

Research Article

Comparing the effects of functional electrical stimulation with different frequencies and time duration to improve lower extremity muscle strength, gait, balance, posture control, and quality of life among stroke patients: A systematic review

Kiran Khushnood^{1*}, Saira Waqar², Ikram Ali³

ABSTRACT

Background: Sufficient literature is available regarding Functional Electrical stimulation (FES) for its effects on the function of both the upper limb and lower limb. However, there is still a lack of literature that describes accurate frequency and time duration of FES in improving lower limb functions. Therefore, this review aimed to report the effects of FES regarding its various frequencies, duration, and intensity in improving lower limb muscle strength, gait, posture, and quality of life in patients with stroke.

Methods: We included all those individuals with stroke (Hemiplegia) both acute and chronic irrespective of its type ischemic and hemorrhagic. All patients were well-oriented without cognitive impairments aged between 45 and 80 years old. Randomized controlled trials in which patients were provided FES either four channels or bi-channels on various muscles of the lower limb only were selected. In addition, we only included those RCTs, where FES was applied with specific frequencies and durations on the lower limb only.

Results: The participants in the included studies ranged from 16 to 61 years of age. The majority of the studies were conducted with a population with post-stroke duration of ≥ 6 months. It was evident that functional electrical stimulation with low frequencies is effective in improving various outcomes related to function in the stroke population ($P < 0.05$).

Conclusion: Functional electrical stimulation with low frequency improves activities of daily living, balance, gait, mobility, postural control, and range of motion, and reduces spasticity and foot drop. For rehabilitation, it would be important to replicate the findings by conducting highly randomized control trials with high quality and a larger number of samples.

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INTRODUCTION

Functional Electrical Stimulation (FES) indemnifies voluntary muscle contractions in patients with spinal cord injury and stroke[1]. In the past, its use was limited to improving the function of the dorsiflexors but now its applications are widely used to improve muscular strength, motor control, posture, gait, and other body functions[2]. It has been demonstrated that giving stroke survivors brief, controlled current bursts to the muscles and nerves in the damaged area improves their ability to use their paretic extremity for performing motor tasks[3, 4]. Electrical stimulation is one such strategy that has the potential to improve motor outcomes, resulting in increased activity performance and involvement following stroke. However, there are other types of electrical stimulation. Functional electrical stimulation (FES) helps improve performance by contracting muscles during activities like sitting, standing, walking, and reaching for objects [5].

A comprehensive review of the literature highlights multiple studies outlining the effects of FES on different mobility outcomes. A systematic review by Shelialah et al. on the effectiveness of FES in improving lower extremity functions. Seven Randomized control trials (RCT) with a pooled sample of 231 subjects were included where a comparison of other interventions was done with FES. The study concluded that FES improves lower extremity functions and gait, although its superiority over gait training interventions was still not clear[4].

Owen et al in their systematic review on the effects of FES on activity after stroke. Eighteen trials included in their review have shown that FES had a modest impact on activity compared with placebo or no intervention and training alone. Subgroup analyses, however, discovered that, in contrast to control groups, FES had a significant effect on upper-limb activity and a negligible impact on walking speed. This concludes that FES could be used on stroke subjects to improve their performance ability in various activities of daily life (ADLs)[5]. A meta-analysis was conducted by Henriette et al on electrical stimulation of the lower limb while exercising to improve functional motor ability and gait speed post-stroke; 8 trials with 191 subjects and an exploratory meta-analysis was done which showed that a combination of electrical stimulation with exercises improves ADLs[6].

According to Emilia et al motricity index and trunk control significantly increase by applying rectangular biphasic pulses having pulse width and frequency of 300 μ s and 20 Hz respectively for 15 minutes [7].

In 2010, Sabut K et al. assessed the therapeutic effectiveness of Biphasic rectangular pulses at 40 Hz frequency, 0.3 ms pulse width, and a maximum tolerated strength of 20 to 60 mA, for the activation of the Tibialis anterior (TA) muscle during locomotion in stroke patients. It was discovered that this 60-minute, five-day-a-week regimen with a 12-week follow-up was beneficial for restoring gait speed[8].

Kafri M et.al (2014) in their systematic review mentioned significant improvement with respect to their outcome variables [9]. Similarly, I.R Anke et.al (2004) carried out a systematic review to determine the orthotic effects of FES on improving walking speed in stroke patients. They mention the intensity and duration of functional electrical stimulations and their effects on walking speed [10].

Various reviews have been conducted regarding the effects of FES as an orthotic device (when it is applied on specific muscles) or as carry-over effects (when not applied) on both upper limb and lower limb function in stroke rehabilitation. However, there is a lack of literature regarding the use of frequency with accurate frequency and time duration in improving lower limb function. Therefore, our aim was to report the effects of FES in regard to its various frequencies, duration, and intensity in muscle strength, gait, posture, and quality of life in individuals with both acute and chronic stroke.

