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Neuromuscular Electrical Stimulation for Infants with Neonatal Brachial Plexus Palsy: A Pilot Study

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Neuromuscular Electrical Stimulation for Infants with Neonatal Brachial Plexus Palsy: A Pilot Study

Abstract

Background: Biceps recovery is a critical determinant for treatment decision-making in patients with neonatal brachial plexus palsy (NBPP). One treatment intervention used by therapists is neuromuscular electrical stimulation (NMES), but its use remains controversial. This study's aim was to determine the effect and safety of NMES on biceps function in infants with NBPP compared to standard therapy.

Methods: In this pilot, randomized controlled study, patients were randomized to the NMES treatment or control/sham group. Inclusion criteria were infants 3 to 9 months of age with a confirmed diagnosis of NBPP and biceps weakness, without other comorbidities. The parents administered the NMES (treatment or control) 30 min daily. Outcomes of active range of motion (AROM), muscle strength, and morphometric measurements were assessed by one of two blinded therapists at enrollment and 1-, 2-, and 3-month follow-up intervals.

Results: Seventeen patients (10 NMES, seven control) participated in the study. Despite equal group demographics, the treatment group demonstrated significant improvement in elbow flexion AROM after the first month of NMES compared to the control group (improvement 31° vs. -3°, $P = .047$). No adverse effects were reported.

Conclusion: Use of NMES can be beneficial and should be considered in the early rehabilitation protocol for infants with NBPP.

Keywords

elbow flexion, electrical stimulation, Erb's palsy, biceps, therapy, treatment

Cover Page Footnote

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Credentials Display

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Neonatal brachial plexus palsy (NBPP) affects 1 to 4 per 1,000 live births (Squitieri et al., 2011). The stretching of the brachial plexus nerves (C5 to T1) during the perinatal period causes arm weakness or paralysis that results in active range of motion (AROM) limitations (Smith et_al., 2018). Recovery varies based on the extent (Narakas classification) (Buterbaugh & Shah, 2016; Foad et al., 2009) and severity (Seddon/Sunderland classification) (Chhabra et al., 2014) of the nerve injury. Around 20%–30% of infants suffer a persistent deficit in upper extremity function and fine motor coordination (Jonsson et al., 2019; Malessy & Pondaag, 2011; Pondaag et al., 2004) and will have difficulties achieving developmental milestones (Fogel et al., 2021; Yang, 2014) or even experience challenges in self-care activities of daily living and instrumental activities of daily living (Hulleberg et al., 2014; Wilson et al., 2016) during their lifetime. Some infants undergo primary nerve surgery to encourage nerve regeneration and muscle re-innervation. Timing for initiation of surgery varies; however, the lack of biceps and shoulder recovery are traditional indicators for primary nerve repair (Bauer et al., 2020; Wilson et al., 2018). Therefore, biceps recovery is usually deemed the focus in treating NBPP. Therapeutic (occupational therapy or physical therapy) intervention is common practice for conservative, preoperative, and postoperative management of infants with NBPP.

One treatment modality used by therapists is neuromuscular electrical stimulation (NMES) (Frade et al., 2019; Schmieg et al., 2020). NMES is a clinical treatment modality that was initially designed for use in patients with central nervous system disorders. A paucity of information exists regarding the use of NMES in peripheral nerve disorders, such as NBPP (Adedeji & Oyelese, 2009; Berggren & Baker, 2015; Elnaggar, 2016; Okafor et al., 2008; Srilakshmi & Chaganti, 2013). Elnaggar (2016) suggests that the benefits of NMES for NBPP include improved range of motion, improved strength, reduced co-contractions, and improved extremity function. NMES involves using a programmable battery-powered handheld device to deliver electrical current via surface electrodes applied to the skin of targeted muscles with the goal of promoting recovery in AROM and/or muscle strength. Electrical stimulation works best on type II muscles and/or muscles that are denervated: The biceps muscle is considered a type II muscle. Various settings on NMES devices have been employed in the literature. When considering intervention with infants and establishing a randomized intervention, safety and comfort are imperative considerations. Elnaggar (2016) reported NMES settings at 15 s on, 15 s off, 300 μs, and 30 Hz, with biphasic input. Berggren and Baker (2015) varied settings throughout the course of treatment, with ranges of 20–25 Hz, 100–150 μs, 10–4 s on, and 10–4 s off. However, opinions vary regarding the use and effectiveness of NMES for the treatment of peripheral nerve disorders, including NBPP (Alon, 2019; Gonçalves et al., 2021; Yilmaz et al., 2018).

