Effects of External Electrical Stimulation on Functional Performance for Individuals with Spinal Cord Injury

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CLINICAL SCENARIO: Allen Dexter is 19 year-old college student who fell 30 feet while rock climbing and sustained a C5-C6 vertebral fracture. He was evaluated for occupational therapy services eleven days post-injury and he showed muscle activity against gravity in the trapezius, deltoid, and biceps brachii. He had trace function in forearm pronation and in wrist extensors. He had sensation to pin prick and some two-point discrimination was seen inconsistently to the elbow joint. Allen's vertebrae were fused and he wore a halo vest until the fusion healed. He is interested in the benefits of electrical stimulation in generating muscle action, especially in muscles with trace or very little movement.

FOCUSED CLINICAL QUESTION: Can external electrical stimulation improve functional performance for individuals with spinal cord injury?

SUMMARY of Search, 'Best' Evidence' appraised, and Key Findings:

- A randomized control trial found that functional electrical therapy is proven to be more effective in treating motor and grasp functioning in individuals with spinal cord injury compared to conventional occupational therapy.
- A randomized control trial found that electrical stimulation therapy improves grasp for individuals with spinal cord injury.
- A cohort study found that a two year personalized home-based FES program can improve denervated muscle structure but does not produce measurable functional movement in lower extremities.
- A cohort study found that electrical stimulation improves muscle strength after spinal cord injury, but does not significantly improve cycling power output.
- A cohort study found that a home-based FES program can decrease lower motor neuron denervation and recover muscles from atrophy.

CLINICAL BOTTOM LINE: Research shows that external electrical stimulation can increase functional performance, muscle strength, and muscle mass in persons with spinal cord injury. Functional performance gains were shown in two studies involving electrical stimulation in upper extremities. No functional improvements were shown in the three studies involving electrical stimulation in lower extremities, but muscle strength and mass were gained.

Limitations of this CAT: There is a general lack of recent research regarding external electrical stimulation. Many articles found studied implanted electrical stimulation and/or functional effects of electrical stimulation after stroke or traumatic brain injury. All studies reviewed in this CAT had relatively small sample sizes. There were no power calculations done to determine sample size necessary to gain statistically significant results.

SEARCH STRATEGY:

Terms used to guide Search Strategy:

Patient/Client Group: Individuals with spinal cord injury

Intervention (or Assessment): Functional electrical stimulation

Comparison: N/A

Outcome(s): Long-term functional effects of electrical stimulation

Databases and sites searched	Search Terms	Limits used
- Cinahl -Cochrane -PubMed	Electric stimulation Spinal cord injury Functional electrical stimulation Electric stimulation AND spinal cord injury Electric stimulation AND paraplegia Electric stimulation AND tetraplegia External electrical stimulation Electrical stimulation AND sci Electrical stimulation AND quadriplegia	English only Human subjects only Holm's level I-III Spinal Cord Injury

INCLUSION and EXCLUSION CRITERIA

Inclusion:
Published between 2001-present

English
Holm's level I-III
Peer reviewed journal
External electrical stimulation
Spinal cord injury
Human subjects

Exclusion:
Internal electrical stimulation

RESULTS OF SEARCH

Five relevant studies were located and categorized as shown in Table 1 below (based on Levels of Evidence, Holm's Criteria, AJOT, 2000.)

Table 1: Summary of Study Designs of Articles retrieved

Study Design/ Methodology of Articles Retrieved	Holm's Level	Number Located	Author (Year)
Randomized control trials	II	2	Popovic, Thrasher, Adams, Takes, Zivanovic, & Tonack (2006). Popovic, Kapadia, Zivanovic, Furian, Craven, McGillivray (2011).
Control trials without randomization; single subject designs; single group pre-post; cohort studies; time series; method case control	III	3	Kern, Carroro, Adami, Biral, Hofer, Forstner,…Zampieiri (2010). Duffell, Rowlerson, Donaldson, Harridge, & Newham (2010). Kern, Carroro, Adami, Hofer, Forstner, Loefler,…Zampieri. (2010).

BEST EVIDENCE

The following studies/papers were identified as the 'best' evidence and selected for critical appraisal:

Duffell, L., Rowlerson, A., Donaldson, N., Harridge, S., & Newham, D. (2010). Effects of endurance and strength-directed electrical stimulation training on the performance and histological properties of paralyzed human muscle: A pilot study. *Muscle and Nerve, 42*(5), 756-763.

Kern, H., Carroro, U., Adami, N., Biral, D., Hofer, C., Forstner, C.,…Zampieiri, S. (2010). Home-based functional electrical stimulation rescues permanently denervated muscles in paraplegic patients with complete lower motor neuron lesion. *Neurorehabilitation and Neural Repair, 24*(8), 709-721.

