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Absorbable suture materials for primary repair of episiotomy and second degree tears (Review)

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Absorbable suture materials for primary repair of episiotomy and second degree tears.
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[Intervention Review]

Absorbable suture materials for primary repair of episiotomy and second degree tears

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ABSTRACT

Background

Approximately 70% of women will experience perineal trauma following vaginal delivery and will require stitches. This may result in pain, suture removal and superficial dyspareunia.

Objectives

To assess the effects of different suture materials on short- and long-term morbidity following perineal repair.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (February 2010).

Selection criteria

Randomised trials comparing different suture materials for perineal repair after vaginal delivery.

Data collection and analysis

Two review authors independently assessed trial quality and extracted data.

Main results

We included 18 trials with 10,171 women; comparisons included: catgut with standard synthetic (nine trials), rapidly absorbing synthetic (two trials), and glycerol impregnated catgut sutures (two trials); and standard synthetic sutures with rapidly absorbing synthetic (five trials) and monofilament sutures (one trial).

Compared with catgut, standard synthetic sutures were associated with less pain up to three days after delivery (risk ratio (RR) 0.83, 95% confidence interval (CI) 0.76 to 0.90); and less analgesia up to ten days postpartum (RR 0.71, 95% CI 0.59 to 0.87). More women with catgut sutures required resuturing (15/1201) compared with synthetic sutures (3/1201) (RR 0.25, 95% CI 0.08 to 0.74); while more women with standard synthetic sutures required the removal of unabsorbed suture material (RR 1.81, 95% CI 1.46 to 2.24). Comparing standard synthetic with rapidly absorbing sutures, short- and long-term pain were similar; in one trial fewer women with rapidly absorbing sutures reported using analgesics at 10 days (RR 0.57, 95% CI 0.43 to 0.77). More women in the standard synthetic suture group required suture removal compared with those in the rapidly absorbed group (RR 0.24, 95% CI 0.15 to 0.36). There was no evidence of significant differences between groups for long-term pain (three months after delivery) or for dyspareunia at three, or at six to 12 months. When catgut and

glycerol impregnated catgut were compared, results were similar for most outcomes, although the latter was associated with more short-term pain. One trial examining monofilament versus standard polyglycolic sutures found no differences for most outcomes.

Authors' conclusions

Catgut may increase short-term pain compared with synthetic sutures. There were few differences between standard and rapidly absorbing synthetic sutures but more women needed standard sutures removing. For other materials, there was insufficient evidence to draw conclusions. Findings should be interpreted in the context of the related Cochrane review on suturing techniques.

PLAIN LANGUAGE SUMMARY

Absorbable stitches for repair of episiotomy and tears at childbirth

Approximately 70% of women who have a vaginal birth will experience some degree of damage to the perineum, due to a tear or cut (episiotomy), and will need stitches. This damage may result in perineal pain during the two weeks after the birth, and some women experience long-term pain and discomfort during sexual intercourse. The impact of perineal trauma can be distressing for the new mother when she is trying to cope with hormonal changes and the demands of her baby, and it can have a long-term effect on her sexual relationship. Most modern materials that are used to stitch the perineum are gradually absorbed and do not need to be taken out. Sometimes, however, stitches have to be removed by the doctor or midwife. A small number of perineal wounds come open (break down) or have delayed healing, and some of these may need to be re-stitched.

This review includes 18 randomised controlled trials with 10,171 women and looks at catgut and synthetic materials used to stitch the perineum after childbirth. It also includes a more recently produced material which has been specially designed to be absorbed more quickly. The main findings were that women stitched with synthetic materials had less pain in the first three days after delivery and needed fewer drugs to relieve pain in the 10 days after giving birth, compared with women stitched with catgut. There was evidence that synthetic stitches were not always readily absorbed and some women with these stitches needed them to be removed. Women experienced similar short and long-term pain with standard absorbable synthetic materials and more rapidly absorbing stitches. However, in one trial, fewer women with rapidly absorbing stitches reported using pain-relieving drugs during the 10 days after delivery, and there was less need for these stitches to be removed. When catgut and glycerol-impregnated catgut were compared the results were similar, although the latter was associated with more short-term pain. One trial examined monofilament and standard synthetic stitches and there was little difference between the two materials in terms of pain and wound healing. As well as the type of material used, other factors such as the technique used to carry out the stitching (using a continuous thread or a series of separately tied stitches) and the skill of the person carrying out the procedure, may also affect the amount of pain and the way perineal wounds heal.

BACKGROUND

Perineal trauma occurs during spontaneous or assisted vaginal delivery, and is usually more extensive after the first vaginal delivery (Sultan 1996). It is defined as any damage to the genitalia during childbirth that occurs spontaneously or is intentionally made by performing a surgical incision (episiotomy). Spontaneous tears are classified as:

First degree: injury to perineal skin only.

Second degree: injury to perineum involving perineal muscles but not involving the anal sphincter.

Third degree: injury to perineum involving the anal sphincter complex:

3a: less than 50% of the external anal sphincter (EAS) thickness torn;

3b: more than 50% of EAS thickness torn;

3c: both EAS and internal anal sphincter (IAS) torn.

Fourth degree: injury to perineum involving the anal sphincter complex (EAS and IAS) and anal epithelium (Sultan 1999).

An episiotomy involves the same structures as a second-degree tear.

In the United Kingdom (UK), approximately 1000 women per day will experience perineal repair following vaginal birth (ONS 2001) and millions more worldwide. The impact of perineal trauma can be extremely distressing for a new mother during the early postnatal period when she is trying to cope with hormonal changes, the demands of her baby and pressures imposed as a result of her changing role. For those women who are unfortunate enough to sustain perineal injury, it is important that skilled operators repair the trauma, using the best suturing techniques and suture materials, in order to minimise any associated short- and long-term morbidity.

There is robust evidence that a continuous non-locking suture technique for repair of the vagina, perineal muscles and skin is superior in terms of reducing postpartum pain compared to the more traditional interrupted method whereby a locking stitch is used to repair the vagina and interrupted stitches are inserted to close the perineal muscles and skin (Kettle 2007). The NICE Intrapartum Guidelines (NICE 2007) also report that the two-stage technique of repair (where the vagina and muscle are sutured, but the perineal skin is left opposed but not sutured) is associated with a reduction in pain (Oboro 2003) and superficial dyspareunia (Gordon 1998; Oboro 2003) up to three months postpartum. However, there is an increased risk of perineal wound skin edges 'gaping' in the two-stage repair groups at two days (Gordon 1998; Oboro 2003) and ten days postpartum (Gordon 1998). Despite this evidence, there are still wide variations between individual practitioners and maternity units in terms of techniques and materials used for perineal repair.

Wound healing

The type of suturing material used for perineal repair may also have an effect on the amount of pain, wound dehiscence (breakdown) and superficial dyspareunia experienced by women following childbirth. The primary function of a suture is to maintain closure of the damaged tissue in order to promote healing by first intention, control bleeding and minimise the risk of infection. Wound edges must be approximated without tension, otherwise the tissue will become devascularised and the healing process will be disrupted (Cuschieri 2000). Perineal trauma which has been carefully sutured generally heals very rapidly by primary intention. This is probably due to the fact that the perineal area immediately after childbirth provides optimal conditions that are necessary for the promotion of quality healing. The most common local factor associated with delayed perineal wound healing and dehiscence is infection, which adversely causes the wound edges to be softened and this may result in sutures 'cutting out' of the tissue with subsequent wound breakdown (Cuschieri 2000).

The ideal suture material should cause minimal tissue reaction and be absorbed once it has served its purpose of holding the tissue in apposition during the healing process (Taylor 1996). Well-aligned perineal wounds heal by primary intention with minimal complications within two weeks of suturing. However, if the stitches remain in the tissues for longer than this period, they act as a foreign body and may excite a significant inflammatory response and impair healing. Once bacteria have colonised along the implanted sutures or knot interstices, it is difficult to eradicate the infection, and this may predispose to abscess formation and wound dehiscence. Local infection of the wound site will prolong the inflammatory phase and cause further tissue damage, which will delay collagen synthesis and epithelialisation (Flanagan 1997). Tissues with good blood supply, that heal rapidly and which are not under mechanical stress can be sutured with absorbable synthetic material. A variety of materials have been used to suture the perineum following childbirth.

Catgut

Plain catgut is manufactured from collagen derived from the intestines of healthy mammals (sheep and cows) and it is reported to cause an inflammatory response in the tissues due to the fact that it is broken down by proteolytic enzymes and phagocytosis (Irvin 1981). It is a very unstable and unpredictable material in terms of time taken to be absorbed, especially if there is wound infection or malnutrition. Catgut can be treated with chromate salts (Chromic catgut) to prevent it absorbing as much water as plain catgut, which slows down the absorption process and decreases the inflammatory reaction. Glycerol impregnated catgut (Softgut) was introduced with claims that it remains supple and it does not dry out during use when compared with plain and chromic catgut (Davis and Geck Ltd, Gosport). In 2001, following discussion with the Medical Devices Agency, catgut was no longer available to the UK market; however, it is still used in other non-European countries.

Absorbable synthetic suture materials

The two most common absorbable synthetic suture materials which are used for perineal repair are polyglycolic acid (*Dexon®* , Davis & Geck Ltd. UK) and polyglactin 910 (*Vicryl®* , Ethicon Ltd., Edinburgh, UK) which were introduced in 1970 and 1974, respectively. Standard polyglactin 910 sutures (*Vicryl®*) are prepared from a copolymer of glycolide and lactide in a ratio of 90/10 and the substances are derived from glycolic and lactic acids (Ethicon 1992). The material is braided to improve handling and is coated with a mixture of a copolymer of lactide and glycolide in the ratio of 65/35 and an equal ratio of calcium stearate to reduce

bacterial adherence and tissue drag (Ethicon 1992; McCaul 2000). During the manufacturing process, the material is dyed a bright violet colour to improve visualisation during surgical procedures (Craig 1975). The material is attached to various sized stainless steel needles and sterilised by ethylene oxide gas. Polyglycolic acid sutures (*Dexon®*) are produced from a homopolymer of glycolide and no dye is added so the resulting material is a light tan colour. The polymer is converted into a braided suture material which is very similar in composition to standard polyglactin 910 (McCaul 2000). The suture material is designed to maintain wound support for up to 30 days and to be totally absorbed by 120 days (polyglactin up to 90 days compared to polyglycolic acid up to 120 days), regardless of the gauge of material (Craig 1975). More recently, a new monofilament absorbable synthetic suture material (Biosyn, Tyco Healthcare), which consists of a mixture of glycolide (60%), dioxanone (14%), and trimethylene carbonate (26%) has become available for perineal repair. The manufacturers claim that Biosyn causes minimal tissue reaction, reduces tissue drag and promotes better wound healing. It is designed to give wound support up to 21 days and is totally absorbed from the tissues in 90 to 110 days.

Rapidly absorbed polyglactin 910 suture material

A new type of polyglactin 910 suture material (Vicryl Rapide) was first released to the German market in 1987, but it was not available in the UK until after the introduction of CE (Conformité Européene) marketing in 1994. The un-dyed synthetic material (Vicryl Rapide) is identical to standard polyglactin 910 (*coated Vicryl®*) in terms of chemical composition, but it is exposed to gamma irradiation during the sterilisation process which results in faster absorption. Vicryl Rapide is designed to give wound support up to 14 days and it is totally absorbed by 42 days, as compared to standard Vicryl which is completely absorbed at 90 days.

The aim of this review is to examine the available research studies and to establish if there is any clear scientific evidence that the type of absorbable suture material used for perineal repair following childbirth influences the rate of morbidity experienced by women during the short- and long-term postpartum period.

This systematic review includes 18 randomised clinical trials and represents an update of the Cochrane systematic review undertaken previously (Kettle 1999).

OBJECTIVES

To determine the effects of absorbable synthetic (polyglycolic acid, standard polyglactin 910, monofilament glycomer 631and fast-absorbing polyglactin 910) and catgut (plain, chromic and glycerol impregnated) suture materials on the amount of short- and long-term morbidity experienced by women following perineal repair. The evidence collated in this review may assist purchasers, providers and consumers of health care to choose the most appropriate material for perineal repair in terms of both health gain and cost-effectiveness (Howard 1995).

The main outcomes of interest are: short- and long-term pain; amount of analgesia used; rate of superficial dyspareunia; removal of suture material; re-suturing of wound; and wound dehiscence.

METHODS

Criteria for considering studies for this review

Types of studies

We have included all identified, relevant randomised controlled trials (RCTs) and quasi-RCTs which compared absorbable synthetic suture materials (e.g. standard polyglactin 910; fast-absorbing polyglactin 910; polyglycolic acid; monofilament glycomer 631 and catgut (plain, chromic and glyceral impregnated)) in this review.

Where trials were reported in abstracts we planned to include them, provided that there was sufficient information on study methods to allow us to assess eligibility and risk of bias. If there was insufficient information reported, then we attempted to contact trial authors requesting further information before deciding to exclude any study.

Types of participants

All primiparous and multiparous women who have sustained perineal trauma and require stitching following an instrumental or spontaneous vaginal delivery.

Types of interventions

All randomised controlled comparisons of absorbable synthetic suture materials (e.g. standard polyglactin 910; fast- absorbing polyglactin 910; polyglycolic acid; monofilament glycomer 631, and catgut (plain, chromic and glycerol impregnated)).

Types of outcome measures

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

Primary outcome measures: short-term pain (maternal pain at up to three and at four to 10 days).

Secondary outcome measures: analgesia use; removal of suture material, resuturing; wound dehiscence; long-term pain; dyspareunia.

As part of the update of the review, we have added a previously unspecified outcome: maternal satisfaction with the repair.

For an earlier version of this review, we sought consumer views regarding what outcomes they thought were important from women's local focus groups and the National Childbirth Trust's Research and Information Group.

The main outcomes of interest from the consumers' point of view were the extent of short- and long-term pain, the removal of suture material, infection 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 (February 2010).

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

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

Details of the search strategies for CENTRAL and MEDLINE, 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

We have set out the methods used for data analysis and management, assessment of risk of bias, and measurement of treatment effect used in the original version of this review in Appendix 1. We have described the methods used in this update below.

Selection of studies

Two review authors independently assessed and selected the trials for inclusion in this review. It was not possible 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 any disagreement on eligibility for inclusion by discussion.

Data extraction and management

For eligible studies, two review authors extracted data. We resolved discrepancies through discussion or, if required, we consulted a third author. One review author entered data into Review Manager software (RevMan 2008) and a second author checked for accuracy. C Kettle was the lead investigator for one of the included studies and was not involved in the assessment of the trial or the data extraction.

Assessment of risk of bias in included studies

Two authors independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2008). We resolved any disagreement by discussion.

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

We have described for each included study the method used to generate the allocation sequence. 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); or
- 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 assessed 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 assessed blinding separately for different outcomes or classes of outcomes, and we have noted where there was partial blinding.

We assessed the methods as:

- adequate, inadequate or unclear for women;
- adequate, inadequate or unclear for clinical staff;
- adequate, inadequate or unclear for outcome assessors.

(4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, 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. We assessed methods as:

- adequate;
- inadequate:
- unclear.

(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 had been reported);
- inadequate (where not all the study's pre-specified outcomes had been 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 noted for each included study any important concerns we had about other possible sources of bias.

We 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 are at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2008) and have explored the impact of the level of bias through undertaking sensitivity analyses - *see* Sensitivity analysis.

Measures of treatment effect

Dichotomous data

For dichotomous data, we present results as summary risk ratio with 95% confidence intervals.

Continuous data

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

Unit of analysis issues

We had planned to include cluster-randomised trials in the analyses along with individually randomised trials, but we identified no such trials.

We did not consider crossover trials would be feasible for this intervention and have not included such trials.

Dealing with missing data

For included studies, we have noted levels of attrition in the Characteristics of included studies tables. 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, i.e. we attempted to include all participants randomised to each group in the analyses. The denominator for each outcome in each trial is the number randomised minus any participants whose outcomes are known to be missing.

Assessment of heterogeneity

We examined the forest plots for the analyses visually to assess any obvious heterogeneity in terms of the size or direction of treatment effect between studies. We used the I^2 and T^2 statistics and the P value of the Chi^2 test for heterogeneity to quantify heterogeneity among the trials in each analysis. For those outcomes where we have identified moderate or high unexplained heterogeneity (I^2 greater than 40%), we have used a random-effects model and have given the values of I^2, P, and T^2 with its 95% prediction interval, to give a sense of the level of heterogeneity. The prediction interval estimates the possible treatment effect in a future study, and if it includes the null value of one it is possible that the direction of the treatment effect in a single study may not be the same as that from the meta-analysis. We would advise that all findings where there are high levels of heterogeneity should be interpreted cautiously.

Data synthesis

We carried out statistical analysis using the Review Manager software (RevMan 2008). We have used fixed-effect meta-analysis for combining data where trials examined the same intervention, and the trials' populations and methods were judged sufficiently similar.

As noted above, if we identified substantial heterogeneity in a fixed-effect meta-analysis we used a random-effects model.

Sensitivity analysis

We carried out a sensitivity analysis excluding those studies with poor allocation concealment or high levels of attrition to see whether this had any impact on the results.

RESULTS

Description of studies

Results of the search

In the original review there were eight included trials (Banninger 1978; Beard 1974; Livingstone 1974; Mackrodt 1998; Mahomed 1989; Olah 1990; Roberts 1983; Rogers 1974) and three excluded (Ketcham 1994; Tompkins 1972; Wikoff 1992). Additional information was required for one study that was awaiting assessment in the original review (Hemsley 1997) and despite several attempts, we have been unable to contact the author, and so we have now excluded it. For this update, the search strategy identified a further 16 reports, representing 13 studies, for possible inclusion. We have included 10 new studies (Dencker 2006; Gemynthe 1996; Greenberg 2004; Kettle 2002; Leroux 2006; McElhinney 2000; Nikolov 2006; Saint 1993; Spencer 1986; Upton 2002), and excluded another three studies (Gaasemyr 1977; Marques 2001; Uslu 1992).

