Conservative management for postprostatectomy urinary incontinence (Review)

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ABSTRACT

Background
Urinary incontinence is common after both radical prostatectomy and transurethral resection. Conservative management includes pelvic floor muscle training, biofeedback, electrical stimulation, compression devices (penile clamps), lifestyle changes, extra-corporeal magnetic innervation or a combination of methods.

Objectives
To assess the effects of conservative managements for urinary incontinence prostatectomy.

Search strategy
We searched the Cochrane Incontinence Group trials register (searched 2 July 2003), MEDLINE (January 1966 to January 2004), EMBASE (January 1988 to January 2004), CINAHL (January 1982 to January 2004), PsycLIT (January 1984 to January 2004), ERIC (January 1984 to January 2004), the reference lists of relevant articles, handsearched conference proceedings and contacted investigators to locate studies.

Selection criteria
Randomised controlled trials evaluating conservative interventions for urinary continence after prostatectomy.

Data collection and analysis
At least two reviewers assessed the methodological quality of trials and abstracted data.

Main results
Ten trials met the inclusion criteria, eight trials amongst men after radical prostatectomy, one trial after transurethral resection of prostate and one after either operation. There was considerable variation in the interventions, populations and outcome measures. The trials were of moderate quality and data were not available for many of the pre-stated outcomes. Confidence intervals were wide: it was not possible to reliably identify or rule out a useful effect.

There was some support from five trials for pelvic floor muscle training with biofeedback being better than no treatment or sham treatment in the short term for men after radical prostatectomy: relative risk for incontinence with pelvic floor muscle training and biofeedback versus no treatment: 0.74 (95% confidence interval 0.60 to 0.93). Analysis of other conservative interventions such as pelvic floor muscle training alone, transcutaneous electrical nerve stimulation and rectal electrical stimulation, or combinations of these interventions were inconclusive. There were too few data to determine effects on incontinence after transurethral resection of the prostate. The findings should be treated with caution as there were few studies, all of moderate quality. Men in one trial reported a preference for one type of external compression device compared to two others or no treatment. The effect of other conservative interventions such as lifestyle changes remains undetermined as no trials involving these interventions were identified. Men's symptoms tended to improve over time, irrespective of management.

Authors' conclusions
The value of the various approaches to conservative management of postprostatectomy incontinence remains uncertain. There may be some benefit of offering pelvic floor muscle training with biofeedback early in the postoperative period immediately following removal

of the catheter as it may promote an earlier return to continence. Long-term incontinence may be managed by external penile clamp, but there are safety problems.

PLAIN LANGUAGE SUMMARY

Overall effectiveness of conservative management of postprostatectomy urinary incontinence remains unclear.

The prostate is a male sex gland that surrounds the outlet of the bladder. Two main diseases of the prostate can be treated by surgery but some men suffer leakage of urine (urinary incontinence) afterwards. Conservative treatment such as pelvic floor muscle training, biofeedback and rectal electrical stimulation are thought to help men control this leakage. The review of trials found that pelvic floor muscle training and biofeedback might help soon after prostate removal (radical) surgery for cancer, but there was not enough information about the longer-term effects, nor the effect in men who had had surgery for benign (non cancerous) enlargement of the prostate (endoscopic resection). Of three external compression devices tested, one type seemed to be better than the others but needs to be used cautiously because of safety risks. More research of better quality is needed to assess conservative managements.

BACKGROUND

It is not uncommon for men to be incontinent after prostatectomy. The reported frequency varies depending on the type of surgery and surgical technique (Grise 2001; Peyromaure 2002), the definition and quantification of incontinence (Grise 2001; Peyromaure 2002), the timing of the evaluation relative to the surgery, and who evaluates the presence or absence of incontinence (physician or patient) (Donnellan 1997; McCammon 1999). Reported prevalence rates of urinary incontinence after radical prostatectomy for prostate cancer vary from 5% to over 60% (Hunskaar 2002). For example, in one study at 3 months after radical prostatectomy (Donnellan 1997), 51% were subjectively wet (self-report) but 36% were wet on pad testing (objective). By 12 months, 20% were subjectively still wet, but only 16% were classed as wet using objective criteria. After transurethral resection for benign prostate disease, urinary incontinence is less common at three months after operation (eg 10% needing to wear pads), but longer term data are not available (Emberton 1996).

After both types of operation, the problem tends to improve with time: it declines and plateaus within one to two years postoperatively (Hunskaar 2002). However, some men are left with incontinence that persists for years afterwards.

Continence mechanisms

Urinary continence depends on a complex interaction of smooth and striated muscle fibres blended together to form the continence mechanism. Considerable debate has existed in the literature as to whether incontinence after prostatectomy is due to an effect on the detrusor (bladder) muscle or on the sphincter, as commonly these abnormalities coexist (Peyromaure 2002). New detrusor overactivity and intrinsic sphincter deficiency due to sphincteric injury (Ficazzola 1998; Groutz 2000; McGuire 1990) are cited as the most important causes of persistent incontinence after radical prostatectomy. Debate continues on whether detrusor overactivity (Leach 1995; Golubuff 1995) is a primary or secondary factor. Whereas some report overactivity as the primary cause of postprostatectomy incontinence (Leach 1995; Golubuff 1995) others argue strongly that even if other factors play a role, intrinsic sphincter deficiency is the primary cause of incontinence after radical prostatectomy (Gudziak 1996; Kondo 2002; Aboseif 1996; Chao 1995; Winters 1997).

Risk factors for postprostatectomy incontinence after radical prostatectomy include pre-existing abnormalities of detrusor contractility (Leach 1995) and older age (Diokno 1997; Kondo 2002) (possibly due to progressive reduction in sphincter striated muscle cells with age) (Strasser 1997)). Other risk factors include previous transurethral resection of prostate (Kondo 2002); pre-operative radiotherapy (Kondo 2002; Rainwater 1988); trauma; spinal cord lesion; new obstruction due to recurrence, bladder neck contracture, or urethral stricture (Litwiller 1997); Parkinson's disease (Kondo 2002, Staskin 1988); dementia; and medications (Khan 1991; Yalla 1982). A surgeon's inadequate skill and expertise (Eastham 1996) and having surgery in a hospital which performs fewer than 20 radical prostatectomies a year have also been implicated (Albertsen 1997).

Incontinence after transurethral resection of prostate is thought to be most likely due to pre-existing abnormalities of bladder function such as poor compliance or detrusor overactivity, rather than direct sphincter injury (Abrams 1991), although in one study, 6% of men who were dry before surgery developed incontinence for the first time afterwards (Emberton 1996).

The treatments recommended for postprostatectomy are usually 'conservative,' not involving drugs or surgery. Six categories of conservative management will be considered in this review, singly and in combination when appropriate.

1. Pelvic floor muscle training

This involves any method of training the pelvic floor muscles to contract, including teaching performance of an accurate voluntary pelvic floor muscle contraction, and coordinating and timing the contraction against increases in intra-abdominal pressure.

The theoretical basis of pelvic floor muscle training is that repeated, volitional contractions of selected pelvic floor muscles may improve their strength and efficiency during periods of increased intra-abdominal pressure. In a systematic review of the literature on female incontinence, Berghmans and colleagues noted that a pelvic floor muscle contraction may raise the urethra and press towards the symphysis pubis, prevent urethral descent, and improve structural support of the pelvic organs (Berghmans 1998). They further pointed out that pelvic floor muscle training may result in hypertrophy of the periurethral striated muscles thereby increasing the 'external mechanical pressure on the urethra'.

2. Biofeedback
Traditionally, biofeedback involves the use of equipment to provide visual or auditory feedback about the pelvic floor muscle function to enable the man to train, strengthen and increase endurance and coordination of the pelvic floor muscles contractions. Simple auditory biofeedback could also be provided by the therapist informing the patient when a contraction is felt through digital anal examination during the pelvic floor muscle contraction.

3. Electrical stimulation (non-invasive) delivered via surface electrodes.

- Anal electrical stimulation

Any type of electrical stimulation using a non-invasive surface anal probe designed for the therapy. The intention of electrical stimulation is to facilitate contraction of the periurethral striated muscle.

- Sticky patch electrodes, also called transcutaneous electrical nerve stimulation (TENS).

Transcutaneous electrical nerve stimulation is a low intensity, sensory nerve stimulation used for detrusor overactivity, delivered at various sites, using patch electrodes. Sites include the sacral dermatomes (Hasan 1996), dorsal penile nerve (Nakamura 1984), hamstring and quadriceps muscle (Okada 1998), and the posterior tibial or perineal nerves (McGuire 1983).

4. Lifestyle adjustment
This includes fluid adjustment, diet, caffeine elimination, physical exercise, weight loss and cessation of smoking.

5. Extra-corporeal magnetic innervation.
This involves the use of a magnetic chair to stimulate contraction of the pelvic floor muscles (Galloway 2000).

6. External penile compression devices
These devices use an external clamp to achieve non-surgical compression of the urethra.

The initial review on the topic of postprostatectomy urinary incontinence, first published in 1999 (Moore 1999b) and updated in 2001 (Moore 2001), only considered pelvic floor muscle training, biofeedback and electrical stimulation. In this update, the review has been broadened to include studies evaluating lifestyle adjustment, external penile compression devices and extracorporeal magnetic innervation.

OBJECTIVES

To determine the effects of conservative management for urinary incontinence after transurethral, suprapubic, laparoscopic, radical retropubic or perineal prostatectomy, including any single conservative therapy or any combination of conservative therapies. Pharmacological agents will be considered in separate reviews. The use of the term 'sham therapy' in this review means any therapy that could not influence the pelvic floor muscles such as placing an electrical stimulation probe in the anus but not turning it on.

The following hypotheses were tested for treatment of urinary incontinence after prostatectomy:

(1) that pelvic floor muscle training is better than no treatment or placebo or sham therapy;
(2) that anal electrical stimulation is better than no treatment or placebo or sham therapy;
(3) that transcutaneous electrical nerve stimulation is better than no treatment or placebo or sham therapy;
(4) that pelvic floor muscle training plus biofeedback is better than no treatment or placebo or sham therapy;
(5) that pelvic floor muscle training plus anal electrical stimulation is better than no treatment or placebo or sham therapy;
(6) that pelvic floor muscle training plus anal electrical stimulation plus biofeedback is better than no treatment or placebo or sham therapy;
(7) that pelvic floor muscle training plus biofeedback is better than pelvic floor muscle training alone;
(8) that pelvic floor muscle training plus anal electrical stimulation is better than pelvic floor muscle training alone;
(9) that pelvic floor muscle training plus transcutaneous electrical nerve stimulation is better than pelvic floor muscle training alone;
(10) that pelvic floor muscle training alone is better than transcutaneous electrical nerve stimulation alone or biofeedback alone or anal electrical stimulation;
(11) that lifestyle adjustment is better than no therapy or sham therapy;
(12) that one type of external penile compression device is better than no therapy or sham therapy, or another type of treatment;
(13) that extracorporeal magnetic innervation is better than no therapy or sham therapy.

We have not listed all possible comparisons here. As and when new trials address new comparisons these will be added to the review.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

Randomised or quasi-randomised controlled trials of conservative management of urinary incontinence after transurethral or radical prostatectomy were sought.

Types of participants

Men who had undergone a prostatectomy for either benign prostatic hyperplasia or prostate cancer. Studies involving men experiencing urinary incontinence prior to prostatectomy were excluded.

Types of intervention

Pelvic floor muscle training, biofeedback, electrical stimulation via a surface electrode (anal probe electrical stimulation or sticky patch electrode transcutaneous electrical nerve stimulation (TENS)), extra-corporeal magnetic innervation, lifestyle adjustment, and external penile compression device compared with no treatment or with each other, alone or in combination.

Types of outcome measures

Primary outcomes:

1. *Patient reported symptoms*
Self report of urinary incontinence (number not cured or improved)
Number of pad/clothing changes (pad changes per 24 hours)
Frequency of incontinence from self-report or diary (incontinent episodes per 24 hours)
Frequency of micturitions per 24 hours
De novo urge symptoms

2. *Objective Measures*
Standardised pad test (24 hour or 1 hour) measuring grams of urine lost

Secondary outcomes:

1. *Patient satisfaction*
Self report of satisfaction with method

2. Health status measures
Impact of Incontinence e.g. Incontinence Impact Questionnaire (Uebersax 1995)
General health status e.g. Short Form 36 (Ware 1993)
Quality of life e.g. European Organisation for Research and Treatment of Cancer (EORTC QLQ-C30), version 2 (Aaronson 1993; Aaronson 1988)
Symptom inventory e.g. International Prostate Symptom Score (IPSS) (Barry 1992)

3. Adverse events due to treatment

4. *Health economics*
Cost of intervention
Resource implications of differences in outcome
Economic analysis (cost effectiveness, cost utility)

5. Other outcomes
Non pre-specified outcomes judged important when performing the review.

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: methods used in reviews.

