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The Use of Episiotomy in Obstetrical Care: A Systematic Review

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-Based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review prior to their release.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

We welcome comments on this evidence report. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to **epc@ahrq.gov.**

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Structured Abstract

Context: In the United States, use of episiotomy varies from less than 10 percent to more than 75 percent of vaginal births. Overall, 30 to 35 percent of vaginal births include episiotomy. Routine episiotomy may not yield maternal benefits traditionally ascribed to it.

Objectives: We addressed five key questions (KQs):

1. Does the practice of liberal or routine episiotomy, compared to more selective use of episiotomy, influence maternal postpartum outcomes?
2. Does episiotomy incision type (i.e., midline or mediolateral), influence maternal postpartum outcomes?
3. Does the repair of the perineal defect (i.e., suture type and repair approach) influence maternal postpartum outcomes?
4. Does episiotomy have a long-term influence on urinary incontinence, fecal incontinence, or pelvic floor defects?
5. Does episiotomy or incision type, or both, influence future sexual function?

Data Sources: We searched MEDLINE®, Cochrane Library, and CINAHL® and did hand–searches, and consulted with experts.

Study Selection: We excluded studies (1) not about outcomes of vaginal birth; (2) in languages other than English; (3) not pertinent to the key questions; (4) with < 40 subjects; and (5) not representing original research. KQs1, 2, and 3 were limited to randomized controlled trials. KQs4 and 5 included nonrandomized prospective cohorts.

Data Extraction: We entered data into pretested abstraction forms; did a second review for accuracy, completeness, and consistency; and graded quality of studies.

Data Synthesis: Literature searches yielded 986 articles; 659 were excluded after abstract review. Of the remaining 327, we included 45 articles.

Conclusions: Fair to good evidence suggests immediate maternal outcomes from routine episiotomy are not better than those from restrictive use; instead, outcomes are worse because some proportion of women who would have had lesser injury instead had a surgical incision. Evidence is insufficient to provide guidance on choice of midline or mediolateral episiotomy when indicated. For perineal injury requiring suturing, fair to good evidence suggests leaving superficial vaginal and perineal skin unsutured is potentially preferable. If used for skin approximation, a continuous, subcuticular repair is superior to an interrupted, transcutaneous method. Evidence is consistent and clear that absorbable suture is preferred and that polyglycolic acid suture is associated with less morbidity than gut and chromic gut suture. Evidence is insufficient to determine whether novel materials, such as tissue adhesive, offer benefits. Evidence regarding long-term sequelae is fair to poor; assessment of pelvic floor dysfunction was not conducted in the age groups of greatest relevance. Limited data show that episiotomy does not prevent fecal and urinary incontinence, pelvic floor relaxation, or impaired sexual function, within months to years from childbirth.

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Agency for Healthcare Research and Quality

Evidence Report/Technology Assessment

Number 112

The Use of Episiotomy in Obstetrical Care: A Systematic Review

Summary

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Introduction

Episiotomy, incision of the perineum at the time of vaginal childbirth, is a common surgical procedure experienced by women in the United States.[1] Based on national hospital discharge data for 1999, just over 35 percent of women who gave birth vaginally had an episiotomy performed; the figure was approximately 33 percent in 2000.[2,3]

Despite several decades of research, which many interpret as definitive evidence against routine (or "liberal") use of episiotomy, little professional consensus has developed about the appropriateness of routine use. Lack of consensus is illustrated by variation in rates of use, ranging from 13.3 percent to 84.6 percent in one study with a prospectively enrolled low-risk population, with an average of 51 percent among spontaneous term births.[4] Variation has been reported by type of clinician,[4] time of day,[5] and facility type, size, and location.[6] Wide practice variations suggest that episiotomy use is heavily driven by local professional norms, experiences in training, and individual provider preference rather than variation in the physiology of vaginal birth. The goal of this synthesis is to inform care providers, professional organizations, advocates, and individual women about the current state of the evidence on routine use of episiotomy.

Key Questions

The RTI–UNC EPC addressed the following Key Questions (KQs):

KQ 1. Does the practice of liberal or routine episiotomy, compared to more selective use of episiotomy, influence maternal postpartum outcomes?

KQ 2. Does episiotomy incision type (i.e., midline or mediolateral) influence the risk of maternal morbidity?

KQ 3. Does the repair of the perineal defect (i.e., suture type and repair approach) influence the risk of maternal morbidity?

KQ 4. Does episiotomy have a long-term impact on urinary incontinence, fecal incontinence, or pelvic floor defects?

KQ 5. Does episiotomy or incision type, or both, influence future sexual function?

Methods

Inclusion and Exclusion Criteria

We excluded studies that (1) did not report on women of reproductive age, (2) were published in languages other than English, (3) did not report information pertinent to the key clinical questions, (4) had fewer than 40 subjects, and (5) were not original studies. Criteria for study design were based on sufficiency and quality of evidence. KQs 1 and 3 have been more commonly examined in randomized controlled trials (RCTs); thus, we elected to limit searches to RCTs. KQs 2, 4, and 5 have been studied less extensively in trials; therefore, we included both RCTs and prospective cohort studies.

Literature Search and Retrieval Process

We used standard electronic databases: MEDLINE®, Cochrane Collaboration resources, and the Cumulative Index to Nursing and Allied Health Literature (CINAHL®). We reviewed

reference lists of relevant articles and consulted with the Technical Expert Advisory Group (TEAG) to obtain additional relevant articles. We conducted a dual review for abstracts and a single review for full articles to decide inclusion according to preset criteria.

Development of Evidence Tables and Data Abstraction Process

Abstractors trained themselves on entering data into evidence tables by abstracting several articles and then reconvening as a group to discuss the utility of the table design. After several iterations and TEAG review, the final table design had all needed, appropriate categories for systematically recording information on the articles.

All team members did initial entry of information onto data abstraction forms. Another team member reviewed articles and edited all initial table entries for accuracy, completeness, and consistency. The two abstractors reconciled all disagreements concerning information in the abstraction tables. We then entered data from the abstraction forms into evidence tables and again checked for consistency and accuracy.

Quality and Strength of Evidence Evaluation

Rating the Quality of Individual Articles

Two article abstractors independently rated each article on each of the categories on our quality assessment form. A third reviewer reviewed the scores and flagged studies with differences in scoring on individual components. We reconciled these differences by consensus.

Grading the Strength of Available Evidence

Our scheme follows the criteria utilized by Berkman et al.[7] That system included three domains: quality of the research, quantity of studies (including number of studies and adequacy of the sample size), and consistency of findings. Grades were assigned by consensus of the four senior staff members.

External Peer Review

As is customary for all evidence reports and systematic reviews done for AHRQ, the RTI–UNC EPC requested review of this report from a wide array of outside experts in the field and from relevant professional societies and public organizations. We compiled comments from 18 respondents and addressed each one individually, revising the text as appropriate.

Results

Literature Search Yield

The literature search yielded 986 articles. Of these, we excluded 659 articles after reviewing the abstracts. Of the remaining 327 articles, we included 45 in our evidence report. Of these, 7 address KQ 1, 1 addresses KQ 2, 20 address KQ 3, 15 address KQ 4, and 10 address KQ 5.

Key Question 1: Episiotomy and Maternal Postpartum Outcomes

Seven primary publications of RCTs addressed liberal versus restrictive use of episiotomy.[8-14] Each trial compared two study arms or groups: (1) an intention to restrict routine use of episiotomy and (2) a liberal-use policy that endorsed routine use. Use of episiotomy in the restrictive groups ranged from lows of 7.6 percent[9] and 10.2 percent[8] to highs of 44 percent[11] and 53 percent.[13] We emphasize that these trials compared policies of episiotomy use, not episiotomy to no episiotomy; six of the seven studies used mediolateral episiotomy.

This literature has high internal consistency with respect to the postpartum effects of differing strategies for episiotomy use. Compared to women in liberal-use groups, women in the restrictive-use groups had less severe posterior perineal trauma, less need for suturing, higher probability of having an intact perineum, no greater or lesser risk of wound healing complications, and higher likelihood of resuming intercourse earlier.

Key Question 2: Episiotomy Incision Type and Maternal Morbidity

Only one RCT compared outcomes of midline episiotomy to those of mediolateral episiotomy.[15] An additional focused literature search did not reveal any prospective cohort studies on this issue. Women in the midline group began sexual intercourse significantly earlier and had a significantly better cosmetic appearance of the scar than women in the mediolateral group. The groups did not differ significantly on pain or satisfaction from sexual intercourse. Women receiving midline episiotomy also had a significantly greater probability of anal sphincter injuries than women in the mediolateral episiotomy group. This study did not assess fecal incontinence as a long-term health outcome. Because of considerable methodologic flaws, any conclusions must be drawn cautiously.

Key Question 3: Repair of Perineal Defect and Maternal Morbidity

We included 17 RCTs (in 21 articles) examining various methods and materials for repairing perineal defects; virtually all episiotomies in these trials were mediolateral.[16,17,17-35]

Four trials investigated techniques of repair.[17,27,29,32,35] Two compared a two-layer approach (leaving the perineal skin unsutured) with a three-layer approach (suturing the perineal skin); two others compared a continuous (subcutaneous) technique with an interrupted (transcutaneous) technique.

Fourteen trials investigated materials for repair;[19 16,17,20-23,25-28,30-34] eight compared polyglycolic-acid sutures with chromic-catgut sutures, both absorbable; two compared absorbable sutures (one polyglycolic acid and one chromic catgut) with an enbucrilate tissue adhesive (Histoacryl®); two compared standard absorbable suture material with its rapidly absorbed

counterpart; and one compared untreated chromic catgut with a glycerol-treated "softgut" chromic catgut. In addition, two trials compared nonabsorbable and absorbable sutures: one compared silk sutures with polyglycolic-acid sutures and one compared silk sutures with both polyglycolic-acid and chromic-catgut sutures.

Finally, two trials combined comparison of both techniques and materials in their design.[18,24]

Most of these trials randomly allocated participants to one of two groups. However, three trials incorporated a factorial design of randomization. Using a 2x2 design, both the so-called Ipswich Childbirth Study[29,30,32] and the Kettle et al. trial[36] randomized to methods of repair and type of sutures. The Mahomed et al. perineal suture study used a 2x3x2 design and randomized to suture type for deep tissue repair (two groups), suture type for the perineal skin (three groups), and method of repair (two groups).[27]

Methods

Two-layer vs. three-layer repair. The trials provided consistent evidence that favored the two-layer approach; differences between the two approaches were not always statistically significant.[29,32,35]

Despite some limitations, collectively these trials suggest that less overall perineal morbidity is associated with the two-layer repair approach than with the traditional three-layer approach. The reduction in pain, need for analgesia, wound healing problems, and sexual morbidity as well as a decrease in the time and cost required for initial suturing of the perineal skin, removal, and possible resuturing, may make the two-layer approach more beneficial than the three-layer approach.

Continuous vs. interrupted sutures. Two good-quality trials produced inconsistent evidence that the continuous method of repair has less perineal morbidity and more patient satisfaction associated with it than the interrupted method.[17,27] In both trials, the authors describe greater familiarity with the interrupted method of repair. One clinical group even suggests that their inconsistencies with other trials might be attributable to lack of practice with the method and subsequent unpopularity with the operators that performed the repair.[27] Whether such differences in outcome arise for clinicians and women outside the United Kingdom, where methods of repair and training of those performing the repair could be different than in other countries, remains to be seen.

Materials

Absorbable vs. tissue adhesive. These two trials were small (n < 65 in both trials) and of poor quality because of poor randomization,[16,33] but they defined and measured perineal pain well and achieved good followup. They contribute possible evidence that repair with tissue adhesive may decrease perineal pain in the immediate postpartum.

Absorbable sutures: standard vs. rapidly absorbed. Mixed results from a good trial[36] and lack of significant differences between groups in a poor trial[31] yielded insufficient evidence, pointing to a difference in perineal pain between standard and rapidly absorbed sutures. Stronger evidence indicated that women who had rapidly absorbed sutures required less removal of the material, presumably because it was absorbed into the skin quickly in the postpartum period. Although the two trials evaluated sexual functioning at different times, rapidly absorbed sutures may decrease the amount and severity of dyspareunia in the puerperium.

Untreated catgut vs. treated catgut. Only one trial addressed treated and untreated chromic catgut.[25] It produced no evidence that treated catgut is superior to untreated catgut with regard to perineal morbidity; in fact, treated catgut may be associated with higher morbidity (more perineal pain in the immediate postpartum period; painful sexual intercourse in the longer term).

Nonabsorbable vs. absorbable suture. Because of the study design of the fair-quality trial[23] and lack of control for possible confounding by method of repair, we cannot draw conclusions about the role of silk sutures in perineal morbidity from this trial. The authors concluded that the subcuticular method lent itself to short-term advantages but did not present supporting data. Thus, although this trial may contribute to a body of evidence about combinations of materials and methods, it does not contribute to the overall understanding of the role of suture materials in perineal morbidity, separate from methods of repair. The Mahomed et al. trial[27] found no differences between the two groups in the short-term postpartum period, but did find differences at 3 months, indicating a possible delayed effect of the suture material.

Polyglycolic acid vs. chromic catgut. In 2004, the Cochrane Library published a systematic review and meta-analysis of information on polyglycolic-acid versus catgut suture material for repair of perineal trauma.[37] The authors reported that polyglycolic-acid sutures were associated with less pain in the short-term postpartum period (odds ratio [OR] = 0.62; 95% confidence interval [CI], 0.54-0.71) and with less need for analgesia (OR = 0.63; 95% CI, 0.52-0.77), but groups did not differ in long-term pain outcomes or reports of dyspareunia.

Our systematic review includes six of the eight trials that appeared in the Cochrane review and two additional trials. Overall, the evidence is from a combination of poor, fair, and good trials; it is consistent with the previous Cochrane review. Polyglycolic-acid sutures are associated with less perineal pain, less need for analgesia use, and fewer healing problems in the short term. Long-term outcomes do not differ substantially between polyglycolic-acid sutures and chromic catgut. One trial not in the Cochrane review reported more perineal pain and dyspareunia in the polyglycolic-acid group at 6 months,[34]

an outcome the authors attributed to the slower absorption rate of polyglycolic-acid sutures; however, these results were neither statistically significant nor precise. Overall, the body of evidence about polyglycolic-acid versus chromic-catgut sutures suggests that polyglycolic-acid sutures offer many short-term advantages.

Combined methods and materials. Two trials compared entire approaches, combining both materials and methods in a single randomization design.[18,24] The poor trial[18] found no differences between the groups; the fair-quality trial[24] found that women repaired with polyglycolic-acid sutures using a continuous, subcuticular approach suffered less perineal morbidity. This result is consistent with other trials that investigated subcuticular suturing and polyglycolic-acid sutures separately, perhaps reinforcing the notion that this method and suture type are superior to other options available to obstetric clinicians.

Key Question 4: Episiotomy and Urinary Incontinence, Fecal Incontinence, and Pelvic Floor Defects

Sixteen publications prospectively collected data about some aspect of continence or pelvic floor muscle function with good documentation of perineal status and episiotomy use at the time of the index birth. Outcomes of interest included physiologic measures of muscle strength, clinical urodynamic testing, or self-report by interview or questionnaire.

The 16 publications include four reports from two RCTs of liberal versus restrictive use of episiotomy and 11 prospective studies of representative cohorts of women delivering at particular facilities or with a particular practice group (including two publications from a cohort of women who participated in an RCT of perineal massage versus none in the third trimester). One study of a cohort of all women in a region who had third-degree lacerations at the time of the index birth followed them to assess risk of fecal incontinence at 3 months.

All studies reflect the dominant practice patterns in the countries in which the studies were conducted. No study directly compared the influence of mediolateral versus midline (also called median) episiotomy on pelvic floor function or continence. For this reason, long-term differences in continence and pelvic floor muscle outcomes that would be anticipated secondary to differences in episiotomy type are unknown.

Randomized Controlled Trials

Both RCTs (Sleep and colleagues in the United Kingdom[8] and Klein and colleagues in Canada[11]) required providers to alter their use of episiotomy. These trials randomized women to "liberal use" or "restricted use" of episiotomy; the latter category intended to restrict use to circumstances such as fetal distress or maternal exhaustion with an "unyielding perineum." Both trials enrolled singleton, vertex presentation pregnancies at term and randomized in the delivery suite close to the time of birth.

Neither trial showed meaningful differences in varied measures of urinary incontinence such as subjective sensation of perineal bulging, perineometry readings, involuntary loss of urine, use of a pad, loss of urine with coughing, sneezing, laughing, and loss with urgent need to void. Neither trial collected data about continence of flatus or stool, descriptive data from physical examination, or urodynamic studies. Both research teams concluded that they did not observe any benefits associated with episiotomy. Klein and colleagues, using perineometry measures, also concluded that episiotomy fails to prevent pelvic floor relaxation.[11]

Prospective Studies

The most global assessment of continence and pelvic floor function concluded that episiotomy is associated with lower pelvic floor muscle strength than spontaneous tears.[38] The clinical significance of this finding is unclear because all self-reported symptoms of urinary and anal incontinence and degree of prolapse on physical examination were equivalent across groups. Overall, episiotomy apparently did not protect against incontinence, prolapse, or decrements in pelvic floor muscle function by 3 months postpartum.

Studies focused on self-reported urinary continence. Excluding the clinical trial populations and the Sartore et al. study above, five studies (in four study populations) evaluated self-reports of urinary continence.[39-43] Overall, episiotomy and spontaneous-tear groups had the same frequency of incontinence symptoms; no evidence emerged that episiotomy prevents pelvic floor damage.

Studies focused on self-reported incontinence of stool or flatus. Three cohort studies asked women about rectal incontinence symptoms; one also conducted physical examinations.[44-46] These authors focused on the high prevalence of anorectal dysfunction at 3 months with episiotomy as a key risk factor. None of these research teams found episiotomy to be statistically associated with reduced risk.

Studies focused on physiologic measures of pelvic floor function. Overall, none of these research teams concluded that episiotomy had advantages,[29,47,48] and one identified a decrease in functional muscle strength. As intermediate measures, these findings concur with the self-report and clinical examination findings of other studies: essentially, episiotomy confers no benefits with respect to preserving continence or pelvic floor muscle function.

Key Question 5: Episiotomy and Future Sexual Function

Nine studies (in 10 publications) prospectively collected outcome data about sexual function among women who did or

did not have a routine episiotomy. One study compared incision type and assessed sexual function;[15] three RCTs examined restrictive versus liberal use of episiotomy;[8,11,49] one trial studied mediolateral versus median episiotomy;[15] and five were prospective cohort studies.[38,42,50-52] One study (the only study conducted in the United States), described by the authors as "retrospective," included a single followup time point (6 months) with prospective data collection about sexual function.[53] Two publications reflect a primary analysis from an RCT with 3 months of followup[8] and a secondary analysis after 3 years[49] in the same UK study population. In two publications with analyses of the same study population, a Canadian research team reported analyses of 3-month followup data: one on randomization to liberal or restrictive episiotomy groups, and the other on perineal trauma at the time of delivery by exposure group.[11,52]

Apart from the one study directly comparing mediolateral to median episiotomy, all studies reflect the dominant practice patterns of the countries in which they were conducted. Thus, the literature reflects two distinct types of procedures, the effects of which need to be addressed separately.

Randomized Controlled Trials

Two publications from RCTs of restrictive compared to liberal use of episiotomy reported intention-to-treat analyses of long-term effects on the sexual outcomes of populations of women. In one study,[8] by 1 month after delivery, 37 percent of the restrictive group and 27 percent in the liberal group had resumed sexual intercourse ($P < 0.01$). The proportion of women with resumption of intercourse by 3 months, current dyspareunia at 3 months, or any dyspareunia within the 3 months of followup did not differ significantly by group. By the third year of followup, the likelihood of "ever suffering painful intercourse" remained comparable across groups.[49]

Klein and colleagues found less episiotomy use in the restrictive group with higher rates of spontaneous lacerations.[11] Women in the restrictive group resumed intercourse an average of 1 week earlier that those in the liberal group; however, all other measures of sexual function were equivalent by 3 months.[11] This team conducted a separate analysis of the relationship between degree of perineal trauma and sexual function using 3-month interview data. They regrouped participants by perineal status that had been systematically documented at the time of the index birth, creating a prospective cohort. Women with episiotomy had the slowest return to intercourse. Pain with the first intercourse followed a similar pattern.

Prospective Cohorts

These cohort studies did not find large or statistically significant differences in sexual function. Only one study identified lasting differences in dyspareunia at 3 months. Current dyspareunia at 3 months can be estimated from three of the cohort studies using 818 women with episiotomy and 938 women without episiotomy.[38,50,51] A meta-estimate from the combined cohorts suggests that women with episiotomy are 54 percent more likely to have pain with intercourse 3 months after delivery, with an absolute increase in risk of dyspareunia of 5 percent among women who had episiotomy. The two studies that assessed any dyspareunia during the 3 months after childbirth revealed no difference in the overall probability of having had painful intercourse.

Discussion

Findings by Key Question

Key Question 1: Episiotomy and Maternal Postpartum Outcomes

Trials of fair to poor quality provide consistent findings that clearly support limited use of episiotomy. Routine episiotomy achieves no short-term goals that it has been hypothesized to achieve. Indeed, routine use is harmful to the degree that it creates a surgical incision of greater extent than many women might have experienced had episiotomy not been performed.

Key Question 2: Episiotomy Incision Type and Maternal Morbidity

A single study found that women with midline episiotomy had a significantly greater rate of anal sphincter injuries than women with mediolateral episiotomy.[15] Treatment groups did not report differences in pain or satisfaction with intercourse at 3 months. Because of considerable methodological flaws in this trial (poor internal validity), any conclusions must be drawn cautiously. However, because differences in sphincter injury rates are clinically important, we consider the finding of increased risk of severe injury with midline episiotomy compared to mediolateral episiotomy to be relevant observational evidence.

Key Question 3: Repair of Perineal Defect and Maternal Morbidity

Limited but consistent evidence favored two-layer repair over three-layer repair; limited and inconsistent evidence favored continuous over interrupted sutures. Evidence was insufficient to comment on comparisons between standard and rapidly absorbed sutures, tissue adhesive and absorbable sutures, or nonabsorbable and absorbable sutures. We found no evidence that treated catgut is superior to untreated catgut with regard to perineal morbidity; the former may in fact be associated with higher morbidity. The evidence suggests short-term advantages for perineal repeat associated with the use of polyglycolic-acid sutures compared to chromic-catgut sutures.

Three major classes of suture material (nonabsorbable, absorbable, and tissue adhesive) and two subtypes of sutures (treated versus untreated and standard versus rapidly absorbed) were studied, all in the presence of different approaches to the method of suturing; thus, individual effects of the materials themselves cannot be examined. Likewise, methods of repair

were examined in the context of different materials both among and within studies for different stages of repair. We are unable to assess the true effects of a certain method of repair because we cannot tell whether outcomes are confounded or modified by suture material.

Key Question 4: Episiotomy and Urinary Incontinence, Fecal Incontinence, and Pelvic Floor Defects

These prospective studies did not identify improvements in continence for urine or stool or in pelvic floor muscle function among women who had had episiotomy compared to those who had not. This finding includes comparison to women who had spontaneous lacerations of similar severity. Several authors reported decrements in pelvic floor function among women who had had episiotomy. Only a single study, using multivariable models, found that episiotomy was an independent predictor of urinary continence.[41] In the majority of other studies using multivariate models, adjusting for factors such as parity, neonatal weight, and length of second-stage labor, episiotomy was not an independent risk factor for incontinence. Taken in total, this literature, predominantly of fair to poor quality, does not support use of episiotomy for the purpose of preventing pelvic floor defects, urinary incontinence, or incontinence of stool or flatus.

These studies are limited because they do not follow women long enough to detect disease occurrence. At present, the assumption that intermediate variables, such as pelvic muscle strength measured by perineometry, urodynamic test results, or early reports of symptoms, can predict later disease has not been validated. Prospective evaluation only during the months after birth when the pelvic floor is still in a recovery and stabilization period may be misleading. Conclusions about whether episiotomy prevents or increases risk for incontinence and prolapse later in adult life cannot be reached from currently available randomized and cohort studies.

Key Question 5. Episiotomy and Future Sexual Function

The studies addressing this question need to be considered in two groups: mediolateral episiotomy and median episiotomy. From the clinical trials of episiotomy strategy—liberal versus restrictive—one trial addressed each type of incision and one directly compared the two incision types. None found substantive differences in sexual function. The preponderance of the studies, however, supported a conclusion that degree of perineal trauma is associated with probability of pain with intercourse, in a dose-response fashion such that greater perineal injury is associated with greater probability of pain.

Measures that are more complex than those typically used in this literature are needed to understand properly the relationships between perineal trauma and future sexual function. Specific factors such as prior sexual function and current libido, in addition to factors such as duration of second-stage labor, size of infant, and lactation status, need to be incorporated into multivariable models to derive more informative and less biased estimates of the long-term effects of episiotomy or to determine that they do not exist.

Limitations

Deficiencies in the Literature

The available studies that met our inclusion criteria for this systematic review contained numerous (and commonly encountered) deficiencies. These included variations in episiotomy rate, violations of protocol, inconsistent reporting of the definitions of measures, inadequate reporting of statistics, infrequent a priori designation of primary and secondary outcomes, infrequent masking of the assessor, infrequent use of multivariate modeling, and infrequent use of validated outcome measures. In all, much of this literature could be regarded as fair in quality, with some studies of good quality and a few of poor quality.

Limitations to Our Review Procedures

Our review process also had some limitations. Because of time and resource constraints, we did not conduct dual, independent, blinded review of articles for inclusion or abstraction of information into evidence tables. Instead, one reviewer performed the initial review, and a second reviewer examined that input and recommended changes. Differences were reconciled between the two reviewers. We used dual review for grading the quality of individual articles, allowing us to evaluate rigorously systematic bias in these assessments.

Future Research

Currently, the evidence suggests that the putative benefits of episiotomy do not outweigh its harms. Instead, outcomes from episiotomy are worse because some proportion of women who would have had lesser injury instead had a surgical incision.

If episiotomy were restricted to indicated uses, an important question remains for women and their care providers: Which, if any, of the prevailing indications for episiotomy are supported by an adequate research base? A two-stage research agenda could address this need. First, a systematic review may clarify current knowledge about outcomes of episiotomy for the leading presumed indications. Second, primary data collection may be needed to fill in research gaps identified by such a review and to improve understanding of whether these are indeed indications for episiotomy.

Work relating to this latter part of such a research agenda is under way on several topics. This work includes a recent publication of a retrospective cohort study that suggests that episiotomy conferred no benefit in averting neonatal injury at the time of births that had been complicated by shoulder dystocia.[54] Additional evidence will be required to investigate fully what circumstances should be considered indications for episiotomy.

Furthermore, if the professional community accepts that routine episiotomy is not an effective means to reduce perineal injury, then that attitude should enable them to redouble efforts to understand fully various other approaches to attending the second stage of labor that can promote maternal and infant safety, minimize perineal trauma, and maximize maternal comfort. These steps might include giving attention to maternal position, avoiding fundal pressure, reducing coached pushing, providing perineal support, and employing "hands poised" versus "hands on" techniques to support the perineum. The role for lubrication and types of lubrication for use during crowning of the infant head are other important research topics that warrant more rigorous investigation.

To understand pelvic floor defects and childbirth experiences properly, including history of episiotomy, studies need to be designed to identify populations of women who have a known episiotomy history. In this way, researchers can evaluate continence and pelvic organ prolapse status in the age groups between 40 and 70 years.

Conclusion

Our systematic review finds no health benefits from episiotomy. We found fair to good evidence suggesting that the immediate outcomes for routine (liberal-use policies) episiotomy are no better than those for indicated use of episiotomy under more restrictive-use policies. Indeed, routine use is harmful to the degree that it creates a surgical incision of greater extent than many women might have experienced had episiotomy not been performed. Weak trial evidence, consistent with observational data, suggests that the harms of midline episiotomy are greater than the harms of mediolateral episiotomy.

For episiotomy repair, fair to good evidence, albeit across different comparisons of methods and materials, suggests that leaving the perineal skin unsutured may confer some benefit; if suturing is indicated, then a continuous, subcuticular method is better than an interrupted, transcutaneous method. Regarding suture material, the evidence is consistent and clear that absorbable sutures are preferred and that polyglycolic-acid sutures have significantly less perineal morbidity associated with them. Newer materials, such as tissue adhesive, may offer further benefits, but the data are at present wholly inadequate to inform care practices.

The level of evidence for long-term sequelae, specifically fecal and urinary incontinence, pelvic floor function, and future sexual function, is fair to poor. Nonetheless, it is consistent in demonstrating the lack of benefit of the procedure in a comparatively early timeframe. For women in later adult life, when morbidity is most likely to occur in the form of severe and persistent incontinence or pelvic organ prolapse, the expected results of routine episiotomy are unknown.

Availability of the Full Report

The full evidence report from which this summary was taken was prepared for the Agency for Healthcare Research and Quality (AHRQ) by the RTI-UNC Evidence-based Practice Center, under Contract No. 290-02-0016. It is expected to be available in May 2005, *The Use of Episiotomy in Obstetrical Care: A Systematic Review*. In addition, Internet users will be able to access the report and this summary online through AHRQ's Web site at www.ahrq.gov.

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Chapter 1. Introduction

Background

Episiotomy, incision of the perineum at the time of vaginal childbirth, is a common surgical procedure experienced by women in the United States.[1] Based on national hospital discharge data for 1999, just over 35 percent of women who gave birth vaginally had an episiotomy performed; the figure was approximately 33 percent in 2000.[2,3] National rates reflect a steady decline over the prior two decades,[1] with 2001 data suggesting that approximately 30 percent of vaginal births include episiotomy.[4]

Actual rates are likely to be higher because administrative data sources are prone to capture fewer events than occur. A study of the validity of birth data for Washington state in 1989 found that hospital discharge data underestimated episiotomy incidence by 44 percent overall when compared with medical records; accuracy of discharge record reporting for individual facilities ranged from recording none of the episiotomies performed at worst, to 86.4 percent at best.[5] In their nationally representative survey of women's childbearing experiences between 2000 and 2002, the Maternity Center Association documented that 35 percent of women who had a vaginal birth reported having an episiotomy.[6]

Likelihood of episiotomy is known to vary based on whether a woman is having a first vaginal birth or a subsequent birth and whether the birth is assisted by use of vacuum or forceps. Both a first birth and assisted vaginal delivery are associated with greater use of episiotomy.[1,7] Likelihood of episiotomy also varies across obstetric care settings. A study of 49,692 vaginal births in 18 hospitals in Philadelphia between 1994 and 1998 examined use of episiotomy among women giving birth for the first time to infants who weighed 2500 to 4000 grams and whose records did not note a difficult labor or assisted delivery. Forty-two percent of women in the study had an episiotomy, with a range of hospital averages from 20 percent to 73 percent.[8]

The precise origins of episiotomy are lost. Descriptions appear in European texts by the 1740s.[9] Taliaferro first described its use in the U.S. medical literature in 1852.[10] While caring for a moribund primiparous woman with eclampsia, he describes "immense distension of the vulva" and proceeding to make "an incision at the vulva, believing that preferable to permitting it [the fetal head] to force its way through [the anus] below." He further noted: "…surely a smooth incised wound would be less injurious and heal more readily than one by rough violence."[10]

These observations foreshadow early uses of episiotomy that became ingrained in hospital obstetric practice beginning in the 1920s: to hasten delivery for maternal or fetal indications; to resolve the "unyielding vulva"; and in cases thought to portend imminent severe laceration, to forestall an extensive spontaneous laceration and substitute a more readily repaired surgical incision. In this decade, Joseph DeLee, an opinion leader in the drive to establish obstetrics as a medical specialty, began to promote the concept that episiotomy should be "used routinely" for the maternal indications above as well as to prevent brain damage, epilepsy, and cerebral palsy that might result from the "battering" of the fetal head against a rigid perinuem.[11,12]

Most obstetric textbooks endorsed episiotomy by the 1930s: "This is a prophylactic procedure, its purpose being: (a) to prevent extensive damage of the posterior vaginal wall and pelvic floor; (b) to save from gross injury the sphincter ani muscle and wall of the anal canal; (c)

to curtail long-drawn-out overdistension of the vaginal wall, and the damage resulting therefore…," providing the advantages of preventing extensive laceration, preserving sphincter integrity, providing a clean-cut wound and making scar tissue less likely to form, and ultimately achieving a result that is more satisfactory from "anatomical, functional, and cosmetic standpoints."[13] (Chapter 22, p. 666) Authors of texts frequently note that the procedure is especially warranted for primiparous patients, observing, "inasmuch as some degree of laceration occurs in the majority of cases episiotomy is a conservative rather than a radical procedure"[14] (Vol 2, Section 10, p. 330).

In the 1940s and 1950s, routine episiotomy was little debated and increasingly used. During subsequent decades, the proposed benefits of episiotomy continued to take on broader scope. These benefits included goals of reducing postpartum perineal pain when compared to spontaneous lacerations, preventing future pelvic organ prolapse and urinary and rectal incontinence, and preserving sexual function both by reducing slackness of the vaginal introitus and by reducing the likelihood of pain with intercourse.[15,16] By the 1980s, episiotomy accompanied 64 percent of vaginal births in this country.[17]

Episiotomy became a routine practice of physicians long before emphasis on using outcomes research to inform practice. In seeking to establish an evidence base to support or refute the use of episiotomy, randomized clinical trials in the mid and late 1980s revealed two key findings: (1) routine mediolateral episiotomy use compared to restricted use was associated with higher risk of anal sphincter and rectal injuries, and (2) such surgery precluded a woman's possibility of giving birth with an intact or minimally damaged perineum.[18] Larger trials in more varied populations of women and providers followed in the 1990s, with similar results. Investigators also sought to assess longer-term effects of perineal management at the time of birth on outcomes such as persistent pain, pelvic floor defects, urinary and rectal continence, and sexual function and satisfaction. The latter topics entered the spotlight as these outcomes became more dominant among the prevention-oriented goals proposed to be achieved by episiotomy.

Despite several decades of research, which many interpret as definitive evidence against routine use of episiotomy, little professional consensus has developed about the appropriateness of routine use. Lack of consensus is illustrated by variation in rates of use. From 1987 to 1992, Kane Low and her colleagues documented provider-level variation from 13.3 percent to 84.6 percent, with an average of 51 percent among spontaneous term births in a prospectively enrolled low-risk population.[19] Episiotomy use varied widely in the midwives and physicians studied. Variation has been reported by time of day[20] and by facility type, size, and location.[21]

Although restricted-use arms of trials have achieved episiotomy rates as low as 8 percent to 10 percent,[22,23] use remains common in many locations. Current obstetric care providers who continue to view episiotomy favorably most strongly agree with survey items that indicate they employ episiotomy to "prevent perineal trauma and to prevent pelvic floor relaxation and the consequences of pelvic floor relaxation, such as bladder prolapse and urinary incontinence." Furthermore, providers endorse the statement that they "prefer to employ episiotomy frequently, because it is easier to repair than the laceration that results when episiotomy is not used."[24]

Five points summarize the long history of episiotomy:

1. routine use of episiotomy evolved from more limited indications;
2. a goal of preventing future problems is eclipsing goals for labor "management";
3. provider type is associated with acceptance or avoidance of its use;

4. among providers of the same type, use varies widely; and
5. rates of use vary distinctively by institution and region.

The last three of these characteristics—wide practice variation—suggest to health services researchers that episiotomy use is heavily driven by local professional norms, experiences in training, and individual provider preference. Variation in biology, in this case the physiology of vaginal birth, rarely explains discrepancies in practice as large as those seen for episiotomy use. When practice variation is prominent, accrual of evidence of benefits and risks should take on a key role in informing care. In this context, episiotomy has the hallmarks of a procedure that warrants repeated synthesis of the evidence of proposed benefits and potential risks. A 1968 *Lancet* editorial aptly captures the issues: "Despite the apparent simplicity of episiotomy, argument continues about how often the operation should be undertaken, the choice of incision, and the method of repair. Moreover, little information is available about the incidence of later complications such as dyspareunia."[25]

This systematic evidence review revisits randomized trials of routine versus restricted use, identifies the sole trial of midline versus median episiotomy, presents evidence for choosing among options for repair methods, and extends prior reviews to encompass longer-term outcomes. Specifically, we have systematically assessed the evidence from trials and prospective cohorts related to the influence of episiotomy on measures of pelvic floor relaxation, continence, and sexual function and satisfaction. The goal of this synthesis is to inform care providers, professional organizations, advocates, and individual women about the current state of the evidence about the routine use of episiotomy.

Key Questions and Conceptual Framework

Key Questions

The original Scope of Work for this review was developed by the American College of Obstetricians and Gynecologists (ACOG) and forwarded by the Agency for Healthcare Research and Quality (AHRQ) to the RTI International–University of North Carolina Evidence-based Practice Center (RTI–UNC EPC). The work assignment proposed four provisional questions for review. Those questions were the basis for a brief review completed by the EPC Coordinating Center (The Lewin Group). Brief reviews help prioritize the topics AHRQ assigns to the 10 "generalist" EPCs.

The RTI–UNC EPC further revised the proposed questions after discussions with internal technical staff, AHRQ staff, and our Technical Expert Advisory Group (TEAG). The final key questions (KQ s) are listed below.

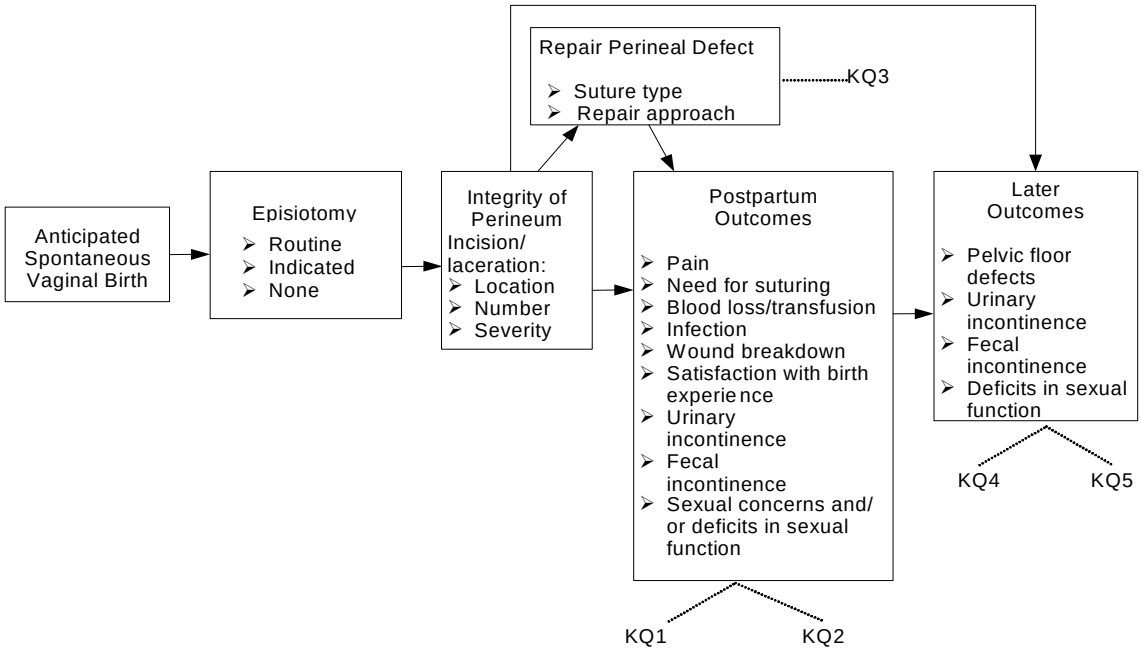
KQ 1. Does the practice of liberal or routine episiotomy compared to more selective use of episiotomy influence maternal postpartum outcomes?
KQ 2. Does episiotomy incision type (i.e., midline or mediolateral) influence maternal postpartum outcomes?
KQ 3. Does the repair of the perineal defect (i.e., suture type and repair approach) influence maternal postpartum outcomes?

KQ 4. Does episiotomy have a long-term influence on urinary incontinence, fecal incontinence, or pelvic-floor defects?
KQ 5. Does episiotomy or incision type, or both, influence future sexual function?

Conceptual Framework for Analysis of the Use of Episiotomy in Obstetric Care

The conceptual framework in Figure 1 (i.e., the causal pathway developed for this systematic review) summarizes the critical issues addressed here and their links to the key questions.

Figure 1. Conceptual framework for routine use of episiotomy in obstetric care



The key questions for this review present several conceptual challenges. Although the conceptual framework (Figure 1) treats episiotomy as the exposure of interest, trial participants cannot feasibly be allocated to receive an episiotomy with 100 percent certainty under any circumstance versus no episiotomy under any circumstance. Relevant controlled clinical trials most often compare a policy of liberal or routine use to a policy of indicated use only (often with varied or unspecified indications). These studies appropriately conduct analyses that compare maternal outcomes by study group as allocated. As a result, authors report on the status of the integrity of the vagina and perineum, including whether episiotomy was performed, as an outcome. In contrast, nonrandomized prospective studies (included for KQ 4 and 5) most often report outcomes, such as pain with intercourse, stratified by actual perineal status after the birth. To address potential differences arising from these variations in exposure categorization as study group versus episiotomy status, we have analyzed outcomes such as type of perineal trauma by strata, including episiotomy versus none, spontaneous versus assisted vaginal birth, and by other potential modifiers such as parity whenever such a summary is possible.

Another issue is how to define "routine episiotomy." Defining the term is a challenge because the category is described in studies by negatives such as "not for fetal distress" and "not for dystocia." We captured the operational definitions provided by authors of included publications and attempted to isolate data that reflect use of episiotomy at the time of uncomplicated spontaneous vaginal births. The text of this review and the evidence tables specify how authors define the terms "indicated" and "routine" so that our readers may use this information as a filter through which to view study findings.

A third concern is how to distinguish immediate versus long-term outcomes. To ensure a broad review of the available literature, we included all studies that report relevant outcomes without regard to the specific followup interval. We abstracted the intervals at which followup data are collected. Studies were later classified into those that report on postpartum versus those that include longer-term followup. If a study provides both types of information—immediate and long-term followup—study results appear in more than one portion of the review.

Production of This Evidence Report

Organization of This Evidence Report

Chapter 2 describes our methods, including our search strategies and inclusion/exclusion criteria; we also document our approach to grading the quality of articles and rating the strength of evidence. In Chapter 3, we present the results of our literature search and synthesis of retained articles by key question. Chapter 4 further discusses the findings, presents our conclusions, and offers recommendations for future research. Our references and included studies and a listing of excluded studies follow Chapter 4. Appendixes include a detailed description of our search strings (Appendix A), abstraction and quality-rating forms (Appendix B), detailed evidence tables (Appendix C), and acknowledgments (Appendix D). Appendixes and evidence tables cited in this report are provided electronically at http://www.ahrq.gov/clinic/tp/epistp.htm.

Technical Expert Advisory Group (TEAG)

We identified technical experts in the field of episiotomy to provide assistance throughout the project. The TEAG (see Appendix D) was expected to contribute to AHRQ's broader goals of (1) creating and maintaining science partnerships as well as public-private partnerships and (2) meeting the needs of an array of potential customers and users of its products. Thus, the TEAG was both an additional resource and a sounding board during the project. The TEAG included eight members: seven technical/clinical experts and one potential user of the final evidence report, an ACOG representative.

To ensure robust, scientifically relevant work, we called on the TEAG to provide reactions to work in progress and advice on substantive issues or possibly overlooked areas of research. TEAG members participated in conference calls and discussions through e-mail to

- refine the analytic framework and key questions at the beginning of the project;
- discuss the preliminary assessment of the literature, including inclusion/exclusion criteria; and
- provide input on the information and categories included in evidence tables.

Because of their extensive knowledge of the literature, including numerous articles authored by TEAG members themselves, and their active involvement in professional societies and as practitioners in the field, we also asked TEAG members to participate in the external peer review of the draft report.

Uses of This Report

This evidence report addresses the key questions outlined in Chapter 2 through systematic review of published literature. We anticipate that the report will be of value to ACOG and other professional societies for their various efforts to inform and educate obstetricians, family physicians, nurses, midwives, childbirth educators, doulas, and women in their reproductive years. This report can bring practitioners up to date about the current state of evidence, and it provides an assessment of the quality of studies that aim to determine the outcomes of the practice of episiotomy. Researchers can obtain a concise analysis of the current state of knowledge in this field and will be poised to pursue further investigations that are needed to improve health for obstetric populations.

Chapter 2. Methods

In this chapter, we document the procedures that the RTI International–University of North Carolina Evidence-based Practice Center (RTI–UNC EPC) used to develop this comprehensive evidence report on episiotomy. We first describe our strategy for identifying articles relevant to our key questions, our inclusion/exclusion criteria, and the process we used to abstract relevant information from the eligible articles and generate our evidence tables. We also discuss our criteria for grading the quality of individual articles and the strength of the evidence as a whole. Finally, we explain the peer-review process.

Literature Review Methods

Inclusion and Exclusion Criteria

Our inclusion and exclusion criteria, documented in Table 1, were relatively complex. The reason is largely that criteria for study design differed for each key question based on the sufficiency and quality of evidence. Key Questions 1 and 3 have been more commonly examined in randomized controlled trials (RCTs); thus, we elected to limit the searches to RCTs. Key Questions 2, 4, and 5 have been studied less extensively in trials; therefore, we searched for both RCTs and prospective cohort studies.

Table 1. Inclusion/exclusion criteria

Category	Criteria
Study population	Humans
Study settings and geography	Inpatient, outpatient, home; all geographical locations subject to publication language and study design criteria
Time period	1950 through 2004
Publication languages	English only
Sample size	N greater than or equal to 40
Admissible evidence (study design and other criteria)	Original research studies that provide sufficient detail regarding methods and results to enable use and adjustment of the data and results For studies on KQ 1 and KQ 3 RCTs: double-blinded and single-blinded designs For studies on KQ 2, KQ 4 and KQ 5 RCTs: double-blinded and single-blinded designs Non-RCTs: prospective cohort studies Relevant outcomes must be able to be abstracted from data presented in the papers

We excluded studies that (1) did not report on women of reproductive age; (2) were published in languages other than English; (3) did not report information pertinent to the key clinical questions; (4) had fewer than 40 subjects; and (5) were not original studies (although we did include systematic reviews and meta-analysis in our discussion).

Literature Search and Retrieval Process

Databases. We used multifaceted search strategies to include all the current valid research on the key questions. We used standard electronic databases: MEDLINE®, Cochrane Collaboration resources, and the Cumulative Index to Nursing and Allied Health Literature (CINAHL®). We also undertook hand-searches of the reference lists of relevant articles to make sure that we were not missing any relevant studies. We consulted with the Technical Expert Advisory Group (TEAG) about any studies or trials that are currently under way that may not be published yet.

Search Terms. Based on the inclusion/exclusion criteria above, we generated a list of Medical Subject Heading (MeSH) search terms (Tables 2 and 3, also Appendix A*). Our TEAG also reviewed these terms to ensure that we were not missing any critical areas, and this list represents our collective decisions as to the MeSH terms used for all searches. MEDLINE® searches for "Episiotomy" articles are fairly straightforward because the concept is well established and the MeSH indexing is standard. In addition to searching on the MeSH term "Episiotomy," we also searched for "Labor Stage, Second."

Table 2. Focused search terms and results from MEDLINE®

Search Terms	Results
"Episiotomy" [MeSH] Field: All Fields, Limits: English, Randomized Controlled Trial, Human	75
"Episiotomy" [MeSH], English, Review, Human	68
Labor Stage, Second [mh], English, Review, Human	40
Labor Stage, Second [mh], English, Randomized Controlled Trial, Human	58

Figure 2 presents the yield and results from our search. We conducted our initial search in late 2003 and updated it in November 2004. Beginning with a yield of 992 articles, we retained 45 articles that we determined were relevant to address our key questions and met our inclusion/exclusion criteria.

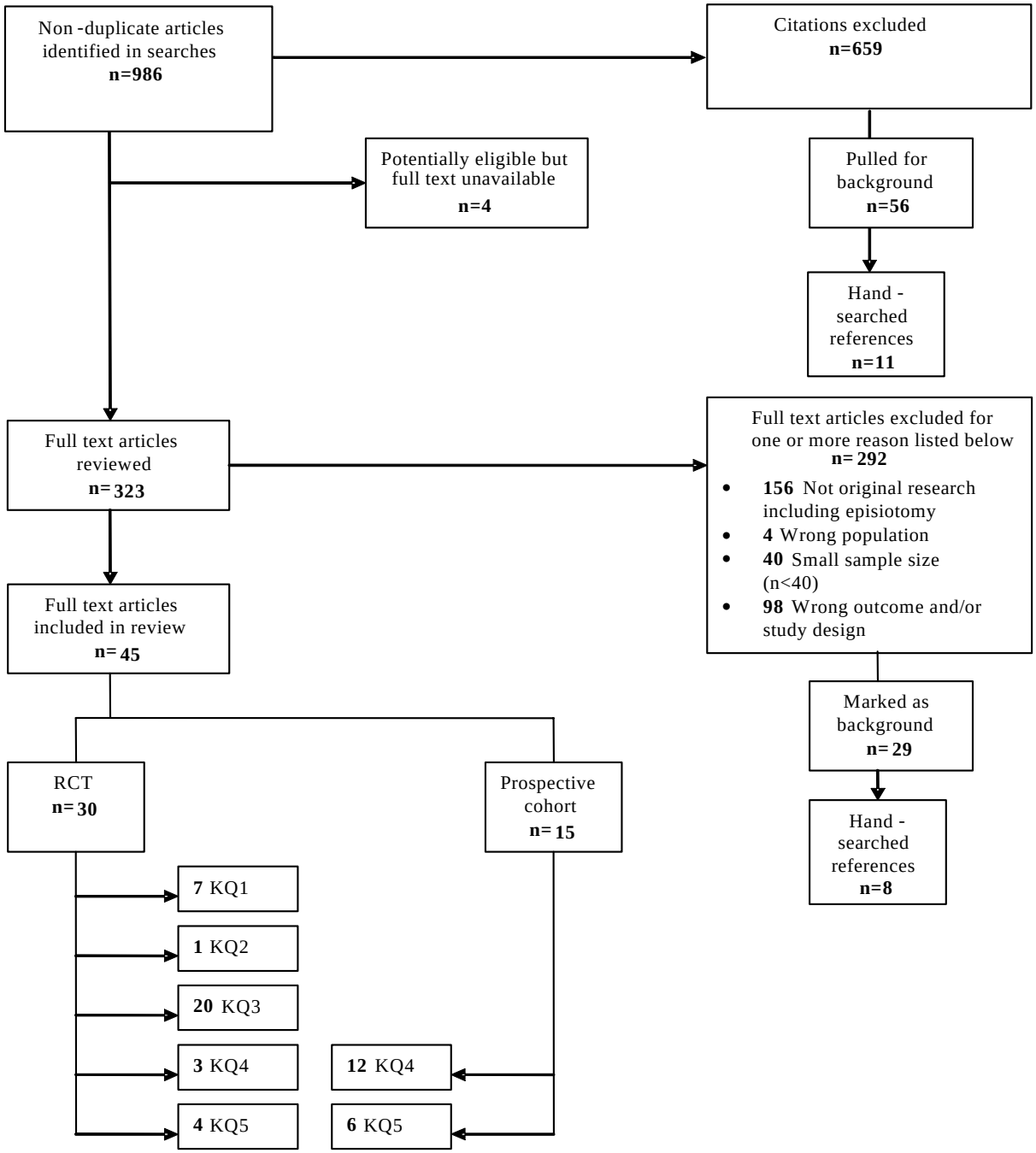
Article Selection Process. Once we had identified articles through the electronic database search, review articles, and bibliographies, we examined abstracts of articles to determine whether studies did, in fact, meet our criteria. Two reviewers separately evaluated the abstracts for inclusion or exclusion, using an Abstract Review Form (see Appendix B). If one abstractor concluded that the article should be included in the review, we retained it. Abstracts initially excluded from the study by one reviewer received a second review. The group included three physician health-services researchers—Katherine Hartmann, MD, PhD (Scientific Director); John Thorp, Jr., MD (Co-Investigator); and Gerald Gartlehner, MD, MPH (Study Coordinator); one health-services researcher—Meera Viswanathan, PhD (Study Director); and one junior epidemiologist—Rachel Palmieri, B.S.

* Appendixes are provided electronically at http://www.ahrq.gov/clinic/tp/epistp.htm

Table 3. Additional search terms and results from MEDLINE®

Search Number	Search Terms	Results
#1	"Episiotomy"[MeSH:NoExp] Field: All Fields, Limits: English, Human	676
#2	"Episiotomy" English, Editorial, Human	14
#3	"Episiotomy" English, Letter, Human	58
#4	"Episiotomy" English, Review, Human	68
#5	"Episiotomy" English, Meta-Analysis, Human	3
#6	"Episiotomy" English, Practice Guideline, Human	0
#7	#2 OR #3 OR #4 OR #5 OR #6	140
#8	#1 NOT #7	536
#9	Repair	138,222
#10	#1 AND #9	86
#11	labor stage, second [mh]	638
#12	#9 AND #11	6
#13	(("Episiotomy" OR “pregnancy”) AND (“midline" AND "mediolateral")) [MeSH:NoExp] Field: All Fields, Limits: English, Human	11
#14	(("Episiotomy" OR “pregnancy”) AND (“sphincter")) [MeSH:NoExp] Field: All Fields, Limits: English, Human	3

Figure 2. Episiotomy article disposition



Approximately 325 articles required review of the full article because of missing or uninformative abstracts. For the full article review, one reviewer read each article and decided whether it met our inclusion criteria, using a Full Text Inclusion/Exclusion Form (see Appendix B[*]). A list of articles excluded at the full-article review stage is provided at the end of this report, along with the reasons for their exclusion.

Literature Synthesis

Development of Evidence Tables and Data Abstraction Process

The five staff members who conducted this systematic review jointly developed the data abstraction tables (see Appendix B) and evidence tables (Appendix C). These tables were designed to provide sufficient information to enable readers to understand the studies and to determine their quality; we gave particular emphasis to essential information related to our key questions. The format of the evidence tables, which was based on successful designs used for prior systematic reviews, varies somewhat by key questions.

