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Continuous and interrupted suturing techniques for repair of episiotomy or second-degree tears (Review)

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[Intervention Review]

Continuous and interrupted suturing techniques for repair of episiotomy or second-degree tears

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ABSTRACT

Background

Millions of women worldwide undergo perineal suturing after childbirth and the type of repair may have an impact on pain and healing. For more than 70 years, researchers have been suggesting that continuous non-locking suture techniques for repair of the vagina, perineal muscles and skin are associated with less perineal pain than traditional interrupted methods.

Objectives

To assess the effects of continuous versus interrupted absorbable sutures for repair of episiotomy and second-degree perineal tears following childbirth.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (20 January 2012).

Selection criteria

Randomised trials examining continuous and interrupted suturing techniques for repair of episiotomy and second-degree tears after vaginal delivery.

Data collection and analysis

Three review authors independently assessed trial quality. Two of the three authors independently extracted data and a third review author checked them. We contacted study authors for additional information.

Main results

Sixteen studies, involving 8184 women at point of entry, from eight countries, were included. The trials were heterogeneous in respect of operator skill and training. Meta-analysis showed that continuous suture techniques compared with interrupted sutures for perineal closure (all layers or perineal skin only) are associated with less pain for up to 10 days' postpartum (risk ratio (RR) 0.76; 95% confidence interval (CI) 0.66 to 0.88, nine trials). There was an overall reduction in analgesia use associated with the continuous subcutaneous technique versus interrupted stitches for repair of perineal skin (RR 0.70; 95% CI 0.59 to 0.84). There was also a reduction in suture removal in the continuous suturing groups versus interrupted (RR 0.56; 95% CI 0.32 to 0.98), but no significant differences were seen in the need for re-suturing of wounds or long-term pain.

Authors' conclusions

The continuous suturing techniques for perineal closure, compared with interrupted methods, are associated with less short-term pain, need for analgesia and suture removal. Furthermore, there is also some evidence that the continuous techniques used less suture material as compared with the interrupted methods (one packet compared to two or three packets, respectively).

PLAIN LANGUAGE SUMMARY

Continuous and individual interrupted sutures for repair of episiotomy or second-degree tears

Continuous stitching causes less pain than interrupted absorbable stitches when used for repairing the perineum after childbirth.

When women give birth, the perineum (the area between the vaginal opening and back passage) sometimes tears or it may be necessary for them to have an episiotomy (surgical cut) to increase the size of the vaginal outlet to facilitate the birth. Episiotomies and tears that involve the muscle layer (second degree) need to be stitched. Millions of women worldwide undergo perineal suturing after childbirth and the type of repair may have an impact on pain and discomfort, and healing. In the UK alone, approximately 1000 women per day will experience perineal stitches following vaginal birth and millions more worldwide. A midwife or doctor will stitch the episiotomy or second-degree tear in three layers (vagina, perineal muscle and skin). Traditionally the vagina is stitched using a continuous locking stitch and the perineal muscles and skin are repaired using approximately three or four individual stitches, each needing to be knotted separately to prevent them from dislodging. Researchers have been suggesting for more than 70 years that the 'continuous non-locking stitching method' is better than 'traditional interrupted methods'. This review looked at 'continuous stitching methods' compared with 'traditional interrupted stitching methods' and identified 16 randomised controlled trials involving 8184 women from eight different countries. Results from the trials showed that stitching just underneath the skin (subcutaneous) was associated with less pain with reduced need for analgesics after the birth, or for the sutures to be removed; however, when the 'continuous stitching method' was used for repair of all three layers, this may be associated with even less pain. The level of operator skill and training varied in the different trials. Other research is needed to assess perineal repair training programmes. In addition, research is needed to look at interventions that may reduce the incidence of perineal trauma during childbirth.

There is also some evidence that the continuous techniques use less suture material when compared with the interrupted methods (one packet compared to two or three packets, respectively).

BACKGROUND

Prevalence and morbidity

Perineal trauma during childbirth affects millions of women throughout the world and can result in long-term maternal morbidity. In the UK approximately 85% of women will sustain some degree of perineal trauma during vaginal birth and 60% to 70% of these will need suturing**,** which equates to approximately 1000 women per day (McCandlish 1998; Sleep 1984). However, rates of perineal trauma will vary considerably according to individual practices and policies of institutions and practitioners throughout the world. Perineal trauma may occur spontaneously during birth, or the midwife or obstetrician may need to make a surgical incision (episiotomy) to increase the diameter of the vaginal outlet to facilitate the baby's birth. Childbirth-related perineal tears are classified according to the anatomical structures involved into; first degree (involving the perineal skin only), second degree (involving the perineal muscles and skin), third degree (injury to the anal sphincter complex - 3a = less than 50% of the external anal sphincter torn; 3b = more than 50% of the external anal sphincter torn; 3c = internal anal sphincter also torn) and fourth degree (injury to the perineum involving the anal sphincter complex and anal epithelium) (Fernando 2006).

The majority of women experience some short-term discomfort or pain following perineal repair, and up to 20% will continue to have long-term problems, such as superficial dyspareunia (painful intercourse) (Glazener 1995; Klein 1994; Sleep 1984). Short- and long-term maternal morbidity associated with perineal repair can lead to major physical, psychological and social problems, affecting the woman's ability to care for her new baby and other members of the family (Sleep 1991). For those women who sustain perineal injury, it is important that skilled operators repair the trauma, and that they use the best suturing techniques and materials, in order to minimise any associated problems.

Techniques of perineal repair

Currently, midwives in the UK are responsible for suturing the majority of second-degree tears and episiotomies sustained during spontaneous vaginal delivery. However, there are wide variations in both techniques and materials used for perineal repair between individual practitioners and maternity units. The rationale for the suturing technique chosen appears to evolve from the way the operator was first taught rather than robust clinical evidence. It could be hypothesised that even if the best suture techniques and materials are used to repair perineal trauma, the short- and long-term outcome will be dependent on the skill of the operator.

Traditional interrupted technique

Perineal trauma is traditionally repaired in three stages: a continuous locking stitch is inserted to close the vaginal trauma, commencing at the apex of the wound and finishing at the level of the fourchette with a loop knot. The proposed rationale for using a locking stitch is to prevent shortening of the vagina; however, good-quality evidence to support this theory is lacking. The perineal muscles are then re-approximated with three or four interrupted sutures and finally, the perineal skin is closed by inserting continuous subcutaneous or interrupted transcutaneous stitches. Another variation of the interrupted suture technique involves placing inverted interrupted stitches to re-approximate the muscle layer. The skin is then closed with inverted interrupted stitches placed in the subcutaneous tissue a few millimetres under the perineal skin edges (not transcutaneously). The rationale for this alternative technique is that the knots are 'hidden' in the depth of the perineal trauma and the interrupted skin suture knots are also buried to facilitate healing.

Two-stage technique

This method is very similar to the traditional interrupted technique whereby the vaginal trauma is closed with a continuous locking stitch, followed by insertion of three or four interrupted stitches to re-approximate the perineal muscles; however, the skin is left apposed but not sutured (skin edges no more than half a centimetre apart). The rationale behind this technique is that the insertion of skin sutures may contribute to some of the morbidity experienced by women following perineal repair. Women often complain of pain and tightness associated with transcutaneous skin sutures; moreover, if standard synthetic material is used there is an increased risk of the stitches having to be removed up to three months following birth (Kettle 2010).

Continuous non-locking technique

This is a three-stage technique: the repair begins with an anchoring stitch above the apex of the vaginal trauma and the deep tissues and mucosa are closed with a single continuous non-locking stitch, in contrast to the locking stitch used for the traditional method. The perineal muscles are then re-approximated using a similar continuous non-locking technique and the repair is completed with a continuous suture inserted well below the skin surface in the subcutaneous fascia. The finished repair is secured with a knot placed in the vagina behind the hymenal remnants. A single length of absorbable suture material is used for the repair with no knots other than the anchoring and terminal knot. The rationale for using this suturing technique is that it is very easy to over tighten locked or interrupted stitches, which may restrict the distribution of tissue oedema and cause increased pain. With the continuous technique, the tension is transferred throughout the whole length of the single suture; also the skin sutures are inserted well below the skin surface, thus avoiding the nerve endings to reduce pain.

Aim of the review

The aim of this review is to examine the available research and to establish if there is any clear scientific evidence that the technique used for perineal repair, following childbirth, has any effect on the amount of pain and superficial dyspareunia experienced by women in the postpartum period.

This systematic review includes 16 randomised clinical trials and represents a substantial update of the previous Cochrane review.

OBJECTIVES

To assess the effects of continuous and interrupted suturing methods (using absorbable suture materials) on the incidence of short- and long-term postpartum maternal morbidity experienced by women following repair of episiotomy or second-degree perineal tears after vaginal birth. The evidence collated in this review will enable purchasers, providers and consumers of health care to choose the most appropriate technique of perineal repair in terms of both health gain and cost.

The main outcomes of interest are: short- and long-term pain, amount of analgesia used, time of resumption of pain-free intercourse, superficial dyspareunia, removal of suture material, re-suturing of wound, time taken to perform the repair and number of suture packets used.

METHODS

Criteria for considering studies for this review

Types of studies

We have included all identified, relevant randomised controlled trials and quasi-randomised trials that compare different continuous and interrupted suturing techniques for perineal closure (all layers or skin only), using absorbable suture materials. We have assessed all of the trials included for risk of bias examining the method of treatment allocation, randomisation, blinding of outcome assessment and handling of exclusions.

We have included studies published as abstracts provided that there was sufficient information to allow us to assess eligibility and risk of bias; if there was not sufficient information in an abstract we planned to contact study authors.

Types of participants

All primiparous and multiparous women who have sustained an episiotomy or second-degree perineal tear and required stitching following a spontaneous or instrumental vaginal delivery.

Types of interventions

All randomised controlled trials comparing different continuous and interrupted suturing techniques for perineal closure (all layers or skin only) following vaginal delivery using absorbable suture material. Trials that compared continuous suturing techniques using absorbable sutures versus interrupted transcutaneous techniques that used non-absorbable sutures for perineal skin closure were excluded to avoid the confounding effect of suture material.

Types of outcome measures

The main focus was on outcome measures relating to short- and long-term postpartum morbidity.

Primary outcomes

- Short-term pain (up to four days' postpartum).
- Short term pain (up to 10 days' postpartum).
- Use of analgesia (up to 10 days' postpartum).
- Superficial dyspareunia.

Secondary outcomes

- Removal of suture material.
- Re-suturing.
- Long-term pain (up to three months).
- Wound dehiscence.
- Failure to resume pain-free intercourse (by three months).

In this updated version of the review we have also included outcomes relating to the number of suture packets used and the time taken to carry out repairs.

For the original version of this review, review authors sought consumer views regarding what outcomes they would expect from local focus groups, members of the National Childbirth Trust and other postnatal support groups.

The main outcomes of interest from the consumers' point of view were short- and long-term pain, removal of suture material and the resumption of pain-free intercourse.

Search methods for identification of studies

Electronic searches

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (20 January 2012).

The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

1. monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE;
3. weekly searches of EMBASE;
4. handsearches of 30 journals and the proceedings of major conferences;
5. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Details of the search strategies for CENTRAL, MEDLINE and EMBASE; the list of handsearched journals and conference proceedings; and the list of journals reviewed via the current awareness service can be found in the 'Specialized register' section within the editorial information about the Cochrane Pregnancy and Childbirth Group.

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords.

We did not apply any language restrictions.

Data collection and analysis

Selection of studies

At least two review authors independently assessed and selected the trials for inclusion in this review. It was not possible for us to assess the relevance of the trials blinded because we knew the authors' names, institution, journal of publication and results when we applied the inclusion criteria. We resolved all disagreements by discussion.

Data extraction and management

We designed a form to extract data. For eligible studies, two review authors extracted the data using the agreed form. We resolved discrepancies through discussion and, if required, we consulted the third review author. We entered data into Review Manager software (RevMan 2011) and checked for accuracy.

When information regarding any of the above was unclear, we attempted to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

We assessed the risk of bias of each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). Two review authors independently assessed the methodological quality of each trial and collected details of method of allocation and treatment concealment, attrition bias, performance bias and whether an intention-to-treat analysis was performed.

(1) Sequence generation (checking for possible selection bias)

We have described for each included study the method used to generate the allocation sequence to allow an assessment of whether it should produce comparable groups.

We assessed the method as:

- adequate (any truly random process, e.g. random number table; computer random number generator);
- inadequate (any non-random process, e.g. odd or even date of birth; hospital or clinic record number);
- unclear.

(2) Allocation concealment (checking for possible selection bias)

We have described for each included study the method used to conceal the allocation sequence and determined whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

We assessed the methods as:

- adequate (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- inadequate (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear.

(3) Blinding (checking for possible performance bias)

We have described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We are aware that achieving blinding for this intervention is not likely to have occurred as the suture technique will be apparent to clinical staff carrying out the repair or assessing the healing of the perineum, and may be apparent to women. It is possible though, that for some outcomes those carrying out outcome assessment may be blind to group allocation. We considered that studies were at low risk of bias if they were blinded, or if we judged that the lack of blinding could not have affected the results. We assessed blinding separately for different outcomes or classes of outcomes.

We assessed the methods as:

- adequate, inadequate or unclear for participants;
- adequate, inadequate or unclear for personnel;
- adequate, inadequate or unclear for outcome assessors.

(4) Incomplete outcome data (checking for possible attrition bias through withdrawals, drop-outs, protocol deviations)

We have described for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We have noted whether attrition and exclusions were reported, the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported, or supplied by the trial authors, we re-included missing data in the analyses. We assessed methods as:

- adequate;
- inadequate;
- unclear.

For outcomes assessed in the early postpartum period loss to follow-up had to be less that 10% for us to judge a study as adequate. For longer-term outcomes (e.g. dyspareunia at three months' postpartum) we expected less than 20% attrition.

(5) Selective reporting bias

We have described for each included study how we investigated the possibility of selective outcome reporting bias and what we found.

We assessed the methods as:

- adequate (where it is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- inadequate (where not all the study's pre-specified outcomes were reported; one or more reported primary outcomes were not pre-specified; outcomes of interest were reported incompletely and so could not be used; study failed to include results of a key outcome that would have been expected to have been reported);
- unclear.

(6) Other sources of bias

We have described for each included study any important concerns we had about other possible sources of bias such as baseline imbalance.

We have assessed whether each study was free of other problems that could put it at risk of bias:

- yes;
- no;
- unclear.

(7) Overall risk of bias

We have made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). With reference to (1) to (6) above, we have assessed the likely magnitude and direction of the bias and whether we considered it was likely to impact on the findings. We have explored the impact of the level of bias through undertaking sensitivity analyses - see Sensitivity analysis.

Measures of treatment effect

We undertook statistical analysis using the Review Manager software (RevMan 2011) for calculation of the treatment effect.

We performed fixed-effect (assumption free) meta-analysis for combining data in the absence of significant heterogeneity.

Dichotomous data

For dichotomous data, we have presented the results as summary risk ratio (RR) with 95% confidence intervals (CI).

Continuous data

For continuous data, we have used the mean difference if outcomes were measured in the same way between trials. We have used the standardised mean difference (SMD) to combine trials that measured the same outcome, but using different methods.

Unit of analysis issues

In this version of the review we did not identify any cluster randomised trials eligible for inclusion. In future updates, if any such trials are identified, we plan to include them in the analyses along with individually randomised trials. We will adjust standard errors, using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) (using an estimate of the intra-cluster correlation co-efficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If we use ICCs from other sources, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomised trials and individually randomised trials, we plan to synthesise the relevant information. We will consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely.

We will also acknowledge heterogeneity in the randomisation unit and perform a sensitivity analysis to investigate the effects of the randomisation unit.

Dealing with missing data

For included studies, we have noted levels of attrition. We have explored the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis.

For all outcomes, we have carried out analyses, as far as possible, on an intention-to-treat basis, that is we have attempted to include all participants randomised to each group in the analyses, with all participants analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention.

Assessment of heterogeneity

We have assessed statistical heterogeneity in each meta-analysis using the T^2, I^2 and Chi^2 statistics. We have regarded heterogeneity as substantial if I^2 is greater than 30% and either T^2 is greater than zero, or there is a low P value (less than 0.10) in the Chi^2 test for heterogeneity.

Assessment of reporting biases

In this version of the review we were not able to explore possible publication bias using funnel plots as too few studies contributed data to the meta-analyses.

We did not have access to the study protocols for most of the included studies, so most of the included studies have been assessed as unclear for reporting bias as we were not clear whether all pre-specified outcomes were reported in published papers. Where we suspected possible bias (e.g. where only statistically significant results were reported) we have noted this.

Data synthesis

We have carried out statistical analysis using Review Manager software (RevMan 2011). We have used fixed-effect meta-analysis for combining data where it seemed reasonable to assume that studies were estimating the same underlying treatment effect: that is where trials are examining the same intervention, and the trials' populations and methods were judged to be sufficiently similar. If we suspected clinical heterogeneity sufficient to expect that the underlying treatment effects differed between trials, or if substantial statistical heterogeneity was detected, we have used random-effects meta-analysis to produce an overall summary, provided that an average treatment effect across trials was considered clinically meaningful. The random-effects summary gives an indication of the average range of possible treatment effects, and we have discussed the clinical implications of treatment effects differing between trials. If we did not think the average treatment effect was clinically meaningful we have not combined trials.

Where we have used random-effects analyses, the results have been presented as the average treatment effect with its 95% CI, and the estimates of T^2 and I^2, along with the 95% prediction interval.

Subgroup analysis and investigation of heterogeneity

For primary outcomes we undertook the following subgroup analyses:

- whether the continuous group used continuous suture techniques for all layers or perineal skin only.

We have assessed differences between subgroups by inspection of the subgroups' CIs; non-overlapping CIs suggesting a difference in treatment effect between the subgroups, we have also carried out subgroup interaction tests.

Sensitivity analysis

For primary outcomes we carried out sensitivity analysis, temporarily excluding those studies with poor methodological quality from the analyses (i.e. with poor allocation concealment or high levels of attrition, or both) to explore whether the inclusion of such studies has any impact on the results. We have not included separate tables with sensitivity analysis in the review, but have noted the results of these analyses in the text of the review.

RESULTS

Description of studies

Results of the search

The search strategy identified 23 studies for possible inclusion in the review. The date of the most recent search was January 2012.

