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FACULTY OF BIOMEDICAL ENGINEERING

Department of Health Sciences and Population Protection

Effect of Focused Shockwave Therapy in Combination with Physiotherapy on Lower Limb Spasticity in Patients with Multiple Sclerosis

Diploma thesis

Study programme: Applied physiotherapy

Author of the thesis: Bc. Irena Křížová

Thesis supervisor: MUDr. Tomáš Nedělka Ph.D.

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MASTER'S THESIS ASSIGNMENT

I. PERSONAL AND STUDY DETAILS

Student's name:	**Křížová Irena**	Personal ID number:	**511051**
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Study program:	**Aplikovaná fyzioterapie**		

II. MASTER'S THESIS DETAILS

Master's thesis title in English:

Effect of Focused Shockwave Therapy in Combination With Physiotherapy on Lower Limb Spasticity in Patients With Multiple Sclerosis

Master's thesis title in Czech:

Efekt fokusované rázové vlny v kombinaci s fyzioterapií na spasticitu dolních končetin u roztroušené sklerózy

Guidelines:

The subject of the thesis will be to investigate the effect of shock wave in combination with physiotherapy on spasticity of lower limbs in patients with multiple sclerosis. The theoretical part of the thesis will summarize the existing literature focused on the application of shock wave on spasticity. In the practical part, focused shock wave and physiotherapy will be used to treat spasticity and then its effect will be assesed after two months of therapy. The research will be quantitative. Spasticity will be ecxamed using the Tardieu Scale and ROM will be measured using a goniometer. Patients will be randomly divided into two groups. One group will undergo shockwave therapy and physiotherapy, the other control group will receive only physiotherapy. The outcomes from baseline and follow-ups will be compared. The results will be presented in the form of graphs. Based on the practical part, the effect of shock wave on spasticity will be evaluated and compared with the results of other authors of similar studies.

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Assignment valid until: **20.09.2024**

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DECLARATION

I sincerely declare that I have managed my thesis entitled *Effect of Focused Shockwave Therapy in Combination with Physiotherapy on Lower Limb Spasticity in Patients with Multiple Sclerosis* by myself using only the sources listed in the bibliographic references.

I have no valid reason against the use of this thesis within the meaning of Section 60 of the Act 121/2000 Coll., on Copyright, on Rights Related to Copyright and on Amendments to Certain Acts (Copyright Act), as amended.

Prague, 16th May 2023

Bc. Irena Křížová

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ABSTRACT

This thesis focused on the use of shock waves in combination with physiotherapy on lower limb spasticity in patients with multiple sclerosis.

In the **theoretical part** I describe the treatment options for spasticity, its examination, and the use of shock wave therapy according to the literature published so far. In the **methodology** and **results** I describe the research itself and look for answers to my research questions in the outcomes. In the **discussion**, I compare my procedure with that of other authors and try to find answers as to why my output differs from that of previous studies.

I included 7 patients with lower limb spasticity in my research. All participants underwent a rehabilitation plan including 4 physiotherapist-led sessions, 4 applications of shock wave and 3 examinations. A focused shock wave was applied to one lower limb, with the other lower limb used as a control group.

The limbs treated with shock wave and physiotherapy tended to show positive changes in spasticity angle, active and passive range of motion in contrast to the limbs to which shockwave was not applied. However, there were no significant changes in the assessment of spasticity itself using the Modified Tardieu Scale.

Keywords

Shock wave; Spasticity; Multiple sclerosis; Physiotherapy; Range of motion

ABSTRAKT

Tato práce se zaměřuje na využití rázové vlny v kombinaci s fyzioterapií na spasticitu dolních končetin u pacientů s roztroušenou sklerózou.

V **teoretické části** se věnuji možnostem léčby spasticity, jejímu vyšetření a využití rázové vlny v terapii dle doposud publikované literatury. V **metodice a výsledcích** popisuji samotný výzkum a hledám ve výsledcích odpovědi na své vědecké otázky. V **diskuzi** porovnávám svůj postup s postupem jiných autorů a snažím se najít odpověď na to, proč se můj výstup liší od výstupu předchozích studií.

Do výzkumu jsem zařadila 7 pacientů se spastickými dolními končetinami. Všichni účastníci podstoupili rehabilitační plán zahrnující 4 terapie pod vedením fyzioterapeuta, 4 aplikace rázové vlny a 3 vyšetření. Na jednu dolní končetinu byla aplikována fokusovaná rázová vlna, přičemž druhá dolní končetina byla použita jako kontrolní skupina.

U končetin ošetřených i rázovou vlnou je tendence k pozitivním změnám spasticity (především úhlu spasticity), aktivního a pasivního rozsahu pohybu v příslušném kloubu na rozdíl od končetin, na které rázová vlna aplikována nebyla. U hodnocení samotné spasticity pomocí Modifikované Tardieuho škály však nedošlo k významným změnám.

Klíčová slova

Rázová vlna; Spasticita; Roztroušená skleróza; Fyzioterapie; Rozsah pohybu

Table of content

1 INTRODUCTION

Multiple sclerosis (MS) is an autoimmune disease that affects the central nervous system and manifests a wide range of symptoms. In my thesis, I would like to focus on one of them, called spasticity, that significantly impacts a patient's quality of life. In the case of MS, it usually affects the lower extremities. Even though there are several treatment options available, including pharmacological and nonpharmacological approaches, the optimal management of this complication remains a challenge.

One emerging non-pharmacological approach is shock wave therapy. In recent years, shock waves have been used quite extensively in musculoskeletal medicine. It is mainly associated with the treatment of heel spurs or tendinopathies. However, according to the literature, it could be used to influence increased muscle tone with a neurological background, even though we are not sure about the exact mechanism.

Unfortunately, in the case of MS patients, the use of shock waves in spasticity management has not been investigated enough. The research that has been published so far is focused mostly on stroke patients or occasionally on children with cerebral palsy. For this reason, I decided to observe in my study patients with multiple sclerosis, because science has not produced enough evidence in this group yet.

As a physiotherapist, I believe physical therapy modalities are just part of complex rehabilitation, and because of this, I combine shock wave with physiotherapy approaches, which are individually applied based on each participant's needs. Because our aim shouldn't be just to decrease muscle tone but to maximise the patient's functional abilities. We must keep in mind that spasticity is not always our enemy, sometimes it could play a supporting role.

2 RESEARCH QUESTIONS

The goal of this thesis is to ascertain whether the combination of focused shock wave treatment and physiotherapy has some impact on lower limb spasticity in patients with multiple sclerosis.

If the research questions below can be answered positively, it could offer another option for patients to solve their spasticity-related difficulties. Physical therapy represents a non-invasive treatment option, and its effectiveness could be supported by physiotherapy, which also represents a conservative approach.

Formulation of the research questions:

1. Does focused shock wave therapy combined with physiotherapy influence the spasticity of the lower limbs compared to the use of physiotherapy without shock wave application?
2. Does focused shock wave therapy combined with physiotherapy influence active range of motion compared to the use of physiotherapy without shock wave application?
3. Does focused shock wave therapy combined with physiotherapy influence passive range of motion compared to the use of physiotherapy without shock wave application?

3 THEORETICAL PART

3.1 Multiple sclerosis

Multiple sclerosis is a chronic autoimmune inflammatory disease that affects the central nervous system. The cause of this illness remains uncertain. However, there are factors, which might be crucial in multiple sclerosis development; namely: Epstein-Barr virus, distance from the equator in early childhood, smoking, lack of vitamin D and genetic background. A wide range of significant symptoms, such as fatigue, cognitive decline, malfunction of the bladder, pain, and spasticity, are experienced by patients. Due to prevalence of MS among young adults, the condition has a significant socioeconomic impact (Safarpour et al., 2017, page 33; Doshi and Chataway, 2016, page 54).

The defining pathogenic trait of the sclerotic MS plaque is demyelination. Both the myelin sheath and the oligodendrocyte itself are destroyed. In the white matter of the brains of multiple sclerosis patients, numerous, well defined focal lesions where demyelination has occurred can be seen. These lesions include a high density of immunohistochemical markers for different immune cells. Also, grey matter in the cortical and subcortical regions has demyelinated plaques. Numerous physiological and metabolic processes may cause activated immune cells to obliterate oligodendrocytes and myelin. In addition to damage to myelin and oligodendrocytes, axonal damage is also characteristic feature. In some cases, sclerotic plaques show signs of remyelination. However, the remyelination is typically incomplete and is characterised by shorter internodal lengths and thinner myelin sheaths than in the original myelin (Brück, 2005, pages 4-6).

3.2 Spasticity associated with multiple sclerosis

Spasticity can be defined as a neurological symptom arising after a lesion of an upper motor neuron such as a stroke, multiple sclerosis, brain or spinal cord injury, etc. For clinical diagnostics of spasticity, there must be the presence of exaggerated tendon reflexes and muscle hypertonia, which is described as a velocity-dependent resistance of a muscle to stretching. In MS, it affects mostly the lower extremities, but it can also affect the upper limbs, trunk, bladder, and vocal cords (Dietz and Sinkajer, 2012, page 197; Hugos and Cameron 2019, page 2).

Spasticity associated with multiple sclerosis can include various signs and symptoms such as spasms, clonus, increased resistance to passive movement, myoclonic jerks, stiffness, co-contractions, heaviness, pain, sleep disturbances, fatigue, incoordination, poor motor control, weakness, slowed movements, and loss of dexterity (Hugos and Cameron, page 2).

According to some sources, spasm is included under the umbrella term of spasticity. Sometimes it is described as a symptom per se of upper motor neuron syndrome because spasms are triggered through many peripheral, noxious, and visceral afferents, not only by muscle stretching (Thompson, page 459).

3.3 Spasticity treatment approaches

In daily living, spasticity could affect physical activities like walking, manipulating with objects, hygiene, transfers, or sexual activities, as well as the mentality of the patient, which could be reflected on mood, motivation, self-perception, etc. Especially clonus could interfere with dressing, washing, or even maintaining the relaxed sitting position with feet on the floor. Nevertheless, it must be mentioned that if the spasticity is reduced by treatment, it could contribute to the disability of the patient as well. The reason is the undercovering of weak paresis by reducing spasticity, which in some cases supports the body by increasing muscle tone. This muscle tone perhaps allows a person to transfer, dress, or even stand. Knowing this, we must always manage the treatment so that it is focused on function (Yelnik et al, 2010, page 802; Thompson, pages 459–460).

Treatment should have following goals: to mitigate pain, reduce complications arising from spasticity, and improve function. In conclusion, to enhance the quality of daily living. A multidisciplinary view of the issue would be appropriate. However, based on sources, the treatment is often focused on influencing reflex activity instead of having an effect on functional movement (Dietz and Sinkjaer, 2012, page 204).

The possibilities of spasticity treatment include oral medication (mostly baclofen, diazepam, or tizanidine), interventional treatments (botulinum toxin injections, intrathecal baclofen, phenol/alcohol injections), nonmedical treatment (which includes physiotherapy, occupational therapy, and many physical therapy modalities), and in severe cases, surgical intervention. Botulinum toxin injections are considered the gold standard for the treatment of muscular spasticity (Chang et al., 2013, pages 11-22; Farr, 2018, page 1).

