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Absorbable synthetic versus catgut suture material for perineal repair

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Abstract

Background—Approximately 70% of women will experience some degree of perineal trauma following vaginal delivery and will require stitches. This may result in perineal pain and superficial dyspareunia.

Objectives—The objective of this review was to assess the effects of absorbable synthetic suture material as compared with catgut on the amount of short and long term pain experienced by mothers following perineal repair.

Search strategy—We searched the Cochrane Pregnancy and Childbirth Group's Trials Register.

Selection criteria—Randomised trials comparing absorbable synthetic (polyglycolic acid and polyglactin) with plain or chromic catgut suture for perineal repair in mothers after vaginal delivery.

Data collection and analysis—Trial quality was assessed independently by two reviewers. Data were extracted by one reviewer and checked by the second reviewer.

Main results—Eight trials were included. Compared with catgut, the polyglycolic acid and polyglactin groups were associated with less pain in first three days (odds ratio 0.62, 95% confidence interval 0.54 to 0.71). There was also less need for analgesia (odds ratio 0.63, 95% confidence interval 0.52 to 0.77) and less suture dehiscence (odds ratio 0.45, 95% confidence interval 0.29 to 0.70). There was no significant difference in long term pain (odds ratio 0.81, 95% confidence interval 0.61 to 1.08). Removal of suture material was significantly more common in the polyglycolic acid and polyglactin groups (odds ratio 2.01, 95% confidence interval 1.56 to 2.58). There was no difference in the amount of dyspareunia experienced by women.

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CONTRIBUTIONS OF AUTHORS The review was carried out by Chris Kettle and peer reviewed by Richard Johanson. All entered data were double checked for accuracy by Richard Johanson and Chris Kettle.

*Deceased

DECLARATIONS OF INTEREST None known.

Authors' conclusions—Absorbable synthetic suture material (in the form of polyglycolic acid and polyglactin sutures) for perineal repair following childbirth appears to decrease women's experience of short-term pain. The length of time taken for the synthetic material to be absorbed is of concern. A trial addressing the use of polyglactin has recently been completed and this has been included in this updated review.

Medical Subject Headings (MeSH)

*Delivery, Obstetric; *Sutures; Catgut; Perineum [injuries; surgery]; Polyglactin 910; Polyglycolic Acid

MeSH check words

Female; Humans; Pregnancy

BACKGROUND

The main goal of midwives and obstetricians should be to provide safe, effective and efficient women centred care. In achieving this, their practice should be based on scientific evidence rather than tradition, personal preference or simple cost considerations. Practice should focus on outcomes that are important to women. Long-term complications after perineal trauma and repair following vaginal delivery are common, however, there have been very few good quality randomised controlled trials in this area. Maybe, as Grant (Grant 1986) stated, this research is seen as 'unglamorous' and not scientific enough to attract the necessary funding required for this work to be carried out.

There appears to be only a limited awareness, amongst most professionals, of the extent of postpartum morbidity experienced by women following perineal repair. The morbidity is not considered to be life threatening, however it does affect a large proportion of women in this country and indeed throughout the world. In fact 750,000 women give birth each year in the United Kingdom and it is estimated that 69% will sustain some degree of perineal trauma and will require stitches (Sleep 1984). The majority of these women will have short term perineal pain and as many as 20% will continue to have long term problems such as superficial dyspareunia (Enkin 1995). The maternal morbidity associated with perineal repair can have a major impact on the woman's general health causing her much discomfort and distress. This in turn can affect the woman's ability to care for her new-born infant and other members of her family and may ultimately lead to a complete marital breakdown (Sleep 1991).

The type of suturing material used for perineal repair following childbirth may have an effect on the amount of pain and superficial dyspareunia experienced by women both in the short and long term. Catgut is manufactured from collagen derived from healthy mammals 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. Chromic catgut suture material is treated in order to slow down the digestive process and decrease the inflammatory reaction. Polyglycolic acid (Dexon) and polyglactin (Vicryl) are synthetic materials and they are both reported to cause less tissue

reaction because they are absorbed by hydrolysis. However, the total absorption rate of polyglactin is reported to be considerably shorter than polyglycolic acid regardless of the gauge of material (90 versus 120 days) (Craig 1975).