The abstractors trained themselves on entering data into the tables by abstracting several articles and then reconvening as a group to discuss the utility of the table design. The abstractors repeated this process through several iterations until they decided that the tables included the appropriate categories for gathering the information contained in the articles. The design was then reviewed by the TEAG through a teleconference.

All team members shared the task of initially entering information into the data abstraction forms. Another member of the team also reviewed the articles and edited all initial table entries for accuracy, completeness, and consistency. The two abstractors reconciled all disagreements concerning the information reported in the abstraction forms. The full research team met regularly during the article abstraction period and discussed global issues related to the data abstraction process.

We then entered the data from the abstraction forms into evidence tables and once again checked for consistency and accuracy.

The final evidence tables are presented in their entirety in Appendix C. Entries in the tables are listed by publication date. A list of abbreviations used in the tables appears at the beginning of that appendix.

Quality and Strength of Evidence Evaluation

Rating the Quality of Individual Articles. The RTI–UNC EPC's approach to assessing the quality of individual articles was developed based on the domains and elements recommended in the evidence report by West and colleagues, *Systems to Rate the Strength of Scientific Evidence*.[26] We developed different rating schemes for RCTs and prospective cohort studies.

For RCTs, we rated studies on the following criteria (see Appendix B for the RCT Quality Rating Form).

[*] Appendixes are provided electronically at http://www.ahrq.gov/clinic/tp/epistp.htm

1. *Randomization Approach and Implementation*: This item judged whether the approach described a valid method of randomization, whether allocation concealment was achieved, and whether balance was documented across study groups.

   Approach: Articles that assigned the groups in a manner inconsistent with true randomization methods automatically received a poor rating for this category and overall. Articles that merely stated that they "randomly assigned" the groups and had either no balance or did not report on balance received a poor rating. Articles with no documentation of concealment were rated poor. Those with potentially inadequate concealment methods were rated poor if the study had poor balance of allocation or if balance was not documented in the paper. Those with potentially poor concealment were rated fair if they documented good balance.

2. *Masking*: This item was relevant only to Key Question (KQ) 3. For KQ 1, masking of the birth attendant is not feasible and for KQ 2, masking the kind of episiotomy the women received was not possible.

   Approach: If the outcome assessors and participants were adequately masked within the possibilities of the study design, we rated the category as good. If there was a mix of masking among the outcomes, we rated the category as fair. If masking was not done at all and not attempted, we rated the category as poor. In the event that the article did not report on masking, we noted this point in the quality assessment table and counted it against the trial in the overall quality rating.

3. *Operational Definitions and Measurements:* This item judged the quality of the operational definitions of the outcomes (i.e., were they adequately described) and whether they were adequately collected (i.e., was the method sufficient and appropriate).

   Approach: If a primary outcome was identified, we gave it more weight in its contribution to this category's score. Otherwise, we rated this category on the basis of an average across all outcomes and the ability to define and measure them. Good definitions and measurement include the following: visual analog scale, detailed Likert scale, detailed time points in question, details about what was asked of the patient, medical chart abstractions, and clinical examination or assessment. If an article simply stated an outcome, such as "perineal pain," and gave no further explanations about it, we rated the category in the fair-to-poor range, depending on how the study collected the information.

4. *Post-Randomization Exclusions:* This item captured how many post-randomization exclusions were explicitly stated.

   Approach: In typical randomized trials, intention to treat analysis is expected. Some investigators represented in this literature enrolled women during prenatal care rather than on labor and delivery in an effort to get a representative sample of prenatal patients. We note exclusions as appropriate when individual gave birth at a hospital not

participating in the study, or when participants had outcomes that made them ineligible to participate in the trial such as preterm birth or cesarean birth. Any other exclusions after randomization were considered inappropriate.

5. *Loss to Followup*: This item collected percentages of followup at every time point in the study at which data were collected; we used it to determine if followup was adequate.

   Approach: An average of followup percentages for short-term and long-term followup contributed to this category. In general, we considered followup greater than or equal to 90 percent in the short term and 80 percent in the long term to be good.

6. *Statistical analysis*: This factor included whether the investigators conducted the study in an appropriate manner and took the effect of multiple comparisons into account. This item also reviewed the study's use of multivariate statistical techniques and/or participant restriction or stratification to control for confounding.

   Approach: This category is not included on the quality assessment form because of the nature of reporting in journals dating back to 1974. *P*-values were sufficient for reporting in the past, whereas point estimates, tests for homogeneity, stratification, and confidence intervals are more widely reported now. Although this category did not explicitly contribute to the overall quality rating, we used it for articles that were on the border between categories.

For RCTs, the two article abstractors independently rated each article on each of the first five categories as indicated by the quality assessment form (Appendix B[*]). A third reviewer flagged studies with differences in scoring on individual components. We reconciled these differences by consensus. We then created a composite rating. If a study had poor randomization approach or implementation with a fatal flaw (e.g., lottery cards), we rated it as poor. For all other scores, we gave each item equal weight. Specifically, studies that received good ratings on all categories were rated as good studies overall. If a study received one or two fair or poor ratings, or the equivalent of a deficiency, it was rated as an overall fair-quality study. Studies with three or more fair ratings or a poor randomization design or implementation with a fatal flaw were rated poor-quality studies.

For classifying the quality of prospective cohort studies included for KQs4 and 5, we assessed the following factors:

1. *Study population:* We sought documentation in the publication of the degree to which the study population was representative of women with uncomplicated spontaneous vaginal births in the study facilities or broader population sampled.

   Approach: To receive a rating of good for this component of study design and conduct, we required a study to describe clearly (1) the base population from which cohort participants were sought, (2) the number of women in that base population (a

[*] Appendixes are provided electronically at http://www.ahrq.gov/clinic/tp/epistp.htm

denominator), (3) clear inclusion and exclusion criteria, and (4) the proportion of eligible women who were ultimately enrolled in the cohort.

Studies lacking only items (2) and (4) were classified as fair, and studies lacking items (1) or (3) with any combination of other missing documentation were rated as poor with respect to documentation of the study population.

2. *Measures:* We sought documentation in the publication of four components of quality of measurements. The first was specification of whether the measure was a primary or secondary measure for the study as noted in any portion of the paper. The second was a clear description of the measures used that is sufficient to allow replication of the measure (e.g., visual analog scale, McGill Pain Score). We accepted references to methods described more fully in other publications as documentation if the reference in fact provided details. The third component was a clear description of how the measure was obtained and by whom if, applicable (e.g., telephone interview, face-to-face interview, mailed questionnaire). The fourth was a clear specification of the time interval in which the data were collected with respect to the index birth.

   Approach: We classified studies that achieved all four document requirements for the measurement of relevance to the key question as having good implementation of the measures component. We classified studies as fair for this component if item (1) was unclear or not noted and if this was the only limitation. If any other item was missing, we considered the quality of documentation of measures to be poor. Of note, a given study could be classified as good for one key question (e.g., the key question about sexual function), while getting a fair rating for another measure that related to a different key question.

3. *Loss to followup:* If data from more than one time interval were reported, we sought documentation of the these followup measures: (1) the number of participants in the sample at the time of followup, (2) analysis of how respondents differed from nonrespondents if loss exceeded 20 percent, and (3) absolute loss to followup by time interval.

   Approach: We rated a study as good quality if the research team accomplished each of the above measures and had ≤ 20 percent loss to followup at 3 months and beyond. A study was rated fair if the investigators accomplished items (1) and (2), had no apparent response bias as investigated by comparison of baseline characteristics, and had up to 30 percent loss to followup; or if they had between 20 percent and 25 percent loss to followup without documentation of comparability. We rated a study as poor for this component if it had more than 30 percent loss to followup or more than 25 percent loss without comparison for response bias.

4. *Analysis:* We sought four tiers of documentation: (1) thorough enumeration of the number of cohort participants, the characteristics of their birth experience and perineal status, and general descriptive characteristics such as parity and number of prior vaginal

births in cohorts that included multiparous women; (2) assessment of confounding and modifying factors by bivariate analysis, stratified analysis, or multivariable modeling; (3) reporting of adjusted estimates for main effects that took into account identified confounding or modifying factors (stratified or separate analyses were acceptable for simple constructs); and (4) presentation of adjusted results with a measure of statistical precision such as a confidence interval or *P*-value.

Approach: We rated a study as having a good analysis implementation if all of these elements were present. Missing or limited detail for item (1) resulted in a fair rating if this was the only deficit; similarly, we rated a study fair if it was missing or providing only limited detail for item (2) if subsequent multivariable modeling implied that the step had been completed and all other items were present. Missing items (3) or (4) or any other two or more items in combination resulted in a poor rating.

Grading the Strength of Available Evidence. Our scheme follows the criteria applied by Berkman et al.[27] That system included three domains: quality of the research, quantity of studies (including number of studies and adequacy of the sample size), and consistency of findings. The four senior staff members assigned grades by consensus.

We graded the body of literature applicable to each of the four components of the two key questions separately and present our findings in Chapter 4. The possible grades in our scheme are as follows:

I. The evidence is from studies of strong design; results are both clinically important and consistent with minor exceptions at most; results are free from serious doubts about generalizability, bias, or flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.
II. The evidence is from studies of strong design, but some uncertainty remains because of inconsistencies or concern about generalizability, bias, research design flaws, or adequate sample size. Alternatively, the evidence is consistent but derives from studies of weaker design.
III. The evidence is from a limited number of studies of weaker design. Studies with strong design either have not been done or are inconclusive.
IV. No published literature.

External Peer Review

As is customary for all evidence reports and systematic reviews done for the Agency for Healthcare Research and Quality (AHRQ), the RTI–UNC EPC requested review of this report from a wide array of outside experts in the field and from relevant professional societies and public organizations. AHRQ also requested review from its own staff and appropriate federal agencies. We received 18 responses; the 17 individuals listed in Appendix D* gave us permission to acknowledge them. We compiled all comments and addressed each one individually, revising the text as appropriate.

* Appendixes are provided electronically at http://www.ahrq.gov/clinic/tp/epistp.htm

Chapter 3. Results

This chapter presents results of our literature search and findings for each key question (KQ) introduced in Chapter 1. KQ 1 examines postpartum maternal outcomes related to liberal or restrictive use of episiotomy. KQ 2 compares postpartum outcomes of midline and mediolateral episiotomy. KQ 3 examines outcomes of methods for repair of perineal defects. KQ 4 summarizes longer-term outcomes of episiotomy related to fecal and urinary incontinence and pelvic floor integrity and function, and KQ 5 examines longer-term sexual function.

We report results in five main sections of this chapter corresponding to the core issues that this systematic review addressed. In each section, we report first on specific details about the yields of the literature searches, population, outcomes, and quality of the studies, and then on the findings for each key question. Summary tables present selected information on each study. Detailed evidence tables are in Appendix C*.

Overall, our literature search yielded 992 articles (Figure 2). Of these, we excluded 662 articles after reviewing the abstracts and obtained 326 articles for complete review (4 were unavailable for full article review). Of the 326 articles retained for full article review, we included 45 articles in this evidence report, some of which address multiple key questions. Of the 45 articles, seven address KQ 1, one addresses KQ 2, 20 address KQ 3, 15 address KQ 4, and 10 address KQ 5.

Key Question 1: Episiotomy and Maternal Postpartum Outcomes

Literature Search and Included Studies

Overview of the Evidence. We identified seven primary publications of randomized controlled trials (RCTs) of liberal versus restrictive use of episiotomy.[22,23,28-32] Evidence Table 1 in Appendix C provides details on each study. Three of these studies were conducted in the United Kingdom;[22,23,28] one at a British military hospital in Saudi Arabia;[31] one in Germany;[32] one in Argentina;[30] and one in Canada.[29] The first trial was performed in the United Kingdom and published in 1984;[23] the most recent, in Germany in 2004.[32] The studies are not evenly distributed over time: three trials were conducted in the early to mid-1980s in the United Kingdom, three in the first half of the 1990s, and a decade passed before the publication by Danneker and colleagues in Germany in 2004. We also identified two secondary reports from randomized clinical trials.[33,34] One publication reports on 3-year followup of a trial cohort;[33] the other is a re-analysis of 3-month followup data grouped by degree of perineal trauma after the birth, rather than by allocated trial group.[34] Discussion of these publications is included in the results for Key Questions 4 and 5 because they focus on continence and sexual function outcomes.

Each trial that we identified compared two study arms or groups: (1) one in which the intention was to restrict routine use of episiotomy and (2) one group in which a liberal-use policy

* Appendixes are provided electronically at http://www.ahrq.gov/clinic/tp/epistp.htm

endorsed routine use. Defining the distinctions between such groups in a manner that can be uniformly achieved is the central challenge for these trials.

The strictest definition of "restrictive" was to avoid episiotomy unless indicated for fetal well-being.[23,32] Other definitions pivoted on instructions to "avoid episiotomy," use only when "medically necessary," or not perform episiotomy for the sole purpose of avoiding a laceration.[22,28,29,31] The largest trial defined restrictive use as only for fetal indications and/or to avoid severe lacerations.[30]

Liberal-use arms were defined in terms such as "routinely conducted," "routine," "usual care," and "elective."[22,28-31] Two studies describeed the liberal-use policy as encouraging routine use of episiotomy when "a tear is imminent"[32] and "to prevent a tear."[23]

Regardless of how the randomization groups were defined for study implementation, neither definition may align with the usual practice of individual clinicians, especially with respect to how they would describe the goal they are trying to achieve when performing an episiotomy. Variation in norms and usual practice patterns are demonstrable in the variation of episiotomy use observed in these trials. Use of episiotomy in the restrictive groups ranged from lows of 7.6 percent[22] and 10.2 percent[23] to highs of 44 percent[29] and 53 percent.[31] We observed up to a seven-fold difference in the use of episiotomy within the restrictive groups across these trials. The routine-use/liberal-use arms had episiotomy use rates from a low of 44.9 percent[22] to a high of 83 percent.[30,31] Wide variation in patterns of use across trials introduces substantial heterogeneity in the "exposures" under study. A large degree of built-in "cross-over" occurred in the setting of higher rates of use in the restrictive groups. In synthesizing these data, we emphasize that these trials compare policies of episiotomy use, not episiotomy versus no episiotomy.

An additional factor that influences generalizability of findings for practice in the United States is that six of the seven studies used mediolateral episiotomy. The only North American study, conducted in Canada, was also the only study in which median (midline) episiotomy was used. Because midline episiotomy is the most common technique used in the United States,[9,35] this means that the majority of the literature reflects outcomes that would be expected with a distinctively different episiotomy approach with respect to anatomic location of the defect and potential complications. Key Question 2, focused on incision type, identified only one poor-quality RCT directly comparing median and mediolateral episiotomy.[36] We review this study in detail in the next section; briefly, the study suggests increased risk of rectal injury and complicated or extended incision with midline episiotomy. This finding is comparable to those of observational studies that report that midline incisions are more likely to result in extensions that injure the anal sphincter and/or rectal mucosa.[37,38]

Study Populations. Six studies restricted participation to term births;[22,23,28-31] the seventh, to births at longer than 34 weeks' gestation.[32] Five studies specified that they enrolled only singleton gestations. The two studies that did not specify singleton gestations were conducted in the 1980s before routine use of ultrasound; in that period, providers were unlikely to miss a multiple gestation clinically, excluding twin gestations before enrollment in a trial might have been difficult to do with complete confidence.[22,23] Two studies required vertex presentations.[28,31] Regardless of stated inclusion criteria, multiple gestations and breech presentations do not seem to be represented in these trials. To this extent the studies do represent episiotomy use in uncomplicated vaginal deliveries.

Three studies enrolled only women having their first births.[22,31,32] This approach eliminates any influence of prior perineal trauma and healing on the trial outcomes. The combined study

populations of these three studies was 409 participants; this is smaller than the entire cohort of each of the other studies. Four studies enrolled multiparous women. In these studies, the proportion of women who were primiparous ranged from 40 percent to 68 percent, generally with good balance across study groups.[23,28-30] The exception occurred in the publication by House and colleagues in which it appears that multiparous women were more likely to have been randomized to the restricted-use group.[28] Within the studies that achieved balanced allocation by parity, analyses that stratify outcomes by parity help inform how outcomes may differ based on prior childbirth experiences. No trial data were identified that allow consideration of whether outcomes vary by race and ethnicity.

Each study focused on normal spontaneous vaginal births. To reduce the number of women who subsequently had operative vaginal deliveries or cesarean births, the majority of studies allocated women to study groups as close to the anticipated time of birth as feasible. The proportion of assisted vaginal births (both forceps and vacuum) in these trials was 2 percent,[30] 3 percent,[29] 4 percent to 5 percent,[31] 11 percent to 14 percent,[28] or not specifically reported. The absence of reporting on instrumental and cesarean births raises the potential of unreported post-randomization exclusions. In two cases, authors noted the number of cesarean births and that those cases are described as part of the trial population and excluded from analyses.[29,32] Both of these studies enrolled women during prenatal care, an approach that improved representativeness of the study population and explains the increased numbers of women with cesarean births who were logically excluded later.

Outcomes. The most common primary outcome was perineal status after the birth. All seven studies reported incidence of episiotomy and of third- or fourth-degree lacerations or extensions. Five studies reported prevalence of intact perineum;[22,23,29,31,32] one reported prevalence of intact perineum combined with first-degree lacerations.[28] One trial did not report data about intact perineum or minor lacerations, but the proportion can be inferred because first-degree or intact should be the converse of the data they do report about "any perineal suturing" required.[30]

A single study incorporated masked assessment of perineal trauma; Sleep and colleagues arranged to have a clinician who did not assist the delivery and was masked to the study group asesss perineal status and perform the repair.[23] Although this design approach does not mask the obvious appearance of an episiotomy compared to a spontaneous tear or intact perineum, it prevents any bias in uniformly recording the extent and location of any perineal trauma. The other studies are at risk of this type of bias.

The most common secondary outcome was pain in the days immediately after the birth. Five of the seven trials assessed pain. Two groups used visual analog scores and classified responses into categories of mild, moderate, or severe.[28,32] One study used an unspecified "standardized questionnaire" and also reported pain severity as mild, moderate, or severe. [23] Another used the McGill Pain Questionnaire and reported the composite score of the 10-item scale.[29] The largest study, conducted in Argentina, did not define how they collected data about "perineal pain."[30] Additional measures include use of pain medications and reports of pain with specific physical activities.

Three publications did not report masking of the assessors to study group.[22,31,32] The remainder of the studies reported that the individual conducting the pain assessment was unaware of allocation of the participants. Two studies clearly noted that women were not aware of the group to which they were allocated.[23,28]

Additional outcomes assessed include resumption of sexual activity, estimated blood loss, and wound-healing appearance and complications, including infection, healing by secondary intention, and persistent granulation tissue. Few of these outcomes were measured uniformly in more than one study.

Results

Perineal Trauma Outcomes. Table 4 summarizes key elements of study design and the perineal outcomes observed in each of the RCTs. The table provides a summary and does not include all outcomes such as anterior tears. Based on quality of the conduct of the trials, the strongest of these studies (rated good quality) was the first RCT conducted; like the majority of these trials, it evaluated the use of mediolateral episiotomy. This first study, conducted in the early 1980s, enrolled 1,000 women, featured an appropriate randomization approach that achieved good balance, and had masked assessment of outcomes with clear definitions.[23] The investigators did not make any post-randomization exclusions and specifically reported conducting an intention-to-treat analysis. The study methods achieved a wide gradient of episiotomy use between the liberal and restrictive groups — a 41 percentage point difference: 51.4 percent in the liberal-use group and 10.2 percent in the restrictive-use group. Women in the restrictive group were more likely to have an intact perineum; 24.3 percent of those in the liberal group had intact perinea compared to 33.9 percent in the restrictive group. Third- and fourth-degree lacerations were rare (0.2 percent in the trial cohort) and did not differ by group. The effects of liberal versus restricted use with respect to any need for suturing were less marked among multiparous women who had similar outcomes: 69 percent of multiparous women in the liberal group and 66 percent in the restrictive group required any suturing for repair. Among nulliparous women, the difference in need for suturing was more pronounced (89 percent in the liberal-use group and 74 percent in the restrictive group). Sleep and colleagues concluded that restricting use of episiotomy neither increased nor decreased maternal morbidity.[23]

The largest trial conducted was a multisite study in Argentina that enrolled 2,606 women and was of fair quality (see evidence tables in Appendix C for details).[30] This study found a 2.4-fold increase in risk of anterior tears among women in the restrictive-use arm (95% confidence interval [CI], 1.9-2.9), and decreased risk of posterior perineal surgical repair (relative risk [RR] = 0.72; 95% CI, 0.68-0.75) when comparing restrictive to liberal use. Eighty-eight percent of women in the liberal group had a surgical repair, as did 63 percent in the restrictive group. Pain, healing complications, and dehiscence were all less frequent in the restrictive-use group. The authors concluded that episiotomy confers no apparent benefit and that high rates of use cannot be justified.

These two studies, which are also the two largest trials, yield results compatible with the findings of the other trials with respect to perineal outcomes (see Table 4 for summary). Intact perineum was uniformly more common in the restrictive groups.[28,29,31,32] With two exceptions,[29,32] studies reported more third- and fourth-degree lacerations among women in the liberal-use group. However, each of these studies was underpowered to distinguish differences in risk across the groups because third- and fourth-degree lacerations were rare. In fact, one study of 200 women had no severe lacerations among participants in either arm.[31] Anterior lacerations, including anterior labial lacerations, were reported to be more common in three

Table 4. Results of randomized controlled trials of liberal versus restrictive use of episiotomy: Perineal trauma

Citation Country Episiotomy Type Number	Inclusion Parity	Groups Episiotomy Use	Outcome(s)	Outcome among Liberal-Use Group	Outcome among Restrictive-Use Group	Authors' Conclusions
Sleep et al., 1984[23] United Kingdom Mediolateral N = 1,000	Term, singleton pregnancy Anticipated NSVD 40%-46% primiparous	G1: Liberal = "try to prevent a tear" G2: Restrictive = "try to avoid episiotomy and restrict to fetal indications" G1: 51.4% G2: 10.2%	Intact Third or fourth degree Any suturing	24.3% n = 1 Primip: 89% Multip: 69%	33.9% n = 4 Primip: 74% Multip: 66%	Restricting use of episiotomy neither increased nor decreased problems experienced by mothers.
Harrison et al., 1984[22] Ireland Mediolateral N = 181	Term, primigravid, anticipated vaginal birth	G1: Mediolateral episiotomy routinely conducted G2: No episiotomy unless "medically necessary" G1: 44.9% G2: 7.6%	Intact Third or fourth degree	Not reported 6%	21% None	Primigravid patients allocated to not undergo episiotomy generally fared better than they would have done with normal hospital practices. Forty-six percent had no or only first-degree tears.
House et al., 1986[28] United Kingdom Mediolateral N = 165	Term, vertex, anticipated NSVD 53%-68% primiparous	G1: Standard current management G2: Episiotomy not performed to prevent laceration G1: 69% G2: 18%	Intact or first degree Second degree = Episiotomy or second degree Third degree	Primip: 4% Multip: 26% Primip: 96% Multip: 70% Primip: 4% Multip: 4%	Primip: 32% Multip: 54% Primip: 68% Multip: 45% Primip: None Multip: None	Restrictive policy resulted in a significant increase in the incidence of patients with intact perineum or only a first-degree tear.

Table 4. Results of randomized controlled trials of liberal versus restrictive use of episiotomy: Perineal trauma (continued)

Citation Country Episiotomy Type Number	Inclusion Parity	Groups Episiotomy Use	Outcome(s)	Outcome among Liberal-Use Group	Outcome among Restrictive-Use Group	Authors' Conclusions
Klein et al., 1992[29] Canada Midline N = 730	Term, singleton; anticipated NSVD 50%-52% primiparous	G1: Liberal = avoid tear G2: Restrictive = attempt to avoid episiotomy G1: Primip: 81% Multip: 52% G2: Primip: 47% Multip: 31%	Intact (no suturing) Episiotomy alone Third or fourth degree	Primip: 6.6% Multip: 19.3% Primip: 67.2% Multip: 45.2% Primip: 7.9% Multip: 0%	Primip: 7.5% Multip: 30.7% Primip: 42.2% Multip: 29.0% Primip: 13.9% Multip: 0%	No evidence that liberal use prevents perineal trauma; restriction of episiotomy use among multiparous women results in significantly more intact perineums and less suturing.
Argentine Episiotomy Trial Collaborative Group, 1993[30] Argentina Mediolateral N = 2,606	Term, singleton first or second vaginal birth; no prior cesarean or severe perineal trauma 40%-41% primiparous	G1: Routine G2: Selective G1: 82.6% G2: 30.1%	Perineal suturing Third or fourth degree	88.1% Primip: 1.8% Multip: 0.9%	63.1% Primip: 1.4% Multip: 0.8%	No evidence that routine use of episiotomy reduces risk of severe perineal trauma.

Table 4. Results of randomized controlled trials of liberal versus restrictive use of episiotomy: Perineal trauma (continued)

Citation Country Episiotomy Type Number	Inclusion Parity	Groups Episiotomy Use	Outcome(s)	Outcome among Liberal-Use Group	Outcome among Restrictive-Use Group	Authors' Conclusions
Eltorkey and Nuaim, 1994[31] Saudi Arabia (British staff) Mediolateral N = 200	Term, singleton, vertex, primiparous; anticipated NSVD	G1: Elective G2: Selective = essential G1: 83%* G2: 53%*	Intact Second degree or episiotomy without extension Third degree or episiotomy with extension	7% 71%* None	28% 49%* None	Selective group more likely to have an intact perineum. No indication that episiotomy offers clear benefit in terms of decreased numbers of lacerations.
Dannecker et al., 2004[32] Germany Mediolateral N = 109	>34 weeks, singleton, primiparous; anticipated NSVD	G1: Liberal = if tear imminent and/or fetal indications G2: Restrictive = fetal indications only G1: 77% G2: 41%	Intact Third degree	10% 8%	29% 4%	Restrictive use resulted in three-fold increase in the rates of intact perinea. No difference with regard to third-degree tears.

G, group; primip, primiparous; multip, multiparous; NSVD, normal spontaneous vaginal delivery.

*Text and tables in this publication are not concordant; overall incidence from text; second degree and episiotomy totals from table.

Table 5. Results of randomized controlled trials of liberal versus restrictive use of episiotomy: Pain outcomes

Citation Country Episiotomy Type Number	Inclusion Parity	Groups Episiotomy Use	Outcome(s): How Measured? When?	Outcome among Liberal-Use Group	Outcome among Restrictive-Use Group	Authors' Conclusions
Sleep, 1984[23] United Kingdom Mediolateral N =1000	Term, singleton pregnancy, anticipated NSVD* 40%-46% primiparous	G1: Liberal = "try to prevent a tear" G2: Restrictive = "try to avoid episiotomy and restrict to fetal indications" G1: 51.4% G2: 10.2%	Pain severity in prior 24 hours; questionnaire administered by midwife; 10 days postpartum Worst pain in past week; postal questionnaire; 3 months postpartum	10 days Mild: 14.6% Mod: 7.8% Severe: 0.2% 3 months Mild: 5.7% Mod: 1.8% Severe: 0.2%	10 days Mild: 14.1% Mod: 7.5% Severe: 0.9% 3 months Mild: 4.6% Mod: 2.5% Severe: 0.5%	No significant differences between the two groups in maternal pain at 10 days and 3 months postpartum.
House et al., 1986[28] United Kingdom Mediolateral N = 165	Term, vertex, anticipated NSVD* 53%-68% primiparous.	G1: Standard current management G2: Episiotomy not performed to prevent laceration G1: 69% G2: 18%	Pain severity; interview by one of authors using VAS scale 1 to 10 with 1-3 grouped as minimal; 4-6 moderate; 7-10 severe; 3 days; 6 weeks; 3 months	3 days Mild: 55% Mod: 34% Severe: 11% No differences at 6 weeks and 3 months	3 days Mild: 68% Mod: 22% Severe: 10% No women in either group with more than minimal pain at 3 months	Pain symptoms on the third day postpartum were on average reduced in the patients in whom the use of episiotomy was restricted and equivalent thereafter.

Table 5. Results of randomized controlled trials of liberal versus restrictive use of episiotomy: Pain outcomes (continued)

Citation Country Episiotomy Type Number	Inclusion Parity	Groups Episiotomy Use	Outcome(s) How Measured? When?	Outcome among Liberal-Use Group	Outcome among Restrictive-Use Group	Authors' Conclusions
Klein et al., 1992[29] Canada Midline N = 730	Term, singleton; anticipated NSVD 50%-52% primiparous	G1: Liberal = avoid tear G2: Restrictive = attempt to avoid episiotomy G1: Primip: 81% Multip: 52% G2: Primip: 47% Multip: 31%	Perineal pain measured by 10 individually scored items using the McGill Pain Questionnaire at 1, 2, and 10 days postpartum	First day Primip: 1.8±0.8 Multip:1.3±0.8 Second day Primip: 1.3±0.7 Multip:0.9±0.7 Tenth day Primip:0.5±0.5 Multip: 0.3±0.4	First day Primip: 1.7±0.8 Multip:1.3±0.9 Second day Primip: 1.4±0.8 Multip: 0.9±0.8 Tenth day Primip: 0.5±0.5 Multip: 0.3±0.5	No significant differences in perineal pain and pain with urination at 1, 2, and 10 days postpartum for individual pain scale items or composite score
Argentine Episiotomy Trial Collaborative Group, 1993[30] Argentina Mediolateral N = 2,606	Term, singleton first or second vaginal birth; no prior cesarean or severe perineal trauma 40%-41% primiparous	G1: Routine = do according to hospital's policy before trial G2: Selective = try to avoid, do only for fetal indications or if severe tear is imminent G1: 82.6% G2: 30.1%	Perineal pain (not clearly defined), assessment method not clearly delineated, physician masked to allocation evaluated on day of discharge	42.5%	30.7%	Perineal pain was less common in the restrictive use group.

G, group; primip, primiparous; mod, moderate; multip, multiparous; NSVD, normal spontaneous vaginal delivery.

Table 5. Results of randomized controlled trials of liberal versus restrictive use of episiotomy: Pain outcomes (continued)

Citation Country Episiotomy Type Number	Inclusion Parity	Groups Episiotomy Use	Outcome(s) How Measured? When?	Outcome among Liberal-Use Group	Outcome among Restrictive-Use Group	Authors' Conclusions
Dannecker et al., 2004[32] Germany Mediolateral N = 109	>34 weeks, singleton, primiparous; anticipated NSVD	G1: Liberal = if tear imminent and/or fetal indications G2: Restrictive = fetal indications only G1: 77% G2: 41%	Perineal pain in postpartum period (days 1 to 5) on 100 mm visual analog scale anchored at "not at all" and "very much" for a range of activities; approach to measurement not clearly specified	Bedrest: 39±28 Sitting: 69±23 Walking: 56±24 Defecation: 36±30	Bedrest: 22±21 Sitting: 51±25 Walking: 37±24 Defecation: 21±21	Women in the restrictive group had considerably lower perineal pain scores in all activities assessed during the first 5 days postpartum.

studies[23,30,32] and equivalent in one study.[32] Anterior lacerations did not contribute to overall higher use of suturing, suggesting that these tears were less severe than posterior tears.

The findings of these studies are fully compatible. None of the authors concluded that episiotomy provides any benefits with respect to perineal trauma. The majority concluded that intact or minimal perineal trauma is more common when episiotomy use is restricted. This synthesis of the data is compatible with the findings of prior systematic evidence reviews that are updated with this report. Although the authors of these research publications appear loath to ascribe harm to the use of episiotomy, in our judgment, concluding from their data that routine use is harmful is accurate, at least to the extent that it creates a surgical incision of greater extent than a woman might have experienced had the episiotomy not been performed.

Pain Outcomes. Five studies assessed pain outcomes (Table 5).[23,28-30,32] The two largest trials collected pain outcome data.[23,30] Sleep and colleagues used midwives masked to study group to assess pain at 10 days postpartum. Participants were asked to assess pain severity in the prior 24 hours. Pain severity groupings were virtually identical by study group. Among those in the liberal-use group, 14.6 percent had mild pain; 7.8 percent, moderate; and 0.2 percent, severe; the comparable proportions for the restricted-use group were 14.1 percent, 7.5 percent, and 0.9 percent, respectively. Use of oral analgesics by postpartum day 10 was rare in both groups — 2 percent and 3 percent, respectively — and not different by group. The Argentine study did not adequately define how they measured pain; pain is reported as "pain on the day of discharge"; the liberal-use group is reported as 42.5 percent with pain, and the restricted-use group as 30.7 percent with pain.

The most recent study, although small, provided the most nuanced approach to pain assessment. The investigators used a visual analog scale to assess pain with four activities: bedrest, sitting, walking, and defecation. Scores were reported in millimeters of the 100 mm-pain scale for each activity. Those in the liberal-use group had the following mean scores (± standard deviation): 39 ± 28 mm with bedrest; 69 ± 23 mm with sitting; 56 ± 24 mm with walking; and 36 ± 30 mm with defecation. The comparable scores in the restrictive group were 22 ± 21 mm; 51 ± 25 mm; 37 ± 24 mm; and 21 ± 21 mm. These differences indicate that the restrictive-use group experienced significantly lower perineal pain during all activities, at levels that are likely clinically significant. These findings could indicate a real difference in pain outcomes or some bias in assessment. The publication does not report masking of the assessors or how the assessments were conducted.

House and colleagues report that pain was more severe on postpartum day 3 among those in the liberal-use group. They also assessed pain outcomes by visual analog scale during an interview conducted by an author; masking of the assessors is not specifically noted. On day 3 in the liberal-use group, 55 percent of women had mild pain; 34 percent, moderate pain; and 11 percent, severe; the comparable categories for those in the restrictive-use group were 68 percent, 22 percent, and 10 percent. They also report tenderness at the time of examination on postpartum day 3. The restricted-use group had less tenderness on examination: 79 percent had mild or minimal pain; 18 percent, moderate; 3 percent, severe; compared to 51 percent, 39 percent, and 10 percent in the liberal-use group. These differences were statistically significant and likely to be clinically relevant.[28] These differences in pain by group had resolved by 6 weeks and 3 months, respectively.

Klein and colleagues, who conducted the only North American trial and the only trial using midline episiotomy, found no difference in McGill pain scores on days 1, 2, and 10 after the birth

for either perineal pain or pain with urination.[29] They reported that they conducted analyses both with individual pain-scale items and composite scores. Across each of the five studies, no study found a pain measure that was improved by routine liberal use of episiotomy.

Healing Outcomes. Two studies assessed healing outcomes by physical examination. The Argentine trial reported no difference in rates of the following adverse outcomes that were adequately defined: hematoma prior to discharge; and infection, healing complications, and dehiscence as assessed on day 7 postpartum. At discharge, they assessed 92 percent and 93 percent of participants in the restricted-use and liberal-use groups, respectively; this dropped to 43 percent of both groups by the evaluation on day 7 postpartum.[30] House and colleagues examined participants on day 3 postpartum and at 6 weeks. Risk of infection was assessed for all participants on day 3; poor wound apposition and granulation tissue indicating secondary healing were assessed at the later visit at which 53 percent of the trial participants were assessed. Each adverse outcome was equivalent across groups.[28]

Other Outcomes. Two trials, both reflecting use of mediolateral episiotomy, reported on timing of resumption of intercourse. One study documented that women in the restricted episiotomy-use group resumed intercourse an average of a week earlier (5.5 ± 3.0 weeks compared to 6.5 ± 3.0 weeks).[28] The other study found that 37 percent of the women in the restrictive group had resumed intercourse by 1 month postpartum compared to 27 percent in the liberal-use group ($P < 0.01$).[23] Longer-term influences on sexual function — those assessed at 3 months or later — are reviewed in the section on KQ 5.

Two studies, also of mediolateral episiotomy use, assessed estimated maternal blood loss. One found no difference in the amount that maternal hemoglobin measures fell.[32] The other found that estimated blood loss (method not defined) was 58 cc greater in the liberal-use group, a statistically significant but likely not clinically relevant mean difference.[23]

Key Question 2: Episiotomy Incision Type and Maternal Morbidity

Literature Search and Included Studies

We found only one RCT comparing outcomes of midline episiotomy to those of mediolateral episiotomy.[36] Evidence Table 2 in Appendix C provides details. An additional focused literature search did not reveal any prospective cohort studies pertaining to this key question.

Study Participants. The study included primigravidas who were admitted to the delivery unit of a university hospital in London. The mean age at delivery was 26 years; the mean gestational age was 40 weeks.

Episiotomy Type. Midline episiotomy — "incisions divided 2 to 3 cm of the perineal tissue in the midline." Mediolateral incisions "were made from the midline and were carried to the right of the anal sphincter for about 3 to 4 cm."[36] Method of repair was identical for both study groups. Standard repair technique for both types of incisions included subcuticular skin closure with polygycolic acid suture.

Outcomes. Outcome measures included the proportion of extended or complicated incisions, recommencement of sexual intercourse, pain, pain during intercourse, satisfaction from intercourse, and the cosmetic appearance of the scar. Investigators did not report methods of

outcomes assessment or the use of objective scales for pain and sexual satisfaction. An exam was conducted and pain was queried before hospital discharge and again at a 3-month followup visit that included the sexual function data collection. The study did not assess differences in fecal incontinence.

Quality. This study had serious methodological flaws; we gave it a poor rating for internal validity. In particular, we viewed an inadequate randomization method, lack of allocation concealment, and failure to blind the outcome assessors as potential sources of severe biases and as a rationale for a poor-quality rating. Consequently, the evidence is insufficient to draw any firm conclusions on differences in adverse outcomes of midline compared to mediolateral episiotomy.

Results

The trial included 407 primigravidas who were randomly assigned to midline or mediolateral episiotomy. Results revealed a significantly higher rate of complicated or extended incisions for the midline group than for the mediolateral group ($P < 0.001$). A total of 23.9 percent of women in the midline group experienced an extension of the episiotomy into or through the sphincter, compared to 9 percent of women in the mediolateral group. The midline group had significantly less bruising of the perineum than the mediolateral group ($P < 0.001$). The investigators did not note any differences in pain in the postpartum timeframe. Of all enrolled women, 76 percent attended a 3-month followup. Women in the midline group began sexual intercourse significantly earlier ($P < 0.01$) and had a significantly better cosmetic appearance of the scar ($P < 0.02$) than women in the mediolateral group. No significant differences in pain or satisfaction from sexual intercourse were detected.

On the question of midline versus mediolateral episiotomy, the only study in our review that met our inclusion criteria found that women receiving midline episiotomy had a significantly greater probability of anal sphincter injuries than women in the mediolateral episiotomy group.[36] This study did not assess fecal incontinence as a long-term health outcome. Because of considerable methodologic flaws, any conclusions must be made cautiously.

Differences in sphincter injury rates are clinically important. As an RCT, this study's internal validity is poor. Nevertheless, considering that this is the only trial pertaining to this key question, the findings regarding sphincter injuries could be viewed as relevant observational evidence. Multiple retrospective cohort studies that did not meet eligibility criteria for this key question support findings regarding high sphincter injury rates and midline episiotomy.[39-45] These studies provide consistent evidence that midline episiotomy leads to significantly higher rates of third- and fourth-degree tears than mediolateral episiotomy. In another study, women with midline episiotomy had a significantly higher rate of fecal incontinence than did women with spontaneous second-degree tears.[46]

Key Question 3:
Repair of Perineal Defect and Maternal Morbidity

Literature Search and Included Studies

Overview. We included 17 randomized controlled trials (RCTs) examining various methods and materials for repairing perineal defects.[47,48,48-66] As shown in the three main sections of Table 6, four trials investigated techniques of repair;[48,58,60,63,66] 14 trials investigated materials for repair;[50 47,48,51-54,56-59,61-65]and two trials combined comparison of both techniques and materials in their design.[49,55] Details on all 17 studies are provided in Evidence Tables 3-10 in Appendix C.

Of the four trials investigating techniques of repair, two compared a two-layer approach (leaving the perineal skin unsutured) with a three-layer approach (suturing the perineal skin) and two trials compared a continuous (subcutaneous) technique with an interrupted (transcutaneous) technique.

Of the 14 trials investigating repair materials, eight compared polyglycolic-acid sutures with chromic-catgut sutures, both absorbable. Two trials compared absorbable sutures (one polyglycolic acid and one chromic catgut) with an enbucrilate tissue adhesive (Histoacryl®). Two trials compared standard absorbable suture material with its rapidly absorbed counterpart, and one trial compared untreated chromic-catgut with a glycerol-treated "softgut" chromic catgut. In addition, two trials compared nonabsorbable and absorbable sutures: one compared silk sutures with polyglycolic-acid sutures and one compared silk sutures with both polyglycolic-acid and chromic-catgut sutures.

Most of these trials randomly allocated participants to one of two groups. Three trials, however, incorporated a factorial design of randomization. Using a 2x2 design, both the Ipswich Childbirth Study[60,61,63] and the Kettle et al. trial[67] randomized to methods of repair and type of sutures. The Mahomed et al. perineal suture study used a 2x3x2 design and randomized to suture type for deep tissue repair (two groups), suture type for the perineal skin (three groups), and method of repair (two groups).[58] These studies contributed to more than one section of the results below.

Country. Approximately 65 percent of the RCTs in this report were conducted in the United Kingdom, including Ireland and Scotland. Australia, Denmark, Israel, Malaysia, Nigeria, and the United States each contributed one trial to this report.

Table 6. Description of trials of episiotomy repair relating to methods, materials, or both

Trial	Trial Groups	Setting	Trial Size	Percentage Primiparous	Percentage Instrumental Delivery	Overall Quality Rating
Type of Repair						
Oboro et al., 2003[66]	2 layer vs. 3 layer	Nigeria	N =1,077	53%	23%	Fair
Ipswich Childbirth Study, Gordon et al., 1998,[60] Grant et al., 2001[63]	2 layer vs. 3 layer	United Kingdom	N =1,780*	61%	17%	Good
Kettle, 2002[67]	Continuous vs. interrupted	United Kingdom	N =1,542	56%	0%	Good
Mahomed et al., 1989[58]	Continuous vs. interrupted	United Kingdom	N =1,574†	51%	23%	Good
Materials for Repair						
Bowen and Selinger, 2002[64]	Absorbable vs. adhesive	United Kingdom	N = 62	100%	NR	Poor
Adoni and Anteby, 1991[47]	Absorbable vs. adhesive	Israel	N = 60	NR	NR	Poor
Kettle, 2002[67]	Absorbable vs. rapidly absorbable	United Kingdom	N = 1,542	56%	0%	Good
McElhinney et al., 2000[62]	Absorbable vs. rapidly absorbable	Ireland	N = 153	55%	NR	Poor
Spencer et al., 1986,[56] Grant et al., 1989[57]	Untreated vs. treated CC	United Kingdom	N = 737	47%	0%	Fair
Buchan and Nicholls, 1980[54]	Nonabsorbable vs. absorbable	United Kingdom	N = 140	100%	0%	Fair
Mahomed et al., 1989[58]	a. Absorbable vs. absorbable vs. nonabsorbable b. PGA vs. CC	United Kingdom	N = 1,574	52%	23%	Good
Upton et al., 2002[65]	PGA vs. CC	Australia	N = 391	47%	0%	Fair

Table 6. Description of trials of episiotomy repair relating to methods, materials, or both (continued)

Trial	Trial Groups	Setting	Trial Size	Percentage Primiparous	Percentage Instrumental Delivery	Overall Quality Rating
Ipswich Childbirth Study, Mackrodt et al., 1998,[61] Grant et al., 2001[63]	PGA vs. CC	United Kingdom	N = 1,780*	61%	17%	Good
Olah, 1990[59]	PGA vs. CC	United Kingdom	N = 120	46%	100%	Fair
Ping and Kee, 1975[53]	PGA vs. CC	Malaysia	N = 122	61%	38%	Fair
Rogers, 1974[52]	PGA vs. CC	United States	N = 600	NR	NR	Poor
Livingstone et al., 1974[51]	PGA vs. CC	Scotland	N = 100	100%	62%	Poor
Beard et al., 1974[50]	PGA vs. CC	United Kingdom	N = 200	51%	NR	Fair
Repair Techniques and Materials						
Doyle et al., 1993[49]	Absorbable sutures (plain catgut, PGA) and combination of methods	United Kingdom	N = 199	72%	NR	Poor
Isager-Sally et al., 1986[55]	Combination of absorbable and nonabsorbable sutures and combination of methods	Denmark	N = 900‡	61%	NR	Fair

Note: CC, chromic catgut; NR, not reported; PGA, polyglycolic acid.

*The Ipswich Childbirth Study[61,63] reported a 1-year followup of results[63] that included a subset (n= 793) of the original trial's population. Percentages shown reflect baseline population.

†The trial used a 2x3x2 factorial design to investigate both methods and materials for repair. The methods for the repair arm of the trial investigated continuous and interrupted methods for absorbable sutures, a subset (N= 1,057) of the entire population (N = 1,574). Percentages of primiparous and instrumental deliveries were calculated with a denominator of 1,057.

‡900 women were randomized but 98 were excluded because they transferred to another hospital or left the hospital before the fifth day after delivery. Three groups did not differ in age, parity, or frequency of previous episiotomy.

Episiotomy Type. These trials included women who had an episiotomy at the time of vaginal childbirth, regardless of the number of previous pregnancies or births. The vast majority of episiotomies repaired in these studies were mediolateral. This reflects the fact that most of the studies were conducted in European countries, the majority contributed by the United Kingdom. Practitioners in North America generally perform midline episiotomy, whereas mediolateral is the rule elsewhere.

Because this question addresses outcomes of repair, we reviewed trials that included women who had forcep- or vacuum-assisted births with an episiotomy. The rationale for inclusion is that the technique of repair and materials can be evaluated with respect to postpartum perineal healing and maternal morbidity, regardless of the mechanisms that led to the perineal trauma. Of these 17 trials, seven explicitly excluded women who had instrumental deliveries; four did not report whether instrumental deliveries were included; one trial included instrumental deliveries but did not report the proportion of women who had them; and five trials reported proportions of participants who had instrumental deliveries (see Table 6). The proportion of participants who had instrumental deliveries ranged from17 percent to 64 percent.

Outcomes. Perineal pain and need for analgesia were assessed during the short-term postpartum period in a majority of the trials and during the long-term postpartum period for some of the trials. Investigators used self-report through interviews administered by midwives or study staff and questionnaires to measure subjective levels of pain and use of analgesia. Trials also reported on specific aspects of healing and wound breakdown including inflammation, bruising, infection, wound gaping, need for removal of sutures, and need for resuturing. In each case, a clinician involved in the trial assessed these outcomes, often without masking to study allocation. Longer-term outcomes related to sexual function, such as dyspareunia, recommencement of sexual intercourse, and timing of resumption of intercourse, were typically measured at 3 months postpartum and up to 3 years by interview or questionnaire. Incontinence and other pelvic-floor-related outcomes were investigated by one trial.[55] Few trials collected data on comfort with daily activities or satisfaction with repair.

Quality. Of the 17 trials, we rated three as good quality, eight as fair quality, and six as poor quality; for the last group, four trials were rated poor because of inadequate randomization techniques and were most likely not truly randomized. We rated trials as fair or poor quality on the basis of inadequate randomization approach and implementation, failure to mask the outcome assessors, and high loss to followup. Specific limitations of the trials are discussed elsewhere in this report.

Results for Methods of Repair

Two-layer vs. Three-layer Repair. One trial of good quality[60,63] and one trial of fair quality[66] compared a two-layer suturing approach with a three-layer suturing approach (Evidence Table 3, Appendix C). Both trials described the standard technique as three-layered, suturing the perineal skin closed after repair of the vagina and deeper tissues with interrupted transcutaneous or continuous subcuticular sutures. The two-layer approach leaves the perineal skin unsutured, a technique that is hypothesized to decrease perineal morbidity.

Pain and analgesia use. Consistent evidence from these two trials suggests that the two-layer suturing technique decreases perineal pain in both the short- and long-term postpartum

periods and requires less analgesia use. When the evidence is limited to the trial of good quality, however, these differences were not statistically significant.

Although both trials reported less perineal pain in the two-layer groups, only one trial[66] found significant differences in the short-term postpartum period (0 to 3 months) and the long-term postpartum period (≥ 3 months). At 48 hours postpartum, fewer participants in the two-layer approach reported perineal pain than those in the three-layer approach (RR = 0.87; 95% CI, 0.78-0.97). Over time, the differences persisted: two-layer was superior at 14 days (RR = 0.77; 95% CI, 0.61-0.98), at 6 weeks (RR = 0.64; 95% CI, 0.44-0.93), and at 3 months postpartum (RR = 0.19; 95% CI, 0.06-0.54). The Ipswich Childbirth Study[60,63] did not note differences between the two groups in self-report of any, mild, moderate, or severe perineal pain at 24 to 48 hours, 10 days, 3 months, or 1 year. At each followup period, however, fewer women in the two-layer group reported perineal pain.

Similar findings extended to analgesia use in the two groups but only in the short-term postpartum period. Participants in the two-layer group of the Oboro et al. trial reported significantly less use of analgesics at 48 hours (RR = 0.71; 95% CI, 0.60-0.83) and at 14 days (RR = 0.54; 95% CI, 0.32-0.90) but not at 6 weeks (RR = 0.56; 95% CI, 0.16-0.1.89) or at 3 months postpartum (RR = 0.16; 95% CI, 0.02-1.34). The Ipswich trial found no differences in analgesia use at followup.[60,63]

Healing and wound breakdown. Despite inconsistent definition and measurement of healing outcomes, the evidence suggesting that the two-layer approach decreases healing complications and that wound gaping associated with leaving the perineal skin unsutured resolves shortly after repair.

Significantly fewer participants in the two-layer group needed sutures removed for pain or infection in both trials at any time. Healing outcomes were assessed at 14 days, 6 weeks, and 3 months in one trial[66] and were generally significant ; these outcomes were also significant at 1 year in the other trial (RR = 0.61, 95% CI, 0.45-0.83, $P = 0.002$).[60,63]

Oboro et al. found that fewer women in the two-layer group reported "tight stitches" than in the three-layer group.[66] Neither trial found a difference in the need for resuturing.

In the Ipswich trials, more women in the two-layer group than the three-layer group had wound gaping, defined in one of the trials as having edges greater than 0.5 cm apart, in the 24- to 48-hour postpartum period.[60] Observing such a separation may be an artifact of the technique used to examine the incision, because only incisions without suture approximation of the skin can appear to "gape" when tension is applied to the posterior perineum to allow visual inspection. Only one trial looked at outcomes at 1 year postpartum; the authors reported that fewer women in the two-layer group reported that the area that had been cut or torn felt different (RR = 0.75; 95% CI, 0.61-0.91; $P < 0.01$).[63]

Incontinence and pelvic floor function. Neither trial investigated outcomes related to incontinence and pelvic floor function in terms of the difference in suturing methods.

Sexual function. These two trials did not investigate the same sexual functioning outcomes. The trend in healing outcomes suggests that the two-layer approach to suturing is associated with less morbidity.

Women in the two-layer repair group were significantly less likely in the Oboro et al. trial to have superficial dyspareunia than women in the three-layer repair group at both 6 weeks and 3 months (RR = 0.60; 95% CI, 0.42-0.85 and RR = 0.52; 95% CI, 0.33-0.81, respectively).[66] These results did not extend to deep dyspareunia, which was comparable between the two

groups. At 6 weeks, more women in the two-layer group had resumed pain-free intercourse (26 percent vs. 10 percent, RR = 2.54; 95% CI, 1.82-3.55);[66] in the Ipswich trial,[60,63] this difference was noted but not statistically significant.

Continuous vs. Interrupted Sutures. Two trials, both of good quality, investigated perineal outcomes in women whose repairs were made with a continuous, subcutaneous suturing method compared to an interrupted, transcutaneous method[48,58] (Evidence Table 4, Appendix C).

Pain and analgesia use. The evidence is inconsistent as to whether the continuous subcutaneous method of suturing decreases perineal pain and need for oral analgesia following repair. In the Mahomed et al. trial,[58] the groups did not differ across the categories of any, mild, moderate, or severe perineal pain at day 2, day 10, and 3 months postpartum. By contrast, the trial by Kettle and colleagues documented significant differences.[48] In this latter trial, at the same time points, women in the continuous-suture group reported less pain than women in the interrupted-suture group. On day 2, 69 percent of the continuous group and 79 percent of the interrupted group reported pain ($P < 0.0001$). The difference in pain outcomes continued at day 10 (26.5 percent vs. 44 percent; $P < 0.0001$), 3 months (9 percent vs. 13 percent; $P = 0.03$) and 1 year (4 percent vs. 7 percent; $P = 0.05$). At day 10, significant differences were also seen in perineal pain reported during walking, sitting, urination, and defecation; the difference in favor of less pain among those with subcutaneous repair ranged from 7 percent to 16 percent.

The former study also did not find significant differences between the two groups in their need for oral analgesia at day 2 (52% vs. 48%) or day 10 (7% vs. 9%). By contrast, the latter trial found that women in the continuous group needed less analgesia at 10 days postpartum (8.5% vs. 13.5%; $P = 0.002$).

Healing and wound breakdown. Evidence was inconsistent with respect to healing and wound breakdown. The Mahomed et al. trial found no significant differences in edema, bruising, or inflammation between the groups on day 2. The trial by Kettle and colleagues reported less morbidity in the continuous suture group on day 2 for uncomfortable stitches (OR = 0.78; 95% CI, 0.64-0.96) and tight stitches (OR = 0.40; 95% CI, 0.22-0.74), but they did not find a difference in wound gaping. They reported significant differences on day 10 for wound gaping (OR = 0.46; 95% CI, 0.29-0.74), uncomfortable stitches (OR = 0.58; 95% CI, 0.46-0.74), and tight stitches (OR = 0.43; 95% CI, 0.27-0.69). The need to remove sutures was significantly lower in the continuous method group on day 10 (OR = 0.17; 95% CI, 0.10-0.28). The Mahomed trial measured this variable only at 3 months; they reported a significant difference in favor of continuous subcutaneous closure (26% vs. 37%; $P < 0.001$).

Incontinence and pelvic floor function. Neither trial investigated the difference in suturing methods regarding outcomes related to incontinence and pelvic floor function.

Sexual function. Neither trial found significant differences between the groups regarding dyspareunia at 3 months postpartum. The trial that measured dyspareunia at 1 year also found equivalent outcomes across the groups.

