary incontinence and other pelvic floor disorders	electromagnet* OR magnet* AND stimulat* "pelvic" "prostatitis" "incontinence" NOT transcranial NOT resonance NOT abdom* NOT "anal sphincter"	PUBMED 90 citations SCOPUS 118 citations Google Scholar 27 citations	5	111	37
Pain management	electromagnet* OR magnet* AND stimulat* "back pain" "musculoskeletal" "migraine" "myofascial pain syndrome" NOT transcranial NOT resonance	PUBMED 95 citations SCOPUS 66 citations Google Scholar 32 citations	2	35	15
Rehabilitation of motor control impairments due to disease or injury	electromagnet* OR magnet* AND stimulat* "repetitive magnetic stimulation" "repetitive peripheral magnetic stimulation" "functional magnetic stimulation" spastic* OR stroke OR rehabilitation OR injury OR neuropath* OR motor control OR sensorimotor* NOT transcranial	PUBMED 64 citations SCOPUS 81 citations Google Scholar 28 citations	1	44	18

III) RESULTS

a) Muscle strengthening, body firming/toning/shaping

In applications where the desired outcomes are the increase in muscle strength, muscle hypertrophy, or prevention of muscle atrophy, HITS™ treatment can provide an alternative or adjunct treatment to standard physical exercise or electrical stimulation due to its ability to efficiently and painlessly induce muscle contraction. The increased muscle activity during magnetic stimulation increases catabolic processes that ensure adenosine triphosphate production from fatty acids.[17] The functional muscle stimulation can therefore, along with diet and exercise, also increase the rate of fat burning.[17] The benefits of magnetic stimulation include successful and well-tolerated induction of muscle contraction resulting in significant improvement in muscle strength, [18–20] endurance,[19] muscle power/exercise capacity, [21,22] Quality of Life related to muscle function, increased muscle size,[23–26] decreased fat layer thickness,[23–27] improved aesthetics and patient satisfaction. Multiple treatment sessions (≥4) with at least 2 days rest between sessions are required for full effect.

In a recent study by Valdivia,[28] HITS™ treatment using Fotona's Starformer was used for abdominal muscle toning in 10 individuals. 8 treatment sessions of 30 minutes were performed, with 2-3 sessions per week. All patients were photographed at baseline and at 10 weeks following the treatments. Waist circumference and weight was also measured, patients also responded to a patient satisfaction questionnaire. The results have shown that visual improvement in abdominal muscle toning and body shape (Fig. 3), as determined by blinded evaluators, was evident in all patients. The patients were very satisfied with the improvement aesthetic results (4.375 on a scale from 1 to 5) as well as their improvement in perceived abdominal strength (4.125 on a scale from 1 to 5). The patients perceived strong muscle contractions and have seen improvement in muscle strength and abdominal body shape (see Figure 3).

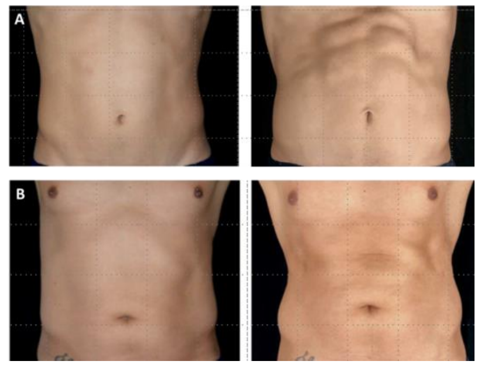

Fig. 3) Digital photos of two patients (A and B) before (left) and 10 weeks after HITS™ treatment (right). Courtesy of Dr Valdivia

A case series performed at LAHA institute has shown marked visual improvement (Fig. 4) and improvement in perceived muscle strength after 6 HITS™ treatment performed in the period of 2 weeks.