Included studies

Six of the trials included in this review compared polyglycolic acid (Dexon) versus chromic catgut and the same material was used throughout for all layers of the perineal repair (vagina, muscle and skin) (Banninger 1978; Beard 1974; Mahomed 1989; Olah 1990; Roberts 1983; Rogers 1974). One trial (Mackrodt 1998) compared polyglactin (Standard Vicryl) to chromic catgut, one plain catgut with Dexon (Livingstone 1974). Two trials compared fast-absorbing polyglactin (Vicryl Rapide) with chromic catgut (Greenberg 2004; Leroux 2006).

Five trials compared standard absorbable polyglycolic or polyglactin sutures with fast-absorbing synthetic sutures (Vicryl Rapide) (Gemynthe 1996; Kettle 2002; Leroux 2006; McElhinney 2000; Nikolov 2006).

Two trials examined catgut compared with glycerol impregnated catgut (Softgut) (Saint 1993; Spencer 1986); and one trial looked at an absorbable monofilament synthetic material (Biosyn) versus polyglycolic acid (Dencker 2006).

One trial (Leroux 2006) included three arms and compared catgut, fast-absorbing and standard synthetic sutures; we have included this in more than one comparison.

Most of the trials included women undergoing episiotomy along with those sustaining second-degree tears, although in five trials women with episiotomy only were included (Banninger 1978; Beard 1974; Livingstone 1974; Nikolov 2006; Roberts 1983), and in one trial only women having an episiotomy following instrumental deliveries were included (Olah 1990).

There was considerable variation in the trials between gauge of suture material and size of needle (*see* Characteristics of included studies tables for details). One of the trials (Banninger 1978) compared chromic catgut gauge 0 (a heavier gauge material) to Dexon 2/0 (a much finer gauge material) in order to match tensile strength. It is possible that the heavier gauge catgut material may have contributed to the degree of pain experienced by the women in this trial group.

The same suturing technique was used for both groups in each of the included trials; however, there were differences between trials in techniques for closure of the vagina, perineal muscles and skin (*see* Characteristics of included studies tables). In three trials the perineal skin was closed with interrupted sutures (Banninger 1978; Livingstone 1974; Roberts 1983), whilst five trials used continuous subcuticular or subcutaneous closure (Beard 1974; Leroux 2006; McElhinney 2000; Olah 1990; Upton 2002). Four of the trials used both continuous subcuticular and interrupted techniques for perineal skin closure (Dencker 2006; Mahomed 1989; Saint 1993; Spencer 1986). and in three of the trials this was based on the operators' preference (Dencker 2006; Saint 1993; Spencer 1986). In one trial operators used the continuous subcuticular technique for skin closure except for one operator that used the interrupted method (Greenberg 2004). The women participating in the Ipswich Childbirth Study (Mackrodt 1998) were randomly assigned to either a two-stage (skin left un-sutured) or a three-stage (skin sutured) technique of perineal repair (50/50). In the group that was assigned to have the perineal skin sutured, it was left to the midwives' discretion and skill as to the method used. In fact, 72% had transcutaneous interrupted sutures and 26% had continuous subcutaneous sutures. The trial carried out by Kettle 2002 used a factorial 2 x 2 design, and women were assigned to either perineal skin closure using a continuous subcutaneous or interrupted technique (50/50). In three trials (Gemynthe 1996; Nikolov 2006; Rogers 1974), the suturing techniques were not described.

Excluded studies

We excluded seven studies; four of these because there was insufficient information in trial reports on methods or results so as to allow assessment of risk of bias, or to allow us to incorporate trial results into the review (Ketcham 1994; Marques 2001; Tompkins 1972; Wikoff 1992). One report was a trial registration, no results were reported, and it was not clear whether the study had ever been completed (Hemsley 1997). In one study the intervention examined was a non-absorbable suture material, which is rarely used in perineal repair nowadays (Gaasemyr 1977). Finally, Uslu 1992 compared mixed materials and different techniques in different arms of the trial, so that the effects of particular materials could not be discerned.

Risk of bias in included studies

The methodological quality of the included trials was mixed and we have carried out a sensitivity analysis to examine the impact of excluding trials at high risk of bias on account of inadequate allocation concealment and high levels of attrition (greater than 20%).

Allocation

Most of the included studies used adequate methods of sequence generation and allocation concealment. Computerised random number generators or random number tables were used in five studies and these studies also used sealed, opaque, sequentially numbered envelopes to conceal group assignment (Dencker 2006; Greenberg 2004; Kettle 2002; Mahomed 1989; Upton 2002). Mackrodt 1998 used a balanced block design with sealed opaque sequentially numbered envelopes for concealment of treatment allocation. In the trials by Spencer 1986; McElhinney 2000; Gemynthe 1996 Rogers 1974 and Leroux 2006, envelopes were also used to conceal allocation, although it was not explicitly stated that the envelopes were opaque, sealed and numbered. Two trials used quasi-random allocation (Banninger 1978; Olah 1990); one trial used 'lottery cards' (Livingstone 1974) and four trials did not describe their method of sequence generation or allocation concealment (Beard 1974; Nikolov 2006; Roberts 1983; Saint 1993).

Blinding

Kettle 2002 and Leroux 2006 (both of which compared standard absorbable with fast-absorbing synthetic materials) reported that both suture materials appeared very similar and packaging was identical. In the Kettle 2002 trial, suture materials were dyed the same colour in order to achieve convincing blinding of clinical staff and outcome assessors. In several of the included trials (Beard 1974; Dencker 2006; Livingstone 1974; Spencer 1986) it was claimed that outcome assessment was 'blinded' due to the different suturing materials appearing the same by day three, but from our own experience, this is not convincing.The Mahomed 1989 trial acknowledged that fully 'blind' outcome assessment was not possible due to obvious differences in suture materials and techniques. Mackrodt 1998 reports that a research midwife 'blinded' to the treatment allocation undertook a 'face-to-face' interview at 24 to 48 hours and 10 days followed by assessment of the woman's perineum. It is possible that an element of observer bias was introduced due to the obvious differences in methods of perineal repair.The remaining trials did not state if any attempt was made to 'blind' outcome assessment.

Incomplete outcome data

Most of the trials had relatively low attrition for outcomes assessed within the first three days after delivery (less than 10% women lost to follow up or missing outcome data). For longer-term follow up (outcomes at 10 to 14 days and at 12 weeks), some trials achieved less than 10% loss to follow up (Kettle 2002; Rogers 1974; Mackrodt 1998); however, other trials had considerable levels of attrition. In Gemynthe 1996, McElhinney 2000, Dencker 2006 and Leroux 2006, attrition at 12 weeks was greater than 20%; and in Banninger 1978 and Greenberg 2004 by this stage, more than half of the sample randomised had been lost to follow up. We have provided information on attrition for all of the included studies in the Characteristics of included studies tables. We would advise caution in the interpretation of results from those studies where

there is high attrition, as those women available to follow up may not be representative of the sample randomised.

Other potential sources of bias

Where information was provided on sample characteristics, in most of the included studies the women in intervention and control groups appeared similar, although in the study by Upton 2002 there was some baseline imbalance in the parity of women in the two groups; the authors carried out further analysis to attempt to adjust for this difference. In Leroux 2006, the study was discontinued as catgut (one of the comparators) was withdrawn from the study hospital drugs list part way through the planned recruitment period. In Greenberg 2004, women were randomised before delivery and of the 1361 randomised, only 908 (67%) required perineal repair, were eligible for the trial's outcomes, and were included in the analysis.

Effects of interventions

For all outcomes there may be an interaction between the type of material used (the focus of this review) the suturing technique, i.e. interrupted versus continuous stitches (the subject of a related Cochrane review (Kettle 2007)); we return to this issue in the discussion.

There was variation in when and how outcomes were measured in different studies; in particular there was variation in the terminologies used to describe wound outcomes. For the purpose of this review we have reported on these outcomes in two categories: (1) wound gaping and partial skin dehiscence, which tends to be a reflection of the repair technique (two-stage versus three-stage perineal wound closure) and type of skin suture placement (interrupted versus continuous subcutaneous or subcuticular) and, (2) wound dehiscence or breakdown.

Absorbable synthetic sutures versus catgut: 11 trials with 5072 women

Primary outcomes

All 11 trials included data on pain at or before three days after delivery.

In trials comparing standard absorbable synthetic sutures with catgut, fewer women with synthetic sutures experienced pain (risk ratio (RR) 0.83, 95% confidence interval (CI) 0.76 to 0.90, nine trials, 4017 women) (Analysis 1.1). However, there is evidence of large heterogeneity in the treatment effect across studies (heterogeneity: I^2 = 57%, T^2 = 0.02 (95% prediction interval 0.59 to 1.18), P = 0.02). Three of these trials collected data on pain at four to 10 days following delivery. Again, results favoured women with synthetic sutures (RR 0.78, 95% CI 0.67 to 0.90, three trials, 2044 women) (Analysis 1.2).

In a single trial (Greenberg 2004) comparing fast-absorbing synthetic sutures and catgut there was no evidence of a difference between groups at either three days (RR 1.02, 95% CI 0.98 to 1.06) or at four to 10 days after delivery (RR 1.05, 95% CI 0.94 to 1.18).

Data from one trial (Leroux 2006) were not reported in a way in which we were able to incorporate them into the meta-analyses; authors reported no significant differences between materials (catgut, standard and fast-absorbing synthetic sutures) for median pain scores at 36 to 48 hours.

Seconday outcomes

In those trials examining analgesia use up to 10 days, women with synthetic sutures had less analgesia than those with catgut sutures (RR 0.71, 95% CI 0.59 to 0.87, five trials, 2820 women) (Analysis 1.3), although there was high heterogeneity for this outcome (heterogeneity: I^2 = 48%, T^2 = 0.05 (95% prediction interval 0.33 to 1.55), P = 0.10). In the single trial looking at fast-absorbing synthetic sutures versus catgut (Greenberg 2004), the difference in analgesia use between groups was not statistically significant (RR 0.96, 95% CI 0.90 to 1.01).

Wound breakdown was measured in five trials (Banninger 1978; Beard 1974; Greenberg 2004; Livingstone 1974; Mackrodt 1998) although there was variability in what was reported and when wound assessment took place. (We have provided details in the Characteristics of included studies tables of how wound breakdown was defined and when it was assessed.) Two of the trials appeared to assess more serious wound dehiscence with complete breakdown of the repair (Greenberg 2004; Mackrodt 1998); relatively few women experienced this outcome and there was no significant evidence of any difference between groups (Analysis 1.4). Four studies (Banninger 1978; Beard 1974; Livingstone 1974; Mackrodt 1998) assessed what we judged, to be more superficial partial skin dehiscence, for example, wound (skin edges) "gaping"; results favoured synthetic sutures compared with catgut (RR 0.58, 95% CI 0.36 to 0.94, four trials, 2219 women) (Analysis 1.5). While 15.7% of those with synthetic sutures had wound gaping, this applied to 25.5% of those with catgut sutures (unweighted percentages). However, there was high heterogeneity for this outcome (heterogeneity: I^2 = 65%, T^2 = 0.14 (95% prediction interval 0.08 to 3.97), P = 0.04) and results should be interpreted with caution. More women with catgut sutures required perineal resuturing (15/1201) compared with those with synthetic sutures in the trials examining this outcome (3/1201) (RR 0.25, 95% CI 0.08 to 0.74, four trials, 1402 women) (Analysis 1.6). On the other hand, more women with standard synthetic sutures required the removal of unabsorbed suture material (RR 1.81, 95% CI 1.46 to 2.24, three trials, 2520 women) (Analysis 1.7).

There was no evidence of any difference in suture materials for pain at eight to 12 weeks postpartum (Analysis 1.8) although approximately 10% of women with either catgut or standard absorbable sutures continued to experience perineal pain three months after the birth of their babies. (Approximately a quarter of the women in the study by Greenberg 2004 reported long-term perineal pain, although these results should be viewed with caution in view of the high levels of attrition in this trial.) Similarly, while there was no evidence of any significant difference between groups for dyspareunia at three months, more than 15% of women (irrespective of suture material) reported painful sexual intercourse three months after delivery (Analysis 1.9).

Sensitivity analysis

Several of the included studies used quasi-randomisation or the method of allocation concealment was unclear (Banninger 1978; Beard 1974; Livingstone 1974; Olah 1990). We temporarily removed these studies from the analysis to examine the impact on results. For longer-term outcomes (pain and superficial dyspareunia at three, six or 12 months), several studies had high levels of attrition (greater than 20%) (Banninger 1978; Greenberg 2004). Again,

for long-term outcomes affected by high levels of attrition, we examined the impact of removing studies from the analysis.

The sensitivity analysis did not indicate that removing studies with higher risk of bias had any important impact on overall findings.

Fast absorbing versus standard synthetic sutures: five trials with 2349 women

Primary outcomes

There was no significant evidence of any difference between groups sutured with standard versus rapidly absorbing sutures in the numbers of women experiencing perineal pain at up to three days after delivery (data were pooled from three trials with 1968 women, RR 1.01, 95% CI 0.92 to 1.10) (Analysis 2.1). Similarly, differences between groups for perineal pain at 10 to 14 days were not statistically significant (RR 0.92, 95% CI 0.81 to 1.03, two trials, 1847 women) (Analysis 2.2).

Secondary outcomes

Use of analgesia for perineal pain was reported in one trial (Kettle 2002), and fewer women with rapidly absorbing sutures were using analgesics at 10 days post delivery (RR 0.57, 95% CI 0.43 to 0.77) (Analysis 2.3).

Two trials (Kettle 2002; Nikolov 2006) provided data on partial skin dehiscence or gaping where this is sometimes considered to be an expected outcome and is a reflection of the repair technique used and suture placement (e.g. subcutaneous or subcuticular sutures). Women sutured with fast-absorbing synthetic sutures were more likely to have wound skin edges gaping at up to 10 days, compared with those with standard synthetic sutures (6% versus 3.6%, unweighted percentages) (RR 1.67, 95% CI 1.07 to 2.60, two trials, 1659 women) (Analysis 2.4).

There were no data reported in these trials for serious wound breakdown, although one trial (Kettle 2002) collected information on wound resuturing and there was no significant difference between groups; three women sutured with fast-absorbing material required resuturing compared with one woman with standard synthetic sutures (Analysis 2.5). More women with standard sutures required the removal of suture material compared with those with rapidly absorbing stitches (RR 0.24, 95% CI 0.15 to 0.36, two trials, 1847 women) (Analysis 2.6).

There was no evidence of any significant differences between groups for long-term pain (at three months after delivery) or for dyspareunia at three, or at six to 12 months (Analysis 2.7; Analysis 2.8; Analysis 2.9). However, dyspareunia at three months was experienced by more than 20% of women regardless of suture material, and in one of the trials where women were followed up for a year after the birth of their babies, more than 10% were still experiencing pain during sexual intercourse (Kettle 2002).

Non-prespecified outcomes

One study (Kettle 2002) collected information on women's satisfaction with repair of their perineum. Slightly more women in the rapidly absorbed suture group compared with the standard Vicryl group expressed satisfaction with the repair at both three months (81.4% versus 77.8%), and at 12 months postpartum (83.1% versus 81.8%) but differences between groups were not significant (Analysis 2.10; Analysis 2.11).

Sensitivity analysis

For longer-term outcomes (pain and superficial dyspareunia at three, six or 12 months) three studies had high levels of attrition (greater than 20%) (Gemynthe 1996; Leroux 2006; McElhinney 2000) and for outcomes affected by high levels of attrition, we examined the impact of temporarily removing studies from the analysis. The sensitivity analysis did not indicate that removing studies with higher risk of bias due to attrition had any important impact on findings.

Standard catgut versus glycerol impregnated catgut: two trials with 1737 women

Primary outcomes

Pain at three days after delivery was examined in one trial (Saint 1993) and there was no evidence of any difference between groups sutured with either chromic catgut or glycerol impregnated catgut (Softgut) (Analysis 3.1). At 10 to 14 days pain was measured in two trials (Saint 1993; Spencer 1986) and Softgut was associated with more women experiencing pain, but the difference between groups was not significant (RR 1.15, 95% CI 0.85 to 1.56) (Analysis 3.2).

Secondary outcomes

There was no strong evidence of any difference between groups in women's use of analgesia up to 10 days after delivery in the one trial (Spencer 1986) that reported this outcome (RR 1.91, 95% CI 0.78 to 4.68). There was no significant difference in the number of women with wound dehiscence at 10 days (Analysis 3.4). More women with standard catgut required the removal of suture material by three months (RR 0.42, 95% CI 0.27 to 0.67, one trial, 655 women). There was no information reported on the number of women requiring resuturing.

There was no strong evidence of differences between groups for longer-term pain or dyspareunia at three or at six to 12 months (Analysis 3.6; Analysis 3.7; Analysis 3.8); overall, approximately 25% of women continued to experience dyspareunia three months after the birth of their babies.

Sensitivity analysis

In one of the studies included in this comparison the method used for allocation concealment was unclear (Saint 1993); for those outcomes where more than one study contributed data, temporarily removing this study from the analysis had no important impact on results.

Absorbable monofilament sutures versus standard polyglycolic: one trial with 1139 women

Primary outcomes

Only one trial contributed data to this outcome (Dencker 2006). There was no evidence of any differences in mean pain scores for women repaired with synthetic monofilament sutures or polyglycolic acid sutures at one to three days after delivery (mean difference 0.13, 95% CI -0.12 to 0.32).

Secondary outcomes

There was no strong evidence of any difference between group for pain at eight to 12 weeks (Analysis 4.3). Women sutured with monofilament material were more likely to report "wound

problems" at eight to 12 weeks (RR 2.42, 95% CI 1.43 to 4.11). One woman in each group had wound breakdown requiring resuturing.