Other outcomes. Kettle et al. collected information from the women about their overall satisfaction with the repair.[48] Significantly more women in the continuous method group reported being satisfied with the repair at both 3 months and 12 months postpartum (OR = 1.64; 95% CI, 1.28-2.11 and OR = 1.68; 95% CI, 1.27-2.21, respectively).

Results for Materials for Repair

Absorbable Suture vs. Tissue Adhesive. Two trials examined use of tissue adhesive in the repair of episiotomy as compared to polyglycolic-acid[64]or chromic-catgut sutures[47] (Evidence Table 5, Appendix C) Both trials were poor quality because randomization methods were either broken[64] or inadequate (odd and even registration numbers).[47] As such, conclusions about perineal morbidity related to the use of tissue adhesive are speculative at best.

Perineal pain and analgesia use. Both trials report less pain during several activities and at rest in women whose episiotomies were repaired with tissue adhesive. Bowen and colleagues[64] used a 10-point visual analog scale (VAS) and Adoni and colleagues[47] used a Likert pain scale of 1 (minimum) to 5 (maximum). Because of the differences in the pain scales, the results are not directly comparable, but the overall differences do contribute to the consistent evidence in these two trials that adhesive may lead to less perineal pain in the immediate postpartum. Both trials reported less pain while walking (1.6 vs. 2.6, $P < 0.001$[47] and 2.7 vs. 4.0, $P = 0.0015$)[64] on day 2. One trial[47] reported significantly less pain on day 3 (2.0 vs. 2.9, $P = 0.029$). Both trials reported less pain during micturition: in the Adoni and Anteby trial[47] on days 1 and 3 (4.5 vs. 6.3, $P = 0.025$ and 3.0 vs. 4.0, $P = 0.025$, respectively) and, in the Bowen and Selinger trial,[64] on day 2 (1.0 vs. 1.7, $P < 0.031$). Bowen and Selinger[64] reported less pain in the adhesive group on day 2 (1.95 vs. 3.3, $P < 0.001$), both while sitting (1.75 vs. 3.6, $P < 0.0001$) and while lying down (1.0 vs. 2.35, $P < 0.001$). Adoni and colleagues reported less pain in the adhesive group during defecation on days 3 and 4 (2.2 vs. 4.3, $P = 0.003$ and 2.1 vs. 3.7, $P = 0.015$, respectively). Nonsignificant differences were reported on other days. Neither trial compared need for analgesia between the two repair groups.

Healing and wound breakdown. Neither trial investigated differences in these outcomes by type of repair materials. One trial[64] did report that they identified no cases of wound infection or dehiscence.

Sexual function. Only one trial reported on sexual functioning postpartum.[64] The group repaired with adhesive, in this case Enbucrilate® tissue adhesive, had a 35 percent reduction in the onset of pain-free sexual intercourse ($P = 0.0009$). Neither trial reported any other outcomes related to sexual functioning.

Absorbable Sutures: Standard vs. Rapidly Absorbed. Two studies compared standard absorbable to rapidly absorbed sutures (Evidence Table 6, Appendix C). McElhinney and colleagues, in a poor-quality trial,[62] compared standard absorbable sutures with rapidly absorbable suture material (Vicryl® polyglycolic acid). Kettle and colleagues, in a trial of good quality,[48] also addressed the continuous versus interrupted methods of suturing in its 2x2 factorial design while comparing standard polyglactin 910 with its rapidly absorbed counterpart.

Perineal pain and analgesia use. The poor-quality trial, although it used good measurements of pain (VAS and Likert scale), found no significant differences in perineal pain between the two groups at 24 hours and 3 days. Analgesic use before discharge also did not differ by group. The good-quality Kettle trial reported mixed results for perineal pain during specific activities and the need for analgesia at 10 days postpartum. Women in the rapidly absorbed suture groups reported less pain while walking, sitting, passing urine, and defecating. Only the differences in pain with walking were statistically significant (OR = 0.74; 95% CI, 0.56-0.97; $P = 0.004$). Women in the rapidly absorbed group also reported less need for analgesia (8% versus 14%, $P = 0.0002$). This trial randomized women to suture method (continuous versus interrupted), so the investigator

was able to complete stratified analyses; they showed nonsignificant results by both method of suturing and degree of trauma. In other words, improvement in pain was independent of method of closure or size of defect.

Healing and wound breakdown. The poor-quality trial combined all healing outcomes, such as infection, gaping wound, or residual material requiring removal, into one group and found that at 6 weeks, 30 percent of women whose episiotomies were repaired with standard material and 1.7 percent of women whose episiotomies were repaired with the rapidly absorbed material reported problems. The good-quality trial examined different healing outcomes separately and did not find significant differences between the two groups with respect to wound gaping, uncomfortable sutures, or tight stitches at 2 or 10 days postpartum. However, groups had meaningful differences in need for removal of sutures between 10 days and 3 months. Women whose episiotomies were repaired with the rapidly absorbed material required removal less often than women who received the standard suture at 10 days, between 10 days and 3 months, and at any point before 3 months postpartum (OR = 0.38, 95% CI, 0.23-0.64; OR = 0.19, 95% CI, 0.13-0.30; and OR = 0.26, 95% CI, 0.18-0.37, respectively).

Sexual function. Both trials measured dyspareunia, although at different time points in the short- and long-term periods of followup. The good-quality trial found no statistically significant differences at 3 months or 12 months postpartum. The poor-quality trial found that women with repairs using rapidly absorbed material had significantly lower dyspareunia scores than women who received standard sutures. This finding extended to 3 months (mean scores 0.05 versus 0.27 in women who had dyspareunia, $P < 0.05$) but the authors noted that the scores were very low in both groups.

Untreated Catgut vs. Treated Catgut. Only one fair-quality trial[56] investigated the use of treated, glycerol-impregnated "softgut" compared to chromic catgut. A followup to the original trial occurred at 3 years[57] (Evidence Table 7, Appendix C).

Perineal pain and analgesia use. Women in the softgut group reported significantly greater perineal pain ($P = 0.015$) at 10 days postpartum. Women in the softgut group were also significantly more likely to have used a perineal salt bath to relieve pain (42% versus 34%, $P = 0.03$) and to use more doses of oral analgesia ($P = 0.18$), though this difference was not statistically significant. At 3 months postpartum, self-report of perineal pain did not differ by type of catgut used.

Healing and wound breakdown. Sutures were removed more often in the chromic-catgut group both by 10 days (2.4% versus 11.5%, $P < 0.001$) and 3 months (6.9% versus 16.4%, $P < 0.0001$). Removals were described as being for maternal discomfort. Based on assessment by a midwife at 10 days, risk of perineal breakdown and healing by secondary intention did not differ by group.

Sexual function. Sexual function was assessed at 3 months postpartum and 3 years. More women in the chromic-catgut group reported pain-free sexual intercourse than women in the softgut group (50.7% versus 38.0%, $P < 0.025$). This difference was significant for both transient and persistent pain. At 3 years, more women in the softgut group still reported painful intercourse (OR = 1.17; 95% CI, 1.1-2.6; $P < 0.02$); a majority with pain described the pain as "soreness."

Nonabsorbable vs. Absorbable. One good-quality trial, the Southmead suture study by Mahomed and colleagues,[58] and one fair trial by Buchan and Nicholls[54]compare absorbable sutures for repair of the perineal skin with nonabsorbable, silk sutures (Evidence Table 8,

Appendix C). The good-quality trial randomized using a 2x3x2 factorial design and randomized women to one of three material groups for suturing of the perineal skin; polyglycolic-acid, chromic-catgut, or silk sutures. Balance was obtained between use of polyglycolic acid and chromic catgut for repair of the deeper tissue and between continuous and interrupted methods of suturing. The fair-quality trial randomized women to either silk sutures or polyglycolic-acid sutures for repair of the perineal skin and chromic catgut was used in both groups for repair of the deeper tissues. In this study, method of repair of the perineal skin has potential to confound outcomes because the silk-suture group was repaired using an interrupted method and the polyglycolic-acid suture group was repaired using a subcuticular method. The trial is included under this heading because the authors frame the primary goal of the trial as a comparison of silk suture and polyglycolic-acid suture.

Perineal pain and analgesia use. The Mahomed et al. study reported no statistically significant differences among the material groups with respect to perineal pain or use of analgesia at 2 and 10 days postpartum or at 3 months. The Buchan and Nicholls trial did report differences between the groups, but the results were inconsistent by the day 6 postpartum. The investigators used the mean number of analgesic tablets used by the women to make inferences about the level of perineal pain experienced by the women. Women with repairs made with silk sutures used more analgesia than women whose episiotomies were repaired with polyglycolic-acid suture, but the results were only significant for days 3 through 5 ($P < 0.001$).

Healing and wound breakdown. The Mahomed et al. study reported no significant differences among the groups with regard to bruising, edema, or healing, outcomes that were clinically assessed at 2 days postpartum. In the long-term postpartum period, the silk suture group needed the absorbable suture materials removed from perineal tissue significantly less than the polyglycolic-acid or chromic-catgut groups (7 percent versus 39 percent versus 23 percent, $P < 0.001$).[58] No other results were reported and the fair-quality trial did not contribute to this outcome assessment.

Sexual function. In the good-quality trial, more women in the silk-suture group had not resumed intercourse by 3 months postpartum (15 percent versus 9 percent and 11 percent, $P < 0.05$). Among women who had resumed intercourse, dyspareunia risk was comparable. Conflicting evidence was reported by the fair-quality trial: at 4 months postpartum, more women in the silk-suture group reported no pain at all during intercourse (21 percent versus 11 percent, $P < 0.001$).

Polyglycolic Acid vs. Chromic Catgut. Eight RCTs compared polyglycolic-acid sutures with chromic-catgut sutures, both absorbable materials (Evidence Table 9, Appendix C). Information on these trials, ordered from the most recent to the oldest, appears in Table 7. Check marks indicate whether one type of sutures had better outcomes than the other; "ND" indicates no difference.

Both the Mahomed et al.[58] and the Mackrodt et al.[61,63] trials were of good quality; they contributed to other sections of this key question because of their factorial design. Four trials were of fair quality.[50,53,59,65] Finally, two trials were of poor quality;[51,52] both used methods of randomization that are not considered to be truly randomized; thus, we considered them to have a fatal flaw.

Table 7. Trial results for polyglycolic-acid and chromic-catgut sutures

Trial Information	Description of Pain Outcome	Superior Material for Pain			Description of Healing Outcome	Superior Material for Healing			Author's Overall Conclusions
		PGA	CC	ND		PGA	CC	ND	
Upton et al., 2002[65]* Australia N = 391 Quality: Fair	Short-term perineal pain (any, moderate to severe)			✔	Short-term problems with sutures			✔	No statistically significant differences between groups but leaned in favor of polyglycolic acid
Ipswich Childbirth Study, Mackrodt et al., 1998 and Grant et al., 2001[61,63]* United Kingdom N = 1,780 Quality: Good	Short-term perineal pain (any, mild, moderate)	✔			Short-term healing problems (tight stitches, uncomfortable stitches, gaping perineum)	✔			Clear advantages of polyglycolic acid
	Long-term perineal pain (mild, moderate, or severe)			✔	Long-term need for resuturing			✔	
Olah, 1990[59] United Kingdom N=120 Quality: Fair	Short-term perineal pain (10 cm VAS)			✔	Short-term edema and bruising			✔	Does not substantiate previous trials that show a benefit to polyglycolic acid
Mahomed et al., 1989[58]* United Kingdom N = 1,574 Quality: Good	Short- and long-term perineal pain (none, mild, mod, severe)			✔	Short- and long-term edema, bruising and healing			✔	Not much evidence to support polyglycolic acid but the little they have is consistent with other trials
	Short-term use of analgesics	✔			Long-term need for removal of sutures			✔	
	Long-term use of analgesics			✔	Long-term need for resuturing			✔	

Table 7. Trial results for polyglycolic-acid and chromic-catgut sutures (continued)

Trial Information	Description of Pain Outcome	Superior Material for Pain			Description of Healing Outcome	Superior Material for Healing			Author's Overall Conclusions
		PGA	CC	ND		PGA	CC	ND	
Ping and Kee, 1975[53] Malaysia N = 122 Quality: Fair	Short-term perineal pain (No pain, mild, moderate, severe)	✔			Not measured	---	---	---	Polyglycolic-acid sutures have considerable advantage over chromic-catgut sutures in episiotomy repair
Beard et al., 1974[50] United Kingdom N = 200 Quality: Fair	Short-term perineal pain (none, mild, moderate, severe)	✔			Short-term wound breakdown and inflammation			✔	Polyglycolic-acid sutures should be used
Livingstone et al., 1974[51] Scotland N = 100 Quality: Poor	Short-term perineal pain (none, uncomfortable, painful, very painful, unbearably painful)	✔			Short-term edema	✔			Significant reduction in pain and edema with polyglycolic acid, no evident disadvantage in the use of polyglycolic acid
Rogers, 1974[52] United States N = 600 Quality: Poor	Short-term perineal pain (none, degree of pain)	✔			Not measured	---	---	---	Polyglycolic acid decreased the pain by half

Note: PGA, polyglycolic acid; CC, chromic catgut; ND, no difference.

*Three trials also investigated long-term sexual function outcomes with regards to polyglycolic-acid and chromic-catgut sutures. Two trials[58,65] found no differences between the sutures and one trial[61,63] found polyglycolic-acid sutures to be superior at 1 year postpartum regarding resumption of pain-free intercourse and dyspareunia.

Perineal pain and analgesia use. All eight trials investigated differences in perineal pain outcomes between the two groups. All but two provided consistent evidence that polyglycolic-acid sutures have an advantage over chromic catgut with regards to perineal pain. Two of the fair-quality trials[59,65] found no significant differences between the groups; in one trial, the estimate of effect favored polyglycolic-acid suture for their pain measures on postpartum day 3 (OR = 0.70; 95% CI, 0.46-1.08). The same group of women who were in the polyglycolic-acid suture group, however, were more likely to have perineal pain at 6 months (OR = 1.77; 95% CI, 0.57-5.47), although the precision of that estimate is much less than that others in the study.

Two fair[50,53] and two poor trials[51,52] also reported less perineal pain and less need for analgesics in women who received polyglycolic-acid sutures in the short-term postpartum period. All four trials used Likert scales (mild, moderate, severe, or the equivalent) to measure pain; one trial[50] counted the proportion of women requiring analgesia (tablets or injections). Although these trials offer only fair- or poor-quality evidence, they do contribute consistent evidence that polyglycolic-acid sutures may be associated with less short-term perineal pain.

The best evidence comes from the two good-quality trials.[58,61,63] In the short-term postpartum period, both trials reported pain outcomes at 24 to 48 hours and 10 days. At 24 to 48 hours, more women in the chromic-catgut group in the Mahomed et al. trial required analgesia (54 percent versus 48 percent, $P < 0.05$;[58] 47 percent versus 42 percent, $P = 0.03$[61,63]). This requirement for analgesia continued at 10 days postpartum in both trials and remained statistically significant in the Ipswich trial (10 percent versus 6 percent, $P = 0.01$). In the Ipswich trial,[61,63] women in the chromic-catgut group reported more perineal pain and greater severity of pain at 24 to 48 hours (P for trend = 0.002) and at 10 days postpartum (P for trend = 0.05). The earlier trial had not identified significant differences for perineal pain at these two time points.[58] Neither trial found significant differences between the groups regarding perineal pain at 3 months. In addition, the Ipswich trial found no differences at 1 year.

Healing and wound breakdown. Six of the eight trials examined healing and wound-breakdown outcomes between the two suture groups. Three fair trials[50,59,65] and the Mahomed et al. study[58] did not report statistically significant differences between the groups with respect to removal of sutures, resuturing, wound breakdown, inflammation, edema, bruising, or infection, most of which were measured before 3 months. One of the poor trials[51] reported significantly more edema ($P < 0.05$ at the perineotomy site on day 3 postpartum) in the chromic-catgut group. The Ipswich trial results favored polyglycolic-acid suture at various followup time points and on various measures. At 24 to 48 hours and 10 days postpartum, more women in the chromic-catgut group reported uncomfortable stitches (40 percent versus 33 percent, $P = 0.003$, and 26 percent versus 19 percent, $P = 0.001$, respectively). The midwives reported more "wound gaping" in the chromic-catgut women at 10 days postpartum (26 percent versus 16 percent, $P < 0.00001$) but not at 24 to 48 hours. By 10 days, neither group was more likely to have sutures removed, but fewer women in the chromic-catgut group reported ever having any sutures removed by 3 months (7 percent versus 12 percent, $P = 0.002$). This finding is the only outcome representing a disadvantage among those who received polyglycolic-acid sutures in this trial.

Sexual function. Three trials, two of good quality[58,61,63] and one of fair quality,[65] investigated the effect of suture type on outcomes of sexual function. The fair-quality trial found no significant differences between the groups at 6 weeks, 3 months, or 6 months postpartum. The adjusted odds ratios (adjusted for parity) indicated a possible association between polyglycolic-acid sutures and less resumption of intercourse and more dyspareunia among

women who had resumed intercourse. In one good-quality trial, women whose repairs were made with polyglactin 910, a polyglycolic acid-based suture, were less likely to suffer from dyspareunia at 1 year (RR = 0.59; 95% CI, 0.39-0.91; $P = 0.002$) and less likely to fail to resume pain-free intercourse (RR = 0.57; 95% CI, 0.38-0.87; $P < 0.01$).[61,63] In both of the good-quality trials, all other comparisons yielded nonsignificant differences between the two suture groups at 3 months and 1 year.

Results on Combined Approaches to Repair: Methods and Materials

Two additional trials investigated approaches to repair of perineal defects but did not distinguish between methods and materials[49] (Evidence Table 10, Appendix C).[55] Because of this, the trials are not directly comparable to other trials included in this review, and they do not contribute to the separate bodies of evidence for methods or materials. However, the results may be more applicable in the clinical setting where using a particular technique with a certain suture material, because of the properties of the materials themselves, may be more practical. We briefly describe these two trials and their results below.

One trial randomized women to one of two groups, both of which used the standard chromic-catgut approach to repair the deeper vaginal defect. In one group, the perineal skin was repaired with chromic catgut using an interrupted method of suturing; in the other, perineal skin was repaired with PROLENE™, a nonabsorbable suture material, using a subcuticular approach.[49] A similar set of groups was seen in the Buchan and Nichols trial (included above in the "Nonabsorbable versus Absorbable" section).[54] However, the Doyle trial, unlike the Buchan and Nicholls trial, was clear in its intent to investigate an entire approach to repair rather than a particular method or material.

The Doyle trial is of poor quality because it used a fair-quality randomization and implementation approach, had a small number of post-randomization exclusions, and had poor retention of subjects at followup, even in the short-term, immediate postpartum period.

As assessed by the midwife at 2 and 10 days, the groups did not differ with respect to perineal pain, need for analgesia, or bruising. The groups did not differ in pain or pain during sexual intercourse at 3 months.

Another trial randomly allocated women to one of three groups.[55] The first group had the episiotomy repaired using chromic catgut for the deep tissues and perineal muscles and an interrupted method using nylon for the perineal skin. The second group received polyglycolic-acid sutures for the deep tissues and perineal muscles and an interrupted method using polyglycolic-acid sutures for the perineal skin. The third group is described more ambiguously and had a repair done with polyglycolic-acid sutures for the deep tissues and perineal muscles and a subcuticular method using polyglycolic-acid sutures for the perineal skin.

This trial is of fair quality because of fair definitions and measurements of the outcomes and post-randomization exclusion of 98 women whom the authors were unable to follow because of relocation. These exclusions were nondifferential across the three randomized groups.

More women who had a repair with subcuticular polyglycolic suturing had no discomfort at 5 days than did women who had repairs with interrupted nylon or interrupted polyglycolic-acid sutures (40%, 12%, and 18%, respectively, $P < 0.001$). The groups that had repairs with the interrupted method did not differ. The authors reported significant differences between women who had repairs with subcuticular polyglycolic-acid sutures and the interrupted method group

including pain during sitting, walking, and bowel movements at 5 days. As assessed by the midwife at 5 days, the group repaired with subcuticular polyglycolic-acid sutures experienced less edema (11 percent versus 30 percent versus 23 percent, $P < 0.005$). No significant differences were found with respect to infection or hematoma.

At 3 months, the polyglycolic-acid suture groups differed significantly. Women whose episiotomies were repaired with the subcuticular approach were less likely to suffer from dyspareunia, discomfort with defecation, incontinence of flatus or discomfort when sitting ($P < 0.025$) than women whose episiotomies were repaired with the interrupted approach.

Key Question 4: Episiotomy and Urinary Incontinence, Fecal Incontinence, and Pelvic Floor Defects

Literature Search and Included Studies

Overview. We identified 16 publications that prospectively collected data about some aspect of continence or pelvic floor muscle function with good documentation of perineal status and episiotomy use at the time of the index birth. Outcomes of interest included physiologic measures of muscle strength, clinical urodynamic testing, or self report by interview or questionnaire. No studies directly compared type of incision and future pelvic floor function. The 16 publications include four reports from two randomized clinical trials (RCTs) of liberal versus restrictive use of episiotomy, 11 prospective studies of representative cohorts of women delivering at particular facilities or with a particular practice group (including two publications from a cohort of women who participated in an RCT of perineal massage versus none in the third trimester), and one cohort composed of all women in a region who had third-degree lacerations at the time of the index birth. The last study followed the cohort to assess risk of fecal incontinence at 3 months.

Two publications came from the same population in the United Kingdom: a primary analysis of the RCT outcomes at 3 months,[23] and a secondary analysis after 3 years of followup.[33] Two Canadian reports also present analyses of the same study population.[29,34] In this case, both publications report 3-month followup data: one analysis by the initial trial groups of liberal versus restrictive use of episiotomy and the other an analysis based on classification of perineal trauma at the index birth. Of the remaining 12 prospective studies, three were conducted in the United Kingdom, two in Denmark (separate populations), two in Canada (separate populations), two in Sweden (separate populations), one in Italy, one in Turkey, and one in the United States. In total, the 16 publications represent 12 unduplicated study populations from seven countries.

Study Participants. All but the study of third-degree lacerations restricted study participants to those with term, singleton gestations at the time of the index birth. Four of 16 studies restricted their study populations to primiparous women;[68-71] four studies restricted to spontaneous vaginal deliveries.[23,33,71,72] To assess what component of change in pelvic floor muscle function could be attributed to pregnancy and what component was most influenced by vaginal births, two studies included a nonpregnant comparison group and a group of women who had cesarean birth in their physiologic measures.[68,73] In each case the comparison groups were

recruited contemporaneously to the women who had vaginal deliveries generally from the same practice.

Episiotomy Type. We did not identify any studies that compared the influence of mediolateral versus midline (also called median) episiotomy on pelvic floor function or continence. The remainder of the studies reflects the dominant practice patterns in the countries in which the studies were conducted. Mediolateral episiotomy was the rule (with very rare exceptions) in European and Turkish cohorts; midline episiotomy predominated in the United States and Canada. This implies that to some degree European and North American studies are investigating fundamentally different exposures. The anatomic location, involved tissue planes, extent of perineal body disruption, and risk for extension associated with mediolateral compared to midline episiotomy would be expected to be distinctly different.

A single randomized trial comparing the two methods has documented that the risk of extension into and/or through the rectal sphincter is more than 2.5 times more likely with midline episiotomy; sphincter involvement occurred in 24 percent of deliveries with midline episiotomy in their trial.[36] They also noted that local extension, not involving the sphincter, was 1.8-fold more likely with midline episiotomy. These differential outcomes are believed to represent differences in the tissue planes involved. They may also represent differences in familiarity with midline episiotomy technique since reported risk of extension is lower in prospective cohorts in countries where midline episiotomy is routine. Because no trials or prospective studies directly compare the pelvic floor muscle function across type of episiotomy, the long-term differences in continence and pelvic floor muscle outcomes that would be anticipated secondary to differences in the type is unknown. These differences must be taken into consideration when synthesizing the findings relevant to this key question.

Outcomes Measured. This question was aimed at identifying research publications that undertook long-term followup, measured in years. However, we identified only five publications from four study populations with followup of a year or longer.[33,68-70,74] In response, we have included the entire literature that assesses continence and pelvic floor function at any time after the arbitrary 8-week window that can be used to define the postpartum period. Shorter-term continence and pelvic floor outcomes in the days and weeks around birth are described in the section on the outcomes of routine use of episiotomy.

To summarize outcomes, we grouped measures into four categories: those that assess urinary incontinence by self-report, those that assess continence of stool and flatus by self-report, those based on physical examination findings to describe anatomy, and those measures intended to document physiologic function, such as perioneometry. Seven studies assessed urinary incontinence by self-report; timeframes for self-report included 3 months,[23,29,34,70,71,75,76] 12 months,[70] 3 years,[33] 4 years,[74] and 5 years.[69] Three studies assessed continence of stool and/or flatus by self-report at 3 months,[71,75,77] and one study collected self-report data at an average of 10 months postpartum. Two studies described physical examination findings related to prolapse[71]and anal sphincter function and anorectal anatomy.[77] Five studies used perineometry measures to document characteristics of muscle function such as maximum strength of contraction and maximum sustained contraction over 10 seconds.[29,34,68,71,73] A single study reports findings from urodynamic testing that included observation of stress incontinence with strain and timing of interval required to stop urine flow;[71] one study used weighted vaginal cones recording the heaviest weight that could be retained while standing or walking antepartum and 2

months postpartum. The highest-quality studies combined types of measures and reported data in standardized fashion that concurs with definitions of the International Continence Society.

Quality. Quality assessment is described in detail in Chapter 2 (Methods); key components of quality assessment and an overall quality score are provided in Evidence Table 11 (Appendix C). Four publications for this key question derive from the conduct of two RCTs that had good-quality ratings for assessing outcomes of liberal versus restrictive use of episiotomy. For this question, we also rated the breadth of measures used to characterize outcomes, the clarity of specification of the outcome measures (including documentation of how participants were asked self-reported measures), use of measures with documented validity and reliability, and loss to followup. For prospective cohort studies, we assessed these features and the representativeness of the participants to reflect a base population of women having births, as well as use of adjusted models to control for potential confounding factors.

Table 8 summarizes the methods and findings of the individual studies identified. Publications are listed in order from older to more recent reports. We then separately consider the findings from randomized trials of liberal versus restrictive use of episiotomy and prospective studies that employ episiotomy or perineal trauma categories as the primary exposure of interest. The findings are further grouped within study type by urinary incontinence outcomes, rectal continence outcomes, anatomic findings, and pelvic muscle function measures obtained using physiologic measurements.

Results

Randomized Clinical Trials. Both randomized clinical trials, Sleep and colleagues in the United Kingdom[23] and Klein and colleagues in Canada,[29] conducted trials that required providers to alter their use of episiotomy. These trials randomized women to receive "liberal use" versus "restricted use" of episiotomy, with the latter category intended to restrict use to circumstances such as fetal distress or maternal exhaustion with an "unyielding perineum." Both trials enrolled singleton, vertex presentation pregnancies at term and randomized in the delivery suite close to the time of birth.

The United Kingdom trial had a 10.2 percent use of episiotomy in the restrictive group (2.6 percent for maternal indications; 6.6 percent for fetal distress), compared to 51.4 percent use of episiotomy in the liberal group. The Canadian trial had greater difficulty modifying provider behavior as background rates of episiotomy exceeded 80 percent. Restrictive use resulted in 57.2 percent of the women having an episiotomy compared to 81.4 percent in the liberal-use arm. Each of these research groups published an analysis as randomized for 3-month postpartum data. The sole violation of intention to treat was Klein's elimination of five women with cesarean section from analysis of pelvic floor outcomes. Both trials achieved good balance of baseline

Table 8. Episiotomy and urinary incontinence, fecal incontinence, and pelvic floor defects

Author, Year Country	Study Design N	Timing of Outcome Assessment after Birth Approach	Outcome(s) Assessed Definitions Provided	Outcome among Those with Episiotomy	Outcome among Those without Episiotomy	Results of Multivariable Models Authors' Conclusions
Sleep et al., 1984[23] United Kingdom	RCT N = 1,000	3 months Mailed questionnaire	Urinary incontinence "involuntary loss of urine" "Need to wear a pad" for loss of urine	Incontinence: 19% Pad: 6%	Incontinence: 19% Pad: 6%	Incontinence was more common among multiparas than primiparas but did not differ significantly between the two trial groups when stratified by parity. There is no evidence that episiotomy prevents urinary incontinence.
Gordon and Logue, 1985[68] United Kingdom	Prospective cohort N = 70	12 months Physiologic testing in women with all perineal outcomes and cesarean	Perineometry pressure readings Methods summarized in text; average of five measures used	Maximum pressure epis: 11.7 mm water Maximum pressure forceps and epis: 9.4 mm water	Maximum pressure intact: 11.1 Maximum pressure second degree: 10.8 Maximum pressure cesarean: 12.5	Not reported No significant difference between the groups. Differences between postnatal exercise levels were highly significant with more exercise associated with greater perineal muscle strength.

Table 8. Episiotomy and urinary incontinence, fecal incontinence, and pelvic floor defects (continued)

Author, Year Country	Study Design N	Timing of Outcome Assessment after Birth Approach	Outcome(s) Assessed Definitions Provided	Outcome among Those with Episiotomy	Outcome among Those without Episiotomy	Results of Multivariable Models Authors' Conclusions
Sleep et al., 1987[33] United Kingdom	RCT N = 674	3 years Mailed questionnaire	Urinary incontinence "Lost urine when they did not mean to"	Incontinence < once past wk: 22% 1-2x past wk: 12% ≥ 3x past wk: 2%	Incontinence < once past wk: 25% 1-2x past wk: 11% ≥ 3x past wk: 2%	Not reported No difference in prevalence of urinary incontinence, even when severity and nature of the incontinence, and subsequent deliveries, were taken into account.
			"Severe enough to wear pad"	Pad sometimes: 8% Pad daily: 2%	Pad sometimes: 7% Pad daily: 1%	
			"Loss when coughing, laughing, sneezing"	SUI: 33%	SUI: 31%	
			"Loss with urgent desire to pass urine but no toilet nearby"	Urge incont.: 13%	Urge incont: 13%	
Rockner, 1990[74] Sweden	Prospective Cohort N = 185	4 years Mailed questionnaire	Urinary incontinence Frequency	Urinary incontinence: Occas.: 37 (26%) 1x/week: 10 (7%) 2-3x/wk: 2 (1%) >3x/wk: 1 (1%)	Urinary incontinence: Occas.: 12 (28%) 1x/week: 1 (2%) 2-3x/wk: 1 (2%) >3x/wk: 1 (2%)	Not reported. Episiotomy and spontaneous tear groups had the same frequency of urinary incontinence symptoms, giving no support to the suggestion that episiotomy prevents long-term damage of the pelvic floor.
			Severity (data corresponds to definitions)	With cough/laugh/sneeze: 48 (34%) Sufficiently severe to wear pad Sometimes: 13 (9%) Always: 1 (1%)	With cough/laugh/ sneeze 13 (30%) Sufficiently severe to wear pad Sometimes: 6 (14%) Always: 0 (0%)	

Table 8. Episiotomy and urinary incontinence, fecal incontinence, and pelvic floor defects (continued)

Author, Year Country	Study Design N	Timing of Outcome Assessment after Birth Approach	Outcome(s) Assessed Definitions Provided	Outcome among Those with Episiotomy	Outcome among Those without Episiotomy	Results of Multivariable Models Authors' Conclusions
Rockner et al, 1991[78] Sweden	Prospective cohort N = 92	2 months Physiologic measure	Pelvic floor muscle function measured using weighted vaginal cones at 36 wks gestation and postpartum Details provided in text	Mean decrease in muscle function (gms): 30.0 ± 11.8	Mean decrease in muscle function (gms) Intact: 19.2 ± 10.2 Spontaneous tear: 18.9 ± 9.1 (*P* < 0.001)	Not reported Pelvic floor muscle function was most decreased in the episiotomy group. The results do not support the concept that episiotomy reduces damage to the pelvic floor muscles.
Klein et al., 1992[29] Canada	RCT N = 703	3 months In-person interview Physiologic measure: Antepartum and 3 months postpartum	Urinary incontinence Not defined – used 4-point scale, dichotomized as present/ absent Subjective sense of "perineal bulging"; 4-point scale dichotomized as present/ absent Perineometry	Incontinence Primip: 14.5% Multip: 21.5% Bulging Primip: 7.9% Multip: 9.5% EMG Primip ante: 2.1 (1.8) Primip post: 2.3 (1.8) Multip ante: 1.7 (1.5) Multip post: 2.1 (1.5)	Incontinence Primip: 21.1% Multip: 12.9% Bulging Primip: 9.1% Multip: 5.4% EMG Primip ante: 2.0 (1.6) Primip post: 2.3 (1.6) Multip ante: 1.9 (1.6) Multip post: 2.1 (1.5)	Not reported None of the differences in urinary incontinence were statistically significant after controlling for antepartum history of urinary incontinence.

Table 8. Episiotomy and urinary incontinence, fecal incontinence, and pelvic floor defects (continued)

Author, Year Country	Study Design N	Timing of Outcome Assessment after Birth Approach	Outcome(s) Assessed Definitions Provided	Outcome among Those with Episiotomy	Outcome among Those without Episiotomy	Results of Multivariable Models Authors' Conclusions
Viktrup et al., 1992[70] Denmark	Prospective cohort N = 305	3 months 12 months	Telephone interview Questionnaire using International Continence Society definitions Urinary incontinence provoked by physical exertion; daily incontinence; incontinence as hygienic or social problem	Data not provided	Data not provided	Not reported Women who had an episiotomy developed stress incontinence significantly *(P* < 0.05) more frequently after delivery. However, episiotomy was performed more often in women with an increased length of second stage (*P* < 0.01). Differences in stress incontinence associated with episiotomy had resolved by 1 year.
Klein et al., 1994[34] Canada	Prospective cohort assembled from participants in liberal vs. restrictive episiotomy trial N = 697	3 months In-person interview Physiologic measures antepartum and postpartum	Self-reported urinary incontinence (4 point scale) Perineometry scores (electronic vaginal myography) Methods described in text	No difference (data not shown) Epis, no exten. Net change: Primip: 0.19 Multip: 0.05 Third/fourth degree Net change: Primip: 0.08 Multip: -0.07	No difference (data not shown) In tact Net change: Primip: 0.47 Multip: 0.57 Spontaneous tear Net change: Primip: 0.29 Multip: 0.39	Not reported Episiotomy fails to prevent the trauma or pelvic floor relaxation that it was designed to prevent.

Table 8. Episiotomy and urinary incontinence, fecal incontinence, and pelvic floor defects (continued)

Author, Year Country	Study Design N	Timing of Outcome Assessment after Birth Approach	Outcome(s) Assessed Definitions Provided	Outcome among Those with Episiotomy	Outcome among Those without Episiotomy	Results of Multivariable Models Authors' Conclusions
Walsh et al., 1996[77] United Kingdom	Prospective cohort of women with Third-degree tears N = 81	3 months	Physical examination by colorectal surgeon	100% of women with abnormal exam and fecal incontinence had episiotomy 60% of women with abnormal exam and no incontinence had episiotomy	No cases of fecal incontinence among women without episiotomy 40% of women with abnormal exam and no incontinence did not have episiotomy	Not reported Obstetric trauma causes significant anorectal dysfunction and patients with third-degree tears require assessment.
MacArthur et al., 1997[79] United Kingdom	Prospective cohort N = 906	10 months N = 906 In-person Interview	Fecal incontinence "Loss of bowel control with no warning needed to go"; "soiling or staining"; "felt need to go but couldn't hold on" One or more considered incontinence	Primp.: 4.6% Multip.:8.8%	Intact Primp.: 5.2% Multip.:2.9% Second degree Primip: 5.2% Multip: 4.2%	In multivariable models: episiotomy not an independent predictor of fecal incontinence

Table 8. Episiotomy and urinary incontinence, fecal incontinence, and pelvic floor defects (continued)

Author, Year Country	Study Design N	Timing of Outcome Assessment after Birth Approach	Outcome(s) Assessed Definitions Provided	Outcome among Those with Episiotomy	Outcome among Those without Episiotomy	Results of Multivariable Models Authors' Conclusions
Viktrup and Lose, 2001[69] Denmark	Prospective cohort N = 305	5 years	Telephone interview Questionnaire using International Continence Society definitions; urinary incontinence provoked by physical exertion; daily incontinence; incontinence as hygienic or social problem	Not provided by episiotomy status Episiotomy contributed to prediction of risk of incontinence at 5 years when comparing women who had incontinence during their pregnancy to those without any incontinence associated with pregnancy or postpartum. Episiotomy not risk factor among women with only postpartum symptoms.		In multivariable modes, episiotomy at the first delivery was significantly associated with stress incontinence 5 years after delivery, even after adjustment for the few with coexistence of anal sphincter rupture.
Eason et al., 2002[75] Canada	Prospective cohort assembled from participants in perineal massage RCT N = 949	3 months Mailed questionnaire	Incontinence of stool Incontinence of flatus "Involuntary loss of stool or flatus" Frequency (never, less than 1 a week, 1 to 6 times a week, daily, or more than once a day)	Loss of stool: RR: 5.4% Loss of flatus: RR: 30.2%	Loss of stool: RR: 2.5% Loss of flatus: RR: 24.4%	Loss of stool/flatus: No perineal injury: RR 1.0 First degree: 1.2 (0.8, 1.7) Episiotomy without extension: 1.3 (0.9, 1.8) Third/fourth degree: 2.1 (1.4, 3.1) Anal incontinence is associated with sphincter laceration, which was more common among those with episiotomy.

Table 8. Episiotomy and urinary incontinence, fecal incontinence, and pelvic floor defects (continued)

Author, Year Country	Study Design N	Timing of Outcome Assessment after Birth Approach	Outcome(s) Assessed Definitions Provided	Outcome among Those with Episiotomy	Outcome among Those without Episiotomy	Results of Multivariable Models Authors' Conclusions
Fleming et al., 2003[73] United States	Prospective cohort N = 102	6 months Baseline perineometry during pregnancy; and at 6 wks Physiologic testing in women with all perineal outcomes and cesarean	Perineometry scores (electronic vaginal myography) Methods detailed in text; average of three measures of each type of contraction used for analysis Difference in antepartum and postpartum scores	Mean score (SD) Peak: -1.7 (2.1) Hold: -1.7 (2.1)	Mean score (SD) Intact Peak: 2.7 (2.8) Hold: 2.8 (3.5) Second- or third-degree laceration Peak: 0.8 (2.6) Hold: 0.8 (2.3)	Not reported No significant differences in absolute postpartum perineal muscle strength or endurance between episiotomy and laceration groups. Women who had episiotomy were only group with net loss of perineal muscle function after delivery.
Karacam and Eroglu, 2003[72] Turkey	Prospective cohort N = 100	3 months Telephone questionnaire	Stress incontinence Not defined	12/50 (24%)	15/50 (30%)	No significant differences in stress incontinence before labor, or if after delivery of first child, or if after delivery of second child that was related to episiotomy.

Table 8. Episiotomy and urinary incontinence, fecal incontinence, and pelvic floor defects (continued)

Author, Year Country	Study Design N	Timing of Outcome Assessment after Birth Approach	Outcome(s) Assessed Definitions Provided	Outcome among Those with Episiotomy	Outcome among Those without Episiotomy	Results of Multivariable Models Authors' Conclusions
Eason et al., 2004[76] Canada	Prospective cohort participants in perineal massage RCT N = 949	3 months Mailed questionnaire	Frequency of involuntary loss of urine when coughing, sneezing, laughing, running	Any stress urinary incontinence: 29%	Any stress urinary incontinence: 35%	OR: 0.68 (0.47, 1.01) No significant association between episiotomy and urinary incontinence.
Sartore et al., 2004[71] Italy	Prospective cohort N = 519	3 months Physical exam Physiologic measures: Perineometry Uroflowmeter In-person interview	Perineometry with highest/best single recording used for analysis	SUI: 12.9% Anal incont: 2.8%	SUI: 12.1% Anal incont: 1.9%	OR: 1.01 (0.61, 1.7) OR: 1.47 (0.46, 4.7)
			Baden and Walker classification of urogenital prolapse	Ante prolapse: 41p.5% Post prolapse: 15.8%	Ante prolapse: 42.1 Post prolapse: 14.6%	OR: 0.97 (0.69, 1.4) OR: 1.1 (0.68, 1.8)
			Urine stream interruption test	Vaginal manometry: 12.2 (5.1)	Vaginal manometry: 13.8 (4.7)	*P* < 0.001
			SVI – visible involuntary loss of urine by ICS standards	Urine stream interrupt: 3.9 (3.5) Vaginal manometry percent abnormal: 40.6%	Urine stream interrupt: 3.8 (2.9) Vaginal manometry: percent abnormal: 27.7%	*P* = 0.85 OR: 1.79 (1.2, 2.6)
			Self-reported urge and anal incontinence of stool or flatus, classified by frequency			Mediolateral episiotomy does not protect against urinary and anal incontinence. Episiotomy is associated with lower pelvic floor muscle strength than spontaneous tears.

characteristics through randomization. Both trials assessed urinary incontinence outcomes; neither assessed continence of stool or flatus.

The Canadian trial also assessed self-reported sensation of perineal "bulging" and conducted perineometry. The Canadian team has published two analyses: an analysis as randomized and an analysis by perineal trauma sustained. The randomized analyses produced no meaningful differences in self-reported urinary incontinence, subjective sensation of perineal bulging, or perineometry readings, including when baseline antepartum readings and parity were incorporated. Likewise, the analysis by perineal status (intact, episiotomy, spontaneous tear, third- and fourth-degree tear) revealed no differences in self-reported incontinence or in perineometry scores. These analyses were stratified by parity and suggest some effect modification; however, the authors did not provide adjusted models or note any statistically significant results.

The research team from the United Kingdom has published two analyses as randomized: a 3-month and 3-year followup, both conducted by mailed questionnaire followup.[23,33] The 3-month followup found no difference by group in risk of involuntary loss of urine (19 percent in both arms) or in need to wear a pad because of urine loss (6 percent in both arms). Their 3-year followup was more detailed and included involuntary loss of urine; use of a pad; loss of urine with coughing, sneezing, laughing; and loss with urgent need to void. No aspect of these symptoms or their severity varied by restrictive versus liberal episiotomy group. For the 3-year followup, this lack of difference across groups persisted when taking into account subsequent obstetric history. The 3-year followup was also marred by loss, although the authors were able to use 3-month data to demonstrate little evidence of response bias. Adjustment using multivariable models is alluded to but numeric data are not provided.

Neither trial collected data about continence of flatus or stool, descriptive data from physical examination, or urodynamic studies. Both research teams concluded that they did not observe any benefits associated with episiotomy. Klein and colleagues, based on perineometry measures, also concluded that episiotomy fails to prevent pelvic floor relaxation.

Prospective Studies. The Italian study by Sartore and colleagues provided the most global assessment of continence and pelvic floor function; they addressed each of our four categories of outcomes.[71] They enrolled 519 primiparous women who had singleton, spontaneous vaginal births in lithotomy position. Women with pre-existing incontinence were excluded. Measures of outcomes at 3 months included in-person interviews, physical examination, perineometry, a test to provoke stress urinary incontinence, and a urine-stream-interruption test. The study team clearly described methods, used a standard scheme for classifying prolapse, and collected data about urinary and anal incontinence. Overall measures and implementation were good. For the entire panel of outcomes (stress urinary incontinence, anal incontinence, anterior prolapse, posterior prolapse, vaginal manometry, and urine-stream interruption), there was only one statistically significant difference in perineometry findings. Women who did not have an episiotomy (all mediolateral) had higher contraction strength on perineometry (13.8 compared to 12.2; $P < 0.001$); moreover, the proportion of women with abnormal manometry was higher among women with episiotomy (40.6 percent compared to 27.7 percent without episiotomy). The adjusted relative risk for abnormal manometry was 1.8 (95% CI, 1.2-2.6). The study team concluded that episiotomy is associated with lower pelvic floor muscle strength than spontaneous tears. All self-reported symptoms of urinary and anal incontinence and degree of prolapse on physical examination were equivalent across groups so the clinical significance of this finding is

unclear. Overall interpretation must be that episiotomy does not protect against incontinence, prolapse, or decrements in pelvic floor muscle function by 3 months postpartum.

Studies focused on self-reported urinary continence. Excluding the clinical trial populations and the study by Sartore et al. described above, five studies (in four study populations) evaluated self-report of urinary continence.[69,70,72,74,76] Two used a telephone interview,[70,72] the other three mailed questionnaires.

Karacam and Eroglu provided the least-detailed information:[72] no details about how stress incontinence was queried or defined for data analysis and no report of adjusting for factors that might influence outcomes by using stratified analyses or multivariable models. They reported, from bivariate data at 3 months (N = 100), that 24 percent of women with episiotomy and 30 percent of women without episiotomy had stress incontinence.

Eason and colleagues asked about occurrence and frequency of "involuntary loss of urine when coughing, sneezing, laughing, or running" in a cohort of 949 women also at 3 months.[76] For analysis, they reported that any stress incontinence occurred in 29 percent of those with episiotomy and in 35 percent of those without. Multivariable models for stress urinary incontinence comparing episiotomy to no episiotomy yielded an odds ratio of 0.68 (95% CI, 0.47-1.01).

Viktrup and colleagues reported using a questionnaire to obtain all the facets of the International Continence Society definitions of incontinence from 305 women.[70] They reported no differences but do not provide numeric data. In summary, they stated that although women with episiotomy had more incontinence postpartum, differences had resolved by 3 months and remained equivalent at 1 year. Their followup survey at 5 years revealed in multivariable models that episiotomy in a first birth was significantly associated with stress incontinence.[69] An adjusted point estimate is not provided.

Rockner's followup of a cohort of 185 women with either episiotomy or spontaneous tear at 4 years after the index pregnancy asked women about symptoms before, during, and after all pregnancies; information about the index pregnancy focused on frequency and severity of urinary incontinence; need for pad; and loss of urine provoked by cough, laugh, or sneeze.[74] Symptom profiles were very similar across groups; for instance, 34 percent of women who had an episiotomy and 30 percent without reported incontinence provoked by cough, laugh, or sneeze. No stratified or adjusted models are provided. The author concluded that episiotomy and spontaneous-tear groups had the same frequency of incontinence symptoms. Overall, each research team investigating self-reported urinary incontinence concluded that no evidence supported the view that episiotomy prevents pelvic floor defects.

Studies focused on self-reported incontinence of stool or flatus. Three cohort studies asked women about rectal incontinence symptoms.[75,77,79] One study also conducted physical examinations.[77]

The earliest of these studies was conducted on a cohort constructed of 81 women who had third-or fourth-degree lacerations.[77] The prevalence of episiotomy among women without third- or fourth-degree lacerations was known as well as their episiotomy history in the index pregnancy. They were followed up at 3 months when their symptoms were evaluated and they received a physical examination. All women who had fecal incontinence and abnormal rectal examination at three months had had an episiotomy. Of those with an abnormal exam and no incontinence 60 percent had had an episiotomy, meaning relative risk of abnormal exam was 50 percent greater among those with history of episiotomy. These authors focused on the high

prevalence of anorectal dysfunction at 3 months with episiotomy as a key risk factor. None of the research teams that focused on incontinence of flatus or stool found episiotomy to be significantly associated with reduced risk.

MacArthur and colleagues sent questionnaires at 6 to 7 months and then followed up all women who had a variety of symptoms at 10-months with an in-person interview. [79] Their questionnaire and interview classified several types of fecal incontinence and staining (not including simple flatus); any one or more of the symptoms was considered evidence of incontinence. At 10 months, episiotomy was not an independent predictor of fecal incontinence in multivariable models. Because episiotomy was not a key focus of their analysis, they do not provide a point estimate.

Eason and colleagues inquired about involuntary loss of stool or flatus and the frequency at 3 months.[75] Women with episiotomy reported higher prevalence of loss of stool (5.4 percent) and loss of flatus (30.2 percent) than did women without episiotomy (2.5 percent and 24.4 percent, respectively). Adjusted models revealed that episiotomy without extension was associated with a relative risk of 1.3 (95% CI, 0.9-1.8), and third- to fourth-degree lacerations (virtually all after episiotomy) were associated with 2.1-fold increased risk of anal incontinence (95% CI, 1.4-3.1). The study team concluded that anal incontinence was associated with severe lacerations that are most likely to result from episiotomy.

Studies focused on physiologic measures of pelvic floor function. In 1985, Gordon and Logue published the first use of perineometry to evaluate prospectively a group of 70 women.[68] They included a nonpregnant and a cesarean comparison group to take into account changes associated with pregnancy and labor, respectively. They did not compare women with their own measures in pregnancy. No difference in maximum contraction strength was seen across groups. However, the researchers did note that postnatal exercise level was highly associated with perinatal muscle strength.

Fleming and colleagues refined the Gordon and Logue study design.[73] They conducted perineometry antepartum, at 6 weeks, and again at 6 months among 102 women with singleton spontaneous vaginal births. Detailed measurement protocols are provided and their analysis focused on mean difference between antepartum scores and 6-month scores. No differences in perineal muscle strength or endurance were identified between laceration and episiotomy groups.

In another approach to measuring muscle strength, Rockner and colleagues conducted studies with weighted vaginal cones at 36 weeks gestation and again at 2 months postpartum. They calculated decrements in weight that could be retained while standing or walking: women with episiotomy had the greatest decrement in function (30 gm decrease in maximum weight held), compared to 19.2 gram decrease with intact perineum, and 18.9 gm decrease with spontaneous tears ($P < 0.001$).[78]

Overall, none of these research teams concluded that episiotomy had advantages, and one identified a decrease in functional muscle strength. These intermediate findings concur with the self-report and clinical examination findings of other studies that detected no evidence of benefit from episiotomy with respect to preserving continence or pelvic floor muscle function.

Key Question 5:
Episiotomy and Future Sexual Function

Literature Search and Included Studies

Overview of the Evidence. Nine publications were identified that prospectively collected outcome data about sexual function among women who did or did not have a routine episiotomy. Evidence Table 12 in Appendix C provides details. One study compared incision type and assessed sexual function.[36] These 10 publications include three randomized trials of restrictive versus liberal use of episiotomy;[23,29,33] one trial of median versus midline episiotomy;[36] and five prospective cohort studies.[34,71,72,80,81] One study (the only study conducted in the United States), described by the authors as "retrospective," included a single followup time point (6 months) for which the data collection about sexual function was prospective.[38] Two publications reflect a primary analysis from a randomized clinical trial (RCT) with 3 months of followup[23] and a secondary analysis after 3 years of followup[33] in the same study population from the United Kingdom. Two publications by a Canadian research team are also analyses of the same study population.[29,34] In this case, both publications report 3-month followup data: one analysis focused on randomization to liberal versus restrictive episiotomy groups, and the other took the perspective of exposure groups classified by perineal trauma at the time of delivery. Two of the prospective studies were conducted in Sweden (separate study populations), one in Italy, and one in Turkey. Thus, in total, this literature represents seven distinctive study populations from six countries.

Study Participants. In current practice in the United States, women who are giving birth for the first time are most likely to have a routine episiotomy. Several studies that evaluated sexual function restricted the study population to primiparous women. This approach assures that the influence of episiotomy, spontaneous laceration, or intact perineum reflects only the potential influences of the index birth, rather than both the index birth and any prior history of perineal trauma among women who have had prior births. Those studies that did not restrict their study of sexual function to primiparous patients adjusted for prior episiotomy in data analysis as a method to account for the influence of prior birth experiences. All studies restricted participation to singleton births; and some specifically included only women who had a spontaneous vaginal birth.

Episiotomy Type. Only one study directly compared mediolateral to median (midline) episiotomy.[36] The remainder of the studies reflects the dominant practice patterns of the countries in which the studies were conducted. Mediolateral episiotomy is routine in the countries represented, with the exception of the United States and Canada, where median episiotomy is routine. Overall, when episiotomy was performed in the U.S. and Canadian studies, it was a median incision;[29,34,38] this phenomenon stands in contrast to 98.9 percent mediolateral episiotomies in the European and Turkish studies.[72 33,71,80,80,81]

This factor introduces a fundamental difference in the "exposure" across studies. The anatomic location, involved tissues plains, extent of perineal disruption, and risk for extension associated with mediolateral as compared to median episiotomy are distinctly different. Once healed, the scar from each type of episiotomy and from spontaneous lacerations will be subject to different amounts and types of contact, pressure, and stretch depending on position of partners

during sexual intercourse. Thus, the literature reflects two distinct types of procedures, the effects of which need to be addressed separately.

Outcome Measures. Of the 10 studies included for this key question, eight were not designed to address sexual function as the primary outcome. Only the Signorello et al. and Karacam and Eroglu studies reported that a primary objective of the study was to assess the relationship between perineal trauma (spontaneous versus episiotomy) and postpartum sexual function.[38,72]

The most consistently reported outcome was "dyspareunia." In three of these 10 publications, the researchers provide no detail to document how they phrased a question or questions about pain with intercourse or how they recorded participant responses; no reports distinguished between pain on insertion, deep dyspareunia with thrusting, or residual pain (deep or perineal) after intercourse. Four studies used a written questionnaire to collect information about sexual function.[23,33,38,80] One study conducted telephone interviews,[72] and four conducted in-person interviews.[29,34,71,81] In-person interview methods for assessing sexual function outcome tended to be more detailed than those obtained from written questionnaires. However, none of the publications distinguish between pain on insertion, deep dyspareunia with thrusting, or residual pain (deep or perineal) after intercourse.

Across all 10 studies, investigators used three approaches for summarizing when women experienced dyspareunia. The most common was to inquire about any dyspareunia since resuming intercourse. Other authors inquired about dyspareunia with episodes of intercourse near the time of the followup. To differentiate this approach from measures of any experience of dyspareunia, we have called inquiry about recent status "current dyspareunia" in this report. Less often, authors reported about pain at the time of the first episode of intercourse after the index birth.