Traditional settings for NMES include a frequency/rate of 20–50 Hz, ramp time of 1–4 s, pulse width/duration of 10–1000 μs, and duty cycle ratio of 1:3 (on time to off time); intensity varies from high for strengthening to low for central nervous system input; and electrode placement can influence depth of muscle stimulation (close together is superficial and further apart is deep). Electrodes can be monophasic, biphasic, or quadraphasic. NMES home units deliver alternative currents (Doucet et al., 2012). Some electrical stimulation entails the use of faradic current inclusive of short pulse width with a duration of .1-1 second and a frequency of 50–100 Hz. Conversely, galvanic current or direct current provides a high-voltage current. Galvanic current can be transformed into alternating current. Machines that deliver galvanic current can administer medications and stimulate the superficial layer of the skin. Various settings on NMES devices have been employed in the literature. When considering intervention with pediatric patients and establishing a randomized intervention, safety and comfort are imperative

considerations. Elnaggar (2016) reported NMES settings at 15 s on, 15 s off, 300 μs, and 30 Hz, with biphasic input. Berggren and Baker (2015) varied settings throughout the course of treatment, with ranges of 20–25 Hz, 100–150 μs, 10–4 s on, and 10–4 s off. The settings used in this study were chosen after considering the practical and theoretical concepts, as well as the comfort and safety of the patient.

In addition, variations in NMES timing, placement, duration, and setting have been reported. Although more structured studies are needed, a literature review of the use of NMES in children with NBPP revealed (Justice et al., 2018; Yan & Vassar, 2021) that the timing of initiation began as early as 22 days of age, for durations of 6 weeks to 4 months, at frequencies of 1 to 3 times a week, for 5 to 15 min per muscle, and the muscles described were deltoid, biceps, and wrist extensors (Adedeji & Oyelese, 2009; Berggren & Baker, 2015; Elnaggar, 2016; Okafor et al., 2008; Srilakshmi & Chaganti, 2013). Two of the studies did not describe the equipment and/or settings used (Okafor et al., 2008; Srilakshmi & Chaganti, 2013). Outcome measures reported in these studies included various combinations of range of motion, limb morphometrics, muscle strength, Assisting Hand Assessment, modified Mallet (Adedeji & Oyelese, 2009; Berggren & Baker, 2015; Okafor et al., 2008; Srilakshmi & Chaganti, 2013), and bone density (Elnaggar, 2016). The most recent case studies (Gonçalves et al., 2021; Jeyanthi, 2015) reported favorable outcomes in improving targeted muscles for infants with NBPP from 5 to 10 months of age. Even with emerging evidence for faradic, functional, galvanic, and neuromuscular electrical stimulation for a variety of age ranges, muscle groups, durations, and machine settings, controversy still exists in improving biceps function in infants with NBPP. Given this paucity of available information, this study aimed to evaluate the effectiveness and safety of NMES for biceps recovery in NBPP infants initiated at 3 to 9 months of age.

Method

This pilot study used a randomized controlled research design to investigate the effectiveness and safety of NMES on biceps recovery in NBPP infants at 3 to 9 months of age. This study was approved by the University of Michigan Institutional Review Board and registered with ClinicalTrials.gov, NCT01999465.

Participants

Seventeen infants diagnosed with NBPP were sequentially recruited from the Michigan Medicine Brachial Plexus and Peripheral Nerve Interdisciplinary Clinic between November 2013 and March 2017. Inclusion criteria were infants, regardless of sex, who were 3 to 9 months of age with a biceps Medical Research Council (MRC; Medical Research Council, 1981) muscle strength (range 0 to 5; 0 as the weakest and 5 as the strongest) of 2- to 4 and elbow flexion AROM (range 0° to 150°, 150° is full range) less than 150°. Infants were excluded from the study if the infant exhibited elbow extension contractures more than 5°, biceps MRC muscle strength of 0 or 5, NMES treatment prior to recruitment, or comorbidities, such as cerebral palsy or neuromuscular or skeletal disorders other than NBPP at the time of recruitment. The Narakas classification was used to determine the extent (numbers of nerve roots involved) of NBPP. Nerves involved in group I = C5–6, group II = C5–7, group III = C5–T1, and group IV = C5–T1 with Horner's syndrome (Al-Qattan et al., 2009; Buterbaugh & Shah, 2016; Foad et al., 2009). The Narakas grade was evaluated by a single surgeon via either (a) physical examination along with neurological assessment at 1 month of age/initial clinic visit or (b) the mother's or obstetrician's report on the infant's arm movement at birth. We grouped Narakas grade into I–II versus III–IV in this study.

Study Design Protocol and Timeline

In this 3-month pilot randomized controlled study, the home NMES units were preprogramed into two settings (treatment vs. control/sham), then a non-blinded research coordinator randomized either treatment or control/sham machine via coin-toss to participating infants and parents. After the machine assignment, the infants were given a study ID, and only the non-blinded researcher knew and kept track of the machine assignment. The parents and the occupational therapists were blinded to the infant's group assignment. The parents were instructed by the occupational therapists on where to place the electrodes (biceps) and how to use the machine within the preset parameters, along with NMES home usage instructions. Tampering with the settings was cause for elimination from the study.

