Perineal lacerations after childbirth

Studies within midwifery practice on suturing and pain relief

PhD Thesis

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1 Papers

The present thesis is based on the following papers:

I  Kindberg, S. Stehouwer, M. Hvidman, L. Henriksen, TB.
Postpartum perineal repair performed by midwives: a randomised trial comparing two suture techniques.

II  Kindberg, S. Klünder L. Strøm, J. Henriksen, TB.
Ear Acupuncture or Local Anesthetics for postpartum pain relief.
Accepted by BJOG September 2008 (in press)

III Kindberg, S. Stehouwer, M. Hvidman, L. Henriksen, TB.
Is clinical experience of midwives who perform perineal repair associated with postpartum perineal pain, delayed wound healing or dyspareunia?
(Submitted to ACTA, September 2008)
### 2 List of abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tbody>
<tr>
<td>BMI</td>
<td>Body mass index. Calculated by weight (kg)/height (cm)^2</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence interval</td>
</tr>
<tr>
<td>CS</td>
<td>Caesarean section</td>
</tr>
<tr>
<td>CPR</td>
<td>Danish civil registration system</td>
</tr>
<tr>
<td>DSOG</td>
<td>Danish Society for Obstetrics and Gynaecology</td>
</tr>
<tr>
<td>EBM</td>
<td>Evidence Based Medicine</td>
</tr>
<tr>
<td>GCP</td>
<td>Good Clinical Practice</td>
</tr>
<tr>
<td>ICD 10</td>
<td>International statistical classification of diseases, tenth version</td>
</tr>
<tr>
<td>OR</td>
<td>Odds ratio</td>
</tr>
<tr>
<td>OSATS</td>
<td>Objective standardised assessment of technical skills</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised controlled trial</td>
</tr>
<tr>
<td>RCOG</td>
<td>Royal College of Obstetricians and Gynaecologists</td>
</tr>
<tr>
<td>RR</td>
<td>Relative risk</td>
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<tr>
<td>SD</td>
<td>Standard deviation</td>
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3 Acknowledgements

This thesis was carried out at the Perinatal Epidemiology Research Unit, Aarhus University Hospital, Skejby between October 2005 and September 2008. Part of the research was performed at the Department of Research and Medical Education at Sønderborg County Hospital.

My interest in this area arises from clinical work as a midwife in busy labour wards in different Danish hospitals. The focus on perineal lacerations and the attempts to improve suturing techniques and pain relief originate from a genuine curiosity: how should we as midwives handle these clinical issues and, can we improve our techniques?

First of all, I wish to thank all the women who participated in the two trials. They willingly spent their valuable time and shared their experiences of intimate health matters following childbirth.

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Thank you also to DMSc Jens Strøm, chairman of the research department at Sønderborg County Hospital, for participation in study design and steering group meetings during the acupuncture trial. The trial was performed in close collaboration with midwife Lis Klünder whom I admire for her clinical skills within acupuncture.

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4 Summary

4.1 English Summary

The overall purpose of this thesis was to explore whether procedures performed by midwives on issues related to perineal repair could be improved. More than 80% of primiparous women and up to 50% of multiparous women sustain a peripartum injury which is sutured after delivery. Perineal repair is therefore the most common surgical procedure that a woman may undergo in her entire lifetime. No Danish evidence based clinical guidelines are available on how midwives and obstetricians should manage the repair of superficial lacerations to the labia, perineal ruptures of 1st and 2nd degree or episiotomies.

Randomised trials conducted primarily in Great Britain in the past 20 years have evaluated different suturing techniques and suture materials for the repair of second degree lacerations and episiotomies. The results of these trials are summarized in recent Cochrane Reviews and a continuous suturing technique using a synthetic, rapidly absorbed suture material has been documented to reduce perineal pain and need for removal of suturing material after delivery. As we tried to implement these recommendations in national clinical guidelines, several issues were raised. One concern was whether the “gold standard” from Britain was comparable to other suture techniques advocated for their simplicity and focus on anatomical structures of the pelvic floor.

The main purpose of this thesis was to investigate if new methods of perineal repair and pain relief performed by midwives could improve maternal morbidity evaluated by outcomes such as pain, wound healing and dyspareunia. Another objective was to investigate whether years of clinical experience of the midwife influenced these outcomes. Concepts from evidence based medicine and the idea of testing a hypothesis in a controlled experimental setting in order to obtain the highest level of evidence has influenced the selection of methods for the studies presented in this thesis.

The effect of different suture techniques was evaluated in a randomised controlled trial conducted at Aarhus University Hospital, Skejby from 2004-2006. The trial compared a continuous suture to a new and locally developed method using interrupted and inverted stitches for perineal repair of 2nd degree lacerations and mediolateral episiotomies. Participants were low-risk primiparous women with vaginal deliveries (n=395). The main outcome was perineal pain 10 days postpartum. Secondary outcomes were wound healing, dyspareunia and need for resuturing. No difference was seen in the primary outcome as perineal pain at 10 days was reported by 33% vs. 37%, p=0.44. Pain evaluated on two different pain rating scales also revealed no differences in maternal pain scores at 24-48 hours or 10 days postpartum. No difference was seen in wound healing, and the number of wounds assessed to be gaping >0.5 cm at 10 days was 15% vs. 20%, p=0.22. Dyspareunia was present among 24% vs. 29% at six months, p=0.20.

Thus, interrupted stitches offered similar results as the continuous suture technique in relation to maternal outcomes. However, the continuous technique was faster to perform and required less suture material.
The effect of different pain relief methods during surgical repair was evaluated in a randomised controlled trial at Sønderborg County Hospital in 2006-2007. This trial compared local anaesthetics with a new approach consisting of ear acupuncture for pain relief during suturing of lacerations to the labia, the vaginal mucosa, perineal lacerations of 1st or 2nd degree or episiotomies. Participants were low-risk primiparous women with vaginal deliveries (n=207). The primary outcome was pain experienced during surgical repair. Secondary outcomes were wound healing, dyspareunia and patient satisfaction. Significantly more patients reported pain during surgical repair if allocated to ear acupuncture (89% vs. 54%, p<0.01). Patient satisfaction was lowest in the acupuncture group (69% vs. 91%, p<0.01). No difference was seen in wound healing for the number of wounds assessed to be gaping at 14 days (15% vs. 17%, p=0.5). Dyspareunia was present among comparable numbers at six months (23% vs. 15%, p=0.13).

Thus, ear acupuncture was significantly less effective for pain relief compared with local anaesthetics.

The effect of seniority of the midwife and maternal postpartum perineal pain, delayed wound healing or dyspareunia was evaluated in an observational study using data from the first trial (n=78 midwives performing a total of 384 perineal repairs). The hypothesis was, that inexperienced midwives performing perineal repair would have worse outcomes than experienced colleagues. Years of clinical experience was categorised into groups: <5, 5-14 and 15+ years. The measured outcome was perineal pain at 10 days, wound gaping > 0.5 cm at 10 days and dyspareunia at six months postpartum. A logistic regression analysis was used to adjust for potential confounders and non-independence in the dataset. Participants who were sutured by a midwife with less than five years of experience had an insignificantly increased risk of perineal pain at 10 days (OR<5years 1.46, 95%CI 0.79-2.70). Delayed wound healing was not associated with the experience of the midwife (OR<5years 1.21, 95% CI 0.58-2.51). Dyspareunia at six months was also not associated with the experience of the midwife (OR<5years 0.91, 95% CI 0.49-1.69).

Thus, years of clinical experience of the midwife performing perineal repair was not associated with perineal pain, delayed wound healing or dyspareunia.

The perspectives are to evaluate methods for effective implementation of evidence based guidelines on perineal repair into busy labour wards with large variations in previous training and suture preferences among staff. Training programs incorporating hands-on-workshops or internet-based learning should be evaluated. Conducting clinical research on manual skills such as suturing techniques could be improved in relation to documentation on pre-trial and peri-trial skills among involved staff. Objective and structured assessment methods to evaluate suturing skills and other manual skills such as application of pain relief methods need to be developed. Patient satisfaction with appropriate health services in relation to postnatal care after perineal repair should be investigated.

Future research should focus on developing and evaluating more effective pain relief methods during and after perineal repair. Research should also be dedicated to the development and validation of assessment methods for clinical competences in relation to surgical repair.
4.2 Danish Summary

Det overordnede formål med denne ph.d.-afhandling var at undersøge, om procedurer foretaget af jordemødre i forhold til suturering af perineale bristninger kunne forbedres. Mere end 80% af førstegangsfødende kvinder og op til 50% af fleregangsfødende der føder vaginalt har behov for suturering. Syning af bristninger er dermed den kirurgiske operation som kvinder hyppigst bliver udsat for i løbet af deres levetid. Der findes ingen danske evidensbaserede kliniske retningslinjer for hvordan jordemødre og obstetrלקikere bør praksiserezie suturering af overfladiske bristninger i labia, perineale bristninger grad et og grad 2 eller episiotomier.

Randomiserede undersøgelser primært fra England har gennem de seneste 20 år evalueret forskellige suturteknikker og suturmaterialer til behandling af grad 2 bristninger og episiotomier. Resultaterne fra disse videnskabelige undersøgelser er sammenfattet i opdaterede Cochrane metaanalyser, og den fortølbende suturteknik med et syntetisk, hurtigt ab sorberet suturmateriale har vist at kunne reducere perineale smerter og behov for suturfjernelse efter fødslen. I forløbet med at implementere disse anbefalinger i nationale kliniske retningsliner blev flere problemstillinger rejst. Et forbehold var om ”guld standarden” fra England kunne sammenlignes med andre suturteknikker, som blev fremhævet for deres mere simple tilgang og fokus på anatomiske strukturer i bækkenbundens muskulatur.

Effekten af forskellige suturteknikker blev evalueret i et randomiseret, kontrolleret forsøg ved Århus Universitetshospital, Skejby i 2004-2006. Forsøget sammenligneved en fortølbende suturteknik med en ny og lokalt udviklet teknik, hvor grad 2 bristninger og episiotomier blev samlet med inverterede knuder. Deltagerne i forsøget var ræke førstegangsfødende med vaginale fødsler efter uge 36+ (n=395). Det primære effektmål var perineale smerter 10 dage postpartum. Andre effektmål var sårheling, dyspareuni og behov for resutur. Der kunne ikke påvises nogen forskel i det primære effektmål idet smerter blev rapporteret af henholdsvis 33% og 37%, p=0.44. Smerte evalueret på to andre smerteskalaer kunne heller ikke påvise nogen forskel efter 24-48 timer og 10 døgn postpartum. Der kunne ikke påvises nogen forskel i sårheling, og antallet af bristninger fremstod mere end 0.5 cm åbne 10 døgn efter fødslen var 15% versus 20%, p=0.22. Dyspareuni optrådte hos 24% versus 29% seks måneder postpartum, p=0.20. Dermed kunne det konstateres, at inverterede sting havde sammenlignelige resultater som den fortølbende suturteknik i forhold til maternelle forhold. Den fortølbende teknik var dog hurtigere at foretage og forbruget af suturmateriale var mindre.
Effekten af forskellige metoder til smertelindring under suturering blev evalueret i et randomiseret, kontrolleret forsøg ved Sønderborg Hospital i 2006-2007. Forsøget sammenlignede lokalbedøvelse med en ny metode, som bestod af øre-akupunktur til smertelindring under suturering af bristninger i labia, i den vaginale slimhinde, ved perineale bristninger grad et og to samt episiotomier. Deltagerne i forsøget var raske førstegangsfødende med vaginale fødsler efter uge 36+ (n=207). Det primære effektmål var smerter under sutureringen. Andre effektmål var sårheling, dyspareuni og patienttilfredshed. Signifikant flere kvinder rapporterede smerter under sutureringen i gruppen med øre-akupunktur (89% versus 54%, p<0.01). Patienttilfredshed var lavest i øre-akupunktur gruppen (69% versus 91%, p<0.01). Der var ingen forskel på sårheling idet antallet af bristninger som fremstod mere end 0.5 cm åbne 14 døgn efter fødslen var 15% versus 17%, p=0.5. Dyspareuni forekom lige hyppigt hos deltagerne i forsøget seks måneder efter fødslen (23% versus 15%, p=0.13). Dermed kunne det konstateres, at øre-akupunktur var mindre effektivt som smertelindring under suturering end lokalbedøvelse.

Effekten af klinisk erfaring blandt jordemødre målt i antal år i erhverv og sammenhængen med perineal smerte, forsinket sårheling og dyspareuni blev undersøgt i et observationsstudie ved brug af data fra det første videnskabelige forsøg (n=78 jordemødre som foretog suturering af 384 perineale bristninger). Hypotesen var, at uerfarne jordemødre ved suturering af perineale bristninger ville have dårligere resultater end mere erfarne kolleger. Antal år i klinisk praksis blev kategoriseret i tre grupper: 5, 5-14 og 15+ år. De primære effektmål var perineale smerter og sår mere end 0.5 cm åbne 10 døgn postpartum samt dyspareuni seks måneder postpartum. Deltagere i forsøget som blev sutureret af en jordemoder med mindre end fem års erfaring havde en insignifikant forhøjet risiko for smerter 10 dage efter fødslen (OR<5år 1.46, 95%CI 0.79-2.70). Forsinket sårheling var ikke associeret med jordemoderens erfaring (OR<5år 1.21, 95% CI 0.58-2.51). Dyspareuni seks måneder efter fødslen var heller ikke associeret med jordemoderens erfaring (OR<5år 0.91, 95% CI 0.49-1.69). Dermed kunne det konstateres, at klinisk erfaring målt i antal år i erhverv for jordemødre ikke var associeret med perineal smerte, forsinket sårheling eller dyspareuni.


Fremtidig forskning bør fokusere på at udvikle og evaluere mere effektive smertelindringsmetoder under og efter suturering af perineale bristninger. Forskning bør også fokusere på udvikling og validering af vurderingsmetoder for kliniske kompetencer hos personalet i relation til behandling af bristninger efter fødsler.
5 Introduction

5.1 Background

Almost 90% of all women undergo pregnancy and childbirth during their lifetime. Spontaneous vaginal deliveries are assisted by midwives in home births and in hospital births according to the preference of the pregnant woman. In 2007, almost 99% of all deliveries in Denmark took place in obstetric departments and the remaining were planned or unplanned home births. Care for women in vaginal deliveries encompasses a broad spectrum of techniques and interventions according to local practices and national guidelines.

The birth of a child can be either spontaneous vaginal, assisted vaginal or by emergency or elective caesarean section. The Danish National Board of Health publishes annual national statistics on the mode of delivery stratified by parity. Primiparous women often have more instrumental deliveries (13.8% vs. 2.6%) or undergo emergency caesarean sections (13.2% vs. 4.9%). The mode of delivery among primiparous and multiparous women in the first six months of 2008 is shown in figure 1.

The selection of appropriate mode of delivery is a health care issue discussed with pregnant women during antenatal visits and during labour. “Informed Choice” and “Informed Consent” have become obligatory before any intervention or treatment is offered to patients. The term “maternal request” has emerged amongst obstetrics in Denmark as a possibility for women who opt for elective caesarean section without any medical indication. For some of these caesarean sections the maternal request is based upon the fear of genital tract trauma. It is therefore of great importance for health care providers to be able to assist women with qualified, safe, effective and evidence-based approaches in prevention and treatment of perineal lacerations obtained during childbirth. Evidence on midwifery strategies and treatment options in order to fulfil this request are insufficient and inconclusive.

Fig. 1: Mode of delivery among women in Denmark in the first six months of 2008 (N=29,842).
5.2 Impact of delivery on maternal morbidity

Research within maternal morbidity after spontaneous vaginal deliveries is sparse and little evidence is available within a Scandinavian context\textsuperscript{15-17}. Research on the psychological health of women during the first year after childbirth has documented that depression is more common after childbirth than in the background population\textsuperscript{18,19}. The research on perineal trauma has primarily focused on long-term urinary incontinence and maternal morbidity after anal sphincter lacerations evaluated in observational or cross-sectional studies\textsuperscript{20,21}. A questionnaire-based cross-sectional study of 376 women with deliveries in 1993-1996 in Aarhus University Hospital, documented that postpartum urinary incontinence immediately after delivery was experienced by 23%. With a spontaneous remission of around 3% at six months postpartum\textsuperscript{16}.

A Danish randomised trial from 1996 on different suture materials for perineal repair of perineal lacerations and episiotomies showed that 94% felt pain when sitting on a chair 2 days after delivery, 91% still had pain at 5 days, 50% at 2 weeks and 8% at 3 months postpartum (n=308 primiparous women)\textsuperscript{22}.

Short-term maternal morbidity after vaginal deliveries is related to pain during healing of scar tissue, problems with wound healing, infection and regaining muscular strength in the perineal muscles. An observational study among 1249 women who participated in a trial on protection against perineal trauma (the HOOPs trial) revealed an incidence of at least one health problem among 85% during the first two weeks postpartum\textsuperscript{23}. The most frequent health problems were tiredness (42%), painful perineum (42%), breast problems (33%), backache (22%), constipation (19%) and tearfulness / depression (16%). Long-term maternal morbidity can encompass physical and psychological aspects. Within the research done on perineal trauma the most frequently used long-term indicator of maternal morbidity is pain during intercourse (dyspareunia), need for resuturing and incontinence\textsuperscript{23-25}.

5.2.1 Perineal pain

Pain is defined as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” by the International Association for the Study of Pain\textsuperscript{26}. Pain and discomfort related to perineal trauma has been reported to cause distress in women for weeks and even months after delivery and can interfere with the new mother’s daily activities such as sitting, walking, lifting her baby or passing urine\textsuperscript{27,28}. Perineal pain is correlated to the extent of trauma and the mode of delivery\textsuperscript{24,28}. Pain from the perineal area affects primiparous and multiparous women differently as shown in figure 2.

Fig. 2. Perineal pain after delivery among primiparous and multiparous women (HOOPs trial, n=1249)\textsuperscript{24}.
Time-intervals of 24-48 hours, ten days, three months, six months and one year postpartum have been those most commonly reported in previous British trials on perineal trauma\textsuperscript{28-30}. The selection of day ten for follow up in British trials was based on the fact that all women were seen routinely for postnatal examinations at this time by community midwives. Perineal pain at 24-48 hours was reported as 62-64\% in the Ipswich Childbirth Study from 1998\textsuperscript{29}, as 69-79\% in the MOMS trial from 2002\textsuperscript{30} and by 70 to 71\% in the HOOP trial from 1998\textsuperscript{28}. Perineal pain at ten days postpartum was reported as 22\% in the West Berkshire trial from 1986\textsuperscript{31}, as 25-28\% in the Ipswich Childbirth Study\textsuperscript{29}, as 26-44\% in the MOMS trial\textsuperscript{30} and as 31-34\% in the HOOP trial\textsuperscript{28}.

**Measurement of pain**

The measurement of pain and changes in pain over time can be performed using different scales. The most frequently used pain rating scale is a four point categorical scale using the explanatory words: none, mild, moderate or severe pain\textsuperscript{32}.

Another pain measurement scale, which has been validated as a reliable instrument to assess intra-personal change in pain intensity over time, is the Visual Analogue Scale (VAS)\textsuperscript{33}. A VAS Scale in the form of a 10 cm horizontal line, with anchor points at both ends ranging from “no pain at all” to “worst pain imaginable”, is shown to patients. The patient adjusts a movable line to the current level of experienced pain and the numeric value from the back side of the VAS scale is registered by the interviewer as a number between 0.0 and 10.0\textsuperscript{33}.

A third assessment tool is the McGill Pain Questionnaire (MPQ) which includes 78 adjectives in 20 categories reflecting sensory, emotional and cognitive components of pain\textsuperscript{34}. The words are assigned in rank order enabling a sum score ranging from 0-78. The MPQ scale has previously been used in one minor trial on perineal suturing\textsuperscript{35}. A validated Danish version was used in the first randomised trial reported in this thesis\textsuperscript{36}. 

![Chart showing hospital stay, 8 weeks postpartum, and 2-18 months postpartum pain levels](chart.png)
5.2.2 Wound healing

A wound is defined as an injury caused by physical means with disruption of the normal continuity of structures\textsuperscript{37}. Wound healing is the process of replacement and restoration of the function of damaged tissues\textsuperscript{38}. The purpose of suturing trauma is to support the injured tissue so it can heal by first intention, without formation of granulation tissue\textsuperscript{37,38}. Perineal trauma in general has a rapid healing potential and infection rates are reported to be less than 1% in large trials on perineal repair of 2\textsuperscript{nd} degree lacerations and episiotomies\textsuperscript{29-31,39}. Infections after anal sphincter injuries are more common and a recent trial on the use of routine antibiotics documented healing problems among 8% those who had been given antibiotics and 24% among women receiving placebo\textsuperscript{40}.

Factors that have been associated with delayed wound healing in general are; malnutrition\textsuperscript{41}, obesity\textsuperscript{42}, age\textsuperscript{43} and smoking\textsuperscript{44}. Within obstetrics several factors have been documented to delay healing: instrumental deliveries\textsuperscript{24,45}, episiotomies\textsuperscript{46-48}, duration of the second stage of labour\textsuperscript{49} and high maternal BMI\textsuperscript{42}.

No evidence on the timing of suturing of 2\textsuperscript{nd} degree lacerations or episiotomies is available and the current practice is to repair such obstetric wounds in the hours immediately following delivery. A recent randomised trial with 165 patients concluded that an 8-12 hour delay of primary repair of anal sphincter injuries did not affect anal incontinence at one year follow up\textsuperscript{50}. A small Danish case-control study, including 22 patients with delayed primary (72 hours +) or early secondary (14 days) reconstruction of anal sphincter injuries without a covering stoma, concluded that it was safe to perform these operations\textsuperscript{51}.

The Scottish HOOPs trial documented the incidence of stitches breaking down within the first weeks postpartum to be 1% among women with vaginal deliveries, 5% in women with assisted vaginal deliveries and 3% in women with caesarean sections\textsuperscript{28}. The incidence of stitch break downs had increased to 11% among those who had assisted deliveries by eight weeks postpartum\textsuperscript{28}. The British MOMS trial reported 1% of the 1541 participants to have a “gaping wound” at two days postpartum increasing to 3-6.5% at 10 days\textsuperscript{30}. A case-control study including 14,124 patients in Michigan, USA, between 1995 and 2005 reviewed all reported perineal repair breakdowns in patients. Some 59 patients were identified and compared in 118 controls. Risk factors for suture break down were longer second stage of labour, operative vaginal delivery (OR 3.6, 95% CI 1.8-7.3), mediolateral episiotomy (OR6.9, 95% CI 2.6-18.7) and anal sphincter injury (OR 3.1, 95% CI 1.5-6.4)\textsuperscript{49}.

Measurement of wound healing

Wound healing of episiotomies and second degree lacerations can be evaluated using objective scales which quantify the incidence of selected healing outcomes. One scale, developed by Steen et al., focuses on the severity of oedema and bruising and has been validated as a categorical scale\textsuperscript{52}. Another scale incorporates a total of five parameters: redness (R), Edema (E), Ecchymosis (E), Discharge (D) and Approximation (A) of the wound edge (the REEDA scale)\textsuperscript{53}. Each healing parameter is assessed with one millimetre of accuracy and a sum score is generated within the range of 0-15 (see appendix 8)\textsuperscript{53}. A pilot study prior to this trial showed acceptable intra and inter-personal variance between research midwives conducting assessments of wound healing\textsuperscript{54}. 
5.2.3 Dyspareunia and sexual health

Dyspareunia can be defined as any pain or soreness that occurs during sexual intercourse\textsuperscript{25}. Dyspareunia can be caused by several factors such as psychological reactions after childbirth, decreased libido, pain in scar tissue and decreased vaginal lubrication correlated to hormonal changes in the early puerperium\textsuperscript{25}.

The prevalence of women suffering from prolonged or severe dyspareunia has been reported to be age-specific in a non-patient population of 3017 women who participated in the Swedish national screening program for cervical cancer\textsuperscript{55}. The prevalence was 9.3\% for the whole group and 13\% for women aged between 20-29 declining to 6.5\% for women aged between 50-60\textsuperscript{55}.

Pre-pregnancy rates of women experiencing pain during intercourse has been reported to be as high as 38\% in a cohort of primiparous women\textsuperscript{45}. Data from British randomised trials on suture techniques and suture materials, including 1780 and 1542 participants, showed that 76-83\% had resumed intercourse at three months and 86-99\% at six months postpartum\textsuperscript{29,30}.

Dyspareunia after childbirth has previously been associated with the extent of trauma\textsuperscript{56}. A cohort analysis of 999 patients from a large randomised trial showed that instrumental deliveries, with or without episiotomies, were significantly more likely to lead to secondary dyspareunia. This is compared with spontaneous deliveries with an intact perineum (26\%) or caesarean section (41\%)\textsuperscript{57}. A similar German observational study of 655 primiparae documented that intact perineum after vaginal delivery or caesarean section was associated with the least dyspareunia at six months postpartum (3.5\% vs. 3.4\%) compared with 11\% among women with episiotomies and 14\% after operative vaginal deliveries\textsuperscript{58}.

Performing caesarean sections does not protect women from experiencing sexual problems after childbirth and dyspareunia is most frequently reported by women who also suffered from dyspareunia before delivery\textsuperscript{59}.

Dyspareunia or sexual problems after childbirth is reported as 17-83\% at 8-12 weeks postpartum declining to 8-64\% at six months postpartum\textsuperscript{23,30,31,45,25,32,47,62}. The large variation in the reported frequencies can be explained by different definitions of dyspareunia or sexual problems and the fact that some of the cited studies calculated the frequency by dividing incident cases by the women who had actually tried to resume intercourse instead of incident cases by the total risk population.

The Ipswich Childbirth Study documented that 8\% of women sutured with polyglactin 910, compared with 14\% sutured with chromic catgut, experienced dyspareunia one year postpartum\textsuperscript{29,60}.

Breastfeeding has been documented to have a strong impact on the incidence of dyspareunia due to hormonal changes, decreased libido and vaginal dryness\textsuperscript{25,45}.

Research into ways of reducing this morbidity is still needed. In the studies performed as part of this thesis, dyspareunia was defined as: “any pain during intercourse within the previous month” evaluated six months postpartum.
5.3 Perineal trauma: diagnosis, incidence and prevention

Most vaginal deliveries are accompanied by trauma to the genital tract from spontaneous lacerations, episiotomy or both. The full extent of genital tract trauma is unknown for several reasons, including underreporting of some types of trauma, incomplete assessment by clinicians, practice variations regarding which forms of trauma need suturing and differences in classification\textsuperscript{27}.

In obstetric units with liberal use of episiotomies, the overall rates of women who need suturing after vaginal deliveries has been reported to be as high as 85-90\textsuperscript{31,61}. Perineal trauma is therefore the most frequent complication in vaginal deliveries and yet, maternal morbidity postpartum is not recognised and properly addressed by health professionals\textsuperscript{33,61}.