In this updated version of the review, we have included nine new studies in addition to the seven included in previous versions. We have excluded five studies and one study is awaiting assessment

pending further investigation (Uslu 1992) and a further study is awaiting translation (Graczyk 1998).

Included studies

In this updated review we have included 16 studies, involving 8184 women at point of entry.

Included trials: Almeida 2008; Banninger 1978; Croce 1997; Detlefsen 1980; Gordon 1998; Isager-Sally 1986; Kettle 2002; Kindberg 2008; Kokanali 2011; Mahomed 1989; Morano 2006; Oboro 2003; Perveen 2009; Stark 2009; Valenzuela 2009; Zafar 2008.

The studies were carried out in a range of countries: the UK (Gordon 1998; Kettle 2002; Mahomed 1989), Denmark (Detlefsen 1980; Isager-Sally 1986; Kindberg 2008), Italy (Croce 1997; Morano 2006), Brazil (Almeida 2008), Switzerland (Banninger 1978), Nigeria (Oboro 2003), Spain (Valenzuela 2009), Turkey (Kokanali 2011) and Pakistan (Perveen 2009; Zafar 2008) (the setting of the study by Stark 2009 was not clear). The studies were published between 1978 and 2011. We requested unpublished data from authors of trial reports for some outcomes, and have indicated in the Characteristics of included studies tables and in the reference list when we have used unpublished data in the analyses.

Twelve trials in this review compared continuous suture techniques with interrupted methods for perineal closure (all layers or skin only). Within the 'interrupted suture' comparison groups, the perineal muscle and skin were closed with interrupted stitches; whereas, in the 'continuous suture' groups, two of the included trials used interrupted sutures to repair the perineal muscles prior to continuous subcutaneous closure of the perineal skin (continuous for perineal skin only) (Banninger 1978; Mahomed 1989). The other 12 trials used a continuous suturing technique throughout to close the vagina and perineal muscles prior to subcutaneous skin closure in the 'continuous suture' groups (continuous for all layers) (Almeida 2008; Croce 1997; Detlefsen 1980; Isager-Sally 1986; Kettle 2002; Kindberg 2008; Kokanali 2011; Morano 2006; Perveen 2009; Stark 2009; Valenzuela 2009); in the trial by Almeida 2008 a separate suture was used to close the perineal skin intradermally following continuous closure of the vagina and perineal muscles in the 'continuous' group.

Two trials in the review compared a two-stage technique of perineal repair to the more traditional three-stage approach (the suture techniques were not clearly described) (Gordon 1998; Oboro 2003). In the two-stage technique the vagina and perineal muscles were sutured and the skin was left apposed but not sutured (skin edges no more than half a centimetre apart). In comparison, in the three-stage method, the vagina and perineal muscles were sutured and the skin was re-approximated with interrupted or continuous subcutaneous sutures (see Characteristics of included studies for details).

Two trials examined other comparisons. In the trial by Zafar 2008 in the 'continuous suture' group the vaginal mucosa was closed with a running stitch and the same suture was used to re-approximate the perineal muscle in two layers, followed by subcuticular sutures to close the skin (finishing at the lower end of the incision). In the 'interrupted' comparison group the vaginal mucosa was closed with a continuous running stitch, followed by interrupted sutures inserted in two layers to re-approximate the perineal muscles and the skin was closed using continuous (subcuticular) sutures. One trial used interrupted inverted sutures in the 'interrupted' comparison group to close the perineal muscles, followed by interrupted inverted stiches to re-approximate the skin (sutures were inserted a few millimetres under the skin edges and not transcutaneously) (Kindberg 2008).

Three of the trials included in the review used polyglycolic acid (Dexon) suture material throughout for repair of the vagina, perineal muscles and skin in each comparison group (Banninger 1978; Detlefsen 1980; Isager-Sally 1986). The Almeida 2008, Morano 2006 and Valenzuela 2009 trial used the more rapidly absorbing Polyglactin 910 (Vicryl Rapide) suture material for perineal repair in both comparison groups, whereas the Croce 1997 trial used catgut suture material in both groups. The trial conducted by Kindberg 2008 used a more rapidly absorbing Polyglactin 910 (Vicryl Rapide) and Polyglactin 910 (Standard Vicryl) suture material (suture material was changed after 50% of the sample had been recruited). The Oboro 2003 trial used chromic catgut or polyglycolic acid suture material in each comparison group; however, it was not clear how it was allocated. The Stark 2009 and Zafar 2008 trial used polyglactin 910 (Standard Vicryl) suture material for both comparison groups, although in the Zafar 2008 trial 16 participants had chromic catgut sutures. A further five trials used a factorial 2 x 2 design whereby they compared suture techniques and materials (Gordon 1998; Kettle 2002; Kokanali 2011; Mahomed 1989; Perveen 2009). Participants in the Gordon 1998 trial were repaired with chromic catgut (approximately 50%) and polyglactin 910 (Standard Vicryl) suture material (approximately 50%); participants in the Mahomed 1989 trial were repaired with chromic catgut (approximately 50%) and polyglycolic acid (Dexon) suture material (approximately 50%); participants in the Kettle 2002 trial were repaired with the more rapidly absorbing Polyglactin 910 (Vicryl Rapide) or Polyglactin 910 (Standard Vicryl) suture material (50%) in each comparison group; participants in the Kokanali 2011 trial were repaired with monofilament or multifilament suture material (50%) in each group and the participants in the Perveen 2009 trial used chromic catgut or Polyglactin 910 (Standard Vicryl) suture material (50%) in each comparison group.

All 16 trials used absorbable suture material; however, there were some variations among type of material, gauge and needle size used. In addition, there was some clinical heterogeneity between trials in respect of skill and training of the operator (see Characteristics of included studies for details).

Excluded studies

We excluded five studies (Bendsen 1980; Buchan 1980; Doyle 1993; Hansen 1975; Roberts 1993); in all cases the reason for exclusion was that in addition to comparing suture techniques, different types of suture materials (non-absorbable versus absorbable) were used in the different arms of trials. The use of different materials is likely to have a confounding effect and results were difficult to interpret.

For details of the excluded studies, see Characteristics of excluded studies.

Risk of bias in included studies

The methodological quality of the trials included review was inconsistent.

Allocation

Sequence generation

Methods used to generate the randomisation sequence were rated as adequate for most of these trials. Authors of five trials described using computer-generated allocation sequences (Almeida 2008; Morano 2006; Oboro 2003; Valenzuela 2009; Zafar 2008). Kindberg 2008 reported using a computerised voice response system and Kettle 2002 used a remote clinical trials unit to generate the randomisation sequence. Random number tables were used in the Mahomed 1989 study. Gordon 1998 used a variable block design, although it was not clear how the order of allocation was decided. Methods were not clearly described in the studies by Detlefsen 1980, Croce 1997, Kokanali 2011, Isager-Sally 1986 and Stark 2009, and the method was rated as inadequate for the Banninger 1978 and Perveen 2009 trials where an alternating sequence or sequential method was used.

Allocation concealment

Treatment allocation was concealed at the point of randomisation by the use of sealed, opaque, numbered envelopes in seven trials (Gordon 1998; Isager-Sally 1986; Kettle 2002, Mahomed 1989; Morano 2006; Oboro 2003; Valenzuela 2009), and Kindberg 2008 described using a remote system. In the remaining eight trials the method was either unclear (Almeida 2008; Croce 1997; Detlefsen 1980; Kokanali 2011; Stark 2009; Zafar 2008), or inadequate: the Banninger 1978 trial used a quasi-random method of treatment allocation by 'alternating sequence' and in the Perveen 2009 trial women were allocated sequentially to four arms; these methods carry a serious risk of introducing selection bias as those carrying out randomisation are able to anticipate sequence order in advance.

Blinding

Blinding the staff carrying out repairs would not be feasible with an intervention of this type. Staff frequently required additional training to be able to participate in trials, and frequently the same staff carried out both types of repair. In some of the trial reports information on protocol deviations was provided, and this indicates that staff may have had a preferred method of repair, and greater skill and confidence using a particular technique.

In most of the studies blinding women was not generally attempted, although authors sometimes claimed that women were blind to group allocation (women were simply not told which group they were in). Kindberg 2008 reported that the two methods "appeared similar", and Morano 2006 referred to a "double-blind" study technique. Blinding women may not have been convincing as women would have been able to feel the repair, could possibly have seen it, discussed it with staff and others, and may well have had access to case notes. Moreover, women would probably have been aware of the type of repair if they had required suture removal, or had particular problems.

Blinding outcome assessors was also unlikely to have been convincing. Gordon 1998 and Valenzuela 2009 reported that interview data were collected by "blind" midwives, and Kindberg 2008 reported that the two techniques would "appear similar" to staff. Most of these studies collected outcome data that would necessitate examination of the perineum, and the type of repair may have been apparent to experienced clinicians.

The difficulties associated with blinding women, clinical staff and researchers to treatment allocation in these studies is potentially a serious source of bias particularly as several key outcomes (pain) involved women reporting to staff who would be aware of treatment allocation, and may even have carried out the repairs themselves.

Incomplete outcome data

Loss to follow-up and missing data were problems in many of these studies and this means that results for some outcomes may be at high risk of bias; this particularly applies to long-term outcomes.

There were missing outcome data in all studies although Kettle 2002, Kindberg 2008, Kokanali 2011 and Gordon 1998 had high response rates and few missing data at all data collection points (less than 10% attrition even for long-term outcomes). Other studies had greater losses, even for outcomes measured in the first few days after delivery.

In the study by Almeida 2008 randomisation occurred at the point of delivery; 95 women were approached and 34 were excluded and replaced. It was not clear whether this exclusion and replacement took place after randomisation. If so, this represents a very high level of attrition (more than 30%) and means the study is at high risk of bias.

Morano 2006 reported approximately 10% loss to follow-up by day 10, Zafar 2008 reported 29% attrition by day seven. Mahomed 1989 had high response rates at day two (97%) but by 10 days this had dropped to 86% and to 87% at three months.

The Isager-Sally 1986 trial randomised 600 women to the two groups that were included in the meta-analysis; however, approximately 11% (70 women) were excluded from the study soon after entry. The authors reported that it was not possible to provide follow-up for these women, as most of them were transferred with their babies to a paediatric department in another unit, or they chose to leave hospital before the fifth day after delivery. These women were also excluded from the three-month follow-up; 86% of those participants who were initially randomised to the trial responded to the three-month questionnaire.

Loss to follow-up was a particular problem for longer-term outcomes. A total of 90% of participants returned for follow-up examination at two months in the Detlefsen 1980 trial; 85% of participants responded at three months in the Mahomed 1989 trial. In the Oboro 2003 study there were approximately 20% missing data for longer-term outcomes, and in the Banninger 1978 trial two-thirds of the sample were lost by three months (we have not included data for long-term outcomes from this trial in the analyses in the review).

Twenty-two randomisation envelopes were unaccounted for in the Mahomed 1989 trial and one in the Kettle 2002 trial.

Other potential sources of bias

There was little evidence of baseline imbalance between groups in these studies. However, there was some evidence of greater protocol deviations for women in particular arms of trials. For example, in the Mahomed 1989 trial 18% of those women allocated to the continuous suture group actually had interrupted sutures, while only 2% of those randomised to the interrupted

group had continuous sutures. Furthermore, in the Mahomed 1989 trial midwives sometimes asked doctors to carry out the repairs (rather than carrying out the repair themselves) if the allocation was to continuous technique. Kettle 2002 reported some protocol deviations and suggested that less-experienced staff were more likely to use interrupted techniques for women in the comparison group of this trial. In both of these trials data were analysed according to randomisation group. However, such protocol deviations may mean that the treatment effect has been underestimated.

Effects of interventions

We have included 16 studies, involving 8184 women at point of entry.

Continuous versus interrupted sutures (Comparisons 1 and 2), 12 studies, 4777 women

Primary outcomes

Short-term pain - up to day 10 postpartum

Nine trials presented data in a suitable format for inclusion in this analysis (Almeida 2008; Banninger 1978; Croce 1997; Isager-Sally 1986; Kettle 2002; Mahomed 1989; Morano 2006; Perveen 2009; Valenzuela 2009). The trials used a variety of categorical scales to measure the pain experienced by women, and data from these were combined and included in the meta-analysis as dichotomous outcomes (pain or no pain). Pooled results indicated that the risk of experiencing short-term pain is less when continuous suture techniques are used for perineal closure versus interrupted sutures (average RR 0.76; 95% CI 0.66 to 0.88; 95% prediction interval 0.49 to 1.19, nine trials, 4231 women) (Analysis 1.1). However, results from individual studies varied considerably, and there was high heterogeneity for this outcome and so a random-effects model was used to provide an average treatment effect (heterogeneity: I^2 = 67%, T^2 = 0.03, Chi^2 test for heterogeneity P = 0.002). In three of the nine studies (Isager-Sally 1986; Kettle 2002; Morano 2006) there was a statistically significant difference between the two groups (RR 0.73; 95% CI 0.65 to 0.81; RR 0.60; 95% CI 0.52 to 0.69; and RR 0.54; 95% CI 0.39 to 0.74, respectively), in other trials the treatment effect was less pronounced or CIs were wide, or both. It is possible that some of the heterogeneity may have been because of differences in the ways women were asked about their pain in different studies. Subgroup analysis suggested that there may have been a reduction in pain associated with continuous suturing for all layers (Almeida 2008; Croce 1997; Isager-Sally 1986; Kettle 2002; Morano 2006; Perveen 2009; Valenzuela 2009) (RR 0.74; 95% CI 0.62 to 0.87) versus continuous subcutaneous for closure of perineal skin only (Banninger 1978; Mahomed 1989) (RR 0.89; 95% CI 0.73 to 1.07); however, there was high heterogeneity in the "all layers" subgroup, there was considerable overlap in the CIs for the two subgroups, and the test for subgroup differences was not statistically significant (Analysis 2.1).

Analgesia use - up to day 10 postpartum

Six of the included trials with data for 2971 women (Almeida 2008; Banninger 1978; Kettle 2002; Mahomed 1989; Morano 2006; Stark 2009) presented data regarding analgesia use in the immediate postpartum period that showed an overall reduction in analgesia use associated with the continuous techniques versus interrupted stitches (all layers or skin only) (RR 0.70; 95% CI 0.59 to 0.84) (Analysis 1.2). There was no significant heterogeneity between the results of the different trials, or when results were stratified by suturing method (subgroup analysis) (Analysis 2.2).

Dyspareunia - reported up to three months after delivery

Nine trials with 3619 women provided data for inclusion in this analysis (Almeida 2008; Croce 1997; Detlefsen 1980; Isager-Sally 1986; Kettle 2002; Mahomed 1989; Morano 2006; Perveen 2009; Valenzuela 2009). Although several trials reported a positive treatment effect associated with continuous suturing, overall, the meta-analysis did not demonstrate any strong evidence of reduction in dyspareunia experienced by participants in the continuous technique groups (all layers or skin only), (average RR 0.86; 95% CI 0.70 to 1.06; 95% prediction interval 0.50 to 1.47). The presence of significant heterogeneity between trials makes any form of summary measure difficult to interpret although much of the heterogeneity was because of the more pronounced treatment effect in one of the trials (Detlefsen 1980) (heterogeneity: I^2 53%, T^2 0.04, Chi^2 test for heterogeneity P = 0.03) (Analysis 1.3).

Secondary outcomes

Re-suturing of wound - reported up to three months after delivery

Data regarding the incidence of re-suturing in the two intervention groups were provided by five trials with 3255 women. The Mahomed 1989 trial reported three cases requiring re-suturing in each comparison group; the Banninger 1978 and Morano 2006 trials reported none in either group, the Kettle 2002 trial reported three cases in the treatment group and one case in the control group and the Valenzuela 2009 study there were no women requiring wound re-suturing in the continuous group compared with two in the interrupted sutures group. Meta-analysis showed that there was no difference in risk of re-suturing between groups; however, with only 12 cases reported (six in each group) the numbers were too small to draw reliable conclusions (Analysis 1.4).

Long-term pain - reported up to three months after delivery

Four trials (2891 women) presented data in a suitable format for inclusion in this analysis (Almeida 2008; Kettle 2002; Mahomed 1989; Valenzuela 2009). Overall the meta-analysis showed that there was no significant difference in long-term pain between the continuous and interrupted groups (average RR 0.88; 95% CI 0.64 to 1.20) (Analysis 1.5). There was some variability in these trials in the proportions of women reporting long-term pain, with the number of women reporting pain being considerably lower in the Almeida 2008 and Valenzuela 2009 trials compared with the number reporting pain in the trials by Kettle 2002 and Mahomed 1989. A random-effects method was used for this meta-analysis.

Failure to resume pain-free intercourse - up to three months after delivery

Two trials (2305 women) presented data for inclusion in this analysis (Kettle 2002; Mahomed 1989). Overall, there was no significant difference in failure to resume pain-free intercourse between the two groups, with no evidence of heterogeneity of treatment effect (RR 1.07; 95% CI 0.93 to 1.24) (Analysis 1.6).

Removal of suture material - up to three months after delivery

Six trials (3453 women) provided data for inclusion in the analysis (Kettle 2002; Mahomed 1989; Morano 2006; Perveen 2009; Stark 2009; Valenzuela 2009). The Morano 2006 trial reported no events of suture removal in either group, and there was no significant

evidence of any difference between groups in the Valenzuela 2009 study, whereas the Kettle 2002, Mahomed 1989 and Perveen 2009 trials reported the removal of suture material to be less frequent in the continuous perineal closure groups. Overall pooled results suggest a marginally statistically significant difference between groups (favouring the continuous suture group) for this outcome but high levels of heterogeneity (I^2 = 82%) in results mean that results should be interpreted with caution (average RR 0.56; 95% CI 0.32 to 0.98; 95% prediction interval 0.11 to 2.97) (Analysis 1.7).

Non pre-specified outcomes: resource use

In the trials by Valenzuela 2009 and Kettle 2002 the amount of suture material used was examined, and although the results of the two trials were very different, both showed that operators were much more likely to use more suture material (two or more packets) when the repair was done using the interrupted technique (RR 0.26; 95% CI 0.22 to 0.30) (Analysis 1.8); Kokanali 2011 also reported a significant reduction in the amount of suture material in the continuous repair group although the difference between groups was reported in centimetres rather than the use of sterile packets of suture material and the cost implications of the difference between groups was not clear (data not shown). Four studies (Almeida 2008; Kettle 2002; Kokanali 2011; Valenzuela 2009) looked at the time taken by operators to carry out the repairs; pooled results suggested there was no statistically significant difference between groups, although suturing time varied considerably between these studies and results were not consistent among the trials. Findings for this outcome are difficult to interpret as operators may have been more used to performing a particular technique and may have completed repairs using the technique with which they were more familiar in less time (mean difference -0.73 minutes; 95% CI -2.24 to 0.78 minutes) (Analysis 1.9). (We noted that for the Kokanali 2011 study the standard deviations were much lower than in any of the other studies; temporarily removing this study from the analysis resulted in a mean difference of -0.64 minutes; 95% CI -3.46 to 2.18 minutes; data not shown.)