The aim of this review is to examine the available evidence and to determine if there is any clear scientific evidence that the type of suturing materials used does influence the amount of postpartum morbidity experienced by women following perineal repair, both in the short and long term.

This systematic review includes eight 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 and polyglactin) versus catgut suture material on the amount of short and long term maternal morbidity experienced by women following perineal repair. The evidence collated in this review will enable 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; extent of superficial dyspareunia; removal of suture material; re-suturing of wound; dehiscence.

METHODS

Criteria for considering studies for this review

Types of studies—All identified, relevant randomised controlled trials which compare polyglycolic acid or polyglactin with catgut have been included in this review. However, none of the included trials actually compared polyglactin (Vicryl) with chromic catgut or catgut suture material. The inclusion criteria is quite broad due to the small number of controlled trials available in this area, all of which have variable methodological quality.

All of the trials included have been assessed according to the method of treatment allocation, randomisation, blinding of outcome assessment and handling of exclusions.

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 polyglycolic acid and polyglactin versus plain catgut and chromic catgut suture material.

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

The main outcome measures include: short term pain; analgesia use; removal of suture material; resuturing; extensive dehiscence; long term pain; superficial dyspareunia.

Consumer views regarding what outcomes they would expect from this review were sought 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 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.

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. monthly searches of MEDLINE;
3. handsearches of 30 journals and the proceedings of major conferences;
4. weekly current awareness search of a further 36 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 'Search strategies for identification of studies' section within the editorial information about the Cochrane Pregnancy and Childbirth Group.

Trials identified through the searching activities described above are given a code (or codes) depending on the topic. The codes are linked to review topics. The Trials Search Co-ordinator searches the register for each review using these codes rather than keywords. We did not apply any language restrictions.

Data collection and analysis

The two reviewers (Chris Kettle and Richard Johanson) 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. All disagreements were resolved by discussion.

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 sub-set 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 writing 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.

RESULTS

Description of studies

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

Included trials: Beard 1974; Livingstone 1974; Rogers 1974; Banninger 1978; Roberts 1983; Mahomed 1989; Olah 1990; Mackrodt 1998.

Six of the eight 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); one trial (Mackrodt 1998) compared polyglactin (Vicryl) to chromic catgut and the (Livingstone 1974), compared plain catgut to Dexon.

There was considerable variation in the reviewed trials between gauge of suture material and size of needle, (see 'Characteristics of Included Studies' 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; in five of the trials a continuous stitch was used to repair the vaginal trauma with interrupted stitches to appose the muscle layers. Four of the trials used transcutaneous, interrupted stitches to appose the perineal skin; two trials used a continuous subcuticular stitch to appose the perineal skin; one of the trials (Olah 1990) used a continuous non-locking stitch throughout the repair with a continuous subcuticular stitch to appose the skin; the Mahomed trial (Mahomed 1989) used interrupted transcutaneous and continuous subcuticular stitches to appose the skin (approximately 50/50 in each group). The women participating in the Ipswich Childbirth Study (Mackrodt 1998) were randomly assigned to either a two stage (skin left unsutured) or a three stage (skin sutured) technique of perineal repair. In the group that were 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. Only one trial (Rogers 1974) did not describe which suturing technique was used.

Excluded trials: Tompkins 1972; Wikoff 1992; Ketcham 1994. See Characteristics of Included and Excluded Studies.

