Surface neuromuscular electrical stimulation for quadriceps strengthening pre and post total knee replacement (Review)

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[Intervention Review]

Surface neuromuscular electrical stimulation for quadriceps strengthening pre and post total knee replacement

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ABSTRACT

Background

Total knee replacement has been demonstrated to be one of the most successful procedures in the treatment of osteoarthritis. However quadriceps weakness and reductions in function are commonly reported following surgery. Recently Neuromuscular Electrical Stimulation (NMES) has been used as an adjunct to traditional strengthening programmes. This review considers the effectiveness of NMES as a means of increasing quadriceps strength in patients before and after total knee replacement.

Objectives

To assess the effectiveness of NMES as a means of improving quadriceps strength before and after total knee replacement.

Search methods

We searched The Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE (1950 to January week 1 2008), EMBASE (1980 to 2008 week 2), Cumulative Index to Nursing and Allied Health Literature (CINAHL)(1982 to 2007/11), AMED (1985 to Jan 2008), Web of Science, and Pedro (Jan 2008) (http://www.pedro.fhs.usyd.edu.au/index.html) for randomised controlled trials and controlled clinical trials. The electronic search was complimented by hand searches and experts in the area and companies supplying NMES equipment were also contacted.

Selection criteria

Randomised controlled trials and controlled clinical trials were accepted that used NMES for the purpose of quadriceps strengthening either pre or post total knee replacement.

Data collection and analysis

Two review authors decided which studies were suitable for inclusion based on the inclusion and exclusion criteria in the protocol and the data was extracted using pre-developed data extraction forms. Two review authors (BM and BC) independently assessed the methodological quality of the included trials using a descriptive approach as advocated by the Musculoskeletal group. Only two studies were included in the review. Neither study presented results in a form suitable for meta-analysis. The authors of both studies were contacted to obtain the raw data but they were no longer available.The data from both studies are described in the review.

Main results

Two studies were identified for inclusion in the review. No significant differences were reported in either study for maximum voluntary isometric torque or endurance between the NMES group and the control group but significantly better quadriceps muscle activation was reported in the exercise and neuromuscular stimulation group compared with the exercise group alone in the second study. This difference was significant at the mid training (six week) time point but not at the twelfth week post training time point. Further analysis of both studies were not possible due to the absence of raw data scores. Both studies carried a high risk of bias. Mean values were not given for strength, endurance, cross sectional area or quality of life. Pain outcomes, patient satisfaction or adverse effects were not reported in either study. The results were presented as percentage improvements from baseline and the number of subjects in each group was unclear.

Authors' conclusions

The studies found in this review do not permit any conclusions to be made about the application of neuromuscular stimulation for the purposes of quadriceps strengthening before or after total knee replacement. At this time the evidence for the use of neuromuscular stimulation for the purposes of quadriceps strengthening in this patient group is unclear.

PLAIN LANGUAGE SUMMARY

Electrical stimulation for thigh muscle strengthening before and after knee replacement surgery

This summary of a Cochrane review presents what we know about the effect of electrical stimulation as a treatment to improve the strength of the thigh muscles before and after knee replacement surgery.

The review shows that we are uncertain whether electrical stimulation affects thigh muscle strength before and after knee replacement surgery because of the very low quality of the evidence.

What is thigh muscle weakness and what is electrical stimulation?

Osteoarthritis of the knee can make the knee joint painful and unstable. Knee replacement surgery is a treatment that can sometimes help this condition. One side effect of having knee surgery, is that people can lose strength in their thigh muscles. When your thigh muscles are weak, it can be difficult to stand from a sitting position. Up to a year later, some people walk and climb stairs more slowly than they did before surgery.

Electrical stimulation means using electricity to make the thigh muscle contract, just as it would if a person were exercising. Electrodes are wires that send the electrical current from a small machine to your thigh muscle. Usually, a doctor or physiotherapist will connect electrodes with tape to the skin on your thigh. The treatment is usually given as part of an overall exercise program.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

Surface neuromuscular electrical stimulation for quadriceps strengthening pre and post total knee replacement

Patient or population: for quadriceps strengthening pre and post total knee replacement
Settings: Any
Intervention: Surface neuromuscular electrical stimulation

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Surface neuromuscular electrical stimulation				
Function Scales: Timed up and go test, Functional stair test and Nottingham health profile Follow-up: 3 to 12 weeks [1]	See comment	See comment	Not estimable	0 (2 studies[2])	See comment	Data not presented in a format to allow meta-analysis to be carried out
Patient Satisfaction - not measured	See comment	See comment	Not estimable	-	See comment	Not measured
Pain - not measured	See comment	See comment	Not estimable	-	See comment	Not measured
Quadriceps strength	See comment	See comment	Not estimable	0 (2 studies[2])	See comment	Data not presented in a format to allow meta-analysis to be carried out
Quadriceps activation	See comment	See comment	Not estimable	34 (1 study)	See comment	Data not presented in a format to allow meta-analysis to be carried out

Adverse effects - burns, skin damage, or cardiac arrhythmias - not measured	See comment	See comment	Not estimable	-	See comment	Not measured

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Patients followed up at three, six, nine, and twelve weeks.
[2] Total numbers for the intervention and control groups are not specified in the study by Oldham (1995) therefore the figures cannot be combined.

BACKGROUND

Total knee replacement has been demonstrated in the literature as a successful means of relieving pain and improving function in people with osteoarthritis of the knee (Pavone 2001). Total knee replacement is one of the most common and successful orthopaedic procedures in the treatment of end stage osteoarthritis (Petterson 2006). The incidence of such replacements is expected to rise steadily over the next few decades as the number of older adults increases. In 2002/2003 there were 45,739 total knee replacements carried out in the UK and this increased to 56,652 in 2004/2005 (hesonline 2007). Similarly in the US there were 418,000 total knee replacements in 2003 and this increased to 478,000 in 2004 (AAOS 2007).