METHODS

Protocol and Registration: We followed Preferred reporting elements for systematic reviews and meta-analyses (PRISMA) criteria in the reporting of the review. This review title was registered prospectively on Prospero with reference number CRD42021227220. There were a few changes when the SR was first designed and later conducted. The revisions were submitted to Prospero later.

Eligibility Criteria: PICOS criteria were used to determine the eligibility of this systematic review. Participants were stroke patients; acute inpatients (less than 3 months) and chronic outpatients (more than 3 months), both genders, aged 20 to 85 years. Treatment sessions lasted for at least 2 weeks' duration. The major outcomes were Gait, Muscle strength, balance, and posture control improvement. The secondary outcome was quality of life assessment using various scales and tools. The selected studies were those RCTs where FES was applied with specific frequency and duration. Comparison was made with either standard rehab exercise protocol or placebo. Only randomized controlled trials (RCTs) were included.

Information Sources and Search Strategy: Three authors did an independent search of four electronic databases (Google Scholar, PubMed, Cochrane, and Physiotherapy Evidence Database). The study's publishing date was limited to be published between 2000 and 2021. Our search strategy started as a broader search that is "functional electrical stimulation" AND stroke, then it was further narrowed down to functional electrical stimulation" AND stroke AND "lower extremity" OR lower limb AND gait OR balance OR muscle strength OR posture OR Quality of life. For further research, the chosen articles' reference lists were examined. The language utilized for the search was only English. After a thorough search of the literature, studies were vetted and chosen using the predetermined format of PICOS. The evidence quality and strength of each study were assessed using the Oxford Centre for Evidence-Based Medicine standards.

Study Selection Process: About 778 results came, out of which 16 duplicates were removed 101 studies were left after initial title screening, and 67 after screening of abstracts. Studies with individuals who suffered from ailments other than stroke, such as neurological disorders, amputations, fractures, cognitive impairments, or incapacity to stand and walk short distances, were eliminated, totaling twenty-three. Excluded studies included non-English language studies, abstracts

only, non-randomized controlled trials, and principal interventions other than functional electrical stimulation. Figure 1 displays the PRISMA flow chart for the literature search.

Data Collection Process and Data Items: The following information was extracted by 2 authors independently to a predesigned Microsoft Excel (Microsoft Corp) sheet: characteristics of the study (first author, year of publication, and study design), characteristics of the participants, the outcomes which included; Fugl-Meyer assessment (FMA) for motor function, Berg Balance Scale (BBS) for balance, timed up and go (TUG) for balance and mobility, Dynamic gait index (DGA), 10 meter walk test (10MWT), 6 minute walk test (6MWT), and G.A.I.T for gait, mobility and ambulation, Composite spasticity scale (CSS), Tardieu scale (TS) and modified Ashworth scale (MAS) for spasticity, modified Barthel index (MBI) for activities of daily living trunk control test, and upright motor control for motor control, manual muscle strength (MMT) for strength, range of motion (ROM), and Stroke Impact Scale (SIS) for overall functions after stroke. Studies with the Functional Ambulation Category (FAC) test, Postural assessment scale for stroke patients (PASS), performance-oriented mobility assessment (POMA), walking speed, and Physiological Cost Index (PCI) of gait were also included. Twenty-three studies fulfilled the criteria and were included in the review.

