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Staples compared with subcuticular suture for skin closure after cesarean delivery: a systematic review and meta-analysis

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Staples Compared With Subcuticular Suture for Skin Closure After Cesarean Delivery

A Systematic Review and Meta-Analysis

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OBJECTIVE: To estimate whether staples or subcuticular suture closure is associated with a higher risk of wound complications when used for transverse skin incisions after cesarean delivery.

DATA SOURCES: A systematic review and meta-analysis were performed through electronic database searches (MEDLINE, Cochrane, and Trial Registries).

METHODS OF STUDY SELECTION: We searched electronic databases from 1966 to September 2010 for randomized controlled trials (RCTs) and prospective cohort studies comparing staples to subcuticular sutures after cesarean delivery. The primary outcome was occurrence of a wound complication (infection or separation). Secondary outcomes were components of the composite outcome, operating time, postoperative pain, cosmesis, and patient satisfaction. Heterogeneity was assessed using the χ^2 test for heterogeneity, and I^2 test. Pooled odds ratios (ORs) were calculated using a fixed-effects model. We assessed publication bias using funnel plots and Egger test.

RESULTS: Six studies met inclusion criteria: five RCTs and one prospective cohort study. Staple closure (n=803) was associated with a twofold higher risk of wound infection or separation compared with subcuticular suture closure (n=684) (13.4% versus 6.6%, pooled OR 2.06, 95% confidence interval [CI] 1.43–2.98). The number needed to harm associated with staple closure was 16. The increased risk persisted when analysis was limited to the RCTs (OR 2.43, 95% CI 1.47–4.02). There was no evidence of significant statistical heterogeneity among

studies ($\chi^2=0.74$, $P=.327$, $I^2=13.7\%$) or publication bias (Egger test, $t=-0.86$, $P=.439$). Staple closure was associated with shorter duration of surgery, whereas the two techniques appeared equivalent overall with regard to pain, cosmesis, and patient satisfaction.

CONCLUSION: Staple closure is faster to perform but associated with a higher risk of wound complications.

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Cesarean delivery is one of the most common major surgical procedures in women worldwide. In 2007, approximately 1.4 million women had cesarean deliveries in the United States, representing 32% of all births.¹ As the rate of cesarean deliveries increases, so do the associated complications. Wound complications occur in 2.5%–16% of cesarean deliveries.² Although several factors contribute to cesarean wound complications, the optimal method of skin closure to minimize these complications is unknown.³ The ideal method of skin closure should be rapidly accomplished, result in minimal wound complications and postoperative pain, and produce cosmetic results that are acceptable to women.⁴

The two most common techniques used for skin closure after cesarean delivery are subcuticular suture and staples. A number of studies have compared these techniques with conflicting results.^{5–10} Many of the studies included small sample sizes, making their individual findings inconclusive.^{6–8,10} The most recent Cochrane review¹¹ comparing subcuticular suture to staples for skin closure after cesarean delivery was performed in 2003 and included only one study.⁷ Since that review, a number of studies have been published.^{5,6,8–10} Whereas two large-scale international trials are underway comparing different techniques of cesarean delivery, none is evaluating methods of skin closure.^{12,13}

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The objective of this study was to review, in a systematic manner, relevant studies comparing staples to subcuticular suture for closure of transverse skin incisions after cesarean delivery. Specifically, we aimed to estimate whether staples or subcuticular suture is associated with a higher risk of wound complications when used for closure of transverse skin incisions after cesarean delivery. It is anticipated that results of this review will guide obstetricians on the choice of skin closure technique after cesarean delivery.

MATERIALS AND METHODS

We developed an a priori protocol that outlined the research question, outcome measures, search strategy, study selection, and methods of data abstraction and analysis. We also prespecified sensitivity analysis to determine relative influence of individual studies on the pooled estimates.

We searched MEDLINE from 1966 to September 2010 using MeSH headings without restrictions for text words and word variations of “skin closure,” “cesarean,” “staples,” and “suture” (“Cesarean” [All Fields] or “Caesarean” [All Fields]; “skin” [MeSH Terms] or “skin” [All Fields] and “closure” [All Fields] and “Staples” [All Fields] and “sutures” [MeSH Terms] or “sutures” [All Fields] or “suture” [All Fields]). Citation lists were independently searched by two authors (M.T., J.C.) to identify relevant studies. Titles and abstracts were screened and articles were retrieved if they were relevant or if there was uncertainty. References of identified studies were manually searched for other relevant citations. We also searched for unpublished literature with the search terms “closure,” “skin” and “cesarean” or “caesarean” from controlled trials registries. Full articles were retrieved and reviewed against inclusion and exclusion criteria. Articles meeting the inclusion criteria were kept for critical appraisal and data collection using a standard data form.