Sensitivity analysis

We did not carry out formal sensitivity analysis for this comparison as only one study contributed data; however, this study had high levels of attrition (> 30%) for outcomes at eight to 12 weeks, and data for longer term outcomes are at high risk of bias and should be interpreted with caution.

DISCUSSION

Summary of main results

The meta-analysis of the data from the included trials comparing catgut and synthetic materials provides significant evidence that synthetic absorbable suture material (polyglactin 910 and polyglycolic acid) is associated with less short-term pain, a reduction in the use of analgesia and less wound dehiscence, but with the need for more suture removal. However, the long-term effects of differences between these materials are less clear.

When standard (polyglactin 910/polyglycolic acid) and rapidly absorbed synthetic sutures were compared, there was no significant evidence of difference in short-term pain. However, one trial (Kettle 2002) suggested that analgesia use up to 10 days postpartum was reduced with rapidly absorbed suture material. There were few cases of serious wound dehiscence, although superficial partial skin dehiscence (skin edges gaping) was slightly increased with rapidly absorbing (6%, 50/829) as compared with standard sutures (3.6%, 30/830). This finding should be interpreted in the context of the whole review, as it was considerably less than the rates of superficial perineal wound dehiscence (gaping) at 10 days postpartum that was reported in the trials comparing standard synthetic material (15.7%, 174/1111) to catgut (25.5%, 283/1108) (unweighted percentages). Moreover, there were more women with standard synthetic material requiring suture removal compared with those sutured with rapidly absorbing material. There was little evidence of differences between materials in terms of longer-term outcomes.

There were a limited number of other research trials included in this review that compared other types of absorbable suture materials; however there was little evidence of differences between groups.

Overall completeness and applicability of evidence

The studies included in the review were carried out over a long period of time (almost 40 years) and in contexts where local custom and practice differed considerably. During this time catgut has been largely superseded in developed countries by absorbable synthetic suture materials for perineal repair.

An important factor to consider when interpreting results is the clinical heterogeneity among the included trials; trials differed considerably in terms of suturing technique used, the calibre of material, size of needle, skill of operators, duration of follow up and outcomes assessed. Therefore, findings must be viewed in the context of the variation between trials. In addition, the extent of perineal trauma, the type of delivery (spontaneous vaginal versus instrumental), the type of episiotomy (medio-lateral versus median), and the performance of an episiotomy versus a tear, may all influence the rate of postpartum perineal pain and dyspareunia, and these must be taken into account when assessing the evidence (Glazener 1995; Graham 1997; Sleep 1984; Thacker 1983; Woolley 1995a; Woolley 1995b). It was not possible to make direct comparisons between the different absorbable suture materials and the different techniques used for perineal repair due to limited availability of information, and therefore, cross reference should be made to the related Cochrane review (Kettle 2007). This related review assessed the effects of continuous versus interrupted absorbable sutures for repair of episiotomy and second-degree perineal tears following childbirth, and found continuous suturing techniques compared with interrupted methods, are associated with less short-term pain.

In some of the included trials, operators were asked to use materials and techniques with which they were unfamiliar. It is possible that, even if the best suture materials and techniques are used, if the operator is relatively unskilled the outcome may be affected. In the Mahomed 1989 trial, midwives carried out only 25% of the subcuticular and 34% of interrupted repairs. The reason why so few midwives carried out this procedure was that repair of perineal trauma was a relatively new extension of their role. Mackrodt and colleagues (Gordon 1998) reported that participating midwives were encouraged to use a subcuticular technique for perineal skin closure for women allocated to the three-stage method of repair (skin sutured), however, 72% of women allocated to this suturing method had interrupted transcutaneous stitches and 12% of women allocated to the two-stage technique had skin sutures inserted. Consideration must be given to the validity of these findings due to the non-compliance with allocated methods and the differing techniques used between groups, which make the interpretation of the data very difficult. The diversity in the skills and preferences of operators may have contributed to the disparity of results presented in the meta-analysis of data.

Quality of the evidence

There were differences between the studies included in the review in research methodologies including those related to treatment allocation, concealment, blinding and attrition levels (*see* Characteristics of included studies tables). Overall, the quality of the studies was mixed, although sensitivity analysis (excluding studies at high risk of bias on account of inadequate allocation concealment or high attrition) suggests that the inclusion of studies with high risk of bias did not affect the general direction of findings, or the size of the treatment effect.

The lack of blinding in most of these studies may be a problem in terms of the overall quality of the evidence. Only two of the included studies provided details of efforts to blind women, clinical staff and outcome assessors to group allocation (Kettle 2002; Leroux 2006). Another possible confounding factor may be the way outcome data were obtained, including the way questions were asked (face-to-face or self-completed questionnaires) and how these outcomes were defined (particularly pain). Additionally, the assessment of perineal healing may have been affected by lack of blinding, in that the outcome assessors may have had preferences (acknowledged or not) for particular types of suturing materials.

For some of the results described in the review (particularly those for pain outcomes), there was evidence of high levels of statistical heterogeneity. Some of this heterogeneity may have occurred as a result of the clinical heterogeneity alluded to above; for example, women may not have been asked about pain in the same way

in different trials. For several outcomes, results seemed to favour a particular suture material; however, where prediction intervals (estimating the possible range of treatment effects in any future study) were very broad, and included the null value of one, results from meta-analysis should be interpreted very cautiously. Thus, although meta-analysis may suggest a treatment effect in favour of a particular suture material, due to heterogeneity we cannot rule out the possibility that the effect would be the same in a single study. Further research is needed to explain the causes of such between study heterogeneity.

Potential biases in the review process

We attempted to reduce bias in the reviewing process wherever possible. Two review authors independently assessed the risk of bias and the findings of the included studies. However, it is very difficult to rule out observer bias; for example, assessing risk of bias is a matter of judgement rather than an exact science. We accept that the interpretation of the findings of the review are likely to be affected by subjective factors.

Agreements and disagreements with other studies or reviews

The findings of this review are in agreement with recommendations made by the NICE Intrapartum Guideline (NICE 2007), RCOG Greentop Clinical Guidelines (RCOG 2007) and Clinical Evidence (Clinical Evidence 2008).

AUTHORS' CONCLUSIONS

Implications for practice

This review provides evidence that perineal repair with catgut may increase short-term pain and wound breakdown compared to absorbable synthetic sutures. There were few differences between standard polyglactin 910 and rapidly absorbed synthetic sutures, however, fewer women in the rapidly absorbed suture material group needed sutures removing up to three months postpartum. This is an important finding, as women report that having perineal sutures removed is an extremely unpleasant procedure. Another factor to consider is that if sutures remain in the tissues for longer than is required, they may excite a significant inflammatory response and predispose infection, abscess formation and wound dehiscence (Flanagan 1997), which could impact on expenditure in health care systems .

Implications for research

We know that the continuous suturing technique for repair of all layers (vagina, perineal muscles and skin) is associated with a significant reduction in pain when compared to the more traditional interrupted method (Kettle 2007). However, what is less clear is the interaction between suture material and suturing technique. It is interesting to note that Olah 1990 compared chromic catgut to polyglycolic acid suture material using a continuous suturing technique and reported no differences in pain between intervention groups. He considered it was the method of repair that was important, and that the type of absorbable suture material used was irrelevant in terms of reducing perineal discomfort. Similarly, Fleming 1990 used chromic catgut and her colleague used polyglactin 910 suture material when performing the loose continuous technique of repair, and she also reported no difference in outcome. Therefore, it may be appropriate to compare standard polyglactin 910 with the more rapidly absorbed suture material in a robust clinical trial, using the continuous suturing technique, in an attempt to obtain the definitive answer as to what is the best absorbable suture material for repair of episiotomies and perineal tears.

There is very little research evidence relating to maternal satisfaction with the management and repair of perineal trauma following childbirth. As highlighted by Walsh 2001, most clinical trials have concentrated on outcomes that are important to professionals and have, on the whole, ignored women's experiences. Only one of the included trials collected information on women's satisfaction with the repair (Kettle 2002). This is potentially an important area for future research, as the longer term impact of perineal trauma and repair may be considerable.

More research is required into evaluating alternative ways of minimising the extent of perineal trauma sustained by women during vaginal delivery and the impact that it has on women's decision to have an elective caesarean section for subsequent births.

There has been limited research carried out to evaluate methods of teaching and assessing surgical skills in obstetrics. More work is required to evaluate the effectiveness and cost implications of using alternative methods of teaching perineal assessment, repair and management skills compared to traditional methods of 'see one, do one, teach one'.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

Banninger 1978

Methods	Quasi-randomised trial.

Banninger 1978 *(Continued)*

	Factorial design (3 arm trial, 2 arms compared different materials (polyglycolic acid vs catgut) using the same method of repair; the third arm included mixed materials and mixed methods of repair; we have not included this arm in the analyses).
Participants	Setting - Zurich, Switzerland. 153 women - these were women in 2 arms of a 3-arm trial and included only those women who had the same suture material (either polyglycolic acid or catgut) and the same technique (as described below) used throughout the repair. Inclusion criteria - women with an episiotomy and without complications. Exclusion criteria - women with a past history of obstetric operations; breech deliveries and those with additional damage to the cervix, vagina and perineum. Parity - primigravida (first-time mothers). Mean age - intervention group = 24.1; comparison group = 25.2. Operator - doctors.
Interventions	Intervention group (n = 80) - vagina, perineal muscle and skin sutured using the interrupted technique with polyglycolic acid (Dexon) No. 2-0 on a 60 mm round bodied needle. Comparison group (n =73) - vagina, perineal muscle and skin sutured using the interrupted technique with chromic catgut No. 0 on a 60 mm round bodied needle.
Outcomes	Short-term pain - day 3 and 7. Analgesia - up to day 7. Suture dehiscence - up to day 7. Resuturing - up to day 7. Dyspareunia - at 3 months.
Notes	Only one-third of participants followed up at 3 months. Cosmetic results were reported at 3 months after delivery (data not included in the paper) - the intervention group had less scarring in the form of 'rope ladder' compared to the comparison group.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Adequate sequence generation?	High risk	Allocated by 'alternating sequence'.
Allocation concealment?	High risk	No information available regarding concealment of treatment allocation, but the alternating randomisation sequence means that group allocation may have been anticipated.
Blinding? Women	Unclear risk	No details given.
Blinding? Clinical staff	High risk	Difference in suture material appearance.
Blinding? Outcome assessors	High risk	Difference in suture material appearance.
Incomplete outcome data addressed? All outcomes	High risk	Low attrition for short-term outcomes. At 3 months follow up only 30% of the original sample remained.

Banninger 1978 *(Continued)*

Free of other bias?	Unclear risk	No baseline imbalance apparent.

Beard 1974

Methods	RCT.
Participants	Setting - Queen Charlotte Maternity Hospital, London, UK. 200 women 'allocated randomly' into 2 groups. Inclusion criteria - women having a 'normal delivery' with an episiotomy. Exclusion criteria - women with lacerations or those booked for 48 hour discharge. Parity - primigravidae and multigravidae. Mean age - not specified. Operator - resident obstetric officers in their second obstetric appointment.
Interventions	Intervention group (n = 100) - 'standard method of repair incorporating a subcuticular suture to the perineal skin' with polyglycolic acid (Dexon) 2-0 suture material on a 40 mm round bodied atraumatic needle. Comparison group (n = 100) - 'standard method of repair incorporating a subcuticular suture to the perineal skin' with chromic catgut 2-0 suture material on a 55 mm 'loose' round bodied needle.
Outcomes	Short-term pain - day 3. Analgesia - day 3. Suture dehiscence - day 3 (classified as superficial and deep). Wound inflammation - day 3.
Notes	Similar number of primigravida and multigravida women in each group. Method of repair not fully described. It was documented in the paper that on the 3rd day after delivery the patients were interviewed and examined by 1 of the operators without knowledge of which suture material had been used. This may have been possible if the skin was closed with a subcuticular suture as the stitches would not be visible.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Adequate sequence generation?	Unclear risk	Allocated "randomly to two groups" - method not described.
Allocation concealment?	Unclear risk	No information available regarding concealment of treatment allocation.
Blinding? Women	Unclear risk	No details given.
Blinding? Clinical staff	High risk	Difference in suture materials and needles used for the repairs.
Blinding? Outcome assessors	Unclear risk	Outcome assessors were described as being "without knowledge of which suture had been used".
Incomplete outcome data addressed? All outcomes	Low risk	All participants entered into the trial were included in the analysis.

Beard 1974 *(Continued)*

Free of other bias?	Unclear risk	Outcomes relating to pain were not simple to interpret, for 1 measure of pain, event rates added up to more than the total sample size and women may have been counted more than once: this outcome has not been included in the review.

Dencker 2006

Methods	RCT.
Participants	Setting - Department of Normal Obstetrics/Ostra, Sahlgrenska University Hospital, Gothenburg, Sweden. 1139 women 'randomly allocated'. Inclusion criteria - women having a vaginal delivery with laceration or episiotomy that required suturing by a midwife; singleton pregnancy; cephalic presentation and gestation between 34 and 42 weeks. Exclusion criteria - not documented. Parity - primigravida and multigravida. Mean age - not documented. Operator - midwives.
Interventions	Method of repair - both continuous and interrupted suturing techniques were used - each midwife used the suturing technique she preferred. Intervention group (n = 554) - monofilament glycomer 631 (Biosyn) (suture material gauge and size of needle not documented). Comparison group (n = 585) - multifilament polyglycolic acid (Dexon II) (suture material gauge and size of needle not documented).
Outcomes	INCLUDED IN ANALYSIS Short-term pain - up to day 3 (data not presented in paper). Wound healing - up to day 3 (data not presented in paper). Perineal discomfort/pain - 8 -12 weeks postpartum. Wound healing - 8 -12 weeks postpartum. Re-suturing - up to six months postpartum.
Notes	The authors of this study provided additional unpublished data on outcomes.

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Low risk	'Random number generator.'
Allocation concealment?	Low risk	Opaque, sealed, serially numbered envelopes.
Blinding? Women	Unclear risk	No details given.
Blinding? Clinical staff	High risk	Difference in suture materials.
Blinding?	High risk	Difference in suture materials.

Dencker 2006 *(Continued)*

Outcome assessors		
Incomplete outcome data addressed? All outcomes	Unclear risk	Drop-out n = 64 (48 envelopes 'discarded' plus 16 questionnaires were missing substantial data). 93% followed up at 1 - 3 days and 64% at 8 - 12 weeks.
Free of other bias?	Unclear risk	The published paper did not provide information on non significant results; the author provided additional unpublished data on request.

Gemynthe 1996

Methods	RCT.
Participants	Setting - Obstetric Unit, Rigshospitalet, Copenhagen, Denmark. 308 women recruited. Inclusion criteria - Danish speaking women with a spontaneous perineal tear or episiotomy requiring suturing. Exclusion criteria - not documented. Parity - primigravida. Mean age - not documented. Operator - not documented.
Interventions	Method of repair - not described (stated that a continuous subcuticular suture is used in practically all departments of obstetrics in Denmark). Intervention group (n = 155) - fast-absorbing polyglactin 910 suture material (Vicryl Rapide) (suture material gauge and size of needle not documented). Comparison group (n = 153) - standard polyglactin 910 suture material (Vicryl) (suture material gauge and size of needle not documented).
Outcomes	Pain or discomfort when sitting, lying, walking and defecation at 2 days, 5 days, 2 weeks and 3 months. Insufficient healing, visible sutures and sutures removed up to 8 weeks' postpartum healing. Time of resumption of intercourse - up to 3 months. Dyspareunia at 3 months postpartum.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Unclear risk	Block randomisation - block size not specified (stratification of randomisation by episiotomy or laceration).
Allocation concealment?	Unclear risk	States 'two sets of sealed envelopes'.
Blinding? Women	Low risk	States mothers were not aware of which suture material was used.
Blinding? Clinical staff	High risk	Obvious differences in colour of suture material and packaging (standard Vicryl is usually dyed purple and Vicryl Rapide is usually undyed).

Gemynthe 1996 *(Continued)*

Blinding? Outcome assessors	Unclear risk	States project midwives were not aware of which suture material was used (this may be possible in subcutaneous stitches were used). The woman's GP performed the check-up at 2 months postpartum and was 'unaware of the suture material used'.
Incomplete outcome data addressed? All outcomes	Unclear risk	Some missing data at all data collection points (pain data 2.9% missing at 48 hrs. 11.7% at 2 weeks and 24% at 3 months).
Free of other bias?	Low risk	No other bias apparent.

Greenberg 2004

Methods	RCT (block randomisation).
Participants	Setting - Brigham & Women's Hospital and the Massachusetts General Hospital, USA. 1361 women enrolled - only two-thirds (n = 908) required suturing of vulval and/or vaginal laceration; and/or episiotomy. Inclusion criteria - women presenting in labour or for induction. Exclusion criteria - not documented. Parity - primigravida and multigravida Maternal age - not documented. Operator - obstetricians and midwives.
Interventions	Method of repair - (not fully described) all practitioners used subcuticular skin closure except 1 operator who used interrupted technique. Intervention group (n = 459) - fast-absorbing polyglactin 910 (gauge of material and needle size not specified). Comparison group (n = 449) - chromic catgut (gauge of material and needle size not specified).
Outcomes	INCLUDED IN ANALYSIS Vaginal pain - 24 - 48 hrs; 10-14 days; 6-8 weeks postpartum. Uterine pain - 24 - 48 hrs; 10-14 days; 6-8 weeks postpartum. Analgesia (used in last 8 hrs) 24 - 48 hrs; 10-14 days; 6-8 weeks postpartum. Painless bowel movement - 24 - 48 hrs; 10-14 days; 6-8 weeks postpartum. Resuturing - up to day 7. Perineal wound breakdown at 6-8 weeks. Dyspareunia - at 3 months.
Notes	87% of participants received allocated suture material.

