

StimaWELL® 120MTRS

HANDBOOK

**EVIDENCE SUPPORTED
BACK TREATMENT**

THERAPY - THEORY - BEST PRACTICES

DEEP WAVES

StimaWELL® 120MTRS



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DEEP WAVES

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1 BACK PAIN

Back pain, because of how often it occurs, is classified as a widespread disease in modern societies. Up to 85% of the population has experienced back pain at least once in their life.

¹ One in two Germans (52%) suffers at least occasionally from back pain. 2016 alone, back pain was the third most common primary diagnosis in care and rehabilitation facilities. ²

Graphic 1: Statistic Common Illnesses Survey & OCT 2017, „How often did you suffer from back pain in 2016?“



Source: Statista 2017³

1.1 CLASSIFICATION

Back pain is a term given to all mild or moderate pain experienced in the back, irrespective of its cause. The pain usually occurs in the lumbar region, and is therefore known as low back pain (lumbago). A distinction is made between specific and non-specific back pain, with 85% of back pain being classed as non-specific. Specific back pain is defined based on a clearly identifiable cause (e.g. tumours, inflammatory rheumatic diseases, etc.). By contrast, chronic non-specific back pain is the term used if no clear somatic cause can be found, and the pain persists or recurs over a period of three to six months. ⁴

With regard to non-specific back pain, medicine generally refers to dorsalgia or, in the more narrow sense, pain in the area of the thoracic spine, as thoracic spine pain. Pain in the cervical spine is often referred to as neck pain, cervicalgia or cervical spine pain. When the pain radiates to the extremities, this is known as sciatica if it occurs in the lumbar spine, and brachialgia or cervico-brachialgia if it occurs in the cervical spine.

The international classification of diseases system (ICD-10-GM Version 2013) refers in Section XIII Diseases of the Musculoskeletal System and Connective Tissue (ICD-10-GM: M00 – M99) to various conditions of the spine and back (ICD-10-GM: M40 – M54). These include spondylopathies (ICD-10-GM: M45 – M49), i.e. diseases of the vertebrae or spinal column with demonstrable structural defects and other diseases of the spine and back (ICD-10-GM: M50 – M54) (see Table 1).⁵

Table 1: Classification of back pain (dorsopathies) according to ICD-10-GM, source: DIMDI

ICD Code	Disease or disorder (example)
M45-M49	Spondylopathies
M45	Ankylosing spondylitis (morbus bechterew)
M46	Other inflammatory spondylopathies (e.g. purulent disc inflammations)
M47	Spondylose
M48	Other spondylopathies (e.g. narrowing of the vertebral canal, fatigue fracture)
M49	Spondylopathies in diseases classified elsewhere (e.g. tuberculosis of the spinal column)
M50-M54	Other diseases of the spinal column and the back
M50	Cervical disc damage in the region of the cervical spine, with or without constriction of nerve roots or spinal cord
M51	Other disc damage in the thoracic and lumbar spine, with or without constriction of nerve roots or spinal cord
M53	Other diseases of the spine and back, not classified elsewhere (e.g. loosening of the structure of the vertebrae).
M54	Back pain M54-5 Lumbar back pain M 54-9 Back pain with no specific origin

The current National Care Guidelines for Sciatica (2nd Edition, 2017) categorises sciatica according to the timing of its occurrence. Specifically, acute back pain occurs when the pain persists for less than 6 weeks. Subacute back pain persists for 6 to 12 weeks and chronic back pain persists for

more than 12 weeks.⁶ Acute back pain occurs either for the first time or after at least a six-month period of being pain-free within one day and lasts for no more than three months. Temporary back pain lasts for no more than three months and does not occur again within a year, while recurrent back pain is associated with more than one episode on fewer than half of the days in a year. Chronic back pain is usually associated with more than one episode on more than half of the days in a year.

There are many common expressions in the German language to describe back pain, which is testimony to the frequency of its occurrence. Lumbago is the common term used to refer to a sudden, stabbing pain in the back caused by irritation of the sensitive nerves in the spine, i.e. the nerves that supply the spine itself - in other words, not compression of the nerves that exit the spine itself and which supply the rest of the body. This is an often acute-onset, initially clearly demarcated and usually stabbing lower back pain that is often associated with a sensation of numbness, forced posture, limitation of movement, tense muscles, pain on palpation of the spinous processes, and so on. After a period of low-grade pain, transition to a chronic form of back pain can occur. Delineation of the condition from symptoms of nerve root irritation, such as sciatica, is not always immediately possible. Doctors occasionally speak of „pseudoradicular symptoms“ if the pain radiates but does not correspond to the dermatomal pattern of a spinal nerve.

1.2 CAUSES

Back pain has many causes. The most common include poor posture and the unbalanced strain of the back muscles. The consequences are often tension and stiffening of the muscles which, as time goes on, can in turn cause back pain. Wear and tear of the intervertebral discs, vertebral bodies and spinal joints can also often cause such problems. Arthrosis (joint wear and tear) and narrowing of the spinal canal (spinal canal stenosis) can irritate the spinal cord nerves and lead to persistent pain. In the case of a slipped disc, the „gel core“ can bulge out of the damaged disc, press on the spinal cord nerves and therefore cause severe pain. As well as physical triggers, back pain can also be caused by psychological ones, such as stress, exhaustion and depression.⁷

According to the American College of Rheumatology, back pain, after the common cold, is the second most common condition to affect humans. People often attempt to alleviate

back pain by resting it. This runs the risk, however, of setting off a chronic process which can lead to further pain, since the muscles provide the spine with stability. Muscular conditions are not just the cause, but also the consequence of back pain: contractions of the deep autochthonous muscles as a result of local pain can lead to chronic muscle contractions, a limited range of movement and unequal load distribution across all of the body's structures. Various components contribute to the development and persistence of back pain, including poor muscle strength, muscular imbalances and neuromuscular deficits. In healthy people, the back muscles are made up of a high proportion of type I fibres, which are required to maintain the posture of the spine. In patients with lower back pain, there is evidence of destruction of the paraspinal muscles with a reduction in their diameter and fibre density. The surface EMG demonstrates increased muscle fatigue. In patients with chronic lower back pain, atrophy is especially pronounced in the paraspinal muscles, the psoas, the quadratus lumborum and the multifidus. Once these atrophies are diagnosed, customised back training is an essential element of these patients' treatment plans.⁸

1.2.1 MUSCULAR STARTING POINT

Moseley (2004) states that both lumbar and cervical back pain is associated with dysfunction of the core muscles.⁹ Cervical pain with altered spinal muscles can play an aetiological role in lumbar pain, just as much as dysfunctional core muscles can be the culprit for lower back pain. It can therefore be concluded that, by preserving functional core muscles, patients can prevent any consequent lumbar back pain. The role of prophylaxis is supported by Maher (2000) in his review of 13 studies, which claims that back exercises have a significant effect in the prophylaxis of occupational lower back pain.¹⁰ Linton et al. (2001) reach a similar conclusion, having analysed 6 randomised and controlled studies and confirmed the prophylactic merit of back exercises.¹¹ Rissanen et al. (2002), in their study involving 535 patients followed up over a period of 12 years or 6,559 person years, conclude that effective and dynamic extendability of the back will prevent an inability to work due to back pain.¹²

In their comparative study involving 105 patients with lower back pain, Manniche et al. (1991) were able to demonstrate that a more intensive training programme improves the condition of the back more effectively than a more gentle one.¹³ Chok et al. (1999) demonstrated in patients with subacute back pain that stamina training reduces pain and functional

impairment after 3 weeks compared to the control group and accelerates the healing process.¹⁴ Rainville et al (2004), in their review, investigated the question of whether patients with chronic back pain benefit from regular exercises. They discovered that exercises do not present any risk to these patients and reduce pain, anxiety and disability.¹⁵ Bala et al. (2012) investigated 38 patients with subacute lower back pain to determine the effect of stamina exercises of the back extensors in 2 exercise groups. In the control group, following the application of heat for 15 minutes, general mobility exercises and strengthening exercises of the lower back muscles were carried out for 30 to 45 minutes, 5 days a week, over a period of 3 weeks. In the experimental group, a programme of stamina exercises on the same scale was used, again after 15 minutes of heat application. The target parameters were the VAS and the modified Biering Sorensen Test, which were assessed on the 8th, 15th and 22nd day. In both groups, significant improvements were achieved in the target parameters.¹⁶ Yasuda et al. (2013) describe a significant, different rotational strength between the two lateralities of patients with lower back pain and, compared to healthy subjects, a significant reduction of the erector spinae and multifidus muscles. They recommend isometric exercises in order to counteract the atrophy.¹⁷

1.2.2 FASCIA

Fascia, derived from the Latin meaning band, is the name used to refer to the soft tissue components of the connective tissue that is found throughout the body and acts as an enveloping and connecting tensional network. Fascia is found almost everywhere in the body, in the skin but also in the cartilage, bones, joints, tendons, muscles and organs, including the brain and the spinal cord. Fascia keeps the body's shape and supports every muscle like a corset. Incorrect strain and lack of exercise can cause the fascia to twist, stick together or stiffen. Possible consequences of this include tension of the muscles in the neck, shoulder, back and legs. Targeted training of the fascia can release this tension and keep the connective tissue soft and elastic.¹⁸

Pain caused by stiffened or sticky fascia

Fascia reacts sensitively to various types of stimulus, including stress or overloading caused by too much sport, but also underactivity caused by a lack of exercise. In these conditions, the elastic fascia can thicken, stick together and become matted, sending signals to the muscles and causing them to excrete inflammatory substances.¹⁹

Fascia researchers particularly suspect the lumbar fascia as being the cause of sciatica based on this scenario. The lumbar fascia is the largest fascia in the body. It is located above the pelvis and connects the back muscles with the sacral and thigh muscles. If a physiotherapist stretches and pushes the fascia back into its natural position, it can be very painful.²⁰

Triggers of back pain can be hard to localise

The discovery of fascia is changing physicians' understanding of how back pain develops. Until now, only 20 per cent of back pain could be attributed to a clear cause: in some patients, vertebrae have become inflamed, in others intervertebral discs have slipped or the vertebrae are so worn that pain results.

The great majority of patients, however, suffer from non-specific back pain. This creates a problem for physicians: often, these patients go to the doctor and are first X-rayed. The images often also show changes in the spine. Countless studies, however, have shown that these changes often have absolutely nothing to do with the symptoms. The trigger point for non-specific back pain has so far been very difficult to identify. This is an unhappy situation both for the patient and the doctor.²¹

If the trigger of back pain cannot be directly localised, which is the case in most incidents of back pain, it is crucial to include all of the back muscles and the fascia structure in any therapy given in order to ensure the best possible treatment outcome.

Pain again after surgery

„Functional problems in muscles and soft tissues cannot be identified with imaging procedures such as X-rays or MRI“, says Professor Siegfried Mense from the Mannheim Faculty of Medicine at the University of Heidelberg, who has been researching the causes of back pain for many years. He believes that non-specific back pain is operated on too quickly and too often. „In some cases, surgery is carried out on normal ageing processes. The success rate is therefore not very good.“ Even if there are demonstrable changes of the spine, surgery is not always necessary. The fact remains that up to 80 per cent of all intervertebral disc operations do not resolve the cause of the pain. 40 per cent of patients who have undergone such surgery have pain again by a year later at the most.

Lack of exercise

Researchers all agree that the causes of non-specific back pain lie elsewhere. Most people do not get enough exercise. The majority of people sit in front of a computer at a desk, staring at the screen and pushing the mouse back and forth. As they do so, their shoulders are raised, and their muscles are tensed in the same position, as though they were in a vice. They constantly contract a small amount to be able to maintain this position. If a manager looks over their shoulder or if a deadline is approaching, the degree of tension in the muscles increases further. They start to hurt.

The explanation for this is simple: „Muscles are not designed for small, repeated movements“, says Mense. They want to stretch, extend and contract in all directions. Even though the research into this is not yet highly detailed, it is likely that inadequate muscle activity is also what causes the fascia to become stiff and immobile.

