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Does perineal suturing make a difference? The SUNS trial

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Objective To examine differences in outcome between primiparous women who do and who do not have suturing to first or second degree perineal lacerations sustained during spontaneous vaginal births after 37 weeks of gestation.

Design Parallel group randomised controlled trial.

Setting Bellshill Maternity Hospital, Lanarkshire, and St John's Hospital, Livingston.

Population Primigravidae with perineal lacerations following spontaneous birth.

Methods One thousand and three hundred fourteen women were recruited to the trial antenatally from whom 74 were randomised either to be sutured or not sutured immediately after giving birth. Randomisation was stratified by degree of tear.

Main outcome measures Using standardised measures, perineal pain and healing were measured at 1 and 10 days and 6 weeks postpartum. In addition, postnatal depression was assessed at 10 days and 6 weeks postpartum.

Results Findings indicated that there were no significant differences between the groups with regard to pain or depression but there were differences with regard to healing. At six weeks, there remained a significant difference in wound closure between the groups, with women who had not been sutured having poorer wound approximation.

Conclusions While acknowledging the small sample size, the results are nonetheless important, showing persistent evidence of poorer wound approximation in those women who had not been sutured. Practitioners need to review the present practices of not suturing perineal lacerations until research examining the longer term implications is undertaken.

INTRODUCTION

Care of the perineum during and after childbirth has been a topic of considerable interest to all involved for many years. As long ago as 1855, a German obstetrician kept meticulous notes commenting that 'although all childbirth attendants know that perineal tears are not life threatening, in many cases they are a sorry sight'[1].

A considerable amount of research has been carried out in the area of perineal care particularly in relation to the practice of performing episiotomy and to the methods of suturing.

For example, on the issue of routine episiotomy, researchers unanimously agree that it is of little benefit to women[2–5]. This was confirmed in a meta-analysis[6], which provided good evidence that avoiding episiotomy decreased subsequent perineal trauma. Such research has clearly influenced the practice of both obstetricians and midwives with episiotomy rates declining dramatically in the last 10 years in western Europe.

In clinical practice, trauma to the perineum has usually been sutured. Other researchers therefore have focussed on the most effective materials and method for this purpose. Three systematic reviews have demonstrated that a subcuticular continuous suture of polyglycolic acid will heal better and be associated with less short term pain than other methods[7–9]. However, it has been cautioned[10] that research needs to be conducted into the long term outcomes of such recommendations.

Other researchers have published the results of their studies into the development of tools for assessing perineal trauma. Despite recent attempts to develop such tools based on photographs[11], the scoring system that remains most often used in research is the REEDA tool[12]. This tool assesses the redness, oedema, ecchymosis, discharge and approximation associated with perineal trauma following childbirth. As a scientific tool, the REEDA has merit in that scoring relies on precise measurement of the degree of trauma in millimetres. It also provides data describing specifically the perineal trauma associated with each individual woman.

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More recently, clinicians have been questioning the need for the suturing of perineal lacerations and calling for research into this area[13,14]. In an audit by Head[15], 75 women, some of whom were sutured and others of whom were not, were surveyed with regard to pain and postpartum healing. Women without perineal sutures appeared to experience less pain, with a large proportion of women 'feeling comfortable' earlier and sexual intercourse being resumed earlier. There were no details of how wound healing or pain were measured, thereby further reducing the value of the non-randomised study.

Gordon *et al.*[16] evaluated, by means of a randomised controlled trial, a two-stage perineal repair compared with a traditional three-stage repair. While no difference in pain between groups was noted at 24–48 hours and day 10 postpartum, women allocated into the two stage repair group were less likely to report tight stitches at both the initial time point and at day 10. There was a significant difference in clinically assessed gaping at 24–48 hours, which was reduced by day 10. There was no difference in the rate of perineal breakdown. No mention is made of the scale used to assess pain or whether the degree of gaping was estimated visually or actually measured by the midwife. By three months, women in the two stage repair reported less pain in the preceding week, and more women had resumed pain-free intercourse with significantly fewer reporting dyspareunia. When the results were stratified by suture material, mode of birth and the operator's method of skin closure, there was no clear differential effect in respect of pain at two days, upon removal of sutures and failure to resume pain-free intercourse. While this study does highlight some differences in pain, the use of a standardised approach to skin suturing may have added more depth and validity to the results.

