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End User Survey on the Use of High Intensity Tesla Stimulation (HITS®) Magnetic Devices

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ABSTRACT

HITS® magnetic stimulation devices can be applied for multiple indications for use and for a variety of types of patients.

AIM: The aim of the end-user survey was to acquire information from end users about frequency of use of magnetic stimulation devices for particular indications, the specifics of their treatments, and to obtain information on side effects observed with the use of magnetic stimulation devices in their practice.

METHODS: The survey was prepared in electronic form. The online survey platform 1ka.si was used to design the survey and to gather the responses. In the first part of the survey, information about the end-user – name (optional), country, length of experience with the device, type of device and accessories used – was collected together with questions about satisfaction with the instructions for use and user interface. Afterwards, the end-users were asked about indications they use the device for, their estimate of efficacy, the procedures used, the number of patients treated, body areas treated and observed side effects.

RESULTS: Of the 96 valid responses, 81% of respondents listed the indications for which they use magnetic stimulation devices. Of those, 81% of respondents reported using it for muscle strengthening/body toning, 67% for treatment of incontinence, 26% for rehabilitation and 33% for treatment of sports injuries. Effectiveness was evaluated on a 5-point scale (1-very poor, 5-very good) and the average rating was above 4 for all indications. Most users rated the effectiveness as "good" or "very good". The end-users reported an average of 5–12 patients treated per week per indication with one device. Responses about known possible side effects and adverse events were mostly rated "never observed" or "uncommon" (<1% of treated patients). The most commonly observed were muscle soreness and muscle pain. Night-time palpitations were suggested as an additional side effect by one user. No other new side effects were reported.

CONCLUSIONS: The results from this survey have recognized HITS® treatments as very effective and safe. The gathered data provides important information on practice patterns, clinical outcomes, safety profiles and other end-user insights. A continuation with future surveys is important to gain information on possible changes and trends in this field.

Key words: magnetic stimulation, muscle toning, incontinence.

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I. INTRODUCTION

Magnetic stimulation is a non-invasive treatment method that can penetrate through skin to stimulate deeper conductive structures in a painless manner. When delivered peripherally, magnetic stimulation can generate electrical stimulation of selected motor nerves, inducing muscle contraction, which is utilized in treatments of muscle toning or strengthening; as well as sensory nerve stimulation, inducing the relay of sensory information to the central nervous system, which is mostly utilized in rehabilitation and pain management. These treatments are also known as functional magnetic stimulation (FMS), repetitive peripheral magnetic stimulation (rPMS), or as the recently introduced High-Intensity Tesla Magnetic Stimulation (HITS®). HITS® denotes a proprietary magnetic technology developed by Fotona d.o.o. and Iskra Medical. Although this technology shares a similar mechanism of action to functional electrical stimulation, magnetic stimulation has a deeper tissue penetration at intensities that do not activate skin pain receptors, making it a more efficient and comfortable method for nerve activation and muscle contraction than electrical stimulation.

It has been demonstrated that magnetic stimulation is an effective tool for 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 [1–3]; for improvement of motor control after disease or injury [4, 5]; for muscle strengthening and/or body toning/shaping [6, 7] and also for alleviating musculoskeletal pain [8, 9]. In various studies conducted since 1995, there have been almost no adverse events reported. Thus, HITS® can be considered as a treatment method with a high level of tolerance and safety.

The advantages of non-invasive body shaping solutions, such as HITS®, over invasive body shaping treatments are: increased safety, faster treatments, no downtime, and the absence of any incision-induced permanent tissue damage. Because of these reasons, the popularity of non-invasive solutions is constantly growing. HITS® treatment of urinary incontinence has similar benefits to those of non-invasive body shaping, leading to a high level of interest in non-invasive treatment of urinary incontinence. Numerous different approaches that are more invasive have been in use for treatment of urinary incontinence, and although they have been greatly refined over the years, complications can still occur[10].

With our end-user survey, we aimed to acquire information directly from the end-users of Iskra Medical's HITS® devices.

There were two primary goals of the present end-user survey. The first goal was to obtain information that would allow for an estimation of the number of patients treated for particular indications. Therefore, the end users were asked which HITS® magnetic stimulation device they use, which indications they treat, and how many patients they see for a particular indication. We also asked the end users how often they use magnetic stimulation devices for particular indications and about the effectiveness of the device for particular indications; The second goal was to obtain more detailed post-market safety data for magnetic stimulation devices. The end users were asked to report any observed side effect for every performed indication, as well as about their frequency.