NMES unit settings for NMES treatment included an on time of 10 s, off time of 30 s, pulse rate of 35 Hz, pulse width of 300 μs, symmetrical waveform, simultaneous cycling, and ramp time of 2 s at Level 4. NMES unit settings for sham treatment were the lowest possible, with an on time of 0 s, off time of 60 s, pulse rate of 35 Hz, pulse width of 48 μs, symmetrical waveform, simultaneous cycling, and ramp time of 0 s at Level 4 (see Appendix A).

At the initial visit, one of the two blinded therapists instructed the parents on the usage of a preprogramed Empi Continuum™ model (Empi, Inc., Clear Lake, South Dakota) device to stimulate the infant's biceps muscle. Empi brand 1.25-cm round electrodes were used (see Appendix B). During Month 1, the parents applied NMES at a comfortable Level 4 daily for 30 min during a play session; at the end of the first month, each family then returned for their monthly NMES data collection and NBPP physical assessment. The same protocol applied at Months 2 and 3. The study was concluded at the end of the 3-month study period.

Data Collection

Patient demographics included mean age, sex, race, NBPP-involved side, Narakas grade, and the presence of biceps substitution patterns at each study visit. After the initial visit, each family returned for monthly NMES data collection and NBPP physical assessment. The data from the NMES Continuum device, such as the number of sessions, average number of min per session, and total hr of machine usage, were retrieved and stored in a secure electronic database by the research coordinator.

One of two occupational therapists with a combined 40+ years' experience evaluated the infant at the initial study appointment (pre-NMES) and each follow-up time of 1, 2, and 3 months (post-NMES) in a consistent fashion to ensure data validity and reliability. Standard clinical assessments included AROM for shoulder flexion (0–180°), shoulder abduction (0–180°), shoulder extension (0–50°), shoulder external rotation in adduction (0–90°), shoulder external rotation in abduction (0–90°), elbow flexion in adduction (0–150°), elbow flexion in abduction (0–150°), elbow extension (-150–0°), forearm supination (0–90°), forearm pronation (0–90°), biceps MRC muscle strength (0–5), and bilateral limb morphometric measurements.

Because of muscle weakness, the infants with NBPP tended to compensate with substituted muscle to achieve certain movements. For example, biceps substitution patterns included the use of the brachialis and/or brachioradialis muscle groups to produce wrist extension that facilitates elbow flexion. In the current study, the occupational therapists recorded biceps substitution patterns via observation during each clinical evaluation. If the infant attempted to perform true biceps-driven elbow flexion, then biceps substitution pattern was recorded as "no." A score of "yes" indicated the use of ancillary muscles to produce elbow flexion. The focus of therapy is to facilitate pure elbow flexion with the shoulder in adduction/neutral external rotation, the forearm in supination, and the wrist in a neutral position.

Statistical Analysis

Patient demographics and NMES data are reported using descriptive statistics. The AROM differences between the treatment and sham groups were compared at pre-NMES and 1-, 2-, and 3-month follow-ups, and morphometric differences were compared at the 3-month follow-up visit. Student's *t*-test for continuous variables and Chi-square for categorical variables were applied. Probability values less than 0.05 were considered statistically significant. SPSS statistical software (version 18, SPSS Inc., Chicago, Illinois) was used to perform all analyses. A post hoc power analysis indicated that 31 infants were required in each group to reach 80% power for detecting 30% group difference. This pilot study had a limited sample size because of funding.

Results

Seventeen infants participated in the study: 10 in the treatment group and seven in the control/sham group. Overall, there were no significant demographic differences in age, sex, race, NBPP-involved side, Narakas classification, or substitution patterns between the groups (see Table 1). Of note, there was a decrease in substitution patterns by the third month in the treatment group, whereas the control/sham group displayed an increase in substitution patterns.

There was little difference in the use of the machine at home between the two groups. The number of sessions was greatest in the first month among the participants in the treatment group at 24/30 sessions versus the control/sham group at 18/30. The number of sessions tapered each subsequent month in both groups (see Figure 1). The average number of minutes per session was equal between the groups, with a range of 21.6 to 26.4 min. The total hour of usage after 1 month was 11 hr in the treatment group and 8 hr in the sham group. Usage declined to 9 hr for each group in the 2nd month and 6 hr for each group in the 3rd month. The average usage in terms of sessions, hours, and minutes per session was equal between the groups (see Figure 1).