This review has drawn on the search strategy developed for the Incontinence Review Group. Relevant trials were identified from the Group's specialised register of controlled trials which is described, along with the group search strategy, under the Incontinence Group's details in *The Cochrane Library*. The register contains trials identified from MEDLINE, CINAHL, The Cochrane Central Register of Controlled Trials (CENTRAL) and hand searching of journals and conference proceedings. The Incontinence Group's trials register was searched using the Group's own keywording system, the search terms used were:
({design.cct*} OR {design.rct*})
AND
({topic.urine.incon.postprost*})
(All searches were of the keyword field of Reference Manager 9.5 N, ISI ResearchSoft).
Date of the most recent search of the register for this review: 2 July 2003.
The trials in the Incontinence Group's specialised register are also contained in The Cochrane Central Register of Controlled Trials (CENTRAL).

For this review extra specific searches were performed by one of the reviewers. These are detailed below.

Systematic searches of electronic bibliographic databases
The following electronic bibliographic databases were searched (date search as performed: 10 February 2004):
MEDLINE - dates searched: January 1966 to January 2004;
EMBASE - dates searched: January 1988 to January 2004;
PsycLIT - dates searched: January 1984 to January 2004;
CINAHL - dates searched: January 1982 to January 2004;
ERIC - dates searched: January 1984 to January 2004.

The following search terms were used in each database (no limits were applied to the searches):
incontinence, urinary, male, postprostatectomy, stimulation, electrical stimulation, biofeedback, pelvic muscle exercises, kegel exercises, behavioural, behaviour, behavior, therapy, behaviour modification, therapy, physiotherapy, lifestyle, weight loss, caffeine, smoking, extracorporeal magnetic innervation, external penile compression devices, continence, bladder control, quality of life, randomised (randomized) controlled trial, evaluation, effectiveness, efficacy, outcomes.

Handsearching of conference proceedings
The following conference proceedings were handsearched:

- American Urological Association (years searched: 1989-2003) Supplement to the Journal of Urology, published as a supplement.
- Society of Urologic Nurses and Associates (SUNA) (formerly American Urologic Association Allied) these abstracts are not published but are available in the SUNA office. Annual meeting (years searched: 1991 to 2003);1991-Las Vegas, NV; 1992-Washington, DC; 1993-San Antonio, TX; 1994-San Francisco, CA; 1995-Las Vegas,NV; 1996-Orlando, FL, 1997-New Orleans, LA. Biannual incontinence meeting (years searched: 1992 to 2001); 1992-Tampa, Fla (1st meeting), 1994-Phoenix, 1996-Dallas, 1998-Orlando, 2000-Nashville, 200; Understanding urodynamics seminar (years searched: 1993-1996); 1993-Denver, CO; 1994-San Antonio, TX; 1995-Cleveland, OH; 1996-St Louis, MO.
- Wound Ostomy and Continence Nurses (years searched: 1996, 1997,1999 to 2003). Annual meeting: 1996- Seattle, WA; 1997-Nashville, TN; Incontinence meeting (biannual); 1997-Beverly Hills (1st meeting); 1999-Austin, TX.
- International Continence Society (years searched: 1980 to 2003). Published proceedings in Neurourology and Urodynamics.

Reference lists of relevant articles
The reference lists of relevant articles were searched for other possibly relevant trials.

Contact with investigators in the field
Investigators were contacted to ask for other possibly relevant trials, published or unpublished.

No language or other limits were imposed on the searches.

METHODS OF THE REVIEW

The methodological quality of the identified trials was assessed using the Cochrane Incontinence Group's criteria presented in the *The Cochrane Library*. For the initial review, this was performed by two reviewers (KM, DJC) with a consensus reached through discussion if there was any disagreement. The same two reviewers also independently performed data abstraction. Any discrepancies were discussed until agreement was reached.

For the current update, a similar approach was used. In phase one, an initial list of 440 titles (some with abstracts) generated for the review was assessed by one reviewer (KH). Sources of the titles were as follows: Cochrane Incontinence group specialised register search (14), MEDLINE (266), EMBASE (87), CINAHL (32), ERIC (1) and ICS proceedings (40). Repeat titles and non relevant articles (primarily descriptions and studies of surgical approaches to prostatectomy) were deleted leaving a list of 125 potentially relevant articles and abstracts. This list was then reviewed independently by two reviewers (KH and KM) and results compared. The full text article of references identified as potentially relevant by either reviewer (48 articles, 5 abstracts) were retrieved by one reviewer (KH) and reviewed by both. Reference lists of relevant review articles were reviewed to identify any further trials. References were assessed based on the population, interventions, control, outcomes and overall study design. From this, thirteen potentially relevant trials for addition to the review were identified.

In phase two, using the full text of the potentially relevant published studies and abstracts, the same two reviewers (KH and KM) independently reviewed the studies for relevance and inclusion, based on the criteria described above.

Methodological quality of eligible trials for the initial review and previous update was assessed independently by two reviewers (Moore 2001). For this update, potentially relevant studies were assessed independently by two reviewers (KH, KM) and results compared. One reviewer (KH) not previously involved with the review also reassessed the quality of trials included in previous versions of the reviews. Two approaches to quality assessment were used. The first was the quality assessment tool published in the Cochrane Incontinence Group module (Grant 2003), the second was the scale developed by Jadad (Jadad 1996). Disagreements were resolved through discussion, third party arbitration was not required.

The Cochrane Incontinence Group assessment tool is not scored. The following methodological parameters are included:
1) identification of study as randomised or quasi-randomised;
2) description of inclusion/exclusion criteria;
3) potential for selection bias (quality of random allocation concealment) rating;
4) potential for bias around time of treatment or during outcome assessment (blinding) rating;
5) potential for selection bias in analysis (description of withdrawals/dropouts/lost to follow up, analysis on intention to treat;
6) appropriate statistical analysis.

The second quality assessment was the Jadad scale (Jadad 1996) which is scored in the following manner:
1) was the study described as randomised (this includes the use of words such as randomly, random, and randomisation)? (yes = 1, no = 0);
2) was the study described as double blind? (yes = 1, no = 0);
3) was there a description of withdrawals and dropouts? (yes = 1, no = 0).
Add points:
Question 1) if randomisation method described and appropriate (1 point)

Question 2) if double blinding method described and appropriate (1 point)
Deduct points:
Question 1) if randomisation method described and inappropriate (1 point)
Question 2) if double blinding method described and inappropriate (1 point)

For the trials added to the review, data were extracted independently by two reviewers (KH and KM) using a standard form developed for this update. In addition, KH extracted the data from the five trials included in previous versions of this review for verification and familiarization purposes. The following information was included on the standard form that was developed:

- study
  method and characteristics (design, method of randomisation, inclusion/exclusion criteria, withdrawals/dropouts);
- participants (population, age);
- type of intervention, timing and duration of therapy, co interventions;
- control (no treatment or sham therapy);
- outcomes (types of outcome measures, reported outcomes, adverse events).

Extracted data were compared by two reviewers (KH and KM) for completeness and accuracy, and cross checked by the other reviewers (CG, DJC). Disagreements were resolved through discussion and review of the trial report. Data were entered into Review Manager software (RevMan 4.2.3) by KH and CG. The data were evaluated for publication bias using graphical (i.e. funnel plot) evaluation only. This is discussed in the results section.

For dichotomous outcomes, data were summarized (e.g. number of people for whom an outcome is present or not) and relative risks (RR) calculated with their 95% CIs. For continuous outcomes, the number in each group was summarised and the mean value for each group calculated as weighted mean differences (WMD) if the same scale (e.g. pad test in grams of urine) was used for the outcome measurement. A fixed effect model was used to calculate the summary statistic and the 95% confidence intervals. Heterogeneity was assessed visually. Forest plots were examined and potential sources influencing heterogeneity identified. Possible sources of heterogeneity were explored statistically through subgroup analysis. Currently, the Cochrane Incontinence Group uses the Chi-squared test for heterogeneity and the I-squared statistic (Higgins 2003). Where synthesis was not appropriate, a narrative overview was planned.

Comparisons of the outcomes of the chosen interventions with no treatment, with each other, and in combination were planned a priori for the review update. Data were not available for all planned comparisons. As there was considerable diversity in the length of time interventions were carried out and in how this time was reported, the data were further divided into categories by length of time. In addition, in planning the update, subgroup analysis based on type of surgery (radical prostatectomy or transurethral resection of the prostate) was planned.

Attempts were made to contact authors of trial reports if clarification was necessary. Included trial data were processed as described in the Cochrane Collaboration Handbook (Clarke 2003). Studies were excluded from the review if they made comparisons other than those pre-specified or if data were unavailable. Excluded studies were listed with reasons for their exclusion.

DESCRIPTION OF STUDIES

At the time of the previous update (Moore 2001), five trials (Franke 1998; Mathewson-Chapman 97; Moore 1999; Opsomer 1994; van Kampen 1998) were included in the review. All involved patients who had undergone some form of radical prostatectomy. A sixth trial (Griebling 1999) had been identified but was in abstract form only with no data available.

Excluded and ongoing trials
For this update, in addition to the five trials previously included in the analysis, fourteen potentially relevant studies on conservative management of postprostatectomy urinary incontinence were identified. Four studies (Pulker 2002; Salinas Casado 1991; Salinas Casado 1996; Zermann 1999) were excluded as they were found to be descriptive studies of conservative interventions and did not include a control group for comparison. Of these, two were English language abstracts (Pulker 2002; Zermann 1999) while the other two (Salinas Casado 1991; Salinas Casado 1996) were Spanish with an English abstract available. Another study (Chang 1998) was excluded as it did not meet the criteria for random assignment to groups. A translation for one German language trial (Bocker 2002) was obtained through the Cochrane Incontinence Group but the trial was not included as the data for the postprostatectomy participants were not separated from a group of female participants who had recovered from polio. A final trial (Bennett 1997) that had been included in the list of ongoing trials in the original review was excluded as it was only available in abstract and attempts to contact the author had not been successful.

Further methodological and background data continue to be sought from the authors of two published studies (Floratos 2002; Wille 2003) and one study available only in abstract form (Ceresoli 2002). These studies are listed as Excluded Studies pending further information. Additionally, one ongoing study (Nehra 2001) was identified in abstract form. Further data are being sought from this author as well.

Included trials

Included in the review update at this time were five additional trials (Bales 2000; Joseph 2000; Moore 2004; Parekh 2003; Porru 2001), bringing the total number of included trials to ten.

Types of populations

Eight trials involved patients undergoing radical prostatectomy (Bales 2000; Franke 1998; Mathewson-Chapman 97; Moore 1999; Moore 2004; Opsomer 1994; Parekh 2003; van Kampen 1998); one trial involved patients after transurethral resection of the prostate (Porru 2001); and one trial included patients with either transurethral resection of the prostate or radical prostatectomy (Joseph 2000). In addition to the variation in surgical approach, participants were recruited in some trials preoperatively (Bales 2000; Parekh 2003), within days or up to two weeks postoperatively (Franke 1998; Mathewson-Chapman 97; Porru 2001; van Kampen 1998), or weeks to months after surgery (Joseph 2000; Moore 1999; Moore 2004; Opsomer 1994). This variation may lead to different populations being studied in the trials: those experiencing early urinary incontinence (many of whom are likely to recover continence spontaneously) and those with persistent urinary incontinence.

Types of interventions

In the included trials, there was considerable variation in the type and intensity of interventions. The duration of the treatment interventions varied from four weeks up to one year. Two trials (Moore 1999; Porru 2001) examined pelvic floor muscle training in comparison to no treatment or sham. Trials in which both intervention and control groups were exposed to standard pre-operative verbal or written information on pelvic muscle exercises followed by a specific pelvic floor muscle training protocol, in the intervention group, only were included in this grouping. Five trials used pelvic floor muscle training with biofeedback as the intervention (Bales 2000; Franke 1998; Mathewson-Chapman 97; Parekh 2003; van Kampen 1998). Moore had a second intervention group that underwent PFMT with anal electrical stimulation (Moore 1999), while another used PFMT with both biofeedback and electrical stimulation of an unspecified type as the intervention (Opsomer 1994). Joseph et al compared verbal feedback with machine-mediated biofeedback as a supplement to pelvic floor muscle training (Joseph 2000). One trial compared external penile compression devices as the intervention (Moore 2004). No trials testing lifestyle changes alone were identified for inclusion.

