Clinical study of high-inductive electromagnetic stimulator
Salus Talent

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Abstract:
This is a pilot study for clinical tests of analgesic effect of electromagnetic stimulator SALUS talent in pain of locomotive organs. It is the first magneto-therapeutic device, with which can be subjective intensity during the application achieved, as well as magnetic induction of 2.5 Tesla. The statistical sample consisted of 89 patients, both rehabilitation clinic and patients undergoing treatment at Spa Dolní Lipová with cutaneous indications. In terms of the locomotor system the problem was mainly a structural failure. Most patients recorded a distinctive, early, long-lasting analgesic effect. As a dominant is the effect of this therapy, which appears to be dispersed, directly and also through the activation of the sympathetic in spinal storey, with following improvements of thixotropic properties of tissue in the area of application.

Key words: magnetotherapy- analgesia- analgesic effect- effect of dispersion- salus talent

Introduction:
In the field low-frequency pulse magneto-therapy are at present changes in opinions about the effect of lower inductions (1, 2) as well as in the possibility of applying a high electromagnetic induction. While the first trend leads to a gradual reduction of the induction and actually getting closer to the effect of distant electrotherapy, tested device SALUS Talent is outcome of the second trend. Professional public perhaps have at the first time at their disposal magneto-therapeutic device, which applicator reaches the magnetic induction of 2.5 T, whereas previously used devices operates with induction of 10 to (rarely) 50 mT. Such high amount of energy induces in the conductive tissues at the place of application the electrical current, which patient perceives as a mild tingling or vibration. This is a significant progress compared with up to now used low-frequency pulse magneto-therapy and distant electrotherapy, which are apperceptive. Recently, it is also possible to work with the application of magnetic therapy with subjective intensity, as in the contact electrotherapy (3).

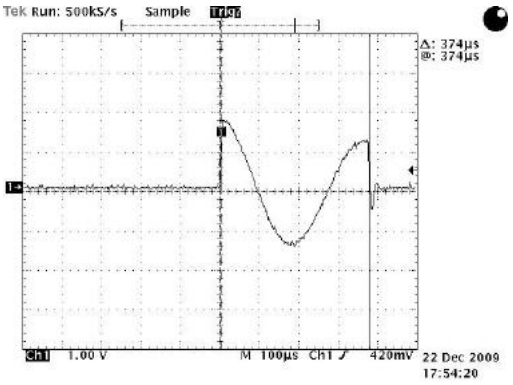
I. Effects

Manufacturer describes in detail analgesic effects, illustrated by classical theories – gate control theory and endorphin theory. Because during this therapy Aβ, Aδ and C fibres are undoubtedly irritated and a frequency modulation of each program is adjusted to that effect, such claim can be accepted. The clinical tests showed other effects (see below), which cannot be explained by analgesia. The main reason why cannot only the analgesic effect be accepted („symptomatic pain softening regardless of aetiology) is finding out the duration of analgesia achieved in a study. Professional literature does not deal with this aspect. From the experience of the author and neurophysiologic explanations of individual theories concerning pain softening emerges that the analgesic effect of procedures, working on the basis of gate control theory, lasts 35-50 minutes after the end of the application. The procedures using the endorphin theory of pain softening is for 45-60 minutes and only the code theory (which cannot be used by SALUS Talent yet) with the analgesic effect lasts up to 2 hours. With this

device a relief has been reported even as a complete disappearance of pain for a few days or weeks (!), what necessarily leads to search for other explanations (see discussion).