3.3.1 Physiotherapy approaches

Physiotherapy represents an essential part of the treatment for immobilised as well as mobile spastic patients. Intervention by a physiotherapist might be beneficial for improving residual motor functions or maintaining the patient’s condition (Dietz and Sinkjaer, 2012, page 204).

There are a variety of physiotherapy approaches that are applied based on divergent empirical evidence. These techniques come with different theories about how to influence a patient’s state. However, the following aims are common to all of them:

1. Avoidance of secondary complications
2. Prevention or treatment of muscle contractures and maintenance of muscle length
3. Reduction of hypertonia
4. Training of posture, automatically performed movements, or coordinated movements (Dietz and Sinkjaer, 2012, page 204).

Types of physiotherapy interventions that are usually used are:

- Passive interventions: passive movements, stretching, taping, splinting, orthosis, or casting.
- Gait-related therapies: this includes various approaches focused on gait. Nowadays, we can also notice the implementation of robot gait training in spasticity management.
- Generic exercises: it means, for instance, strengthening, balance, or fitness exercises.
- Physical therapy modalities: ultrasound, shock wave, functional electrical stimulation etc.
- Other approaches include: hydrotherapy, heat therapy, or vibration therapy (Barbosa et al., 2021, page 237; Etoom et al., 2018, page 793; Knobloch and Nedělka, 2022, page 324).

Even though including physiotherapy in the treatment schedule is highly recommended for spastic patients, there is a lack of evidence of any positive effect, which would be statistically significant. The meta-analysis focused on multiple sclerosis patients published in 2018 claims that physiotherapy interventions showed some benefits on spasticity outcomes, but more evidence is still needed, so no solid conclusion can be made. The authors of this meta-analysis admitted that the quality of the included studies is extremely low (Dietz and Sinkjaer, 2012, page 204; Etoom et al., 2018, page 804).

Gracies' method

In this chapter, I would like to expand on the method of Jean-Michael Gracies because I used this physiotherapy approach in the case of every patient in the practical part of my thesis. This method is based on the principle of "agonist-antagonist" relations. This relation is disrupted by overactivation of the agonist and antagonist muscle groups, which causes shortening of the overactive agonist and negatively affects the position of a certain joint. As a result, it influences the functional movement of the limb (Gracies, 2001, page 752).

Based on this, Gracies' method uses stretching and fast repetitive movements to avoid shortening of the overactive muscle group. Each exercise is designed to be doable in a home environment as an autotherapy. The book for therapists trained in this concept describes in detail the execution of each exercise and its recommended interval. According to the authors, it is advisable to do stretching exercises for between 2 and 20 minutes (Gracies, 2022, pages 12–15).

3.3.2 Physical therapy modalities

These modalities could be included in physiotherapy techniques, but in this thesis, there is a separate chapter about them by intent. A variety of techniques could be used, such as the application of ultrasound, transcranial magnetic stimulation, functional electrical stimulation, transcutaneous electrical nerve stimulation, or shock waves (Barbosa et al., 2021, page 237; Safarpour et al., 2017, page 33).

3.3.3 Medications

For the treatment of spasticity, a number of drugs are available. These drugs relieve spasticity by either relaxing the muscles or decreasing the impulses that trigger it. Among the drugs frequently used to treat spasticity are:

1. *Botulinum toxin injections (BTX-A):* The hyperactive target muscles, which are in responsible for the clinical image, are injected with BTX-A. It is a strong neurotoxin that prevents neurotransmitter chemical release. Due to its properties, it is well suited for long-term acetylcholine release suppression blocking of neuromuscular transmission. This results in muscle paralysis over the course of three to four months; however, this can be prolonged by an exercise regimen. In terms of response to BTX-A therapy in the MS-related spasticity compared to the stroke-related spasticity, there is considerable debate in the research. In a 99-patient study (33 MS, 33 stroke, and 33 CP patients), the researchers discovered that MS spasticity required significantly larger dosages of BTX-A to be successful. On the other hand, a large prospective registry of 508 patients who had over 2000 injections found no differences in the dose and amplitude of response to BTX-A between the various kinds of spasticity (stroke, MS, CP, and traumatic brain injury) (Ward, 2008, page 611; Phadke et al., 2001, pages 406-411; Schramm, 2014, pages 1-10).
2. *Baclofen:* Patients with secondary dystonia or spasticity are frequently given the drug baclofen orally. The drug acts as a GABA-type B receptor agonist. By blocking the release of excitatory neurotransmitters by interference with voltage-gated calcium channels, baclofen prevents reflexive muscular contraction. Despite these benefits, the blood-brain barrier prevents the medication from being fully absorbed at the site of action in the central nervous system. Due to it the intrathecal infusions in

some cases have been used (in MS rarely) (Lake and Shah, 2019, pages 203-204).

3. *Diazepam:* Diazepam, also known as Valium, primarily affects flexor reflexes, although it can also affect extensors in higher concentrations. Diazepam may therefore be helpful for spinal spasticity but not much for cerebral spasticity. As a tranquillizer, diazepam also reduces neuronal activity in the reticular formation, which helps to relax muscles but may also have the unintended side effect of sleepiness (Lapeyre et al., 2010, page 196).
4. *Dantrolene:* A medication called dantrolene sodium has significant antispastic effects on skeletal muscle. It prevents the sarcoplasmic reticulum from releasing calcium. The main adverse effect of this medication is a dose-dependent loss of grip and stretch reflexes along with generalised weakness. It may also result in moderate drowsiness, nausea, vomiting, diarrhoea, and paraesthesia in addition to these negative effects. Hepatotoxicity and severe hepatitis have both been observed in some situations (Chung et al., 2011, page 217).
5. *Tizanidine:* Tizanidine helps muscles relax by affecting specific nerve signals in the brain and spinal cord. It is frequently recommended for illnesses including multiple sclerosis, spinal cord damage, or other neurological problems that cause muscle stiffness. It can also be used to alleviate pain from injuries or musculoskeletal problems as well as muscular spasms (Malanga et al., 2008, pages 2209-2211).

The evidence is in favour of first-line treatment with baclofen, tizanidine, and gabapentin. If the prior medications do not show a clinical improvement, diazepam or dantrolene may be considered. In individuals who have a poor response and/or intolerance to first-line oral therapies, nabiximols (specific cannabis extract) has a beneficial effect when used as an add-on therapy. Despite a lack of evidence, intrathecal baclofen and intrathecal phenol are effective in treating severe spasticity and poor oral medication response (Otero-Romeo et al., 2016, page 1386).

3.4 Clinical evaluation of spasticity

3.4.1 Spasticity grade

The most commonly used scales for measuring spasticity are the Ashworth Scale (AS), the Modified Ashworth Scale (MAS), the Tardieu Scale (TS), and the Modified Tardieu Scale (MTS). The AS and MAS are the most used scales in research studies and are also very popular in the practise of physical and occupational therapists. Both the AS and the MAS are scored on a 0–4 scale, but the difference is an additional score of 1+ in the MAS. The TS/various MTS is used mainly in cerebral palsy patients (Hugos and Cameron, 2019, pages 2-3).

In 2010, a study that was concerned with the validity of AS and TS showed quite interesting results. The Tardieu Scale recognised 18 of 27 participants as having ankle plantar flexor spasticity, whereas the Ashworth Scale identified 26 of 27 people as having spasticity. The findings of the laboratory test showed that 21 of the 27 participants had ankle plantar flexor spasticity. As a result, the Tardieu Scale produced three false negative results and the Ashworth Scale five false positive results. The percentage of accurate agreement between the Tardieu Scale and the laboratory measure of ankle plantar flexor spasticity in determining the presence or absence of spasticity was 88.9%, demonstrating a noticeably good agreement. The Ashworth Scale's precise agreement percentage with the laboratory test was 81.5% (Alhusaini et al., 2010, pages 1244–1245).

And already in 2005, a study published by Mehrholz et al. revealed that the Modified Tardieu Scale has stronger test-retest and inter-rater reliability in individuals with severe brain injuries and decreased consciousness than the Modified Ashworth Scale, suggesting that it might be a more reliable adult spasticity scale (Mehrholz et al., 2005, page 751).

3.4.2 Angle of catch or clonus

For evaluation of the angle of the catch or clonus, we must stretch the corresponding muscles as fast as it is possible. We measure the angle of onset of this pathology (Yelnik et al., 2010, page 803).

3.4.3 Active range of motion

Before each passive range of motion (PROM) assessment we should ask the patient to perform an active movement as far as it is possible. The range of motion in corresponding joint is restricted by maximal stretch of antagonist muscle and other structures or by spastic reaction of antagonist (Yelnik et al., page 803).

3.4.4 Passive range of motion

During the examination of PROM, the therapist stretches the corresponding muscles at a very slow speed. At the moment of the greatest tissue resistance, we measure the angle and determine this measured value as a passive range of movement for a given joint (Yelnik et al., 2010, page 803).

3.4.5 Rapid alternating movement frequency

For this examination, the subject is asked to perform fast repetitive movements in the corresponding joint in the maximal range of motion as many times as it is possible. The outcome indicates the patient's ability to repeat fast, active movements, which are necessary for some activities of daily living. This assessment also reveals the spasticity very well (Yelnik et al., 2010, page 803).

3.4.6 Functional assessment

Functional assessments of spasticity evaluate the impact of muscle stiffness and increased tone on a person's ability to perform daily activities (such as dressing, eating, hygiene, gait, transfers, etc.). The goal is to identify specific functional limitations caused by spasticity and develop treatment plans based on this. Simple examination could be done by observation or conversation. However, there are specific assessment tools that can help healthcare providers objectively check progress over time.

For example:

1. Timed Up and Go (TUG): In this test we measure time since the subject stands up from the chair, walks 3 metres set distance, turns around, walks back to the chair and until sits safely down. The patient should try it at least once before being timed to become familiar with this test. Better measured score predicts better functional performance. Time ≥ 13.5 was chosen as the breakpoint to evaluate the increased risk of falling (Barry et al., 2014, page 14).
2. 10 metre walk test (10MWT): By using this test we measure how long it takes to walk 10 meters. 10MWT is widely used in neurological diagnoses (Hirsch et al., 2014, pages 1115-1116).
3. 6-minutes walk test (6MWT): 6MWT is mostly used in people with pulmonary problems. However, it can be used in cases where we need to objectify walking ability, endurance, and overall functional capacity. A thirty-meter track is prepared for the subject, and after six minutes we count how many meters the patient has walked. After obtaining consent, the therapist can videotape the patient's gait so after they can assess any progress at the follow-up appointment (Agarwala and Salzman, 2020, pages 603-611).
4. Dynamic Gait Index (DGI): This assessment tool was meant to be used in peripheral vestibular disease. However, balance dysfunction also affects

people with multiple sclerosis. It evaluates adaptability of the subject to adapt gait abilities to diverse environment and surface. DGI contains 8 dimensions of environmental categories (McConvey and Bennet, 2005, page 130; Shumway-Cook et al., 2013, page 1494).

5. More complex tests such as Rivermead: Rivermead Mobility Index represents assessment tool to evaluate subject's mobility. This index consists of 15 items based on which we examine patient's abilities (Collen et al., 2023, pages 50-54).