Risk of bias in included studies

The methodological qualities of the eight trials included in this review were found to be inconsistent. Therefore, we decided to rate all of them as 'B' in that one or more criteria were partially met, (Mulrow 1997). Only three trials used sealed opaque envelopes for random allocation with adequate concealment of treatment allocation (Mackrodt 1998; Mahomed 1989; Rogers 1974); two trials used quasi-random allocation (Banninger 1978; Olah 1990); one trial used 'lottery cards' (Livingstone 1974) and two trials did not describe their method of 'random allocation' (Beard 1974; Roberts 1983). In five of the included trials it was not clear if treatment allocation was concealed and only the Mahomed (Mahomed 1989) and Mackrodt (Mackrodt 1998) trials demonstrated that analysis was by 'intention to treat'. In the Roberts 1983 trial, eighteen (9.5%) of the women who were entered into the trial were excluded from the analysis because they were unable to complete the study due to lost tablets or early discharge from hospital. All women who were randomised in the other seven trials were included in the analysis, however in the Mahomed 1989 study, twenty-two randomisation envelopes were unaccounted for.

Two of the trials (Beard 1974; Livingstone 1974) claimed that outcome assessment was 'blinded' due to the different suturing materials (catgut and Dexon) 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 24-48

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 both methods of perineal repair. The other four remaining trials did not state if any attempt was made to 'blind' outcome assessment.

Out of the eight included studies only two trials (Mackrodt 1998; Mahomed 1989; Banninger 1978) provided any long term follow-up. Unfortunately, only 46/153 women in the Banninger trial returned for assessment at three months after delivery as compared to 465/538 response rate to a postal questionnaire in the Mahomed trial (Mahomed 1989) and 1644/1780 in the Mackrodt trial (Mackrodt 1998).

Effects of interventions

Short term pain—All of the trials showed consistent results of lower rates of pain in the absorbable synthetic groups. However, in four of the trials (Beard 1974; Roberts 1983; Mahomed 1989; Olah 1990) it was not possible to demonstrate statistically significant differences between the groups. Nevertheless, the meta analysis revealed that the odds of experiencing short term pain are lower in the absorbable synthetic groups than in the catgut group.

Analgesia use—Only five of the trials (Banninger 1978; Beard 1974; Mahomed 1989; Roberts 1983; Mackrodt 1998) presented data regarding analgesia use in the immediate postpartum period. The results showed that women who had their perineal trauma repaired with polyglycolic acid or polyglactin had reduced analgesia requirements and therefore one could presume that they experienced less pain.

Suture dehiscence - up to day 10—Superficial suture dehiscence was reported in four trials; results from the Beard (Beard 1974), Livingstone (Livingstone 1974) and Mackrodt (Mackrodt 1998) trials revealed no statistical significance between the two groups. However, the chromic catgut group in the Banninger (Banninger 1978) trial had a significantly higher rate of suture dehiscence than the polyglycolic acid group (37/71 against 12/77). From the paper, it is not possible to explain the extremely high rates (52%) of suture dehiscence which occurred in the Banninger study. No cases of suture dehiscence were reported in the Olah 1990 trial up to day five. Overall perineal repair with absorbable synthetic material resulted in less suture dehiscence.

Resuturing of wound - up to day 10—Only three trials reported cases which required resuturing; two cases in the Banninger 1978 trial and three cases in the Mahomed 1989 trial, all of which were in the chromic catgut groups. The Mackrodt (Mackrodt 1998) trial reported 3/829 in the polyglactin group required resuturing as compared to 10/835 in the chromic catgut group.

Long term pain - reported at three months after delivery—Only the Mahomed (Mahomed 1989) and Mackrodt (Mackrodt 1998) trials provide any data regarding long term pain. At three months after delivery results revealed that there was no significant difference in the amount of reported pain in both the absorbable synthetic and catgut groups

(56/228 against 56/227) in the Mahomed (Mahomed 1989) trial and (67/829 against 84/835) in the Mackrodt (Mackrodt 1998) trial.

Dyspareunia - reported at three months after delivery: Only three trials (Mahomed 1989; Banninger 1978; Mackrodt 1998) included any data on dyspareunia at three months after delivery and this was similar in both groups.