Types of outcome measures

There was also lack of consistency in the reporting of outcome measures. In terms of the primary outcomes of interest in this review, only four of the included trials (Joseph 2000; Mathewson-Chapman 97; Moore 1999; Moore 2004) reported results of the standardized pad test (grams of urine lost in 1, 4 or 24 hour test). Two other authors (Franke 1998; Opsomer 1994) reported using a pad test, but data were not reported or were incomplete. Moore (Moore 1999) and van Kampen (van Kampen 1998) set different limits for incontinence (2 grams as opposed to less than 1 gram). Bladder or voiding diaries recording patient-reported symptoms of incontinence (the second primary outcome of interest in this review) were used in seven of the trials (Bales 2000; Franke 1998; Mathewson-Chapman 97; Moore 1999; Parekh 2003; Porru 2001; van Kampen 1998). One trial (Porru 2001) reported using the American Urological Association symptom score and a five point grading scale to assess strength of pelvic floor muscle contraction by digital evaluation. Definitions of incontinence, on which the number of patients remaining incontinent at the end of the trial was based, varied from the use of pads (Bales 2000; Parekh 2003) to a specified amount of urine lost (van Kampen 1998). Many authors did not specify a definition of incontinence for their trial.

Secondary outcomes for this review pertaining to quality of life issues were included in some trials, but the findings were often provided as a narrative summary rather than numerically, and so were not available in a form suitable for statistical analysis. No trials reported on economic issues.

METHODOLOGICAL QUALITY

The quality assessment criteria of the Cochrane Incontinence Group assume that the avoidance of bias is best achieved by: a randomised trial with secure concealment of allocation prior to formal entry; adequate blinding of patients, outcome assessors and health care providers; description of reasons and numbers of withdrawals and dropouts; and analysis on an intention to treat basis. None of the trials fulfilled all these criteria.

Overall, the quality of trials included in the review was low. Although all ten studies were identified as randomised controlled trials, only three (Moore 1999; Moore 2004; van Kampen 1998) clearly described that a secure technique of concealment of allocation had been used (sealed envelopes). Blinding was not described in most of the trials, with just a handful indicating an attempt to minimize bias in intervention or outcome measurement. Bales (Bales 2000) and van Kampen (van Kampen 1998) had people not involved in provision of the intervention act as outcomes assessors. Moore indicated that a single therapist, blinded to control group outcomes, provided all treatment (Moore 1999). Bales (Bales 2000) and Mathewson-Chapman (Mathewson-Chapman 97) do not mention withdrawals or dropouts: there are apparently no dropouts in the first of these two trials, but the issue is unclear in the second trial. All others reported the number of withdrawals or dropouts, but the reasons were not consistently reported. Only two trials discussed how this was dealt with in the analysis (Moore 1999; Parekh 2003).

The Jadad scale was also used for measuring quality (Jadad 1996). One study (Moore 1999) received 2/5 points on this scale, three trials (Franke 1998; Parekh 2003; van Kampen 1998) received 1 point, and the rest received a score of zero. This reflects the lack

of adequate information on randomisation technique and failure to mention or inadequate blinding in most of the trials.

RESULTS

REPORTING OF OUTCOMES

Most trials appeared to base reporting of primary outcomes on patient reported symptoms such as leakage or pad use, recorded in a bladder diary (Franke 1998), reported on interview (Bales 2000), or measured in a symptom questionnaire (Porru 2001). Three trials reported an objective measure based on the amount of urine lost in a pad test (Joseph 2000; Moore 1999; van Kampen 1998), although Moore and Van Kampen set different limits (2 grams as opposed to less than 1 gram). In one trial (Mathewson-Chapman 97), this appears to have been derived from a combination of pad test results and patient reported symptoms.

None of the secondary outcomes identified for this review were included in the analysis as few trials reported on these. Three trials reported measures of quality of life or satisfaction, but they were very different measures and not reported in a format that allowed them to be included in analysis. Moore used two validated quality of life measures (Moore 1999). Although there was a moderate correlation between one measure and the amount of urine lost, there were no differences between intervention and control groups. Satisfaction with the treatment was reported as high, based on face to face interview. Porru used a standardized questionnaire of seven questions, some of which were open-ended allowing for written concerns from participants (Porru 2001). The intervention group was found to have a significantly higher satisfaction rate.

COMPARISONS BASED ON INTERVENTIONS

1. Pelvic floor muscle training versus no treatment or placebo or sham therapy (Comparison 01)

Two of the included trials (Moore 1999; Porru 2001) compared pelvic floor muscle training with no treatment, and reported data on the review primary outcomes. One included men after transurethral resection of prostate for benign prostatic disease (Porru 2001) and the other was amongst men after radical prostatectomy (Moore 1999). The transurethral resection of prostate men started the intervention protocol on the first or second day postoperatively at the time of catheter removal. The Moore trial Moore 1999) involved men incontinent eight or more weeks postoperatively (some were recruited more than a year after surgery), and may represent a group with persistent incontinence and perhaps more complex underlying reasons for incontinence. The intervention group participants in the former were taught to perform pelvic floor muscle trainig daily at home (varying frequency) with weekly digital anal reassessment and grading of pelvic muscle contraction (Porru 2001). In the Moore trial, the active intervention group underwent twice weekly pelvic floor muscle training exercises under the direction of a physiotherapist (Moore 1999).

Number not cured

There were no significant differences between the groups in the rates of men incontinent at three or six months, but both trials were small and the confidence intervals were wide (Comparison 01.01).

Pad test

There were no significant differences between the groups in terms of amount of urine lost estimated from pad tests at 3, 6 and 12 months in one small trial, and the standard deviations (SDs) were larger than the means, suggesting highly skewed data (Moore 1999).

These findings should be interpreted with caution as both trials were small and there was clinical heterogeneity in terms of type of operation and pathology. However, individually, neither trial provided enough data to identify or rule out a useful effect of pelvic floor muscle training.

2. Anal electrical stimulation versus no treatment or placebo or sham therapy (Comparison 02)

No trials were identified.

3. Transcutaneous electrical nerve stimulation (TENS) versus no treatment or placebo or sham therapy (Comparison 03)

No trials were identified.

4. Pelvic floor muscle training plus biofeedback versus no therapy or sham therapy (Comparison 04)

Five trials compared pelvic floor muscle training plus biofeedback with a no-treatment or placebo-treatment control group (Bales 2000; Franke 1998; Mathewson-Chapman 97; Parekh 2003; van Kampen 1998). All trials involved men who had undergone radical prostatectomy for cancer. In the Bales trial, randomisation occurred preoperatively and initial instruction on pelvic floor muscle training and biofeedback training (surface electrodes) for the intervention group was provided two to four weeks prior to retropubic prostatectomy (Bales 2000). The control group received only postoperative verbal instruction on pelvic floor muscle training, and both groups were encouraged to practice pelvic floor muscle training four times daily once the catheter was removed at two weeks after surgery. In the Franke trial the intervention group starting pelvic floor muscle training with biofeedback (perineal patch electromyography through weeks 6, 7, 9, 11 and 16 postoperatively), supplemented with home exercises (Franke 1998). The control group received no instruction. This was a small trial, with a high drop out rate. Mathewson-Chapman had the intervention group perform pelvic floor muscle training with biofeedback (anal probe) at home from weeks 3 to 12 after surgery, whereas the control group received no treatment (Mathewson-Chapman 97). Men in the Parekh trial had postoperative pelvic floor muscle training, and digital or anal-probe biofeedback (Parekh 2003). Van Kampen recruited men who were incontinent after catheter removal, and 7 of 50 men received additional anal electrical stimulation if their contractions were found to be weak (van Kampen 1998). In addition men in both groups received bladder training. The control group received placebo (skin) electrostimulation.

Number not cured

All five trials reported in some way on incontinence rates. The data at three months or less favoured the intervention (RR for failure 0.74; 95% CI 0.60 to 0.93). There were no significant differences at 6 months or 12 months, although the estimates of effect at these time points were consistent with the findings at three months. However, the trials were small and there was significant statistical heterogeneity at three months, with wide confidence intervals (Comparison 04.01).

Pad test

Only one small trial reported data on the pad test as an outcome measure (Mathewson-Chapman 97). Mean losses were similar (120 grams versus 126 grams) with large standard deviations, indicating skewed data (Comparison 04.04).

Episodes of incontinence

Although there were fewer incontinence episodes in the intervention group in one small trial, this was not statistically significant (Mathewson-Chapman 97). Data for pad changes and incontinence episodes over 24 hours were consistent with this (Comparisons 04.03 and 04.05).

Trial differences

There was clinical heterogeneity regarding incontinence status at baseline, timing of recruitment and intervention, content of intervention and control treatments. The rates of incontinence in the Bales trial (Bales 2000) were much higher than those in the others and may be related to variation in author definition and measurement of incontinence. Bales defined incontinence as use of more than one pad per day (Bales 2000), Franke used percentage of participants pad free (Franke 1998), while Mathewson-Chapman does not specify whether the incontinence rates are based on objective or subjective data (Mathewson-Chapman 97). Parekh based incontinence on pad use (Parekh 2003). Van Kampen used subjective report and amount of urine lost on pad test (2 grams) (van Kampen 1998). There was a high drop out rate in the Franke trial (Franke 1998).

Because of this heterogeneity, it is questionable whether or not the data from the trials should be used to derive summary estimates, and this should be borne in mind when interpreting the data. When the trials are considered individually, there are statistically significant differences following the intervention only in the van Kampen trial (van Kampen 1998) but not in the other trials.

5. Pelvic floor muscle training plus rectal electrical stimulation versus no treatment or placebo or sham therapy (Comparison 05)

One trial reported using pelvic floor muscle training with anal electrical stimulation (Moore 1999). This was the second intervention group in the Moore trial. There were no statistically significant differences between the groups in terms of reported incontinence symptoms (Comparison 05.01) or urine lost (pad test, Comparison 05.04), but the SDs were large, indicating skewed distribution of data, and the confidence intervals were wide.

6. Pelvic floor muscle training plus rectal electrical stimulation plus biofeedback versus no treatment or placebo or sham therapy (Comparison 06)

One trial reported using pelvic floor muscle training with anal electrical stimulation as well as biofeedback (Opsomer 1994). Incontinent men (loss of more than 1 gram of urine on pad test) at six weeks after radical prostatectomy were randomised to intervention and control groups. Thus, the men were selected because they had persistent incontinence after surgery. The intervention group had two sessions of biofeedback and electrical stimulation (type unspecified) in addition to continuing the pelvic floor muscle training taught to both intervention and control groups earlier after surgery. There were no significant differences between the groups for cure rates, but this was based on only four men having incontinence at 3 to 6 months (comparison 06.01). Pad test results were not reported in a form that could be used and attempts to contact the author were unsuccessful.

7. Pelvic floor muscle training plus biofeedback versus pelvic floor muscle training alone (Comparison 07)

One trial compared use of machine-led biofeedback to augment pelvic floor muscle training versus exercises taught using the standard method of verbal feedback from digital anal assessment (Joseph 2000). The verbal feedback group was treated as "control" or "pelvic floor muscle training alone" for the analysis. The trial was very small (a total of only 11 men) and reported as a pilot. One man had incontinence after transurethral resection of prostate, the remainder after radical prostatectomy. Patients who were incontinent at least six months after surgery were randomised to either the biofeedback or verbal feedback groups. The results were not published, but the author supplied raw data on the pad test results so that means and standard deviations could be calculated by the review authors. Two men (of four still followed up) in the biofeedback group had urine loss on the pad test compared to none of three in the verbal group after three months. There are many potentially confounding variables in this trial, acknowledged by the author. Also, as all the men were incontinent for some time after surgery, they may represent a group with persistent incontinence.

8. Pelvic floor muscle training plus rectal electrical stimulation versus pelvic floor muscle training alone (Comparison 08)

One trial reported two arms with a total of 37 men addressing this comparison (Moore 1999). There was no difference in incontinence rates but with wide confidence intervals (Comparison 08.01). The distribution of pad test results was again very skewed (Comparison 08.04).

