Very Low and Low – energetic Extracorporeal Shock Wave Treatment of Spasticity in Children and Adults – A Systematic Review

Article · June 2022

DOI: 10.13107/jrs.2022.v02.i01.027

Very Low and Low-energetic Extracorporeal Shock Wave Treatment of Spasticity in Children and Adults - A Systematic Review

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Abstract

Introduction: This systemic review aims to assess the modes and treatment parameters of radial and focused extracorporeal shockwave therapy (ESWT) in spasticity based on the technologies and energy levels involved.

Materials and Methods: 1086 patients from 31 randomized-controlled trials (RCT) or cohort studies are included. 300 children were studied in seven studies (3 RCTs) with two radial and four focused electromagnetic ESWT devices and 14 studies with 443 patients using focused ESWT (electrohydraulic 46 patients, electromagnetic 367 patients, and piezoelectric 30 patients).

Results: In electromagnetic focused ESWT 8 RCTs (n = 323 patients) and three cohort studies (n = 44) used either very low-energetic (0.03–0.05 mJ/mm2) with 1500–2000 shots and 4–5 Hz with 3–5 focused sessions, or low-energetic 0.07–0.12 mJ/mm2 with 1500–2000 shots with 4–5 Hz and 1–3 sessions. The 64 children in the five electromagnetic focused trials were treated with very low-energetic 0.03 mJ/mm2, 1500 shots, and three sessions. 17 studies (n = 687) were using radial technologies with 7 RCTs (n = 349) and ten cohort studies (n = 338). Among the 17 trials, four studies (1 RCT, 3 cohort studies) included 236 children treated with either very low-energetic 0.6–1 bar (two trials) or low-energetic 1.5–3 bar with 5–10 Hz. Energy-wise three radial studies were very low-energetic 0.6–1 bar and 14 studies applied low-energetic radial pressures 1.5–3 bar. Notably, the frequency was mainly 4–8 Hz in the radial studies.

Conclusion: Both, radial and focused very low- to low-energetic ESWT improve function and reduce spasticity significantly. Adverse effects were not noted with the applied very low- to low-energetic device parameters neither among children nor in adults.

Keywords: Spasticity, Extracorporeal shock wave therapy, Extracorporeal shockwave therapy, Children

Introduction

Extracorporeal shock wave therapy (ESWT) has evolved in various clinical disciplines since its first clinical application for urological kidney stone destruction on February 7, 1980, at Munich University Hospital. The impetus for the treatment of spastic symptoms with ESWT was given in 1994 by positive clinical observations during the treatment of painful osteoarthritis of the knee. Already during the ESWT session, the painful muscular flexion contracture of the osteoarthritic knee joints decreased because of the greatly increased viscoelasticity and tonicity of the muscles. Muscles are subject to reciprocal antagonist inhibition and consequent contracture formation in pain paralysis as well as spastic paresis. Therefore, it was obvious to apply ESWT also for spastic contractures. In neurology, shock wave therapy was used clinically from 1996 in children with cerebral palsy with very low energy levels of 0.01–0.024 mJ/mm2 with an electromagnetic focused device. As a result, Lohse-Busch et al. highlighted the positive clinical effects of very low and low energetic ESWT in a variety of neurological conditions in a series of clinical papers [1, 2, 3, 4].

Since the early 1990 experience in spasticity, a number of different shockwave technologies with substantial physical differences have evolved. Different focused shockwave technologies have been established based on the shockwave generator in electromagnetic, electrohydraulic and piezoelectric devices. Radial shockwaves started in 1998, on the other hand, apply ballistic pressure waves similar to an air gun. As far as both, radial and focused ESWT in spasticity are concerned within the past 5 years a number of meta-analysis have mainly focused on the outcome of the Modified Ashworth Scale (MAS) [5, 6, 7, 8, 9] with very narrow inclusion criteria. In addition, the methodological quality of the

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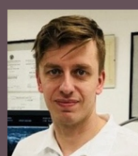
Dr. Tomas Nedelka

Submitted Date: 12 Jan 2022, Review Date: 17 Jan 2022, Accepted Date: 4 Feb 2022 & Published: 31 July 2022