Kern, H., Carroro, U., Adami, N., Hofer, C., Forstner, C., Loefler, S.,…Zampieri, S. (2010). One year of home-based daily FES in complete lower motor neuron paraplegia: Recovery of tetanic contractility drives the structural improvements of denervated muscle. *Neurological Research, 32*(1), 5-12.

Popovic, M., Kapadia, N., Zivanovic, V., Furian, J., Craven, C., & McGillivray, C. (2011). Functional electrical stimulation therapy of voluntary grasping versus only conventional rehabilitation for patients with subacute incomplete tetraplegia: A randomized clinical trial. *Neurorehabilitation and Neural Repair*, *20*(10), 1-11.

Popovic, M., Thrasher, T., Adams, M., Takes, V., Zivanovic, V., & Tonack,. (2006). Functional electrical therapy: retraining grasping in spinal cord injury. *Spinal Cord, 44*, 143-151.

Reasons for selecting these studies were:
- Studies met inclusion criteria
- Studies used external electrical stimulation on human subjects from 2001-present
- Studies evaluated functional and/or physical outcomes

SUMMARY OF BEST EVIDENCE

Table 1: Description and appraisal of randomized control trial by Popovic, Thrasher, Adams, Takes, Zivanovic, & Tonack, (2006).

Aim/Objective of the Study: To assess the effectiveness of functional electrical therapy (FET) in treating SCI patients at a C3-C7 level with decreased motor and grasp functioning

Study Design: Randomized control trial.

Setting: Rehabilitation hospital for individuals with spinal cord injuries in Toronto, Canada.

Participants: A convenience sample of 21 individuals with spinal cord injuries ranging from

C3 to C7 were randomly assigned to 2 groups. Most participants were 8 months post-injury. The control group had 9 individuals while the intervention group contained 12 individuals. Participants were recruited from an inpatient SCI unit at the Toronto Rehabilitation Institute and received invitations to participate in the study. All participants had either a complete or incomplete spinal cord injury.

Intervention Investigated: Functional electrical therapy was used as the intervention. This consisted of grasping exercises using a neuroprosthesis that applied surface electrical stimulation to the arm to generate or assist in grasping movements. The control group received conventional occupational therapy interventions pertaining to hand functioning. Both groups received therapy from occupational therapists for 12 weeks, 5 days per week, for 45 minutes per session.

Control: The control group received conventional occupational therapy interventions pertaining to hand functioning.

Experimental: Functional electrical therapy consisting of grasping exercises using a neuroprosthesis that applied surface electrical stimulation to the arm to generate or assist in grasping movements was used on the experimental group. The experimental group also received conventional occupational therapy in addition to the FET.

Outcome Measures*:* Functional Independence Measure (FIM), Spinal Cord Independence Measure (SCIM), and the Rehabilitation Engineering Laboratory Hand Function Test (REL) were performed without stimulation by occupational therapist on all participants pre and post intervention at the Toronto Rehabilitation hospital. Total scores were looked at for the FIM and SCIM, as well as a total score for each arm on the REL. The REL consists of five components (objects, blocks, cylinder, credit card, and wooden bar) and evaluates improvements in gross motor functioning of unilateral grasp due to neuroprothesis for grasping treatment. Hand functions tested with the REL included lateral and palmer grasps.

Main Findings: At baseline the data did not show statistically significant results. Although participants who received FET in addition to traditional occupational therapy services did show more improvement in overall functional movement more than those who did not receive FET.

Original Authors' Conclusions: "Functional electrical therapy has the potential to be an effective treatment modality to restore grasping function in quadriplegia (p. 143)." FET can be implemented by occupational therapists in a clinical setting. Results showed that participants treated with a neuroprothesis for grasping showed overall better outcomes than the control group, but the improvements were not statistically significant. Further research is advised to establish suitable indications for participant selection as well as a larger participant base to provide statistical significance.

Critical Appraisal: Holm's Level II

Validity: AACPDM 5/7 (strong); weaknesses were lack of power analysis and assessor was not blinded

Interpretation of Results: This study showed that FET can be effective in treating individuals with C3-C7 spinal cord injuries, although it did not show statistically significant data. More research including larger groups of participants is needed.

Summary/Conclusion: Functional electrical therapy is proven to be more effective in treating motor and grasp functioning in individuals with spinal cord injuries compared to conventional occupational therapy.

Table 2: Description and appraisal of randomized controlled trial by Popovic, Kapadia, Zivanovic, Furian, Craven, & McGillivray, (2011).