5.3.1 Diagnosis of perineal trauma

Diagnosis of perineal trauma after childbirth is classified according to involvement of anatomical structures in the perineal body according to the International Classification of Diseases published by the World Health Organisation (ICD 10)\textsuperscript{62}. The four categories range from superficial lacerations in the skin, to involvement of the anal sphincter and rectal mucosa\textsuperscript{63}. The definitions have been adapted by national obstetric societies, with a minor change in classification of the 3\textsuperscript{rd} degree laceration, as a partial or total anal sphincter laceration\textsuperscript{63,64}. Table 1 shows the classification system as described by the Royal College of Obstetricians and Gynaecologists (RCOG)\textsuperscript{63}.

<table>
<thead>
<tr>
<th>Classification of perineal lacerations after vaginal delivery</th>
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<tr>
<td><strong>First degree</strong></td>
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<td><strong>Fourth degree</strong></td>
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The classification system itself has not been subject to extensive validation\textsuperscript{65}. A survey among doctors responsible for perineal repair of third and fourth degree lacerations concludes: “an agreed classification of OASI (Obstetric Anal Sphincter Injuries), development of national guidelines, formalised training, multidisciplinary management and further definitive research is strongly recommended”\textsuperscript{66}.

Midwives from Birmingham have developed a Peri-Rule\textsuperscript{TM}, which is a pragmatic tool for the measurement and assessment of perineal tears. Newly qualified midwives and student midwives found the tool useful as it helped them improve their clinical skills in assessing perineal trauma\textsuperscript{67}. 

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5.3.2 Incidence of perineal lacerations after vaginal deliveries

For women who undergo their first vaginal delivery, approximately 60% will experience perineal lacerations or episiotomies that require suturing. Around 40% of primiparous women also sustain injury to the labia, leaving the overall frequency of surgical repairs around 70-80% among primiparous women. Aarhus University Hospital, Skejby has approximately 4800 deliveries annually. As every Danish citizen has a unique personal identification number (civil registration system number, CPR) data on different health outcomes are easily accessible from hospital or national databases. In Denmark, the Aarhus Birth Cohort consists of data on all deliveries at Aarhus University Hospital, Skejby since 1989. An analysis of perineal outcomes after all vaginal deliveries during 2003-2007 (n=14,422) is shown in figure 3.

The extent of perineal trauma is related to parity and factors such as birth weight of the infant, instrumental delivery, ethnicity and maternal BMI. Risk factors associated with anal sphincter lacerations are primiparity instrumental deliveries, long duration of the second stage of labour, large infant and midline episiotomies. A Swedish population-based register study, including all vaginal deliveries from 1994 to 2004 (n=365,886), showed that the incidence of 3rd degree anal sphincter tears increased from 3.4% to 5.2% in spontaneous births and from 8.7% to 14.8% in instrumental deliveries. A similar study from The Netherlands, including 284,783 vaginal deliveries, identified assisted vaginal deliveries to be a risk factor for sphincter injuries (forceps OR: 3.33, 95% CI 2.97-3.74). A valid explanation for the increase and difference in incidences of anal sphincter lacerations has not been documented. However, part of the increase may be explained by increased focus on correct anatomical diagnosis and the reporting of obstetric outcomes correctly in patient records, as suggested by Fernando et al. in a recent national survey among obstetric departments in Great Britain.

Inexperience of the midwife and lack of manual protection of the perineum during crowning of the head has been associated with perineal injury in historic textbooks. Evidence on the role of experience and skills of the midwife or obstetrician attending at the time of delivery is therefore needed.
5.3.3 Prevention of perineal trauma

Randomised trials summarized in a recent Cochrane Review have documented that antenatal perineal massage during the last trimester of pregnancy can reduce the likelihood of perineal trauma and postpartum pain. The position of the woman at the time of delivering the head and shoulders is not well described in the literature and due to the lack of reliable evidence women are encouraged to deliver in the position they find most comfortable.

The place of birth is associated with perineal outcomes as birth clinics or home births are associated with less perineal trauma. A comparison of risks for having perineal trauma between home births and hospital births is usually compromised by the fact that we compare different populations; one of healthy women to one of women who have had complicated deliveries to some extent. Furthermore, diagnosis in such settings might suffer from detection bias, as accuracy in diagnosis and clinical skills depend on common definitions and training.

The most dramatic form of prevention of perineal trauma is to avoid vaginal delivery. Observational data on the consequences of elective caesarean versus intended vaginal delivery has failed to show improvements of long-term maternal morbidity or health economics. A cohort study within a randomised trial with 999 participants has documented that the prevalence of urinary incontinence at three months postpartum (17% vs. 16%) and dyspareunia (31% vs. 32%) was comparable between multiparous women with vaginal deliveries and women having caesarean section.

Caesarean sections have been linked to an increase in maternal deaths in Norway and the operation is therefore not free of risk. Prevention of perineal injuries therefore seems to require a multifactorial approach, where assisting women to have spontaneous vaginal deliveries without unnecessary medical interventions plays a significant role. One method that has proven to be beneficial for women in labour, in relation to supporting spontaneous deliveries, is the continuous attendance during labour by trained birth attendance. This has been documented in trials over the past 30 years but this “low-tech” or “non-interventional” approach has not yet been implemented as a primary care measure by many obstetric departments throughout the world.

5.3.4 Episiotomy: does it help or does it harm?

Historically, it was believed that episiotomy reduced perineal injury and anal sphincter tears by controlling the direction and extent of tissue damage. An instrumental incision was considered easier to repair than a perineal laceration and it was presumed that episiotomies could prevent disruption of the perineal body. A recent update on the global rates of episiotomies reports that primiparous women are more likely than multiparous women to undergo episiotomies. With an overall risk of 9.7% in Sweden and up to 100% of all vaginal deliveries in Taiwan.

The evidence from various trials on episiotomies is summarised in systematic reviews stating that routine episiotomy, in spite of all clinical beliefs and assumptions, does not prevent anal sphincter lacerations, urinary or fecal incontinence, dyspareunia postpartum or the overall risk of requiring surgical repair of lacerations after delivery. Data from a randomised trial on the use of episiotomies verified that routine
episiotomy was not beneficial, as no difference was observed with regard to EMG perineometry 3 months postpartum, urinary incontinence or other pelvic floor symptoms. The direction of an episiotomy can be either midline or mediolateral but neither has proven effective in the prevention of anal sphincter injuries when used as a routine intervention. One randomised trial on the use of routine or selective midline episiotomy in Canada among 703 low-risk women documented that 46 of the 47 3rd or 4th degree lacerations were associated with median episiotomy.

The effect of using routine mediolateral episiotomies has been tested in two large randomised trials: The West Berkshire perineal management trial in the United Kingdom (n=1000) and The Argentine Episiotomy Trial (n=2606). The rates of routine episiotomies were 10-30% versus 51-83% but neither trial could document any protective effect as anal sphincter ruptures occurred in comparable numbers (1.5% and less). An intact perineum was more common among those allocated to the restrictive policy with no significant differences in relation to neonatal state or urinary symptoms three months postpartum. Perineal pain and healing complications including suture break down was significantly higher in the routine episiotomy groups, leading the authors to conclude that episiotomy rates above 30% should be abandoned. In 1994 a Danish research group made similar recommendations based on an observational study after providing individual feedback to 30 midwives responsible for 3919 deliveries.

Fig. 4. Illustration of a right mediolateral episiotomy. The mediolateral angle is 45-60 degrees.
Observational studies on muscular function of the pelvic floor after childbirth have documented that women with episiotomies had decreased contraction performance, compared with women with an intact perineum or minor perineal lacerations during labour\textsuperscript{48,100-102}. An American study, on 6052 first vaginal deliveries in one hospital during 1995-2005, documented that the risk of a subsequent episiotomy was highest among those who had an episiotomy at the time of their first vaginal delivery in comparison with those with spontaneous lacerations or an intact perineum (51% vs. 27%, p<0.001)\textsuperscript{103}. A retrospective study from all labour wards in Sweden in 1995 showed wide variations in episiotomy rates among nulliparous women in different hospitals (4%-50%)\textsuperscript{104}. The episiotomy rates among low-risk primiparous women in Danish hospitals in 2006 illustrate this point. Even though these women, as a group, supposedly have similar risks of sustaining an episiotomy, the individual risk is very closely linked to the hospital where the delivery takes place (Fig. 5)\textsuperscript{6}. This example illustrates the challenges of implementing evidence into clinical practice.

Fig. 5. Episiotomy rates among low-risk primiparous in Danish hospitals 2006 (N=15,688)\textsuperscript{6}. 
5.4 Suturing of perineal trauma

The aim of suturing perineal lacerations is to restore vital functions of the perineal body and to secure wound healing by primary intention. Suturing of lacerations has traditionally been the responsibility of medical doctors and the surgical skill was passed on to midwives in the 20th century.

In the history of treatments for perineal trauma, several methods and materials have been used. In 1920, the incomplete lacerations were adapted using metal clips which caused considerable maternal pain and increased the risk of postpartum infection. Suturing materials consisted of metallic suture material or silk which was removed from the wound 7-10 days after delivery.

Current legislation and practices in most European countries is that midwives are authorised to suture superficial lacerations of the labia, vagina and perineal lacerations of 1st and 2nd degree including episiotomies. Lacerations involving the anal sphincter or the rectal mucosa are classified as 3rd and 4th degree tears; these lacerations are repaired by obstetricians.

5.4.1 Current evidence on non-suturing in case of minor perineal lacerations

As suturing itself is painful and tight sutures may lead to maternal discomfort, non-suturing of perineal trauma has been practiced throughout history. Many midwives currently prefer to leave minor perineal lacerations of the 1st degree and superficial lacerations in the vulva area unsutured.

Only a few small randomised trials have compared the wound healing process and postpartum pain among women who had 1st or 2nd degree lacerations. The healing of the wound seemed to be delayed when 2nd degree lacerations were not sutured but patients evaluated non-suturing positively as they avoided pain during anesthesia and suturing. Non-suturing is also associated with the lesser use of oral analgesia in the postpartum period, compared with sutured laceration of similar degrees.

No evidence is available on long-term effects or pelvic floor muscle function after non-suturing of 2nd degree lacerations or episiotomies.
5.4.2 Current evidence on suture materials
Maternal morbidity postpartum has been linked to the suture material used for perineal repair\textsuperscript{114}. The results from several randomised trials have shown that using animal gut ("Catgut") is associated with more short term perineal pain and suture break down than synthetic materials ("Vicryl" or "Dexon")\textsuperscript{39,60,115,116}.

Dyspareunia has also been linked to the use of chromic catgut one year after delivery\textsuperscript{114}. Synthetic materials on the other hand, tended to stay in the wound area for longer than necessary. This led to a higher frequency of material removals postpartum, as shown in randomised trials (12\% vs. 7\%, $p<0.01$)\textsuperscript{60,114,117}.

Comparisons of animal gut ("Catgut"), to a fast-absorbing polyglactin 910 ("Vicryl Rapid"), have shown comparable profiles in terms of maternal discomfort, suture break down and need for removal of suture material\textsuperscript{115,118}.

As European legislation prohibits the use of animal products in suture materials, the focus of research changed into comparisons of different synthetic sutures\textsuperscript{119}. Large trials on episiotomies and second degree perineal lacerations have evaluated standard polyglactin 910 ("Vicryl") versus fast-absorbing polyglactin 910 ("Vicryl Rapid")\textsuperscript{22,30,120}.

The fast-absorbing material was associated with less perineal pain during healing and fewer women needed to have the sutures removed (3\% vs. 13\%, $p<0.01$)\textsuperscript{30}. No differences were seen in suture break down or need for subsequent resuturing after 12-month follow up postpartum\textsuperscript{22,30,120}.

Fig. 6. Illustration of a monofilament, a multifilament and a coated multifilament suture material
5.4.3 Current evidence on suture techniques for 2\textsuperscript{nd} degree lacerations and episiotomies

Textbooks on suture techniques suggest different approaches for suturing of 2\textsuperscript{nd} degree lacerations and episiotomies. Throughout history, suture techniques have been influenced by the available suture material; as silk was the only option and needed removal after 5-7 days, large stitches through the perineal skin and deep into the perineal body were recommended\textsuperscript{79}. Episiotomies have also been approximated with few, large stitches through the perineal skin and perineal muscles using silk sutures\textsuperscript{94}.

A Danish trial on suture techniques for episiotomies, conducted in 1981-82 (n=900, mixed parity), documented that pain from the perineal area was significantly less common among women sutured with a continuous technique compared with interrupted stitches in the muscles and through the perineal skin\textsuperscript{121}.

Randomised trials conducted in Britain and Nigeria confirmed these results as they evaluated continuous versus interrupted stitches (Fig. 7). The continuous technique was associated with less perineal pain, 10 days postpartum, as well as a reduction in pain relieving drugs and a reduction in dyspareunia (fig. 8)\textsuperscript{30, 122, 123}.

Fig. 7. Interrupted technique for episiotomies and 2\textsuperscript{nd} degree lacerations in the MOMS trial, Lancet 2002\textsuperscript{30}.

It is unclear if there is any difference in postpartum wound healing or perineal pain if lacerations of the 2\textsuperscript{nd} degree or episiotomies are sutured with a continuous technique or interrupted stitches leaving the skin unsutured.
Fig. 8. Continuous technique for episiotomies and 2nd degree lacerations, the MOMS trial, Lancet 2002.

The randomised trial from Ipswich (n=1780) and another trial from Nigeria (n=823) documented that a two layer technique, leaving the perineal skin unsutured, reduced postpartum pain and dyspareunia without compromising issues related to breakdown of the repair or need for resuturing. Not suturing the perineal skin has been evaluated as cost-effective, as fewer women need subsequent removal of suture material. These concerns led us to initiate a randomized, controlled trial in order to evaluate two standardised suture techniques: the continuous technique described by Kettle et al. in the MOMS trial 2002, compared with a locally developed method using interrupted stitches for 2nd degree lacerations and episiotomies leaving the skin unsutured (KM Bek, University of Aarhus. fig. 9).

Fig. 9. Interrupted, inverted technique for 2nd degree perineal laceration leaving the skin unsutured.

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5.4.4 Pain relief during postpartum surgical repair

There is only limited evidence of effective and safe pain relieving methods during perineal repair. The most frequently used pain relief method is that of local anaesthetics, applied directly into the wound. It is a clinical concern that the use of local anaesthetics might cause tissue oedema and can make correct identification of anatomical structures difficult. As wound approximation becomes difficult this could lead to suboptimal anatomical reconstruction of important structures in the perineal body and delay wound healing.

Other options are available for pain relief: a pudendal blockade, topical Lidocaine gel, sedation of the mother using Entonox (N₂O-0₂) and topping up an existing epidural analgesia.

Data from the randomised trial on different suture techniques at Aarhus University Hospital, Skejby (n=395) documented that 50% of patients experienced pain during surgical repair. The method used for standard pain relief during the trial was local anaesthetics using 1% lidocain without adrenalin.

Complementary medicine such as acupuncture and other non-pharmacological therapies have been introduced into childbirth as increasing numbers of pregnant women opt for non-medical treatments during labour. Recent randomised trials have also documented a positive effect of acupuncture treatment on pain during delivery. Ear acupuncture used specifically for postpartum perineal pain relief has been used by midwives and obstetricians with intensive training in the use of acupuncture. The effect has not been documented and complementary therapies should be tested for safety and effectiveness using the same study designs and methods as other medical interventions.

The experience from Study 1 in Aarhus left a window of opportunity to improve pain relief methods as women are sutured after delivery. Ear acupuncture was introduced into clinical practice during the same time period and showed promising results when applied by midwives and obstetricians with special interest and training in the use of acupuncture. This led us to evaluate ear acupuncture compared with local anaesthetics in a randomised study reported in Paper 2.
5.4.5 Educational issues in relation to perineal repair

Teaching midwifery students to diagnose and suture perineal lacerations is part of the curriculum for midwifery education in most European countries. Midwifery has been deeply rooted within traditions of one-to-one care and a strong professional autonomy. Clinical skills are taught from one midwife to another based on a “see one, do one, and now you are on your own” educational principle of transferring knowledge and skills to new colleagues. Midwifery seems to lack the language and power of how to describe “best practice” for the work we do in assisting pregnant and women in labour. It is thus very rare to see documentation of “midwifery interventions” in patient records, e.g. for manual techniques to deliver the baby’s head or shoulders as they emerge over the perineum.

The clinical skills to diagnose and treat perineal lacerations are currently taught to midwifery students and medical trainees during their clinical training. Only a few obstetric departments have guidelines on the suturing of perineal trauma of 2nd degree or episiotomies. Many suture techniques and individual modifications of textbook recommendations are therefore practised without formal quality assurance or structured evaluation and feedback.

Virtual reality training of core clinical skills seems to have proven successful for teaching young doctors to handle suture instruments, knot tying techniques and suturing techniques for laparoscopic surgery. Studies within this area have also shown that there is a strong correlation between competences in virtual reality simulations and clinical performance in subsequent procedures.

Whenever evaluation of technical skills is performed, researchers use some kind of Objective Structured Assessment of Technical Skills (OSATS). The only study which has evaluated the skills of medical staff performing episiotomy repair by an OSATS showed that 11 out of 18 residents could not perform episiotomy repair according to a defined standard for “good surgical skills.”

The inexperienced midwife, doctor or trainee may prefer to use an interrupted approach, as this enables them to replace one insufficient stitch instead of undoing a continuous suture. No evidence has been produced on which suture technique midwives, obstetricians or trainees actually find easy to learn or how they use acquired skills in clinical practice. There is currently a large, ongoing, randomised trial in the United Kingdom that looks into the effect of the focused training of midwives and implementation of evidence based guidelines in clinical practice (The PEARLS study).

It is hypothesized that the more experienced midwives and obstetricians obtain better results after perineal repair than inexperienced colleagues. In order to investigate this hypothesis, a secondary analysis of data from the suture trial was performed. This work is presented in Paper III.
6 Aim of thesis

The overall aim of this thesis was to investigate if new methods of perineal repair and pain relief could improve the results of maternal morbidity after vaginal delivery. The method used to evaluate this was to conduct two randomised trials in two different Danish obstetrical departments.

Another area of focus was to evaluate whether the experience of the operator was associated with adverse results in relation to perineal repair.

The specific aims of the papers in this thesis were:

1. To compare two standardised suture techniques, leaving the skin unsutured for perineal repair of second degree lacerations or episiotomies in a double-blind randomised clinical trial.
2. To evaluate ear acupuncture as a new approach to pain relief during perineal repair, compared with standard local anaesthetics in a randomised clinical trial.
3. To investigate if experience of the midwife performing perineal repair was associated with perineal pain, wound healing and dyspareunia postpartum using data from the first study.

The methods, results and conclusions of each of these aims are described in papers I, II and III.

The following is a presentation of these papers with a strong focus on methodology and perspectives.
7 Paper I. Randomised trial on suture techniques for perineal repair

7.1 Methodology

Study design
The trial was designed as a prospective, double-blind, randomised, controlled clinical trial performed at the Department of Obstetrics and Gynaecology, Aarhus University Hospital, Skejby from 2004 to 2006\(^1\). This hospital had approximately 4800 annual deliveries and 78 midwives were trained to perform the two standardised suture techniques. Midwives were trained during 3-hour hands-on workshops using episiotomy trainers and other artificial models. There were monthly workshops to ensure suture technique training of new employees. Randomisation was done using a computer controlled voice response system using stratification on episiotomy\(^2\). All participants were interviewed face-to-face within 24-48 hours and 10 days postpartum by one of four trained research midwives. A telephone interview was performed by one of two research midwives six months after delivery in order to make a long-term follow up. Wound healing was documented by digital photographs in order to facilitate an intra and inter-rater comparison of wound healing assessments.

Sample size
Based on an estimate of 25% of women reporting perineal pain 10 days after delivery if sutured in a continuous manner, a total of 366 women were needed to detect a reduction from 25% down to 13% with a power of 80% and an alpha of 0.05. Incorporating a possible 10% “lost-to-follow up”, the trial was designed to include a total of 400 participants\(^3\).

Study population
The trial used strict inclusion criteria in order to minimise random variation and control for potential confounders in the study sample\(^1\). Inclusion criteria were primiparity, spontaneous or instrumental vaginal birth of a singleton baby in the occipital position of 36 weeks of gestation or later. Participants had to be able to understand and speak Danish. The perineal laceration should be of either 2\(^{nd}\) degree or a mediolateral episiotomy (appendices 2 and 3). Exclusion criteria were multiparity, multiple pregnancy, diabetes, or severe maternal illness. As well as injuries involving the anal sphincter, forceps delivery, postpartum haemorrhage exceeding 1000 ml., manual removal of the placenta or delivery of a sick or stillborn infant.

Ethics
The trial followed rules for clinical trials according to the Helsinki II declaration\(^4\). The regional scientific ethics committee approved the trial (J.no: 2004-0070)\(^5\) and the trial was registered with the Danish Data Protection Agency\(^6\) (J.no: 2004-53-0993) as well as the international database for clinical trials (www.clinicaltrials.gov)\(^7\).
**Outcome measures**

The primary result was perineal pain in the previous 24 hours reported 10 days postpartum. Results of secondary interest were perineal pain at 24-48 hours, wound healing 10 days postpartum, dyspareunia or resuturing within six months postpartum. Similar follow up time intervals as in previous trials on suturing were selected in order to make trial comparisons possible.

Pain was registered as a continuous variable using the Visual Analogue Scale (VAS) and as categorical variables on a 4-point Present Pain Intensity Scale. A Danish version of the short form McGill Pain Questionnaire was included and the Pain Rating Index was used to generate numeric values of the descriptive words (appendix 7).

Wound healing was assessed by making a systematic evaluation of redness, oedema, ecchymosis, discharge and approximation of skin edges and visual judgement of appearance while the woman was placed in the lithotomy position (the REEDA scale, appendix 8). Delayed wound healing was recorded by 10 days if wound edges were gaping >0.5 cm, due to poor approximation of tissue or signs of wound break down. Dyspareunia was evaluated in the final follow up six months after delivery. Dyspareunia was defined as any pain upon penetration or during intercourse within the previous month. As in previous trials on perineal repair.

**Questionnaire design**

There were no available Danish standard questionnaires that specifically evaluated postpartum perineal repair, wound healing or associated maternal morbidity using validated scales or questions. Researchers who had conducted similar trials in the UK, Nigeria, Sweden and Denmark were contacted in order to obtain their trial questionnaires. The questionnaires most relevant to our study were the questionnaires from the HOOPS trial and the MOMS trial. We included the VAS and the McGill Pain Questionnaire and the REEDA scale for evaluating perineal healing. Construct validity was evaluated with experienced researchers and epidemiologists. The face validity was evaluated with focus groups of women in the postnatal ward and hospital midwives. Open-ended questions were included in order to allow participants to express concerns and experiences which were not covered by the structured questionnaire.

**Intervention**

Illustrations and detailed text descriptions were provided for all midwives in the department as hard copies and on the trial homepage. The continuous suture technique was described as loose, continuous non-locking sutures to close the vaginal mucosa and the muscular layer of the perineum. The perineal skin should be approximated using the same continuous suture in the subcutaneous tissue a few millimetres under the perineal skin edges, finishing the suture with a knot in the vaginal mucosa (fig. 8, page 25).

The interrupted suture technique involved loose, non-locking continuous sutures to close lacerations in the vaginal mucosa. The muscular layer and the subcuticular layer were then approximated using interrupted stitches, with the knot hidden in depth of the trauma. No stitches were placed through the perineal skin (fig. 9, page 25).
Data management and statistics
EpiData version 3.1 was used as the data entry program. Data were entered twice in order to evaluate any data entry errors and correct typing errors. The results were analysed using STATA software version 8.2. Trial analyses and reports were made in accordance with CONSORT requirements.

Two sample t-tests were performed to compare means from continuous data that were normally distributed. A Mann-Whitney rank sum test was performed in case of non-parametric distribution of data. Pearson’s Chi squared test was performed for analysis of frequencies. The 2-sided Fishers´ exact test was used for analysis when expected frequencies were less than 5. Values of normally distributed continuous data were reported as mean and standard deviation (SD). Non-parametric data were reported as medians with 10-90% percentiles. Frequencies were reported as exact numbers and relative frequencies. Analysis was made on an intention-to-treat basis. P-values less than 0.05 were considered significant.

7.2 Results
400 women were randomised in the period 1st of August 2004 till 23rd of October 2005. During the randomisation period, 1820 primiparous women delivered vaginally, of which 400 were randomised to each suture technique. Five women withdrew their consent to participate, leaving 395 participants for follow up. Randomisation distributed 198 participants to continuous suture and 197 to interrupted stitches. The two groups were similar at the time of trial entry in terms of demographics, delivery details and perineal injury (table 1 in Paper 1). Both groups were also comparable in relation to management after trial entry, e.g. compliance to allocated suture technique and operator experience. The interviews and assessments of wound healing were performed within the intended time limits and had a follow up rate of more than 98%.

Primary and secondary outcomes
No difference was seen in perineal pain 10 days after delivery. Evaluated as either, “any perineal pain within the previous 24 hours”, as “any pain right now” using a 100 mm VAS scale or as pain described in words using the McGill Pain Questionnaire (table 3). Wound healing evaluated by the REEDA scale was similar at 24 to 48 hours and 10 days postpartum. Wound healing on day 10, evaluated by the number of gaping wounds was also similar between groups. Patient satisfaction with repair and occurrence of dyspareunia was similar in the two groups six months after delivery and the need for subsequent revision of the repair did not differ between groups. The only significant difference in the trial was the cost-effectiveness of the two treatment regimes. The continuous suture technique was less time consuming to perform (median 15 vs. 17, range 4-60 minutes, p=0.03). The continuous suture technique also required less suture material than the interrupted method (median 1 vs. 2 packets, p<0.01).
The Department changed the standard suture material during the trial period from the rapidly absorbed 910 to standard 910 polyglactin. The conclusion of this trial did not change after taking in the difference in suture materials into account in a stratified secondary analysis (data not shown).

Table 3. Perineal pain, wound healing and dyspareunia according to suture technique in trial.