Many unanswered questions in research

Lecturer Dr Christoph Anders is a pathophysiological and a specialist in core muscles at the University Hospital of Jena. He examines patients with chronic back pain. They are wired up with electrodes, run on a treadmill or swing an elastic bar. As they do so, Anders measures the tension of their individual muscles. He is attempting to understand how the core muscles are functioning. „Time and time again, we hear that a strong back doesn't experience pain, but there are still many other questions that need to be answered.“ Sometimes pain is not a problem of strength, for example, but rather one of coordination between the parts of the body. His measurements show that the muscles of patients who are experiencing pain react differently to those of healthy patients. It is as yet unclear why this is. Anders is also looking for the explanation in the fascia, however. It may be that the interaction between the fascia and the muscles is being disturbed. „Imagine if you were constantly tensing your muscles in a forced posture over and over again. They will swell and bulge. But the fascia around the muscle is fixed“, explains Anders. This causes the pressure inside the muscle to rise. The flow of blood is reduced to almost nothing, with a resulting lack of oxygen and the muscle nutrient „ATP“. Without ATP, a contracted muscle cannot relax. „This causes hardening of the muscle, just as rigor mortis is caused by a shortage of energy“, says Anders. If the complex comprising the muscle and fascia is activated again, the muscle could also relax again. He is looking to explore this relationship in his next project.

Conventional muscle strength training is not enough

Other researchers have also marginalised the theory that it is primarily incorrectly burdened or untrained muscles, as well as worn intervertebral discs, that cause back pain. More and more researchers are citing the notion that the fascia plays a crucial role as fact. „It supplements the previous model“, says Mense. Just what role it plays and how it can be most beneficially influenced is currently the subject of research.²²

It is therefore essential that back pain treatment includes both strengthening and mobilisation exercises, as well as stimulation of the fascia.

1.2.3 STRESS

Stress lets loose a whole chain of physical responses. Stress hormones are produced that cause the heart to beat faster and the blood pressure to rise. Muscle activity is also increased. For sporting activities, this is a useful physical reaction that can lead to outstanding performances. But not in everyday situations. When long-term stress becomes a constant companion and there are no adequate phases of rest, the internal tension is mirrored by the muscles of the back. The back muscles become overstressed, causing symptoms. The result can be back pain. According to the Professional Association of German Psychologists (BDP), 85% of back pain has a psychological cause or the pain is prolonged as a result.²³ As in all areas of the spine, psychosomatic difficulties can also play a role in the development of pain: the spine is an important „effector organ“ for this. Formulations such as: „Someone has a heavy burden to bear“, „That broke somebody’s back“, „Someone is going to have to grovel“ are all common expressions that highlight this relationship. After various investigations, back pain is found to have no organic cause in at least 40 per cent of cases. It is accordingly attributed to psychological stress. Pain states without an organic background can occur as a manifestation of depression.

Summary: It is evident that, by positively influencing the muscles, back pain can be significantly reduced. Conventional strength training, however, does not appear to be sufficient to counteract the complexity of back pain. Instead, a comprehensive approach is needed, one that not only strengthens the muscles but also takes account of the dynamic interaction of the spinal muscles, integrates the importance of the fascia in the treatment concept and not least adequately reduces stress levels for many patients.

1.3 COSTS

The majority of overall costs are made up of indirect costs, mainly reductions in productivity due to the inability to work or earn money.²⁴ Sciatica has for years topped the table of statistics in terms of reasons for inability to work and medical rehabilitation. In relation to the causes of early retirement due to diminished earning ability, the diseases of the musculoskeletal system rank second after psychological conditions and behavioural disorders in recent years.²⁵ Diseases of the spine (ICD M40-M54) occur in the superordinate diagnostic section of the „Diseases of the spine and back“, which is responsible for around a quarter of all sick days. Back pain (M54) was the second-most prevalent single diagnosis in 2016, occurring in 5.6 per cent of all sick days among people

insured by the German insurance company DAK and 5.8 per cent of all cases of inability to work.²⁶

These tremendous costs, however, do not just impact on the performance of the economy as a whole. Patients experience direct costs as a result of the reduction in their direct income caused by missed days of work, but also as a result of the gradual restriction of their capacity and reduction in earning ability associated with this. If patients are made aware of this situation, their willingness to tackle their back symptoms - even if this involves spending their own money - also increases.

Invalidity day due to back pain in Germany in construction, ancillary construction and woodworking professions (per 100 insurance years)	159 	Percentage of back pain on days of incapacity to work	5.8% 
Sick day costs for acute back pain (per case)	661 € 	Percentage of back pain in cases of incapacity for work	5.8% 
Percentage of back complaints in the macroeconomic costs due to sickness absenteeism	24.9% 	Percentage of back pain in physiotherapy prescriptions	21.1% 
Percentage of adults with back pain during the last year	83% 	Confirmed treatment errors for back pain	92 
		Average work incapacity period for back pain	13.5 days 
		Most commonly used product for back pain	Medication 

Source: Statista 2017

2 BACK PAIN TREATMENT WITH STIMAWELL®

One proven form of treatment for back pain is TENS (Transcutaneous Electrical Nerve Stimulation). With this, nerves are stimulated using gentle electrical impulses and the body's own pain-relieving messenger substances („happy hormones“) are released. Strengthening of the back muscles also helps to reduce pain of muscular origin and to relieve the strain on the vertebrae and discs. Heat therapy is a reliable method of relaxing stiff back muscles and relieving pain. Therapeutic massages are also usually used alongside the treatment of back problems. For stress-related back pain, relaxation methods can also be of benefit.²⁷

2.1 EXPLANATION

Linking in to this realisation, the StimaWELL® system was developed especially to treat back pain. The stimulation mat combines beneficial heat and gentle dynamic deep waves to create a unique overall experience. The StimaWELL® system can optionally be used as pain treatment, to strengthen the muscles and to provide relaxing, deep massages. By combining a variety of programmes, a wide range of treatment options becomes available.

PAIN THERAPY The targeted stimulation of nerves and muscles through the gentle stimulation pulses of dynamic deep waves causes endorphins („happy hormones“) to be released. These messenger substances are responsible in the human body for the relief of pain, among other things.

STRENGTHENING OF THE BACK MUSCLES The dynamic deep waves of the StimaWELL® system stimulate the muscles to work without them having to be consciously tensed. As a result, even patients with restrictions of movement due to pain can be assisted with the rehabilitation of their back muscles.

MASSAGES The special stimulation mat with a total of 12 channels means that the StimaWELL® system provides a stimulating, deep massage of the back that is barely distinguishable from a manual massage. Alongside classic massage effects, the dynamic deep waves also allow you to simply relax and forget your stress for a few moments.

HEAT THERAPY The StimaWELL® stimulation mat can be heated to up to 40°C. This means that additional heat therapy is possible that can contribute to greater relaxation and pain relief.

As a result, StimaWELL® not only supports back muscle training, but it also brings movement to the individual muscle sections and fascia, ultimately producing a relaxing and stress-relieving effect.

2.2 MECHANISMS OF ACTION

2.2.1 CURRENT

StimaWELL® builds on the experiences of electrical stimulation in healthy and diseased striated muscle (NMES, Neuro Muscular Electro-Stimulation, EMS Electrical Muscle Stimulation). These experiences have been investigated thoroughly in experiments and clinical studies. After a brief period of NMES, increased muscle recruitment occurs, most likely as a result of neural adaptations and central processes. After prolonged NMES, the volume and electrical activity of the muscle increase, and its maximum strength increases. These effects can still be demonstrated up to 4 weeks after stimulation finishes. Histological analyses also show a low double-digit increase in the number of fibres and volume of type IIa fibres. Longer stimulations cause the fibre types to change. An increase in interfibrillar mitochondria and capillary density has also been documented.²⁸

Following the body's intrinsic economy, during voluntary contraction it is primarily the low-fatigue type I fibres that are recruited. Training of the type II fibres requires higher muscle strain from around 80% of the maximum voluntary strength. With NMES, on the other hand, because of their low electrical resistance, these fibres are also affected, which in terms of training effect creates a clear advantage both for untrained as well as trained users. This difference between voluntary and electrically induced muscle contraction provides one explanation as to why the combination of both training methods is the most effective and brings the best results. The stimulation parameters, especially the frequency and pulse width, determine the effect on the individual muscle fibre groups. Since individually, the parameters used in literature differ on a not inconsiderable scale, there are no generally recognised stimulation protocols. Type II fibres are generally stimulated at 50 - 80 Hz and wider impulses (> 300 µs). The muscle fatigue that occurs of type II fibres is counteracted by a stim-

ulation and pause ratio of 1:1 to 1:5, depending on the training level. Low-fatigue, conditional type I fibres require frequencies between 1 and 25 Hz and narrower pulse widths. These frequencies are also produced in medium-frequency stimulators which rhythmically adapt their baseline frequency of e.g. 4,000 Hz by modulating the amplitude or frequency to produce low-frequency stimulation.

During voluntary contraction, muscle tension is produced through asynchronous innervation of the motor units: relaxed and tensed muscle fibres lie alongside each other and replace each other. As a result of the position of the electrodes and the limited penetrative ability of the electrical stimuli, local NMES flowing through the muscles causes the fibres reached to be stimulated in synchrony, however, producing a limited local effect and increased fatigue in the fibres reached. The alternative stimulation of the muscle via a system of electrodes at the motor point or the use of the deep-penetrating medium-frequency current with its asynchronous Gildemeister effect can offset this disadvantage. On the other hand, the central fatigue effects caused by peripheral passive stimulation can be avoided, resulting in an increase in the potentially overlaid voluntary maximum contractions.

The training effects are directly related to the intensity of the stimulation. A pleasant feeling of current that allows corresponding current intensities to be used is therefore essential for efficient NMES. In this case, medium-frequency stimulation exhibits advantages. Its baseline frequency, which is usually in the range of 1,000 and 6,000 Hz, overcomes the resistance of the skin more easily, penetrates more deeply and is considerably more pleasant than the lower frequency.

Despite these differences, NMES is comparable with conventional training of striated muscle.²⁹ Numerous positive results indicate that NMES increases strength-specific parameters; only a few papers reach a different conclusion. Filipovic et al., based on their review involving 89 randomised controlled trials (RCTs), point out a significant increase in the maximum strength and various other parameters that occurred after 3 to 6 weeks of NMES in trained individuals and elite athletes. The authors regard see the greatest effects in its combination with conventional training.³⁰

Electrical muscle stimulation facilitates muscle build-up or muscle preservation with minimal systemic stress, allowing not only healthy people but also people who would otherwise not be able to cope with such strain, such as those with sys-

temic diseases, to undergo this therapy. The effect of circuit training as part of conventional training cannot be replaced by NMES. A significant influence of NMES on the central sensory and motor representation is likely, however. As a result, multiple studies describe positive effects on the user's performance, for example among ice hockey players and swimmers.³¹

2.2.2 MEDIUM FREQUENCY

Medium-frequency electrotherapy, by its very definition, comprises the range from 1 to 100 kHz, with pain and muscle therapy being targeted from 1 to 15 kHz. In these frequency ranges, there is stimulus release after a summation process, but this only occurs after multiple periods of stimulation (Gildemeister effect).

Ward et al. (1998) investigated various carrier frequencies between 1 and 15 kHz in order to determine the ideal frequency for motor stimulation of the wrist extensor. They found out that a carrier frequency of 10 kHz is ideal for mild motor stimulation with low sensory stress; for powerful contraction associated with greater sensory stress, on the other hand, 1 kHz is appropriate.³²

In a second study by the same authors in 1998, in which the sensory, motor and pain threshold was determined at frequencies between 1 and 35 kHz, it was also demonstrated that the sensory stress reduced up to 10 kHz. At this frequency, there was also the greatest difference between the motor and sensory threshold.³³ In 2001, the authors state in relation to the frequency spectrum of muscle stimulation that the strength induced by electrical stimulation falls and fatigue increases at frequencies between 1 kHz and 15 kHz. Frequencies above 10 kHz are therefore not classified as useful.³⁴ Selkowitz et al. (2009)³⁵ evaluated muscle stimulation with a carrier wave of 2500 Hz, determining it to be much more efficient than 5000 Hz. Parker et al. (2005)³⁶ came to the same conclusion when comparing 2500 Hz, 3750 Hz and 5000 Hz. Laufer et al. (2001)³⁷ investigated the effect of three different wave forms of a medium-frequency carrier wave of 2500 Hz on quadriceps muscle strength in healthy participants and established that monophasic and biphasic wave forms had the best effect in comparison to polyforms.