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Low risk	Treatment allocated by block randomisation (block size 10) using validated SAS program (Cary, NC).
Allocation concealment?	Low risk	Numbered opaque sealed envelopes.
Blinding? Women	High risk	Stated that 'women were not blinded to suture material used'.
Blinding?	High risk	Unable to ‘blind’ operators due to obvious difference in suture material.

Greenberg 2004 *(Continued)*

Clinical staff		
Blinding? Outcome assessors	Unclear risk	Stated 'nurses were blinded to suture material used when asking questions at 24-48 hrs and 10-14 days postpartum'.
Incomplete outcome data addressed? All outcomes	Unclear risk	1361 women randomised, however, only 908 women required perineal repair and were included in analysis. Intention-to-treat analysis carried out amongst women who received sutures (women were recruited prior to delivery and therefore some women did not require perineal suturing). 64% of participants were lost to follow up at 6-8 weeks postpartum.
Free of other bias?	Unclear risk	Groups appeared similar at baseline. There were some protocol violations but analysis by randomisation group for those women requiring repair.

Kettle 2002

Methods	RCT. Factorial 2 x 2 design.
Participants	Setting - University Hospital of North Staffordshire, UK. 1542 women randomised. Inclusion criteria - women who had a spontaneous vaginal delivery with a second-degree tear or episiotomy, who had given their preliminary informed consent. Exclusion criteria - instrumental vaginal delivery; extensive perineal trauma beyond the midwife's scope of practice; previous perineal surgery other than primary repair after childbirth; delivery of a stillborn infant or baby with extensive congenital abnormalities; women with AIDS or hepatitis B virus infection, severe perineal warts or extensive varicose veins of the genital area; women who were younger than 16 years and those unable to read, write or understand English language. Parity - primigravida and multigravida. Mean age - intervention group = 27.3; comparison group = 27.1. Operators - midwives (n = 150) (29 women sutured by a doctor).
Interventions	Method of repair - described as below. Intervention group (n = 772) - un-dyed fast-absorbing polyglactin 910 (Vicryl Rapide) 2/0 on a 35 mm tapercut needle (50% had vaginal trauma, perineal muscle and skin repaired with a continuous non-locking suture technique and 50% had vaginal trauma repaired with a locking continuous stitch; perineal muscle and skin sutured using the interrupted method). Comparison group (n = 770) un-dyed standard polyglactin 910 (Vicryl) on a 35 mm tapercut needle (50% had vaginal trauma, perineal muscle and skin repaired with a continuous non-locking suture technique and 50% had vaginal trauma repaired with a locking continuous stitch; perineal muscle and skin sutured using the interrupted method).
Outcomes	Short-term pain - day 2 and 10. Pain when walking, sitting, passing urine, opening bowels at 10 days. Analgesia - day 10. Long-term pain - 3 months and 12 months. Dyspareunia - 3 and 12 months. Removal of suture material and resuturing before 3 months; sutures uncomfortable; sutures tight; wound gaping; satisfaction with the repair and feeling back to normal within 3 months of birth.

Kettle 2002 *(Continued)*

Notes	Treatment envelopes were packed by Birmingham Clinical Trials Unit (envelopes contained 2 packets of masked suture material and instructions for method of repair on different coloured cards). Concealed interim analysis after 400 women entered the trial. Ethics Committee Approval. 9 women with a third degree tear and 1 with a fourth degree tear were recruited in error but were included in the analysis.

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Low risk	By external trials unit - computer-generated random permuted block with block size of 20 (5 of each treatment combination).
Allocation concealment?	Low risk	Serially numbered, sealed opaque envelopes
Blinding? Women	Low risk	The suture material was masked at source (suture material looked the same).
Blinding? Clinical staff	Low risk	The suture material was masked at source (suture material looked the same, packed in identical packets and coded to prevent identification). (Not possible to blind the suturing technique.)
Blinding? Outcome assessors	Low risk	The suture material was masked at source (suture material looked the same, packed in identical packets and coded to prevent identification).
Incomplete outcome data addressed? All outcomes	Low risk	Only 3 women did not complete a questionnaire at day 10. Response rate high at each time-point throughout the study. One envelope unaccounted for. 96.7% response rate at 3 months and 90% at 12 months.
Free of other bias?	Low risk	No other bias apparent; most women received suture material according to randomisation group.

Leroux 2006

Methods	RCT - 3-arm trial.
Participants	Setting - not clear - Tertiary care hospital (first author from Canada). 192 women - spontaneous or operative vaginal delivery and enrolled in early labour or when comfortable under regional anaesthesia. Inclusion criteria - haemodynamically stable patients with a second-degree perineal laceration or an uncomplicated episiotomy (median or mediolateral) and maternal age ≥18 years. Exclusion criteria - third- and fourth-degree perineal lacerations; allergy to non-steroidal anti-inflammatory agents or aspirin; thrombocytopenia; pregnancy induced hypertension; a history of coagulation disorders; unexplained haemorrhage or gastroduodenal ulcer. Parity - primigravida and multigravida. Mean age - group A = 29.7; group B = 30.5; group C = 30.2. Operator - obstetrician/gynaecologist or resident under direct supervision.
Interventions	Method of repair - continuous technique as described in Williams Obstetrics textbook (2001). 2-0 gauge suture material used for continuous suturing of vagina; 2 - 4 interrupted sutures inserted using a 2-0

Leroux 2006 *(Continued)*

	gauge suture material to approximate perineal muscle and continuous 3 - 0 gauge suture material to close superficial fascia and skin (same technique used for all 3 groups). Participants divided into 3 groups: group A (n = 66) - chromic catgut 2-0 and 3-0 gauge (size and type of needle not documented); group B (n = 60) - standard polyglactin 910 (Vicryl) (size and type of needle not documented); group C (n = 66) - fast-absorbing polyglactin 910 (Vicryl Rapide) (size and type of needle not documented).
Outcomes	Short-term pain - 36 to 48 hrs postpartum. Analgesia - 36 to 48 hrs. Pain - 6 weeks and 3 months; breastfeeding - 6 weeks and 3 months; dyspareunia before pregnancy; resumption of sexual intercourse - 6 weeks and 3 months; pain free of sexual intercourse - 6 weeks; residual suture - 6 weeks; incomplete healing - 6 weeks.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Unclear risk	'Assigned randomly.'
Allocation concealment?	Low risk	Consecutively numbered opaque envelopes (not stated if sealed).
Blinding? Women	Unclear risk	Stated 'women not informed of the treatment allocation'.
Blinding? Clinical staff	High risk	Unable to ‘blind’ due to differences in suture material
Blinding? Outcome assessors	Unclear risk	Stated 'colour of suture were approximately the same therefore difficult to differentiate type of material at 48 hrs and 6 weeks after delivery'
Incomplete outcome data addressed? All outcomes	Unclear risk	5% missing data at 36 - 48 hrs. 20% attrition at 6 weeks and 40% at 12 weeks.
Free of other bias?	Unclear risk	Premature discontinuation of the study due to catgut being withdrawn from the 'hospital inventory' for reasons not related to the trial.

Livingstone 1974

Methods	Quasi-randomised trial.
Participants	Setting - Queen Mother's Hospital, Glasgow. 100 women randomised. Inclusion criteria - first-time mothers having spontaneous vaginal, rotation forceps, forceps or ventouse with a medio-lateral episiotomy. Exclusion criteria - women with additional lacerations or extended episiotomy. Parity - primigravidae. Mean age - not specified. Operators - not specified.

Livingstone 1974 *(Continued)*

Interventions	Method of repair - standard continuous suture of vaginal epithelium and interrupted sutures for muscle layers and skin (for purpose of comparison similar gauge of suture material and size of needle was used). Intervention group (n = 50) sutured with polyglycolic acid No. 1 on a 40mm round bodied needle (vaginal and muscle) and No. 0 polyglycolic acid on a 37 mm diamond taper needle (skin). Comparison group (n = 50) sutured with plain catgut No. 1 on a 40 mm round bodied needle (vaginal and muscle) and No. 0 plain catgut on a 35 mm tapercut needle (skin).
Outcomes	Short-term pain - day 3. Suture dehiscence - day 3 (introital dehiscence and total superficial dehiscence). Ease of movement - day 3. Oedema - day 3.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Unclear risk	Allocated by quasi-randomisation - 'treatment allocation was determined on a random basis by drawing lottery cards'.
Allocation concealment?	Unclear risk	No information available regarding concealment of treatment allocation.
Blinding? Women	Unclear risk	Not stated.
Blinding? Clinical staff	Unclear risk	Described as "double blind" but not convinced that blinding was possible due to obvious differences in suture materials.
Blinding? Outcome assessors	Unclear risk	Researchers stated that by day 3 catgut had lost its distinguishing colour and was identical in appearance to Dexon, thus allowing the assessment to be described as 'double-blind'. However, this is not convincing because interrupted sutures were used to appose the perineal skin and any differences in the suture material would be obvious.
Incomplete outcome data addressed? All outcomes	Unclear risk	All participants entered into the trial were included in the analysis but it was not clear whether analysis was by 'intention to treat'.
Free of other bias?	Low risk	No other bias apparent.

Mackrodt 1998

Methods	RCT. Factorial 2 x 2 design.
Participants	Setting - Ipswich Hospital (NHS Trust), Ipswich, UK. 1780 women randomised. Inclusion criteria - initially women who sustained an episiotomy or laceration (first or second degree) during a spontaneous vaginal delivery and had given their informed consent to participate were included. However, the trial was extended to include women who were delivered by a simple instrumental delivery (nonrotational forceps or vacuum extraction).

Mackrodt 1998 *(Continued)*

	Exclusion criteria - not documented. Parity - primigravida and multigravida included (split equally between groups). Mean age - intervention group = 28.2; comparison group B = 28.4. Operator - midwives and doctors.
Interventions	Method of repair - each group had 50% of women randomly assigned for perineal repair using a 2-stage (skin unsutured) technique and 50% assigned for perineal repair using the 3-stage (skin sutured) method. Intervention group (n = 889) - sutured with polyglactin 910 (Vicryl), gauge 2-0 on 35 mm needle. Control group (n = 891) - sutured with chromic catgut on 40 mm needle.
Outcomes	Short-term pain - day 2 and 10. Analgesia - day 2 and 10 and 3 months. Tight stitches - 2 and 10 days. Removal of sutures - 10 days and 3 months. Resumption of sexual intercourse - 3 months. Failure to achieve pain-free intercourse - 3 months. Suture dehiscence - day 10 and 3 months (appearance of perineum, gaping, healing by first intention, healing by secondary intention, breaking down at 10 days and resuturing at 3 months).
Notes	The operator could 'choose' method of repair for perineal skin (subcutaneous or interrupted). In the group that had the perineal skin sutured - 26% had subcuticular stitches inserted; 72% had interrupted transcutaneous stitches;1% had skin left unsutured and 1% had no sutures. 6 women who had a third degree laceration were recruited in error but were included in the analysis. Interim analysis carried out.

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Low risk	Allocated randomly using balanced blocks varying in size between 4 and 12 - stratified by type of delivery.
Allocation concealment?	Low risk	Concealed treatment allocation - serially numbered; sealed opaque envelopes containing allocation details, suture material and data sheet. All envelopes accounted for.
Blinding? Women	Unclear risk	No details given.
Blinding? Clinical staff	High risk	Unable to blind operator due to obvious difference in suture methods and materials.
Blinding? Outcome assessors	High risk	Outcome assessment not fully blinded (unable to fully blind outcome assessment due to obvious difference in suture methods and materials).
Incomplete outcome data addressed? All outcomes	Low risk	99% completed questionnaires at 24-48 hours and 93% at 3 months postpartum.
Free of other bias?	Low risk	No baseline imbalance apparent.

Mahomed 1989

Methods	RCT.

Mahomed 1989 *(Continued)*

	Modified factorial - 2 x 3 x 2 design.
Participants	Setting - Southmead Hospital, Bristol, UK. 538 women needing perineal repair following delivery (all tears and episiotomies included). This was a subgroup of the main trial and included only those women who had the same material, either polyglycolic acid or catgut, used throughout the repair. Method of delivery - spontaneous and operative vaginal deliveries. Parity - primigravidae and multipara. Mean age - intervention group = 26.0; comparison group = 26.1. Operators - midwives, senior house officers, registrars, consultants, medical students.
Interventions	Method of repair - continuous suture for vaginal epithelium and interrupted sutures for muscle layers. Skin was sutured with either the interrupted or continuous subcuticular method. Intervention group (n = 275) sutured with polyglycolic acid (Dexon plus) gauge 2-0 on a 30 mm, half-circle multipurpose needle. Comparison group (n = 263) sutured with chromic catgut gauge 2-0 on a 35 mm, half-circle tapercut needle.
Outcomes	Short-term pain - day 3. Long-term pain - 3 months. Analgesia - up to day 7. Resuturing - up to 3 months. Dyspareunia - 3 months. Removal of suture material - up to 3 months.
Notes	No interim analysis. Ethics committee approval. Preset trial size had 80% chance of detecting significant clinical differences.

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Low risk	Randomly allocated.
Allocation concealment?	Low risk	Concealed treatment allocation - serially numbered, sealed opaque envelopes (envelopes contained suture material and instructions for method of repair). 22 envelopes were unaccounted for.
Blinding? Women	Unclear risk	No details given.
Blinding? Clinical staff	High risk	Blinding not possible due to obvious differences in suture materials and techniques.
Blinding? Outcome assessors	High risk	Acknowledged that fully blind assessment was not possible due to obvious differences in suture materials and techniques.
Incomplete outcome data addressed? All outcomes	Low risk	1574 women randomised and data available for 97% at day 2, 86% at day 10 and 87% at 3 months follow up.
Free of other bias?	Unclear risk	Factorial design meant that some of the results were difficult to interpret. Unpublished data relating to the comparison of polyglycolic acid versus catgut were obtained directly from Professor Adrian Grant.

McElhinney 2000

Methods	RCT.
Participants	Setting - Ulster Hospital, Dundonald, Northern Ireland, UK. 153 women randomised. Inclusion criteria - women with a parity of 0 to 2; between 18 and 40 years of age; singleton fetus; had a normal vaginal delivery and required an episiotomy or had sustained a second degree tear (skin and perineal muscle). Exclusion criteria - not documented. Parity - primigravida and multigravida. Maternal age - 18 to 40 years. Operator - not documented.
Interventions	Method of repair - all repairs carried out using the same technique with 1 length of suture material and subcuticular perineal skin closure. Method not fully described. Intervention group (n = 75) - fast-absorbing polyglactin 910 (Vicryl Rapide) (gauge of material and needle size not specified). Comparison group (n = 78) - standard polyglactin 910 (Vicryl) (gauge of material and needle size not specified).
Outcomes	Perineal pain - 24 hrs and 3 days. Analgesia at 3 days. Wound infection, gaping wound (no data), suture removal - 6 and 12 weeks. Dyspareunia - 6 and 12 weeks postpartum.
Notes	All women received a diclofenac suppository (100 mg) for pain relief, following completion of the repair.

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Unclear risk	Treatment allocated by block randomisation (block size not clear).
Allocation concealment?	Unclear risk	"Two sets of sealed envelopes."
Blinding? Women	Unclear risk	Not stated.
Blinding? Clinical staff	Unclear risk	Not stated, however, this would be difficult due to possible differences in suture materials.
Blinding? Outcome assessors	Unclear risk	Not stated.
Incomplete outcome data addressed? All outcomes	Unclear risk	77% of participants followed up at 12 weeks.
Free of other bias?	Unclear risk	Non-significant results were not reported in full (stated that differences were not significant).

Nikolov 2006

Methods	Not clear. ? Quasi-randomised trial. 180 women separated into 3 groups of 60.
Participants	180 women (120 used in the analysis in the review) after episiotomy repair. Women who had had spontaneous tearing or anal sphincter repair were not included. Parity, age and method of repair not described.
Interventions	Intervention group: polyglactin 910 sutures (Vicryl-Rapide) (60 women). Comparison group: polyglycolic acid sutures (60 women). (Women (60) in the third arm of this trial had mixed materials - catgut and silk - and are not included in the analysis.)
Outcomes	Pain (moderate or strong pain in the first 5 days after repair, not clear when measured); partial wound dehiscence (partial skin dehiscence and full dehiscence at 5 days post delivery); redness and swelling.
Notes	The paper was not published in English and translation notes were used for data extraction.

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Unclear risk	No information (bias assessed from translation notes).
Allocation concealment?	Unclear risk	"separated into 3 groups of 60."
Blinding? Women	Unclear risk	Not specified.
Incomplete outcome data addressed? All outcomes	Unclear risk	No missing data apparent.

Olah 1990

Methods	Quasi-randomised trial.
Participants	Setting - Selly Oak Hospital, Birmingham. 120 women randomised. Inclusion criteria - episiotomy repair following an instrumental delivery (forceps or ventouse extraction). Exclusion criteria - details not documented. Parity - primigravida and multigravida. Mean age - intervention group = 27.0; control group = 26.5 Operators - single operator familiar with technique.
Interventions	Method of repair - continuous non-locking stitch with subcuticular to skin (similar method as described by Isager-Sally 1986). Intervention group (n = 60) polyglycolic acid (Dexon) gauge 0 (needle size not specified).

Olah 1990 *(Continued)*

	Comparison group (n = 60) chromic catgut gauge 0 (needle size not specified).
Outcomes	Short-term pain - day 3 and 5. Dehiscence of wound - day 5. Removal of suture material - day 5. Resuturing - day 5. Oedema - day 5 Bruising - day 5.
Notes	No long-term follow up. Additional information included in the review was obtained directly from the author.

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	High risk	Odd and even case note numbers.
Allocation concealment?	High risk	Not concealed therefore, treatment allocation could be anticipated in advance.
Blinding? Women	Unclear risk	Not stated.
Blinding? Clinical staff	High risk	Blinding not possible due to obvious differences in suture materials.
Blinding? Outcome assessors	High risk	Blinding not possible due to obvious differences in suture materials.
Incomplete outcome data addressed? All outcomes	Low risk	No loss to follow up apparent.
Free of other bias?	Low risk	Women in the 2 groups were described as being similar at baseline.