In a related measure, four research teams also asked women to recall when they resumed having intercourse. This question allows the investigators to report both continuous and categorical data about the proportion of women who had resumed intercourse by particular points in time, for example, by 2 months postpartum.[23,29,34,80] Few authors clearly explained if the prevalence of dyspareunia reported is appropriately calculated as a proportion (number of women with pain with intercourse divided by number of women who have resumed intercourse). The most common timeframe for assessment of outcomes was 3 months. One group assessed dyspareunia at postpartum exams between 2 and 3 months;[81] one used a mailed questionnaire at 6 months;[38] and the longest followup was conducted by questionnaire mailed at 3 years.[33]

The two publications by Klein and colleagues had the most elaborate approach to collecting several types of information. These authors reported greater detail about how participant responses were collected and analyzed. In interviews at 3 months postpartum, they asked women when they resumed intercourse and assessed recalled pain at the first postpartum episode of intercourse using the McGill Pain Scale. They inquired about sexual satisfaction using an unspecified number of items measured on a 4-point scale and reported a summary measure of "sexual satisfaction" in their tables.[29,34] Two other groups classified degree of pain with intercourse using an approach that assigned levels: none, mild, moderate, and severe.[71 34]

Quality. None of the identified studies was designed exclusively to examine sexual function. We classified primary and secondary outcomes based on objectives provided in the introduction of the publication or used stated research questions to classify primary and secondary objectives.

None of the 10 studies met criteria that we consider necessary to be a good study of sexual function after episiotomy. Our criteria included (1) documentation of a representative sample of women who had spontaneous vaginal births, (2) use of outcomes that provide a well-rounded picture of sexual function, (3) clear specification of outcome measurement approach (including specification of items asked of participants on surveys or in interviews), (4) use of measures with documented validity and reliability, (5) use of adjusted models in prospective data to control for potential confounding factors, (6) minimal to modest loss to followup, and (7) use of intention-to-treat analysis in randomized clinical trials.

Results

Table 9 summarizes the methods and findings of the individual studies identified. Publications are listed in order from older to more recent reports. We also separately consider the findings of controlled trials of liberal use versus restricted use of episiotomy and other prospective cohort studies of episiotomy that include sexual function outcomes (Table 10). The single study that compared type of episiotomy incision and included assessment of sexual function is reviewed on pages 30 and 31; no differences in pain with initiation of intercourse or with satisfaction with intercourse were noted by episiotomy type.

Randomized Controlled Trials. Two publications present results from RCTs of restrictive compared to liberal use of episiotomy; the investigators used an intention-to-treat analysis. These trials provide evidence about the long-term effects of a particular type of policy about episiotomy use on the sexual outcomes of populations of women. The earlier of the two trials was conducted in the United Kingdom in 1982.[23] Perineal outcomes in the West Berkshire Perineal Management Trial differed clinically and statistically by group. Among women in the liberal-use group, 51.4 percent had had an episiotomy (all mediolateral), 6.0 percent had an episiotomy with extension to third- or fourth-degree laceration, 24.5 percent had a spontaneous perineal tear only, and 24.3 percent had no perineal trauma. In the restrictive-use group, 10.2 percent had an episiotomy, 1.2 percent had an episiotomy with extension, 55.8 percent had a spontaneous perineal tear only, and 33.9 percent had no trauma. By 1 month after delivery, 37 percent of the restrictive group and 27 percent in the liberal group had resumed sexual intercourse ($P < 0.01$). The proportion of women with resumption of intercourse by 3 months, current dyspareunia at 3 months, or any dyspareunia within the 3 months of followup did not differ significantly by group.[23] By the third year of followup, the likelihood of "ever suffering painful intercourse" remained comparable across groups.[33]

The trial conducted by Klein and colleagues in Canada also found less episiotomy use in the restrictive group with higher rates of spontaneous lacerations.[29] Among women in the liberal-use group, 67.2 percent had an episiotomy (midline), 14.2 percent had an episiotomy with extension to third- or fourth-degree laceration or sulcal tear high in the vaginal vault, 12 percent had a spontaneous perineal tear only, and 6.6 percent had no perineal trauma. In the restrictive-use group, 42 percent had an episiotomy, 15 percent had an episiotomy with extension, 35 percent had a spontaneous perineal tear only, and 7.5 percent had no perineal trauma. Women in the restrictive group resumed intercourse an average of 1 week earlier that those in the liberal group; however, all other measures of sexual function were equivalent by 3 months.[29]

Table 9. Episiotomy and future sexual function

Citation Epis. Type Country	Study Design N	Timing of Outcome Assessment after Birth; Approach	Outcome Assessed Definitions Provided	Outcome among Those with Episiotomy	Outcome among Those without Episiotomy	Results of Multivariable Models Authors' Conclusions
Sleep et al., 1984[23] Mediolateral UK	RCT N = 1000	3 months Mailed questionnaire	Resumption of intercourse by 3 months (not defined)	90%	90%	Not reported Only difference was tendency for women allocated to restrictive episiotomy to resume intercourse sooner.
			Current dyspareunia: "pain during sexual intercourse"	22%	18%	
			Any dyspareunia: "pain during sexual intercourse, at some time" in prior 3 months	52%	51%	
Sleep and Grant, 1987[33] Mediolateral UK	Prospective cohort that included RCT participants N =326	3 years Mailed questionnaire	Any dyspareunia: "ever suffering painful sexual intercourse"	16%	13%	RR 1.21 (0.84, 1.75); No significant difference
Rockner et al., 1988[80] Mediolateral (88%) Sweden	Prospective cohort N =205	3 months Questionnaire (setting not specified)	Resumption of intercourse (Y/N)	92%	92%	Not reported No significant difference
			Current dyspareunia (not defined)	20%	20%	
			Any dypareunia in prior 3 months (not defined)	44%	43%	
Larsson et al., 1991[81] Mediolateral Sweden	Prospective cohort N =1889	2 to 3 months In-person interview with midwife	Dyspareunia (not defined)	16%	11%	Not reported None made regarding sexual function

Table 9. Episiotomy and future sexual function (continued)

Citation Epis. Type Country	Study Design N	Timing of Outcome Assessment after Birth; Approach	Outcome Assessed Definitions Provided	Outcome among Those with Episiotomy	Outcome among Those without Episiotomy	Results of Multivariable Models Authors' Conclusions
Klein et al., 1992[29] Midline Canada	RCT: Liberal vs restrictive N = 703	3 months In-person interview	Resumption of intercourse ("weeks between birth and first intercourse")	Primip: 5.8 (2.1) Multip: 5.8 (2.6)	Primip: 5.9 (2.5) Multip: 5.4 (2.3)	Time to resumption of intercourse similar; those with intact perineum began intercourse 1 week earlier than others. Pain with resumption, 3-month sexual satisfaction and proportion not resuming by 3 months similar across groups.
			Dyspareunia: "Pain at first postpartum intercourse" assessed using McGill Pain Scale	Primip: 2.2 (1.3) Multip: 1.3 (1.1)	Primip: 2.2 (1.3) Multip: 1.2 (1.0)	
			Sexual satisfaction at 3 months X items using "4 point scale" – actual items not provided	Primip: 3.1 (0.7) Multip: 3.3 (0.7)	Primip: 3.0 (0.8) Multip: 3.3 (0.6)	

Table 9. Episiotomy and future sexual function (continued)

Citation Epis. Type Country	Study Design N	Timing of Outcome Assessment after Birth; Approach	Outcome Assessed Definitions Provided	Outcome among Those with Episiotomy	Outcome among Those without Episiotomy	Results of Multivariable Models Authors' Conclusions
Klein et al., 1994[34] Midline Canada	Prospective cohort derived from RCT N = 697	3 months In-person interview	Resumption of intercourse by week 6	Epis alone: 61.7% Third-/fourth-degree: 55.4%	Intact: 76.5% Spont. tear: 62.5%	Women with spontaneous perineal tears had less pain on first intercourse than those with episiotomy alone. Those with third- to fourth-degree episiotomy extensions had the most pain on resumption of intercourse.
			Dyspareunia: "Pain at first postpartum intercourse: none, mild, discomforting, distressing-horrible"	Epis alone: Mild: 22.7% Discomf: 34.1% Distress: 28.8% Third-/fourth-degree: Mild: 23.0% Discomf: 39.3% Distress: 29.5%	Intact: Mild: 37.6% Discomf: 22.8% Distress: 6.9% Spont. tear: Mild: 27.3% Discomf: 27.3% Distress: 24.6%	
			Sexual satisfaction at 3 months; items using "4-point scale" – actual items not provided	Epis alone: Not satisfied: 16.3% Third/fourth degree: Not satisfied: 21.3%	Intact: Not satisfied: 5% Spont: Not satisfied: 15.8%	
Signorello et al., 2001[38] Midline United States	Cohort with a single prospective window N = 921	6 months Mailed questionnaire	Current dyspareunia: "pain on sexual intercourse" at 6 months	Multivariate models for type of perineal trauma: None: Referent Second degree:1.3 (0.8, 2.2) Third/fourth degree: 1.5 (0.7, 3.5)		Degree of perineal trauma, not episiotomy per se associated with dyspareunia.

Table 9. Episiotomy and future sexual function (continued)

Citation Epis. Type Country	Study Design N	Timing of Outcome Assessment after Birth; Approach	Outcome Assessed Definitions Provided	Outcome among Those with Episiotomy	Outcome among Those without Episiotomy	Results of Multivariable Models Authors' Conclusions
Karacam and Eroglu, 2003[72] Mediolateral Turkey	Prospective cohort N = 100	3 months Telephone interview	Any dyspareunia (not defined)	64.58%	54.17%	Not reported No significant differences between groups in rate of mothers' dyspareunia.
Sartore et al., 2004[71] Mediolateral Italy	Prospective cohort N = 519	3 months In-person interview	Current dyspareunia (not defined); classified as "absent, mild, moderate, severe"; reported Y/N	7.9%	3.4%	Summary measure: RR: 2.43 (1.05, 5.45)

These trials were designed primarily to assess rates of episiotomy and perineal trauma under different strategies to guide use of episiotomy. Restrictive use, as addressed in KQ 1, was hypothesized to result in less severe trauma among women with lacerations and in a higher proportion of women without perineal lacerations. If women experienced less perineal trauma, this improvement would be expected to be associated with less pain with future intercourse. Therefore, the Canadian trial team also undertook a separate analysis of the relationship between the degree of perineal trauma and sexual function. Using data from the 3-month interviews, they regrouped participants by perineal status that was systematically documented at the time of the index birth, creating a prospective cohort. In this cohort analysis, women with an intact perineum were most likely to have resumed intercourse by 6 weeks (76.5 percent), followed by those with spontaneous tears (62.5 percent), episiotomy alone (61.7 percent) and third- and fourth-degree lacerations (55.4 percent). Women with episiotomy had the slowest return to intercourse. Pain with the first intercourse followed a similar pattern.[34]

Prospective Cohorts. Signorello and colleagues were the sole research team from the United States to assess sexual function.[38] They documented trauma at the time of childbirth by chart review and followed up women at 6 months. They reported that the degree of trauma, rather than whether it resulted from episiotomy or spontaneous tear, was the primary determinant of pain with intercourse at 6 months. In prospective 6-month data, the risk of pain with intercourse was higher among those with second-degree trauma compared to no trauma (RR 1.3, 95% CI, 0.8-2.2), and highest with third- and fourth-degree trauma (RR 1.5; 95% CI, 0.7-3.5), although not statistically significant.

Table 10. Episiotomy and dyspareunia

Citation Country	Study Design Episiotomy Type	Timing of Outcome Assessment after Birth Approach	Outcome Assessed Definitions Provided	Outcome among Those with Episiotomy*	Outcome among Those without Episiotomy*	Authors Conclusions
Dyspareunia at 3 Months						
Rockner et al., 1988[80] Sweden	Prospective cohort Mediolateral: 88%	3 months Questionnaire (method not specified)	Current dyspareunia (not defined)	31/154 (20%)	9/46 (20%)	No significant difference
Larsson et al., 1991[81] Sweden	Prospective cohort Mediolateral: 98%	2 to 3 months In-person interview with midwife	Dyspareunia (not defined)	66/410 (16%)	69/627 (11%)	None made regarding sexual function
Sartore et al., 2004[71] Italy	Prospective cohort Mediolateral: 100%	3 months In-person interview	Current dyspareunia (not defined); classified as "absent, mild, moderate, severe"; reported Y/N	20/254 (7.9%)	9/265 (3.4%)	RR: 2.43 (1.08, 5.45)
Dyspareunia within 3 Months						
Rockner et al., 1988[80] Sweden	Prospective cohort Mediolateral: 88%	3 months Questionnaire (method not specified)	Any dyspareunia (not defined)	68/154 (44%)	20/46 (43%)	No significant difference
Karacam and Eroglu, 2003[72] Turkey	Prospective cohort Mediolateral: 100%	3 months Telephone interview	Any dyspareunia (not defined)	31/48 (64.58%)	26/48 (54.17%)	No significant differences between groups in rate of mothers' dyspareunia

Note: RR, relative risk; Y, yes; N, no.

These cohort studies do not find large or statistically significant differences in sexual function. Only one study identified lasting differences in dyspareunia at 3 months. Sartore and colleagues reported that women with episiotomy were more than twice as likely to have pain than those without episiotomy.[71] An aggregate estimate for current dyspareunia at 3 months can be estimated from three of the cohort studies using 818 women with episiotomy and 938 women without episiotomy.[71,80,81] We used meta-analysis techniques to calculate an aggregate risk ratio for the combined population of the prospective cohorts. In these studies, women with episiotomy were 54 percent more likely to have pain with intercourse 3 months after delivery (RR: 1.54, 95% CI: (I: 1.19, 2.00), with an absolute increase in risk of dyspareunia of 5 percent among women who had episiotomy: 14.3 percent versus 9.3 percent. Similar estimates for the two studies that assessed any dyspareunia during the 3 months after childbirth reveal no difference in the overall probability of having had painful intercourse. Among 50 women with episiotomy, 65 percent have had pain with intercourse and 50 women without episiotomy, 54 percent had had pain with intercourse but this was not statistically significant.[72]

Chapter 4. Discussion

The RTI International–University of North Carolina Evidence-based Practice Center (RTI–UNC EPC) identified a modest body of literature addressing the relationship between episiotomy and maternal outcomes. This chapter presents the conclusions from each of our key questions and discusses these conclusions in the context of our ratings of the strength of the body of evidence that we reviewed in detail in Chapter 3. Additionally, we discuss limitations of the review and this literature in general. Finally, we summarize needs for future research.

The focus of this systematic review is on maternal outcomes of "routine" episiotomy, with specific emphasis on five key questions:

KQ 1. Does the practice of liberal or routine episiotomy, compared to more selective use of episiotomy, influence maternal postpartum outcomes?
KQ 2. Does episiotomy incision type (i.e., midline or mediolateral) influence maternal postpartum outcomes?
KQ 3. Does the repair of the perineal defect (suture type and repair approach) influence maternal postpartum outcomes?
KQ 4. Does episiotomy have a long-term influence on urinary incontinence, fecal incontinence, or pelvic floor defects?
KQ 5. Does episiotomy or incision type, or both, influence future sexual function?

We have not assessed literature on maternal or fetal outcomes at the time of use in response to a maternal or fetal emergency or concurrent with use of vacuum or forceps. Moreover, much of the literature we did review to answer these key questions did not examine a full range of maternal outcomes.

Several elements of our review and approach to documentation warrant emphasis. First, conceptualizing "routine use" is a challenge because many studies describe the category by negatives such as "not for fetal distress" and "not for dystocia." Thus, we provide the operational definitions of "routine" (sometimes denoted as "liberal") and "restricted" use that authors of included publications used; in this way, readers may apply this information as a filter through which to view study findings. Second, readers need to appreciate that the majority of the included studies reflect outcomes of mediolateral episiotomy, rather than midline; the latter is the predominant approach used in the United States. For that reason, we specifically note the type of episiotomy used in individual studies in the text and tables throughout this report. Finally, we have developed detailed evidence tables (Appendix C[*]) that include these details as well as numerous other specifics of study design, measurement methods, and outcomes.

This systematic evidence review assessed 7 randomized controlled trials of routine versus restricted use of episiotomy and identifies the sole trial of midline versus median episiotomy. We present evidence from 17 randomized controlled trials (RCTs) that is relevant to choosing among options for repair methods. We have also extended prior reviews to encompass longer-term maternal outcomes. Specifically, we have systematically assessed the evidence from 3 trials and 12 prospective cohorts related to the influence of episiotomy on measures of pelvic floor relaxation and urinary and fecal continence and the evidence from 4 trials and 6 prospective cohorts that provide information about sexual function and satisfaction.

[*] Appendixes are provided electronically at http://www.ahrq.gov/clinic/tp/epistp.htm

As described in Chapter 3 and documented in our evidence tables, we gave close attention to grading the quality of individual studies. To complete the picture of the strength of evidence, we used that information and the collective picture of relevant work on each key question to arrive at a systematic rating of the overall strength of the evidence. To accomplish this, we created four ratings, based largely on past methods for this step from previous evidence reports of the RTI-UNC EPC, including systematic reviews performed for the U.S. Preventive Services Task Force. This approach employs four categories to describe the strength of evidence, as defined below:

I. The evidence is from studies of strong design; results are both clinically important and consistent with minor exceptions at most; results are free from serious doubts about generalizability, bias, or flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.
II. The evidence is from studies of strong design, but some uncertainty remains because of inconsistencies or concern about generalizability, bias, research design flaws, or adequate sample size. Alternatively, the evidence is consistent but derives from studies of weaker design.
III. The evidence is from a limited number of studies of weaker design. Studies with strong design either have not been done or are inconclusive. No published literature.

Table 11 uses these four categories to document our assessment of the strength of evidence for our main key questions (or subquestions). No key question reflected Grade I evidence (the best possible). The strength of evidence was Grade II for KQ 1 and one part of KQ 3. The evidence was poorer – Grade III – for KQ 2, most of KQ 3, KQ 4, and KQ 5. All key questions had some degree of evidence, so Grade IV was not relevant.

Table 11. Overall strength of the evidence for this body of literature

Key Question	Grade (I-IV Scale)*
1. Episiotomy and maternal postpartum outcomes	II
2. Episiotomy incision type and maternal morbidity	III
3. Repair of perineal defect and maternal morbidity	
Methods: 2-layer vs. 3-layer repair	III
Methods: Continuous vs. interrupted sutures	III
Materials: Absorbable vs. tissue adhesive	III
Materials: Absorbable sutures — standard vs. rapidly absorbed	III
Materials: Untreated catgut vs. treated catgut	III
Materials: Nonabsorbable vs. absorbable	III
Materials: Polyglycolic acid vs. chromic catgut	II
Combined methods and materials	III
4. Episiotomy and urinary incontinence, fecal incontinence, and pelvic floor defects	II
5. Episiotomy and future sexual function	II

Principal Findings

Key Question 1: Episiotomy and Maternal Postpartum Outcomes

This literature, spanning two decades from the mid-1980s to the present, has high internal consistency with respect to the postpartum effects of routine (or liberal) versus restrictive strategies for episiotomy use.[22,23,28-32] We found few if any meaningful discrepancies in findings, and overall we regarded this body of evidence as Grade II.

Across studies, women in the restrictive-use groups had less severe posterior perineal trauma, more frequent but not severe anterior vaginal trauma, less overall need for suturing, and higher probability of having an intact perineum when compared to routine- or liberal-use policies. These differences in perineal trauma were associated with less pain in the short term among those in restrictive-use groups, with fairly prompt resolution of pain regardless of trial arm. Women in restrictive use arms had no greater or lesser risk of wound healing complications and were more likely to resume intercourse earlier. Overall loss to followup was pronounced during the weeks after birth; remarkably little is known about recovery trajectory or complications thereafter.

Although these trials are of fair to poor quality overall, we base our conclusion that this evidence does not support routine use of episiotomy on the notable consistency of findings. Routine episiotomy does not achieve any of the short-term goals it has been hypothesized to achieve. Indeed, routine use is harmful to the extent that it creates a surgical incision of greater extent than many women might have experienced had episiotomy not been performed.

Key Question 2: Episiotomy Incision Type and Maternal Morbidity

On the question of midline vs. mediolateral episiotomy, only a single study found that women who had a midline episiotomy had a significantly greater rate of anal sphincter injuries than women in the mediolateral episiotomy group.[36] Treatment groups did not report differences in pain or satisfaction with intercourse at 3 months after the intervention.

Because of considerable methodological flaws in this trial (poor internal validity), any conclusions must be drawn cautiously, and we rate this "body" of evidence as Grade III. However, because differences in sphincter injury rates are clinically important, we consider the finding of increased risk of severe injury with midline episiotomy compared to mediolateral to be relevant observational evidence.

Key Question 3: Repair of Perineal Defect and Maternal Morbidity

Methods. Because of the heterogeneity of methods used for repair of episiotomies and perineal lacerations, overall conclusions are applicable only to the repair method under study. Generally, we rate the strength of evidence for these issues as Grade III except in one instance, mentioned below.

Two trials[60,63,66] studied a two-layer approach, in which the perineal skin is left unsutured, against a three-layer approach, in which the skin is sutured closed. Two trials[48,58] investigated the differences between a continuous (or subcuticular) method and an interrupted (or transcutaneous) method. Specific limitations of the trials and conclusions can be found below,

grouped by the particular method comparison under study. Overall limitations in this body of evidence and suggestions for future research are presented later in this chapter.

Two-layer vs. three-layer repair. Both trials provided consistent evidence that favored the two-layer approach, although statistically significant differences between the two approaches were not always found. The Ipswich Childbirth study had an overall good quality with adequate definitions and measurement of outcomes, reported masking of the outcome assessors and patients, and less than 15 percent loss to followup at 1 year.[60,63] Definitions and measurement of the outcomes were only fair in the other trial,[66] making it harder to compare to other trials. The latter trial also reported outcomes only on women who had completed all followup assessments; it did not report on possible differences between completers and the women who missed one or more followup assessments.

Because the two-layer approach involves less suturing, it also means less inflammation and bruising; this in turn could result in less pain and perineal morbidity. Another explanation for the differences may lie with suture type. In the first trial, which produced fewer significant differences between the approaches, the investigators balanced polyglycolic acid and chromic catgut sutures.[60,63]In the other trial, a portion of the significant differences between the groups may be explained by an imbalance in suture type used. Chromic catgut was predominantly used and is hypothesized to be associated with increased pain, edema, and inflammation.[66]

Even with the limitations discussed above, the pool of evidence from both trials suggests that less overall perineal morbidity is associated with the two-layer repair approach, which leaves the perineal skin unsutured, than with the three-layer approach. The reduction in pain, need for analgesia, wound healing problems, and sexual morbidity, as well as a decrease in the time and cost required for initial suturing of the perineal skin, removal, and possible resuturing, may make the two-layer approach more beneficial than the traditional three-layer approach.

Continuous vs. interrupted sutures. Although the evidence is unclear, it suggests that a continuous method of repair, though it may be technically more difficult, may be superior to the interrupted method. Two good-quality trials produced inconsistent evidence that the continuous method of repair has less perineal morbidity and more patient satisfaction associated with it than the interrupted method of repair.[48,58]

Both trials, through a factorial design of randomization, also randomized women to different suture material groups. Both trials achieved valance with respect to suture type; authors represented results for methods of repair regardless of suture type. Both trials defined and measured outcomes well and achieved good followup. In both trials, the authors describe greater familiarity with the interrupted method of repair, which is said to be technically easier to perform than the continuous method. One clinical group (for the trials conducted in Southmead, United Kingdom) even suggests that their inconsistencies with other trials might have be attributable to the lack of practice with the method and subsequent unpopularity with the operators that performed the repair.[58] Whether such differences in outcome arise for clinicians and women outside the United Kingdom, where methods of repair and training of those performing the repair could be different compared to other countries, remains to be seen.

Materials. Because this review includes trials dating back to 1974, the materials used differ over time. Two trials[47,64] compared absorbable sutures with tissue adhesive; two trials[48,62] compared absorbable sutures with their rapidly absorbed versions; one trial[56] compared untreated with treated catgut; two trials[54,58] compared nonabsorbable sutures with absorbable sutures; and eight trials[50-53,58,59,61,63,65] compared polyglycolic acid with chromic catgut. Because of this heterogeneity, specific limitations of the trials and conclusions can be found below, grouped by

the particular material comparison under study. Overall limitations in this body of evidence and suggestions for future research can be found later in this chapter.

Absorbable vs. tissue adhesive. Both trials[47,64] were of poor quality because the method of randomization was inadequate or broken. However, even though sample size was small ($n < 65$ in both trials), both groups did define and measure perineal pain well and achieved good followup. These trials contribute possible evidence that repair with tissue adhesive may decrease perineal pain experienced in different situations in the immediate postpartum. This conclusion must be weighed in light of the inadequate randomization of these studies. Our review suggests that this question merits further study in a well-randomized trial.

Absorbable sutures: standard vs. rapidly absorbed. The mixed results from the good trial[48] and lack of significant differences between groups in the poor trial[62] suggest that evidence is insufficient about any difference in perineal pain between standard and rapidly absorbed sutures. We saw stronger evidence that women who had rapidly absorbed sutures required less removal of the material, presumably because it had been absorbed more quickly in the postpartum period. We had difficulty assessing the effect of type of absorbable suture on other healing outcomes because the poor trial grouped all outcomes together. Although the two trials evaluated sexual functioning at different time points, evidence suggests that rapidly absorbed sutures may decrease the amount of dyspareunia and the severity thereof in the puerperium. One item to note in the good-quality trial was the masking of the suture material. The trial acquired undyed sutures direct from the manufacturer, thereby achieving a very high level of internal validity and decreasing the amount of bias in assessment of the outcomes.

Untreated catgut vs. treated catgut. Only one trial addressed treated and untreated catgut.[56] This trial achieved fair randomization and was able to blind the assessors and the patients. Loss to followup at 10 days and 3 months was minimal, but at 3 years, loss to followup was only fair (70 percent). A small amount of crossover to the other suture material group occurred, but the investigations did perform an intent-to-treat analysis.

This trial produced no evidence that "softgut" (i.e., treated catgut) is superior to untreated catgut with regard to perineal morbidity. In fact, the trial may indicate that softgut may be associated with higher morbidity, as there appeared to be more perineal pain in the immediate postpartum period and more painful sexual intercourse in the longer-term period. Though untreated catgut sutures needed to be removed more often, the authors attributed the difference to the tendency for the sutures to dry out. However, they speculated that such drying out could not completely explain the differences in perineal pain.

The women were repaired using different techniques, but the randomized groups were balanced in that respect. Investigators used the interrupted method approximately 60 percent of the time in both groups. Stratifying by technique of repair showed more marked dyspareunia and need for suture removal in women who were repaired using interrupted sutures, a finding that is consistent with other trials investigating method of repair

Nonabsorbable vs. absorbable. Because of the study design of the fair-quality trial[54] and lack of control for possible confounding by method of repair, we cannot draw conclusions about the role of silk sutures in perineal morbidity from this trial. The authors present data by suture material and then do not mention differences in the methods until the conclusions section of their article. They concluded that the subcuticular method lent itself to short-term advantages, but they did not present the data to support their conclusion. Thus, although this trial may contribute to a body of evidence that looks at combinations of materials and methods, it does not contribute to the overall understanding of the role of suture materials in perineal morbidity, separate from methods of repair. The Mahomed et al. trial[58] found no differences between the two groups in

the short-term postpartum period, but did find differences at 3 months, indicating a possible delayed effect of the suture material.

Polyglycolic acid vs. chromic catgut. In 2004, the Cochrane Library published a systematic review and meta-analysis of information on polyglycolic acid versus catgut suture material for repair of perineal trauma.[82] In it, they report that polyglycolic acid sutures were associated with less pain in the short-term postpartum period (Odds ratio [OR] = 0.62; 95% confidence interval [CI], 0.54-0.71) and with less need for analgesia (OR = 0.63; 95% CI, 0.52-0.77). No differences were found in long-term pain outcomes or in reports of dyspareunia.

Our systematic evidence review includes six of the eight trials that were included in the Cochrane review and an additional two trials. Overall, the evidence is from a combination of poor, fair, and good trials, but we considered the strength of evidence as Grade II; moreover, it is consistent with the previous Cochrane review. Basically, evidence indicates that polyglycolic acid sutures are associated with less perineal pain, a lesser need for analgesia use, and fewer healing problems in the short-term postpartum. For long-term outcomes, the evidence is consistent that outcomes of the use of polyglycolic acid sutures and chromic catgut do not differ substantially. One trial not in the Cochrane review[65] did report more perineal pain and dyspareunia in the polyglycolic-acid group at 6 months, an outcome the authors attributed to the slower absorption rate of polyglycolic-acid sutures; however, these results were neither statistically significant nor precise. Overall, the body of evidence for the comparison of polyglycolic-acid sutures versus chromic-catgut sutures suggests that using polyglycolic-acid sutures for perineal repair offers many short-term advantages.

Combined Methods and Materials. Instead of investigating methods and materials separately, two trials[49,55] compared entire approaches, combining both materials and methods in a single randomization design. The poor trial[49] found no differences between the groups; the fair-quality trial[55] found that women repaired with polyglycolic-acid sutures using a continuous, subcuticular approach suffered less perineal morbidity. This result is consistent with other trials that investigated subcuticular suturing and polyglycolic-acid sutures separately, perhaps reinforcing the notion that this method and suture type are superior to other options available to obstetric clinicians. Overall limitations in this body of evidence and suggestions for future research are provided later in this chapter.

Summary. The heterogeneity of methods and materials used for repair of episiotomy and perineal laceration arises in part from the passage of time and differences in practice across continents. Another set of issues to consider in studying the repair of episiotomy are the economic and geographic differences among clinical practices across the world. The choice of suture material might be restricted in resource-poor settings. If a clinic cannot afford or does not have access to polyglycolic acid, which, as reported in one of the studies,[66] is more expensive than other absorbable sutures, then the clinic may have to make do with available sutures but perhaps supplement them with a method of repair that can decrease perineal morbidity.

During the time period that this review encompasses, investigators studied three major classes of suture material (nonabsorbable, absorbable, and tissue adhesive) and two subtypes of sutures (treated versus untreated and standard versus rapidly absorbed). These materials were all studied in the presence of different approaches to the method of suturing; therefore, individual effects of the materials themselves cannot be examined. Likewise, the methods of repair were examined in the context of different materials among the studies and within them for different stages of repair. For these reasons, truly determining the effects of a certain method of repair is impossible, because we are unable to tell whether the outcomes are confounded or modified by suture material.

Key Question 4: Episiotomy and Urinary Incontinence, Fecal Incontinence, and Pelvic Floor Defects

The literature that provides evidence about routine episiotomy, continence, and pelvic floor defects and function is limited in several domains. All but two of the cohorts[34,75] report outcomes for use of mediolateral episiotomy rather than midline episiotomy. The length and incompleteness of followup limits the usefulness of the data. We aimed to identify publications with followup ranging from years to decades after births to women with known episotomy histories. However, at completion, only five of 16 publications provide data with followup at 1 year or longer;[33,68-70,74] the longest interval was 5 years.[69] Followup conducted within 6 months of birth, as in 10 percent of the 16 studies, does not reflect full recovery of the pelvic floor from vaginal birth. For that reason, we considered 6 months followup as an intermediate point of comparison rather than an evaluation of final pelvic floor and continence status.

All measures for followup at or beyond a year were self-reported by interview or questionnaire except a single study with perineometry conducted at 12 months.[68] Neither self-report for many urinary and rectal continence symptoms nor perineometry and physiologic measures have been adequately validated. These measures do not relate directly to physical examination findings or individual functional status. Indeed, urodynamic testing and physical examination have very limited documentation of their ability to predict or classify continence status. These limitations must be kept in mind. The greatest clinical relevance would be to assess continence and pelvic floor deficits among women with known episiotomy histories beginning in their 40s and proceeding through their lifetimes. None of the identified studies provided such data.

Given these limitations of timing and methods of followup, these prospective studies did not identify improvements in continence for urine or stool or in pelvic floor muscle function among women who had had episiotomy compared to those who had not. This finding includes comparison to women who had spontaneous lacerations of similar severity. Several authors reported decrements in pelvic floor function among women who had episiotomy. Only a single study, using multivariable models, found that episiotomy was an independent predictor of urinary continence.[69] In the majority of other studies using multivariate models, adjusting for factors such as parity, neonatal weight, and length of second-stage labor revealed that episiotomy was not an independent risk factor for incontinence. Taken in total, this literature, predominantly of fair to poor quality, does not support use of episiotomy for the purpose of preventing pelvic floor defects, urinary incontinence, or incontinence of stool or flatus. Table 11 shows this as graded strength of evidence Grade III.

In summary, these prospective studies are limited because they do not follow women long enough to detect disease occurrence. At present, the assumption that intermediate variables such as pelvic muscle strength measured by perineometry, urodynamic test results, or early reports of symptoms can predict later disease has not been validated. Prospective evaluation only during the months after birth when the pelvic floor is still in a recovery and stabilization period may be misleading. Conclusions about whether episiotomy prevents or increases risk for incontinence and prolapse later in adult life cannot be reached from currently available randomized and cohort studies.

Key Question 5: Episiotomy and Future Sexual Function

The studies addressing this question need to be considered in three groups: the six studies that virtually exclusively evaluate effects of mediolateral incision,[23,33,71,72,80,81] three that evaluate midline (median) incision,[29,34,38] and one that compared the two incision types.[36] From just the clinical trials of episiotomy strategy — liberal versus restrictive — one trial addresses each type of incision, and one directly compares the two incision types. None finds substantive differences in sexual function. Overall, this body of literature supports a conclusion that perineal trauma is associated with probability of pain with intercourse in a dose-response fashion such that greater perineal injury is associated with greater probability of pain.

The quality of the evidence (to which we assigned Grade III) to assess this question is limited for reflecting on the consequences of episiotomy. Both the clinical trials and the prospective cohorts assess overly simplified measures of sexual function. Definitions and specification of approaches to measurement are insufficient in many studies to assure accurate interpretation of findings. Validated instruments intended to assess nuances of sexual function such as type of pain, location of pain, severity of pain, orgasm, lubrication, and libido have not been deployed in the published research to assess prospectively the influence of perineal trauma in childbirth on future sexual function. More complex measures would need to be used to understand properly relationships between perineal trauma and future sexual function. Specific factors such as prior sexual function and current libido, in addition to factors such as duration of second-stage labor, size of infant, and lactation status need to be incorporated into multivariable models to generate more-informative and less-biased estimates of the long-term effects of episiotomy in this area. With these caveats, the evidence does not suggest that episotomy results in improved sexual function outcomes.

Limitations of This Review and the Literature

Deficiencies in The Literature

Our systematic review should be interpreted in the context of several limitations. First, as with all systematic reviews, its findings depend on the predefined approach to searching the literature and on the quality of the published literature identified. The limitations of the available studies (see Chapter 3) include the following:

- age of the data (trials from the 1980s and early 1990s were conducted in an era when background rate of episiotomy was higher);
- insufficient size of most trials for assessing clinically relevant endpoints (third- and fourth-degree lacerations, long-term incontinence);
- inadequate specification of *a priori* primary and secondary outcomes with few references to power calculations to determine required study size;
- infrequent use of multivariate modeling to account for shortcomings of randomization or need for stratification within RCTs or potential confounders in prospective cohort studies;
- infrequent use of masking of the assessor for outcomes;

- use of a wide variety of measures and timepoints for maternal postpartum outcomes, making comparisons among studies difficult;
- rare use of validated outcome measures;
- limited reporting of precise definitions of self-reported outcomes, particularly for pain, sexual function, and incontinence; and
- inconsistent reporting of appropriate statistical measures (i.e., use of *P* values without measures of magnitude or confidence intervals), making it difficult to determine if null findings represent lack of effect or limitations in power.

An additional limitation of the literature on KQ 1 results from the nature of the intervention. In essence, KQ 1 reviews studies of clinician behavior when asked to implement different policies for episitomy use. Differences in episiotomy rates observed in groups assigned to routine (i.e., liberal) use vary from a low of 23 percent[29] to a high of 52 percent,[30] suggesting that clinician behavior is not easily modified, even in the context of an RCT. Inconsistencies in the way that clinicians define and interpret routine use and restricted use of episiotomy within and across trials may temper differences between protocol groups. Additionally, violations of protocol can invalidate initial power calculations and lead to results that cannot be interpreted.

Limitations to Our Review Procedures

Our review process also had some limitations. Because of time and resource constraints, we did not conduct dual, independent, blinded review of articles for inclusion or abstraction of information into evidence tables. Instead, one reviewer performed the initial review, and a second reviewer examined that input and recommended changes. Differences were reconciled between the two reviewers. We used dual review for grading the quality of individual articles, allowing us to evaluate rigorously systematic bias in these assessments.

Future Research

Studies comparing restrictive to liberal use of episiotomy report that, even under a restrictive approach, episiotomy rates vary between 8 percent and 52 percent.[22,23,28-32] This disparity suggests that episiotomy is considered to be clinically indicated for a substantial number of women even at the lowest levels recorded by our review. Currently, the evidence suggests that the putative benefits of episiotomy do not outweigh the harms in the general population. Instead, outcomes from episiotomy are worse because some proportion of women who would have had lesser injury instead had a surgical incision.

The majority of these studies to assess outcomes of routine episiotomy used mediolateral episiotomy. We do not, however, conclude that additional study of outcomes of routine use versus liberal use of *midline* episiotomy is warranted. Observational studies other than RCTs clearly and consistently relate midline episiotomy to higher rates of anal sphincter and rectal injury than those observed with mediolateral episiotomy.[9,40,42,83] Thus, we would expect trials of routine use of midline episiotomy to have more numerous unfavorable outcomes than those observed in these studies, an effort not worth replicating given the lack of benefit of episiotomy supported by existing evidence.

If episiotomy were restricted to indicated use, an important question remains for women and their care providers: Which, if any, of the prevailing indications for episiotomy are supported by an adequate research base? A two-stage research agenda could address this need. First, a

systematic review may clarify current knowledge about outcomes of episiotomy for the leading presumed indications. Second, primary data collection may be needed to fill in research gaps identified by such a review and to improve understanding of whether these are indeed indications for episiotomy. Work relating to the latter element of such a research agenda is under way on several topics including recent publication of a retrospective cohort study that suggests that use of episiotomy conferred no benefit in averting neonatal injury at the time of births complicated by shoulder dystocia.[84] Additional evidence will be required to fully investigate what circumstances should be considered indications for episiotomy.

Establishing an evidence base for indications would lead to a health services research agenda focused on variations in rates and outcomes. Several issues are paramount: What safe and conservative rates of episiotomy are attainable? Should measures of quality of childbirth care include episiotomy rates? What approaches are most successful in reducing unnecessary use of episiotomy?

Furthermore, if the professional community accepts that routine episiotomy is not an effective means to reduce perineal injury, that attitude should enable them to redouble efforts to understand fully various (other) approaches to attending the second stage of labor that can promote maternal and infant safety, minimize perineal trauma, and maximize maternal comfort. The failure of one intervention-oriented method such as episiotomy to deliver such results does not reduce the likelihood that other approaches, or combinations of approaches, may be useful. These approaches include giving attention to maternal position, avoiding fundal pressure, reducing coached pushing, providing perineal support, and employing "hands poised" versus hands on techniques to support the perineum, and the role for lubrication and types of lubrication for use during crowning of the infant head. Any or all of these techniques may help women and their care providers reach desired outcomes more frequently and deserve to be subjected to rigorous study.

Researchers must also continue to investigate the relationship between self-care practices such as Kegel pelvic floor exercises, general physical fitness, and nutrition, and the risk for pelvic floor defects including incontinence and prolaspes. To the degree that pelvic floor recovery can be facilitated or "rehabilitation" achieved by nonsurgical means, numerous women would benefit from such research. To understand pelvic floor defects and childbirth experiences properly, including history of episiotomy, studies need to be designed to identify populations of women who have a known episiotomy history to evaluate their continence and pelvic organ prolapse status in the age groups between 40 and 70 years.

Understanding the relationship of pelvic floor morbidity to childbirth experiences will require increasingly sophisticated analysis methods and study designs. Evaluation and incorporation of confounders and modifiers of the effect of exposure must become the norm for prospective data analysis. Factors such as maternal race and ethnicity, body mass index, infant birth weight, duration of second-stage labor, duration of strenuous pushing, and elements of reproductive history such as outcomes of prior births require attention. Cohorts of women who participated in perinatal research in the 1980s will soon enter the timeframe in which meaningful followup of pelvic floor status can be obtained.

Future research on sexual function and sexuality after childbirth is needed. Very limited data are available even to describe what women should expect as normal. Research will need to take into account breastfeeding status, episiotomy and laceration history, repair methods, and contraceptive type. Greater attention is needed to distinguish dyspareunia and characteristics that help describe dypareunia (an anatomic symptom), from "satisfaction" with its components of relationship quality, sexual aptitude, and cerebral contribution, and from ability to achieve and

consistency of achieving orgasm. Sexual function outcomes need to be regarded as appropriate primary research aims so that these concerns do not remain secondary measures with insufficient attention to reach meaningful answers.

Our review of the literature on the repair of perineal defects points to another avenue for further research. Clinical judgment suggests that the perineal outcome of repair is a function of both materials and methods. Consistencies in the evidence from the studies of repair (e.g., polyglycolic-acid sutures are better than chromic catgut; continuous suturing is better than interrupted suturing) can be used to inform future studies in more creative randomization designs or multivariate analyses. More sophisticated designs might allow a trial to compare complete approaches to repair rather than individual components, such as the studies performed by Doyle et al.[49] and Isager-Sally et al.[55]

One clinically relevant study might compare combinations of the materials and methods that seem to decrease morbidity (e.g., subcuticular polyglycolic-acid sutures) with new materials such as tissue adhesive that enter the market with (unproven) claims of reduced perineal morbidity. Unless multivariate models are used to tease out mixed-effects of methods and materials or future research begins randomizing groups to entire approaches to repair, results can be informative and applicable to a population only to a certain point. The gap in information may mean that, in the future, women who are receiving appropriate episiotomies may still not receive a thorough repair. Some observers, however, may regard mounting such a trial as questionable. Thus, a useful first step might be to develop sample-size estimates based on a range of important outcomes and, in this way, to determine whether such a trial is even feasible to attempt.

Conclusion

Our systematic review finds no health benefits from episiotomy. We found fair to good evidence suggesting that the immediate outcomes for routine (liberal-use policies) episiotomy are no better than those for indicated use of episiotomy under more restrictive-use policies. Indeed, routine use is harmful to the extent that it creates a surgical incision of greater extent than many women might have experienced had episiotomy not been performed. Weak trial evidence, consistent with observational data, suggests that the harms of midline episiotomy are greater than the harms of mediolateral episiotomy.

For outcomes of repairing an episiotomy, fair to good evidence, albeit across different comparisons of methods and materials, suggests that leaving the perineal skin unsutured may confer some benefit; if suturing is indicated, then a continuous, subcuticular method is better than an interrupted, transcutaneous method. Regarding suture material, the evidence is consistent and clear that absorbable sutures are preferred and that polyglycolic-acid sutures have significantly less perineal morbidity associated with them. Newer materials, such as tissue adhesive, may offer further benefits, but the data are at present wholly inadequate to inform care practices.

The level of evidence for long-term sequelae, specifically fecal and urinary incontinence, pelvic floor function, and future sexual function is fair to poor. Nonetheless, it is consistent in demonstrating the lack of benefit of the procedure in a comparatively early timeframe. For women in later adult life, when morbidity is most likely to occur in the form of severe and persistent incontinence or pelvic organ prolapse, the expected results of routine episiotomy are unknown.

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Listing of Excluded Studies

Codesheet for Episiotomy SER ProCite Database

Field in ProCite	Code	Meaning of Code	Description & Comments
Field Number: 11 Original field name: Title **Labeled as: Abstract Inclusion/Exclusion** *(From the Abstract Review Form)*	**I**	Abstract included	Article was pulled for review
	E	Abstract excluded	Article was NOT pulled for review
	B	Background	Article was excluded from the review but pulled for background
Field in ProCite	**Code***	**Meaning of Code**	**Description & Comments**
Field number: 12 Original field name: Reprint Status **Labeled as: Full Text Inclusion/Exclusion** *(From the Full Text Inclusion/Exclusion form)*	**I**	Full text included	"Full text INCLUDED" is checked at the end of the form
	B	Background	"Full text EXCLUDED but used for BACKGROUND CITATION" is checked at the end of the form; these articles, because they are excluded, will also have an exclusion code(s) in this field
	U	Unavailable	The article was to be pulled for review but was not retrievable by the libraries
	E	Full text excluded-Unclassified	These articles are obvious excludes but the reviewers did not agree on the reason…this may be settled in the future **SETTLED 11/12/04**
	E1	Full text excluded - Not original research	#1 is "No"

**Please note: An article could be excluded for more than one reason if the reasons are E3-E6*	**E2**	Full text excluded - Wrong population	#2 is "No"
	E3	Full text excluded - N<40	#3 is "No"
	E4	Full text excluded - Wrong outcome and/or study design	#4 is "No"
	E5	Full text excluded - Foreign language	#5 is "No"
	E6	Full text excluded - Wrong time period	#6 is "No"

**More than one code can be entered into this field. Separate codes with a comma*

Field in ProCite	**Code***	**Meaning of Code**	**Description & Comments**
Field number: 13 Original field name: Place of Meeting **Labeled as: Key Questions Addressed** *(From the Full Text Inclusion/Exclusion form)*	1	Addresses KQ1	Enter if box is checked under "Outcomes and Key Questions"
	2	Addresses KQ2	Enter if box is checked under "Outcomes and Key Questions"
	3	Addresses KQ3	Enter if box is checked under "Outcomes and Key Questions"
	4	Addresses KQ4	Enter if box is checked under "Outcomes and Key Questions"
	5	Addresses KQ5	Enter if box is checked under "Outcomes and Key Questions"

**More than one code can be entered into this field. Separate codes with a comma*

Field in ProCite	Code	Meaning of Code	Description & Comments*
Field Number: 14 Original field name: Medium Designator **Labeled as: Background-Hand Searched**	**Y**	Yes	The reference list of this background article was hand-searched for additional references
	N	No	The reference list of this background article was not hand-searched for additional references

**These articles have a "B" in field number 11 or field number 12. This field will be blank for all other articles.*

Field in ProCite	Code	Meaning of Code	Description & Comments
Field Number: 15 Original field name: Edition **Labeled as: Study Design**	**RCT**	RCT	This study was a randomized-controlled trial
	COHORT	Prospective Cohort	This study was a prospective cohort

Episiotomy no longer routine procedure. Health News 2000-2001; 17(6):3.
Full text inclusion/exclusion: E1

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Full text inclusion/exclusion: E1

Solutions, techniques and pressure for wound cleansing. Best Practice 2003; 7(1):1-6.
Full text inclusion/exclusion: E1

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Table 1. Inclusion/exclusion criteria

Category	Criteria
Study population	Humans
Study settings and geography	Inpatient, outpatient, home; all geographical locations subject to publication language and study design criteria
Time period	1950 through 2004
Publication languages	English only
Sample size	N greater than or equal to 40
Admissible evidence (study design and other criteria)	Original research studies that provide sufficient detail regarding methods and results to enable use and adjustment of the data and results For studies on KQ 1 and KQ 3 RCTs: double-blinded and single-blinded designs For studies on KQ 2, KQ 4 and KQ 5 RCTs: double-blinded and single-blinded designs Non-RCTs: prospective cohort studies Relevant outcomes must be able to be abstracted from data presented in the papers

Table 2. Focused search terms and results from MEDLINE®

Search Terms	Results
"Episiotomy" [MeSH] Field: All Fields, Limits: English, Randomized Controlled Trial, Human	75
"Episiotomy" [MeSH], English, Review, Human	68
Labor Stage, Second [mh], English, Review, Human	40
Labor Stage, Second [mh], English, Randomized Controlled Trial, Human	58

Table 3. Additional search terms and results from MEDLINE®

Search Number	Search Terms	Results
#1	"Episiotomy"[MeSH:NoExp] Field: All Fields, Limits: English, Human	676
#2	"Episiotomy" English, Editorial, Human	14
#3	"Episiotomy" English, Letter, Human	58
#4	"Episiotomy" English, Review, Human	68
#5	"Episiotomy" English, Meta-Analysis, Human	3
#6	"Episiotomy" English, Practice Guideline, Human	0
#7	#2 OR #3 OR #4 OR #5 OR #6	140
#8	#1 NOT #7	536
#9	Repair	138,222
#10	#1 AND #9	86
#11	labor stage, second [mh]	638
#12	#9 AND #11	6
#13	(("Episiotomy" OR “pregnancy”) AND (“midline" AND "mediolateral")) [MeSH:NoExp] Field: All Fields, Limits: English, Human	11
#14	(("Episiotomy" OR “pregnancy”) AND (“sphincter")) [MeSH:NoExp] Field: All Fields, Limits: English, Human	3

Table 4. Results of randomized controlled trials of liberal versus restrictive use of episiotomy: Perineal trauma

Citation Country Episiotomy Type Number	Inclusion Parity	Groups Episiotomy Use	Outcome(s)	Outcome among Liberal-Use Group	Outcome among Restrictive-Use Group	Authors' Conclusions
Sleep et al., 1984[23] United Kingdom Mediolateral N = 1,000	Term, singleton pregnancy Anticipated NSVD 40%-46% primiparous	G1: Liberal = "try to prevent a tear" G2: Restrictive = "try to avoid episiotomy and restrict to fetal indications" G1: 51.4% G2: 10.2%	Intact Third or fourth degree Any suturing	24.3% n = 1 Primip: 89% Multip: 69%	33.9% n = 4 Primip: 74% Multip: 66%	Restricting use of episiotomy neither increased nor decreased problems experienced by mothers.
Harrison et al., 1984[22] Ireland Mediolateral N = 181	Term, primigravid, anticipated vaginal birth	G1: Mediolateral episiotomy routinely conducted G2: No episiotomy unless "medically necessary" G1: 44.9% G2: 7.6%	Intact Third or fourth degree	Not reported 6%	21% None	Primigravid patients allocated to not undergo episiotomy generally fared better than they would have done with normal hospital practices. Forty-six percent had no or only first-degree tears.
House et al., 1986[28] United Kingdom Mediolateral N = 165	Term, vertex, anticipated NSVD 53%-68% primiparous	G1: Standard current management G2: Episiotomy not performed to prevent laceration G1: 69% G2: 18%	Intact or first degree Second degree = Episiotomy or second degree Third degree	Primip: 4% Multip: 26% Primip: 96% Multip: 70% Primip: 4% Multip: 4%	Primip: 32% Multip: 54% Primip: 68% Multip: 45% Primip: None Multip: None	Restrictive policy resulted in a significant increase in the incidence of patients with intact perineum or only a first-degree tear.

Table 4. Results of randomized controlled trials of liberal versus restrictive use of episiotomy: Perineal trauma (continued)

Citation Country Episiotomy Type Number	Inclusion Parity	Groups Episiotomy Use	Outcome(s)	Outcome among Liberal-Use Group	Outcome among Restrictive-Use Group	Authors' Conclusions
Klein et al., 1992[29] Canada Midline N = 730	Term, singleton; anticipated NSVD 50%-52% primiparous	G1: Liberal = avoid tear G2: Restrictive = attempt to avoid episiotomy G1: Primip: 81% Multip: 52% G2: Primip: 47% Multip: 31%	Intact (no suturing) Episiotomy alone Third or fourth degree	Primip: 6.6% Multip: 19.3% Primip: 67.2% Multip: 45.2% Primip: 7.9% Multip: 0%	Primip: 7.5% Multip: 30.7% Primip: 42.2% Multip: 29.0% Primip: 13.9% Multip: 0%	No evidence that liberal use prevents perineal trauma; restriction of episiotomy use among multiparous women results in significantly more intact perineums and less suturing.
Argentine Episiotomy Trial Collaborative Group, 1993[30] Argentina Mediolateral N = 2,606	Term, singleton first or second vaginal birth; no prior cesarean or severe perineal trauma 40%-41% primiparous	G1: Routine G2: Selective G1: 82.6% G2: 30.1%	Perineal suturing Third or fourth degree	88.1% Primip: 1.8% Multip: 0.9%	63.1% Primip: 1.4% Multip: 0.8%	No evidence that routine use of episiotomy reduces risk of severe perineal trauma.

Table 4. Results of randomized controlled trials of liberal versus restrictive use of episiotomy: Perineal trauma (continued)

Citation Country Episiotomy Type Number	Inclusion Parity	Groups Episiotomy Use	Outcome(s)	Outcome among Liberal-Use Group	Outcome among Restrictive-Use Group	Authors' Conclusions
Eltorkey and Nuaim, 1994[31] Saudi Arabia (British staff) Mediolateral N = 200	Term, singleton, vertex, primiparous; anticipated NSVD	G1: Elective G2: Selective = essential G1: 83%* G2: 53%*	Intact Second degree or episiotomy without extension Third degree or episiotomy with extension	7% 71%* None	28% 49%* None	Selective group more likely to have an intact perineum. No indication that episiotomy offers clear benefit in terms of decreased numbers of lacerations.
Dannecker et al., 2004[32] Germany Mediolateral N = 109	>34 weeks, singleton, primiparous; anticipated NSVD	G1: Liberal = if tear imminent and/or fetal indications G2: Restrictive = fetal indications only G1: 77% G2: 41%	Intact Third degree	10% 8%	29% 4%	Restrictive use resulted in three-fold increase in the rates of intact perinea. No difference with regard to third-degree tears.

G, group; primip, primiparous; multip, multiparous; NSVD, normal spontaneous vaginal delivery.

*Text and tables in this publication are not concordant; overall incidence from text; second degree and episiotomy totals from table.

Table 5. Results of randomized controlled trials of liberal versus restrictive use of episiotomy: Pain outcomes

Citation Country Episiotomy Type Number	Inclusion Parity	Groups Episiotomy Use	Outcome(s): How Measured? When?	Outcome among Liberal-Use Group	Outcome among Restrictive-Use Group	Authors' Conclusions
Sleep, 1984[23] United Kingdom Mediolateral N =1000	Term, singleton pregnancy, anticipated NSVD* 40%-46% primiparous	G1: Liberal = "try to prevent a tear" G2: Restrictive = "try to avoid episiotomy and restrict to fetal indications" G1: 51.4% G2: 10.2%	Pain severity in prior 24 hours; questionnaire administered by midwife; 10 days postpartum Worst pain in past week; postal questionnaire; 3 months postpartum	10 days Mild: 14.6% Mod: 7.8% Severe: 0.2% 3 months Mild: 5.7% Mod: 1.8% Severe: 0.2%	10 days Mild: 14.1% Mod: 7.5% Severe: 0.9% 3 months Mild: 4.6% Mod: 2.5% Severe: 0.5%	No significant differences between the two groups in maternal pain at 10 days and 3 months postpartum.
House et al., 1986[28] United Kingdom Mediolateral N = 165	Term, vertex, anticipated NSVD* 53%-68% primiparous.	G1: Standard current management G2: Episiotomy not performed to prevent laceration G1: 69% G2: 18%	Pain severity; interview by one of authors using VAS scale 1 to 10 with 1-3 grouped as minimal; 4-6 moderate; 7-10 severe; 3 days; 6 weeks; 3 months	3 days Mild: 55% Mod: 34% Severe: 11% No differences at 6 weeks and 3 months	3 days Mild: 68% Mod: 22% Severe: 10% No women in either group with more than minimal pain at 3 months	Pain symptoms on the third day postpartum were on average reduced in the patients in whom the use of episiotomy was restricted and equivalent thereafter.