Dramatic improvement in levels of pain and enhanced quality of life are well documented after total knee replacement (Fortin 1999; Jones 2003). However, residual quadriceps weakness and reductions in function are also commonly recorded post-surgery (Stevens 2003; Walsh 1998). Quadriceps strength is highly correlated with functional performance in people after total knee replacement and weakness has been shown to contribute to asymmetries in gait and in sit-to-stand activities (Mizner 2005a). Correlations between quadriceps strength and dynamic stability in sit-to-stand activities and gait have also been established in the wider functionally limited elderly population (Moxley 1999). Although quadriceps strength is often not recorded in studies evaluating outcomes post knee replacement (Minns Lowe 2007), strength training has always been core to rehabilitation programmes post surgery in addition to range of movement and functional activities (Frost 2002; Kramer 2003; Mockford 2004; Moffett 2004). Post operative quadriceps strength has been demonstrated to be reduced by as much as 62% at four weeks post surgery when compared with preoperative values (Mizner 2005a). Reductions in walking speed, stair climbing time, and extensor knee strength in both males and females have been reported at one year post surgery when compared to an age and gender matched control group (Walsh 1998). It is noteworthy that in this study by Walsh 1998 that these functional impairments were present in the absence of muscle atrophy. Quadriceps weakness has been found to persist even following physical therapy in people post total knee replacement (Mizner 2005b; Stevens 2003). It has been suggested that changes in neuromuscular recruitment may alter muscle torque thus indicating the need for an adjunct to traditional strengthening. As reduced physical capacity long term in this group of individuals has been shown to both hinder functional independence, and also to be highly predictive of subsequent disability (Guralnik 1995) successful rehabilitation of this group is critical.

Recently Neuromuscular Electrical Stimulation (NMES) has been used as an adjunct to traditional strengthening programmes in patients post total knee replacement. It has been suggested that NMES may provide a more effective means of increasing muscle strength than traditional strengthening programmes (Lewek 2001). Although electrical stimulation is used extensively as an adjunct to physiotherapy, the use of NMES to strengthen muscles is relatively new (Ward 2006). This is believed to occur by increasing the capacity of the muscle to generate force. This review will examine the effectiveness of NMES in the context of muscle strengthening only, specifically in the strengthening of the quadriceps muscle in people following total knee replacement.

NMES is the application of an electrical current to the neuromuscular junction and the surrounding muscle fibres to cause a muscle contraction (Goitlin 1994; Petterson 2006). It can increase the muscle strength by increasing the load on the muscle using an electrically induced contraction to cause a training effect. Different parameters of the electrical current have different effects on the neuromuscular junction. Changes in these specific parameters have led to classification of NMES under different categories. Classification of NMES stimulators has in part been on the basis of their output frequency. Robinson 1994 classifies stimulators producing 1to1000 pulses per second as low frequency, 1000 to 10,000 as medium frequency and in excess of 10,000 as high frequency. Smooth tetanic muscle contraction will occur with a frequency of 50 pulses per second (Robinson 1994) although contraction at lower frequencies has been successfully employed in some studies (Caggiano 1994). With regard to muscle strengthening, the current application needs to cause a tetanic contraction at the highest torque level, that is 35% to 50% of the client's maximum volitional isometric contraction (Lewek 2001). Both pulsed and alternating current are used in NMES devices (Ward 2006). Pulsed current may be interrupted direct current or interrupted alternating current. Interrupted direct current is described as being monophasic and pulsed, as the current travels in one direction only. Alternating current moves in two directions and can also be interrupted and is described as biphasic (Robinson 1994). The shape created by the visual representation of either a single pulse or a cycle of alternating current is described in the literature as a waveform (Laufer 2001). Recently studies have compared the effect of different current types and frequencies on maximal torque production or muscle strength (Laufer 2001; Ward 2006). These studies have also investigated the most comfortable type of stimulation (Laufer 2001; Ward 2006). In a study of 32 healthy subjects Ward 2006 demonstrated that both a current at 2.5 kHz alternating current with a 50% duty cycle (called 'Russian current' in the literature) and low frequency pulsed current elicited lower mean torque than another current at 1kHz alternating current with a 20% duty cycle (called 'Aussie current'). The duty cycle is the percentage of time the current is on. In this same study, participants described the stimulation produced by the 'Russian current' as the most comfortable. The size of electrode selected also has a direct effect on the density of the current. If the electrode is too small the high current density produced can cause painful stimulation before a sufficient contraction is reached to allow for muscle strengthening (Robinson 1994). Selection of appropriate electrode size is therefore critical to comfortable stimulation and

application of the electrode over the motor point of the muscle reduces the current threshold required. The duration of the pulse, that is the length of time the electrical current is on, is also a relevant parameter to assess in improving muscle strength. Although the optimal current duration for strengthening pre and post total knee replacement has not been established (Robinson 1994), the current must be of sufficient duration to cause an increase in strength. Ward 2004 recently established that a duty cycle of 2 milliseconds rather than 10 milliseconds was optimal for force production in the wrist extensor muscles.

Some of the literature focuses on the differences in muscle torque generating capacities between clinical (or plug in) electrical stimulators and portable devices. In a study of 40 normal subjects, Lyons 2005 demonstrated no difference between the two machines in the peak torque of the quadriceps femoris muscle contractions of normal subjects. Previously Snyder-Mackler 1994b in a study of people following anterior cruciate ligament reconstruction reported lower muscle torque with lower intensity portable stimulators. It is clear from the literature that any evaluation of the effects of neuromuscular electrical stimulation to improve strength in quadriceps post total knee replacement must take into account all the different parameters of the stimulation current including pulse duration, amplitude, waveform, frequency, type of contraction, number of contractions per second, type of stimulator used and the number of treatment sessions. Only then can it be determined if studies are directly comparable and whether the various parameters outlined have an impact on the muscle strength outcomes.