II. MATERIALS AND METHODS

This study was conducted using a web-based survey (1ka, Version 21.02.16, Fakulteta za družene vede, Ljubljana). An invitation to respond to the survey was sent to registered users of Iskra Medical magnetic devices. Data collection took place from 19.10.2020 to 7.3.2021. Responses were automatically recorded and analysed using an online software program (1ka, Version 21.02.16, Fakulteta za družene vede, Ljubljana).

The following metrics were calculated/reported:
-Global distribution of respondents.
-The distribution of respondents according to starting year of use of a magnetic stimulation device.
-For each question the proportion of respondents who answered the question.
-The proportion of respondents who use a particular Iskra Medical magnetic stimulation device.
-The proportion of respondents who use a particular accessory with their Iskra Medical magnetic stimulation device.
-For each indication for use the average number of treated patients per week.
-The proportion of end-user respondents who perform specific indications.
-For each indication of use, the average estimate of effectiveness.
-The proportion of respondents who treat a specific body area.
-For each listed possible side effect, the average estimate of frequency.

III. RESULTS

A total of 96 practitioners from 22 different countries responded to the survey. The average duration of use of a magnetic stimulation device was three years. Out of 66.7% (n=64) of respondents who provided information on the devices they use, 70.3% (n=45) reported owning only one Iskra Medical magnetic stimulation device, whereas 29.7% of the respondents (n=19) reported owning more than one Iskra Medical FMS device. The most frequently used device was the TESLA Former (18%), followed by the TESLA Stym (15%), TESLA Former prestige (15%), Magneto STYM (13%), TESLA Care prestige (9%), FMS Former (7%), TESLA Stym prestige (5%), FMS Stym (4%), TESLA Care (4%), Magneto STYM prestige (3%), FMS Former prestige (3%), FMS Stym prestige (1%), FMS Care (1%) and FMS Care prestige (1%).

81% (n=78) of all respondents provided information on indications for which they use their magnetic stimulation device. The most performed indication was strengthening of healthy muscle, i.e. muscle toning (81%), followed by urinary incontinence (67%), sports injuries (33%) and rehabilitation after immobilization (27%). Other listed indications that users reported to perform but were not listed in the survey were: *neuropathic pain, cosmetic, neurological pathology, v. complete rehabilitation, pelvic pain, radicular pain, pains, anal incontinence, low backache, edema, erectile dysfunction.*

The reported mean effectiveness score was very

high for all indications - 4.3 or more (on a 1-5 scale, 5 representing maximum effectiveness), with rehabilitation after immobilization having the highest score of 4.6 (Table 1). The highest number of patients per week were treated for muscle toning (n=12), followed by rehabilitation after immobilization (n=11), and sport injuries (n=8) and urinary incontinence (n=5), (Table 1).

The most frequently used programs for muscle strengthening (muscle toning) and urinary incontinence are presented in Figures 1 and 2. Due to heterogeneity of the answers regarding the program used for rehabilitation after immobilization and sports injuries, quantitative analysis was deemed inappropriate and was not included in the analysis.

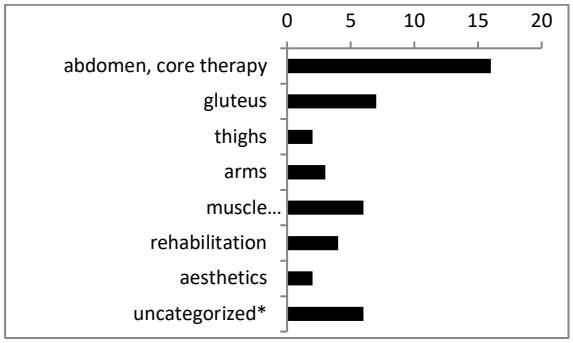

Figure 1: Most frequently used programs for muscle toning (n=31).