Table 5. Results of randomized controlled trials of liberal versus restrictive use of episiotomy: Pain outcomes (continued)

Citation Country Episiotomy Type Number	Inclusion Parity	Groups Episiotomy Use	Outcome(s) How Measured? When?	Outcome among Liberal-Use Group	Outcome among Restrictive-Use Group	Authors' Conclusions
Klein et al., 1992[29] Canada Midline N = 730	Term, singleton; anticipated NSVD 50%-52% primiparous	G1: Liberal = avoid tear G2: Restrictive = attempt to avoid episiotomy G1: Primip: 81% Multip: 52% G2: Primip: 47% Multip: 31%	Perineal pain measured by 10 individually scored items using the McGill Pain Questionnaire at 1, 2, and 10 days postpartum	First day Primip: 1.8±0.8 Multip:1.3±0.8 Second day Primip: 1.3±0.7 Multip:0.9±0.7 Tenth day Primip:0.5±0.5 Multip: 0.3±0.4	First day Primip: 1.7±0.8 Multip:1.3±0.9 Second day Primip: 1.4±0.8 Multip: 0.9±0.8 Tenth day Primip: 0.5±0.5 Multip: 0.3±0.5	No significant differences in perineal pain and pain with urination at 1, 2, and 10 days postpartum for individual pain scale items or composite score
Argentine Episiotomy Trial Collaborative Group, 1993[30] Argentina Mediolateral N = 2,606	Term, singleton first or second vaginal birth; no prior cesarean or severe perineal trauma 40%-41% primiparous	G1: Routine = do according to hospital's policy before trial G2: Selective = try to avoid, do only for fetal indications or if severe tear is imminent G1: 82.6% G2: 30.1%	Perineal pain (not clearly defined), assessment method not clearly delineated, physician masked to allocation evaluated on day of discharge	42.5%	30.7%	Perineal pain was less common in the restrictive use group.

G, group; primip, primiparous; mod, moderate; multip, multiparous; NSVD, normal spontaneous vaginal delivery.

Table 5. Results of randomized controlled trials of liberal versus restrictive use of episiotomy: Pain outcomes (continued)

Citation Country Episiotomy Type Number	Inclusion Parity	Groups Episiotomy Use	Outcome(s) How Measured? When?	Outcome among Liberal-Use Group	Outcome among Restrictive-Use Group	Authors' Conclusions
Dannecker et al., 2004[32] Germany Mediolateral N = 109	>34 weeks, singleton, primiparous; anticipated NSVD	G1: Liberal = if tear imminent and/or fetal indications G2: Restrictive = fetal indications only G1: 77% G2: 41%	Perineal pain in postpartum period (days 1 to 5) on 100 mm visual analog scale anchored at "not at all" and "very much" for a range of activities; approach to measurement not clearly specified	Bedrest: 39±28 Sitting: 69±23 Walking: 56±24 Defecation: 36±30	Bedrest: 22±21 Sitting: 51±25 Walking: 37±24 Defecation: 21±21	Women in the restrictive group had considerably lower perineal pain scores in all activities assessed during the first 5 days postpartum.

Table 6. Description of trials of episiotomy repair relating to methods, materials, or both

Trial	Trial Groups	Setting	Trial Size	Percentage Primiparous	Percentage Instrumental Delivery	Overall Quality Rating
Type of Repair						
Oboro et al., 2003[66]	2 layer vs. 3 layer	Nigeria	N =1,077	53%	23%	Fair
Ipswich Childbirth Study, Gordon et al., 1998,[60] Grant et al., 2001[63]	2 layer vs. 3 layer	United Kingdom	N =1,780*	61%	17%	Good
Kettle, 2002[67]	Continuous vs. interrupted	United Kingdom	N =1,542	56%	0%	Good
Mahomed et al., 1989[58]	Continuous vs. interrupted	United Kingdom	N =1,574†	51%	23%	Good
Materials for Repair						
Bowen and Selinger, 2002[64]	Absorbable vs. adhesive	United Kingdom	N = 62	100%	NR	Poor
Adoni and Anteby, 1991[47]	Absorbable vs. adhesive	Israel	N = 60	NR	NR	Poor
Kettle, 2002[67]	Absorbable vs. rapidly absorbable	United Kingdom	N = 1,542	56%	0%	Good
McElhinney et al., 2000[62]	Absorbable vs. rapidly absorbable	Ireland	N = 153	55%	NR	Poor
Spencer et al., 1986,[56] Grant et al., 1989[57]	Untreated vs. treated CC	United Kingdom	N = 737	47%	0%	Fair
Buchan and Nicholls, 1980[54]	Nonabsorbable vs. absorbable	United Kingdom	N = 140	100%	0%	Fair
Mahomed et al., 1989[58]	a. Absorbable vs. absorbable vs. nonabsorbable b. PGA vs. CC	United Kingdom	N = 1,574	52%	23%	Good
Upton et al., 2002[65]	PGA vs. CC	Australia	N = 391	47%	0%	Fair

Table 6. Description of trials of episiotomy repair relating to methods, materials, or both (continued)

Trial	Trial Groups	Setting	Trial Size	Percentage Primiparous	Percentage Instrumental Delivery	Overall Quality Rating
Ipswich Childbirth Study, Mackrodt et al., 1998,[61] Grant et al., 2001[63]	PGA vs. CC	United Kingdom	N = 1,780*	61%	17%	Good
Olah, 1990[59]	PGA vs. CC	United Kingdom	N = 120	46%	100%	Fair
Ping and Kee, 1975[53]	PGA vs. CC	Malaysia	N = 122	61%	38%	Fair
Rogers, 1974[52]	PGA vs. CC	United States	N = 600	NR	NR	Poor
Livingstone et al., 1974[51]	PGA vs. CC	Scotland	N = 100	100%	62%	Poor
Beard et al., 1974[50]	PGA vs. CC	United Kingdom	N = 200	51%	NR	Fair
Repair Techniques and Materials						
Doyle et al., 1993[49]	Absorbable sutures (plain catgut, PGA) and combination of methods	United Kingdom	N = 199	72%	NR	Poor
Isager-Sally et al., 1986[55]	Combination of absorbable and nonabsorbable sutures and combination of methods	Denmark	N = 900‡	61%	NR	Fair

Note: CC, chromic catgut; NR, not reported; PGA, polyglycolic acid.

*The Ipswich Childbirth Study[61,63] reported a 1-year followup of results[63] that included a subset (n= 793) of the original trial's population. Percentages shown reflect baseline population.

†The trial used a 2x3x2 factorial design to investigate both methods and materials for repair. The methods for the repair arm of the trial investigated continuous and interrupted methods for absorbable sutures, a subset (N= 1,057) of the entire population (N = 1,574). Percentages of primiparous and instrumental deliveries were calculated with a denominator of 1,057.

‡900 women were randomized but 98 were excluded because they transferred to another hospital or left the hospital before the fifth day after delivery. Three groups did not differ in age, parity, or frequency of previous episiotomy.

Table 7. Trial results for polyglycolic-acid and chromic-catgut sutures

Trial Information	Description of Pain Outcome	Superior Material for Pain			Description of Healing Outcome	Superior Material for Healing			Author's Overall Conclusions
		PGA	CC	ND		PGA	CC	ND	
Upton et al., 2002[65]* Australia N = 391 Quality: Fair	Short-term perineal pain (any, moderate to severe)			√	Short-term problems with sutures			√	No statistically significant differences between groups but leaned in favor of polyglycolic acid
Ipswich Childbirth Study, Mackrodt et al., 1998 and Grant et al., 2001[61,63]* United Kingdom N = 1,780 Quality: Good	Short-term perineal pain (any, mild, moderate)	√			Short-term healing problems (tight stitches, uncomfortable stitches, gaping perineum)	√			Clear advantages of polyglycolic acid
	Long-term perineal pain (mild, moderate, or severe)			√	Long-term need for resuturing			√	
Olah, 1990[59] United Kingdom N=120 Quality: Fair	Short-term perineal pain (10 cm VAS)			√	Short-term edema and bruising			√	Does not substantiate previous trials that show a benefit to polyglycolic acid
Mahomed et al., 1989[58]* United Kingdom N = 1,574 Quality: Good	Short- and long-term perineal pain (none, mild, mod, severe)			√	Short- and long-term edema, bruising and healing			√	Not much evidence to support polyglycolic acid but the little they have is consistent with other trials
	Short-term use of analgesics	√			Long-term need for removal of sutures			√	
	Long-term use of analgesics			√	Long-term need for resuturing			√	

Table 7. Trial results for polyglycolic-acid and chromic-catgut sutures (continued)

Trial Information	Description of Pain Outcome	Superior Material for Pain			Description of Healing Outcome	Superior Material for Healing			Author's Overall Conclusions
		PGA	CC	ND		PGA	CC	ND	
Ping and Kee, 1975[53] Malaysia N = 122 Quality: Fair	Short-term perineal pain (No pain, mild, moderate, severe)	√			Not measured	---	---	---	Polyglycolic-acid sutures have considerable advantage over chromic-catgut sutures in episiotomy repair
Beard et al., 1974[50] United Kingdom N = 200 Quality: Fair	Short-term perineal pain (none, mild, moderate, severe)	√			Short-term wound breakdown and inflammation			√	Polyglycolic-acid sutures should be used
Livingstone et al., 1974[51] Scotland N = 100 Quality: Poor	Short-term perineal pain (none, uncomfortable, painful, very painful, unbearably painful)	√			Short-term edema	√			Significant reduction in pain and edema with polyglycolic acid, no evident disadvantage in the use of polyglycolic acid
Rogers, 1974[52] United States N = 600 Quality: Poor	Short-term perineal pain (none, degree of pain)	√			Not measured	---	---	---	Polyglycolic acid decreased the pain by half

Note: PGA, polyglycolic acid; CC, chromic catgut; ND, no difference.

*Three trials also investigated long-term sexual function outcomes with regards to polyglycolic-acid and chromic-catgut sutures. Two trials[58,65] found no differences between the sutures and one trial[61,63] found polyglycolic-acid sutures to be superior at 1 year postpartum regarding resumption of pain-free intercourse and dyspareunia.

Table 8. Episiotomy and urinary incontinence, fecal incontinence, and pelvic floor defects

Author, Year Country	Study Design N	Timing of Outcome Assessment after Birth Approach	Outcome(s) Assessed Definitions Provided	Outcome among Those with Episiotomy	Outcome among Those without Episiotomy	Results of Multivariable Models Authors' Conclusions
Sleep et al., 1984[23] United Kingdom	RCT N = 1,000	3 months Mailed questionnaire	Urinary incontinence "involuntary loss of urine" "Need to wear a pad" for loss of urine	Incontinence: 19% Pad: 6%	Incontinence: 19% Pad: 6%	Incontinence was more common among multiparas than primiparas but did not differ significantly between the two trial groups when stratified by parity. There is no evidence that episiotomy prevents urinary incontinence.
Gordon and Logue, 1985[68] United Kingdom	Prospective cohort N = 70	12 months Physiologic testing in women with all perineal outcomes and cesarean	Perineometry pressure readings Methods summarized in text; average of five measures used	Maximum pressure epis: 11.7 mm water Maximum pressure forceps and epis: 9.4 mm water	Maximum pressure intact: 11.1 Maximum pressure second degree: 10.8 Maximum pressure cesarean: 12.5	Not reported No significant difference between the groups. Differences between postnatal exercise levels were highly significant with more exercise associated with greater perineal muscle strength.

Table 8. Episiotomy and urinary incontinence, fecal incontinence, and pelvic floor defects (continued)

Author, Year Country	Study Design N	Timing of Outcome Assessment after Birth Approach	Outcome(s) Assessed Definitions Provided	Outcome among Those with Episiotomy	Outcome among Those without Episiotomy	Results of Multivariable Models Authors' Conclusions
Sleep et al., 1987[33] United Kingdom	RCT N = 674	3 years Mailed questionnaire	Urinary incontinence "Lost urine when they did not mean to"	Incontinence < once past wk: 22% 1-2x past wk: 12% ≥ 3x past wk: 2%	Incontinence < once past wk: 25% 1-2x past wk: 11% ≥ 3x past wk: 2%	Not reported No difference in prevalence of urinary incontinence, even when severity and nature of the incontinence, and subsequent deliveries, were taken into account.
			"Severe enough to wear pad"	Pad sometimes: 8% Pad daily: 2%	Pad sometimes: 7% Pad daily: 1%	
			"Loss when coughing, laughing, sneezing"	SUI: 33%	SUI: 31%	
			"Loss with urgent desire to pass urine but no toilet nearby"	Urge incont.: 13%	Urge incont: 13%	
Rockner, 1990[74] Sweden	Prospective Cohort N = 185	4 years Mailed questionnaire	Urinary incontinence Frequency	Urinary incontinence: Occas.: 37 (26%) 1x/week: 10 (7%) 2-3x/wk: 2 (1%) >3x/wk: 1 (1%)	Urinary incontinence: Occas.: 12 (28%) 1x/week: 1 (2%) 2-3x/wk: 1 (2%) >3x/wk: 1 (2%)	Not reported. Episiotomy and spontaneous tear groups had the same frequency of urinary incontinence symptoms, giving no support to the suggestion that episiotomy prevents long-term damage of the pelvic floor.
			Severity (data corresponds to definitions)	With cough/laugh/sneeze: 48 (34%) Sufficiently severe to wear pad Sometimes: 13 (9%) Always: 1 (1%)	With cough/laugh/ sneeze 13 (30%) Sufficiently severe to wear pad Sometimes: 6 (14%) Always: 0 (0%)	

Table 8. Episiotomy and urinary incontinence, fecal incontinence, and pelvic floor defects (continued)

Author, Year Country	Study Design N	Timing of Outcome Assessment after Birth Approach	Outcome(s) Assessed Definitions Provided	Outcome among Those with Episiotomy	Outcome among Those without Episiotomy	Results of Multivariable Models Authors' Conclusions
Rockner et al, 1991[78] Sweden	Prospective cohort N = 92	2 months Physiologic measure	Pelvic floor muscle function measured using weighted vaginal cones at 36 wks gestation and postpartum Details provided in text	Mean decrease in muscle function (gms): 30.0 ± 11.8	Mean decrease in muscle function (gms) Intact: 19.2 ± 10.2 Spontaneous tear: 18.9 ± 9.1 (*P* < 0.001)	Not reported Pelvic floor muscle function was most decreased in the episiotomy group. The results do not support the concept that episiotomy reduces damage to the pelvic floor muscles.
Klein et al., 1992[29] Canada	RCT N = 703	3 months In-person interview Physiologic measure: Antepartum and 3 months postpartum	Urinary incontinence Not defined – used 4-point scale, dichotomized as present/ absent Subjective sense of "perineal bulging"; 4-point scale dichotomized as present/ absent Perineometry	Incontinence Primip: 14.5% Multip: 21.5% Bulging Primip: 7.9% Multip: 9.5% EMG Primip ante: 2.1 (1.8) Primip post: 2.3 (1.8) Multip ante: 1.7 (1.5) Multip post: 2.1 (1.5)	Incontinence Primip: 21.1% Multip: 12.9% Bulging Primip: 9.1% Multip: 5.4% EMG Primip ante: 2.0 (1.6) Primip post: 2.3 (1.6) Multip ante: 1.9 (1.6) Multip post: 2.1 (1.5)	Not reported None of the differences in urinary incontinence were statistically significant after controlling for antepartum history of urinary incontinence.

Table 8. Episiotomy and urinary incontinence, fecal incontinence, and pelvic floor defects (continued)

Author, Year Country	Study Design N	Timing of Outcome Assessment after Birth Approach	Outcome(s) Assessed Definitions Provided	Outcome among Those with Episiotomy	Outcome among Those without Episiotomy	Results of Multivariable Models Authors' Conclusions
Viktrup et al., 1992[70] Denmark	Prospective cohort N = 305	3 months 12 months	Telephone interview Questionnaire using International Continence Society definitions Urinary incontinence provoked by physical exertion; daily incontinence; incontinence as hygienic or social problem	Data not provided	Data not provided	Not reported Women who had an episiotomy developed stress incontinence significantly *(P* < 0.05) more frequently after delivery. However, episiotomy was performed more often in women with an increased length of second stage (*P* < 0.01). Differences in stress incontinence associated with episiotomy had resolved by 1 year.
Klein et al., 1994[34] Canada	Prospective cohort assembled from participants in liberal vs. restrictive episiotomy trial N = 697	3 months In-person interview Physiologic measures antepartum and postpartum	Self-reported urinary incontinence (4 point scale) Perineometry scores (electronic vaginal myography) Methods described in text	No difference (data not shown) Epis, no exten. Net change: Primip: 0.19 Multip: 0.05 Third/fourth degree Net change: Primip: 0.08 Multip: -0.07	No difference (data not shown) In tact Net change: Primip: 0.47 Multip: 0.57 Spontaneous tear Net change: Primip: 0.29 Multip: 0.39	Not reported Episiotomy fails to prevent the trauma or pelvic floor relaxation that it was designed to prevent.

Table 8. Episiotomy and urinary incontinence, fecal incontinence, and pelvic floor defects (continued)

Author, Year Country	Study Design N	Timing of Outcome Assessment after Birth Approach	Outcome(s) Assessed Definitions Provided	Outcome among Those with Episiotomy	Outcome among Those without Episiotomy	Results of Multivariable Models Authors' Conclusions
Walsh et al., 1996[77] United Kingdom	Prospective cohort of women with Third-degree tears N = 81	3 months	Physical examination by colorectal surgeon	100% of women with abnormal exam and fecal incontinence had episiotomy 60% of women with abnormal exam and no incontinence had episiotomy	No cases of fecal incontinence among women without episiotomy 40% of women with abnormal exam and no incontinence did not have episiotomy	Not reported Obstetric trauma causes significant anorectal dysfunction and patients with third-degree tears require assessment.
MacArthur et al., 1997[79] United Kingdom	Prospective cohort N = 906	10 months N = 906 In-person Interview	Fecal incontinence "Loss of bowel control with no warning needed to go"; "soiling or staining"; "felt need to go but couldn't hold on" One or more considered incontinence	Primp.: 4.6% Multip.:8.8%	Intact Primp.: 5.2% Multip.:2.9% Second degree Primip: 5.2% Multip: 4.2%	In multivariable models: episiotomy not an independent predictor of fecal incontinence

Table 8. Episiotomy and urinary incontinence, fecal incontinence, and pelvic floor defects (continued)

Author, Year Country	Study Design N	Timing of Outcome Assessment after Birth Approach	Outcome(s) Assessed Definitions Provided	Outcome among Those with Episiotomy	Outcome among Those without Episiotomy	Results of Multivariable Models Authors' Conclusions
Viktrup and Lose, 2001[69] Denmark	Prospective cohort N = 305	5 years	Telephone interview Questionnaire using International Continence Society definitions; urinary incontinence provoked by physical exertion; daily incontinence; incontinence as hygienic or social problem	Not provided by episiotomy status Episiotomy contributed to prediction of risk of incontinence at 5 years when comparing women who had incontinence during their pregnancy to those without any incontinence associated with pregnancy or postpartum. Episiotomy not risk factor among women with only postpartum symptoms.		In multivariable modes, episiotomy at the first delivery was significantly associated with stress incontinence 5 years after delivery, even after adjustment for the few with coexistence of anal sphincter rupture.
Eason et al., 2002[75] Canada	Prospective cohort assembled from participants in perineal massage RCT N = 949	3 months Mailed questionnaire	Incontinence of stool Incontinence of flatus "Involuntary loss of stool or flatus" Frequency (never, less than 1 a week, 1 to 6 times a week, daily, or more than once a day)	Loss of stool: RR: 5.4% Loss of flatus: RR: 30.2%	Loss of stool: RR: 2.5% Loss of flatus: RR: 24.4%	Loss of stool/flatus: No perineal injury: RR 1.0 First degree: 1.2 (0.8, 1.7) Episiotomy without extension: 1.3 (0.9, 1.8) Third/fourth degree: 2.1 (1.4, 3.1) Anal incontinence is associated with sphincter laceration, which was more common among those with episiotomy.

Table 8. Episiotomy and urinary incontinence, fecal incontinence, and pelvic floor defects (continued)

Author, Year Country	Study Design N	Timing of Outcome Assessment after Birth Approach	Outcome(s) Assessed Definitions Provided	Outcome among Those with Episiotomy	Outcome among Those without Episiotomy	Results of Multivariable Models Authors' Conclusions
Fleming et al., 2003[73] United States	Prospective cohort N = 102	6 months Baseline perineometry during pregnancy; and at 6 wks Physiologic testing in women with all perineal outcomes and cesarean	Perineometry scores (electronic vaginal myography) Methods detailed in text; average of three measures of each type of contraction used for analysis Difference in antepartum and postpartum scores	Mean score (SD) Peak: -1.7 (2.1) Hold: -1.7 (2.1)	Mean score (SD) Intact Peak: 2.7 (2.8) Hold: 2.8 (3.5) Second- or third-degree laceration Peak: 0.8 (2.6) Hold: 0.8 (2.3)	Not reported No significant differences in absolute postpartum perineal muscle strength or endurance between episiotomy and laceration groups. Women who had episiotomy were only group with net loss of perineal muscle function after delivery.
Karacam and Eroglu, 2003[72] Turkey	Prospective cohort N = 100	3 months Telephone questionnaire	Stress incontinence Not defined	12/50 (24%)	15/50 (30%)	No significant differences in stress incontinence before labor, or if after delivery of first child, or if after delivery of second child that was related to episiotomy.

Table 8. Episiotomy and urinary incontinence, fecal incontinence, and pelvic floor defects (continued)

Author, Year Country	Study Design N	Timing of Outcome Assessment after Birth Approach	Outcome(s) Assessed Definitions Provided	Outcome among Those with Episiotomy	Outcome among Those without Episiotomy	Results of Multivariable Models Authors' Conclusions
Eason et al., 2004[76] Canada	Prospective cohort participants in perineal massage RCT N = 949	3 months Mailed questionnaire	Frequency of involuntary loss of urine when coughing, sneezing, laughing, running	Any stress urinary incontinence: 29%	Any stress urinary incontinence: 35%	OR: 0.68 (0.47, 1.01) No significant association between episiotomy and urinary incontinence.
Sartore et al., 2004[71] Italy	Prospective cohort N = 519	3 months Physical exam Physiologic measures: Perineometry Uroflowmeter In-person interview	Perineometry with highest/best single recording used for analysis	SUI: 12.9% Anal incont: 2.8%	SUI: 12.1% Anal incont: 1.9%	OR: 1.01 (0.61, 1.7) OR: 1.47 (0.46, 4.7)
			Baden and Walker classification of urogenital prolapse	Ante prolapse: 41p.5% Post prolapse: 15.8%	Ante prolapse: 42.1 Post prolapse: 14.6%	OR: 0.97 (0.69, 1.4) OR: 1.1 (0.68, 1.8)
			Urine stream interruption test	Vaginal manometry: 12.2 (5.1)	Vaginal manometry: 13.8 (4.7)	*P* < 0.001
			SVI – visible involuntary loss of urine by ICS standards	Urine stream interrupt: 3.9 (3.5) Vaginal manometry percent abnormal: 40.6%	Urine stream interrupt: 3.8 (2.9) Vaginal manometry: percent abnormal: 27.7%	*P* = 0.85 OR: 1.79 (1.2, 2.6)
			Self-reported urge and anal incontinence of stool or flatus, classified by frequency			Mediolateral episiotomy does not protect against urinary and anal incontinence. Episiotomy is associated with lower pelvic floor muscle strength than spontaneous tears.

Table 9. Episiotomy and future sexual function

Citation Epis. Type Country	Study Design N	Timing of Outcome Assessment after Birth; Approach	Outcome Assessed Definitions Provided	Outcome among Those with Episiotomy	Outcome among Those without Episiotomy	Results of Multivariable Models Authors' Conclusions
Sleep et al., 1984[23] Mediolateral UK	RCT N = 1000	3 months Mailed questionnaire	Resumption of intercourse by 3 months (not defined)	90%	90%	Not reported Only difference was tendency for women allocated to restrictive episiotomy to resume intercourse sooner.
			Current dyspareunia: "pain during sexual intercourse"	22%	18%	
			Any dyspareunia: "pain during sexual intercourse, at some time" in prior 3 months	52%	51%	
Sleep and Grant, 1987[33] Mediolateral UK	Prospective cohort that included RCT participants N =326	3 years Mailed questionnaire	Any dyspareunia: "ever suffering painful sexual intercourse"	16%	13%	RR 1.21 (0.84, 1.75); No significant difference
Rockner et al., 1988[80] Mediolateral (88%) Sweden	Prospective cohort N =205	3 months Questionnaire (setting not specified)	Resumption of intercourse (Y/N)	92%	92%	Not reported No significant difference
			Current dyspareunia (not defined)	20%	20%	
			Any dypareunia in prior 3 months (not defined)	44%	43%	
Larsson et al., 1991[81] Mediolateral Sweden	Prospective cohort N =1889	2 to 3 months In-person interview with midwife	Dyspareunia (not defined)	16%	11%	Not reported None made regarding sexual function

Table 9. Episiotomy and future sexual function (continued)

Citation Epis. Type Country	Study Design N	Timing of Outcome Assessment after Birth; Approach	Outcome Assessed Definitions Provided	Outcome among Those with Episiotomy	Outcome among Those without Episiotomy	Results of Multivariable Models Authors' Conclusions
Klein et al., 1992[29] Midline Canada	RCT: Liberal vs restrictive N = 703	3 months In-person interview	Resumption of intercourse ("weeks between birth and first intercourse")	Primip: 5.8 (2.1) Multip: 5.8 (2.6)	Primip: 5.9 (2.5) Multip: 5.4 (2.3)	Time to resumption of intercourse similar; those with intact perineum began intercourse 1 week earlier than others. Pain with resumption, 3-month sexual satisfaction and proportion not resuming by 3 months similar across groups.
			Dyspareunia: "Pain at first postpartum intercourse" assessed using McGill Pain Scale	Primip: 2.2 (1.3) Multip: 1.3 (1.1)	Primip: 2.2 (1.3) Multip: 1.2 (1.0)	
			Sexual satisfaction at 3 months X items using "4 point scale" – actual items not provided	Primip: 3.1 (0.7) Multip: 3.3 (0.7)	Primip: 3.0 (0.8) Multip: 3.3 (0.6)	

Table 9. Episiotomy and future sexual function (continued)

Citation Epis. Type Country	Study Design N	Timing of Outcome Assessment after Birth; Approach	Outcome Assessed Definitions Provided	Outcome among Those with Episiotomy	Outcome among Those without Episiotomy	Results of Multivariable Models Authors' Conclusions
Klein et al., 1994[34] Midline Canada	Prospective cohort derived from RCT N = 697	3 months In-person interview	Resumption of intercourse by week 6	Epis alone: 61.7% Third-/fourth-degree: 55.4%	Intact: 76.5% Spont. tear: 62.5%	Women with spontaneous perineal tears had less pain on first intercourse than those with episiotomy alone. Those with third- to fourth-degree episiotomy extensions had the most pain on resumption of intercourse.
			Dyspareunia: "Pain at first postpartum intercourse: none, mild, discomforting, distressing-horrible"	Epis alone: Mild: 22.7% Discomf: 34.1% Distress: 28.8% Third-/fourth-degree: Mild: 23.0% Discomf: 39.3% Distress: 29.5%	Intact: Mild: 37.6% Discomf: 22.8% Distress: 6.9% Spont. tear: Mild: 27.3% Discomf: 27.3% Distress: 24.6%	
			Sexual satisfaction at 3 months; items using "4-point scale" – actual items not provided	Epis alone: Not satisfied: 16.3% Third/fourth degree: Not satisfied: 21.3%	Intact: Not satisfied: 5% Spont: Not satisfied: 15.8%	
Signorello et al., 2001[38] Midline United States	Cohort with a single prospective window N = 921	6 months Mailed questionnaire	Current dyspareunia: "pain on sexual intercourse" at 6 months	Multivariate models for type of perineal trauma: None: Referent Second degree:1.3 (0.8, 2.2) Third/fourth degree: 1.5 (0.7, 3.5)		Degree of perineal trauma, not episiotomy per se associated with dyspareunia.

Table 9. Episiotomy and future sexual function (continued)

Citation Epis. Type Country	Study Design N	Timing of Outcome Assessment after Birth; Approach	Outcome Assessed Definitions Provided	Outcome among Those with Episiotomy	Outcome among Those without Episiotomy	Results of Multivariable Models Authors' Conclusions
Karacam and Eroglu, 2003[72] Mediolateral Turkey	Prospective cohort N = 100	3 months Telephone interview	Any dyspareunia (not defined)	64.58%	54.17%	Not reported No significant differences between groups in rate of mothers' dyspareunia.
Sartore et al., 2004[71] Mediolateral Italy	Prospective cohort N = 519	3 months In-person interview	Current dyspareunia (not defined); classified as "absent, mild, moderate, severe"; reported Y/N	7.9%	3.4%	Summary measure: RR: 2.43 (1.05, 5.45)

Table 10. Episiotomy and dyspareunia

Citation Country	Study Design Episiotomy Type	Timing of Outcome Assessment after Birth Approach	Outcome Assessed Definitions Provided	Outcome among Those with Episiotomy*	Outcome among Those without Episiotomy*	Authors Conclusions
Dyspareunia at 3 Months						
Rockner et al., 1988[80] Sweden	Prospective cohort Mediolateral: 88%	3 months Questionnaire (method not specified)	Current dyspareunia (not defined)	31/154 (20%)	9/46 (20%)	No significant difference
Larsson et al., 1991[81] Sweden	Prospective cohort Mediolateral: 98%	2 to 3 months In-person interview with midwife	Dyspareunia (not defined)	66/410 (16%)	69/627 (11%)	None made regarding sexual function
Sartore et al., 2004[71] Italy	Prospective cohort Mediolateral: 100%	3 months In-person interview	Current dyspareunia (not defined); classified as "absent, mild, moderate, severe"; reported Y/N	20/254 (7.9%)	9/265 (3.4%)	RR: 2.43 (1.08, 5.45)
Dyspareunia within 3 Months						
Rockner et al., 1988[80] Sweden	Prospective cohort Mediolateral: 88%	3 months Questionnaire (method not specified)	Any dyspareunia (not defined)	68/154 (44%)	20/46 (43%)	No significant difference
Karacam and Eroglu, 2003[72] Turkey	Prospective cohort Mediolateral: 100%	3 months Telephone interview	Any dyspareunia (not defined)	31/48 (64.58%)	26/48 (54.17%)	No significant differences between groups in rate of mothers' dyspareunia

Note: RR, relative risk; Y, yes; N, no.

Table 11. Overall strength of the evidence for this body of literature

Key Question	Grade (I-IV Scale)*
1. Episiotomy and maternal postpartum outcomes	II
2. Episiotomy incision type and maternal morbidity	III
3. Repair of perineal defect and maternal morbidity	
Methods: 2-layer vs. 3-layer repair	III
Methods: Continuous vs. interrupted sutures	III
Materials: Absorbable vs. tissue adhesive	III
Materials: Absorbable sutures — standard vs. rapidly absorbed	III
Materials: Untreated catgut vs. treated catgut	III
Materials: Nonabsorbable vs. absorbable	III
Materials: Polyglycolic acid vs. chromic catgut	II
Combined methods and materials	III
4. Episiotomy and urinary incontinence, fecal incontinence, and pelvic floor defects	II
5. Episiotomy and future sexual function	II

Figure 1. Conceptual framework for routine use of episiotomy in obstetric care

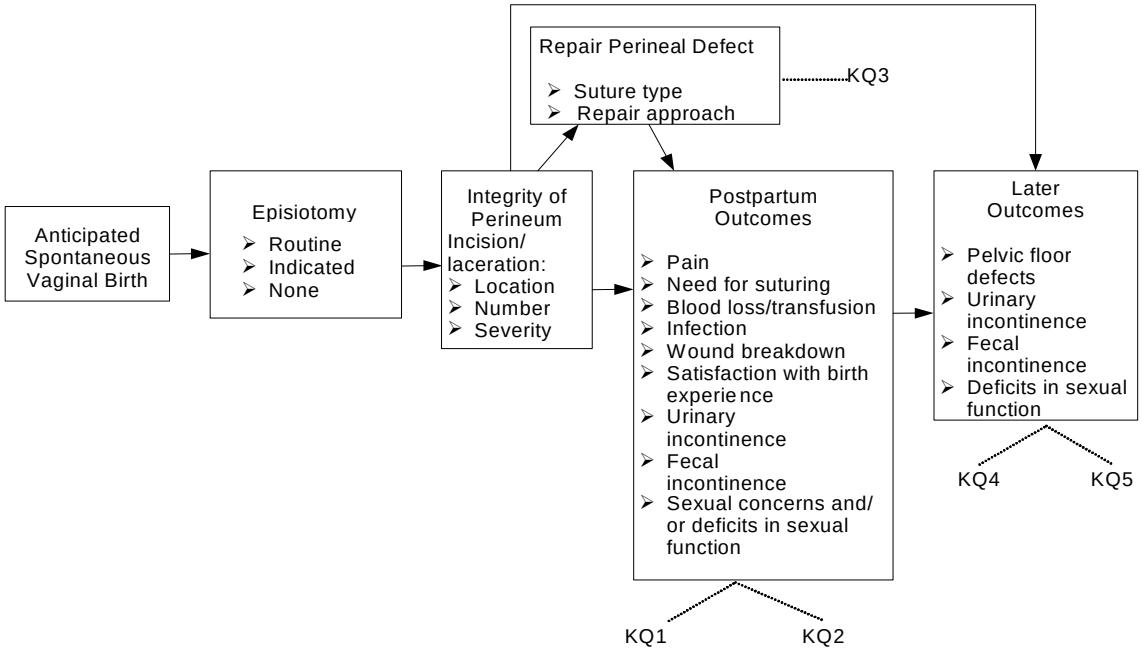
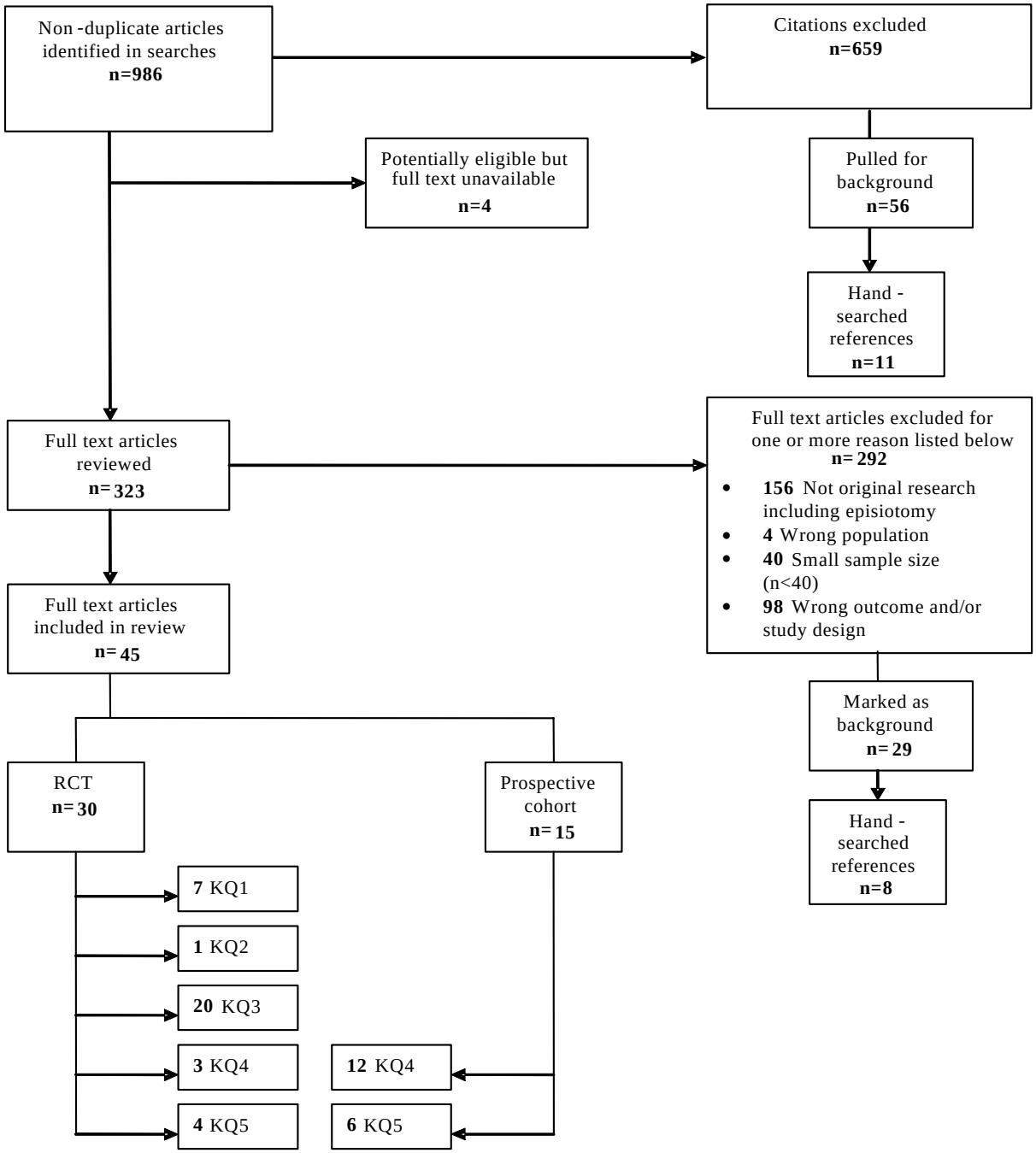


Figure 2. Episiotomy article disposition



Appendix A
Exact Search Strings

Exact Search Strings

Focused search terms and results from MEDLINE

Search Terms	Results
"Episiotomy"[MeSH] Field: All Fields, Limits: English, Randomized Controlled Trial, Human	75
"Episiotomy"[MeSH], English, Review, Human	68
Labor Stage, Second [mh], English, Review, Human	40
Labor Stage, Second [mh], English, Randomized Controlled Trial, Human	58

Additional Search Terms and Results from MEDLINE

Search Number	Search Terms	Results
#1	"Episiotomy"[MeSH:NoExp] Field: All Fields, Limits: English, Human	676
#2	"Episiotomy" English, Editorial, Human	14
#3	"Episiotomy" English, Letter, Human	58
#4	"Episiotomy" English, Review, Human	68
#5	"Episiotomy" English, Meta-Analysis, Human	3
#6	"Episiotomy" English, Practice Guideline, Human	0
#7	#2 OR #3 OR #4 OR #5 OR #6	140
#8	#1 NOT #7	536
#9	Repair	138222
#10	#1 AND #9	86
#11	labor stage, second [mh]	638
#12	#9 AND #11	6

Search Terms and Results from CINAHL

Search Number	Search Terms	Results
#1	"Episiotomy"[MeSH:NoExp] Field: All Fields, Limits: English, Human	306

Search Terms and Results from COCHRANE

Search Number	Search Terms	Results
#1	"Episiotomy"[MeSH:NoExp] Field: All Fields, Limits: English, Human	49

Appendix B
Sample Abstraction Forms/ Quality Rating Forms

Systematic Review of Episiotomy

Abstract Review Form

First Author: _____

Journal: _____

Year of Article: _____ Abstractor Initials: ___ ___ ___

1. Original research (Exclude editorials, commentaries, letters to editor, reviews, etc.)	Yes	No	Cannot Determine
2. Includes females of reproductive age	Yes	No	Cannot Determine
3. Addresses one or more of the following. (*Check all that apply*.) ____ Outcomes of routine episiotomy (KQ1) ____ Outcomes of episiotomy incision type (KQ2) ____ Approach/outcomes of repair of perineal defects (KQ3) ____ Urinary/fecal incontinence/pelvic floor defects/prolapse (KQ4) ____ Sexual function (KQ5) *If any KQ is checked, circle "Yes" in box.*	Yes	No	Cannot Determine
4. Study N is greater than or equal to 40 subjects.	Yes	No	Cannot Determine
5. Study published between 1950 and 2004.	Yes	No	Cannot Determine
6. If KQ1, 2 or 3 (outcomes of routine episiotomy / episiotomy incision type / repair of the perineal defect on maternal postpartum outcomes): RCT study design used.	Yes	No	Cannot Determine
7. If KQ4 or KQ5 (outcomes of episiotomy on urinary and fecal incontinence/pelvic floor/prolaspe/sexual function): ____ RCT study design used ____ Prospective cohort *If either is checked, circle "Yes" in box.*	Yes	No	Cannot Determine
8. Published in English. If non-English, specify language: _____ Applies to key question # _____	Yes	No	Cannot Determine

_____ CHECK HERE IF ARTICLE TO BE PULLED FOR BACKGROUND CITATION.

- IF ANY ITEMS IN GRAY BOX, THE ARTICLE IS EXCLUDED.
- IF ITEMS 7, 8 OR 9 MARKED "NO," ARTICLE MAY BE EXCLUDED IN FUTURE.
- IF CANNOT DETERMINE, ARTICLE WILL BE PULLED FOR REVIEW.

Systematic Review of Episiotomy
Full Text Inclusion/Exclusion Form

Article #: _____ First Author: _____ Reviewer's Initials: ___ ___

Criteria for Inclusion/Exclusion	Meets criteria	
1. Original research that includes routine episiotomy (i.e., not for distress or assisted vaginal deliveries) *(Excludes editorials, commentaries, letters to editor, reviews, etc.)*	Yes	No *(STOP!)*
2. Addresses sequelae of vaginal child birth	Yes	No *(STOP!)*
3. N is greater than or equal to 40 subjects	Yes	No
4. Addresses at least one of the key questions with the appropriate study design *(See below to determine. If **at least one** line has both columns of boxes checked, circle Yes. Otherwise, circle No.)*	Yes	No
5. Published in English If no, what language: _____	Yes	No
6. Published between 1950 and 2004	Yes	No

Please check all outcomes that apply. If outcome is checked, please check if the listed design applies to the study:

Outcomes and Key Questions		Study Design
KQ1	☐ Outcomes of routine episiotomy	☐ RCT
KQ2	☐ Outcomes of episiotomy incision type	☐ RCT
KQ3	☐ Outcomes of repair and/or repair method of perineal defects	☐ RCT
KQ4	☐ Urinary/fecal incontinence/pelvic floor defects/prolapse	☐ RCT ☐ Prospective cohort
KQ5	☐ Sexual function	☐ RCT ☐ Prospective cohort

If "Yes" is circled for ***ALL*** criteria… ☐ **Full text INCLUDED**

If ***ANY*** "No" is circled… ☐ **Full text EXCLUDED** *OR…*

☐ **Full text EXCLUDED but used for BACKGROUND CITATION**

SYSTEMATIC REVIEW OF EPISIOTOMY: Data Abstraction Form

SECTION 1: ABSTRACTION IDENTIFIERS

1. Article number: _____

2. Abstractor Name: _____

3. Date of abstraction: __ / __ / ___

4. Name of second abstractor/reviewer: _____

5. Date of review: __ / __ / ___

SECTION 2: ARTICLE IDENTIFIERS

6. Year Published: _____

7. Surname of first author: _____

SECTION 3: HEALTH & GEOGRAPHIC SETTINGS

8. Healthcare Setting

a. Labor & Delivery/Maternity Unit	☐ Yes	☐ No
b. ED	☐ Yes	☐ No
c. ICU	☐ Yes	☐ No
d. Other (Please specify :_____)	☐ Yes	☐ No
e. Not specified	☐ Yes	☐ No

9. Where was the study conducted? (List all countries)

_____
_____
_____
_____

SECTION 4: FUNDING SOURCE

10. What is the funding source of the study? (Mark all that apply)		
a. Industry	☐ Yes	☐ No
b. Government	☐ Yes	☐ No
c. Professional Society	☐ Yes	☐ No
d. Hospital/Managed Care Organization	☐ Yes	☐ No
e. Foundation	☐ Yes	☐ No
f. Consumer/Patient Organization	☐ Yes	☐ No
g. Not reported	☐ Yes	☐ No
h. Unclear	☐ Yes	☐ No
i. Other (specify): _____	☐ Yes	☐ No

SECTION 5: OBJECTIVE OF THE STUDY

11. _____

_____

_____

_____

_____

_____

SECTION 6: INCLUSION/EXCLUSION CRITERIA, STUDY DESIGN, DATA COLLECTION

12. Inclusion Criteria _____

_____

_____

_____

13. Exclusion Criteria _____

_____

_____

_____

14. Is the study an RCT?

☐ Yes *(Continue)*
☐ No *(Skip to Question #18)*

15. Total number of randomization arms in this study _____

16. Description of each randomization arm

Group 1: _____
Group 2: _____
Group 3. _____

17. Describe randomization methods

_____

_____

_____

_____

18. Describe blinding/masking methods and how maintained

_____

_____

_____

_____

Comments: _____

_____

_____

SECTION 7: CHARACTERISTICS OF PARTICIPANT

	Group #1	Group #2	Group #3 or Totals for Whole Study	Overall (t tests/p values were given)
19. Defining characteristic of each group/ trial arm ***(Please label all subsequent table columns with characteristic)***				
20. Age at enrollment/randomization				
a. Minimum age				
b. Maximum age				
c. Mean age				
d. Standard deviation				
21. Number of participants at enrollment/randomization *(see section #10 on page 9 for numbers of participants available at followup)*				
22. Race (Record as presented in article, as N or %. Follow percent with %. If race categories do not match the below list, please describe each category as explained in the article)*				
a. White				
b. Hispanic				
c. African-American				
d. Asian				
e. Native American				
f. Other *(describe)*				
23. Parity (Record as presented in article, as N or %. Follow percent with %)*				
a. Nulliparous				
b. Primiparous				
c. Multiparous				
24. Education (please describe categories)				
a.				
b.				
c.				
d.				
e.				
f.				
g.				

SECTION 7: CHARACTERISTICS OF PARTICIPANT (continued)

Don't forget to label your columns! →	**Group #1** _____ _____ _____ _____ _____	**Group #2** _____ _____ _____ _____ _____	**Group #3 or Totals for Whole Study** _____ _____ _____	**Overall (t tests/p values were given)**
25. Other demographic variable #1 (please describe)				
26. Other demographic variable #2 (please describe)				
27. Other demographic variable #3 (please describe)				

*If percent is calculated from the numbers abstracted from the table, please describe how calculated.

Comments: _____

_____

_____

SECTION 8: CHARACTERISTICS OF LABOR & DELIVERY

Don't forget to label your columns! →	**Group #1** _____	**Group #2** _____	**Group #3 or Totals for Whole Study** _____	**Overall (t tests/p values were given)**
28. Duration of second stage labor ***(Describe definition from article and list quantitative values if possible)***				
29. Delivery attendant (Record as presented in article, as N or %. Follow percent with %. If categories below do no match those presented in article, please adjust the categories)				
a. Unspecified				
b. Student				
c. Midwife				
d. Obstetrician				
e. Other *(e.g., family physician…please specify)*				
30. Anesthesia at time of delivery (Record as presented in article, as N or %. Follow percent with %)				
a. None				
b. Local				
c. Epidural				
d. Spinal				
e. Sacral block				
31. Delivery Position ***(Describe-will be classified at a later time. Possible positions include: dorsal/supine, horizontal, lateral, semisitting, squatting, kneeling)***				
32. Episiotomy use (Record as presented in article, as N or %. Follow percent with %)				
a. None				
b. Midline				
c. Mediolateral				
d. Done, not specified				
33. Mode of Delivery (Record as presented in article, as N or %. Follow percent with %)				
a. Spontaneous				
b. Vacuum				
c. Forceps				
d. Other (specify)				

SECTION 8: CHARACTERISTICS OF LABOR & DELIVERY (continued)

Don't forget to label your columns! →	**Group #1** _____ _____ _____ _____ _____	**Group #2** _____ _____ _____ _____ _____	**Group #3 or Totals for Whole Study** _____ _____ _____	**Overall (t tests/p values were given)**
34. Birthweight (Specify units of weight)				
a. Minimum weight				
b. Maximum weight				
c. Mean weight				
d. Standard deviation				
e. Other *(please specify)*				
35. Estimated gestational age (specify units)				
a. Minimum age				
b. Maximum age				
c. Mean age				
d. Standard deviation				
e. Other *(please specify)*				

Comments: _____

_____

_____

SECTION 9: CHARACTERISTICS OF REPAIR

Don't forget to label your columns! →	**Group #1** _____ _____ _____ _____ _____	**Group #2** _____ _____ _____ _____ _____	**Group #3 or Totals for Whole Study** _____ _____ _____	**Overall (t tests/p values were given)**
36. Description of repair approach				
37. Repair done by (Record as presented in article, as N or %. Follow percent with %. If categories below do no match those presented in article, please adjust the categories)				
a. Unspecified				
b. Student				
c. Midwife				
d. Obstetrician				
e. Other *(e.g., family physician…please specify)*				
38. Suture Type (Record as presented in article, as N or %. Follow percent with %)				
a. Chromic catgut				
b. Polyglycolic acid				
c. Other (specify)				

Comments: _____

_____

_____

SECTION 10: DESCRIPTION OF PARTICIPANTS AVAILABLE @ EACH POINT OF FOLLOWUP

Please describe the number of participants that contributed data to each timepoint of followup during the study and reasons for missing data if applicable. Please refer to section 7, question #20 on page 4 of this form for number of participants in each group at the time of randomization or enrollment.

Don't forget to label your columns! →	**Group #1** _____ _____ _____ _____ _____	**Group #2** _____ _____ _____ _____ _____	**Group #3 or Totals for Whole Study** _____ _____ _____	**If data is missing, please describe why**
39. Timepoint #1:				
40. Timepoint #2:				
41. Timepoint #3:				
42. Timepoint #4:				
43. Timepoint #5:				

Comments: _____

_____

_____

_____

_____

SECTION 11: OUTCOMES (Record as presented in article, as N or %. Follow percent with %)

**Additional space for outcomes can be found in the section 11 addendum on page 16.*

Definition of Outcome ***(Please describe how the authors defined/operationalized the outcome in the space below the outcome name)***	**How is outcome measured? (e.g., visual inspection, interview)**	**Length of time since delivery (Specify units)**	**Group #1** _____ _____ _____ _____ _____	**Group #2** _____ _____ _____ _____ _____	**Group #3 or Totals for Whole Study** _____ _____ _____	**Overall (RR/OR with CI & p values where given)**
44.Posterior Lacerations/Defects						
a. Intact perineum _____ _____ _____						
b. First degree tear _____ _____ _____						
c. Second degree tear _____ _____ _____						
d. Third degree tear _____ _____ _____						
Definition of Outcome ***(Please describe how the authors defined/operationalized the outcome in the space below the outcome name)***	**How is outcome measured? (e.g., visual inspection, interview)**	**Length of time since delivery (Specify units)**	**Group #1** _____ _____ _____ _____ _____	**Group #2** _____ _____ _____ _____ _____	**Group #3 or Totals for Whole Study** _____ _____ _____	**Overall (RR/OR with CI & p values where given)**

e. Fourth degree tear _____ _____ _____						
f. Third/fourth degree tear combined _____ _____ _____						
45. Other Lacerations/Defects						
a. Anterior _____ _____ _____						
b. Other vaginal _____ _____ _____						
46. Perineal Pain *(see page 17 for additional room)* _____ _____ _____						
Definition of Outcome ***(Please describe how the authors defined/operationalized the outcome in the space below the outcome name)***	**How is outcome measured? (e.g., visual inspection, interview)**	**Length of time since delivery (Specify units)**	**Group #1** _____ _____ _____ _____ _____	**Group #2** _____ _____ _____ _____ _____	**Group #3 or Totals for Whole Study** _____ _____ _____	**Overall (RR/OR with CI & p values where given)**
47. Analgesia Requirements _____ _____ _____						

48. Suturing Required _____ _____ _____						
49. Infection _____ _____ _____						
50. Wound breakdown _____ _____ _____						
51. Texture/appearance of scar _____ _____ _____						
52. Satisfaction with birth experience _____ _____ _____						
Definition of Outcome ***(Please describe how the authors defined/operationalized the outcome in the space below the outcome name)***	**How is outcome measured? (e.g., visual inspection, interview)**	**Length of time since delivery (Specify units)**	**Group #1** _____ _____ _____ _____ _____	**Group #2** _____ _____ _____ _____ _____	**Group #3 or Totals for Whole Study** _____ _____ _____	**Overall (RR/OR with CI & p values where given)**
53. Pelvic floor defects _____ _____ _____						
54. Urinary Incontinence						

a. Stress incontinence _____ _____ _____						
b. Urgency incontinence _____ _____ _____						
55. Fecal Incontinence						
a. Incontinence of flatus _____ _____ _____						
Definition of Outcome ***(Please describe how the authors defined/operationalized the outcome in the space below the outcome name)***	**How is outcome measured? (e.g., visual inspection, interview)**	**Length of time since delivery (Specify units)**	**Group #1** _____ _____ _____ _____ _____	**Group #2** _____ _____ _____ _____ _____	**Group #3 or Totals for Whole Study** _____ _____ _____	**Overall (RR/OR with CI & p values where given)**
56. Fecal Incontinence (continued)						
b. Incontinence of liquid stool _____ _____ _____						
c. Incontinence of formed stool _____ _____ _____						

57. Dyspareunia _____ _____ _____						
58. Recommencement of sexual intercourse _____ _____ _____						

Definition of Outcome ***(Please describe how the authors defined/operationalized the outcome in the space below the outcome name)***	**How is outcome measured? (e.g., visual inspection, interview)**	**Length of time since delivery (Specify units)**	**Group #1** _____ _____ _____ _____ _____	**Group #2** _____ _____ _____ _____ _____	**Group #3 or Totals for Whole Study** _____ _____ _____	**Overall (RR/OR with CI & p values where given)**
59. Satisfaction from sexual intercourse _____ _____ _____						
60. Additional outcome #1 _____ _____ _____						
61. Additional outcome #2 _____ _____ _____						

62. Additional outcome #3 _____ _____ _____						

ADDENDUM: SECTION 11

Please use this table for additional information on outcomes from above

Definition of Outcome ***(Please describe how the authors defined/operationalized the outcome in the space below the outcome name)***	**How is outcome measured? (e.g., visual inspection, interview)**	**Length of time since delivery (Specify units)**	**Group #1** _____ _____ _____ _____ _____	**Group #2** _____ _____ _____ _____ _____	**Group #3 or Totals for Whole Study** _____ _____ _____	**Overall (RR/OR with CI & p values where given)**
Additional information for outcome # _____ in section 11 above. *(Enter a number between 42 and 60)*						
Additional information for outcome # _____ in section 11 above. *(Enter a number between 42 and 60)*						
Additional information for outcome # _____ in section 11 above. *(Enter a number between 42 and 60)*						

PAIN ADDENDUM: SECTION 11, #46 PERINEAL PAIN

Please use this table for additional information on perineal pain

Definition of perineal pain ***(Please describe how the authors defined/operationalized the outcome in the space below the outcome name)***	**How is outcome measured? (e.g., visual inspection, interview)**	**Length of time since delivery (Specify units)**	**Group #1** _____ _____ _____ _____ _____	**Group #2** _____ _____ _____ _____ _____	**Group #3 or Totals for Whole Study** _____ _____ _____	**Overall (RR/OR with CI & p values where given)**

SECTION 12: QUALITY ASSESSMENT

Abstractor's Initials ___ ___

Article #: _____

63. Was the randomization plan adequate?	☐ Yes	☐ No	☐ N/A (prospective cohort)
64. Was the randomization plan carried out adequately?	☐ Yes	☐ No	☐ N/A (prospective cohort)
65. Was similarity of groups at baseline reported?	☐ Yes	☐ No	
a. Were statistics reported?	☐ Yes	☐ No	
b. Were there statistically significant differences between the groups at baseline?	☐ Yes	☐ No	☐ Not reported

66. Were eligibility criteria specified?	☐ Yes	☐ No	
67. Were the outcome assessors masked?	☐ Yes	☐ No	☐ Not reported
68. Was crossover (from one group to another) reported?	☐ Yes	☐ No	
69. Was loss-to-followup reported?	☐ Yes	☐ No	
70. Please give the number of participants remaining in the analyses for each group in the study for the primary outcome *(see section 10)***.** *i.e.: # remaining / # at randomization*	**Group 1** _____	**Group 2** _____	**Group 3** _____

71. Were there post-randomization exclusions?	☐ Yes	☐ No	☐ Not reported
72. Was intention-to-treat (ITT) analysis reported?	☐ Yes	☐ No	☐ Not reported
73. Overall quality rating	☐ Good	☐ Fair	☐ Poor

Assessment of Quality of Individual Articles for RCT's

<table>
<tr><th>Randomization Approach</th><th>Randomization Implementation</th><th>Masking of Outcome Assessors and/or Participants</th><th>Operational Definitions and Measurements</th></tr>
<tr><td>Is there description of the approach to randomization?