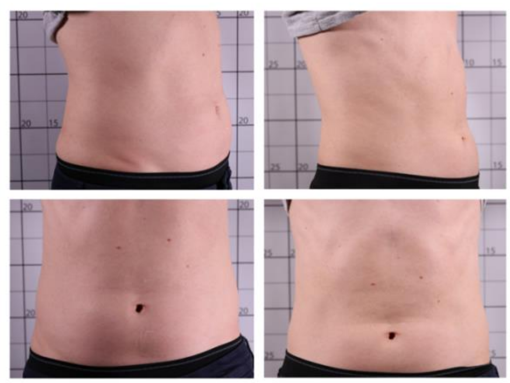

Fig. 4) Before (left) and after (right) 6 treatments using TightWave HITS™ *(right). Courtesy of LAHA Institute*

A case series with patients ranging in age from 28-37 and in BMI from 19-23, performed in the clinic of dr. Jorge Baños has shown the positive effect of HITS™ treatment on hypertrophy of the *rectus abdominalis* muscle and toning of the abdomen as demonstrated by a reduction in volume (Fig. 5; above) and circumference (Fig. 5 below). Another case of a female patient showed the effect of treatment on gluteal augmentation via hypertrophy of the *gluteus maximus* muscle as demonstrated by an increase in volume (Fig. 6; above) and circumference (Fig. 6; below) after 8 HITS™ treatment performed twice per week.

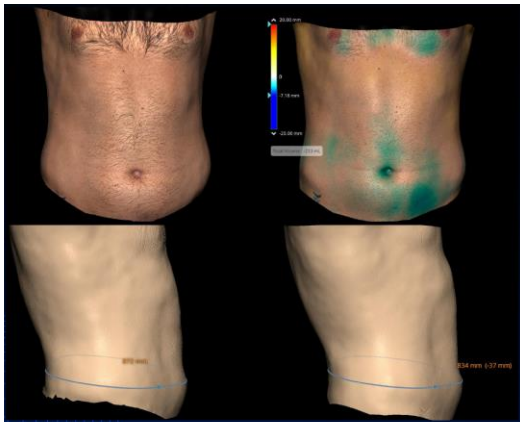

Fig. 5) Digital photos of a patients before (left) and after (right) 8 sessions with HITS™ *treatment. Courtesy of Dr Baños*

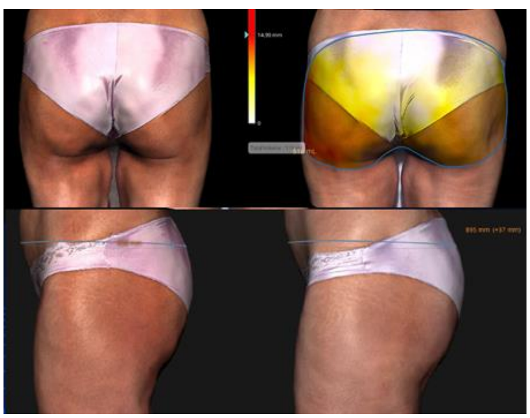

Fig. 6) Digital photos of a patients before (left) and after (right) 8 sessions with HITS™ *treatment. Courtesy of Dr Baños*

b) Stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of male and female urinary incontinence and other pelvic floor disorders

Magnetic stimulation technology of pelvic floor muscles has been in use ever since its approval by the Food and Drug Administration (FDA) in 1998. Here, the magnetic field generator is located within a chair. In the seated patient the perineum is centered naturally in the middle of the seat, placing the muscles of the pelvic floor and sphincters directly on the primary axis of the pulsing magnetic field. Repeated activation of the motor nerve fibers in the pelvic floor will tend to build pelvic floor muscle strength and endurance. It may also change the pattern and rate of firing of the motor nerve fibers responsible for the resting tone of the pelvic floor and sphincter muscles.[29]