All full English language text randomized controlled trials (RCTs) and prospective cohort studies that compared outcomes of transverse cesarean wounds closed with staples to subcuticular suture were eligible. We excluded retrospective cohort studies, case-control studies, and studies involving vertical skin incisions. We also excluded case reports, case series, reviews, editorials, comments, and studies that did not provide sufficient information on population characteristics, surgical procedures, or outcomes.

Two reviewers (M.T., J.C.) independently reviewed each eligible article and extracted data for the number of patients, closure technique, number of

wound infections or separation, operating time, post-operative pain, cosmesis, and patient satisfaction. The two databases were then compared. The two reviewers (M.T., J.C.) each critically appraised the quality of each study using the Physiotherapy Evidence Database critical appraisal tool. This is an 11-item scoring system that has been shown to be reliable and valid in the assessment of RCTs.¹⁴ Disagreements regarding study selection, data extraction, and study appraisal were resolved through arbitration and discussion with the senior author (A.O.).

The primary outcome for this review was wound complication, defined as the occurrence of wound infection or separation. Secondary outcomes were the individual components of the primary outcome, operating time, pain, cosmesis, and patient satisfaction.

Abstracted data were analyzed using STATA 10.1 (Stata, College Station, TX). Meta-analysis was considered when there were at least two studies for a given outcome. Statistical heterogeneity was assessed using the χ^2 test for heterogeneity (Cochran Q statistic), and the magnitude of heterogeneity quantified using I^2 ($I^2 = [Q - \text{degrees of freedom}] \times 100 / Q$), where degrees of freedom = $k - 1$, Q = Cochran Q statistic, and k = number of studies).¹⁵ We calculated pooled odds ratios (ORs) with 95% confidence intervals (CIs) from a fixed effects model using the Mantel-Haenszel method when there was no evidence of clinical or statistical heterogeneity.¹⁶ Otherwise, we considered a

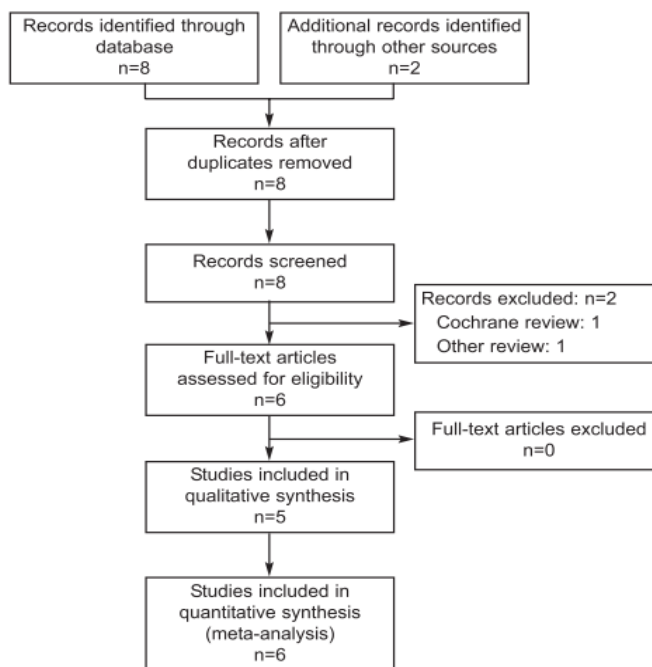


Fig. 1. Flow diagram of studies in meta-analysis. Tuuli. Staples Compared With Suture. *Obstet Gynecol* 2011.



random effects model. A correction factor of 0.5 was used when the data from a study included a value of zero to permit calculation of ORs and 95% CIs.¹⁷ We assessed for potential publication bias using funnel plots and Egger test.^{18,19} We then performed a planned sensitivity analysis that involved removing individual studies, one at a time, and repeating the meta-analysis to determine the influence of each study on the pooled ORs and 95% CI.