Table 1

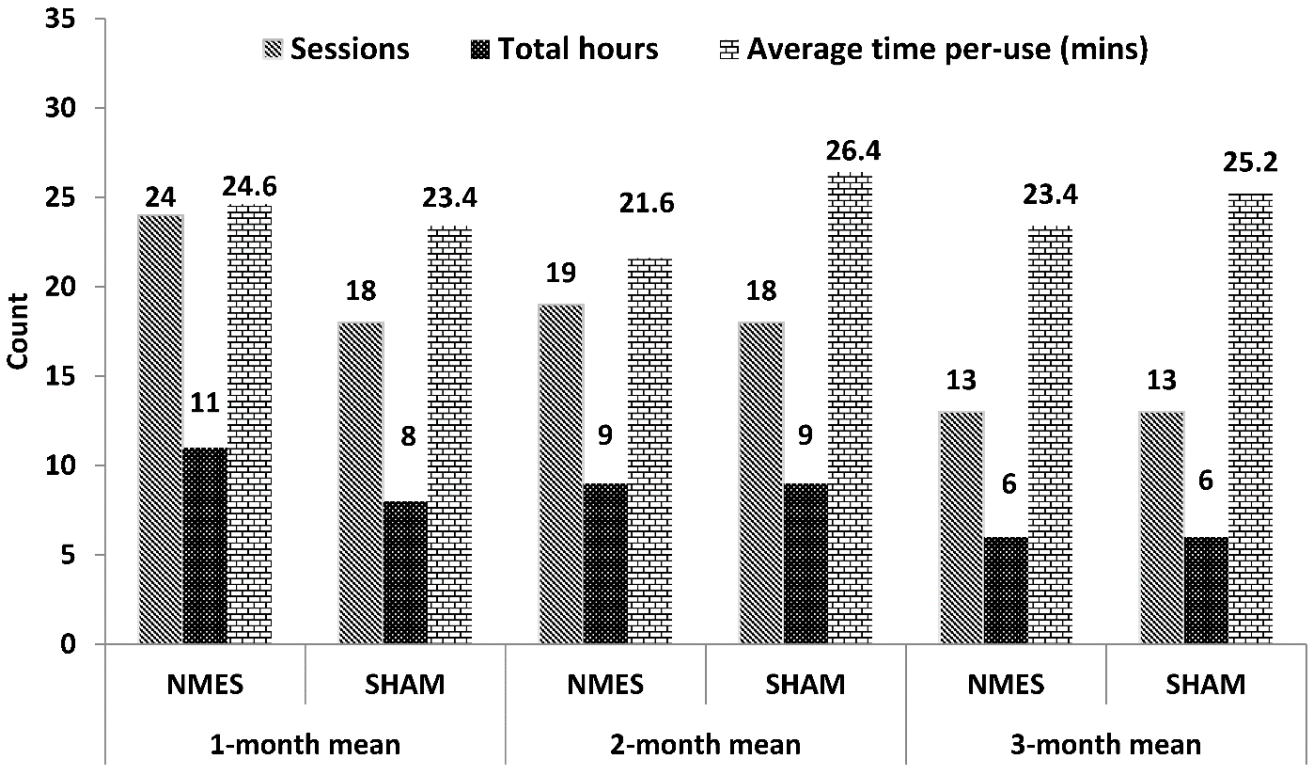
Patient Demographics

	Treatment N (%) N = 10	**Sham N (%) N = 7**	***P***
Mean age at NMES initiation ± *SD* (months)	4 ± 2	4 ± 1	.26
Sex			.51
Male	4 (40%)	1 (14%)	
Female	6 (60%)	6 (86%)	
Race			.32
Caucasian	9 (90%)	5 (71%)	
Other	1 (10%)	2 (29%)	
NBPP-involved side			.38
Left	5 (50%)	2 (29%)	
Right	5 (50%)	5 (71%)	
Narakas classification			.68
I-II	8 (80%)	5 (71%)	
III-IV	2 (20%)	2 (29%)	
Biceps Substitution Patterns			
Yes initial	2 (20%)	1 (14%)	.99
Yes-1 month	6 (60%)	3 (43%)	.63
Yes-2 months	3 (38%)	4 (57%)	.45
Yes-3 months	1 (10%)	2 (29%)	.51

Note. NBPP = neonatal brachial plexus palsy; NMES = neuromuscular electrical stimulation; *SD* = standard deviation.

Figure 1

Average Usage of Neuromuscular Electrical Stimulation (NMES) was Similar Between Groups Over the 3-Month Study Enrollment



Before the initiation of NMES, the active range of motion and muscle strength were similar in both groups. After the first month of NMES, the treatment group demonstrated significant improvement in AROM for elbow flexion with the shoulder in adduction to 86° (P = .048); overall, the amount of change in elbow flexion against gravity between the initial visit and 1 month of intervention was 31° (P = .047). In the first month, there was no other significant change in AROM or strength for either group (see Table 2).

In Months 2 and 3 there were no significant differences in AROM in the shoulder, elbow, forearm, or biceps strength between the groups (see Tables 3 and 4).

Morphometric measurements are reported in Table 5. The difference in the measurements for limb length and girth between the involved and un-involved extremity was averaged and reported for each cohort. The findings were statistically insignificant between groups over the 3-month study. No significant loss of muscle bulk or limb length was noted between the groups (see Table 5).