<table>
<thead>
<tr>
<th></th>
<th>Continuous suture</th>
<th>Interrupted stitches</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Perineal pain</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAS Score at 24-48 hours</td>
<td>1.8 [0.0-5.0]</td>
<td>1.5 [0.0-5.0]</td>
<td>p=0.63</td>
</tr>
<tr>
<td>VAS Score at 10 days</td>
<td>0.1 [0.0-2.5]</td>
<td>0.1 [0.0-3.0]</td>
<td>p=0.94</td>
</tr>
<tr>
<td>McGill Score at 24-48 hours</td>
<td>11 [2-25]</td>
<td>9 [2-22]</td>
<td>p=0.17</td>
</tr>
<tr>
<td>McGill Score at 10 days</td>
<td>4 [0-16]</td>
<td>4 [0-15]</td>
<td>p=0.96</td>
</tr>
<tr>
<td>Any perineal pain at 10 days</td>
<td>6 (33%)</td>
<td>72 (37%)</td>
<td>p=0.44</td>
</tr>
<tr>
<td><strong>Perineal healing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>REEDA Score at 24-48 hours</td>
<td>3 [1-6]</td>
<td>3 [1-7]</td>
<td>p=0.78</td>
</tr>
<tr>
<td>REEDA Score at 10 days</td>
<td>1 [0-4]</td>
<td>1 [0-4]</td>
<td>p=0.34</td>
</tr>
<tr>
<td>Wound gaping &gt;0.5 cm at 24-48 hours</td>
<td>18 (9%)</td>
<td>21 (13%)</td>
<td>p=0.25</td>
</tr>
<tr>
<td>Wound gaping &gt;0.5 cm at 10 days</td>
<td>30 (15%)</td>
<td>39 (20%)</td>
<td>p=0.22</td>
</tr>
<tr>
<td>Revision of wound within six months</td>
<td>4 (2%)</td>
<td>4 (2%)</td>
<td>p=1.00</td>
</tr>
<tr>
<td></td>
<td>126 (64%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dyspareunia</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dyspareunia at 1st resumed intercourse</td>
<td>47 (24%)</td>
<td>111 (56%)</td>
<td>p=0.14</td>
</tr>
<tr>
<td>Dyspareunia at six months postpartum</td>
<td>58 (29%)</td>
<td></td>
<td>p=0.20</td>
</tr>
</tbody>
</table>

Data presented as median [10-90% percentile] or number (%).

1 Reasons for gaping wound at 10 days were recorded as total suture break down (1% vs. 2%), superficial break down (7% vs. 8%) and suboptimal approximation (7% vs. 10%).
7.3 Discussion

This study on suture techniques showed that a locally developed and new suturing method using interrupted and inverted stitches for perineal repair of second-degree lacerations and episiotomies had the same impact on postpartum perineal pain, wound healing and dyspareunia as the continuous suture technique.

Data on perineal pain were obtained during face-to-face interviews with trial participants. Both participants and research midwife were blinded towards treatment allocation as both suture techniques approximated perineal skin edges using subcuticular stitches. It is possible that participants responded differently to questions posed during an interview compared with self-administered questionnaires. On the other hand, the face-to-face interview method was considered useful as an introduction between research staff and participants before assessment of perineal healing.

Ideally, a trial with high internal validity should permit suturing only by midwives who competently managed to perform both suture techniques adequately. This would ensure that the trial actually compared two standardised techniques performed by experienced clinicians and would have low, non-compliance rates towards the allocated treatment. This trial did not provide such an “ideal setting” because it was a pragmatic clinical study including 78 different midwives with differing levels of experience and skills.

The results were also obtained on the basis of specific training of perineal suturing among all midwives in order to ensure good clinical performance during the trials. However, we did not test each midwife in order to evaluate if she could actually perform the suture technique as prescribed. One way to test the skills of the involved midwives could have been to make individual assessments of skills and competence before the recruitment of patients. The test should ideally be done again half way during the trial in order to secure “calibration” of the staff involved in terms of suturing perineal lacerations according to treatment allocation. The issue of “calibration” is to ensure precision and reliability of trial results.

An issue concerning the external validity of this randomised trial is that we still have limited knowledge of how the suture techniques work in the hands of staff that are not trained systematically as well as among patients with prolonged healing.

The main idea of conducting the trial using a randomised controlled study design was to distribute known and unknown potential confounders equally among the two treatment groups. As our knowledge on causality of suture break down is limited, there may be unknown confounders that influence the results if they are unevenly distributed among the treatment groups. This phenomenon known as “residual confounding” is supposedly more evenly represented in treatment groups as numbers increase. A potential confounder in the trial could be the learning curve seen in other studies on surgical performance. The standardised suture techniques studied were new to most of the midwives and they reported favouring a mixture of interrupted stitches and continuous sutures prior to the trial. This might contribute to the insignificant results, whereas comparing “usual practice” to an entirely new suture method might have shown more significant results.
Comparison with other studies
The MOMS trial compared continuous subcuticular stitches to interrupted stitches showing significant differences in postpartum pain scores at ten days (26% vs. 44%, p<0.01)\textsuperscript{30}. Our trial showed no difference in postpartum pain between the continuous and the interrupted technique (33% vs. 37%, p=0.44). One obvious reason could be that our interrupted technique was different from the MOMS technique, as stitches through the perineal skin were avoided in our trial.

Our trial documented a substantial number of delays in wound healing at ten days postpartum: 15% vs. 20% in the continuous and interrupted technique groups, respectively. We obtained these results when women were placed in the lithotomy position, using adequate lightning and gently touching the wound area in order to make photographs for documentation purposes. The reason for higher incidences of delayed wound healing caused by poor initial approximation of wound edges or subsequent superficial wound break down at 10-14 days postpartum is unclear. One possibility could be that systematic evaluation of wound healing performed by few, trained research midwives using objective wound assessment scales, could document higher incidences than if participants are seen by a number of different midwives without a tool to assess healing.

The MOMS trial reported gaping wounds at 10 days among 3% in the continuous group and 6.5% in the interrupted group\textsuperscript{32}. Their information on gaping wounds was assessed by different midwives and the lack of objective assessments of wound healing might contribute to this lower incidence.

Implications
We interpret the results of this trial as an opportunity for clinicians to choose among continuous sutures or interrupted and inverted stitches for perineal repair of second-degree lacerations and episiotomies according to preference and surgical competence. From a health-economic perspective, the interrupted suture method in this trial was less favourable than the continuous suture technique due to use of more suture material. The interrupted technique was also slightly more time consuming. However, we question the relevance of a significant finding of a 2-minute time difference in operating time, as this is of little clinical relevance. The next challenge for research on perineal traumas is to develop reliable, objective and validated measures for detecting whether the performed repair actually succeeded in approximating the perineal muscles in order to restore muscular strength and function of the perineal body\textsuperscript{100,169}. Immediate pain postpartum can be treated easily but an inadequately approximated perineal body might affect a woman’s reproductive long-term health.

7.4 Conclusion
The aim of this study was to compare a continuous suture technique to Interrupted, inverted stitches for perineal repair leaving the skin unsutured. The two suture techniques appeared to be comparable in relation to perineal pain, wound healing, patient satisfaction, dyspareunia and need for resuturing. The continuous technique however, was faster and required less suture material thus making it the more cost-effective of the two techniques.
8. Paper II. Ear acupuncture versus local anaesthetics for pain relief during repair

8.1 Methodology

Study design
The study was designed as a prospective, randomised controlled clinical trial. The trial was conducted at Sønderborg County Hospital, Denmark, from May 2006 to July 2007. The trial was single-blinded on the part of the research team responsible for postnatal interviews, inspections of wound healing and data entry into the research database. Randomisation was made using a computer controlled voice response system using stratification on epidural and episiotomy. All participants were interviewed face-to-face within 24-48 hours and 14 days postpartum. A telephone interview was performed six months after delivery in order to make a long-term follow up. This hospital has approximately 1600 annual deliveries and 36 midwives were trained to perform ear acupuncture. The trial tested a pragmatic set-up of brief training of clinicians.

Sample size
The power calculation was based on an assumption of a 20% absolute difference in numbers of expected “pain free surgical repairs”. in a previous trial using similar local anaesthetics, 50% of the participants reported pain during perineal repair. In order to detect an increase in pain-free repairs from 50% to 70% or a decrease to 30% with the power of 80% and an alpha of 0.05, a total of 206 participants were needed for the trial using a 2-sided power calculation.

Study population
Inclusion criteria were primiparity, spontaneous or instrumental vaginal birth of a singleton baby in the cephalic position at 36 weeks of gestation or later. The surgical repairs included in this trial were lacerations in the labia, vaginal mucosa, superficial perineal tissue (1st or 2nd degree) or mediolateral episiotomy (appendices 1-3). Participants should be able to understand Danish. Exclusion criteria were multiparity, twin pregnancy, diabetes and severe maternal illness As well as injuries involving the anal sphincter, forceps delivery, postpartum haemorrhage exceeding 1000 ml., manual removal of the placenta and delivery of a sick or stillborn infant.

Ethics
The regional scientific ethics committee approved the trial (J.no: 2006-1011) and the trial was registered with the Danish Data Protection Agency (J.no: 2006-53-1300). According to international standards the trial was registered with an international database for clinical trials (J.no: NCT00328796 at www.clinicaltrials.gov). Rules of Good Clinical Practice and the Helsinki II declaration were followed.
Result measures, questionnaires, data management and statistics

The primary result was pain experienced during surgical repair reported by women at 24-48 hours postpartum. Secondary results were needed for additional pain relief, wound healing assessed at 24-48 hours and 14 days postpartum, participant satisfaction with allocated treatment evaluated 14 days postpartum and superficial dyspareunia as reported six months postpartum. The same measurement scales and questionnaires from the previous trial were used with minor alterations. Data management and statistics were also identical to the previous trial.

Intervention

The ear acupuncture treatment was standardised and consisted of six acupuncture needles. Three needles were placed in the ear, covering the “genital area”, the Shen Men point according to French Auriculotherapy. Supplementary acupuncture in two other points was used to facilitate relaxation and pain relief. After insertion, the needles were stimulated to evoke needle sensation (“De Qi”). Acupuncture was compared with local anaesthetics using Lidocaine 10mg/ml applied directly to the wound. This was the most commonly used pain relieving method in the department prior to this trial.

Fig 10: Incision and location of ear acupuncture needles (Photo: S. Kindberg, 2006).

Midwives were encouraged to offer further pain relief regardless of trial allocation if participants experienced pain during the surgical repair. The first choice was Lidocaine Gel 4% in order to avoid mixture of the two compared pain relieving methods between the randomised groups.
8.2 Results

During the randomisation period, 623 primiparous women delivered vaginally. Of these, 207 were randomised. A total of 105 women were allocated to ear acupuncture and 102 to local anaesthetics.

The follow up rate was 99% at 24-48 hours, 97% at 14 days and 92% at six months postpartum. The two groups were comparable at baseline in terms of demographics and distribution of genital tract injury.

Treatment with either pain relief method was provided by 36 different midwives during the study period. The average number of enrolled participants throughout the study period per midwife was five (ranging from 1 to 18 participants per midwife). No difference was observed with regarding the time for completion of repair or usage of suture material. Compliance to allocated treatment was 96% in both groups.

Primary and secondary outcomes

Pain during surgical repair was significantly more frequently reported by women allocated to ear acupuncture than those receiving local anaesthetics (89% vs. 53%, p<0.01). The median VAS score was significantly higher in the ear acupuncture group compared with the local anaesthetics group (median 3.5 vs. 1.5, p<0.01). The ear acupuncture group also received significantly more additional pain relief during surgical repair (table 4).

No difference was seen in wound healing at 24-48 hours or 14 days postpartum. A similar number of wounds were gaping at 24-48 hours and this number also declined to comparable numbers at 14 days postpartum. Need for subsequent wound revision was rare and did not differ between the two groups. The occurrence of dyspareunia was similar in the two groups six months postpartum.

Pain from the wound decreased over time and at 14 days postpartum no difference was seen between the groups. No difference was seen in use of oral analgesia.

Patient satisfaction with the allocated pain relief method was lower in the ear acupuncture group (69% vs. 91%, p<0.01). Fewer women in this group would recommend it to a friend (74% vs. 91%, p<0.01). Willingness to choose the same pain relief method at a future delivery did not differ between the groups and an equal proportion of women were generally satisfied with the repair (table 4).

In the ear acupuncture group 59% felt pain when the method was applied, compared with 68% among those allocated to local anaesthetic (p=0.15).

No difference was seen in dyspareunia, which was evaluated at six months postpartum.

Excluding patients with epidurals from the analysis of primary results did not change the conclusions (data not shown).
Table 4. Pain during repair, wound healing, dyspareunia and patient evaluation in acupuncture trial.

<table>
<thead>
<tr>
<th></th>
<th>Ear acupuncture</th>
<th>Local anaesthetics</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pain during repair</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAS Score for pain during repair</td>
<td>3.5 [0.9-8.6]</td>
<td>1.5 [0.0-5.2]</td>
<td>p&lt;0.01</td>
</tr>
<tr>
<td>Any pain during repair (4-point scale)</td>
<td>93 (89%)</td>
<td>55 (53%)</td>
<td>p&lt;0.01</td>
</tr>
<tr>
<td>Received additional pain relief during repair</td>
<td>56 (53%)</td>
<td>22 (22%)</td>
<td>p&lt;0.01</td>
</tr>
<tr>
<td><strong>Perineal healing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>REEDA Score at 24-48 hours</td>
<td>3 [1-7]</td>
<td>3 [1-7]</td>
<td>p=0.30</td>
</tr>
<tr>
<td>REEDA Score at 14 days</td>
<td>1 [0-3]</td>
<td>1 [0-3]</td>
<td>p=0.90</td>
</tr>
<tr>
<td>Wound gaping &gt;1 cm at 24-48 hours</td>
<td>28 (27%)</td>
<td>25 (25%)</td>
<td>p=0.72</td>
</tr>
<tr>
<td>Wound gaping &gt;1 cm at 10 days</td>
<td>14 (15%)</td>
<td>17 (17%)</td>
<td>p=0.50</td>
</tr>
<tr>
<td>Revision of wound within six months</td>
<td>0 (0%)</td>
<td>2 (2%)</td>
<td>p=0.24</td>
</tr>
<tr>
<td><strong>Dyspareunia</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dyspareunia at 1st resumed intercourse</td>
<td>51 (49%)</td>
<td>47 (46%)</td>
<td>p=0.72</td>
</tr>
<tr>
<td>Dyspareunia at six months postpartum</td>
<td>24 (23%)</td>
<td>15 (15%)</td>
<td>p=0.13</td>
</tr>
<tr>
<td><strong>Patient satisfaction</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Satisfied with pain relief method in trial</td>
<td>72 (69%)</td>
<td>93 (91%)</td>
<td>p&lt;0.01</td>
</tr>
<tr>
<td>Would recommend method to a friend</td>
<td>78 (74%)</td>
<td>93 (91%)</td>
<td>p&lt;0.01</td>
</tr>
<tr>
<td>Would choose same method again</td>
<td>77 (73%)</td>
<td>79 (77%)</td>
<td>p=0.49</td>
</tr>
</tbody>
</table>

Data presented as median [10-90% percentile] or number (%).
8.3 Discussion
We found that the ear acupuncture shown in this study was statistically less effective for pain relief during postpartum surgical repair compared with local anaesthetics. More patients were also satisfied with the pain relief method if a local anaesthetic was used. Most of the reported pain scores were in the “mild” end of the verbal descriptive scale and in the lower end of the VAS scale. This may reflect the relatively small extent of trauma, as most participants had sutures in the labia area or minor perineal lacerations only. Although trial participants reported more pain and less satisfaction when they were randomised to ear acupuncture, this did not seem to affect their willingness to choose ear acupuncture for pain relief after a subsequent delivery. This contradiction was by most participants explained, as a strong wish to give birth without use of any pharmacological interventions.

The questionnaires in this trial were filled out by researchers during interviews with trial participants. A potential disadvantage of this data collection strategy was the information bias that can occur, as trial participants might respond differently if the same questions were asked in self administered questionnaires. Another limitation in the data collection method was the potential for recall bias, as patients reported their experience during surgical repair 1-2 days after delivery.

The training program to perform ear acupuncture
To evaluate a low budget, easy to apply training programme in the use of ear acupuncture, we set out to evaluate a brief training package of a 2-hour hands-on workshop for a group of midwives. All midwives had attended a 3-day course on the use of traditional Chinese acupuncture and were able to use acupuncture to stimulate contractions and for general pain relief purposes. This design was chosen as a pragmatic solution in order to evaluate a realistic clinical situation of implementing a new pain relief method. Acupuncturists might argue that the ability to offer relevant treatment with acupuncture and especially ear acupuncture, requires far more training and continuous practising of skills in order to maintain a certain level of competence than we provided in this trial (Kirstine Münster, personal communication). The average number of participants per midwife was five (ranging from 1-18) over the study period of 15 months. Thus, it is plausible that not all midwives who provided ear acupuncture for pain relief in this trial were sufficiently qualified at the time of enrolment of the participants. The limited number of enrolled participants per midwife limited the possibility to analyse data for any time trend.

Comparison with other trials
We could not identify any previous trials on ear acupuncture for obstetric pain relief via PubMed. A search for future or ongoing trials on www.clinicaltrials.gov revealed one on-going trial on the effect of ear acupuncture on lower back pain during pregnancy which is currently recruiting patients at the Yale University (Identified as number NCT00571480). The standard acupuncture evaluated in trials on obstetric pain relief use Chinese acupuncture, where trigger points are located primarily on the legs and arms of patients. A Danish randomised trial from Aarhus University Hospital, Skejby conducted during 1999-2003 tested a longer training course for involved staff: all midwives were trained in four or five-day courses and were encouraged to practice on patients before they could recruit a participant for the trial. Another and more frequent approach in acupuncture trials, is to train a limited number of staff members to perform
a very specific treatment as seen in another Danish trial by Westergaard et al. in 2006 on the effect of acupuncture on fertility rates following fertility treatments.

Blinding

The gold standard for evaluation of new treatments within health science is the double-blind controlled trial. Blinding should ideally be at three levels: the care provider, the patient and the researcher. As the trial was designed to blind only the researcher some issues could be raised about the effect of placebo.

We found that double-blinding was not an option in this trial. A pre-trial pilot test of placebo acupuncture and placebo local anaesthetics indicated that blinding of participants and midwives was unrealistic because both were able identify the active treatment. The swelling of the tissue after application of local anaesthetics or placebo could not be camouflaged. Experienced acupuncturists also argued that placebo acupuncture in the ear would not be possible because of the very superficial location of the acupuncture points. The midwives in this trial constituted a heterogeneous group with different previous experiences in the use and effect of acupuncture. This may also have influenced the trial results in any given direction depending on the midwives’ attitudes towards acupuncture due to the way they interacted verbally and non-verbally with participants in the trial.

Implications

Improving postpartum pain relief methods for surgical repair of any genital laceration is of great importance in order to secure maternal comfort for women who deliver vaginally. From a quality improvement point of view, it should be questioned whether our current “best practice” with the use of local anaesthetics is good enough, with 68% reporting some pain when pain relief is applied in the wound area, and another 54% reporting some degree of pain during surgical repair.

Thus, we still have to improve the gold standard for treating pain during postpartum repair. It is possible that pain relief should consist of several methods according to local standards and women’s needs.

Further trials aiming to improve the effectiveness and acceptability of pain relieving methods are still needed for pain relief during postpartum surgical repair. A general concern for research within manual and ‘clinician dependent’ therapies is, how to ensure that involved staff have gained sufficient and similar skills in providing the health care methods that are evaluated. Evidence on how to evaluate clinical competence and manual skills within the use of acupuncture is still needed. Ear acupuncture and acupuncture in general have proven very effective for some types of pain and discomfort. We suggest that future trials evaluate more elaborate training packages of the staff involved.

8.4 Conclusion

The aim of this study was to compare a new approach to postpartum pain relief during suturing using ear acupuncture compared with local anaesthetics. Ear acupuncture as used in this trial was significantly less effective in relieving pain compared with the use of local anaesthetics. No difference was observed in wound healing, need for revision of wound or dyspareunia. Patient satisfaction with allocated pain relief method was significantly lower in the ear acupuncture group.
9. Paper III. Experience of the midwife and results after perineal repair

9.1 Methodology

Study design
This study was designed as a secondary cohort analysis of participants within a randomised trial. Data originated from a double blinded randomised controlled trial on different suture techniques described in Paper I\textsuperscript{173}. The aim was to study the association between experience of midwives performing perineal repair and postpartum perineal pain, wound healing and dyspareunia. Experienced clinicians and researchers within perineal trauma have suggested that lack of clinical experience of the person performing the surgical repair might be linked to poorer surgical outcomes\textsuperscript{114}. Short seniority has also been documented to increase the risk of severe perineal trauma during childbirth\textsuperscript{174}.

Study population
The study population consisted of 78 midwives responsible for the perineal repair of second degree perineal lacerations or episiotomies in 384 primiparous women. Midwives in the department were interviewed about their experience and suture preference prior to trial initiation. Seniority of the midwife was categorised into three categories: <5 years, 5-15 years and > 15 years. The most experienced midwives were used as the reference group. Data on the distribution of midwives in the three experience groups is presented in Table 5.

Table 5. Description of study in Aarhus University Hospital, Skejby (78 midwives and 384 trial participants).

<table>
<thead>
<tr>
<th>Seniority\textsuperscript{1}</th>
<th>Sutures performed</th>
<th>Recruitment rate</th>
<th>Minutes spent on suturing</th>
<th>Episiotomy rate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>median [range]</td>
<td>median [range]</td>
<td>N=384, n (%)\textsuperscript{2}</td>
</tr>
<tr>
<td>&lt; 5 years (n=25)</td>
<td>121 (32%)</td>
<td>5 [1-13]</td>
<td>15 [4-60]</td>
<td>21 (17%)</td>
</tr>
<tr>
<td>5-14 years (n=28)</td>
<td>137 (36%)</td>
<td>4 [1-15]</td>
<td>15 [5-50]</td>
<td>32 (23%)</td>
</tr>
<tr>
<td>15 years + (n=25)</td>
<td>126 (33%)</td>
<td>3 [1-17]</td>
<td>15 [5-45]</td>
<td>33 (26%)</td>
</tr>
<tr>
<td>Total (n=78)</td>
<td>384 (100%)</td>
<td>4 [1-17]</td>
<td>15 [4-60]</td>
<td>86 (22%)</td>
</tr>
</tbody>
</table>

\textsuperscript{1} Median years of experience = 7 years (range 0-39 years). Data not normally distributed.

\textsuperscript{2} Episiotomy rate not significantly different among groups: Pearson’s chi square = 2.89, p=0.24.
Data management and statistics

The association between years of clinical experience of the midwife and perineal pain or delayed wound healing at day 10 and dyspareunia at six months, were presented as crude odds ratios with 95% Confidence Intervals (CI). Potential confounders included in the logistic regression model were chosen as a priority based on risk factors reported in similar studies. Adjustment for potential, confounding factors was carried out by logistic regression analyses. Potential confounders were entered as a number of dummy variables equal to the number of categories-1. All statistical tests were two-tailed, and p values <0.05 were considered statistically significant. As each midwife contributed with the suturing of several participants, a robust variance estimation taking non-independence into account was obtained. Data were analysed using the statistical software package STATA version 8.2.

9.2. Results

The episiotomy rate was 22% in the randomised trial, and the median time spent on suturing was 15 minutes (range 4-60). Perineal pain was reported by 133/380 (35%) at 10 days after delivery. Wound gaping more than 0.5 cm at day 10 was present among 65/342 (19%). Sexual intercourse was resumed by 348/379 (92%) at six months postpartum. Dyspareunia during the previous month was reported by 103/348 (30%) at six months.

Table 6. Association between experience of the midwife and perineal pain, wound healing and dyspareunia.

<table>
<thead>
<tr>
<th></th>
<th>Numbers</th>
<th>OR (95%CI) 1</th>
<th>Adjusted OR (95% CI) 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Perineal pain 10 days postpartum</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 5 years</td>
<td>44/120 (37%)</td>
<td>1.49 (0.81-2.75)</td>
<td>1.46 (0.79-2.70)</td>
</tr>
<tr>
<td>5-14 years</td>
<td>54/135 (40%)</td>
<td>1.71 (0.93-3.15)</td>
<td>1.78 (0.95-3.36)</td>
</tr>
<tr>
<td>15 years +</td>
<td>35/125 (28%)</td>
<td>Ref.</td>
<td>Ref.</td>
</tr>
<tr>
<td><strong>Wound gaping at 10 days postpartum</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 5 years</td>
<td>21/107 (20%)</td>
<td>1.17 (0.58-2.37)</td>
<td>1.21 (0.58-2.51)</td>
</tr>
<tr>
<td>5-14 years</td>
<td>25/125 (20%)</td>
<td>1.20 (0.62-2.30)</td>
<td>1.28 (0.67-2.48)</td>
</tr>
<tr>
<td>15 years +</td>
<td>19/110 (17%)</td>
<td>Ref.</td>
<td>Ref.</td>
</tr>
<tr>
<td><strong>Dyspareunia at six months postpartum</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 5 years</td>
<td>29/110 (26%)</td>
<td>0.96 (0.53-1.74)</td>
<td>0.91 (0.49-1.69)</td>
</tr>
<tr>
<td>5-14 years</td>
<td>43/124 (35%)</td>
<td>1.42 (0.85-2.37)</td>
<td>1.33 (0.78-2.27)</td>
</tr>
<tr>
<td>15 years +</td>
<td>31/114 (27%)</td>
<td>Ref.</td>
<td>Ref.</td>
</tr>
</tbody>
</table>

1 Crude Odds Ratio adjusted for non-independence as most midwives recruited more than one participant
2 Adjusted Odds Ratio adjusted for maternal age, body mass index, smoking, mode of delivery, duration of active second stage, type of perineal laceration, suture material, breastfeeding status and non-independence in dataset.
No association was detected between the experience of the midwife and any of these results (table 8). Adjustment for maternal age, maternal pre-pregnancy body mass index, smoking habits, mode of delivery, duration of active second stage, type of perineal laceration, suture material or breastfeeding status did not change the results. Categorizing years of experience into two groups (< 15 and 15+ years), did not change this conclusion. The effect of selected confounders and their association with perineal pain and wound healing 10 days postpartum is shown in table 7.

Table 7. Distribution of potential confounders in the dataset (N=380).