9. Pelvic floor muscle training plus transcutaneous electrical nerve stimulation versus pelvic floor muscle training alone (Comparison 09)

One study addressing this comparison is awaiting further assessment (Ceresoli 2002).

10. Pelvic floor muscle training versus transcutaneous electrical nerve stimulation alone or biofeedback alone or rectal electrical stimulation alone or no treatment (Comparison 10)
No trials were identified that made any of these comparisons.

11. Lifestyle adjustment versus no therapy or sham therapy (Comparison 11)
No trials were identified.

12. Extracorporeal magnetic innervation versus no therapy or sham therapy (Comparison 12)
One ongoing study was identified but not included at this time as no data were available (Nehra 2001).

13. External penile compression devices (penile clamp) versus no therapy or sham therapy (Comparison 13, Other Data Tables 13)
One trial compared three different penile compression devices (Cunningham clamp, U-Tex Male Adjustable Tension Band and C3 penile compression device) with a control period of no device (Moore 2004). A randomised block assignment was used with a multiple period crossover design, so that each of the 12 participants had a control period of no device and three periods in which the different devices were used. All external compression devices reduced the weight of urine lost on a four-hour pad test compared to the control period (P<0.05, Other Data Table 13.02), but none completely eliminated urine loss. Satisfaction was based on ease of application, comfort and efficacy. The device preferred by the largest number of men was also that with the lowest urine loss (Cunningham) (Other Data Table 13.01).

However, this was also the device with the greatest reduction in systolic blood flow velocity (P<0.05 versus control period, Other Data Table 13.03, 04), raising the possibility of safety issues if applied too tightly. In the trial, men were able to judge when to release the device, and the authors recommended that its use should therefore be limited to men who are cognitively intact, are aware of bladder filling, have normal genital sensation and intact penile skin, and have sufficient manual dexterity to open and close the device (Moore 2004).

SENSITIVITY ANALYSIS

Scores from the Jadad scale for each trial were entered into RevMan under the user column in an overall analysis and the resulting forest plot ordered by this score. Of the four trials that scored zero on the Jadad scale, three favoured control (Bales 2000; Mathewson-Chapman 97; Opsomer 1994), while one (Porru 2001) favoured the intervention. Although poorer quality did not appear to be exaggerating the effect of the intervention, it may have played a role along with the heterogeneity of populations, interventions and outcome measurement in the inconclusive results.

POTENTIAL FOR PUBLICATION BIAS

Potential for publication bias was examined graphically using a funnel plot. Using the extracted data from all ten included trials (relative risk, random effects), a funnel plot was generated in MetaView. Funnel plot asymmetry was present, with the smaller trials favouring treatment missing from the left of the funnel, but those favouring control present. Since small studies usually tend to overestimate rather than underestimate the effect of an intervention (Sterne 2001), attributing the asymmetry to publication bias is counterintuitive. A more plausible explanation of funnel asymmetry lies in the poor quality of the studies or variations in treatment type or intensity. As there were only ten trials included in this review, no statistical analysis to examine publication bias was undertaken. In meta-analyses of less than 20 trials, sensitivity of these methods (rank correlation or linear regression) is considered low (Sterne 2001).

DISCUSSION

This review incorporates a broad array of possible interventions under the umbrella term of conservative management of postprostatectomy urinary incontinence. The populations studied included men undergoing prostatectomy for different reasons (both benign and malignant disease). Although casting such a broad net in an area where controlled trials are scarce captures a number of studies, it also contributes to considerable clinical heterogeneity. This opens the question as to whether other factors, such as population, length and type of intervention or even approaches to measurement influenced the results. Summary estimates derived from combining data from these studies must therefore be interpreted very cautiously.

Overall, trials included in this review were of moderate quality. All the trials claimed to be randomised but only three provided details of adequate concealment of randomisation (Moore 1999; Moore 2004; van Kampen 1998). Blinding to intervention was not possible, and blinding of outcome assessment appeared to be absent in most trials as it was not discussed. Therefore, most of the included trials were vulnerable to allocation, intervention and measurement biases.

Attrition bias may have played a role in the results of some of the included trials and therefore affected the outcome of this review. One of the smaller trials (Franke 1998) lost half of the randomised participants by the end of the data collection period. Although most of those trials that lost participants provided an explanation of these losses, none of them accounted for the missing data in their analyses. The intention to treat principle mandates, at minimum, that patients stay in the group to which they are randomised (Juni 2001), which the included trials appeared to do. It is also suggested that primary outcomes for all patients randomised to groups should be recorded or estimated if not available. Only one of the included trials (Parekh 2003) reported an analysis that estimated missing values, so attrition bias is possible in a number of the trials.

Few trials used the primary outcomes of interest, patient reported symptoms and the standardized pad test. Most appeared to use a

variety of subjective outcomes derived from patient reported symptoms in determining whether or not continence was achieved. There were no trials which examined lifestyle adjustments in alleviating urinary incontinence after prostatectomy. One ongoing study (Nehra 2001) using extra-corporeal magnetic innervation was identified but there was insufficient information to include it at this time.

There may be some enhancement of quality of life in men after prostatectomy through the support provided by attending a clinic offering these interventions (Moore 1999).

It is acknowledged that postprostatectomy urinary incontinence will resolve over time in many men. There is some evidence that use of pelvic floor muscle training augmented with biofeedback by men with early incontinence may help to resolve this more quickly (based mostly on the results from one trial) (van Kampen 1998). The effectiveness of conservative measures in the longer term, or in those with persistent incontinence, remains inconclusive. Persistent incontinence may require surgical intervention such as injection of an endo-urethral bulking agent, insertion of an artificial urinary sphincter, or use of a suburethral sling. These approaches need to be tested by randomised controlled trial.

Type of operation
Only one trial presented data from men after transurethral resection of the prostate (Porru 2001). It was too small to be conclusive, although at three weeks the men in the intervention group were less likely to be incontinent than in the control group (data not shown). However, this difference had disappeared by four weeks (Comparison 01.01.01). No longer-term data were available. The finding of less persistant incontinence, in men who had radical prostatectomy managed with pelvic floor muscle training and biofeedback, largely depended on one trial (van Kampen 1998).

However, one particular type of alternative intervention, a Cunningham clamp fitted to the shaft of the penis, proved satisfactory to 10 of 12 men with intractable incontinence (Moore 2004). This may be a viable alternative for some men providing they take into account safety issues such as adequate sensation and ability to remove the device when it feels too tight or the bladder is full.

Conservative interventions tend to be resource-intensive strategies that require people, equipment and clinic space, so administrators will look for evidence of efficacy. Funding has been an issue given the inconclusive nature of the evidence to date. For example, in the United States, the centres for both Medicare and Medicaid Services were considering whether to withdraw funding for biofeedback and pelvic floor electrical stimulation in the treatment of urinary incontinence of any etiology based on a lack of evidence regarding effectiveness. Through a lobbying effort from service providers and manufacturers, these modalities continued to be covered (Thompson 2002). As controversy about funding is likely to continue, there is a need for continued research in the area to determine which groups of patients are most likely to benefit from conservative interventions.

AUTHORS' CONCLUSIONS

Implications for practice

In keeping with conclusions from earlier versions of this review, at this point there remains no clear support that conservative management of any type for postprostatectomy urinary incontinence is either helpful or harmful. The most promising evidence of benefit relates to pelvic floor muscle training with biofeedback early in the postoperative period immediately following removal of the catheter after radical prostatectomy. However, this finding was dependent on one particular trial. No trials have tested the effect of lifestyle changes alone. Long-term incontinence may be managed by external penile clamp, but there are safety problems.

Implications for research

Postprostatectomy urinary incontinence is a distressing problem and, although conclusive evidence does not exist, conservative approaches form part of current management. Clinical trials with improved methodology are needed to clarify the role of these therapies.

As there are known differences in the causes and prevalences of urinary incontinence between men after transurethral resection of prostate and after radical prostatectomy, these groups of men should be studied separately. One promising area is the potential for a quicker return to continence from early treatment.

Most of the trials included in this review used very different protocols of intervention type, timing and intensity. In order to determine the effects of specific protocols and modalities, large adequately powered trials using common protocols are needed. Replication studies using similar protocols in different populations would also assist in identifying the populations in which specific conservative management approaches are likely to be most effective.

Definitions and measurement of outcomes varied in the included trials. Future trials should attempt to use broadly accepted definitions, such as those of the International Continence Society and to make use of objective measures such as the pad test in determining if continence has been achieved.

Lastly, authors of trials on conservative management of urinary incontinence should be encouraged to ensure appropriate randomisation and blinding of trials and to report these adequately in published reports of their work, using the guidelines of the CONSORT statement.

POTENTIAL CONFLICT OF INTEREST

One of the reviewers (KNM) was an investigator in two of the ten included trials. She is also the Principal Investigator in an ongoing trial of conservative treatment for postprostatectomy urinary incontinence.

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** Indicates the major publication for the study*

TABLES

Characteristics of included studies

Study	Bales 2000
Methods	Randomised: yes Method of allocation: not stated Blinding: Outcome assessment nurse not involved in intervention. Dropouts: None mentioned.
Participants	N=100 consecutive patients with stage T1c-T2c prostate cancer undergoing radical retropubic prostatectomy by a single surgeon randomised into 2 groups.
Interventions	Intervention group: 2-4 weeks prior to surgery, participants underwent a 45- minute session with nurse trained in biofeedback. Patients were instructed to perform graded PFMT. Contractions of 5-10 seconds, 10-15 repetitions were performed with surface electrodes used to measure muscle strength. Advised to practice the exercises 4 times per day until surgery. Control: No biofeedback training. Written and brief verbal instructions from a nurse on how to perform PFMT (isolate muscle that stops urine flow, practice 4 times per day, 10-15 repetitions). Both: Encouraged to perform PME 4x per day after catheter removal 2 weeks post op.
Outcomes	Time to return of continence measured by number of pads used Continence defined as use of 1 pad or less per day Data collected at 1, 2, 3, 4, and 6 months postoperatively.
Notes	There was no significant difference in incontinence between the groups.
Allocation concealment	B – Unclear

Study	Franke 1998
Methods	Randomised: yes Method of allocation: not stated Blinding: none Dropouts: 2 with gravitational incontinence consistent with intrinsic sphincter deficiency Intention to treat: not clear.
Participants	30 men 6 weeks post radical prostatectomy with post void residual of <50ml; no previous TURP, no urinary tract infection, no neurological conditions.
Interventions	Biofeedback enhanced PFMT; exercises provided at 6, 7, 9, 11, and 16 weeks postoperatively; control group completed bladder diary but did not have any other intervention. Duration: 12 months.
Outcomes	All patients completed a voiding diary, 48 hour pad test, and incontinence questionnaire at all measurement points.
Notes	There were no significant differences between treatment or control groups on any of the outcome measures. This information is based on an abstract only. The authors did not return the reviewer's telephone calls.
Allocation concealment	B – Unclear

Study	Joseph 2000
Methods	Randomisation: yes Method of allocation: Not described. Blinding: None. Dropouts: 3 did not return to clinic for all appointments, one had other health problems

Characteristics of included studies (*Continued*)

	Intention to treat: No.
Participants	N= 11 patients at least 6 months post surgery (4 radical retropubic, 6 radical peritoneal, 1 TURP).
Interventions	Biofeedback group: Biofeedback as well as verbal to assist in identifying and discriminating muscles Control: Verbal feedback group received instruction, squeezing of finger during digital rectal exam Both groups received weekly visit for a total of 4 clinic visits
Outcomes	Pretreatment video- urodynamics standardised pad test, Joseph Continence Assessment Tool, bladder diary, subjective estimation of degree of incontinence. Measured at baseline, 3, 6, and 12 months.
Notes	No differences between the groups. Improvement seen in all patients at 12 months. Data not published in article. Raw data supplied to reviewer (KFH) who calculated means and standard deviations. These were reviewed by a second reviewer (KNM).
Allocation concealment	B – Unclear