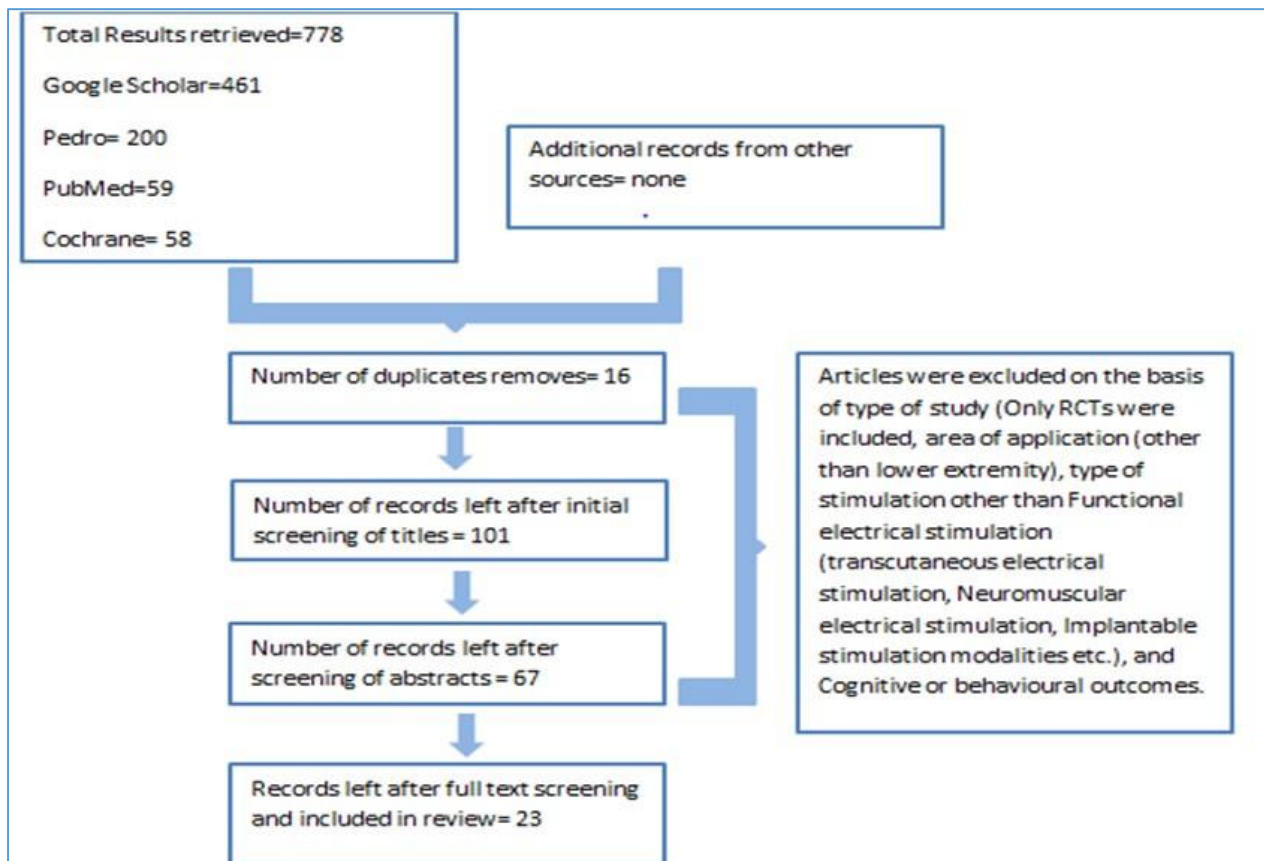


Figure 1: PRISMA diagram

RESULTS

Study Selection: 778 articles were found in the first search. Duplicate titles were removed after screening them. After evaluating the remaining 135 papers for eligibility, 109 more were disqualified for not meeting the pre-established PICOS standards. The studies where frequency and pulse width were not mentioned or in which implantable FES device used were also excluded. The final qualitative review included twenty-three randomized controlled trials, out of which two didn't mention the number of participating subjects.

Study Characteristics: The participants in the included studies ranged from 16 to 61 years of age. The majority of the studies were conducted with a population with post-stroke duration of ≥ 6 months. There was 1 study that included subjects with ≥ 3 months post-stroke. Given that the gender distribution was not addressed in much of the research, comments on it were not possible. Table 1. lists each study's interventions, features, length of study, results, and level of evidence.

When Functional electrical stimulation training of low frequency from 10 to 65 HZ of pulse width 100 to 400 microseconds from 2 to 12 weeks for 30 minutes FES training compared with standard rehab protocols, according to the Fugl-Meyer Assessment, Berg Balance Scale, and Time Up and Go test, a substantial difference ($p > 0.05$) was seen between the post-intervention scores of intervention and control groups for improving the mobility and balance in the FES group. Nevertheless, these investigations showed that the FES training group had a significant statistical change ($p < 0.05$). One study reported FMA; of 0.471 and 0.338, and BBS; of 0.123 and 0.442. According to that, no statistical difference was found on balance in the FES group along with electromechanical gait trainer on (BBS) $P = 0.170$. For gait assessment Dynamic gait index, G.A.I.T, walking speed, and Physiologic cost of gait index indicated significant statistical improvement to FES effectiveness in stroke. Mobility in stroke patients was measured through a 10-meter, 6-minute walk test that indicated a statistical significant improvement $p < 0.05$.

A study of functional electrical stimulation along with exercises done for weight transfer and standing balance done for 2 weeks in acute stroke has not shown any significant difference $P > 0.05$ for improvement in gait, mobility, balance, and weight Transfer. The postural assessment was done through PASS, trunk control, and upright motor control postural assessment scale of stroke that indicated a statistically significant difference in the FES group $P < 0.05$. The 2 weeks of FES training for

functional independence did not improve along with the electro-mechanical trainer.

Another 4-week study of 1-19 minutes of FES training along with cycling on POMA, leg subscale MI, and MAS didn't indicate a significant difference. No statistically significant change was seen in the walking speed of chronic foot drop stroke patients who were treated with a peroneal nerve stimulator along AFO with an alternative set of FES frequencies from 1-2 MHz Similar to intensive 2 daily sessions of 30 minutes of 200 Hz high-frequency FES didn't statistically improved walking speed on functional ambulatory category test in stroke patients.

A modest sample size, lack of information about gender ratio, lack of information about dropout rate, only a single study of high-frequency FES with less reported outcomes, no study found on the impact of low and high-frequency FES training on stroke patient quality of life and lack of a description of the random assignment are the study's shortcomings. 2014 saw the release of the checklist "Template for Intervention Description and Replication (TIDieR)", an expansion of "Consort 2010". The purpose of developing this guideline and checklist was to help enhance the completeness of reporting interventions in research studies. This review's studies that were published after 2014 did not use the TIDieR checklist or report findings.