The sensory strain caused by medium-frequency currents is usually referred to as low. Current strengths several times higher than with low-frequency therapy, e.g. TENS, can

therefore be tolerated. Synder-Mackler et al. (1994)³⁸ determined that patients undergoing quadriceps stimulation following cruciate ligament surgery with a medium-frequency mains-powered device used a higher current intensity and achieved better training effects than with portable, low-frequency, battery-powered devices.

The cause of the lower sensory strain is a reduced capacitive electrical resistance in the epidermis at higher frequencies. The voltage drop is therefore lower, resulting in a greater depth of action.³⁹

A response that is independent of the stimulation frequency is deemed responsible for the motor effects of a direct, medium-frequency stimulation. According to Senn (1990), spontaneous activity develops in the muscle fibres under the continued action of medium-frequency currents. This is caused by a localised, long-lasting reactive depolarisation on the individual muscle fibre membrane. Different depolarisation phases on the muscle fibre membranes trigger individual muscle cells to contract for different amounts of time, causing a rhythmic juxtaposition of relaxed and contracted muscle sections. This effect, referred to as “toning”, is much more like voluntary physiological recruitment than low-frequency “tetanisation”. This physiological muscle activation makes medium-frequency therapy appear to be ideal for muscular disorders, which is why it is primarily referred to as a muscle therapy.

Another characteristic of medium-frequency currents is the polarity neutrality based on the zero-line symmetric pulse waveform. Both anodes and cathodes therefore play the same active role in effectively feeding the current and no differentiation is made between them. Fibres are also stimulated when medium-frequency pulses are then applied to both stimulation poles. For therapy, this then has the benefit that electrolytically induced skin damage can be disregarded.⁴⁰

Furthermore, medium frequencies excel due to their spatial effect. Since the full volume covered by medium-frequency currents is influenced, Senn (1990) talks of the volume effect, which also depends on the local current density and the current distribution between the electrodes.

During interference processes, two current circuits with a different frequency, e.g. 4000 and 3900 Hz, are used. The appropriate positioning of the electrodes produces a subtraction frequency of 100 Hz in the tissue as a result of the overlapping and interference of these frequencies. With the bipolar amplitude modulation method, which is also the one that the StimaWELL® uses, the carrier wave has low-frequency stimulation added to it through rhythmic amplitude modulation. Ozcan et al. (2004)⁴¹ found pre-modulated medium-frequency therapy to be superior to classical interference in terms of penetration depth, strength stimulation and tolerability.

According to Lange (2003)⁴², the low-frequency frequencies produced through interference or bipolar amplitude modulation have a similar effect to low-frequency muscle stimulation and low-frequency pain therapy. The medium frequency solution goes beyond singular therapy through combined pain therapy and muscle stimulation.

The range of indication for medium frequency in the pain sector comprises:

refractory pain when other electrical therapies have failed or cannot be tolerated

myogenic and neurogenic pain

painful reflex muscle tension and centrally mediated spasticity

combined lesions of the musculoskeletal system with articular and peri-articular pain syndromes

soft tissue rheumatic pain

post-traumatic symptoms

Anti-oedematous and perfusion-promoting effects are also discussed.

There is no fundamental difference between the indication ranges for low-frequency and medium-frequency muscle stimulation. According to Sadil (1991)⁴³, the same indications and contraindications generally apply as for low-frequency therapy. Alongside the restoration, preservation or improvement of condition and muscle strength, NMES helps to overcome reflex and pathological postural or movement patterns and to de-tonify muscles. One effect beyond the muscles relates to the associated structures such as tendons and joints. According to Senn (1990)⁴⁴, Drexel (1993)⁴⁵ and Gillert (1995)⁴⁶, the indications for medium-frequency muscle stimulation include:

- » Voluntary innervation weakness
- » Muscle weakness
- » Reflex muscle tension
- » Lack of muscle sensation

Lang (1996)⁴⁷, in her dissertation, investigated the analgesic influences of galvanic current, diadynamic current at 100 Hz and a 5 kHz medium-frequency current modulated with low frequency with 10 Hz. The greatest rise in the pain on palpation threshold was reached by the treatment with the medium frequency modulated with low frequency. During treatment, this produced an increase of 50% (from approx. 2.6 kg/1.27 cm² to around 3.9 kg / 1.27 cm²), which was able to be maintained at virtually the same level for a further 20 minutes. This analgesic effect can be attributed to the fact that the medium frequency modulated with a low frequency results in pulse stimulation in the low frequency range. The same physiological effects that are also responsible for analgesia in the low-frequency range dominate.

Rocha et al. (2012)⁴⁸ detected a significant reduction in the mechanical pain threshold of the dorsal thigh muscles with muscle soreness after 30 minutes of interference compared to the placebo in 41 healthy test subjects.

Cheing et al. (2008)⁴⁹, investigating 70 patients with frozen shoulder (adhesive capsulitis), compared electro-acupuncture with interference, which differed with equal significance from the control group and maintained its effect until follow-up after 6 months. Taylor et al. (1987)⁵⁰ found there to be no analgesic effect after three interference treatments over a period of 30 minutes in 20 patients with cranio-mandibular dysfunction compared to a placebo group of the same size. Moretti et al. (2011)⁵¹ achieved a significant reduction in pain in 50 patients with fibromyalgia using combined ultrasound and interference therapy. Almeida et al. (2003) treated 17

fibromyalgia patients with 12 combined interference and ultrasound sessions and were able to document a significant reduction in pain. Soomro et al. (2012)⁵² treated 31 patients with trigeminal neuralgia over 6 months. 26 patients reported a significant improvement on the VAS. Tugay et al. (2007)⁵³ confirmed a pain-reducing effect of interference in patients with dysmenorrhoea. There were no side effects. Defrin et al. (2005)⁵⁴ treated 62 patients with knee arthrosis with painful or non-painful stimulation and compared them with a control and placebo group. 12 sessions of treatment were given of 20 minutes each over 4 weeks. Both stimulation methods turned out to have a highly significant pain-reducing effect compared to the control group with the advantages of painful stimulation. Van der Heijden et al. (1999)⁵⁵ were able to produce any effect on shoulder pain in 180 patients either with bipolar interference nor therapeutic ultrasound as monotherapy or combined. Atamaz et al. (2012)⁵⁶ randomised 203 patients with knee arthrosis into a placebo-TENS, TENS, placebo-interference, interference, placebo-short wave and short wave group. Treatment was given at home five times a week for 20 minutes each, over three weeks. Exercises and behavioural training were also carried out. There were significant improvements in all groups, but it was only in the verum groups that significantly less paracetamol was required as a prn medication. From these results, the authors conclude that there is an additional benefit from the physical therapies used. Gundog et al. (2012)⁵⁷ demonstrated using 60 patients with knee arthrosis a significant improvement in WOMAC compared to a placebo at various frequencies. Coban et al. (2012)⁵⁸ reduced abdominal symptoms in patients with irritable colon.

In summary, it would appear that medium-frequency therapy allows significant increases in the strength and performance of the muscular apparatus to be achieved.

2.2.3 LOW FREQUENCY

Low-frequency pain therapy has become established in particular in the form of TENS (Transcutaneous Electrical Nerve Stimulation). With their parameters, TENS form the basis for various StimaWELL® programmes. With TENS, a distinction is made between different frequency ranges and intensities:

„High-frequency“ stimulation

In this case, frequencies between 80 and 120 Hz are commonly used. Work by Wang et al. (1992)⁵⁹ indicates that even frequencies from approx. 20 Hz can exhibit high-frequency characteristics. The mechanism of effectiveness of high-frequency stimulation is usually explained with the gate-control theory. According to this theory, as a result of segmental mechanisms, the non-painful stimulation of the thicker, myelinated A β fibres causes suppression of the forwarding of pain stimulus by the thinner C fibres and A δ fibres. Han (2003)⁶⁰ discovered a highly significant rise in dynorphin A in human cerebrospinal fluid under high-frequency stimulation (100 Hz). Compared to low-frequency stimulation, the stimulation effect can only be antagonised by a dose of Naloxone that is 10 to 100 times higher, and even then is only antagonised by up to 60% in some cases. The fast analgesic effect that occurs within a few minutes is offset by a shorter period of effectiveness once the stimulation ends (Morgan 1995)⁶¹, although as procedural practice has demonstrated, this is prolonged with regular use.

High-frequency stimulation is especially suitable for acute pain due to its properties.

„Low-frequency“ stimulation

With low-frequency stimulation, frequencies of between 1 and 10 Hz, as well as a higher stimulation intensity (or wider pulses), also stimulate motor nerves and provoke visible muscle twitching. Since this frequency stimulates tonic muscle fibres, no muscle fatigue occurs. The effect of this stimulation lies in a primarily supraspinal activation of pain-suppressing processes. Han (2003)⁶² discovered a significant increase in Met-Enkephalin-Arg-Phe in the cerebrospinal fluid following low-frequency stimulation. The effect of high-frequency stimulation can be blocked by the administration of a κ receptor antagonist, while the effect of low-frequency stimulation can be blocked by the pre-therapeutic administration of μ receptor and δ receptor antagonists.

Low-frequency stimulation is especially suitable for chronic pain due to its properties.

HAN stimulation

Based on these findings, it would make sense to attempt to combine high and low-frequency treatment to achieve a combined and synergistic effect of different neuropeptides with an increased analgesic effect. It is on this principle that „HAN stimulation“ is based. It was developed by comparing the analgesic effect of using different frequencies and times in animal testing (rat, tail flick test). With the simultaneous application of 100 Hz and 2 Hz, this test revealed the same excretion of dynorphin A as would be seen in conventional high-frequency stimulation. It is likely that a frequency synthesis of 102 Hz is created on a reticular basis through this approach. The application of both frequencies at alternating times, on the other hand, achieves significantly higher analgesia which, as demonstrated with anti-sera, is effected through the excretion of the neuropeptides of high and low-frequency stimulation. Interestingly, endomorphine can only be detected under these conditions. The most powerful analgesic effect is achieved with alternating stimulation, ideally in 3-second cycles, between 2 Hz and 100 Hz. Under these conditions, frequent chronological overlap periods occur in which the opioids involved are able to work simultaneously. By virtue of its properties, HAN stimulation is the first-choice treatment for virtually all types of pain.

Low-frequency currents therefore represent an effective, low-side-effect weapon in the pain therapy arsenal.

2.2.4 HEAT THERAPY

Heat therapy leads to pain reduction, increased blood flow and metabolic activation, muscle relaxation and the increased flexibility of collagen tissue.⁶³

According to Demir (2012), heat therapy activates the heat receptors and produces reflex pain relief as well as vasodilatation.⁶⁴ Numerous studies report reduced pain, limitation of function and muscle tension following heat treatment in acute low back pain compared to a placebo medication⁶⁵ or Ibuprofen and Paracetamol.⁶⁶ Exercise therapy in such patients, when combined with heat, is superior to exercise therapy alone.⁶⁷ Heat therapy during ambulance transport reduced pain, heart rate and fear compared to passive warming with a woollen blanket.⁶⁸ In a Cochrane review (2006) on the application of heat and cold for acute and subacute lower back pain, there was moderate evidence to suggest that heat therapy has a positive effect on pain and function. The analgesic effect and function is amplified with additional exercises.⁶⁹

Heat can also have a therapeutic effect in cases of chronic back pain. Lewis et al. (2012) treated 24 patients with lower back pain with the application of 40 degrees of heat to the lumbar region over a period of 20 minutes. Target parameters included a paraspinal EMG (electromyogram) to monitor the muscle activity correlating with pain and functional restriction, posture restoration on treatment, pain, functional limitation and psychological factors. The treatment resulted in a reduction in muscle activity and a temporary improvement in various psychological parameters.⁷⁰

2.2.5 MUSCLE TRAINING

Low-frequency muscle stimulation (NMES, EMS) is supported by a growing body of evidence. With its parameters, low-frequency NMES forms the basis for the relevant Stimawell® programmes. In his paper, Lake (1992)⁷¹ states that NMES following knee surgery can preserve muscle strength, muscle mass and the oxidative capacity of the thigh muscles and also has an apparent influence on functional performance. In their review of 35 RCTs involving 1,345 test subjects, Bax et al. (2005)⁷² come to the tentative conclusion that NMES increases quadriceps strength compared to patients who do not receive any further treatments. Filipovic et al. (2011)⁷³, based on their review involving 89 RCTs, point out a significant increase in the maximum strength and various other parameters that occurred after 3 to 6 weeks of NMES, even in trained individuals and elite athletes. The authors witnessed the greatest effect in combination with conventional training. In their review involving 8 RCTs on NMES, Kim et al. (2010)⁷⁴ documented Ia evidence for NMES of the quadriceps in combination with exercises for patients who have undergone cruciate ligamentoplasty. In their review of 21 studies on NMES in patellofemoral syndrome, Santos et al. (2013)⁷⁵ come to the conclusion that medium-frequency muscle stimulation combined with exercises for the disease-specific cause of muscular dysfunction achieves both muscular rebalancing and pain relief.