Three-stage versus two-stage approaches (Comparison 3), two studies, 2857 women

Two studies compared a two-stage repair technique (where the skin was opposed but remained unsutured) with a more traditional three-stage approach (Gordon 1998; Oboro 2003).

Primary outcomes

Short-term pain - up to day 10 postpartum

Pooled results suggested that two-stage repair techniques were associated with fewer women experiencing pain at up to two days and at up to 14 days (average RR 0.92; 95% CI 0.84 to 1.02 and RR 0.86; 95% CI 0.76 to 0.98, respectively) although the difference between groups did not reach statistical significance at two days (Analysis 3.1; Analysis 3.2).

Analgesia use - up to day 10 postpartum

There was no statistically significant evidence of any difference between groups for use of analgesia up to 10 days, although there was high heterogeneity between these two studies and result should be interpreted with caution (Analysis 3.3).

Dyspareunia - reported up to three months after delivery

Women undergoing two-stage repairs were less likely to report dyspareunia compared with those having three-stage repairs, although there was evidence of moderate heterogeneity for this outcome (average RR 0.72; 95% CI 0.56 to 0.94) (heterogeneity I^2 = 41%, T^2 = 0.02, Chi^2 test for heterogeneity 0.19) (Analysis 3.4).

Secondary outcomes

Long-term pain - reported up to three months after delivery

There was no clear evidence of any difference between groups for long-term pain (Analysis 3.5).

Resumption of pain-free intercourse

Gordon 1998 and Oboro 2003 both reported failure to resume pain-free intercourse, and again results favoured women having two-stage repairs (RR 0.86; 95% CI 0.80 to 0.92) (Analysis 3.6).

Wound 'gaping' - reported up to three months after delivery

It was more likely for women who had two-stage repairs to have wounds that appeared to be 'gaping' (more than 0.5 cm) in the first week to 10 days after repair, although there was considerable heterogeneity between the findings from the two studies contributing data (Analysis 3.7).

Re-suturing of wound - reported up to three months after delivery

Women having two-stage repairs seemed less likely to require their wounds to be re-sutured (average RR 0.56; 95% CI 0.31 to 1.00) (Analysis 3.8).

Removal of suture material - up to three months after delivery

Three-stage repairs were associated with more women requiring the removal of suture material at up to three months after delivery (RR 0.60; 95% CI 0.46 to 0.77) (Analysis 3.9).

Non pre-specified outcomes: resource use

Oboro 2003 examined the time taken to carry out two- and three-stage repairs, two-stage repairs took, on average, four minutes less to complete (21 versus 25 minutes) (Analysis 3.10).

Other techniques (Comparison 4), two trials, with 550 women

Two studies described findings for other suturing techniques. Kindberg 2008 compared two groups of women; in the 'continuous suture' group the vagina and perineal muscles were closed with a continuous suturing technique followed by subcutaneous skin closure (continuous for all layers); in the comparison group the vagina was closed with a continuous non-locking suture, followed by interrupted 'inverted' sutures to close the perineal muscles, and interrupted inverted stiches to re-approximate the skin (sutures were inserted a few millimetres under the skin edges and not transcutaneously). Zafar 2008 compared the 'continuous' technique whereby the vaginal mucosa was closed with a running stitch and the same suture was used to re-approximate the perineal muscle in two layers, followed by subcuticular sutures to close the skin (finishing at the lower end of the incision). In the 'interrupted' comparison group the vaginal mucosa was closed with a continuous running stitch, followed by interrupted sutures inserted in two layers to re-approximate the perineal muscles and the skin was closed using continuous (subcuticular) suture. In view of the differences in the techniques used in these two trials we have

not pooled results from studies in meta-analysis, rather we have provided subgroup totals only.

Primary outcomes

Short-term pain and analgesia use - up to day 10 postpartum

Kindberg 2008 examined pain at 10 days after delivery and found no significant differences between groups (Analysis 4.1).

In the Zafar 2008 trial, data on short-term pain was collected at 12 hours after delivery and, at this early stage, the single knot approach appeared to be associated with lower pain scores compared with the more traditional technique (Analysis 4.2).

Both studies collected information on the use of analgesics; neither study reported statistically significant differences between groups (Analysis 4.3).

Dyspareunia - reported up to three months after delivery

Kindberg 2008 collected information on dyspareunia and found no statistically significant differences between groups (Analysis 4.4).

Secondary outcomes

Wound breakdown at up to three months

Zafar 2008 examined superficial wound gaping and found no significant differences between groups. Kindberg 2008 found no evidence of differences between groups for wound re-suturing at up to three months (Analysis 4.5; Analysis 4.6).

Removal of suture material up to three months

Kindberg 2008 reported findings for the number of women requiring the removal of suture material. There was no clear evidence of a difference between treatment groups for this outcome (Analysis 4.7).

Non pre-specified outcomes: resource use and satisfaction with repair

Zafar 2008 reported that the single knot (continuous repair) took less time than the traditional technique (all repairs were carried out by the same person and in both arms of this trial repairs were completed much more speedily than in other studies examining different types of repairs) (Analysis 4.8).

Kindberg 2008 reported that repairs using the continuous technique required one packet of suture material, whereas the inverted interrupted method required two and that the continuous technique was quicker to perform compared with the inverted interrupted technique (15 minutes versus 17 minutes; standard deviations not reported).

Kindberg 2008 reported that similar numbers of women in both arms of this trial were satisfied with their perineal repairs (Analysis 4.9).

DISCUSSION

Summary of main results

The meta-analysis of data provides evidence that continuous techniques for perineal closure (all layers or skin only) cause less pain in the immediate postpartum period, less need for analgesia and less need for suture removal compared with interrupted stitching methods. However, there is a significant degree of heterogeneity between trials for several outcomes that may be a result of clinical heterogeneity in terms of input in perineal repair training, different suturing techniques and materials used (see Characteristics of included studies tables for details).

There is also some evidence that the continuous technique uses less suture material when compared with the interrupted methods (one packet compared to two or three packets, respectively). This is important information, as the introduction of a continuous suturing policy would reduce the overall suture material expenditure for maternity units worldwide.

To investigate the heterogeneity of results between the different trials, in line with the philosophy of Greenland 1987, we considered the possible sources of heterogeneity. In particular, we looked at the heterogeneity of treatment effects stratified by continuous suturing for all layers versus continuous subcutaneous for closure of perineal skin only. Six of the included trials (Croce 1997; Detlefsen 1980; Isager-Sally 1986; Kettle 2002; Morano 2006, Perveen 2009) used a non-locking continuous suturing technique to repair the vagina and perineal muscles with a continuous subcutaneous stitch inserted to close the skin in the experimental group; four trials (Croce 1997; Detlefsen 1980; Isager-Sally 1986; Kettle 2002) used a locking suture for the vagina, and interrupted sutures to repair perineal muscle and skin in the control group and the Morano 2006 trial used a non-locking suture for repair of the vaginal mucosa, three or four interrupted stitches to repair the deep and superficial perineal muscles, and interrupted transcutaneous stitches inserted to close the skin. The other two trials by Mahomed 1989 and Banninger 1978 used a locking continuous stitch and interrupted stitches to repair the vagina, respectively; interrupted stitches for the muscle layer and continuous subcutaneous stitches versus interrupted for skin closure.

The rationale for performing continuous suturing indicates that any benefit would be larger in those trials that use continuous suturing throughout for all layers, therefore this was investigated by performing stratified subgroup analysis. However, there remained considerable heterogeneity within the continuous 'all layers' group.

The Mahomed 1989 trial reported that the subcutaneous method of perineal skin closure was less practiced and unpopular with some operators and there was some cross-over of treatment allocation (96 women in the subcutaneous group had interrupted transcutaneous stitches inserted). In the Almeida 2008 trial, there was also evidence of treatment cross-over for women allocated to the interrupted suture group. Deviation from protocol and variation in technique within trial arms mean that results were more difficult to interpret. In the Kettle 2002 trial, adherence to treatment allocation was very high. Perhaps the better results produced by the Isager-Sally 1986 trial were because of the continuous technique being introduced several months prior to the trial starting, thus ensuring that all members of staff were familiar with the new technique of perineal repair. In the Kettle 2002 trial, midwives received standardised training in both techniques (interrupted and continuous) prior to the study commencing. However, owing to rotation of midwives from the delivery suite and delay in starting the study, many of the participating midwives were not familiar with the continuous technique and were trained during the early part of the recruitment phase. During the first phase of the Kettle 2002 trial, senior midwives were more likely to undertake the continuous suturing. This imbalance was considered in a

subsequent association analysis; however, there was no evidence of significant heterogeneity between groups.

Meta-analysis also showed that continuous techniques were associated with a reduction in the need for suture removal up to three months following childbirth. It could be argued that this finding may be because continuous subcutaneous stitches are less accessible than interrupted transcutaneous stitches. Nevertheless, this finding is important, as most women find the experience of having sutures removed from perineal wounds very distressing.

Quality of the evidence

Overall, the quality of the evidence on which conclusions of the review are based was mixed. For methods of randomisation approximately half of the studies used methods of sequence generation and allocation concealment that we assessed as low risk of bias, while in other trials' methods were either not described, not clear or were at high risk of bias. Blinding operatives for this type of intervention may not be feasible and attempts to blind outcome assessors may not be convincing. It is difficult to assess whether lack of blinding of staff carrying out repairs affected other aspects of care, and for us to judge the overall impact of lack of blinding on outcomes. As we discussed above, some staff may have been more familiar with (and possibly preferred) one technique and this may have affected the quality of their repair and the way they assessed outcomes. An additional problem in some studies was the loss to follow-up; even relatively small losses to follow-up may be important for outcomes such as removal of suture material and the need for re-suturing where event rates are relatively low.

Potential biases in the review process

We are aware that there is a risk of introducing bias at all stages in the review process. Assessing risk of bias, for example, involves individual judgements. We took a number of steps to reduce bias such as having two review authors assess each paper independently. One review author was an investigator in one of the included trials (Kettle 2002) and this author was therefore not involved in the assessment of evidence for this trial.

AUTHORS' CONCLUSIONS

Implications for practice

The evidence produced by this review shows that continuous suturing techniques for perineal closure is associated with less short-term pain. There is also some evidence that if the continuous technique is used for all layers (vagina, perineal muscles and skin), the benefit in terms of reducing pain may be even greater.

The continuous technique is easily performed by the novice or inexperienced operator. In addition, it has economical advantages in that the continuous technique requires one packet of suture material per perineal repair compared to two or more packets for the interrupted method (Kettle 2002). Therefore, the non-locking continuous suturing technique is recommended for repair of vagina and perineal muscles with a continuous subcutaneous stitch to close the perineal skin.

Implications for research

The review has highlighted the following areas that are worthy of further evaluation.

- Future trials relating to perineal trauma need to address outcomes that are important to women, including sexual problems and pelvic floor muscle dysfunction in the immediate- and long-term period following childbirth.
- Research into the impact of standardised training programmes for the identification, management and repair of perineal trauma on short- and long-term maternal morbidity.
- Clinical trials to investigate techniques for the prevention of perineal trauma.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

Almeida 2008

Methods	RCT (individual randomisation).
Participants	Setting: birth centre in a general hospital in Brazil. Dates of recruitment: July 2001 to April 2002. 61 women requiring perineal repair after episiotomy or second-degree tear. Parity: primigravid and multigravid women included (16/31 in group 1 and 15/30 in group 2 had had a previous vaginal delivery). Mean age: group 1 = 24.2 years; group 2 = 24.2 years. Operator: 1 of 10 trained nurse/midwives.
Interventions	Method of repair: described as below. Women divided into 2 groups. Group 1 (N = 31),vaginal trauma and perineal muscle re-approximated with the continuous non-locking suture technique using polyglactin 910 (Vicryl Rapide) on a 1/2 circle, taper point needle (4 or 5 cm). The skin was approximated separately with a continuous intradermal suture using a 3/8 circle, reverse cutting needle. Group 2 (N = 30), vaginal trauma continuous locking and perineal muscle sutured using the interrupted technique with polyglactin 910 (Vicryl Rapide) using a 1/2 circle needle, taper point of 4 or 5 cm The skin was approximated separately with a 3/8 circle reverse cut needle of 3 cm using interrupted sutures.
Outcomes	Included in analysis: • short-term pain measured at day 4; • analgesia at day 4; • long-term pain at 6 to 8 weeks' postpartum; • dyspareunia at 6 to 8 weeks; • time taken to carry out the repair (minutes).
Notes	Women in both groups had antisepsis of the vulva and perineum. Data collection from women by interview by researcher or midwife.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Described as by "electronic table".
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding (performance bias and detection bias) Clinical staff	High risk	Different techniques used.
Blinding (performance bias and detection bias) Women	High risk	Different techniques.
Blinding (performance bias and detection bias)	High risk	Method used would be recorded in notes.

Almeida 2008 *(Continued)*

Outcome assessors		
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Randomisation was "applied at the moment of delivery to 95 women. A total of 34 women were excluded from the study and replaced by others according to the randomization table". It was not clear whether women were excluded after randomisation.
Selective reporting (reporting bias)	Unclear risk	Not apparent.
Other bias	Unclear risk	Data collection from women by interview by researcher or midwife. There was some baseline imbalance.

Banninger 1978

Methods	Quasi-RCT.
Participants	Setting: Switzerland. 160 women having an episiotomy without complications. This was a subgroup of the main trial. Method of delivery: spontaneous vaginal with cephalic presentation. Parity: primigravidae. Mean age: group 1 = 25.2 years; group 2 = 24.8 years. Operator: doctors.
Interventions	Method of repair: described as below. Women divided into 2 groups. Group 1: (N = 80), vagina, perineal muscle and skin sutured using the interrupted technique with Dexon 2/0 on a 60-mm round bodied needle. Group 2: (N = 80), vagina and perineal muscle sutured using the interrupted technique with polyglycolic acid (Dexon) 2/0 on a 60-mm round bodied needle. Perineal skin closed using a continuous intracutaneous (subcutaneous) technique with Dexon 3/0 on a 16-mm 3/8 circle atraumatic cutting needle.
Outcomes	Included in analysis: • short-term pain at day 7; • analgesia at day 7; • re-suturing at day 7; • dyspareunia at 3 months.
Notes	Method of repair: described. Training period: not described. Exclusion criteria: described. Participant inclusion criteria described. Does not state if trial had Research Ethics Committee approval.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Alternate sequence.
Allocation concealment (selection bias)	High risk	Allocated by 'alternating sequence' - quasi (non)-randomised.

Banninger 1978 *(Continued)*

Blinding (performance bias and detection bias) Clinical staff	High risk	Different suturing techniques.
Blinding (performance bias and detection bias) Women	High risk	Not stated but women may have been aware of suturing technique.
Blinding (performance bias and detection bias) Outcome assessors	High risk	Different suturing techniques.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	All participants entered into the trial were included in the analysis. No information available on whether analysis was by 'intention to treat'. Only one-third of participants followed up at 3 months. Observation of cosmetic results at 3 months: no data available.
Selective reporting (reporting bias)	Unclear risk	Not apparent.

Croce 1997

Methods	RCT.
Participants	Setting: single centre (Codogno Civic Hospital, Italy). 202 women with selective episiotomy. Mean age: group A = 29.5 years; group B = 27.7 years. Operator: not stated.
Interventions	Method of repair: as described below. Women divided into 2 groups. Group 1 (N = 100), vaginal trauma sutured with a continuous (Guilmen-Pontonnier technique) with catgut. Group 2 (N = 102), interrupted (Blair-Donatti technique) with catgut.
Outcomes	Included in analysis: • short-term pain at 24 and 76 hours; • long-term pain at 1, 2 and 3 months' postpartum; • dyspareunia; • infection, haematoma and cosmetic results (not reported).
Notes	Method of repair: described.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Allocated by 'randomisation' but matched for age, socioeconomic status and parity.
Allocation concealment (selection bias)	Unclear risk	No information available regarding concealment of treatment allocation.

Croce 1997 *(Continued)*

Blinding (performance bias and detection bias) Clinical staff	High risk	Different suture techniques.
Blinding (performance bias and detection bias) Women	High risk	Not stated but women may have been aware of suturing technique.
Blinding (performance bias and detection bias) Outcome assessors	High risk	Not stated but assessment was likely to have included perineal examination.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Analyses apparently ITT (202 women included in the analyses) but it was not clear how many women were originally randomised.
Selective reporting (reporting bias)	Unclear risk	Not apparent.

Detlefsen 1980

Methods	RCT.
Participants	Setting: Denmark. 117 women with a medio-lateral episiotomy. This was a subgroup of the main trial. Method of delivery: spontaneous vaginal with cephalic presentation. Parity: primigravida and multigravida included. Mean age: not specified between groups. Operator: doctors and midwives.
Interventions	Method of repair: as described below. Women divided into 2 groups. Group 1 (N = 65), vaginal trauma sutured with a continuous locking stitch, perineal muscle and skin sutured using the interrupted technique with Dexon 1/0 on a T-125 needle. Group 2 (N = 52), vaginal trauma sutured with a continuous locking stitch, perineal muscle closed with a continuous non-locking (running) stitch and perineal skin closed using an intracutaneous (subcuticular) technique with Dexon 1/0 on a T-125 needle.
Outcomes	Included in analysis: • dyspareunia at 2 months; • not included in analysis owing to data being presented in unsuitable format; • short-term pain at day 5; • analgesia at day 5.
Notes	Method of repair: described. Training period: midwives and doctors underwent training for 1 month in the new suturing technique used in group 2. All women delivered between 1 April 1978 and 31 July 1978 with an episiotomy were randomised into the trial. Long-term follow-up: 2 and 6 months' postpartum. Does not state if trial had Research Ethics Committee approval.
Risk of bias	

Detlefsen 1980 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Allocated by 'randomisation': method not described.
Allocation concealment (selection bias)	Unclear risk	Allocated by 'randomisation'. No information available regarding concealment of treatment allocation.
Blinding (performance bias and detection bias) Clinical staff	High risk	Different suture techniques.
Blinding (performance bias and detection bias) Women	High risk	Not stated but women may have been aware of suturing technique.
Blinding (performance bias and detection bias) Outcome assessors	High risk	
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not clear and not clear whether analysis was by 'intention to treat'.
Selective reporting (reporting bias)	Unclear risk	Not apparent.

