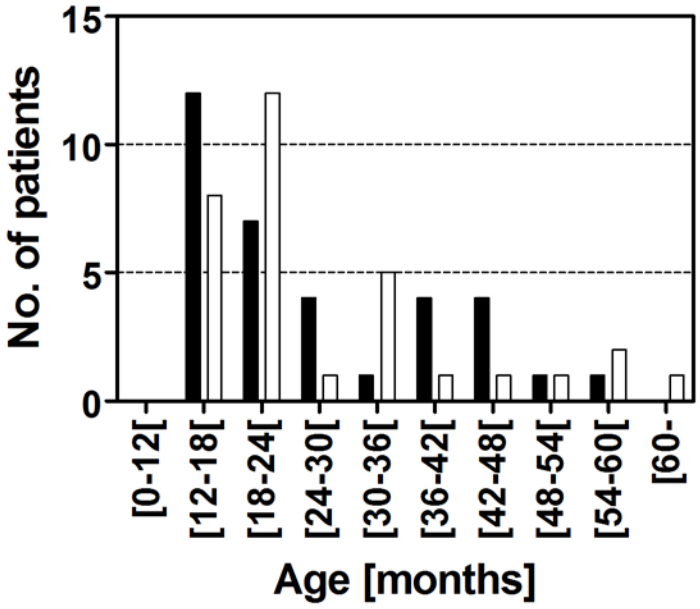
Wang et al.

A prospective case control study of radial extracorporeal shock wave therapy for spastic plantar flexor muscles in young children with cerebral palsy



SUPPLEMENTAL FIGURE 1. Age distribution of the patients in the rESWT group (closed bars) and the control group (open bars) of the present study.

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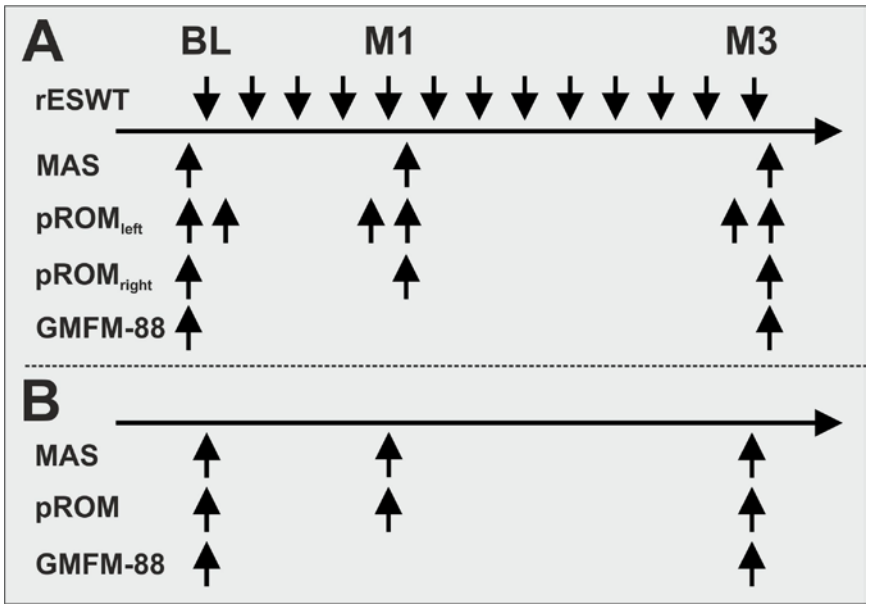

SUPPLEMENTAL FIGURE 2. Design of the present study. (A) Patients in the rESWT group (n=34) received one session of radial extracorporeal shock wave therapy (rESWT) per week for a total of three months. The Modified Ashworth Scale (MAS) grade (primary outcome measure) was determined before rESWT at baseline (BL) and after rESWT one month after the first treatment (M1) and and three months after the first treatment (M3). Passive range of motion (pROM) of the left foot was assessed immediately before and after rESWT at BL, M1 and M3. Passive range of motion of the right foot was assessed immediately before rESWT at BL and after rESWT at M1 and M3. Gross Motor Function Measure (GMFM)-88 was collected before rESWT at BL and after the rESWT session at M3. (B) For the patients in the control group (n = 32) MAS score and pROM were determined at BL, M1 and M3, and GMFM-88 was collected at BM and M3.