<table>
<thead>
<tr>
<th></th>
<th>Perineal pain</th>
<th>Gaping wound</th>
<th>Dyspareunia</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>At 10 days</td>
<td>at 10 days</td>
<td>at six months</td>
</tr>
<tr>
<td>Age &lt; 29 years</td>
<td>251 (32%)</td>
<td>224 (21%)</td>
<td>233 (31%)</td>
</tr>
<tr>
<td>Age 30 years +</td>
<td>131 (40%)</td>
<td>118 (22%)</td>
<td>115 (29%)</td>
</tr>
<tr>
<td>BMI &lt; 25</td>
<td>314 (35%)</td>
<td>281 (20%)</td>
<td>289 (32%)</td>
</tr>
<tr>
<td>BMI 25 +</td>
<td>65 (37%)</td>
<td>60 (17%)</td>
<td>58 (19%)</td>
</tr>
<tr>
<td>Smoking –</td>
<td>354 (34%)</td>
<td>320 (18%)</td>
<td>227 (29%)</td>
</tr>
<tr>
<td>Smoking +</td>
<td>25 (52%)</td>
<td>21 (43%)</td>
<td>20 (40%)</td>
</tr>
<tr>
<td>Spontaneous delivery</td>
<td>326 (35%)</td>
<td>291 (20%)</td>
<td>296 (30%)</td>
</tr>
<tr>
<td>Instrumental delivery</td>
<td>54 (37%)</td>
<td>51 (14%)</td>
<td>52 (25%)</td>
</tr>
<tr>
<td>Second stage &lt; 60 min</td>
<td>274 (34%)</td>
<td>250 (19%)</td>
<td>251 (30%)</td>
</tr>
<tr>
<td>Second stage ≥ 60 min</td>
<td>99 (35%)</td>
<td>90 (19%)</td>
<td>95 (28%)</td>
</tr>
<tr>
<td>Laceration of 2nd degree</td>
<td>279 (35%)</td>
<td>265 (15%)</td>
<td>267 (28%)</td>
</tr>
<tr>
<td>Mediolateral episiotomy</td>
<td>83 (36%)</td>
<td>77 (31%)</td>
<td>81 (35%)</td>
</tr>
<tr>
<td>Suture material V.Rapide</td>
<td>194 (39%)</td>
<td>174 (16%)</td>
<td>171 (33%)</td>
</tr>
<tr>
<td>Suture material Vicryl</td>
<td>186 (31%)</td>
<td>168 (22%)</td>
<td>177 (27%)</td>
</tr>
</tbody>
</table>

1 Pain at 10 days postpartum was present in 133/380 participants (35%).
2 Information about wound healing was available for 342/380 (90%). Wound edges appeared gaping > 0.5 cm in 65/342 (19%).
3 Intercourse was resumed by 348/379 (92%) at six months postpartum. Dyspareunia was reported by 103/348 (30%). Dyspareunia was present before pregnancy in 19/103 (18%).
9.3 Discussion

In this secondary cohort analysis of participants within a randomised trial, the years of clinical experience of the midwife performing perineal repair did not seem to be associated with postpartum pain, delayed wound healing or dyspareunia following childbirth. Due to careful collection of information on obstetric history, socio-demographic factors and factors related to the perineal repair, we could adjust for a number of potential confounders. Adjustment for these variables and non-independence in the dataset did not, substantially or systematically change the results.

Each midwife contributed with a median of four participants and the recruitment was on a voluntary basis when the midwives felt confident in performing either of the two suture techniques studied. Selection bias was possible if inexperienced midwives enrolled only minor second degree lacerations which were easy to repair and had a quick and uncomplicated healing potential. The more experienced midwives may have enrolled more complex and ragged second degree lacerations and mediolateral episiotomies which were more difficult to repair and per se, had a different prognosis for maternal postpartum pain and delayed healing. However, episiotomy rates were not significantly different among groups, indicating that a differential bias was not present in the dataset. Also, the median time spent on suturing did not differ between the groups of midwives. Seniority did thus, not seem to contribute to the clinical performance of suturing second degree lacerations or episiotomies.

The limitations of this study are that the patients used in the randomised trial were a homogenous group of healthy primiparous women. It is unclear whether the results can be generalised into a more diverse patient population with variations in parity, ethnicity and co-morbidity. In order to further explore the association between experience of the caregiver and relevant obstetric outcomes, it would be preferable to investigate a large, unselected cohort of pregnant women. The hands-on skills training of staff prior to this trial might have biased the results towards the null, as this training option was an intervention in how midwives might suture without the focus of a trial. Research on the effect of a brief hands-on workshop has shown that midwives and obstetricians felt continuous medical education and regular updates on surgical skills were useful for their clinical practice\textsuperscript{144,176}. However, no study has yet proven the transfer value of such workshops from skills laboratories to clinical practice and there is a need for research on the subsequent clinical performance\textsuperscript{177,178}.

It is possible that experience in years is simply a poor indicator for surgical competence among midwives. From a clinical point of view there might be another reason which can explain why increasing experience does not improve surgical skills: No formal evaluation and feedback on surgical performance or patient evaluation is provided for midwives working in busy delivery wards. Clinicians can therefore practice with the level of skills obtained during their education without subsequent improvement of competence or adjustment of suturing techniques and tissue handling. Whether a specific number of years of experience working in the health care profession are a valid measure of clinical skills has been questioned within assessments of other obstetric skills. A recent Danish study involving 203 midwives and obstetricians
undergoing structured emergency obstetric skills training, documented that years of clinical experience was associated with increased self-confidence but not necessarily with better test scores in skills performance or formal evaluations of knowledge. This raises new questions about the research of how to estimate clinical competence in handling surgical repair after delivery. A more specific method to estimate competence in relation to perineal sutures could be to index the midwives according to a formal evaluation of their skills. A new research area could therefore be, to develop and validate an Objective Structured Assessment of Technical Skills (OSATS) test in order to quantify midwifery skills and competence in suturing perineal trauma. Another research area that may help to increase our knowledge about results after perineal repair is clinical decision-making on how midwives diagnose and choose to suture perineal lacerations.

This study is, to our knowledge, the first study on perineal pain and wound healing in relation to perineal repair performed by midwives which includes control for confounding and non-independence in the dataset. Previous suggestions by Grant et al. that inexperience of the operator may lead to poorer outcomes of suturing perineal laceration could thus not, be verified in our cohort of 78 midwives performing sutures in a randomised trial.

9.4 Conclusion
The aim of this study was to evaluate the association between years of experience of the midwife performing postpartum perineal repair and perineal pain or delayed wound healing at 14 days after delivery or dyspareunia at six months postpartum. We found no significant association between years of experience and the maternal postpartum results. Further research into evaluation of clinical skills and competence in relation to perineal repair of second degree perineal lacerations and episiotomies is needed.
10 Perspectives

The results from the trials in this thesis have answered only a few of the questions raised in relation to perineal care during vaginal delivery. The following section lists a number of perspectives raised for clinical practice and for further research within postpartum issues related to suturing of perineal ruptures and pain relief methods.

Evaluation of suture techniques

Pain was selected as a primary outcome in order to make results comparable with similar international trials. As the intention of suturing is to approximate torn muscles and restore the function of the perineal body, we might need to carefully reconsider the most relevant results for future trials. A basic research question that still needs methodological attention is the development of objective methods to evaluate if different suture techniques or suture materials have an impact on muscular strength postpartum.

The continuous suture technique throughout all layers is recommended in British evidence based guidelines as the optimal suture technique for perineal repair of second degree lacerations and episiotomies. The result from the suture trial at Aarhus University Hospital, Skejby was that an interrupted technique leaving the skin unsutured provided similar maternal results regarding pain, healing and dyspareunia as the continuous technique using a subcuticular approximation of perineal skin. We concluded that clinicians should be able to choose either of the two suture techniques according to preference.

Evaluation of pain relief methods during and after perineal repair

The trials in this thesis clearly demonstrated that there is still a need for improvement within the provision of sufficient pain relief during surgical repair. The gold standard of using local anaesthetics with the doses and application methods currently practiced in most delivery wards should be improved, as more than 50% of women report pain during surgical repair.

No single pain relief method should be considered the “gold standard” before effectiveness and patient satisfaction have been documented. Our midwifery profession needs to develop and evaluate other treatment options which could include a combination of several pain relieving methods.

The trial on ear acupuncture did not contribute to finding a non-pharmacologic pain relief method for pain during surgical repair of lacerations in the labia, the vagina or the perineum. Nevertheless, most trial participants were willing to try the method again at a subsequent delivery.

Pain relief in the first days after delivery is also an issue which we, in the midwifery profession need to focus on and improve. Several trials have compared topical anaesthetics to placebo in order to evaluate the postpartum perineal pain relief effect. A total of eight trials, including 976 patients included in a Cochrane Review, could not document any significant effect on postpartum pain. Another Cochrane Review, evaluating the effect of rectal analgesia (non-steroid anti-inflammatory drugs) on postpartum pain...
including three randomised trials and 249 participants, documented that NSAID rectal suppositories significantly reduced pain at 24 hours.  

Patient experiences with perineal healing
The follow up rate in the suture trial was >98% at 24-48 hours, 10 days and six months postpartum. A very interesting dataset is provided from the open-ended questions that trial participants provided as a supplement to the questionnaires. Participants mentioned several reasons for agreeing to participate in a blinded trial. One argument for participation was that the women felt they could contribute to an increased knowledge of maternal health issues which might be beneficial for other women in the future. Another reason was the concern for their individual health and lack of systematic follow up under the standard health care. A common comment in the open-ended part of the questionnaires was “I appreciate that someone cares about me. Even though everything is normal, it is nice to be reassured that my body heals well.” (Participant no. 77, unpublished data). The informal conclusion of the trial was therefore, that there was a call for professional attention for women with vaginal deliveries.

Experience and learning perspectives
The Royal College of Obstetricians and Gynaecologists highlights that “obstetric anal sphincter repair should be performed by appropriately trained practitioners” in the RCOG Green-top Guideline No. 29, 2007 on management of third and fourth-degree perineal tears. Our studies indicated that identical standards for midwifery practice should be defined. In addition it is important to focus on how a clinician is “appropriately trained”.

It is commonly believed that the more experience we gain as clinicians, the better we perform. This hypothesis was not confirmed by the observational study in this thesis. Experience in years since graduation did not affect the results. Information on how the midwives were trained during their education or an individual assessment of the clinical qualifications of each midwife was missing. A new approach in the evaluation of results after perineal repair would be to have a profile of each staff member based on an objective structured assessment of technical skills (OSATS). However, this requires definitions of standards and development of evaluation methods.

The learning perspective on how to teach midwifery students should be an issue investigated in future research. We have limited evidence based knowledge about which teaching strategies most effectively support the inexperienced operator in learning manual skills such as secure knot tying techniques, correct handling of instruments and identification of anatomical structures involved in perineal lacerations or on suturing. Hands-on workshops or virtual training by e-learning programs as a supplement to bed-side teaching, are methods that ought to be evaluated.
Can results from a trial be implemented into clinical practice?

For many years, procedures and routines within midwifery care and obstetrics have mostly been based on expert opinions. Substantial variations in practice are evident between different Danish hospitals (fig. 5, page 21)\(^6\)\(^{184}\). Research on the differences of clinical performance in relation to performing episiotomies during labour has also highlighted that large variations occur between individuals working in the same department\(^99\).

Clinicians working within the health care sector are obligated to keep their knowledge up to date but there is currently no demand for continuous medical education or formal tests in order to ensure competences on a regular basis\(^108\). The introduction of Evidence Based Medicine into obstetrics and the development of national evidence based guidelines have challenged the practice of traditional midwifery\(^185\).

The classification of knowledge into levels of evidence and the implied acknowledgement that strict, methodological research is the “gold standard” has led to debates on which paradigm of knowledge is right for midwifery and childbirth in general\(^185;186\). Other study designs than the randomised, controlled trial can contribute to our knowledge and have proven less time consuming to carry out\(^187\).

Clinical practice is often heterogeneous and complex: the best treatment for each individual patient may depend on several factors including psychological, socio-cultural and other contextual issues. The randomised trial is limited to create evidence on the very specific research question among a well-defined population under circumstances that are manipulated to facilitate a “clean laboratory environment”, including trial-specific training of involved staff. As dedicated clinicians and researchers, we need to focus on the gap between “best practice under optimal circumstances” evaluated in a trial and the level of “everyday practice under normal circumstances” which is the place where evidence needs to be implemented.

Implementation of evidence based guidelines into clinical practice is therefore an issue which needs further investigation. Participating in a clinical trial was the first formal training option for many midwives on suturing techniques since they graduated. The experience from the trials in this thesis was that the involved staff appreciated individual feedback regarding how they performed in relation to perineal repair. Structured feedback to clinicians who perform perineal repair may be an effective method to improve clinical practice which could complement patient evaluations.

Perspectives on evidence and systematic evaluation of practice

The concepts of Evidence Based Medicine (EBM) was introduced in midwifery in the late 1990s as a paradigmatic change in the way the profession should aim to document and develop procedures and technologies around childbirth\(^2;142\).

The definition by Sackett et al. in BMJ 1996 was: “Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients”\(^2;188\).

A graduation of evidence into five levels, according to study design and strength of the studied association, has been defined by the Oxford Centre for Evidence Based Medicine\(^189\). Evidence on the highest level
consists of systematic reviews of randomised trials with follow up rates $\geq 80\%$. The lowest grade of evidence is the expert opinion without explicit critical appraisal\textsuperscript{189}.

Randomised controlled trials (RCTs) are experimental studies where the treatment allocation is given by random sampling in order to distribute known and unknown confounders evenly in treatment groups\textsuperscript{156;190}. The effect of a certain intervention or specific technology is ideally evaluated with both participants and health care professionals blinded towards treatment allocation in order to avoid contamination of results by the placebo effect\textsuperscript{156;190}.

From a methodological perspective it is relevant to define which patients to use as the “population at risk” when we compare labour results such as episiotomy rates, caesarean sections and instrumental deliveries. The risk population can be considered as all pregnant women regardless of parity, previous mode of delivery, co-morbidity and other health related issues. This definition is the most widely used international definition when national birth statistics are compared\textsuperscript{62;191}. Obstetricians have argued that in order to compare relevant obstetric outcomes, patients should be grouped according to parity, previous mode of delivery, co-morbidity and previous pregnancy results\textsuperscript{14;192}.

This thesis relies on the perception of knowledge embedded in deductive research. This research method has limitations; the most obvious is that we only gain knowledge on the very narrow research question we, as researchers, had the competence to rise in the initial phase of designing the trials. An inductive research approach enquiring into the fact of why we as clinicians perform certain standardised skills with large interpersonal variation and outcomes is needed in order to understand and explain phenomena classified as “random variation” within the deductive research paradigm.

Improving health care is done as we continuously gain knowledge from trials and systematic evaluations of different interventions. However, trials are often very expensive and time-consuming to perform. The midwifery profession therefore needs to develop strategies on how to describe “best practice” in clinical guidelines even though evidence is sometimes absent. A simple, rapid and yet effective method is to perform quality improvement interventions after identifying the desired standards.

The most obvious strategy to avoid problems related to postpartum perineal repair would be to prevent the occurrence of lacerations in the first place. A simple way to identify potential preventive strategies within the midwifery scope of practice could start with evaluation of individual rates of perineal results among a group of midwives. The methods used by the midwives with the lowest rate of perineal traumas could then be identified through observational studies in order to raise new research hypothesis.

Involvement of patient perspectives in the selection of primary results for future trials might also improve the usability and clinical validity of trials in maternal health.

It is imperative that women receive high quality evidence-based care relating to the management and repair of perineal trauma. We, who professionally work with pregnant and childbearing women, should continue to combine research and patient values in our practice in order to secure high standards and low maternal morbidity after vaginal deliveries.
11 Further research

The work conducted in this thesis is only a minor contribution to the many unsolved questions within the clinical practice on suturing of perineal lacerations and pain relief during postpartum repair.

Further research that could increase our knowledge could focus on:

- Validation of diagnosis and classification of perineal injury. We currently have limited knowledge on the inter-rater reliability of the RCOG classification system for perineal lacerations. The use of clinical second opinions or ultrasound for diagnostics purposes requires solid evaluation.

- Suture techniques and suture materials which support approximation and healing of the superficial pelvic floor muscles. Evidence on perineal repair of second degree lacerations and episiotomies currently favors the technique which is documented to reduce short-term perineal pain.

- Evaluations of wound healing using the current objective scoring systems primarily focus on superficial closure of the wound and temporary processes of bruising and oedema. Development of assessment tools for the evaluations of muscle function and deeper tissue healing is needed.

- Photographs of perineal healing are an option in order to document patient results after vaginal deliveries for research purposes. Testing of intra and inter-rater variability is needed in order to evaluate the correlation between photo assessments versus clinical assessment.

- Pain relief postpartum. The findings from the two trials in this thesis highlight the need to improve midwifery standards, dispensing methods and effectiveness of the drugs for pain relief purposes.

- Dyspareunia is present in every fourth woman six months after delivery. Evidence on effective strategies to decrease this number would benefit millions of women each year.

- Women-centered perineal clinics with expert knowledge on postpartum healing have started in a few British hospitals following trials for prevention and treatment of perineal injuries. A formal evaluation of the effect of such interventions could highlight the short- and long-term implications of different postpartum care models for women after vaginal deliveries.

- Training of students in midwifery core skills such as diagnosing and suturing lacerations after vaginal deliveries needs to be evaluated with research focusing on transfer and retention. Learning on a one-to-one basis and practicing on humans is an ineffective and expensive leaning program that might be optimized by using simulations on artificial training models.

- The evaluation of surgical skills and clinical competence is a major concern, especially in situations when certain procedures are seldom practiced. Objective and validated measurement scales for the evaluation of midwifery skills on suturing and providing pain relief are needed.
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13 Appendices

Appendix 1: Perineal rupture of the 1st degree

Appendix 2: Perineal rupture of the 2nd degree, involved muscles indicated

Appendix 3: Mediolateral episiotomy wound, involved muscles indicated

Appendix 4: Questionnaire used in the acupuncture trial on day 1-2 (Danish version)*

Appendix 5: Questionnaire used in the suture technique trial day 10 (Danish version)*

Appendix 6: Questionnaire for 6 month follow up (Danish version)*

Appendix 7: The McGill Pain Questionnaire (English version)

Appendix 8: The REEDA Scale (English version)

* English versions of the questionnaires are available at the trial homepage: www.suturprojekt.dk

The original research protocols for both randomised trials are also available in Danish and English versions on the trial homepage: www.suturprojekt.dk
Kindberg, S. Stehouwer, M. Hvidman, L. Henriksen, TB.

Postpartum perineal repair performed by midwives: a randomised trial comparing two suture techniques.

Postpartum perineal repair performed by midwives: a randomised trial comparing two suture techniques leaving the skin unsutured*

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Accepted 5 October 2007.

Objective To compare a continuous suture technique with interrupted stitches using inverted knots for postpartum perineal repair of second-degree lacerations and episiotomies.

Design A double-blind randomised controlled trial.

Setting A Danish university hospital with more than 4800 deliveries annually.

Population A total of 400 healthy primiparous women with a vaginal delivery at term.

Method Randomisation was computer-controlled. Structured interviews and systematic assessment of perineal healing were performed by research midwives blinded to treatment allocation at 24–48 hours, 10 days and 6 months postpartum. Pain was evaluated using a visual analogue scale and the McGill Pain Questionnaire. Wound healing was evaluated using the REEDA scale and by assessment of gaping wounds >0.5 cm. Analysis complied with the intention-to-treat principle.

Main outcome measures The primary outcome was perineal pain 10 days after delivery. Secondary outcomes were wound healing, patient satisfaction, dyspareunia, need for resuturing, time elapsed during repair and amount of suture material used.

Results A total of 400 women were randomised; 5 women withdrew their consent, leaving 395 for follow up. The follow-up rate was 98% for all assessments after delivery. No difference was seen in perineal pain 10 days after delivery. No difference was seen in wound healing, patient satisfaction, dyspareunia or need for resuturing. The continuous suture technique was significantly faster (15 versus 17 minutes, $P = 0.03$) and less suture material was used (one versus two packets, $P < 0.01$).

Conclusion Interrupted, inverted stitches for perineal repair leaving the skin unsutured appear to be equivalent to the continuous suture technique in relation to perineal pain, wound healing, patient satisfaction, dyspareunia and need for resuturing. The continuous technique, however, is faster and requires less suture material, thus leaving it the more cost-effective of the two techniques evaluated.

Keywords Episiotomy, perineal pain, perineal repair, randomised trial, wound healing.

Introduction Perineal trauma is a frequent complication to vaginal delivery, and more than 80% of primiparous women sustain injury to the labia, vagina or perineum. Pain and discomfort related to perineal trauma have been reported to interfere with women’s daily activities postpartum, such as sitting, walking and lifting the baby. Pain related to perineal trauma and suturing is known to have a negative impact on sexual activities in the first year after childbirth. Midwives and obstetricians increasingly face women who wish to have a caesarean section due to fear of genital tract injuries or following previous childbirth-related trauma.

Surgical repair of lacerations in the genital area is performed by midwives or obstetricians according to extent of trauma. Trauma involving the vaginal mucosa, perineal skin and superficial perineal muscles are defined as first- or second-degree injuries. Lacerations involving the anal sphincter are defined as third-degree tears and of the anal mucosa as fourth-degree tears.

*The research protocol is available online in both Danish and English at: http://www.suturprojekt.dk
Choice of suture material for repair, suture technique and the operator’s surgical competence can influence the short- and long-term morbidity related to perineal repair.6–10 Rapidly absorbed synthetic materials are reported to be superior to monofilament sutures and other synthetic products with slower absorption when perineal pain and wound healing are evaluated.6–10 Pain can also be reduced if the perineal skin is not sutured.11,12 In relation to suture techniques, a continuous suture technique for approximating second-degree lacerations and episiotomies has been documented to be less painful and causes less need for subsequent suture material removal than interrupted stitches, including closure of the perineal skin.6,13

Midwives and obstetricians at Aarhus University Hospital, Skejby in Denmark, have developed a new suture technique for perineal repair that uses interrupted stitches when suturing perineal tissue without applying stitches directly to the skin surface. The hypothesis is that this new method is fast to perform, simple to implement into clinical practice and it might even reduce postpartum pain compared with a continuous suture technique. It has been argued that less-experienced midwives and doctors prefer to use interrupted stitches because of the step-wise approach. To test this hypothesis, we conducted a double-blind randomised controlled clinical trial in healthy, low-risk primiparous women requiring surgical repair of second-degree perineal lacerations and episiotomies. Acknowledging previous research on pain and healing related to sutures in the perineal skin, both suture techniques left the perineal skin unsutured.

Methods

The trial was designed as a prospective, randomised controlled clinical trial with recruitment from August 2004 through October 2005.

The trial was conducted at the Department of Gynaecology and Obstetrics, Aarhus University Hospital, Skejby, which has approximately 4800 deliveries annually. The population of the hospital catchment area is predominately Caucasian and encompasses a wide range of socio-economic classes.

A research protocol including methods, primary and secondary outcomes, sample size and ethical considerations was produced prior to trial initiation.

The Scientific Ethics Committee for the County of Aarhus in Denmark granted approval of this trial. The trial was registered in an international database on clinical trials (www.clinicaltrials.gov).

Eligibility and recruitment

Women were eligible to participate if they were primiparous, expecting a healthy child, had a spontaneous or instrumental delivery using a silastic ventouse cup after 36 weeks of gestation and had a second-degree perineal laceration or an episiotomy. Only women who were able to read and speak Danish were included. Exclusion criteria were delivery by metal cup or forceps, perineal injuries involving the anal sphincter and/or anal mucosa, postpartum haemorrhage, previous perineal surgery, diabetes or severe mental illness.

Women randomised but not meeting the eligibility criteria were included in the analysis according to the intention-to-treat principle.

Written information about the study was given to all primiparous women with intended vaginal delivery at Aarhus University Hospital, Skejby, during antenatal visits. Informed written consent was obtained from all participants if they decided to participate in the trial after the midwife responsible for delivery had diagnosed a perineal laceration.

Randomisation

Randomisation to suture method was carried out by the use of a computer-assisted voice response system. Data entry at randomisation was accomplished by the use of touch-tone keys using the participants’ unique personal identification number. A voice synthesiser spoke input prompts and regimen assignment. The randomisation programme used varying block sizes and stratified by laceration or episiotomy.

Sample size

The sample size calculation was based on an assumption of different perineal pain prevalence among the suture techniques 10 days after delivery. Based on the assumption that 25% of women would report perineal pain at day 10 after delivery if sutured with a continuous technique,6,12 a total of 366 women would need to be randomised to detect a reduction from 25 to 13% at a statistical significance level of 5% and a power of 80%. Incorporating a potential 10% lost to follow up, the trial was designed to include a total of 400 participants.

Suture techniques studied in this trial

The aim of both suture techniques was to restore muscular strength of the perineum by identifying and approximating the bulbocavernous and superficial transverse perineal muscle. The superficial part of the wound was approximated using subcuticular stitches a few millimetres below the skin surface. For both suture techniques, nonsuturing of the perineal skin was recommended.

Continuous suture technique

The continuous suturing technique is a loose, continuous nonlocking suture to close the vaginal mucosa and the muscular layer of the perineum. The perineal skin is approximated with the same continuous suture in the subcutaneous tissue a few millimetres under the perineal skin edges, finishing with a terminal knot in the vaginal mucosa in front of the hymenal ring.
Interrupted suture technique

The inverted, interrupted suture method involves a loose, continuous nonlocking suture to close the vaginal mucosa ending at the hymenal ring. Two to four interrupted, inverted stitches are applied to the muscular layer of the perineum. The perineal skin is approximated using inverted, interrupted stitches in the subcutaneous tissue a few millimetres under the perineal skin edges. Technically, the knots are ‘hidden’ by inverting the stitches so the knot is tied in the depth of the trauma. Thus, no suture material is visible at the skin surface where it might delay healing.

The standard suture material used in the department was the rapidly absorbed polyglactin 910 suture, gauge 2/0, 90 cm long on a 1/2c, 36 mm needle (Vicryl® Rapide; Ethicon GmbH, Norderstedt, Germany). After inclusion of the first 198 participants, the suture material used routinely for second-degree perineal repair changed to the standard polyglactin 910 material, same gauge and needle (Vicryl®; Ethicon GmbH).

Women were placed in lithotomy position for repair. The standard analgesia for perineal repair was infiltration analgesia in the wound area using 5–20 ml mepivacaine 10 mg/ml.

Prior to trial initiation, all midwives were trained in performing both suture techniques during theoretical introduction and hands-on workshops. The continuous suture technique was recommended in the department guideline, but most midwives preferred to mix suture techniques according to preference and surgical skills. Individual supervision and training was provided 3 months before and throughout the trial to optimise suture competences and standardisation of both suture techniques. Years of clinical experience and suture technique preference were noted for each midwife before and after the trial.

Main outcome measures

The primary outcome was perineal pain 10 days postpartum. Secondary outcome measures were perineal pain and wound healing 24–48 hours and 10 days after delivery, patient satisfaction with perineal repair at 6 months, dyspareunia in the preceding month and subsequent need for resuturing. Time elapsed to perform the perineal repair and number of suture material packets used were recorded to perform a cost-effectiveness analysis.

At 24–48 hours and 10 days after the birth, a research midwife, blinded to the suture technique, made a face-to-face structured interview followed by an examination of the woman’s perineum in the lithotomy position. Pain was registered using a 100-mm visual analogue scale (VAS) and the McGill Pain Questionnaire (MPQ). The question ‘have you experienced any pain from the sutured area within the previous 24 hours’ was included 10 days postpartum.

Wound healing was evaluated by a systematic assessment of redness, oedema, bruising, discharge and approximation of the wound edges known as the REEDA scale. Digital photographs of the healing process enabled researchers to discuss wound healing scores in case of uncertainty of wound assessment scores. Wounds gaping more than 0.5 cm were recorded as insufficiently healed and further categorised as wound break down or poor approximation of perineal tissue.

A telephone interview was performed 6 months after delivery, enquiring about perineal pain, dyspareunia, need for subsequent resuturing and patient satisfaction.

Blinding and compliance

Participants were not told which suture technique was used for perineal repair. Research midwives with no previous knowledge of treatment allocation collected the data. The compared suture techniques were both two-layered and the perineal wounds thus appeared similar.