Table 1: Characteristics of the studies

Author with Year	Population	Intervention	Comparison	Outcome measures	Mean + SD/Pre-test post-test/ median/ mean difference	P value/ effect size	Level of evidence
Gouging You, Huiying Liang, Tiebin Yan. 2014 [3]	37 stroke subjects, ≥ 6 months post-stroke	FES applied 5x/week for 30 min, 3 weeks. Dual channel stimulator, 30 Hz, 200 μs	Standard rehab	CSS, lower-extremity FMA, PASS, BBS, MBI	Intervention Group (Pre-post mean±SD): CSS 9.9±2.8 to 10.9±1.8, FMA 11.3±4.8 to 22.3±7.9, PASS 20.1±9.4 to 30.8±5.1, BBS 15.9±17.3 to 46.4±20.1. Control Group: CSS 9.9±2.8 to 13.1±0.6, FMA 11.4±5.9 to 17.2±7.2, PASS 18.3±10 to 28.4±6.2, BBS 15.4±20.3 to 34.2±14.6	p<0.05 for all outcome measures	A1b
Fareeha Shafi, Samina Ghulam, Arshad Nawaz Malik, Quratulain Saeed. 2017 [11]	NA	FES on tibialis muscle in alternating mode, 20-30 min, 5x/week for 6 weeks. Frequency 40 Hz, pulse width 7-365 μs	Conventional electrical stimulation on tibialis anterior, 10 min/day, 5x/week for 6 weeks	FMA, MAS, BBS, TUG, DGI	Intervention Group (Pre-post mean±SD): FMA 12.26±1.56 to 22.42±2.89, TUG 35.42±12.98 to 17.00±5.81, BBS 25.35±7.5 to 47.63±2.7. MAS Mean rank: 19.55 to 19.45, GDI: 17.95 to 23.97. Control Group: FMA 12.31±2.10 to 15.36±2.52, TUG 36.37±13.76 to 33.00±12.74, BBS 25.58±7.06 to 29.42±6.5	Significant improvement: FMA (p<0.001), MAS (p=0.027), BBS (p<0.001), TUG (p<0.001), DGI (p=0.012)	A1b
Yan T et al. [12]	46	FES, 60 min, 5x/week for 3 weeks (15 sessions), 30 Hz, 0.3 ms width	Placebo stimulation	CSS, ankle dorsiflexion torque	Intervention Group: CSS 7.3±3.1 to 30.5±35.3, MIVS torque 2.0±2.2 to 9.0±4.6, EMG co-contraction ratio 34.9±17.5 to 7.8±5.3, TUG 66.0±29.5 to 39.2±30.4. Control Group: CSS 6.1±2.6 to 64.6±64.8, MIVC torque 2.3±2.0 to 4.4±5.2	p≥0.05 for CSS and TUG, P<0.05 for MIVC	A1b
Dujović SD, Malešević J, Malešević N, Vidaković AS, Bijelić G Keller T, Konstantinović L. 2017 [13]	16	FES, 60 min (20 min for 1st week, 30-40 min for rest of 4 weeks)	Conventional rehab	10 MWT, FMA, BBS, MBI	Intervention Group Mean Difference: Gait 0.13±0.05, FMA 3.5±2.3, BBS 10.7±8.1, BI 11.9±11.6. Control Group: Gait 0.03±0.09, FMA 2.5±3, BBS 5.4±4.4, BI 9.3±13.6	Gait: p=0.022, effect size 0.326; FMA: P=0.471, effect size 0.338; BBS: P=0.123, effect size 0.442; BI: P=0.684, effect size 0.612	A1b
Salhab G, Sarraj AR, Saleh S. 2016 [14]	18	50 min mirror therapy with ES (symmetrical biphasic, <10 Hz, 300 μs)	Conventional therapy	Ankle ROM	Ankle dorsiflexion t-value: -5.188, F=31.844, P<0.001. FMA t-score: -4.945, F=11.228, P<0.001. 10 M score t-value: -1.423, F=16.775, P=0.011	P<0.0001	A1b
Ambrosini E et al. 2011 [7]	36	Low (20Hz) with 300 μs pulse, 5 times/week, 20 sessions of 25 minutes each. Muscle strengthening, conditioning, stretching, trunk control, standing exercises with walk training.	Placebo FES cycling	Motorcity index leg subscale, gait speed, trunk control test (TCT), upright motor control test (UMCT), single limb standing	Intervention Group: Motorcity index: 39±29 - 69±29, Gait speed: 0.11±0.25 - 0.39±0.30, TCT: 46±19 - 78±25, UMCT: 1.4±1.5 - 3.7±1.7, Control Group: Motorcity index: 45±34 - 55±29, Gait speed: 0.11±0.24 - 0.29±0.28, TCT: 58±20 - 67±17, UMCT: 1.7±1.9 - 2.3±1.9	Between-group P value: - Motorcity index: < 0.01 (0.36) - Gait: 0.366 (0.030) - TCT: 0.001 (0.331) - UMCT: 0.005 (0.258)	A1b
Sukanta K. Sabut, Chhanda Sikdar, Ratnesh Kumar, Manjunatha mahadevappa. 2011 [15]	51	Conventional rehabilitation, stimulation of anterior tibial muscle and peroneal nerve for 20-30 minutes, 1 hour/session for 12 weeks (5 days/week), at 35 Hz and 0.28 ms pulse width.	-	MAS, MMT, ROM, Handheld goniometer, FMA	Active ankle dorsiflexors: 7.9±8.5 - 9.8±8.9, Passive ROM: 38.9±10.4 - 47.3±10.6, FMA: 19.3±4.7 - 21.6±5.5	p-value for all outcome measures: < 0.05	A1b