Removal of suture material - up to three months after delivery—The Mahomed (Mahomed 1989) and Mackrodt (Mackrodt 1998) trials provided data regarding the removal of suture material in the postpartum period. This was more common in the absorbable synthetic group 77/230 against 27/232 within the first ten days postpartum in the Mahomed (Mahomed 1989) trial and 51/884 against 42/887 in the Mackrodt (Mackrodt 1998) trial. In the Mahomed (Mahomed 1989) trial, absorbable suture materials removed up to three months post delivery (94/232 against 48/233) women and 97/829 against 60/835 in the Mackrodt (Mackrodt 1998). This was reported in the Mahomed (Mahomed 1989) trial to be due to 'irritation' and 'tightness'.

DISCUSSION

Six of the trials included in this review compared polyglycolic acid (Dexon) with chromic catgut, one trial (Livingstone 1974) compared plain catgut with Dexon and the eighth trial (Mackrodt 1998) compared polyglactin (Vicryl) to chromic catgut. The same suture material was used for all layers of the perineal repair in each of the groups. However, there is clinical heterogeneity among the trials in that they differ considerably in terms of suturing technique, calibre of material, size of needle, skill of operators, duration of follow-up and outcomes assessed. Furthermore, there are other possible factors that might influence postpartum perineal pain and dyspareunia besides the suturing technique or materials used which must be taken into account when assessing the evidence. These include 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 allowing a tear (Thacker 1983; Sleep 1984; Glazener 1995; Woolley 1995; Graham 1997).

There was also methodological differences in the randomisation processes and concealment of treatment allocation (see table of 'Characteristics of Included Studies' for details).

In the analysis of the Mahomed 1989 trial there was no significant difference between the two groups in short term pain. However, the effects across the trials were generally consistent and the differences between them are compatible with random error. The confidence intervals in five of the trials included in the analysis were wide reflecting the small number of participants.

The meta-analysis of the data from the included trials provides significant evidence that absorbable suture material (Dexon and Vicryl) is associated with less short term pain, reduction in the use of analgesia and less suture dehiscence. However, the long term effects of this material are less clear.

AUTHORS' CONCLUSIONS

Implications for practice

The evidence produced by this review indicates that the use of Dexon and Vicryl for perineal repair following childbirth is associated with less short term pain but is associated with increased rates of removal. The limited data, provided by the trials regarding long term effects, do not provide any evidence of a clinically important difference between groups in terms of pain and dyspareunia. The overall results of this review indicate that absorbable synthetic materials should be used for all layers of the repair but there are still concerns regarding the frequent need for removal in the postpartum period.

Implications for research

Research into the repair of perineal trauma remains surprisingly neglected and such work, as stated by Grant 1989 should be paramount if the extent of morbidity, both short and long term, is to be reduced for women throughout the world. Given the large numbers of women who require perineal repair and the amount of women who suffer morbidity, further research should be encouraged to minimise these problems. Concern still lies with the need to remove absorbable synthetic materials such as Dexon and Vicryl. Further research into alternative suture materials is urgently needed and this must include long term follow-up. It is vital that any new suture material should be evaluated in a randomised controlled trial before it is widely adopted.

Acknowledgments

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Professor Adrian Grant compiled the first version of this review and he provided us with the additional unpublished data from the Olah 1990 trial which he had previously obtained in writing from Karl Olah.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- Keele University, UK.
- North Staffordshire Hospital Trust, UK.

CHARACTERISTICS OF STUDIES

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

Banninger 1978

Methods	Allocated by 'alternating sequence' - quasi experimental. No information available regarding concealment of treatment allocation or whether analysis was by 'intention to treat'.
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Outcome assessment - not blinded. All participants entered into the trial were included in the analysis		
Participants	153 women having an episiotomy without complications. Method of delivery - spontaneous vaginal with cephalic presentation. Parity - primigravidae. Mean age - Group A = 24.1; Group B = 25.2. Operator - doctors.	
Interventions	Method of repair - described as below. Participants divided into 2 groups:- Group A (n =73) - vagina, perineal muscle and skin sutured using the interrupted technique with chromic catgut No. 0 on a 60mm round bodied needle. Group B (n = 80) - vagina, perineal muscle and skin sutured using the interrupted technique with polyglycolic acid (Dexon) No. 2/0 on a 60mm round bodied needle	
Outcomes	INCLUDED IN ANALYSIS 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	Setting - Switzerland. Method of repair - described. Exclusion criteria - described. Only one third of participants followed-up at 3 months. Observation of cosmetic results at 3 months - no data available. Participant inclusion criteria described.	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Beard 1974