Midwives were instructed to follow the allocated suture technique when possible. If the midwife made a clinical judgement that the performed repair was insufficient, she was allowed to supply additional stitches and document the reason on special trial forms.

For the interrupted suture technique, noncompliance was defined as applying interrupted stitches to perineal muscles or if interruption of the suture was reported due to technical difficulties handling the suture material.

For the interrupted suture technique, noncompliance was defined as applying noninverted stitches to the perineal wound or if a continuous suture had been applied in the surface of the wound.

Data analysis

The trial was analysed and reported according to CONSORT requirements. All statistical analyses were undertaken on an intention-to-treat basis. Data were entered twice into the software program EpiData Entry version 3.1 to correct for typing errors (The EpiData Association, Odense, Denmark 2005).

Two-sample t tests were used for analysis of continuous data. Continuous data without normal distribution were analysed by Mann–Whitney U test. The chi-square and Fisher’s exact tests were used for categorical variables. All statistical tests were two-tailed, and P values of <0.05 were considered statistically significant. Values are reported as the mean (SD) or the median (10–90% range) if not normally distributed. Risk ratio and 95% CIs are shown for binary outcomes. Stata statistical software version 8.2 was used for analysis (Stata Corp, College Station, TX, USA, 2003).

Results

During the randomisation period, 1820 primiparous women delivered vaginally, of whom 400 were randomised to either suture technique. Five women withdrew their consent to participate, leaving 395 participants for follow up (Figure 1).
The two groups were similar at the time of trial entry in terms of demographics, delivery details and perineal injury (Table 1). Both groups were also comparable in relation to management after trial entry, for example compliance to allocated suture technique and operator experience (Table 2). The interviews and assessments of wound healing were performed within the intended time limits and had a follow-up rate of more than 98% (Table 2).

No difference was seen in perineal pain 10 days after delivery evaluated as ‘any perineal pain within the previous 24 hours’, ‘any pain right now’ using a 100-mm VAS scale or pain described in words using the MPQ (Table 3). Wound healing evaluated by the REEDA scale was similar at 24–48 hours and 10 days postpartum. Wound healing on day 10 evaluated by number of gaping wounds >0.5 cm was also similar between groups (Table 3).

**Figure 1.** CONSORT diagram. Vaginal deliveries in primiparous women during study period.
Patient satisfaction with repair and occurrence of dyspareunia was similar in the two groups 6 months after delivery, and the need for subsequent revision of the repair did not differ between groups (Table 4).

The only significant difference in the trial was the cost-effectiveness of the two treatment regimes. The continuous suture technique was less time consuming to perform (15 versus 17 minutes, \( P = 0.03 \)). The continuous suture technique also required less suture material than the interrupted method (one versus two packets, \( P < 0.01 \)).

Compliance to the allocated suture technique was 77% with the continuous suture technique and 80% with the interrupted stitches. A per-protocol analysis was performed to investigate whether the noncompliance had contributed to nullifying a true difference between the suture techniques. The per-protocol analysis showed essentially no difference in any outcome measure (data not shown).

The department changed the standard suture material during the trial period from the rapidly absorbed 910 to standard 910 polyglactin. This change in suture material may have influenced our results. However, taking the change in suture material into account by a logistic regression analysis also showed unchanged results (data not shown).

**Discussion**

This study showed that a two-layer method using interrupted and inverted stitches for perineal repair of second-degree lacerations and episiotomies is an effective suture technique with the same impact on postpartum perineal pain and healing as the two-layer continuous suture technique. Previous trials comparing interrupted stitches with other suturing techniques have included stitches through the perineal skin.

We find it likely that applying stitches to the perineal skin (the third layer in three-layer techniques) could be the main reason for higher pain scores and discomfort in the postnatal period related to interrupted stitches as reported in previous trials.8,13 This interpretation of our results is consistent with findings in other clinical trials showing that a three-layer technique for perineal repair including skin sutures was associated with more postpartum pain and discomfort than a two-layer approach leaving the skin unsutured.11,12

Performing a randomised clinical trial in a homogeneous population of healthy primiparous women delivering their first child in a university hospital offers methodological advantages in terms of minimising potential confounders and random variation. However, we have no reason to believe...
that the results should not be representative for more heterogeneous populations in other clinical settings.

The compliance to the allocated suture technique in this trial was 77% using the continuous technique and 80% using the interrupted technique.

We can only speculate about the reasons for this rather low compliance to the allocated suture techniques. One reason could be that the midwives did not find the studied two-layer suture techniques adequate for perineal repair. Most midwives had a pretrial suture preference involving a mixture of techniques, some which also involved suturing the perineal skin (Table 2). Another reason could be that more than 70 midwives were involved in the trial, reflecting great variation in surgical skills and clinical competences. A third reason could be the strict compliance interpretation we applied in this trial: no minor or major deviations from the allocated suture technique was allowed.

During the trial, we experienced more than 98% follow up in all three postpartum evaluations. This is a reflection of a strong trial project steering process, of highly motivated research midwives and the fact that the enrolled women felt ‘safe and comfortable’ being seen by a healthcare professional and having the perineal wound healing assessed. Most of the experienced pain or discomfort and complications related to wound healing were handled within a 15-minute consultation using a structured interview guide. These findings indicate that labouring women appreciate a postpartum check-up dedicated to their physical wellbeing.

**Implications for practice**

We interpret the results of this trial as an opportunity for clinicians to choose among continuous sutures or interrupted and inverted stitches for perineal repair of second-degree lacerations and episiotomies according to preference and surgical competence. From a health economic perspective, the interrupted suture method in this trial was less favourable than the continuous suture technique due to use of more suture material packets. The interrupted technique was also slightly more time consuming. However, we question the relevance of a significant finding of a 2-minute time difference in operating time as this is of little clinical relevance.

<table>
<thead>
<tr>
<th>Table 2. Management after entry into trial (n = 395)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous technique (n = 198)</td>
</tr>
<tr>
<td>Experience of operator in years</td>
</tr>
<tr>
<td>Follow-up precision in trial</td>
</tr>
<tr>
<td>Hours from birth to first interview</td>
</tr>
<tr>
<td>Days from birth to second interview</td>
</tr>
<tr>
<td>Days from birth to third interview</td>
</tr>
<tr>
<td>Time taken to complete repair (minutes)</td>
</tr>
<tr>
<td>Material used, packets</td>
</tr>
<tr>
<td>Status of operator</td>
</tr>
<tr>
<td>Midwife</td>
</tr>
<tr>
<td>Supervising midwife</td>
</tr>
<tr>
<td>Registrar/senior house officer</td>
</tr>
<tr>
<td>Compliance with allocated policy</td>
</tr>
<tr>
<td>Interruption of continuous suture</td>
</tr>
<tr>
<td>Noninverted, interrupted stitches</td>
</tr>
<tr>
<td>Perineal skin sutures applied</td>
</tr>
<tr>
<td>Follow up: numbers interviewed</td>
</tr>
<tr>
<td>Follow up at first interview</td>
</tr>
<tr>
<td>Follow up at second interview</td>
</tr>
<tr>
<td>Follow up at third interview</td>
</tr>
<tr>
<td>Operator’s initial suture preference</td>
</tr>
<tr>
<td>Continuous technique as in trial</td>
</tr>
<tr>
<td>Interrupted technique as in trial</td>
</tr>
<tr>
<td>Mixed technique</td>
</tr>
<tr>
<td>Not known</td>
</tr>
</tbody>
</table>

*P value reaches the significance level of <0.05.
Implications for research
This trial has demonstrated that approximating perineal muscles and the subcutaneous layer can be performed with either of the two-layer suture techniques when short-term perineal pain and wound healing postpartum are considered. The next challenge for research on perineal traumas is to develop reliable, objective and validated measures for detecting whether the performed repair actually succeeded in approximating the perineal muscles to restore muscular strength and function of the perineal body. Immediate pain postpartum can be treated easily, but an inadequately approximated perineal body might affect a woman’s long-term reproductive health.

<p>| Table 3. Comparison between continuous suture and interrupted stitches at 24–48 hours and 10 days after delivery |
|---------------------------------|----------------|----------------|---------|</p>
<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>Continuous suture (n = 198)</th>
<th>Interrupted stitches (n = 197)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>VAS score (0.0–10.0 possible)</strong></td>
<td>Median (10–90% range)</td>
<td>Median (10–90% range)</td>
<td></td>
</tr>
<tr>
<td>At 24–48 hours</td>
<td>1.8 (0.0–5.0)</td>
<td>1.5 (0.0–5.0)</td>
<td>0.63</td>
</tr>
<tr>
<td>At 10 days</td>
<td>0.1 (0.0–2.5)</td>
<td>0.1 (0.0–3.0)</td>
<td>0.94</td>
</tr>
<tr>
<td><strong>McGill Pain Questionnaire (0–78 possible)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At 24–48 hours</td>
<td>11 (2–25)</td>
<td>9 (2–22)</td>
<td>0.17</td>
</tr>
<tr>
<td>At 10 days</td>
<td>4 (0–16)</td>
<td>4 (0–15)</td>
<td>0.96</td>
</tr>
<tr>
<td><strong>REEDA score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At 24–48 hours</td>
<td>3 (1–6)</td>
<td>3 (1–7)</td>
<td>0.78</td>
</tr>
<tr>
<td>At 10 days</td>
<td>1 (0–4)</td>
<td>1 (0–4)</td>
<td>0.34</td>
</tr>
<tr>
<td><strong>Pain in wound area last 24 hours, day 10</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild pain</td>
<td>65 (33)</td>
<td>72 (37)</td>
<td>0.90 (0.68–1.18)</td>
</tr>
<tr>
<td>Moderate pain</td>
<td>47 (24)</td>
<td>55 (28)</td>
<td></td>
</tr>
<tr>
<td>Severe pain</td>
<td>14 (7)</td>
<td>15 (8)</td>
<td></td>
</tr>
<tr>
<td><strong>Wound gaping &gt;0.5 cm, 24–48 hours</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suture break down, total</td>
<td>18 (9)</td>
<td>21 (13)</td>
<td>0.72 (0.40–1.27)</td>
</tr>
<tr>
<td>Suboptimal approximation</td>
<td>16 (8)</td>
<td>21 (11)</td>
<td></td>
</tr>
<tr>
<td><strong>Wound gaping &gt;0.5 cm, day 10</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suture break down, total</td>
<td>30 (15)</td>
<td>39 (20)</td>
<td>0.77 (0.50–1.18)</td>
</tr>
<tr>
<td>Suture break down, superficial</td>
<td>2 (1)</td>
<td>4 (2)</td>
<td></td>
</tr>
<tr>
<td>Suboptimal approximation</td>
<td>15 (7)</td>
<td>20 (10)</td>
<td></td>
</tr>
<tr>
<td><strong>Oral analgesia used</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At 24–48 hours</td>
<td>44 (22)</td>
<td>53 (27)</td>
<td>0.83 (0.58–1.17)</td>
</tr>
<tr>
<td>At 10 days</td>
<td>21 (11)</td>
<td>20 (10)</td>
<td>1.04 (0.59–1.87)</td>
</tr>
</tbody>
</table>

| Table 4. Comparison between continuous suture and interrupted stitches 6 months after delivery (n = 395) |
|----------------------------------|-----------|-----------|---------|
| Outcome measure                      | Continuous suture (n = 198), n (%) | Interrupted stitches (n = 197), n (%) | Risk ratio (95% CI) | P value |
|----------------------------------|-----------|-----------|---------|
| **Revision of wound**             | 4 (2)     | 4 (2)     | 0.99 (0.25–3.92) | 1.00 |
| **Satisfaction with repair**      | 165 (83)  | 166 (84)  | 0.99 (0.91–1.08) | 0.80 |
| **Sutures removed, in total**     | 25 (13)   | 21 (11)   | 1.18 (0.69–2.04) | 0.54 |
| **At day 10 follow up in trial**  | 11 (6)    | 10 (5)    |         |       |
| **GP between day 10 and 6 months**| 14 (7)    | 11 (6)    |         |       |
| **Dyspareunia at first intercourse**| 126 (64) | 111 (56)  | 1.13 (0.96–1.33) | 0.14 |
| **Dyspareunia at 6 months**       | 47 (24)   | 58 (29)   | 0.81 (0.58–1.12) | 0.20 |

*Reasons for revision of wound: suture break down (2), pain in wound area (5), too tight (1).
Continuous or interrupted stitches for second-degree perineal repair

### Conclusion

This trial showed no difference in perineal pain or wound healing at 24–48 hours, 10 days and 6 months after delivery when comparing a continuous suture technique with interrupted and inverted stitches for perineal repair of second-degree perineal lacerations and episiotomies. Patient satisfaction, number of resutured wounds and frequency of dyspareunia 6 months after delivery were similar.

We conclude that using interrupted and inverted stitches for perineal repair of second-degree perineal lacerations and episiotomies is an effective suture method, offering similar results as the continuous suture technique. The continuous suture technique is most cost-effective as it is faster to perform and requires less suture material.

### Contribution to authorship

S.K. and M.S. conceived the idea for this trial and wrote the study protocol, coordinated data collection and performed data analyses. L.H. and T.B.H. contributed to study design, funding applications and supervised study implementation and data collection. All authors contributed to writing and editing this article.

### Acknowledgements

We wish to thank the women who participated in the trial and the many midwives and doctors at Aarhus University Hospital whose contributions made our research possible. We also wish to thank Dr Karl Moeller Bek, Consultant PhD, Associated Professor, Aarhus University Hospital, for his contributions of clinical expertise on suturing techniques and Dr Brenda Kelly, University of Oxford, for insightful comments to the study protocol, analyses of data and corrections of the final drafts for this article. The trial was sponsored by The Research Fund at Aarhus University Hospital, The Danish Midwifery Organisation, The Danish Midwifery Society, The Danish Medical Research Council, Aase and Ejnar Danielsen’s Foundation, Frode Nygaard’s Foundation, Else and Mogens Wedell-Wedellborgs Foundation, The Ib Rohde Foundation, The Sophus Jacobsen Foundation and King Christian the 10th Foundation. A PhD grant for S.K. was provided by Grethe Hylleberg, The South Danish Midwifery Council.

### References

Kindberg, S. Klünder L. Strøm, J. Henriksen, TB.

Ear Acupuncture or Local Anesthetics for postpartum pain relief.

Accepted by BJOG September 2008 (in press)
Ear acupuncture or local anaesthetics as pain relief during postpartum surgical repair: a randomised controlled trial

S Kindberg, L Künder, J Strøm, TB Henriksen

Objective To evaluate two methods of pain relief during postpartum surgical repair in regard to effectiveness, wound healing and patient evaluation.

Design A randomised controlled trial testing a pragmatic set-up of brief training of clinicians.

Setting Delivery ward at a Danish district hospital with approximately 1600 annual deliveries.

Population Primiparous women with a vaginal delivery at term who needed surgical repair of lacerations to the labia or the vagina, perineal lacerations of first or second degree or mediolateral episiotomies.

Methods The trial was set up to evaluate the effect of a brief 2-hour hands-on training in the use of ear acupuncture. All midwives (n = 36) in the department had previous experience in using acupuncture for obstetric pain relief. Pain and wound healing were evaluated using validated scores. Data collection was performed by research assistants blinded towards treatment allocation. Randomisation was computer assisted. A total of 207 women were randomised to receive ear acupuncture (105) and local anaesthetics (102), respectively.

Main outcome measures The primary outcome was pain during surgical repair. Secondary outcomes were wound healing at 24–48 hours and 14 days postpartum, participant satisfaction, revision of wound or dyspareunia reported 6 months postpartum.

Results Pain during surgical repair was more frequently reported by participants allocated to ear acupuncture compared with participants receiving local anaesthetics (89 versus 54%, P < 0.01). Pain intensity during surgical repair was also reported higher (Visual Analogue Scale score 3.5 versus 1.5, P < 0.01). The ear acupuncture group received more additional pain relief during repair (53 versus 19%, P < 0.01). No difference was observed in wound healing at 24–48 hours or 14 days postpartum. Revision of wounds was rare, and no difference occurred in this trial. Comparable proportions of participants reported dyspareunia at 6 months. Patient satisfaction with the allocated pain-relief method was lower in the ear acupuncture group (69 versus 91%, P < 0.01) and fewer women would recommend the method to a friend (74 versus 91%, P < 0.01).

Conclusions Ear acupuncture as used in this trial was less effective for pain relief compared with a local anaesthetic. No difference was observed in wound healing, need for revision of wound or dyspareunia. Patient satisfaction with allocated pain-relief method was lower in the ear acupuncture group.

Keywords Acupuncture, local anaesthetics, midwives, pain relief, postpartum surgical repair.

Introduction

Genital tract trauma is a frequent complication to vaginal delivery, and more than 80% of primiparous women sustain injury to the labia, vagina or perineum. Midwives usually perform the repair of labia tears, vaginal lacerations, perineal lacerations of first or second degree and episiotomies. Lacerations involving the anal sphincter or the rectal mucosa are classified as third and fourth degree tears; these lacerations are repaired by doctors.

Women can experience pain and discomfort related to sutures for weeks and even months after delivery. Several, large randomised trials have shown that the continuous suturing technique with subcutaneous stitches placed well
Pain and discomfort can also be reduced using a rap-

There is scanty evidence on effective pain-relieving methods during perineal repair.\textsuperscript{8} A recent trial on different suture techniques reported that 50% of the participants experienced pain during perineal repair.\textsuperscript{9} A clinical observation from the use of local anaesthetics is that the injection of the anaesthetic itself causes pain and may induce oedema of the tissue.\textsuperscript{10} Therefore, there is a need to improve the quality and effectiveness of pain-relief methods for the repair of perineal and vaginal injuries following childbirth.

In recent years acupuncture has been used for several obstetric indications.\textsuperscript{11} Randomised trials have also evaluated the effect of acupuncture on pain during labour.\textsuperscript{12,13} Ear acupuncture provided by intensively trained midwives and obstetricians and specifically for postpartum perineal pain relief has been proposed. However, the effectiveness in clinical practice has not been evaluated systematically.\textsuperscript{14} A randomised controlled clinical trial was therefore conducted to compare the effect of ear acupuncture with local anaesthetics during surgical repair after vaginal delivery. The trial tested a brief acupuncture treatment in order to perform a clinically relevant evaluation of a focused introduction to a new pain-relief method.

Methods

Study design

The study was designed as a prospective, randomised controlled clinical trial. The trial was initiated in May 2006, and inclusion of participants stopped in July 2007. The trial was conducted at Sønderborg Hospital, Denmark. This hospital has approximately 1600 annual deliveries, and 36 midwives were trained to perform ear acupuncture treatment.

Clinical setting and standards of practice in relation to surgical repair

All midwives working at the delivery ward were experienced in the use of acupuncture for general pain relief during labour. Standard acupuncture points for obstetric purposes were primarily located on the hands, arms, legs and on the back as described by Chinese acupuncture traditions.\textsuperscript{15} Prior to enrolment of participants in this trial, all 36 midwives were trained to provide ear acupuncture specifically for perineal pain relief in a 2-hour hands-on course. The course was chaired by a certified acupuncturist who also worked as a clinical midwife. When the first 100 participants were enrolled, a mandatory individual 1-hour refresher workshop was arranged in order to secure uniformity of treatment throughout the trial period.

The standard suture material in the department was a rapidly absorbed multifilament suture with a 3/8 atraumatic needle (Vicryl Rapide\textsuperscript{8} gauge 2-0 or 3-0, Ethicon GMBH, Norderstedt, Germany). The suture technique recommended in local guidelines was a continuous suture for vaginal mucosa and perineal repair based on recommendations in a recent Cochrane Review.\textsuperscript{16} Labia tears were sutured according to the preference of the midwife.

Women requiring surgical repair of lacerations in the vulva area or perineal lacerations of first or second degree or mediolateral episiotomies were randomly allocated to receive either of the two pain-relief methods. Additional pain relief could be supplied at any time during the surgical repair upon request from patients. Application of 5-mL gel with 4% Lidocaine was first choice for both treatment groups.

Ear acupuncture

The acupuncture treatment consisted of six acupuncture needles.

Two 15-mm needles were placed on top of the helix of the ear covering the ‘genital’ area according to French Auriculotherapy.\textsuperscript{17} The Shen Men point in the ear was used to increase the anaesthetic effect according to both French and Chinese traditions.\textsuperscript{15,17} Supplementary acupuncture was used: Bilaterally, a 40-mm needle was placed in the ‘Bladder 36’ point located at the tuber ischiadicus. One 15-mm needle was used for general relaxation in the ‘Governor Vessel 20’ point located on top of the head according to Chinese TCM tradition.\textsuperscript{15} The six prescribed acupuncture needles generally took a few minutes to insert. Acupuncture needles were stimulated by manual rotation of the needle to evoke needle sensation (De Qi). No electrostimulation was used. Acupuncture needles were covered with silicone, which facilitates easy incision and removal (Seirin GMBH, Jeu-Isenburg, Germany).

Charts and photographs showing the acupuncture points and needle insertion techniques were available in all delivery suites for display during the trial.

Local anaesthetics

Local anaesthetics were the usual pain-relief method in the department for most postpartum surgical repairs. The midwife was encouraged to use the amount estimated necessary with an upper limit of 20 mL. Lidocaine 10 mg/mL local anaesthetic was applied directly into the wound using a plastic syringe with an appropriately sized needle. Suturing could start after 5 minutes.

Outcome measures

The primary outcome was pain experienced during surgical repair reported by women at 24–48 hours postpartum. Secondary outcomes were need for additional pain relief, wound healing assessed at 24–48 hours and 14 days postpartum, participant evaluation, need for wound revision and
superficial dyspareunia as reported 6 months postpartum. Other outcomes of interest were pain experienced during application of both pain-relief methods and pain from the sutured area during healing postpartum.

**Eligibility and recruitment**

All healthy primiparous women with intended vaginal delivery at Sønderborg Hospital, Denmark, received written patient information about the trial at antenatal visits. The written informed consent was obtained prior to inclusion into the trial if the midwife diagnosed a laceration that required suturing, and the patient was still willing to participate. Primiparous women were eligible if they expected a healthy child and had a spontaneous or instrumental delivery using a ventouse after 36 weeks of gestation. The surgical repairs included in this trial were lacerations in the labia, vaginal mucosa, superficial perineal tissue (first or second degree) or mediolateral episiotomy. Participants were required to understand Danish.

Exclusion criteria were delivery by forceps, perineal injuries involving the anal sphincter and/or anal mucosa (third or fourth degree), postpartum haemorrhage >1000 ml, previous perineal surgery or severe mental illness. The laceration should not have extended into the anal sphincter complex, as these repairs were usually sutured by an experienced obstetrician under spinal analgesia in the operating theater. Enrollment of patients with epidurals into the trial was only possible, if the patient requested additional pain relief prior to surgical repair. In this case a ‘top-up’ of the epidural was not offered and women were randomised to one pain-relief method or the other as described in the study protocol.

**Randomisation**

Randomisation was made by the use of touch-tone telephone keys using the participant’s unique personal identification number with a computer-assisted Voice Response System. In order to ensure equal distribution in treatment groups, the randomisation programme stratified patients by epidural for pain relief during delivery and whether an episiotomy had been performed. The midwife in charge of the delivery was responsible for conducting the allocated treatment to suture the laceration and to fill in special trial forms.

**Blinding**

The trial was single blinded on the part of the research team responsible for postnatal interviews, inspections of wound healing and data entry into the research database. All trial participants were encouraged not to disclose their randomisation group during follow up.

**Data collection**

All participants were interviewed using structured questionnaires. The interviews were performed by a specialist midwife (S.K.) or two research nurses. Interviews and wound-healing assessments were conducted in the hospital at 24–48 hours and 14 days postpartum. The research midwife or nurse filled out the questionnaires during the interview and after inspection of wound healing. The final follow-up interview at 6 months postpartum was conducted as a telephone interview.

Pain was assessed using a simple Verbal Descriptive Pain Scale (no pain, mild pain, moderate pain or severe pain). The Visual Analogue Scale (VAS) was used for evaluation of pain intensity. Wound healing was evaluated by assessing whether the wound was gaping more than 0.5 cm as well as by systematic evaluation of redness, oedema, ecchymosis, discharge and approximation of skin edges using the REEDA scale. The questionnaires were developed on the basis of questionnaires used in similar trials in the UK and Denmark.

**Sample size**

The power calculation was based on an assumption of a 20% absolute difference in numbers of expected ‘pain-free surgical repairs’ following the use of ear acupuncture. In a previous trial using similar local anaesthetics, 50% of the participants reported pain during perineal repair. In order to detect an increase from 50 to 70% or a decrease from 50 to 30% with the power of 80% and an alpha of 0.05, a total of 206 participants were needed for the trial.

**Data analyses**

Trial analyses and reports were made in accordance with CONSORT requirements. All statistical analyses were performed based on the intention-to-treat principle. Data were entered twice into the software program EpiData Entry version 3.1 in order to correct for typing errors (The EpiData Association, Odense, Denmark). Stata statistical software version 8.2 was used for analysis (StataCorp College Station, TX, USA).

Two-sample t tests were used for analyses of continuous data with normal distribution. Mean values were reported with SD. Continuous data without normal distribution were analysed by the Mann–Whitney U test and median values were reported with 10/90% percentiles. The chi-square test was used for analyses of categorical variables. The Fisher’s exact test was used if expected frequencies were less than five. All statistical tests were two tailed, and P values <0.05 were considered statistically significant. Risk ratios (RR) and 95% CI are shown for selected binary outcomes.

**Results**

During the randomisation period, 623 primiparous women delivered vaginally. Of these, 207 were randomised. A total of 105 women were allocated to ear acupuncture and 102 to local anaesthetics. Two women were enrolled without meeting the
inclusion criteria but remained in the trial according to the intention-to-treat principle (Figure 1).

The follow-up rate was 99% at 24–48 hours, 97% at 14 days and 92% at 6 months postpartum (Figure 1). The two groups were comparable in terms of baseline characteristics, distribution of genital tract injury and usage of obstetric acupuncture during labour. The use of epidural for pain relief during labour was comparable (Table 1). No side-effects were reported in either treatment group.

Treatment with either pain-relief method was provided by 36 different midwives during the study period. The average number of enrolled participants per midwife was five throughout the study period (range 1–18). No difference was seen with respect to time for completion of repair or usage of suture material. Compliance to allocated treatment was 96% in both groups. The interviews and assessments of wound healing were performed within the intended time limits for follow up (Table 2).

Blinding of the interviewer was assessed during the trial. The blinding during interviews was successful in 63% within the acupuncture group and 64% in the local analgesia group ($P = 0.99$). Additional pain-relief methods were more commonly used in the acupuncture group than among those allocated to local anaesthetics (Table 2).

Pain during surgical repair was more frequently reported by women allocated to ear acupuncture than those receiving local anaesthetics (Table 3). The median VAS score was significantly higher in the ear acupuncture group compared with the local anaesthetics group: 3.5 versus 1.5, $P < 0.01$. Significantly more women also reported pain on a verbal descriptive scale and felt that the repair was uncomfortable (Table 3). The ear acupuncture group more frequently received additional pain relief methods than those allocated to local anaesthetics (Table 2).