3.5 Shock wave in the treatment of spasticity

A shock wave is a brief pressure anomaly that spreads quickly in three dimensions. It is connected to a sharp increase in pressure from the surrounding atmosphere to its highest point. Cavitation caused by the wave propagation's negative phase is a significant tissue effect. Extracorporeal shock wave therapy (ESWT) has been widely used in the treatment of musculoskeletal disorder, but for medical purposes it was first applied to destroy kidney stones (Ogden et al., 2001, page 8 ; Yang et al., 2021, page 3; Taheri et al., 2017, page 338).

The use of low-energy ESWT on spastic muscles was first mentioned in a German published article by Lohse-Busch in 1997. 500 non-focused pulses were sent into the flexor hypertonic muscles. The energy applied was approximately thirty percent of the threshold value at which the endothelium of the human umbilical cord had shown signs of cellular damage following targeted treatment with ESWT. Increased range of motion and decreased muscle stiffness, spastic co-contractions, ataxia, dyskinesia, or myofascial viscoelasticity were noted. Surprisingly, changes were also observed on limbs that were not treated with pulses. The biomechanical changes persisted for the next few weeks (Lohse-Busch et al., 1997, page 109).

We distinguish two types of physical effects of ESWT: primary and secondary. The primary effect is described as a result of the direct generation of mechanical forces, concentrated at the treatment point. On the other hand, secondary effects are a result of indirect mechanical forces caused by cavitation (Gonkova et al., 2013, page 286).

The mechanism of influencing spasticity by ESWT remains uncertain, however, and there are a few theories trying to explain that:

1. The first possibility could be increased nitric oxide (NO) production. NO plays an important role in the function of peripheral and central nervous system. It affects the increase of muscle and tendon neovascularization and reduces muscle stiffness. In 2005, research by Mariotto confirmed that shockwave potentiates endothelial nitric oxide synthase activity, leading to NO production, which has anti-inflammatory effect (Xiang et al., 2018, pages 852-858; Mariotto et al., 2005, page 95).
2. Other sources mentioned the possibility of reducing alpha motor neuron excitability. On the contrary, some recently published studies claim that ESWT doesn't have neuronal effects (Yang et al., 2021, page 3; Leng et al., 2021, pages 1-16).
3. One study (experiment on rats) has reported degenerating acetylcholine receptors, which causes dysfunction in neuromuscular transmission. On the side treated by shockwave there were found to be significantly lower motor action potential amplitudes in comparison with the control side. However, these are only temporary changes (Kenmoku et al., 2012, pages 1662-1663; Yang et al., 2021, pages 3-4).
4. The last theory mentions the peripheral effect, which is explained as influencing the rheological properties and fibrosis of chronically hypertonic muscles. This effect was observed by Dymarek et al. using infrared thermal

imaging and by Leng et al. using the neuroflexor method, a myotometer, and electrical impedance myography. Both found significant changes in areas treated with shockwaves. This theory is supported also by review published in 2020 by Cabanas-Valdés (Leng et al., 2021, page 4-13; Dymarek et al., 2016, pages 4-6; Yang et al., 2021, page 4; Cabanas-Valdés et al., 2020, page 14).

Martínez et al. have gathered evidence about the positive influence of ESWT on spasticity, motor function, motor impairment, pain, or functional independence. They collected research published in any language over the last 10 years. The shock wave treatment protocols are quite heterogeneous. The total number of sessions varies, ranging from 1 session at the very least to more than 20 sessions. It is possible to give 500–4000 pulses, with energies ranging from 1.5 bar to 3.5 bar and for fESWT it was 0.03 mJ/mm^2, and frequencies ranging from 4 Hz to 10 Hz. More than half of the trials did not say whether the intervention group received radial or focused shock waves. Focused waves were applied to just one of them. 21 of the 25 studies that used MAS or other tools to examine motor impairment found statistically significant findings. 10 of the 15 studies found statistically significant improvements in motor function using the passive range of movement, the active range of movement, and the gross motor function classification system. As far as the muscles of the lower limbs were concerned, only the soleus and gastrocnemius were treated, whereas a wider range of muscle groups were treated in the upper limb. Further studies are still required to determine the conditions under which the best results can be obtained (Martínez et al., 2021, pages 1-18).

Two years later, Zhang and his collective made a meta-analysis of articles published from 2010 until 2021, where all the outcomes were reported in MAS. He confirmed the claim of Martínez about the alleviation of spasticity after shock waves. Plus, he mentioned interesting points such as that ESWT lowered the

MAS score more in children with cerebral palsy (CP) than in stroke survivors, or that higher pressure or frequency of ESWT showed a better antispasmodic effect (Zhang et al., 2023, 615-623).

In 2017 Guo et al. published the meta-analysis consisted of a small number of selected articles. They included just 6 studies focused on post-stroke patient with outcomes in MAS scale. Almost all of them were observing the changes immediately after the application. Three of them were also observing the spasticity value 4 weeks after the intervention. Three of the cases involved treating the upper limbs, while the remaining three involved treating the soleus and gastrocnemius muscles. In all cases there were reported significant positive changes (Guo et al., 2017, 2471-2475).

3.5.1 Focused vs radial

Two main types of generators are used in shock wave therapy: radial (rESWT) and focused (fESWT). Regarding radial shock waves, according to The International Society for Medical Shockwave Treatment this is not the correct term. A more accurate term is "radial pressure wave therapy." The difference between rESWT and fESWT is in the wave propagation and the physical characteristics of the energy. The energy of the radial wave is absorbed into the skin approximately 3 cm deep and spreads a beam to the wider diffused target area. These waves are produced by pneumatic devices located in the generator, and their effect is very superficial. On the contrary, the focused waves concentrate the beam energy into a penetration depth of 12 cm with a very small target area. Focused ESWT could be generated by electromagnetic, electrohydraulic, or piezoelectric devices (ISMST Guidelines, 2019; Dymarek et al., 2014, page 27).

In 2020, Dymarek et al. published a review comparing the influence of focused ESWT and radial ESWT on spasticity. They collected studies that focused on post-stroke patients. It turned out the effect of reducing spasticity is similar for both types of shock wave. Slightly better effect of rESWT wasn't significant. Assessment of range of motion showed better influence of fESWT, but also without statistical significance. Nevertheless, authors point out the limitations of spasticity measurement. They consider Modified Ashworth scale to be qualitative and subjective tool with lack of validity and reliability (Dymarek et al., 2020, pages 22-23).

In the studies collected in Dymarek's review, the lower limbs were mainly treated with fESWT, whereas rESWT was applied mostly to the upper limbs. The number of ESWT sessions for the fESWT was 1–6, and for the rESWT it was 1–8. The recommended interval is once per week for fESWT and every 2-3 days for rESWT (Dymarek et al., 2020, page 24).

In the study by Wu et al. in 2018, the focused and radial shock waves were compared in patients after stroke, and the results didn't show any significant difference between the groups for MAS scores or Tardieu angles. However, the radial one seemed to show greater improvement in passive range of motion. During the study period, no adverse events were detected in either type of shock wave (Wu et al., 2018, pages 11-13).

Zhang claims in the article written in 2022 that rESWT is superior to fESWT in relieving spasticity. Nevertheless, it is important to say that fESWT was used in only six studies out of 34 (but not every author has disclosed which type they used) (Zhang et al., 2022, page 618).

Radial ESWT is reportedly more widely used by therapists because it is less invasive, cheaper, and more practical to operate than fESW. Martinéz concluded that radial waves are less expensive, require less precise focus, cover a bigger treatment area, and don't require local anaesthesia (Zhang et al., 2022, page 621; Martínez, 2021, page 15).

3.5.2 In multiple sclerosis patients

So far, only one article has been published about the shock wave treatment in MS patients. The study was written by L. Marinelli and a collective in 2014. Patients were divided into two groups: the first underwent 4 applications of rESWT, and the control group received just sham shock waves. Only one limb was treated, and if both sides met the conditions, the most painful leg received the treatment. The programme included four rESWT sessions once per week. 2000 shots were applied to calf muscles (even the Achilles tendon). Physiotherapists used a frequency of 4 Hz with a pressure of 1.5 bars. The shock wave treatment wasn't considered by patients as painful. The assessment was done just before the first session (T0), one week after the first session (T1), one week (T2), and four weeks (T3) after the last session. Pain was evaluated with the visual analogue scale (VAS) and spasticity with the modified Ashworth scale (MAS). VAS values significantly decreased in each follow-up assessment, the most at T2. According to MAS, spasticity is significantly released only at T2. There weren't any noticeable changes in gait speed examined by the 10-metre walk test or in muscle strength. The placebo treatment didn't have any significant results (Marinelli, 2015, pages 2–5).

3.5.3 In upper limbs spasticity

Cabanas-Valdés published two systematic reviews and meta-analyses in 2020. One of them focused on the efficacy of ESWT on the upper extremities, and the other on the efficacy of ESWT on the lower extremities, both in post-stroke patients. In the case of the upper limbs, four of the included studies used focused waves and twelve used radial waves, which corresponds to Dymarek's claim that radial waves are applied to the upper limbs more often than focused. Twelve research combined extracorporeal shockwave therapy with traditional physiotherapy, but just two trials used it alone. For the spasticity assessment the MAS was used in most cases. The range of energy flux density was quite wide, from 0.03 to 1.95 mJ/mm^2. Other parameters substantially oscillated as well. In terms of impulses, about 1500 shots were mostly applied, the frequency was usually 4–5 Hz, and energy levels ranged between 1 and 4 bars. The frequency was often 1 per week, and the number of applications was from 1 to 6. A study published by Li et al. reported that three applications of ESWT showed better results than one session. All included studies reported statistically significant positive outcomes of ESWT combined with physiotherapy in the case of decreasing muscle tone. Nevertheless, the extracorporeal shockwaves have a minimal impact on motor function. In the study of Kim and collective, four adverse events were identified during the final intervention after the eight rESWT sessions. Three patients experienced petechiae at the treatment site, which cleared on their own, and one patient had a minor bulla, which totally healed with just a simple dressing in a matter of days (Cabanas-Valdés et al., 2020, pages 1141-1156; Li et al., 2016, page 246; Kim et al., 2016, page 515).

3.5.4 In lower limbs spasticity

In the same year, Cabanas-Valdés published a review including studies focused on lower extremities in post-stroke patients. Of 12 studies, 6 used fESWT, 5 used rESWT, and 1 compared both. The most common frequency was again 4/5 Hz, the energy flux density ranged from 0.03 to 0.340 mJ/mm^2, and the number of shots was usually 1 500. Shock waves were mostly targeted on the triceps surae muscle, and once they were applied to the semitendinosus muscle. Some of the authors applied ESWT just once, but some of them applied it three times or more, with a frequency of one session per week. Regarding spasticity, the review shows a positive effect of ESWT alone or in combination with physiotherapy. The authors also mentioned statistically significant differences for ultrasonographic evaluation, Hmax/Mmax ratio, and H-reflex latency. In terms of range of motion, a few studies reported positive changes after ESWT application (Cabanas-Valdés et al., 2020, pages 3–6).