Gordon 1998

Methods	RCT, factorial 2 x 2 design.
Participants	Setting: Ipswich hospital, UK. Data collection from 1992 to 1994. 1780 women requiring perineal repair after spontaneous or simple instrumental delivery. First- and second-degree tears included. Mean age: 2-stage repair 28.5 years; 3-stage repair 28.2 years. Both primiparous and multiparous women included. 40% in the 2-stage and 38% in the 3-stage repair groups had had a previous vaginal delivery.
Interventions	2-stage versus 3-stage technique. Group 1: 2-stage repair (skin opposed but unsutured) with chromic catgut. Group 2: 3-stage repair (skin sutured) with chromic catgut. Group 3: 2-stage repair with polyglactin 910. Group 4: 3-stage repair with polyglactin 910. In the analyses in this review we have combined groups 1 and 3 (2-stage repairs) versus combined results from groups 2 and 4 (3-stage repairs). 75% of the repairs were carried out by midwives. For 3-stage repairs operators were encouraged to use a continuous subcuticular techniqu.e for skin closure; however, 72% had interrupted sutures inserted and 26% subcuticular
Outcomes	Included in analysis:

Gordon 1998 *(Continued)*

- any pain in last 24 hours (mild, moderate, severe) at 2 and 10 days and 3 months;
- analgesia in last 24 hours at 2 and 10 days and 3 months;
- removal of suture material up to 3 months;
- gaping at 2 and 10 days;
- re-suturing at 3 months;
- dyspareunia at 3 months;
- resumption of pain-free intercourse by 3 months.

Notes	Suture techniques not clearly described. There was a change in recruitment criteria during the trial. Initially only women with spontaneous deliveries were included, during the second year of the trial deliveries by non-rotational forceps or vacuum extraction were also included. There were some protocol deviations but analyses was according to randomisation group.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation at completion of the third stage of labour. Balanced block design (variable block size) stratified by type of delivery.
Allocation concealment (selection bias)	Low risk	Serially numbered, sealed opaque envelopes containing suture material prepared in advance by independent researcher.
Blinding (performance bias and detection bias) Clinical staff	High risk	Materials and technique obviously different.
Blinding (performance bias and detection bias) Women	Unclear risk	Not clear, women would be aware that skin had not been sutured.
Blinding (performance bias and detection bias) Outcome assessors	High risk	It was stated that data collection was by a "research midwife blinded to the allocation". The outcome assessment included face-to-face interviews and examination of the perineum so it is very unlikely that the assessor would be blinded to the type of repair for short-term outcome assessment.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	It was stated that primary analysis was by ITT. 1780 women were recruited, 99% followed up at 48 hours and 93% at 3 months.
Selective reporting (reporting bias)	Unclear risk	Not apparent.
Other bias	Low risk	No baseline imbalance apparent. All randomisation envelopes accounted for. Double data entry. Some protocol deviation with 12% of those allocated to the 2-stage repair technique having skin sutured but ITT analysis.

Isager-Sally 1986

Methods	RCT.
Participants	Setting: Herlev Hospital, Denmark. 530 women with medio-lateral episiotomy were analysed. This was a subgroup of the main trial Method of delivery: spontaneous or instrumental vaginal deliveries.

Isager-Sally 1986 *(Continued)*

	Parity: primigravidae and multiparae. Mean age: group 1 = 27.5 years; group 2 = 27.1 years. Operators: midwives and experienced obstetricians.
Interventions	Method of repair: described as below. Women divided into 2 groups. Group 1 (N = 263), vaginal trauma sutured with a continuous locking stitch, perineal muscle and skin sutured using the interrupted technique with polyglycolic acid (Dexon) suture material gauge 0. Needle size not specified. Group 2 (N = 267), vaginal trauma sutured with a continuous locking stitch, perineal muscle closed with a continuous non-locking (running) stitch and perineal skin closed using an intracutaneous (subcuticular) technique with polyglycolic acid (Dexon) suture material gauge 0. Needle size not specified.
Outcomes	Included in analysis: • short-term pain at day 5; • long-term pain at 3 months; • dyspareunia at 3 months.
Notes	Method of repair: method described. Training period: introductory period of several months to make sure all members of staff were familiar with the new suturing technique used in group 2. Does not state if trial had Research Ethics Committee approval. Response rate at 3 months: group 1 = 95%; group 2 = 99% (of those who responded at 5 days - numbers randomised per arm not given).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised immediately after delivery. Method not described.
Allocation concealment (selection bias)	Low risk	"Closed envelopes containing the number of the method to be used for the repair".
Blinding (performance bias and detection bias) Clinical staff	High risk	Not blinded owing to obvious differences in suturing techniques.
Blinding (performance bias and detection bias) Women	High risk	Not stated but women may have been aware of suturing technique.
Blinding (performance bias and detection bias) Outcome assessors	Unclear risk	Differences in suturing techniques apparent.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Analysis for only those participants still in the hospital at 5th day (not 'intention to treat' - missing data possibly outcome dependent). Of 900 women randomised, 98 were not followed up at day 5. 781 women responded to the questionnaire at 3 months.
Selective reporting (reporting bias)	Unclear risk	Not apparent.
Other bias	Unclear risk	No baseline imbalance apparent.

Kettle 2002

Methods	RCT. Factorial - 2 x 2 design.
Participants	Setting: UK district general hospital. 1542 women needing perineal repair following delivery (second-degree tears and episiotomies included). Method of delivery: spontaneous vaginal deliveries. Parity: primiparous and multiparous. Mean age: continuous (group A) 27.2 years; interrupted (group B) 27.2 years. Operators: midwives (N = 150), 29 women sutured by doctor.
Interventions	Method of repair: described as below. Women divided into 2 groups. Group A (N = 771) vaginal trauma, perineal muscle and skin repaired with a continuous non-locking suture technique. 50% were repaired with undyed Vicryl Rapide 2/0 on a 35-mm tapercut needle and 50% were repaired with undyed standard Vicryl on a 35-mm tapercut needle. Group B (N = 771) vaginal trauma repaired with a locking continuous stitch; perineal muscle and skin sutured using the interrupted method. 50% were repaired with undyed Vicryl Rapide 2/0 on a 35-mm tapercut needle and 50% were repaired with undyed standard Vicryl on a 35-mm tapercut needle.
Outcomes	Included in analysis: • short-term pain at days 2 and 10; • pain when walking, sitting, passing urine, opening bowels at 10 days; • analgesia at day 10; • long-term pain at 3 and 12 months; • dyspareunia at 3 and 12 months; • removal of suture material at 3 months; • Additional analyses in Kettle 2002.
Notes	Method of repair: described. Training period: described Concealed interim analysis after 400 women entered the trial. Ethics Committee Approval. 1 envelope unaccounted for.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Allocated randomly by remote clinical trials unit. Random permuted block design.
Allocation concealment (selection bias)	Low risk	Concealed treatment allocation - serially numbered, sealed opaque envelopes, (envelopes contained 2 packets of masked suture material and instructions for method of repair on different coloured cards).
Blinding (performance bias and detection bias) Clinical staff	High risk	Differences in suture techniques.
Blinding (performance bias and detection bias) Women	High risk	Women may have been aware of suturing technique.

Kettle 2002 *(Continued)*

Blinding (performance bias and detection bias) Outcome assessors	High risk	Fully blind assessment was not possible owing to obvious differences in suture techniques.
Incomplete outcome data (attrition bias) All outcomes	Low risk	1542 women randomised and primary analysis was by ITT. High response rate at day 10 and at 3 and 12 months' follow-up (96.7% response rate at 3 months and 90% at 12 months).
Selective reporting (reporting bias)	Unclear risk	Not apparent.
Other bias	Unclear risk	No baseline imbalance apparent. There were some protocol deviations (less experienced staff were more likely to use interrupted sutures).

Kindberg 2008

Methods	RCT (individual randomisation), 2-arm trial.
Participants	Setting: Arrhus hospital, Denmark. Recruitment 2004 to 2005. 400 healthy low-risk women > 36 weeks' gestation, requiring perineal repair following spontaneous or instrumental (silastic cup ventouse) vaginal delivery with second-degree laceration or episiotomy. Exclusions: unable to speak English or Danish, metal cup ventouse or forceps delivery, third-degree tears, PPH, previous perineal surgery, diabetes or severe mental illness. Parity: primiparous women only. Mean age: continuous 28.2 years; interrupted 28.2 years. Operators: midwives trained in suturing techniques.
Interventions	Method of repair: described below. Both groups were sutured using rapidly absorbing polyglactin 910 (Vicryl Rapide) gauge 2/0, 90-cm long on 1/2c, 36-mm needle. (There was a change in the protocol to standard polyglactin 910 using the same gauge and needle, this was after approximately half of the sample had been recruited). Group 1: (continuous) loose, continuous non-locking suture to close vaginal mucosa and muscular layer of perineum. The perineal skin was approximated with the same continuous suture in the subcutaneous tissue, a few millimetres under the perineal skin, finishing with a terminal knot in front of the hymenal ring. Group 2: (inverted interrupted) loose continuous non-locking suture to the vaginal mucosa, 2 to 4 inverted interrupted stitches to the muscular layer of the perineum. Perineal skin approximated with inverted, interrupted sutured to the subcutaneous tissue a few millimetres under the skin edges (not transcutaneously).
Outcomes	Included in analysis: • pain at 24 to 48 hours (100-mm VAS); • pain at 10 days (100-mm VAS and McGill pain score); • patient satisfaction at 6 months (telephone interview); • dyspareunia; • re-suturing; • time taken to carry out the repair; • wound healing (redness, oedema and approximation of skin edges); • wound dehiscence (wound gaping more than 0.5 cm).

Kindberg 2008 *(Continued)*

Notes	Change in suture material part way through the trial; authors stated that this did not affect the results when a logistic regression analysis was carried out.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-assisted voice response system, using stratified block randomisation (variable block size). Stratification by episiotomy/laceration.
Allocation concealment (selection bias)	Low risk	Remote telephone randomisation.
Blinding (performance bias and detection bias) Clinical staff	Unclear risk	Different techniques; while the trial authors claim that the 2 techniques appeared similar this may not have been convincing in practice.
Blinding (performance bias and detection bias) Women	Unclear risk	Women were not told about the method of repair.
Blinding (performance bias and detection bias) Outcome assessors	Unclear risk	Research midwife carrying out assessments described as blind to the 2 techniques.
Incomplete outcome data (attrition bias) All outcomes	Low risk	400 women randomised, 395 followed up. "All statistical analyses were undertaken on an intention-to-treat basis".
Other bias	Unclear risk	Considerable amount of non-compliance (23% in the continuous group and 20% in the interrupted group were not treated according to randomisation group although ITT analyses were carried out).

Kokanali 2011

Methods	RCT factorial design, 4-arm trial.
Participants	Setting: Dr Zekai Tahir Burak Women's Health Education and Research Hospital, Ankara, Turkey. Study period: March to August 2009. Inclusion criteria: **w**omen with live, singleton birth at 37 to 42 weeks' gestation; spontaneous vaginal delivery with right mediolateral episiotomy. Exclusion criteria: assisted vaginal delivery, perineal-cervical tears, episiotomy involving the anal sphincter or rectum, viable baby with congenital abnormalities and extensive varicose veins of external genitalia.
Interventions	Experimental intervention (2 groups). Group 1: continuous technique with monofilament suture material (40 women). Group 2: continuous technique with multi-filament suture material (40 women). Continuous technique: "Vaginal wall sutured with a continuous locking stitch. The same suture is continued in the muscles which are sutured continuously reaching the end of the incision. The same stitch is then carried in the skin and the perineal skin is approximated with the same continuous suture in the

Kokanali 2011 *(Continued)*

	subcutaneous tissue a few millimetres under the perineal skin edges finishing with a terminal knot in the vaginal mucosa in front of the hymeneal ring". Control/comparison intervention (2 groups). Group 1: interrupted technique with monofilament suture material (40 women). Group 2: interrupted technique with multifilament suture material (40 women). Interrupted technique: "three-layer technique, in which the vaginal mucosa was sutured with a continuous locking stitch. Two to four interrupted stitches were applied to the muscular layers and skin separately". Suture material (experimental and control groups): monofilament suture was polyglycolide-co-caprolactone material – gauge 0, 75-cm long on a 1/2c 40-mm needle. The multi-filament suture was polyglactin 910-Rapide material, gauge 0, 90-cm long on a 1/2c 40-mm needle.
Outcomes	Included in analysis: • perineal pain in movement, while sitting; urinating and defecating on days 1 and 10 postpartum (mean on VAS 0 to 10); • resumption of sexual intercourse and pain on intercourse at 6 weeks (continuous). Complications (wound infection, haematoma, healing, removal of suture material) up to 6 weeks.
Notes	The 4 study groups have been combined to form 2 groups so that we could carry out pair-wise comparisons by suture technique (continuous versus interrupted). For dichotomous outcomes event rates and totals were added and for continuous outcomes means and standard deviations were combined using the methods set out in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	It was stated that women were allocated "using a computer for random selection" but the methods were not clear; "the treatment allocations were written on papers (40 of each) and placed in numbered, sealed, opaque envelopes" that were kept on the delivery ward concealing the assignment of treatment.
Allocation concealment (selection bias)	Unclear risk	It was stated that women were allocated "using a computer for random selection" but the methods were not clear; "the treatment allocations were written on papers (40 of each) and placed in numbered, sealed, opaque envelopes" that were kept on the delivery ward concealing the assignment of treatment.
Blinding (performance bias and detection bias) Clinical staff	Unclear risk	It was not clear whether or not women were told about which group they were allocated to.
Blinding (performance bias and detection bias) Women	High risk	All repairs were carried out by the same operator (unable to blind operator to technique of repair or materials used).
Blinding (performance bias and detection bias) Outcome assessors	Low risk	It was stated that outcomes were assessed by a blinded investigator.
Incomplete outcome data (attrition bias) All outcomes	Low risk	160 women were randomised and it was stated that no women were lost to follow-up. It was not clear whether there were any protocol violations.

Kokanali 2011 *(Continued)*

Selective reporting (reporting bias)	Unclear risk	Assessed from published study report.
Other bias	Unclear risk	Methods section was not clear regarding the method of randomisation. Unclear if all eligible women were approached as the repairs were carried out by the same operator (unable to be available 24 hours a day).

Mahomed 1989

Methods	RCT. Modified factorial - 2 x 3 x 2 design.
Participants	Setting: Southmead Hospital, Bristol. 1057 women needing perineal repair following delivery (all tears and episiotomies included). This was a subgroup of the main trial. Method of delivery: spontaneous or instrumental vaginal deliveries. Parity: primigravidae and multiparae. Mean age: group 1 = 26.0 years; group 2 = 25.9 years. Operators: midwives, senior house officers, registrars, consultants, medical students.
Interventions	Method of repair: described as below. Women divided into 2 groups. Group 1 (N = 524) vaginal trauma repaired with a continuous stitch, perineal muscle and skin sutured using the interrupted technique. 50% were repaired with Dexon (plus) 2/0 on a multipurpose needle and 50% were repaired with chromic catgut on a 35-mm tapercut needle. Group 2 (N = 533) vaginal trauma repaired with a continuous stitch, perineal muscle apposed with interrupted stitches and skin sutured using the continuous subcuticular technique. 50% were repaired with Dexon (plus) 2/0 on a multipurpose needle and 50% were repaired with chromic catgut on a 35-mm tapercut needle.
Outcomes	Included in analysis: • short-term pain at day 2 and 10; • long-term pain at 3 months; • analgesia at day 2 and 10; • re-suturing at up to 3 months; • dyspareunia at 3 months; • removal of suture material at 3 months; • resumption of intercourse at 3 months;
Notes	Method of repair: method described. Subcuticular technique was unpopular with some operators. Training period: not described. No interim analysis. Ethics Committee Approval. Pre-set trial size had 80% chance of detecting significant clinical differences.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not clear.

Mahomed 1989 *(Continued)*

Allocation concealment (selection bias)	Low risk	Serially numbered, sealed opaque envelopes (envelopes contained suture material and instructions for method of repair). 22 envelopes were unaccounted for.
Blinding (performance bias and detection bias) Clinical staff	High risk	Differences in suture materials and techniques.
Blinding (performance bias and detection bias) Women	High risk	Women may have been aware of suturing technique.
Blinding (performance bias and detection bias) Outcome assessors	High risk	Fully blind assessment was not possible owing to obvious differences in suture materials and techniques.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	1574 women randomised. 97% response rate at day 2, 86% at day 10 and 87% at 3 months (1366 women).
Other bias	Unclear risk	There were some protocol deviations; of those allocated to continuous sutures 18% had interrupted, only 2% of those allocated to interrupted had continuous sutures. "some midwives preferred the interrupted technique... sometimes a midwife called a senior house officer if the allocation was to subcuticular suturing".

Morano 2006

Methods	RCT.
Participants	Setting: single centre (University Hospital, Italy). 214 women with a second-degree tear or episiotomy. Method of delivery: spontaneous vaginal deliveries after 37 weeks' gestation. Parity: primiparous. Mean age: continuous (group A) = 28 years; interrupted (group B) = 27 years. Operators: young medical doctors with supervision provided by an experienced doctor.
Interventions	Method of repair: as described below. Women divided into 2 groups. Group A (N = 107), vaginal trauma, perineal muscles and skin repaired with loose, continuous non-locking technique. Suture material rapidly absorbed polyglactin 910 (Vicryl Rapide) - gauge 0 for vagina, perineal muscles and skin. Needle size not specified. Group B (N = 107) vaginal trauma repaired with a continuous non-locking stitch; perineal muscle and skin sutured with interrupted method. Suture material: rapidly absorbed polyglactin 910 (Vicryl Rapide) - gauge 0 for vagina, 1 for perineal muscles and 2/0 for skin. Needle size not specified.
Outcomes	Included in analysis: • short-term pain at 48 hours and 10 days; • suture removal, wound dehiscence at 10 days; • oral analgesia at 48 hours; • dyspareunia at 3 months.
Notes	Method of repair: method described. Training period: doctors had opportunity to practice 2 methods prior to commencement of study.

