There is strong evidence (level 1a) that electrical stimulation applied early after stroke, increasing from one to six hours per day, can prevent 6.5 mm of shoulder subluxation

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Date: June 2004
Review date: June 2006

CLINICAL SCENARIO: Shoulder subluxation, pain and paralysis of muscles can have a negative impact on occupational and role performance. Electrical stimulation (ES) is often applied to the shoulder muscles to treat shoulder subluxation. The muscles stimulated are typically posterior deltoid and supraspinatus because they hold the humeral head in the glenohumeral joint (GHJ). Electrical stimulation causes these muscles to contract and maintains muscle bulk, thereby helping to prevent the humerus from separating from the GHJ. What is the effectiveness of this intervention in treating shoulder subluxation?

FOCUSSED CLINICAL QUESTION: Does electrical stimulation prevent or reduce shoulder subluxation in people with hemiplegia following stroke, compared to no electronic stimulation?

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

- 18 citations were located that met the inclusion/exclusion criteria.
- 3 systematic reviews were located and reviewed to determine trial quality.
- 1 systematic review by Ada and Foongchomcheay (2002) which synthesised seven RCTs was deemed to be the highest level of evidence and was appraised.
- This systematic review reported that conventional therapy combined with electrical stimulation, within two months of stroke, prevented shoulder subluxation on average by 6.5mm (weighted mean difference, 95% CI 4.4 to 8.6). Conventional therapy combined with electronic stimulation two months after stroke-reduced subluxation on average by 1.9mm (weighted mean difference, 95% CI –2.3 to 6.1) (Ada & Foongchomcheay, 2002).
- Electrical stimulation was found to be effective in preventing but not reducing subluxation after the problem has developed.

CLINICAL BOTTOM LINE: Electrical stimulation early after stroke to the posterior deltoid and supraspinatus muscles can prevent shoulder subluxation when used in conjunction with conventional upper limb therapy.

Limitation of this CAT:

- This critically appraised paper has been individually prepared as part of a university subject, reviewed and marked by a lecturer, but has not been externally peer-reviewed.

SEARCH STRATEGY:

Using the levels of evidence as defined by the Oxford Centre for Evidence-based Medicine (Phillips, Ball, Sackett, et al., 2001), the search strategy aimed to locate the following study designs:

- Systematic reviews and meta-analyses of randomised controlled trials (level 1a);
- Systematic reviews and meta-analyses of randomised and non-randomised controlled trials (level 2a);
- Randomised controlled trials (level 1b or 2b);
- Controlled trials, cohort (level 2b) or case-control studies (level 3b);
- Case series (level 4); or
- Expert opinion including literature/narrative reviews, consensus statements, descriptive studies and individual case studies (level 5).

A search was also conducted for clinical practice guidelines.

Terms used to guide Search Strategy:

- **P**atient/Client: stroke patients with hemiplegia
- **I**ntervention: surface electrical stimulation
- **C**omparison: no electronic stimulation
- **O**utcome(s): prevention or reduction in subluxation of the shoulder

Table 1: Summary of search

Databases and sites searched	Search Terms	Limits used
New Zealand Guidelines Group	electrical stimulation and or subluxation	Published from January 1990 to May 2004
Scottish Intercollegiate Guidelines Network (SIGN)	electrical stimulation and or subluxation	nil
National Health and Medical Research Council	electrical stimulation and or subluxation	nil
UK Guidelines: National Clinical Guidelines for Stroke	electrical stimulation and or subluxation	nil
National Guidelines Clearinghouse	Keyword: *subluxation* Disease/Condition: *stroke* Treatment/Intervention: *electrical stimulation* Guideline Categories: *Prevention* Sort Order: *Relevance*	nil
The National Institute for Clinical Effectiveness (NICE)	electrical stimulation or subluxation and stroke	nil
Cochrane Library (Issue 2 2004)	((electrical stimulation) and subluxation)	nil
Database of Abstracts of Reviewers of Effectiveness (DARE)	electrical stimulation or subluxation	Published from February 1995 to May 2004