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SUPPLEMENTAL TABLE 1. Studies Performed on Focused and Radial Extracorporeal Shock Wave Therapy for Spasticity

Study	Study type	fESWT[a] or rESWT[b]	Device	N[c]	Mean age	Age range
Lohse-Busch et al. (1997)[20]	Pilot[d]	fESWT	Minilith[i]	33	≈9[q]	4-26
Manganotti and Amelio (2005)[21]	Pseudo-controlled[e]	fESWT	Modulith[i]	20	63[r]	38-76
Trompetto et al. (2009)[22]	Pseudo-controlled[e]	fESWT	Modulith[i]	6	43.8 ± 18.9 (SD[s])	25-76
Amelio and Manganotti (2010)[23]	Pseudo-controlled[e]	fESWT	Modulith[i]	12	8 ± 2.31 (SD[s])	6-11
Vidal et al. (2011)[24]	RCT[f]	rESWT	DolorClast[j]	15	31[q]	10-46
Sohn et al. (2011)[25]	Pilot[d]	fESWT	Evotron[k]	10	44.9 ± 11.3[s]	[u]
Manganotti et al. (2012)[26]	Pseudo-controlled[e]	fESWT	Modulith[i]	10	30[q]	26-45
Gonkova et al. (2013)[27]	Pseudo-controlled[e]	rESWT	BTL-5000[h]	25	4.84 ± 3.11[s]	[u]
Troncati et al. (2013)[28]	Pilot[d]	fESWT	Modulith[i]	12	68 (median)	34-86
Santamato et al. (2013)[29]	RCT[f]	fESWT + BoNT[h]	Minilith[i]	16	64.4 ± 6.09 (SD[s])	[u]
Moon et al. (2013)[30]	Pseudo-controlled[e]	fESWT	Piezowave[m]	30	52.6 ± 14.9 (SD[s])	[u]
Kim et al. (2013)[31]	Pilot[d]	rESWT	Masterpuls MP200[i]	57	55.4[r]	20-70
El-Shami et al. (2014)[32]	RCT[f]	fESWT	Modulith[i]	15	6.93 ± 0.8 (SD[s])	[u]
Santamato et al. (2014)[33]	Pilot[d]	fESWT	Evotron RFL0300[n]	30	57.6 ± 10.8 (SD[s])	[u]
Mirea et al. (2014)[34]	Pilot[d]	rESWT	BTL-5000[l]	63	8.30 ± 4.48 (SD[s])	[u]
Daliri et al. (2015)[35]	Pseudo-controlled[e]	rESWT	BTL[o]	15	54.4± 9.4[t]	38-71
Marinelli et al. (2015)[36]	RCT[g]	rESWT	BTL-6000[l]	34	51.7 ± 11.3 (SD[s])	[u]
Park et al. (2015)[37]	RCT[f]	fESWT	AR2[p]	6	6.8 ± 2.3 (SD[s])	[u]

[a], focused extracorporeal shock wave therapy; [b], radial extracorporeal shock wave therapy; [c], number of patients in the fESWT/rESWT group. [d], pilot study without control group; [e], each patient served as her/his own control, i.e., one placebo treatment followed by one ESWT treatment one or two weeks later; [f], randomized controlled trial; [g], all patients affected by multiple sclerosis and suffering from painful hypertonia of ankle extensor

muscles; [h], ESWT + BoNT injection. i, Storz Medical, Tägerwilen, Switzerland; [j], Electro Medical Systems, Nyon, Switzerland; [k], SwiTech, Kreuzlingen, Switzerland; [l], BTL, Prague, Czech Republic; [m], Richard Wolf, Knittlingen, Germany; [n], Sanuwave, Lengwil, Switzerland; [o], device not further specified. [p], Dornier MedTech, Wessling, Germany; [q], 19 males with mean age of 8.9 years (range, 4-26) and 14 females with mean age of 9.7 years (range, 4-23); [r], standard deviation not provided; [s], standard deviation; [t], not specified whether standard deviation or standard error of mean; [u], data not provided.
References are provided in the main text.