No adverse effects (such as skin irritation, emotional distress, joint contractures, or lack of growth) were reported by the parents or noted by the therapists at follow-up visits.

Table 2

Active Range of Motion (Degrees) at 1-Month Follow-up

	AROM Pre-NMES Trial Mean ± *SD*				AROM at 1 Month Post-NMES Mean ± *SD*				AROM Improvement (Pre- vs. 1 Month Post-NMES) Mean ± *SD*			
	Treatment (N = 10)	**Sham (N = 7)**	**95% CI**	***P***	**Treatment (N = 10)**	**Sham (N = 7)**	**95% CI**	***P***	**Treatment (N = 10)**	**Sham (N = 7)**	**95% CI**	***P***
Elbow flexion in adduction	56 ± 39	56 ± 37	[-40.66, 40.23]	.99	86 ± 28	53 ± 36	[0.39, 65.89]	**.048**	31 ± 35	-3 ± 25	[0.46, 66.26]	**.047**
Elbow flexion in abduction	96 ± 19	89 ± 38	[-21.94, 36.8]	.60	105 ± 25	106 ± 21	[-26.41, 23.56]	.91	9 ± 35	18 ± 30	[-43.47, 25.75]	.59
Elbow extension	-11 ± 28	-4 ± 8	[-30.14, 16.71]	.55	-15 ± 28	-1 ± 4	[-35.78, 9.63]	.24	-4 ± 37	3 ± 5	[-36.61, 23.90]	.66
Forearm supination	-21 ± 54	-56 ± 41	[-16.56, 88.41]	.17	-8 ± 43	-20 ± 50	[-36.49, 60.49]	.61	13 ± 55	36 ± 52	[-80.49, 32.64]	.38
Forearm pronation	90 ± 0	90 ± 0	-	-	90 ± 0	90 ± 0	-	-	0 ± 0	0 ± 0	-	-
MRC strength of biceps, median (range)	2 (2–3)	2 (2–3)	-	.99	2 (2–3)	2 (2–3)	-	.99	0 (0)	0 (0)	-	.99
Shoulder flexion	71 ± 28	48 ± 31	[-7.99, 54.28]	.13	86 ± 35	77 ± 44	[-31.99, 49.7]	.65	15 ± 37	29 ± 46	[-57.06, 28.49]	.49
Shoulder extension	3 ± 9	0 ± 0	[-4.72, 10.72]	.42	3 ± 9	0 ± 0	[-4.72, 10.72]	.42	0 ± 0	0 ± 0	[-11.51, 11.51]	.99
Shoulder external rotation in adduction	-9 ± 61	-41 ± 50	[-28.39, 91.82]	.28	13 ± 48	-30 ± 54	[-9.84, 95.84]	.10	22 ± 54	11 ± 58	[-46.93, 69.51]	.69
Shoulder external rotation in abduction	2 ± 60	-39 ± 48	[-18, 99.14]	.16	22 ± 58	-23 ± 46	[-11.19, 100.9]	.11	20 ± 54	16 ± 62	[-55.73, 64.30]	.88

Note. AROM = active range of motion; CI = confidence interval; MRC = Medical Research Council; NMES = neuromuscular electrical stimulation; *SD* = standard deviation.

Table 3

Active Range of Motion (Degrees) at 2-Month Follow-up

	AROM Pre-NMES Trial Mean ± *SD*				AROM at 2 Months Post-NMES Mean ± *SD*				AROM Improvement (Pre- vs. 2 Months Post-NMES) Mean ± *SD*			
	Treatment (N = 10)	**Sham (N = 7)**	**95% CI**	***P***	**Treatment (N = 8)**	**Sham (N = 7)**	**95% CI**	***P***	**Treatment (N = 8)**	**Sham (N = 7)**	**95% CI**	***P***
Elbow flexion in adduction	56 ± 39	56 ± 37	[-40.66, 40.23]	.99	91 ± 4	64 ± 48	[-16.90, 72.25]	.18	29±39	8 ± 36	[-21.15, 62.94]	.30
Elbow flexion in abduction	96 ± 19	89 ± 38	[-21.94, 36.8]	.60	113 ± 31	90 ± 85	[-46.80, 91.81]	.50	15 ± 28	1 ± 57	[-35.15, 62.29]	.56
Elbow extension	-11 ± 28	-4 ± 8	[-30.14, 16.71]	.55	-4 ± 6	-4 ± 5	[-7.06, 5.46]	.79	8 ± 30	1 ± 7	[-17.43, 32.26]	.53
Forearm supination	-21 ± 54	-56 ± 41	[-16.56, 88.41]	.17	-1 ± 43	-5 ± 52	[-48.82, 56.32]	.88	26 ± 42	51 ± 40	[-71.41, 21.05]	.26
Forearm pronation	90 ± 0	90 ± 0	-	-	90 ± 0	90 ± 0	-	-	0 ± 0	0 ± 0	-	-
MRC strength of biceps, median (range)	2 (2–3)	2 (2–3)	-	.99	3 (2–3)	3 (2–3)	-	.99	1 (0–1)	1 (-1–1)	-	.50
Shoulder flexion	71 ± 28	48 ± 31	[-7.99, 54.28]	.13	99 ± 27	101 ± 42	[-39.69, 37]	.94	26 ± 33	53 ± 54	[-79.88, 25.41]	.28
Shoulder extension	3 ± 9	0 ± 0	[-4.72, 10.72]	.42	10 ± 18	4 ± 5	[-9.39, 20.82]	.43	6 ± 18	4 ± 5	[-13.72, 17.65]	.79
Shoulder external rotation in adduction	-9 ± 61	-41 ± 50	[-28.39, 91.82]	.28	6 ± 45	-17 ± 57	[-33.39, 80.18]	.39	6 ± 35	24 ± 55	[-67.92, 33.28]	.47
Shoulder external rotation in abduction	2 ± 60	-39 ± 48	[-18, 99.14]	.16	35 ± 60	30 ± 39	[-52.51, 62.52]	.85	21 ± 40	69 ± 54	[-99.92, 5.28]	.07