Yes No

Is there a fatal flaw in the approach (such as lottery cards)?

Yes[1] No

Explain:</td><td>Is there proven good balance with statistical significance?

Yes No

Is there good balance achieved as shown in table?

Yes No</td><td rowspan="3">(Please circle one)

Good Fair Poor

NR

Notes:</td><td rowspan="3">(Please circle one)

Good Fair Poor

Notes:</td></tr>
<tr><td colspan="2">Overall Randomization Approach and Implementation</td></tr>
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Good[2] Fair Poor</td></tr>
<tr><th>Post-Randomization Exclusions</th><th>Loss to Follow-up: Short-term</th><th>Loss to Follow-up: Long-term</th><th>Overall Quality[3]</th></tr>
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Yes No

Please describe:</td><td>(Please list numbers and percentages for each follow-up time point)

T1 (describe):

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T4 (describe):</td><td>(Please list numbers and percentages for each follow-up time point)

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GOOD

FAIR

POOR</td></tr>
</table>

[1] If fatal flaw in randomization approach exists, overall randomization approach and implementation is poor and overall quality of the article/trial is also poor

[2] Approach must be described and there must be good balance in order to achieve an overall randomization and implementation score of good

[3] All component ratings must be good with minimal loss to follow-up for the article/trial to receive an overall quality rating of good. If an article has one or two fair or poor ratings, an overall quality score of fair should be assigned. If an article/trial has three or more fair or poor ratings and/or large loss to follow-up, the overall quality should be poor.

Appendix C
Evidence Tables

Glossary for Evidence Tables

AP	antepartum
BMI	body mass index
CC	chromic catgut
cm	centimeter
cont	continuous
deg	degree
diff	difference
ext	extension
G	group
g	grams
GA	gestational age
GP	General Practitioner
hrs	hours
instr	instrumental
interr	interrupted
int	interview
L&D/MU	Labor and Delivery Maternity Unit
LSCS	lower segment cesarean section
mL	millileter
mm	millimeter
mod	moderate
mos	months
N	number
NA	not applicable
NR	not reported
NS	not significant
OR	odds ratio
PFMS	pelvic floor muscles
PGA	polyglycolic acid
PNC	prenatal care
pt	point
quest	postal questionnaire, self-report questionnaire
RCT	randomized controlled trial
RR	relative risk/risk ratio
SD	standard deviation
sec	second (adjective)
SHO	senior house officer
sig diff	significant differences
spont	spontaneous
subcut	subcuticular
transcut	transcutaneous
UK	United Kingdom
VAS	Visual Analog Scale
wks	weeks
yr	year

Evidence Table 1. Key Question 2: Liberal versus restrictive use of episiotomy

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics	Perineal Trauma Outcomes	Pain Outcomes
Author Sleep, 1984 **Setting** UK **Study design** RCT **Inclusion criteria** • Live singleton fetus of at least 37 wks GA • Presented cephalically • Spont vaginal delivery expected at end of sec stage labor **Exclusion criteria** • Elected episiotomy • No consent • Private patient • Precipitate delivery **Groups** **G1: Liberal** (instructed to "try to prevent a tear") **G2: Restrictive** (instructed to "try to avoid episiotomy and restrict episiotomy to fetal indications") **N at enrollment** **G1:** 502 **G2:** 498 **Total:** 1000 **Followup** 10 days to 3 mos	**Age (mean ± SD)** **G1:** 26.7yrs ± 5.3 **G2:** 26.6yrs ± 5.2 **Primiparous** **G1:** 46.3% **G2:** 40.4%	**Delivery by** **Student and midwife** **G1:** 35.9% **G2:** 35.2% **Midwife** **G1:** 32.1% **G2:** 30.1% **Obstetrician** **G1:** 1.8% **G2:** 8% **Other ("sister")** **G1:** 31.3% **G2:** 32.7% **Estimated GA** **G1:** 39.8wks ± 1.2 **G2:** 39.8wks ± 1.2 **Birthweight (mean+ SD)** **G1:** 3367g ± 438 **G2:** 3393g ± 4.48 **Episiotomy rate (all mediolateral)** **G1:** 51.4% **G2:** 10.2%	**Third/fourth deg tear** (ext through anal sphincter or through to the rectal mucosa or to the upper third of vagina) **G1:** 1 **G2:** 4 **Anterior labial tears** **G1:** 17.3% **G2:** 26.3% $\chi^2 = 11.29$ *P* < 0.00l RR = 1.52 (1.19-1.94)	**Short term: 10 days** **Mild pain** **G1:** 14.6% **G2:** 14.1% **Mod pain** **G1:** 7.8% **G2:** 7.5% **Severe pain** **G1:** 0.2% **G2:** 0.9% **All levels:** **G1:** 22.6% **G2:** 22.6% $\chi^2 = 1.91$ NS **Long term: 3 mos** **Mild pain** **G1:** 5.7% **G2:** 4.6% **Mod pain** **G1:** 1.8% **G2:** 2.5% **Severe pain** **G1:** 0.2% **G2:** 0.5% **All levels** **G1:** 7.7% **G2:** 7.6% χ2=2.58 NS

Evidence Table 1. Key Question 1: Liberal versus restrictive use of episiotomy (continued)

Sexual Function Outcomes	Repair and Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Short term: 1 mo **Recommencement of sexual intercourse** **G1:** 27% **G2:** 37% $\chi^2 = 8.67$ *P* < 0.01 **Long term: 3 mos** **Resumed sexual intercourse** 90% overall, similar within groups **Dyspareunia** **G1:** 18% **G2:** 22% **Dyspareunia "At some time"** **G1:** 51% **G2:** 52% **Long term** NR	**Short term** **Required suturing** **G1:** 78% **G2:** 69% $\chi^2 = 9.99$ *P* = < 0.01 **Long term** NR	**Short term** **Involuntary loss of urine (3 mos)** **G1:** 19% **G2:** 19% NS **Long term** NR	**Short term** NR **Long term** NR	**Overall quality** Good **Randomization approach and implementation** Good **Masking** Good+ **Operator performing repair blind to allocation** Mother in most cases blind to allocation **Operational definitions and measures** Good **Post-randomization exclusions** No **Retention of participants** Good **10 days** **G1:** 446 (89%) **G2:** 439 (88%) **Total:** 885 (89%) **3 mos** **G1:** 457 (91%) **G2:** 438 (88%) **Total:** 895 (90%)

Evidence Table 1. Key Question 1: Liberal versus restrictive use of episiotomy (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics	Perineal Trauma Outcomes	Pain Outcomes*
Author Harrison, 1984 **Setting** Ireland **Study design** RCT **Inclusion criteria** • 16 yrs and older • ≥ 38 wks GA • Vaginal delivery • Primigravid **Exclusion criteria** • Psychiatric or medical condition • Eclampsia **Groups** **G1: Routine** Defined as mediolateral episiotomy routinely conducted **G2: Restrictive** Defined as no episiotomy except when medically necessary **N at randomization** **G1:** 89 **G2:** 92 **Total:** 181 **Followup** 1 to 5 days	**Age** NR **Primiparous** **G1:** 100% **G2:** 100%	**Mode of delivery** **G1:** NR **G2:** • Spont: 92% • Vacuum: 2% • Forceps: 3% **Birthweight (mean ± SD)** NR **Episiotomy rate** **G1:** 44.9% (40/89) **G2:** 7.6% (7/92) **Suture method and type** **G1** and **G2:** Mattress sutures with CC	**Intact perineum** **G1:** NR **G2:** 21% **First deg tears** **G1:** 0 to 2% **G2:** 25% **Sec deg tears** **G1:** None **G2:** 47% **Third deg tears** **G1:** 6% **G2:** 0%	**Short term** NR **Long term** NR **Comment** *All analyses were completed on a subset of participants: 40 participants from G1 who had a spont vertex delivery and 37 participants from G2 who had sustained a sec deg tear during delivery (these participants had not undergone episiotomy). Outcomes analyzed do not address differences between routine and restrictive policies of episiotomy and are not reported here

Evidence Table 1. Key Question 1: Liberal versus restrictive use of episiotomy (continued)

Sexual Function Outcomes	Repair and Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Short term NR **Long term** NR	**Short term** NR **Long term** NR	**Short term** NR **Long term** NR	**Short term** NR **Long term** NR	**Overall quality** Poor: Not possible to see outcome as randomized analysis does not take advantage of having done a trial **Randomization approach and implementation** Poor: No detail about method, allocation, concealment or balance **Masking** NR **Operational definitions and measures** Good **Post-randomization exclusions** Yes **Retention of participants** Good **G1:** NR **G2:** NR **Total:** NR

Evidence Table 1. Key Question 1: Liberal versus restrictive use of episiotomy (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics	Perineal Trauma Outcomes	Pain Outcomes
Author House et al., 1986 **Setting** UK **Study design** RCT **Inclusion criteria** NR **Exclusion criteria** • Labor at < 37 wks pregnant • Presentation other than vertex • Cesarean section • Forceps delivery **Groups** **G1: Liberal** Defined: Received standard current management Episiotomy was performed if perineum appeared too rigid to permit delivery without laceration **G2: Restricted** Defined: Episiotomy not performed specifically to prevent laceration **N at enrollment** **G1:** 71 **G2:** 94 **Total:** 165 **Followup** 3 mos (no data in article)	**Age** NR **Primiparous** **G1:** 68% **G2:** 53%	**Mode of delivery** **G1:** • Spont: 86% • Forceps: 14% **G2:** • Spont: 89% • Forceps: 11% **Duration of sec stage labor (mean ± SD)** **G1:** 53min ± 41 **G2:** 46min ± 40 **Birthweight (mean ± SD)** **G1:** 3400g ± 429 **G2:** 3282g ± 399 **Episiotomy rate (all mediolateral)** **G1:** 69% **G2:** 18%	**Among primigravidae participants** **Intact or first deg tear (exam)** **G1:** 4% **G2:** 32% *P* < 0.001 **Sec deg tear (exam)** Defined: Laceration involving more than superficial mucosa requiring more than three sutures to repair **G1:** 17% **G2:** 36% *P* < 0.05 **Third deg tear (exam)** Defined: Involved anal sphincter **G1:** 0% **G2:** 0% NS **Among multigravidae participants** **Intact or first deg tear (exam)** **G1:** 26% **G2:** 54% *P* < 0.05 **Sec deg tear (exam)** Defined: Laceration involving more than superficial mucosa requiring more than three sutures to repair **G1:** 22% **G2:** 43% NS **Third deg tear (exam)** Defined: Involved anal sphincter **G1:** 4% **G2:** 0% NS	**Short term: 3 days** **Perineal pain (int) (10 pt VAS scale where 1 to 3 minimal, 4 to 6 mod, 7 to 10 severe)** **G1:** • Mild: 55% • Mod: 34% • Severe: 11% **G2:** • Mild: 68% • Mod: 22% • Severe: 10% **Short term: 6 wks** No diff, details NR **Long term: 3 mos** No diff, details NR

Evidence Table 1. Key Question 1: Liberal versus restrictive use of episiotomy (continued)

Sexual Function Outcomes	Repair and Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Short term NR **Long term** NR	**Short term: 3 days** **Tenderness (int) (10 pt VAS scale where 1 to 3 minimal, 4 to 6 mod, 7 to 10 severe)** **G1:** • Minimal: 51% • Mod: 39% • Severe: 10% **G2:** • Minimal: 79% • Mod: 18% • Severe: 3% *P* = 0.001 **Infection (exam)** **G1:** 4% **G2:** 5% **Primary healing (exam)** Defined: Complete skin apposition **G1:** 92% **G2:** 88% **Secondary healing (exam)** Defined: Significant granulation **G1:** 8% **G2:** 12% **Long term** NR	**Short term** NR **Long term** NR	**Short term** **Blood loss** **G1:** 214mL ± 162 **G2:** 272mL ± 160 *P* = 0.01 **Long term: 3 mos** Prolapse, details NR but NS	**Overall quality** Poor **Randomization approach and implementation** Good **Masking** NR **Operational definitions and measures** Good **Post-randomization exclusions** Yes: loss of multigravidae participants from early discharge, loss to immediate postnatal follow-up by one of the authors. The method is adequate, describes concealment and reports balance in multiple factors except imbalance that resulted from post-randomization exclusions **Retention of participants** **Short term: 3 days** Good **G1:** 71 (100%) **G2:** 94 (100%) **Total:** 165 (100%) **Short term: 6 wks** Good **G1:** NR **G2:** NR **Total:** 88 (53%) **Long term: 3 mos** Poor **G1:** NR **G2:** NR **Total:** 88 (53%)

Evidence Table 1. Key Question 1: Liberal versus restrictive use of episiotomy (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics	Perineal Trauma Outcomes	Pain Outcomes
Author Klein et al., 1992 **Setting** Canada **Study design** RCT **Inclusion criteria** • 18 to 40 yrs old • Parity of 0, 1, 2 • Single fetus • Spoke English or French • Low medical and obstetrical risk **Exclusion criteria** • Prematurity (gestation < 37 wks) • Fetal distress • Cesarean deliveries • Planned forceps • Medical condition developed late in pregnancy **Groups** **G1: Primiparous** **G1a: Liberal** (attempted to avoid a tear/separated by parity) **G1b: Restricted** (attempted to avoid an episiotomy/ separated by parity) **G2: Multiparous** **G2a: Liberal** **G2b: Restricted** **N at enrollment** **G1a:** 184 **G1b:** 175 **G2a:** 166 **G2b:** 178 **Total:** 703 **Followup** 1 day to 3 mos	**Age (mean ± SD)** **G1a:** 27.9yrs ± 3.9 **G1b:** 27.9yrs ± 4.4 **G2a:** 31.0yrs ± 3.7 **G2b:** 30.3yrs ± 9.1 **Primiparous** **G1:** 100% **G2:** 100% Previous episiotomy NS **Education (yrs) (sig diff NR)** **G1a:** 15.4 **G1b:** 15.0 **G2a:** 15.4 **G2b:** 15.0 **Stable Relationship** Diff NS **Employment** Diff NS	**Episiotomy rate (all median)** **G1a:** 81% **G1b:** 52% **G2a:** 47% **G2b:** 31% **Birthweight (mean +SD)** **G1a:** 3325g ± 416 **G1b:** 3377g ± 432 **G2a:** 3496g ± 449 **G2b:** 3467g ± 497 **GA** NS	**Intact Perineum** **Measured at delivery** **G1a:** 12 (6.6%) **G1b:** 13 (7.5%) OR = 1.16 (0.48, 2.8) **G2a:** 32 (19.3%) **G2b:** 54 (30.7%) OR = 1.85 (1.1, 3.2) **Sec degree tear measured at delivery** **G1a:** 22 (12.6%) **G1b:** 61 (35.3%) OR = 3.99 (2.2, 7.1) **G2a:** 56 (33.7%) **G2b:** 68 (38.6%) NS	**Short term: 1 day** **G1a:** 1.8 ± 0.8 **G1b:** 1.7 ± 0.8 **G2a:** 1.3 ± 0.8 **G2b:** 1.3 ± 0.9 **Short term: 2 days** **G1a:** 1.3 ± 0.7 **G1b:** 1.4 ± 0.8 **G2a:** 0.9 ± 0.7 **G2b:** 0.9 ± 0.8 **Short term: 10 days** **G1a:** 0.5 ± 0.5 **G1b:** 0.5 ± 0.5 **G2a:** 0.3 ± 0.4 **G2b:** 0.3 ± 0.5 **Long term** NR

Evidence Table 1. Key Question 1: Liberal versus restrictive use of episiotomy (continued)

Sexual Function Outcomes	Repair and Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Short term: 3 mos **Time to resumption of sexual intercourse** NS **Mean degree of pain at resumption of sexual intercourse** NS **Female sexual satisfaction** NS **Long term** NR	**Short term** NR **Long term** NR	**Short term: 3 mos** **Urinary incontinence** **G1a:** 26 (14.5%) **G1b:** 35 (21.1%) *P* = 0.11 **G2a:** 34 (21.5) **G2b:** 22 (12.9) *P* = 0.04 **Long term** NR	**Short term: 3 mos** **Pelvic floor function** NS **Perineal bulging** NS **Long term** NR	**Overall quality** Fair **Randomization approach and implementation** Good **Masking** Fair **Operational definitions and measures** Good for short term Poor for long term **Post-randomization exclusions** Cesarean only **Retention of participants** Fair

Evidence Table 1. Key Question 1: Liberal versus restrictive use of episiotomy (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics	Perineal Trauma Outcomes	Pain Outcomes
Author Argentine, 1993 **Setting** Argentina **Study design** RCT **Inclusion criteria** • Uncomplicated labor at 37 to 42 wks • Nulliparous or primiparous gestation • Single fetus in cephalic presentation • No history of cesarean delivery or severe perineal tears **Exclusion criteria** NR **Groups** **G1: Routine** Defined: Performed episiotomy according to hospital's policy prior to the trial **G2: Selective** Defined: Tried to avoid episiotomy unless fetal distress or severe perineal trauma judged to be imminent **N at randomization** **G1:** 1298 **G2:** 1308 **Total:** 2606 **Followup** 7 days	**Age** NR **Primiparous*** **G1:** 60% **G2:** 59% **Previous episiotomy** **G1:** 33% **G2:** 34% *Note: The article identifies the women, at the time of gestation, as nulliparous or primiparous. For our purposes, the nullips from the article are our primips (meaning this was their first birth).	**Mode of delivery** **G1:** Operative: 3% **G2:** Operative: 2% **Oxytocin at sec stage** **G1:** 59% **G2:** 58% **Birthweight (mean ± SD)** **G1:** 3244g ± 418.3 **G2:** 3244g ± 427.3 **Cephalic perimeter (mean ± SD)** **G1:** 34.2cm ± 15.5 **G2:** 34.3cm ± 17.5 **Episiotomy rate (all mediolateral)** **G1:** 83% **G2:** 30% **Suture type** NR **Suture method** NR	**Third deg tear (exam)** Defined: Vaginal middle and/or upper third tear **G1:** 2.2% **G2:** 2.9% RR = 1.38 (0.84, 2.21) NS **Severe perineal trauma (exam)** Defined: Ext through the anal sphincter and/or the anal or rectal mucosa; third deg and fourth deg lacerations **G1:** 1.8% **G2:** 1.4% RR = 0.78 (0.40, 1.54) NS **Anterior perineal trauma (exam)** **G1:** 8% **G2:** 19% RR = 2.36 (1.89, 2.94)	**Short term:** **Discharge** **Perineal pain (int)** **G1:** 43% **G2:** 31% RR = 0.72 (0.65, 0.81) **Long term** NR

Evidence Table 1. Key Question 1: Liberal versus restrictive use of episiotomy (continued)

Sexual Function Outcomes	Repair and Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Short term NR **Long term** NR	**Short term: Discharge** **Hematoma (exam)** **G1:** 4% **G2:** 4% RR = 0.96 (0.65, 1.42) NS **Short term: 7 days** **Healing complications (exam)** **G1:** 30% **G2:** 21% RR = 0.69 (0.56, 0.85) **Local infection (exam)** **G1:** 2% **G2:** 2% RR = 0.91 (0.37, 2.21) NS **Dehiscence (exam)** **G1:** 9% **G2:** 5% RR = 0.45 (0.30, 0.75) **Long term** NR	**Short term** NR **Long term** NR	**Short term** NR **Long term** NR	**Overall quality** Fair **Randomization approach and implementation** Good+ **Masking** Fair **Operational definitions and measures** Fair **Post-randomization exclusions** No **Retention of participants** Good **At discharge** **G1:** NR (93%) **G2:** NR (93%) **Total:** NR (93%) **7 days** **G1:** NR (43%) **G2:** NR (43%) **Total:** NR (43%)

Evidence Table 1. Key Question 1: Liberal versus restrictive use of episiotomy (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics	Perineal Trauma Outcomes	Pain Outcomes
Author Eltorkey and Nuaim, 1994 **Setting** Saudi Arabia **Study design** RCT **Inclusion criteria** • Live singleton fetus of at least 37 wks GA • Presenting cephalically • No important medical or psychiatric illness • Spont vaginal delivery expected toward the end of sec stage labor **Exclusion criteria** NR **Groups** **G1: Elective episiotomy** Defined: Performed unless it was considered absolutely unnecessary **G2: Selective episiotomy** Defined: Only to prevent extensive perineal laceration or to accelerate labor for fetal distress **N at randomization** **G1:** 100 **G2:** 100 **Total:** 200 **Followup** Immediate postpartum	**Age (mean ± SD)** **G1:** 21.0yrs ± 3.5 **G2:** 21.2yrs ± 3.9 **Primiparous** **G1:** 100% **G2:** 100%	**Mode of delivery** **G1:** • Spont: 95% • Forceps: 3% • Vacuum: 2% **G2:** • Spont: 96% • Forceps: 2% • Vacuum: 2% **Anesthesia at delivery** **G1:** • Epidural: 14% • Pethidine: 56% • Gas and air: 30% **G2:** • Epidural: 20% • Pethidine: 47% • Gas and air: 33% **Birthweight (mean ± SD)** **G1:** 3080g ± 399 **G2:** 3069g ± 438 **Estimated GA (mean ± SD)** **G1:** 279days ± 8 **G2:** 280days ± 9 **Episiotomy rate (all mediolateral)** **G1:** 83% **G2:** 53% *P* < 0.001 **Suture type** **G1** and **G2:** CC **Suture method** **G1** and **G2:** "Continuous suture was used to repair the vagina, interrupted sutures were used for the deeper tissues and interrupted or subcuticular sutures to repair the perineal skin."	**Intact perineum (exam)** **G1:** 7% **G2:** 28% OR = 5.17 *P* < 0.001 **No posterior trauma (exam)** **G1:** 25% **G2:** 40% *P* < 0.05 **No anterior trauma (exam)** **G1:** 82% **G2:** 88% NS **First deg tear** Defined: Injury only to anterior of perineum and related posterior wall of vagina (exam) **G1:** 3% **G2:** 4% NS **Sec deg tear** Defined: Tear up to but not including anal sphincter (exam) **G1:** 1% **G2:** 8% *P* < 0.05 **Episiotomy alone (exam)** **G1:** 64% **G2:** 41% *P* <0.01 **Ext of episiotomy (exam)** **G1:** 7% **G2:** 7% NS **Para-urethral laceration (exam)** **G1:** 4% **G2:** 5% NS **Lateral vaginal wall laceration (exam)** **G1:** 14% **G2:** 7% NS	**Short term** NR **Long term** NR

Evidence Table 1. Key Question 1: Liberal versus restrictive use of episiotomy (continued)

Sexual Function Outcomes	Repair and Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Short term NR	**Short term** NR	**Short term** NR	**Short term** NR	**Overall quality** Fair
Long term NR	**Long term** NR	**Long term** NR	**Long term** NR	**Randomization approach and implementation** Good
				Masking NR
				Operational definitions and measures Good
				Post-randomization exclusions No
				Retention of participants Good
				1 to 5 days **G1:** 100 (100%) **G2:** 100 (100%) **Total:** 100 (100%)

Evidence Table 1. Key Question 1: Liberal versus restrictive use of episiotomy (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics	Perineal Trauma Outcomes	Pain Outcomes
Author Dannecker et al., 2004 **Setting** Germany **Study design** RCT **Inclusion criteria** • Primiparous • > 34 wks of gestation • Uncomplicated pregnancy • Live singleton fetus • Intention of vaginal delivery **Exclusion criteria** • Previous surgery at pelvic floor • Neurological disorder **Groups** **G1: Liberal** Defined: Tear imminent, fetal indications **G2: Restrictive** Defined: Fetal indications only **N at randomization (randomized at outpatient clinic)** **G1:** 76 **G2:** 70 **Total:** 146 **N at delivery** **G1:** 60 **G2:** 49 **Followup** 1 to 5 days	**Age (mean ± SD)** **G1:** 28.6yrs ± 4.5 **G2:** 28.3yrs ± 5.0 **Primiparous** **G1:** 100% **G2:** 100%	**Mode of delivery** **G1:** Vacuum: 7% **G2:** Vacuum: 18% **Anesthesia at delivery** **G1:** Epidural: 72% **G2:** Epidural: 63% **Birthweight (mean ± SD)** **G1:** 3535g ± 429 **G2:** 3313g ± 455 **Cephalic perimeter (mean ± SD)** **G1:** 35.2cm ± 1.6 **G2:** 34.8cm ± 1.4 **Episiotomy rate (all mediolateral)** **G1:** 77% **G2:** 41% RR = 0.47 (0.3, 0.7) *P* < 0.001 **Suture type** NR **Suture method** **G1** and **G2:** "Continuous suture was used to repair the vagina, deeper perineal tissues, subcuticular and skin."	**Intact perineum (exam)** **G1:** 10% **G2:** 29% RR = 2.9 (1.2, 6.9) *P* = 0.023 **Minor perineal trauma (exam)** Defined: First deg tear or intact perineum **G1:** 13% **G2:** 39% RR = 2.9 (1.6, 10.5) *P* = 0.003 **Third deg tear (Severe perineal trauma) (exam)** Defined: Ext through the anal sphincter or through rectal mucosa **G1:** 8% **G2:** 4% RR = 0.43 (0.1, 2.1) *P* = 0.46 **Anterior trauma (exam)** Defined: Labial and vaginal tears **G1:** 42% **G2:** 55% RR = 1.1 (0.8, 1.8) *P* = 0.25	**Short term 1 to 5 days** **Perineal pain during bedrest (int)** **mean ± SD from 100mm VAS** **G1:** 39 ± 28 **G2:** 22 ± 21 Diff = 16 (2, 30) *P* = 0.025 **Perineal pain during sitting (int)** **mean ± SD from 100mm VAS** **G1:** 69 ± 23 **G2:** 51 ± 25 Diff = 18 (5, 31) *P* = 0.009 **Perineal pain during walking (int)** **mean ± SD from 100mm VAS G1:** 56 ± 24 **G2:** 37 ± 24 Diff = 19 (6, 33) *P* = 0.005 **Perineal pain during defecation (int)** **mean ± SD from 100mm VAS** **G1:** 36 ± 30 **G2:** 21 ± 21 Diff = 15 (0, 30) *P* = 0.048 **Long term** NR

Evidence Table 1. Key Question 1: Liberal versus restrictive use of episiotomy (continued)

Sexual Function Outcomes	Repair and Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Short term NR	**Short term** NR	**Short term** NR	**Short term** NR	**Overall quality** Fair
Long term NR	**Long term** NR	**Long term** NR	**Long term** NR	**Randomization approach and implementation** Good **Masking** NR **Operational definitions and measures** Good **Post-randomization exclusions** Yes: but given enrollment during PNC appropriate. 37 participants did not receive allocated intervention due to cesarean section (n = 24), preterm labor (n = 4), delivery elsewhere (n = 8), and refusal (n = 1) **Retention of participants*** **Short term: 1 to 5 days** Good **G1:** 31 (52%) **G2:** 22 (45%) **Total:** 53 (49%) **Long term** Poor 48% in postpartum pain measures **Comment** *Percentage of participants retained for follow-up in the 1 to 5 days postpartum period was calculated with a denominator of randomized participants who were not post-randomization exclusions.

Evidence Table 2. Key Question 2: Midline versus mediolateral episiotomy

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics	Perineal Trauma Outcomes	Pain Outcomes
Author Coats et al., 1980 **Setting** UK **Study design** RCT **Inclusion criteria** • Primigravidae • Admitted to delivery suite **Exclusion criteria** NR **Groups** **G1:** Midline episiotomy **G2:** Mediolateral episiotomy **N at randomization** **G1:** 163 **G2:** 244 **Total:** 407 Note: Only women who were randomized and underwent episiotomy were reported. Total number randomized, including women who did not undergo episiotomy, was not reported. **Followup** 3 mos	**Age (mean ± SD)** **G1:** 26.38yrs ± 6.94 **G2:** 26.58yrs ± 7.22 **Primiparous** **G1:** 100% **G2:** 100%	**Mode of delivery** **G1** • Spont: 75% • Breech: 1% • Forceps: 21% • Venthouse: 4% **G2** • Spont: 68% • Breech: 5% • Forceps: 23% • Venthouse: 3% **Anesthesia** **G1** • Local: 71% • Pudendal block: 15% • Epidural: 14% • General: 1% **G2** • Local: 65% • Pudendal block: 14% • Epidural: 18% • General: 3% **GA (mean ± SD)** **G1:** 40.3wks ± 1.78 **G2:** 40.0wks ± 1.48 **Birthweight (mean ± SD)** NR **Suture type and method** **G1** and **G2:** Subcut skin closure with PGA suture **Sutured by** **G1** • SHO: 69% • Registrar: 12% • Student: 19% **G2** • SHO: 65% • Registrar: 17% • Student: 19%	**No ext of episiotomy** **G1:** 54% **G2:** 79% **Local ext of episiotomy** **G1:** 22% **G2:** 12% **Ext of episiotomy into sphincter** **G1:** 12% **G2:** 7% **Ext of episiotomy through sphincter** **G1:** 6% **G2:** 2% **Ext of episiotomy into rectal mucosa** **G1:** 6% **G2:** 0.4% *P* < 0.001 across all groups	**Short term: At discharge** "The total pain experienced by the women from their episiotomies was similar." "The numbers who required analgesics were also not significantly different." **Long term: 3 mos** "No difference was experienced in the pain felt from their episiotomies."

Evidence Table 2. Key Question 2: Midline versus mediolateral episiotomy (continued)

Sexual Function Outcomes	Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Outcomes reported apply to KQ5 and are included in Evidence Table 5	**Short term discharge** **Bruising** **G1** had significantly less bruising than **G2** *P* < 0.001 **Texture of scar** **G1:** • Thick: 14% • Normal: 79% • Lax: 7% **G2:** • Thick: 19% • Normal: 79% • Lax: 2% NS **Appearance of scar** **G1:** • Good: 43% • Fair: 44% • Poor: 13% **G2:** • Good: 27% • Fair: 56% • Poor: 18% *P* < 0.02 across all groups **Long term** NR	Outcomes reported apply to KQ4 and are included in Evidence Table 4	**Short term** NR **Long term** NR	**Overall quality** Poor **Randomization approach and implementation** Poor **Masking** NR **Operational definitions and measures** Poor **Post-randomization exclusions** Yes: If episiotomy performed was other than allocated, participant was removed from trial **Retention of participants** **Before discharge** **G1:** 163 (100%) **G2:** 244 (100%) **Total:** 407 (100%) **3 mos** **G1:** NR **G2:** NR **Total:** 311 (76%)

Evidence Table 3. Key Question 3: Methods of repair – 2-layer versus 3-layer repair

Study Characteristics	Demographic Characteristics	Labor and Delivery Characteristics	Episiotomy and Repair Characteristics	Pain Outcomes
Author Oboro et al., 2003 **Setting** Nigeria **Study design** RCT **Inclusion criteria** Episiotomy or a sec deg tear during vaginal delivery **Exclusion criteria** • First deg lacerations (rarely require suturing) • Third deg tears (need for specialist repair) **Groups** **G1:** 2-layered: perineal skin not sutured **G2:** 3-layered: skin repair with either subcut or interr number 00 CC or polyglycolic sutures **N at randomization** **Total:** 1077 **N at 48 hrs** **G1:** 417 **G2:** 406 **Total:** 823 **Followup** 6 wks 3 mos	**Age (mean ± SD)** **G1:** 26.3yrs ± 4.0 **G2:** 26.2yrs ± 3.8 **Primiparous** **G1:** 54% **G2:** 52% NS **Previous perineal repair** **G1:** 31% **G2:** 29% NS	**Mode of delivery** **G1:** • Spont: 76% • Vacuum/forceps: 24% **G2:** • Spont: 77% • Vacuum/forceps: 23% **Birthweight (mean ± SD)** **G1:** 3184g ± 461 **G2:** 3188g ± 459 NS	**Episiotomy rate vs. sec deg tear** **G1:** 38% vs. 62% **G2:** 36% vs. 64% NS **Duration of repairs (mean time ± SD)** **G1:** 21min ± 11.3 **G2:** 25min ± 12 *P* < 0.001 **Delivery attendant** **G1:** • Midwife: 71% • Medical officers/ consultants: 29% **G2:** • Midwife: 68% • Medical officers/ consultants: 32%	**<u>Short term: 48 hrs</u> (int)** **Perineal pain** **G1:** 57% **G2:** 65% RR = 0.87 (0.78, 0.97) **Analgesia use** **G1:** 34% **G2:** 49% RR = 0.71 (0.60, 0.83) **<u>Short term: 14 days</u> (int)** **Perineal pain** **G1:** 22% **G2:** 29% RR = 0.77 (0.61, 0.98) **Analgesia use** **G1:** 5% **G2:** 9% RR = 0.54 (0.32, 0.90) **<u>Short term: 6 wks</u> (int)** **Perineal pain** **G1:** 10% **G2:** 15% RR = 0.64 (0.44, 0.93) **Analgesia use** **G1:** 1% **G2:** 2% RR = 0.56 (0.16, 1.89) **<u>Long term: 3 mos</u> (quest)** **Perineal pain** **G1:** 1% **G2:** 5% RR = 0.19 (0.06, 0.54) **Analgesia use** **G1:** 0% **G2:** 1% RR = 0.16 (0.02, 1.34) NS

Evidence Table 3. Key Question 3: Methods of repair – 2-layer versus 3-layer repair (continued)

Sexual Function Outcomes	Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Short term: 6 wks (int) **Superficial dyspareunia** **G1:** 11% **G2:** 18% RR = 0.60 (0.42, 0.85) **Deep dyspareunia** **G1:** 8% **G2:** 9% RR = 0.89 (0.56, 1.41) **Resumed intercourse pain free** **G1:** 26% **G2:** 10% RR = 2.54 (1.82, 3.55) **Tried but too painful** **G1:** 10% **G2:** 22% RR = 0.43 (0.39, 0.99) **Long term: 3 mos (quest)** **Resumed intercourse < 2 mos** **G1:** 59% **G2:** 50% RR = 1.16 (1.03, 1.32) **Resume intercourse 2 to 3 mos** **G1:** 22% **G2:** 16% RR = 1.39 (1.05, 1.85)	**Short term: 48 hrs (exam)** **Tight stitches** **G1:** 25% **G2:** 38% RR = 0.67 (0.54, 0.82) **Inflammation/ bruising** **G1:** 7% **G2:** 14% RR = 0.50 (0.33, 0.77) **Wound gaping (edges > 0.5 cm apart)** **G1:** 26% **G2:** 5% RR = 4.96 (3.17, 7.76) **Primary healing (skin edges apposed)** **G1:** 56% **G2:** 62% RR = 0.91 (0.81, 1.02) **Secondary healing (skin edges not apposed but < 0.5 cm apart)** **G1:** 53% **G2:** 59% RR = 0.89 (0.79, 1.01)	**Short term** NR **Long term** NR	**Short term** NR **Long term** NR	**Overall quality** Fair **Randomization approach and implementation** Good **Masking** **Assessor blind to allocation** Good **Operational definitions and measures** Fair **Intention-to-treat analyses** No **Post-randomization exclusions** Yes **Retention of participants** **48 hrs** **Total:** 1077 (100%) **14 days** **Total:** 823 (76%) **6 wks** **Total:** 823 (76%) **3 mos** **Total:** 823 (76%)

Evidence Table 3. Key Question 3: Methods of repair – 2-layer versus 3-layer repair (continued)

Study Characteristics	Demographic Characteristics	Labor and Delivery Characteristics	Episiotomy and Repair Characteristics	Pain Outcomes
Author Oboro et al., 2003 (continued)				

Evidence Table 3. Key Question 3: Methods of repair – 2-layer versus 3-layer repair (continued)

Sexual Function Outcomes	Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Long term: 3 mos **Superficial dyspareunia** **G1:** 6% **G2:** 12% RR = 0.52 (0.33, 0.81) **Deep dyspareunia** **G1:** 4% **G2:** 5% RR = 0.83 (0.44, 1.56)	**Short term: 14 days (exam/int)** **Suturing removed** **G1:** 5% **G2:** 9% RR = 0.58 (0.35, 0.96) **Wound breakdown** **G1:** 3% **G2:** 2% RR = 1.27 (0.56, 2.85) **Wound gaping (edges > 0.5 cm apart)** **G1:** 21% **G2:** 17% RR = 1.25 (0.94, 1.67) **Short term: 6 wks (exam/int)** **Suturing removed** **G1:** 6% **G2:** 10% RR = 0.58 (0.36, 0.93) **Resuturing required** **G1:** 3% **G2:** 4% RR = 0.63 (0.30, 1.33) **Long term: 3 mos (quest)** **Suturing removed** **G1:** 6% **G2:** 10% RR = 0.62 (0.39, 0.99) **Resuturing required** **G1:** 3% **G2:** 5% RR = 0.60 (0.31, 1.19)	**Short term** NR **Long term** NR	**Short term** NR **Long term** NR	

Evidence Table 3. Key Question 3: Methods of repair – 2-layer versus 3-layer repair (continued)

Study Characteristics	Demographic Characteristics	Labor and Delivery Characteristics	Episiotomy and Repair Characteristics	Pain Outcomes
Author Gordon et al., 1998 **Setting** UK **Study design** RCT 2x2 factorial **Inclusion criteria** • First and sec deg laceration or episiotomy • Spont delivery • Simple instr delivery (non-rotational forceps or vacuum extraction) **Exclusion criteria** NR **Groups** **G1:** 2-stage (unsutured perineal skin) **G2:** 3-stage (sutured perineal skin) **N at randomization** **G1:** 890 **G2:** 890 **Total:** 1, 780 **Followup** 3 mos	**Age (mean ± SD)** **G1:** 28.5yrs ± 4.8 **G2:** 28.2yrs ± 5.0 **Primiparous** NR **Previous vaginal delivery** **G1:** 40% **G2:** 43% **Previous perineal suturing** **G1:** 37% **G2:** 35%	**Mode of delivery** **G1:** • Spont: 83% • Instr: 17% **G2:** • Spont: 82% • Instr: 18% **Birthweight (mean ± SD)** **G1:** 3507g ± 500 **G2:** 3503g ± 482	**Episiotomy rate** **G1:** 36% **G2:** 38% **Lacerations** **G1:** • First deg: 1% • Sec deg: 62% • Third deg: 1% **G2:** • First deg: 2% • Sec deg: 60% • Third deg: 0% **Suture type** **G1:** • PGA: 49% • CC: 51% • Both: 1% **G2:** • PGA: 50% • CC: 49% • Both: 1% **Suture method** **G1:** • 2-stage only: 87% • Subcut: 2% • Interr: 10% • Both: 0% **G2:** • 2-stage only: 1% • Subcut: 26% • Interr: 72% • Both: 0%	**Short term: 24 to 48 hrs (int)** **Any pain in past 24 hrs** Mild: NS Mod: NS Severe: NS **Analgesia requirements in past 24 hrs** **G1:** 42% **G2:** 7% *P* = 0.03 **Short term: 10 days (int)** **Any pain in past 24 hrs** Mild: NS Mod: NS Severe: NS **Analgesia requirements in past 24 hrs** NS **Long term: 3 mos (quest)** **Any pain in past 24 hrs** **G1:** • Mild: 6% • Mod: 1% • Severe: 0% **G2:** • Mild: 7% • Mod: 2% • Severe: 0% *P* (for trend) = 0.01

Evidence Table 3. Key Question 3: Methods of repair – 2-layer versus 3-layer repair (continued)

Sexual Function Outcomes	Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Short term NR **Long term: 3 mos** **Resumption of sexual intercourse (quest)** Tried but too painful: NS By 3 mos: NS By 2 mos: NS By 1 mo: NS Not known: NS **Dyspareunia at first, if resumed (quest)** NS **Dyspareunia now, if resumed (quest)** Mild: NS Mod: NS Severe: NS Not known: NS	**Short term: 24 to 48 hrs (int)** **Gaping perineum (exam)** **G1:** 23% **G2:** 4% *P* < 0.0000001 **Tight stitches** NS **Stitches not comfortable** NS **Short term: 10 days** **Tight stitches (int)** **G1:** 14% **G2:** 18% *P* = 0.02 **Stitches not comfortable (int)** NS **Gaping perineum (exam)** **G1:** 26% **G2:** 16% *P* < 0.00001 **Nature of healing: First intention (exam)** **G1:** 75% **G2:** 84% *P* < 0.0001 **Nature of healing: Other levels (exam)** Sec intention: NS Breaking down: NS Not known: NS **Sutures removed (exam)** **G1:** 3% **G2:** 8% *P* < 0.0001 **Long term: 3 mos (quest)** **Sutures removed at any time** **G1:** 7% **G2:** 11% *P* = 0.002 **Resutured** NS	**Short term** NR **Long term** NR	**Short term** NR **Long term** NR	**Overall quality** Good **Randomization approach and implementation** Good **Masking** Good **Operational definitions and measures** Good **Post-randomization exclusions** No **Retention of participants** **24 to 48 hrs** **G1:** 885 (99%) **G2:** 889 (100%) **Total:** 1774 (100%) **10 days** **G1:** 886 (100%) **G2:** 885 (99%) **Total:** 1771 (99%) **3 mos** **G1:** 828 (93%) **G2:** 836 (94%) **Total:** 1664 (93%)

Evidence Table 3. Key Question 3: Methods of repair – 2-layer versus 3-layer repair (continued)

Study Characteristics	Demographic Characteristics	Labor and Delivery Characteristics	Episiotomy and Repair Characteristics	Pain Outcomes
Author Grant et al., 2001 **Setting** UK **Study design** RCT 2x2 factorial **Inclusion criteria** • First and sec deg laceration or episiotomy • Spont delivery • Simple instr delivery (non-rotational forceps or vacuum extraction) from early 1993 **Exclusion criteria** NR **Groups** **G1:** Unsutured perineal skin (2-stage) **G2:** Sutured perineal skin (3-stage repair including skin closure with interr or subcut sutures) **N at randomization** **G1:** 890 **G2:** 890 **Total:** 1789 **Followup** 1 yr (restricted to a subset of those randomized) **N at 1 yr** **G1:** NR **G2:** NR **Total:** 919	**Age (mean ± SD)** **G1:** 29.1yrs ± 4.7 **G2:** 28.6yrs ± 4.9 **Primiparous** **G1:** 48% **G2:** 55% **Previous vaginal delivery** **G1:** 35% **G2:** 36% **Previous perineal suture** **G1:** 34% **G2:** 33%	**Mode of delivery** **G1:** • Spont: 69% • Instr: 31% **G2:** • Spont: 69% • Instr: 31% **Other labor characteristics** **Birthweight (mean ± SD)** **G1:** 3556g ± 528 **G2:** 3504g ± 487 **Episiotomy use** **G1:** 43% **G2:** 47%	**Episiotomy rate** **G1:** 36% **G2:** 38% **Lacerations** **G1:** • First deg: 1% • Sec deg: 62% • Third deg: 1% **G2:** • First deg: 2% • Sec deg: 60% • Third deg: 0% **Repair by** **G1:** • Student: 1% • Midwife: 60% • Registrar: 33% • SHO: 7% **G2:** • Student: 1% • Midwife: 62% • Registrar: 32% • SHO: 6% **Suture type** **G1:** • PGA: 49% • CC: 50% • Both: 1% **G2:** • PGA: 50% • CC: 50% • Both: 1% **Suture method** **G1:** • Subcut: 2% • Subcut and interr: 0% • Interr: 0% • 2-stage only: 89% **G2:** • Subcut: 34% • Subcut and interr: 0% • Interr: 64% • 2-stage only: 2%	**Short term** NR **Long term: 1 yr (quest)** **Still pain or general discomfort where stitched** Mild: NS Mod: NS Severe: NS

Evidence Table 3. Key Question 3: Methods of repair – 2-layer versus 3-layer repair (continued)

Sexual Function Outcomes	Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Long term: 1 yr (quest) **Timing of resumption of sexual intercourse** Tried but too painful: NS By 6 mos: NS By 3 mos: NS Could not remember: NS No partner: NS Not known: NS **Dyspareunia at first, if resumed** NS **Dyspareunia now, if resumed** NS **Failure to resume pain-free intercourse** NS	**Long term: 1 yr (quest)** **Area cut or torn feels different** **G1:** 30% **G2:** 40% *P* < 0.01 **Resutured** NS	**Long term** NR	**Long term** NR	**Overall quality** Good **Randomization approach and implementation** Good **Masking** Good **Operational definitions and measures** Good **Post-randomization exclusions** No **Retention of participants** **1 yr** **G1:** 396 **G2:** 397 **Total:** 793

Evidence Table 4. Key Question 3: Methods – Continuous versus interrupted sutures

Study Characteristics	Demographic Characteristics	Labor and Delivery Characteristics	Episiotomy and Repair Characteristics	Pain Outcomes
Author Kettle et al, 2002 **Setting** UK **Study design** RCT 2x2 factorial **Inclusion criteria** Spont vaginal delivery with sec deg perineal tear or episiotomy **Exclusion criteria** • Instr delivery • Extensive perineal trauma beyond scope of midwife's practice • Previous perineal surgery other than primary repair after childbirth • Stillbirth or baby with extensive congenital abnormalities • Women with AIDS or Hepatitis B, severe perineal warts, or extensive varicose veins of external genitalia • < 16 yrs • Unable to read, write or understand English	**Age (mean ± SD)** **G1:** 27.2yrs ± 5.4 **G2:** 27.2yrs ± 5.3 **Previous sutured perineal trauma** **G1:** 41% **G2:** 39% **Primiparous** **G1:** 54% **G2:** 57%	**Mode of delivery** **Spont** **G1:** 100% **G2:** 100% **Birthweight (mean ± SD)** NR	**Episiotomy rate** **G1:** 41% **G2:** 42% **Lacerations** **G1:** • Sec deg: 58% • Third/fourth deg: <1% **G2** • Sec deg: 58% • Third/fourth deg**:** <1% **Episiotomy extend to third deg tear** **G1:** 1% **G2:** 0% **Identity of the operator** **Student midwife** **G1:** 0 **G2:** <1% **Midwife grade E** **G1:** 25% **G2:** 29% **Midwife grade F** **G1:** 26% **G2:** 32% **Midwife grade G/H** **G1:** 48% **G2:** 36% **Doctor/other** **G1:** 2% **G2:** 2% *P* < 0.0001 **Suture method** **G1:** Cont: 100% **G2:** Interr: 100%	**<u>Short term: 24 hrs</u> (quest)** **Pain relief** **G1:** 8.5% **G2:** 13.5% OR = 0.60 (0.40, 0.92) *P* = 0.002 **Pain walking** **G1:** 32% **G2:** 43% OR = 0.62 (0.47, 0.82) *P* < 0.0001 **Pain sitting** **G1:** 39% **G2:** 55% OR = 0.54 (0.41, 0.70) *P* < 0.0001 **Pain passing urine** **G1:** 26% **G2:** 36% OR = 0.63 (0.47, 0.83) *P* < 0.0001 **<u>Short term: 2 days</u> (quest)** **Pain at the time of response** **G1:** 69% **G2:** 79% OR = 0.59 (0.44, 0.79) *P* < 0.0001 **<u>Short term: 10 days</u> (quest)** **Pain at the time of response** **G1:** 26% **G2:** 44% OR = 0.47 (0.35, 0.61) *P* < 0.0001

Evidence Table 4. Key Question 3: Methods – Continuous versus interrupted sutures (continued)

Sexual Function Outcomes	Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Long term: 3 mos (quest filled by mother) **Dyspareunia** NS **Long term: 12 mos (quest filled by mother)** **Dyspareunia** NS	**Short term: 2 days (quest)** **Wound gaping** OR = 0.69 (0.30, 1.61) NS **Sutures uncomfortable** **G1:** 35% **G2:** 41% OR = 0.78 (0.64, 0.96) **Sutures tight** **G1:** 2% **G2:** 4% OR = 0.40 (0.22, 0.74) **Short term: 10 days (quest)** **Wound gaping** **G1:** 3% **G2:** 7% OR = 0.46 (0.29, 0.74) **Sutures uncomfortable** **G1:** 17% **G2:** 27% OR = 0.58 (0.46, 0 .74) **Sutures tight** **G1:** 3% **G2:** 7% OR = 0.43 (0.27, 0.69) **Sutures removed** **G1:** 0.5% **G2:** 7.2 OR = 0.17 (0.10, 0.28)	**Short term** NR **Long term** **NR**	**Short term** NR **Long term: 3 mos** **Back to normal** **G1:** 59% **G2:** 48% OR: 1.55 (1.26, 1.92) **Satisfaction with repair** **G1:** 84% **G2:** 76% OR: 1.64 (1.28, 2.11) **Long term: 12 mos** **Satisfaction with repair** **G1:** 86% **G2:** 77% OR: 1.68 (1.27, 2.21)	**Overall quality** Good **Randomization approach and implementation** Good **Masking** Good **Operational definitions and measures** Good **Post-randomization exclusions** 2 fetal deaths **Retention of participants** **24 to 48 hrs** **Total:** 1540 (100%) **Day 10** **Total:** 1539 (100%) **3 mos** **Total:** 1492 (96.7%) **12 mos** **Total:** 1389 (90.1%)

Evidence Table 4. Key Question 3: Methods – Continuous versus interrupted sutures (continued)

Study Characteristics	Demographic Characteristics	Labor and Delivery Characteristics	Episiotomy and Repair Characteristics	Pain Outcomes
Author Kettle et al., 2002 (continued) **Groups** **G1:** Cont suture **G2:** Interr suture **N at randomization** **G1:** 771 **G2:** 771 **Followup** 1 yr			**Materials (all PGA)** **G1:** • Rapidly absorbed: 50% • Standard: 50% **G2:** • Rapidly absorbed: 50% • Standard: 50% **Number of sutures packets used** **1** **G1:** 79% **G2: 32**% **2** **G1:** 21% **G2:** 67% **3** **G1:** < 1% **G2:** 1%	**<u>Short term: 24 hrs</u> (quest) (cont)** **Pain opening bowels** **G1:** 41% **G2:** 48% OR = 0.74 (0.57, 0.97) *P* = 0.004 **<u>Long term: 3 mos</u> (quest)** **Pain at the time of response** **G1:** 9% **G2:** 13% OR = 0.70 (0.46, 1.07) *P* = 0.03 **<u>Long term: 12 mos</u> (quest)** **Pain at the time of response** **G1:** 4% **G2:** 7% OR = 0.64 (0.35, 1.16) *P* = 0.05

Evidence Table 4. Key Question 3: Methods – Continuous versus interrupted sutures (continued)

Sexual Function Outcomes	Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
	Short term: 10 days **Sutures** **G1:** 3% **G2:** 9% OR = 0.36 (0.23, 0.55) **Short term: before 3 mos (after 10 days)** **Sutures removed** **G1:** 3% **G2:** 12.5% OR: 0.27 (0.19, 0.40)	**Short term** NR **Long term** NR	**Short term** NR **Long term: 3 mos** **Back to normal** **G1:** 54% **G2:** 48% OR: 1.55 (1.26, 1.92) **Satisfaction with repair** **G1:** 84% **G2:** 76% OR: 1.64 (1.28, 2.11) **Long term: 12 mos** **Satisfaction with repair** **G1:** 86% **G2:** 79% OR: 1.68 (1.27, 2.21)	

Evidence Table 4. Key Question 3: Methods – Continuous versus interrupted sutures (continued)