Figure 1. CONSORT flowchart. Vaginal deliveries in primiparous women during study period.
additional pain relief during surgical repair (53 versus 22%, \( P < 0.01; \text{RR} 2.50, 95\% \text{CI} 1.66–3.79\)) (Table 3). Excluding patients with epidurals from the analysis of primary outcomes did not change the conclusions (data not shown).

However, no difference was seen in numbers of patients who would have preferred more analgesia (14 versus 8%, \( P = 0.14 \)).

No difference was seen in wound healing at 24–48 hours or 14 days postpartum. Comparable proportions of wounds were gaping at 24–48 hours, and these proportions also declined to comparable levels at 14 days postpartum (Table 3). Need for subsequent wound revision was rare and did not differ between the two groups (Table 3). The occurrence of dyspareunia was similar in the two groups 6 months postpartum (Table 3).

Patient satisfaction with allocated pain-relief method evaluated 14 days postpartum was lower in the ear acupuncture group (69 versus 91%, \( P < 0.01 \)). Fewer women in the ear acupuncture group would recommend it to a friend

---

**Table 1. Baseline characteristics for participants in trial**

<table>
<thead>
<tr>
<th></th>
<th>Ear acupuncture ((n = 105))</th>
<th>Local anaesthetics ((n = 102))</th>
<th>(P) value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mothers</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, years</td>
<td>26.4 (4.4)</td>
<td>27.6 (4.6)</td>
<td>0.06</td>
</tr>
<tr>
<td>BMI ((\text{kg/m}^2))</td>
<td>20.1 (3.8)</td>
<td>20.2 (3.6)</td>
<td>0.79</td>
</tr>
<tr>
<td>Smoker</td>
<td>16 (15)</td>
<td>9 (9)</td>
<td>0.14</td>
</tr>
<tr>
<td><strong>Babies</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gestational age, days</td>
<td>281 (9.7)</td>
<td>280 (9.3)</td>
<td>0.85</td>
</tr>
<tr>
<td>Birthweight, grams</td>
<td>3383 (427)</td>
<td>3459 (442)</td>
<td>0.21</td>
</tr>
<tr>
<td><strong>Delivery</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acupuncture used during labour</td>
<td>40 (38)</td>
<td>47 (46)</td>
<td>0.29</td>
</tr>
<tr>
<td>Epidural used during labour</td>
<td>25 (24)</td>
<td>27 (26)</td>
<td>0.72</td>
</tr>
<tr>
<td>Duration of second stage, minutes</td>
<td>29 (13–65)</td>
<td>30 (15–60)</td>
<td>0.64</td>
</tr>
<tr>
<td><strong>Sutured injury in genital tract</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Labia minora</td>
<td>45 (43)</td>
<td>41 (40)</td>
<td>—</td>
</tr>
<tr>
<td>Vaginal mucosa</td>
<td>35 (33)</td>
<td>25 (25)</td>
<td></td>
</tr>
<tr>
<td>First-degree perineal laceration</td>
<td>16 (15)</td>
<td>24 (24)</td>
<td></td>
</tr>
<tr>
<td>Second-degree perineal laceration</td>
<td>32 (30)</td>
<td>33 (32)</td>
<td></td>
</tr>
<tr>
<td>Episiotomy (mediolateral)</td>
<td>19 (18)</td>
<td>16 (16)</td>
<td></td>
</tr>
<tr>
<td>Third degree (enrolled in error)</td>
<td>—</td>
<td>1 (1)</td>
<td></td>
</tr>
</tbody>
</table>

Data presented as number (%), mean (SD) or median (10–90% percentile).
*Genital tract trauma could be one or several of the mentioned. The total therefore exceeds 100%.

**Table 2. Treatment after inclusion into trial and precision of data collection**

<table>
<thead>
<tr>
<th></th>
<th>Ear acupuncture ((n = 105))</th>
<th>Local anaesthetics ((n = 102))</th>
<th>(P) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliance to pain-relieving method</td>
<td>101 (96)</td>
<td>98 (96)</td>
<td>0.89</td>
</tr>
<tr>
<td>Supplementary pain relief during repair*</td>
<td>56 (53)</td>
<td>22 (22)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Lidocaine gel 4%</td>
<td>54 (51)</td>
<td>15 (15)</td>
<td></td>
</tr>
<tr>
<td>Entonox ((\text{N}_2\text{O–O}_2))</td>
<td>7 (7)</td>
<td>6 (6)</td>
<td></td>
</tr>
<tr>
<td>Other methods</td>
<td>6 (6)</td>
<td>4 (4)</td>
<td></td>
</tr>
<tr>
<td><strong>Suturing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minutes to perform repair</td>
<td>15 (5–40)</td>
<td>17 (7–30)</td>
<td>0.46</td>
</tr>
<tr>
<td>Material used, packets</td>
<td>1 (1–2)</td>
<td>1.5 (1–2)</td>
<td>0.12</td>
</tr>
<tr>
<td><strong>Follow-up precision in trial</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hours from birth to first interview</td>
<td>36 (17–71)</td>
<td>33 (18–70)</td>
<td>0.36</td>
</tr>
<tr>
<td>Days from birth to second interview</td>
<td>15 (13–20)</td>
<td>15 (13–18)</td>
<td>0.95</td>
</tr>
<tr>
<td>Days from birth to third interview</td>
<td>171 (153–223)</td>
<td>174 (156–210)</td>
<td>0.80</td>
</tr>
</tbody>
</table>

Data presented as number (%), mean (SD) or median (10–90% percentile).
*Additional pain relief provided by midwife during suturing on request from trial participants.
Willingness to choose the same pain-relief method at a future delivery did not differ between the groups, and an equal proportion of women were generally satisfied with the repair (Table 3).

Patient evaluation of pain and discomfort during application of either pain-relief method was also evaluated. Application of the pain-relief method itself was less painful when ear acupuncture was provided compared with local anaesthetics (VAS 1.5 versus 2.1, \( P = 0.02 \)) (Table 4). In the ear acupuncture group 59% felt pain when the method was applied compared with 68% among those allocated to local anaesthetics (\( P = 0.15 \)) (Table 4).

### Table 3. Primary and secondary outcomes in trial

<table>
<thead>
<tr>
<th>Effectiveness of pain-relief method</th>
<th>Ear acupuncture ((n = 105))</th>
<th>Local anaesthetics ((n = 102))</th>
<th>( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS during repair ((0.0–10.0 \text{ possible}))</td>
<td>3.5 ((0.9–8.6))</td>
<td>1.5 ((0.0–5.2))</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Pain during repair ((\text{any pain}))</td>
<td>93 ((89))</td>
<td>55 ((54))</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Verbal description of pain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild pain</td>
<td>51 ((49))</td>
<td>37 ((36))</td>
<td>0.23</td>
</tr>
<tr>
<td>Moderate pain</td>
<td>30 ((29))</td>
<td>15 ((15))</td>
<td></td>
</tr>
<tr>
<td>Severe pain</td>
<td>12 ((12))</td>
<td>3 ((3))</td>
<td></td>
</tr>
<tr>
<td>Wound healing and dyspareunia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>REEDA score day 1–2 ((0–15 \text{ possible}))</td>
<td>3 ((1–7))</td>
<td>3 ((1–7))</td>
<td>0.30</td>
</tr>
<tr>
<td>REEDA score day 14 ((0–15 \text{ possible}))</td>
<td>1 ((0–3))</td>
<td>1 ((0–3))</td>
<td>0.90</td>
</tr>
<tr>
<td>Wound gaping day 1–2 ((&gt;0.5 \text{ cm}))</td>
<td>28 ((27))</td>
<td>25 ((25))</td>
<td>0.72</td>
</tr>
<tr>
<td>Wound gaping day 14 ((&gt;0.5 \text{ cm}))</td>
<td>14 ((15))</td>
<td>17 ((17))</td>
<td>0.50</td>
</tr>
<tr>
<td>Revision of wound area ((6 \text{ months}))</td>
<td>0 ((0))</td>
<td>2 ((2))</td>
<td>0.24</td>
</tr>
<tr>
<td>Dyspareunia at first intercourse</td>
<td>51 ((49))</td>
<td>47 ((46))</td>
<td>0.72</td>
</tr>
<tr>
<td>Dyspareunia at 6 months postpartum</td>
<td>24 ((23))</td>
<td>15 ((15))</td>
<td>0.13</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient evaluation</th>
<th>Ear acupuncture ((n = 105))</th>
<th>Local anaesthetics ((n = 102))</th>
<th>( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Would prefer more analgesia*</td>
<td>15 ((14))</td>
<td>8 ((8))</td>
<td>0.14</td>
</tr>
<tr>
<td>Felt repair was uncomfortable*</td>
<td>57 ((54))</td>
<td>30 ((29))</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Satisfied with pain-relieving method**</td>
<td>72 ((69))</td>
<td>93 ((91))</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Would recommend method to friend**</td>
<td>78 ((74))</td>
<td>93 ((91))</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Would choose same method again**</td>
<td>77 ((73))</td>
<td>79 ((77))</td>
<td>0.49</td>
</tr>
<tr>
<td>Generally satisfied with repair**</td>
<td>89 ((85))</td>
<td>88 ((86))</td>
<td>0.77</td>
</tr>
</tbody>
</table>

Data presented as number (%), mean (SD) or median (10–90% percentile).

*Question answered in questionnaire 1–2 days postpartum.

**Question answered in questionnaire 14 days postpartum.

### Table 4. Pain during application of pain-relief method and pain in wound area postpartum

<table>
<thead>
<tr>
<th>Evaluation of application of pain-relieving method</th>
<th>Ear acupuncture ((n = 105))</th>
<th>Local anaesthetics ((n = 102))</th>
<th>RR ((95% \text{ CI}))</th>
<th>( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS score for application of method</td>
<td>1.5 ((0.1–4.9))</td>
<td>2.1 ((0.3–5.7))</td>
<td>–</td>
<td>0.02</td>
</tr>
<tr>
<td>Application was painful</td>
<td>62 ((59))</td>
<td>70 ((68))</td>
<td>0.86 ((0.70–1.06))</td>
<td>0.15</td>
</tr>
<tr>
<td>Application was uncomfortable</td>
<td>11 ((11))</td>
<td>29 ((28))</td>
<td>0.37 ((0.19–0.70))</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Pain from wound area postpartum</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAS Score at 24–48 hours</td>
<td>1.9 ((0.0–6.6))</td>
<td>2.7 ((0.0–6.0))</td>
<td>–</td>
<td>0.06</td>
</tr>
<tr>
<td>VAS Score At 14 days postpartum</td>
<td>0.0 ((0.0–1.6))</td>
<td>0.0 ((0.0–2.9))</td>
<td>–</td>
<td>0.48</td>
</tr>
<tr>
<td>Any pain in wound area at 24–48 hours</td>
<td>61 ((58))</td>
<td>74 ((73))</td>
<td>0.80 ((0.65–0.98))</td>
<td>0.03</td>
</tr>
<tr>
<td>Any pain in wound area at 14 days postpartum</td>
<td>15 ((14))</td>
<td>15 ((15))</td>
<td>0.97 ((0.51–1.88))</td>
<td>0.93</td>
</tr>
<tr>
<td>Oral analgesia usage at 24–48 hours</td>
<td>14 ((13))</td>
<td>13 ((13))</td>
<td>1.05 ((0.52–2.11))</td>
<td>0.90</td>
</tr>
<tr>
<td>Oral analgesia usage at 14 days postpartum</td>
<td>2 ((2))</td>
<td>1 ((1))</td>
<td>1.94 ((0.18–21.1))</td>
<td>1.00*</td>
</tr>
</tbody>
</table>

Data presented as number (%), mean (SD) or median (10–90% percentile).

*Fisher's exact test.
Pain from the wound 24–48 hours postpartum was also less common in women randomised to ear acupuncture (RR 0.80, 95% CI 0.65–0.98). The median VAS score at this point was also lowest in the acupuncture group, although the difference was non-significant (VAS 1.9 versus 2.7, \( P = 0.06 \)). Pain from the wound decreased over time, and at 14 days postpartum no difference was seen between the groups (Table 3). No difference was seen in use of oral analgesia.

**Discussion**

We found that ear acupuncture as provided in this study was less effective for pain relief during postpartum surgical repair than local anaesthetics. More patients were satisfied with the pain-relief method if local anaesthetics had been used. However, the wound healing was reported as less painful if ear acupuncture had been used during repair.

Immediate postpartum wound healing was similar in the two study groups. Long-term healing indicators, such as need for revision of wound or dyspareunia, were also not different.

To evaluate a low-budget training programme we set out to evaluate a brief training package of a 2-hour hands-on workshop for a group of midwives with some previous experience in the use of acupuncture. This design was chosen as a pragmatic solution in order to evaluate a realistic clinical situation of implementing a new pain-relief method. Acupuncturists might argue that the ability to offer relevant treatment with ear acupuncture requires far more training and practice in order to maintain a certain competence level. The average number of participants per midwife was 5 (range 1–18) over the study period of 15 months. Thus, it is plausible that not all midwives who provided ear acupuncture for pain relief in this trial were sufficiently qualified at the time of enrolment of participants. The limited number of enrolled participants per midwife limits the possibility to analyse data for any time trend as a trace of a learning curve.

The gold standard for evaluation of new treatments within health science is the double-blind controlled trial. Blinding should ideally be on three levels: the care provider, the patient and the researcher. In this trial, only the investigator was blinded and some questions may be raised about the effect of placebo. However, double blinding was not possible in this trial. A pretrial pilot test of placebo acupuncture and placebo local anaesthetics indicated that blinding of participants and midwives was unrealistic because both were able to identify the active treatment. The swelling of the tissue after application of local anaesthetics or placebo could not be camouflaged. Experienced acupuncturists might also argue that placebo acupuncture in the ear would not be possible because of the very superficial location of the acupuncture points. The midwives in this trial had different attitudes to the effect of acupuncture. This may have influenced the trial results in any direction depending on the midwives’ attitude towards acupuncture.

The questionnaires in this trial were filled out by researchers during interviews with trial participants. A potential disadvantage of this data collection strategy was the information bias that could occur as trial participants might have responded differently if the same questions were asked in self-administered questionnaires. Another limitation in the data collection method was the potential for recall bias as patients reported their experience during surgical repair 1–2 days after delivery. Most of the reported pain scores were in the ‘mild’ end of the verbal descriptive scale and in the lower end of the VAS scale. This might reflect the relatively small extent of trauma as most participants had sutures in the labia area or minor perineal lacerations only. Although trial participants reported more pain and less satisfaction when they were randomised to ear acupuncture, this did not seem to affect their willingness to choose ear acupuncture for pain relief after a subsequent delivery. This contradiction was by most participants explained as a strong wish to give birth without use of any pharmacological interventions.

Improving postpartum pain-relief methods for surgical repair of genital laceration during childbirth is important. Ear acupuncture for pain relief during postpartum surgical repair as used in this trial was less effective compared with local anaesthetic using Lidocaine 1% for repair of superficial genital tract lacerations. From a quality improvement point of view, the question should be asked whether our current ‘best practice’ with the use of local anaesthetics is good enough, when some 68% report pain when pain relief is applied in the wound area, and another 54% report some degree of pain during surgical repair. Further trials aiming to improve the effectiveness and acceptability of pain-relief methods are required. A general concern for research within manual- and clinician-dependent therapies is how to ensure that clinical staff has acquired sufficient skills in providing the healthcare intervention that is evaluated. Evidence is required on how best to evaluate clinical competence and manual skills within the use of acupuncture. Ear acupuncture and acupuncture in general have proved very effective for some types of pain and discomfort. We suggest that future trials evaluate more elaborate training packages of the involved staff.

**Conflict of interests**

There are no conflicts of interest.

**Contribution to authorship**

Sara Kindberg and Lis Klünder conceived the idea for this trial and wrote the study protocol, coordinated training of the involved staff, planned data collection and performed data analyses. Jens Strøm and Tine Brink Henriksen contributed to study design, funding.
applications and supervised study implementation and data collection. All authors contributed to the writing and editing of this article.

Details of ethics approval
The regional scientific ethics committee approved the trial (J.no: 2006-1011) and the trial was registered with the Danish Data Protection Agency (J.no: 2006-53-1300).

Funding
The Department of Obstetrics and Gynecology at Sønderborg Hospital, Denmark provided funding for this trial. Funding was also provided by the Danish Midwifery Organisation, the Aase and Einar Danielsen Foundation, the Augustinus Foundation, the Sophus Jacobsen Foundation and the Frode Nygaard Foundation. Economical assistance did not influence the research design, data collection, data analyses or publication of the results.

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We wish to thank the women who participated in the trial and the many midwives at Sønderborg Hospital, Denmark whose contributions made this research possible. We also wish to thank Consultant Obstetrician and Gynaecologist, Kirstine Münster, Hillerød Hospital, Denmark, for her contribution on selecting the relevant acupuncture points used in this trial.

References
PAPER III

Kindberg, S. Stehouwer, M. Hvidman, L. Henriksen, TB.

Is clinical experience of midwives who perform perineal repair associated with postpartum perineal pain, delayed wound healing or dyspareunia?

(Submitted to ACTA, September 2008)
Is clinical experience of midwives who perform perineal repair associated with postpartum perineal pain, delayed wound healing or dyspareunia?

Perineal repair and operator’s experience.

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Perineal repair, Clinical skills, Experience
2. ABSTRACT

Objective
The objective was to study the association between years of clinical experience of midwives, in relation to maternal postpartum perineal pain, wound healing and dyspareunia following perineal repair of second degree lacerations and mediolateral episiotomies.

Design and setting
The study was a secondary cohort analysis within a previous randomised trial conducted at Aarhus University Hospital during 2004-2005.

Population
The study population consisted of 78 midwives responsible for perineal repair of 384 healthy primiparous women.

Methods and outcomes
Years of clinical experience was categorised into groups: <5, 5-14 and 15 + years. The outcome measures were perineal pain, wound gaping > 0.5 cm at 10 days and dyspareunia evaluated six months postpartum. Wound healing assessments were performed by trained research midwives. A logistic regression analysis was used to adjust for potential confounders and non-independence in the dataset.

Results
The episiotomy rate was 22% and the median time spent on suturing was 15 minutes (range 4-60). Participants who were sutured by a midwife with less than 5 years of experience had an insignificantly increased risk of perineal pain at 10 days (OR 1.46, 95%CI 0.79-2.70). The risk for delayed wound healing was not associated with the experience of the midwife (OR 1.21, 95% CI 0.58-2.51). Dyspareunia at six months was not associated with the experience of the midwife either (OR 0.91, 95% CI 0.49-1.69).

Conclusion
Duration of the clinical experience of the midwife performing postpartum surgical repair was not associated with increased perineal pain, delayed wound healing or dyspareunia after childbirth.
Introduction
Perineal trauma is a frequent complication to vaginal delivery and more than 80% of primiparous women sustain injury to the labia, vagina or perineum(1). Pain and discomfort related to perineal trauma have been reported to interfere with women’s daily activities postpartum such as sitting, walking and lifting the baby(2). Pain related to perineal trauma and suturing is known to have a negative impact on sexual activities in the first year after childbirth(3;4).

Surgical repair of lacerations in the genital area is performed by either midwives or obstetricians depending on the extent of the trauma and clinical circumstances. Trauma involving the vaginal mucosa, perineal skin and superficial perineal muscles are defined as first or second degree injuries. Lacerations involving the anal sphincter are defined as third degree tears and lacerations of the anal mucosa as fourth degree tears(5). The extent of trauma is highly correlated with maternal morbidity postpartum. An intact perineum is associated with the lowest level of pain, whereas lacerations involving the anal sphincter or episiotomies are associated with the highest levels of pain, wound healing problems and pain during sexual intercourse(4;6).

We have recently shown in a randomised trial that, two suture techniques have similar properties with respect to postpartum perineal pain, wound healing and dyspareunia(7). Other potential risk factors for increased perineal pain or dyspareunia postpartum are: instrumental deliveries(8;9), episiotomies(10-12) and breastfeeding(8). The duration of the second stage of labour may also influence postpartum perineal pain and suture break down(13). Wound healing has shown itself to be impaired among obese and older women and smoking has also been associated with wound-related complications(14). Dyspareunia after childbirth is correlated to dyspareunia prior to pregnancy and to the extent of trauma(4;15).

Experienced clinicians and researchers within perineal trauma have suggested that lack of clinical experience of the person performing the surgical repair might be linked to poorer surgical outcomes(16). Short attendant experience has also been documented to increase the risk of severe perineal trauma during childbirth(17). Therefore, in this secondary cohort analysis of participants within the randomised trial, we set out to investigate the association between the years of clinical experience of the midwife performing the perineal repair and perineal pain, delayed wound healing and occurrence of dyspareunia at six months after delivery.
Material and Methods
The data for this observational study originate from a double blinded randomised controlled trial of different suture techniques performed in the Department of Obstetrics and Gynaecology at Aarhus University Hospital, Skejby, Denmark during 2004-2006. The Department has approximately 4800 deliveries annually. The primary results and methodological issues have been reported previously(7).

Population
Participants in the randomised trial were all low-risk primiparous women: Women were eligible to participate if they expected a healthy child and had a spontaneous or ventouse instrumental delivery after 36 weeks of gestation. All patients had a perineal laceration of second degree (78%) or a mediolateral episiotomy (22%) which was repaired by a midwife. Exclusion criteria were perineal injuries involving the anal sphincter, postpartum haemorrhage (< 1000 ml), previous perineal surgery, diabetes or severe illness.

Midwives in the department were interviewed about their experience and suture preference prior to trial initiation. A total of 78 midwives performed perineal repair for trial participants. All midwives participated in hands-on-workshops, focusing on surgical skills and anatomical correct approximation of superficial perineal muscles before they were allowed to recruit participants for the trial.

The experience of the midwife was categorised into three groups: <5 years, 5-14 years and 15 + years. The most experienced midwives were used as reference group. The categorisation assured an equal number of midwives and perineal repairs in each category; and the higher cut-off was considered equivalent to the experience required for supervision of perineal repairs among midwives in our labour ward.

Clinical practice in the Department
Midwives in the Department were responsible for the diagnosis and surgical repair of lacerations to the labia, the vaginal mucosa and perineal lacerations of first and second degree. Mediolateral episiotomies were only performed in cases of foetal distress. Patients were placed in lithotomy position during perineal repair in order to secure optimal facilities and light for the midwife performing the perineal repair. The standard analgesic treatment during perineal repair was infiltration analgesia in the wound area using 5-20 ml carbocaine 1%.

The standard suture material in the Department was a rapidly absorbed polyglactin 910 suture, gauge 2/0, 90 cm long on a 1/2c, 36 mm needle (Vicryl® Rapide, Ethicon, GmbH Germany). During the trial, the department changed this to a standard polyglactin 910 material with the same gauge and needle (Vicryl®, Ethicon, GmbH Germany).
Data collection
Data were obtained by structured interview performed by a trained research midwife. A total of 384 participants were sutured by a midwife in the randomised trial. Follow up information was available for 380 (99%) at 10 days postpartum and for 379 (99%), six months postpartum. Specific details on the randomised trial have been reported previously (7).

The interviews were completed face-to-face followed by an examination of the woman’s perineum in the lithotomy position at 10 days postpartum. If the women could not manage to come to the hospital for the interview she was interviewed by phone. Wound healing assessments were performed in 342/380 (90%) of the potential study population at 10 days postpartum. A telephone interview was performed six months after delivery enquiring about ongoing perineal pain, dyspareunia, need for subsequent resuturing and patient evaluation. Intercourse was resumed by 348/379 (92%) at six months postpartum.

Perineal pain was recorded on a 4-point Verbal Rating Scale. For this study we created a dichotomous outcome: “No pain” versus “Any pain” (Mild pain, Moderate pain or Severe pain).

Wounds still gaping at 10 days were recorded as insufficiently healed. Gaping wounds were a clinical combination of inadequately approximated wound edges, superficial wound break down and total wound break down. For this study we created a dichotomous outcome: Healed perineal wound versus wound gaping > 0.5 cm.

Dyspareunia at six months postpartum was defined as any pain experienced by the woman upon penetration or during intercourse within the previous month. If the participants reported dyspareunia, subsequent questions revealed if dyspareunia had also occurred prior to the pregnancy.

Statistical methods
The association between years of clinical experience of the midwife and perineal pain or delayed wound healing at day 10 and dyspareunia at six months was presented as crude odds ratios with 95% Confidence Intervals (CI).

Potential confounders included in the logistic regression model were chosen a priori, based on risk factors reported in similar studies. Potential confounders were categorised as shown in Table 1. Adjustment for potential confounding factors was carried out by logistic regression analyses including all variables in table 1. Potential confounders were entered as a number of dummy variables equal to the number of categories minus one. All statistical tests were two-tailed, and p values <0.05 were considered statistically significant.
As each midwife contributed with the suturing of several participants, the participants themselves cannot be considered independent observations hence, robust variance estimates taking into account this non-independence were obtained. Data was analysed using the statistical software package STATA version 8.2 (StataCorp. College Station, TX, USA 2003).

**Results**
A total of 78 different midwives were involved in perineal repairs in the study. The median experience for the midwives was seven years ranging from 0-39 years. The median number of perineal repairs performed in the trial by each midwife was four ranging from 1 to 17 repairs (Table 2). The overall episiotomy rate was 22%, with non-significant variations between 17-26% among groups. The median time spent on suturing was 15 minutes, range 4-60 minutes (Table 2).

Perineal pain was reported by 133/380 (35%) at 10 days after delivery. We found no significant association between experience of the midwife performing perineal repair and perineal pain 10 days after delivery (Table 3). Wound gaping more than 0.5 cm at day 10 was present among 65/342 (19%). Women with wound gaping were more often smokers and more prone to episiotomies, compared to non-smokers and spontaneous perineal lacerations of second degree (Table 1). No significant association was seen between experience and the risk of wounds gaping > 0.5 cm at 10 days after delivery (Table 4).

Sexual intercourse was resumed by 348/379 (92%) at six months postpartum. Dyspareunia during the previous month was reported by 103/348 (30%) at six months. No association was detected between experience of the midwife and subsequent occurrence of dyspareunia among study participants (Table 5). Adjustment for maternal age, maternal pre-pregnancy body mass index, smoking habits, mode of delivery, duration of active second stage, type of perineal laceration, suture material or breastfeeding status did not change the results of ‘no significant association between experience of the operator and the three main outcomes studied’ (Tables 3, 4 and 5).
Discussion

To our knowledge, this is the first study on perineal pain and wound healing in relation to perineal repair performed by midwives which includes control for confounding and non-independence in the dataset. Previous suggestions by Grant et al., that inexperience of the operator may lead to poorer suturing of perineal laceration, could not be verified in our cohort of 78 midwives performing sutures in a randomised trial(16). Years of clinical experience of the midwife performing perineal repair was not significantly associated with postpartum pain, delayed wound healing or dyspareunia following childbirth.