We summarized operating times for studies in which this was reported. We did not perform formal meta-analysis because different studies reported different summary statistics for different

segments of operating times. Finally, we performed qualitative synthesis and made overall conclusions (“staples superior,” “sutures superior,” or “equivalent”) when substantial differences in scales of measurements of outcomes hindered quantitative meta-analysis. This involved evaluating the data reported in each study for these outcomes and determining which closure method was considered superior. An overall conclusion was based on the preponderance of studies supporting the superiority of a given closure method. When similar numbers of studies supported each method, we concluded that they were equivalent.

Table 1. Characteristic of Studies Comparing Staples With Subcuticular Skin Closure After Cesarean Delivery

Study	Design	Closure Material	Definition or Description of Wound Infection and Separation	Population		
				Staples	Suture	Total
Frishman et al	RCT	Suture (4-0 polyglycolic), staples (removed at discharge and steri-strips placed)	Infection: not explicitly defined, follow-up to 6 wk postpartum Separation: any separation, follow-up to 6 wk postpartum	25	25	50
Johnson et al	Prospective cohort	Suture (type not stated), staples	Infection: clinical evidence of infection from inpatient and outpatient medical records, follow-up to 30 d postpartum Separation: not reported	454	252	706
Gaertner et al	RCT	Suture (3-0 vicryl), staples (removed on postoperative day 6)	Infection: swelling and reddening of the wound needing opening, follow-up to 4 mo postpartum Separation: dehiscence of the skin needing conservative treatment with patches, follow-up to 4 mo postpartum	51	49	100
Rousseau et al	RCT	Suture (4-0 monocryl), staples (removed on postoperative day 3)	Infection: as stated by patients including any treatment, follow-up to 6 wk postpartum Separation: not reported	45	47	92
Cromi et al	RCT	Suture (3-0 monosyn, Dafilon, or Safil), staples	Infection: information on wound infection requiring drainage and debridement, follow-up to 8 wk postpartum visit Separation: any separation, follow-up to 8 wk postpartum	31	92	123
Basha et al	RCT	Suture (4-0 monocryl, with steri-strips), staples (removed typically on postoperative day 3 or 4 and steri-strips)	Infection: wound infection requiring antibiotics as reported by patient or medical records, follow-up to 2–4 wk postpartum Separation: any separation identified by patient or medical records, follow-up to 2–4 wk postpartum	197	219	416
Total				803	684	1,487

RCT, randomized control trial.



Table 2. Critical Appraisal of Selected Studies Comparing Staples With Subcuticular Suture for Skin Closure After Cesarean Delivery Using the PEDro Scale^{14*}

	Frishman et al	Johnson et al	Gaertner et al	Rousseau et al	Cromi et al	Basha et al
Eligibility criteria	Yes	Yes	Yes	Yes	Yes	Yes
Random allocation	Yes	No	Yes	Yes	Yes	Yes
Concealed allocation	Yes	No	Yes	Yes	Yes	Yes
Baseline comparability	Yes	No	Yes	Yes	Yes	Yes
Blinded clinician	No	No	No	No	No	No
Blinded patient	No	No	No	No	No	No
Blinded assessor	No	Yes	No	Yes	Yes	No
Adequate follow-up	Yes	Yes	Yes	Yes	Yes	Yes
Intention-to-treat analysis	Yes	No	Yes	Yes	Yes	Yes
Between-group analysis	Yes	Yes	Yes	Yes	Yes	Yes
Point estimates and variability	Yes	Yes	Yes	Yes	Yes	Yes
Total score	8	5	8	9	9	8

* One point is awarded for each criterion met; maximum score is 11.

RESULTS

A flow diagram of study identification for the meta-analysis is shown in Figure 1. A total of eight publications were identified from the initial MEDLINE search.^{5-11,20} Two of these studies were reviews of previous studies and were excluded.^{11,20} The remaining six studies met inclusion criteria.⁵⁻¹⁰ A search of the bibliographies of these studies did not reveal any additional studies. The Cochrane database search yielded one systematic review¹¹ that was previously identified and contained only one study that was also already identified from the MEDLINE search.⁷ Two ongoing randomized trials were noted in the clinical trials registries. Characteristics of the included studies are shown in Table 1. Five were RCTs^{5-8,10} and one was a prospective cohort study.⁹ The studies included primary and repeat as well as elective and emergent cesarean deliveries. A total of 803 wounds were closed with staples and 684 were closed with subcuticular sutures.