SUPPLEMENTAL TABLE 2. Gross Motor Function Measure Scores of the Present Study With or Without Patients Older Than 36 Months

Group	Time	GMFM-88 (all patients)	GMFM-88 (patients <36 months of age)
		Mean, SD	
rESWT	BL	36.6, 28.3	23.5, 20.5
rESWT	M3	52.9, 24.4	42.1, 19.2
Control	BL	40.2, 30.3	41.3, 31.58
Control	M3	53.1, 27.7	53.9, 29.52
		p	
Time		**<.01**	**<0.1**
Time * Age		.05	**<.01**
Time * Sex		.78	.69
Time * Treatment		.27	.20
Age		**<.01**	**<.01**
Sex		**.03**	.09
Treatment		.79	.06

GMFM-88, Gross Motor Function Measure 88 score. BL, baseline; M1, one month after BL; M3, three months after BL.

SUPPLEMENTAL TABLE 3. Protocols of Studies Performed on Focused and Radial Extracorporeal Shock Wave Therapy for Spasticity

Study	Treated muscles	N-S	I	N-ESW	EFD	Control	N-C	H	TS	PA
Lohse-Busch et al. (1997)[20]	Hip, knee and ankle flexors	1	N/a	500	0.06[f]	None	N/a	-	-	-
Sohn et al. (2011)[25]	Plantar flexors	1	N/a	1500	0.10	None	N/a	-	-	-
Troncati et al. (2013)[28]	Upper extremity	2	1 week	1600[b]	0.08[g]	None	N/a	-	-	-
Kim et al. (2013)[31]	Subscapularis	5	2-3 days	3000	1.6 bar[h]	None	N/a	-	-	-
Santamato et al. (2014)[33]	Plantar flexors	1	N/a	1500	0.10	None	N/a	-	-	-
Mirea et al. (2014)[34]	Plantar flexors	3	[a]	500	0.15	None	N/a	-	-	-
Manganotti and Amelio (2005)[21]	Finger flexors	1	N/a	800	0.03	Pseudo-placebo[j]	(20)	-	-	-
Trompetto et al. (2009)[22]	Hand and forearm	4	1 week	800[c]	0.03	Pseudo-placebo[j]	(6)	-	-	-
Amelio and Manganotti (2010)[23]	Plantar flexors	1	N/a	1500	0.03	Pseudo-placebo[j]	(12)	-	-	-
Manganotti et al. (2012)[26]	Hand muscles	1	N/a	1600	0.03	Pseudo-placebo[j]	(10)	-	-	-
Gonkova et al. (2013)[27]	Plantar flexors	1	N/a	1500	1.5 bar[i]	Pseudo-placebo[j]	(25)	-	-	-
Moon et al. (2013)[30]	Plantar flexors	3	1 week	1500	0.089	Pseudo-placebo[j]	(30)	-	-	-
Daliri et al. (2015)[35]	Wrist flexors	1	N/a	1500	1.5 bar[j]	Pseudo-placebo[j]	(15)	-	-	-
Vidal et al. (2011)[24]	Upper limb muscles	3	1 week	2000	0.10	Placebo[k]	7	-	-	-
Santamato et al. (2013)[29]	Finger flexors	5	1 day	1000[d]	0.03	ESWT + ES[l]	16	-	-	+
El-Shami et al. (2014)[32]	Plantar flexors	12	1 week	1500	0.03	PT[m]	15	-	-	-
Marinelli et al. (2015)[36]	Ankle extensor muscles	4	1 week	600[e]	1.5 bar[i]	Placebo	34	-	-	-
Park et al. (2015)[37]	Plantar flexors	3	1 week	1500	0.03	[n]	6	-	-	-
Present study	Plantar flexors	12	1 week	1500	0.03	PT[o]	32	+	+	+

N-S, number of fESWT/rESWT sessions; I; interval between sessions; N-SW, number of extracorporeal shock waves per session; EFD, energy flux density; N-C, number of patients in the control group. H, hypothesis provided; TS, definition of treatment success provided; PA, power analysis performed; N/a, not applicable. [a], data not provided; [b], 1600 impulses for flexor muscles of the forearm, and 800 impulses for each interosseus muscle of the hand; [c], 800 impulses for intrinsic hand muscles, 2000 impulses for forearm muscles and 3000 impulses for hand and forearm; [d], 1,000 impulses on the belly of the muscle plus 1,000 impulses on the muscle-tendon junction; [e], 600 impulses on the belly of each gastrocnemius muscle, 600 impulses on the belly of the soleus muscle and 200 impulses in the Achilles tendon; [f], focus of the shock waves placed within the coupling cushion of the therapy source or outside the patient's body; [g], 0.105 mJ/mm^2 in case of flexor hypertonic muscles; [h], the authors reported an EFD of 0.63 mJ/mm^2 at 1.6 bar air pressure for the Masterpuls MP200 (Storz Medical) which is not correct; [i], no conversion of bar in mJ/mm^2 provided; [j], each patient served as her/his own control; one placebo treatment followed by one ESWT treatment one or two weeks later; [k], the total number of spastic muscles was 40, and was randomly distributed into 3 groups (RSWT for agonist, RSWT for agonist and antagonist, placebo); [l], ESWT + electrical stimulation; [m], conventional physical therapy comprising neurodevelopmental techniques, muscle stretching, strengthening exercises, proprioceptive training, and balance and gait training (1h, 3 x per week); [n], one session of ESWT followed by two sessions of placebo-ESWT; [o], physical therapy, Chinese massage, meridian mediation and muscle stimulation.
References are provided in the main text.