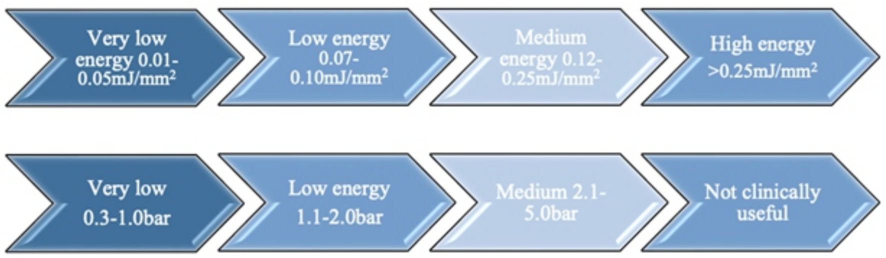

Figure 1: Energy-levels from very low (0.01–0.05 mJ/mm2 corresponding to 0.3–1.0 bar), low (0.07–0.1 mJ/mm2 corresponding to 1.1–2.0 bar), medium (0.12–0.25 mJ/mm2 corresponding to 2.1–5.0 bar), and high-energetic (>0.25 mJ/mm2).

aforementioned meta-analysis is rated in between critically low and moderate [10]. Furthermore, the physical and clinical differences in the various radial and focused shockwave technologies with special emphasis on the treatment parameters in children [11] and adults have not been addressed thoroughly, though.

Energy levels in ESWT

Energy flux density can be differentiated in low energetic (<0.1 mJ/mm2), medium energetic (0.12–0.25 mJ/mm2), and high-energetic (>0.25 mJ/mm2). We herein propose to add an additional category named "very low-energetic." Very low-energetic are energy flux densities 0.01–0.05 mJ/mm2, corresponding to 0.3–1.0 bar with radial techniques (Fig. 1).

Clinical successful shockwave therapy is based on proper application. As such, the energy flux densities in focused devices and the treatment pressure in radial devices, respectively, might play a role in treating and ameliorating spasticity as well as other main parameters - the number of shots applied, the frequency (measured in Hertz) used, as well as the number of ESWT sessions. Furthermore, ESWT in children with cerebral palsy might be different to the regimen in adults, respectively.

Both technologies have been applied in controlled studies over the past two decades. However, as of now a number of issues of ESWT in spasticity are open:

- Is it safe to apply radial or focused ESWT in children with spasticity?
- What are the common treatment parameters in radial ESWT as far as a number of sessions, treatment pressure (bar), frequency (Hz), and number of shots are concerned in adults and in children?
- What are the common treatment parameters in focused ESWT based on the generator, speaking electrohydraulic, electromagnetic, or piezoelectric as far as number of sessions, energy flux density (EFD mJ/mm2), frequency (Hz), and number of shots are concerned in adults and in children?

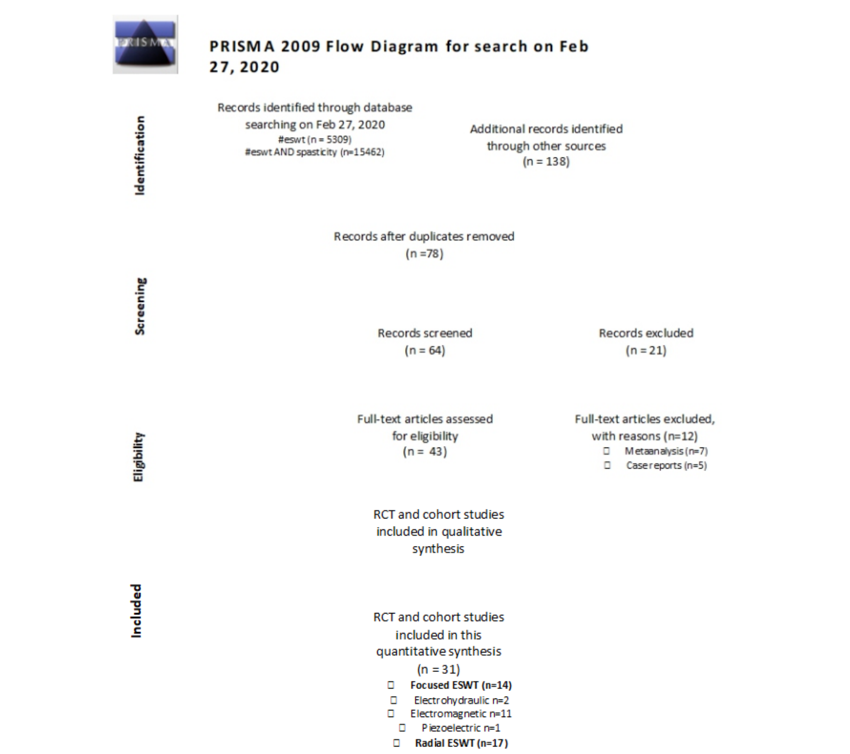

Figure 2: PRISMA flow chart.