Min-Kwon Cho et al. 2015 [16]	34 stroke patients (>6 months), 31 analyzed (19 males, 12 females)	Treadmill with FES (GM and TA muscles); 30 minutes/session, 5 days/week for 4 weeks. Also received regular PT for an hour 5 days/week for 4 weeks. FES had 40 Hz frequency and 200 ms pulse width.	Intervention Group 2: Treadmill with FES applied to TA muscle (TTFES-TA) Control Group: Treadmill alone	GAITrite, 6MWT, MMT, BBS	TTFES-GM + TA group: Gait velocity: 42.5±15.9 - 62.3±19.8, Cadence: 67.0±19.8-83.1±11.7, 6MWT: 208.8±92.7 - 255.6±94.4, BBS: 46.7±7.5 - 51.9±3.8, TA MMT: 4.4±3.7 - 6.1±3.9, GM MMT: 8.9±3.2 - 10.3±2.9, TTFES-TA group: Velocity: 40.3±14.5 - 50.6±11.4, Cadence: 72.7±11.9 - 80.0±10.5, 6MWT: 187.8±69.3 - 200.4±62.6, BBS: 47.8±4.3 - 50.1±4.0, TA MMT: 2.7±2.4 - 4.3±3.3, GM MMT: 7.5±2.4 - 7.7±2.2 Control Group: Velocity: 47.4±18.1 - 48.4±20.4, Cadence: 76.1±17.0 - 74.2±15.7, 6MWT: 204.1±74.9 - 215.7±85.4, BBS: 49.3±6.0 - 51.0±5.0, TA MMT: 4.0±3.8 - 4.1±3.7, GM MMT: 7.3±2.4 - 7.4±2.5	p-value for all outcome measures: < 0.05	A1b
David G. Embrey, Sandra L. Holtz, Gad Alon, Brenna A. Brandsma, Sarah Westcott McCoy. 2009 [17]	Randomized cross-over design, 28 subjects (16 males, 12 females; mean age 60±10.9 years)	FES system for 3 months while walking for 6-8 hours/day, 7 days/week, plus one hour/day, six days/week. Asymmetrical waveform at 35 or 50 Hz.	Walking for 1 hour/day, 6 days/week without FES for 3 months.	6MWT, Emory Functional Ambulatory Profile (EFAP), SIS	Intervention A: 6MWT: 47.7±40.3 m, EFAP: Decrease in A-B group: 23.7±23.9 seconds vs. B-A group: 9.8±8.9 seconds, SIS: 23.5±26.6 points (A-B group) vs. 3.6±28.0 points (B-A group)	p-value for all interventions: <0.05	A1b
Lee et. Al 2013 [18]	16	Biphasic symmetrical square pulse with 60 Hz frequency, 300 μs pulse width, 1-second on/off cycle.	Ergometer training	6MWT, BBS, MET	Intervention Group: 6MWT: 193.6±102.97 - 266.25±113.38, BBS: 43.88±7.14 - 47.13±6.98, MET: 4.55±0.82 - 5.10±0.82 Control Group: 6MWT: 291.0±82.61 - 331.50±60.22, - MET: 5.75±1.66 - 5.79±2.01	p-value for all outcome measures: < 0.05	A1b
Hwang, Dal-Yeona, Lee, Hwang-Jaeb, Lee, Gyu-Changc, Lee, Suk-Mina. 2014 [19]	32	Tilt sensor in FES with treadmill training (25 Hz, 150 μs, 60-150 V) for 4 weeks, 30 min/day	Conventional physical therapy	TUG, BBS, 10MWT	Intervention group: 10MWT: 28.02±4.05 → 20.51±2.94, TUG: 23.31±3.94 → 15.03±2.75, BBS: 37.87±3.94 → 50.00±1.89, Control group: 10MWT: 31.23±5.07 → 25.99±4.35, TUG: 21.85±3.55 → 16.96±2.74, BBS: 38.20±3.97 → 45.20±2.65	p<0.05 for all outcome measures	A1b
Daly. Et al 2011 [20]	53	Electrical stimulation (4-20 mA, 1-150 μs, 15-50 Hz) for 1.5 hours/session, 4 sessions/week for 12 weeks, combined with strength training, BIODEX, and on-ground training	Strength training, BIODEX, and on-ground training	GAIT, MMT, 6MWT	Intervention group: GAIT: 33.25±9.75 → 25.0±7.75, 6MWT: 161.54±80.0 → 218.89±107.4, MMT: 2.17±1.20 → 3.15±1.20, BBS: 13±4.74 → 15±2.0. Control group: GAIT: 33.5±9.75 → 27.5±9.0, MMT: 1.99±0.91 → 2.46±1.27, BBS: 11.5±5.75 → 14.5±3.75, 6MWT: 126.85±93.2 → 171.37±125.2	-	A1b
Subeen Bae, Jin Lee, Byoung-Hee Lee 2020 [21]	26	Electrical stimulation (35 Hz, 250 μs) and physical therapy for 30 min/session, 4 weeks (20 sessions)	Standard physical therapy	WBLT, TS, TUG, BBS	Intervention group: WBLT: 1.92±1.44, TS: -0.55±0.50, TUG: -7.81±7.84, BBS: 7.15±3.93 Control group: WBLT: 0.73±0.78, TS: -0.11±0.60, TUG: -2.35±3.51, BBS: 4.00±3.08	-	A1b