Studies have suggested that deficits in muscle activation account for a greater proportion of impaired quadriceps strength post knee replacement than muscle atrophy alone (Mizner 2005a; Petterson 2006). Muscle inhibition is thought to occur either by a failure of the central motor drive to recruit all the available motor units in the muscle or by reducing the maximal discharge rate of contraction of the motor units (Newham 1989). The proposed reduction in the central motor drive may be caused by an ongoing reflex inhibition secondary to joint distension or damage (Hopkins 2000). Stevens 2003 reported that a deficit in muscle activation accounted for up to 65% of the variability in quadriceps strength in a group of 28 people post total knee replacement. In support of this study some authors argue that muscles cannot be strengthened to their full potential if they cannot be activated sufficiently to overload the muscle and therefore recommend a combination of NMES and traditional strength training (Petterson 2006). Studies have also assessed both muscle activation and quadriceps strength in people pre total knee replacement (Mizner 2005d; Rossi 2005; Stevens 2003). These studies reported reduced strength as expected but also reported reduced muscle activation levels in the pre surgical population when compared either with their non-affected knee or with normal control groups. Beaupre 2004 reported no difference in strength outcomes in a group subjected to a pre operative exercise programme when compared with a control pre operative knee replacement group. These findings are similar to those reported by (Mizner 2005b) with the post operative knee replacement group. In the pre operative group, inadequate activation may also contribute to the poor response to traditional strengthening programmes. Since NMES can enhance muscle activation in addition to improving strength, its investigation as an adjunct to rehabilitation is valid in both the preoperative and post operative total knee replacement populations. Pre operative quadriceps strength has been shown to be a predictor of functional ability at one year post total knee replacement (Mizner 2005c).

Some studies suggest that electrical stimulation may activate a greater proportion of type 2 or fast twitch muscle fibres than a voluntary contraction and thus produce higher levels of force production (Delitto 1990; Ward 2002). Trimble 1991 stated that NMES activated faster contracting motor units preferentially, some of which would only be activated at high exercise levels during a voluntary contraction. However, much debate exists in the literature regarding the mechanisms by which NMES affects fibre recruitment (Gregory 2005). Some evidence supports NMES as a means of increasing quadriceps strength after knee surgery in other clinical populations (Snyder-Mackler 1994a). Reflex inhibition has also been documented in this patient group (Snyder-Mackler 1994b).

How widely NMES is used post total knee replacement is not documented in the literature although anecdotal reports claim it is used frequently. There are reports of its use as an adjunct to therapy in people with quadriceps weakness in both outpatient and inpatient settings. NMES is widely available and is inexpensive to provide. Given the specific nature of quadriceps weakness in people both pre and post total knee replacement it may provide a valuable addition to traditional strengthening programmes in both populations. This systematic review will assess the effectiveness of NMES in improving quadriceps strength in the pre and post operative knee replacement population. It will explore in detail the parameters of the currents used for muscle strengthening. Specifically the frequencies, waveforms, contraction times, ramp times, electrode placements and current intensities which maximise improvements in quadriceps strength both generally and specifically pre and post total knee replacement will be evaluated.

OBJECTIVES

The primary objective was to assess the effectiveness of surface neuromuscular electrical stimulation (NMES) for quadriceps strengthening when administered pre and/or post total knee replacement.

Specific Objectives

1. To compare the effectiveness of NMES administered in different ways, including the frequency used, the intensity, or duration of treatment sessions, and its effect on the activation and strength of the quadriceps muscle in patients pre and/or post total knee replacement.

2. To compare, if possible the effectiveness of the addition of NMES in the pre operative stage on muscle strength and activation, the effectiveness of NMES in the post operative stage, and the effectiveness of NMES if applied in both stages.

3. To examine the published literature on NMES as it relates to clinical practice in the total knee replacement client group.

The hypotheses are:

- that NMES is better than no treatment in improving quadriceps strength either pre and/or post total knee replacement;

- that NMES is better than traditional active muscle strengthening programmes in the pre and/or post knee replacement surgical group;

- that NMES added to a rehabilitation programme is better than a rehabilitation programme without NMES in people pre and/or post total knee replacement.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised control trials and controlled clinical trials.

Types of participants

This review included all studies involving adults who had either had or were listed for cemented or un cemented total knee prostheses for osteoarthritis. Participants must have had their quadriceps strength assessed pre and post NMES intervention. All subjects were eligible regardless of their age, range of movement or level of strength.

All adults were included who had NMES as a treatment or part of treatment in any setting from one year pre surgery to one year post surgery. Participants pre surgery must have been listed for surgery. Participants were excluded if they had undergone revision total knee replacement, unicompartmental replacement or if they have any history of inflammatory diagnosis such as rheumatoid arthritis or ankylosing spondylitis, or had any history of nerve palsy pre, post or intraoperatively.

Types of interventions

Studies which used NMES (at any frequency, duration, and intensity) were included when used for the purpose of muscle strengthening, or to induce changes in muscle activation. The parameters given in each study were carefully scrutinized to ensure a strengthening effect was possible that is that the current application was capable of causing a tetanic contraction at 35% to 50% of the client's maximum volitional isometric contraction thus the patients maximum isometric contraction needed to be recorded. Studies of NMES in combination with any other intervention or active muscle strengthening programme were also included. NMES parameters were assessed using the primary and secondary outcome measurements outlined. NMES for the purpose of pain relief with transcutaneous nerve stimulation (TENS) were not included.

Types of outcome measures

Primary outcomes

Quadriceps strength, endurance, or power as measured by validated assessment tools.

Quadriceps activation as measured by supramaximal electrical stimulus (Stevens 2003).

Quadriceps hypertrophy as indicated by thigh girth or magnetic resonance imaging.

Patient satisfaction as measured by validated assessment tools.

Functional measurement scales like timed sit-to-stand, timed up-and-go (Podsiadlo 1991), WOMAC scores (Bellamy 1988).

Recordings of any long duration direct current will be recorded (i.e. monophasic pulses of at least 10 millisecond duration (Robertson 2001). Pulses of this duration may lead to concentrations in current flow and potential for burns or skin damage (Robertson 2001; Robinson 1994).

Measurement of any adverse effects of neuromuscular stimulation, for example any unwanted effect on the autonomic nervous system will be recorded. NMES over the thoracic region may interfere with functioning of the vital organs including the heart (Robertson 2001; Robinson 1994).