Only one trial comparing suturing with non-suturing of perineal lacerations was found[17]. This study compared perineal and vaginal healing and pain in 40 primiparous women who were sutured, with 40 who were not. Assessments were carried out at two to three days and eight weeks postpartum. The authors concluded (p. 83) that 'lacerations that were left to heal spontaneously healed as well as the sutured ones; that they healed at the same time and with as much or as little discomfort'. However, as non-standardised data collection instruments and procedures were utilised, it is hard to ascertain the rigour of this study. Additionally, this study used a specially trained team of midwives to administer the intervention, thereby limiting the generalisability of the findings.

The objective of the present study was to examine, by parallel group randomised controlled trial, differences in outcome between primiparous women who did and who did not have suturing to first or second degree perineal lacerations sustained during spontaneous vaginal births after 37 weeks of gestation.

METHODS

Participants in this research were primiparous women who had given birth spontaneously to singleton, cephalic presenting babies after 37 weeks of gestation and who had sustained first or second degree perineal lacerations. Excluded from the trial were women with pre-existing medical conditions that may adversely affect healing, women who required assisted births, women who developed pyrexia and women who developed primary postpartum haemorrhages.

The main study site was Bellshill Maternity Hospital, Lanarkshire; however, St John's Hospital, Livingston, participated from July 2000. Ethical approval was granted by the Health Boards concerned, and permission from the NHS Trusts to access potential participants was obtained.

The primary outcome measures were perineal pain, measured using McGill Pain Questionnaire[18] and Visual Analogue Scales[19], and perineal healing measured using the REEDA tool[13] at 1 and 10 days and 6 weeks postpartum. Post-natal depression was a secondary outcome and was measured using the Edinburgh Postnatal Depression Scale[20] in women at 10 days and 6 weeks postpartum. For all measures, lower scores indicate better outcome. Data on potential confounding variables, such as age, post code, gestation, length of labour, length of second stage, length of active pushing, weight of baby and non-pregnant weight of participant, were gathered for each woman.

It was calculated that a sample size of 340 would be required to detect clinically significant differences in pain and wound healing at the 1% level of significance with 80% power[21]. Since no controlled trials comparing suturing and non-suturing existed at the study outset, the effect sizes for these calculations were determined from studies in related areas using the same outcome measures and from a non-randomised pilot study carried out by the authors.

A pool of random numbers, sufficient for the intended size of the trial, was computer-generated by SH. Even and odd numbers were assigned the instructions 'suture' and 'not suture', respectively. These instructions, in their original random order, were transferred to cards. Each card was then placed in an opaque envelope and sealed. This process was used to produce separate supplies of randomisation envelopes for first and second degree tears, to facilitate stratification by degree of tear.

The sealed, opaque envelopes, were held by a neighbouring hospital switchboard where staff operated the randomisation. The labour ward midwife wishing to randomise an eligible woman telephoned this switchboard, informed them of the degree of tear and received instructions regarding whether to suture or not.

Healthy primiparous women with singleton pregnancies were approached by a midwife recruiter at an antenatal clinic and given an introductory information sheet. Although the research team realised there would be many

women recruited who would be ineligible finally to enter the trial, it was considered unethical to recruit women in labour or immediately after they had given birth. Written consent was therefore sought in the antenatal period. After giving birth, those women who remained eligible were entered into the study and randomly allocated to the suturing or non-suturing group.