Morano 2006 *(Continued)*

	Local research ethics committee approval obtained.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Computer-generated list of random numbers.
Allocation concealment (selection bias)	Low risk	Sealed and consecutively numbered opaque envelopes (instructions for method of repair written on cards within envelopes).
Blinding (performance bias and detection bias) Clinical staff	High risk	Different suture techniques.
Blinding (performance bias and detection bias) Women	Unclear risk	Stated that trial was double blind, but women may have been aware of sutures.
Blinding (performance bias and detection bias) Outcome assessors	High risk	It would be difficult to blind the assessment of wound healing due to obvious differences in suturing techniques.
Incomplete outcome data (attrition bias) All outcomes	Low risk	214 women randomised, 19 lost to follow-up by day 10.
Other bias	Unclear risk	No baseline imbalance apparent.

Oboro 2003

Methods	RCT (individual randomisation) 2-arm trial.
Participants	Setting: 4 district government hospitals in Nigeria. Data collection 2000 to 2001. 1077 women requiring perineal repair after episiotomy or second-degree tears (women with first- or third-degree tears were excluded). Operators: over 75% repairs by midwives. Parity: both primi- and multiparous women included. Mean age: group 1 (2-layer technique) = 26.3 years; group 2 (3-layer technique) = 26.2 years.
Interventions	Group 1: 2-stage approach (not clear) but with the skin left unsutured using number 00 chromic catgut or polyglycolic sutures. Group 2: 3-stage approach (not clear) with skin closure with interrupted or subcuticular continuous sutures (the subcuticular technique was encouraged) using number 00 chromic catgut or polyglycolic sutures.
Outcomes	Included in analysis: • perineal pain (at 48 hours, 2, 6 and 12 weeks' postpartum); • analgesia use (at 48 hours, 2, 6 and 12 weeks' postpartum); • wound gaping (< 0.5 cm) (at 48 hours, 2, 6 and 12 weeks' postpartum); • wound breakdown (at 2 weeks' postpartum); • suture removal (2, 6 and 12 weeks' postpartum); • re-suturing (6 and 12 weeks' postpartum);

Oboro 2003 *(Continued)*

- dyspareunia (deep and superficial) (6 and 12 weeks' postpartum);
- resumption of pain-free intercourse (6 weeks' postpartum);
- time taken to carry out the repair (minutes).

Notes	Suture techniques not clearly described. Not clear what materials were used and whether there were any differences in materials in different arms of the trial

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation when women completed the third stage of labour. Envelopes were prepared by "a statistician using computer generated block randomisation with varying block sizes".
Allocation concealment (selection bias)	Low risk	Sequentially numbered opaque sealed envelopes.
Blinding (performance bias and detection bias) Clinical staff	High risk	Different techniques.
Blinding (performance bias and detection bias) Women	High risk	Noy clear, although women would be aware from the appearance of the wound whether or not the skin had been sutured.
Blinding (performance bias and detection bias) Outcome assessors	High risk	Technique used would be apparent to assessors who carried out an examination of the perineum to assess gaping and bruising.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	1077 randomised, 823 completed both the 2 and 6 weeks questionnaires (approximately 20% attrition for longer-term outcomes), loss to follow-up balanced across groups. The level of missing data was not clear in the results tables.
Other bias	Unclear risk	No baseline imbalance apparent.

Perveen 2009

Methods	RCT, factorial design (4 arms). Quasi-randomised, alternating sequence.
Participants	Setting: Darul-Sehat Hospital (private teaching tertiary care hospital) Karachi, Pakistan. Inclusion criteria: 200 primiparous and multiparous women who sustained an episiotomy or second-degree tear after spontaneous vaginal delivery. Exclusion criteria: women under 18 years of age, requiring instrumental delivery, with severe anaemia (Hb < 6 g/dL), pre-existing vaginal discharge or coagulation disorder.
Interventions	4 arms (50 women in each group). Experimental intervention: (owing to resource constraints chromic catgut is still used in the study setting). Group 1: continuous repair with chromic catgut No 0 and 00 (chromic surgical gut – Ethicon).

Perveen 2009 *(Continued)*

	Group 2: continuous repair with polyglactin 910 No 0 and 00 (Vicryl-Ethicon). Continuous technique: first suture inserted above apex of vaginal mucosa; mucosa and muscles sutured with continuous non-locking stitches and subcuticular stitches used to close skin. Control/comparison intervention: Group 3: interrupted repair with chromic catgut No 0 and 00 (chromic surgical gut – Ethicon). Group 4: interrupted repair with polyglactin 910 No 0 and 00 (Vicryl-Ethicon). Interrupted technique: first suture inserted above apex of vaginal mucosa; vaginal mucosa approximated with continuous sutures and muscles and skin with interrupted sutures. All repairs were carried out by 1 of 2 operators with similar experience. All women received diclofenac 50 mg every 8 hours for 5 days and cephalosporin 500 mg every 8 hours for 5 days as part of routine postnatal care.
Outcomes	Included in analysis: • number of packets of suture material; • pain and discomfort at 48 hours', 10 days' and 6 weeks' postpartum (pain rated as none or unbearable and needing additional analgesics); • healing problems (redness, swelling, gaping, infection, residual suture); • removal of sutures at 6 weeks; • resumption of sexual intercourse and dyspareunia at 6 weeks.
Notes	The 4 study groups have been combined to form 2 groups so that we could carry out pair-wise comparisons by suture technique (continuous versus interrupted). For dichotomous outcomes event rates and totals were added and for continuous outcomes means and standard deviations were combined using the methods set out in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Women allocated in sequence (quasi-randomised).
Allocation concealment (selection bias)	High risk	Women allocated in sequence (quasi-randomised).
Blinding (performance bias and detection bias) Clinical staff	High risk	Women were informed about the suture material and repair.
Blinding (performance bias and detection bias) Women	High risk	Staff carrying out repair could not be blinded to technique.
Blinding (performance bias and detection bias) Outcome assessors	High risk	Staff including outcome assessors were not stated to be blinded to allocated intervention.
Incomplete outcome data (attrition bias) All outcomes	High risk	200 women randomised. There was no information about loss to follow-up and denominators were not provided in the results tables although it was stated that any women lost to follow-up at 6 weeks were excluded from the analysis.

Perveen 2009 *(Continued)*

Selective reporting (reporting bias)	Unclear risk	Assessment from published study report.
Other bias	Unclear risk	Women were described as similar at baseline.

Stark 2009

Methods	Described as randomised prospective pilot study. Method of randomisation not described (2 arms).
Participants	Setting: not described. Inclusion criteria: 89 primiparous women with an episiotomy (no details on type of episiotomy, e.g. midline or right or left medio lateral). Exclusion criteria: not described.
Interventions	Experimental intervention: (46 women) 2 layer closure. Described as modified closure (continuous suturing of the deep layers starting high as possible, 1 suture at the lower point and using the rest of the suture material to close the skin continuously all the way up back to the introitus where the final knot is done). It was also documented that "bleedings from the vaginal wall in women who were sutured with the 2 layers were handled with punctual stitching of the bleeding points". Suture material: polyglactin (Vicryl) (not clear if it was standard vicryl or vicryl rapide, suture material gauge and type of needle not described). Control/comparison intervention: (43 women) described as traditional 3-layer closure (vaginal wall continuously, deep layer and skin with interrupted sutures). Suture material: polyglactin (Vicryl) (not clear if it was standard vicryl or vicryl rapide, suture material gauge and type of needle not described).
Outcomes	Included in analysis: • haematoma after 24 and 48 hours; • local redness and swelling after 24 and 48 hours; • use of pain killers after 24 and 48 hours; • distortion of anatomy at 6 to 8 weeks (not clear).
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described.
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding (performance bias and detection bias) Clinical staff	Unclear risk	Not mentioned.

Stark 2009 *(Continued)*

Blinding (performance bias and detection bias) Women	High risk	The person carrying out the repair would not be blinded.
Blinding (performance bias and detection bias) Outcome assessors	Unclear risk	Not mentioned.
Incomplete outcome data (attrition bias) All outcomes	High risk	89 women randomised, 54 available for follow-up at 6 to 8 weeks.
Selective reporting (reporting bias)	Unclear risk	Assessment from published study report. Inconsistencies in data tables.
Other bias	Unclear risk	Very little information on methods. Not clear if there was any baseline imbalance between groups (group characteristics not described).

Valenzuela 2009

Methods	RCT. Individual randomisation.
Participants	Setting: The Hospital Universitario Principe de Asturias (state hospital), Madrid. Recruitment period: September 2005 to July 2007. Ethics committee approval obtained. 445 women with an episiotomy or second-degree tear. Method of delivery: ? spontaneous vaginal birth. Parity: ? primigravidae and multigravidae. Mean age: group 1 = 30.2 years; group 2 = 30.1 years. Operator: ? 4 midwives with more than 5 years' experience of attending deliveries and trained in both suturing techniques. Inclusion criteria: vaginal childbirth; viable foetus at least 37 weeks' gestation; delivered by 1 of the 4 matrons participating in the research; episiotomy or second-degree tear affecting the skin and muscle. Exclusion criteria: instrumental delivery; episiotomy or perineal tear involving the anal sphincter or rectum; baby born with serious congenital malformations.
Interventions	Method of repair: described as below. Women divided into 2 groups. Group 1 (N = 222) continuous non-locking sutures in the vagina, perineum and subcutaneous tissue using Polyglactin 910 (Vicryl Rapide) on a 36-mm needle, calibre/gauge 0. Group 2 (N = 223) vaginal trauma repaired with a continuous locking suture; interrupted sutures in the perineal muscle and interrupted transcutaneous sutures to close the skin using Polyglactin 910 (Vicryl Rapide) on a 36-mm needle, calibre/gauge 0.
Outcomes	Included in analysis: • short-term pain (pain now) at day 2 and 10; • pain when moving, sitting, passing urine, opening bowels at 2 and 10 days; • use of painkillers (analgesia) analgesia at 2 and 10 days' and 3 months' postpartum; • long-term pain at 3 months; • dyspareunia at 3 months; • re-suturing;

Valenzuela 2009 *(Continued)*

- removal of suture material;
- number of packets of suture material used;
- time taken to complete the repair.

Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated.
Allocation concealment (selection bias)	Low risk	Numbered opaque envelopes.
Blinding (performance bias and detection bias) Clinical staff	High risk	Different techniques used.
Blinding (performance bias and detection bias) Women	High risk	
Blinding (performance bias and detection bias) Outcome assessors	Low risk	"The midwife who conducted the questioning did not know the technique that had been used and was also blinded to other patient data".
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	445 women randomised and primary analysis was by ITT. High response rate at 2 and 10 days and at 3 months (3.6% in the continuous group and 6.7% in the interrupted group were lost to follow-up at 3 months' postpartum).
Other bias	Unclear risk	All women received intervention as allocated. No baseline imbalance apparent.

Zafar 2008

Methods	RCT, 2-arm trial (individual randomisation).
Participants	Setting: hospital in Islamabad, Pakistan (the hospital was described as having a high episiotomy rate). Data collection 2002 to 2006. 150 women requiring perineal repair following a mediolateral episiotomy after a spontaneous vaginal delivery. Women who had assisted deliveries or perineal tears were excluded. Parity: both primi- and multiparous women included. Mean age: group 1 = 27.2 years; group 2 = 27.2 years. All repairs were carried out by the same surgeon.
Interventions	Group 1: continuous (all layers and skin) with single knot at the apex of the vaginal mucosa. Continuous running stitch to vaginal wall, and muscles sutured in 2 layers, subcuticular sutures to skin, the repair is finished with the needle passing through the muscles lateral to the episiotomy and 4 to 5 cm of suture material is left to hang without a knot. Group 2: 3-layer technique with continuous stitch to vaginal mucosa, interrupted sutures in 2 layers and continuous (subcuticular) sutures to the skin.

Zafar 2008 *(Continued)*

	Both groups: the repairs were mainly carried out with polyglactin 910 2/0 although 16 had chromic catgut 2/0 sutures (9 versus 7 cases in the 2 groups).
Outcomes	Included in analysis: • pain (10-cm VAS) at 12 hours' and 7 days' postpartum; • use of analgesia at 7 days; • time taken to carry out the repair.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated numbers.
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding (performance bias and detection bias) Clinical staff	High risk	Same operator for both study groups.
Blinding (performance bias and detection bias) Women	Unclear risk	Not discussed.
Blinding (performance bias and detection bias) Outcome assessors	High risk	Outcome assessors would be aware of the type of repair.
Incomplete outcome data (attrition bias) All outcomes	High risk	150 women were randomised (it was not clear how many in each group). Full data for only 1 outcome (time taken to carry out the repair) with 29% attrition by day 7 (110/150 available at follow-up).
Selective reporting (reporting bias)	Unclear risk	Not apparent.
Other bias	Unclear risk	High attrition and not clear how many randomised to each group.

ITT: intention to treat
PPH: postpartum haemorrhage
RCT: randomised controlled trial
VAS: visual analogue scale

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

Study	Reason for exclusion
Bendsen 1980	This study was excluded from the meta-analysis owing to non-absorbable and absorbable material being compared that may have had a confounding effect on the results.
Buchan 1980	This study was excluded from the meta-analysis owing to non-absorbable and absorbable material being compared that may have had a confounding effect on the results.

Study	Reason for exclusion
Doyle 1993	This study was excluded from the meta-analysis owing to non-absorbable and absorbable material being compared that may have had a confounding effect on the results.
Hansen 1975	This study was excluded from the meta-analysis owing to non-absorbable and absorbable material being compared that may have had a confounding effect on the results.
Roberts 1993	This study was excluded from the meta-analysis owing to non-absorbable and absorbable material being compared that may have had a confounding effect on the results.

Characteristics of studies awaiting assessment *[ordered by study ID]*

Graczyk 1998

Methods	This paper is in Polish. We are awaiting a translation before we are able to assess whether the study is eligible for inclusion. It is not clear that this was a randomised trial.
Participants	117 women after episiotomy (44 lost to follow-up).
Interventions	Interrupted versus subcuticular suture.
Outcomes	Wound healing and pain.
Notes	

Uslu 1992

Methods	This paper is very similar to another study already included in the review (Isager-Sally 1986). The study is awaiting assessment pending further investigation.
Participants	
Interventions	
Outcomes	
Notes	

DATA AND ANALYSES

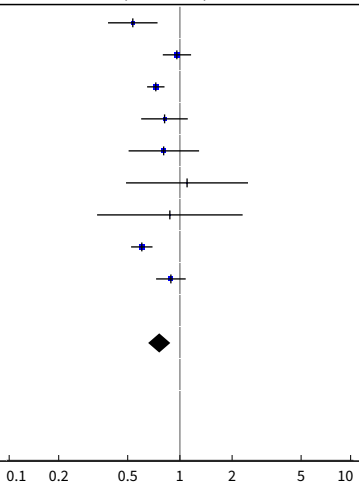
Comparison 1. Continuous versus interrupted sutures for repair of all layers or perineal skin only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Short-term pain - up to day 10	9	4231	Risk Ratio (M-H, Random, 95% CI)	0.76 [0.66, 0.88]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2 Analgesia - up to day 10	6	2971	Risk Ratio (M-H, Fixed, 95% CI)	0.70 [0.59, 0.84]
3 Dyspareunia - up to 3 months' postpartum	9	3619	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.70, 1.06]
4 Re-suturing - up to 3 months	5	3255	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.33, 2.91]
5 Long-term pain - up to 3 months' postpartum	4	2891	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.64, 1.20]
6 Failure to resume pain-free intercourse - 3 months' postpartum	2	2305	Risk Ratio (M-H, Fixed, 95% CI)	1.07 [0.93, 1.24]
7 Removal of suture material - up to 3 months' postpartum	6	3453	Risk Ratio (M-H, Random, 95% CI)	0.56 [0.32, 0.98]
8 Suture material use (used 2 or more packets of suturing material)	2	1985	Risk Ratio (M-H, Fixed, 95% CI)	0.26 [0.22, 0.30]
9 Time taken to carry out the repair (minutes)	4	2206	Mean Difference (IV, Random, 95% CI)	-0.73 [-2.24, 0.78]

Analysis 1.1. Comparison 1 Continuous versus interrupted sutures for repair of all layers or perineal skin only, Outcome 1 Short-term pain - up to day 10.

Study or subgroup	Continuous n/N	Interrupted n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Morano 2006	32/99	58/96		10.27%	0.54[0.39,0.74]
Valenzuela 2009	109/222	113/221		15.74%	0.96[0.8,1.16]
Isager-Sally 1986	156/262	214/261		18.65%	0.73[0.65,0.81]
Croce 1997	40/100	50/102		10.82%	0.82[0.6,1.11]
Almeida 2008	15/31	18/30		6.73%	0.81[0.51,1.29]
Perveen 2009	11/100	10/100		2.84%	1.1[0.49,2.47]
Banninger 1978	7/80	8/80		2.08%	0.88[0.33,2.3]
Kettle 2002	204/770	338/769		17.58%	0.6[0.52,0.69]
Mahomed 1989	129/447	150/461		15.3%	0.89[0.73,1.08]
Total (95% CI)	**2111**	**2120**		**100%**	**0.76[0.66,0.88]**
Total events: 703 (Continuous), 959 (Interrupted)					
Heterogeneity: Tau^2=0.03; Chi^2=24.26, df=8(P=0); I^2=67.03%					
Test for overall effect: Z=3.66(P=0)					



Analysis 1.2. Comparison 1 Continuous versus interrupted sutures for repair of all layers or perineal skin only, Outcome 2 Analgesia - up to day 10.

Study or subgroup	Continuous n/N	Interrupted n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Morano 2006	36/107	58/107		23.79%	0.62[0.45,0.85]
Almeida 2008	9/31	11/30		4.59%	0.79[0.38,1.63]
Mahomed 1989	33/447	41/461		16.56%	0.83[0.53,1.29]
Stark 2009	4/46	6/43		2.54%	0.62[0.19,2.06]
Banninger 1978	23/80	24/80		9.84%	0.96[0.59,1.55]
Kettle 2002	66/770	104/769		42.68%	0.63[0.47,0.85]
Total (95% CI)	**1481**	**1490**		**100%**	**0.7[0.59,0.84]**
Total events: 171 (Continuous), 244 (Interrupted)					
Heterogeneity: Tau^2=0; Chi^2=3.36, df=5(P=0.64); I^2=0%					
Test for overall effect: Z=3.97(P<0.0001)					

Favours treatment — Favours control

Analysis 1.3. Comparison 1 Continuous versus interrupted sutures for repair of all layers or perineal skin only, Outcome 3 Dyspareunia - up to 3 months' postpartum.