Continued

Continued

Author with Year	Population	Intervention	Comparison	Outcome measures	Mean + SD/Pre-test post-test/ median/ mean difference	P value/ effect size	Level of evidence
Kyunghoon K. el. Al 2015 [22]	22	FES (400 μ s, 40 Hz), 30 min/session, 5 times/week for 6 weeks (30 sessions), with stretching and proprioception training	FES with stretching (400 μ s, 40 Hz), 30 min/session, 5 times/week for 6 weeks (30 sessions)	BBS, TUG	Intervention group: BBS: 48.9 \pm 4.1 \rightarrow 50.8 \pm 3.5, TUG: 19.2 \pm 4.1 \rightarrow 12.8 \pm 2.7, Control group: BBS: 47.3 \pm 3.0 \rightarrow 52.2 \pm 2.1, TUG: 19.3 \pm 4.3 \rightarrow 11.7 \pm 2.7	-	A1b
Tsubasa Mitsutakea , Maiko Sakamoto and Etsuo Horikawab 2019 [23]	36	Tilt sensor FES (300 μ s, 33 Hz), 60 min/session for 2 weeks	Combined electrical stimulation group (conventional intervention + EMG-triggered NMES + tilt sensor FES, 20 min each)	10MWT, body sway	Single stimulation group: 10MWT: 0.66 \pm 0.25 \rightarrow 0.76 \pm 0.28, Body sway (vertical): 4.87 \pm 6.56 \rightarrow 4.17 \pm 4.40, Body sway (mediolateral): 3.94 \pm 5.20 \rightarrow 3.41 \pm 4.30, Body sway (anteroposterior): 4.40 \pm 6.23 \rightarrow 3.37 \pm 3.44 Combined group: 10MWT: 0.63 \pm 0.13 \rightarrow 0.81 \pm 0.13, Body sway (vertical): 4.34 \pm 1.75 \rightarrow 2.73 \pm 0.89, Body sway (mediolateral): 3.70 \pm 2.00 \rightarrow 2.28 \pm 1.11, Body sway (anteroposterior): 3.17 \pm 1.33 \rightarrow 2.04 \pm 1.04	10MWT: d=1.39, p<0.001 Body sway (vertical): d=1.16, P=0.002 Body sway (mediolateral): d=0.88, p=0.002 Body sway (anteroposterior): d=0.95, p=0.001	A1b
Zhimei Tan 2014 [24]	45	4-channel FES, 30 Hz and 200 μ s for 30 minutes, 5 days/week for 3 weeks with 3-month follow-up	2-channel GP & placebo	FMA, PASS, BBS, FAC, MBI	Interventional Group: FMA: 14.5 \pm 5.1 \rightarrow 21.8 \pm 4.9, PASS: 18.9 \pm 8.8 \rightarrow 29.8 \pm 4.3, BBS: 17.2 \pm 14.9 \rightarrow 39.1 \pm 13.5, MBI: 48.9 \pm 23.8 \rightarrow 80.3 \pm 16.5, FAC: 1.1 \pm 1.4 \rightarrow 2.6 \pm 1.6 Control Group: FMA: 14.8 \pm 5.6 \rightarrow 18.2 \pm 5.4, PASS: 20.4 \pm 9.1 \rightarrow 24.1 \pm 8.1, BBS: 16.5 \pm 16.7 \rightarrow 25.4 \pm 18.3, MBI: 48.5 \pm 21.7 \rightarrow 66.7 \pm 19.1, FAC: 0.8 \pm 1.3 \rightarrow 1.5 \pm 1.3	FMA, MBI scores improved significantly (p<0.05) in the 4-channel group after 3 weeks. The 4-channel group also had significantly higher PASS, BBS, MBI, and FAC scores than the placebo group.	A1b
I.A. Solopova, D.Y. Tihonov, A.A. Grishina, and Y.P. Ivanenkov 2011 [25]	61	16-channel stimulator (MNS 16-02) with 65 Hz, 80 mA max amplitude, and 100 μ s pulse width	Conventional therapy	FMA, NIHSS, ESS, BI	Interventional Group: FMA: 10.6 \pm 3.1 \rightarrow 28.5 \pm 3.8 Control Group: FMA: 8.7 \pm 2.9 \rightarrow 16.4 \pm 3.9	p<0.05	A1b
Dorit Kunkel et.al 2012 [26]	21	2-channel Odstock stimulator (40 Hz, 162 ms) for 2 weeks with follow-up	Balance training	Balance, weight transfer, symmetry, mobility, gait	Interventional Group: Berg Balance: 44.7 (3.4) \rightarrow 49.1 (5.4), Rivermead Mobility Index: 10.1 (3.4) \rightarrow 11.6 (3.3) Control Group: Berg Balance: 27.5 (10.6) \rightarrow 35.8 (12.0), Rivermead Mobility Index: 5.3 (2.6) \rightarrow 7.0 (2.9)	p>0.05 (all outcome measures)	A1b