3.5.5 Long term effect

Already in 2005, Manganotti and Amelio had been observing a long-term effect of fESWT in spastic post-stroke patients. Twenty people were included in the study, and after one application, they were examined immediately after the treatment and 1, 4, and 12 weeks later. Measurement using the Ashworth Scale showed prompt changes in muscle tone after shock wave treatment. In the case of the finger flexors, the effect remained after the first week (P 0.001), at 4 weeks (P 0.02), and at 12 weeks (P 0.05). Worse results were noted in wrist flexors, because significant outcomes persisted just after 1 week (P 0.001) and 4 weeks (P 0.05). Significant differences were also observed with regard to passive range of motion until the fourth week. The long-term effect after 12 weeks was not reported at all (Manganotti et al., 2005, pg. 1968–1969).

3.5.6 In combination with botulinum toxin injection

Botulinum toxin type A is a widely used treatment approach in spasticity management within many neurological diagnoses like post-stroke, cerebral palsy, multiple sclerosis, brain injury, etc. BTX-A has been found to be a safe approach, but it is highly recommended to combine it with a complex rehabilitation programme. The effect of the toxin comes a few days after injection; the best result could be observed during the first month and persists for approximately 90 days (Picelli et al., 2019, pg. 291-294; Jost et al., 2005, pages 909–910).

Picelli et al. carried out a study in 2016 focusing on the efficacy of BTX-A combined with ESWT in children with cerebral palsy. The control group received just botulinum toxin. All ten participants had botulinum toxin A injected into their spastic muscles. After the injection, all patients underwent 12 sessions of conventional physiotherapy. Each session took 60 minutes and consisted of neurodevelopmental techniques, stretching of injected muscles, and strengthening exercises. One group received the first of three shock wave applications seven days after the BTX-A injection. ESWT was applied at 1-week intervals. The parameters were: 2400 shots; energy 0.030 mJ/mm^2; frequency 4 Hz. During shock wave treatment, no pain was described. Children were assessed before and after the whole treatment (1 week after the last ESWT session for the first group). Interestingly, both the MAS and the Tardieu scale were used to measure spasticity. The Tardieu scale measures the spasticity grade (TSG) and the spasticity angle (TSA). In MAS scores, there was a significantly greater reduction in the group with ESWT and BTX-A than in the group with BTX-A. In TSG and TSA scores, no significant difference between groups was observed (Picelli et al., 2017, pages 160-164).

Santamanto in 2012 compared the difference between ESWT and electrical stimulation (ES) after botulinum toxin injections. ESWT was used immediately after BTX-A injection in an interval of once per day for 5 days. 1000 pulses with a frequency of 4 Hz and an energy flux density of 0.003 mJ/mm^2 were focused on the belly of the flexor digitorum superficialis muscle. Another 1000 pulses were administered at the proximal muscle-tendon junction. According to the study, BTX-A combined with ESWT or ES may effectively lessen upper limb stiffness in stroke patients. The combination of BTX-A and ESWT has shown up as more effective than BTX-A and ES (Santamanto et al., 2013, pages 285-287).

3.5.7 In comparison with botulinum toxin

A study comparing the effects of shockwave therapy and botulinum toxin on spasticity (measured by MAS), passive range of motion, and upper extremity motor skills (assessed by the Fugl-Meyer Assessment) was released in 2018. In the current research, it was discovered that ESWT was comparable to BTX-A in lowering wrist flexor spasticity according to the MAS score four weeks after treatment. During the study period, spasticity in the wrist and elbow flexors decreased similarly with both interventions. Based on this article, ESWT was more effective than BTX-A therapy at improving the PROM of the wrist and elbow joints as well as the Fugl-Meyer score (Wu et al., 2018, pages 2143-2150).

4 METHODS

Inclusion criteria

Patients were contacted by two centres for demyelinating diseases (the CfDD of the General University Hospital in Prague and the Motol University Hospital) or approached at the Rehabilitation Hospital of Beroun. Some of them contacted me based on my advertisement on social networks. Patients were enrolled according to the following criteria:

1. Multiple sclerosis is diagnosed;
2. spasticity of lower limbs (on the Tardieu Scale 1-4);
3. without application of botulinum toxin to the treated area (for at least 3–4 months);
4. without application of corticosteroids to the treated area (in the past 6 months);
5. no bleeding disorders or use of anticoagulants.

A total of nine subjects were examined, and all of them met the inclusion criteria and joined the study. Unfortunately, two of them did not comply with the frequency and had to be excluded from the study.

Selection for the groups

To achieve relevant results, I planned to divide the patients into two groups. One of them would undergo a combination of physiotherapy (PT) and ESWT; the other would receive just physiotherapy. But I faced the problem of finding participants. I have been contacted by many applicants; however, only a few of them were willing to come to the examination and undergo the whole therapy programme. The most common excuse was the inability to commute.

Due to this situation, I was forced to change the structure of my study with the goal of maintaining the highest possible quality of work. After the initial examination of everyone, I realised that 87.5% of the patients have spastic both lower limbs. Based on this finding, I decided to treat one spastic leg of each subject with ESWT and the other not, and in the end, I compared them. Both legs received physiotherapy. ESWT was applied on the leg with more severe spastic finding according to the Modified Tardieu Scale.

Time and space management

The beginning of the study was planned for autumn 2022. Patients were assessed and treated during October, November, December 2022, and January 2023. Every part of the study took place in the Health Centre of Řepy (Centre for Rehabilitation and Neurology MUDr. Nedělka). It included examination, physiotherapy, and shock wave treatment. ESWT treatment was under the supervision of MUDr. Tomáš Nedělka. It is necessary to mention that the entrance and space must be wheelchair accessible.

All participants underwent the following schedule:

Week No. 1: Examination, Physiotherapy, and ESWT
Week No. 2: Physiotherapy and ESWT
Week No. 3: Physiotherapy and ESWT
Week No. 4: Physiotherapy and ESWT
Week No. 5: Examination
Week No. 6: No intervention
Week No. 7: No intervention
Week No. 8: Examination

Each session lasted 45 minutes. All patients received exercises for following autotherapy at home to support the effect of the shock wave and improve their condition.

If the patient does not adhere to the frequency, he or she has to be excluded from the study.

Clinical outcome measures

The primary outcome was spasticity grading by the Modified Tardieu Scale for the evaluation of the muscle response on the fast stretch. The secondary outcomes were passive and active ranges of motion, and the spasticity angle measured with a goniometer. All the examinations, just like the therapies, were done by the same physiotherapist.

ESWT application

After the spasticity examination, ESWT was applied to the muscle group of the leg with the higher spasticity grade. I've been using the BTL-6000 focused shock wave machine under the supervision of MUDr. Nedělka. The focused shock wave was applied dynamically with three parameters: frequency (6 Hz), energy flux density (0.07 mJ/mm^2), and the number of shots (2 000). ESWT was used four times, with a frequency of once per week. I applied the pulses evenly throughout the whole muscle before the physiotherapy. Either the calf muscles or the hamstrings were treated.

Physiotherapy

Physiotherapy was applied to support the effects of the shock wave. As the main therapeutic approach used in every case in this study, I chose Jean-Gracies' method. For the spastic muscle groups, I set the appropriate stretching exercise according to Gracies' method. For the antagonistic muscle group, I set some strengthening exercises. In general, I individually selected exercises for each patient with the aim of achieving greater self-sufficiency. For example: squats, balance exercises, exercises on the stairs, getting up from the table, turning to the sides, etc.

Characteristics of the observed group

The group of patients consisted of 7 people (6 women and 1 man). The average age was 45.9 years, with the youngest patient being 38 years old and the oldest being 57 years old. 5 of them have been able to walk (with some compensation aid for longer distances), the other two have used a wheelchair.

5 RESULTS

Case study No. 1

Gender: female

Age: 46

Occupation: accountant – she works from home and looks after one kid

Sport anamnesis: she used to be a gymnast

Current course of illness: urine incontinence, walking difficulties (the left leg gets tired quickly), spasticity of the left hamstring muscles, left knee buckles, without any current attack

Self-reliance: without any compensation aid; she owns orthosis supporting ankle dorsal flexion, but she does not wear it

Pharmacotherapy: she just finished her biological treatment

Previous application of botulotoxin: 3 times, side effects

Functional restrictions: difficulties with doing squats and lifting the left leg up (for example walking upstairs), walking on an uneven surface (risk of stumbling)

Patient's goal: be able to do jogging again

Date: 13th of October 2022

	Right leg	Left leg
VAS	0	0
Spasticity grade (hamstrings)	1	2
AROM (knee extension)	5°	-50°
PROM (knee extension)	5°	5°
Spasticity angle	--	-80°

The shock wave was applied to the hamstring muscle group of the left leg.

Date: 10th of November 2022

	Right leg	Left leg
VAS	0	0
Spasticity grade (hamstrings)	1	2
AROM (knee extension)	5°	0°
PROM (knee extension)	5°	5°
Spasticity angle	--	-50°

Any side effects: none

Evaluation: The patient feels much better. She is able to squat and lift her left leg more easily. She still stumbles on uneven surfaces. The active knee extension is improved, and the spasticity angle is smaller (the catch shows up later).

Date: 1st of December 2022

	Right leg	Left leg
VAS	0	0
Spasticity grade (hamstrings)	1	2
AROM (knee extension)	5°	0°
PROM (knee extension)	5°	5°
Spasticity angle	--	-50°

Any side effects: none

Evaluation: The patient still feels very well. She is able to do squat and lift her left leg more easily. She stumbles less on the uneven surfaces. Improved knee extension is maintained, smaller spasticity angle is maintained either.

Case study No. 2

Gender: male

Age: 43

Occupation: he works in the office

Sport anamnesis: he used to play tennis

Current course of illness: spasms in both lower limbs; he doesn't suffer from attacks; the illness has a slow progressive case

Self-reliance: he uses a wheelchair and is able to do few steps with French crutches; he sometimes has difficulties with turning to the sides from the lying (supine) position

Pharmacotherapy: biological treatment, baclofen, zoxon, fampira

Previous application of botulotoxin: 2, before the covid pandemic

Functional restrictions: the spasticity limits him during verticalization and rolling over onto his sides

Patient's goal: greater self-sufficiency

Date: 6th of October 2022

	Right leg	Left leg
VAS	0	0
Spasticity grade (m.soleus)	3	2
AROM (ankle dorsiflexion)	-10°	-12°
PROM (ankle dorsiflexion)	-5°	-10°
Spasticity angle	-20°	-18°

The shock wave was applied to the m. soleus of the right leg.

Date: 3rd of November 2022

	Right leg	Left leg
VAS	0	0
Spasticity grade (m.soleus)	3	2
AROM (ankle dorsiflexion)	-10°	-15°
PROM (ankle dorsiflexion)	-5°	-10°
Spasticity angle	-15°	-18°

Any side effects: none

Evaluation: The patient describes that his calf muscles are less stiff, but in general, he has not noticed any change so far.

Date: 24th of November 2022

	Right leg	Left leg
VAS	0	0
Spasticity grade (m.soleus)	3	2
AROM (ankle dorsiflexion)	-10°	-15°
PROM (ankle dorsiflexion)	-5°	-10°
Spasticity angle	-15°	-18°

Any side effects: none

Evaluation: In the patient's case, there was not any change in the spasticity grade or in active or passive range of motion. A small improvement was noticed in the spasticity angle. There did not seem to be any functional improvement.