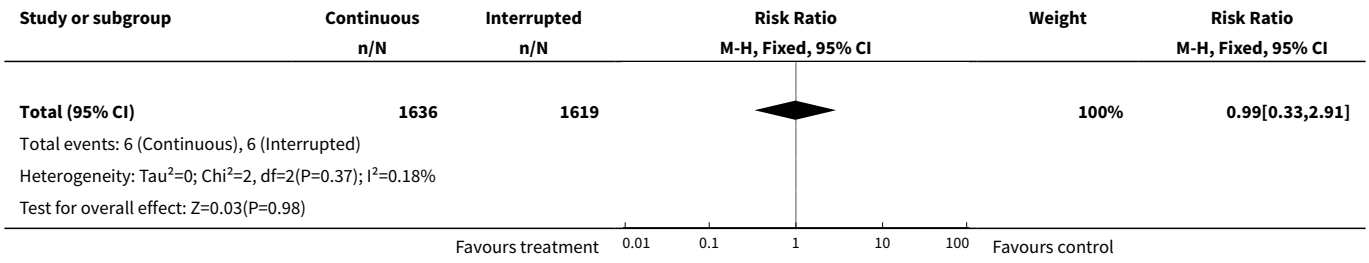
Study or subgroup	Continuous n/N	Interrupted n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Perveen 2009	5/100	5/100		2.58%	1[0.3,3.35]
Valenzuela 2009	52/215	60/207		15.36%	0.83[0.61,1.15]
Croce 1997	24/100	25/102		10.26%	0.98[0.6,1.59]
Isager-Sally 1986	45/265	58/250		14.31%	0.73[0.52,1.04]
Morano 2006	18/87	18/78		8.32%	0.9[0.5,1.6]
Detlefsen 1980	11/45	32/48		8.83%	0.37[0.21,0.64]
Kettle 2002	98/581	102/593		17.82%	0.98[0.76,1.26]
Mahomed 1989	116/424	94/401		18.48%	1.17[0.92,1.48]
Almeida 2008	5/12	5/11		4.05%	0.92[0.36,2.33]
Total (95% CI)	**1829**	**1790**		**100%**	**0.86[0.7,1.06]**
Total events: 374 (Continuous), 399 (Interrupted)					
Heterogeneity: Tau^2=0.04; Chi^2=16.97, df=8(P=0.03); I^2=52.85%					
Test for overall effect: Z=1.44(P=0.15)					

Favours treatment — Favours control

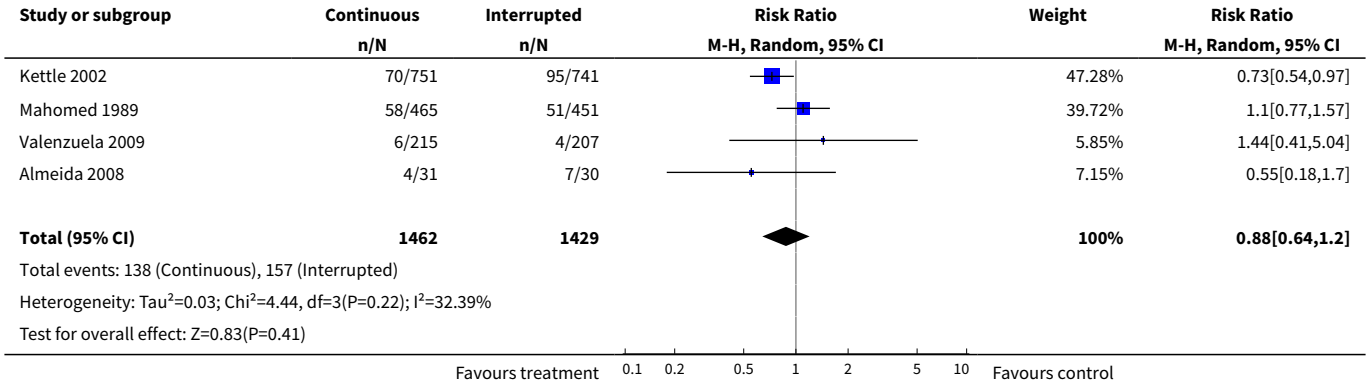
Analysis 1.4. Comparison 1 Continuous versus interrupted sutures for repair of all layers or perineal skin only, Outcome 4 Re-suturing - up to 3 months.

Study or subgroup	Continuous n/N	Interrupted n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Mahomed 1989	3/465	3/451		46.5%	0.97[0.2,4.78]
Banninger 1978	0/80	0/80			Not estimable
Morano 2006	0/99	0/96			Not estimable
Kettle 2002	3/770	1/771		15.26%	3[0.31,28.81]
Valenzuela 2009	0/222	2/221		38.25%	0.2[0.01,4.12]

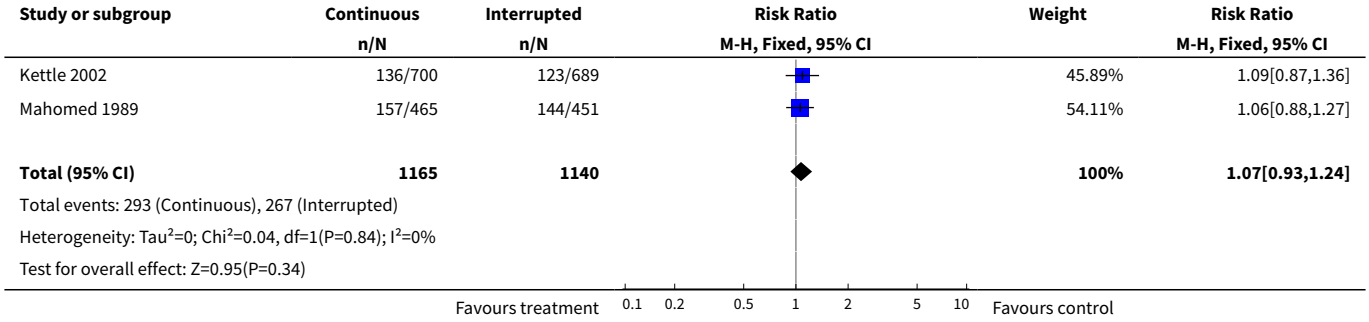
Favours treatment — Favours control



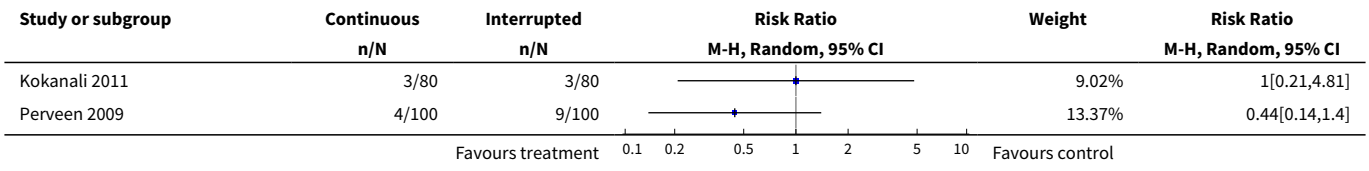
Analysis 1.5. Comparison 1 Continuous versus interrupted sutures for repair of all layers or perineal skin only, Outcome 5 Long-term pain - up to 3 months' postpartum.

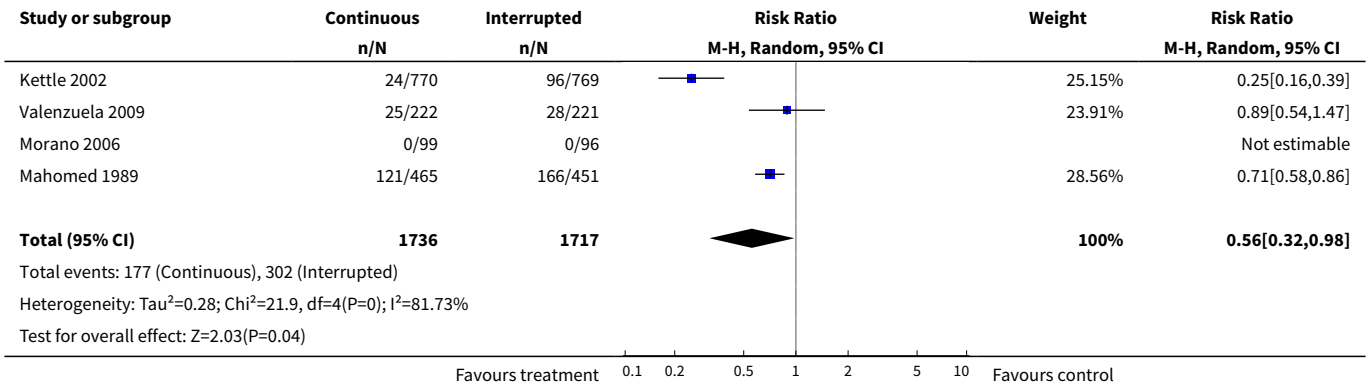


Analysis 1.6. Comparison 1 Continuous versus interrupted sutures for repair of all layers or perineal skin only, Outcome 6 Failure to resume pain-free intercourse - 3 months' postpartum.

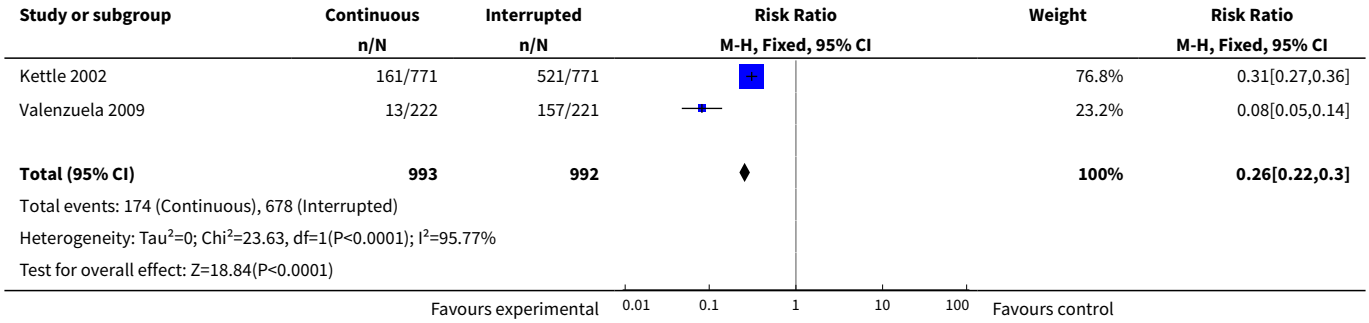


Analysis 1.7. Comparison 1 Continuous versus interrupted sutures for repair of all layers or perineal skin only, Outcome 7 Removal of suture material - up to 3 months' postpartum.

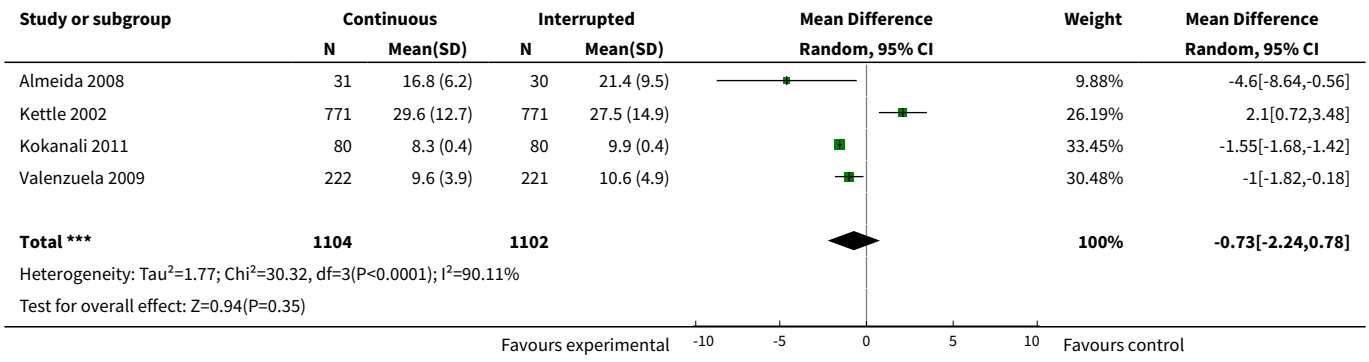




Analysis 1.8. Comparison 1 Continuous versus interrupted sutures for repair of all layers or perineal skin only, Outcome 8 Suture material use (used 2 or more packets of suturing material).



Analysis 1.9. Comparison 1 Continuous versus interrupted sutures for repair of all layers or perineal skin only, Outcome 9 Time taken to carry out the repair (minutes).

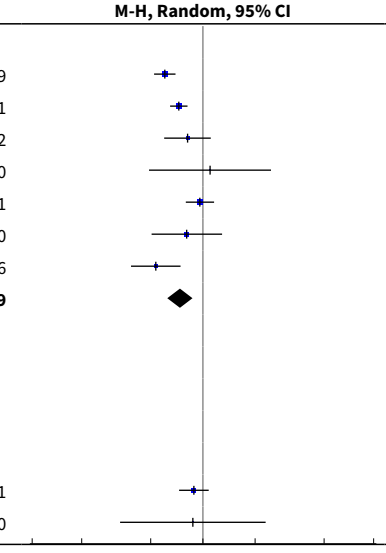


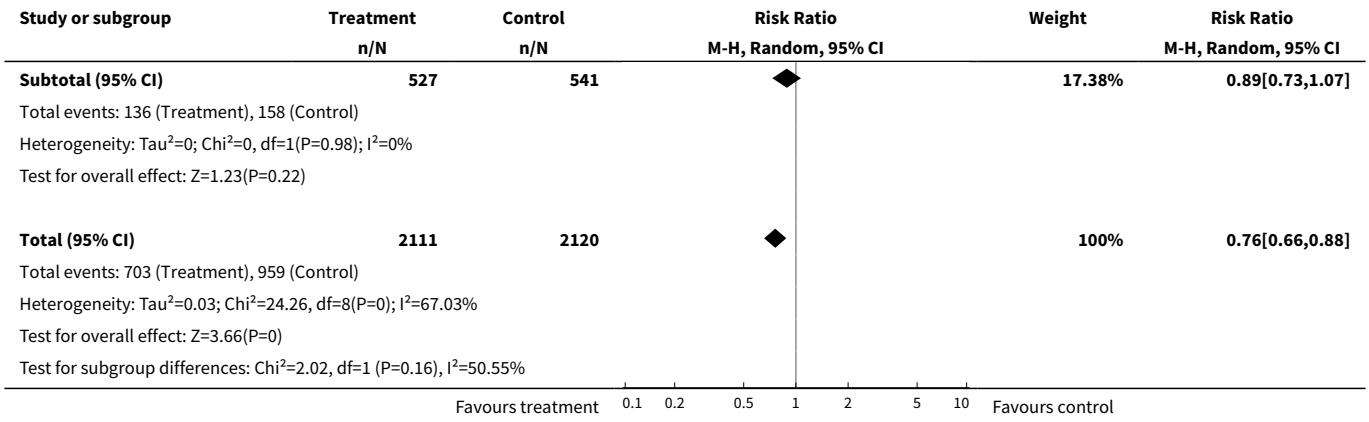
Comparison 2. Subgroup analysis: continuous versus interrupted (all layers or skin only))

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Short-term pain - up to day 10	9	4231	Risk Ratio (M-H, Random, 95% CI)	0.76 [0.66, 0.88]
1.1 Continuous versus interrupted: all layers	7	3163	Risk Ratio (M-H, Random, 95% CI)	0.74 [0.62, 0.87]
1.2 Continuous versus interrupted: skin only	2	1068	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.73, 1.07]
2 Analgesia - up to day 10	6	2971	Risk Ratio (M-H, Fixed, 95% CI)	0.70 [0.59, 0.84]
2.1 Continuous versus interrupted: all layers	4	1903	Risk Ratio (M-H, Fixed, 95% CI)	0.64 [0.52, 0.79]
2.2 Continuous versus interrupted: skin only	2	1068	Risk Ratio (M-H, Fixed, 95% CI)	0.88 [0.63, 1.22]
3 Dyspareunia - up to 3 months' post-partum	8	3197	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.67, 1.09]
3.1 Continuous versus interrupted: all layers	7	2372	Risk Ratio (M-H, Random, 95% CI)	0.79 [0.61, 1.03]
3.2 Continuous versus interrupted: skin only	1	825	Risk Ratio (M-H, Random, 95% CI)	1.17 [0.92, 1.48]

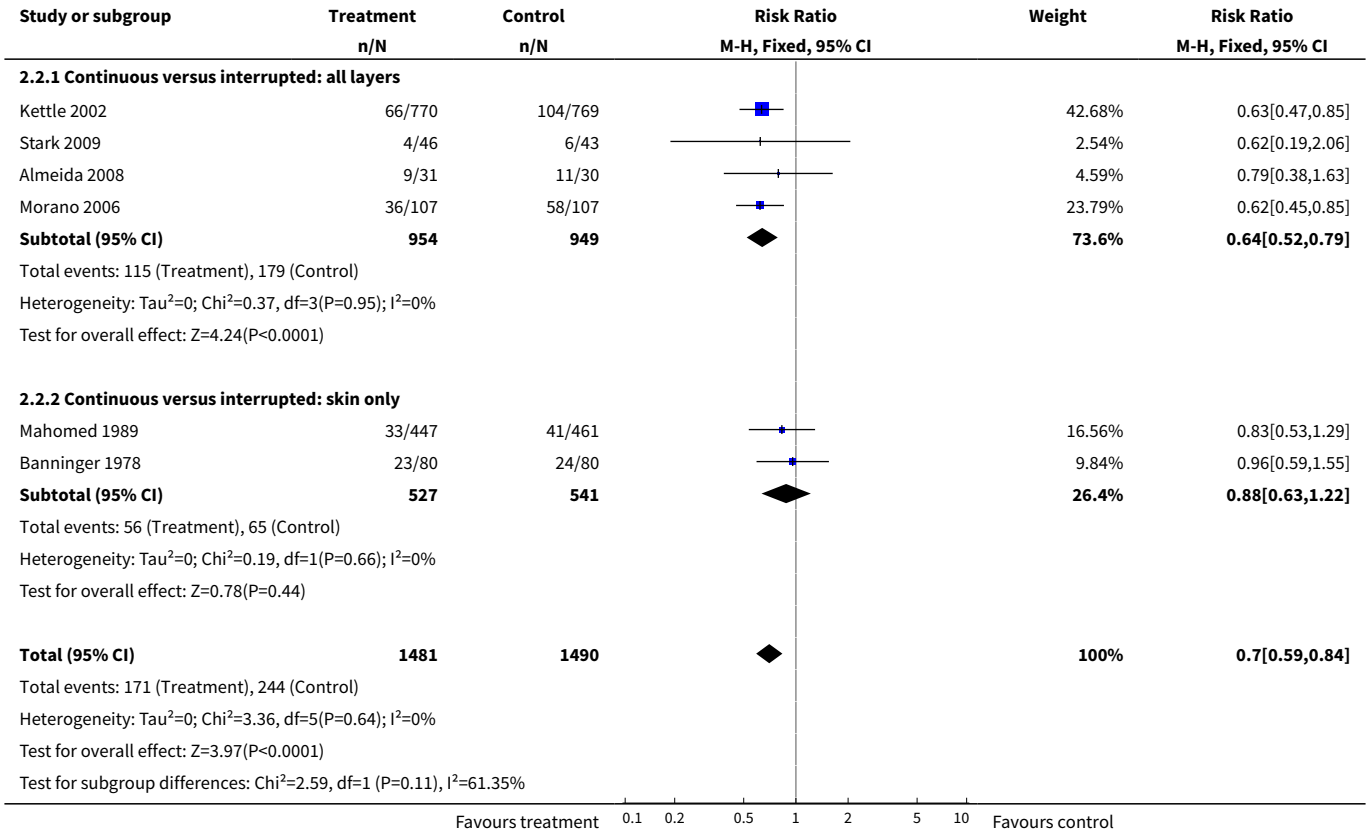
Analysis 2.1. Comparison 2 Subgroup analysis: continuous versus interrupted (all layers or skin only)), Outcome 1 Short-term pain - up to day 10.