Magnetic pelvic floor muscle strengthening is increasingly used as an alternative to electrical stimulation methods.[30] The advantage of magnetic pelvic muscle stimulation is the absence of direct skin contact in contrast to electrodes that need to be applied into patient's vagina or anus in electrostimulation therapy, which can generate discomfort, pain, irritation and might have psychosocial consequences. Numerous studies demonstrated that magnetic stimulation results in well-tolerated induction of pelvic muscle contraction results in significant improvement of symptoms of stress urinary incontinence,[7,29,31–40] urge incontinence,[7,32,33,35–37,39,41–44] mixed incontinence, [32,37,43] undefined incontinence, [31,45–49] postpartum incontinence[40], urinary incontinence following (radical) prostatectomy, [35,50,51] fecal incontinence, [52–54] and chronic prostatitis/chronic bladder pain syndrome,[55–57] as determined by various standardized outcome measures used in the studies analyzed. Quality of life improves, which is evident from high patient satisfaction. Multiple treatment sessions (> 3; preferably 8–16) with at least 2 treatment sessions per week are required for optimal effect. A dose-response is evident, since the beneficial effects are related to the number of sessions more sessions result with better improvement, while the discontinuation of therapy usually leads to recurrence of symptoms.

The effect of magnetic stimulation (MS) was compared to electrostimulation (ES) in 3 studies treating incontinence. Silantyeva et al., [58] observed significant ($P < 0.05$) changes in pelvic floor integrity only in the group receiving MS (MS-group), while the changes in the group receiving ES (ES-group) were not significantly different from the control. In addition, the MS-group achieved greater level of improvement in Pelvic Floor Disability Index 20 questionnaire compared with the group receiving ES (52% and 18% respectively; P < 0.001). Compared to ES-group, substantially fewer patients in the MS-group reported urine leakage after treatments. Another study by Silantyeva [49] that included both patients with urinary incontinence and other pelvic floor disorders found significantly greater restoration of muscle strength in MS-group compared to ES-group, inferred from electro myographic recordings (EMG). The EMG measurements coincided with the results of the patient's subjective evaluation, which showed more pronounced improvement in the MS-group (57.16%) than in the ES-group (32.18%). In a study by Yokoyama[35] no statistically significant differences were noted between the MS-group and ES-group, but both groups offered earlier continence compared with the control group after radical prostatectomy.

In a study by Strumbelj,[40] HITS™ was used to treat static urinary and post-partum incontinence in 61 and 21 female patients, respectively. 16 20 min treatment sessions were performed, with 2 sessions per week. Effectiveness of treatment was assessed with patient questionnaires. In 80.3 % of patients with static urinary incontinence the treatment resulted in complete recovery (Fig. 7), while 14.8 % of patients reported significant improvement of symptoms and only 4.9 % of patients have seen no improvement. In case of post-partum incontinence 95.2 % of patients reported complete recovery and 4.8 % reported significant improvement.

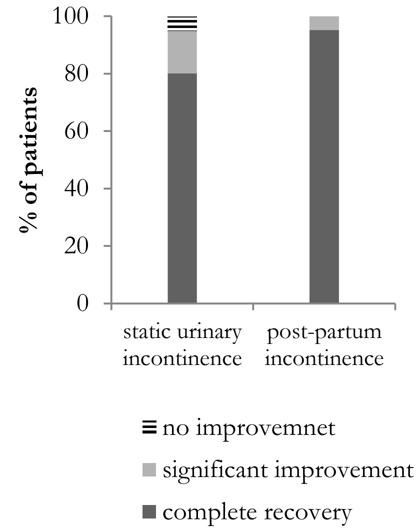

Fig. 7) Effectiveness of HITS™ treatment for urinary incontinence. Adapted from Strumbelj et al.[40]

In a study by Vadala et al. [32] with 20 urinary incontinence patients, significant reductions ($p<0.01$) of micturition number and nocturia after HITS™ treatment were evidenced. The urodynamic tests recorded a significant increase in cystometric capacity (147±51.3%), in maximum urethral closure pressure (110±34%), in urethral functional length (99.8±51.8%), and in pressure transmission ratio (147±51.3%) values compared with the baseline values.