Each midwife contributed with a median of four participants and the recruitment was on a voluntary basis when the midwives felt confident in performing either of the two suture techniques studied. Selection bias or confounding was possible if inexperienced midwives only enrolled median second degree lacerations which were easy to repair and the more experienced midwives enrolled more complex second degree lacerations or mediolateral episiotomies. However, episiotomy rates were not significantly different among groups, indicating that a differential bias in diagnosis was not present in the dataset. The median time spent on suturing also did not differ between the groups of midwives. Experience in years did therefore not seem to contribute to clinical performance of suturing second degree lacerations or episiotomies.

The limitations of this study are, that patient in the randomised trial were a homogenous group of healthy primiparous women with uncomplicated deliveries. Generalisation of study results into more diverse populations must therefore be done with caution. The hands-on skills training of staff prior to the randomised trial might have biased the results towards null as this training option was an intervention in how midwives might suture under normal clinical circumstances. Other studies have documented that brief, hands-on workshops on surgical skills and suturing techniques among midwives and obstetricians were positively evaluated. Participants reported that continuous medical education and regular updates on surgical skills were useful for their clinical practice(18;19).

It is possible that experience in years is simply a poor indicator for surgical competence among midwives. From a clinical point of view there might be another reason which can explain why increasing experience does not improve surgical skills: No formal evaluation and feedback on surgical performance or patient evaluation is provided for midwives working in busy delivery wards. Clinicians can therefore practice with the level of skills obtained during their education without the subsequent improvement of competence or adjustment of suturing techniques and tissue handling. It has been questioned within assessments of other obstetric skills whether a specific number of years of experience working in the health care profession is a valid measure of clinical skills.
This raises new questions in the field of research about how to estimate clinical competency in handling surgical repair after delivery. A more specific method to estimate competency in relation to perineal sutures could be to index the clinical staff members according to a formal evaluation of their skills(21). A new field of research could therefore be, to develop and validate an Objective Structured Assessment of Technical Skills (OSATS) test in order to quantify midwifery skills and competence in suturing perineal trauma(21;22). Another field of research, that may help to increase our knowledge about outcomes after perineal repair, is clinical decision making on how midwives diagnose and choose to suture perineal lacerations(23).

**Conclusion**

We found that years of experience of the midwife performing postpartum perineal repair of second degree lacerations or mediolateral episiotomies was not significantly associated with perineal pain, wound healing at 10 days postpartum or dyspareunia among study participants six months after childbirth. Further research into evaluation of clinical skills and competence in relation to perineal repair of second degree perineal lacerations and episiotomies is needed.
Contribution to authorship
SK was responsible for study design, data collection, data analyses and writing of the draft for this article. TBH contributed to study design and preparation of data analyses strategy. All authors contributed to the interpretation of data, critical revision of the manuscript and approved the final version for publication.

Disclosure of interests
None.

Acknowledgment
We thank the women who participated in the Danish Suture Trial and the midwives working at Aarhus University Hospital whose contributions made this study possible. A PhD grant for Sara Kindberg was financed by the Department of Obstetrics and Gynaecology at Sønderborg Hospital, Denmark.
Reference lists


Table 1. Distribution of potential confounders in relation to outcomes in trial (N=384).

<table>
<thead>
<tr>
<th></th>
<th>Perineal pain$^1$</th>
<th>Gaping wound$^2$</th>
<th>Dyspareunia$^3$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analysis possible (%)</td>
<td>380 (99%)</td>
<td>342 (90%)</td>
<td>348 (91%)</td>
</tr>
<tr>
<td>Age &lt; 29 years</td>
<td>251 (32%)</td>
<td>224 (21%)</td>
<td>233 (31%)</td>
</tr>
<tr>
<td>Age 30 years +</td>
<td>131 (40%)</td>
<td>118 (22%)</td>
<td>115 (29%)</td>
</tr>
<tr>
<td>BMI &lt; 25</td>
<td>314 (35%)</td>
<td>281 (20%)</td>
<td>289 (32%)</td>
</tr>
<tr>
<td>BMI 25 +</td>
<td>65 (37%)</td>
<td>60 (17%)</td>
<td>58 (19%)</td>
</tr>
<tr>
<td>Smoking-</td>
<td>354 (34%)</td>
<td>320 (18%)</td>
<td>227 (29%)</td>
</tr>
<tr>
<td>Smoking +</td>
<td>23 (52%)</td>
<td>21 (43%)</td>
<td>20 (40%)</td>
</tr>
<tr>
<td>Spontaneous delivery</td>
<td>326 (35%)</td>
<td>291 (20%)</td>
<td>296 (30%)</td>
</tr>
<tr>
<td>Instrumental delivery</td>
<td>54 (37%)</td>
<td>51 (14%)</td>
<td>52 (25%)</td>
</tr>
<tr>
<td>Second stage &lt; 60 min</td>
<td>274 (34%)</td>
<td>250 (19%)</td>
<td>251 (30%)</td>
</tr>
<tr>
<td>Second stage ≥ 60 min</td>
<td>99 (35%)</td>
<td>90 (19%)</td>
<td>95 (28%)</td>
</tr>
<tr>
<td>Perineal rupture</td>
<td>279 (35%)</td>
<td>265 (15%)</td>
<td>267 (28%)</td>
</tr>
<tr>
<td>Episiotomy</td>
<td>83 (36%)</td>
<td>77 (31%)</td>
<td>81 (35%)</td>
</tr>
<tr>
<td>Rapid suture material</td>
<td>194 (39%)</td>
<td>174 (16%)</td>
<td>171 (33%)</td>
</tr>
<tr>
<td>Standard suture material</td>
<td>186 (31%)</td>
<td>168 (22%)</td>
<td>177 (27%)</td>
</tr>
</tbody>
</table>

Data presented as distribution of potential confounders and frequency (%) of participants who reported the outcome.

$^1$ Pain at 10 days postpartum was present in 133/380 participants (35%).

$^2$ Wound edges appeared gaping > 0.5 cm in 65/342 (19%).

$^3$ Intercourse was resumed by 348/379 (92%) at six months postpartum. Dyspareunia was reported by 103/348 (30%).
Table 2. Description of midwives and repairs performed in trial (N=78 midwives, 384 repairs).

<table>
<thead>
<tr>
<th>Years of experience</th>
<th>Repairs in trial</th>
<th>Recruitment rate in trial</th>
<th>Minutes spent on repair</th>
<th>Episiotomy rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 5 years (n=25)</td>
<td>121 (32%)</td>
<td>5 [1-13]</td>
<td>15 [4-60]</td>
<td>21 (17%)</td>
</tr>
<tr>
<td>5-14 years (n=28)</td>
<td>137 (36%)</td>
<td>4 [1-15]</td>
<td>15 [5-50]</td>
<td>32 (23%)</td>
</tr>
<tr>
<td>15 years + (n=25)</td>
<td>126 (33%)</td>
<td>3 [1-17]</td>
<td>15 [5-45]</td>
<td>33 (26%)</td>
</tr>
<tr>
<td>Total (n=78)</td>
<td>384 (100%)</td>
<td>4 [1-17]</td>
<td>15 [4-60]</td>
<td>86 (22%)</td>
</tr>
</tbody>
</table>

Data shown as number (percentage) or median [range].

1 Median years of experience = 7 years (range 0-39 years).

2 Episiotomy rate not significantly different among groups: Chi-square: 2.89, p=0.24.

---

Table 3. Association between experience of midwife performing perineal repair and perineal pain 10 days postpartum (N=380)

<table>
<thead>
<tr>
<th>Years of experience</th>
<th>N</th>
<th>Perineal pain</th>
<th>OR (95% CI)</th>
<th>Adjusted OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 5 years</td>
<td>120</td>
<td>44 (37%)</td>
<td>1.49 (0.81-2.75)</td>
<td>1.46 (0.79-2.70)</td>
</tr>
<tr>
<td>5-14 years</td>
<td>135</td>
<td>54 (40%)</td>
<td>1.71 (0.93-3.15)</td>
<td>1.78 (0.95-3.36)</td>
</tr>
<tr>
<td>15 years +</td>
<td>125</td>
<td>35 (28%)</td>
<td>Ref.</td>
<td>Ref.</td>
</tr>
</tbody>
</table>

Data shown as number (percentage) or Odds Ratio with 95% Confidence Intervals.

1 Adjusted for non-independence as most midwives recruited more than one participant.

2 Adjusted for all variables in Table 1 and non-independence in dataset.
Table 4. Association between experience of midwife performing perineal repair and wound gaping at 10 days postpartum (N=342)

<table>
<thead>
<tr>
<th>Years of experience</th>
<th>N</th>
<th>Wound gap &gt; 0.5 cm</th>
<th>OR (95% CI)(^1)</th>
<th>Adjusted OR (95% CI)(^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 5 years</td>
<td>107</td>
<td>21 (20%)</td>
<td>1.17 (0.58-2.37)</td>
<td>1.21 (0.58-2.51)</td>
</tr>
<tr>
<td>5-14 years</td>
<td>125</td>
<td>25 (20%)</td>
<td>1.20 (0.62-2.30)</td>
<td>1.28 (0.67-2.48)</td>
</tr>
<tr>
<td>15 years +</td>
<td>110</td>
<td>19 (17%)</td>
<td>Ref.</td>
<td>Ref.</td>
</tr>
</tbody>
</table>

Data shown as number (percentage) or Odds Ratio with 95% Confidence Intervals.
\(^1\) Adjusted for non-independence as most midwives recruited more than one participant.
\(^2\) Adjusted for all variables in Table 1 and non-independence in dataset.

Table 5. Association between experience of midwife performing perineal repair and dyspareunia at six months postpartum (N=348).

<table>
<thead>
<tr>
<th>Years of experience</th>
<th>N</th>
<th>Dyspareunia</th>
<th>OR (95% CI)(^1)</th>
<th>Adjusted OR (95% CI)(^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 5 years</td>
<td>110</td>
<td>29 (26%)</td>
<td>0.96 (0.53-1.74)</td>
<td>0.91 (0.49-1.69)</td>
</tr>
<tr>
<td>5-14 years</td>
<td>124</td>
<td>43 (35%)</td>
<td>1.42 (0.85-2.37)</td>
<td>1.33 (0.78-2.27)</td>
</tr>
<tr>
<td>15 years +</td>
<td>114</td>
<td>31 (27%)</td>
<td>Ref.</td>
<td>Ref.</td>
</tr>
</tbody>
</table>

Data shown as number (percentage) or Odds Ratio with 95% Confidence Intervals.
\(^1\) Adjusted for non-independence as most midwives recruited more than one participant.
\(^2\) Adjusted for all variables in Table 1 and non-independence in dataset.
APPENDICES
Appendix 1. Perineal laceration of the 1st degree.

International classification of perineal lacerations as by RCOG Green-top Guideline No 29.

<table>
<thead>
<tr>
<th>Degree</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>First degree</td>
<td>Injury to the perineal skin only</td>
</tr>
<tr>
<td>Second degree</td>
<td>Injury to the perineum involving perineal muscles but not involving the anal sphincter</td>
</tr>
<tr>
<td>Third degree</td>
<td>Injury to perineum involving the anal sphincter complex:</td>
</tr>
<tr>
<td>Fourth degree</td>
<td>Injury to perineum involving the anal sphincter complex and anal epithelium</td>
</tr>
</tbody>
</table>
Appendix 2. Perineal laceration of the 2\textsuperscript{nd} degree, involved muscles indicated

<table>
<thead>
<tr>
<th>Degree</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>First</td>
<td>Injury to the perineal skin only</td>
</tr>
<tr>
<td>Second</td>
<td>Injury to the perineum involving perineal muscles but not involving the anal sphincter</td>
</tr>
<tr>
<td>Third</td>
<td>Injury to perineum involving the anal sphincter complex:</td>
</tr>
<tr>
<td>Fourth</td>
<td>Injury to perineum involving the anal sphincter complex and anal epithelium</td>
</tr>
</tbody>
</table>
Appendix 3. Mediolateral episiotomy, involved muscles indicated

<table>
<thead>
<tr>
<th>Degree</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>First</td>
<td>Injury to the perineal skin only</td>
</tr>
<tr>
<td>Second</td>
<td>Injury to the perineum involving perineal muscles but not involving the anal sphincter</td>
</tr>
<tr>
<td>Third</td>
<td>Injury to perineum involving the anal sphincter complex:</td>
</tr>
<tr>
<td>Fourth</td>
<td>Injury to perineum involving the anal sphincter complex and anal epithelium</td>
</tr>
</tbody>
</table>

Illustration by Media Farm – Denmark. Printed with permission from Gynzone.dk
Struktureret interview 24-48 timer post partum

Mundtlig intro før interviewet starter i et lokale ved barselsafdelingen.

- Goddag, tak fordi du vil deltage i dette forskningsprojekt.
- Mit navn er XX, jeg er jordemoder / sygeplejerske her ved Sønderborg sygehus.
- Det er meningen, at jeg ikke må vide hvilken bedøvelse, du fik til syningen.
- Du vil blive interviewet, og jeg læser spørgsmål og svar op samt krydser svarerne af.
- Til sidst vil jeg gerne se til ophelingen af syningen.
- Hvis du har kommentarer eller spørgsmål, kan vi drøfte dem til sidst.

<table>
<thead>
<tr>
<th>1. Deltager nummer</th>
<th>Label med ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Dato for 1.besøg:</td>
<td>_______________ (dd/mm/år)</td>
</tr>
<tr>
<td>3. Klokkeslæt:</td>
<td>_______________ (xx.xx)</td>
</tr>
<tr>
<td>4. Hvor foretages 1. interview:</td>
<td>□1 Sønderborg □2 Haderslev □3 Andet</td>
</tr>
<tr>
<td>5. Hvem foretager det?</td>
<td>□1 Anne Pors □2 Anja Lausen □3 Sara Kindberg</td>
</tr>
<tr>
<td>(5b) Årsag til manglende data:</td>
<td>□1 - orientering til projekt □2 Interview ikke muligt □3 Pt. udgået, eget ønske □4 Pt. udgået, faglig vurdering</td>
</tr>
</tbody>
</table>

Nu følger nogle generelle spørgsmål til fødslen af dit barn.

6. Er denne fødsel din første fødsel? □1 Ja □2 Nej

7. Fik du epidural bedøvelse under fødslen (rygbedøvelse)? □1 Ja □2 Nej

8. Fik du akupunktur til selve fødslen (inden barnet var født)? □1 Ja □2 Nej

9. Hvor meget vejede jeres barn ved fødslen? _______ gram
Appendix 4. Questionnaire (in Danish) used in the trial on ear acupuncture
Sønderborg County Hospital (n=207). Interview 24-48 hours postpartum.

Nu følger nogle generelle spørgsmål til dit helbred og din baggrund.

10. Hvor høj er du? cm __________
11. Hvor meget vejede du før graviditeten? kg __________
12. Bor du sammen med barnets far / en fast partner? □ 1 Ja □ 2 Nej
13. Hvilken uddannelse har du? (kryds aktuel status) □ 1 ≤ 9. klasse □ 2 Faglært (håndværker etc.) □ 3 Gymnasium, HF, HH □ 4 Stud. ved videreuddannelse □ 5 Mellemlang videregående □ 6 Akademisk uddannelse
14. Er du ryger? □ 1 Ja (gå til a) □ 2 Nej
   a: Hvor mange cigaretter ryger du dagligt Antal __________
15. Får du medicin hver dag? □ 1 Ja (gå til a+b) □ 2 Nej
   a: Hvilken medicin indtager du? (produkttype) ____________________
   b: Hvilken sygdom behandles? ____________________

De følgende spørgsmål handler om, hvordan det var at blive bedøvet FØR selve syningen.

16. I hvilken grad oplevede du smerter, fordi jordemoderen lagde bedøvelse i mellemkødet eller stak dig med akupunkturmålne? □ 1 Ingen smerter □ 2 Milde smerter □ 3 Moderate smerter □ 4 Stærke smerter
   a: Hvor ondt gjorde det på en skala fra ingen smerte til værst tænkelig smerte at blive bedøvet?
      SMERTER ved at bedøvelsen blev lagt (samlet vurdering) ____________ (VAS: 0.0-10.0)

17. Oplevede du at det var ubehageligt at få bedøvelsen, selvom det måske ikke gjorde ondt? □ 1 Ja (gå til a) □ 2 Nej
   a: På en skala fra intet ubehag til værst tænkelig ubehag, hvordan var det så at få bedøvelsen?
      UBEHAG ved at bedøvelsen blev lagt (samlet vurdering) ____________ (VAS: 0.0-10.0)
Appendix 4. Questionnaire (in Danish) used in the trial on ear acupuncture
Sønderborg County Hospital (n=207). Interview 24-48 hours postpartum.

Nu følger et spørgsmål om tiden, IMENS jordemoderen syede bristningen eller klippet.

18. I hvilken grad var det smertefuldt at blive syet?  
(smerter ved stik fra nålen)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>a: Hvor ondt gjorde det på en skala fra ingen smerte til værst tænkelig smerte at blive syet?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SMENTERIMENS syning blev foretaget (samlet vurdering)</td>
<td>__________</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(VAS: 0.0-10.0)

19. Oplevede du at det var ubehageligt at blive syet, selvom det måske ikke gjorde ondt?  

<table>
<thead>
<tr>
<th></th>
<th>1. Ja (gå til a)</th>
<th>2. Nej</th>
</tr>
</thead>
<tbody>
<tr>
<td>a: På en skala fra intet ubehag til værst tænkeligt ubehag, hvordan var det så at blive syet?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UBEHAGIMENS syning blev foretaget (samlet vurdering)</td>
<td>__________</td>
<td></td>
</tr>
</tbody>
</table>

(VAS: 0.0-10.0)

20. Fik du mere bedøvelse end enten lokalbedøvelse eller akupunktur, imens du blev syet?  
(f.eks. ekstra bedøvende gele, lattergas, ekstra lokalbedøvelse, pudendus..)

|---|-----|------|------------|

21. Ville du ønske, at du havde fået mere bedøvelse, mens du blev syet?  
(f.eks. ekstra bedøvende gele, lattergas, ekstra lokalbedøvelse, pudendus..)

|---|-----|------|------------|

22. Har du de seneste 6 timer brugt smertelindring  
pga. smerter fra syningen?  
a: Hvilken smertelindring har du anvendt?

<table>
<thead>
<tr>
<th></th>
<th>1. Ja (gå til a)</th>
<th>2. Nej</th>
</tr>
</thead>
</table>

3
De følgende spørgsmål handler om eventuelle smerter fra syningen.

23. Hvordan er dine smerter fra syningen LIGE NU?  
    (tidsrum indenfor de seneste 5 minutter) 
    □ 1 Ingen smerter 
    □ 2 Milde smerter 
    □ 3 Moderate smerter 
    □ 4 Stærke smerter 

    a: Hvor ondt har du på en skala fra ingen smerte til værst tænkelig smerte fra syningen lige nu? 
    VAS Score pga. selve syningen lige nu ________ (VAS: 0.0-10.0)

24. Har du smerter fra syningen, når du rejser dig fra eller sætter dig på en stol? 
    □ 1 Ja 
    □ 2 Nej 
    □ 3 Kan ikke besvares

Spørgsmål om anvendelse af fotos til forskning og undervisning.

25. Vil du tillade, at der tages fotos af syningen (dokumentation)? 
    □ 1 Ja 
    □ 2 Nej

26. Vil du tillade, at billederne anvendes anonymt i undervisningssammenhænge for jordemødre og læger? 
    □ 1 Ja 
    □ 2 Nej

Inspektion af bristningens opheling i gynækologisk leje.

27. Fremtræder suturområdet pænt og korrekt samlet? 
    □ 1 Ja 
    □ 2 Nej (gå til a)

    a: Hvordan kan dette beskrives; 
    □ 1 Skævt samlet 
    □ 2 For løs trådspænding 
    □ 3 Andet ____________

28. Er der synligt suturskred? 
    □ 1 Ja (gå til a) 
    □ 2 Nej

    a: Hvordan kan dette beskrives; 
    □ 1 Subcutant skred 
    □ 2 Totalt skred 
    □ 3 Andet ____________

29. Er der synlige hæmorider, som generer kvinden? 
    □ 1 Ja 
    □ 2 Nej
Vurdering af opheling i sårområdet. Anvende centimetermål til vurderingen.

30a: Er der rødme omkring bristningen?  

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>ingen</td>
</tr>
<tr>
<td>1</td>
<td>max 0.25 cm bilateral</td>
</tr>
<tr>
<td>2</td>
<td>max 0.5 cm bilateral</td>
</tr>
<tr>
<td>3</td>
<td>over 0.5 cm bilateral</td>
</tr>
</tbody>
</table>

Score: ________

30b: Er der ødem omkring bristningen?  

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>ingen</td>
</tr>
<tr>
<td>1</td>
<td>max 1 cm fra sårrande</td>
</tr>
<tr>
<td>2</td>
<td>1 cm fra sårrande</td>
</tr>
<tr>
<td>3</td>
<td>&gt; 2 cm fra sårrande</td>
</tr>
</tbody>
</table>

Score: ________

30c: Er der hæmatomer / blå mærker omkring bristningen?  

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>ingen</td>
</tr>
<tr>
<td>1</td>
<td>max 0.25 cm bilateral eller 0.5 –2 cm unilat.</td>
</tr>
<tr>
<td>2</td>
<td>max 1 cm bilateral eller 0.5 cm unilat.</td>
</tr>
<tr>
<td>3</td>
<td>&gt; 1 cm bilateral eller &gt; 2 cm unilateralt</td>
</tr>
</tbody>
</table>

Score: ________

30d: Er der puds eller sekret omkring bristningen?  

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>ingen</td>
</tr>
<tr>
<td>1</td>
<td>serum</td>
</tr>
<tr>
<td>2</td>
<td>blodig væske</td>
</tr>
<tr>
<td>3</td>
<td>frisk blod eller gulligt pus</td>
</tr>
</tbody>
</table>

Score: ________

30e: Lukkes sårrandene?  

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>lukket</td>
</tr>
<tr>
<td>1</td>
<td>huden gaber max 3 mm</td>
</tr>
<tr>
<td>2</td>
<td>hud og subcutant fedt adskilt max 1 cm.</td>
</tr>
<tr>
<td>3</td>
<td>hud og subcutant fedt adskilt &gt; 1 cm.</td>
</tr>
</tbody>
</table>

Score: ________

31: Samlede points for REEDA skalaen  

Total: ________

Kommentarer:

SPØRGSMÅL TIL FORSKNINGSASSISTENTEN, DER FORETAGER INTERVIEWET

32. Er der indgået aftale om interview 14 dage efter fødslen?  

☐ 1 Ja  

☐ 2 Nej

33. Bedømmelse af blinding (internt spørgsmål i projektet)  

Hvilken bedøvelse tror du, at kvinden blev randomiseret til  

☐ 1 Akupunktur  

☐ 2 Lokalinfiltration  

☐ 3 Ved ikke
Struktureret interview 10 døgn efter fødslen

Deltager nummer

Label med ID

39. Dato for 2. besøg: __________________________ (dd/mm/år)

40. Forskningsjordemoder: □ 1 Misan □ 2 Assistent □ 3 Sara

41a. Hvor foretages undersøgelsen □ 1 Sutur-us. □ 2 Eget hjem □ 3 Afdeling/ hotel □ 4 Telefoninterview

Hvis eget hjem, afdeling eller telefonisk, hvorfor: __________________________

41b. Årsag til manglende data

□ 1 Manglende papirer fra fødejdm.
□ 2 Pt. er udgået efter eget ønske
□ 3 Pt. er udgået, faglig vurdering
□ 4 Ingen kontakt med deltager / flyttet / logistik

De følgende spørgsmål handler om hvordan du trives som nybagt mor.

42. Føler du at dine nærmeste omgivelser (mand og evt. familie) støtter dig som spædbarnsmor?

□ 1 Ja □ 2 Nej

43. Føler du dig træt og udmattet pga. manglende hvile og søvn?

□ 1 Ja □ 2 Nej

44. Ernæres dit barn udelukkende af brystmælk?

□ 1 Ja □ 2 Nej
De følgende spørgsmål handler om din vurdering af området ved syningen.

45. Fornemmer du, at syningen er helet nu?  
   1. Ja  
   2. Nej  
   3. Ved ikke

46. Har du set på syningen i et spejl?  
   1. Ja (gå til a)  
   2. Nej

   a: Er du tilfreds med, hvordan det ser ud?  
   1. Ja  
   2. Nej  
   3. Ved ikke

47. Har der været problemer med syningen, så du er blevet undersøgt af en læge eller sygeplejerske eller jordemoder udover Suturprojektets undersøgelser?  
   1. Ja (gå til a)  
   2. Nej

   a: Hvorfor: _____________________________

48. Har du efter fødslen fået antibiotika pga. betændelse i det område, hvor du er blevet syet?  
   1. Ja  
   2. Nej

49. Er der blevet fjernet sting eller knuder fra syningen?  
   1. Ja  
   2. Nej

De følgende spørgsmål handler om eventuelle smeter fra syningen de seneste 24 timer.

50. Har du haft smerter pga. syningen det seneste døgn?  
   1. Ja (gå til a)  
   2. Nej

   a: Vil du beskrive disse smerter som;  
   1. Milde smerter  
   2. Moderate smerter  
   3. Stærke smerter

51. VAS Score LIGE NU(linien midt på linealen) _____________ (0.0-10.0)

52. Har du de seneste 24 timer brugt smertestillende medicin pga. smerter fra syningen?  
   1. Ja  
   2. Nej
Appendix 5. Questionnaire (in Danish) used in the trial on suture techniques
Aarhus University Hospital (n=395). Interview planned for 10 days postpartum.

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>53.</strong> Føler du stingene strammer?</td>
<td>1 Ja, 2 Nej</td>
</tr>
<tr>
<td><strong>54.</strong> Har du smerter fra syningen, når du sidder på en stol?</td>
<td>1 Ja, 2 Nej</td>
</tr>
<tr>
<td><strong>55.</strong> Har du smerter fra syningen, når du rejser dig fra eller sætter dig på en stol?</td>
<td>1 Ja, 2 Nej, 9 Uoplyst / ikke spurgt</td>
</tr>
<tr>
<td><strong>56.</strong> Har du smerter fra syningen, når du går?</td>
<td>1 Ja, 2 Nej</td>
</tr>
<tr>
<td><strong>57.</strong> Har du smerter fra syningen ved vandlanding?</td>
<td>1 Ja, 2 Nej</td>
</tr>
<tr>
<td><strong>58.</strong> Har du smerter fra syningen ved afføring?</td>
<td>1 Ja, 2 Nej</td>
</tr>
</tbody>
</table>

De følgende spørgsmål handler om træning af bækkenbundens muskler efter fødslen.