Note. AROM = active range of motion; CI = confidence interval; MRC = Medical Research Council; NMES = neuromuscular electrical stimulation; *SD* = standard deviation.

Table 4

Active Range of Motion (Degrees) at 3-Month Follow-up

	AROM Pre-NMES Trial Mean ± *SD*				AROM at 3 Months Post-NMES Mean ± *SD*				AROM Improvement (Pre- vs. 3 Months Post-NMES) Mean ± *SD*			
	Treatment (N = 10)	Sham (N = 7)	95% CI	*P*	Treatment (N = 9)	Sham (N = 5)	95% CI	*P*	Treatment (N = 9)	Sham (N = 5)	95% CI	*P*
Elbow flexion in adduction	56 ± 39	56 ± 37	[-40.66, 40.23]	.99	111 ± 26	104 ± 26	[-24.67, 38.90]	.64	55 ± 38	29 ± 25	[-15.39, 67.39]	.20
Elbow flexion in abduction	96 ± 19	89 ± 38	[-21.94, 36.8]	.60	136 ± 24	138 ± 27	[-32.83, 27.94]	.86	39 ± 28	36 ± 33	[-32.90, 38.68]	.86
Elbow extension	-11 ± 28	-4 ± 8	[-30.14, 16.71]	.55	-12 ± 29	-1 ± 2	[-40.42, 17.97]	.42	-1 ± 44	5 ± 7	[-49.84, 37.62]	.77
Forearm supination	-21 ± 54	-56 ± 41	[-16.56, 88.41]	.17	40 ± 26	28 ± 40	[-26.24, 50.24]	.51	69 ± 50	71 ± 60	[-66.38, 63.27]	.96
Forearm pronation	90 ± 0	90 ± 0	-	-	90 ± 0	90 ± 0	-	-	0 ± 0	0 ± 0	-	-
MRC strength of biceps, median (range)	2 (2–3)	2 (2–3)	-	.99	3 (2–4)	3 (2–4)	-	.99	1 (0–1)	1 (0–1)	-	.40
Shoulder flexion	71 ± 28	48 ± 31	[-7.99, 54.28]	.13	110 ± 33	132 ± 35	[-63.18, 19.18]	.27	41 ± 50	87 ± 31	[-99.74, 7.97]	.09
Shoulder extension	3 ± 9	0 ± 0	[-4.72, 10.72]	.42	12 ± 17	8 ± 13	[-15.80, 23.13]	.69	8 ± 22	8 ± 13	[-23.41, 24.08]	.98
Shoulder external rotation in adduction	-9 ± 61	-41 ± 50	[-28.39, 91.82]	.28	23 ± 49	34 ± 31	[-64.47, 43.14]	.67	33 ± 57	64 ± 58	[-100.76, 39.43]	.36
Shoulder external rotation in abduction	2 ± 60	-39 ± 48	[-18, 99.14]	.16	47 ± 60	52 ± 37	[-70.10, 59.43]	.86	44 ± 62	88 ± 67	[-121.14, 34.03]	.25

Note. AROM = active range of motion; CI = confidence interval; MRC = Medical Research Council; NMES = neuromuscular electrical stimulation; *SD* = standard deviation.