Boeckh-Behrens W et al. (2005)⁷⁶ compared the impact of different pause durations with electrical whole-body muscle stimulation and the behaviour of creatine kinase in 52 people. 3 groups were created: Group 1 with a 4-second pause duration (n=21), group 2 with a 10-second pause duration (n=20) and a control group of 11 people. With NMES training, maximum strength increased by 12.2% and strength endurance increased by 69.3%. The body circumference reduced significantly. The subjective mood of the participants improved.

The same author (2006) compared the impact of different training durations in 55 people divided into 3 groups with 5 minutes of training (n=22), 10 minutes of training (n=22) and a control group of 11 people. Whole-body NMES training increased dynamic strength endurance and dynamic maximum strength; the CK (creatine kinase) increased significantly in both groups. In concert with previous studies, the authors conclude that the ideal training time is 15 minutes.

Kemmler W et al. (2009) randomised 30 late-menopausal women as part of a pilot study into 2 groups. Conventional strength training was carried out on both, but electrical whole-body muscle stimulation was additionally carried out on one of the groups. Whole-body vibration served as the control. Participants were treated every 4-5 days for 30 minutes over 14 weeks. The electrostimulation group showed a significant reduction in waist circumference and skin fold thickness and demonstrated increased strength when extending the trunk, pressing the legs and jumping. Hip circumference and body weight was reduced in both groups. The stimulated was tolerated very well. The authors recommend whole-body muscle stimulation as an alternative to conventional training, particularly for patients with low cardiac or orthopaedic capacity.

Atabas E et al. (2008)⁷⁷, in their case study on medium-frequency stimulation, reported on a 37-year-old male patient with previous stroke and left-sided spasticity of the gastrocnemius muscle. They established a regression of the paraesthesia on the VAS scale after 6 treatments in 3 weeks lasting 20 minutes each using medium-frequency stimulation, which correlated to a reduction in the EMG value of the tone of the gastrocnemius muscle. The gait improved. Currier D et al. (1983)⁷⁸ compared the quadriceps muscle strength of 34 healthy participants following 15 training sessions in 4 groups: isometric training, electrostimulation, combination of both procedures, control group. No isokinetic increase in strength was established in the active groups but a comparable isometric increase in strength was seen. Side effects occurred in the form of paraesthesias in some participants in the electrostimulation group. Bircan C et al. (2002)⁷⁹ compared the quadriceps muscle strength of 30 healthy participants following 15 training sessions in 3 groups using either low-frequency electrostimulation, bipolar interference therapy or a control group. A comparable, significant, isokinetic increase in strength was achieved in the active groups. Side effects occurred in the form of paraesthesias in both stimulation groups. Chida et al. (2011)⁸⁰ compared muscle contractions triggered

by low-frequency and medium-frequency electrostimulation, and the impact of medium frequency on hemiplegic shoulder subluxation in a 64-year-old male patient. Medium-frequency stimulation reduced the patient's paraesthesia without affecting the subluxation itself after 15 treatments.

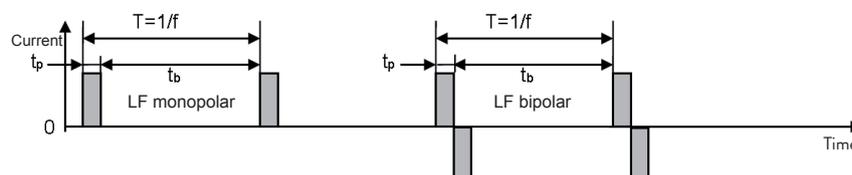
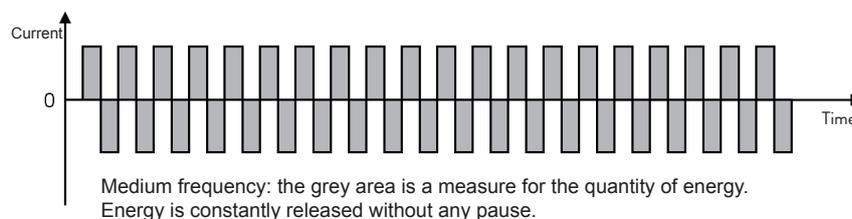
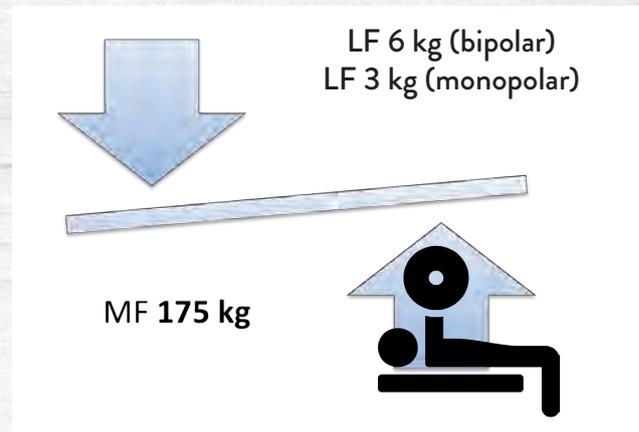
Comparison of low-frequency and medium-frequency muscle stimulation

Fundamentally in EMS technology, a distinction is made between devices with low-frequency (LF) output currents and medium-frequency (MF) output currents. With regard to acceptance, possibly also as a result of an unfamiliarity with the other technique, there are conflicting views. In order to make the outcomes more transparent, this article will look at the amounts of energy delivered compared to their mechanical equivalent.

The picture comparison shows that, with medium-frequency (MF) stimulation, energy is delivered without a break. The amount of energy (= entire grey area) is continuously present over the entire period of review. The polarity of the current is unimportant. The current levels are identical in the positive and negative range. In comparison to this, the entire area of the amount of energy (= entire grey area) with low-frequency (LF) application is much smaller, since energy is only delivered for a short period and no energy is delivered for the majority of the time. The current level is the same as in the medium-frequency illustration.

Mechanical equivalent of bench presses

The amount of electrical energy can be translated into mechanical energy using the relationship of units. If the traditional bench press is used for comparison, this would give rise to the following picture.



2.3 EVIDENCE

Chronic non-specific back pain affects more than 70% of people in industrial countries and causes more limitations than any other medical condition worldwide. A range of treatment strategies, including drug-based treatments, injections, back exercises, acupuncture, behavioural therapy, massage, biofeedback and even TENS, have been investigated in detail. Electrical muscle stimulation to treat chronic, non-specific back pain has only attracted more attention in recent times. StimaWELL® is currently used at more than

400 facilities in over 30 countries. Numerous studies confirm the effectiveness of this dynamic deep wave treatment in acute and chronic back pain. Complex waves are transferred via the StimaWELL® stimulation mat to the back, reaching even the deep muscle layers. The focus of this treatment is on pain therapy, muscle therapy and massage. The treatment success and benefits for patients will be illustrated below with evidence from recent studies.



2.3.1 KLAGENFURT STUDY

In a study by the Centre for Interdisciplinary Pain Therapy and Palliative Medicine (ZISOP) at the Klagenfurt am Wörthersee Hospital between 2015 and 2017, the effectiveness of multi-dimensional, dynamic deep wave therapy was tested on 100 patients with chronic, non-specific back pain. The study confirmed the effectiveness of StimaWELL® at significantly

reducing patients' pain in the back and describes multi-dimensional dynamic deep wave therapy as a highly convincing and safe method for the treatment of chronic back pain. Electrical muscle stimulation combined with heat was able to contribute to a significant reduction in pain and improvement in subjective and objective data compared to standard treatment without electrotherapy.⁸¹

Efficacy of multidimensional dynamic deep wave therapy in patients with chronic non-specific low back pain: a randomized, double-blind, stratified, placebo controlled clinical trial

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Introduction

Chronic non-specific low back pain (LBP) which persists for > 12 weeks and is not attributed to a recognisable pathology, affects more than 70% of individuals in developed countries at some time in their lives, and causes more disability than any other medical condition worldwide (1,2). A myriad of therapy strategies including drug treatment, injection therapies (e.g. epidural corticosteroid injections, local injections), back exercises, acupuncture, behavioural therapy, massage, biofeedback, and TENS have been described. Electrical muscle stimulation (EMS) for management of chronic non-specific low back pain has yet not been properly studied.

EMS leads to muscle contraction by activation of myelinated motor neurons before activation of pain fibres and so differs from TENS. Studies demonstrated that EMS improves lumbar spine function significantly in a low back pain population, improves back pain/disability scores and functional capacity, quality of life and muscle strength (3). It has been shown (4) that hot treatment reduces pain by vasodilatation effect and moves reflex arcs that inhibit pain by means of heat receptors. There are few secondary effects when applied regularly. A combination of heat therapy and medium frequency EMS may provide addition benefit for patients with chronic non-specific low back pain.

Our hypothesis was that electric muscle stimulation in combination with heat could provide better pain relief and improvement of subjective and objective data compared to standard treatment without electrotherapy.

Participants

Adult (>18 years) patients with a medical diagnosis of non-specific low back pain for > 6 months with a pain intensity of NRS ≥ 4/10 were enrolled. Patients with planned spinal surgery or previous spinal surgery less than 12 months ago, spinal disorders like e.g. tumors, fractures or disk herniation with nerve compression with neurological disorders and actual or previous treatment with electrical stimulation, including TENS were excluded. In addition, patients with concomitant illnesses (e.g. cardiopulmonary, inflammatory, malignancy, osteoporosis, epilepsy or neurological, psychiatric, rheumatologic disorders) or cardiac demand pacemakers, defibrillators, spinal stimulators or other implanted electronic devices, or with a history of alcohol abuse, substance abuse, or substance dependence were not eligible. Pregnant patients, patients who become pregnant during the study, patients who were not able to read and speak German or patients with pension process were also excluded.

StimaWell

In this clinical trial, a StimaWell 120 MTRS was used. This system administers a dynamic, wavelike stimulation, via 12 sequentially operating channels. Different effects can be achieved depending on the frequency used. In addition, the stimulation mattress with integrated electrodes heats up to 40°C and further integrates heat therapy effects.

Study design

Between March 2015 and January 2017, we conducted a 6 week randomized, double-blind, stratified, placebo controlled clinical trial, comparing two different forms of multidimensional dynamic deep wave therapy with placebo treatment with a follow-up 12 weeks after randomization. The local Ethics committee of Carinthia approved the study protocol and informed consent (protocol number A15/14). The study design included a screening day (baseline evaluation before randomization); a double-blind, placebo-controlled, randomized, stratified treatment phase (18 treatments in 6 weeks; 3 days a week); and a 12-week follow-up. Electrical stimulation was discontinued after the 18th treatment.

After randomization in one of 4 groups, patients get either one of the multidimensional dynamic deep wave therapy programs in combination with heat (40°C) (Group A and B), a sham electrotherapy with reducing electrical current output and reducing heat (Group C, placebo group), or standard treatment without electrotherapy (Group D, control group).

Results

In summary 100 patients, from 217 patient screened, were recruited. Most of the patients (60%) successfully completed the trial. The most common causes of withdrawal were lack of efficacy (11%), increasing back pain during and after treatment (9%), protocol violations (3%), headache (1%), recognition of placebo treatment (1%), skin irritation (1%), and AEs (1% - increasing pain after improper use of dynamometer). 14% discontinued because they were randomized to the control group. Discontinuation rates were 5 in Group A (20%), 7 in group B (26.9%), 16 in group C (64%), and 12 in group D (50%). Statistical analysis showed that patients in group C and D discontinue more likely (p = 0.005) than patients in groups A and B.

Demographic data were similar for the 100 patients who were randomized. Patient demographic characteristics were representative of a LBP population.

During and after treatment negligible side effects e.g. skin irritations were present and EMS was shown to be safe.