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>59.</strong> Deltog du på sygehuset i barselsgymnastik, hvor bækkenbundsøvelser blev gennemgået?</td>
<td>1 Ja, 2 Nej</td>
</tr>
<tr>
<td><strong>60.</strong> Træner du på nuværende tidspunkt din bækkenbund?</td>
<td>1 Ja, mindst 5 min. dagligt, 2 Ja, et par minutter dagligt, 3 Ja, et par gange om ugen, 4 Nej</td>
</tr>
<tr>
<td><strong>61.</strong> Har du den seneste uge haft problemer med luftafgang fra skeden, når du rejser dig op eller sætter dig ned? (&quot;vaginale prutter&quot;)</td>
<td>1 Ja (gå til a), 2 Nej</td>
</tr>
</tbody>
</table>

a: Var det også tilfældet før graviditeten?  | 1 Ja, 2 Nej |
---------------------------------------------|-------------|
De følgende spørgsmål handler om problemer med at holde på urin, luft eller afføring før, under og efter graviditeten.

62. Havde du svært ved at holde på urin, før du blev gravid?  
   1. Ja (gå til a + b)  
   2. Nej  
   a: Hvor ofte var det tilfældet?  
   1. Dagligt  
   2. Flere gange ugentligt  
   3. Max. 1 gang pr. uge  
   4. Max. 1 gang pr. måned  
   b: Var det særligt ved latter, nys, løft, hop, løb?  
   1. Ja  
   2. Nej

63. Havde du svært ved at holde på urin de sidste tre måneder af graviditeten?  
   1. Ja (gå til a + b)  
   2. Nej  
   a: Hvor ofte var det tilfældet?  
   1. Dagligt  
   2. Flere gange ugentligt  
   3. Max. 1 gang pr. uge  
   4. Max. 1 gang pr. måned  
   b: Var det særligt ved latter, nys, løft, hop, løb?  
   1. Ja  
   2. Nej

64. Har du den seneste uge haft svært ved at holde på urin?  
   1. Ja (gå til a)  
   2. Nej  
   a: Hvor ofte har det været tilfældet?  
   1. Flere gange dagligt  
   2. En gang dagligt  
   3. Få gange i ugen  
   4. Ved ikke / kan ikke svare

65. Har du den seneste uge haft problemer med at holde på luft?  
   1. Ja  
   2. Nej  
   3. Ved ikke

66. Har du den seneste uge haft problemer med at holde på tynd afføring?  
   1. Ja  
   2. Nej  
   3. Ikke relevant

67. Har du den seneste uge haft problemer med at holde på normal afføring?  
   1. Ja  
   2. Nej
**McGill Smerteskema (Sæt et kryds ved de ord, der bedst beskriver din smerte lige nu).**

<table>
<thead>
<tr>
<th>1.</th>
<th>2.</th>
<th>3.</th>
<th>4.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitrende</td>
<td>Springende</td>
<td>Prikkende</td>
<td>Skarp</td>
</tr>
<tr>
<td>Vibrerende</td>
<td>Lynende</td>
<td>Stikkende</td>
<td>Skærende</td>
</tr>
<tr>
<td>Pulserende</td>
<td>Jagende</td>
<td>Borende</td>
<td>Sønderrivende</td>
</tr>
<tr>
<td>Dunkende</td>
<td>Bankende</td>
<td>Stødende</td>
<td>Huggende</td>
</tr>
<tr>
<td>Hamrende</td>
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<th>5.</th>
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<tbody>
<tr>
<td>Knibende</td>
<td>Trækkende</td>
<td>Varm</td>
<td>Snurrende</td>
</tr>
<tr>
<td>Klemmende</td>
<td>Hivende</td>
<td>Brændende</td>
<td>Kloende</td>
</tr>
<tr>
<td>Gnavende</td>
<td>Vridende</td>
<td>Svidende</td>
<td>Snertende</td>
</tr>
<tr>
<td>Snavrende</td>
<td></td>
<td>Skoldende</td>
<td>Tærende</td>
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<td>Murrende</td>
<td>Svag</td>
<td>Trættende</td>
<td>Kvalmende</td>
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<tr>
<td>Dump</td>
<td>Spændt</td>
<td>Udmattende</td>
<td>Kvælende</td>
</tr>
<tr>
<td>Værkende</td>
<td>Kradsende</td>
<td>Kradsende</td>
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<td>Kløvende</td>
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<tbody>
<tr>
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<td>Nederdægtig</td>
<td>Irriterende</td>
</tr>
<tr>
<td>Forfærdelig</td>
<td>Opslindende</td>
<td>Ødelæggende</td>
<td>Plagsom</td>
</tr>
<tr>
<td>Grufuld</td>
<td>Modbydelig</td>
<td>Intens</td>
<td>Pinagtig</td>
</tr>
<tr>
<td>Grusom</td>
<td>Dræbende</td>
<td>Uudholdelig</td>
<td></td>
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<th>19.</th>
<th>20.</th>
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<tbody>
<tr>
<td>Udstrålende</td>
<td>Stram</td>
<td>Kølig</td>
<td>Nagende</td>
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<tr>
<td>Udbredende</td>
<td>Følelsesløs</td>
<td>Kold</td>
<td>Væmmelig</td>
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<td>Gennemtrængende</td>
<td>Sammentrækkende</td>
<td>Isnende</td>
<td>Pinelfuld</td>
</tr>
<tr>
<td>Gennemborende</td>
<td>Knugende</td>
<td>Røedselsfuld</td>
<td>Røedselsfuld</td>
</tr>
<tr>
<td></td>
<td>Flænsende</td>
<td></td>
<td>Torterende</td>
</tr>
</tbody>
</table>

68. McGill Total Score (udregnet af interviewer) ................... (0-78)
Appendix 5. Questionnaire (in Danish) used in the trial on suture techniques
Aarhus University Hospital (n=395). Interview planned for 10 days postpartum.

Spørgsmål om anvendelse af fotos til forskning og undervisning.

69. Vil du tillade, at der tages fotos af syningen (dokumentation) ?
   1  Ja
   2  Nej

70. Vil du tillade, at billederne anvendes anonymt i
       undervisningssammenhænge for jordemødre og læger ?
   1  Ja
   2  Nej

Inspektion af bristningens opheling i gynækologisk leje.

71. Er der foretaget inspektion af perinæum?
   1  Ja
   2  Nej

72. Er der smerter ved berøring af perinæum?
   1  Ja
   2  Nej

73. Fremtræder perinæum / introitus symmetrisk?
   1  Ja
   2  Nej

74. Er perinæum fuldstændig helet ved introitus?
   1  Ja
   2  Nej

75. Er suturen skredet eller er suturen udført suboptimalt?
   1  Ja (gå til a + b)
   2  Nej
   a: Hvordan kan dette beskrives;
      1  Subcutant skred (grad 1)
      2  Totalt skred (grad 2)
      3  Suboptimal sutur
      4  Andet ________________
   b: Henvises kvinden til resutur?
      1  Ja
      2  Nej

76. Bliver kvinden tilset og vurderet af læge i dag?
   (vagthavende / speciallæge på Skejby Sygehus)
   1  Ja
   2  Nej

77. Fjernes der sting eller knuder fra syningen?
   1  Ja
   2  Nej
Appendix 5. Questionnaire (in Danish) used in the trial on suture techniques
Aarhus University Hospital (n=395). Interview planned for 10 days postpartum.

Reeda skala score.

78: Er der rødme omkring bristningen? .................................................. Score: ______
   0= ingen
   1= max 0.25 cm bilateralt
   2= max 0.5 cm bilateralt
   3= over 0.5 cm bilateralt

79: Er der ødem omkring bristningen? .................................................. Score: ______
   0= ingen
   1= perineum max 1 cm fra sårrande
   2= perineum / vulva 1 cm fra sårrande
   3= perineum / vulva > 2 cm fra sårrande

80: Er der hæmatomer / blå mærker omkring bristningen? ....................... Score: ______
   0= ingen
   1= max 0.25 bilateralt eller 0.5 cm unilateral
   2= max 1 cm bilateralt eller 0.5 –2 cm unilateral
   3= > 1 cm bilateralt eller > 2 cm unilateral (svarende til episiotomi hæmatom)

81: Er der puds eller sekret omkring bristningen? ............................. Score: ______
   0= ingen
   1= serum
   2= blodig væske
   3= frisk blod eller gulligt pus

82: Lukkes sårrandene? ................................................................. Score: ______
   0= lukket
   1= huden gaber max 3 mm (herunder ikke helet ved introitus dag 10)
   2= hud og subcutant fedt adskilt (svarende til suturskred 1. grad)
   3= hud, subcutant fedt og fascie adskilt (svarende til suturskred 2. grad)

83: Samlede points for Reeda skalaen .................................................. Total: ______

Kommentarer:
Struktureret interview seks måneder efter fødslen

Vi beder dig i dette spørgeskema svare på nogle spørgsmål om gener, der kan forekomme efter en normal fødsel. Nogle af spørgsmålene handler om dit helbred generelt og andre er af intim karakter. Hvis det er svært at finde et svar, som passer dig, beder vi dig vælge den svarmulighed, som passer bedst muligt. Interviewet tager ca. 15 minutter i alt.

Deltager nummer

<table>
<thead>
<tr>
<th>Label med ID</th>
</tr>
</thead>
</table>

84. Dato for 3. interview: _______________ (dd/mm/år)

85. Forskningsjordemoder:  □ 1 Misan □ 2 Assistent □ 3 Sara

86 a. Hvor foretages 3. interview?  □ 1 Sutur-us. □ 2 Telefoninterview □ 3 Skriftligt, kvinden udfylder selv spørgeskemaet

86 b. Årsag til manglende data:  □ 1 Manglende papirer fra fødejdm. □ 2 Pt. er udgået efter eget ønske □ 3 Pt. er udgået, faglig vurdering □ 4 Ingen kontakt med deltager / flyttet / logistik

De følgende spørgsmål handler om til dit helbred og din trivsel siden fødslen:

87. Hvordan vil du vurdere dit fysiske helbred i forhold til før du blev gravid?
   □ 1 Meget bedre □ 2 Bedre □ 3 Det samme □ 4 Dårligere □ 5 Meget dårligere

88. Hvordan vil du vurdere dit psykiske helbred i forhold til før du blev gravid?
   □ 1 Meget bedre □ 2 Bedre □ 3 Det samme □ 4 Dårligere □ 5 Meget dårligere
**Appendix 6. Questionnaire (in Danish) used in the trial on suture techniques**

*Aarhus University Hospital. Telephone interview six months postpartum.*

---

<table>
<thead>
<tr>
<th>Spørgsmål</th>
<th>Valg</th>
<th>Beskrivelse</th>
</tr>
</thead>
<tbody>
<tr>
<td>89. Får du lægeordineret medicin dagligt? (incl. antikonception)</td>
<td>1</td>
<td>Ja (gå til a)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Nej</td>
</tr>
<tr>
<td>a: Hvilken medicin indtager du?</td>
<td></td>
<td>Produkttype</td>
</tr>
<tr>
<td>90. Ryger du dagligt?</td>
<td>1</td>
<td>Ja (gå til a)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Nej</td>
</tr>
<tr>
<td>a: Hvor mange cigaretter ryger du dagligt?</td>
<td></td>
<td>Antal</td>
</tr>
<tr>
<td>91. Har du på noget tidspunkt efter fødslen følt dig mere trist end du normalt er?</td>
<td>1</td>
<td>Ja</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Nej</td>
</tr>
<tr>
<td>92. Har du på noget tidspunkt efter fødslen tænkt at du kunne have en depression?</td>
<td>1</td>
<td>Ja (gå til a + b + c)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Nej</td>
</tr>
<tr>
<td>a: Har du da søgt behandling ved din egen læge?</td>
<td>1</td>
<td>Ja</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Nej</td>
</tr>
<tr>
<td>b: Har du da søgt behandling ved psykolog?</td>
<td>1</td>
<td>Ja</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Nej</td>
</tr>
<tr>
<td>c: Har du da søgt behandling ved en anden behandler?</td>
<td>1</td>
<td>Ja</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Nej</td>
</tr>
<tr>
<td>De følgende spørgsmål handler om lægeundersøgelsen 8-9 uger efter fødslen.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>93. Har du været til undersøgelse hos din egen læge 8-9 uger efter fødslen?</td>
<td>1</td>
<td>Ja</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Nej (gå til spg. 96)</td>
</tr>
<tr>
<td>94. Undersøgte din læge knibefunktionen i bækkenbunden?</td>
<td>1</td>
<td>Ja (gå til a)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Nej</td>
</tr>
<tr>
<td>3</td>
<td>Ved ikke</td>
<td></td>
</tr>
<tr>
<td>a: Hvordan undersøgte din læge knibefunktionen i bækkenbundens muskler?</td>
<td>1</td>
<td>Så dig knibe sammen</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Med fingrene i skeden</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Ud fra spørgsmål</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Husker det ikke</td>
</tr>
<tr>
<td>95. Hvordan omtalte din læge ophelingen af syningen?</td>
<td>1</td>
<td>Det så normalt ud</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Det så ikke normalt ud</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Ingen omtale</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Husker det ikke</td>
</tr>
</tbody>
</table>
### De følgende spørgsmål handler om smertefrihed efter fødslen.

**96. Hvor lange efter fødslen havde du smerte i mellemkødet eller skeden pga. syningen?**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ingen smerte (0 dage)</td>
</tr>
<tr>
<td>2</td>
<td>1 uge (ca. 7 dage)</td>
</tr>
<tr>
<td>3</td>
<td>2 uger (ca. 14 dage)</td>
</tr>
<tr>
<td>4</td>
<td>3 uge (ca. 21 dage)</td>
</tr>
<tr>
<td>5</td>
<td>4 uger (ca. 28 dage)</td>
</tr>
<tr>
<td>6</td>
<td>2 måneder (ca. 60 dage)</td>
</tr>
<tr>
<td>7</td>
<td>3 måneder (ca. 90 dage)</td>
</tr>
<tr>
<td>8</td>
<td>4 måneder (ca. 120 dage)</td>
</tr>
<tr>
<td>9</td>
<td>5 måneder (ca. 150 dage)</td>
</tr>
<tr>
<td>10</td>
<td>6 måneder (ca. 180 dage)</td>
</tr>
<tr>
<td>99</td>
<td>Husker det ikke</td>
</tr>
</tbody>
</table>

**97. Har du den seneste uge haft smertefrihed i mellemkødet eller skeden pga. syningen?**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ja (gå til a + b)</td>
</tr>
<tr>
<td>2</td>
<td>Nej</td>
</tr>
</tbody>
</table>

**a: Hvornår oplever du specielt disse smertefrihed?**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Konstant</td>
</tr>
<tr>
<td>2</td>
<td>Ved bevægelse / normal aktivitet</td>
</tr>
<tr>
<td>3</td>
<td>Ved at sidde på en stol</td>
</tr>
<tr>
<td>4</td>
<td>Ved at cykle (direkte tryk)</td>
</tr>
<tr>
<td>5</td>
<td>Ved samleje</td>
</tr>
<tr>
<td>6</td>
<td>Andet________________</td>
</tr>
</tbody>
</table>

**b: Hvorledes vil du vurdere smertefrihed, når de er stærkest?**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Milde smerte</td>
</tr>
<tr>
<td>2</td>
<td>Moderate smerten</td>
</tr>
<tr>
<td>3</td>
<td>Stærke smerten</td>
</tr>
</tbody>
</table>

### De følgende spørgsmål handler om din vurdering af ophelingen ved syningen.

**98. Hvor lang tid gik det fra fødslen før du fornemmede, at bristningen var helet?**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Med det samme(0 dage)</td>
</tr>
<tr>
<td>2</td>
<td>1 uge (ca. 7 dage)</td>
</tr>
<tr>
<td>3</td>
<td>2 uger (ca. 14 dage)</td>
</tr>
<tr>
<td>4</td>
<td>3 uger (ca. 21 dage)</td>
</tr>
<tr>
<td>5</td>
<td>4 uger (ca. 28 dage)</td>
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<tr>
<td>7</td>
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</tr>
<tr>
<td>8</td>
<td>4 måneder (ca. 120 dage)</td>
</tr>
<tr>
<td>9</td>
<td>5 måneder (ca. 150 dage)</td>
</tr>
<tr>
<td>10</td>
<td>6 måneder (ca. 180 dage)</td>
</tr>
<tr>
<td>11</td>
<td>Husker det ikke</td>
</tr>
</tbody>
</table>
Appendix 6. Questionnaire (in Danish) used in the trial on suture techniques
Aarhus University Hospital. Telephone interview six months postpartum.

99. Har der siden sidste interview været problemer med ophelingen, så du har været til ekstra undersøgelser enten her, ved din egen læge eller ved speciallæge?

1   Ja (gå til a + b + c)
2   Nej

a: Hvor blev undersøgelsen foretaget;
1   Ved suturjordemoder
1   Ved egen læge
1   Ved læge på SKS
1   Henvist til gynækolog

b: Hvorfor: ____________________________________________

c: Antal ekstra undersøgelser i suturprojekten: ____________

100. Er der blevet fjernet sting fra syningen efter fødslen? (alt incl. også af suturjdm. ved 10.døgns besøg)
1   Ja
2   Nej

101. Er syningen blevet korrigeret af en speciallæge?
1   Ja (gå til a + b)
2   Nej
3   Nej, men det overvejes

a: Hvor lang tid efter fødslen? ____________ uger

b: Hvilken årsag var der til omsyningen?
1   Stingene sprang op
2   Uacceptabelt udseende
3   Syet for stramt sammen
4   Syet for løst sammen
5   Smerter ved arvæv
6   Andet ____________________________

102. Ser området, hvor du blev syet ud, som før du blev gravid?
1   Ja
2   Nej
3   Ved ikke

103. Er du tilfreds med, hvordan det ser ud nu?
1   Ja
2   Nej
3   Ved ikke
4   Har ikke set efter
De følgende spørgsmål handler om samliv og følsomhed i området, hvor du blev syet.

104. Har området, hvor du blev syet, samme følsomhed nu som før graviditeten?  
   1. Ja  
   2. Nej, det er mere følsomt (gå til a)  
   3. Nej, det er mindre følsomt (gå til a)  

   a. Oplever du dette som en gene?  
      1. Ja  
      2. Nej  

105. Har du siden fødslen haft samleje?  
   1. Ja  
   2. Nej (gå til spg. 110)  

106. Hvor lang tid efter fødslen gik der, til i havde det første samleje?  
   1. < 1 måned (ca. 15 dage)  
   2. 1 måned (ca. 30 dage)  
   3. 2 måneder (ca. 60 dage)  
   4. 3 måneder (ca. 90 dage)  
   5. 4 måneder (ca. 120 dage)  
   6. 5 måneder (ca. 150 dage)  
   7. 6 måneder (ca. 180 dage)  
   8. Husker det ikke  

107. Var der smertes ved det første samleje efter fødslen?  
   1. Ja  
   2. Nej  

108. Har du oplevet smerte ved samleje i den seneste måned?  
   1. Ja (gå til a -i)  
   2. Nej  
   3. Ved ikke (-samleje)  

   Vil du beskrive disse smertes som;  

   a. Huden ved skedeindgangen er for stram ("sejl")  
      1. Ja  
      2. Nej  

   b. I området ved arret generelt  
      1. Ja  
      2. Nej  

   c. Muskelspændinger i skeden (myoser)  
      1. Ja  
      2. Nej  

   d. Muskelkramper i skeden (vaginisme)  
      1. Ja  
      2. Nej  

   e. Fra livmoderhalsen (langt inde i skeden)  
      1. Ja  
      2. Nej  

   f. Svamp i skeden / på kønslæberne  
      1. Ja  
      2. Nej  

   g. Manglende fugtighed i skeden  
      1. Ja  
      2. Nej  

   h. Andet _____________________________________________  
      1. Ja  
      2. Nej  

   i. Har du oplevet lignende smertes før graviditeten?  
      1. Ja  
      2. Nej  
      3. Husker det ikke
Appendix 6. Questionnaire (in Danish) used in the trial on suture techniques  
Aarhus University Hospital. Telephone interview six months postpartum.

109. Føles skeden ved samleje som før fødslen?  
1 Ja, som før fødslen  
2 Nej, mere åben end før fødslen (gå til a)  
3 Nej, mere stram end før fødslen (gå til a)  

a. Oplever du dette som en gene?  
1 Ja  
2 Nej  
9 Uoplyst  

De følgende spørgsmål handler om træning af bækkenbundens muskler og problemer med at holde på urin, luft og afføring efter fødslen.

110. Har du deltaget i et efterfødselskursus, hvor der blev lavet bækkenbundstræning?  
1 Ja  
2 Nej  

111. Har du den seneste uge haft problemer med luftafgang fra skeden, ”vaginale prutter”, når du rejser dig op eller sætter dig ned?  
1 Ja  
2 Nej  

112. Har du den seneste uge lavet bækkenbundsøvelser?  
1 Ja, dagligt  
2 Ja, et par gange  
3 Nej, slet ikke  

113. Har du den seneste uge haft problemer med at holde på urin?  
1 Ja  
2 Nej  

114. Har du den seneste uge haft problemer med at holde på luft?  
1 Ja  
2 Nej  
9 Uoplyst  

115. Har du den seneste uge haft problemer med at holde på afføring?  
1 Ja  
2 Nej  
9 Uoplyst
De følgende spørgsmål handler om amning.

116. Ammer du fortsat dit barn dagligt?
1 Ja (gå til a)  
2 Nej

   a: Ernæres dit barn udelukkende af brystmælk?
1 Ja  
2 Nej

117. Har du i ammeperioden haft sårede brystvorter?
(hudløshed, revner, vabler eller hul med blødning)
1 Ja (gå til a + b + c)  
2 Nej

   a: Hvor slemt vil du vurdere, at det var?
1 Mild grad  
2 Moderat grad  
3 Svær grad

   b: Hvornår, efter fødslen, kom der sår på brystvorterne?
1 De første dage  
2 I den første uge  
3 Efter én uge  
4 Efter to uger

   c: Hvor længe havde du sår på brystvorterne?
1 Et par dage  
2 1 uge  
3 2 uger  
4 1 måned

Deltagertilfredshed:

118. Er du generelt tilfreds med den syning, der blev foretaget efter fødslen?
1 Ja  
2 Nej  
9 Uoplyst

119. Har du været tilfreds med at deltage i suturprojektet?
1 Ja  
2 Nej

120. Har du en kommentar, du ønsker at få tilføjet?
1 Ja  
2 Nej

Kommentar: ____________________________________________________________

How would you characterise your pain?

Some of the words I will read to you describe your present pain. Tell me which words best describe it. Leave out any word-group that is not suitable. Use only a single word in each appropriate group—the one that describes you pain in the best way.

<table>
<thead>
<tr>
<th>1.</th>
<th>2.</th>
<th>3.</th>
<th>4.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flickering</td>
<td>Jumping</td>
<td>Pricking</td>
<td>Sharp</td>
</tr>
<tr>
<td>Quivering</td>
<td>Flashing</td>
<td>Boring</td>
<td>Cutting</td>
</tr>
<tr>
<td>Pulling</td>
<td>Shooting</td>
<td>Drilling</td>
<td>Lacerating</td>
</tr>
<tr>
<td>Throbbing</td>
<td></td>
<td>Stabbing</td>
<td></td>
</tr>
<tr>
<td>Beating</td>
<td></td>
<td>Lancinating</td>
<td></td>
</tr>
<tr>
<td>Pounding</td>
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<th>5.</th>
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<tbody>
<tr>
<td>Pinching</td>
<td>Tugging</td>
<td>Hot</td>
<td>Tingling</td>
</tr>
<tr>
<td>Pressing</td>
<td>Pulling</td>
<td>Burning</td>
<td>Itchy</td>
</tr>
<tr>
<td>Gnawing</td>
<td>Wrenching</td>
<td>Scalding</td>
<td>Smarting</td>
</tr>
<tr>
<td>Cramping</td>
<td></td>
<td></td>
<td>Stringing</td>
</tr>
<tr>
<td>Crushing</td>
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</table>

<table>
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<tr>
<th>9.</th>
<th>10.</th>
<th>11.</th>
<th>12.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dull</td>
<td>Tender</td>
<td>Tiring</td>
<td>Sickening</td>
</tr>
<tr>
<td>Sore</td>
<td>Taut</td>
<td>Exhausting</td>
<td>Suffocating</td>
</tr>
<tr>
<td>Hurting</td>
<td>Raspaging</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aching</td>
<td>Splitting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heavy</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>13.</th>
<th>14.</th>
<th>15.</th>
<th>16.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fearful</td>
<td>Punishing</td>
<td>Wretched</td>
<td>Annoying</td>
</tr>
<tr>
<td>Frightful</td>
<td>Gruelling</td>
<td>Blinding</td>
<td>Troublesome</td>
</tr>
<tr>
<td>Terrifying</td>
<td>Cruel</td>
<td></td>
<td>Miserable</td>
</tr>
<tr>
<td></td>
<td>Vicious</td>
<td></td>
<td>Intense</td>
</tr>
<tr>
<td></td>
<td>Killing</td>
<td></td>
<td>Unbearable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>17.</th>
<th>18.</th>
<th>19.</th>
<th>20.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spreading</td>
<td>Tight</td>
<td>Cool</td>
<td>Nagging</td>
</tr>
<tr>
<td>Radiating</td>
<td>Numb</td>
<td>Cold</td>
<td>Nauseating</td>
</tr>
<tr>
<td>Penetrating</td>
<td>Drawing</td>
<td>Freezing</td>
<td>Agonizing</td>
</tr>
<tr>
<td>Piercing</td>
<td>Squeezing</td>
<td>Dreadful</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tearing</td>
<td></td>
<td>Torturing</td>
</tr>
</tbody>
</table>

McGill Total Score (total count) …………… ______________ (0-78)

### REEDA SCALE FOR ASSESSMENT OF PERINEAL WOUND AREA

Redness of the perineal area .............................................................. Score: _______

0 = None  
1 = Within .25 cm. of incision bilaterally  
2 = Within .5 cm. of incision bilaterally  
3 = Beyond 0.5 cm. of incision bilaterally

Edema of the perineal area ............................................................... Score: _______

0 = None  
1 = Perineal, less than 1 cm. from incision  
2 = Perineal and/or Vulvar, between 1 to 2 cm. from incision  
3 = Perineal and/or Vulvar, greater than 2 cm. from incision

Ecchymosis of the perineal area ....................................................... Score: _______

0 = None  
1 = Within .25 cm. bilaterally or 0.5 cm. unilaterally  
2 = Between 0.25 to 1 cm. bilaterally or between 0.5 to 2 cm. unilaterally  
3 = Greater than 1 cm. bilaterally or 2 cm. unilaterally

Discharge from the wound .............................................................. Score: _______

0 = None  
1 = Serum  
2 = Serosanguinous  
3 = Bloody, purulent

Approximation of skin edges .......................................................... Score: _______

0 = Closed  
1 = Skin separation 3 mm. or less  
2 = Skin and subcutaneous fat separation  
3 = Skin, subcutaneous fat and fascial layer separation

Total REEDA Score ................................................................. Total: _______

---

Source: Davidson N. *REEDA: evaluating postpartum healing*.  
J Nurse Midwifery 1974; 19(2):6-8