Table 5

Mean Difference Between Extremities for Morphometric Measurements in Centimeters

	Pre-NMES Trial Mean ± *SD*				3 Months Post-NMES Trial Mean ± *SD*				Improvement (Pre- vs. 3 Months Post-NMES Trial) Mean ± *SD*			
	Treatment (N = 10)	Sham (N = 7)	95% CI	*P*	Treatment (N = 9)	Sham (N = 5)	95% CI	*P*	Treatment (N = 9)	Sham (N = 5)	95% CI	*P*
Circumference, biceps	0.15 ± 0.24	0.64 ± 0.69	[-0.99, 0.01]	.11	0.06 ± 0.17	0.20 ± 0.27	[-0.48, 0.19]	.33	-0.06 ± 0.30	-0.20 ± 0.57	[-0.35, 0.64]	.54
Circumference, forearm	0.20 ± 0.35	0.14 ± 0.24	[-0.27, 0.38]	.72	0.06 ± 0.17	0.10 ± 0.22	[-0.27, 0.18]	.68	-0.17 ± 0.43	0 ± 0	[-0.60, 0.26]	.28
Length, upper arm	0.20 ± 0.42	0.43 ± 0.45	[-0.68, 0.23]	.30	0.17 ± 0.25	0.20 ± 0.45	[-0.43, 0.37]	.86	-0.06 ± 0.46	-0.20 ± 0.76	[-0.56, 0.85]	.66
Length, forearm	0.05 ± 0.16	0.21 ± 0.39	[-0.46, 0.13]	.33	0 ± 0	0.20 ± 0.27	[-0.54, 0.14]	.18	-0.06 ± 0.17	-0.10 ± 0.22	[-0.18, 0.27]	.68

Note. CI = confidence interval; NMES = neuromuscular electrical stimulation; *SD* = standard deviation.

Discussion

Therapy and/or surgical management for the care of infants with NBPP is imperative. To determine if an infant meets the indications for surgical intervention for NBPP, serial examinations by specialists (Wilson et al., 2018), preferably at an interdisciplinary clinic (Pandey et al., 2015), are required. One of the traditional indicators for surgical intervention is the lack of recovery of deltoid and/or biceps function, so the focus of therapeutic management on the biceps is appropriate. However, controversy exists regarding the use of NMES for infants with NBPP. Our study results showed the use of NMES for 30 min daily at home by attentive parents who are properly trained can be considered effective and safe for improving active elbow flexion, especially in the first month.

Timing to initiate NMES also varies. Among the few studies in the literature, treatment was initiated at 3 weeks (Adedeji & Oyelese, 2009; Okafor et al., 2008), 6 weeks (Berggren & Baker, 2015), 4.5 months (Srilakshmi & Chaganti, 2013), and 3–5 years of age (Elnaggar, 2016). In this study, NMES was initiated between 3 to 9 months of age, with the rationale that this timing would allow for nerve regeneration and prevent interference with collateral nerve sprouting. Regardless of the age at initiation of NMES (range 3–9 months), infants in the treatment group demonstrated a significant gain in active elbow flexion with continuous progress throughout the study period. However, the optimal duration for NMES remains unclear. In published reports of use in peripheral nerve conditions, the durations for NMES use were three sessions in 28 days (Srilakshmi & Chaganti, 2013), three sessions weekly for 6 weeks (Okafor et al., 2008), two sessions weekly for 4 months (Adedeji & Oyelese, 2009), two sessions at home daily for 6 weeks (Berggren & Baker, 2015), and daily sessions for 12 weeks (Elnaggar, 2016). In this study, families were encouraged to use the NMES unit at home for 30 min daily for 3 months; we believe this duration was appropriate given the reported average number of minutes per use was fairly equal in both groups. Regarding compliance with the NMES study protocol at home, our results revealed equivalent NMES use between treatment and control groups. Even though both groups showed diminished usage in sessions and total hours over the study period, they maintained consistent average minutes of usage in each session. Compliance is an important consideration for home programs (Murphy et al., 2012). A prior study on home exercise program compliance using an exercise DVD showed that parents reported the highest usage of DVD and high home exercise compliance right after receiving the home exercise DVD. Therefore, we suggest reviewing a home program with parents regularly to ensure compliance and maximize potential recovery.

The biceps muscle was targeted in this study, given its acceptance as an indicator for nerve reconstruction (Wilson et al., 2018). Biceps muscle is also one of the key factors contributing to active elbow flexion movement. Among children affected by NBPP, Srilakshmi and Chaganti (2013) reported a recovery of biceps MRC grade from 0 to 3 in 28 days, and Adedeji and Oyelese (2009) reported biceps MRC improvement from 1 to 3 in infants who were 4 months of age (Chang et al., 2018). However, for children with persistent NBPP and weakness in targeted muscles, NMES might be beneficial in increasing muscle strength (Elnaggar, 2016). In the present study, muscle strength improved from MRC Grade 2 to 3 over the course of 3 months, along with significant improvement in active elbow flexion at 1 month in the NMES treatment group. In light of natural recovery, it may be possible that NMES contributed to the improved biceps muscle strength and range of motion. These study results exceed the improvement in elbow flexion reported by Okafor et al. (2008), from 10° to 35° after 6 weeks of NMES. Further studies with multiple centers, larger sample sizes, and/or additional muscle groups should be considered.