Critical appraisal of the studies using the Physiotherapy Evidence Database scale showed fairly good

methodological quality of all the RCTs (score of 8–9 points out of a maximum of 11; Table 2). All described eligibility and exclusion criteria, reported acceptable methods of randomization, and concealed allocations had comparable baseline characteristics of the study groups and reported adequate follow-up for most key outcome variables. All RCTs also appeared to follow the intent-to-treat principle, compared results of groups using inferential statistics, and reported point estimates with measures of variability. However, except for the studies by Cromi et al⁶ and Rousseau et al¹⁰ in which the assessor was blinded, none of the RCTs blinded the clinicians, assessors, or patients. Using the same tool, critical appraisal of the prospective cohort study⁹ revealed poor methodological quality (score of 5 points out of 11). Its strengths were in the specification of eligibility criteria, adequate follow-up, comparison of results between groups, and reporting point estimates with measures of variability.

Four studies evaluated both components of the primary outcome (wound infection and wound sepa-

Table 3. Quantitative Data of Wound Complications From Selected Studies Comparing Staples to Subcuticular Suture for Skin Closure After Cesarean Delivery

Study	Wound Infection		Wound Separation		Wound Infection or Separation	
	Staples	Suture	Staples	Suture	Staples	Suture
Frishman et al	1/25	0/25	1/25	0/25	2/25	0/25
Johnson et al	59/454	20/252	—	—	59/454	20/252
Gaertner et al	0/51	4/49	3/51	0/49	3/51	4/49
Rousseau et al	0/45	1/47	—	—	0/45	1/47
Cromi et al	0/31	1/92	1/31	1/92	1/31	2/92
Basha et al	10/197	8/219	33/197	10/219	43/197	18/219

Data are n/N.

—, the data was not reported.



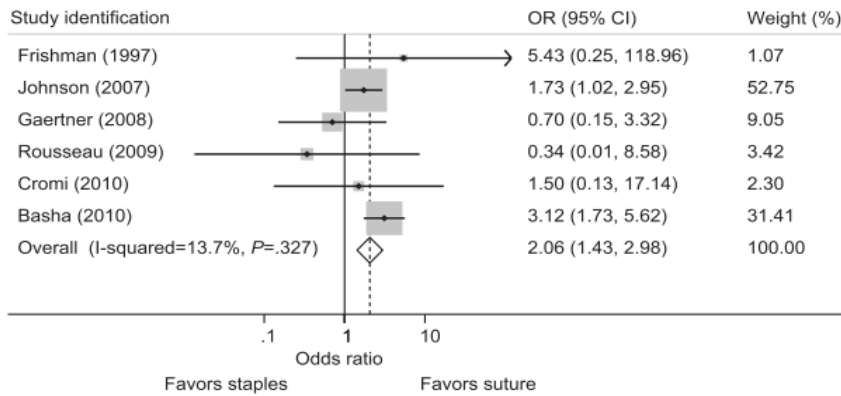


Fig. 2. Forest plot of the composite outcome of wound complications (separation or infection) in selected studies comparing staples to subcuticular suture for skin closure after cesarean delivery. The pooled odds ratio (OR) is 2.06 (95% confidence interval [CI] 1.43–2.98), with number needed to harm of 16 and 64 excess events per 1000 (95% CI 36–85). χ^2 for heterogeneity=5.79, $P=.327$, $I^2=13.7\%$. Tuuli. Staples Compared With Suture. *Obstet Gynecol* 2011.

ration).^{5–8} Two additional studies reported wound infection but not wound separation^{9,10} (Table 3). From the meta-analysis, staple closure was associated with a twofold higher risk of wound infection or separation (13.4%) compared with suture closure (6.6%) (OR 2.06, 95% CI 1.43–2.98; Fig. 2). The associated number needed to harm was 16, with number of excess events (wound complications) being 64 per 1,000 cesarean deliveries (95% CI 36–85).