Primary endpoint

Our primary outcome was a change from baseline at 18 days in low back pain pain-intensity score (NRS). Actual pain-intensity scores showed no statistical difference between the 4 groups before treatment. Mean actual pain intensity score at baseline was 5.7 (SD 0.9). After 18 treatments mean actual average pain-intensity score was 2.6 (SD 2.1); in follow-up, mean actual average pain-intensity score was 3.8 (SD 2.4).

After 18 treatments there was a statistical significant pain reduction in group A (p = 0.000), which was also shown for follow-up (p = 0.001). A significant pain reduction (p = 0.000) after 18 treatments and in follow-up (p = 0.001) was also shown for the treatment group B. Also a placebo effect for group C (p = 0.006) has been shown after 18 treatments, but not in follow-up (p = 0.302). There was no significant change from baseline in the control group D.

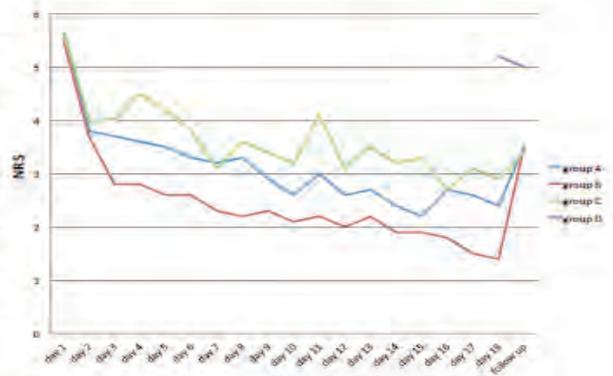
Group comparison NRS:

There was no statistical difference between Group A and B (p = 0.061). Statistical analysis showed that group A had a significantly (p = 0.000) greater pain reduction than the control group D after the last treatment. Treatment group B had a statistical significant (p = 0.029) pain reduction compared to group C and group D (p = 0.000). Also a placebo effect (group C significantly greater pain reduction compared to the control group D (p = 0.004) has been shown.

Conclusion

A reduction of 3 points for treatment group A in mean actual pain (5.7 to 2.4) and 4 points for treatment group B (5.5 to 1.4) on the 11-point numerical rating scale is highly clinically relevant, as is the statistical significant persistent effect.

In conclusion, multidimensional dynamic deep wave therapy is a very effective and safe method for treating chronic low back pain.



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2.3.2 BICÊTRE HOSPITAL STUDY, PARIS (FRANCE)

In 2016, Oliveira and Nègre from the Pain Centre at the Bicêtre Hospital (France) investigated the use of dynamic deep wave stimulation technology in patients with chronic pain. During the initial phase, the effects of a single session, which the patient described themselves at the end of the session, were evaluated. In the second phase, two clinical cases of iterative sessions were presented. Out of the 28 patients treated, 19 returned written feedback. 73.6% of these reported an improvement in the state of their health. The im-

provement in pain was not quantified by patients, however six improvement criteria were formulated for the following areas: Pain, Sleep, Mobility, Relaxation, Flexibility and Emotions. In the two clinical cases reported, the pain evaluated using the EVA, QDSA and EDUQ improved significantly and this was associated with a reduction in treatment. The sessions also allowed the patients to express intense emotions which enabled a strong therapeutic connection to be established in order to create a modified, personalised treatment pathway. Finally, the study described deep wave therapy as highly promising in the treatment of patients with rachiagia.⁸²

Les Ondes Dynamiques Profondes (ODP Stimawell) : Etude observationnelle Centre d'Evaluation et de Traitement de la Douleur - Hôpital Bicêtre - Paris

Gloria OLIVEIRA – IRD, Dr. Isabelle NÈGRE – Etude réalisée de Mars à Septembre 2016

ETUDE RÉALISÉE EN PLUSIEURS PHASES :

Phase 1 : prise en main et questionnement

- Maîtriser le matériel
 - Exploration des programmes
 - Manipulation, stockage, crâneaux de mise à disposition
- Préciser les indications sur des éléments objectifs
- Relever les répercussions sur
 - Composante douloureuse
 - Qualité de vie
 - Tout autre élément signalé par le patient
- Trouver les outils d'évaluation adaptés
- Etablir nombre et rythme des séances nécessaires
- 1 séance/personne
- 11 séances au total

Phase 2 : analyse de la 1ère séance - méthodologie

- Patients sélectionnés par le Dr Nègre lors d'une consultation sur des critères multiples
 - Contracture musculaire
 - Résistance au traitement
 - Tableau complexe
 - Fatigue extrême
- Explication et consentement
- Engagement du patient d'un retour (par mail) du ressenti pendant/après la 1ère séance
- Analyse des commentaires de 19 patients (mars-juin 2016)

RÉFLEXIONS SUR L'ÉVALUATION ET LE CHOIX D'ÉCHELLES ADAPTÉES

- Échelles globales nécessaires mais insuffisantes : ENS, QDSA
- Échelles de qualité de vie nécessaires : EDUQ, QDSA

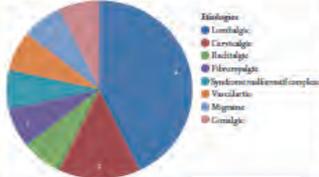
EDUQ

Activités	Score
1 Vous lever de votre lit	<input type="checkbox"/>
2 Dormir six heures d'affilée	<input type="checkbox"/>
3 Vous retourner dans votre lit	<input type="checkbox"/>
4 Voyager pendant une heure en voiture	<input type="checkbox"/>
5 Se tenir debout pendant une durée de 20 à 30 minutes	<input type="checkbox"/>
6 Devenir assis pendant quinze heures	<input type="checkbox"/>
7 Monter un étage d'escalier	<input type="checkbox"/>
8 Débrancher le long de plusieurs plates de maisons (environ 300 à 400 mètres)	<input type="checkbox"/>
9 Marcher plusieurs kilomètres	<input type="checkbox"/>
10 Ancrer des étagères hautes	<input type="checkbox"/>
11 Lancer une balle	<input type="checkbox"/>
12 Couvrir le long de deux plates de maisons	<input type="checkbox"/>
13 Sortir de la courtoisie du réfrigérateur	<input type="checkbox"/>
14 Faire son lit	<input type="checkbox"/>
15 Mettre des chaussettes (ou des collants)	<input type="checkbox"/>
16 Se pencher en avant au-dessus d'un évier (durée) 10 minutes	<input type="checkbox"/>
17 Déplacer une table	<input type="checkbox"/>
18 Pousser ou tirer une lourde porte	<input type="checkbox"/>
19 Porter deux paquets à proximité	<input type="checkbox"/>
20 Soulever 18 kilos	<input type="checkbox"/>
Score total	<input type="checkbox"/>

Echelle dorso-lombaire du Québec (0-100), note de 0 à 5

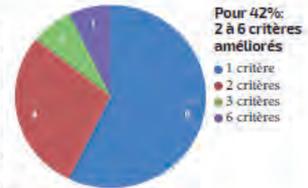
RÉSULTATS APRÈS UNE SÉANCE

Patients améliorés: 73,6% (14/19)



CRITÈRES AMÉLIORÉS SELON LE PATIENT APRÈS 1 SÉANCE (N:14)

Critères	Nb	%	Evolution
Déroule, souplesse	8	57 %	Diminution des contractures
Douleur physique	6	42%	Diminution mais difficile à quantifier
Bien-être	6	42 %	Sensation d'apaisement
Émotions	6	42 %	Verbalisation des émotions
Sommeil	3	21 %	Amélioration en durée et en qualité
Mobilité	2	14 %	Amélioration de la marche



RÉSULTATS APRÈS SÉANCES MULTIPLES

Cas clinique 1 : Mme L..., 50 ans

- Historique:
 - lombalgie depuis 2003
 - 2010: Prothèse discale L4-L5 pour discopathie dégénérative
 - 2014 Arthrolyse L5-S1
- Douleurs persistantes, baisse majeure de mobilité, position assise impossible, allongée en permanence depuis 4 mois
- Mal soulagée par opioïdes
- Mars 2016: prise en charge au CETD
- Mise en place de séances: Natte ODP
- 15 séances (2 /sem)
- Chiropraxie - Infiltration de cicatrice

Cas clinique 2 : Mme R... 44 ans

- Historique:
 - Scoliose connue
 - lombalgie depuis 15 ans
 - 2001 Hernie Discale L3-L4, plusieurs infiltrations
 - Janv 2016 : Lumbago aigu, sciatalgie, traitement symptomatique, avis chirurgical: proposition d'arthrodèse
- Fev 2016: aggravation, infiltrations, cannes anglaises, arrêt de travail
- Sept 2016 : prise en charge par le CETD KB
- Mise en place de séances avec la natte ODP
- 6 séances réalisées
- 2 /sem synchronisée avec chiropraxie

Résultats Patient 1

Mme L...	1 ^{er} Juin 2016	30 septembre 2016	% Amélioration
ENS	7	4	43
QDSA*	22 (S19/A3)	2 (S1/A1)	91
EDUQ	77	50	36
TI	Oxycodone 75 Néfopam 120 Ibuprofène	Oxycodone 20/30 Néfopam	47

* S (sensuel), A (affectif)

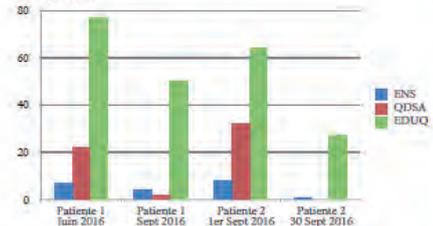
Résultats Patient 2

+ Après 3 séances abandon des cannes
+ Après 5 séances: reprise du travail à temps plein

Mme R...	1 ^{er} sept 2016	30 sept 2016	% Amélioration
ENS	8	1	90
QDSA*	32 (S15/A17)	0	100
EDUQ	64	27	58
TI	Ibuprofène 300 Paracétamol 4g Prednisolone 70mg	Paracétamol 1gr	>90

* S (sensuel), A (affectif)

ÉVOLUTION



DISCUSSION

- Amélioration rapide chez 75% des patients
 - de la souplesse
 - Du bien-être
 - de la douleur
- Enthousiasme et gratitude des patients
- Décharges émotionnelles fréquentes pendant les séances: réflexion sur une évaluation en cours

CONCLUSION

- Matériel simple d'emploi
- Ergonomique, surtout grâce au chariot de transport
- Technique thérapeutique prometteuse à développer
- Parfaitement adapté à la prise en charge des douloureux chroniques



2.3.3 THANN HOSPITAL STUDY, MULHOUSE (FRANCE)

In a study carried out between 2015 and 2016 at the Thann Hospital (France), Finkelstein and Marck report on results from the use of dynamic deep wave stimulation therapy as a non-drug, non-invasive and effective treatment for pain relief. The study shows that this form of treatment can in particular be described for patients who fail to respond to conventional therapies, as a replacement for or as an adjunct to other treatments. The primary indications are chronic back pain, chronic neck pain, spinal osteoarthritis and fibromyalgia. For some of the study participants, the treatment given

in the study came too late. Earlier prescribing could therefore be considered since, according to Finkelstein et al., no side effects were reported. Deep wave stimulation therapy has its place in the therapeutic arsenal of a pain facility when it comes to alleviating chronic pain. The impacts on the improvement in patient mobility also appear to provide interesting results. These were not explored in more detail in this study, however. Other large studies would be needed in order to confirm the effectiveness of deep dynamic waves in the treatment of chronic pain and to measure the actual impacts on mobility and quality of life.

Utilisation des Ondes Dynamiques Profondes (ODP Stimawell) dans le Traitement de la Douleur Chronique : Etude descriptive rétrospective

Dr. N. Finkelstein, C. Marck (IDE) - Consultation Douleur au Centre Hospitalier de Thann (Groupe Hospitalier de la Région de Mulhouse et Sud Alsace)



Mécanisme / effets :
La thérapie par Ondes Dynamiques Profondes est une technique d'électrothérapie par ondes de moyennes fréquences associée à de la chaleur appliquée sur toute la zone du dos par le biais d'une natte de stimulation. Elle combine une fréquence porteuse de stimulation entre 2000 et 6000 Hz avec une modulation en basse fréquence (100 Hz ou 2 Hz).