II. Modes

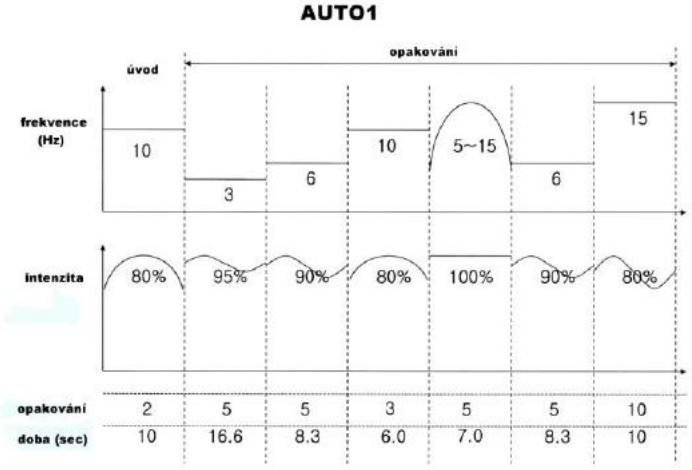
Device has pre-programmed 4 automatic and 4 manual modes, in study only automatic modes have been used, due to lack of experience with setting up individual parameters. Biphasic pulse length is 350 μs±20% (practically 280 to 420 μs).- pic. 1.



Pic. 1: Biphasic impulse used by SALUS Talent device

A) Mode A1

Low-frequency stimulation, also frequency and amplitude modulations are used. Frequency modulation runs in variably long periods (see pic.2), the lowest frequency is 3 Hz, and the highest is 15 Hz. Amplitude modulation runs always at the constant frequency and vice versa.

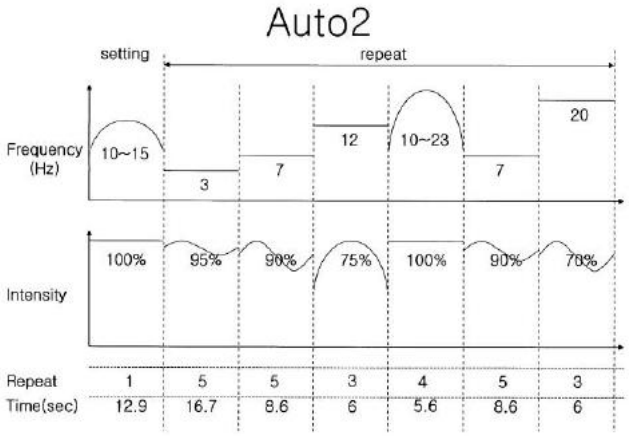


Pic. 2: Modulation in mode A1

This mode has been tested on the structural joint disorders – activated gonarthrosis, coxathrosis, and psoriatic artropathy in various localisations. For the acute pain the subjective intensity is threshold sensitive and for chronic ones it is over-threshold sensitive.

B) Mode A2

Low-frequency stimulation, also frequency and amplitude modulations are used. Frequency modulation runs in variably long periods (see pic.3), the lowest frequency is 3 Hz, and the highest is 23 Hz. Amplitude modulation runs always in constant frequency and vice versa.

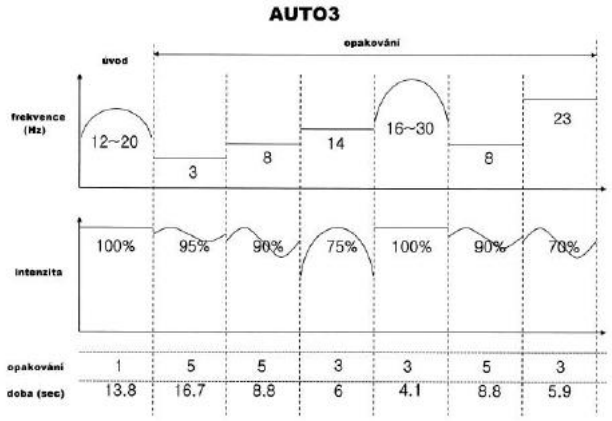


Pic. 3: Modulation in mode A2

This mode has been used in structural disorders with significant reaction of soft tissues (with muscles exception) around damaged joints in diagnosis same as in mode A1. For acute pain the subjective intensity is threshold sensitive, for chronic ones it is over-threshold sensitive.

C) Mode A3

Low-frequency stimulation, also frequency and amplitude modulations are used. Frequency modulation runs in variably long periods (see pic.4), the lowest frequency is 3 Hz, and the highest is 30 Hz. Amplitude modulation runs always in constant frequency and vice versa.