Study Characteristics	Demographic Characteristics	Labor and Delivery Characteristics	Episiotomy and Repair Characteristics	Pain Outcomes
Author Mahomed et al., 1989 **Setting** UK **Study design** RCT 2x3x2 factorial **Inclusion criteria** Required perineal repair **Exclusion criteria** NR **Groups** **G1:** Cont subcut sutures **G2:** Interr transcut sutures **N at randomization** **G1:** 533 **G2:** 524 **Followup** 3 mos	**Age (mean ± SD)** **G1:** 26.0yrs ± 4.8 **G2:** 25.9yrs ± 5.0 **Primiparous** **G1:** 48% **G2:** 55%	**Mode of delivery Operative** **G1:** 23% **G2:** 23% **Birthweight (mean ± SD)** **G1:** 3383g ± 477 **G2:** 3341g ± 480	**Episiotomy rate** **G1:** • Episiotomy alone: 54% • Episiotomy+ext: 10% • Tear: 36% **G2:** • Episiotomy alone: 48% • Episiotomy+ext: 16% • Tear: 37% **Suture type** **Vagina, deep tissues** **G1:** • PGA: 49% • CC: 51% **G2:** • PGA: 48% • CC: 52% **Perineal skin** **G1:** • PGA: 46% • CC: 49% • Silk: 2% **G2:** • PGA: 45% • CC: 48% • Silk: 2% **Skin closure** **G1:** • Subcut: 70% • Interr: 18% • Both: 9% • None: 3% **G2:** • Subcut: 2% • Interr: 93% • Both: 1% • None: 4% **Operator** **G1:** • Midwife: 25% • SHO: 64% • Registrar: 9% • GP: 3% **G2:** • Midwife: 34% • SHO: 53% • Registrar: 0% • GP: 3%	**Short term: 48 hrs (assessed by postnatal staff or community midwife)** **Use of oral analgesia** NS **Perineal pain "now" measured** NS **Short term: 10 days** **Use of oral analgesia** NS **Perineal pain (assessed by mother)** None: NS Mild: NS Mod: NS Severe: NS **Long term: 3 mos (assessed by mother)** **Perineal pain** None: NS Mild: NS Mod: NS Severe: NS

Evidence Table 4. Key Question 3: Methods – Continuous versus interrupted sutures (continued)

Sexual Function	Repair and Healing	Incontinence	Other description of Outcome	Quality and Comments
Short term NR **Long term: 3 mos** **Sexual intercourse not resumed** NS **Dyspareunia** NS	**Short term** NR **Long term: 3 mos (quest)** **Absorbable material removed** **G1:** 26% **G2:** 37% *P* < 0.001 **Resutured** NS	**Short term** NR **Long term** NR	**Short term** NR **Long term** NR	**Overall quality** Good **Randomization approach and implementation** Good **Masking** Good **Operational definitions and measures** Good **Post-randomization exclusions** No **Retention of participants** **Short term: <3 mos** **48 hrs** **G1:** 509 (95%) **G2:** 515 (98%) **Total:** 1024 (97%) **Day 10** **G1:** 447 (84%) **G2:** 461 (88%) **Operator** **G1:** • Midwife: 25% • SHO: 64% • Registrar: 9% • GP: 3% **G2:** • Midwife: 34% • SHO: 53% • Registrar: 0% • GP: 3% **Long term: 3 mos** **GI:** 465 (87%) **G2:** 451 (86%) **Total:** 916 (87%)

Evidence Table 5. Key Question 3: Materials – Absorbable sutures versus tissue adhesive

Study Characteristics	Demographic Characteristics	Labor and Delivery Characteristics	Episiotomy and Repair Characteristics	Pain Outcomes
Author Bowen and Selinger, 2002 **Setting** UK **Study design** RCT **Inclusion criteria** Primiparous female expecting a normal delivery and requiring an episiotomy repair **Exclusion criteria** • Multiparous • Perineal tear • Unable to give consent • Prenatal treatment of vulvo-vaginal problems and symptoms where subjective assessment of pain scores would be difficult **Groups** **G1:** Enbucrilate tissue adhesive **G2:** Subcut PGA sutures **N at randomization** **G1:** 32 **G2:** 30 **Followup** 3 to 6 wks	**Age (mean ± SD)** **G1:** 26yrs ± 4.2 **G2:** 26yrs ± 5.4 **Primiparous** **G1:** 100% **G2:** 100%	**Mode of delivery** NR **Birthweight (mean ± SD)** NR	**Episiotomy rate** **G1:** 100% mediolateral **G2:** 100% mediolateral **Suture type** **G1:** 100% enbucrilate tissue adhesive **G2:** 100% PGA **Repair by** **G1:** Gynecologist: 100% **G2:** Midwife: at least 90% or greater (not specified)	**Short term: Days 1 to 6** Definition: Mean score of perineal pain (1 to 10 VAS) days 1, 2, 3, 4, 5 **Short term: Day 1** **Micturation** **G1:** 4.5 **G2:** 6.3 *P* = 0.025 **Other pain measures** NS **Short term: Day 2** **Walking** **G1:** 2.7 **G2:** 4.0 *P* = 0.0015 **Other pain measures** NS **Short term: Day 3** **Micturation** **G1:** 3.0 **G2:** 4.0 *P* = 0.025 **Defecation** **G1:** 2.2 **G2:** 4.3 *P* = 0.003 **Other pain measures** NS **Short term: Day 4** **Walking** **G1:** 2.1 **G2:** 2.8 *P* = 0.029 **Defecation** **G1:** 2.1 **G2:** 3.7 *P* = 0.015 **Other pain measures** NS **Short term: Day 5** **All pain measures** NS **Short term: 3 to 6 wks** **Mean time taken to achieve zero pain score** **G1:** 18 **G2:** 25 *P* = 0.0017 **Long term** NR

Evidence Table 5. Key Question 3: Materials – Absorbable sutures versus tissue adhesive (continued)

Sexual Function Outcomes	Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Short term: 3 to 6 wks **(quest)** **Mean time taken to achieve pain-free sex** **G1:** 34 **G2:** 52 *P* = 0.0009 **Long term** NR	**Short term** • No cases of wound infection or dehiscence • No patients required the suture to be removed **Long term** NR	**Short term** NR **Long term** NR	**Short term** NR **Long term** NR	**Overall quality** Poor **Randomization approach and implementation** Poor (randomization broken) **Masking** Fair **Operational definitions and measures** Good **Post-randomization exclusions** Yes **Retention of participants** **Days 1 to 5** **Total:** 57 (92%)

Evidence Table 5. Key Question 3: Materials – Absorbable sutures versus tissue adhesive (continued)

Study Characteristics	Demographic Characteristics	Labor and Delivery Characteristics	Episiotomy and Repair Characteristics	Pain Outcomes
Author Adoni and Anteby, 1991 **Setting** Israel **Study design** RCT **Inclusion criteria** Episiotomy **Exclusion criteria** NR **Groups** **G1:** First episiotomy, cont CC stitches **G2:** Repeat episiotomy, cont CC stitches **G3:** First episiotomy, Histoacryl-tissue adhesive **N at randomization** **G1:** 20 **G2:** 20 **G3:** 20 (G2 not randomized, not included in outcomes) **Followup** 2 days	**Age (mean ± SD)** NR **Parity** NR **Other demographics** NR	**Mode of delivery** NR **Other labor characteristics** **Birthweight (mean ± SD)** NR	**Suture type** **G1:** CC: 100% **G2:** CC: 100% **G3:** Histoacryl: 100%	**<u>Short term: 48 hrs</u> (quest)** **Needed analgesia drugs** **G1:** 40% **G3:** 0% **Mean score of perineal pain (1=minimum, 5=maximum)** **At episiotomy site** **G1:** 3.3 **G3:** 1.95 *P* < 0.001 **Walking** **G1:** 2.6 **G3:** 1.6 *P* < 0.001 **Sitting** **G1:** 3.6 **G3:** 1.75 *P* < 0.0001 **Lying down** **G1:** .2.35 **G3:** 1.0 *P* < 0.001 **Micturition** **G1:** 1.7 **G3:** 1.0 *P* < 0.03 **<u>Long term</u>** NR

Evidence Table 5. Key Question 3: Materials – Absorbable sutures versus tissue adhesive (continued)

Sexual Function Outcomes	Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Short term NR **Long term** NR	**Short term** NR **Long term** NR	**Short term** NR **Long term** NR	**Short term** **Needed sitting aids** **G1:** 20% **G3:** 0% **Long term** NR	**Overall quality** Poor **Randomization approach and implementation** Poor **Masking** Good **Operational definitions and measures** Good **Post-randomization exclusions** No **Retention of participants** **2 days** **Total:** 60 (100%)

Evidence Table 6. Key Question 3: Materials: Absorbable sutures – standard versus rapidly absorbed sutures

Study Characteristics	Demographic Characteristics	Labor and Delivery Outcomes	Episiotomy and Repair Characteristics	Pain Outcomes
Author Kettle et al., 2002 **Setting** UK **Study design** RCT 2x2 factorial **Inclusion criteria** Spont vaginal delivery with sec deg perineal tear or episiotomy **Exclusion criteria** • Instr delivery • Extensive perineal trauma beyond scope of midwife practice • Previous perineal surgery other than primary repair after childbirth • Stillbirth or baby with extensive congenital abnormalities • Women with AIDS or Hepatitis B, severe perineal warts, extensive varicose veins of external genitalia • <16 yrs • Unable to read, write, understand English **Groups** **G1:** Rapidly absorbed (polyglactin) **G2:** Standard (polyglactin) **N** **G1:** 772 **G2:** 770 **Followup** 1 yr	**Age (mean ± SD)** **G1:** 27.3yrs ± 5.4 **G2:** 27.1yrs ± 5.4 **Primiparous** **G1:** 54% **G2:** 57% **Previous sutured perineal trauma** **G1:** 41% **G2:** 39%	**Mode of delivery** **Spont** **G1:** 100% **G2:** 100% **Birthweight (mean ± SD)** NR	**Episiotomy rate** **G1:** 40% **G2:** 43% **Lacerations** **G1:** • Sec deg: 59% • Third/fourth deg: <1% • Extend to third deg: <1% **G2:** • Sec deg: 56% • Third/fourth deg tear: <1% • Extend to third deg tear: 1% **Suture type** **Method** **G1:** • Cont: 50% • Interr: 50% **G2:** • Cont: 50% • Interr: 50% **Materials** **G1:** • Rapidly absorbed: 99% • Standard: 1% **G2:** • Standard: 100% **Operator** **Doctor** **G1:** 2% **G2:** 2% **Midwife E** **G1:** 27% **G2:** 26% **Midwife F** **G1:** 30% **G2:** 28% **Midwife G/H** **G1:** 27% **G2:** 26% **N suture packets used** **1** **G1:** 56% **G2:** 55% **2** **G1:** 43% **G2:** 45% **3** **G1:** 1% **G2:** < 1%	**<u>Short term: 10 days</u>** **Pain** **Cont** **G1:** 27% **G2:** 26% OR = 1.06 (0.70, 1.62) **Interr** **G1:** 39% **G2:** 48% OR = 0.70 (0.48, 1.01) Test for heterogeneity between groups: *P* = 0.05 (*P* for heterogeneity = 0.3) NS **<u>Short term: 24 hrs relief</u> (10 days quest from mother and midwife)** **Pain** **G1:** 8% **G2:** 14% OR = 0.55 (0.3, 0.83) *P* = 0.0002 **Pain walking** **G1:** 34% **G2:** 41% OR = 0.74 (0.56, 0.97) *P* = .004 **Pain sitting** **G1:** 45% **G2:** 49% OR = 0.84 (0.65, 1.10) *P* = 0.10 **Pain passing** NS **Pain opening bowels** NS **<u>Long term</u>** NR

Evidence Table 6. Key Question 3: Materials: Absorbable sutures – standard versus rapidly absorbed sutures (continued)

Sexual Function Outcomes	Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Short term NR **Long term: 3 mos (quest)** **Dyspareunia** NS **Long term: 12 mos (quest)** **Dyspareunia** NS	**Short term: 2 days (quest)** **Wound gaping** OR = 1.20 (0.52, 2.79) **Sutures uncomfortable** OR = 1.02 (0.83, 1.25) **Sutures tight** OR = 1.15 (0.63, 2.12) **Short term: 10 days (quest)** **Wound gaping** OR = 1.83 (1.14, 2.92) **Sutures uncomfortable** OR = 0.88 (0.69, 1.12) **Sutures tight** OR = 0.77 (0.48, 1.24) **Sutures removed** **G1:** 2% **G2:** 6% **OR:** 0.38 (0.23, 0.64) **Short term: 10 days to 3 mos** **Sutures removed** **G1:** 1% **G2:** 10% **OR**: 0.19 (0.13, 0.30)	**Short term** NR **Long term** NR	**Short term** NR **Long term: 3 mos** **Back to normal** OR = 1.22 (0.99, 1.51) **Satisfaction with repair** OR = 1.25 (0.97, 1.61) **Long term: 12 mos** **Satisfaction with repair** OR = 1.09 (0.83, 1.44)	**Overall quality** Good **Randomization approach and implementation** Good **Masking** Good **Operational definitions and measures** Good **Post-randomization exclusions** 2 fetal deaths **Retention of participants** **24 hrs** **G1:** 770 (100%) **G2:** 770 (100%) **Total:** 1540 (100%) **Day 10** **G1:** 769 (100%) **G2:** 770 (100%) **Total:** 1539 (99.9%) **3 mos** **G1:** 753 (98%) **G2:** 739 (96%) **Total:** 1492 (96.9%) **12 mos** **G1:** 703 (91%) **G2:** 686 (89%) **Total:** 1389 (90.2%)

Evidence Table 6. Key Question 3: Materials: Absorbable sutures – standard versus rapidly absorbed sutures (continued)

Study Characteristics	Demographic Characteristics	Labor and Delivery Characteristics	Episiotomy and Repair Characteristics	Pain Outcomes
Author McElhinney et al., 2000 **Setting** Ireland **Study design** RCT **Inclusion criteria** • Parity of 0 to 2 • 18 to 40 yrs old • Singleton fetus • Normal vaginal delivery • Required an episiotomy or sustained a sec deg floor tear **Exclusion criteria** NR **Groups** **G1:** Vicryl rapide **G2:** Vicryl **N at completion** **G1:** 75 **G2:** 78 **Total:** 153 **Followup** 12 wks	**Age** NR **Primiparous** **G1:** 53% **G2:** 56%	**Mode of delivery** NR **Birthweight (mean ± SD)** NR	NR	**Short term: 24 hrs** **Perineal pain (measured with VAS)** NS **Short term: 3 days** **(Measured by 4-pt pain scale)** NS **Analgesic use (Prior to discharge)** NS **Long term** NR

Evidence Table 6. Key Question 3: Materials: Absorbable sutures – standard versus rapidly absorbed sutures (continued)

Sexual Function Outcomes	Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Short term NR **Long term: 12 wks** **Dyspareunia (int)** **G1:** Mean score of 0.05 in 5% of patients who had dyspareunia **G2:** Mean score of 0.27 in 20% of patients who had dyspareunia *P* < 0.05	**Short term: 6 wks** **Wound problems (infection, gaping wound, pain or residual material requiring removal)** **G1:** 2% **G2:** 30% **Long term: 12 wks** **Wound problems of women experiencing wound problems at 6 wks** **G1:** 5% **G2:** 95% "Still very significant"	**Short term** NR **Long term** NR	**Short term** NR **Long term** NR	**Overall quality** Poor **Randomization approach and implementation** Fair **Masking** Poor **Operational definitions and measures** Fair **Post-randomization exclusions** No **Retention of participants** **24 hrs** **Total:** 153 (100%) **Day 3** **Total:** 153 (100%) **6 wks** **Total:** 118 (77%) **12 wks** **Total:** 118 (77%)

Evidence Table 7. Key Question 3: Materials – Untreated catgut versus treated catgut

Study Characteristics	Demographic Characteristics	Labor and Delivery Characteristics	Episiotomy and Repair Characteristics	Pain Outcomes
Author Spencer et al., 1986 Grant et al., 1989 **Setting** UK **Study design** RCT **Inclusion criteria** • Spont vaginal deliveries • Required perineal repairs **Exclusion criteria** NR **Groups** **G1:** Chromic "softgut" **G2:** Untreated CC **N at randomization** **G1:** 377 **G2:** 360 **Total:** 737 **Followup** 3 mos	**Age (mean ± SD)** **G1:** 26.5yrs ± 5.1 **G2:** 27.1yrs ± 5.3 **Primiparous** **G1:** 49.1% **G2:** 44.4% **Married** **G1:** 89.9% **G2:** 88.8 % **Babies born since study** **G1:** • 0: 56% • 1: 41% • 2: 3% **G2:** • 0: 62% • 1: 37% • 2: 1%	**Mode of delivery** Spont: 100% **Birthweight (mean ± SD)** **G1:** 3419g ± 440 **G2:** 3384g ± 435 **(Collected at 3 year followup)** **GA** **G1:** 39.9wks ± 1.2 **G2:** 39.8wks ± 1.1 (mean, SD) **Episiotomy performed in next pregnancy** **G1:** 25% **G2:** 14%	**Episiotomy rate** **G1:** 36.1% **G2:** 7.8% Note: Article reports 7.8%, which we believe is a typo because the percentages in that particular column would add to 100%. We believe the correct value is 37.8% **Episiotomy and ext** **G1:** 5.0% **G2:** 4.7% **Posterior tear alone** **G1:** 53.8% **G2:** 53.9% **Labial tear alone** **G1:** 5.0% **G2:** 3.6% **Suture type** **G1:** • CC: 8.0% • Soft-gut: 91.8% **G2:** • CC: 95.3% • Soft-gut: 4.4% **Suture method** **G1:** • Subcut: 31.9% • Interr: 60.9% • Both: 7.2% **G2:** • Subcut: 32.4% • Interr: 59.5% • Both: 8.1% **Repair done by** **G1:** • SHO: 87% • Student: 8.5% • Registrar: 4.5% **G2:** • SHO: 85.8% • Student: 9.7% • Registrar: 4.5%	**Short term: 10 to 12 days (quest)** **Experienced perineal pain within last 24 hrs (asked at 10 to 12 days)** **None** **G1:** 68.1% **G2:** 76.6% **Mild** **G1:** 20.9% **G2:** 14.3% **Mod** **G1:** 9.6% **G2:** 9.0% **Severe** **G1:** 1.5% **G2:** 0% *P* = 0.15 (overall) **Used oral analgesics** NS **Use of salt bath for pain on that day** **G1:** 42% **G2:** 34% *P* = 0.03 **Long term: 3 mos** **Experienced perineal pain within last 7 days (asked at 3 mos, quest)** None: NS Mild: NS Mod: NS Severe: NS

Evidence Table 7. Key Question 3: Materials – Untreated catgut versus treated catgut (continued)

Sexual Function	Repair and Healing	Incontinence	Other description of Outcome	Quality and Comments
Short term NR **Long term: 3 mos (quest)** **Dyspareunia** **None:** **G1:** 38.0% **G2:** 50.7% **At first but not at 3 mos** **G1:** 36% **G2:** 29.8% **Mild** **G1:** 23.3% **G2:** 18.1% **Mod** **G1:** 2.7% **G2:** 1.4% *P* < 0.025 **Recommencement of sexual intercourse** NS **Long term: 3 yrs (quest)** **Sexual intercourse painful** **G1:** 19% **G2:** 11% OR: 1.7 (1.1, 2.6) *P* < 0.02 **Soreness** **G1:** 16% **G2:** 11% **Tightness** **G1:** 0.8% **G2:** 0% **Other** **G1:** 2.3% **G2:** 0.4%	**Short term: 10 days (assessed by midwife)** **Sutures removed** **G1:** 2.4% **G2:** 11.5% *P* < 0.0001 **Short term: 10 to 12 days (assessed by midwife)** **Perineal breakdown** NS **Healing by secondary intention** NS **Long term: 3 mos (quest)** **Sutures removed** **G1:** 6.9% **G2:** 16.4% *P* < 0.001	**Short term** NR **Long term** NR	**Short term** NR **Long term** NR	**Quality** Fair **Randomization approach and implementation** Fair **Masking** Good **Post-randomization exclusions** No **Retention of participants** **10 to 12 days** **G1:** 336 (89%) **G2:** 322 (89%) **Total:** 658 (89%) **3 mos** **G1:** 332 (88%) **G2:** 323 (90%) **Total:** 655 (89%) **3 yrs** **G1:** 263 (70%) **G2:** 253 (70%) **Total:** 516 (70%)

Evidence Table 8. Key Question 3: Materials – Nonabsorbable versus absorbable

Study Characteristics	Demographic Characteristics	Characteristics of Labor, Delivery and Repair	Episiotomy and Repair Characteristics	Pain Outcomes
Author Buchan and Nicholls, 1980 **Setting** UK **Study design** RCT **Inclusion criteria** • Primigravidae • Spont vaginal delivery • Mediolateral episiotomy **Exclusion criteria** • Extended episiotomy • Additional lacerations **Groups** **G1:** Interr black silk sutures (Ethicon 562) **G2:** Absorbable subcut Dexon suture **N at randomization** **G1:** 70 **G2:** 70 **Total:** 140 **Followup** 4 mos	**Age (mean ± SD or median)** NR **Primiparous** **G1:** 100% **G2:** 100%	**Mode of delivery** **G1:** Spont: 100% **G2:** Spont: 100% **Birthweight (mean ± SD)** NR	**Suture type** **G1:** CC/black silk: 100% **G2:** CC/Dexon: 100%	**<u>Short term: (Days 1 to 6)</u>** Analgesic requirements (mean N of tablets ± SD) **Day 1** **G1:** 3.42 ± 2.83 **G2:** 2.82 ± 2.93 NS **Day 2** **G1:** 5.80 ± 2.89 **G2:** 5.77 ± 2.63 NS **Day 3** **G1:** 5.31 ± 2.66 **G2:** 4.34 ± 2.93 (*P* < 0.001) **Day 4** **G1:** 5.85 ± 3.23 **G2:** 3.93 ± 3.34 (*P* < 0.001) **Day 5** **G1:** 5.62 ± 2.94 **G2:** 3.38 ± 3.28 (*P* < 0.001) **Day 6** **G1:** 2.61 ± 2.34 **G2:** 2.28 ± 2.06 NS **<u>Long term</u>** NR

Evidence Table 8. Key Question 3: Materials – Nonabsorbable versus absorbable (continued)

Sexual Function Outcomes	Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Short term NR **Long term: 4 mos (quest)** **Coital assessment** **No pain at all** **G1:** 21% **G2:** 11% *P* < 0.001 **Pain for <4 wks after initial coitus** **G1:** 33% **G2:** 27% **Pain for <8 wks after initial coitus** **G1:** 33% **G2:** 45% *P* < 0.001 **Pain for > 8 wks after initial coitus** **G1:** 13% **G2:** 17% *P* < 0.001 **No association between timing of first coitus and presence or persistence of dyspareunia** NR	**Short term** NR **Long term** NR	**Short term** NR **Long term** NR	**Short term** NR **Long term** NR	**Overall quality** Fair **Randomization approach and implementation** Poor **Masking** NR **Operational definitions and measures** Poor **Post-randomization exclusions** No **Retention of participants** **1 to 6 days:** **G1:** 70 **G2:** 70 **Total:** 140 **4 mos** **G1:** 45 (64%) **G2:** 55 (79%) **Total:** 100

Evidence Table 8. Key Question 3: Materials – Nonabsorbable versus absorbable (continued)

Study Characteristics	Demographic Characteristics	Labor and Delivery Characteristics	Episiotomy and Repair Characteristics	Pain Outcomes
Author Mahomed et al., 1989 **Setting** UK **Study design** RCT 2x3x2 factorial **Inclusion criteria** Required perineal repair **Exclusion criteria** NR **Groups** **G1:** PGA **G2:** CC **G3:** Silk **N at randomization** **G1:** 535 **G2:** 522 **G3:** 517 **Followup** 3 mos	**Age (mean ± SD)** **G1:** 26.1yrs ± 5.0 **G2:** 26.2yrs ± 4.8 **G3:** 26.2yrs ± 4.9 **Primiparous** **G1:** 52% **G2:** 51% **G3**. 52%	**Mode of delivery** **Operative vaginal deliveries** **G1:** 27% **G2:** 21% **G3:** 21% **Birthweight (mean ± SD)** **G1:** 3386g ± 480 **G2:** 3338g ± 472 **G3.** 3358g ± 488	**Episiotomy rate** **G1:** • Episiotomy alone: 52% • Episiotomy+ext: 13% • Tear: 35% **G2:** • Episiotomy alone: 50% • Episiotomy+ext: 13% • Tear: 37% **G3:** • Episiotomy alone: 50% • Episiotomy+ext: 12% • Tear: 38% **Suture type** **Vagina, deep tissues** **G1:** • PGA: 52% • CC: 48% **G2:** • PGA: 44% • CC: 55% **G3:** • PGA: 48% • CC: 51% **Perineal skin** **G1:** • PGA: 87% • CC: 7% • Silk: 2% • None: 4% **G2:** • PGA: 3% • CC: 90% • Silk: 2% • None: 5% **G3:** • PGA: 2% • CC: 3% • Silk: 89% • None: 5% **Skin closure** **G1:** • Subcut: 36% • Interr: 54% • Both: 6% • None: 3% **G2:** • Subcut: 36% • Interr: 56% • Both: 4% • None: 3% **G3:** • Subcut: 1% • Interr: 93% • Both: 0% • None: 4%	**<u>Short term: 48 hrs</u>** **Use of oral analgesia (assessed by postnatal staff or community midwife)** NS **Perineal pain "now" measured** NS **<u>Short term: Day 10</u>** **(assessed by mother)** **Use of oral analgesia** NS **Perineal pain** None: NS Mild: NS Mod: NS Severe: NS **<u>Long term: 3 mos</u>** **(assessed by mother)** **Perineal pain** None: NS Mild: NS Mod: NS Severe: NS

Evidence Table 8. Key Question 3: Materials – Nonabsorbable versus absorbable (continued)

Sexual Function Outcomes	Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Short term NR **Long term: 3 mos** **Sexual intercourse not resumed** **G1:** 11% **G2:** 9% **G3:** 15% *P* < 0.05 between G2 and G3 **Dyspareunia** NS	**Short term: 48 hrs** **Edema, bruising, healing (clinically assessed)** NS **Long term** **Absorbable material removed** **G1:** 39% **G2:** 23% **G3:** 7% *P* < 0.001 **Long term: 3 mos** **Resutured (quest)** NS	**Short term** NR **Long term** NR	**Short term** NR **Long term** NR	**Overall quality** Good **Randomization approach and implementation** Good **Masking** Good **Operational definitions and measures** Good **Post-randomization exclusions** No **Retention of participants** **48 hrs** **G1:** 519 (97%) **G2:** 505 (97%) **G3:** 498 (96%) **Total:** 1522 (97%) **Day 10** **G1:** 450 (84%) **G2:** 458 (88%) **G3:** 444 (86%) **Total:** 1352 (86%) **3 mos** **G1:** 458 (86%) **G2:** 458 (88%) **G3:** 450 (87%) **Total:** 1366 (87%)

Evidence Table 9. Key Question 3: Materials – Polyglycolic acid versus chromic catgut

Study Characteristics	Demographic Characteristics	Labor and Delivery Characteristics	Episiotomy and Repair Characteristics	Pain Outcomes
Author Upton et al., 2002 **Setting** Australia **Study design** RCT **Inclusion criteria** • Singleton gestation • ≥ 34 wks • Episiotomy or first/sec deg laceration • Spont vaginal delivery **Exclusion criteria** • Third deg tear • Forceps/vacuum ("instr delivery") • Repair by "medical officer" **Groups** **G1:** PGA **G2:** CC **N at randomization** **G1:** 194 **G2:** 197 **Total:** 391 **Followup** 6 mos	**Age (mean ± SD)** **G1:** 29.6yrs ± 5.5 **G2:** 29.5yrs ± 5.2 NS **Primiparous** **G1:** 54.6% **G2:** 40.1%	**Mode of delivery** **G1:** Spont: 100% **G2:** Spont: 100% **Birthweight (mean ± SD)** **G1:** 3440g ± 467 **G2:** 3410g ± 498 **Estimated GA** **G1:** 39.5wks ± 1.4 **G2:** 39.4wks ± 1.4	**Episiotomy rate** **G1:** 20.6% **G2:** 17.8% **Lacerations** **G1:** • First deg: 11.9% • Sec deg: 67.0% **G2:** • First deg: 10.7% • Sec deg: 70.6% **Suture method** Interr for perineal muscle and subcut perineal skin (all repairs)	**<u>Short term: 1 day</u>** **Any perineal pain** **G1:** 71% **G2:** 76% **OR:** 0.75 (0.47, 1.22) NS **Mod to severe suture pain** **G1:** 24% **G2:** 20% NS **<u>Short term: 3 days</u>** **Any perineal pain** **G1:** 60% **G2:** 66% **OR:** 0.77 (0.51, 1.17) **Mod to severe suture pain** **G1:** 9% **G2:** 8% NS **<u>Short term: 6 wks</u>** **Any perineal pain** **G1:** 15% **G2:** 13% **OR:** 1.15 (0.63, 2.07) NS **<u>Long term: 3 mos</u>** **Any perineal pain** **G1:** 10% **G2:** 8% **OR:** 1.3 (0.62, 2.72) **<u>Long term: 6 mos</u>** **Any perineal pain** **G1:** 6% **G2:** 3% **OR:** 1.86 (0.61, 5.68)

Evidence Table 9. Key Question 3: Materials – Polyglycolic acid versus chromic catgut (continued)

Sexual Function Outcomes	Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Short term 6 wks (int) **Dyspareunia** **G1:** 35% **G2:** 35% OR: 1.03 (0.51, 2.12) **Recommencement of sexual intercourse** **G1:** 35% **G2:** 39% OR: 0.83 (0.54, 1.27) **Long term: 3 mos (int)** **Dyspareunia** **G1:** 27% **G2:** 19% OR: 1.56 (0.89, 2.76) **Recommencement of sexual intercourse** **G1:** 79% **G2:** 85% **OR:** 0.66 (0.38, 1.16) **Long term: 6 mos** **Dyspareunia** **G1:** 16% **G2:** 13% **OR:** 1.30 (0.68, 2.50) **Recommencement of sexual intercourse** **G1:** 96% **G2:** 95% OR: 1.00 (0.95, 1.05) NS **Long term** NR	**Short term: 6 wks (measured by quest)** **Problems with sutures** **G1:** 4.4% **G2:** 1.6% OR: 2.74 (0.65, 13.26) **Long term** NR	**Short term** NR **Long term** NR	**Short term** NR **Long term** NR	**Overall quality** Fair **Randomization approach and implementation** Fair **Masking** Fair **Operational definitions and measures** Good **Post-randomization exclusions** No **Retention of participants** **Day 1** **G1:** 172 (89%) **G2:** 174 (88%) **Total:** 346 (88%) **Day 3** **G1:** 187 (96%) **G2:** 188 (95%) **Total:** 375 (96%) **6 wks** **G1:** 184 (95%) **G2:** 184 (93%) **Total:** 368 (94%) **3 mos** **G1:** 167 (86%) **G2:** 174 (88%) **Total:** 341 (87%) **6 mos** **G1:** 158 (81%) **G2:** 159 (81%) **Total:** 317 (81%)

Evidence Table 9. Key Question 3: Materials – Polyglycolic acid versus chromic catgut (continued)

Study Characteristics	Demographic Characteristics	Labor and Delivery Characteristics	Episiotomy and Repair Characteristics	Pain Outcomes
Author Mackrodt et al., 1998 **Setting** UK **Study design** RCT **Inclusion criteria** • First and sec deg laceration or episiotomy • Spont delivery • Simple instr delivery (non-rotational forceps or vacuum extraction) **Exclusion criteria** NR **Groups** **G1:** PGA sutures **G2:** CC sutures **N at randomization** **G1:** 889 **G2:** 891 **Total:** 1780 **Followup** 3 mos	**Age (mean ± SD)** **G1:** 28.2yrs ± 5.1 **G2:** 28.4yrs ± 4.7 **Primiparous** **G1:** 62% **G2:** 60%	**Mode of delivery** **G1:** • Spont: 82% • Instr: 18% **G2:** • Spont: 83% • Instr: 17% **Birthweight (mean ± SD)** **G1:** 3517g ± 480 **G2:** 3492g ± 502 **Previous perineal suturing** **G1:** 36% **G2:** 37%	**Episiotomy rate** **G1:** 39% **G2:** 35% **Laceration** **G1:** • First deg: 1% • Sec deg: 59% • Third deg: 0% **G2:** • First deg: 2% • Sec deg: 62% • Third deg: 0% **Suture type** **G1:** • PGA: 98% • CC: 1% • Both: 1% **G2:** • PGA: 99% • CC: 1% • Both: 0% **Method** **G1:** • Subcut: 14% • Interr: 41% • 2-Stage only: 44% • None: 1% **G2:** • Subcut: 13% • Interr: 42% • 2-Stage only: 44% • None: 1%	**<u>Short term: 24 hrs</u>** **(int)** **Analgesia requirements** **G1:** 42% **G2:** 7% *P* = 0.03 **Any pain** **Mild** **G1:** 35% **G2:** 37% **Mod** **G1:** 21% **G2:** 28% **Severe** **G1:** 3% **G2:** 2% *P* (for trend) = 0.002 **<u>Short term: 10 days</u>** **(int)** **Analgesia requirements** **G1:** 6% **G2:** 10% *P* = 0.01 **Any pain** **Mild** **G1:** 14% **G2:** 17% **Mod** **G1:** 7% **G2:** 10% **Severe** **G1:** 2% **G2:** 2% *P* (for trend) = 0.05 **<u>Short term: 24 hrs</u>** **Analgesia requirements** NS **Any pain** Mild: NS Mod: NS Severe: NS **<u>Long term: 3 mos</u>** **(quest)** NS

Evidence Table 9. Key Question 3: Materials – Polyglycolic acid versus chromic catgut (continued)

Sexual Function Outcomes	Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Short term NR **Long term: 3 mos (quest)** **Timing of resumption of sexual intercourse** Tried but too painful: NS By 3 mos: NS By 2 mos: NS By 1 mo: NS Not known: NS **Dyspareunia at first, if resumed** NS **Dyspareunia now, if resumed** Mild: NS Mod: NS Severe: NS Not known: NS **Failure to resume pain-free intercourse** NS	**Short term: 24 to 48 hrs (int)** **Tight stitches** **G1:** 17% **G2:** 23% *P* = 0.001 **Stitches not comfortable** **G1:** 33% **G2:** 40% *P* = 0.003 **Short term: 24 to 48 hrs (midwife exam)** **Appearance of perineum (gaping)** NS **Short term: 10 days (int)** **Tight stitches** NS **Stitches not comfortable** **G1:** 19% **G2:** 26% *P* < 0.001 **Appearance of perineum (midwife exam)** **G1:** 16% **G2:** 26% *P* < 0.00001 **Nature of healing (midwife exam)** **First intention** **G1:** 84% **G2:** 74% *P* < 0.00001 **Sec intention** NS **Breaking down** NS **Sutures removed** NS **Long term: 3 mos (quest)** **Suture material removed at any time** **G1:** 12% **G2:** 7% *P* = 0.002 **Resutured** NS	**Short term** NR **Long term** **NR**	**Short term** NR **Long term** **NR**	**Overall quality** Good **Randomization approach and implementation** Good **Masking** Good **Operational definitions and measures** Good **Post-randomization exclusions** No **Retention of participants** **24 to 48 hrs** **G1:** 886 (100%) **G2:** 888 (100%) **Total:** 1774 (100%) **10 days** **G1:** 884 (99%) **G2:** 887 (99%) **Total:** 1771 (99%) **3 mos** **G1:** 829 (93%) **G2:** 835 (94%) **Total:** 1664 (93%)

Evidence Table 9. Key Question 3: Materials – Polyglycolic acid versus chromic catgut (continued)

Study Characteristics	Demographic Characteristics	Labor and Delivery Characteristics	Episiotomy and Repair Characteristics	Pain Outcomes
Author Grant et al., 2001 **Setting** UK **Study design** RCT **Inclusion criteria** • First and sec deg laceration or episiotomy • Spont delivery • Simple instr delivery (non-rotational forceps or vacuum extraction) **Exclusion criteria** NR **Groups** **G1:** PGA sutures **G2:** CC sutures **N at randomization** **G1:** 889 **G2:** 891 **Total:** 1780 **Followup** 1 yr **N eligible at followup** **G1:** NR **G2:** NR **Total:** 919 Note: The 1-yr postpartum followup was not part of the original plan for the study. All women recruited after June 1993 who had responded at the 3-mo followup were eligible for 1-yr followup (n = 919).	**Age (mean ± SD)** **G1:** 28.5yrs ± 5.0 **G2:** 29.2yrs ± 4.6 **Primiparous** **G1:** 65% **G2:** 64% **Previous perineal suturing** **G1:** 33% **G2:** 33%	**Mode of delivery** **G1:** • Spont: 68% • Instr: 32% **G2:** • Spont: 70% • Instr: 30% **Birthweight (mean ± SD)** **G1:** 3556g ± 504 **G2:** 3504g ± 512	**Episiotomy rate** **G1:** 48% **G2: 4**3% **Laceration** **G1:** • First deg: 1% • Sec deg: 50% • Third deg: 1% **G2:** • First deg: 2% • Sec deg: 65% • Third deg: 0% **Repair by** **G1:** • Student: 1% • Midwife: 60% • Registrar: 34% • SHO: 6% **G2:** • Student: 1% • Midwife: 62% • Registrar: 30% • SHO: 7% **Suture type** **G1:** • PGA: 99% • CC: 1% • Both: 1% **G2:** • PGA: 1% • CC: 99% • Both: 1% **Suture method** **G1:** • Subcut: 21% • Interr: 34% • 2-Stage only: 45% • None: 0% **G2:** • Subcut: 15% • Interr: 38% • 2-Stage only: 45% • None: 1%	**Long term: 1 yr (quest)** **Pain or general discomfort where stitched** Mild: NS Mod: NS Severe: NS

Evidence Table 9. Key Question 3: Materials – Polyglycolic acid versus chromic catgut (continued)

Sexual Function	Repair and Healing	Incontinence	Other description of Outcome	Quality and Comments
Long term: 1 yr (quest) **Timing of resumption of sexual intercourse** Tried but too painful: NS By 6 mos: NS By 3 mos: NS Could not remember: NS No partner: NS Not known: NS **Dyspareunia at first, if resumed** **G1:** 32% **G2:** 41% *P* = 0.01 **Dyspareunia now, if resumed** **G1:** 8% **G2:** 13% *P* = 0.02 **Failure to resume pain-free intercourse** **G1:** 8% **G2:** 14% *P* = 0.01	**Long term: 1 yr (quest)** **Area cut or torn feels different** **G1:** 31% **G2:** 38% *P* = 0.07 **Resutured** NS	**Long term** NR	**Long term** NR	**Overall quality** Good **Randomization approach and implementation** Good **Masking** Good **Operational definitions and measures** Good **Post-randomization exclusions** No **Retention of participants** **1 yr** **G1:** 395 **G2:** 398 **Total:** 793 (86%)

Evidence Table 9. Key Question 3: Materials – Polyglycolic acid versus chromic catgut (continued)

Study Characteristics	Demographic Characteristics	Labor and Delivery Characteristics	Episiotomy and Repair Characteristics	Pain Outcomes
Author Olah, 1990 **Setting** UK **Study design** RCT **Inclusion criteria** Require episiotomy repair following instr delivery (forceps or venthouse extraction) **Exclusion criteria** NR **Groups** **G1:** CC **G2:** PGA **N at randomization** **G1:** 60 **G2:** 60 **Total:** 120 **Followup** 5 days	**Age (mean ± SD)** **G1:** 26.5yrs ± 5.1 **G2:** 27.0yrs ± 5.0 **Primiparous** **G1:** 47% **G2:** 45%	**Mode of delivery** Instr 100% for both groups **Anesthesia at time of delivery** **G1:** 22% epidural/ spinal anesthesia **G2:** 26% epidural/ spinal anesthesia **Estimated GA** • 39.5wks ± 1.2 • 39.8wks ± 1.1 **Birthweight (mean ± SD)** **G1:** 3.4kg ± 0.4 **G2:** 3.4kg ± 0.4	**Episiotomy rate:** **G1:** Type not specified 100% **G2:** Type not specified 100% **Ext of episiotomy** **G1:** 4% **G2:** 6%	**Short term: Days 1 to 5** Patient's subjective assessment of discomfort/pain using a 10cm visual analog scale on (mean ± SD) **Day 1** NS **Day 3** NS **Day 5** NS **Long term** NR

Evidence Table 9. Key Question 3: Materials – Polyglycolic acid versus chromic catgut (continued)

Sexual Function Outcomes	Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Short term NR **Long term** NR	**Short term** **Edema (observer assessment, 0 (none) to 3 (severe))** NS **Bruising (observer assessment, 0 (none) to 3 (severe))** NS **Long term** NR	**Short term** NR **Long term** NR	**Short term** NR **Long term** NR	**Overall quality** Fair **Randomization approach and implementation** Fair **Masking** NR **Operational definitions and measures** Good **Post-randomization exclusions** No **Retention of participants** **1 day** **G1:** 60 (100%) **G2:** 60 (100%) **Total:** 120 (100%) (Assumed, not stated) **3 days** **G1:** 60 (100%) **G2:** 60 (100%) **Total:** 120 (100%) (Assumed, not stated) **5 days** **G1:** 60 (100%) **G2:** 60 (100%) **Total:** 120 (100%) (Assumed, not stated)

Evidence Table 9. Key Question 3: Materials – Polyglycolic acid versus chromic catgut (continued)

Study Characteristics	Demographic Characteristics	Labor and Delivery Characteristics	Episiotomy and Repair Characteristics	Pain Outcomes
Author Mahomed, 1989 **Setting** UK **Study design** RCT 2x3x2 factorial **Inclusion criteria** Required perineal repair **Exclusion criteria** NR **Groups** **G1:** PGA **G2:** CC **N at randomization** **G1:** 796 **G2:** 778 **Total:** 1574 **Followup** 3 mos	**Age (mean ± SD or median)** **G1:** 26.0yrs ± 4.9 **G2:** 26.1yrs ± 4.9 **Primiparous** **G1:** 53% **G2:** 50%	**Mode of delivery** **Operative vaginal delivery** **G1:** 23% **G2:** 23% **Birthweight (mean ± SD)** **G1:** 3371g ± 488 **G2:** 3350g ± 475	**Episiotomy rate** **G1:** • Episiotomy alone: 49% • Episiotomy+ext: 13% • Tear: 38% **G2:** • Episiotomy alone: 52% • Episiotomy+ext: 12% • Tear: 35% **Suture type** **Vagina, deep tissues** **G1:** • PGA: 93% • CC: 7% **G2:** • PGA: 2% • CC: 98% **Perineal skin** **G1:** • PGA: 35% • CC: 30% • Silk: 31% • None: 4% **G2:** • PGA: 28% • CC: 36% • Silk: 31% • None: 5% **Skin closure** **G1:** • Subcut: 25% • Interr: 68% • Both: 3% • None: 3% **G2:** • Subcut: 25% • Interr: 67% • Both: 4% • None: 4% **Midwife** **G1:** 30% **G2:** 30% **SHO** **G1:** 55% **G2:** 57% **GP** **G1:** 4% **G2:** 3% **Registrar** **G1:** 11% **G2:** 9% **Student** **G1:** 0% **G2:** 0%	**Short term: 48 hrs** **Use of oral analgesia (assessed by postnatal staff or community midwife)** **G1:** 48% **G2:** 54% RR = 0.9 (0.8, 1.0) *P = 0.03* **Perineal pain "now" measured** NS **Short term: 10 days** **Use of oral analgesia** NS **Perineal pain (assessed by mother)** None: NS Mild: NS Mod: NS Severe: NS **Long term: 3 mos** **Perineal pain (assessed by mother)** None: NS Mild: NS Mod: NS Severe: NS

Evidence Table 9. Key Question 3: Materials – Polyglycolic acid versus chromic catgut (continued)

Sexual Function Outcomes	Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Long term: 3 mos **Sexual intercourse not resumed** NS **Dyspareunia** NS	**Short term: 48 hrs (clinically assessed)** **Edema, bruising, healing** NS **Short term: 10 days** **Edema, bruising, healing** NS **Long term** **Absorbable material removed** **G1:** 25% **G2:** 21% RR = 1.2 (1.0, 1.5) *P* = 0.06 **Long term: 3 mos (quest)** **Resutured** NS	**Short term** NR **Long term** NR	**Short term** NR **Long term** NR	**Overall quality** Good **Randomization approach and implementation** Good **Masking** Good **Operational definitions and measures** Good **Post-randomization exclusions** No **Retention of participants** **2 days** **G1:** 768 (96%) **G2:** 752 (97%) **Total:** 1520 (97%) **10 days** **G1:** 679 (85%) **G2:** 670 (86%) **Total:** 1349 (86%) **3 mos** **G1:** 687 (86%) **G2:** 679 (87%) **Total:** 1366 (87%)

Evidence Table 9. Key Question 3: Materials – Polyglycolic acid versus chromic catgut (continued)

Study Characteristics	Demographic Characteristics	Characteristics of Labor, Delivery and Repair	Episiotomy and Repair Characteristics	Pain Outcomes
Author Ping and Kee, 1975 **Setting** Malaysia **Study design** RCT **Inclusion criteria** Mediolateral episiotomy **Exclusion criteria** • Additional lacerations • Exts **Groups** **G1:** PGA (Dexon) **G2:** CC (Ethicon) **N at randomization** **G1:** 61 **G2:** 61 **Total:** 122 Note: Not explicitly stated but can be inferred from first paragraph of results section **Followup** 18 to 36 hrs	**Age (mean ± SD)** **G1:** 26.7yrs ± 4.9 **G2:** 26.4yrs ± 4.8 **Primiparous** **G1:** Nulliparous: 59% **G2:** Nulliparous: 65%	**Mode of delivery** **G1:** • Spont: 66% • Vacuum: 8%, • Forceps: 23% • Breech: 3% **G2:** • Spont: 59% • Vacuum: 8% • Forceps: 26% • Breech: 7% **Birthweight** NR	**Episiotomy rate (all mediolateral** **G1:** 100% **G2:** 100%	**Short term (NR)** **Patients without pain at the episiotomy site** **G1:** 13% **G2:** 1.6% *P* < 0.05 **Deg of pain at episiotomy site** Note: 1 = mild pain, only volunteered on questioning; 2 = mod pain, complained of when patient moved; 3 = severe, discomfort even at rest, needing analgesics **G1:** 1.207 **G2:** 1.666 *P* < 0.05 **Long term** NR

Evidence Table 9. Key Question 3: Materials – Polyglycolic acid versus chromic catgut (continued)

Sexual Function Outcomes	Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Short term NR **Long term** NR	**Short term** NR **Long term** NR	**Short term** NR **Long term** NR	**Short term: (3 days)** **Ease of movement** **Good** **G1:** 66% **G2:** 56% **Restricted** **G1:** 18% **G2:** 56% **Very restricted** **G1:** 0% **G2:** 5% *P* < 0.01 **Long term** NR	**Overall quality** Fair **Randomization approach and implementation** Fair **Masking** NR **Operational definitions and measures** Good **Post-randomization exclusions** No **Retention of participants** **18 to 36 hrs** **G1:** 61 (100%) **G2:** 61 (100%)

Evidence Table 9. Key Question 3: Materials – Polyglycolic acid versus chromic catgut (continued)

Study Characteristics	Demographic Characteristics	Labor and Delivery Characteristics	Episiotomy and Repair Characteristics	Pain Outcomes*
Author Rogers, 1974 **Setting** USA **Study design** RCT **Inclusion criteria** Episiotomy **Exclusion criteria** NR **Groups** **G1:** PGA **G2:** CC **N at randomization** **G1:** 299 **G2:** 301 Note: These numbers were not explicitly stated in the article but can be inferred from the first paragraph of the results section **Followup** NR	**Age (mean ± SD)** **G1:** 23.5yrs ± 4.5 **G2:** 22.8yrs ± 4.7 **Parity** NR	**Mode of delivery** **G1:** NR **G2:** NR **Birthweight** NR	**Episiotomy rate** **Midline** **G1:** 90% **G2:** 88%	**<u>Short term: 6 wks</u>** **Pain absent in stitches** **G1:** 48% **G2:** 25% *P* < 0.001 **Deg of pain in stitches** **G1:** 3.35 **G2:** 7.08 *P* < 0.001 **<u>Subanalysis by type of episiotomy</u>** **Deg of pain for median episiotomies only** **Stitches** **G1:** 3.13 **G2:** 6.39 *P* <0.001 **Deg of pain for mediolateral episiotomies only** **Stitches** **G1:** 5.33 **G2:** 12.03 *P* <0.001 **<u>Subanalysis by complication in delivery</u>** **Deg of pain in stitches in complicated delivery** **G1:** 4.06 **G2:** 7.75 *P* < 0.05 **Deg of pain in stitches in uncomplicated delivery** **G1:** 3.26 **G2:** 7.01 *P* < 0.001 **<u>Long term</u>** NR *Note: Definition: At time of analgesic request up to 6 wks, deg of pain calculated as a relative pain code (1 = mild, 2 = mod, 3 = severe) summed across each site and divided by total N; in addition, a total pain factor entered by experienced obstetric nurses

Evidence Table 9. Key Question 3: Materials – Polyglycolic acid versus chromic catgut (continued)

Sexual Function Outcomes	Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Short term NR	**Short term** NR	**Short term** NR	**Short term** NR	**Overall quality** Poor
Long term NR	**Long term** NR	**Long term** NR	**Long term** NR	**Randomization approach and implementation** Poor (suture materials in envelopes) **Masking** NR **Operational definitions and measures** Fair **Post-randomization exclusions** No **Retention of participants** NR

Evidence Table 9. Key Question 3: Materials – Polyglycolic acid versus chromic catgut (continued)

Study Characteristics	Demographic Characteristics	Labor and Delivery Characteristics	Episiotomy and Repair Characteristics	Pain Outcomes
Author Livingstone et al., 1974 **Setting** Scotland **Study design** RCT **Inclusion criteria** • Primigravidae • Mediolateral episiotomy **Exclusion criteria** • Additional lacerations • If episiotomy extended **Groups** **G1:** PGA (Dexon) **G2:** Catgut (Ethicon) **N at randomization** **G1:** 50 **G2:** 50 **Followup** 3 days	**Age** NR **Parity** NR	**Mode of delivery** **G1:** • Spont: 40% • Forceps or venthouse: 38% • Rotation and forceps: 22% **G2:** • Spont: 36% • Forceps or venthouse: 46% • Rotation and forceps: 18% **Birthweight (mean ± SD)** NR	**Episiotomy rate** **Mediolateral** **G1:** 100% **G2:** 100%	**Short term: Day 3** Pain definition: Measured by interview using a card with a short explanation and a choice of deg of pain felt **No pain** **G1:** 22% **G2:** 4% **Uncomfortable** **G1:** 56% **G2:** 48% **Painful** **G1:** 18% **G2:** 26% **Very painful** **G1:** 4% **G2:** 14% **Unbearably painful** **G1:** 0% **G2:** 8% *P* < 0.005 **Long term** NR

Evidence Table 9. Key Question 3: Materials – Polyglycolic acid versus chromic catgut (continued)

Sexual Function Outcomes	Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Short term NR **Long term** NR	**Short term: Day 3 (exam)** **Stitch line integrity** NS **Edema at perineotomy site** **None** **G1:** 86% **G2:** 64% **Mod** **G1:** 14% **G2:** 32% **Marked** **G1:** 0% **G2:** 4% **Long term** NR	**Short term** NR **Long term** NR	**Short term: Day 3 (exam)** **Ease of movement** **Good** **G1:** 68% **G2:** 52% **Restricted** **G1:** 28% **G2:** 40% **Very restricted** **G1:** 4% **G2:** 4% **Bad** **G1:** 0 **G2:** 4% **Long term** NR	**Overall quality** Poor **Randomization approach and implementation** Poor (lottery cards) **Masking** Good **Operational definitions and measures** Good **Post-randomization exclusions** No **Retention of participants** Good **Day 3** **G1:** 100 (100%) **G2:** 100 (100%) **Total:** 200 (100%)

Evidence Table 9. Key Question 3: Materials – Polyglycolic acid versus chromic catgut (continued)

Study Characteristics	Demographic Characteristics	Labor and Delivery Characteristics	Episiotomy and Repair Characteristics	Pain Outcomes
Author Beard et al., 1974 **Setting** UK **Study design** RCT **Inclusion criteria** • Mediolateral episiotomy • Normal deliveries **Exclusion criteria** • Patients with lacerations or those booked for 48-hr discharge **Groups** **G1:** PGA **G2:** CC **N at randomization** **G1:** 100 **G2:** 100 **Followup** 3 days	**Age** NR **Primiparous** **G1:** 53% **G2:** 48%	**Mode of delivery** NR **Birthweight** NR	**Episiotomy rate** **Mediolateral** **G1:** 100% **G2:** 100%	**Short term: Days 1 to 3** **N in each pain category** **Days 1 to 2** NS **Day 3** **G1:** • None: 36 • Slight: 54 • Mod: 10 • Severe: 0 **G2:** • None**:** 28 • Slight**:** 45 • Mod: 23 • Severe**:** 4 0.02 > *P* > 0.01 **Short term: 3 days** **N of patients in perineal pain category** **G1:** • None/slight: 90 • Mod/severe: 10 **G2:** • None/slight: 73 • Mod/severe: 27 *P* > 0.01 **Short term: Day 1** **N of patients requiring analgesia** **None** **G1:** 49 **G2:** 31 **Tablets** **G1:** 46 **G2:** 69 **Injections** **G1:** 5 **G2:** 0 *P* < 0.01 **Short term: Day 2** **N of patients requiring analgesia** **None** **G1:** 63 **G2:** 43 **Tablets** **G1:** 36 **G2:** 57 **Injections** **G1:** 2 **G2:** 0 *P* < 0.02

Evidence Table 9. Key Question 3: Materials – Polyglycolic acid versus chromic catgut (continued)

Sexual Function Outcomes	Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Short term NR **Long term** NR	**Short term** • Wound breakdown: NS • Inflammation: NS **Long term** NR	**Short term** NR **Long term** NR	**Short term** NR **Long term** NR	**Overall quality** Fair **Randomization approach and implementation** Poor **Masking** Good **Operational definitions and measures** Good **Post-randomization exclusions** No **Retention of participants** **3 days** **G1:** 100 (100% **G2:** 100 (100%) **Total:** 200 (100%)