Roberts 1983

Methods	RCT.
Participants	Setting - Stobhill General Hospital, Glasgow, UK. 190 women randomised. Inclusion criteria - all women who had either a spontaneous vaginal delivery or forceps with an episiotomy. Exclusion criteria - no details given. Parity - not stated.. Mean age - not specified. Operator - not clear.
Interventions	Method of repair - continuous suture to close vaginal epithelium and interrupted sutures for muscle layers and skin (buried knots).

Roberts 1983 *(Continued)*

	Intervention group (n = 88) vagina and muscle sutured with polyglycolic acid (Dexon gauge1-0) and skin sutured with polyglycolic acid (Dexon gauge2-0) using an interrupted technique and buried knots. Comparison group (n = 84) vagina and muscle sutured with chromic catgut (gauge1-0) and skin sutured with plain catgut (gauge 2-0) using an interrupted technique and buried knots.
Outcomes	Short-term pain on rest - 1 to 10 days. Short-term pain on movement - 1 to 10 days. Analgesia - up to day 5. Bruising - day 2 and 4. Oedema - day 2 and 4.
Notes	Not clear if all repairs were carried out by a single investigator. Patients were assessed daily for 5 days after delivery by the obstetrician. Assessed at home on tenth day by district midwife.

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Unclear risk	Allocated by a "randomisation schedule".
Allocation concealment?	Unclear risk	No information available regarding concealment of treatment allocation.
Blinding? Women	Unclear risk	Described as "double-blind trial".
Blinding? Clinical staff	Unclear risk	This would be difficult due to differences in suture materials
Blinding? Outcome assessors	Unclear risk	This would be difficult due to differences in suture materials.
Incomplete outcome data addressed? All outcomes	Unclear risk	18 of 190 women randomised were excluded from the analysis because 'they were unable to complete the study due to being discharged early or tablets were lost'. Authors state that loss was balanced across groups.
Free of other bias?	Unclear risk	Women in the 2 study groups were described as having similar characteristics.

Rogers 1974

Methods	RCT.
Participants	Setting - Department of Obstetrics and Gynecology, Madigan Army Centre, Tacoma, Washington, USA. 600 women randomised. Inclusion criteria - women who had a median and medio-lateral episiotomies (episiotomies with lacerations also included). Exclusion criteria - not documented. Method of delivery - not clear, defined as complicated or not complicated. Parity - not specified. Mean age - intervention group = 23.45; comparison group = 22.81. Operators - not specified.

Rogers 1974 *(Continued)*

Interventions	Method of repair - not described. Intervention group (n = 301) sutured with chromic catgut (gauge 3-0), needle size not specified. Comparison group (n = 299) sutured with polyglycolic acid (Dexon) (gauge 3-0), needle size not specified.
Outcomes	Short-term pain - period of time not specified. Pain in relation to type of episiotomy. Wound healing at 6 weeks' postpartum (unsure how this was assessed/followed up).
Notes	Period of follow up not specified.

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Unclear risk	Allocated using 'random technique'.
Allocation concealment?	Unclear risk	Suture packs were inside sealed plain envelopes.
Blinding? Women	Unclear risk	Not documented.
Blinding? Clinical staff	Unclear risk	Not documented, however, this would be difficult due to differences in suture materials.
Blinding? Outcome assessors	Unclear risk	Not documented, however, this would be difficult due to differences in suture materials.
Incomplete outcome data addressed? All outcomes	Low risk	All participants entered into the trial were included in the analysis.
Free of other bias?	Low risk	No baseline imbalance apparent.

Saint 1993

Methods	Randomised trial.
Participants	Setting - Princess Anne Wing, Royal United Hospital, Bath, UK. 1000 women randomised. Inclusion criteria - women who delivered spontaneously or with assistance with perineal trauma 'deemed worthy of repair'. Exclusion criteria - women with third degree tear. Parity - not specified. Mean age - not specified. Operators - midwives and doctors.
Interventions	Method of repair - continuous suture to close posterior vaginal wall, deeper layer were opposed with interrupted stitches and skin closed with interrupted or continuous subcuticular (depending on operator's preference). The actual number of women allocated to each group is not stated.

Saint 1993 *(Continued)*

	Intervention group - glycerol-impregnated catgut (Softgut, no details given regarding gauge of suture material or size of needle). Comparison group - untreated chromic catgut (no details given regarding gauge of suture material or size of needle).
Outcomes	Pain at 24 hours; 10 days; 6 weeks; 3 and 6 months postpartum. Dyspareunia at 3 and 6 months postpartum.
Notes	No description of the groups at trial entry to assess if baseline data were similar. There was also no description of the actual intervention received.

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Unclear risk	'Randomly allocated.'
Allocation concealment?	Unclear risk	Very little information provided on study methods.
Blinding? Women	Unclear risk	Not stated.
Blinding? Clinical staff	Unclear risk	Not stated.
Blinding? Outcome assessors	Unclear risk	Not stated.
Incomplete outcome data addressed? All outcomes	Unclear risk	Loss to follow up was not clear but there was missing data at all data collection points (10 - 15% missing data).
Free of other bias?	Unclear risk	Insufficient information on methods.

Spencer 1986

Methods	RCT.
Participants	Setting - Royal Berkshire Hospital, Reading, UK. 737 women randomised. Inclusion criteria - women requiring perineal repair (including episiotomies and lacerations). Exclusion criteria - not documented. Parity - primigravida and multigravida. Mean age - intervention group = 26.5; comparison group = 27.1. Operators - doctors and supervised medical students.
Interventions	Method of repair - continuous suture to repair the vagina and interrupted sutures to oppose the deeper tissues. The perineal skin was closed with either interrupted or subcuticular as preferred by the operators (each operator used the same technique regardless of the material used). Intervention group - (n = 377) glycerol-impregnated catgut (Softgut, gauge 2-0 on a 37 mm diamond point half circle needle).

Spencer 1986 *(Continued)*

	Comparison group - (n = 360) untreated chromic catgut (gauge 2-0 on a 35 mm taper cut half circle needle).
Outcomes	Pain at 10 days and 3 months postpartum. Removal of suture material at 10 days and 3 months. Healing by secondary intention and perineal breakdown at 10 days, resuturing by 3 months. Dyspareunia at 3 months postpartum.
Notes	Data were analysed primarily by allocated suture material group. Secondary analysis based on suture material actually used and on technique of repair were also performed.

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Unclear risk	Randomly allocated.
Allocation concealment?	Unclear risk	Not stated.
Blinding? Women	Low risk	'Women were unaware of the allocated suture material.'
Blinding? Clinical staff	Unclear risk	Not stated.
Blinding? Outcome assessors	Low risk	'Community midwives were unaware of the allocated suture material.'
Incomplete outcome data addressed? All outcomes	Unclear risk	89% response rate at 10 days, 70% at 3 years.
Free of other bias?	Low risk	No baseline imbalance apparent.

Upton 2002

Methods	RCT.
Participants	Setting - King George V Memorial Tertiary Hospital, Sydney, Australia. 391 women randomised. Inclusion criteria - women with live singleton birth at > 34 weeks' gestation with a spontaneous vaginal birth requiring perineal repair (first or second degree tear or episiotomy - median or mediolateral). Exclusion criteria - women who had an instrumental delivery; third degree tear or needing repair by medical officer. Parity - primigravida and multigravida. Mean age - intervention group = 29.6; comparison group = 29.5. Operator - midwives.

Upton 2002 *(Continued)*

Interventions	Method of repair - standard closure technique with interlocking suture to close vaginal tissue, interrupted stitching to perineal muscle and continuous subcuticular closure to close the skin. The same suture material was used to close all layers. Intervention group (n = 194) - coated polyglycolic suture material (gauge 2-0 on a 40 mm, half-circle taper needle). Comparison group (n = 197) - chromic catgut (gauge 2-0 on a 40 mm, half-circle taper needle).
Outcomes	Perineal pain at day 1, day 3, 6 weeks, 3 and 6 months. Wound infection at 6 weeks. Resuturing at 6 weeks. Intercourse resumption at 6 weeks, 3 and 6 months. Dyspareunia at 6 weeks, 3 and 6 months.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Low risk	Random number generator.
Allocation concealment?	Low risk	Sealed, numbered opaque envelopes.
Blinding? Women	Low risk	Described as "blinded".
Blinding? Clinical staff	High risk	Not feasible. Different suture materials.
Blinding? Outcome assessors	High risk	Not feasible. Different suture materials.
Incomplete outcome data addressed? All outcomes	Unclear risk	Day 1 follow up 89%, day 3 96%, 81% at 6 months. Missing data for some outcomes.
Free of other bias?	Unclear risk	Some baseline imbalance (e.g. there were more primiparous women in the synthetic suture group (54.6%) vs 40% in the catgut group; the authors carried out further analysis to adjust for this).

mm: millimetre
RCT: randomised controlled trial
vs: versus

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

Study	Reason for exclusion
Gaasemyr 1977	This trial examined a nylon, non-absorbable suture material (supramid).

Study	Reason for exclusion
Hemsley 1997	Trial registration; it was not clear that the trial took place. We have carried out further searches to try to locate any publications from this study and have attempted to contact the author but have had no response.
Ketcham 1994	Not a randomised controlled trial. The methodological quality of the study was poor in that no scientific principles were applied to the randomisation process and therefore, results could be subject to bias.
Marques 2001	This study was reported in a brief abstract with no clear information on study methods. Results were not reported by randomisation group. We attempted to trace the authors for further information on study methods and results but had no response.
Tompkins 1972	Unable to obtain additional information such as method of randomisation, or results (which were not presented in a suitable form to include in this review).
Uslu 1992	In this 3-arm trial there was a mixture of materials used within arms (e.g. catgut and silk) and different techniques were used in different arms.
Wikoff 1992	Abstract only. Unable to obtain additional information or data from trialists, therefore unable to include the study in this review.

DATA AND ANALYSES

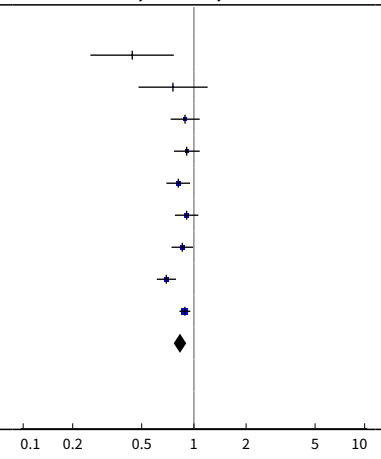
Comparison 1. Synthetic sutures versus catgut

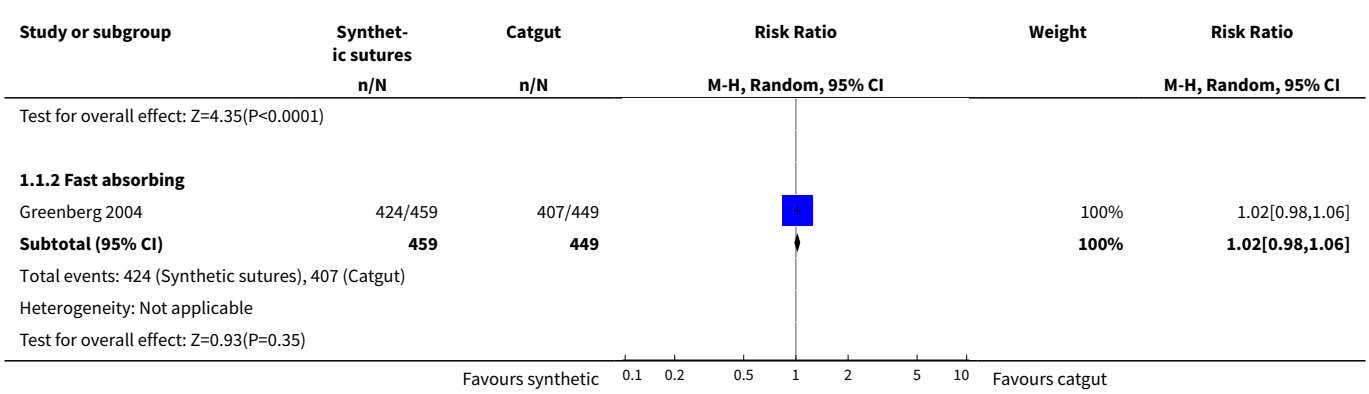
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Short-term pain: pain at day 3 or less (women experiencing any pain)	10		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.1 Standard synthetic	9	4017	Risk Ratio (M-H, Random, 95% CI)	0.83 [0.76, 0.90]
1.2 Fast absorbing	1	908	Risk Ratio (M-H, Random, 95% CI)	1.02 [0.98, 1.06]
2 Short-term pain: pain at day 4 - 10	4		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 Standard synthetic	3	2044	Risk Ratio (M-H, Fixed, 95% CI)	0.78 [0.67, 0.90]
2.2 Fast absorbing	1	846	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [0.94, 1.18]
3 Analgesia use - up to day 10	6		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
3.1 Standard synthetic	5	2820	Risk Ratio (M-H, Random, 95% CI)	0.71 [0.59, 0.87]
3.2 Fast absorbing	1	908	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.90, 1.01]
4 Suture dehiscence (wound breakdown)	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
4.1 Standard synthetic	1	1771	Risk Ratio (M-H, Fixed, 95% CI)	0.72 [0.23, 2.25]

Outcome or subgroup title	No. of studies	No. of partici-pants	Statistical method	Effect size
4.2 Fast absorbing	1	309	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.23, 4.48]
5 Superficial wound dehiscence, wound gaping up to day 10	4	2219	Risk Ratio (M-H, Random, 95% CI)	0.58 [0.36, 0.94]
5.1 Standard synthetic	4	2219	Risk Ratio (M-H, Random, 95% CI)	0.58 [0.36, 0.94]
6 Resuturing of wound - up to 3 months	4	2402	Risk Ratio (M-H, Fixed, 95% CI)	0.25 [0.08, 0.74]
6.1 Standard synthetic	4	2402	Risk Ratio (M-H, Fixed, 95% CI)	0.25 [0.08, 0.74]
7 Removal of suture material - up to 3 months	4		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
7.1 Standard synthetic	3	2520	Risk Ratio (M-H, Fixed, 95% CI)	1.81 [1.46, 2.24]
7.2 Fast absorbing	1	309	Risk Ratio (M-H, Fixed, 95% CI)	0.77 [0.11, 5.37]
8 Long-term pain - at 3 months postpartum	5		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
8.1 Standard synthetic	4	2525	Risk Ratio (M-H, Fixed, 95% CI)	0.86 [0.68, 1.09]
8.2 Fast absorbing	2	370	Risk Ratio (M-H, Fixed, 95% CI)	0.80 [0.55, 1.17]
9 Dyspareunia - at 3 months postpartum	5		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
9.1 Standard synthetic	5	2506	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.70, 1.24]
9.2 Fast absorbing	1	61	Risk Ratio (M-H, Random, 95% CI)	0.57 [0.33, 0.97]

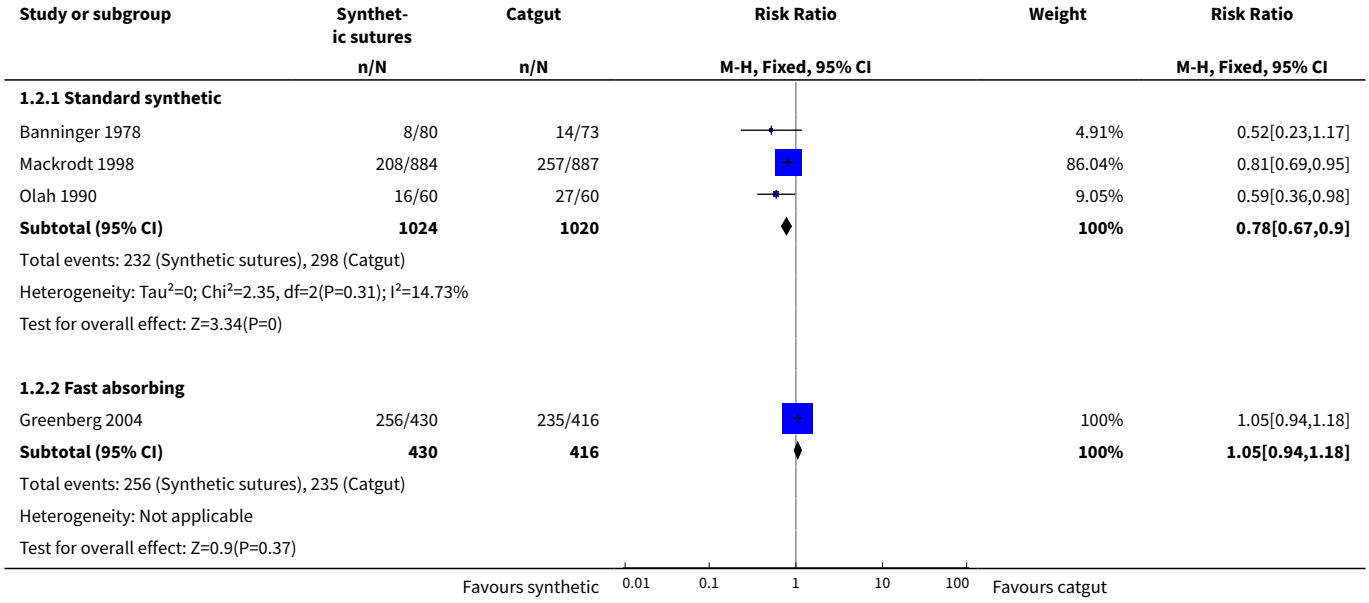
Analysis 1.1. Comparison 1 Synthetic sutures versus catgut, Outcome 1 Short-term pain: pain at day 3 or less (women experiencing any pain).