In the intervention group, suturing was carried out in accordance with hospital protocols in a standardised manner by the midwife attending the birth. Dexon was used as follows:

1. Continuous suture to the posterior vaginal wall
2. Intermittent sutures to the muscle layer
3. Continuous subcutaneous sutures to the perineal skin.

Given the nature of the intervention, it was not possible to blind participants, hospital or research staff to a woman's group allocation.

Analysis was carried out using the SPSS and Minitab packages. A 5% level of significance was used throughout.

Differences in outcome scores between the sutured and non-sutured group were initially tested using the two-sided Mann Whitney *U* test. Logistic regression was used to examine the effect on dichotomous outcomes (dichotomised REEDA component scores) of suturing group and other possible explanatory variables simultaneously (age of woman, length of gestation, tear classification, weight of baby, length of first stage labour, length of second stage labour, Carstairs Deprivation Category). Repeated measures analysis (using the SPSS Generalised Linear Model procedure) was performed on the continuous variables to assess the effects of time (day 1, day 10 and six weeks), suturing group and their interaction, alongside the other possible explanatory variables listed previously; the significance of the associated F tests is reported. All these analyses were prespecified in the research proposal.

RESULTS

As shown in Fig. 1, the total number of woman recruited to the study was 1314 with 74 being randomised; 33 (44.6%) were randomised to the sutured group and 41 (55.4%) to the non-sutured group. The imbalance was due to the effect of the smaller than expected sample size on the randomisation process. By 10 days, 73 women (98.6%) (33 sutured and 40 not sutured) remained in the study, and by 6 weeks, 70 (94.6%) (33 and 37, respectively) remained in the study showing a high retention rate.

Study recruitment took place from January 1999 to September 2000 and data collection from March 1999 to December 2000.

Analysing separately the women with first and second degree tears, there were no significant differences between those who were sutured and those who were not in terms of age, level of deprivation as measured by the Carstairs Deprivation Category or booking weight (Table 1). Neither were there significant differences between the groups in length of labour (or any stage of labour) nor birthweight (Table 1).

Numbers varied with time point and outcome measure and are indicated in the results table.

There was no significant difference in total McGill Pain Questionnaire score between the sutured and non-sutured groups at day 1, day 10 or six weeks (Table 2). Repeated measures analysis showed a significant decrease in scores with time, but this decrease was similar in both groups, confirming that there was no significant effect of suture group. There were no significant differences between groups in any of the McGill Pain Questionnaire subscores, at any time point (results not shown). There were no significant differences between groups in Visual Analogue Scale pain scores at any time point (Table 2).

There were no significant differences in the use of analgesia or other treatments (ice packs, bed baths, baths, showers, ultrasound, honeytule, arnica and calendula) for perineal pain at any time point (results not shown).

The REEDA score for wound approximation score was significantly lower (better) in the sutured group at day 1, day 10 and 6 weeks, and the total REEDA score was significantly lower in the sutured group at 6 weeks (Table 2). At six weeks, there was a significantly higher ($P = 0.001$) proportion of women with a closed tear (REEDA approximation score of zero) in the sutured group (26/31) compared with the non-sutured group (16/36) (84% *versus* 44%; 95% confidence interval [CI] 16.5% to 56.9%). Further investigation using regression analysis showed that the suturing group ($P = 0.004$) and length of labour ($P = 0.033$) were the only variables significantly associated with the probability of having a closed tear at six weeks; women in the sutured group and those with shorter labours had increased odds of a closed tear.

There were no significant differences in EPDS scores between the sutured and non-sutured groups at 10 days (median 6 *versus* 5; 95% CI −1.999 to 2.001) ($P = 0.6680$) or 6 weeks (median 2.5 *versus* 4; −3 to 0.999) ($P = 0.214$) postpartum. Repeated measures analysis confirmed the lack of difference between groups in the scores across time (Time × Group interaction term: $P = 0.090$), but showed a significant decreasing effect of time on scores in general ($P = 0.010$).