Aim/Objective of the Study/Systematic Review: The purpose of the study was to examine the effectiveness of 40 hours of function electrical stimulation with conventional occupational therapy compared to only conventional occupational therapy to improve grasping.

Study Design: This was a randomized controlled trial study design. The staff who performed the outcome assessments were blinded to the study intervention and group allocation.

Setting: Inpatient rehabilitation

Participants: The study began with twenty-four participants, but there were three drop outs. The participants were recruited through staff referrals, poster campaign, and local advertisement during their initial inpatient rehabilitation after spinal cord injury. Females and males were involved in this study. The sample was convenience sampling. The inclusion criteria includes: (a) individuals who had sustained a traumatic incomplete spinal cord injury between C4 and C7, AIS B, C, or D, less than six months prior to the baseline assessment; (b) individuals 18 years old or older; (c) and individuals unable to grasp and manipulate objects either unilaterally or bilaterally to allow independent performance of activities of daily living. The exclusion criteria includes: (a) individuals who had contraindications for FES such as a cardiac pacemaker, skin lesions, or a rash at a potential electrode site; (b) individuals who suffered from cardiovascular conditions such as uncontrolled hypertension or autonomic dysreflexia requiring medication; or (c) individuals with denervated muscles (i.e., individuals who sustained partial or complete damage of the peripheral nerves that were innervating muscles of interest in addition to spinal cord injury). Indicate time frame of outcome measure.

Intervention Investigated: The adults who met inclusion criteria were randomized into the control and experimental group. They received 1 hour of conventional occupational therapy and 1 hour of functional electrical stimulation therapy or 2 hours of conventional occupational therapy between the right and left hands between the performed the outcome assessments were blinded to the study intervention and group allocation. Conventional occupational therapy included: (a) muscle facilitation exercises emphasizing the neurodevelopmental treatment approach; (b) task-specific, repetitive functional approaching; (c) strengthening and motor control training using resistance to available arm motion to increase strength; (d) stretching exercises; (e) electrical stimulation applied primarily for muscle strengthening; (f) practice of activities of daily living; (g) caregiver training.

Control: conventional occupational therapy

Experimental: 40 hours of functional electrical stimulation therapy paired with conventional occupational therapy

Outcome Measures:

Primary outcome measure: The FIM was used to measure the level of independence.

Secondary outcome measure: The spinal cord independence measure (SCIM) was used to measure the degree of disability in patients with traumatic and non traumatic spinal cord injury. It assesses functions in self care and is scored in a range of 0-20, respiration and sphincter management and is scored in a range of 0-40, and mobility which is also scored in a range of 0-40. The Toronto Rehabilitation Institute Hand Function Test (TRI-HFT) evaluates gross motor function of unilateral grasp. There are three components: The first component consists of power grasp, lateral pinch, and precision grip. The second and third components evaluate the strength and of both power and lateral grasps. The scoring system is a 0-7 scale.

There was no information regarding who administered the outcome measures.

Main Findings: There were no clinically significant differences between the two groups at baseline. Both intervention and control groups improved at the time of completion, but the FET group improved more.

Original Authors' Conclusions: This study shows that functional electrical stimulation pared with conventional occupational therapy is more effective in improving grasping than with conventional occupational therapy alone.

Critical Appraisal: Holm's Level II

Validity*:* AACPDM 6/7 (strong); weaknesses due to lack of power calculations

Interpretation of Results: This study has favourable findings in regards to using electrical stimulation therapy to improve grasp. Statistically significant findings were found in favor of the electrical stimulation therapy. One of the limitations of this study is the researchers were not able to follow up with the participants.

Summary/Conclusion: The findings were statistically significant in favor of using electrical stimulation therapy to improve grasp for individuals with spinal cord injuries.

Table 4: Description and appraisal of cohort study by Kern, Carroro, Adami, Biral, Hofer, Forstner,…Zampieiri, (2010).

Aim/Objective of the Study: To assess the long-term effectiveness of a home-based functional electrical stimulation program on individuals with spinal cord injury.

Study Design: Repeated measures within subjects design

Setting: Home based program; Assessments

Participants: 25 Participants (5 drop-outs); Inclusion criteria: complete lesion of conus and cauda and/or of pelvis plexus with chronic denervation of the quadriceps muscles, complete denervation time span between 9 months and 9 years, absence of sensation in the thigh, flaccid paralysis, intact skin; Exclusion criteria: implants, hazardous infections, pregnancy; Individuals who formerly participated in a short-term study were screened for eligibility in this study and 38 were eligible- 25 agreed to participate; Convenience sampling; Ages 20-55, 5 females, 20 males

Intervention Investigated: Participants were provided with home-based functional electrical stimulation (FES) program**,** which they performed five days a week. Every twelve weeks, a physiatrist assessed the participant and modified their home-based FES program based on their improvement. Follow-up lasted 2.2 years on average.