SUPPLEMENTAL TABLE 4. MAS Grades Reported in Studies Performed on Focused and Radial Extracorporeal Shock Wave Therapy for Spasticity

	First ESWT session			Last ESWT session			Last follow-up	
Study	MAS before ESWT (mean ± SD)	MAS after ESWT (mean ± SD)	Time	MAS before ESWT (mean ± SD)	MAS after ESWT (mean ± SD)	Time	MAS (mean ± SD)	
Sohn et al. (2011)[25]	2.7 ± 1.2	1.2 ± 1.0	-	-	-	-	-	
Kim et al. (2013)[31]	2.7 ± 0.9	-	W2	1.8 ± 0.8	1.7 ± 0.7[d]	M2	2.1 ± 0.9	
Santamato et al. (2014)[33]	3.5 ± 1.0	2.1 ± 1.1	-	-	-	M1	2.6 ± 1.2	
Mirea et al. (2014)[34]	2.5[a]	-	N.s.	-	1.7[a]	-	-	
Manganotti and Amelio (2005)[21]	3.3 ± 0.6	2.0 ± 0.9	-	-	-	M3	3.0 ± 0.5	
Amelio and Manganotti (2010)[23]	3.1 ± 0.4	1.8 ± 0.4	-	-	-	M3	2.8 ± 0.6	
Gonkova et al. (2013)[27]	2.8 ± 0.1[b]	2.0 ± 0.1[b]	-	-	-	M1	2.2 ± 0.1	
Moon et al. (2013)[30]	2.5 ± 0.7	-	W3	-	1.4 ± 0.7	M2	1.8 ± 0.6	
Daliri et al. (2015)[35]	3[a]	2[a]	-	-	-	W5	2[a]	
Vidal et al. (2011)[24]	[c]	-	W3	-	-1[e]	M4	0[e]	
Santamato et al. (2013)[29]	3.5 ± 0.5	-	D5	-	1.4 ± 0.5[f]	M3	1.6 ± 0.5	
El-Shami et al. (2014)[32]	2.3 ± 0.5	-	M3	-	1.6 ± 0.2	-	-	
Marinelli et al. (2015)[36]	2.7 ± 0.8	-	M1	-	1.9 ± 1.0[g]	M2	2.6 ± 0.9	
Park et al. (2015)[37]	2.3 ± 0.4	-	W3	-	1.0 ± 0.4	W7	1.1 ± 0.5	
Present study (left side)	2.6 ± 1.0	-	M3	-	1.5 ± 1.0	-	-	
Present study (right side)	1.9 ± 0.6	-	M3	-	1.2 ± 0.7	-	-	

ESWT, extracorporeal shock wave therapy; MAS, Modified Ashworth Scale; D5, W2, W3, W5, W7, M1, M2, M3, M4, five days, two weeks, three weeks, five weeks, seven weeks, one month, two months, three months or four months after baseline, respectively; [a], measure of variation not provided; [b], standard error of the mean; [c], mean and measure of variation at baseline not provided; [d], at W3; [e]; mean improvement in absolute grades compared to baseline at M2; [f], at W2; [g], at W5. Note that the studies by Lohse-Busch et al. (1997)[1], Trompetto et al. (2009)[3], Manganotti et al. (2012)[7] and Troncati et al. (2013)[9] listed in Supplemental Tables 1 and 3 are not considered in Supplemental Table 4 because these studies either did not provide mean MAS grades or provided no MAS grades at all.

References are provided in the main text.