Multiple categories per single user were possible. Results are presented as number of respondents. *uncategorized answers: per requirements, various programs, medium, manual, many different

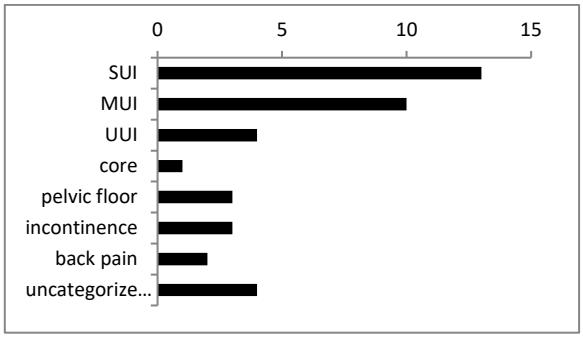

Figure 2: Most frequently used programs for urinary incontinence (n=29).

Per single user, multiple categories are possible. Results are presented as number of respondents. * uncategorized answers: different/many different, as per requirements programs for incontinence

Users have reported using magnetic intensity ranges from 2 to 100%. The most frequently used magnetic intensity range for muscle toning was from 72 to 100%; for urinary incontinence from 62 to 70%; for rehabilitation after immobilization from 42 to 70%; and for sport injuries from 62 to 70%.

The most frequently targeted body areas on which users have used the HITS® device are presented in Fig 3.

Table 1: Effectiveness of Iskra Medical magnetic stimulation devices for specific indications; estimation of the number of patients treated per week per indication per device; mean number of sessions. ***[i] Percentage of active users performing a specific indication. [ii] Mean effectiveness, calculated on the basis of effectiveness scores provided by respondents[iii]. N_p=Estimated number of patients treated per practitioner per year (number of weeks=52).***

Indication	Mean effectiveness [ii]	SD	Number of respondents[iii]	Number of patients treated per week	Number of respondents [i]	N_p	Mean number of sessions				
							1–5	6–10	11–15	16–20	21–25
Strengthening of healthy muscle, e.g. muscle toning	4.3	0.68	n=63	12	n=44*	624	25.0%	67.5%	12.5%	2.5%	0.0%
Urinary incontinence	4.3	0.69	n=49	5	n=34*	260	20.6%	61.8%	17.6%	11.8%	2.9%
Rehabilitation after immobilization	4.6	0.6	n=20	11	n=10*	572	30.0%	60.0%	20.0%	0.0%	0.0%
Sports injuries	4.4	0.75	n=26	8	n=14*	416	42.9%	50.0%	21.4%	0.0%	0.0%
Other: neurological pathology, pain, radicular pain etc.	4.1	0.9	n=7	2	n=3	104	66.7%	33.3%	0.0%	0.0%	0.0%

*One respondent excluded from analysis due to invalid value.

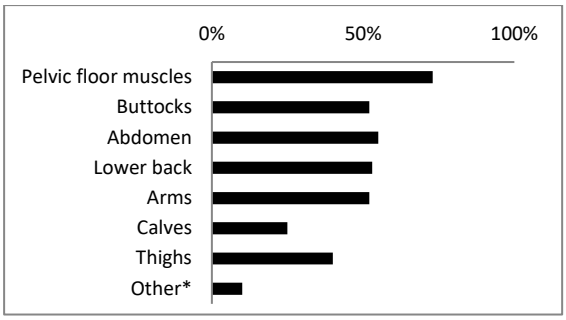

Figure 3: Most frequently targeted body areas (n= 60).
* Other: deltoids, arti, diaphragm, shoulders, upper back

A majority, 61% (n=59), of all users answered the question about known side effects following the magnetic stimulation treatment. Known possible side effects were mostly rated as "never observed" or "uncommon". The most commonly observed side effects were delayed onset muscle soreness (24%) and muscle pain (22%) (Table 2). Palpitations were suggested as an additional side effect by one user. No other new side effects were reported.

IV. DISCUSSION

Contemporary lifestyle and healthcare trends are strongly moving towards treatment personalization, so it is essential to consider not only technological and clinical aspects during the product and service development cycle, but also the users' experiences and demands. In this context, the end-user surveys can provide important information on attitudes, beliefs, practice patterns, behaviors and concerns of health care providers and patients. An additional benefit of conducting end-user surveys is obtaining real world safety and effectiveness data from every-day clinical practice.

The results of this user survey offer valuable insights into the most frequently performed HITS® procedures and their effectiveness, as well as the most commonly used parameters for performing HITS® treatments. The end-user respondents reported positive clinical outcomes from HITS® treatments without treatment-related complications.