In a study by Brusciano[54] with 30 fecal incontinence patients, significant reductions ($p<0.05$) of stool leakage per week and significant improvement according to Cleveland clinic fecal incontinence scale (CCFIS) and Fecal incontinence quality of life (FIQL) after HITS™ treatment were evidenced. The significant improvement of the CCIFS was recorded in 24 patients (80%), with a mean value reduction of 60% ($p<0.05$). FiQL scores improved in 27 out of 30 patients (90%), with significant ($p<0.05$) reduction of values for lifestyle, coping, depression and embarrassment patterns.

In a study by Valetic et al,[59] 57 female patients with urgent, stress and mixed urinary incontinence were treated twice a week for 8 weeks. The results were obtained using a patient self-evaluation questionnaire and collected before starting the treatment and after finishing the last HITS™ therapy. 58% of patients suffering from UUI were completely dry, 31% of patients showed significant improvement and 11% did not show any improvement after the treatment. 80% of patients suffering from SUI were completely dry after the therapy, 15% of patients showed significant improvement and 5% did not show any improvement. 69% of patients suffering from MUI were dry, 29% of patients showed significant improvement and 2% of women did not show any improvement.

In a study by Lukanovic et al.,[60] a statistically significant reduction in the frequency of urine leakage and a reduced amount of urine leaked was determined for all three UI types. A statistically significant reduction in the daytime frequency of urine leakage was determined only for UUI and MUI, and a reduction in the frequency of daytime and nighttime micturition was established for UUI. The use of pads was reduced for all UI types. Improvement was largely established in younger, premenopausal subjects that do not have a neurological disease and/or diabetes. No statistical correlation was established between the intensity of magnetic stimulation and the success rate of UI treatment.

In a study by Serdinsek et al.,[61] the number of daytime and night-time voids in women with refractory neuropathic over active bladder (OAB) has significantly decreased. In OAB, magnetic stimulation of the sacral nerve roots may suppress detrusor muscle activity.[62]
Moreover, HITS had positive short-term effect on lower urinary symptoms in the group of patients, which are often found most difficult to treat. The therapy was well accepted by the patients.

c) Pain management

Pain is caused when specialized nerves called nociceptors are activated in response to adverse chemical, thermal or mechanical stimulus.[63,64] The standard method for treatment acute or chronic pain is analgesic medication, with possibility of systemic side effects and addiction. Peripheral magnetic stimulation is used as an alternative method. As mode of action, studies mostly refer to evidence from the electrical stimulation literature where intensity of pure sensory stimulation (i.e. insufficient to induce muscle contraction) is effective to reduce pain in various disorders. However, some studies use supra-threshold intensities to reach deep spinal roots, and suggest an effect of induced proprioceptive afferents on cortical sensorimotor plasticity on pain relief.[9] Pain relief after magnetic stimulation was demonstrated in several studies recruiting patients with low back pain, [65–69] musculoskeletal pain, [70–73] myofascial pain syndrome[74,75] and migraine,[76,77] and reported no discomfort during intervention and no serious adverse effects following treatment. Significant pain relief is frequently accompanied by reports of high patient satisfaction and increased quality of life. Several treatment sessions in 3 day intervals is typically applied. As pain treatment relies on nerve stimulation without the need of muscle contractions, lower intensities of stimulation are used. Studies commonly report starting intensities of 15 % MSO and subsequently increasing in 5% steps up to the intensity that is still comfortable for the patient.

In a study by Koleva et al.,[78] of 40 patients, which were treated with HITS™ due to low-back pain, 70 % reported significant improvement, 24 % reported some improvement and only 6 % reported no improvement.

In a study by Radakovic,[69] HITS™ was successfully applied to treat sciatica syndrome in 28 male patients with lower back pain. 6 20 min treatment sessions were performed every other day. Mobility of the lumbar spine in flexion and extension, together with the straight leg raise test (Lasegue sign) were measured with a goniometer to assess the effect of treatment in comparison to control. Both the control and treatment group received standard physical therapy. Study concluded that by adding functional magnetic stimulation to the regular physical therapy treatment, improvements of patient's mobility are achieved faster. Most of the patients have reported significant pain relief already after the first session.