Objective of this study

Therefore, this evidence-based systematic review examines all available published studies on using ESWT with either radial or focused technology in muscular spasticity in both, children and adults in a standardized and systematic way. We sought to elucidate successful treatment parameters for all age groups studied depending on the shockwave technology used in this regard.

Materials and Methods

The inclusion criteria, the search strategy as well as the collection and analysis of the data, were based on a protocol for this systematic review. We opted for the systematic review and against a classical meta-analysis of only randomized controlled trials (RCTs) due to the variety of shock wave technologies (radial and focused, focused: Electromagnetic, electrohydraulic, and piezoelectric generators), treatment parameters (energy flux densities, number of shots, frequency, and number of sessions), and patients (children and adults with different genesis of spasticity, localization of spasticity, etc.). Thus, this systematic review covers all previously published extracorporeal shock wave studies in spasticity among all age groups in an evidence-based way.

Search strategy

This systematic review includes 1086 patients from 31 RCTs or cohort studies according to the PRISMA statement assessed on February 27, 2020, in MEDLINE, EMBASE, Web of Science, and SCOPUS. In addition, for all results considered relevant, the reference lists of the included publications were probed manually for further potential studies. The following keywords have been reviewed (sample information for PubMed):

- ESWT: #5309 hits
- ESWT AND spasticity: #15462 hits.

The PRISMA flow chart is highlighted in Fig.

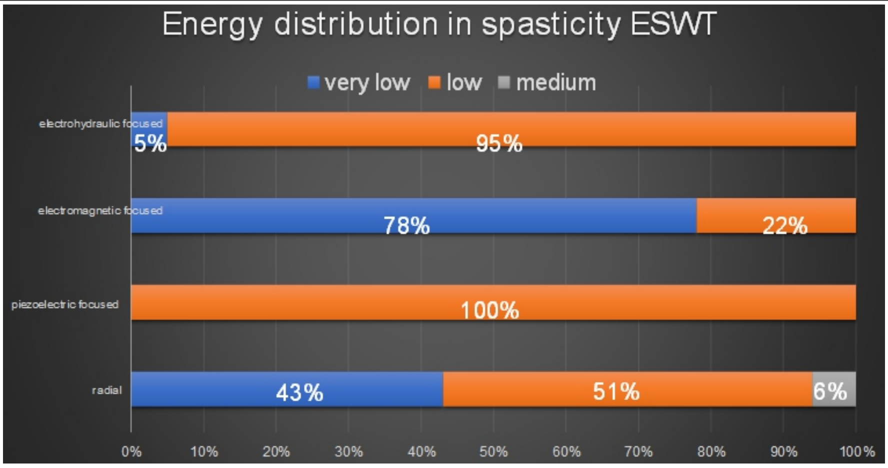

Figure 3: Energy distribution of focused electrohydraulic, focused electromagnetic, focused piezoelectric, and radial extracorporeal shockwave therapy in terms of very low energetic (0.01–0.05 mJ/mm2, 0.3–1.0 bar), low energetic (0.07–0.1 mJ/mm2, 1.1–2.0 bar), or medium energetic (0.12–0.25 mJ/mm2, 2.1–5 bar) among the spasticity studies included in this systematic review.

2.
All abstracts were assessed for relevance and the full-text analysis was correspondingly included for the relevant articles. The inclusion of all relevant studies (RCTs and cohort studies) was independently decided by two reviewers. Meta-analysis or case reports were not included in this systematic review. In addition to the respective level of evidence, the patient characteristics as well as different shock wave parameters were analyzed in detail. Data extraction was based on the full text using predefined data extraction form. Any disagreement unresolved by discussion was reviewed by a third author in this trial.

Results
Overall, 31 Evidence-based clinical studies with 1086 patients as either RCTs or cohort studies were included in this systematic review (Tables 1-3).