DISCUSSION

Although the reasons for non-randomisation of women are clear from Fig. 1, the low number of women being randomised was of great concern to the research team. Far more women than expected were excluded immediately after the birth prior to randomisation. For example, 74% of women recruited to the study were ineligible through

medical intervention or intact perinea compared with the 65% anticipated from hospital statistics prior to undertaking the study. In addition, following closure of a nearby maternity hospital, there was a greatly increased workload in the labour ward of the main study site causing women simply to be missed. It was of concern to the research team that many women appeared to be 'changing their minds' about participating following the births of their babies. The attending midwife may have influenced this decision, particularly in cases where, having withdrawn, the women would not then be sutured. There is speculation that midwives want to avoid suturing because they do not feel fully confident in undertaking this procedure. In addition, there were some midwives who remained hostile to the study saying that they were unable to exercise their clinical judgement. The small proportion of women randomised brings into question the laborious and costly process of patient recruitment in the antenatal period. If women are considered fit to make informed decisions about their care immediately postnatally, they may also be fit at this time to give their informed consent to study participation, an approach that had been used elsewhere[12,22].

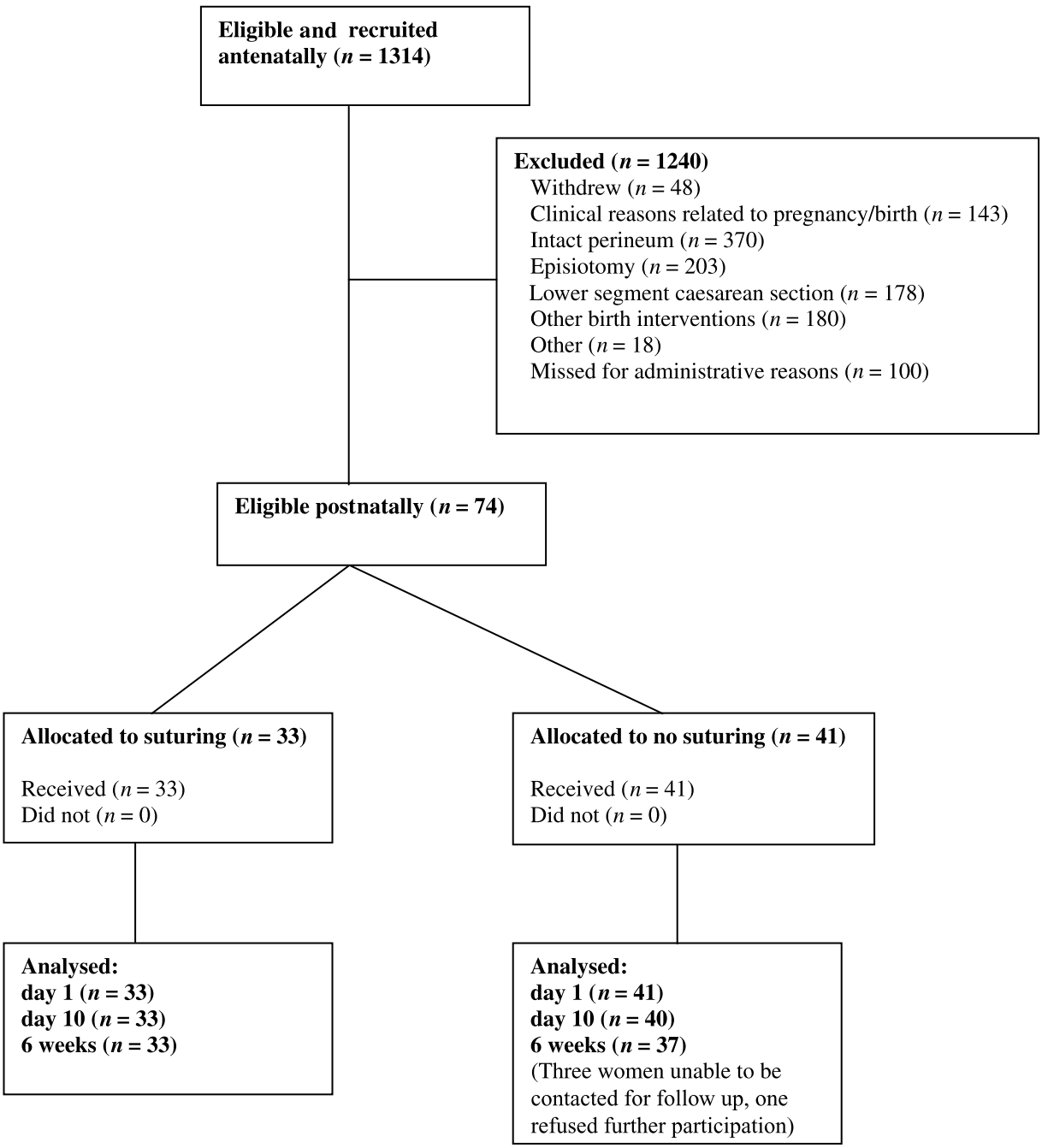

Fig. 1. Diagram showing the flow of participants through each stage of the randomised controlled trial.

Table 1. Summary of sample characteristics by degree of tear and study group. Values are given as *n* (%) and median [range].

	First degree tear		Second degree tear	
	Sutured ($n = 3$)	Not sutured ($n = 15$)	Sutured ($n = 30$)	Not sutured ($n = 26$)
Age	24 [21–34]	24 [16–32]	26 [16–34]	26 [18–37]
Deprivation categories 5–7	1 (33)	11 (73)	21 (70)	14 (54)
Booking weight (kg)	68.5 [60–70]	58.5 [42–72]*	63.1 [50–96.8]*	65.0 [46.9–110]#
Length of labour (hours:minutes)	8:17 [1:27–8:55]	5:18 [1:45–21:45]	8:14 [3:18–17:32]	8:00 [3:15–15:42]