Study or subgroup	Synthetic sutures n/N	Catgut n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
1.1.1 Standard synthetic					
Banninger 1978	14/80	29/73		2.06%	0.44[0.25,0.77]
Roberts 1983	23/88	29/84		2.89%	0.76[0.48,1.2]
Beard 1974	64/100	72/100		10.35%	0.89[0.73,1.08]
Mahomed 1989	130/270	134/253		11.7%	0.91[0.77,1.08]
Livingstone 1974	39/50	48/50		12.53%	0.81[0.69,0.95]
Upton 2002	112/187	124/188		12.66%	0.91[0.78,1.06]
Olah 1990	48/60	56/60		13.58%	0.86[0.74,0.99]
Rogers 1974	155/299	225/301		14.83%	0.69[0.61,0.79]
Mackrodt 1998	523/886	591/888		19.41%	0.89[0.83,0.95]
Subtotal (95% CI)	**2020**	**1997**		**100%**	**0.83[0.76,0.9]**
Total events: 1108 (Synthetic sutures), 1308 (Catgut)					
Heterogeneity: Tau²=0.01; Chi²=18.65, df=8(P=0.02); I²=57.1%					

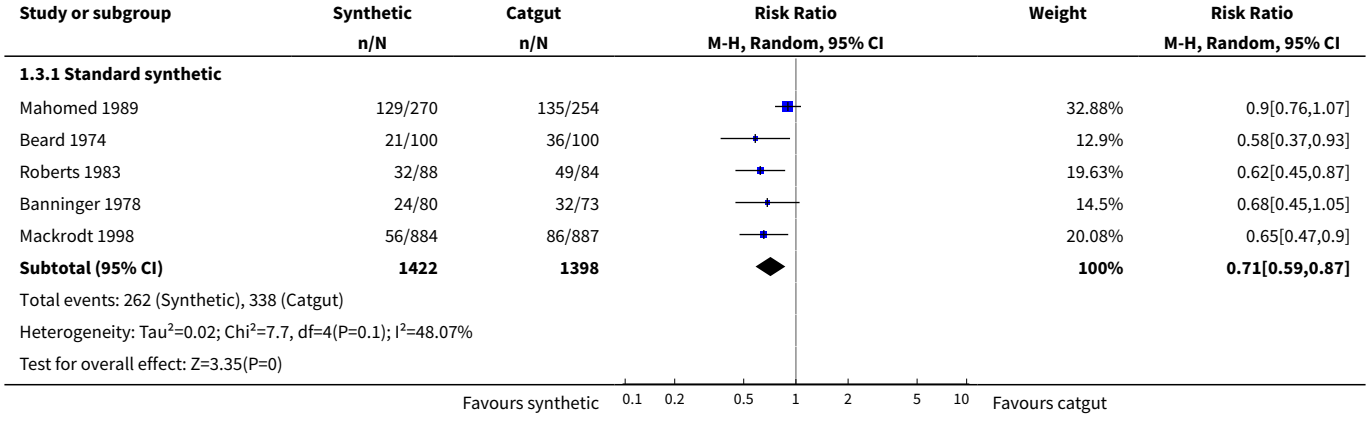


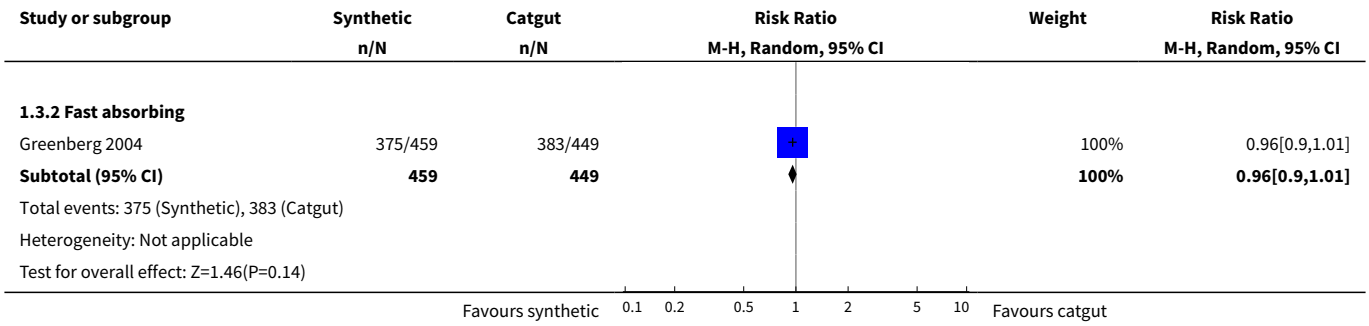


Analysis 1.2. Comparison 1 Synthetic sutures versus catgut, Outcome 2 Short-term pain: pain at day 4 - 10.

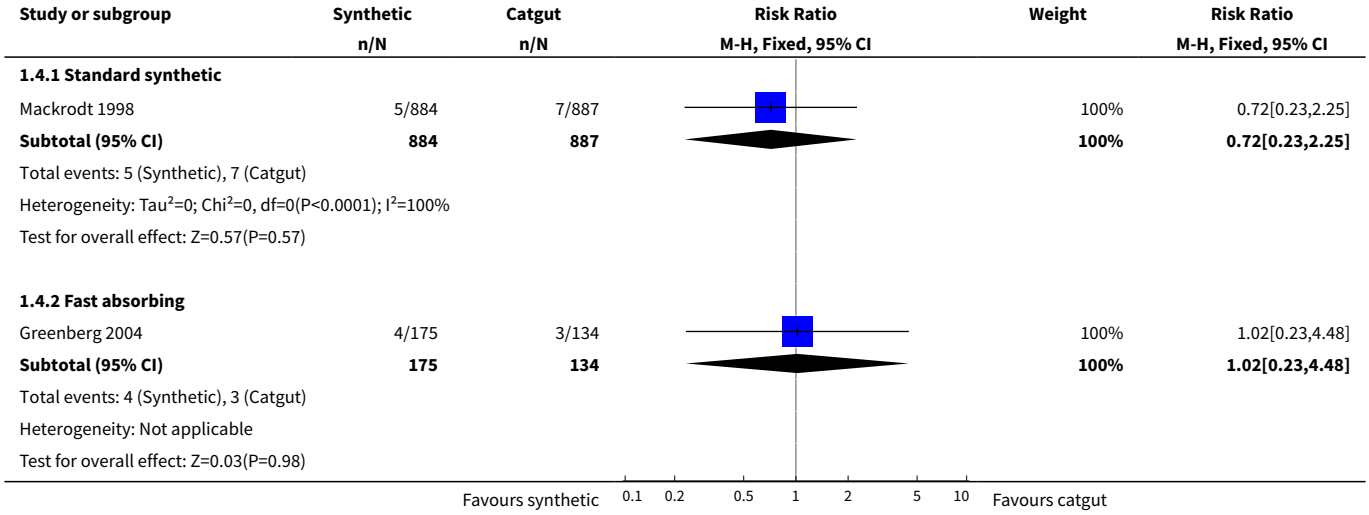


Analysis 1.3. Comparison 1 Synthetic sutures versus catgut, Outcome 3 Analgesia use - up to day 10.

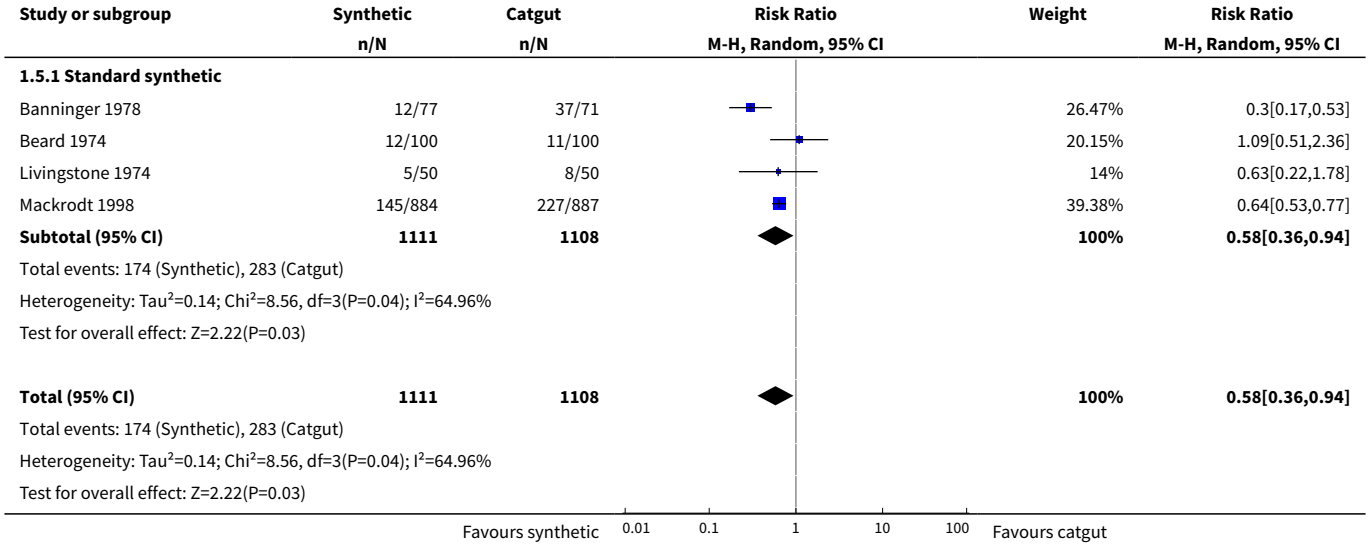




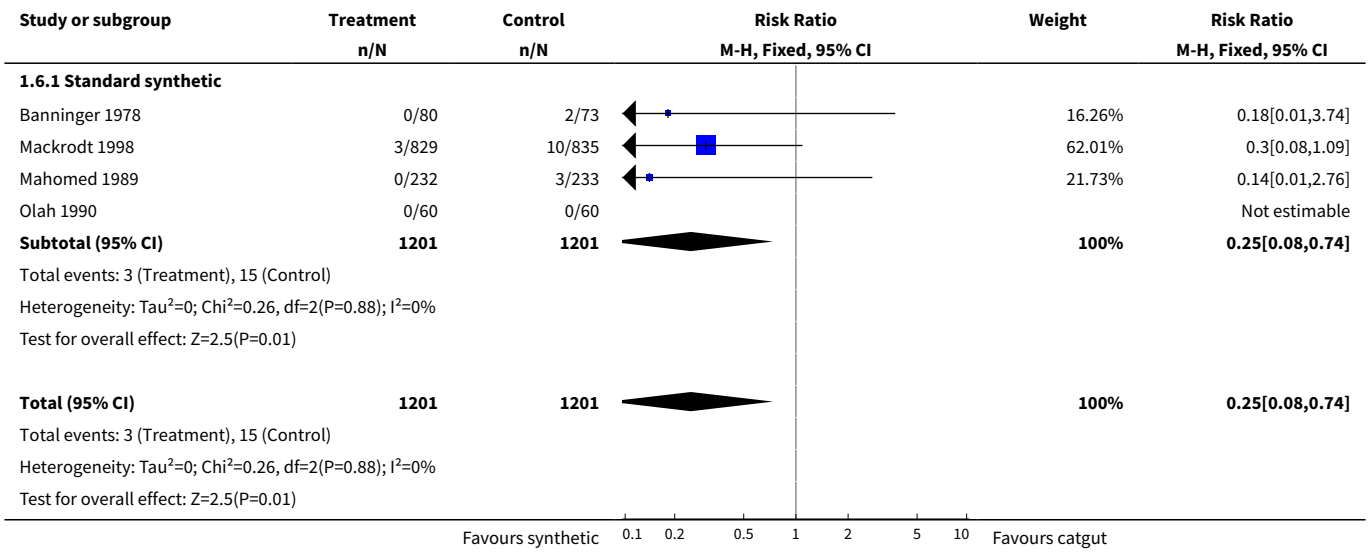
Analysis 1.4. Comparison 1 Synthetic sutures versus catgut, Outcome 4 Suture dehiscence (wound breakdown).



Analysis 1.5. Comparison 1 Synthetic sutures versus catgut, Outcome 5 Superficial wound dehiscence, wound gaping up to day 10.

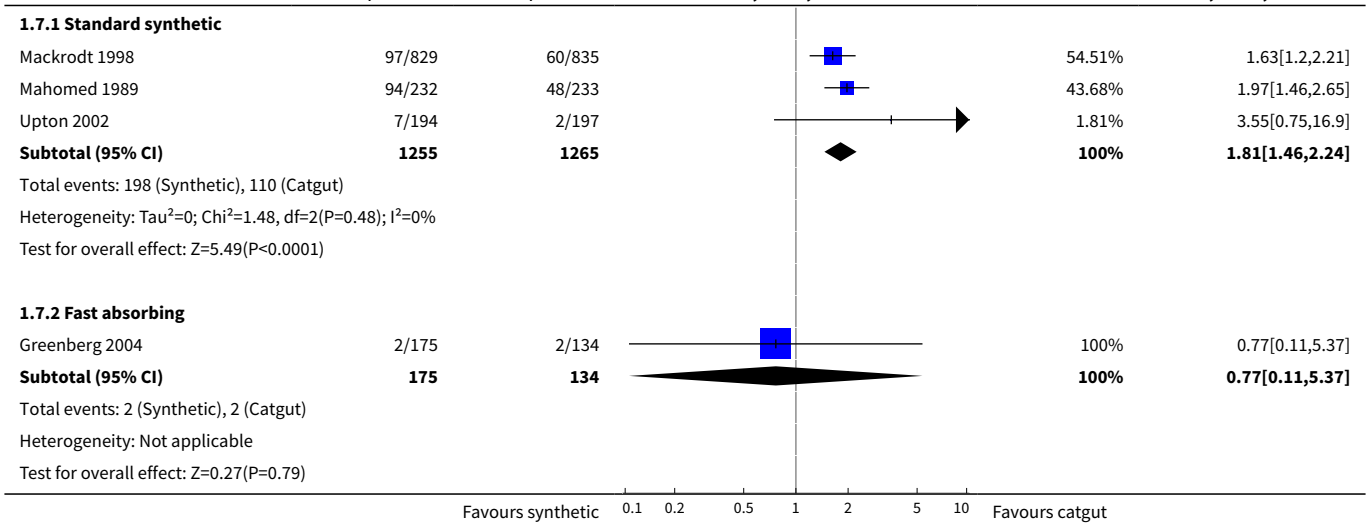


Analysis 1.6. Comparison 1 Synthetic sutures versus catgut, Outcome 6 Resuturing of wound - up to 3 months.



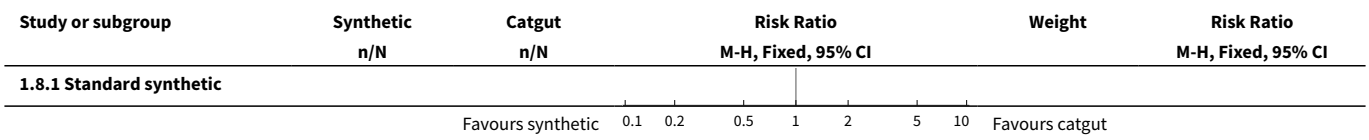
Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
1.6.1 Standard synthetic					
Banninger 1978	0/80	2/73		16.26%	0.18[0.01,3.74]
Mackrodt 1998	3/829	10/835		62.01%	0.3[0.08,1.09]
Mahomed 1989	0/232	3/233		21.73%	0.14[0.01,2.76]
Olah 1990	0/60	0/60			Not estimable
Subtotal (95% CI)	**1201**	**1201**		**100%**	**0.25[0.08,0.74]**
Total events: 3 (Treatment), 15 (Control)					
Heterogeneity: Tau^2=0; Chi^2=0.26, df=2(P=0.88); I^2=0%					
Test for overall effect: Z=2.5(P=0.01)					
Total (95% CI)	**1201**	**1201**		**100%**	**0.25[0.08,0.74]**
Total events: 3 (Treatment), 15 (Control)					
Heterogeneity: Tau^2=0; Chi^2=0.26, df=2(P=0.88); I^2=0%					
Test for overall effect: Z=2.5(P=0.01)					

Analysis 1.7. Comparison 1 Synthetic sutures versus catgut, Outcome 7 Removal of suture material - up to 3 months.