Case study No. 3

Gender: female

Age: 47

Occupation: real estate agent – she must walk daily

Sport anamnesis: she used to play basketball for 25 years

Current course of illness: she has difficulties with walking (longer distances, stairs, hills); feeling of heavy, stiff and cold legs; spasticity in the both calves; cramps in the both calves (once per week)

Self-reliance: usually she doesn't use any compensation aid, sometimes she uses sticks

Pharmacotherapy: she doesn't use any medicine, just CBD, herbs, and food supplements

Previous application of botulotoxin: none

Functional restrictions: walking difficulties (gets tired fast, risk of stumbling); the biggest troubles with walking upstairs or to the hills

Patient's goal: to improve the leg's function

Date: 6th of October 2022

	Right leg	Left leg
VAS	0	0
Spasticity grade (gastrocnemii)	3	2
AROM (ankle dorsiflexion)	0°	2°
PROM (ankle dorsiflexion)	0°	2°
Spasticity angle	-20°	-20°

The shock wave was applied to the mm. gastrocnemii of the right leg.

Date: 3rd of November 2022

	Right leg	Left leg
VAS	0	0
Spasticity grade (gastrocnemii)	3	2
AROM (ankle dorsiflexion)	5°	-4°
PROM (ankle dorsiflexion)	10°	0°
Spasticity angle	-20°	-20°

Any side effects: none

Evaluation: She reported less incidence of cramps; the movement of the ankle and fingers is subjectively easier; she feels her foot to be warmer; a better sensitivity; a better passive range of motion.

Date: 24th of November 2022

	Right leg	Left leg
VAS	0	0
Spasticity grade (gastrocnemii)	3	2
AROM (ankle dorsiflexion)	0°	0°
PROM (ankle dorsiflexion)	0°	0°
Spasticity angle	-20°	-20°

Any side effects: none

Evaluation: The cramps came back a week ago (one attack) in the right calf. The subjective positive changes persist. However, there is no objective improvement reported in comparison with the initial examination.

Case study No. 4

Gender: female

Age: 57

Occupation: disability pension

Current course of illness: walking difficulties caused by paresis of the left leg (impossible ankle dorsal flexion), spasticity, and cramps in the calf

Self-reliance: she uses a stick or WalkAide

Pharmacotherapy: she takes many pills, the most important are baclofen and fampyra

Previous application of botulotoxin: none

Functional restrictions: walking difficulties – high risk of stumbling caused by persistent plantar flexion of the left ankle (when she doesn't use WalkAide)

Patient's goal: to improve the left leg function

Date: 6th of October 2022

	Right leg	Left leg
VAS	0	0
Spasticity grade (gastrocnemii)	0	3
AROM (ankle dorsiflexion)	10°	-30°
PROM (ankle dorsiflexion)	15°	-10°
Spasticity angle	-	-25°

The shock wave was applied to the mm. gastrocnemii of the left leg.

Date: 3rd of November 2022

	Right leg	Left leg
VAS	0	0
Spasticity grade (gastrocnemii)	0	3
AROM (ankle dorsiflexion)	10°	-20°
PROM (ankle dorsiflexion)	15°	0°
Spasticity angle	-	-20°

Any side effects: none

Evaluation: She reports subjective relief in her calf muscles and also got rid of the cramps.

Date: 24th of November 2022

	Right leg	Left leg
VAS	0	0
Spasticity grade (gastrocnemii)	0	3
AROM (ankle dorsiflexion)	10°	-30°
PROM (ankle dorsiflexion)	15°	-5°
Spasticity angle	-	-25°

Any side effects: none

Evaluation: She has positive feelings about the treatment. The leg is subjectively described as „lighter“ and „relieved.“ Objectively, almost all of the measured values are the same as in the initial assessment. The cramps returned one week ago.

Case study No. 5

Gender: female

Age: 38

Occupation: she works for a charity, and in her free time she is into diving, dancing, archery or culture

Current course of illness: until 2018, she was able to walk, but her treatment plan was changed, and it led to a dramatic deterioration of her condition. Since this moment, she is wheelchair-bound and suffers from spasticity of the trunk and both legs.

Self-reliance: she uses a wheelchair; the transfer to the therapeutic table/bed is possible, however, there is a problem with transfers to the sofa.

Pharmacotherapy: baclofen, truxima infusions…

Previous application of botulotoxin: once in 2020, without any positive effect

Functional restrictions: difficulty getting up to stand, during transfers, etc. she uses her arms more than would be necessary at the expense of the legs.

Patient's goal: release of spasticity

Date: 13th of October 2022

	Right leg	Left leg
VAS	0	0
Spasticity grade (hamstrings)	1	2
AROM (knee extension)	0°	-50°
PROM (knee extension)	0°	-8°
Spasticity angle	--	-110°

The shock wave was applied to the hamstring muscle group of the left leg.

Date: 10th of November 2022

	Right leg	Left leg
VAS	0	0
Spasticity grade (hamstrings)	1	2
AROM (knee extension)	0°	-40°
PROM (knee extension)	0°	-5°
Spasticity angle	--	-110°

Any side effects: none

Evaluation: The value of spasticity has not changed either subjectively or objectively. She is now able to stand up from the table with my assistance after five weeks of physical therapy (and shock waves). In the standing position, she can stay still for a while.

Date: 1st of December 2022

	Right leg	Left leg
VAS	0	0
Spasticity grade (hamstrings)	1	2
AROM (knee extension)	0°	-40°
PROM (knee extension)	0°	-5°
Spasticity angle	--	-105°

Any side effects: none

Evaluation: Same as the 10th of November. No changes in spasticity, but she has improved in standing up from the table with minimal support.

Case study No. 6

Gender: female

Age: 44

Occupation: administrative work, home-office

Current course of illness: she considers her legs to be the biggest problem. Sometimes she feels confident during walking and daily living, but sometimes she has a period, when she has very weak and stiff legs or even falls down. She describes it as though she does not have her lower limbs under control.

Self-reliance: she uses a walking stick

Pharmacotherapy: fampyra, CBD, gilenya…

Previous application of botulotoxin: it was applied twice (September 2021 and May 2022) on the calf muscle group of the right leg, without any positive effect

Functional restrictions: difficulty walking up the stairs

Patient's goal: to improve gait

Date: 24th of November 2022

	Right leg	Left leg
VAS	0	0
Spasticity grade (gastrocnemii)	2	1
AROM (ankle dorsiflexion)	0°	5°
PROM (ankle dorsiflexion)	0°	6°
Spasticity angle	- 15°	--

The shock wave was applied to the mm. gastrocnemii of the right leg.

Date: 22nd of December 2022

	Right leg	Left leg
VAS	0	0
Spasticity grade (gastrocnemii)	1	1
AROM (ankle dorsiflexion)	0°	5°
PROM (ankle dorsiflexion)	2°	6°
Spasticity angle	--	--

Any side effects: none

Evaluation: she describes her condition as „up and down." She is very into the exercises because she feels better afterward.

Date: 12th of January 2023

	Right leg	Left leg
VAS	0	0
Spasticity grade (gastrocnemii)	1	1
AROM (ankle dorsiflexion)	5°	5°
PROM (ankle dorsiflexion)	6°	6°
Spasticity angle	--	--

Any side effects: none

Evaluation: I observed objectively that ESWT treatment resulted in improvements on the spasticity scale. Although the patient claims to feel better, they did not detect any changes in their gait.

Case study No. 7

Gender: female

Age: 46

Occupation: office work

Current course of illness: problems with movements of the right eyeball, pain in the hands, paresis of lower limbs (she explains the condition of her leg is always unpredictable)

Self-reliance: she uses trekking poles

Pharmacotherapy: fampyra, viregyt….

Previous application of botulotoxin: once many years ago, without any positive effect

Functional restrictions: difficulty doing a squat, risk of tripping, feeling of heavy legs

Patient's goal: loosen her tight leg muscles

Date: 13th of October 2022

	Right leg	Left leg
VAS	0	0
Spasticity grade (hamstrings)	2	2
AROM (knee extension)	-8°	-4°
PROM (knee extension)	-5°	-2°
Spasticity angle	- 120°	-105°

The shock wave was applied to the mm. gastrocnemii of the right leg.

Date: 10th of November 2022

	Right leg	Left leg
VAS	0	0
Spasticity grade (hamstrings)	2	2
AROM (knee extension)	-6°	-4°
PROM (knee extension)	-4°	-2°
Spasticity angle	- 100°	-110°

Any side effects: none

Evaluation: Evaluation: The patient claims to not perceive any change, but she also admits to not adhering to her at-home physiotherapy regimen. I haven't objectively observed any substantial changes in the measured numbers (only the spasticity angle), nor can I see the patient's motivation.

Date: 1st of December 2022

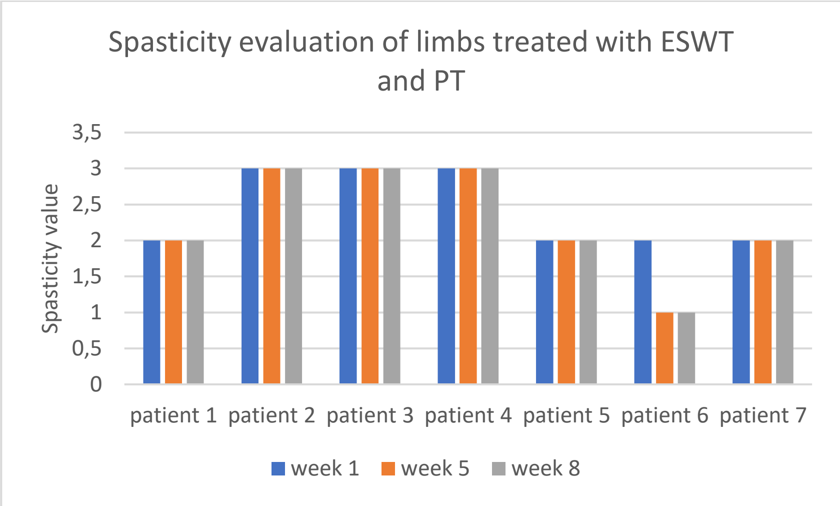
	Right leg	Left leg
VAS	0	0
Spasticity grade (hamstrings)	2	2
AROM (knee extension)	-6°	-4°
PROM (knee extension)	-4°	-2°
Spasticity angle	- 95°	-110°

Any side effects: none

Evaluation: Any significant subjective or objective changes have been reported. This patient did not cooperate very actively during treatment.