Study	**Mathewson-Chapman 97**
Methods	Randomised: yes, block procedure Method of allocation: unclear Blinding: none Dropouts: 2 - not accounted for. Intention to treat: not clear.
Participants	53 men pre and post radical prostatectomy. Preoperatively, both groups received 30 mintues prostate education programme and baseline 'perineal muscle evaluation' (not defined); as well all were taught to contract the perineal muscle and hold for a few seconds prior to standing, lifting or coughing and limit the amount of tea, chocolate, alcohol and over-the-counter medications.
Interventions	Group 1 (control) no further interventions until week 5 when pelvic muscle strength was assessed. Group 2: (treatment): Home exercises and biofeedback using (Incare 8900); practiced at home 3 times a week, starting with daily 15 PFMT and increasing by 10 every 4 weeks to a maximum of 35 PFMT. Duration: 12 weeks.
Outcomes	Perineal muscle strength (method not described) frequency of micturitions (self-recorded bladder diary), number of pads used; days to achieve continence from baseline.
Notes	Inclusion of other modalities such as caffeine limitation and using perineal muscles during any event which increased abdominal stress may have masked any treatment benefit.
Allocation concealment	B – Unclear

Study	**Moore 1999**
Methods	Randomised: yes Method of allocation: sealed envelopes. Blinding: physiotherapist blinded to results of control group. Dropouts: 5 Intention to treat: yes.
Participants	141 men post radical prostatectomy who were a median of 8 weeks post operation (range 4-200 weeks).
Interventions	Group 1(control) oral and written information about PFMT pre and post- operatively (standard treatment); Group 2: PFMT alone; Group 3: PFMT plus rectal electrical stimulation treated by one physiotherapist 30 minutes twice a week for 12 weeks. Groups 2 & 3 did home exercises three times a day gradually working up to 30 minutes per session lying, standing, sitting; strength, endurance, speed and control with maximum contractions of 5-10 seconds, 10-20 second relaxation and 12-20 repetitions; submaximum contractions at 65-75% of maximum strength with hold 20-30 seconds and equal rest time, 8-10 repetitions; speed was sets of quick repetitive contractions

	in a 10 second time span; control involved gradual recruitment to maximum contraction in 3 stages with 5 second hold at each stage and a slow release with rest 15-30 seconds. Duration of study: 24 weeks.
Outcomes	24 hour pad test, quality of life measures (Incontinence Impact Questionnaire, European Organization for the research and treatment of Cancer-EORTC QLQ C-30, version 2), physical symptom inventory (adapted from Herr 1994). Measured at baseline, 12, 16 & 24 weeks after baseline.
Notes	Intervention perhaps administered too early - all subjects improved at the same rate; wide range of severity of urinary incontinence at study entry and size of SD of pad test results also may have resulted in Type II error
Allocation concealment	A – Adequate

Study	**Moore 2004**
Methods	Randomised: yes (order of product testing: in 3s to treatment block of 4 periods (1 no device, 3 with devices) Block, multiple period crossover design using Latin square configuration; Method of allocation: sealed envelopes. Blinding: Research assistant not involved in study chose envelope; but research assistant and participants could not be blinded to intervention Dropouts: None Intention to treat: Not discussed.
Participants	N = 12 men post radical prostatectomy who required continuous pad protection for stress incontinence Inclusion: normal perineal and penile sensation, intact penile skin, sufficient manual dexterity Exclusion: overactive bladder, neurological disorders affecting sensation or circulation, cognitive impairment.
Interventions	Each participant had 4 periods (each lasted 1 day) 1. No device 2. C3 device 3. U-Tex device 4. Cunningham clamp.
Outcomes	4 hour pad test. None of the devices completely eliminated urine loss when applied at a comfortable pressure. Each device showed improvement in terms of urine lost, with Cunningham clamp having the lowest mean loss. Other outcomes: resistive index (no effect), cavernosal flow (Cunningham clamp significantly lowered flow) Cunningham clamp ranked positively by participants.
Notes	Unable to blind participants and research assistant to intervention Sample size calculation given and required size achieved.
Allocation concealment	A – Adequate

Study	**Opsomer 1994**
Methods	Randomised: yes Method of allocation: method not described Blinding: none Drop outs: 4 Intention to treat: unclear.
Participants	43 men who were still incontinent 6 weeks after prostatectomy.
Interventions	Patients who lost more than 1gram of urine on pad test (International Continence Society (ICS) recommendations) 6 weeks postoperatively were allocated to 2 groups; Group 1; 21 PFMT plus biofeedback plus electrical stimulation directed by physiotherapist. Group 2; PFMT on their own without medical supervision. Duration: 12 weeks.
Outcomes	Numbers not cured Pad test.

Characteristics of included studies (*Continued*)

Notes	No statistical difference between groups as to recovery of continence. Abstract only - previous attempts to contact author unsuccessful in gaining more data.
Allocation concealment	B – Unclear

Study	**Parekh 2003**
Methods	Randomised: yes Method of allocation: Not described. Blinding: None Dropouts: 1 from each of the control and treatment groups. Reasons not described. Intention to treat: Yes, dropouts categorised as incontinent.
Participants	N= 38 patients scheduled for radical retropubic prostatectomy for localised cancer of the prostate.
Interventions	Control group: No formal education on PFMTpre- operatively, telephone or face to face follow-up at least monthly. Intervention: 2 treatment sessions postoperatively. Session 1 consisted of PFMT in a hook lying position. Session 2 was on an exercise ball. Teaching methods varied and included verbal cues, visualization with an anatomical model, palpation or biofeedback with rectal probe. Postoperatively, PFMT was reviewed and participants were seen every 3 weeks for 3 months by a physiotherapist.
Outcomes	Incontinence measured by number of pads used daily. Continence defined a 0 pads or 1 precautionary pad.
Notes	Greater number of the intervention group gained continence earlier than the control group at 3 months (only point of statistical difference). Minimal long term effect as continence rates the same at 1 year.
Allocation concealment	B – Unclear

Study	**Porru 2001**
Methods	Randomised: yes Method of allocation: Not described. Blinding: Report stated that urologist performing digital evaluation of pelvic floor muscle contraction was blinded to the study group. Dropouts: Intervention - 2, control - 1. Reason reported was non-attendance at all clinic appointments. Intention to treat: None.
Participants	N=58 consecutive patients undergoing TURP for benign prostatic hypertrophy.
Interventions	Intervention group: Initial visit before surgery, digital evaluation of pelvic muscle contraction strength. Verbal instruction, feedback and reinforcement on contraction was given to teach selective contraction of anal sphincter and relaxation of abdominal muscles. Verbal and written instruction given for home PFMT. Instructed to practice contractions 45 times per day (3 groups of 15 contractions). Both groups: Voiding diaries initated after catheter removal.
Outcomes	Grading of perineal and anal contraction by digital evaluation of muscle contraction. Scale 0-4 [0=none, 4=strong]. Urine flowmetry preoperatively and 1 month postoperatively. AUA (American Urological Association) symptom score preoperatively and 30 days after surgery. 48-hour voiding diary weekly. Data collected at catheter removal and weekly for 4 weeks.
Notes	Significant increase in muscle strength in intervention group by week 4. Both groups showed improvement in symptom score and quality of life postoperatively, no significant difference between groups. Significantly better satisfaction with life in intervention group compared to control at 4 weeks. Significant difference in voiding intervals between the groups at weeks 2 and 3, but not week 4. No difference in uroflowmetry. Significantly less incontinence in the intervention group at weeks 1, 2, and 3. No difference at week 4.

	Concluded that PFMT quickens the return to normal voiding post TURP.
Allocation concealment	B – Unclear

Study	**van Kampen 1998**
Methods	Randomised: yes Method of allocation: stratified randomisation with sealed envelopes. Blinding: yes Dropouts:5. Intention to treat: yes Outcome assessor not involved with the study.
Participants	Of 181 men after radical prostatectomy, 16 subjects dry, 63 unable to attend clinic (lived too far away), remainder (102 eligible) randomised on day of catheter removal; stratified by gms of urine loss (<50 , >50, <250, >250 gm)
Interventions	PFMT and biofeedback after catheter removal versus no systematic PFMT Group 1 had 1 session of PFMT in hospital before discharge and saw the physiotherapist for 1-2 weeks for as long as UI persisted and 90 daily home exercises sitting, standing and lying. 7 men received electrical stimulation Group 2 did not receive any formal PFMT instruction but saw the therapist at 1-2 weeks and received placebo stimulation and information about aetiology of UI Both groups received bladder training to increase bladder capacity Duration: 12 months
Outcomes	Numbers cured defined as <2gm urine loss 1 hour pad test (subject conducted in the home) Number of days to continence Visual Analogue Scale, Fluid Volume Chart, Quality of Life questionnaire designed for the study.
Notes	Pragmatic study; policy of management left to clinical judgment as to which protocols to add to PFMT regime. 63 of the eligible subjects were unable to participate because of geographical reasons; demographics and post- operative variables did not differ from the 102 subjects who were in the treatment groups.
Allocation concealment	A – Adequate

PFMT=pelvic floor muscle training; UI=urinary incontinence; TURP=transurethral resection of the prostaste; gm(s)=gram(s)

Characteristics of excluded studies

Study	**Reason for exclusion**
Bennett 1997	Abstract only, no data included. Attempts to contact the author for data unsuccessful.
Bocker 2002	Data from study that included male postprostatectomy and female post-polio patients. Translation obtained as reported in German. Data from the two groups were not separated and therefore not in a usable form.
Ceresoli 2002	Awaiting further information from authors
Chang 1998	Data from study which involved post TURP patients. Two groups, treatment and control. Not randomly assigned to groups, first 25 consecutively assigned to control, next 25 to intervention.
Floratos 2002	Awaiting further information from authors.
Griebling 1999	Data reported in paper presentation and in later published report did not contain sufficient detail of analysis to include in tables of comparison. Attempts to contact authors not successful in providing further data.
Pulker 2002	Descriptive study. No control group.
Salinas Casado 1991	Descriptive study. No control group. Article in Spanish with English abstract.

Characteristics of excluded studies (*Continued*)

Salinas Casado 1996	Descriptive study. No control group. Article in Spanish with English abstract.
Wille 2003	Awaiting further information from authors
Zermann 1999	Descriptive study. No control group.

TURP=transurethral resection of the prostate

Characteristics of ongoing studies

Study	**Glazener 2004**
Trial name or title	Conservative treatment for urinary incontinence in men after prostate surgery (MAPS)
Participants	Men after radical prostatectomy (RP)and endoscopic resection of prostate (ERP)
Interventions	Plevic floor muscle training and bladder training
Outcomes	Urinary incontinence, faecal incontinence, sexual function, quality of life, economic outcomes
Starting date	Autumn 2004
Contact information	Glazener CMA c.glazener@abdn.ac.uk
Notes	Duration of trial 4.5 years

Study	**Moore 2003**
Trial name or title	The effectiveness of biofeedback assisted pelvic floor muscle exercises in the treatment of incontinence post radical prostatectomy.
Participants	228 men post radical prostatectomy from 3 centres.
Interventions	Biofeedback assisted pelvic floor muscle exercises.
Outcomes	24 hour pad test, IPSS, IIQ-7.
Starting date	October 2002
Contact information	Moore, KN katherine.moore@ualberta.ca
Notes	Recruitment should be completed December 2004.

Study	**Nehra 2001**
Trial name or title	Interim analysis of a multi-centre study of ExMI for urinary incontinence following radical prostatectomy.
Participants	Had enrolled 33 out of a target of 60, 11 included in interim analysis.
Interventions	Intervention group: ExMI via magnetic chair 2 times weekly for 6 weeks. Control: Sham treatment in chair. Those randomised to sham crossed over to treatment at 6 weeks.
Outcomes	Bladder diary, standardised pad test, quality of life survey (name not provided). Measured at baseline, 6, 8, 10 and 18 weeks.
Starting date	Not given.
Contact information	Nehru, A - Mayo clinic - attempting to contact. Second author (Rover, E) contacted by email - no data available.
Notes	Described as randomised controlled cross over study. Interim analysis had shown decreased urinary incontinence and leakage on coughing in treatment group.