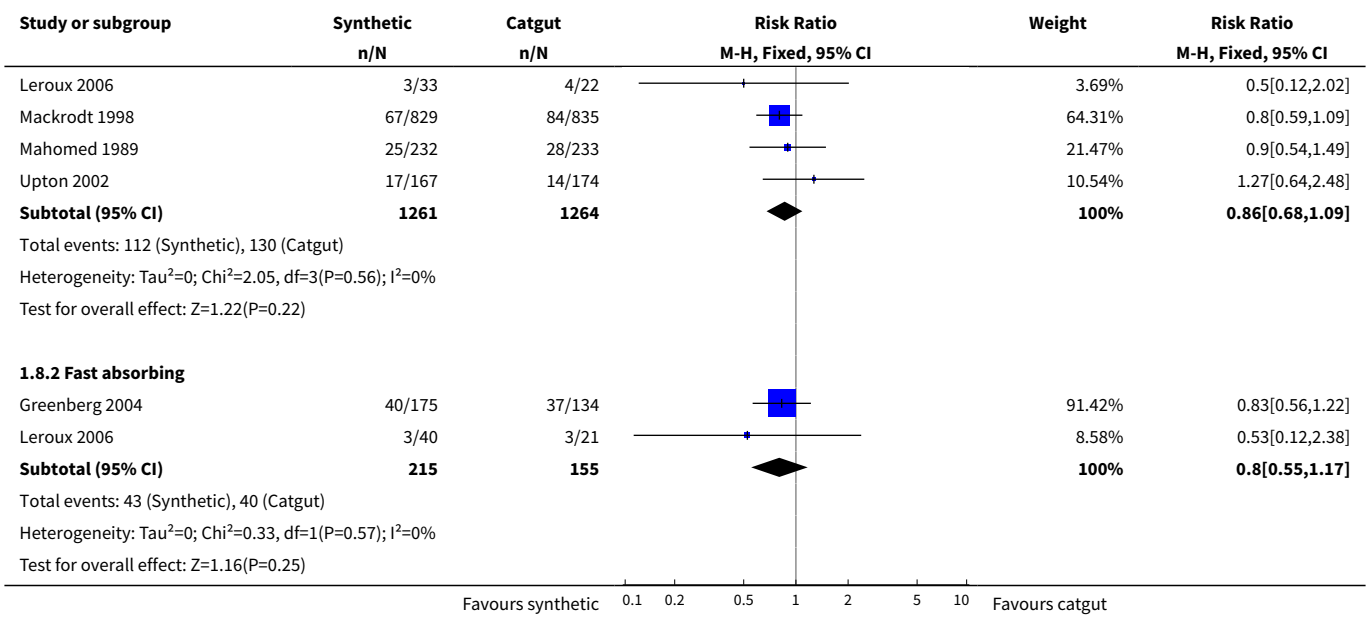


Study or subgroup	Synthetic n/N	Catgut n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
1.7.1 Standard synthetic					
Mackrodt 1998	97/829	60/835		54.51%	1.63[1.2,2.21]
Mahomed 1989	94/232	48/233		43.68%	1.97[1.46,2.65]
Upton 2002	7/194	2/197		1.81%	3.55[0.75,16.9]
Subtotal (95% CI)	**1255**	**1265**		**100%**	**1.81[1.46,2.24]**
Total events: 198 (Synthetic), 110 (Catgut)					
Heterogeneity: Tau^2=0; Chi^2=1.48, df=2(P=0.48); I^2=0%					
Test for overall effect: Z=5.49(P<0.0001)					
1.7.2 Fast absorbing					
Greenberg 2004	2/175	2/134		100%	0.77[0.11,5.37]
Subtotal (95% CI)	**175**	**134**		**100%**	**0.77[0.11,5.37]**
Total events: 2 (Synthetic), 2 (Catgut)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.27(P=0.79)					

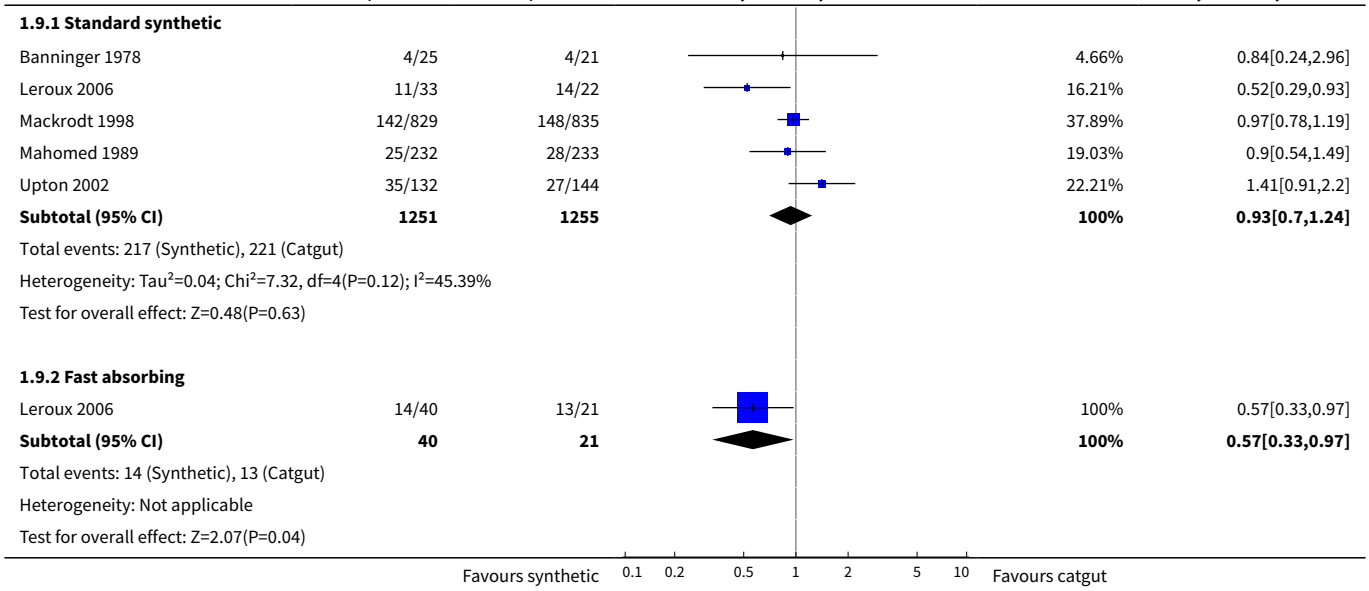
Analysis 1.8. Comparison 1 Synthetic sutures versus catgut, Outcome 8 Long-term pain - at 3 months postpartum.



Study or subgroup	Synthetic n/N	Catgut n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
1.8.1 Standard synthetic					



Analysis 1.9. Comparison 1 Synthetic sutures versus catgut, Outcome 9 Dyspareunia - at 3 months postpartum.



Comparison 2. Fast-absorbing synthetic versus standard absorbable synthetic material

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Short-term pain: at 3 days or less	3	1968	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.92, 1.10]

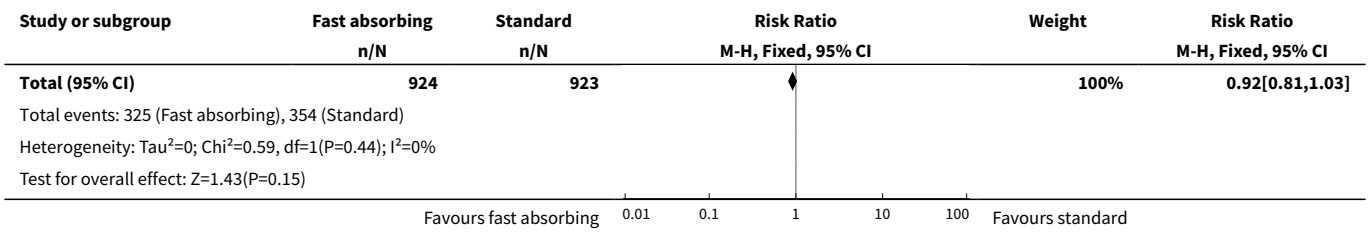
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2 Short-term pain: at 10 - 14 days	2	1847	Risk Ratio (M-H, Fixed, 95% CI)	0.92 [0.81, 1.03]
3 Use of analgesics at 10 days	1	1539	Risk Ratio (M-H, Fixed, 95% CI)	0.57 [0.43, 0.77]
4 Wound gaping - up to 10 days	2	1659	Risk Ratio (M-H, Fixed, 95% CI)	1.67 [1.07, 2.60]
5 Resuturing at 3 months postpartum	1	1174	Risk Ratio (M-H, Fixed, 95% CI)	3.01 [0.31, 28.86]
6 Suture material removed - up to 3 months	2	1847	Risk Ratio (M-H, Fixed, 95% CI)	0.24 [0.15, 0.36]
7 Long-term pain: pain at 3 months	2	369	Risk Ratio (M-H, Fixed, 95% CI)	0.79 [0.37, 1.67]
8 Dyspareunia at 3 months	4	1708	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.67, 1.29]
9 Dyspareunia at 6 - 12 months	1	1325	Risk Ratio (M-H, Fixed, 95% CI)	0.88 [0.68, 1.16]
10 Maternal satisfaction: satisfied with repair at 3 months	1	1492	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [0.99, 1.10]
11 Maternal satisfaction: satisfied with repair at 12 months	1	1389	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.97, 1.07]

Analysis 2.1. Comparison 2 Fast-absorbing synthetic versus standard absorbable synthetic material, Outcome 1 Short-term pain: at 3 days or less.

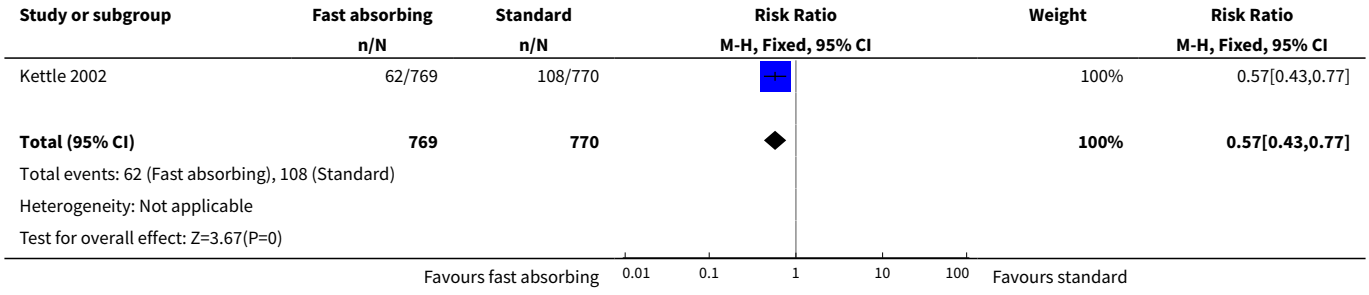
Study or subgroup	Fast absorbing n/N	Standard n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Gemynthe 1996	143/155	139/153		31.73%	1.02[0.95,1.09]
Kettle 2002	297/770	294/770		66.68%	1.01[0.89,1.15]
Nikolov 2006	6/60	7/60		1.59%	0.86[0.31,2.4]
Total (95% CI)	**985**	**983**		**100%**	**1.01[0.92,1.1]**
Total events: 446 (Fast absorbing), 440 (Standard)					
Heterogeneity: Tau^2=0; Chi^2=0.13, df=2(P=0.94); I^2=0%					
Test for overall effect: Z=0.21(P=0.83)					

Analysis 2.2. Comparison 2 Fast-absorbing synthetic versus standard absorbable synthetic material, Outcome 2 Short-term pain: at 10 - 14 days.

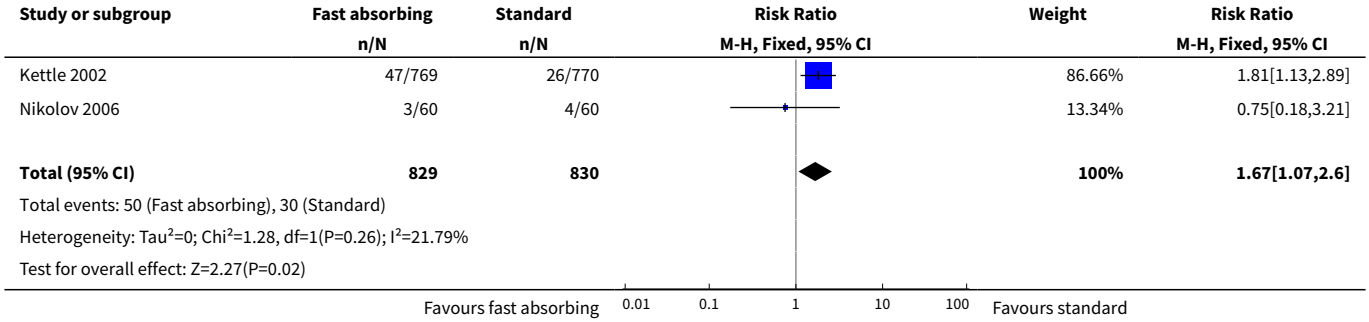
Study or subgroup	Fast absorbing n/N	Standard n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Gemynthe 1996	69/155	68/153		19.32%	1[0.78,1.29]
Kettle 2002	256/769	286/770		80.68%	0.9[0.78,1.03]



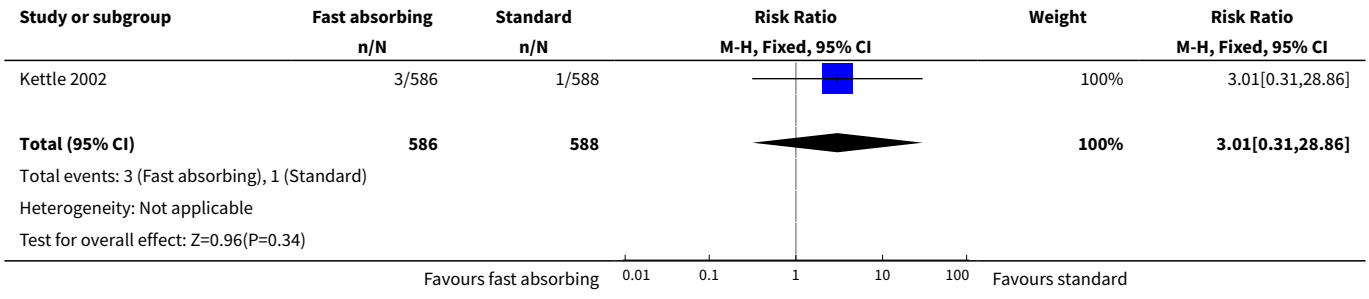
Analysis 2.3. Comparison 2 Fast-absorbing synthetic versus standard absorbable synthetic material, Outcome 3 Use of analgesics at 10 days.



Analysis 2.4. Comparison 2 Fast-absorbing synthetic versus standard absorbable synthetic material, Outcome 4 Wound gaping - up to 10 days.

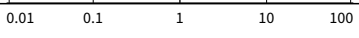


Analysis 2.5. Comparison 2 Fast-absorbing synthetic versus standard absorbable synthetic material, Outcome 5 Resuturing at 3 months postpartum.



Analysis 2.6. Comparison 2 Fast-absorbing synthetic versus standard absorbable synthetic material, Outcome 6 Suture material removed - up to 3 months.

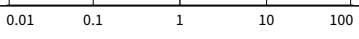
Study or subgroup	Fast absorbing n/N	Standard n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Gemynthe 1996	2/155	4/153		3.95%	0.49[0.09,2.66]
Kettle 2002	22/769	98/770		96.05%	0.22[0.14,0.35]
Total (95% CI)	**924**	**923**		**100%**	**0.24[0.15,0.36]**
Total events: 24 (Fast absorbing), 102 (Standard)					
Heterogeneity: Tau^2=0; Chi^2=0.78, df=1(P=0.38); I^2=0%					
Test for overall effect: Z=6.52(P<0.0001)					



Favours fast absorbing — Favours standard

Analysis 2.7. Comparison 2 Fast-absorbing synthetic versus standard absorbable synthetic material, Outcome 7 Long-term pain: pain at 3 months.

Study or subgroup	Fast absorbing n/N	Standard n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Gemynthe 1996	9/155	10/153		71.9%	0.89[0.37,2.13]
Leroux 2006	3/40	3/21		28.1%	0.53[0.12,2.38]
Total (95% CI)	**195**	**174**		**100%**	**0.79[0.37,1.67]**
Total events: 12 (Fast absorbing), 13 (Standard)					
Heterogeneity: Tau^2=0; Chi^2=0.35, df=1(P=0.55); I^2=0%					
Test for overall effect: Z=0.63(P=0.53)					



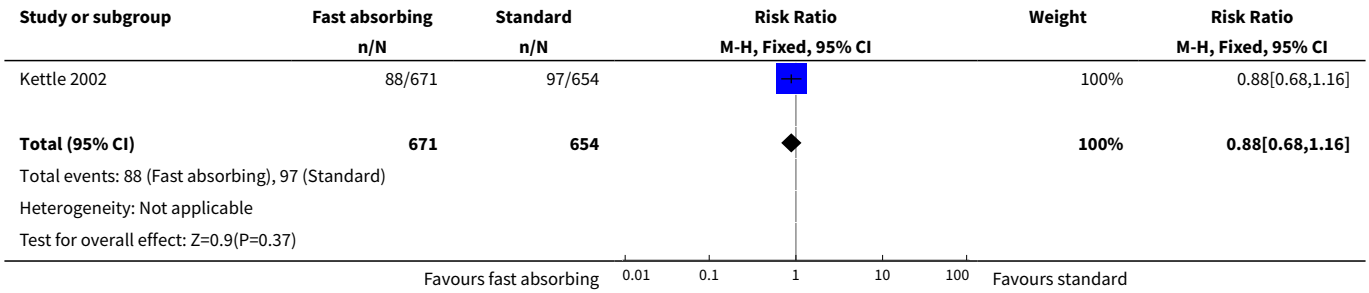
Favours fast absorbing — Favours standard

Analysis 2.8. Comparison 2 Fast-absorbing synthetic versus standard absorbable synthetic material, Outcome 8 Dyspareunia at 3 months.