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
2.1.1 Continuous versus interrupted: all layers					
Kettle 2002	204/770	338/769		17.58%	0.6[0.52,0.69]
Isager-Sally 1986	156/262	214/261		18.65%	0.73[0.65,0.81]
Croce 1997	40/100	50/102		10.82%	0.82[0.6,1.11]
Perveen 2009	11/100	10/100		2.84%	1.1[0.49,2.47]
Valenzuela 2009	109/222	113/221		15.74%	0.96[0.8,1.16]
Almeida 2008	15/31	18/30		6.73%	0.81[0.51,1.29]
Morano 2006	32/99	58/96		10.27%	0.54[0.39,0.74]
Subtotal (95% CI)	**1584**	**1579**		**82.62%**	**0.74[0.62,0.87]**
Total events: 567 (Treatment), 801 (Control)					
Heterogeneity: Tau^2=0.03; Chi^2=20.58, df=6(P=0); I^2=70.84%					
Test for overall effect: Z=3.58(P=0)					
2.1.2 Continuous versus interrupted: skin only					
Mahomed 1989	129/447	150/461		15.3%	0.89[0.73,1.08]
Banninger 1978	7/80	8/80		2.08%	0.88[0.33,2.3]

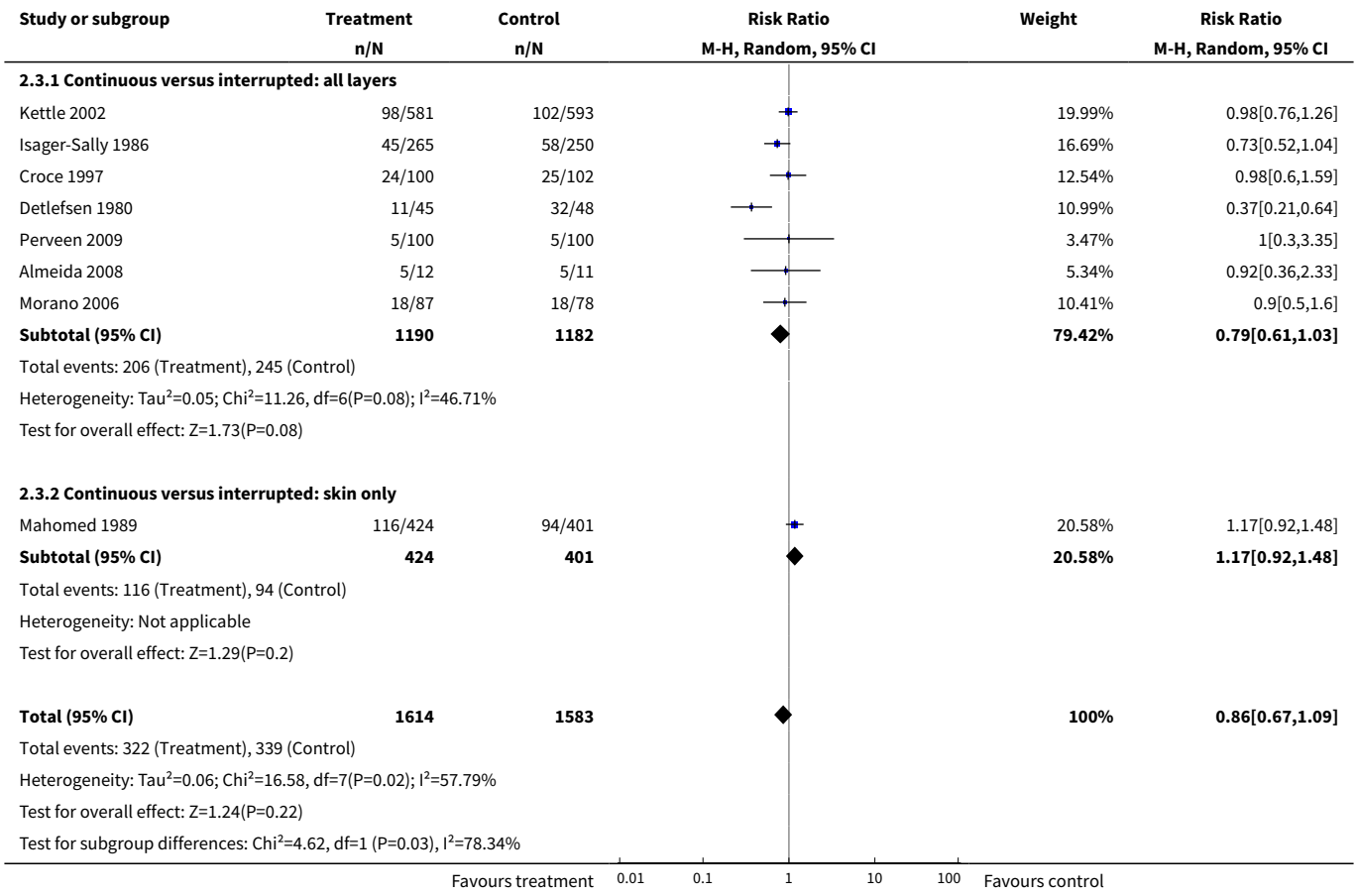




Analysis 2.2. Comparison 2 Subgroup analysis: continuous versus interrupted (all layers or skin only)), Outcome 2 Analgesia - up to day 10.



Analysis 2.3. Comparison 2 Subgroup analysis: continuous versus interrupted (all layers or skin only)), Outcome 3 Dyspareunia - up to 3 months' postpartum.



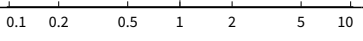
Comparison 3. Three -stage versus two- stage (skin not sutured) approach

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Short-term pain: number of women with perineal pain (up to 48 hours)	2	2597	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.84, 1.02]
2 Short-term pain up to 14 days	2	2594	Risk Ratio (M-H, Fixed, 95% CI)	0.86 [0.76, 0.98]
3 Analgesia use up to 10 days	2	2597	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.59, 1.23]
4 Dyspareunia up to 3 months	2	2487	Risk Ratio (M-H, Random, 95% CI)	0.72 [0.56, 0.94]
5 Long-term pain (up to 3 months)	2	2487	Risk Ratio (M-H, Random, 95% CI)	0.41 [0.10, 1.59]
6 Failure to resume pain-free intercourse up to 3 months	2	2487	Risk Ratio (M-H, Fixed, 95% CI)	0.86 [0.80, 0.92]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
7 Wound 'gaping' (< 0.5 cm) up to 10 days	2	2594	Risk Ratio (M-H, Random, 95% CI)	2.74 [0.87, 8.63]
8 Wound re-sutured up to 3 months	2	2487	Risk Ratio (M-H, Fixed, 95% CI)	0.56 [0.31, 1.00]
9 Removal of suture material up to 3 months	2	2603	Risk Ratio (M-H, Fixed, 95% CI)	0.60 [0.46, 0.77]
10 Time (in minutes) taken to carry out the repair	1	823	Mean Difference (IV, Fixed, 95% CI)	-4.0 [-5.59, -2.41]

Analysis 3.1. Comparison 3 Three -stage versus two- stage (skin not sutured) approach, Outcome 1 Short-term pain: number of women with perineal pain (up to 48 hours).

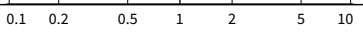
Study or subgroup	Two stage n/N	Three stage n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Gordon 1998	545/885	569/889		59%	0.96[0.9,1.03]
Oboro 2003	237/417	265/406		41%	0.87[0.78,0.97]
Total (95% CI)	**1302**	**1295**		**100%**	**0.92[0.84,1.02]**
Total events: 782 (Two stage), 834 (Three stage)					
Heterogeneity: Tau^2=0; Chi^2=2.23, df=1(P=0.14); I^2=55.17%					
Test for overall effect: Z=1.62(P=0.11)					



Favours 2 stage — Favours 3 stage

Analysis 3.2. Comparison 3 Three -stage versus two- stage (skin not sutured) approach, Outcome 2 Short-term pain up to 14 days.

Study or subgroup	Two stage n/N	Three stage n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Gordon 1998	221/886	244/885		67.31%	0.9[0.77,1.06]
Oboro 2003	93/417	117/406		32.69%	0.77[0.61,0.98]
Total (95% CI)	**1303**	**1291**		**100%**	**0.86[0.76,0.98]**
Total events: 314 (Two stage), 361 (Three stage)					
Heterogeneity: Tau^2=0; Chi^2=1.17, df=1(P=0.28); I^2=14.71%					
Test for overall effect: Z=2.24(P=0.03)					



Favours experimental — Favours control

Analysis 3.3. Comparison 3 Three -stage versus two- stage (skin not sutured) approach, Outcome 3 Analgesia use up to 10 days.

Study or subgroup	Two stage n/N	Three stage n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Gordon 1998	400/885	392/889		51.59%	1.03[0.92,1.14]
Oboro 2003	143/417	197/406		48.41%	0.71[0.6,0.83]
Total (95% CI)	**1302**	**1295**		**100%**	**0.86[0.59,1.23]**
Total events: 543 (Two stage), 589 (Three stage)					
Heterogeneity: Tau^2=0.06; Chi^2=13.84, df=1(P=0); I^2=92.78%					
Test for overall effect: Z=0.83(P=0.4)					

Analysis 3.4. Comparison 3 Three -stage versus two- stage (skin not sutured) approach, Outcome 4 Dyspareunia up to 3 months.

Study or subgroup	Two stage n/N	Three stage n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Gordon 1998	128/828	162/836		64.21%	0.8[0.65,0.99]
Oboro 2003	43/417	69/406		35.79%	0.61[0.43,0.87]
Total (95% CI)	**1245**	**1242**		**100%**	**0.72[0.56,0.94]**
Total events: 171 (Two stage), 231 (Three stage)					
Heterogeneity: Tau^2=0.02; Chi^2=1.69, df=1(P=0.19); I^2=40.7%					
Test for overall effect: Z=2.47(P=0.01)					

Analysis 3.5. Comparison 3 Three -stage versus two- stage (skin not sutured) approach, Outcome 5 Long-term pain (up to 3 months).

Study or subgroup	Two stage n/N	Three stage n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Gordon 1998	64/828	87/836		56.83%	0.74[0.55,1.01]
Oboro 2003	4/417	21/406		43.17%	0.19[0.06,0.54]
Total (95% CI)	**1245**	**1242**		**100%**	**0.41[0.1,1.59]**
Total events: 68 (Two stage), 108 (Three stage)					
Heterogeneity: Tau^2=0.82; Chi^2=6.18, df=1(P=0.01); I^2=83.83%					
Test for overall effect: Z=1.29(P=0.2)					

Analysis 3.6. Comparison 3 Three -stage versus two- stage (skin not sutured) approach, Outcome 6 Failure to resume pain-free intercourse up to 3 months.

Study or subgroup	Two stage n/N	Three stage n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Gordon 1998	252/828	285/836		43.4%	0.89[0.78,1.03]
Oboro 2003	310/417	365/406		56.6%	0.83[0.77,0.88]
Total (95% CI)	**1245**	**1242**		**100%**	**0.86[0.8,0.92]**
Total events: 562 (Two stage), 650 (Three stage)					
Heterogeneity: Tau^2=0; Chi^2=1.4, df=1(P=0.24); I^2=28.75%					
Test for overall effect: Z=4.27(P<0.0001)					

Analysis 3.7. Comparison 3 Three -stage versus two- stage (skin not sutured) approach, Outcome 7 Wound 'gaping' (< 0.5 cm) up to 10 days.

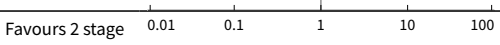
Study or subgroup	Two stage n/N	Three stage n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Gordon 1998	227/886	145/885		51.56%	1.56[1.3,1.88]
Oboro 2003	107/417	21/406		48.44%	4.96[3.17,7.76]
Total (95% CI)	**1303**	**1291**		**100%**	**2.74[0.87,8.63]**
Total events: 334 (Two stage), 166 (Three stage)					
Heterogeneity: Tau^2=0.66; Chi^2=22.52, df=1(P<0.0001); I^2=95.56%					
Test for overall effect: Z=1.72(P=0.09)					

Analysis 3.8. Comparison 3 Three -stage versus two- stage (skin not sutured) approach, Outcome 8 Wound re-sutured up to 3 months.

Study or subgroup	Two stage n/N	Three stage n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Gordon 1998	4/828	9/836		29.62%	0.45[0.14,1.45]
Oboro 2003	13/417	21/406		70.38%	0.6[0.31,1.19]
Total (95% CI)	**1245**	**1242**		**100%**	**0.56[0.31,1]**
Total events: 17 (Two stage), 30 (Three stage)					
Heterogeneity: Tau^2=0; Chi^2=0.18, df=1(P=0.67); I^2=0%					
Test for overall effect: Z=1.96(P=0.05)					

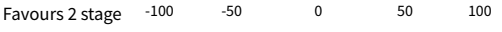
Analysis 3.9. Comparison 3 Three -stage versus two- stage (skin not sutured) approach, Outcome 9 Removal of suture material up to 3 months.

Study or subgroup	Two stage n/N	Three stage n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Gordon 1998	59/890	98/890		69.72%	0.6[0.44,0.82]
Oboro 2003	25/417	42/406		30.28%	0.58[0.36,0.93]
Total (95% CI)	**1307**	**1296**		**100%**	**0.6[0.46,0.77]**
Total events: 84 (Two stage), 140 (Three stage)					
Heterogeneity: Tau^2=0; Chi^2=0.02, df=1(P=0.9); I^2=0%					
Test for overall effect: Z=3.92(P<0.0001)					



Analysis 3.10. Comparison 3 Three -stage versus two- stage (skin not sutured) approach, Outcome 10 Time (in minutes) taken to carry out the repair.

Study or subgroup	Two stage N	Two stage Mean(SD)	Three stage N	Three stage Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Oboro 2003	417	21 (11.3)	406	25 (12)		100%	-4[-5.59,-2.41]
Total ***	**417**		**406**			**100%**	**-4[-5.59,-2.41]**
Heterogeneity: Not applicable							
Test for overall effect: Z=4.92(P<0.0001)							

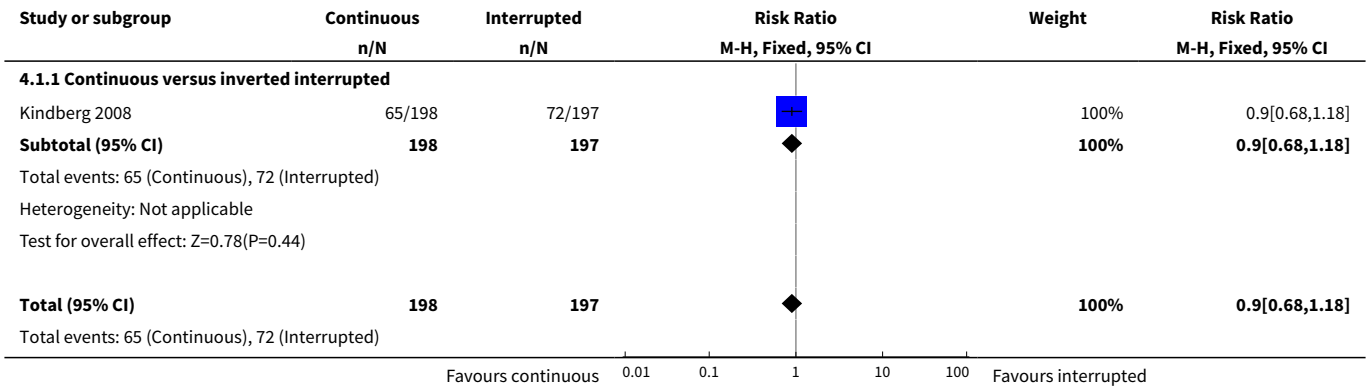


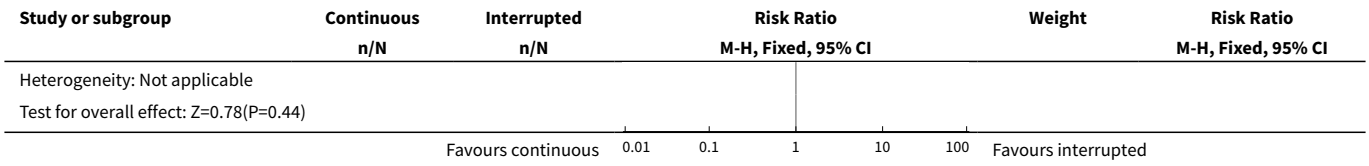
Comparison 4. Other techniques using continuous versus interrupted sutures