Intérêt :
Les courants utilisés par les ODP sont considérés comme étant plus efficaces et plus confortables que les courants TENS traditionnels^{1,2}.
Limites d'utilisation : la thérapie par ODP ne peut se pratiquer qu'en centre hospitalier ou chez un professionnel de la santé.

Matériel et méthodes :
Etude descriptive et monocentrique, réalisée entre Mars 2015 et Août 2016. Recueil des caractéristiques démographiques et cliniques des patients, des modalités d'utilisation. Evaluation de l'efficacité par l'échelle visuelle analogique (EVA) ou échelle numérique (EN), le pourcentage de soulagement décrit par le patient au mois M0, M1 et M3 et le pourcentage d'amélioration de la mobilité au mois M0 et M3.

Protocole :
Thérapie ODP Stimawell avec natte de stimulation du rachis à raison d'une séance hebdomadaire de 30 minutes.

Objectif :

- Réduire la douleur
- Améliorer la mobilité
- Réduire la consommation médicamenteuse

Indications principales :

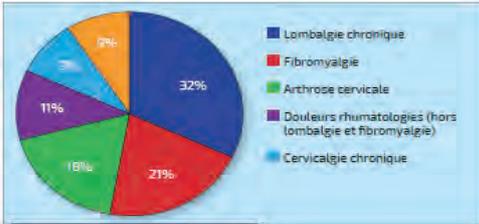
- Lombalgie chronique
- Cervicalgie chronique
- Arthrose rachidienne
- Fibromyalgie
- Contractures musculaires du dos

Contre-indications principales :

- Troubles psychiatriques sévères
- Dispositif médical implantable actif (pacemaker,...)
- Région cutanée lésée ou insensibilisée



Résultats :
34 patients ont été étudiés dont 18 hommes et 16 femmes pour un âge médian de 63 ans. Les principales indications étaient les suivantes :



- Lombalgie chronique
- Fibromyalgie
- Arthrose cervicale
- Douleurs rhumatoïdes (hors lombalgie et fibromyalgie)
- Cervicalgie chronique

L'ensemble de ces douleurs avaient une composante neuropathique franche ou mixte neuropathique et nociceptive.

La thérapie par ODP a été prescrite après échec des autres thérapeutiques dans 60% des cas, pour un délai médian entre le début de la prise en charge douloureuse et le début de la thérapie par ODP de 1,2 an [0,5 à 4 ans].

Les séances d'ODP se pratiquent exclusivement à la consultation douleur à raison d'une séance par semaine. La première consultation ODP se fait avec le médecin qui définit le protocole ODP à suivre en fonction du diagnostic patient.

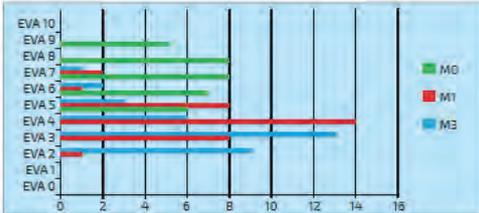
34 patients ont été évalués à M0, M1 (4 semaines) et M3 (12 semaines).

Evaluation de la douleur
A M0, la douleur médiane a été mesurée à 7 [5 - 9].

Entre M0 et M1, la médiane de la variation de l'intensité douloureuse était de **-3 points**, et celle du pourcentage de soulagement de **+40%**.

Entre M0 et M3, la médiane de la variation de l'intensité douloureuse était de **-4 points**, et celle du pourcentage de soulagement de **+60%**.

Le recours à la thérapie par ODP Stimawell a donc été bénéfique au niveau du soulagement de la douleur.



- M0
- M1
- M3

Conclusion :
Nos résultats sont difficiles à extrapoler en raison du caractère monocentrique de notre étude et donc du recueil de nos données. Néanmoins des données caractéristiques apparaissent : l'utilisation de la thérapie par ODP est une thérapeutique non-médicamenteuse, non-invasive et sans effet secondaire qui semble donner des résultats intéressants en terme de soulagement de la douleur. Elle peut donc facilement être prescrite à des patients réfractaires aux traitements classiques, en remplacement ou en complément avec d'autres traitements. Les principales indications sont la lombalgie chronique, la cervicalgie chronique, l'arthrose rachidienne ou encore la fibromyalgie.

La prescription de cette thérapeutique s'est révélée tardive pour certains patients dans notre étude, une prescription plus précoce aurait pu être envisagée, compte tenu de l'absence d'effets indésirables.

Pour le **soulagement de la douleur chronique**, la thérapie par ODP trouve donc toute sa place dans l'arsenal thérapeutique d'une structure douleur. L'impact sur l'**amélioration de la mobilité** du patient a aussi semblé donner des résultats intéressants mais n'a pas été évalué dans cette étude.

D'autres études de plus grande échelle seraient nécessaires pour confirmer l'efficacité des ondes dynamiques profondes dans le **traitement des douleurs chroniques** et aussi mesurer l'**impact** réel sur la **mobilité** et la **qualité de vie**.

Références bibliographiques :

1. DIORNO A, GUIHARD R, KAYSER D. De la modulation des courants de moyenne fréquence médicale. (Compte Rendu des Séances de la Société de Biologie - 1958, 152(2) : 236-7)
2. DUMDULIN J, DEBISSCHOP G. Electrothérapie. 5e édition. Maloine (1987).

2.3.4 TUNIS MILITARY HOSPITAL STUDY (TUNISIA)

In 2017, a study by Khiari et al. from the Department of Physical Medicine and Functional Rehabilitation at the military hospital in Tunis (Tunisia) was carried out into the effectiveness of dynamic deep wave therapy for spinal rehabilitation.⁸³ 26 patients participated in the study (24 with lower back pain and 2 with neck pain). The average age was 42 years. Patients with rachialgia took part in eight 20-minute sessions with the StimaWELL® system. A significant reduction in pain was achieved in 17 patients. The study indicates that spinal reha-

bilitation through deep dynamic waves is a non-medical and non-invasive therapy that can be carried out effectively and without side effects and which brings patients significant pain relief. The treatment can therefore in particular be described for patients who fail to respond to conventional therapies, as a replacement for or as an adjunct to other treatments. Treatment with StimaWELL®, unlike many other back therapy approaches, is therefore validated not just in the context of everyday practice and observations of its use, but also in a strict clinical environment. This gives the system an excellent position in the array of therapies used to treat back pain.

Rééducation du rachis par les ondes dynamiques profondes

Khiari H, Maaoui R, Ksibi I, Mouhli N, Rahali H
Service de Médecine Physique et réadaptation Fonctionnelle
Hopital Militaire Principal d'instruction de Tunis



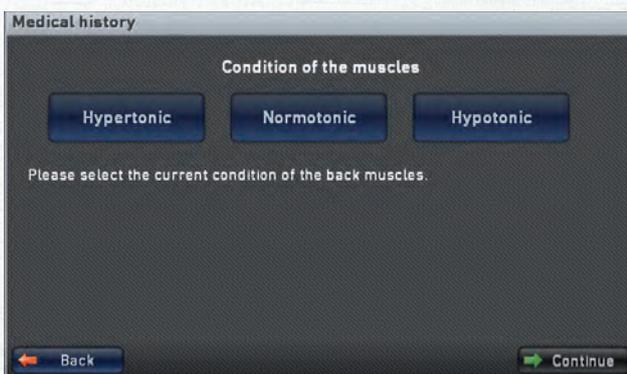
3 TREATMENT PLANS

3.1 HISTORY

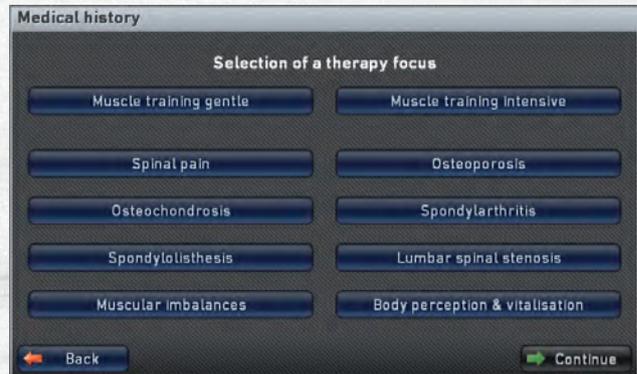
With the StimaWELL® device, the form of treatment can be adapted to the nature of the pain. The „Therapy mode“ button can be used to enter details about the nature of the pain, its localisation in the thoracic or lumbar spines or generally, and it can be classified using a scale.



To determine the form of the patient’s pain condition, a choice is made between acute and chronic. You then specify the location of the pain. You can choose between the cervical, thoracic or lumbar spine, or generalised. A pain scale is used to determine the intensity of the pain described by your patient. The scale ranges from 0 to 10, with 0 representing zero pain and 10 representing the worst pain imaginable.



This is where you specify the condition of your patient’s muscles. You can choose between hypertonic, normotonic and hypotonic. You are also shown an explanation of the selected condition beneath the three buttons.

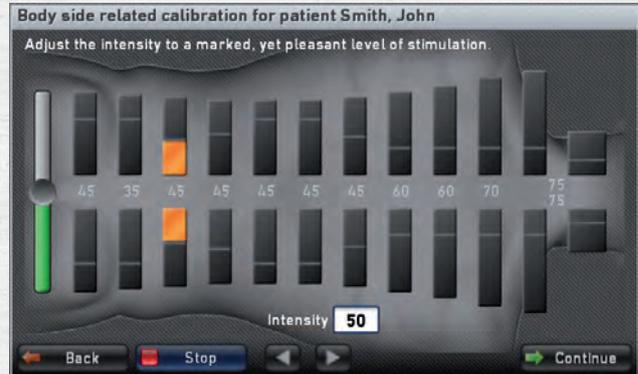


Later on, a focus of therapy is chosen for the muscle treatment area.

3.2 CALIBRATION

Successful treatment with the StimaWELL® system requires an examination of the sections of the back beforehand, as well as a trial of the ideal intensities of the individual channels (calibration). Using this calibration step, you are able to adapt the StimaWELL® system to your patient’s individual back muscles as well as to their specific pain symptoms, providing access to optimised therapy. Calibration involves the fine-tuning of the intensity of the individual channels. Calibration is very important for the following reason: a given stimulation intensity is perceived with different intensity in different parts of the body. For this reason, the individual channels of the StimaWELL® stimulation mat do not stimulate with the same intensity. To ensure that the stimulation feels the same on all channels, a percentage intensity of the main intensity is assigned to each channel in the StimaWELL® device’s basic settings. This means that channel 3, for example, can stimulate at 70% of the main intensity, while channel 4 stimulates at 60%. This ensures that the stimulation feels the same in each part of the back. Of course, however, this cannot compensate for the sensitivity of each individual. For this reason, you can adjust the individual channels during the calibration process, i.e. fine-tune them. For each new patient, it is a good idea to carry out laterality-differentiated calibration first. This can be repeated at any time as required. The calibration process takes around 10 minutes.

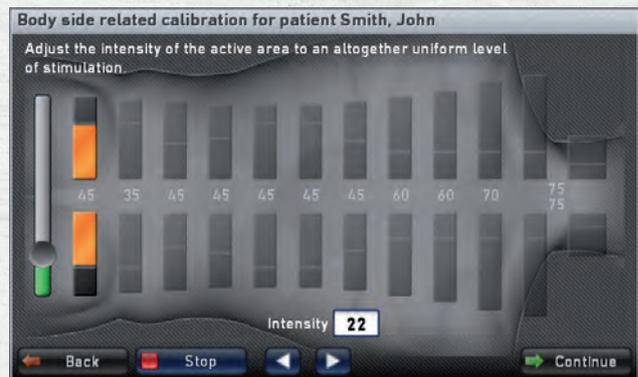
Generally speaking, a current intensity that triggers a visible contraction and largely incorporates the muscle in question is sufficient for muscle stimulation. Maximum tensions should be avoided in untrained or weakened muscles; the muscle contractions should not generally be painful. During pain therapy, muscle contractions are only required in the lower modulation range of up to 15 Hz. This range is especially suitable for the treatment of chronic pain. At higher frequency modulations up to 100 Hz, sensory stimulation is crucial for its effect. Muscle contractions are not required for this, which allows longer stimulation without muscle fatigue. The intensity is therefore selected at a lower level. Due to the specific stimulus quality of medium-frequency pulses, muscle responses and as a result a limitation of the amount of time that the stimulation can be applied for cannot be avoided altogether.