Characteristics of ongoing studies (*Continued*)

ExMI=extracorporeal magnetic innervation

ANALYSES

Comparison 01. PFMT versus no treatment or placebo or sham

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Number not cured (worse, unchanged or improved)			Relative Risk (Fixed) 95% CI	Subtotals only
02 Number not improved (worse or unchanged)			Relative Risk (Fixed) 95% CI	Subtotals only
03 Pad changes over 24 hours			Weighted Mean Difference (Fixed) 95% CI	Subtotals only
04 Pad test (grams of urine lost)			Weighted Mean Difference (Fixed) 95% CI	Totals not selected
05 Incontinent episodes over 24 hours	0	0	Weighted Mean Difference (Fixed) 95% CI	Not estimable
06 Frequency of micturitions per 24 hours	0	0	Weighted Mean Difference (Fixed) 95% CI	Not estimable
07 De novo urge symptoms	0	0	Relative Risk (Fixed) 95% CI	Not estimable

Comparison 02. Anal electrical stimulation versus no treatment or placebo or sham

No outcomes currently reported

Comparison 03. TENS versus no treatment or placebo or sham

No outcomes currently reported

Comparison 04. PFMT + biofeedback vs no treatment or placebo or sham

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 No. not cured (worse, unchanged or improved)			Relative Risk (Fixed) 95% CI	Subtotals only
03 Pad changes over 24 hours			Weighted Mean Difference (Fixed) 95% CI	Totals not selected
04 Pad test (grams of urine lost)			Weighted Mean Difference (Fixed) 95% CI	Subtotals only
05 Incontinent episodes over 24 hours			Weighted Mean Difference (Fixed) 95% CI	Subtotals only

Comparison 05. PFMT + anal E stim versus no treatment or placebo or sham

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 No. not cured (worse, unchanged or improved)			Relative Risk (Fixed) 95% CI	Totals not selected
04 Pad test (grams of urine lost)			Weighted Mean Difference (Fixed) 95% CI	Totals not selected

Comparison 06. PFMT + anal E stim + biofeedback versus no treatment or placebo or sham

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 No. not cured (worse, unchanged or improved)			Relative Risk (Fixed) 95% CI	Totals not selected

Comparison 07. PFMT + biofeedback vs PFMT alone

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 No. not cured (worse, unchanged or improved)			Relative Risk (Fixed) 95% CI	Subtotals only
04 Pad test (grams of urine lost)	3	27	Weighted Mean Difference (Fixed) 95% CI	28.16 [-57.92, 114.24]

Comparison 08. PFMT + anal E stim versus PFMT alone

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 No. not cured (worse, unchanged or improved)			Relative Risk (Fixed) 95% CI	Totals not selected
04 Pad test (grams of urine lost)			Weighted Mean Difference (Fixed) 95% CI	Totals not selected

Comparison 09. PFMT + TENS versus PFMT alone

No outcomes currently reported

Comparison 10. PFMT versus TENS or biofeedback

No outcomes currently reported

Comparison 11. Lifestyle adjustment versus no treatment or sham

No outcomes currently reported

Comparison 12. ExMI versus no treatment or sham

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 No. not cured (worse, unchanged)	0	0	Relative Risk (Fixed) 95% CI	Not estimable

Comparison 13. External penile compression versus no treatment or sham

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Number of men satisfied with device			Other data	No numeric data
02 Mean urine loss (grams of urine on pad test)			Other data	No numeric data
03 Penile Doppler blood flow (mean systolic velocity)			Other data	No numeric data

04 Penile Doppler blood flow (mean resistence to flow index)	Other data	No numeric data

INDEX TERMS

Medical Subject Headings (MeSH)

Biofeedback (Psychology); Exercise Therapy; Prostatectomy [*adverse effects]; Randomized Controlled Trials; Urinary Incontinence [etiology; *therapy]

MeSH check words

Humans; Male

COVER SHEET

Title	Conservative management for postprostatectomy urinary incontinence
Authors	Hunter KF, Moore KN, Cody DJ, Glazener CMA
Contribution of author(s)	For the update, the original lead author (KNM) and a new reviewer (KFH) independently undertook the quality assessment, data extraction and collation. The new reviewer took the lead in updating the text and completed the data entry, which were then checked and commented upon by the other reviewers. For the earlier versions, two of the original reviewers undertook the quality assessment of the trials and the data extraction independently. This information was then collated and checked by the original lead reviewer (KNM) for agreement and in the few instances where this did not occur, consensus was reached after checking with the other reviewers. The lead reviewer updated the text and entered the data. These were checked by the other reviewers, whose additional comments and edits were then incorporated.
Issue protocol first published	1998/3
Review first published	1999/4
Date of most recent amendment	18 July 2005
Date of most recent SUBSTANTIVE amendment	25 February 2004
What's New	In this update, five trials have been added to the review. One trial previously listed as included was excluded after attempts to contact the author to access data were unsuccessful. The total number of studies now included is 10. In one trial, participating men had undergone transurethral resection (TURP), in eight trials, radical prostatectomy (RP) and in one trial either TURP or RP. The literature search was widened to include "lifestyle" interventions and extra-corporeal magnetic innervation. One trial was found comparing penile compression devices but no completed trials evaluating extra-corporeal magnetic innervation were found. The new conclusions suggested that pelvic floor muscle training with biofeedback may help incontinence in the short term after radical prostatectomy, and that one type of penile compression device was better than two others or no treatment, but the data were few.
Date new studies sought but none found	Information not supplied by author
Date new studies found but not yet included/excluded	Information not supplied by author

Date new studies found and included/excluded	10 February 2004
Date authors' conclusions section amended	24 February 2004
Contact address	Kathleen Hunter PhD Student /Nurse Practitioner Faculty of Nursing/Geriatric Services University of Alberta/Royal Alexandra Hospital Edmonton Alberta CANADA E-mail: Kathleen.Hunter@ualberta.ca Tel: + 1 780 477 4389 Fax: + 1 780 491 5199
DOI	10.1002/14651858.CD001843.pub2
Cochrane Library number	CD001843
Editorial group	Cochrane Incontinence Group
Editorial group code	HM-INCONT

GRAPHS AND OTHER TABLES

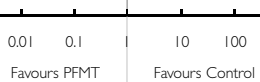
Analysis 01.01. Comparison 01 PFMT versus no treatment or placebo or sham, Outcome 01 Number not cured (worse, unchanged or improved)

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 01 PFMT versus no treatment or placebo or sham

Outcome: 01 Number not cured (worse, unchanged or improved)

Study	PFMT n/N	Control n/N	Relative Risk (Fixed) 95% CI	Weight (%)	Relative Risk (Fixed) 95% CI
01 less than 3 months					
Moore 1999	12/18	14/21		80.6	1.00 [0.64, 1.56]
Porru 2001	1/30	3/28		19.4	0.31 [0.03, 2.82]
Subtotal (95% CI)	48	49		100.0	0.87 [0.55, 1.38]
Total events: 13 (PFMT), 17 (Control)					
Test for heterogeneity chi-square=1.23 df=1 p=0.27 I=18.5%					
Test for overall effect z=0.61 p=0.5					
02 within 3-6 months					
Moore 1999	8/18	7/21		100.0	1.33 [0.60, 2.95]
Subtotal (95% CI)	18	21		100.0	1.33 [0.60, 2.95]
Total events: 8 (PFMT), 7 (Control)					



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Study	PFMT n/N	Control n/N	Relative Risk (Fixed) 95% CI	Weight (%)	Relative Risk (Fixed) 95% CI
Test for heterogeneity: not applicable					
Test for overall effect z=0.71 p=0.5					
03 within 6-12 months					
Subtotal (95% CI)	0	0		0.0	Not estimable
Total events: 0 (PFMT), 0 (Control)					
Test for heterogeneity: not applicable					
Test for overall effect: not applicable					
04 after 12 months					
Subtotal (95% CI)	0	0		0.0	Not estimable
Total events: 0 (PFMT), 0 (Control)					
Test for heterogeneity: not applicable					
Test for overall effect: not applicable					

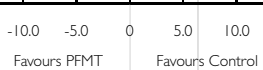
Analysis 01.03. Comparison 01 PFMT versus no treatment or placebo or sham, Outcome 03 Pad changes over 24 hours

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 01 PFMT versus no treatment or placebo or sham

Outcome: 03 Pad changes over 24 hours

Study	PFMT N Mean(SD)	Control N Mean(SD)	Weighted Mean Difference (Fixed) 95% CI	Weight (%)	Weighted Mean Difference (Fixed) 95% CI
01 less than 3 months					
Subtotal (95% CI)	0	0		0.0	Not estimable
Test for heterogeneity: not applicable					
Test for overall effect: not applicable					
02 within 3-6 months					
Subtotal (95% CI)	0	0		0.0	Not estimable
Test for heterogeneity: not applicable					
Test for overall effect: not applicable					
03 within 6-12 months					
Subtotal (95% CI)	0	0		0.0	Not estimable
Test for heterogeneity: not applicable					
Test for overall effect: not applicable					
04 after first year					



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Study	PFMT N Mean(SD)	Control N Mean(SD)	Weighted Mean Difference (Fixed) 95% CI	Weight (%)	Weighted Mean Difference (Fixed) 95% CI
Subtotal (95% CI)	0	0		0.0	Not estimable
Test for heterogeneity: not applicable					
Test for overall effect: not applicable					

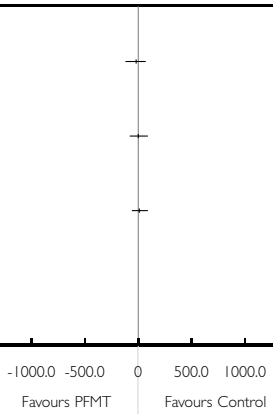
Analysis 01.04. Comparison 01 PFMT versus no treatment or placebo or sham, Outcome 04 Pad test (grams of urine lost)

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 01 PFMT versus no treatment or placebo or sham

Outcome: 04 Pad test (grams of urine lost)

Study	PFMT N	PFMT Mean(SD)	Control N	Control Mean(SD)	Weighted Mean Difference (Fixed) 95% CI	Weighted Mean Difference (Fixed) 95% CI
01 less than 3 months						
Moore 1999	18	87.00 (123.00)	21	104.00 (176.00)		-17.00 [-111.31, 77.31]
02 within 3-6 months						
Moore 1999	18	74.00 (131.00)	21	67.00 (137.00)		7.00 [-77.24, 91.24]
03 within 6-12 months						
Moore 1999	17	70.00 (114.00)	16	54.00 (103.00)		16.00 [-58.05, 90.05]
04 after first year						



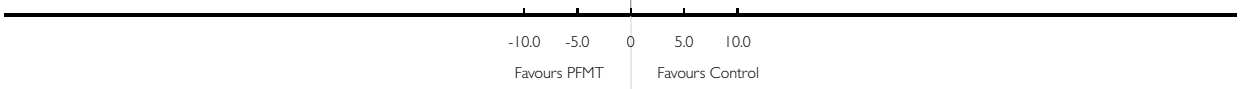
Analysis 01.05. Comparison 01 PFMT versus no treatment or placebo or sham, Outcome 05 Incontinent episodes over 24 hours

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 01 PFMT versus no treatment or placebo or sham

Outcome: 05 Incontinent episodes over 24 hours

Study	PFMT N Mean(SD)	Control N Mean(SD)	Weighted Mean Difference (Fixed) 95% CI	Weight (%)	Weighted Mean Difference (Fixed) 95% CI
01 less than 3 months					
Subtotal (95% CI)	0	0		0.0	Not estimable
Test for heterogeneity: not applicable					
Test for overall effect: not applicable					
02 within 3-6 months					
Subtotal (95% CI)	0	0		0.0	Not estimable
Test for heterogeneity: not applicable					
Test for overall effect: not applicable					
03 within 6-12 months					
Subtotal (95% CI)	0	0		0.0	Not estimable
Test for heterogeneity: not applicable					
Test for overall effect: not applicable					
04 after first year					
Subtotal (95% CI)	0	0		0.0	Not estimable
Test for heterogeneity: not applicable					
Test for overall effect: not applicable					
Total (95% CI)	0	0		0.0	Not estimable
Test for heterogeneity: not applicable					
Test for overall effect: not applicable					



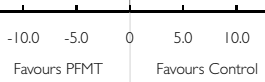
Analysis 01.06. Comparison 01 PFMT versus no treatment or placebo or sham, Outcome 06 Frequency of micturitions per 24 hours

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 01 PFMT versus no treatment or placebo or sham

Outcome: 06 Frequency of micturitions per 24 hours

Study	PFMT N Mean(SD)	Control N Mean(SD)	Weighted Mean Difference (Fixed) 95% CI	Weight (%)	Weighted Mean Difference (Fixed) 95% CI
01 less than 3 months					
Subtotal (95% CI)	0	0		0.0	Not estimable
Test for heterogeneity: not applicable					
Test for overall effect: not applicable					
02 within 3-6 months					
Subtotal (95% CI)	0	0		0.0	Not estimable
Test for heterogeneity: not applicable					
Test for overall effect: not applicable					
03 within 6-12 months					
Subtotal (95% CI)	0	0		0.0	Not estimable
Test for heterogeneity: not applicable					
Test for overall effect: not applicable					
04 after first year					
Subtotal (95% CI)	0	0		0.0	Not estimable
Test for heterogeneity: not applicable					
Test for overall effect: not applicable					
Total (95% CI)	0	0		0.0	Not estimable
Test for heterogeneity: not applicable					
Test for overall effect: not applicable					