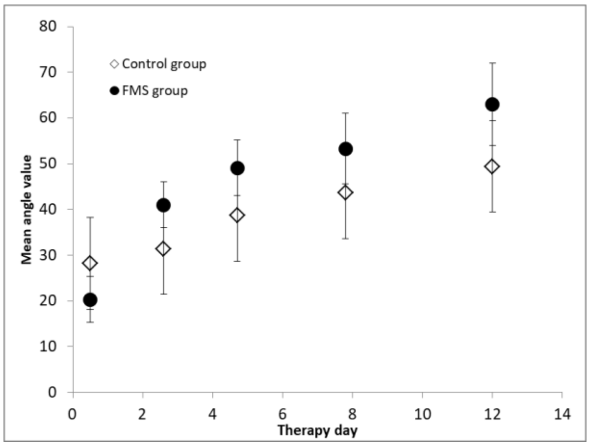

Fig. 8) Improvement in lumbosacral flexion angle in patients receiving rehabilitation with magnetic stimulation (MS group) compared to control (Control group). Adapted from Radaković T and Radaković N [69]

d) Rehabilitation of motor control impairments due to disease or injury

Neuromuscular rehabilitation aims to help the individual recover after injury or impairment of the nervous or musculoskeletal system, affecting sensorimotor control. Peripheral magnetic stimulation improves motor function via increased somatosensory input. In patients with motor deficits secondary to stroke, it has been suggested that stimulation of peripheral nerves and enhances the effectiveness of neurorehabilitation.[79] The induction of proprioceptive afferents by peripheral magnetic stimulation resembles movement therapy that has already demonstrated to increase motor control in stroke patients.[5]

Several studies demonstrated improvement of motor control and spasticity in patients that suffered injuries to the nervous system, as in case of stroke,[80–88] spinal cord injury,[89,90] brain injury,[85,91] brachial plexopathy,[92] lumbar radiculopathy[93] and carpal tunnel syndrome.[94] Treatment is also being used for motor control improvement and prevention of muscle atrophy in persons with musculoskeletal injuries and/or surgery[95] and for stimulating abdominal muscles to relieve neurogenic bowel related constipation. [91,96] Most studies report significant improvement immediately after intervention with the magnetic stimulation, but treatment with several sessions is frequently employed, with an interval ranging from one to ten days. Treatment is generally performed on patients that have sustained an injury relatively recently, although it has also been successful in improving motor control up to 8 years after stroke[84] and in a 7-year old patient with congenital cerebral palsy.[97] It is frequently performed in combination with standard physical therapy.
Similarly as in pain management, as the mechanism of action is through afferent nerve stimulation, lower intensities are used during treatment with Fotona's Starformer®. Stimulation at the motor threshold is generally applied, which is achieved with intensities in the range of 0.4 - 0.6 T.[12]

The efficacy of magnetic stimulation (MS) and electrostimulation (ES) was compared by 2 studies in case of rehabilitation after stroke. A study by Szecsi et al.,[87] with hemiplegic stroke patients found that stimulation-supported cycling led to significantly higher muscle torque output, smoothness, and symmetry of pedaling in MS-group compared to ES-group. In a study by Yang et al, [98] improvement of upper limb function was significantly higher in MS group compared with ES-group group, demonstrated by a difference in the Fugl-Meyer score [$t = 7.194$, $P < 0.01$].

In a report by Dimitrov et al. , [99] rehabilitation with HITS™ was compared with electrostimulation (ES). Combined rehabilitation with therapeutic exercises and respiratory therapy was aimed at relieving symptoms related to neuromuscular weakness in patients that underwent prolonged (>7 days) mechanical respiratory ventilation. The average hospitalization time in patients receiving HITS™

was significantly shorter ($p<0.05$) compared to patients receiving ES (Fig. 9).