Secondary outcomes

Length of stay in either acute hospital and/or rehabilitation facility.

Pain scores.

McGill pain score.

Where possible treatment outcomes were measured pre and post NMES intervention within one year pre and post surgery.

Depending on the data reported outcomes will be evaluated on a weekly basis during the first month and every month thereafter pre and post surgery.

Search methods for identification of studies

See: Cochrane Musculoskeletal Group methods used in reviews.

Electronic searches

The Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE (1950 to January week 1 2008), EMBASE (1980 to 2008 week 2), Cumulative Index to Nursing and Allied Health Literature (CINAHL)(1982 to 2007/11), AMED (1985 to Jan 2008), Web of Science, and Pedro (Jan 2008) (http://www.pedro.fhs.usyd.edu.au/index.html) were searched for randomised controlled trials and controlled clinical trials.

Companies that produce NMES equipment, Neurotech Galway (www.bmr.ie), Odstock Medical limited (www.odstockmedical.com) and Innovative neurotronics (www.inic.us) were contacted at the WCPT world conference in June 2007 to identify any missing or unpublished data. No additional studies were identified. Study authors and other experts in the field were contacted by email in April 2008 to identify any missing or unpublished data. One additional study was located but this was not yet released for consideration (see characteristics of ongoing studies). No language restrictions were applied. The search terms in Appendix 1 were used in the MEDLINE search and were modified for the other databases using a combination of MeSH terms and key words.

Searching other resources

We scanned the reference lists of articles, review papers and textbooks for additional references. In addition ClinicalTrials.gov was searched for unpublished and/or ongoing clinical trials. Published and unpublished dissertations (using for example, UMI/ProQuest and NDLTD) were also searched.

Grey Literature

Conference proceedings and papers from congresses and symposia were searched through the database Online Computer Library Centre (OCLC). The proceedings from the annual conferences of the following organisations were handsearched, American Physical Therapy Association 2000 to 2007, Canadian Physiotherapy Association 2000 to 2007, National Association of Orthopaedic Nurses 2003 to 2007. In addition the following journals were hand searched for 2000 to 2007.

Clinical Orthopaedics and Related Research
Journal of Arthroplasty
Journal of Bone and Joint Surgery (both American and British volumes)
Physical Therapy
Physiotherapy Canada
Arthritis and Rheumatism
Arthritis Care and Research (ceased publication in 2000)
Australian Journal of Physiotherapy

Data collection and analysis

Timeframe for the Review

The protocol was submitted for the January 2008 deadline.
The search was completed, including the hand searching by March 2008.
Data analysis was completed by June 2008.
Review draft completed by October 2008.
Final draft completed by December 2008.

Selection of studies

Two authors (BM and BC) independently selected trials for inclusion, extracted data, assessed trial quality and analysed the results. If there were disagreements it was planned a third author (DOM) would be consulted. This was not necessary. Data was not included in the review until a consensus was reached.

Both review authors screened the titles and the abstracts of all publications obtained by the search strategy. The full text of all included articles and those deemed unclear from the abstract were obtained. Data were extracted from all studies fulfilling the inclusion criteria, including data concerning methodological issues, characteristics of participants, interventions to include NMES frequency, intensity, pulse duration, waveform, contraction times, relaxation times and all recorded outcome measures. If there was sufficient detail provided in the studies identified it was proposed to explore the effectiveness of NMES in groups stratified in terms of the degree of muscle weakness reported pre and post intervention. Insufficient studies were identified to do this. In order to carry out this subgroup analyses a sufficient number of studies reporting objective measurement of muscle strength pre and post intervention needed to have been identified. The data was extracted independently using a standard data extraction form.

Assessment of risk of bias in included studies

Two review authors (BM and BC) independently assessed the methodological quality of the included trials using a descriptive approach as advocated by the Musculoskeletal group (Tugwell 2004). The methodological quality of all included trials was assessed using a standard form.

1. Concealment of treatment allocation
2. Blinding of intervention provider, recipient and outcome assessor
3. Handling of withdrawals and dropouts:

a. Accounting for the numbers - were the number of withdrawals and dropouts reported for both groups?

b. Accommodating withdrawals (intention to treat/imputation) - were the number of withdrawals and dropouts accounted for in the analysis (for example through intention to treat or last observation carried forward)?

Definitions for allocation concealment

A. Adequate concealment - allocation of participants to different groups was not known until the point of allocation (e.g. sequentially numbered, sealed, opaque envelopes; onsite computer system with locked, unreadable files).
B. Unclear concealment (e.g. stating only that a list or table was used).
C. Inadequate concealment - transparent before allocation (e.g. alternating sequence; case record numbers; dates of birth or days of the week).
D. Not used - clear that allocation concealment was not used.
All components of the checklist will be individually assessed as to whether they (A) are met (B) are not met or (C) are unclear.
In February 2008 following publication of the protocol for this review the handbook for systematic reviews was updated. In addition to the method of assessment of methodological quality described above the updated tool for assessing risk of bias (Higgins 2008) was included. The criteria described for judgement of risk of bias, that is describing criteria as 'Yes' (i.e. low risk of bias), 'No' (i.e. high risk of bias) or Unclear (uncertain risk of bias) uses the criteria outlined in the risk of bias assessment tool as described by Higgins 2008.
Summary assessments for each study are described within each study as low, unclear or high risk of bias depending on the findings in each domain (Higgins 2008).
Independent quality assessment using separate, pre-piloted, forms was undertaken by two review authors (BM) and (BC). Where differences in opinion could not be resolved, it was planned to have arbitration by a third review author (DOM). This was not necessary.
Masking of trial identifiers such as authors and journal names was not carried out.
Initial inter-observer reliability of both the screening (include or exclude) and quality assessment on a limited sample of papers demonstrated the two authors graded the methodological quality without disagreement. This high level of agreement in the pilot test phase resulted in no changes to the data extraction form. These studies were drawn from a pool of studies that did not meet the inclusion criteria.

Assessment of reporting biases

It was planned that data would be plotted on a funnel graph in RevMan to allow assessment of publication bias. This was not done as there were insufficient numbers of studies identified.