Focused ESWT
14 studies with 399 patients are included in this systematic review using focused ESWT. Based on the different generators in focused technologies, the distribution is as follows (Fig. 3):
•Electrohydraulic ESWT
otwo cohort studies with 46 adult patients treated on the gastrocnemius muscle belly, no RCTs on electrohydraulic focused ESWT available
oEnergy flux density was 0.1 mJ/mm2, so low-energetic electrohydraulic focused ESWT with one session only with either 1500 shots on the gastrocnemius belly
oNo children were treated with electrohydraulic focused ESWT.
•Electromagnetic ESWT
oEight RCTs with a total of 323 patients, 52 of them in four RCTs were children and three cohort studies with 44 patients (12 children in one cohort study), so in total 64 children treated with electromagnetic focused ESWT. The 64 children in the five trials were treated with very low-energetic 0.03 mJ/mm2, 1500 shots and 3 sessions.
oEnergy-wise 6 trials were using very low-energetic 0.03–0.05 mJ/mm2 with 1500–2000 shots and 4–5 Hz and at mean 3–5 focused sessions, 5 trials were using low-energetic 0.07–0.12 mJ/mm2 with 1500–2000 shots with 4–5 Hz and 1–3 sessions.
• Piezoelectric ESWT: One cohort study on plantar flexors in 30 adults with low-energetic 0.089 mJ/mm2. No children were treated with piezoelectric focused ESWT.

Radial ESWT
17 studies with a total number of 687 patients are included using radial technologies. From an evidence-based point of view there are 7 RCTs with 349 patients and ten cohort studies with 338 patients. Among the 17 trials, four studies (1 RCT, 3 cohort studies) included 236 children treated with either very low-energetic 0.6–1 bar (two trials) or low-energetic 1.5–3 bar in the two other trials with 5–10 Hz. Energy-wise three radial studies were very low-energetic 0.6–1 bar and 14 studies applied low-energetic radial pressures 1.5–3 bar. Notably, the frequency was mainly 4–8 Hz in the radial studies.

Localization of focused/radial ESWT
The majority of the included radial and focused trials treated the gastrocnemius muscle complex. Using focused ESWT, both electrohydraulic trials, six out of the eleven electromagnetic trials and the piezoelectric trial were performed on the gastrocnemius and soleus muscle. In radial technique, five studies focused the gastrocnemius muscle. The forearm flexors were treated in three electromagnetic focused studies and in five radial studies.

Duration of the shockwave effect
Amalio first reported in 2004 on the IFSSH Hand Congress 2004 [43] in Budapest and then in 2005 as a full paper [27] on the

Table 1: Electromagnetic focused or radial extracorporeal shock wave therapy in children with spasticity

Author	Study type	Age (years)	*n*	Generator	Energy level
Park *et al*. 2015 [12]	RCT 1:1	7±3	12	Electromagnetic focused ESWT	Very low-energetic (0.03 mJ/mm^2)
El-Shamy *et al*. 2014 [13]	RCT 1:1	6–8	30	Electromagnetic focused ESWT	Very low-energetic (0.03 mJ/mm^2)
Picelli *et al*. 2017 [14]	RCT 1:1	3–14	10	Electromagnetic focused ESWT	Very low-energetic (0.03 mJ/mm^2)
Amelio and Manganotti 2010 [15]	Cohort	8±2	12	Electromagnetic focused ESWT	Very low-energetic (0.03 mJ/mm^2)
Lin *et al*. 2018 [16]	RCT 1:1	7.8±1.3	82	Radial	Low-energetic (2 bar, 10 Hz)
Wang *et al*. 2016 [17]	Cohort	1–6	66	Radial	Very low-energetic (0.6 bar, 8 Hz)
Mirea *et al*. 2014 [18]	Cohort	8±4	63	Radial	Low-energetic (3 bar, 10 Hz)
Gonkova *et al*. 2013 [19]	Cohort	4.8±3	25	Radial	Low-energetic (1.5 bar, 5 Hz)

ESWT: Extracorporeal shock wave therapy, RCT: Randomized-controlled trial

Table 2: Focused extracorporeal shock wave therapy in adults with electrohydraulic, electromagnetic or piezoelectric generator depending on level of evidence as well as on very low (0.01–0.05 mJ/mm²) or low (0.07–0.01 mJ/mm²) energetic treatment