Joanna Briggs Institute	subluxation	nil
PEDro –Physiotherapy Evidence database	electrical stimulation or subluxation	Sub discipline: neurology
OT seeker – The Occupational Therapy Evidence Database	electrical stimulation or subluxation	Diagnosis / Sub discipline: neurology and neuromuscular disorders
EMBASE	electrical stimulation and subluxation	nil
Centre for Clinical Effectiveness (Monash University) – Evidence Reports	electronic stimulation or subluxation	nil
PubMed	1. stroke 2. electrical stimulation 3. #1 AND #2 4. shoulder subluxation 5. #3 AND #4	nil
CINAHL – Pre CINAHL, Art Abstracts	electrical stimulation and subluxation	Language: English; Limit by population: human;
Medline – Pre Medline	electrical stimulation and subluxation	Limit by population: human; Limit by publication type: clinical trial
GOOGLE	electric$ and stimulate$ and shoulder and subluxation	nil
Reference lists from articles.		

INCLUSION and EXCLUSION CRITERIA

- Inclusion:
  - Studies published in English
  - Electrical stimulation greater than 30 Hz, or sufficient to result in a motor response in the supraspinatus and posterior deltoid muscles
  - Patient had a clinical diagnosis of stroke (with or with out a CT scan)
  - Subluxation measured as an outcome

- Exclusion:
  - Patients with neurological conditions other than stroke
  - Studies where electrical stimulation was one component of a multiple complex intervention
  - Only shoulder pain reported as an outcome

RESULTS OF SEARCH

Eighteen relevant studies were located and categorised as shown in Table 2 (based on Levels of Evidence, Centre for Evidence Based Medicine, 1998)

Table 2: Summary of Study Designs of Articles retrieved

Level of Evidence	Study Design/ Methodology of Articles Retrieved	Number Located	Source(s)
	Evidence Based Guidelines	0	
1a	**Systematic reviews and meta-analyses of randomised controlled trials**	2	Citation appeared in PEDro (**1**) OT Seeker (**1**) Cochrane Library (2) PubMed (**1**,2)
2a	Systematic reviews and meta-analyses of randomised and non-randomised controlled trials	1	Citation appeared in Joanna Briggs Institute (3)
1b	Randomised controlled trials (Score $\geq$6/10 PEDro, OT Seeker)	1	Citation appeared in PEDro (4) OT Seeker (4) Cochrane Library (4) PubMed (4)
2b	Randomised controlled trials, Controlled trials, cohort studies (Score <6/10 PEDro, OT Seeker)	7	Citation appeared in PEDro (5,7,10,11) OT Seeker (6,7,10,11) Cochrane Library (6,7,8,10,11) PubMed (5,6,7) Reference list 1 (9) CINAHL (6,7)
3	Case-control studies	0	
4	Case series studies	0	
5	Expert opinion including literature/narrative reviews, consensus statements, descriptive studies and individual case studies	7	Citation appeared in PubMed (14,15,17,18) CINAHL (12,13,16,17, 18)

BEST EVIDENCE

The systematic review by Ada and Foongchomcheay (2002) was identified as the 'best' evidence and selected for critical appraisal. Reasons for selecting this paper were:

- The primary outcome of interest in this review was subluxation. The systematic reviews by Price and Pandyan (2003) and Page and Lockwood (2003) investigated subluxation as a secondary outcome measure.
- Most methodologically sound with search strategy, raw data and statistical analysis presented in review.
- Individual studies in the review answered my clinical question.

SUMMARY OF BEST EVIDENCE

Table 3: Description and appraisal of systematic review by Ada and Foongchomcheay 2002)

Aim of the Study

To examine the efficacy of surface electrical stimulation (ES) for the prevention or reduction of shoulder subluxation after stroke.

Methodology

Data Sources – One reviewer searched the following data sources: Medline, CINAHL, AMED, EMBASE, Cochrane Library (Issue 2 2002) using MeSH headings, reference lists of relevant trials, hand searched conference proceedings.

Design of included studies – Randomised or quasi-randomised trials.