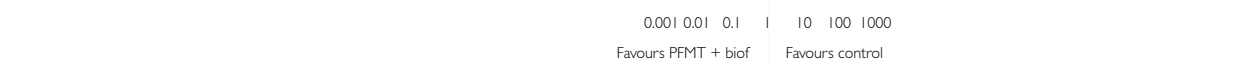
Analysis 04.01. Comparison 04 PFMT + biofeedback vs no treatment or placebo or sham, Outcome 01 No. not cured (worse, unchanged or improved)

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 04 PFMT + biofeedback vs no treatment or placebo or sham

Outcome: 01 No. not cured (worse, unchanged or improved)

Study	PFMT + biofeedback n/N	control n/N	Relative Risk (Fixed) 95% CI	Weight (%)	Relative Risk (Fixed) 95% CI
01 less than 3 months					
Bales 2000	38/47	38/50		43.4	1.06 [0.86, 1.31]
Franke 1998	6/13	3/10		4.0	1.54 [0.50, 4.69]
Mathewson-Chapman 97	8/27	10/24		12.5	0.71 [0.34, 1.50]
Parekh 2003	6/19	12/19		14.1	0.50 [0.24, 1.05]
van Kampen 1998	5/48	23/52		26.0	0.24 [0.10, 0.57]
Subtotal (95% CI)	154	155		100.0	0.74 [0.60, 0.93]
Total events: 63 (PFMT + biofeedback), 86 (control)					
Test for heterogeneity chi-square=20.53 df=4 p=0.0004 I =80.5%					
Test for overall effect z=2.64 p=0.008					
02 within 3-6 months					
Bales 2000	20/47	19/50		48.0	1.12 [0.69, 1.82]
Franke 1998	1/7	1/8		2.4	1.14 [0.09, 15.08]
Mathewson-Chapman 97	1/27	0/24		1.4	2.68 [0.11, 62.81]
Parekh 2003	4/19	7/19		18.2	0.57 [0.20, 1.63]
van Kampen 1998	2/48	12/52		30.0	0.18 [0.04, 0.77]
Subtotal (95% CI)	148	153		100.0	0.76 [0.51, 1.14]
Total events: 28 (PFMT + biofeedback), 39 (control)					
Test for heterogeneity chi-square=7.24 df=4 p=0.12 I =44.8%					
Test for overall effect z=1.33 p=0.2					
03 within 6-12 months					
Bales 2000	3/47	2/50		13.1	1.60 [0.28, 9.13]
Parekh 2003	3/19	4/19		26.9	0.75 [0.19, 2.91]
van Kampen 1998	2/48	9/49		60.0	0.23 [0.05, 1.00]
Subtotal (95% CI)	114	118		100.0	0.55 [0.24, 1.23]
Total events: 8 (PFMT + biofeedback), 15 (control)					
Test for heterogeneity chi-square=3.02 df=2 p=0.22 I =33.7%					
Test for overall effect z=1.46 p=0.1					
04 after 12 months					
Subtotal (95% CI)	0	0		0.0	Not estimable
Total events: 0 (PFMT + biofeedback), 0 (control)					
Test for heterogeneity: not applicable					
Test for overall effect: not applicable					



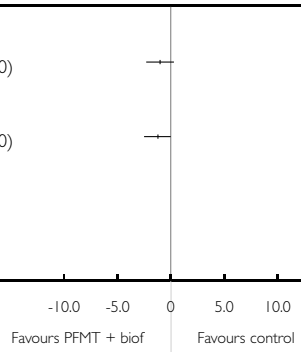
Analysis 04.03. Comparison 04 PFMT + biofeedback vs no treatment or placebo or sham, Outcome 03 Pad changes over 24 hours

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 04 PFMT + biofeedback vs no treatment or placebo or sham

Outcome: 03 Pad changes over 24 hours

Study	PFMT + biofeedback N	Mean(SD)	control N	Mean(SD)	Weighted Mean Difference (Fixed) 95% CI	Weighted Mean Difference (Fixed) 95% CI
01 less than 3 months						
Mathewson-Chapman 97	27	1.10 (2.10)	24	2.04 (2.70)		-0.94 [-2.28, 0.40]
02 within 3-6 months						
Mathewson-Chapman 97	27	0.60 (1.60)	24	1.80 (2.70)		-1.20 [-2.44, 0.04]
03 within 6-12 months						
04 after first year						



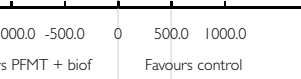
Analysis 04.04. Comparison 04 PFMT + biofeedback vs no treatment or placebo or sham, Outcome 04 Pad test (grams of urine lost)

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 04 PFMT + biofeedback vs no treatment or placebo or sham

Outcome: 04 Pad test (grams of urine lost)

Study	PFMT + biofeedback N	Mean(SD)	control N	Mean(SD)	Weighted Mean Difference (Fixed) 95% CI	Weight (%)	Weighted Mean Difference (Fixed) 95% CI
01 less than 3 months							
Mathewson-Chapman 97	27	120.40 (249.20)	24	126.00 (215.60)		100.0	-5.60 [-133.18, 121.98]
Subtotal (95% CI)	27		24			100.0	-5.60 [-133.18, 121.98]
Test for heterogeneity: not applicable							
Test for overall effect z=0.09 p=0.9							
02 within 3-6 months							
Subtotal (95% CI)	0		0			0.0	Not estimable
Test for heterogeneity: not applicable							
Test for overall effect: not applicable							
03 within 6-12 months							
Subtotal (95% CI)	0		0			0.0	Not estimable
Test for heterogeneity: not applicable							
Test for overall effect: not applicable							
04 after first year							
Subtotal (95% CI)	0		0			0.0	Not estimable
Test for heterogeneity: not applicable							
Test for overall effect: not applicable							



Analysis 04.05. Comparison 04 PFMT + biofeedback vs no treatment or placebo or sham, Outcome 05 Incontinent episodes over 24 hours

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 04 PFMT + biofeedback vs no treatment or placebo or sham

Outcome: 05 Incontinent episodes over 24 hours

Study	PFMT + biofeedback N	Mean(SD)	control N	Mean(SD)	Weighted Mean Difference (Fixed) 95% CI	Weight (%)	Weighted Mean Difference (Fixed) 95% CI
01 less than 3 months							
Mathewson-Chapman 97	27	1.50 (3.20)	24	5.60 (20.40)		100.0	-4.10 [-12.35, 4.15]
Subtotal (95% CI)	27		24			100.0	-4.10 [-12.35, 4.15]
Test for heterogeneity: not applicable							
Test for overall effect z=0.97 p=0.3							
02 within 3-6 months							
Mathewson-Chapman 97	27	0.84 (1.99)	24	1.00 (0.27)		100.0	-0.16 [-0.92, 0.60]
Subtotal (95% CI)	27		24			100.0	-0.16 [-0.92, 0.60]
Test for heterogeneity: not applicable							
Test for overall effect z=0.41 p=0.7							
03 within 6-12 months							
Subtotal (95% CI)	0		0			0.0	Not estimable
Test for heterogeneity: not applicable							
Test for overall effect: not applicable							
04 after first year							
Subtotal (95% CI)	0		0			0.0	Not estimable
Test for heterogeneity: not applicable							
Test for overall effect: not applicable							

Analysis 05.01. Comparison 05 PFMT + anal E stim versus no treatment or placebo or sham, Outcome 01 No. not cured (worse, unchanged or improved)

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 05 PFMT + anal E stim versus no treatment or placebo or sham

Outcome: 01 No. not cured (worse, unchanged or improved)

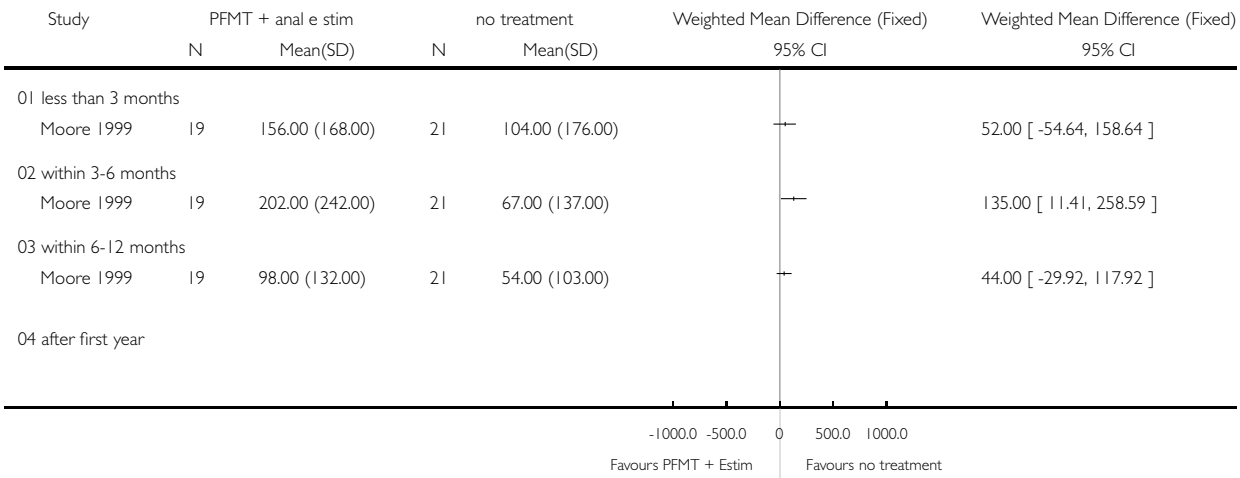
Study	PFMT + anal e stim n/N	no treatment n/N	Relative Risk (Fixed) 95% CI	Relative Risk (Fixed) 95% CI
01 less than 3 months				
Moore 1999	11/19	14/21		0.87 [0.53, 1.42]
02 within 3-6 months				
03 within 6-12 months				
04 after 12 months				

Analysis 05.04. Comparison 05 PFMT + anal E stim versus no treatment or placebo or sham, Outcome 04 Pad test (grams of urine lost)

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 05 PFMT + anal E stim versus no treatment or placebo or sham

Outcome: 04 Pad test (grams of urine lost)

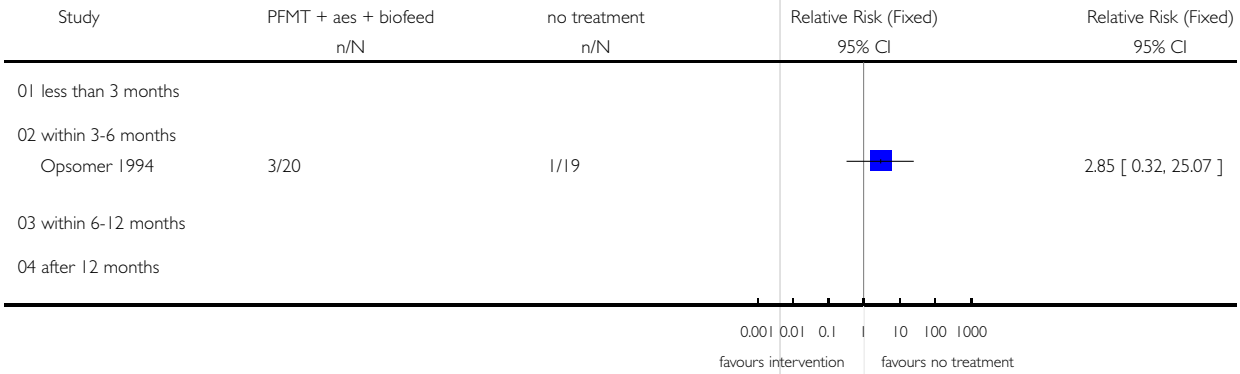


Analysis 06.01. Comparison 06 PFMT + anal E stim + biofeedback versus no treatment or placebo or sham, Outcome 01 No. not cured (worse, unchanged or improved)

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 06 PFMT + anal E stim + biofeedback versus no treatment or placebo or sham

Outcome: 01 No. not cured (worse, unchanged or improved)