Author	Study type	Age (years)	*n*	Location	Generator	Energy level	Energy flux density (mJ/mm²)	Shots	Sessions
Santamato *et al*. 2014 [20]	Cohort	58±11	23	Gastrocnemius	Electrohydraulic	Low energetic	0.1	4500	1×
Sohn *et al*. 2011 [21]	Cohort	45±11	20	Gastrocnemius	Electrohydraulic	Low energetic	0.1	1500	1×
Lee *et al*. 2019 [22]	RCT	30–70	18	Gastrocnemius	Electromagnetic	Low energetic	0.1	2000	1×
Wu *et al*. 2018 [23]	RCT	60±11	42	Gastrocnemius	Electromagnetic	Low energetic	0.12	3000	3×
Taheri *et al*. 2017 [24]	RCT	56±10	28	Gastrocnemius	Electromagnetic	Low energetic	0.1	1500	3×
Yoon *et al*. 2017 [25]	RCT	64±15	151	Elbow flexors and knee flexors	Electromagnetic	Low energetic	0.068–0.093	1500	3×
Santamato *et al*. 2013 [26]	RCT	64±6	32	Forearm flexors	Electromagnetic	Very low energetic	0.03	2000	5×
Manganotti and Amelio 2005 [27]	Cohort	38–76	20	Forearm flexors	Electromagnetic	Very low energetic	0.03	1500+3200	1×
Troncati *et al*. 2013 [28]	Cohort	34–86	12	Forearm flexors and shoulder	Electromagnetic	Low energetic	0.08–0.1	1600+3200	2×
Moon *et al*. 2013 [29]	Cohort	53±15	30	Plantar flexors	Piezoelectric	Low energetic	0.089	1500	3×

RCT: Randomized-controlled trial

kinetics of a one-time focused electromagnetic shock wave therapy session in spasticity. The single focused ESWT session immediately resulted in an improvement of the Ashworth score from 3.2 ± 0.7 to 0.8 with a consistent improvement even after 4 weeks. After 3 months, a significantly improved Ashworth score was still detectable compared to previously.

Side effects of shock wave therapy

In the present studies, no side effects were reported using the ESWT device parameters and technologies as described. This applies to adults as well as to ESWT in children.

Discussion

This systematic review sought to address the current experience of radial and focused ESWT in spasticity among children and adults. The following observations can be delineated from this systemic review:

With more than 1000 patients included in 31 RCTs or cohort studies in this systematic review, there is a profound and substantial level of evidence using both, radial and focused ESWT in spasticity in children as well as in adults. Both radial as well as focused (electrohydraulic, electromagnetic, and piezoelectric) ESWT improve function and significantly reduce spasticity (most often displayed by improved MAS) in adults and in children. As of now, based on all available studies, it is unclear whether one technique is superior to the other due to the lack of large comparative trials as RCTs in the moment.

Very low/low-energetic ESWT

Energy-wise, the majority of spasticity trials applied substantially low energy levels, meaning either very low-energetic (0.01–0.05 mJ/mm2 or <1 bar) or low-energetic (0.07–0.1 mJ/mm2 or 1–2 bar) when using either focused or radial ESWT. Historical-wise, kidney stone resolution as well as bone treatment with ESWT necessitated high-energetic focused shockwaves (>0.25 mJ/mm2). In the landmark Lancet study [44] from 1980 Professor Chaussy reported the course of 21 patients with kidney stones who were treated with high-energetic electrohydraulic focused shockwaves. Recently [45], a RCT compared ultrasound-guided needling versus high-energetic ESWT in calcific tendinitis of the shoulder again applying high energy. In plantar fasciitis a recent meta-analysis [46] of RCTs stated that medium-energy ESWT appears to be more effective than control, however due to limited number of trials for low- and for high-energetic ESWT in plantar fasciitis, this is unclear for the latter energy levels. Therefore, not only the type of