Study inclusion/ exclusion criteria – For studies to be included both reviewers had to agree that the following inclusion criteria were met: participants had a clinical diagnosis of stroke; average age of participants was more than 50 years; intervention was surface electrical stimulation; stimulation frequency was greater than 30 Hz or stimulated a muscle contraction; subluxation, pain or function were measured as outcomes. Excluded: studies that included participants with other neurological conditions; electrical stimulation was part of a complex intervention.

Number of studies screened vs accepted – Number of studies screened = 12; Number of studies accepted = 7.

Patient population – Patients from individual RCTs were placed into one two groups for the purpose of this systematic review: Early ES (n=144) and late ES (n=38). Early ES: trials that included participants with a stroke less than two months before being admitted to the study (Baker & Parkes, 1986; Faghri, et al 1994; Linn, et al 1999; Wang, 2000). Late ES: trials that included participants who had a stroke more than two months before being admitted into the study (Kobayashi-D, Kobayashi-S, 1999, Wang, 2002).

Quality of RCTs included in the systematic review – One reviewer assessed the methodological quality of the included trials using the PEDro scale, which was developed to rate RCTs on for use of the Physiotherapy Evidence Database (PEDro, at www.pedro.fhs.usyd.edu.au). The mean PEDro score was 5.8 for early ES trials and 4.3 for late ES trials, out of a possible 10 points. The five RCTs were assessor blinded with baseline comparability between control and treatment groups. Two trials (Kobayashi-D, Kobayashi-S, 1999) were quasi-randomised and blinding was not reported. There was no report of dropouts in any trial with one exception: Linn et al (1999).

Analysis – Trials using similar methods of measuring subluxation, at similar times post-intervention were pooled. Number of participants, means and standard deviations were extracted and entered into the Cochrane Collaboration Review Manager Software program (Rev Man 4.1). Where the same method of measurement was used, pooling was carried out using the fixed effect model and effect sizes were reported as weighted mean differences and 95% CI. When different methods of measurement were used the random effects model was used to calculate standard mean differences and 95% CI. Heterogeneity of the data was tested and if significant (at $p<0.1$, Q statistic) source was investigated through a sensitivity analysis.

Follow up – Early ES: Ranged from 6 to 8 weeks . Late ES: Ranged from no follow up, to 6 weeks.

Intervention Investigated

Intervention was surface electrical stimulation. The included studies used electrical stimulation in conjunction with conventional therapy in the experimental group compared to the control group who received conventional therapy. The application of electrical stimulation in the early group intervention ranged from 4 to 6 weeks, for 5-7 days a week, and the wearing duration increased over time from 1.5 up to 6 hrs a day. In the late electrical stimulation group, intervention was carried out over 6 weeks, 5 days a week and the wearing duration increased over time from 15 mins up to 6 hours a day. All trials progressively increased the application of electrical stimulation. They increased both duration (hours worn per day) and duty cycle (ON: OFF) when the subjects were able to complete sessions without fatigue of the stimulated muscles.

Outcome Measures (Primary and Secondary)

The primary outcome of interest in the systematic review was prevention or reduction of shoulder subluxation.

Subluxation was measured in millimetres from plain antero-posterior x-rays of the shoulder in all 7 trials. Four trials compared the unaffected and affected shoulders and three trials measured the affected side. Data were pooled when subluxation was measured in millimetres. The secondary outcomes of the systematic review were reduction or prevention of shoulder pain, and improvement in shoulder function, early and late after stroke.

Pain was measured via self report, request for drugs, pain-free passive shoulder external rotation, pain- free active shoulder external rotation, verbal grading on passive shoulder external rotation, or visual analogue scale on active shoulder abduction.

Function was represented through measures of strength, tone, EMG activity, performance on functional scales, or not at all.

Results

Table 3 displays the results of early electrical stimulation in the prevention of subluxation (mm) by pooling post-intervention data from four trials.