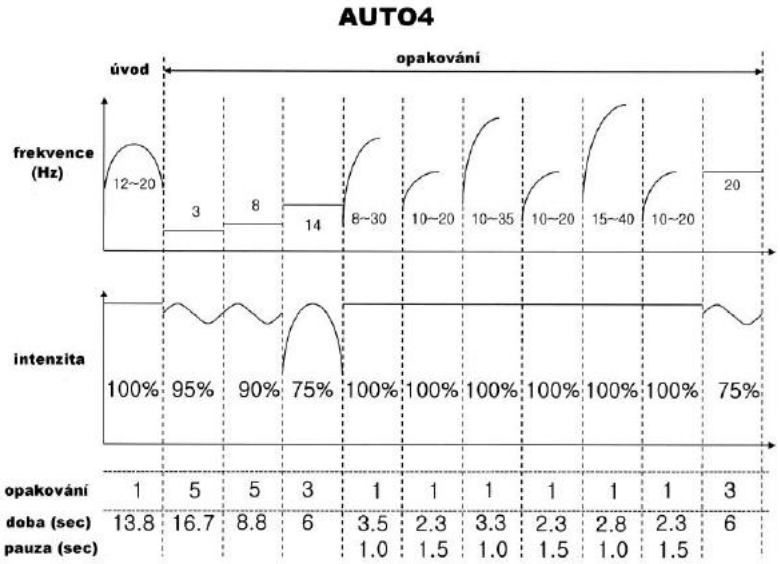


Pic. 4: Modulation in mode A3

This mode has been used in structural disorders with significant reaction of soft tissues, and also muscles around damaged joints in diagnosis same as in mode A1. Moreover, it was used in the muscular hypertonia of back muscle. For acute pain the subjective intensity is threshold sensitive, for chronic ones it is over-threshold sensitive.

D) Mode A4

Low-frequency stimulation, also frequency and amplitude modulations are used. Frequency modulation runs in variably long periods (see pic.5), the lowest frequency is 3 Hz, and the highest is 40 Hz. Amplitude modulation runs always in constant frequency and vice versa. During frequency modulation and 100% set up intensity are automatic pauses inserted.



Pic. 5: Modulation in mode A4

Indication was mainly pain in axis organ with muscular hypertonia and reflexive changes, sticking fascias. For acute pain was prescribed the subjective intensity of threshold sensitive, and for chronic ones the over-threshold sensitive.

III. UNWANTED EFFECTS, CONTRAINDICATIONS

Unlike the manufacturers of currently used devices, of which contra-indications and safety guidelines are extensive, the instrument SALUS Talent with practically hundred times higher magnetic induction is contra-indications more than brief:

- high fever (without further specification)
- Gravidity, advanced age (!)
- Heart diseases, particularly cardiostimulator
- Metal implantants, particularly endoprothesis

In clinical manual (4) are among contra-indications mentioned spinal and bladder stimulators, st.p. brain surgery, stroke and brain accident.

In manufacturer´s manual (5) is further recommended:

- Place the device in sufficient (?) distance from generators, devices using high-frequency waves and loose cables (?)
- Necessary condition is a separate electrical circuit and a stable power supply
- Do not use the device simultaneously with other electronic medical devices
- Usage of cell phones, radios, portable wireless receivers and radio-controlled toys is prohibited

Methodology

SALUS Talent device was borrowed for testing by Drott Medizintechnik GmbH, Austria, www.drott.at. Manufacturer is CRTechnology CO., LTD.,, Korea, www.c-r.co.kr. The statistical sample consisted of patients of rehabilitation clinic Spa Dolní Lipová and patients undergoing treatment at Spa Dolní Lipová with cutaneous indications in the period from April to June 2010. Given sensitive perception of each patient and the opto-acoustic indication of the applied electromagnetic energy, it could not be possible to create a control group which received placebo (for these purposes, the manufacturer usually supplies the device with zero induction, but maintaining the acoustic and visual signalisation, which during the realisation of the study was not available). To the statistical sample were placed all patients with pain in the locomotive apparatus, with the exception of a clear functional disorders that were treated causally. The statistical sample consisted of 89 patients - 28 men in the age range 25-71 years, average age 51.5 and 61 women, age range 32-73 years, average age 55.6.