Birthweight (g)	3560 [3020–3820]	3180 [2180–4020]	3300 [2040–4170]	3450 [2240–4260]

* Three women with booking weight information missing.
\# Four women with booking weight information missing.

At no time point was a significant difference shown between the groups with regard to perineal pain using either of the measures. Our findings are supported by other published research[7]. Most surprising were the results on day 10 in the light of the clinical experiences of the midwives involved in data collection and analysis, all of whom felt that sutured women often experienced tightening of the sutures and an increase in pain at this point. Although the results in relation to analgesia taken for perineal pain are consistent with those for reported pain (i.e. no differences in analgesia use were detected between study groups), a higher rate of breastfeeding in the non-sutured group was noted at each time point. The latter may indicate less perineal discomfort in the non-sutured group. The lack of difference in reported pain between sutured and non-sutured groups does not appear to be due to the smaller than anticipated sample size. This finding concurred with Gordon *et al.*[16] who found, in a sample of 1780 women requiring perineal repair, no difference in pain at 10 days postpartum. The differences in pain scores detected in this study were so small that, even had a much larger sample size been attained, statistical significance would not have been achieved. Perhaps, if perineal pain does differ according to whether or not tears are sutured, the standard pain measures are not sensitive enough to detect this.

A significant difference was found at six weeks with the total REEDA score and at day 1, day 10 and six weeks with the approximation aspect, with better healing being associated with sutured tears. The day 1 results are unsurprising in the light of both published research[7] and the clinical experience of the research team. That there was a significant difference shown in the approximation at all time points supports the findings of Gordon *et al.*[16] who, in a comparison of two *versus* three stage perineal repair, found that women having a two stage repair, in which the skin was left open showed more gaping initially and at 10 days postpartum.