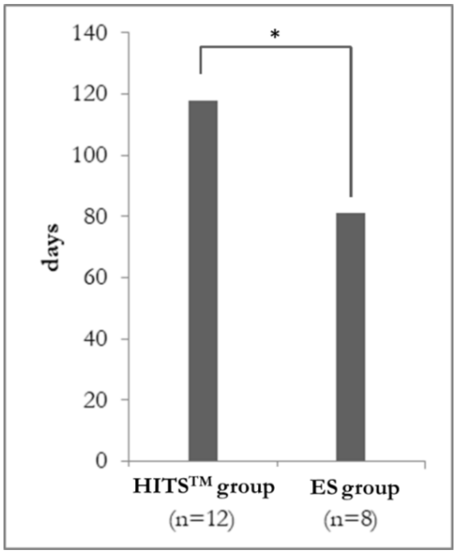

*Fig. 9) Average hospitalization time of patients receiving rehabilitation with magnetic stimulation (HITS™) and electrostimulation (ES). * $p<0.05$. Adapted from of Dimitrov et al.*[99]

Table 2: Summary of selected parameters obtained from reviewed studies

Clinical application/ indication	Muscle strengthening, body firming/toning/ shaping		Stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and male and female urinary incontinence and other pelvic floor disorders		Pain management		Rehabilitation of motor control impairments due to disease or injury	
No. of reviewed studies (Cumulative no. of patients)	**17 (406)**		**37 (1498)**		**15 (280)**		**18 (256)**	
	Range	**Median**	**Range**	**Median**	**Range**	**Median**	**Range**	**Median**
No. of sessions	**1-24**	**4**	**1-20**	**12**	**1-15**	**6**	**1-60**	**10**
Interval between sessions (day)	**2-4**	**3**	**2-7**	**3**	**1-3**	**1**	**1-5**	**1**
Session duration (min)	**15-30**	**30**	**15-30**	**20**	**10-25**	**20**	**15-30**	**20**
Stimulation frequency (Hz)	**/ $^{\alpha}$**	**/**	**5-60 $^{\beta}$**	**20**	**10-20**	**20**	**5-40**	**20**
Stimulation intensity (% MSO*)	**40-100 $^{\delta}$**	**/ $^{\theta}$**	**15-100 $^{\delta}$**	**/ $^{\theta}$**	**5-100 $^{\delta}$**	**/ $^{\theta}$**	**20-100 $^{\delta}$**	**/ $^{\theta}$**
ON time (s)	**1-5**	**5**	**2-10**	**5**	**1-25**	**5**	**0.5-10**	**2**
OFF time (s)	**4-25**	**5**	**4-6**	**5**	**0.1-30**	**25**	**1-30**	**5**

$^{\alpha}$ Not reported in the majority of reviewed studies

$^{\beta}$ Frequently the session is divided in 2 phases, with frequency of stimulation in the first phase being lower (5-10 Hz) and higher (50 Hz) in the second

$^{\delta}$ Up to patients tolerance

$^{\theta}$ Only a range is reported the majority of reviewed studies – median value not applicable

* Intensity of stimulation is presented in percent of maximal stimulator output (MSO). Although not all magnetic stimulator devices used in the reviewed studies have the same MSO, it is nevertheless in a narrow range (2.1 ± 0.4 T) with a median value of 2T.

IV. DISCUSSION

In recent years, magnetic stimulation has been gaining popularity, especially in the field of body shaping, pelvic floor muscle strengthening, rehabilitation and pain management, which is reflected in a high number of published studies. In many studies reviewed here, stimulation with Electro Magnetic Field Devices serves as an alternative to electrical stimulation, due to an equivalent mode of action. Currently there are only a limited number of studies directly comparing the efficacy of magnetic stimulation versus ES and other treatment modalities. Nevertheless based on the this review, it may be concluded that MS is equally or more efficient compared to ES specifically in treating urinary incontinence and improving motor control as part of stroke rehabilitation. Moreover, the studies usually compare MS to a control group, or group receiving sham treatment, where a significant effect of the MS is generally demonstrated in case of all indication representing the scope of this review.