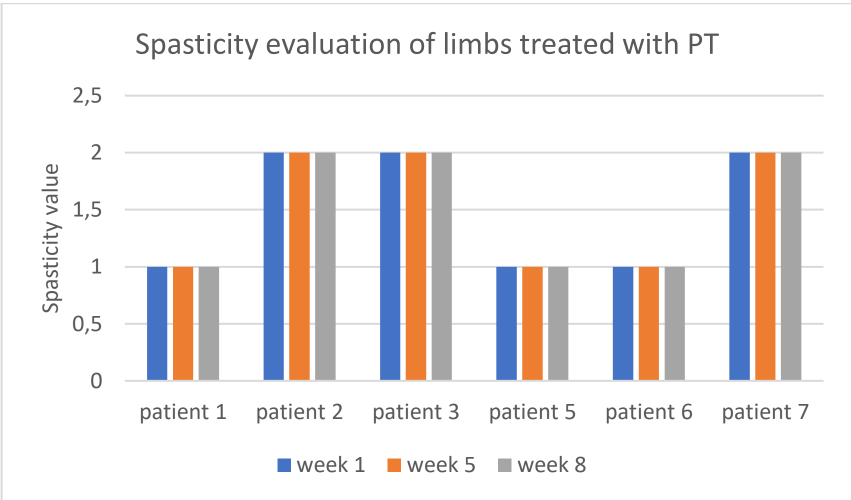
Summary

Spasticity evaluation



Graph n. 1 - Spasticity evaluation (ESWT and PT)

Unfortunately, I have not noticed a great tendency to reduce the spasticity value according to the MTS after ESWT and PT (physiotherapy). Only one patient showed a decrease in value due to the disappearance of catch. The average value of spasticity was 2.43 and decreased to 2.29 in week 5 and 8.

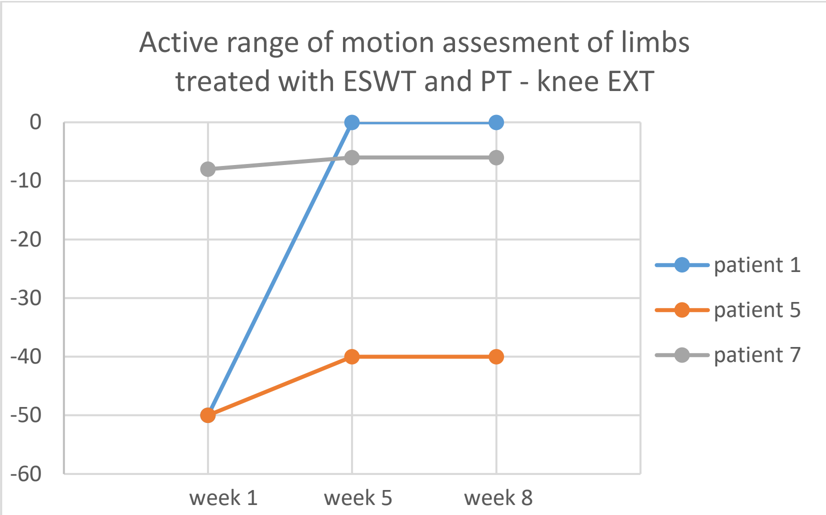


Graph n. 2 - Spasticity evaluation (PT)

In the case of limbs treated just with physiotherapy, I did not see any tendency to reduce spasticity according to the MTS at all. The average spasticity value remained 1.5 throughout.

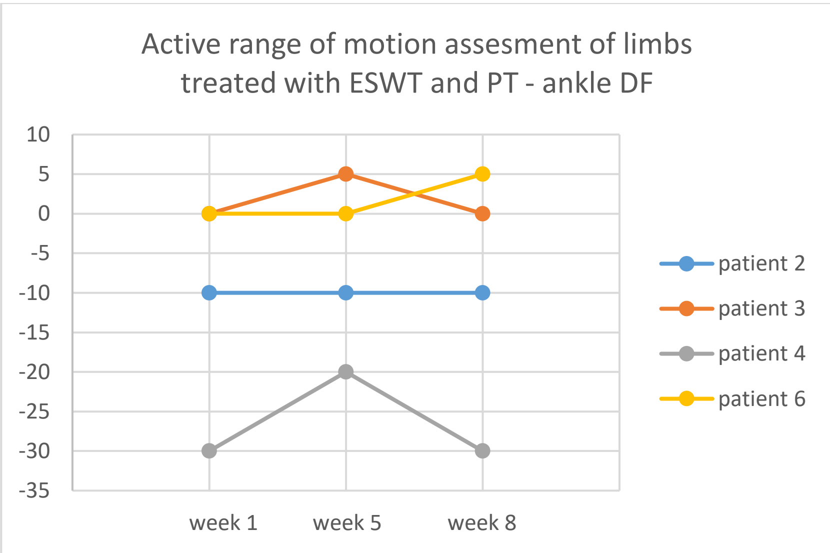
The y-axis of the following graphs (up to the end of the chapter) shows the range of motion values.

Active range of motion



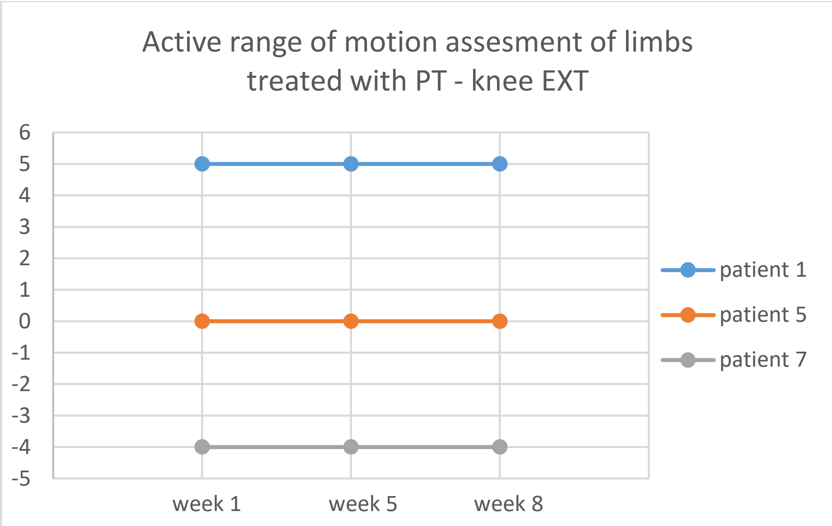
Graph n. 3 - Active ROM assessment, knee EXT, (ESWT and PT)

All patients who received shockwave treatment to the hamstrings experienced an increase in the active range of motion (knee extension) after one month of therapy. This change persisted until the control in the eighth week. On average, the range of motion improved by 20.7° in week 5 in comparison with initial examination and the improvement remained by the same value until the week 8.



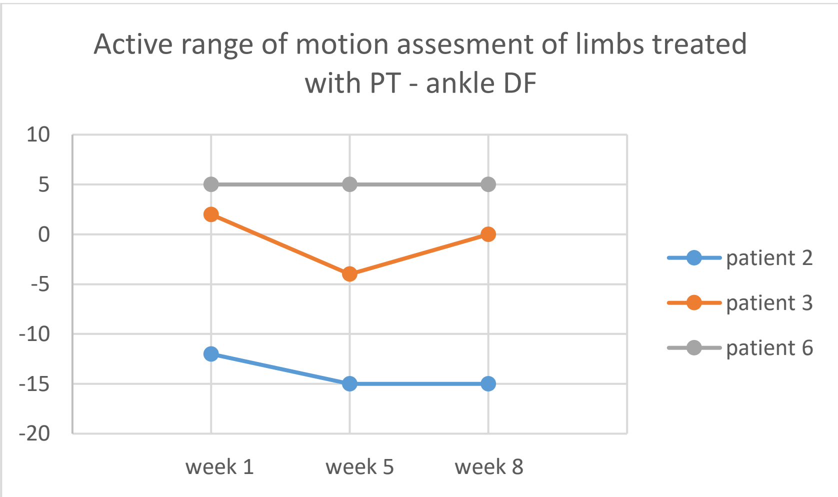
Graph n. 4 - Active ROM assessment, ankle DF, (ESWT and PT)

However, after application of ESWT to the calf musculature, the patients had diverse reactions, and no conclusion can be drawn from this. On average, the range of motion improved by 3.75° in week 5 and by 1.25° in week 8 in comparison with the initial assessment.



Graph n. 5 - Active ROM, knee EXT, (PT)

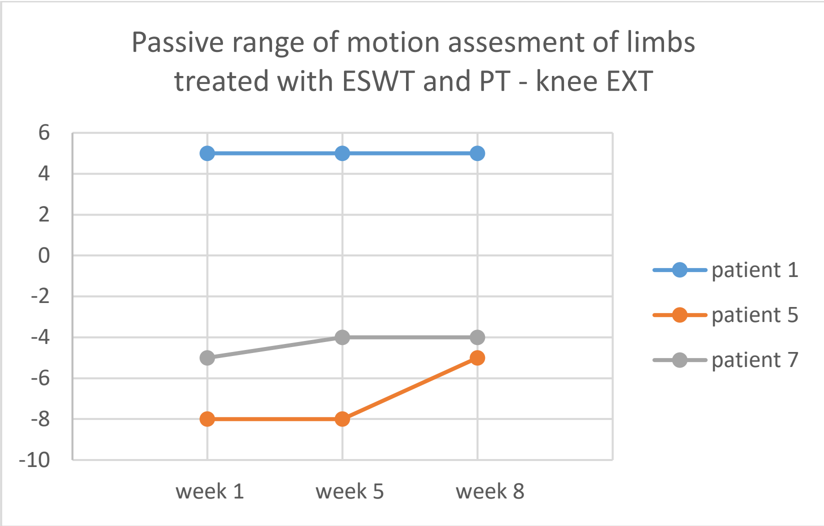
The values of active knee extension for the limbs to which the shock wave was not applied remained the same throughout. However, it is important to mention that the initial values were physiological in two patients.



Graph n. 6 - Active ROM, ankle DF, (PT)

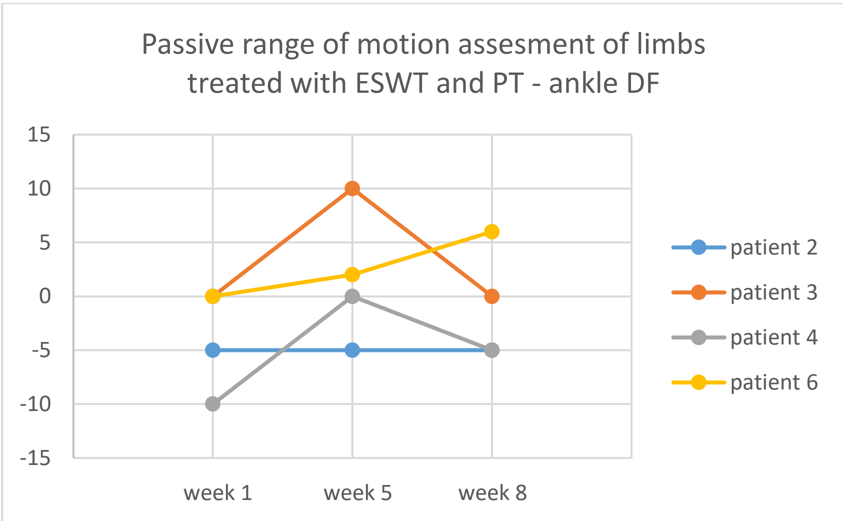
In case of active dorsiflexion in the ankle, I have observed a different response in each patient when they did not undergo the shock wave treatment. The graph also shows a slight worsening of the range of motion. On average, the range of motion worsened by 1° in week 5 and improved by 1.6° in week 8 in comparison with week 1.