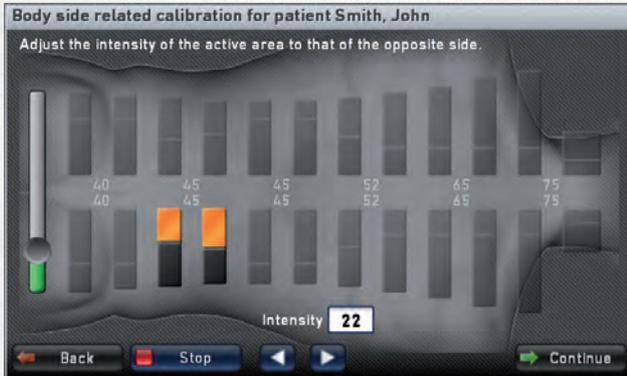
The main intensity currently set can be seen in the Intensity display. The figures shown between the two bars of each channel indicate the percentage at which the set intensity on a channel is actually stimulating the muscle.



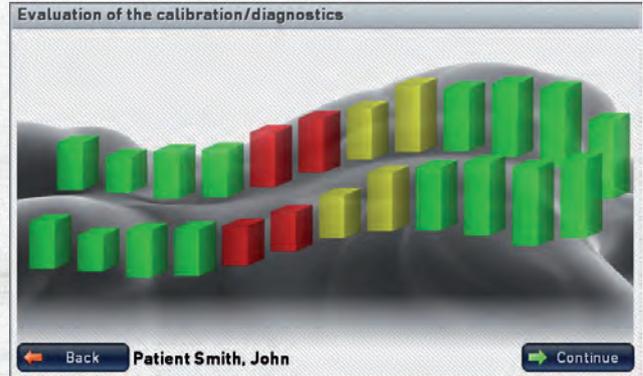
The upper section of the screen shows the number of therapy sessions, as well as the time period over which these have taken place. Below it are indicators of how frequently the patient has specified their pain status or condition as better, the same or worse after the treatment session. If the treatment history involves pain therapy, you will find further details of the analysis.



After adjusting the main intensity, you can change to channel setting mode for the channels running across. A channel in this case always consists of two opposing electrodes that are indicated by the orange flashing bars. In this window you can adjust the intensity of each individual channel and adapt it to your patient's personal perception.



This is the channel setting mode for the channels that run longitudinally. Each channel is represented by two adjacent electrodes. The current intensity of each channel is the mean value of the intensities of both of the channels running across that form longitudinal channel 12. The intensity of longitudinal channel 12 is therefore the mean value of channels 11 and 12 across, since the bottom two electrodes of these channels running across form longitudinal channel 12. The intensity of all of the longitudinal channels is now set. This is done in exactly the same way as the setting of the channels running across.



The illustration shows the evaluation of the calibration process as a bar chart. The level of the green bar shows you the ratio between the intensities of the individual channels relative to each other. The higher a bar, the higher the intensity on this channel. If channels running in opposite longitudinal directions to each other display different intensities, both channels are shown in a different colour. Smaller deviations are shown in yellow, while larger ones are shown in red.

3.3 FREQUENCY OF USE AND TREATMENT STEPS

Use of the StimaWELL® is well tolerated and can in principle even be used several times a day and repeated regularly over a long period of time. For pain conditions, treatment should be given often, e.g. every day, in acute cases. For chronic conditions, use every 2 to 3 days is a good idea, and this can be reduced as the symptoms improve. Increases in pain can occur as a side effect, especially at the start of treatment, and should prompt a reduction in the intensity and frequency of the treatment until an improvement occurs. Changing to a sensitive programme can also be helpful. For muscle therapy, regular applications are needed in order to achieve sufficient training and build-up of the muscles. Depending on the training objective, application at least twice a week is recommended, which can be increased up to daily stimulation. Weakened muscles will initially require slow and gradual training. With phasic stimulation especially, muscle soreness can occur which may require the intensity and frequency of the stimulation to be adjusted. Crucial for the success of treatment in everyday practice is also the therapy's user-friendliness. If a technology is difficult for therapists to use, it means it will be used less often. Accordingly, the development of StimaWELL® attached considerable importance to how the product can be integrated into everyday practice. The documentation of the StimaWELL® treatments at a reference location serves as an example. See below.

a) Example of a treatment process: Therapy programme

Acute pain

1. Physical examination of the patient
2. Acute treatment in the consultation room with chirotherapy, injection, possibly medication
3. Rapid start of the StimaWELL® therapy
 - » Initial calibration by the doctor
 - » 2 to 3 times a week (connection between the patient and the effectiveness)
 - » Recalibration at the 5th session (by the doctor)
 - » Only as many sessions as the patient wants/needs (important so that they will come back for more therapy and the long-term success of the therapy can become established)

b) Example of a treatment process: Therapy programme

Chronic pain

1. Physical examination of the patient
2. Required treatment in the consultation room with chirotherapy, injection, possibly medication
3. Planned start of the StimaWELL® therapy with 25 sessions
 - » Initial calibration by the doctor
 - » Twice a week (sustainability of muscle build-up and consolidation of successes)
 - » Recalibration at the 5th and 15th sessions (by the doctor)

c) Time required

In the consultation room

- » By the doctor, consultation (sales) encounter according to medical skill: 2-3 minutes
- » By the nurse, possibly preparation of the private agreement, possible cost coverage in the case of private patients: 2 minutes
- » For calibration
 - By the doctor, setting of the StimaWELL®: 2-3 minutes
 - Possible ear acupuncture for private patients: 1 minute
 - By the nurse, preparation of the patient and device settings: 2-5 minutes

3.4 EXAMPLES OF APPLICATION

Patient profile 1

- » Male, 41
- » Profession: Teacher
- » Sporty and active (football, mountain biking, amateur triathlon)
- » Neck pain with limitation of rotation, inclination and reclining for 1/2 year, worse for the past 3 weeks (never had problems before)
- » Clinical examination/imaging: No disc prolapse, age-appropriate wear and tear, no misalignment, no cervicobrachialgia
- » Does not want to simply take painkillers
- » Also reports that he is currently in the middle of exam season and is having to mark a lot of work

StimaWELL® application

- » Hypertonic muscles of the cervical spine
- » Precise calibration of the StimaWELL®
- » Relaxation for 10-15 min, programme recommendation: Muscle relaxation
- » Strengthening for 10-15 min, programme recommendation: Combined muscle stimulation

Patient profile 2

- » Female, 28
- » Profession: Architect / currently on parental leave (mother of two children (one aged 3 and one aged 6 months))
- » Worsening lower back pain for 3 months
- » Used to play tennis at amateur level - Currently has only moderate to zero regular sporting activity
- » Occasional discrete sciatica in the L5/S1 dermatome on the left
- » Pseudo-Lasègue's sign positive at 60°
- » No clear evidence of disc prolapse, but isolated protrusions without root involvement
- » Normotonic back muscles

StimaWELL® application

- » Normotonic lower back muscles
- » Precise calibration of the StimaWELL®
- » Strengthening programme for normotonic muscles 15 min, programme recommendation: Combined muscle stimulation
- » Harmonisation of the normotonic muscles 15 min, programme recommendation: Focus wave or muscle wave or Wyvern wave or e.g. Dysbalance wave

Patient profile 3

- » Female, 67
- » Retired
- » Back pain for more than 3 years
- » Severe deterioration for the last week
- » X-ray: degenerative wear and tear (C and L spines)
- » Hypotonic muscles
- » No sporting activity due to knee pain
- » Pain non-specific without real dermatomal pattern

StimaWELL® application

- » Hypotonic muscles (C, T and L spines)
- » Precise calibration of the StimaWELL®
- » Strengthening programme of hypotonic muscles 15 min, programme recommendation: Combined muscle stimulation
- » Harmonisation of hypotonic muscles 15 min, programme recommendation: Dynamic deep wave such as Gentle wave or Comfort wave or Revitalisatio

4 MARKETING

4.1 PUBLIC IMAGE

To draw your patients' attention to your new treatment service, we have put together an extensive marketing package for you. Framed and roll-up posters alert patients to the treatment options available with the StimaWELL® system at your practice or facility. Information stands and patient flyers for reception or waiting rooms provide targeted patient appeal and make them curious about this innovative therapy. With the personal StimaWELL® treatment plan, you are able to give your patients the opportunity to document their pain over a given period of time and get an overview of how they are progressing during the treatment cycle.

4.1.1 FILM

Untrained back muscles, poor posture, unilateral strain or stress can cause tension or stiffness of the muscles and lead to long-term wear and tear on the intervertebral discs, spine and the intervertebral joints. The brief film on the StimaWELL® picks up on how this gentle and effective treatment system works, and specifically shows how pain can be alleviated and other back problems can be effectively prevented. The short film shows the ergonomic mat, equipped with 12 pairs of electrodes, which emits electrical impulses. Thanks to its adaptation to the shape of the individual's back, heat therapy, wave stimulation and massage are able to reach structures even deep inside the back. Pain is alleviated and tense muscles are relaxed, stimulated and strengthened. By using different stimulation programmes, the film demonstrates that other symptoms can be prevented and even patients with physical limitations can experience an improvement. Different massage effects such as kneading, rolling, percussion or rubbing complement the medical treatment. The short film is available on the StimaWELL® website (<https://schwa-medico.de/de/stimawell%C2%AE120mtrs>) or on YouTube via the following link: <https://www.youtube.com/watch?v=A6sVBVehflg>

4.1.2 ADVERTISING IMAGES



4.1.3 ROLL-UPS

The roll-up display systems are a highly flexible solution your communication and advertising activities around the StimaWELL® in your practice. A tensioned banner is rolled upwards out of the display and secured in place by a supporting bar. schwa-medico offers various designs. The banners are approximately 85 to 100 cm wide and 2.06 m tall, and are supplied in a carrying bag. They weigh just 3 kg.



4.1.4 FLYERS

The StimaWELL® patient flyers provide the most important information on the successful treatment of back pain. A brief and comprehensible explanation is provided to patients of how pain therapy, muscle treatment and dynamic deep massage can lead to a positive overall treatment outcome.



4.1.5 WEB PRESENCE

The StimaWELL® website sets out the unique way in which the device works to create a strong back and specifically describes the „4-in-1“ treatment concept designed to combat back pain. The history-based choice of programme on the device makes back therapy simpler, ensuring the ideal level of adaptability to each individual patient. The StimaWELL® offers maximum functionality with simple operation and, thanks to databases and patient histories, ensures constant monitoring. In addition to product information, technical data and contact options, as well as further information to download is available at <https://www.stimawell-ems.de/en/shop/ems/devices/stimawellr-120-mtrs-system>



4.2 CHOICE OF LANGUAGE

The StimaWELL® is available with system languages of German, English, French, Dutch and Spanish. The setting is made by choosing the relevant language and confirming this with the OK button. Please be aware that to change the language, the StimaWELL® system must be restarted. Cancel exits the menu without changing the current language setting.

5 INTEGRATION INTO EVERYDAY PRACTICE

5.1 TOWELS AND WIPES

For hygiene purposes, the StimaWELL® mat is covered with paper towel or a towel before stimulation is carried out, and the covering is then moistened. The relevant coverings with a white waffle structure measure 50 x 80 cm and are available via schwa-medico. Alternatively, a thin damp towel can be heated in a microwave and then placed on the mat. This also allows the effect of a heat pack or fango pack to be achieved.



5.2 SPACE REQUIREMENTS AND TROLLEY

The StimaWELL® system can be integrated in various ways into all kinds of structures and procedures in your everyday practice. Thanks to the StimaWELL® trolley, it requires only just a small amount of space and can, when required, be easily moved between treatment rooms. This means that your StimaWELL® system is always ready to use quickly and with great flexibility, even when space is at a premium.



The StimaWELL® 120MTRS mat on the couch in your practice or compactly stored away in the trolley.



6 SUPPORTIVE NUTRITION

6.1 BACK PAIN & WEIGHT

A high body weight puts significant additional strain on the spine and joints. Being overweight not only puts extra strain on the hip, knee and ankle joints, but it also puts undue stress on the spine. The consequences are early signs of wear and tear (arthrosis) with pain in the back and the affected joints. In most cases, a normal weight can be achieved through a healthy diet and plenty of exercise.