Outcome Measures

Computed tomography: The participants' thighs were scanned using tomography and changes in muscle tissue composition were color-coded and assessed.

Measurement of knee extension torque and functional outcomes: While seated with knees at 90 degrees, participants had quadriceps electrically stimulated. Amount of torque produced was measured using strain gauges attached to a torque leaver attached between the participants' knees and ankle.

Analyses of human muscle biopsies: Muscle biopsies were taken at enrolment and after 2 years of the home-based FES program. The biopsies were analysed using light or electron microscope.

Main Findings: CT scans of quadriceps muscles demonstrated increased mass and density after two years of a home-based FES program. Muscle growth and knee torque was more prominent in clients who began the program earlier after their injury. Muscle growth was significant after the first year of home-based FES, but any further increase was not statistically significant. 23 of the 25 subjects could perform knee extension and 5 could stand and step in place with the support of parallel bars and assistance from FES.

Original Authors' Conclusions: The home-based FES program used in the study improves muscle mass and contractility of lower motor neuron denervated muscles, but showed limited knee torque changes.

Critical Appraisal: Holm's Level III

Validity: AACPDM 4/7 (Moderate); weaknesses were due to lack of assessor blinding, lack of power calculations, and uneven study dropouts

Interpretation of Results: A personalized home-based FES program can recover muscle fibers after a long period of time. This shows promise for the recovery of voluntary movement in individuals with spinal cord injury resulting in paraplegia.

Summary/Conclusion: Two years of a personalized home-based FES program can improve denervated muscle structure but does not produce measurable functional movement.

Table 5: Description and appraisal of cohort study by Duffell, Rowlerson, Donaldson, Harridge, & Newham, (2010).

Aim/Objective of the Study: The purpose of this study was to investigate the effects of endurance and strength training using electrical stimulation on strength, fatigue, cycling power output, and muscle biopsies in paralyzed muscles.

Study Design: Within subjects design

Setting: Not addressed; Study authorization given to King's College London

Participants: Three participants with spinal cord injuries (SCI) between T4-T10, American Spinal Injury Association (ASIA) score A, who had just completed long-term FES cycling endurance training were recruited to participate in a 12-week strengthening program. Mean age: 49.8 years; Mean injury duration: 12.3 years; Mean height: 168.5 cm; Mean weight: 64.5 kg. One participant with T10 SCI, ASIA A, who had participated in a one-year functional electrical stimulation (FES) rowing strengthening program was also recruited for comparison. Age: 52 years; Injury duration: 10 years; Height: 171 cm; Weight: 72 kg. There was no baseline data gathered for the rower. No further information was provided regarding recruitment strategy.

Intervention Investigated: The three cyclists carried out a 12-week strength training program that involved weight training three times per week in addition to their cycling program. The weight training consisted of 40 resisted full knee extensions with ankle weights varying between .5-10 kg. The cycling program consisted of FES cycling for 1 hour per day on 5 days per week at a frequency of 50 Hx and 45-55rpm. The rower had participated in a year-long FES rowing strengthening program before assessment that included unresisted knee extensions and two to three 30-minute rowing sessions each week with the use of FES. No information was provided regarding when or where intervention took place.

Outcome Measures: Outcomes for effects of strength training in combination with the cycling program were measured by determining strength and maximal cycling power output. No information was provided regarding measurement administration, tools, timeframe, or location.
Muscle biopsies were collected from each of the participants before and after the training program.

Main Findings: Quadriceps strength increased by 31.6% and cycling power output improved by 1.7%. After the strength training program, the rower and the cyclist group had comparable strength and maximal cycling power output.
Muscle biopsies were examined for capillary density and type of fiber. No significant change

was present in the muscle biopsies for any participant.

Original Authors' Conclusions: This study shows that strength-based training with the use of electrical stimulation in individuals with spinal cord injury can improve muscle strength but does not significantly change cycling power output.

Critical Appraisal: Holm's Level III

Validity: AACPDM 3/7 (moderate); weaknesses due to lack of blinding, no power calculations, and lack of control for confounding variables.