Passive range of motion



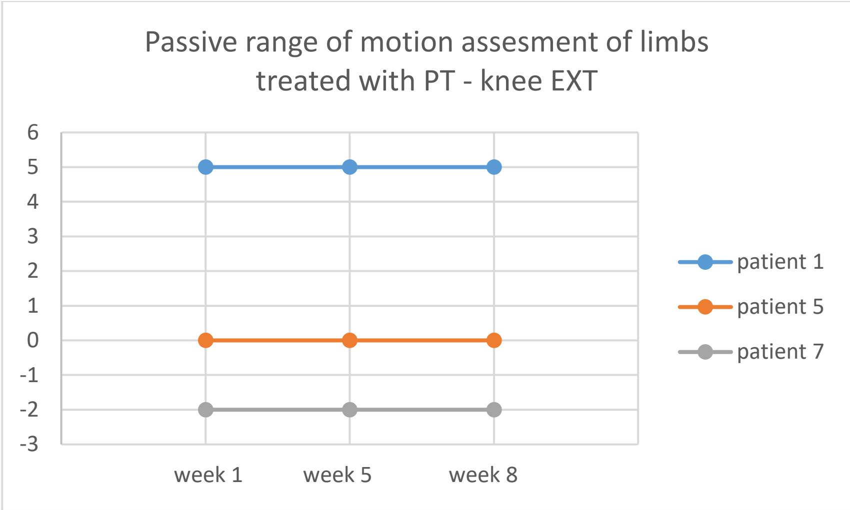
Graph n. 7 - Passive ROM, knee EXT, (ESWT and PT)

After application of the shock wave in combination with physiotherapy on the hamstrings, we can see (Graph 7) a slight tendency to increase the passive range of knee extension. On average, the range of motion improved by 0.3° in week 5 and by 1.3° in week 8 in comparison with the initial examination.



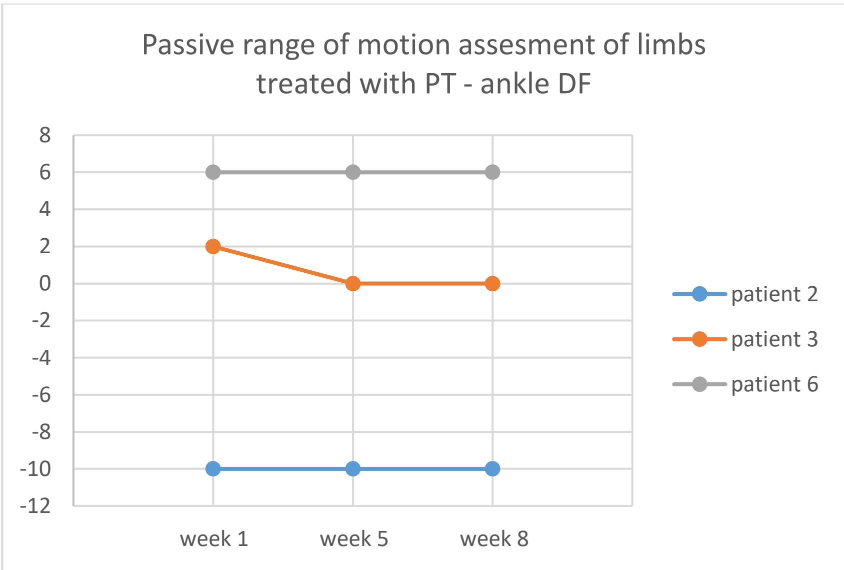
Graph n. 8 - Passive ROM, ankle DF, (ESWT and PT)

Changes in passive dorsal flexion after treatment of the calf muscles with shock wave and physiotherapy are different in each patient. On average, the range of motion improved by 5.5° one week after the therapy program and by 2.75° one month after the last therapy.



Graph n. 9 - Passive ROM, knee EXT, (PT)

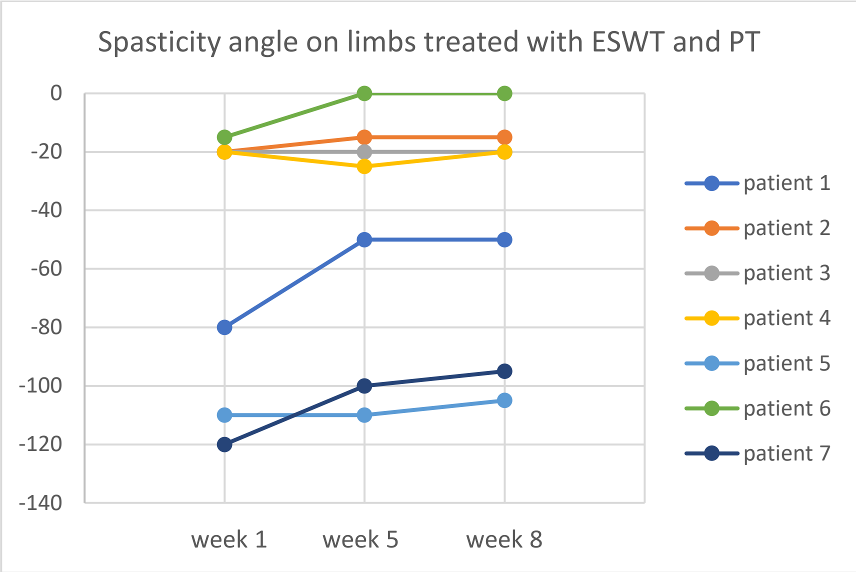
Here (in Graph 9) we have a similar situation as in Graph 5. Values of passive knee extension did not change and in two of three participants the numbers were physiological.



Graph n. 10 - Passive ROM, ankle DF, (PT)

This graph (Graph 10) does not show any positive effect of physiotherapy on passive range of ankle dorsiflexion. On average, the range of motion worsened by 0.7° in week 5 in comparison with week 1. The worsened average value persisted to week 8.

Spasticity angle



Graph n. 11 - The spasticity angle on the limbs treated with ESWT and PT

According to the graph, we can see that the spasticity angle tends to decrease or remain the same between the first and the last measurement. On average, the angle improved by 9° in week 5 and by 11.4° in week 8 in comparison with the initial examination.

In lower limbs that were treated with physiotherapy only, the spasticity angle is unnecessary to show in graph. Spasticity values were often in the range of 1, where no catch could be recorded.

Table 1 - ESWT and PT - changes of measured average values over time

	Between week 1 and week 5	Between week 1 and week 8
Spasticity grade	0,14	0,14
Spasticity angle	9°	11.4°
Active ROM, knee EXT	20.7°	20.7°
Active ROM, ankle DF	3.75°	1.25°
Passive ROM, knee EXT	0.3°	1.3°
Passive ROM, ankle DF	5.5°	2.75°

Table 2 - Only PT - changes of measured average values over times

	Between week 1 and week 5	Between week 1 and week 8
Spasticity grade	0	0
Spasticity angle	---	---
Active ROM, knee EXT	0°	0°
Active ROM, ankle DF	-1°	1.6°
Passive ROM, knee EXT	0°	0°
Passive ROM, ankle DF	-0.7°	-0.7°

Research questions:

The lack of participants in my study has a large impact on the significance of the results. It was not possible to process the data statistically, so I resorted to graphs, from which I tried to read the trend of the measured values.

1. *Does focused shock wave therapy combined with physiotherapy influence the spasticity of the lower limbs compared to the use of physiotherapy without shock wave application?*

   From the graphs, we can see that ESWT and physiotherapy, as well as physiotherapy itself, had no significant effect on the reduction of the spasticity value within weeks. However, from the average values (even from the graphs) we might notice, the combination of ESWT and PT had at least some influence on spasticity in comparison with PT alone.

   The spasticity angle has successfully decreased in almost all participants after ESWT and physiotherapy.

2. *Does focused shock wave therapy combined with physiotherapy influence active range of motion compared to the use of physiotherapy without shock wave application?*

   Only the values of active knee extension after ESWT and physiotherapy show some visible improvement in each patient (on average 20.7° in weeks 5 and 8). In cases of active dorsiflexion after ESWT and PT, the difference was negligible. The values after PT without ESWT slightly worsened (negligibly) or did not change at all.

3. *Does focused shock wave therapy combined with physiotherapy influence passive range of motion compared to the use of physiotherapy without shock wave application?*

The limbs treated with the combination of ESWT and PT slightly improved in passive knee extension and ankle dorsiflexion. The improvement was more significant in the case of ankle dorsiflexion. The values after PT without ESWT slightly worsened or did not change.

6 DISCUSSION

In my thesis it was not possible to evaluate the data statistically, and therefore I used graphs to follow the changes in each patient's outcomes, and I calculated the average changes in the observed values. Unfortunately, unlike promising studies and meta-analyses, according to my work, shockwave does not have a significant effect on spasticity assessed by spasticity grade. Nevertheless, I observed slight changes in the spasticity angle and range of motion after the combination of ESWT and PT. Also, most patients had subjectively positive feelings about the treatment. Specifically, five of the seven participants felt better or made some functional progress after the programme. Only two people did not experience any change. Patients who had fewer muscle groups affected by spasticity (e.g., calves only or thighs only) responded better to treatment. Participants with significant spasticity in more muscle groups did not experience any positive changes after treatment. The effect of the shock wave on cramps and tenderness in the shins and feet are worth mentioning. It may happen thanks to the influence of the shock wave on the peripheral nerves, which is described in great detail, for example, in the book *ESWT in Neurology* by Tomáš Nedělka and Karsten Knobloch.

In my investigation, a total of 7 patients were involved. According to the original proposed methodology, I planned to recruit at least 20 participants for the results to have any meaningful value, which unfortunately did not happen. The lack of people was due to several factors. From my point of view, I decided on a narrowly specified category of patients who could enrol in the study. From the patients' point of view, the most frequent issues were the inability to commute, the excessive frequency of clinic visits, and the need to maintain this frequency. Another obstacle was that many candidates had already had botulinum toxin injected into the area they wanted to affect with the shockwave.

Purely hypothetically, based on these findings, the concept of hospitalisation in a rehabilitation institute where the patient would be accommodated and undergo intensive rehabilitation and the application of shock waves could prove useful.

I originally intended to divide the patients into two groups, one would undergo physiotherapy only, and the other would undergo both physiotherapy and ESWT. I included physiotherapy along with the ESWT application, because I am convinced that physical methods are only a supplement to complex treatment and should be supported by physiotherapy in order to achieve the desired effect and avoid undesirable effects (for example, weak paresis). There are several authors who have investigated the effect of combining physiotherapy and shockwave therapy, while the control group received only physiotherapy. For example: AbdelGawad et al. (2015), Duan et al. (2016), El-Shamy et al. (2014), Tirbisch et al. (2015), Wang et al. (2016), etc.