Notwithstanding, magnetic stimulation has other advantages over electrical. Patients receiving HITS™ do not need to remove their clothes because the procedure does not require placement of electrodes on their skin. Treatment by magnetic stimulation allows painless stimulation of deep muscle structures that cannot be reached by electrical stimulation. The magnetically induced electric field decreases less with tissue depth compared to electrical stimulation, which may improve fiber recruitment in large muscles or overweight individuals. The magnetically induced electrical field at a depth of 40 mm may be up to ten times greater than that produced by a large surface electrode pair.[100] HITS™ over a muscle belly can trigger muscle contractions at relatively low intensities with minimal cutaneous sensations, resulting with much lower discomfort of magnetic stimulation, compared to electric stimulation. [100,101]
The technology has few transient negative side effects. The most common side effects appear to be muscle fatigue and muscle soreness the day after treatment, comparable to post-voluntary-workout fatigue.

In the following paragraph indication names corresponding to a), b) and d) are shortened to *Body shaping*, *Pelvic floor strengthening* and *Rehabilitation*, respectively, for the purpose of conciseness. Based on available data from the reviewed studies (Table 2) it is evident that the parameters of magnetic stimulation protocols exhibit a considerably wide range. Comparatively, the median number of sessions administered for *Rehabilitation* and *Pelvic floor strengthening* was higher than in *Body shaping* or *Pain management*. In *Pain management* and *Rehabilitation* the sessions are administered daily, whereas in *Body shaping* and *Pelvic floor strengthening* these are spaced 3 days apart. The duration of one treatment session is frequently longer in *Body shaping*, compared to other indications. Considering also ON and OFF time ratio, the shortest times of magnetic stimulation are typical for Pain management and *Rehabilitation*. The median frequency used for *Rehabilitation*, Pain management and *Pelvic floor strengthening* is 20 Hz. In case of *Body shaping* the frequency is mostly not reported, possibly due to proprietary nature of information. Regarding intensity of stimulation, the majority of studies only reported a range of intensities used. This partly reflects the fact that intensity is frequently adjusted to the patient tolerance level, which varies between patients and also between sessions for a specific patient. However, from the range reported in studies it is evident that lowest intensities are applicable in *Pain management*, followed by *Pelvic floor strengthening* and *Rehabilitation*.

V. CONCLUSIONS

Electro Magnetic Field Devices demonstrate clinical application in the fields of aesthetics, urology, rehabilitation, physiotherapy and pain management, which is based on stimulation of motor and sensory nerves inducing muscle contraction and neuromodulation effects. There does not seem to be one particular preferred protocol for each application. For example, similar strength improvements might be obtained by a variety of protocols and the same protocol might result in variable improvement. However, most of the studies with the aim to improve muscle strength apply a maximal tolerated intensity to generate strong muscle contractions, and lower intensities are more frequently used in Pain management. It is important to note that the intensity of stimulation depends on tolerability as indicated by the patient. Increasing the stimulus may lead to unpleasant sensations, while stimulation at a lower level of the maximum may lead to suboptimal outcomes. Aside for *Muscle strengthening, body firming/toning/shaping* where frequency of stimulation is mostly not reported, 20 Hz is most frequently used for clinical applications. Several sessions are needed to achieve a clinically relevant result, with the highest number of sessions typical for *Rehabilitation of motor control impairments due to disease or injury* and *Pain Management*, and the lowest number of sessions needed for *Muscle strengthening, body firming/toning/shaping*. A dose-response was noted in some studies on *Pelvic floor strengthening* with more sessions resulting in better improvement, and the discontinuation of therapy usually leading to recurrence of symptoms.

Based on the outcomes of this review we conclude that magnetic stimulation leads to improvement in muscle strength endurance, muscle power/exercise capacity, Quality of Life related to muscle function, increased muscle size, improved aesthetics and patients satisfaction, improvement in musculoskeletal pain, motor control, reduction of spastic tone and paresis, improved joint range of motion and improvement of symptoms of incontinence.

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