Data synthesis

Dichotomous data

In the analysis of dichotomous data it was intended that the risk ratio would be calculated with 95% confidence intervals according to intention-to-treat principles, and using the assumption that patients who dropped out had a negative outcome. If meta-analysis had been deemed to be appropriate, a fixed effect model of meta-analysis would have been preferred but the DerSimonian and Laird random effects method would have been used if heterogeneity was present. However if substantial heterogeneity had been found in terms of clinical diversity for example in differences in dose or duration of contraction and/or relaxation periods or differences in neuromuscular stimulation or differences in outcome assessment, meta-analysis would be deemed inappropriate. In this review there were no studies identified which were suitable for meta-analysis.
It was intended that if meta-analysis was not appropriate, subgroup analysis would then be completed for these parameters. However an insufficient number of studies was identified in this review for subgroup analysis. To assess for heterogeneity it had been proposed that the I^2 statistic would be used where I^2 = [(Q-DF)/Q] X 100% where Q is the chi squared statistic and df is its degrees of freedom (Higgins 2002; Higgins 2003). This describes the percentage of variability of effect that is due to heterogeneity rather than chance (Higgins 2005). A value greater than 50% would have been considered substantial heterogeneity and meta-analysis would then not be performed. However in this review no studies were identified where it was possible to use the statistic and heterogeneity was not tested.

Continuous data

It had been proposed that continuous data would be analysed if the mean and the standard deviation values were presented. If the standard deviation was not reported this value would be calculated from standard errors, confidence intervals, t statistics or P values, if available. It was intended to test for skewness prior to meta-analysis. It was proposed that the standard deviations and the means would be reported or obtained from the authors and the standard deviation when multiplied by two should be less than the mean. If the mean had been found to be less than the standard deviation multiplied by two the mean would have been unlikely to be an appropriate measure of the centre of distribution and the sample would have been said to be skewed (Altman 1996). If skewness had been found, meta-analysis would not be performed on those studies with small sample sizes. It was proposed that with normally distributed data the weighted mean difference would be used for continuous data using the same measurement scales and the standardised mean difference will be used for continuous outcomes using different scales.

Grading of evidence

In February 2008 following publication of the protocol for this review the handbook for systematic reviews was updated. The grading system to rank the evidence in the systematic review has been modified. The Cochrane Collaboration has adopted the principles of the GRADE system for evaluating the quality of evidence for outcomes reported in systematic reviews (Schünemann 2008) and

this system is also recommended by the Musculoskeletal group. Both studies included in this review although described as randomised are quality rated as low due to limitations in the study design and imprecision in the results section. However as the overall results of the review are inconclusive there is no grade overall given for the quality of the body of evidence.

Clinical relevance tables

Clinical relevance tables were planned to be compiled under additional tables to improve the readability of the review. For dichotomous outcomes, the weighted absolute risk difference would be calculated using the risk difference (RD) statistic in RevMan. RR-1 calculates the weighted relative percent change. The number needed to treat (NNT) would be calculated from the control group event rate, i.e. the rate of events in the control group (unless the population event rate is known) and the relative risk using the Visual Rx NNT calculator (Cates 2004).

Continuous outcome tables were also planned to be presented under additional tables. Weighted absolute change would be calculated from the weighted mean difference (WMD) statistic in RevMan when trials using the same scale are pooled. For outcomes pooled on different scales, the standardized mean difference (SMD) would be multiplied by the baseline standard deviation in the control group to obtain the weighted absolute change. Relative percent change from baseline would be calculated as the absolute benefit divided by the baseline mean of the control group. NNT was planned to be calculated using the Wells calculator software available at the CMSG editorial office. The minimal clinically important difference (MCID) for each outcome was planned to be determined for input into the calculator.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies.

Electronic and manual searches identified a total of seven hundred and six citations of which fifteen abstracts were selected as being potentially relevant. Full text papers were sought for 14, one paper could not be located with the reference supplied (Zizic 1995). Two studies met the criteria for inclusion in the review (Oldham 1995; Stevens 2002).

The study by Oldham 1995 had 30 participants, 13 male and 17 female with a median age of 69 years (range 57 to 77 years). They were recruited from a waiting list of people awaiting knee replacement surgery. This study compared the effect of patterned neuromuscular stimulation (PNMS) with uniform neuromuscular stimulation, random neuromuscular stimulation and sham stimulation on the strength, endurance, cross sectional area, function, and quality of life of people waiting for knee replacement surgery (end stage osteoarthritis). The PNMS group received a pattern of stimulation replicating the discharge of a fatigued quadriceps femoris motor unit. The random NMS group received a stimulation pattern generated by randomly shuffling the inter pulse intervals in the fatigued motor unit, and the uniform group were stimulated at the same mean rate as the PNMS and random groups i.e. 8.4Hz. The sham group received stimulation comprising a single 33 microsecond impulse every three minutes. The waveform was asymmetrical biphasic, the contraction time was 30 seconds on and the relaxation time was 15 seconds for all groups. The treatment intensity was the minimum required to produce a visible and palpable muscle contraction although there was no assessment of the individual's maximum voluntary contraction reported. It is therefore unclear if these parameters could effect muscle strength. Subjects stimulated their weaker quadriceps for three consecutive hours per day for six weeks.

The outcome measurements were reported as being taken by experienced clinical staff but it is unclear whether or not the staff were blinded or independent. Maximum quadriceps voluntary isometric torque, quadriceps endurance, timed sit-to-stand, walking velocity, stride length and quality of life outcomes are reported. All results are presented graphically as percentages in change from baseline. No numerical data were provided on the number of clients in each group or the group means or standard deviations. No raw data were presented in table form independently of the graphical presentation. The author was contacted but none of the raw data was still available. Two patients withdrew from the study at weeks 7 and 11 and it is unclear to which group they were originally allocated to.