Petra Bauer, Carmen Krewer, Stefan Golaszewski, Eberhard Koenig, Friedemann Müller 2015 [27]	40	Cycling with FES (20-60 Hz, 300-450 μ s pulse)	Active leg cycling without FES	FAC, POMA, MI (leg subscale), MAS	Interventional Group: FAC: 0 \pm 0 \rightarrow 2 \pm 0, POMA: 2 \pm 1 \rightarrow 6 \pm 1, MI: 25 \pm 4 \rightarrow 36 \pm 5 Control Group: FAC: 0 \pm 0 \rightarrow 1 \pm 0, POMA: 3 \pm 1 \rightarrow 4 \pm 1, MI: 22 \pm 4 \rightarrow 34 \pm 5	Between Group Difference: FAC: U=105, z=2.11, p=0.042, r=0.35 POMA: U=115, z=1.73, p=0.086, r=0.28 MI: U=159, z=0.37, p=0.730, r=0.06	A1b
Catherine et al. 2002 [28]	21 (12 months post-stroke)	Stimulation (40 Hz, 350 ms, 100 mA) + Botulinum neurotoxin injection + physiotherapy	Physiotherapy	Walking speed, Physiological Cost Index (PCI)	Significant changes were observed in the treatment group compared to control. Walking speed improved in both groups (median, p=0.02 for control, p=0.042 for treatment). PCI showed a significant downward trend for the treatment group (p=0.007). Trend lines differed significantly between groups (p=0.038).	Significant differences between groups	A1b
Shin-Jun Park, PT, MS1, Joong-San Wang 2017 [29]	Tested subjects using 35 Hz frequency, 280 μ s pulse, at tolerance level.	TENS programmed to change frequency (0-100 Hz) and pulse (20-700 μ s).	Control group received no electrical stimulation.	Cadence, Speed, Stride Length, Swing Phase Duration, Stance Phase Duration, Double Support Duration	Intervention group improved: Cadence 67.6 \pm 14.3 to 80.58 \pm 15.5 steps/min, Speed 0.6 \pm 0.1 to 0.78 \pm 0.1 m/s, Stride Length 1.1 \pm 0.1 to 1.17 \pm 0.7 m, Swing Phase Duration 37.0 \pm 5.6% to 39.95 \pm 9.7%, Stance Phase Duration 62.9 \pm 5.6% to 60.05 \pm 9.7%, Double Support Duration 16.7 \pm 4.0% to 17.95 \pm 4.8%. Control group showed lesser changes in gait parameters.	Significant difference before and after the electrical stimulation in each group (p<0.05).	A1b
Sukanta K. Sabut1, Chanda Sikdar2, Ramkrishna Mondal2, Ratnesh Kumar2 & Manjunatha Mahadevappa 2010 [8]	30 hemiparetic participants (24 males, 6 females) with spastic foot-drop, 3 months post-stroke.	Electrical stimulation applied to tibialis anterior (TA) muscle: bi-phasic rectangular pulse, 40 Hz, pulse width 0.3 ms, for 30 mins.	Standard stroke rehabilitation: physiotherapy based on neurodevelopmental facilitation, occupational therapy for 60 mins/day, 5 days/week, for 12 weeks.	Gait parameters, Fugl-Meyer Assessment (FMA), Modified Ashworth Scale (MAS), Range of Motion (ROM)	Calf spasticity reduced by 0.8 points on Ashworth scale, ROM improved by 60%, FMA score improved from 17.2 to 25.1 (45.93% increase) in FES group compared to 17.9 to 21.4 (19.5%) in control group.	Significant changes observed in treatment group. (p<0.05)	A1b
Zheng X et.al 2018 [30]	NA	Four-channel FES for 30 mins over 3 weeks: 30 Hz, pulse width 0.2 ms.	Dual-channel group and placebo group (control).	FMA, Postural Assessment Scale for Stroke (PASS), Brunel Balance Assessment (BBA), Barthel Balance Scale (BBS), Modified Barthel Index (MBI)	Four-channel group showed significant improvement in MBI, PASS, BBA, BBS, and FMA scores compared to dual-channel and placebo groups (p<0.05). Improvement sustained at 3 weeks (PASS, BBS, FMA, MBI; p \leq 0.001).	< 0.05	A1b