Table 3: Radial extracorporeal shock wave therapy in adults

Author	Study type	Age (years)	*n*	Location	Pressure (bar) and energy level	Frequency (Hz)	Shots	Sessions
Radinmehr *et al*. 2019 [30]	RCT	42–78	32	Plantar	1.0 bar very low	5	2000	1×
Marinelli *et al*. 2015 [31]	RCT	51±12	68	Ankle extensors	1.5 bar low	4	2000	4×
Vidal *et al*. 2011 [32]	RCT	10–46	15	Upper and lower extremity	2.2 bar low	8	2000	3×
Li *et al*. 2016 [33]	RCT	55±3	60	Foream flexors and intrinsics	3.0 bar (intrinsics) and 3.5 bar (FCU/FCR)	5	4000 (intrinsics) +1500 (FCU/FCR)	3×
Wu *et al*. 2018 [34]	RCT radial versus focused	60±11	32	Gastrocnemius	2.0 bar low versus 0.1 mJ/mm² focused low	5	1500 gastroc + 1500 soleus	3×
Dymarek *et al*. 2016 [35]	RCT	Adults	60	Forearm flexors	1.5 bar low	4	1500	1×
Marisa 2019 [36]	Cohort	59±6	30	Gastrocnemius belly	1.5 bar low	Not mentioned	1500	3×
Kim *et al*. 2013 [37]	Cohort	55	57	Subscapularis	1.6 bar low	8	3000	5×
Sawan *et al*. 2017 [38]	Cohort	40–60	40	Gastrocnemius	Not mentioned	Not mentioned	1500	6×
Radinmehr *et al*. 2017 [39]	Cohort	59±13	12	Gastrocnemius	1.0 bar very low	Not mentioned	2000	1×
Kim *et al*. 2015 [40]	Cohort	64±4	10	Plantar	1.7 bar low	4	1500	3×
Dymarek *et al*. 2016 [41]	Cohort	63±12	20	Forearm flexors	1.5 bar low	4	1500	1×
Daliri *et al*. 2015 [42]	Cohort	54±9	15	Forearm flexors	1.5 bar low	Not mentioned	1500	1×

RCT: Randomized-controlled trial, FCU: FCR:

technology (focused or radial, focused electrohydraulic/focused electromagnetic/focused piezoelectric), but also the energy levels applied play a role when treating a given tissue.

In spasticity with ESWT focusing on spastic muscles, a number of mechanisms might be involved. Regarding ESWT effects on muscle, in addition to the described detonating effect of ESWT, further mechanisms of action appear conceivable. A randomized sports medical study on "sore muscles" as delayed onset muscle soreness showed positive effects in terms of reduced pain and improved strength in the biceps brachii muscle [3]. In healthy athletes, the 3-time focused ESWT on the quadriceps and biceps femoris muscle leads to increased elasticity and reduced muscle tone [4]. In urethral muscle cells, the stimulation of myogenesis could be shown experimentally via the PERK/ATF4 signaling pathway, which is responsible for the formation of myotubes [5]. The focused ESWT also improves the muscular microcirculation [6]. Another potential effect of ESWT is the manipulation of muscular satellite cells. In an animal experiment, an Austrian research group showed the accelerated muscular regeneration after ESWT treatment by proliferation and differentiation of muscular satellite cells [7]. Notably, even a direct interaction of ESWT and mechanosensors in the muscles appears conceivable. Muscle spindles regulate muscle length, while Golgi tendon organ regulate muscle tension. Thus, both radial and focused ESWT might modulate muscle spindles and/or Golgi tendon organs potentially with further effects on Pacinian corpuscles and/or free nerve endings. Based on the clinical findings of this systematic review, that very low- to low-energetic radial and focused ESWT can improve spasticity, it is tempted to speculate that besides the applied energy level, even the frequency of ESWT play a role in this regard.

Adverse effects

Given the aforementioned history of ESWT, starting with electrohydraulic focused machines with high-energy >0.25 mJ/mm2, local adverse effects such as petechial bleedings and hematoma have been observed more than decades ago. In the included trials with the majority of spasticity ESWT treatment regimen with either very low- to low-energetic ESWT, no adverse effects were noted. This is especially notably, since 300 spastic children have been included and treated successfully in this systematic review. By lowering the energy levels the adverse effect profile is likely to be substantial more beneficial. In terms of number of ESWT treatments, an average of 3–5 ESWT sessions were reviewed in the majority of trials. However, as well as up to 12 ESWT sessions have been administered in two studies with no reported adverse events.

Conclusions for Clinical Practice

- Both radial and focused ESWT with very low- to low energy improve clinical neurological function and significantly reduce spasticity in children as well as adults
- There were no negative side effects when using very low- to low-energetic shockwave treatment regimens, neither in adults after stroke nor in children with cerebral palsy

Ethical Approval

This a systematic review based on published data with the local IRB approval given for each paper of the included studies.

Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given his consent for his images and other clinical information to be reported in the Journal. The patient understands that his name and initials will not be published, and due efforts will be made to conceal his identity, but anonymity cannot be guaranteed.

Conflicts of Interest: Nil. **Source of Support:** None.

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Conflict of Interest: NIL
Source of Support: NIL

How to Cite this Article

Knobloch K, Lohse-Busch H, Gohritz A, Nedelka T | Very Low and Low-energetic Extracorporeal Shock Wave Treatment of Spasticity in Children and Adults–A Systematic Review | Journal of Regenerative Science | December 2021; 2(1): 51-54.