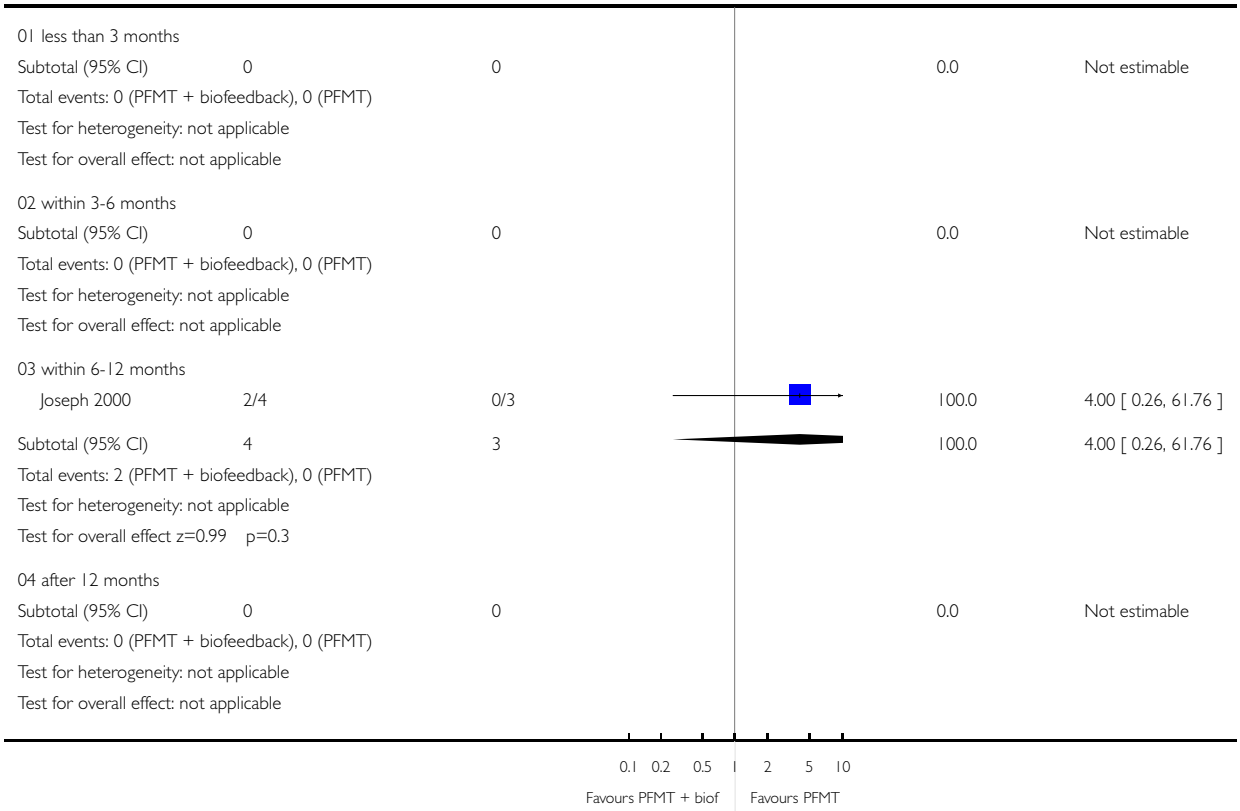
Analysis 07.01. Comparison 07 PFMT + biofeedback vs PFMT alone, Outcome 01 No. not cured (worse, unchanged or improved)

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 07 PFMT + biofeedback vs PFMT alone

Outcome: 01 No. not cured (worse, unchanged or improved)

Study	PFMT + biofeedback n/N	PFMT n/N	Relative Risk (Fixed) 95% CI	Weight (%)	Relative Risk (Fixed) 95% CI
01 less than 3 months					
Subtotal (95% CI)	0	0		0.0	Not estimable
Total events: 0 (PFMT + biofeedback), 0 (PFMT)					
Test for heterogeneity: not applicable					
Test for overall effect: not applicable					
02 within 3-6 months					
Subtotal (95% CI)	0	0		0.0	Not estimable
Total events: 0 (PFMT + biofeedback), 0 (PFMT)					
Test for heterogeneity: not applicable					
Test for overall effect: not applicable					
03 within 6-12 months					
Joseph 2000	2/4	0/3		100.0	4.00 [0.26, 61.76]
Subtotal (95% CI)	4	3		100.0	4.00 [0.26, 61.76]
Total events: 2 (PFMT + biofeedback), 0 (PFMT)					
Test for heterogeneity: not applicable					
Test for overall effect z=0.99 p=0.3					
04 after 12 months					
Subtotal (95% CI)	0	0		0.0	Not estimable
Total events: 0 (PFMT + biofeedback), 0 (PFMT)					
Test for heterogeneity: not applicable					
Test for overall effect: not applicable					



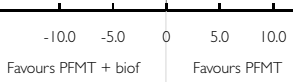
Analysis 07.04. Comparison 07 PFMT + biofeedback vs PFMT alone, Outcome 04 Pad test (grams of urine lost)

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 07 PFMT + biofeedback vs PFMT alone

Outcome: 04 Pad test (grams of urine lost)

Study	PFMT + biofeedback N	Mean(SD)	PFMT N	Mean(SD)	Weighted Mean Difference (Fixed) 95% CI	Weight (%)	Weighted Mean Difference (Fixed) 95% CI
01 less than 3 months							
Joseph 2000	6	58.66 (97.90)	5	30.50 (40.71)		100.0	28.16 [-57.92, 114.24]
Subtotal (95% CI)	6		5			100.0	28.16 [-57.92, 114.24]
Test for heterogeneity: not applicable							
Test for overall effect z=0.64 p=0.5							
02 within 3-6 months							
× Joseph 2000	5	4.40 (6.26)	4	0.00 (0.00)		0.0	Not estimable
Subtotal (95% CI)	5		4			0.0	Not estimable
Test for heterogeneity: not applicable							
Test for overall effect: not applicable							
03 within 6-12 months							
× Joseph 2000	4	6.25 (9.46)	3	0.00 (0.00)		0.0	Not estimable
Subtotal (95% CI)	4		3			0.0	Not estimable
Test for heterogeneity: not applicable							
Test for overall effect: not applicable							
04 after first year							
Subtotal (95% CI)	0		0			0.0	Not estimable
Test for heterogeneity: not applicable							
Test for overall effect: not applicable							
Total (95% CI)	15		12			100.0	28.16 [-57.92, 114.24]
Test for heterogeneity: not applicable							
Test for overall effect z=0.64 p=0.5							

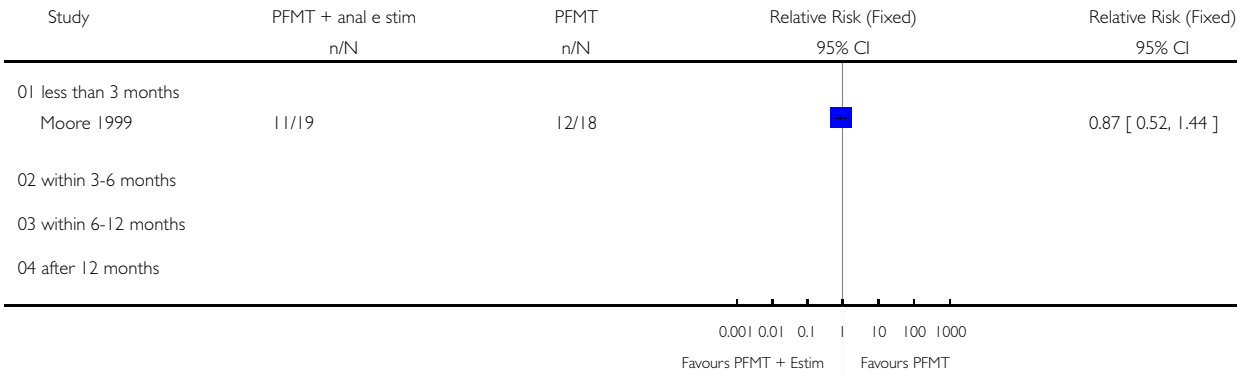


Analysis 08.01. Comparison 08 PFMT + anal E stim versus PFMT alone, Outcome 01 No. not cured (worse, unchanged or improved)

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 08 PFMT + anal E stim versus PFMT alone

Outcome: 01 No. not cured (worse, unchanged or improved)

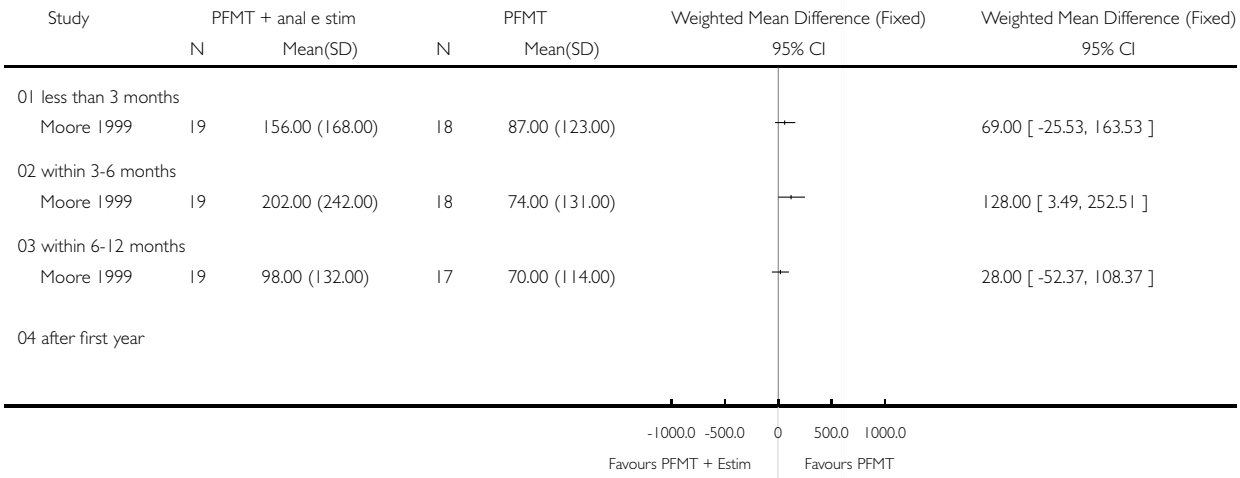


Analysis 08.04. Comparison 08 PFMT + anal E stim versus PFMT alone, Outcome 04 Pad test (grams of urine lost)

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 08 PFMT + anal E stim versus PFMT alone

Outcome: 04 Pad test (grams of urine lost)



Analysis 13.01. Comparison 13 External penile compression versus no treatment or sham, Outcome 01 Number of men satisfied with device

Number of men satisfied with device

Study	Control (no device)	U-Tex	C3	Cunningham
Moore 2004	0/12	0/12	2/12	10/12

Analysis 13.02. Comparison 13 External penile compression versus no treatment or sham, Outcome 02 Mean urine loss (grams of urine on pad test)

Mean urine loss (grams of urine on pad test)

Study	Control (no device)	U-Tex	C3	Cunningham
Moore 2004	122.8 gm (SD 130.8)	53.3 gm (SD 65.7) P<0.05 vs Control (no device)	32.3 gm (SD 24.3) P<0.05 vs Control (no device)	17.1 gm (SD 21.3) P<0.05 vs Control (no device)

Analysis 13.03. Comparison 13 External penile compression versus no treatment or sham, Outcome 03 Penile Doppler blood flow (mean systolic velocity)

Penile Doppler blood flow (mean systolic velocity)

Study	Control (no device)	U-Tex	C3	Cunningham
Moore 2004	N=12 men R: 12.4 (SD 2.8) L: 12.3 (SD 3.0)	N=12 men R: 11.9 (SD 4.4) L: 13.8 (SD 7.3)	N=12 men R: 12.4 (SD 5.5) L: 11.7 (SD 4.7)	N=12 men R: 9.5 (SD 2.3) L: 7.3 (SD 3.0) P<0.05 vs Control (no device)

Analysis 13.04. Comparison 13 External penile compression versus no treatment or sham, Outcome 04 Penile Doppler blood flow (mean resistence to flow index)

Penile Doppler blood flow (mean resistence to flow index)

Study	Control (no device)	U-Tex	C3	Cunningham
Moore 2004	N=12 men R: 0.9 (SD 0.1) L: 0.87 (SD 0.1)	N=12 men R: 0.93 (SD 0.08) L: 0.91 (SD 0.11)	N=12 men R: 0.92 (SD 0.1) L: 0.92 (SD 0.11)	N=12 men R: 0.92 (SD 0.13) L: 0.86 (SD 0.29)