Our findings contradict those of Lundquist *et al.*[17] whose research showed that healing occurred equally quickly in the two groups of women. However, these researchers

Table 2. Summary of scores on primary outcome measures. Values given are median (range), differences in medians [95% CI] and results of Mann–Whitney *U* tests.

Outcome measure	Sutured	Not sutured	Difference in median [95% CI]	*P*
McGill Pain Questionnaire total score				
Day 1 ($n_s = 33$, $n_{ns} = 41$)	11 (0–33)	10 (0–44)	1 [−2, 4.999]	0.586
Day 10 ($n_s = 33$, $n_{ns} = 40$)	0 (0–18)	0 (0–33)	0 [0, 0.001]	0.752
6 weeks ($n_s = 33$, $n_{ns} = 37$)	0 (0–28)	0 (0–7)	0 [0, 0]	0.802
Visual Analogue Scale				
Day 1 ($n_s = 33$, $n_{ns} = 41$)	22 (0–49)	22 (0–75)	0 [−8, 8]	0.991
Day 10 ($n_s = 33$, $n_{ns} = 40$)	0 (0–61)	2 (0–76)	0 [−2.004, 0.001]	0.638
6 weeks ($n_s = 32$, $n_{ns} = 37$)	0 (0–63)	0 (0–12)	0 [0, 0.0002]	0.495
REEDA				
Day 1 ($n_s = 33$, $n_{ns} = 39$)				
Approximation	1 (0–3)	2 (1–3)	−1 [−1.0001, 0]	<0.001
Total	4 (0–9)	5 (1–10)	−1 [−2, 0]	0.073
Day 10 ($n_s = 33$, $n_{ns} = 40$)				
Approximation	1 (0–2)	2 (0–3)	*−1 [−1.0001, −0.0003]*	0.003
Total	1 (0–6)	2 (0–8)	*0 [−1, 0]*	0.444
6 weeks ($n_s = 31$, $n_{ns} = 36$)				
Approximation	0 (0–1)	1 (0–3)	0 [−0.9999, 0.0001]	0.001
Total	0 (0–3)	1 (0–3)	0 [−0.9998, 0]	0.003

n_s is the sample size for sutured group.
n_{ns} is the sample size for non-sutured group.

acknowledged that they did not use any standard measures of healing and several midwives were involved in assessing the wounds.

It is unlikely that unless a wound is infected, differences in the other aspects of healing (bleeding, discharge) would have been seen at this point.

The findings at the six week time point in our study also contrast with those of Lundquist *et al.*[17] who found that healing was the same between the two groups. Again, lack of standard measures of healing may have rendered their results less robust than those of the present study.

It is acknowledged that the research midwives in the present study could not be blinded to the women's study group allocation. It may therefore be argued that the research midwives could have biased the results as they recorded the healing scores. This is an inevitable weakness of this type of study where it is not possible to blind data collectors to group allocation. To limit other sources of bias, there were only two research midwives in this study, who had received training in collecting the data using the REEDA tool. Prior to the study, the midwives made independent, simultaneous assessments of 20 perineal wounds and their scoring concurred in 92% of measurements.

There were no significant differences between the groups at 10 days or six weeks with regard to depression. It did not confound the results with regard to pain where more depression might be predicted to be associated with more pain.

CONCLUSION

Despite the failure to achieve the desired sample size, the findings of this study are convincing. There is no evidence that women who are sutured experience more (or less) pain than those who are not sutured. There is evidence that the perineum does not heal so well in women up to six weeks postpartum who are not sutured. The practices in many hospitals of not suturing perineal wounds cannot therefore be supported by the findings from this study. Given the minimal increase in costs associated with suturing, it is recommended that until a long term study is undertaken, women with perineal tears be sutured.