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Table 3: From Ada & Foongchomcheay (2002) examining early electrical stimulation in the prevention of shoulder subluxation

	Early ES+CT			Early CT			Weight	WMD
Study	n	mean	(SD)	n	mean	(SD)	%	(95% CI Random)
Baker	31	-8.6	(4.9)	32	-13.3	(7.9)	42.2	4.7 [1.5, 7.9]
Faghri	13	-2.5	(3.2)	13	-9.9	(6.4)	29.8	7.4 [3.5, 11.3]
Linn	19	-26.2	(5.6)	20	-31.3	(11.7)	13.5	5.1 [-0.6, 10.9]
Wang-E	8	-13.0	(2.7)	8	-24.0	(7.5)	14.6	11.0 [5.5, 16.5]
Total	**71**			**73**			**100.00**	**6.5 mm [4.4, 8.6]**

Test for heterogeneity chi-square = 4.16 df = 3 p = 0.24. Test for overall effect z = 6.03 p < 0.001

Abbreviations: CI = Confidence Interval; p = p value; WDM = Weighted mean difference; z = z score; df = degrees of freedom; mm = millimetres; CT = Conventional Therapy; ES = Electrical Stimulation

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The weighted mean difference suggests that early electrical stimulation plus conventional therapy prevented 6.5mm of subluxation of the shoulder after stroke, and was superior to conventional therapy alone.

Table 4 displays the results of late electrical stimulation in the reduction of subluxation (mm) by pooling post-intervention data from 3 trials that measured subluxation in millimetres from plain Anterior-Posterior x-rays of the shoulder.

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Table 4: From Ada & Foongchomcheay (2002) examining late electrical stimulation in the reduction of shoulder subluxation

	Late ES+CT			Late CT			Weight	WMD
Study	n	mean	(SD)	n	mean	(SD)	%	(95% CI Random)
Kobayashi-D	6	-7.2	(7.3)	5	-7.4	(8.2)	20.3	0.2 [-9.1, 9.5]
Kobayashi-S	6	-5.8	(5.4)	5	-7.4	(8.2)	24.8	1.6 [-6.8, 10.0]
Wang-L	8	-24.0	(5.5)	8	-26.7	(6.0)	54.8	2.7 [-2.9, 8.3]
Total	**20**			**18**			**100.00**	**1.9 mm [-2.3, 6.1]**

Test for heterogeneity chi-square = 0.21 df = 2 *p* = 0.90
Test for overall effect z = 0.90 *p* = 0.40

Abbreviations: CI = Confidence Interval; p = p value; WDM = Weighted mean difference; z = z score; df = degrees of freedom; mm = millimetres; CT = Conventional Therapy; ES = Electrical Stimulation.

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The weighted mean suggests that late electrical stimulation plus conventional therapy reduced subluxation of the shoulder after stroke by only 1.9mm, and was not superior to conventional therapy.

Original Authors' Conclusions

There is evidence to support the early use of electronic stimulation combined with conventional therapy (motor training) to prevent shoulder subluxation and increase function. There is also evidence that the use of late electrical stimulation, combined with conventional therapy, is effective in reducing hemiplegic shoulder pain (Ada & Foongchomcheay, 2002).

"*Electrical stimulation should be applied to patients whose shoulder muscles are inactive after a stroke resulting in a loss of function in the patient. Therefore, it is recommended that for those patients, early after their stroke, who score less than 4 on Item 6 of the Motor Assessment Scale, should receive electrical stimulation daily to the posterior deltoid and supraspinatus muscles. Stimulation of these muscles should be greater than 30Hz, beginning at 1 hour a day and progressing to 6 hours a day. This should continue until the patient reaches 4 on Item 6 on the Motor Assessment Scale*" (Ada & Foongchomcheay, 2002, p 265).

Critical Appraisal:

Validity *(Methodology, rigour, selection, bias)*

- The reviewers addressed a clear focused clinical question.
- A thorough search was conducted which used a number of electronic databases. Additional studies were located through follow up from reference lists and hand searching conference proceedings. The search was not restricted by language; searches were conducted for non – English studies.
- Pre-determined criteria were used to determine which studies were included. Both reviewers had to agree that a trial met the inclusion criteria; disagreements were resolved through discussion. This helps to minimise selection bias.
- One reviewer used the PEDro scale to rate the methodology of each RCT. The PEDro scale uses a standardised scoring system.
- Data extraction was carried out for each study. If data were not available in the published studies, details were requested from the first named author.