No adverse effects from NMES were noted in our study. No significant difference was found between the treatment and control/sham groups related to the morphometric measurements of the infants. The use of NMES did not hinder the growth of the extremity, in particular, the circumference of the biceps. Infants did not develop elbow flexion contractures. No skin integrity issues were reported or noted. Similar to our study, no other studies using NMES with children report adverse effects (Adedeji & Oyelese, 2009; Berggren & Baker, 2015; Elnaggar, 2016; Okafor et al., 2008; Srilakshmi & Chaganti, 2013). Elnaggar (2016) reported increased bone density when NMES was coupled with weight bearing. When

administered under proper supervision and with appropriate settings, NMES can be an effective therapeutic modality for infants with NBPP without noticeable complications or contra-indications.

In our study, an unexpected finding was that 1 of 10 infants (10%) in the NMES treatment group required primary nerve surgery, whereas 3 of 7 infants (43%) in the control/sham group required nerve surgery. In both groups, the average age at the time of primary nerve surgery was 8 months. Overall, irrespective of demographics, NMES seems to have a potentially significant role in the management of infants with NBPP. However, further studies are warranted.

Limitations

Several limitations exist regarding this study. Only one muscle group was employed, and in infants, the biceps muscle is very small. The smallest electrodes available were used; however, it would be potentially possible for input from the NMES to overflow into muscles surrounding the biceps; therefore, infants under 3 months of age were not considered for this study. To adhere to a strict protocol and ensure patient safety, the 1.25-cm electrodes were not altered in any way. The sample size was limited because of the incidence of NBPP, funding, and the stringent inclusion and exclusion criteria of the study design. All attempts were made to include a diverse patient population, but the achievable demographics, although not ideal, are representative of the population in our clinic. Analysis of AROM and muscle strength was included in lieu of the Active Movement Scale (AMS) and the Toronto Test Score (TTS). Although the AMS and TTS are widely applied as assessment and outcome measurements for the condition of NBPP, measurements of strength using the MRC and range of motion are also recognized as valid assessment and outcome measures for infants with NBPP (Chang et al., 2013). Moreover, improvements in AROM can be detected in smaller increments, which are not derived from the use of the AMS alone. For practical reasons, the follow-up timeframe for this study was 3 months. However, the length of intervention and/or post intervention follow up should be considered in future studies. Lastly, the Empi Continuum™ NMES unit is no longer manufactured, so any subsequent application of the findings may need to employ currently available equipment.

Clinical Guidelines

Based on the current study, we suggest that the use of NMES at home by attentive and trained parents is a safe and effective method for improving biceps function. NMES can be applied on infants with NBPP from 3 to 9 months of age at home or in the clinic setting, 30 min a day during functional activities, such as playtime or eating. Suggested machine setting: on time of 10 s, off time of 30 s, ramp time of 2 s, pulse rate of 35 Hz, pulse width of 300 μs, symmetrical waveform, simultaneous cycling, and amplitude of 4. Use of NMES at home and in the clinic can be beneficial and should be included in the early rehabilitation protocol for infants with NBPP.

Conclusion

Before surgical intervention to the nerves of the brachial plexus, the functional outcomes of therapeutic intervention should be maximized. Beyond maintaining a passive range of motion, improving active elbow flexion is essential. In addition to the standard therapeutic techniques, we recommend initiation of NMES in infants with NBPP between 3 and 9 months of age with a biceps MRC > 1 and < 5. This study suggests that using NMES for 30 min daily at home by attentive parents who are properly trained is a significantly effective method for augmenting active elbow flexion, especially in the first month of use. Additional improvements may include decreased substitution patterns. NMES is not harmful to the participant when training is appropriate and precautions are followed. Given that NMES is effective

for improving active elbow flexion, reimbursement for this intervention in therapy and coverage for a home unit is warranted.

Further studies using NMES for infants with NBPP relative to long-term outcomes should consider timing of initiation, use among other weak muscle groups, application to muscles with MRC strengths < 2-, and postoperative benefits. In addition, analysis of arm function beyond body structure and function between treatment groups should be considered. Specifically, studies related to the quality, quantity, frequency, and incorporation of arm movement after use of NMES are indicated and would significantly enhance the knowledge of the effects of this treatment modality. Alternative study designs could also be considered among infants younger than 3 months or multi-center setting.

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Appendix A

Neuromuscular Electrical Stimulation (NMES) Empi Continuum™ Device Settings

	NMES Treatment	**Sham / Control**
Small muscle	Biceps	Biceps
On time	10 s	0 s
Off time	30 s	60 s
Rate (pulse/sec)	35 Hz	35 Hz
Width	300 μs	48 μs
Waveform	Symmetrical	Symmetrical
Cycling	Simultaneous	Simultaneous
Ramp time	2 s	0 s
Automatic shut off	30 min	30 min
Amplitude*	4	4

Note. Parents in both groups instructed to turn machine to Level 4.

Appendix B

Placement of Electrodes on Biceps for Neuromuscular Electrical Stimulation