When evaluating the decrease of pain by visual analogue scale there was generally a decrease of pain on average of 26.46 mm at men and 27.27 mm at women.

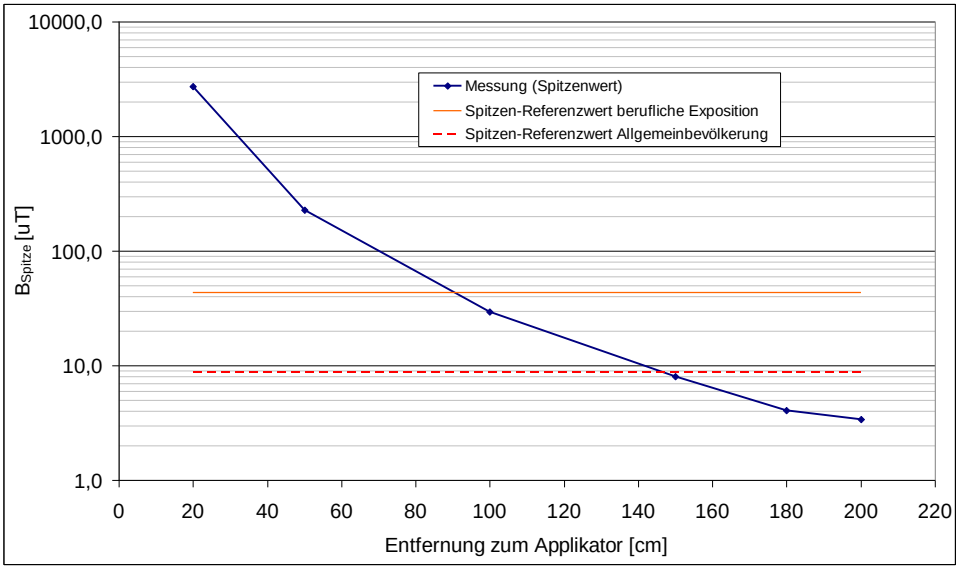
Input data: anamnesis, clinical examination by a doctor, input visual analogue scale of pain (visual analogue scale = VAS)

Parameters: AUTO program due to recommendation of the manufacturer, subjective intensity with threshold sensitive (TS) for acute conditions, over-threshold sensitivity for chronic conditions. Number of procedures is 10; length of application is as follows 5-5-10-10-15-15-15-15-15-15 minutes.

Output data: a subjective patient assessment, clinical examination by a doctor, final visual analogue scale of pain (VAS 2).

On all probands was pulse magneto-therapy by SALUS Talent device lead as mono-therapy to prevent distortion of results. Although it can be applied across the clothes, in a study was selected the application to the uncovered area, the applicator was in a standard distance of 1 cm from the most prominent part of the application domain. The study included only the patients with a total number of completed applications 10.

During planning the study was the risk of damage eliminated: the operating personnel and other equipment for physical therapy. Propagation of electromagnetic field from the applicator has been verified by simple, affordable methods – by the permanent magnet in hand and the monitor switched on. Both methods gave indicatively similar results as exact measurements (see pic.6). At the time of the study the device was placed in a separate room (building) for fear of possible interference with other devices. It is now located at the workplace of physical therapy and it is only operationally separated from the workplace of shortwave inductive diathermy.



Pic. 6: Lowering gradient of the magnetic induction at application of SALUS TALENT

The clinical study was approved by ethic commitee of Spa Dolní Lipová. All patients were treated voluntarily.

Results

The overview provides a basic diagnosis of patients treated, the number of patients and changes in pain sensitivity converted to mm VAS.