Stevens 2002 had 39 participants. All were post primary, unilateral, total knee arthroplasty with 18 participants in the control group and 16 in the experimental group. There were 12 males and six females in the control group of average age 63.7 years. The experimental group had 12 males and 4 females and the average age was 65.9 years. The body mass index in the control group was 30.2 ± 3.2kgs in the control group and 28.6 ± 4.6kgs in the experimental group.

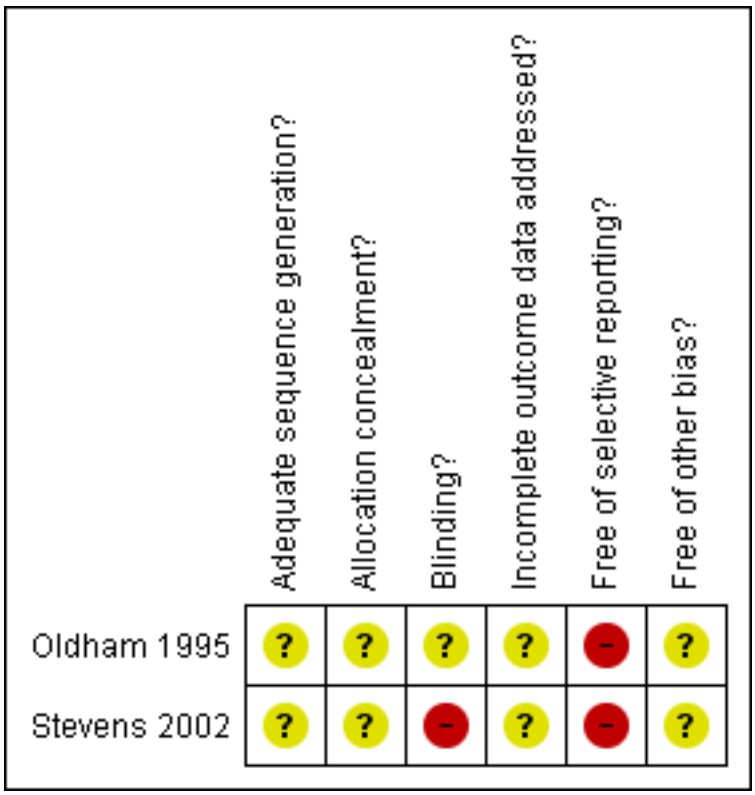
This study compared the effectiveness of a rehabilitation programme incorporating neuromuscular electrical stimulation (NMES) with high-intensity voluntary exercise against high-intensity voluntary exercise alone. Both groups participated in identical exercise programmes but the NMES group also received 10 NMES elicited quadriceps contractions during each treatment session at a dosage ranging from 29% to 69% of their maximum voluntary isometric contractions.

The outcome assessors were blinded to group allocation and assessed quadriceps strength and activation together with functional testing, health status questionnaires at initial evaluation, and in the 3rd, 9th and 12th week post surgery.

Risk of bias in included studies

Both studies carried an overall high risk of bias See Figure 1.

Figure 1. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.



Oldham 1995 stated it was a randomised control trial, but the randomisation process was not described. Thus the risk of bias in sequence generation must be judged as unclear. Similarly, insufficient information was given about allocation concealment and the risk of bias there is also unclear. Whilst the study is described as being double blinded, no information was given about who was blinded or how. The level of potential bias in the blinding must also be deemed unclear. Two patients in the study are reported as dropping out at 7 and 11 weeks and it is not possible to identify which of the four groups these subjects were from. The study does not address how incomplete data was dealt with again rendering the potential for bias from incomplete outcome data as unclear. In conclusion the selective reporting of outcomes with no group means presented and results given as graphical representation of percentage improvement from baseline does not allow for outcomes to be entered in a meta-analysis. This demonstrates potential for a high risk of bias. In addition the absence of raw data to illustrate the baseline outcome measurements does not allow us to assume the groups were similar at baseline. This is an additional threat to the validity of the study and overall his study demonstrated a high risk of bias.

Stevens 2002, like the study of Oldham 1995 gives no information on how the randomisation process was carried out. The risk of bias in sequence generation therefore is unclear. No method of concealment allocation was described and therefore the potential for bias here is also unclear. Although it was stated that the outcome assessments were carried out by those blinded to the study question, it was no stated whether or not the subjects or the treating therapists were blinded, this potentially introduces a high risk

of bias in the study. Although the patients who did not complete the study were accounted for it is not clear to which groups these subjects were initially allocated, making it unclear whether or not there is a risk of bias from incomplete data. The results in this study are presented as repeated measurements of analysis of variance (ANOVA results) and there are no mean group values or standard deviations presented. The findings were thus not presented in a form suitable for meta-analysis. Thus overall there is potentially a high risk of bias in this study.

Effects of interventions

See: **Summary of findings for the main comparison** Surface neuromuscular electrical stimulation for quadriceps strengthening pre and post total knee replacement

No significant differences were reported in the study by Oldham 1995 for maximum voluntary isometric torque or endurance between groups. No significant differences were reported in function or quality of life. Further analysis of the study findings was not possible due to the absence of raw data scores. Mean values were not given for strength, endurance, cross sectional area or quality of life. The results are presented as percentage improvements from baseline and the number of subjects in each group is unclear. The author was contacted with regard to the raw data but this was no longer available.

No significant differences in the quadriceps index were reported between the NMES and exercise groups in the study by Stevens 2002. Significantly better quadriceps muscle activation was reported in the exercise and neuromuscular stimulation group compared with the exercise group alone. This difference was significant at mid training at six weeks but not at twelve weeks post training. The repeated measures ANOVA indicated significant differences in the timed up and go test but there were no significant differences in univariate ANOVA scores at any time. No significant differences were reported at any time in the response to the other health status questionnaires. Further analysis of the outcomes of this study was not possible as the mean group values were not given and the standard deviation values could not be extracted from the P values. The author was contacted to obtain the raw data but it was no longer available.

Pain outcomes, patient satisfaction or adverse effects were not reported in either study.