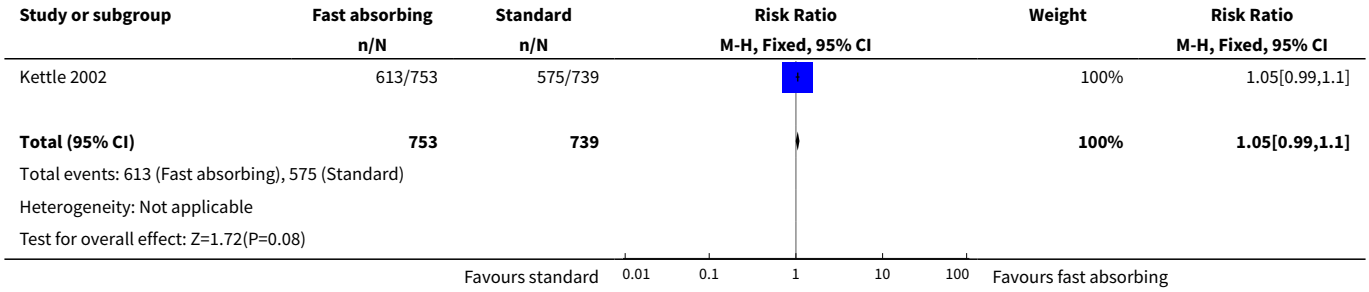
Study or subgroup	Fast absorbing n/N	Standard n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Gemynthe 1996	57/155	58/153		35.89%	0.97[0.73,1.3]
Kettle 2002	105/586	95/588		38.35%	1.11[0.86,1.43]
Leroux 2006	14/40	11/33		17.4%	1.05[0.55,1.99]
McElhinney 2000	4/75	16/78		8.35%	0.26[0.09,0.74]
Total (95% CI)	**856**	**852**		**100%**	**0.93[0.67,1.29]**
Total events: 180 (Fast absorbing), 180 (Standard)					
Heterogeneity: Tau^2=0.06; Chi^2=7.08, df=3(P=0.07); I^2=57.64%					
Test for overall effect: Z=0.44(P=0.66)					

Favours fast absorbing — Favours standard

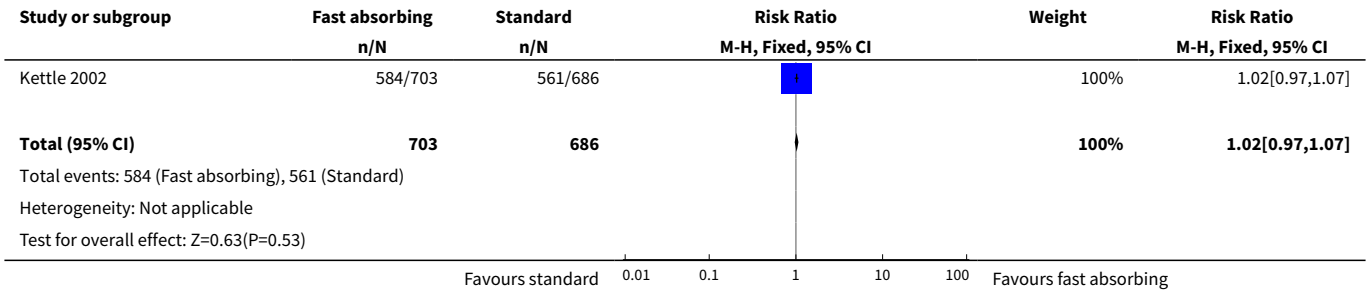
Analysis 2.9. Comparison 2 Fast-absorbing synthetic versus standard absorbable synthetic material, Outcome 9 Dyspareunia at 6 - 12 months.



Analysis 2.10. Comparison 2 Fast-absorbing synthetic versus standard absorbable synthetic material, Outcome 10 Maternal satisfaction: satisfied with repair at 3 months.



Analysis 2.11. Comparison 2 Fast-absorbing synthetic versus standard absorbable synthetic material, Outcome 11 Maternal satisfaction: satisfied with repair at 12 months.



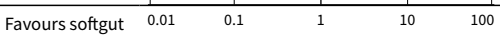
Comparison 3. Glycerol impregnated catgut (softgut) versus chromic catgut

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Short-term pain: pain at 3 days or less	1	836	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.94, 1.04]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2 Short-term pain: pain at 10 - 14 days	2	1541	Risk Ratio (M-H, Random, 95% CI)	1.15 [0.85, 1.56]
3 Analgesia at day 10	1	737	Risk Ratio (M-H, Fixed, 95% CI)	1.91 [0.78, 4.68]
4 Wound dehiscence at 10 days	1	737	Risk Ratio (M-H, Fixed, 95% CI)	1.75 [0.65, 4.68]
5 Suture removal by 3 months	1	655	Risk Ratio (M-H, Fixed, 95% CI)	0.42 [0.27, 0.67]
6 Long-term pain: pain at 3 months	2	1639	Risk Ratio (M-H, Fixed, 95% CI)	1.13 [0.78, 1.64]
7 Dyspareunia at 3 months	2	1473	Risk Ratio (M-H, Random, 95% CI)	1.16 [0.92, 1.46]
8 Dyspareunia at 6 - 12 months	1	917	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.70, 1.33]

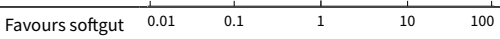
Analysis 3.1. Comparison 3 Glycerol impregnated catgut (softgut) versus chromic catgut, Outcome 1 Short-term pain: pain at 3 days or less.

Study or subgroup	Glycerol impregnated n/N	Standard catgut n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Saint 1993	365/418	369/418		100%	0.99[0.94,1.04]
Total (95% CI)	**418**	**418**		**100%**	**0.99[0.94,1.04]**
Total events: 365 (Glycerol impregnated), 369 (Standard catgut)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.42(P=0.67)					



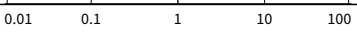
Analysis 3.2. Comparison 3 Glycerol impregnated catgut (softgut) versus chromic catgut, Outcome 2 Short-term pain: pain at 10 - 14 days.

Study or subgroup	Glycerol impregnated n/N	Standard catgut n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Saint 1993	189/445	187/440		55.25%	1[0.86,1.16]
Spencer 1986	107/335	75/321		44.75%	1.37[1.06,1.76]
Total (95% CI)	**780**	**761**		**100%**	**1.15[0.85,1.56]**
Total events: 296 (Glycerol impregnated), 262 (Standard catgut)					
Heterogeneity: Tau^2=0.04; Chi^2=4.39, df=1(P=0.04); I^2=77.21%					
Test for overall effect: Z=0.89(P=0.37)					



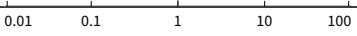
Analysis 3.3. Comparison 3 Glycerol impregnated catgut (softgut) versus chromic catgut, Outcome 3 Analgesia at day 10.

Study or subgroup	Glycerol impregnated n/N	Standard catgut n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Spencer 1986	14/377	7/360		100%	1.91[0.78,4.68]
Total (95% CI)	**377**	**360**		**100%**	**1.91[0.78,4.68]**
Total events: 14 (Glycerol impregnated), 7 (Standard catgut)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1.42(P=0.16)					



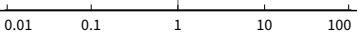
Analysis 3.4. Comparison 3 Glycerol impregnated catgut (softgut) versus chromic catgut, Outcome 4 Wound dehiscence at 10 days.

Study or subgroup	Glycerol impregnated n/N	Standard catgut n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Spencer 1986	11/377	6/360		100%	1.75[0.65,4.68]
Total (95% CI)	**377**	**360**		**100%**	**1.75[0.65,4.68]**
Total events: 11 (Glycerol impregnated), 6 (Standard catgut)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1.12(P=0.26)					



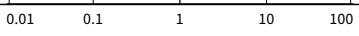
Analysis 3.5. Comparison 3 Glycerol impregnated catgut (softgut) versus chromic catgut, Outcome 5 Suture removal by 3 months.

Study or subgroup	Glycerol impregnated n/N	Standard catgut n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Spencer 1986	23/332	53/323		100%	0.42[0.27,0.67]
Total (95% CI)	**332**	**323**		**100%**	**0.42[0.27,0.67]**
Total events: 23 (Glycerol impregnated), 53 (Standard catgut)					
Heterogeneity: Not applicable					
Test for overall effect: Z=3.64(P=0)					



Analysis 3.6. Comparison 3 Glycerol impregnated catgut (softgut) versus chromic catgut, Outcome 6 Long-term pain: pain at 3 months.

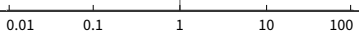
Study or subgroup	Glycerol impregnated n/N	Standard catgut n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Saint 1993	26/483	25/485		50.71%	1.04[0.61,1.78]
Spencer 1986	30/339	24/332		49.29%	1.22[0.73,2.05]
Total (95% CI)	**822**	**817**		**100%**	**1.13[0.78,1.64]**
Total events: 56 (Glycerol impregnated), 49 (Standard catgut)					
Heterogeneity: Tau^2=0; Chi^2=0.18, df=1(P=0.67); I^2=0%					
Test for overall effect: Z=0.66(P=0.51)					



Favours softgut — Favours standard catgut

Analysis 3.7. Comparison 3 Glycerol impregnated catgut (softgut) versus chromic catgut, Outcome 7 Dyspareunia at 3 months.

Study or subgroup	Glycerol impregnated n/N	Standard catgut n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Saint 1993	109/441	104/440		57.99%	1.05[0.83,1.32]
Spencer 1986	78/300	57/292		42.01%	1.33[0.99,1.8]
Total (95% CI)	**741**	**732**		**100%**	**1.16[0.92,1.46]**
Total events: 187 (Glycerol impregnated), 161 (Standard catgut)					
Heterogeneity: Tau^2=0.01; Chi^2=1.55, df=1(P=0.21); I^2=35.35%					
Test for overall effect: Z=1.23(P=0.22)					



Favours softgut — Favours standard catgut

Analysis 3.8. Comparison 3 Glycerol impregnated catgut (softgut) versus chromic catgut, Outcome 8 Dyspareunia at 6 - 12 months.

Study or subgroup	Glycerol impregnated n/N	Standard catgut n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Saint 1993	62/457	65/460		100%	0.96[0.7,1.33]
Total (95% CI)	**457**	**460**		**100%**	**0.96[0.7,1.33]**
Total events: 62 (Glycerol impregnated), 65 (Standard catgut)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.25(P=0.8)					

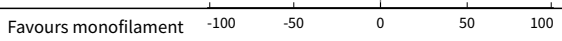
Favours softgut — Favours standard catgut

Comparison 4. Monofilament versus standard polyglycolic sutures

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Short-term pain: mean pain scores at 3 days	1	1042	Mean Difference (IV, Fixed, 95% CI)	0.10 [-0.12, 0.32]
2 Long-term pain: pain score greater than 2 at 8 - 12 weeks	1	705	Risk Ratio (M-H, Fixed, 95% CI)	1.40 [1.01, 1.95]
3 Long-term pain: mean pain scores at 8 - 12 weeks	1	705	Mean Difference (IV, Fixed, 95% CI)	0.22 [0.01, 0.43]
4 Wound problems at 8 - 12 weeks: women seeking professional help for problem with perineal repair	1	727	Risk Ratio (M-H, Fixed, 95% CI)	2.42 [1.43, 4.11]

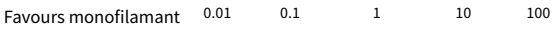
Analysis 4.1. Comparison 4 Monofilament versus standard polyglycolic sutures, Outcome 1 Short-term pain: mean pain scores at 3 days.

Study or subgroup	Monofilament N	Monofilament Mean(SD)	Polyglycolic N	Polyglycolic Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Dencker 2006	505	2.5 (1.8)	537	2.4 (1.8)		100%	0.1[-0.12,0.32]
Total ***	**505**		**537**			**100%**	**0.1[-0.12,0.32]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.89(P=0.37)							

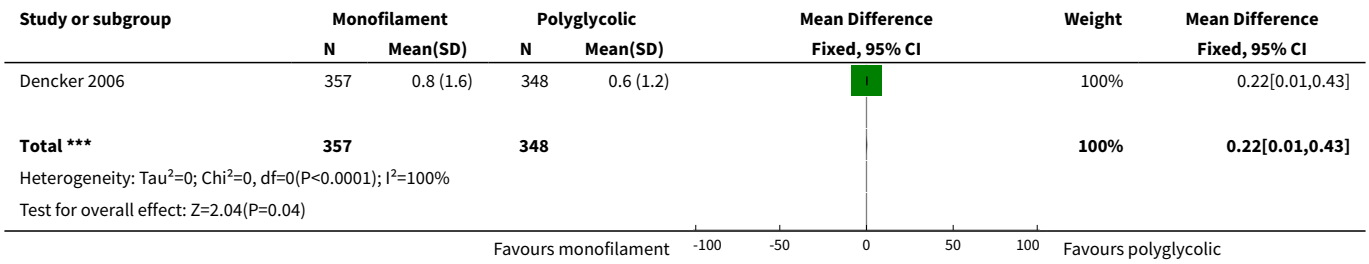


Analysis 4.2. Comparison 4 Monofilament versus standard polyglycolic sutures, Outcome 2 Long-term pain: pain score greater than 2 at 8 - 12 weeks.

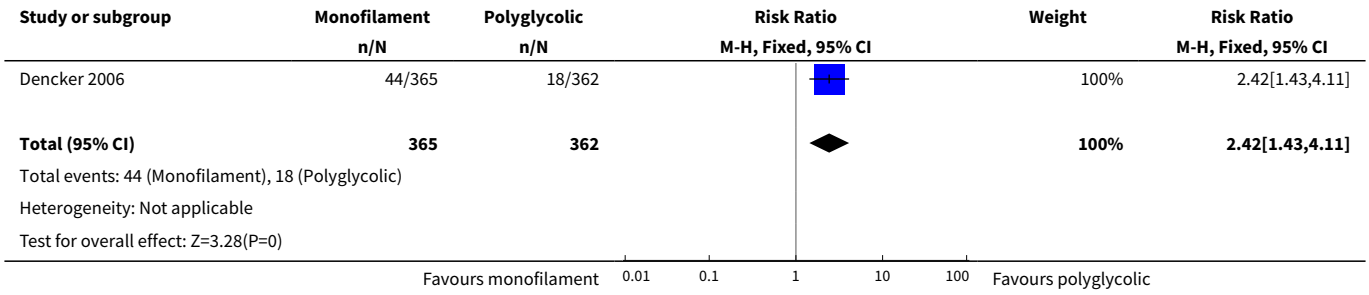
Study or subgroup	Monofilament n/N	Polyglycolic n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Dencker 2006	72/357	50/348		100%	1.4[1.01,1.95]
Total (95% CI)	**357**	**348**		**100%**	**1.4[1.01,1.95]**
Total events: 72 (Monofilament), 50 (Polyglycolic)					
Heterogeneity: Not applicable					
Test for overall effect: Z=2.02(P=0.04)					



Analysis 4.3. Comparison 4 Monofilament versus standard polyglycolic sutures, Outcome 3 Long-term pain: mean pain scores at 8 - 12 weeks.



Analysis 4.4. Comparison 4 Monofilament versus standard polyglycolic sutures, Outcome 4 Wound problems at 8 - 12 weeks: women seeking professional help for problem with perineal repair.



APPENDICES

Appendix 1. Methods used in earlier versions of the review

The trials were assessed according to the following four main criteria:

1. adequate concealment of treatment allocation (e.g. opaque sealed numbered envelopes);
2. method of allocation to treatment (e.g. by computer randomisation, random number tables or by quasi-randomisation methods such as alternation or medical record numbers);
3. adequate documentation of how exclusions were handled after treatment allocation - to facilitate intention to treat analysis;
4. adequate blinding of outcome assessment.

Letters were used to indicate the quality of the included trials, for example A was used to indicate a trial which has a high level of quality in which all the criteria were met; B was used to indicate that one or more criteria were partially met or if it is unclear if all the criteria were met and C was used if one or more criteria were not met (Mulrow 1997). We independently assessed the methodological quality of each individual trial and collected details of method of treatment allocation, randomisation, blinding of outcome assessment, handling of exclusions and whether an intention to treat analysis was performed. If any of the above data were not available in the publication or if it was unclear if the criteria were met, it was planned that additional information would be sought from the trialists. However, no additional information was obtained. Included trial data were processed as described by Chalmers et al (Chalmers 1989).

Data were entered directly from the published reports into the Review Manager software (RevMan) and the second reviewer (Richard Johanson) checked the accuracy of the entered data. Where data were not presented in a suitable format for data entry, or if data were missing, additional information was sought from the trialists by personal communication in the form of a letter or telephone call. The subset of data for the Mahomed and Grant trial (Mahomed 1989) was obtained by Professor Adrian Grant for the Pre-Cochrane review in 1993 and is presented in a similar format in 'Effective Care in Pregnancy and Childbirth' (Grant 1989). Missing data from the Olah (Olah 1990) trial were obtained in witting from Karl Olah indirectly via Professor Grant.

Statistical analysis was undertaken using the RevMan software for calculation of the treatment effect as represented by the odds ratio, proportional and absolute risk reductions.

Analysis was performed using the Peto method for odds ratio.

A sensitivity analysis was performed and it was reassuring to find that the treatment effect still held when the poorer quality trials were excluded.

WHAT'S NEW

Date	Event	Description
9 November 2009	New search has been performed	Search updated. In addition to the eight studies included in previous versions of the review, we have included 10 new studies (Dencker 2006; Gemynthe 1996; Greenberg 2004; Kettle 2002; Leroux 2006; McElhinney 2000; Nikolov 2006; Saint 1993; Spencer 1986; Upton 2002). We have excluded another four studies (Gaasemyr 1977; Hemsley 1997; Marques 2001; Uslu 1992). The updated review uses updated methods, examines a broader range of suture materials (including fast-absorbing synthetic materials) and includes results for new comparisons.
9 November 2009	New citation required and conclusions have changed	There is new evidence on synthetic suture materials; rapidly absorbing materials may reduce the need for suture removal.

HISTORY

Protocol first published: Issue 1, 1997
Review first published: Issue 3, 1997

Date	Event	Description
16 June 2008	Amended	Converted to new review format.
1 July 1999	New search has been performed	Search updated. One new trial identified - Mackrodt 1998.

CONTRIBUTIONS OF AUTHORS

The original review was carried out by Chris Kettle and commented on by Richard Johanson. All entered data were double checked for accuracy by Richard Johanson and Chris Kettle.

In the 2009 update, Chris Kettle and Therese Dowswell carried out data extraction, assessed risk of bias, conducted analyses and drafted the text. Khaled Ismail commented on drafts.

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

C Kettle was the lead investigator for one of the included studies (Kettle 2002) and was not involved in the assessment of the trial or the data extraction.

SOURCES OF SUPPORT

Internal sources

- The University of Liverpool, UK.

External sources

- Keele University, UK.
- North Staffordshire Hospital Trust, UK.
- National Institute for Health Research, UK.

  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 background and methods sections have been updated.

INDEX TERMS

Medical Subject Headings (MeSH)

*Sutures; Absorbable Implants; Catgut; Delivery, Obstetric [*adverse effects]; Episiotomy [adverse effects]; Perineum [*injuries] [surgery]; Polyglactin 910; Polyglycolic Acid; Randomized Controlled Trials as Topic

MeSH check words

Female; Humans; Pregnancy