Evidence Table 9. Key Question 3: Materials – Polyglycolic acid versus chromic catgut (continued)

Study Characteristics	Demographic Characteristics	Labor and Delivery Characteristics	Episiotomy and Repair Characteristics	Pain Outcomes
Author Beard et al., 1974 (continued)				**Short term: Day 3** **N of patients requiring analgesia** NS **Short term: Days 1 to 3** **N of patients requiring analgesia** **None** **G1:** 191 **G2:** 138 **Tablets** **G1:** 103 **G2:** 162 **Injections** **G1:** 7 **G2:** 0 *P* < 0.001 **Long term** NR

Evidence Table 9. Key Question 3: Materials – Polyglycolic acid versus chromic catgut (continued)

Sexual Function Outcomes	Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments

Evidence Table 10. Key Question 3: Combination of methods and materials

Study Characteristics	Demographic Characteristics	Labor and Delivery Characteristics	Episiotomy and Repair Characteristics	Pain Outcomes
Author Doyle et al., 1993 **Setting** UK **Study design** RCT **Inclusion criteria** Female with perineal trauma following childbirth that required a surgical repair **Groups** **G1:** • Vagina: Cont CC • Skin: 2-layer interr CC **G2:** • Vagina: Cont CC • Skin: Subcut Prolene suture **N at randomization** **G1:** 95 **G2:** 104 **Total:** 199 **Followup** 3 mos	**Age at enrollment** NR **Primiparous** **G1:** 68% **G2:** 76% **Other demographics** **Previous repair** **G1:** 31% **G2:** 18%	**Mode of delivery** **Normal delivery** **G1:** 58% **G2:** 45% **Other baseline differences in clinical characteristics** NS **Birthweight** NR	NR	**<u>Short term: Day 3</u>** **Perineal pain** Mild: NS Mod: NS Severe: NS **"Analgesia"** Mild: NS Mod: NS Severe: NS **<u>Short term: Day 10</u>** **Perineal pain** Mild: NS Mod: NS Severe: NS **"Analgesia"** Mild: NS Mod: NS Severe: NS **<u>Long term: 3 mos</u> (quest)** **Perineal pain** Mild: NS Mod: NS Severe: NS

Evidence Table 10. Key Question 3: Combination of methods and materials (continued)

Sexual Function Outcomes	Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Short term NR **Long term: 3 mos (assessed by quest)** **Pain** NS **Intercourse yet** NS **Painful now** NS **Mild, mod, severe** Mild: NS Mod: NS Severe: NS	**Short term: Day 3** **Bruising** NS **Long term** NR	**Short term** NR **Long term** NR	**Short term** NR **Long term** NR	**Overall quality** Poor **Randomization approach and implementation** Fair **Masking** NR **Operational definitions and measures** Good **Post-randomization exclusions** Yes: Loss-to-follow-up (n = 2), declined after randomization (n = 2), third deg tear (n = 1) **3 days** **G1:** 72 **G2:** 82 **Total:** 154 (77%) **10 days** **G1:** 40 (42%) **G2:** 58 (56%) **Total:** 98 (49%) **3 mos** **G1:** 58 (61%) **G2:** 76 (73%) **Total:** 132 (66%) **Retention of participants** Note: The text reports total followup of 153 but the tables show a total of 154. **3 days** **Total:** 153 (77%) **10 days** **Total:** 98 (50%) **3 mos** **Total:** 132 (66%)

Evidence Table 10. Key Question 3: Combination of methods and materials (continued)

Study Characteristics	Demographic Characteristics	Labor and Delivery Characteristics	Episiotomy and Repair Characteristics	Pain Outcomes
Author Isager-Sally et al., 1986 **Setting** Denmark **Study design** RCT **Inclusion criteria** Mediolateral episiotomy **Exclusion criteria** NR **Groups** **G1:** • Vagina: Cont catgut • Muscle: Interr catgut • Skin: Interr nylon **G2:** • Vagina: Cont PGA • Muscle: Interr PGA • Skin: Interr PGA **G3:** • Vagina: Subcut PGA • Muscle: Subcut PGA • Skin: Subcut PGA **N at randomization** **Total:** 802 **G1:** 272 **G2:** 263 **G3:** 267 Note: 900 women were randomized but 98 were excluded because they transferred to another hospital or left the hospital before the fifth day after delivery. Three groups did not differ in age, parity, or frequency of previous episiotomy. **Followup** 3 mos	**Age (mean)** **G1:** 27.0 yrs **G2:** 27.5 yrs **G3:** 27.1 yrs **Primiparous** **G1:** 60% **G2:** 60% **G3:** 61% **Previous episiotomy** **G1:** 34% **G2:** 31% **G3:** 33%	**Mode of delivery** NR	**Episiotomy alone** **G1:** 95% **G2:** 93% **G3:** 95% **Episiotomy and tear of perineal muscle** **G1:** 3% **G2:** 5% **G3:** 4% **Episiotomy and partial tear of sphincter** **G1:** 2% **G2:** 2% **G3:** 2%	**Short term: 5 days** **Perineal pain** **No discomfort** **G1:** 12% **G2:** 18% **G3:** 40% *P* < 0.001 G3 was better **Slight discomfort** **G1:** 60% **G2:** 59% **G3:** 49% *P* < 0.001 G3 was better **Pain** **G1:** 25% **G2:** 21% **G3:** 8% *P* < 0.001 G3 was better **Severe pain** **G1:** 2% **G2:** 2% **G3:** 1% *P* < 0.001 G3 was better **Hurts when sitting** **G1:** 59% **G2:** 53% **G3:** 28% *P* < 0.001 G3 was better **Hurts when walking** **G1:** 42% **G2:** 37% **G3:** 29% **Hurts during bowel motion** **G1:** 17% **G2:** 13% **G3:** 6% *P* < 0.001 G3 was better **Long term** NR

Evidence Table 10. Key Question 3: Combination of methods and materials (continued)

Sexual Function Outcomes	Healing Outcomes	Incontinence and Pelvic Floor Outcomes	Other Outcomes	Quality and Comments
Short term NR **Long term: 3 mos (quest)** **Dyspareunia** **G1:** 21% **G2:** 23% **G3:** 17% (No individual statistic reported. Combined with other complaints and tested, $P < 0.025$ for G2 vs. G3)	**Short term: 5 days (exam)** **Edema of perineum** **G1:** 30% **G2:** 23% **G3:** 11% $P < 0.005$ G3 was better **Infection of the wound** NS **Hematoma** NS **Long term: 3 mos (quest)** **Cosmetically unsatisfactory:** **G1:** 5% **G2:** 6% **G3:** 3% (No individual statistic reported. Combined with other complaints and tested, $P < 0.025$ for G2 vs. G3)	**Short term** NR **Long term: 3 mos (quest)** **Discomfort with defecation** **G1:** 5% **G2:** 8% **G3:** 4% (No individual statistic reported. Combined with other complaints and tested, $P < 0.025$ for G2 vs. G3) **Incontinence or flatus** **G1:** 14% **G2:** 20% **G3:** 13% (No individual statistic reported. Combined with other complaints and tested, $P < 0.025$ for G2 vs. G3) **Discomfort when sitting** **G1:** 2% **G2:** 1% **G3:** 2% (No individual statistic reported. Combined with other complaints and tested, $P < 0.025$ for G2 vs. G3) **Discomfort during micturation** **G1:** 2% **G2:** 1% **G3:** 2% (No individual statistic reported. Combined with other complaints and tested, $P < 0.025$ for G2 vs. G3)		**Overall quality** Fair **Randomization app and imp** Good **Masking** Good **Operational defs and measures** No **Post-randomization exclusions** Yes (98 women who left hospital before follow-up) **Retention of participants** **3 days** **G1:** 272 (100%) **G2:** 263 (100%) **G3:** 267 (100%) **Total:** 802 (100%) **5 days** **G1:** 272 (100%) **G2:** 263 (100%) **G3:** 267 (100%) **Total:** 802 (100%) **3 mos** **G1:** 266 (100%) **G2:** 250 (100%) **G3:** 265 (100%) **Total:** 802 (100%)

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence, and pelvic floor defects

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics
Author Sleep et al., 1984 **Setting** UK **Study design** RCT **Inclusion criteria** • Live singleton fetus of at least 37 wks GA • Presented cephalically • Spont vaginal delivery expected at end of sec stage labor **Exclusion criteria** • Elected episiotomy • No consent • Private patient • Precipitate delivery **Groups** **G1:** Liberal (instructed to "try to prevent a tear") **G2:** Restrictive (instructed to "try to avoid episiotomy and restrict episiotomy to fetal indications") **N at enrollment** **G1:** 502 **G2:** 498 **Total:** 1000 **Followup** 10 days to 3 mos	**Age (mean ± SD)** **G1:** 26.7yrs ± 5.3y **G2:** 26.6yrs ± 5.2y **Primiparous** **G1:** 46.3% **G2:** 40.4%	**Delivery by** Student and midwife **G1:** 35.9% **G2:** 35.2% **Midwife** **G1:** 32.1% **G2:** 30.1% **Obstetrician** **G1:** 1.8% **G2:** 8% **Other ("sister")** **G1:** 31.3% **G2:** 32.7% **Episiotomy rate (all mediolateral)** **G1:** 51.4% **G2:** 10.2% **Estimated GA** **G1:** 39.8wks ± 1.2 **G2:** 39.8wks ± 1.2 **Birthweight (mean ± SD)** **G1:** 3367g ± 4.38 **G2:** 3393g ± 4.48

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence, and pelvic floor defects (continued)

Perineal Trauma Outcomes	Incontinence and Pelvic Floor Outcomes	Quality and comments
Third/fourth deg tear (ext through anal sphincter or through to the rectal mucosa or to the upper third of vagina) **G1:** 1 **G2:** 4 **Anterior labial tears** **G1:** 17.3% **G2:** 26.3% *P* < 0.00l RR = 1.52 (1.19 to 1.94)	**Short term: 3 mos** **Involuntary loss of urine** **G1:** 19% **G2:** 19% NS **Need to wear pad for loss of urine** **G1:** 69% **G2:** 6% NS **Long term** NR	**Overall quality** Good **Population** Good **Measures** Good **Analysis** Good **Retention of participants** Good

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics
Author Gordon and Logue, 1985 **Setting** UK **Study design** Prospective cohort **Inclusion criteria** • Participation in a prior prospective study of perineal wound healing • European primipara • All degs of perineal trauma **Exclusion criteria** NR **Groups** **G1:** Intact perineum **G2:** Sec deg perineal laceration **G3:** Episiotomy assisted with normal vaginal delivery **G4:** LSCS **N at enrollment** **G1:** 14 **G2:** 14 **G3:** 14 **G4:** 14 **Control:** 14 **Total:** 70 **Followup** 1 yr	**Age** NS, details NR **Primiparious** 100%	**Mode of delivery** **Spont** **G1:** Spont: 100% **G2:** Spont: 100% **G3:** Spont: 100% **G4:** Cesarean: 100% **Birthweight (mean ± SD)** NS, details NR **Suture type** NR

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Perineal Trauma Outcomes	Incontinence and Pelvic Floor Outcomes	Quality and Comments
Short term NR	**Short term** NR	**Overall quality** Poor
Long term NR	**Long term** NR	**Population** Poor
		Measures Fair: Operator performing repair blind to allocation, mother in most cases blind to allocation
		Analysis Poor
		Retention of participants Good

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics
Author Sleep et al., 1987 **Setting** UK **Study design** RCT **Inclusion criteria** Ability to find address **Exclusion criteria** • 8 spoke little English • 3 gave babies up for adoption • 1 baby was given to social services • 1 neonatal death • 2 refused **Groups** **G1:** Restricted **G2:** Liberal **N at enrollment** **G1:** 329 **G2:** 345 **Total:** 674	**Age (mean ± SD)** **NS** **G1:** 27.0yrs ± 4.9 **G2:** 27.0yrs ± 5.0 **Primiparous** **G1:** 41% **G2:** 44% **Percent unmarried** **G1:** 91% **G2:** 92%	**Episiotomy use** **G1:** 12% **G2:** 46% **Episiotomy rate** **G1:** 49% (329/674) **G2:** 51% (345/674) **Birthweight (mean ± SD)** **G1:** 3426g ± 430 **G2:** 3407g ± 451 NS **Estimated GA** **G1:** 39.8wks ± 1.2 **G2:** 46.0wks ± 1.2

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Perineal Trauma Outcomes	Incontinence and Pelvic Floor Outcomes	Quality and Comments
Short term NR	**Short term** NR	**Overall quality** Good
Long term NR	**Long term** **(quest)**	**Population** Good
	Urine	**Measures** NA
	<1x in past week **G1:** 22% **G2:** 25%	**Analysis** NA
	1 to 2 x in past week **G1:** 12% **G2:** 11%	**Retention of participants** NA
	3+ in past week **G1:** 2% **G2:** 2%	
	Total **G1:** 34% **G2:** 36% RR = 0.97 (0.79-1.19) *P* = 0.77	
	Incontinence of urine sufficiently severe to wear a pad, urgency and stress incontinence all NS	

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics
Author Rockner, 1990 **Setting** Sweden **Study design** Prospective cohort **Inclusion criteria** Consecutive primiparas with episiotomy **Exclusion criteria** • Consecutive primiparas with spont tears **Groups** **G1:** Episiotomy **G2:** Spont tears **N at enrollment** **G1:** 157 **G2:** 48 **N responders** **G1:** 140 **G2:** 45 Total: 185 **Followup** 4 yrs	**Age (mean)** **G1:** 30yrs **G2:** 31yrs **Parity** NR **Maternal weight (mean)** **G1:** 61kg **G2:** 63kg **Infants born since earlier study** **G1** • 0 to 39% • 1 to 58% • 2 to 3% • 3 to 0.7% **G2:** • 0 to 36% • 1 to 59% • 2 to 5% • 3 to 0%	**Mode of delivery** **G1:** • Spont: 83% • Vacuum: 16% • Forceps: 1% **G2:** • Spont: 95% • Vacuum: 5% **Episiotomy use** **G1:** 100% done, not specified **Birthweight (mean ± SD)** NR

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Perineal Trauma Outcomes	Incontinence and Pelvic Floor Outcomes	Quality and comments
Short term NR **Long term** NR	**Urinary incontinence after delivery** **G1:** 25% **G2:** 26% NS **Short term** NR **Long term: 4 yrs** **quest** **Urinary incontinence** • After first delivery • After sec delivery • After third delivery • Overall NS **Involuntary loss of urine (coughing, laughing, sneezing)** NS **Climbing stairs** NS **Urinary incontinence severe enough to wear a pad** • Sometimes • Always NS **Severe urinary incontinence symptoms:** • Occasionally • Once a wk • 2 or 3 times/wk • > 3 times/wk NS	**Overall quality** Fair **Population** Fair **Measures** Good **Analysis** Poor **Retention of participants** Good

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics
Author Rockner et al., 1991 **Setting** Sweden **Study design** Prospective cohort **Inclusion criteria** • > 36 wks gestation • Every sec mother **Exclusion criteria** NR **Groups** **G1:** Episiotomy **G2:** Spont laceration **G3:** Intact perineum **G4:** Cesarean section **N at enrollment** 92 **N at completion** **G1:** 21 **G2:** 26 **G3:** 24 **G4:** 16 **Followup** 8 wks	**Age** NR **Parity** NR	**Mode of delivery** **G1** • Spont: 81% • Vacuum: 19% **G2:** • Spont: 92.3 % • Vacuum: 7.7% **G3:** Spont: 100% **G4:** Cesarean: 100% **Episiotomy rate** **G1:** 22% (21/97) **G2:** 27% (26/97) **G3:** 25% (24/97) **G4:** 27% (26/97) **Episiotomy rate** **G1:** 100% mediolateral **G2:** 0% **G3:** 0% **G4**: 0% **Birthweight (mean)** **G1:** 3596g **G2:** 3640g **G3:** 3366g **G4**: 3190g

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Perineal trauma characteristics	Incontinence and Pelvic Floor Outcomes	Quality and Comments
Short term NR **Long term** NR	**Short term: 8 wks** **Decrease in pelvic floor muscle** (PFMS measured by weight of heaviest cone retained in vagina for 1 min while standing erect or walking) **G1:** 30.0 ± 11.8 **G2:** 18.9 ± 9.1 **G3:** 19.2 ± 16.2 **G4:** 0 *P* < 0.001 PFMS in episiotomy group continues to be significantly decreased compared with spont laceration or intact perineum **Long term** NR	**Overall quality** Fair **Population** Fair **Measures** Good **Analysis** Poor **Retention of participants** Good • 2 patients changed their minds • 3 had emergency cesareans

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics
Author Klein et al., 1992 **Setting** Canada **Study design** RCT **Inclusion criteria** • 18 to 40 yrs old • Parity of 0, 1, 2 • Single fetus • Spoke English or French • Low medical and obstetrical risk **Exclusion criteria** • Prematurity (gestation < 37wks) • Fetal distress • Cesarean deliveries • Planned forceps • Medical condition developed late in pregnancy **Groups** **G1:** Primiparous **G1a:** Liberal (attempted to avoid a tear/separated by parity) **G1b: Restricted** (attempted to avoid an episiotomy/separated by parity) **G2:** Multiparous **G2a:** Liberal **G2b:** Restricted **N at enrollment** **G1a:** 184 **G1b:** 175 **G2a:** 166 **G2b:** 178 **Total:** 703 **Followup** 1 day to 3 mos	**Age (mean ± SD)** **G1a:** 27.9yrs ± 3.9 **G1b:** 27.9yrs ± 4.4 **G2a:** 31.0yrs ± 3.7 **G2b:** 30.3yrs ± 9.1 **Primiparous** **G1:** 100% **G2:** 100% **Education (yrs) (Sig diff NR)** **G1a:** 15.4 **G1b:** 15.0 **G2a:** 15.4 **G2b:** 15.0 **Stable Relationship** (Diff NS) **Employment** (Diff NS)	**Episiotomy rate (all median)** **G1a:** 81% **G1b:** 52% **G2a:** 47% **G2b:** 31% **Height** Sig diff NR **Weight during pregnancy** Sig diff NR **Previous episiotomy** NS **Birthweight (mean ± SD)** **G1a:** 3325g ± 416 **G1b:** 3377g ± 432 **G2a:** 3496g ± 449 **G2b:** 3467g ± 497 **GA** NS

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Perineal Trauma Outcomes	Incontinence and Pelvic Floor Outcomes	Quality and Comments
Intact perineum Measured at delivery **G1a:** 12 (6.6%) **G1b:** 13 (7.5%) OR = 1.16 (0.48, 2.8) **G2a:** 32 **G2b:** 56 OR = 1.85 (1.1, 3.2) **Sec deg tear** Measured at delivery **G1a:** 22 (12.6%) **G1b:** 61 (35.3%) OR = 3.99 (2.2, 7.1) **G2a:** 56 **G2b:** 68 NS	**Short term** NR **Long term: 3 mos** **Urinary incontinence** **G1a:** 26 (14.5%) **G1b:** 35 (21.1%) *P* = 0.11 **G2a:** 34 (21.5) **G2b:** 22 (12.9) *P* = 0.04	**Overall quality** Fair **Population** Fair **Measures** Fair **Analysis** Good **Retention of participants** Fair

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics
Author Viktrup et al., 1992 **Setting** Denmark **Study design** Prospective cohort **Inclusion criteria** • Primiparas • 17 to 42 yrs of age **Exclusion criteria** Did not speak Danish **Groups for multivariate analysis** **G1:** Episiotomy **G2:** No episiotomy **N for Study** **Total:** 305 **N at 3 mos** **Total:** 293 **N at 12 mos** **Total:** 292 **Followup** 3 mos to 1 yr	**Age (median)** **Total:** 26yrs **Primiparous** **G1:** 100% **G2:** 100% **GA (median)** **Total:** 40wks **Length of first stage (median)** **Total:** 495 min **Length of sec stage (median)** **Total:** 35 min **Head circumference (median)** **Total:** 33 cm	**Mode of delivery** Spont: 69% Vacuum: 13% Cesarean: 18% Details NR by group **Episiotomy rate** 72% **Birthweight (median)** Total: 3300g Details by group

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Perineal Trauma Outcomes	Incontinence and Pelvic Floor Outcomes	Quality and Comments
Short term NR	**Short term** NR	**Overall quality** Poor
Long term NR	**Long term** NR	**Population** Good
		Measures Good
		Analysis Fair
		Retention of participants Good

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics
Author Klein et al., 1994 **Setting** Canada **Study design** Prospective cohort, secondary analysis of an RCT of liberal vs. selective midline episiotomy **Inclusion criteria** • Parity: 0, 1, 2 • Low risk • 18 to 40 yrs of age • Singleton fetus • Spoke English or French **Exclusion criteria** NR **Groups** **G1:** Intact **G2:** Spont tear **G3:** Episiotomy alone **G4:** Third or fourth deg tear **N at enrollment** **G1:** 110 **G2:** 208 **G3:** 313 **G4:** 66 **Followup** 3 mos	**Age** NR **Parity** • Overall: Primiparous: 51% • Details NR by group **Other demographics** • Race • Employment • Marital status • Intendedness of pregnancy • “No difference”	**Mode of delivery** NR **Suture type** NR **Birthweight (mean ± SD)** NR

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Perineal Trauma Outcomes	Incontinence and Pelvic Floor Outcomes	Quality and Comments
See groups for rates **OR of third and fouth deg tears for primiparous women in the presence of episiotomy compared with those not receiving episiotomy** 22.08 (2.84, 171.53)	**Short Term** NR **Long Term** NR	**Overall quality** Fair **Population** Good **Measures** Good **Analysis** Fair/poor **Retention of participants** Good

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics
Author Walsh et al., 1996 **Setting** UK **Study design** Prospective cohort **Inclusion criteria** Third deg tear **Exclusion criteria** NR **Groups** **G1:** Patients with third deg tears **G2:** Total population **N** **G1:** 81 **Followup** 3 mos	**Age (mean)** **Total:** 27.9yrs **Parity** **Total:** 79% (*P* < 0.001)	**Mode of delivery** NR by groups **Suture type** NR **Birthweight (mean ± SD)** NR

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Perineal Trauma Outcomes	Incontinence and Pelvic Floor Outcomes	Quality and Comments
Third deg tears 93/16583 (0.6%)	**Short term** NR	**Overall quality** Poor
Episiotomy use (not exclusive of breech and/or instr delivery) **G1:** 74% **G2:** 28% (*P* < 0.001)	**Long term** NR	**Population** Poor **Measures** Fair **Analysis** Poor **Retention of participants** Good

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics
Author MacArthur et al., 1997 **Setting** UK **Study design** Cohort study, selection based on a group of symptoms including incontinence (final outcome) **Inclusion criteria** • Delivered between April and September at a maternity hospital in Birmingham (UK) • After enrollment in the study, 760 women with one or more of 9 symptoms (including incontinence) within 3 mos of birth and lasting 6 wks were recruited. In addition 146 women were randomly chosen from the nonsymptomatic group **Exclusion criteria** Women with fecal or urge incontinence related to a previous birth **Groups** **G1a:** Primiparae new fecal incontinence **G1b:** Primiparae, never had fecal incontinence **G2a:** Multiparae, new fecal incontinence **G2b:** Multiparae, never had fecal incontinence **N eligible for enrollment** 1667 **N interviewed** 906 **Followup** Contacted 6 to 7 mos, interviewed 45 wks on average	**Age (mean ± SD)** **G1a:** 27.9yrs ± 5.5 **G1b:** 26.7yrs ± 5.2 **G2a:** 30.9yrs ± 4.8 **G2b:** 29.6yrs ± 4.6 **Parity** **G1:** Primiparous: 41% **G2:** Multiparous: 59%	**Mode of delivery** **G1a:** • Spont: 27.8% • Vacuum: 16.7% • Forceps: 27.8% • Emergency (cesarean) section: 27.8% **G1b:** • Spont: 53.3% • Vacuum: 3.2% • Forceps: 23.5% • Emergency (cesarean) section: 15.7% • Elective (cesarean) section: 3.8% **G2a:** • Spont: 72.2% • Vacuum: 5.6% • Forceps: 16.7% • Emergency (cesarean) section: 5.6% **G2b:** • Spont: 74.1% • Vacuum: 0.6% • Forceps: 4.3% • Emergency (cesarean) section: 10.7% • Elective (cesarean) section: 9.7% **Episiotomy use** **G1a:** 33.3% **G1b:** 36.2% **G2a:** 27.8% **G2b:** 10.5% First stage labor ≥ 10hrs Sec stage labor ≥ 2hrs Active sec stage labor ≥ 2hrs Head circumference **Birthweight (mean ± SD)** **G1a:** 3306g ± 804.7 **G1b:** 3318g ± 661.3 **G2a:** 3443.9g ± 435.3 **G2b:** 3431.7g ± 633.5

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Perineal Trauma Outcomes	Incontinence and Pelvic Floor Outcomes	Quality and Comments
Short term NR **Long term** NR	**Short term: 10 mos** Episiotomy has no effect on incontinence **Long term** NR	**Overall quality** Good **Population** Fair **Measures** Good **Analysis** Good **Retention of participants** Good

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics
Author Viktrup and Lose, 2001 **Setting** Denmark **Study design** Prospective cohort **Inclusion criteria** • Nulliparous • 17 to 41 yrs of age **Exclusion criteria** NR **Groups (for multivariate analysis)** **G1:** Episiotomy **G2:** No episiotomy **N at enrollment** 305 **Followup** 5 yrs	**Age** NR **Nulliparous** **G1:** 100% **G2:** 100%	**Mode of delivery** NR **Suture type** NR **Birthweight (mean ± SD)** NR

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Perineal Trauma Outcomes	Incontinence and Pelvic Floor Outcomes	Quality and Comments
Short term NR **Long term** NR	**Short term** NR **Long term** **Adjusted OR for episiotomy on long-lasting stress incontinence (quest)** 2.0 (0.9, 4.1)	**Overall quality** Good **Population** Fair **Measures** Good **Analysis** Good **Retention of participants** Good

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics
Author Eason et al., 2002 **Setting** Canada **Study design** Prospective cohort **Inclusion criteria** • Participant of an RCT of perineal massage • 34 to 35 wks gestation **Exclusion criteria** • NR **Groups (multivariate analysis)** **G1:** No episiotomy **G2:** Episiotomy **N at enrollment** 1198 **N for prospective cohort** 949 **Followup** 3 mos	**Age** NR **Parity** NR	**Mode of delivery** **NR by groups overall** **G1:** for subset for first vaginal birth • Spont: 52.4% • Vacuum: 16.4% • Forceps: 31.2% **G2:** for subset for first vaginal birth • Spont: 83.9% • Vacuum: 10.9% • Forceps: 5.2% **Anesthesia at time of delivery (epidural)** NR by groups **Episiotomy rate** 26.7% NR by groups **Birthweight (mean ± SD)** NR by groups

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Perineal Trauma outcomes	Incontinence and Pelvic Floor Outcomes	Quality
Intact perineum 25.7% **First deg tear** 19.2% **Sec deg tear** 27.1% **Episiotomy without ext into anal sphincter** 21.9% **Third and fourth deg tear** 22.7%	**<u>Short term</u>** NR **<u>Long term: 3 mos</u>** **Frequency of incontinence of stool** • None: 96.9% • < once/wk: 2.3% • 1 to 6 wks: 0.4% • Once daily: 0.2% • > once daily: 0.1% **Frequency of incontinence of flatus** • None: 74.5% • < once/wk: 16.0% • 1 to 6 wks: 6.8% • Once daily: 1.2% • > once daily: 1.5% **Risk ratio for episiotomy** NS in univariate or multivariate models **Risk ratio for perineal injury (classified by extent of laceration including episiotomy as a category)** NS in univariate models. Only third or fourth deg tears significant in multivariate models compared to intact perineum RR: 2.1 (1.4-3.1) **Adjusted risk ratio compared to spont with no episiotomy** • Spont with episiotomy: 9.6 (3.2, 28.5) • Vacuum with no episiotomy: 7.4 (1.9, 28.5) • Vacuum with episiotomy: 15.7 (4.6, 53.2) • Forceps with no episiotomy: 12.3 (3.0, 50.4) • Forceps with episiotomy: 25.3 (8.9, 72.0)	**Overall quality** Good **Population** Good **Measures** Good **Analysis** Good **Retention of participants** Fair

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics
Author Fleming et al., 2003 **Setting** USA **Study design** Prospective cohort **Inclusion criteria** • Singleton pregnancies • Vertex presentation • Term birth • Normal pregnancies **Exclusion criteria** • Forceps/vacuum deliveries • Epidural analgesia • Gestational diabetes • Preterm pregnancies • Multiple gestations • Medical complications • Those requiring medical induction of labor **Groups (for multivariate analysis)** **G1:** Episiotomy **G2:** No episiotomy **N at enrollment** 102 **Followup** 6 mos	**Age** **G1:** 28.8yrs **G2:** 29.8yrs (weighted mean of means calculated) **Parity** NR	**Mode of delivery** **Overall** Cesarean: 9.8% **Suture type** NR Women with episiotomy had higher muscle function scores AP than other groups, reason for this unclear **Birthweight (mean ± SD)** **G1:** 8.1lbs ± 1.2lbs. **G2:** 8.3lbs (weighted mean average)

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Perineal Trauma Outcomes	Incontinence and Pelvic Floor Outcomes	Quality and Comments
Short term NR	**Short term** NR	**Overall quality** Fair
Long term NR	**Long term** NR	**Population** Poor
		Measures Good
		Analysis Fair
		Retention of participants Good

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics
Author Karacam and Eroglu 2003 **Setting** Turkey **Study design** Prospective cohort **Inclusion criteria** • Multiparous • Resident of the relevant city boundaries • Had telephone • Age 18 to 35 yrs • 37 and 42 wks GA • Singleton live birth • Birthweight 2500 to 4500g • Vaginal vertex position delivery **Exclusion criteria** • Experienced medical illness (cardiac disease, diabetes, vaginal/ perineal infection, anemia, renal disease, pre-eclampsia and/or antepartum hemorrhage during pregnancy) • Malpresented/malpositioned babies • "Large" babies • Intrauterine growth retardation • Congenital abnormality • Rigid perineal tissue • Vacuum/forceps **Groups** **G1:** Episiotomy (mediolateral) **G2:** No episiotomy **N at enrollment** **G1:** 50 **G2:** 50 **Followup** 6 wks	**Age (mean ± SD)** **G1:** 25.96yrs ± 3.9 **G2:** 24.34yrs ± 2.7 **Multiparous** **G1:** 100% **G2:** 100% **Other demographics** • Had health insurance NS • Graduated from primary school NS • Did not have paying jobs NS	**Mode of delivery** All 100% spont **Types of intervention in labor** NS **Duration of labor** NS **Duration of the first stage** NS **Duration of the sec stage** NS **Involvement of women in labor** NS **Birthweight** **2500 to 3499g** **G1:** 59.18% **G2:** 63.27% NS **3500 to 4310g** **G1:** 40.82% **G2:** 36.73% NS **Diameter of infant's head** NS

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Perineal Trauma Outcomes	Incontinence and Pelvic Floor Outcomes	Quality and comments
Spont laceration **G1:** 54% **G2:** 78% *P* = 0.011	**Short term: 12 wks** **Stress incontinence** **G1:** 24% **G2:** 30% *P* = 0.49 **Long term** NR	**Overall quality** Poor **Population** Poor **Measures** Poor **Analysis** Poor **Retention of participants** Good

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics
Author Eason et al., 2004 **Setting** Canada **Study design** Prospective cohort **Inclusion criteria** • Pregnant with or without a previous vaginal birth • Delivering in five secondary and tertiary care hospitals in Quebec • 30 to 35 wks GA • Participants in an RCT of perineal massage **Exclusion criteria** NR **Groups (multivariate analysis)** **G1:** No episiotomy **G2:** Episiotomy **Followup** 3 mos	**Age (mean)** 29.8yrs **Parity** NR **Other demographics** **Education** 15.8 yrs mean education of responders	**Mode of delivery** NR **Suture type** NR **Birthweight (mean ± SD)** NR

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Perineal Trauma Outcomes	Incontinence and Pelvic Floor Outcomes	Quality and Comments
Short term NR **Long term** NR	**Short term** NR **Long term: 3 mos** **Stress incontinence** **G1:** • 35% risk • Crude OR: 1.00 **G2:** • 29% risk • Crude OR: 0.75 (0.54, 1.05) **Adjusted for maternal age, BMI, previous vaginal birth, timing, onset of urinary incontinence, type of delivery, duration of sec stage and episiotomy** **G1:** OR: 1.00 **G2:** OR: 0.68 (0.47, 1.01)	**Overall quality** Good **Population** Good **Measures** Good **Analysis** Good **Retention of participants** Fair

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics
Author Sartore et al., 2004 **Setting** Italy **Study design** Prospective cohort **Inclusion criteria** • Primiparous • Singleton pregnancy • Spont vaginal delivery • Fetal head in occiput anterior position **Exclusion criteria** • Delivered in position other than lithotomy position • Cesarean delivery • Third and fourth deg perineal lacerations • Preterm breech • Operative delivery • Anal and urinary incontinence that pre-existed vaginal delivery • History of vaginal or anal surgery **Groups** **G1:** Received mediolateral episiotomy **G2:** Intact perineum and spont perineal lacerations (first/sec deg) **N at enrollment** **G1:** 254 **G2:** 265 **Followup** 3 mos	**Age (mean ± SD)** **G1:** 30.9yrs ± 3.9 **G2:** 30.7yrs ± 4.3 **Primiparous** **G1:** 100% **G2:** 100%	**Mode of delivery** **Spont** **G1:** 100% **G2:** 100% **Maternal weight before pregnancy** NS **Weight gain in pregnancy** NS **Epidural rate** **G1:** 14.2% **G2:** 7.9% *P* = 0.023 **Episiotomy type** **G1:** Mediolateral: 100% **Birthweight (mean ± SD)** **G1:** 3334.7g ± 429.5 **G2:** 3222.8g ± 428.1 *P* = 0.003

Evidence Table 11. Key Question 4: Urinary incontinence, fecal incontinence and pelvic floor defects (continued)

Perineal Trauma Outcomes	Incontinence and Pelvic Floor Outcomes	Quality and Comments
G2: Intact perineum: 82 **G2:** First deg tear: 127 **G2:** Sec deg tear: 56	**Short term** NR **Long term: 3 mos** **Stress incontinence** **G1:** 12.9% **G2:** 12.1% OR = 1.01 (0.61, 1.69) *P* = 0.95 **Urge incontinence** **G1:** 1.9% **G2:** 0.7% *P* = 0.23 **Incidence of frequency and urgency** **G1:** 0.8% **G2:** 2.3% *P* = 0.17 **Incidence of dyspuria** **G1:** 1.2% **G2:** 0.8% *P* = 0.61 **Anal incontinence** **G1:** 2.8% **G2:** 1.9% OR = 01.47 (0.46, 4.1) *P* = 0.51	**Overall quality** Poor **Population** Good **Measures** Fair **Analysis** Poor **Retention of participants** Good

Evidence Table 12. Key Question 5: Future sexual function

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics
Author Sleep et al., 1984 **Setting** UK **Study design** RCT **Inclusion criteria** • Live singleton fetus of at least 37 wks GA • Presented cephalically • Spont vaginal delivery expected at end of sec stage labor **Exclusion criteria** • Elected episiotomy • No consent • Private patient • Precipitate delivery **Groups** **G1:** Liberal (instructed to "try to prevent a tear") **G2:** Restrictive (instructed to "try to avoid episiotomy and restrict episiotomy to fetal indications") **Followup** 10 days to 3 mos **N at enrollment** **G1:** 502 **G2:** 498 **N at 10 days** **G1:** 446 **G2:** 439 **N at 3 mos** **G1:** 457 **G2:** 438 **N at Followup** **G1**: 329 **G2:** 345 **Total:** 674	**Age (mean ± SD)** **G1:** 26.7yrs ± 5.3 **G2:** 26.6yrs ± 5.2 **Primiparous** **G1:** 46.3% **G2:** 40.4%	**Mode of delivery** NR **Delivery performed by** **Student and midwife** **G1:** 35.9% **G2:** 35.2% **Midwife** **G1:** 32.1% **G2:** 30.1% **Obstetrician** **G1:** 1.8% **G2:** 8% **Other ("sister")** **G1:** 31.3% **G2:** 32.7% **Episiotomy rate (all mediolateral)** **G1:** 51.4% **G2:** 10.2% **Suture type** NR by group **Estimated GA** **G1:** 39.8wks ± 1.2 **G2:** 39.8wks ± 1.2 **Birthweight (mean ± SD)** **G1:** 3367g ± 438 **G2:** 3393g ± 4.48

Evidence Table 12. Key Question 5: Future sexual function (continued)

Perineal Trauma Outcomes	Sexual function outcomes	Quality and Comments
Third/fourth deg tear (ext through anal sphincter or through to the rectal mucosa or to the upper third of vagina) **G1:** 1 **G2:** 4 **Anterior labial tears** **G1:** 17.3% **G2:** 26.3% *P* < 0.00l RR = 1.52 (1.19 to 1.94)	**<u>Short term: 1 mo</u>** **(quest)** **Recommencement of sexual intercourse** **G1:** 27% **G2:** 37% $\chi^2 = 8.67$ *P* < 0.01 **<u>Long term: 3 mos</u>** **(quest)** **Resumed sexual intercourse** 90% overall, similar within groups **Dyspareunia** **G1:** 18% **G2:** 22% **Dyspareunia "at some time"** **G1:** 51% **G2:** 52%	**Overall quality** Good **Population** Good **Measures** Good: Operator performing repair blind to allocation, mother in most cases blind to allocation **Analysis** Good **Retention of participants** Good

Evidence Table 12. Key Question 5: Future sexual function (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics
Author Sleep et al., 1987 **Setting** UK **Study design** RCT **Inclusion criteria** Ability to find address **Exclusion criteria** • 8 spoke little English • 3 gave babies up for adoption • 1 baby was given to social services • 1 neonatal death • 2 refused **Groups** **G1:** Restricted **G2:** Liberal	**Age (mean ± SD)** **NS** **G1:** 27.0yrs ± 4.9 **G2:** 27.0yrs ± 5.0 **Primiparous** **G1:** 41% **G2:** 44% **Percent unmarried** **G1:** 91% **G2:** 92%	**Mode of delivery** NR **Episiotomy use** **G1:** 12% **G2:** 46% **Episiotomy rate (all mediolateral per Sleep et al., 1984)** **G1:** 49% (329/674) **G2:** 51% (345/674) **Birthweight (mean ± SD)** **NS** **G1:** 3426g ± 430 **G2:** 3407g ± 451 **Estimated GA** **G1:** 39.8wks ± 1.2 **G2:** 46.0wks ± 1.2

Evidence Table 12. Key Question 5: Future sexual function continued

Perineal Trauma Outcomes	Sexual function outcomes	Quality and comments
Short term NR **Long term** NR	**Short term** NR **Long term: 3 yrs** **Ever suffering painful sexual intercourse** **G1:** 16% **G2:** 13% RR = 1.21 (0.84 to 1.75) *P* = 0.31 **Subanalysis of those with no more children** **G1:** 15% **G2:** 12% NS	**Overall quality** Good **Population** Good **Measures** NA: Operator performing repair blind to allocation, mother in most cases blind to allocation **Analysis** NA **Retention of participants** NA

Evidence Table 12. Key Question 5: Future sexual function (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics
Author Rockner et al., 1988 **Setting** Sweden **Study design** Prospective cohort **Inclusion criteria** • ≥ 18 yrs of age • ≥ 37 wks gestation • Singleton fetus • Swedish • Spont tear of ≥ 2 cm • Consecutive • Primiparous **Exclusion criteria** NR (refusal) **Groups** **G1:** Episiotomy **G2:** Spont tear **N at enrollment** **G1:** 157 **G2:** 48 **Followup** 1 day to 3 mos	**Age (median)** **G1:** 25.5yrs **G2:** 26.6yrs NS **Parity** All primiparous **Attended antenatal classes** NS **Feeling during pregnancy** NS	**Mode of delivery** **G1:** Vacuum: 15% **G2:** Vacuum: 4% NS **Duration of sec stage labor** NS **Episiotomy type** **G1:** • Midline: 12% • Mediolateral: 88% **Suture type** PGA: 100% **Head circumference** NS **Birthweight (mean)** **G1:** 3463g **G2:** 3587g NS

Evidence Table 12. Key Question 5: Future sexual function (continued)

Perineal Trauma Outcomes	Sexual function outcomes	Quality and comments
First deg tear **G1:** Mediolateral: 15% **G1:** Midline: 3% **G2:** 90% **Third deg tear** **G1:** Mediolateral: 5% **G1:** Midline: 0 **G2:** 6% **Fourth deg tear** **G1:** Mediolateral: 0% **G1:** Midline: 1% **G2:** 4% **Anterior (labia/clitoris)** **G1:** Mediolateral: 18% **G1:** Midline: 0 **G2:** 33% (*P* < 0.05)	**Short term** NR **Long term: 3 mos** **Dyspareunia** **G1:** 44% **G2:** 43% NS	**Overall quality** Poor **Population** Good **Measures** Poor **Analysis** Poor **Retention of participants** Good

Evidence Table 12. Key Question 5: Future sexual function (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics
Author Larsson et al., 1991 **Setting** Sweden **Study design** Prospective cohort **Inclusion criteria** Consecutive vaginal deliveries **Exclusion criteria** Cesarean sections **Groups** **G1:** Episiotomy **G2:** Spont laceration **G3:** Nontraumatic birth **N at enrollment** **G1:** 569 **G2:** 627 **G3:** 693 **Followup** 1 to 5 days; 8 to 12 wks	**Age (mean ± SD)** Overall: 27.2yrs ± 3.4 Diff NS **Primiparous** **G1:** 52% **G2:** 30% **G3:** 38%	**Mode of delivery** NR **Anesthesia at time of delivery** **Paracervical blockade** **G1:** NA **G2:** 36.7% **G3:** NA **Pudendal block** **G1:** 72.4% **G2:** 61.1% **G3:** 53.9% *P* < 0.001 **Epidural** **G1:** 29.8% **G2:** 9.7% **G3:** 12.3% *P* < 0.001 **Episiotomy type** **G1:** Mediolateral: 98% **Suture type** NR **Birthweight (mean ± SD)** Overall: 3548g ± 518 Diff NS

Evidence Table 12. Key Question 5: Future sexual function (continued)

Perineal Trauma Outcomes	Sexual function outcomes	Quality
Third and fourth deg tear (partial or total rupture of the anal sphincter) **G1:** 3.9% **G2:** 2.6% NS **Primiparous only** **G1:** 4.3% **G2:** 4.8% NS	**Short term** **Dyspareunia** **G1:** 16% **G2:** 11% *P* < 0.05 **Long term** NR	**Overall quality** Poor **Population** Fair **Measures** Poor **Analysis** Poor **Retention of participants** Good

* Tables do not match text on time period

Evidence Table 12. Key Question 5: Future sexual function (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery and Repair Characteristic
Author Klein et al., 1992 **Setting** Canada **Study design** RCT **Inclusion criteria** • 18 to 40 yrs old • Parity = 0, 1, 2 • Single fetus • Spoke English or French • Low medical and obstetrical risk **Exclusion criteria** • Prematurity (gestation < 37wks) • Fetal distress • Cesarean deliveries • Planned forceps • Medical condition developed late in pregnancy **Groups** **G1:** Primiparous **G1a:** Liberal (attempted to avoid a tear/separated by parity) **G1b:** Restricted (attempted to avoid an episiotomy/ separated by parity) **G2:** Multiparous **G2a:** Liberal **G2b:** Restricted	**Age (mean ± SD)** **G1a:** 27.9yrs ± 3.9 **G1b:** 27.9yrs ± 4.4 **G2a:** 31.0yrs ± 3.7 **G2b:** 30.3yrs ± 9.1 **Parity** **G1:** Primiparous: 100% **G2:** Multiparous: 100% **Education** **G1a:** 3.0% **G1b:** 3.1% **G2a:** 3.0% **G2b:** 3.0% **Sig diff** NR **Stable Relationship** Diff NS **Employment** Diff NS	**Mode of delivery** NR **Episiotomy rate (all median)** **G1a:** 81% **G1b:** 52% **G2a:** 47% **G2b:** 31% **Suture type** NR **Height** Sig diff NR **Weight during pregnancy** Sig diff NR **Previous episiotomy** NS **Birthweight (mean ± SD)** **G1a:** 3325g ± 416 **G1b:** 3377g ± 432 **G2a:** 3496g ± 449 **G2b:** 3467g ± 497 **GA** NS

Evidence Table 12. Key Question 5: Future sexual function (continued)

Perineal Trauma Outcomes	Sexual function outcomes	Quality and comments
Intact perineum Measured at delivery **G1a:** 12 (6.6%) **G1b:** 13 (7.5%) OR = 1.16 (0.48, 2.8) **G2a:** 32 **G2b:** 56 OR = 1.85 (1.1, 3.2) **Sec deg tear** Measured at delivery **G1a:** 22 (12.6%) **G1b:** 61 (35.3%) OR = 3.99 (2.2, 7.1) **G2a:** 56 **G2b:** 68 NS	**Short term: 3 mos** **Time to resumption of sexual intercourse** NS **Mean deg of pain at resumption of sexual intercourse** NS **Female sexual satisfaction** NS **Long term** NR	**Overall quality** Fair **Population** Fair **Measures** Fair **Analysis** Good **Retention of participants** Fair

Evidence Table 12. Key Question 5: Future sexual function (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics
Author Klein et al., 1994 **Setting** Canada **Study design** Prospective cohort, secondary analysis of an RCT of liberal vs. selective midline episiotomy **Inclusion criteria** • Parity: 0, 1, 2 • Low risk • 18 to 40 yrs • Singleton fetus • Spoke English or French **Exclusion criteria** NR **Groups** **G1:** Intact **G2:** Spont tear **G3:** Episiotomy alone **G4:** Third or fourth deg tear **N at enrollment** **G1:** 110 **G2:** 208 **G3:** 313 **G4:** 66 **Followup** 3 mos	**Age** NR **Parity** • Overall: Primiparous: 51% • Details NR by group **Other demographics** • Race • Employment • Marital status • Intendedness of pregnancy • “No difference”	**Mode of delivery** NR **Suture type** NR **Birthweight (mean ± SD)** NR

Evidence Table 12. Key Question 5: Future sexual function (continued)

Perineal Trauma outcomes	Sexual function outcomes	Quality and Comments
See groups for rates **Odds ratio of third and fourth deg tears for primiparous women in the presence of episiotomy compared with those not receiving episiotomy** 22.08 (2.84, 171.53)	**Short term: 6 wks** **Resumed sex** **G1:** 76.5% **G2:** 62.5% **G3:** 61.7% **G4:** 55.4% *P* < 0.016 **Pain on first sex** **None vs. mild vs. discomforting vs. distressing (%)** **G1:** 32.7 vs. 37.6 vs. 22.8 vs. 6.9 **G2:** 20.8 vs. 27.3 vs. 27.3 vs. 24.6 **G3:** 14.4 vs. 22.7 vs. 34.1 vs. 28.8 **G4:** 8.2 vs. 23.0 vs. 39.3 vs. 29.5 *P* < 0.001 **Long term: 3 mos** **Sexual satisfaction** **Not satisfied vs. satisfied vs. very satisfied (%)** **G1:** 5 vs. 50 vs. 45 **G2:** 15.8 vs. 54.6 vs. 29.5 **G3:** 16.3 vs. 51.0 vs. 32.3 **G4:** 21.3 vs. 44.3 vs. 34.4 *P* = 0.022	**Overall quality** Fair **Population** Good **Measures** Good **Analysis** Fair/poor **Retention of participants** Good

Evidence Table 12. Key Question 5: Future sexual function (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics
Author Signorello et al., 2001 **Setting** USA **Study design** Cohort identified retrospectively, data mostly retrospective with the exception of one time point **Inclusion criteria** • Parity: 1 • Singleton fetus • Vertex • Term • Vaginal delivery **Exclusion criteria** NR **Groups at initial assignment** **G1:** Episiotomy **G2:** No episiotomy but sec, third, or fourth deg spont perineal laceration **G3.** Intact perineum **Groups for analysis** **G1:** Intact **G2:** Sec deg **G3:** High deg **G4:** Not classified **N eligible from retrospective identified cohort** 921 **Followup** 6 mos	**Age** **Overall** • < 20yrs: 4.7% • 20 to 24yrs: 10.1% • 25 to 29yrs: 28.8% • 30 to 34yrs: 38.5% • ≥ 35yrs: 17.9% **Parity** NR	**Mode of delivery** NR **Episiotomy rate** 33.3% overall **Suture type** NR **Birthweight (mean ± SD)** NR

Evidence Table 12. Key Question 5: Future sexual function (continued)

Perineal Trauma Outcomes	Sexual function outcomes	Quality and Comments
Long term NA **Short term** NA	**Short term** NA **Long term** Sexual function at 6 mos (possibly includes pain, sexual sensation, sexual satisfaction, likelihood of reaching orgasm) NS, details NR	**Overall quality** Fair **Population** Good **Measures** Fair **Analysis** Good **Retention of participants** Poor

Evidence Table 12. Key Question 5: Future sexual function (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics
Author Karacam and Eroglu 2003 **Setting** Turkey, L&D/MU **Study design** Prospective cohort **Inclusion criteria** • Multiparous • Resident of the relevant city boundaries • Had telephone • Age 18 to 35 yrs • 37 and 42 wks GA • Singleton live birth • Birthweight 2, 500g to 4, 500g • Vaginal vertex position delivery **Exclusion criteria** • Experienced medical illness (cardiac disease, diabetes, vaginal/ perineal infection, anemia, renal disease, pre-eclampsia and/or antepartum hemorrhage during pregnancy) • Malpresented/ malpositioned babies • "Large" babies • Intrauterine growth retardation • Congenital abnormality • Rigid perineal tissue • Vacuum/forceps **Groups** **G1:** Episiotomy (mediolateral) **G2:** No episiotomy **N at enrollment** **G1:** 50 **G2:** 50 **Followup** 1, 3, and 12 wks	**Age (mean ± SD)** **G1:** 25.96yrs ± 3.9 **G2:** 24.34yrs ± 2.7 **Parity** 100% multiparous **Other demographics** • Had health insurance NS • Graduated from primary school • NS • Did not have paying jobs NS	**Mode of delivery** All 100% spont **Types of intervention in labor** NS **Duration of labor** NS **Duration of the first stage** NS **Duration of the sec stage** NS **Involvement of women in labor** NS **Suture type** NR **Birthweight** **2, 500 to 3, 499g** **G1:** 59.18% **G2:** 63.27% NS **3, 500 to 4, 310g** **G1:** 40.82% **G2:** 36.73% NS **Diameter of infant's head** NS

Evidence Table 12. Key Question 5: Future sexual function (continued)

Perineal trauma characteristics	Sexual function outcomes	Quality
Spont laceration **G1:** 54% **G2:** 78% *P* = 0.011	**Short term** **Dyspareunia** **G1:** 64.6% **G2:** 54.2% *P* = 0.299 **Long term** NR	**Overall quality** Poor **Population** Poor **Measures** Poor **Analysis** Poor **Retention of participants** Good

Evidence Table 12. Key Question 5: Future sexual function (continued)

Study Characteristics	Demographic Characteristics	Labor, Delivery, and Repair Characteristics
Author Sartore et al., 2004 **Setting** Italy **Study design** Prospective cohort **Inclusion criteria** • Primiparous • Singleton pregnancy • Spont vaginal delivery • Fetal head in occiput anterior position **Exclusion criteria** • Delivered in position other than lithotomy position • Cesarean delivery • Third and fourth deg perineal lacerations • Preterm breech • Operative delivery • Anal and urinary incontinence that pre-existed vaginal delivery • History of vaginal or anal surgery **Groups** **G1:** Received mediolateral episiotomy **G2:** Intact perineum and spont perineal lacerations (first/sec deg) **N at enrollment** **G1:** 254 **G2:** 265 **Followup** 3 mos	**Age (mean ± SD)** **G1:** 30.9yrs ± 3.9 **G2:** 30.7yrs ± 4.3 **Primiparous** **G1:** 100% **G2:** 100%	**Mode of delivery** **Spont** **G1:** 100% **G2:** 100% **Birthweight (mean ± SD)** **G1:** 3334.7g ± 429.5 **G2:** 3222.8g ± 428.1 *P* = 0.003 **Maternal weight before pregnancy** NS **Weight gain in pregnancy** NS **Epidural rate** **G1:** 14.2% **G2:** 7.9% *P* = 0.023 **Episiotomy type** **G1:** Mediolateral: 100%

Evidence Table 12. Key Question 5: Future sexual function (continued)

Perineal Trauma Outcomes	Sexual function outcomes	Quality and Comments
G2: Intact perineum: 82 **G2:** First deg tear: 127 **G2:** Sec deg tear: 56	**Short term: 3 mos** **Mild dyspareunia** **G1:** 5.9% **G2:** 2.6% **Mod dyspareunia** **G1:** 1.9% **G2:** 0.8% **Overall dyspareunia** **G1:** 7.9% **G2:** 3.4% OR = 2.43 (1.08, 5.45) *P* = 0.26 **Long term** NR	**Overall quality** Good **Population** Good **Measures** Fair **Analysis** Good **Retention of participants** Good

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Appendix D
Acknowledgments

Appendix D. Acknowledgments

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Technical Expert Advisory Group

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Peer Reviewers

We gratefully acknowledge the following individuals who reviewed the initial draft of this report and provided us with constructive feedback. External reviewers comprised clinicians, researchers, representatives of professional societies, and potential users of the report. We would also like to extend our appreciation to David Atkins, MD, and Susan Meikle, MD MSPH from AHRQ for contributing peer review comments. Our peer review panel also includes all members of the TEAG. Peer review was a separate duty for these individuals and not part of their commitment as TEAG members. All are active professionals in the field. The peer reviewers were asked to provide comments on the content, structure, and format of the evidence report and to complete a checklist. The peer reviewers' comments and suggestions formed the basis of our revisions to the evidence report. Acknowledgments are made with the explicit statement that this does not constitute endorsement of the report.

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