There was no evidence of statistical heterogeneity among studies ($\chi^2=5.79$, $P=.327$, $I^2=13.7\%$). Sensitivity analysis revealed no significant change in ORs and 95% CIs when individual studies were removed. Most notably, the increased risk of wound complications associated with staple closure did not significantly change when analysis was limited to the five randomized trials (OR 2.43, 95% CI 1.47–4.02). Both visual inspection of the funnel plot and Egger test suggested absence of publication bias ($\chi^2=-0.86$, $P=.439$; Fig. 3).

We examined components of the primary outcome individually to determine whether the technique of skin closure differentially affected these complications. Staple closure was associated with a significantly higher risk of wound separation (OR 4.24, 95% CI 2.16–8.34; Fig. 4), whereas the increased risk of wound infection (OR 1.41, 95% CI 0.92–2.17) was not statistically significant (Fig. 5). There was no evidence of heterogeneity for either outcome ($\chi^2=0.21$, $P=.977$, $I^2=0\%$ and $\chi^2=4.73$, $P=.450$, $I^2=0\%$, respectively).

Operating times were reported in four studies. Table 4 shows the different segments of operating times reported by the different studies. Surgical duration was measured as total operating time in some studies and as skin closure time in one study. Two studies reported mean operating times plus or minus standard deviations, one reported only mean operating time, and the other reported median

operating time and range. However, all four studies demonstrated shorter operating times for staple closure compared with suture closure. The estimated time saved by staple closure ranged from 3.3 to 9.3 minutes.

Results of qualitative synthesis of outcomes with substantially different scales of measurement that hindered quantitative meta-analysis are shown in Table 5. The two closure techniques appeared equivalent with regard to postoperative pain, cosmetic outcome, and patient satisfaction. In the three studies that evaluated postoperative pain, one concluded that staples were superior, another considered sutures to be superior, and a third considered them equivalent. Our overall conclusion was equivalence with regard to postoperative pain. Patient satisfaction was assessed in five studies. In one study, staples were considered

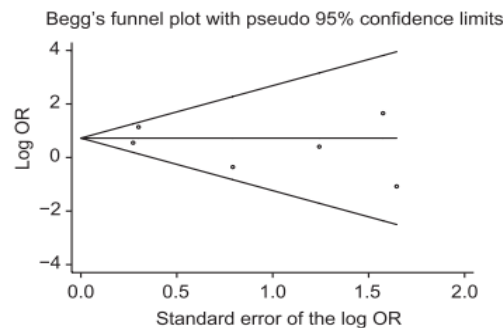


Fig. 3. Begg funnel plot of the composite outcome of wound complications (separation or infection) in selected studies comparing staples to subcuticular suture for skin closure after cesarean delivery. This is a plot of the logarithm of odds ratios (log_OR) against standard errors of the log_ORs with pseudo 95% confidence interval limits. Visual inspection suggests absence of publication bias since small studies favoring staples and subcuticular suture are both present. This is confirmed by the Egger test ($t=-0.86$, $P=.439$). Tuuli. Staples Compared With Suture. *Obstet Gynecol* 2011.



Meta-analysis: wound separation

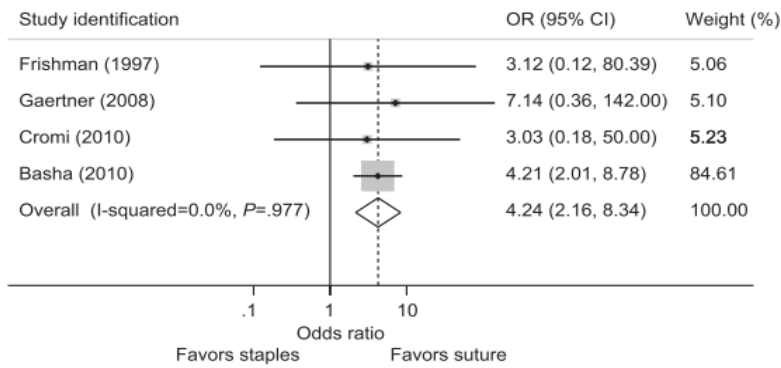


Fig. 4. Forest plot of the outcome of wound separation in selected studies comparing staples to subcuticular suture for skin closure after cesarean delivery. Pooled odds ratio is 4.24 (95% confidence interval 2.16–8.34). χ^2 test for heterogeneity=0.21, $P=.977$, $I^2=0$.