Results *(Favourable or unfavourable, specific outcomes of interest, size of treatment effect, statistical and clinical significance; minimal clinically important difference)*

- Statistical analysis of the studies was done by pooling raw data from the included studies; this method was explained in detail by the authors. The mean, standard deviation and confidence intervals were reported for each individual study. Confidence intervals were reported for the overall score for the two groups (early and late ES) and all results were reported in mm. The analysis methods chosen were appropriate for the purpose of the systematic review and its outcomes.
- The pooled results for the four studies in the early ES group were seen to be statistically and clinically significant at $p<0.001$ with narrow confidence intervals. The three studies used for the late ES group did not report a statistically significant improvement, with wide confidence intervals, suggesting that the studies were underpowered.
- No data were analysed at follow up.
- The study by Linn et al (1999) (which was in the early ES group) was found to have a selection bias towards patients with left sided hemiplegia. This meant that overall, in the early ES group, there were more participants with left sided hemiplegia [63%].
- In two studies by Kobayashi-D and Kobayashi-S, it is uncertain wether the assessors were blinded, allowing for a measurement detection bias in these studies. All the other studies had blinded assessors.
- Participants in each trial were treated in different settings with different therapists. Conventional therapy was found not to be consistent across the trials allowing for the possibility of an intervention bias.
- The cost effectiveness of ES was not analysed in this systematic review, as this information was not addressed in the individual studies.

IMPLICATIONS FOR PRACTICE/ APPLICABILITY

- This systematic review used quality methods. The authors used sound search strategies, appropriate and specific inclusion/exclusion criteria, and conducted a comprehensive analysis/appraisal of studies. Due to the efforts made by the authors to limit biases, the results of this systematic review are considered valid. However, due to the small and unequal number of participants in studies, and with no economic evaluation, some caution should be used when interpreting results.
- Not all occupational therapists are taught how to use ES during their education at university. In Australia at least, ES tends to be viewed as the role and responsibility of physiotherapists on a rehabilitation team. In such situations, where ES is being implemented by a physiotherapist, occupational therapists can complement this intervention by providing extra opportunities for task-specific motor training during the day (and practice outside therapy), and making sure the shoulder is supported.
- Where a physiotherapist is not using ES, or where there is no physiotherapist on the team/in the region, occupational therapists should endeavour to provide this intervention. Some undergraduate/graduate entry programs in Australia teach occupational therapy students how to use ES, and review the evidence on ES (for example, UWS). Occasional graduate workshops are also available on motor training following stroke, and include a practical session on ES application to help professionals acquire these skills.
- All articles included in this systematic review reported using ES with conventional upper limb therapy. Most did not state what exactly the upper limb therapy consisted of. Ada and Foongchomcheay argue that ES should not be used alone. ES was effective when used in conjunction with conventional upper limb therapy. Therefore, upper limb management should ideally be planned collaboratively between physiotherapists and occupational therapists, in order to prevent subluxation from occurring.

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Article critically appraised:

1. Ada, L., & Foongchomcheay, A. (2002). Efficacy of electrical stimulation in preventing or reducing subluxation of the shoulder after stroke: a meta-analysis. Australian Journal of Physiotherapy, 48(4), 257-267.

Related Articles (not individually appraised)

Level 1a Evidence

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Level 2a Evidence

3. Page, T., & Lockwood, C. (2003). Prevention and management of shoulder pain in the hemiplegic patient. JBI Reports, 1(5), 149-165.

Level 1b Evidence

4. Linn, S., Granat, M., & Lees, K. (1999). Prevention of shoulder subluxation after stroke with electrical stimulation. Stroke, 30(5), 963-968.

Level 2b Evidence

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Level 3 & 4 Evidence Nil

Level 5 Evidence

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