Methods	Allocated randomly to two groups - method not described. No information available regarding concealment of treatment allocation or whether analysis was by 'intention to treat'. Not convinced that assessment was 'double-blind'. All participants entered into the trial were included in the analysis
Participants	200 women having medio-lateral episiotomies. Method of delivery - spontaneous vaginal. Parity - primigravida and multigravida included (similar number in each group). Mean age - not specified. Operator - resident obstetric officers in second obstetric appointment
Interventions	Method of repair - 'standard' with subcuticular suture to perineal skin. Participants divided into 2 groups:- Group 1 (n = 100) women sutured with polyglycolic acid (Dexon) 2/0 on a 40mm round bodied atraumatic needle. Group 2 (n = 100) women sutured with chromic catgut 2/0 on a 55mm loose round bodied needle
Outcomes	INCLUDED IN ANALYSIS Short term pain - day 3 Analgesia - day 3 Suture dehiscence - day 3 NOT INCLUDED IN ANALYSIS Inflammation - days 1, 2 and 3 Cost analysis of suturing materials and needles used.
Notes	Setting - Queen Charlotte Maternity Hospital, London. Method of repair - 'standard' (technique not described fully - subcuticular to skin). Exclusion criteria - women with lacerations or those booked for 48 hour discharge. Double-blind may have been possible because a subcuticular stitch was used to appose skin and therefore sutures should not be visible
<i>Risk of bias</i>	

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Livingstone 1974

Methods	Allocated by quasi-randomisation - 'drawing lottery cards'. No information available regarding concealment of treatment allocation or whether analysis was by 'intention to treat'. Not convinced that 'double-blind' assessment was possible. All participants entered into the trial were included in the analysis
Participants	100 women having a medio-lateral episiotomy (all included in this analysis). Method of delivery - spontaneous vaginal, rotation and forceps, forceps or ventouse. Parity - all primigravidae. Mean age - not specified. Operators - not specified.
Interventions	Method of repair - standard continuous suture of vaginal epithelium and interrupted sutures for muscle layers and skin. Participants divided into 2 groups:- Group 1 (n = 50) sutured with plain catgut No. 1 on a 40mm round bodied needle (vaginal and muscle) and No. 0 plain catgut on a 35mm tapercut needle (skin). Group 2 (n = 50) sutured with polyglycolic acid No. 1 on a 40mm round bodied needle (vaginal and muscle) and No. 0 polyglycolic acid on a 37mm diamond taper needle (skin)
Outcomes	INCLUDED IN ANALYSIS Short-term pain - day 3 Suture dehiscence - day 3 NOT INCLUDED IN ANALYSIS Ease of movement - day 3 Oedema - day 3.
Notes	Setting - Queen Mother's Hospital, Glasgow. Method of repair - 'standard' (method described). Exclusion criteria - women with additional lacerations or extended episiotomy. 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

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Mackrodt 1998

Methods	Allocated randomly using balanced blocks varying in size between 4 and 12 - stratified by type of delivery. Concealed treatment allocation - serially numbered; sealed opaque envelopes containing allocation details, suture material and data sheet. Outcome assessment not fully blinded. Analysis was by intention to treat. Trial design - factorial 2 x 2.
Participants	1780 women having an episiotomy or lacerations (first or second degree). Method of delivery- 1469 women having spontaneous vaginal delivery, 311 women having instrumental delivery. Parity - primigravida and multigravida included (split equally between groups). Mean age - Group A 28.2/Group B - 28.4. Operator - doctors and midwives.
Interventions	Method of repair - randomly assigned to two stage (skin unsutured) or three stage (skin sutured) techniques.