Tuuli. Staples Compared With Suture. *Obstet Gynecol* 2011.

superior, in another sutures were superior, and in three studies staples and sutures were considered equivalent. In that case, we concluded that the two techniques were equivalent with regard to patient satisfaction. Finally, for cosmesis, two studies concluded that staples and sutures were equivalent and one favored sutures. Because the assessor in the two studies that concluded equivalence were blinded whereas the study that favored sutures was not blinded, we concluded that the two techniques were equivalent.

DISCUSSION

Postoperative wound complication is one of the most common complications of cesarean delivery. Although rarely life-threatening, wound separation and infection are associated with significant psychological stress for patients and increased cost to the health care system.^{21,22} Whereas the beneficial effects of interventions such as preoperative antibiotics for preventing wound infection have been established,²³ the role of wound closure technique is less clear. In addition to preventing wound complications, the desirable wound closure technique should be fast and simple to

perform, cost-effective, and result in minimal pain while maximizing wound cosmesis and patient satisfaction.⁴ The conflicting results of individual previous studies, most of which included small numbers of patients, provided inconclusive evidence on their own to guide clinical practice. In this review, we identified six studies considered appropriate for inclusion. Results of our meta-analysis show that staple closure is associated with a significantly higher risk on wound complications. The number needed to harm of 16 implies that one excess wound complication occurs for every 16 cesarean deliveries (or approximately 64 per 1,000) when staples are used instead of subcuticular suture for skin closure. However, operating time was significantly shorter with staple closure. Qualitative analysis of the other outcomes suggests that the two techniques were equivalent with regard to postoperative pain, cosmesis, and patient satisfaction.

Staple closure gained popularity in the 1980s when initial studies in general surgery demonstrated shorter operating times and reduction in wound infection.²⁴ It was hypothesized that staples may cause less damage to the wound's defenses than sutures that act as foreign bodies.²⁵ Subsequent RCTs in general

Meta-analysis: wound infection

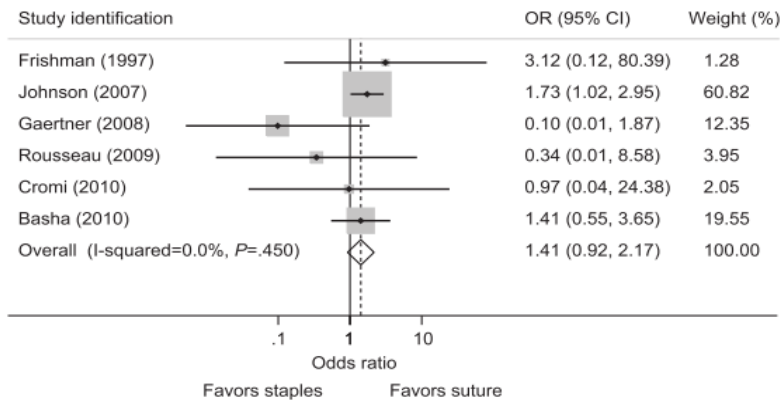


Fig. 5. Forest plot of the outcome of wound infection in selected studies comparing staples to subcuticular suture for skin closure after cesarean delivery. Pooled odds ratio (OR) is 1.41 (95% confidence interval [CI] 0.92–2.17). χ^2 test for heterogeneity=4.73, $P=.450$, $I^2=0\%$.

Tuuli. Staples Compared With Suture. *Obstet Gynecol* 2011.



Table 4. Operating Times Reported in Selected Studies Comparing Staples With Subcuticular Suture for Skin Closure After Cesarean Delivery

Study	Operating Time Reported	Duration (min)		
		Staples	Suture	Estimated Time Saved by Staples
Frishman et al	Mean skin closure time±SD	0.78±0.07	10.08±0.55	9.3
Johnson et al	—	—	—	—
Gaertner et al	Mean total operating time	23.8	27.1	3.3
Rousseau et al	Mean total operating time±SD	31.9±9.1	40.9±10.7	9.0
Cromi et al	—	—	—	—
Basha et al	Median total operating time (range)	49 (21–230)	57 (26–182)	8

SD, standard deviation.
—, the data was not reported.

surgery failed to confirm a beneficial effect of staple closure for preventing wound infections.^{26,27} Our finding that staple closure is associated with a higher risk of wound complications is contrary to the conventional wisdom that interrupted closure techniques should be used for skin closure of clean contaminated wounds such as cesarean incisions.³ The near-universal use of preoperative antibiotics at cesarean delivery reduces wound infection rates overall,²³ but whether the apparent superiority of subcuticular suture is attributable to staples being metallic or subcuticular suture achieving better wound coaption is unclear. We posit that the continuous nature of subcuticular suture and its concealment below the skin without connection to the external environment reduces the entry of bacteria, thus reducing wound separation and infection.