DISCUSSION

The aim of this review was to assess the effects of FES on lower limb function; balance, gait, postural control, spasticity, mobility, strength, activities of daily living, and quality of life. In this systematic review, it was evident that functional electrical stimulation with different frequencies and pulse widths is effective in improving several outcomes for functional performance in subjects with stroke. Functional electrical stimulation is safe and has been used in the population with neurological disorders especially stroke for more than 2 decades. FES is well well-established intervention for motor rehabilitation. Motor neurons when stimulated via electrical stimulation result in muscle contraction and create or increase a moment around a joint. Transcutaneous electrodes provide the most instant and clinically viable therapeutic approach. The electrodes are non-invasive and may enable home-based treatment as well. FES has been widely used for research purposes post-stroke lower limb rehabilitation and has also been incorporated into treatment guidelines [6, 30, 31].

Functional electrical stimulation training with low frequency plays a significant role in improving mobility and balance in post-stroke patients as compared to standard rehabilitation[11, 32]. Improvements in mobility and gait parameters; gait speed, cadence, stance and swing duration, and double support duration have also been seen in the stroke subjects receiving FES along with standard rehabilitation as compared to standard rehabilitation alone [12, 17, 28].

Postural control is another important parameter for the rehabilitation of the stroke population and was seen to be improved in the group receiving FES. Positive effects have been reported by various studies conducted for postural control[33]. Lower limb muscle spasticity was also reported to be improved by the application of FES in stroke patients[11]. Whereas a combination of FES with cycling wasn't found to be effective in reducing spasticity [7].

Ankle range of motion, the strength of dorsiflexion and planter flexors as well as foot drop has also been found to improve by FES[14, 15, 31]. Various studies used FES for peroneal nerve stimulation to treat foot drop in the stroke population; which was targeted to ultimately improve the stroke gait pattern [13, 20, 31].

Duration after stroke is found to be an important aspect of the rate of improvement in various outcomes. It was seen that the post-stroke duration of more than 6 months has shown more improvement as compared to the population of acute stroke.[17, 28] A study on standing balance

and weight transfer in acute stroke subjects didn't show any differences in the outcome among both FES and control groups. Frequencies and pulse width are also major factors for improvement. It was observed that low frequencies have shown better results and were frequently used, whereas there was only one study with high frequency and the improvement in outcomes; walking speed and ambulation, wasn't seen in the participants. Quality of life consists of physical, psychological, and social factors, no study has found the effects of FES on quality of life, making a gap in the literature to look for these aspects too.

Patient-oriented evidence that matters (POEM) is a useful strategy for the up-gradation of practice. FES is found to be safe and non-invasive for subjects with stroke and has been shown to improve balance, motor control, strength, and range of motion; which ultimately prevents the person from falling. There is still a need for research to fill the long-term effects of FES on all outcomes. Blinding of participants in FES is not easy as every participant can accurately guess whether they belong to the FES group or control group. RCTs which follow the highest standards for external and internal validity are important to make better decisions for patients. Thus, it is compulsory to rule out confounders as well as sources of bias. Factors i.e. allocation concealment, blinding, and randomization are important in reducing biases in clinical trials.

The use of FES for stroke population is safe and by far no adverse effects have been reported. Studies reported very few or no adverse events. FES is feasible to use and can be used at home with guidance. Based on the strength of recommendation taxonomy, the evidence would be graded as level A. There is scarce literature about the assessment of the long-term effects of FES on mobility outcomes after stroke.

The major limitation of the review is the inclusion of articles in the English language; there were a few studies in other languages too, which couldn't be included because of the inability to translate.

CONCLUSION

It is concluded that functional electrical stimulation with low frequency improves activities of daily living, balance, gait, mobility, postural control, and range of motion reducing spasticity and foot drop. For rehabilitation, it would be important to replicate the findings by conducting highly randomized control trials with high quality and a larger number of samples along with a clear and equal distribution of males and females.

DECLARATIONS & STATEMENTS

Author's Contribution

KK, SW: substantial contributions to the conception and design of the study.

KK, SW and IA: acquisition of data for the study.

KK, SW and IA: interpretation of data for the study.

KK, SW and IA: analysis of the data for the study.

KK, SW: drafted the work.

KK, SW: revised it critically for important intellectual content.

KK: final approval of the version to be published and agreement to be accountable for all aspects.

Of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

All authors contributed to the article and approved the submitted version.

Ethical Statement

The review was registered at Prospero review registry.

Data Availability Statement

Data could be available on request from the corresponding author.

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Conflicts of Interest

The authors declare no conflict of interest.

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