	<p>In the group that had the perineal skin sutured: 26% had subcuticular stitches inserted 72% had interrupted transcutaneous stitches 1% had skin left unsutured 1% had no sutures Equally divided between groups. Group A (n = 889) - sutured with polyglactin 910 (Vicryl 2/0 on 35 mm needle) Group B (n = 891) - sutured with chromic catgut on 40mm needle</p>	
Outcomes	<p>INCLUDED IN ANALYSIS 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 Dyspareunia - 3 months Suture dehiscence - day 10 and 3 months.</p>	
Notes	<p>Setting - Ipswich Hospital (NHS Trust), Ipswich. Method of repair - described operator could 'choose' method of repair for perineal skin (subcutaneous or interrupted). Unable to fully blind outcome assessment due to obvious difference in methods and materials. 93% follow-up at 3 months. All envelopes accounted for. Interim analysis carried out.</p>	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Mahomed 1989

Methods	<p>Allocated randomly - random number tables. Concealed treatment allocation - serially numbered, sealed opaque envelopes, (envelopes contained suture material and instructions for method of repair). Acknowledged that fully blind assessment was not possible due to obvious differences in suture materials and techniques. Analysis by 'intention to treat'. Modified factorial - 2 × 3 × 2 design.</p>
Participants	<p>538 women needing perineal repair following delivery, (all tears and episiotomies included). This was a sub-group 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 multiparae. Mean age - 26.0/26.1 Operators - midwives, senior house officers, registrars, consultants, medical students</p>
Interventions	<p>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. Group 1 (n = 275) sutured with polyglycolic acid (Dexon plus) No. 2/0 on a 30mm, half-circle multipurpose needle. Group 2 (n = 263) sutured with chromic catgut No. 2/0 on a 35mm, half-circle tapercut needle</p>
Outcomes	<p>INCLUDED IN ANALYSIS Short-term pain - day 3 Long-term pain - 3 months Analgesia - up to day 7 Resuturing - up to day 7 Dyspareunia - 3 months Removal of suture material - up to 3 months.</p>

Notes
 Setting - Southmead Hospital, Bristol.
 Method of repair - method described.
 No interim analysis.
 Ethics committee approval.
 22 envelopes were unaccounted for.
 Preset trial size had 80% chance of detecting significant clinical differences.
 86% response rate at 3 months.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Olah 1990

Methods	Allocated by quasi-randomisation - case note numbers (odd/even numbers). No information available regarding concealment of treatment allocation or whether analysis was by 'intention to treat'. Outcome assessment - not blinded. All participants entered into the trial were included in the analysis
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Participants	120 women with an episiotomy. Method of delivery - instrumental delivery (forceps or ventouse). Parity - multips and primips. Mean age - 26.5 catgut group and 27.0 polyglycolic acid group. Operators - single operator familiar with technique.
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Interventions	Method of repair - continuous non-locking stitch with subcuticular to skin (similar method as described by Isager-Sally 1986). Participants divided into 2 groups:- Group 1 (n = 60) sutured with chromic catgut 0, needle size not specified. Group 2 (n = 60) sutured with polyglycolic acid 0, needle size not specified
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Outcomes	INCLUDED IN ANALYSIS Short-term pain - day 3 and 5 Dehiscence of wound - day 5 Removal of suture material - day 5 Resuturing - day 5 NOT INCLUDED IN ANALYSIS Oedema - day 5 Bruising - day 5.
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Notes	Setting - Selly Oak Hospital, Birmingham. Method of repair - described. Exclusion criteria - not described. No long-term follow-up. Additional information obtained so that trial could be included in review
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Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Roberts 1983