DISCUSSION

Summary of main results

Although the main findings reported in both included studies were not significant for quadriceps strength, the two studies included in this review have a high risk of bias due to limitations in the study design and imprecision in the results presented. This would indicate a serious weakness in the confidence in the study findings. In addition the data in the studies were not presented in a format allowing meta-analysis to be conducted. The summary of findings table is incomplete and therefore the current evidence base is inconclusive. In addition the study by Oldham 1995 did not assess the subjects maximum voluntary contraction pre treatment therefore it is not possible to assess if a muscle strengthening effect could be obtained with the dosage applied.

Overall completeness and applicability of evidence

The data from the studies identified does not allow any conclusion to be made with regard to the use of neuromuscular stimulation pre or post total knee arthroplasty. This review is therefore inconclusive regarding the effectiveness of neuromuscular stimulation and further evidence is required to support or negate the use of neuromuscular electrical simulation as a means of quadriceps strengthening pre or post total knee replacement. The authors are aware that this review topic is the subject of ongoing research and the review will be updated to accommodate new evidence as it becomes available.

Quality of the evidence

The current body of evidence does not support or negate the use of neuromuscular electrical stimulation pre or post total knee replacement. The two studies included in the review had 69 subjects in total. Both studies had a high risk of bias and the results presented were incomplete and did not allow any meta-analysis to be conducted. The results of the review are therefore inconclusive.

Potential biases in the review process

Due to the timeframe within which this review was written it is acknowledged that the evidence considered for inclusion was published prior to December 2008. Relevent studies published after that date have therefore not been included but will be included in the next review update. This limitation of the review is acknowledged by the authors as a potential source of bias but is due to the constraints of the editing process.

Agreements and disagreements with other studies or reviews

The authors are unaware of any other systematic review specifically on this topic

AUTHORS' CONCLUSIONS

Implications for practice

The studies found in this review do not permit any conclusions to be made about the application of neuromuscular stimulation for the purposes of quadriceps strengthening pre or post total knee arthroplasty. At this time the evidence for the use of neuromuscular stimulation for the purposes of quadriceps strengthening in this patient group is unclear.

Implications for research

Well designed randomised controlled trials that compare quadriceps strength pre and post neuromuscular stimulation in both the pre and post total knee arthroplasty groups are needed. It is imperative that future studies assess quadriceps strength pre and post neuromuscular stimulation using reliable and valid assessment tools. It is important that the dosage of neuromuscular stimulation is stated clearly in the study design and its relationship to the clients maximum voluntary contraction is clarified. It is also critical that appropriate study designs are used and that the outcomes are presented in a manner suitable for meta-analysis. Future studies should also consider patient orientated outcomes including functional performance and self reported measures.

ACKNOWLEDGEMENTS

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Oldham 1995

Methods	A pre test, post test randomised double blind control group design. There were 30 subjects randomly assigned to one of four groups. Patterned neuromuscular stimulation (PNMS) group received a pattern of stimulation replicating the discharge of a fatigued quadriceps femoris motor unit (QFMU), uniform frequency neuromuscular group received stimulation with the same mean rate as the PNMS stimulation (8.4Hz), random pattern neuromuscular stimulation received a stimulation pattern generated by randomly shuffling the inter pulse intervals in the fatigued QFMU and the sham stimulation group received stimulation comprising a single 300 microsecond impulse every three minutes
Participants	All subjects were recruited from a waiting list of people listed for knee replacement surgery. There were 13 male and 17 females with a median age of 69 years (range 57 to 78). There were 30 subjects in total although the numbers allocated to each group were not specified
Interventions	All subjects stimulated their quadriceps using a pre-set programme of neuromuscular stimulation for three consecutive hours per day for 6 weeks. Output intensity was set by the subjects as the minimal intensity required to produce a visible and palpable muscle contraction
Outcomes	Strength, endurance, cross sectional area, timed 10 meter walk, timed sit to stand and quality of life using part two of the Nottingham health profile was recorded
Notes	The results are presented as percentage change values in isometric torque, quadriceps endurance, timed sit to stand, mean velocity of walking, and mean stride length graphically. No numerical data were provided. The author was contacted but the raw data were no longer available. Interpretation of results directly from the graphs was not attempted. There was no significant difference reported between the frequencies with regard to strength and endurance and no significant difference between frequencies for function, cross sectional area and quality of life

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Trial stated as randomised but no method described.
Allocation concealment?	Unclear	No information given to permit judgement on method of concealment allocation. No method of attempting to conceal allocation of subjects to either the control or experimental groups is stated

Oldham 1995 (*Continued*)

Blinding? All outcomes	Unclear	Study described as double blinded but it is not stated who was blinded i.e. patients treatment staff or assessors. The text stated that patients were instructed not to discuss treatment with staff to maintain blindness but no further detail was included
Incomplete outcome data addressed? All outcomes	Unclear	Two participants dropped out at weeks 7 and 11. No information was given as to which group they belonged to. No method of dealing with participant attrition was described
Free of selective reporting?	No	No raw data was available for this study and the outcomes were not given as group means but described in percentage improvements from baseline in graphical representation only. It was therefore not possible to carry out a meta-analysis on this data thus indicating a high risk of bias of selective reporting
Free of other bias?	Unclear	Insufficient information was given to assess whether or not the groups were similar at baseline. Thus the overall risk of bias is uncertain

Stevens 2002

Methods	This study was a randomised control trial with participants allocated to either an 'exercise group' or an 'exercise and neuromuscular stimulation' group for 6 weeks post total knee replacement
Participants	39 participants post primary total knee arthroplasty randomly assigned to one of two treatment groups. The control group received voluntary exercise only with exercises twice daily, 5 days per week and the neuromuscular stimulation group received the same exercise programme plus 10 NMES quadriceps contractions at each treatment session. There were 18 participants (12 male and 6 female) in the control group aged in years 63.7 ± 7.7, and 16 participants in the experimental group (12 male and 4 female) aged 65.9 ± 7.6 years in the experimental group
Interventions	Participants received 6 weeks of treatment 3 times weekly with both groups participating in a high intensity exercise programme. The NMES group also received 10 NMES quadriceps contractions at greater than 30% of quadriceps strength.This consisted of ten, 10 second isometric contractions with an 80 second rest between contractions. The intensity was set to the maximum intensity tolerated by the participant with the dosage $\geq$ 30% of the voluntary quadriceps strength