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Short-term pain (up to day 10)	1	395	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.68, 1.18]
1.1 Continuous versus inverted interrupted	1	395	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.68, 1.18]
2 Short-term pain (at 12 hours after the repair)	1	110	Mean Difference (IV, Fixed, 95% CI)	-2.2 [-2.88, -1.52]
2.1 Single knot continuous versus mixed method	1	110	Mean Difference (IV, Fixed, 95% CI)	-2.2 [-2.88, -1.52]
3 Analgesia use up to 10 days	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
3.1 Single knot continuous versus mixed method	1	89	Risk Ratio (M-H, Fixed, 95% CI)	0.43 [0.18, 1.00]
3.2 Continuous versus inverted interrupted	1	395	Risk Ratio (M-H, Fixed, 95% CI)	1.04 [0.59, 1.87]

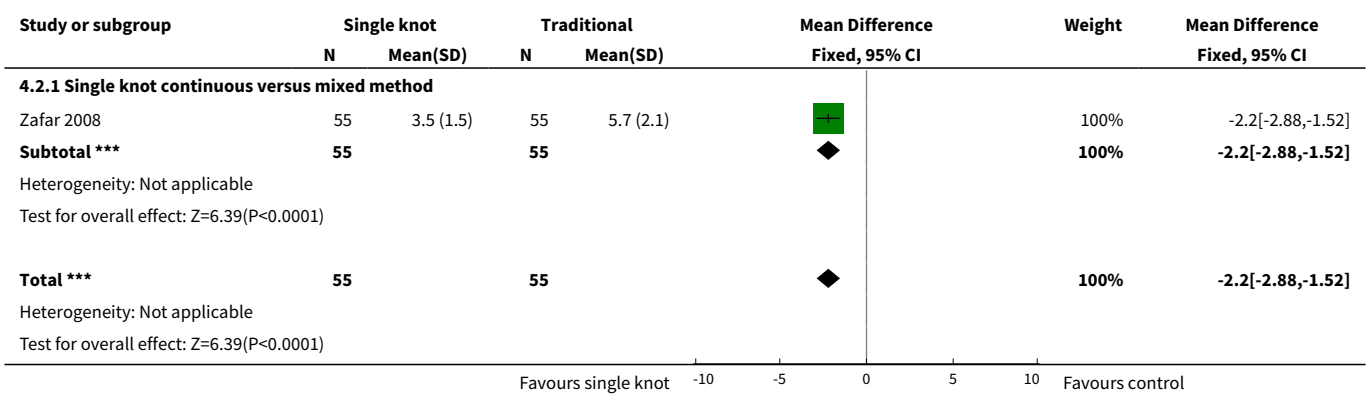
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4 Dyspareunia up to 3 months	1	395	Risk Ratio (M-H, Fixed, 95% CI)	0.81 [0.58, 1.12]
4.1 Continuous versus inverted interrupted	1	395	Risk Ratio (M-H, Fixed, 95% CI)	0.81 [0.58, 1.12]
5 Re-suturing up to 3 months	1	395	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.25, 3.92]
5.1 Continuous versus inverted interrupted	1	395	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.25, 3.92]
6 Superficial skin gaping	1	110	Risk Ratio (M-H, Fixed, 95% CI)	5.0 [0.25, 101.81]
6.1 Single knot continuous versus mixed method	1	110	Risk Ratio (M-H, Fixed, 95% CI)	5.0 [0.25, 101.81]
7 Removal of suture material - up to 3 months' postpartum	1	395	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [0.69, 2.04]
7.1 Continuous versus inverted interrupted	1	395	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [0.69, 2.04]
8 Time (minutes) taken to carry out the repair	1	110	Mean Difference (IV, Fixed, 95% CI)	-1.35 [-1.59, -1.11]
8.1 Single knot continuous versus mixed method	1	110	Mean Difference (IV, Fixed, 95% CI)	-1.35 [-1.59, -1.11]
9 Satisfied with repair	1	395	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.91, 1.08]
9.1 Continuous versus inverted interrupted	1	395	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.91, 1.08]

Analysis 4.1. Comparison 4 Other techniques using continuous versus interrupted sutures, Outcome 1 Short-term pain (up to day 10).

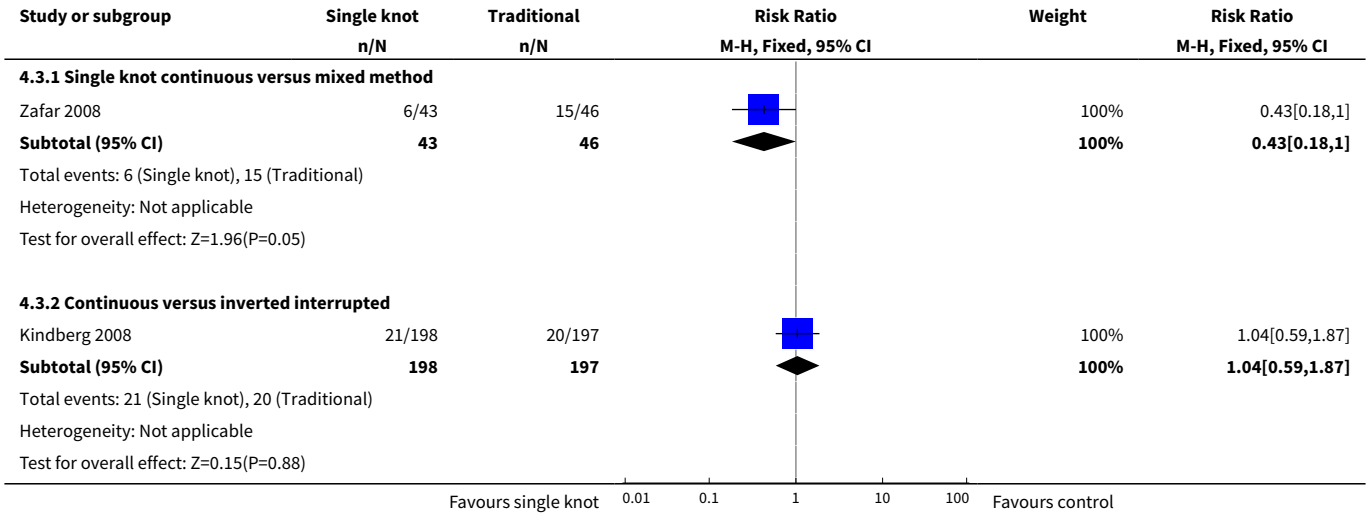




Analysis 4.2. Comparison 4 Other techniques using continuous versus interrupted sutures, Outcome 2 Short-term pain (at 12 hours after the repair).



Analysis 4.3. Comparison 4 Other techniques using continuous versus interrupted sutures, Outcome 3 Analgesia use up to 10 days.



Analysis 4.4. Comparison 4 Other techniques using continuous versus interrupted sutures, Outcome 4 Dyspareunia up to 3 months.

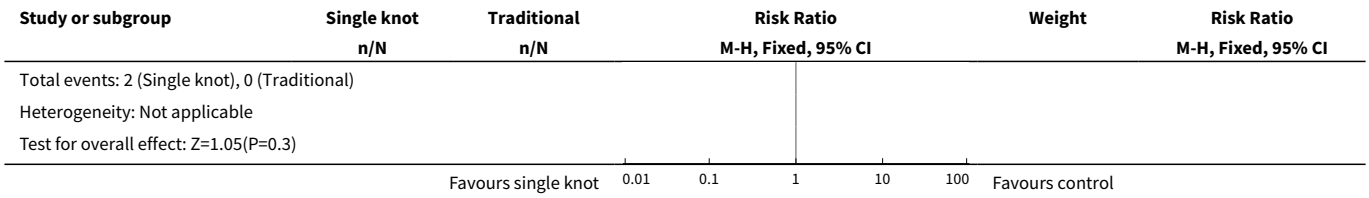
Study or subgroup	Continuous n/N	Interrupted n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
4.4.1 Continuous versus inverted interrupted					
Kindberg 2008	47/198	58/197		100%	0.81[0.58,1.12]
Subtotal (95% CI)	**198**	**197**		**100%**	**0.81[0.58,1.12]**
Total events: 47 (Continuous), 58 (Interrupted)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1.28(P=0.2)					
Total (95% CI)	**198**	**197**		**100%**	**0.81[0.58,1.12]**
Total events: 47 (Continuous), 58 (Interrupted)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1.28(P=0.2)					

Analysis 4.5. Comparison 4 Other techniques using continuous versus interrupted sutures, Outcome 5 Re-suturing up to 3 months.

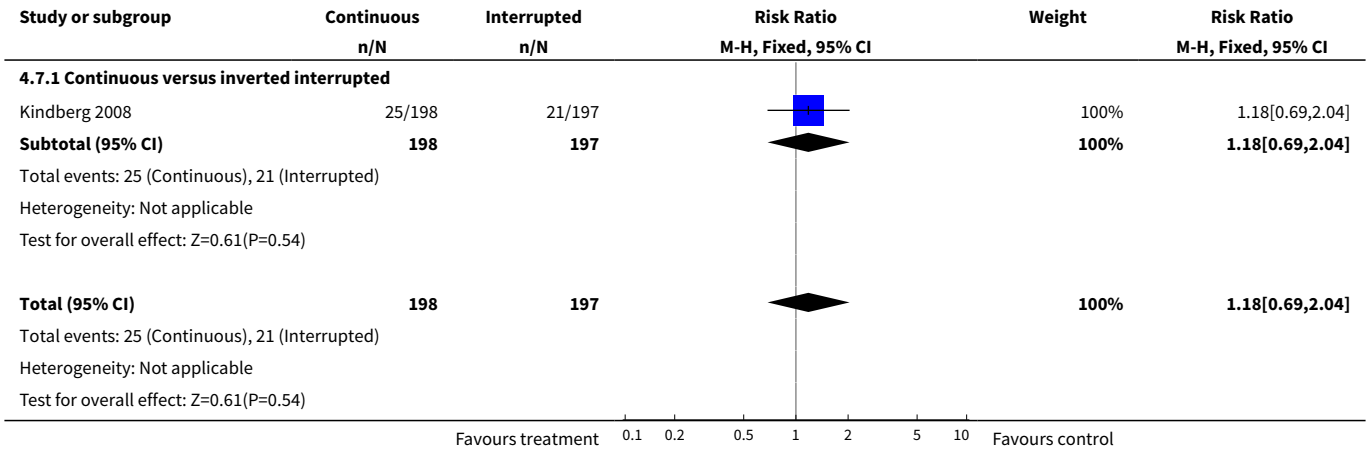
Study or subgroup	Continuous n/N	Interrupted n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
4.5.1 Continuous versus inverted interrupted					
Kindberg 2008	4/198	4/197		100%	0.99[0.25,3.92]
Subtotal (95% CI)	**198**	**197**		**100%**	**0.99[0.25,3.92]**
Total events: 4 (Continuous), 4 (Interrupted)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.01(P=0.99)					
Total (95% CI)	**198**	**197**		**100%**	**0.99[0.25,3.92]**
Total events: 4 (Continuous), 4 (Interrupted)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.01(P=0.99)					

Analysis 4.6. Comparison 4 Other techniques using continuous versus interrupted sutures, Outcome 6 Superficial skin gaping.

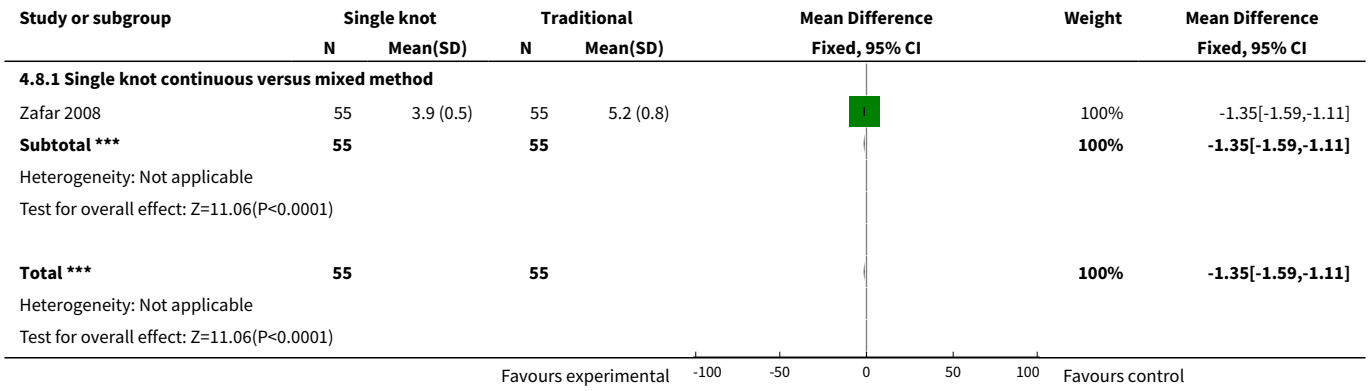
Study or subgroup	Single knot n/N	Traditional n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
4.6.1 Single knot continuous versus mixed method					
Zafar 2008	2/55	0/55		100%	5[0.25,101.81]
Subtotal (95% CI)	**55**	**55**		**100%**	**5[0.25,101.81]**
Total events: 2 (Single knot), 0 (Traditional)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1.05(P=0.3)					
Total (95% CI)	**55**	**55**		**100%**	**5[0.25,101.81]**



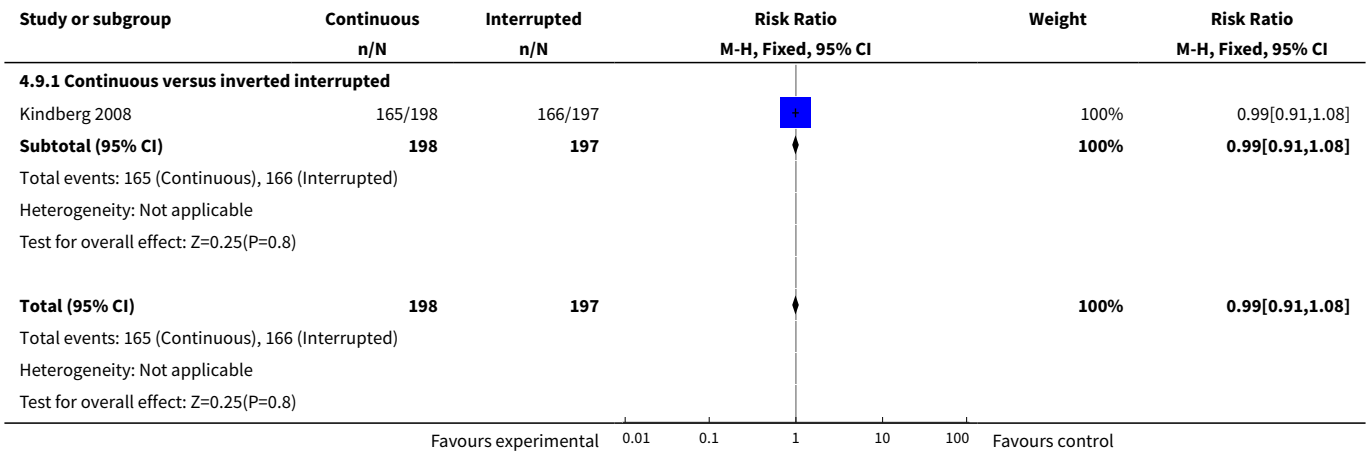
Analysis 4.7. Comparison 4 Other techniques using continuous versus interrupted sutures, Outcome 7 Removal of suture material - up to 3 months' postpartum.



Analysis 4.8. Comparison 4 Other techniques using continuous versus interrupted sutures, Outcome 8 Time (minutes) taken to carry out the repair.



Analysis 4.9. Comparison 4 Other techniques using continuous versus interrupted sutures, Outcome 9 Satisfied with repair.



WHAT'S NEW

Date	Event	Description
12 March 2012	New search has been performed	The most recent search was in January 2012. In this updated version of the review, we have included nine new studies in addition to the seven included in previous versions.
12 March 2012	New citation required but conclusions have not changed	The main conclusions of the review have not changed but we have added new comparisons and analysis.

HISTORY

Protocol first published: Issue 1, 1997
Review first published: Issue 1, 1998

Date	Event	Description
1 September 2008	Amended	Converted to new review format.
12 July 2007	New citation required and conclusions have changed	Meta-analysis indicates that the subcutaneous suturing technique for perineal skin closure is associated with less short-term pain, however a subgroup analysis showed that if the continuous technique is used for all layers (vagina, perineal muscles and skin) the reduction in pain is more significant.
30 June 2007	New search has been performed	Search updated. Three new studies were added to the included studies and four were added to the excluded studies. Changes to the text have been made to reflect new data.

CONTRIBUTIONS OF AUTHORS

This update was based on the previous Cochrane review 'Continuous versus interrupted sutures for perineal repair' by Christine Kettle (CK) and Richard B Johanson (Kettle 1998).

CK co-ordinated the update. All three review authors critically appraised all papers for quality and eligibility independently. CK and Therese Dowswell (TD) independently extracted the data and TD entered them onto the Review Manager software. CK checked all entered data for accuracy. CK and TD drafted the updated review and Khaled Ismail commented on drafts and checked the final document for accuracy, including data interpretation prior to submission.

DECLARATIONS OF INTEREST

Christine Kettle (CK) was the recipient of a fellowship from the Iolanthe Midwifery Research Trust 1996, which provided funding to enable her to carry out a randomised controlled trial of perineal repair following childbirth (Kettle 2002). The Iolanthe Midwifery Research Trust and Ethicon Ltd, UK (manufacturers of suture material) provided funding for employment of a part-time data management clerk for that trial.

CK and Khaled Ismail run perineal repair workshops both nationally and internationally and have developed an episiotomy and second-degree tear training model with Limbs & Things, UK.

SOURCES OF SUPPORT

Internal sources

- The University of Liverpool, UK.

External sources

- National Institute for Health Research (NIHR), UK.

  TD is supported by the NIHR NHS Cochrane Collaboration Programme grant scheme award for NHS-prioritised centrally-managed, pregnancy and childbirth systematic reviews: CPGS02.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The methods section of the review has been updated. We have changed the title - see Kettle 2007 for the title of the previous version of this review.

INDEX TERMS

Medical Subject Headings (MeSH)

*Episiotomy; *Suture Techniques; Analgesics [administration & dosage]; Delivery, Obstetric; Obstetric Labor Complications [*surgery]; Perineum [*injuries] [surgery]; Randomized Controlled Trials as Topic

MeSH check words

Female; Humans; Pregnancy