6.2 EMS & NUTRITIONAL SUPPLEMENTS

During EMS training, the muscles are stimulated by electrodes that are integrated into the mat. This means that individual muscle sections can be targeted and built up. Muscle build-up can therefore be supported with a healthy diet. At over 50-60%, nutrition has a significant role to play in muscle build-up. Therefore a balanced and varied diet is especially important. Balanced in this case means that the diet should contain sufficient amounts of fibre, vitamins, protein, carbohydrate and omega 3 fatty acids. The choice and mix of foods is also crucial. Supplementary foods from **StimaWELL® EMS Nutrition**, which are produced in Germany and selected with tremendous care, support the EMS training in muscle build-up, stimulate the metabolism, fight cellulite, provide energy and accentuate the figure.⁸⁴



Supportive Nutrition:
[STIMAWELL-EMS.DE/EN/
 SHOP/NUTRITION](https://www.stimawell-ems.de/en/shop/nutrition)

STIMAWELL® Nutrition	Physique	Cellulite	Metabolism	Energy	Buildup of muscles
JOINT RELIEVER (MSM 1000 – 120 capsules)			✓		✓
CELL PROTECTOR (OPC grape seed extract – 60 capsules)	✓		✓	✓	
HEART & BONE SAVER (Vitamine D3 – 100 capsules)		✓		✓	
FUNCTIONALITY SUPPORTER (Multivitamine – 90 capsules)	✓		✓		
HEALTH GUARDIAN (Omega 3 Plus – 90 capsules)		✓	✓		
POWER GAINER (L-Arginin + Maca Gold – 120 capsules)	✓			✓	✓
HEALTH BOOSTER (Green coffee extract – 92 capsules)	✓		✓		
STRENGTH PROVIDER CHOCOLATE (Whey protein, Psyllium, Probiotics – 630 gram)		✓ or ✓	✓ or ✓		
STRENGTH PROVIDER VANILLA (Whey protein, Psyllium, Probiotics – 630 gram)					
MUSCLE COACH (BCAA + Glutamine – 500 gram)		✓		✓	✓
MUSCLE VITALIZER (Creatine – 120 capsules)				✓	✓
STRENGTH PROVIDER V+ VANILLA (Protein shake Vegan Vanilla – 630 gram)					✓ or ✓
STRENGTH PROVIDER V+ CHOCOLATE (Protein shake Vegan Chocolate – 630 gram)					✓ or ✓
BODY SHAPER (Green coffee, Guarana, Green Tea – 90 capsules)	✓	✓	✓	✓	✓



7 USER REPORTS & REFERENCES

The effectiveness of the StimaWELL® has been proven by numerous delighted users. A small excerpt from our customer feedback will show you how much the StimaWELL® improves the quality of life of patients with acute and chronic pain.

„The StimaWELL® device is extremely popular in our practice, and many patients with chronic low back pain, for example, are happy to keep using it for prolonged periods. In other, less chronic cases, often just a few treatments are enough to alleviate symptoms or get rid of them altogether. The option of personalised settings offers tremendous scope for customisation to each individual patient's needs.“
(Dr. Stefan Gobisch, Kiel, Germany, 2018)

„In my specialist orthopaedic practice, we have been using the StimaWELL® method for a good 4 years now, and we've integrated it firmly into the practice's everyday routines. A large proportion of our back pain patients have muscle weakness or imbalance of the postural muscles as the cause of their symptoms. Unfortunately, these patients have omitted to prevent these symptoms through active back training or regular sport in their everyday lives. But that's human nature for you. Everyone knows there are times when time is short and the workload is high. The combined heat produces an improvement in blood flow and at the same time, thanks to TENS and EMS, pain relief and hypertrophy of the deep muscles. The massage effect is an additional bonus. If you look at this method from the perspective of the interaction of the muscle agonist and antagonist, we actually „only“ treat the dorsal chain of muscles. However this produces a significant improvement, both in the pain situation and in muscular strengthening, even if the abdominal muscles are not directly involved. And although the StimaWELL® actually „passively“ strengthens the patient's muscles, in my view the treatment acts as a wonderful „kick-starter“ for the patient to step up their own levels of activity later on. Our goal is to break this vicious circle of back pain > inactivity > further weakness > more pain, etc., so as to motivate patients to once again take proactive care of their own back.

(Dr. Paul Schepers, Cologne, Germany, 2018)

„StimaWELL® has long since been used effectively in our practice, and is hugely popular, especially with patients who have chronic back pain. In acute cases, just a few treatments are sufficient to produce significant relief and rapid freedom from symptoms. Some patients like to use the StimaWELL® treatment for prevention, in order to stay symptom-free. Personalised intensity settings allow the patient to tackle their pain efficiently, and also experience a beneficial treatment.“

(Dr. Sebastian Schneider, Eschborn, Germany, 2018)

„StimaWELL® deep wave therapy has given us a more efficient option compared to manual techniques for relaxing the paravertebral muscles and at the same time improving the quality of our services. We are convinced that we have made the right choice. The best proof for us is the fact that our patients keep coming back, as well as the high demand for treatment.“

(Kinesiologists Stéphane Robert & Guillaume Brimont, Poncharra, France)

„I've always been an enthusiastic advocate of manual massage, and I use very little equipment. I was looking for new tools to help me alleviate back pain, and I tried deep wave therapy. I had no idea that a device could be so effective. I'm very happy with it, and I recommend it to my colleagues.“

(Kinesiologist, David Ollivier, Velaux, France)

„I'm delighted by my StimaWELL® device and my patients have very quickly come to share this delight. It's a fantastic machine, and it's very effective in acute and chronic pain. It also allows me to treat older or heavier patients who would be unable to tolerate manual massages such as for fibromyalgia. Ultimately, I'm less busy with my hands, which means I get more done in a shorter space of time.“

(Kinesiologist Cécile Bergeret, Thônes, France)

„It's the best physiotherapy instrument to have been developed in the last 5 years. It helps me to work more efficiently and makes my work easier. The results for patients are rapid and sustainable, and quite simply astonishing. It allows dorsal back therapy on overweight patients or patients with poor airways. It's an exceptional physiotherapy device that my patients absolutely love. It makes the lives of patients as well as physiotherapists easier, especially those who have been in practice for many years.“

(Kinesiologist Frédéric Baille, Longuyon, France)

„Deep wave therapy helped me to change the way I work. The results are outstanding, and patient demand for the treatment is tremendous. I use it to alleviate pain, but also to relax the muscles of stressed people, or to build up the muscles of people with poor mobility. I've also been able to establish a better pace of work. I'm also less stressed, and I have to admit that this device provides a good addition to my income.“

(Serge Tchakmichian, La Valette du Var, France)

„The dynamic deep wave are an excellent adjunct to the treatment of my patients and their painful spines. I use this form of treatment very often: between 10 and 15 patients a day. It provides great relief for me, because I work very long days. I often use the StimaWELL® device combined with an Imoove (6 sessions of StimaWELL® followed by 6 sessions on the rehabilitation platform), and the results I'm getting are excellent.“

(Jean-Philippe Piacentini, St Marcellin, France)

„I'm 60 years old, and because my working days are long, I needed a tool such as dynamic deep wave therapy with StimaWELL®. The tool gives me more efficiency and makes my work easier on a daily basis. From a therapeutic perspective, the results are very interesting and patients like to avail themselves of it. I use it on average on 10 patients a day.“

(Simon Maschino, Morschwiller-le-Bas, France)

„I use StimaWELL® dynamic deep wave therapy on all of my patients with back pain, older people or people with limited mobility. Generally, I draw up plans of 6 to 10 sessions, usually combined with manual mobilisation or sometimes on their own. Patients are happy and their symptoms are reduced. They love the comfort that the waves and the heat of the mat give them. As a result, I can organise my work better, achieve better results with my patients and also save time.“

(Fabienne FREIN, Acigné, France)

„Ich möchte diese Gelegenheit nutzen, um meine aufrichtige Wertschätzung über den gesamten Behandlungsprozess mit StimaWELL® auszudrücken. Ich hatte lange chronische Rückenschmerzen. Ich brauchte Schmerzmittel, um jeden Tag mit Schmerzen fertig zu werden, daher konsultierte ich viele Ärzte, bekam aber nur vorübergehende Schmerzlinderung. Letzte Woche, als mein Mann eine Anzeige in der Zeitung sah, brachte er mich zur Cool Sculpting Clinic, Bangalore, Indien, die eine Dynamische Tiefenwellenstimulation anbot. Im Gespräch mit dem Arzt fühlte ich mich fähig zu erklären, unter welchen Schmerzen ich litt. Nach der Behandlung wurde eine Besserung meines Gesundheitszustandes beobachtet. Ich fühlte mich entspannt nach jeder Behandlung, erfuhr Schmerzlinderung, bekam einen guten Schlaf und allmählich ein positives und selbstbewusstes Gefühl. Ich schätze die gute Terminplanung und Betreuung durch die Mitarbeiter. Dankeschön für das hohe Niveau an Professionalität und Einfühlungsvermögen.“

(Jayashree Amanesh, Bangalore, Indien 2016 in Behandlung bei Dr. Pahska, Therapieanbieter mit StimaWELL®120MTRS)

„I'd like to use this opportunity to express my absolute delight with the entire StimaWELL® treatment process. I had chronic back pain for a long time. I needed painkillers to manage the pain every day, so I consulted a long list of doctors but only ever got temporary pain relief. Last week, when my husband saw an advertisement in the paper, he took me to the Cool Sculpting Clinic in Bangalore, India, which offered dynamic deep wave stimulation. Talking to the doctor, I felt able to explain the type of pain I was experiencing. After the treatment, I noticed an improvement in my health. I felt relaxed after every treatment, experienced relief from my pain, slept well and gradually developed a feeling of positivity and self-confidence. I really appreciate the good appointment planning and support I get from the staff. Thank you for the excellent professionalism and empathy.“

(Jayashree Amanesh, Bangalore, India 2016, treated by Dr. Pahska, therapist, with StimaWELL®120MTRS)

„I'm Lily Parvin from Bangladesh. I travelled with my niece, Garegi Mondo, to Bangalore in India because I've been suffering with back pain for 15 years. In 2014, I visited vellorce and was given advice from the Christian Medical College (CMC) and Shree Narayani. The advisors at Shree Narayani recommended surgery as soon as possible, but the CMC doctors told me surgery was not necessary. Here in Bangalore, a surgeon from the Applo Hospital also advised me to have an operation as soon as possible. I then came to see Dr. Lokenath Kumar and consulted him and his team. They advised me to have 10 days of dynamic deep wave stimulation. I suffer from spinal degenerative disease and diabetes, so I cannot sit for long periods of time. After having this 10-day treatment, I think it represents a very effective and wonderful programme of treatment for myself and other patients with pain. I think, if I'm able, I'll have 10 sessions every 6 months, and my life will be free from pain. Thank you so much to the practice team!“

(Lily Parvin, 2016, Bangalore, India)

„Dear Sirs, I would recommend to anyone with back problems to consult Dr. Vivek Kakkar in Mumbai, India, and experience instant pain relief. I had back pain for almost a year, and I was unable to do my day to day work. I felt pain in almost every position, and I was constantly restless. I visited him because of my knee and ankle pain, and also mentioned by back problems. After a discussion about my past medical history and the screening investigations, he advised me to have a treatment with his StimaWELL® device. I felt much better after the treatment, and I didn't have pain anywhere. All of my pain had gone, and I was able to bend down, move around, and so on. I recommended it immediately to my wife, since she had always complained of back pain since the birth of our child. She too had a consultation with Dr. Vivek Kakkar, and she too was prescribed treatment with the StimaWELL® device. She was incredibly happy to see that her pain had disappeared after one session. Dr. Vivek Kakkar's physiotherapy has been the answer to many of our health problems over the last 3 years, and we are blessed to have him in our lives.“

(AbdulRab Kazi, Mumbai, India, 2018)

„I use the StimaWELL® every 2 weeks because I stand up a lot in my job, so I occasionally get back problems. This device has made my life easier. In the past, I had to spend half of my salary on treatments for my back. Now, after the treatment, I've been pain-free for two weeks and I'm amazed. My muscle strength has improved significantly, and my body is able to work for longer under stress. I've even been able to start going to the gym again. Thank you, StimaWELL® team, for bringing this fantastic technology onto the market.“

(Jigyasu Vivek, Mumbai, India, 2018)

FOOTNOTES

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