This study has provided results in a small group of participants, which show statistically significant differences in the healing between the two groups. The meaning of this is not yet clear with regard to the quality of life for the women, in the short and longer term. A longitudinal study to follow up women throughout their childbearing years and beyond needs to be carried out. However, given the difficulty in randomising women into the present study, there needs to be an open and honest debate with ethicists regarding the most appropriate recruitment strategy.

Qualitative research may elicit the reasons behind midwives decisions to suture or not.

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References

1. Ritgen G. Über sein dammschutzverfahren. *Monatsschr Geburtskd Frauenkrankheiten Ver Ges Geburtshilfe* 1855;**6**:321–347.
2. Sleep J, Grant A, Garcia J, Elbourne D, Spencer J, Chalmers I. West Berkshire perineal management trial. *BMJ* 1984;**289**:587–590.
3. Argentine Episiotomy Trial Group. Routine vs selective episiotomy: a randomised controlled trial. *Lancet* 1993;**342**:1517–1518.
4. Larsson P, Platz-Christensen J, Bergman B, Wallstersson G. Advantage or disadvantage of episiotomy compared with spontaneous perineal laceration. *Gynaecol Obstet Invest* 1991;**41**(4):213–216.
5. Klein M, Gauthier RJ, Jorgensen S, et al. Does episiotomy prevent perineal trauma and pelvic floor relaxation? *Online J Clin Trials* 1992;**1** (Doc 10).
6. Eason E, Labreque M, Wells G, Feldman P. Preventing perineal trauma during childbirth: a systematic review. *Obstet Gynecol* 2000;**95**(3): 464–471.
7. Grant A. The choice of suture materials and techniques for repair of perineal trauma; an overview of the evidence from controlled trials. *Br J Obstet Gynaecol* 1989;**96**:1281–1289.
8. Kettle C, Johanson RB. Absorbable synthetic versus catgut suture material for perineal repair. *Cochrane Database of Systematic Reviews*, Issue 3, 1998.
9. Kettle C, Johanson R. Continuous versus interrupted sutures for perineal repair. *Cochrane Database of Systematic Reviews*, Issue 31, 1998.
10. Calvert S, Fleming V. Minimizing postpartum pain: a review of research pertaining to perineal care in childbearing women. *J Adv Nurs* 2000;**32**:407–415.
11. Steen M, Cooper K. A tool for assessing perineal trauma. *J Wound Care* 1997;**6**(9):432–436.
12. Davidson N. REEDA: evaluating postpartum healing. *J Nurse Midwifery* 1974;**19**:6–9.
13. Fleming V, Hagen S. To suture or not to suture? *Br J Midwifery* 1998;**6**:737.
14. Lewis P. Poor science makes poor practice. *Mod Midwife* 1997;**7**(6): 4–5.
15. Head M. Dropping stitches. *Nurs Times* 1993;**89**(33):64–65.
16. Gordon B, Mackrodt C, Fern E, Truesdale A, Ayers S, Grant A. The Ipswich childbirth study: 1. A randomised evaluation of two-stage postpartum perineal repair leaving the skin unsutured. *Br J Obstet Gynaecol* 1998;**105**:435–440.
17. Lundquist M, Olsson A, Nissen E, Norman M. Is it necessary to suture all lacerations after a vaginal delivery? *Birth* 2000;**27**(2): 79–85.
18. Melzak R. The McGill Pain Questionnaire: major properties and scoring methods. *Pain* 1975;**1**:277–299.
19. Scott J, Huskisson E. Graphic representation of pain. *Pain* 1976;**2**: 175–184.
20. Cox J, Holden J, Sagovsky R. Detection of postnatal depression: development of the 10-item Edinburgh Postnatal Depression Scale. *Br J Psychiatry* 1987;**150**:782–786.
21. Machin D, Campbell MJ. *Statistical Tables for the Design of Clinical Trials*. Oxford: Blackwell, 1987.
22. Steen M. The FemePad, a breakthrough in perineal pain relief. . .gel pads. *Br J Midwifery* 1999;**7**(4):222, 224.

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