Outcomes	Testing was performed at 3, 6, 9, and 12 weeks after total knee arthroplasty. The outcomes assessed were quadriceps strength, quadriceps activation, timed up and go test, functional stairs test, and health status questionnaires (including the SF36, Knee outcome survey, and activities of daily living scale)
Notes	Five patients did not complete the study.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Method of randomisation was not stated leaving insufficient information to decide whether or not the sequence generation was adequate
Allocation concealment?	Unclear	Method of concealment was not described.
Blinding? All outcomes	No	Testers were blinded to the group assignment of subjects but there is no blinding reported of either the patients or the therapists involved both in the study. Both of these factors indicate a high risk of bias in the study
Incomplete outcome data addressed? All outcomes	Unclear	5 subjects did not complete the study. The groups to which these subjects were originally randomly allocated to were not reported
Free of selective reporting?	No	No raw data was available for any of the outcome measurements. Outcomes were given as P values only. This information is insufficient to permit meta-analysis and may indicate the potential for a high risk of bias with regard to selective reporting
Free of other bias?	Unclear	The absence of group mean numbers for all time frames prevents full assessment of potential bias

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Avramidis 2003	No strength measurement recorded pre or post neuromuscular stimulation
Gibson 1989	No strength outcomes recorded for the control group. No comparison possible with regard to strength
Goitlin 1994	No measurement of quadriceps strength recorded pre or post neuromuscular electrical stimulation
Haug 1988	Group contained two people with rheumatoid arthritis but which group they were assigned to was unclear.It was not possible to differentiate the study findings for the non rheumatoid group alone
Lewek 2001	Single case study.
Martin 1991	No strength measurement recorded pre and post neuromuscular stimulation
Mintken 2007	Single case study.
Novak 1991	No strength measurement recorded pre and post neuromuscular stimulation
Petterson 2006	Single case study.
Rodgers 1998	Content of Physiotherapy programme unclear from abstract. The full article showed that no neuromuscular stimulation was used in the preoperative physiotherapy programme
Stevens 2004a	Case series
Toro 1997	No strength measurement recorded pre and post neuromuscular stimulation
Zizic 1995	Abstract only available, Full paper sought but was found impossible to locate with the stated reference. No measurement of quadriceps strength pre or post neuromuscular stimulation is reported in the abstract

Characteristics of ongoing studies *[ordered by study ID]*

Stevens 2008

Trial name or title	Early neuromuscular electrical stimulation improves functional performance after total knee arthroplasty
Methods	31 participants randomized to either a standardized rehabilitation group for 9 weeks post surgery (control group n=14) or a standardized rehabilitation group with additional NMES twice daily for 15 minutes for 6 weeks (experimental group n = 17)
Participants	31 patients with end stage arthritis (20 women and 11 men).

Stevens 2008 (*Continued*)

Interventions	Standardized rehabilitation group which included 3 to 5 days on inpatient physical therapy, 2 weeks of home physical therapy and 6 weeks of outpatient physical therapy. In addition the experimental group received NMES twice daily for 15 minutes for 6 weeks. The average NMES dosage was quantified as a percentage of maximal voluntary quadriceps strength
Outcomes	Timed up and go test, stair climbing test, 100ft walk test and 6 minute walk test
Starting date	Not given
Contact information	Jennifer Stevens, Assistant Professor, UCD Physical Therapy Program
Notes	Correspondence by email stated that the preliminary results only had been presented but research findings will be presented formally in February 2009

DATA AND ANALYSES

This review has no analyses.

APPENDICES

Appendix 1. MEDLINE search strategy

MEDLINE search; (97)
1. Exp Arthroplasty/
2. Exp Joint Prosthesis/
3. Exp "Prostheses and Implants"/
4. Exp KNEE/
5. Exp Knee Joint/
6. or/1-3
7. 4 or 5
8. 6 and 7
9. Exp Arthroplasty, Replacement, Knee/
10. Exp Knee Prosthesis/
11. kat.
12. (knee$ and (replace$ or arthroplasty$ or prosthe$ or endoprosthe$ or implant$)).tw.
13. or/8-12
14. Exp Electric Stimulation Therapy/
15. ((neuro$ or muscle$ or muscular or electr$ or trans cutaneous nerve) adj stim$).tw.
16. Electrophysiology.tw.
17. Electrotherap$.tw.
18. Myostim$.tw.
19. Electrostim$.tw.
20. Neurotech$.tw.
21. Electroneurostim$.tw.
22. Neurostim$.tw.
23. EMS$.tw.
24. or/14-23
24. 13 and 24

WHAT'S NEW

Last assessed as up-to-date: 7 January 2008.

Date	Event	Description
11 November 2009	Amended	CMSG ID C152-R

HISTORY

Protocol first published: Issue 2, 2008

Review first published: Issue 1, 2010

Date	Event	Description
2 May 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

Brenda Monaghan (BM); Main review author, designed and coordinated the review; coordinated the searching process and critically appraised the papers identified; prepared the protocol and wrote the review

Donal O Mathuna (DOM); Supervisor and Co-Review author; provided feedback at all stages of the protocol and review preparation; assisted in critically appraising the papers to achieve a consensus between the two other co-reviewers; provided feedback and guidance as the review progressed.

Brian Caulfield (BC); Co-Review author; provided clinical feedback at the protocol preparation stage: assisted in the identification and screening of papers following the searching process: extracted data from the papers and provided clinical guidance on the interpretation of information and provided feedback on the overall review.

DECLARATIONS OF INTEREST

None known

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Internal sources

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External sources

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

None

INDEX TERMS

Medical Subject Headings (MeSH)

*Quadriceps Muscle; Arthroplasty, Replacement, Knee [*adverse effects]; Electric Stimulation [*methods]; Muscle Strength; Muscle Weakness [*therapy]; Osteoarthritis, Knee [*surgery]; Randomized Controlled Trials as Topic

MeSH check words

Humans