Two previous reviews^{11,20} evaluated studies that compared staples to subcuticular suture closure for transverse cesarean delivery incisions. The Cochrane review in 2003 included only the study by Frishman et al⁷ and concluded that there is insufficient evidence to recommend one skin closure method over the other.¹¹ Altman et al²⁰ reviewed skin closure techniques for Pfannenstiel incisions. That review was

performed before the three recent RCTs were published,^{5,6,10} and included animal, general abdominal, gynecologic, and obstetric surgical procedures. Although no meta-analysis was performed, the authors concluded that there is insufficient evidence to guide surgeons in their choice of skin closure technique after cesarean delivery and other procedures using Pfannenstiel incisions.²⁰ Because we included more studies and limited our analysis to cesarean deliveries, we were able to reach more definitive conclusions regarding wound complications.

The combination of six studies enabled us to overcome some of the sample size limitations that characterize many of the individual studies. The absence of significant heterogeneity and publication bias in this analysis lends credence to the pooled risk estimates. As a major limitation, not all studies reported wound infection and wound separation. Wound separation and wound infection also were variously defined in the different studies. Whereas wound separation was defined as any separation in most studies, definitions of wound infection ranged from infections requiring antibiotics or drainage to superficial infections. A distinction between superficial and deep infection or separation is important

Table 5. Qualitative Data of Outcomes of Selected Studies Comparing Staples With Subcuticular Suture for Skin Closure After Cesarean Delivery

Study	Pain Score	Patient Satisfaction	Cosmesis
Frishman et al	Suture superior	Suture superior	Suture superior
Johnson et al	—	—	—
Gaertner et al	—	Equivalent	—
Rousseau et al	Staples superior	Staples superior	Equivalent
Cromi et al	Equivalent	Equivalent	Equivalent
Basha et al	—	Equivalent	—
Overall conclusion	Equivalent	Equivalent	Equivalent

—, the data was not reported.



because their management and associated sequelae differ. In addition, other wound complications such as seromas and hematomas were not reported in most studies and are not included in this review. Also, the lack of blinding in some of the studies could have introduced bias. The use of different suture types could have also affected the outcomes. However, the study by Cromi et al⁶ in which three different suture types were used did not demonstrate any difference in outcomes by suture type. Another potential criticism of a review such as this, which evaluates the effect of a single variable on outcomes of multifactorial nature, is confounding by the other factors such as obesity, emergency of the procedure, skin preparation, preoperative antibiotics, and subcutaneous tissue closure. Most of the studies included in this review reported a near-universal use of antibiotics and closure of the subcutaneous layer either in all patients or when it was more than 2 cm. For the RCTs in which subcutaneous tissue closure was not universally or systematically performed, we expect that any potential confounding would be minimized by the process of randomization.

We included one prospective cohort study in this review. The absence of randomization in cohort studies raise concerns for confounding and bias that could result in spurious results. However, the absence of significant statistical heterogeneity and results of sensitivity tests that showed unchanged pooled estimates after excluding the one cohort study suggests that confounding and bias are likely minimal. Finally, we were unable to quantitatively combine measures of operating time, cosmesis, pain, and patient satisfaction because they were measured on different scales. The qualitative methods used to draw conclusions were careful but largely subjective.

In conclusion, this review suggests that as compared with subcuticular suture, staple closure is associated with shorter operating times but higher risk of wound complications. The two techniques appear equivalent in terms of postoperative pain, cosmesis, and overall patient satisfaction. We recommend that subcuticular suture generally be used for transverse skin closure after cesarean delivery to minimize wound complications. Future research should use standardized outcome measures and focus on groups at high risk for wound complications such as obese women, diabetic women, and those undergoing emergent cesarean deliveries. This will help clarify whether subcuticular suture is associated with a lower risk of wound complications in these populations at high risk. Outcomes stratified by primary and repeat

cesarean deliveries also would be useful to guide clinical practice.

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