Interpretation of Results: This pilot study had favourable findings for the use of electrical stimulation after spinal cord injury to improve muscle strength. The study did not find the strengthening program effective in increasing cycling power output. Therefore, if the clinical goal requires increased strength but not necessarily increased power output, this study shows that electrical stimulation would be a good option for use in therapy. This study also looks at the histological properties of participants' muscles before and after the strength-training program. Though the type of training had no effect on muscle histology, the authors' note that they believe future studies may find that electrical stimulation improves oxidative properties.

Summary/Conclusion: Electrical stimulation improves muscle strength after spinal cord injury, but does not significantly improve cycling power output.

Table 6: Description and appraisal of cohort study by Kern, Carroro, Adami, Hofer, Forstner, Loefler,…Zampieri, (2010).

Aim/Objective of the Study: The purpose of the study is to compare functional and structural thigh muscle properties before and after 2 years of home-based daily training by functional electrical stimulation therapy.

Study Design: The study design is a repeated measures, within subjects design. Clinical assessments, functional assessments, follow-up biopsies, and muscle biopsies were performed at Wilhelminenspital, Vienna, Austria.

Setting: Home-based program

Participants: The researchers use a convenience sampling. There were 25 European participants who sustained a complete spinal cord injury. The participants were volunteers and were given clinical and functional assessments as well as follow-up and muscle biopsies. The inclusion criteria included: complete spinal cord injury with paraplegia and lesions with pelvis plexus with chronic denervation of the quadriceps muscles; complete denervation time span between 6 months and 9 years; absence of sensation in the thigh; neurologically demonstrated flaccid paralysis without spasticity and segmental reflex activation; intact skin. The exclusion criteria included: implants in hip, thigh, or knee; pacemaker; disease and hazardous infections; pregnancy; pain simulator. Participant ges varied from 20 years old to 55 years old.

Intervention Investigated: This is a longitudinal study comparing functional and structural thigh muscle properties before and after 2 years of home-based daily training by functional and electrical stimulation (FES).

Outcome Measures: Force measurements were used by knee extension torque which measures isometric knee extension torque at 90 degrees of knee flexion by activating the quadriceps muscles with a standardized stimulation program. CT scans were also used of the cross sectional area in density of quadriceps muscles and hamstrings. Finally, an analysis of a human muscle biopsy was used which was taken before and after the 2 years of home-based daily FES training, with results analyzed via microscope.

Main Findings: Refer to table 4 on page 9 as well as figure 2 and 3 on page 10. As above, briefly list the main findings.

Original Authors' Conclusions: "The EU Project Rise is confirming that home-based daily FES training is a safe and effective therapy based on physical exercise induced by electrical stimulation of complete LMN denervated paraplegic subjects (pg. 10)."

Critical Appraisal: Holmes Level III

Validity*:* AACPDM is 6 out of 7 (strong); weakness due to lack of assessor blinding

Interpretation of Results: Beginning FES early is necessary to have clinically relevant improvements during the first year after injury. It was concluded that home-based FES program is safe for participants. One year of the home-based FES program, muscle bulk of denervated quadriceps increased and 20% of participants were able to stand in parallel bars after one year of home-based FES.

Summary/Conclusion: A home-based FES program can decrease lower motor neuron denervation and recover muscles from atrophy.

IMPLICATIONS FOR PRACTICE, EDUCATION and FUTURE RESEARCH

The purpose of this CAT was to evaluate the functional effects of external electrical stimulation for people with spinal cord injury. The findings suggest that external electrical stimulation can improve function when used with upper extremities and can improve muscle strength and mass with lower extremities.

In most settings, external electrical stimulation may be easily integrated into existing occupational therapy programs. The cost is limited to the actual purchase price of the electrical stimulation unit and prices vary.

Some further education and training may be necessary for existing therapists based on therapists' knowledge and state requirements regarding modalities. Educational institutions should continue to train entry-level practitioners on external electrical stimulation, with an increased emphasis on evidence-based practice.

This CAT demonstrates a need for future research on this topic with stronger evidence, larger sample sizes, and increased follow-up. Research should assess long-term functional effects of electrical stimulation for both upper extremities and lower extremities.

REFERENCES

Duffell, L., Rowlerson, A., Donaldson, N., Harridge, S., & Newham, D. (2010). Effects of endurance and strength-directed electrical stimulation training on the performance and histological properties of paralyzed human muscle: A pilot study. *Muscle and Nerve, 42*(5), 756-763.

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Kern, H., Carroro, U., Adami, N., Hofer, C., Forstner, C., Loefler, S.,…Zampieri, S. (2010). One year of home-based daily FES in complete lower motor neuron paraplegia: recovery of tetanic contractility drives the structural improvements of denervated muscle. *Neurological Research, 32*(1), 5-12.

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