However, as I already mentioned, I could enrol into my study just a very few participants, so it was not possible to separate them into two groups. The problem is that the absence of a control group would significantly reduce the quality of my work. Therefore, I created a new methodology. Since I treated only one lower limb of the patient with ESWT, I could use the other limb as a control, because almost all my patients have spastic both legs. Although I tried to resolve the situation and form a control group in the best possible way, these complications reduced the validity of my work. This decision may also be the subject of many discussions. My expectation based on the infinite number of sources was that compared to PT alone, the combination of ESWT and PT would be significantly more effective. With this in mind, I applied ESWT to the limb that appeared worse during the examination to avoid significant differences between the patient's limbs and achieve the best possible leg function. The disadvantage is that a number of studies (even those that did not focus on spasticity) have shown that shock waves do not necessarily have only a local effect. For example, Lohse-Busch, in the source *"A pilot investigation into the effects of extracorporeal shock waves on muscular dysfunction in children with spastic movement disorders,"* mentioned the visible differences on the untreated side. The question remains: what is the real correlation between the changes on the untreated side of the body and the application of the shock wave?

Designing a methodology was not an easy task, as there is only one published study that examined the effect of shock waves on spasticity in patients with multiple sclerosis. Marinelli et al. published the study *"Effect of radial shock wave therapy on pain and muscle hypertonia: a double-blind study in patients with multiple sclerosis"* in 2015. However, they used radial ESWT. I decided to use the focused ESWT because it has the ability to reach greater depths. Also, I have been inspired by the meta-analyses of Cabanas-Valdés in 2020 *("The effectiveness of extracorporeal shock wave therapy to reduce lower limb spasticity in stroke patients: a systematic review and meta-analysis"* and *"The effectiveness of extracorporeal shock wave therapy for improving upper limb spasticity and functionality in stroke patients: a systematic review and meta-analysis").* He found out from the collected studies that the focused shock wave was applied more often to the lower limbs, whereas the radial shock wave was applied to the upper limbs.

There is a lot of heterogeneity in the parameters of the pulse application. In selecting the parameters for my study, I have followed Marinelli's study in MS patients and Cabanas-Valdés' meta-analysis focused on the lower limbs, although the sources included research conducted on post-stroke patients. The most difficult part was determining energy flux density because, in the meta-analysis, there is a wide range of values (from 0.03 to 0.340 mJ/mm^2). Most often, the value of 0.10 mJ/mm^2 was used. After discussion with my thesis supervisor, we agreed on 0.07 mJ/mm^2. The frequency was ranging from 2 to 10 Hz (usually

4 or 5 Hz), so I chose a value of 6 Hz, which is roughly in the middle. The number of administered pulses was 1500 or 2000, from which I chose the higher number in view of a possible greater chance of success. The frequency of the sessions was in all cases 1 per week, usually for 3 weeks. I was wondering to create a one-month therapy programme, so I designed 4 sessions (like Marinelli et al. with radial ESWT) of fESWT followed by individual physiotherapy. I also came up with individual home exercises for each patient to enhance the effect of my therapy. As far as the choice of physiotherapy concept is concerned, there is no direction that is considered by the evidence to be demonstrably effective. Therefore, I decided to base my rehabilitation approach on my experience and the experience of my colleagues who were willing to consult with me about it. I used elements of the Jean-Michael Gracies' method as well as balance, mobility, and strengthening exercises depending on the patient's weaknesses and goals. In one case, I also did kinesiotaping of the ankle at the patient's request due to her weak paresis for a greater feeling of security while walking.

In terms of painfulness, six out of seven patients found shock wave treatment to be painless. One of them considered the application to be painful, even on the muscle belly (hamstring muscles). Nevertheless, with every other therapy, the pain got better and better, and the last application was not painful at all. It is important to mention that this patient had a significant atrophy of the lower limb muscles in general. I haven't noticed any other side effects. In Cabanas-Valdés meta-analysis, three trials noted minor side effects after application of the ESWT, such as lower limb muscular discomfort and mild pain, which resolved quickly. In a meta-analysis by Guo in 2017, "*Positive Effects of Extracorporeal Shock Wave Therapy on Spasticity in Poststroke Patients: A Meta-Analysis,"* one included study reported post-therapy pain. Also, authors of the study "*Spasticity and Electrophysiologic Changes after Extracorporeal Shock Wave Therapy on Gastrocnemius"* (Sohn et al., 2011) have noticed that in a few instances, patients complained of pain while undergoing treatment, but it was not severe (VAS 3), and usually it disappeared afterwards. Overall, the level of pain experienced during SWT for spasticity treatment depends on several factors, including the individual's pain threshold, the specific condition being treated, and the treatment protocol used by the healthcare provider. In general, the pain during the treatment itself or afterwards has occurred rarely so far. As well as the adverse effects. In my thesis, I have not reported any, but for example, in a meta-analysis of *"Extracorporeal Shock Wave Therapy on Spasticity After Upper Motor Neuron Injury"* (Zhang et al., 2022), 5 of 15 studies found mildly unfavourable consequences like skin damage, numbness, discomfort, petechiae, and weakness in the muscles.

In my thesis, I evaluated the spasticity grade, spasticity angle, passive and active range of motion. For the spasticity assessment, I used the Modified Tardieu Scale for the evaluation of the muscle response on the fast stretch. In my collected sources, I noticed that almost every author uses the Modified Ashworth Scale. Nevertheless, in several articles, the validity of this scale is questioned, for example, in *"Shock Waves as a Treatment Modality for Spasticity Reduction and Recovery Improvement in Post-Stroke Adults – Current Evidence and Qualitative Systematic Review,"* published by Dymarek et al. in 2020, and many others. Studies have also been published observing the success of TS and MAS in evaluation. For instance, in *"Evaluation of Spasticity in Children With Cerebral Palsy Using Ashworth and Tardieu Scales Compared With Laboratory Measures"* by Alhusaini et al. (2010), the TS showed a greater percentage of accurate agreement with the laboratory spasticity examination than the MAS. In *"Reliability of the Modified Tardieu Scale and the Modified Ashworth Scale in adult patients with severe brain injury: a comparison study,"* Mehrholz et al. claim that MTS might be a more reliable adult spasticity scale than MAS because MTS has stronger test-retest and inter-rater reliability in individuals with severe brain injuries and decreased consciousness. Based on these findings, I've chosen MTS. Unfortunately, this may be one of the reasons why my results differ from those of other authors. This speculation is supported by a 2016 study, *"Sonographic and clinical effects of botulinum toxin type A combined with extracorporeal shock wave therapy on spastic muscles of children with cerebral palsy,"* by Picelli et al. They used the MAS and Tardieu scales for the spasticity evaluation of their patients. In the MAS scores, there was a significant reduction, but in the TSG and TSA scores, no significant difference between groups was observed.

I measured the spasticity angles and the ranges of motion with a goniometer. This may have had a negative impact on my results, as measurement by one therapist without assistance can be quite inaccurate. Recently, I've noticed a trend of using mobile apps to measure range of motion and wondered if it would be more beneficial to replace the goniometer with a more modern technology. And it could also be motivating for the patient. When we search the literature, we might find several research studies about this innovation. In *"Comparison of ankle joint range of motion measurements using a smartphone application and goniometer,"* Cho et al. (2015) claim, a smartphone app can accurately and validly quantify the range of motion of the ankle joint. Handford et al. (2016), in *"A comparison of smartphone and goniometric measurements of shoulder range of motion,"* discovered that a smartphone app was more practical and equally reliable than goniometry for evaluating shoulder range of motion. And according to Sijobert et al. (2019), an inertial measurement device for measuring knee flexion angle was more practical to use and just as reliable as a goniometer *("A comparison of goniometer and inertial measurement unit for measuring knee flexion angle").*

I had originally planned to include the 10MWT to the examination, (just like Marinelli et al. did), but not all the participants could undergo this test due to their inability to walk. In retrospect, I consider it a deficiency of the thesis that not a single functional test was used. After some reflection, I've come to the conclusion that it would be ideal to establish some observable functional baselines for each patient to compare. For instance, in one patient, I noticed that after five weeks, she was finally able to squat. The other patient was able to stand up from the table without use of wall bars after eight weeks with minimal assistance from me. Thus, establishing some baseline could be beneficial for the patient, the therapist, and the research.

The fact that I conducted the examination and even the therapy does not improve the work's quality. Ideally, the evaluation should be carried out by another person, e.g., a doctor, as there is a risk of skewing the results.

Most studies are done on chronic stroke patients. There are also a few studies on cerebral palsy, but only one on multiple sclerosis patients. Therefore, it was a challenge to focus treatment on multiple sclerosis, as I was unsure whether the parameters proven in post-stroke conditions would be effective for this diagnosis. However, since this area is unexplored, it motivated me to create this thesis with the belief that it could benefit my field. In multiple sclerosis, and therefore in research, the unpredictable course of the disease can be an obstacle. Unlike the relatively stable chronic condition after a stroke, the picture of MS can change out of the blue. This may be due to an attack, but also to minor external and internal aspects. Another obstacle is the significant heterogeneity of patients. It is well known that every patient is different, and this is "doubly true" in multiple sclerosis. Although criteria are established to select only a narrow group of people, symptoms and reactions of the body vary from person to person.

7 CONCLUSION

The aim of my study was to investigate the influence of the combination of ESWT and physiotherapy on spasticity and range of motion. The study is unique in that it was carried out on patients with multiple sclerosis. To date, only one article has been published on this topic for this diagnosis. Otherwise, the research has been conducted in a chronic condition following stroke. Despite my efforts, due to the complications that occurred, the validity of the outcomes is lower than I would have liked. Without statistical tests, it is difficult to respond to the research questions I posed. Nevertheless, I was still able to identify some trends in the observed values. According to my study, the combination of ESWT and physiotherapy had a positive influence on spasticity and range of motion compared to physiotherapy without shock wave. According to the scale assessing spasticity, there was no significant change, but more interesting was the difference in measured values of the spasticity angle. It should also be mentioned that there have been positive subjective changes that I have not observed objectively. And these results may be more important to the patient and the therapist than the values on the spasticity scale. The limitations of my study, which have previously been covered in the debate, could be the reason why the findings differ slightly from those of earlier research. These are: the lack of participants; the use of a Modified Tardieu scale (mostly MAS is used in the literature); the lack of homogeneity of patients; the absence of functional tests in the examination, the second patients' limbs used as a control group. This thesis could serve as inspiration for the possibility of spasticity treatment when botulinum toxin is not used. When conducting any other research, it is also possible to avoid the mistakes of this study.

8 ABBREVIATIONS

10MWT - 10 metre walk test

6MWT – 6-minutes walk test

AROM – active range of motion

AS – Ashworth Scale

BTX-A – botulinum toxin

CfDD – centres for demyelinating diseases

CP – cerebral palsy

DF - dorsiflexion

DGI - Dynamic Gait Index

ES – electrical stimulation

ESWT – extracorporeal shockwave therapy

EXT - extension

fESWT – focused extracorporeal shockwave therapy

GABA – gamma-aminobutyric acid

MAS - Modified Ashworth Scale

MS – multiple sclerosis

MTS – Modified Tardieu Scale

NO – nitric oxide

PROM – passive range of motion

PT - physiotherapy

rESWT - extracorporeal shockwave therapy

ROM – range of motion

TS – Tardieu Scale

TSA – the spasticity angle

TSG – the spasticity grade

TUG – Time Up and Go

VAS – Visual Analog Scale

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10 LIST OF USED GRAPHS AND TABLES