Representation of diagnoses:	number of patients	pain sensitivity decrease on VAS (mm)
gonarthrosis (M17.*)	19	24
coxarthrosis (M16.*)	15	43
other arthrosis (M19.*)	16	23
syndrom of stubbed shoulder (M75.4)	9	27
vertebral alg.sy. LS (54.9)	9	27
psoriatic arthropathy (M07.*)	8	12*
other enthesopathia (M77.*)	6	25
vertebral alg. sy. CB	4	12
reumathoides artrithis (M05.9)	1	16
other determined arthropathy (M12.8)	1	-8**
polyarthrosis (M15.9)	1	3

* 3 patients had subjective and objective deterioration. All this was primarily an acute exacerbation with typical signs of inflammation - swelling, local temperature increase, redness.

** Problems with understanding of VAS

Discussion

The biggest surprise of the author, and all of the patients was the analgesic effect, often noticeable even after the first application. Although the study has only evaluated the analgesic

effect (in correspondence with the manufacturer's recommendations) and also the effects of dispersion, anti-swelling and less myorelaxation, trofotropness were observed at the structural problems.
Repeatedly noted decrease in pain, swelling and improved range of motion in the afflicted joint, persisting even after the 1-2 applications in weeks range, what cannot be explained by a decreasing pain under gate control and endorphin theory of pain decreasing. Already during the first weeks it has been clear that (high-inductive) electromagnetic stimulation must be subject to the different rules than the classical (low-inductive) magneto-therapy.
Although the group of patients for each diagnosis is small, it seems to be, that the dominant effect of the therapy is the effect of dispersion (hydration of hyaluronic acid in synovial fluid and in amorphous intercellular tissue mass) both direct, and also via activation of the sympathetic spinal storey, with subsequent improvements of thixotropic properties of listed tissues. It, as well as causal intervention, leads also to a reduction in pain, improving mobility and decreasing of swelling. This working hypothesis will need to be tested in the workplace with required background.

Conclusion

Despite the well-known opinion of the author on the use of physical therapy at the structural (especially degenerative) diseases of the musculoskeletal system, in the interest of objectivity it must be conceded that in case of tested device the situation is different. Retreat of pain, swelling, improving mobility and consequently the quality of life, often even after the first application, lasting for weeks is a phenomenon, which existence in the physical therapy is unrecorded. Obviously, it will be necessary to verify the individual effects on other workplaces and selectively compiled files. However, already these first clinical tests lead to the conclusion that the initial sizeable investment in equipment is returned as a significant therapeutic effect.

Recommendations for further research and study:

- Number of procedures is 5-6, the optimal frequency for the procedure is the first two daily, then every other day
- Length of applications - application longer than 10 minutes does not lead to increased effect, therefore scheme 5-5-10-10-10 (10) minutes is recommended
- subjective intensity with threshold-sensitive (TS) for acute conditions, over-threshold sensitive (OTS) for chronic conditions,
- when applied to the joints, these joints should be positioned to preferably in centred position
- application on clothes uncovered area.

Recommendations for contraindications (supplement):

- children and adolescents before the termination of growth due to the potential damage to growth plates,
- neurological seizure (epilepsy) and psychiatric (psychosis) diseases when applied to the head,
- Pregnancy, esp. beginning. For women of childbearing age tied the initiation of therapy at the time of just ended period
- myasthenia gravis

Use of the device within the network of health facilities would be optimal at rehabilitation clinics, bedded rehabilitation wards, and especially in the spa, where dominantly disorders of musculoskeletal system (i.e., indicating the group VII) are treated and where the structural (degenerative) disorders form most of the treated diagnoses. Preliminary results of this pilot study give better and quicker effect than used natural medicinal resources. Finally, this device can be used by workplaces and individual physical therapists who work with rheumatologists and orthopaedists, and plenty of suitable patients will be able to use the device throughout the work period.

In terms of performance reporting to health insurance companies in the Czech Republic is device reported under the code 21113 - Physical Therapy II. In terms of the inclusion of instrumental techniques in its codes, however, it should belong to the Physical Therapy III (code 21115) with regard to the cost of the device, the required number of procedures and expected number of treatments per year. This should be the task for the professional public and its Section of Physical therapy - when the effect is proved in other workplaces, it should be an argument for health insurance companies, for savings on long-term pharmacotherapy of the structural musculoskeletal system.

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