Methods	Allocated by a 'randomisation schedule' - method not described. No information available regarding concealment of treatment allocation or whether analysis was by 'intention to treat'. Outcome assessment - not blinded. 18 (9.5%) participants excluded from analysis - reasons stated
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Participants	190 women with an episiotomy. Method of delivery - spontaneous or forceps vaginal deliveries. Parity - not stated.
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	Mean age - not specified. Operators - not specified.	
Interventions	Method of repair - continuous suture to close vaginal epithelium and interrupted sutures for muscle layers and skin (buried knots). Participants divided into 2 groups:- Group 1 (n = 84) vagina and muscle sutured with chromic catgut 1/0 and skin sutured with plain catgut 2/0 using the interrupted technique and buried knots. Group 2 (n = 88) vagina and muscle sutured with Dexon 1/0 and skin sutured with Dexon 2/0 using the interrupted technique and buried knots	
Outcomes	INCLUDED IN ANALYSIS Short-term pain - day 3 Analgesia - day 3 NOT INCLUDED IN ANALYSIS Bruising - day 2 and 4 Oedema - day 2 and 4 Mobility - up to day 10.	
Notes	Setting - Stobhill General Hospital, Glasgow. Method of repair - described. Assessed at home on tenth day by district midwife.	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Rogers 1974

Methods	Allocated randomly - using 'random technique'. Concealed treatment allocation - suture packs sealed in plain envelopes (method not described fully). No information available whether analysis was by 'intention to treat'. Outcome assessment - not blinded. All participants entered into the trial were included in the analysis	
Participants	600 women having median and medio-lateral episiotomies (episiotomies with lacerations included) (all included in this analysis). Method of delivery - not clear, defined as complicated or not complicated. Parity - not specified. Mean age - 23.45 group 1 and 22.81 group 2. Operators - not specified.	
Interventions	Method of repair - not described. Participants divided into 2 groups:- Group 1 (n = 299) sutured with polyglycolic acid 000 (3/0), needle size not specified. Group 2 (n = 301) sutured with chromic catgut 000 (3/0), needle size not specified	
Outcomes	INCLUDED IN ANALYSIS Short-term pain - period of time not specified NOT INCLUDED IN ANALYSIS Pain in relation to type of episiotomy Dehiscence of wound - 6 weeks postpartum, (unsure how this was assessed/followed-up)	
Notes	Setting - Madigan Army Centre, Washington, USA. Method of repair - not described. Exclusion criteria - not described. Presume that all women entered into trial were included in the study. Period of follow-up not specified.	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

mm = millimetre

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Ketcham 1994	Not a randomised controlled trial. The methodological quality of the trial was poor in that no scientific principles were applied to the randomisation process and therefore, results could be subject to bias
Tompkins 1972	Unable to obtain additional information such as method of randomisation, or data presented in a suitable form to include this study in this review
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

Polyglycolic acid vs catgut

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Short term pain	8		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
1.1 Pain - day 3 or less if data is not available	8	3642	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.62 [0.54, 0.71]
1.2 Pain - day 4-10	3	2044	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.71 [0.58, 0.87]
2 Analgesia use - up to day 10	5	2820	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.63 [0.52, 0.77]
3 Suture dehiscence - up to day 10	5	2339	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.45 [0.29, 0.70]
4 Resuturing of wound - up to 3 months	4	2402	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.26 [0.10, 0.66]
5 Long-term pain - at 3 months postpartum	2	2129	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.81 [0.61, 1.08]
6 Dyspareunia - at 3 months postpartum	3	2175	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.94 [0.75, 1.19]
7 Removal of suture material - up to 3 months	2	2129	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.01 [1.56, 2.58]

HISTORY

Protocol first published: Issue 1, 1997

Review first published: Issue 3, 1997

Date	Event	Description
1 July 1999	New search has been performed	Search updated. One new trial identified - Mackrodt 1998.

WHAT'S NEW

Last assessed as up-to-date: 30 June 1999.

Date	Event	Description
16 June 2008	Amended	Converted to new review format.

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* Indicates the major publication for the study

PLAIN LANGUAGE SUMMARY

Absorbable synthetic versus catgut suture material for perineal repair

To be prepared.