The data obtained through this survey allowed us to estimate the numbers of patients and the frequency of use of the surveyed HITS® magnetic stimulation devices for particular indications for use. Based on the number of patients treated per week per specific indication, the estimated number of patients treated was highest for muscle toning (n=624 patients per practitioner per year) followed by rehabilitation after immobilization (n=572 per practitioner per year). Although the number of patients per week was higher for rehabilitation than for pelvic floor strengthening, rehabilitation was reported to be performed by fewer users, indicating that while rehabilitation might be a niche application for a smaller group of HITS® device users, it appears to attract a high number of patients to their practices.

When looking only at the number of respondents that reported to perform specific indications, the highest number of correspondents reported to perform muscle toning treatments, followed by pelvic floor strengthening (urinary incontinence). This confirms that these indications share the highest demand from patients, which is useful information for current and future device users. The effectiveness of the HITS® treatments was evaluated on a 5-point scale (1-very poor, 5-very good) and the average rating was above 4 for all indications. Most users rated the effectiveness as "good" or "very good". Users reported a high degree of effectiveness for all indications. As a possible option to further increase the effectiveness and success rate of the treatments, further emphasis should be made on appropriate patient selection.

We have also collected important real-world data about the number of treatment sessions used for specific treatment groups. Similar average numbers of sessions

Table 2: Side effects and estimation of their frequency.

Side effect	Number of respondents		Answers				Mean score (max. 4)	SD	Median
			Never observed	Uncommon (< 1%)	Common (1–10%)	Very common (> 10%)			
Skin burns	100%	n=59	75%	17%	8%	0%	1.3	0.6	1
Paresthesia	98%	n=58	79%	14%	7%	0%	1.3	0.6	1
Delayed onset muscle soreness	98%	n=58	41%	33%	24%	2%	1.9	0.9	2
Muscle pain	100%	n=59	32%	44%	22%	2%	1.9	0.8	2
Skin redness	98%	n=58	59%	28%	12%	2%	1.6	0.8	1
Other	18%	n=18	89%	6%	6%	0%	1.2	0.5	1

were reported across all indications. For muscle toning, urinary incontinence and rehabilitation, the mean number of sessions was 6-10 in 60% or more of cases. For treating sports injuries, 6-10 sessions were performed in 50% of cases and 1-5 sessions in 43% of cases.

Although there is still no consensus about the optimal number of sessions for the treatment of urinary incontinence, the existing literature reports the range of 8-16 sessions, and also shows that the beneficial effects improve with an increasing number of sessions[11]. Although the published clinical trials often used high session numbers, the data from our survey has revealed that only 6-10 sessions are usually performed, and only in 17.6% cases the mean number of session is 11-15. Although the number of sessions was often lower than reported in published clinical trials, the effectiveness reported by the users was high; indicating that wider clinical use in daily practice results in an optimization of the number of sessions.

Another important insight from this user survey was the range of most-often-used treatment intensities, which revealed that the highest intensities are being used for muscle toning treatments.

In addition, the HITS® treatments have been confirmed to have an excellent safety profile. Previously known listed side effects were mostly rated as "never observed" or "uncommon" (<1% of treated patients) by the survey respondents. The most commonly observed side effects were muscle soreness and muscle pain. Night-time palpitations were suggested as a potential side effect by one user. Palpitations have been previously identified as a potential rare side effect through the manufacturer's clinical evaluation.

Proactive gathering of the safety data, such as this end-user survey, is very important, since users usually do not regularly report device-related side effects, especially when these are minor and transient, as is mostly the case with HITS® therapy. Furthermore, some more serious side effects (such as e.g. burns) are often not reported, since they may be caused by user error. Proactive gathering of anonymized end-user data, such as with this survey, can paint a better and much clearer picture of the treatments' safety profile.

The collected real-world data in our study gives important insights and builds a more comprehensive picture of the frequency of specific treatments and their efficacy and safety in every day clinical practice. This will allow the manufacturers, clinicians and patients to better understand the effectiveness and safety of HITS® treatments in a larger pool of patients, for a longer period of time, and enable more informed decision-making at all levels.

V. CONCLUSIONS

Results from this survey have confirmed HITS® treatments as very effective and safe. The gathered data provides important information on practice patterns, clinical outcomes, safety profiles and other end-user insights. A continuation with future surveys is important to gain information on possible changes and trends in this field.

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