Surgical Staples Compared With Subcuticular Suture for Skin Closure After Cesarean Delivery: A Randomized Controlled Trial

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Abstract

OBJECTIVE: To compare the risk of cesarean wound disruption or infection after closure with surgical staples compared with subcuticular suture.

METHODS: Women with viable pregnancies at 24 weeks of gestation or greater undergoing scheduled or unscheduled cesarean delivery were randomized to wound closure with surgical staples or absorbable suture. Staples were removed at postoperative days 3–4 for low transverse incisions and days 7–10 for vertical incisions. Standardized wound evaluations were performed at discharge (days 3–4) and 4–6 weeks postoperatively. The primary outcome was a composite of wound disruption or infection within 4–6 weeks. Secondary outcomes included operative time, highest pain score on analog scale, cosmesis score, and patient scar satisfaction score. Analyses were by intent to treat.

RESULTS: Of 398 patients, 198 were randomized to staples and 200 to suture (but four received staples). Baseline characteristics including body mass index, prior cesarean delivery, labor, and type of skin incision were similar by group. The primary outcome incidence at hospital discharge was 7.1% for staples and 0.5% for suture (P<.001, relative risk 14.1, 95% confidence interval [CI] 1.9–106). Of 350 (87.9%) with follow-up at 4–6 weeks, the cumulative risk of the primary outcome at 4–6 weeks was 14.5% for staples and 5.9% for suture (P=.008, relative risk 2.5, 95% CI 1.2–5.0). Operative time was longer with suture closure (median time of 58 versus 48 minutes; P<.001). Pain scores at 72–96 hours and at 6 weeks, cosmesis score, and patient satisfaction score did not differ by group.

CONCLUSION: Staples closure compared with suture is associated with significantly increased composite wound morbidity after cesarean delivery.

Cesarean delivery is the most common major surgical procedure performed in the United States and elsewhere. Currently, approximately one third of pregnant women in the United States and 15% worldwide deliver by cesarean, and this prevalence is on the

rise.[1] Given these trends, cesarean wound complications such as disruption or infection remain an important cause of postcesarean morbidity at considerable costs to the patient and health system.[2–5]

The skin is typically closed with surgical staples or sutures after cesarean delivery. Until recently there has been little evidence regarding the best cesarean skin closure material.[6] It has been postulated that sutures act as a foreign body and damage tissue leading to increased infections.[7] Initial small studies regarding cesarean skin closure materials examined operative time, pain scores, cosmesis scores, patient satisfaction, or all of these and yielded contradictory findings.[8,9] One randomized controlled trial of wound disruption or infection (evaluated by phone interview supplemented with record review) at 2–4 weeks as the primary outcome suggested increased rates with staple compared with suture closure.[10] Given the paucity of trials that adequately examined wound morbidity outcomes of cesarean closure methods, the objective of our study was to compare the risk of cesarean wound disruption or infection after closure with surgical staples compared with absorbable subcuticular suture.

MATERIALS AND METHODS

We conducted a single-center randomized controlled trial that included women with viable pregnancies (24 weeks or greater) undergoing cesarean delivery at University Hospital, Birmingham, Alabama. All cesarean delivery types were included—scheduled or unscheduled and primary or repeat cesarean deliveries. Women were excluded for the following reasons: inability to obtain informed consent, fetal death, immune-compromising disease (eg, acquired immunodeficiency syndrome), chronic steroid use, contraindication to routine postpartum pain medications (ibuprofen, acetaminophen, narcotics), or planned postpartum visit at another facility. The study was approved by the institutional review board of the University of Alabama at Birmingham and was registered at ClinicalTrials.gov (NCT01008449).

Eligible women were approached and consented at the time of admission for delivery. Those who required cesarean delivery underwent usual perioperative management (surgical skin preparation with povidone–iodine solution and prophylactic antibiotics). Women were randomized to either surgical metallic staples or 4-0 Monocryl (absorbable sutures) according to a predetermined computer-generated block randomization scheme prepared by a study statistician. The block size was four.

Sequentially numbered and sealed opaque envelopes were prepared according to the randomization scheme and were delivered to a secure container in the operating room suite to maintain concealed treatment allocation. At the time of fascia closure, the next numbered envelope was pulled and opened by the circulating nurse to reveal the designated closure method. At this point the patient was considered randomized.

The cesarean delivery technique was left to the discretion of the health care provider but generally followed usual practice at our center including perioperative prophylactic antibiotics (azithromycin and cefazolin) after cord clamp, closure of the fascia with #1 polydioxanone running stitch, saline irrigation of the subcutaneous layer, and use of cautery to obtain hemostasis. In addition, the subcutaneous layer was closed with 3-0 Vicryl for all women with a subcutaneous layer greater than 2.0 cm. Women in the surgical staples group had the skin edges everted for staple placement. Those in the subcuticular suture group had absorbable sutures placed in one continuous closure with knots buried at the lateral edges of the wound. Skin closures were generally performed by resident physicians with attending supervision. First-year residents did not perform skin closures for study participants in the first 3 months of their training and required a minimum of 10 observed skin closures and approval by their supervisory obstetric physician before performing skin closures for this study. The wound was dressed with an abdominal pad and Elastoplast tape (thin adhesive strips were not placed at skin closure). The wound dressing was removed on postoperative day 1. Women showered by 24 hours postoperatively. Staples were removed and thin adhesive strips placed on postoperative day 3 or 4 before hospital discharge for low transverse abdominal incisions; patients with vertical incisions in the staple group returned on postoperative days 7–10 for removal.

A standardized physical examination of the wound was performed by trained obstetric providers (residents or attending) at hospital discharge (postoperative days 3–4) and at the postpartum examination (4–6 weeks postoperatively) for patients in both groups. For patients who did not return for their postpartum visit at 4–6 weeks, a standardized phone assessment was implemented by trained study personnel; any report of a wound complication was validated by medical record review. The primary outcome was a composite of wound disruption or infection occurring within 4–6 postoperative weeks. Wound disruption was defined as subcutaneous skin dehiscence (from any cause including seroma or hematoma) or fascial dehiscence. Wound infection was defined as purulent drainage, cellulitis, abscess or wound requiring drainage, débridement, and

antibiotics associated with a clinical diagnosis of infection. Key prespecified secondary outcomes included: operative time (from skin incision to end of skin closure), analog pain score at postoperative days 3–4 (the highest pain score as recorded by nursing staff at a minimum of every 8 hours between 72 and 96 hours postoperatively) and postoperative weeks 4–6, cosmesis score (as defined by the Stony Brook Scar Evaluation Scale[11]) 4–6 weeks postoperatively, and patient satisfaction score (patients rated general appearance, location, and comfort of scar on a 1 [worst] to 5 [best] scale) 4–6 weeks postoperatively.

Assuming a conservative baseline composite primary outcome of 8%, α=0.05 and power of 80%, we initially estimated that a sample size of 1,204 (602 per group) was required for a 50% reduction in the primary composite outcome. During the course of the study, newly reported data with similar exposure groups indicated a higher rate of wound complication prompting us to reevaluate our postulated baseline rate.[10] Examination of our institutional data (external to the study) suggested a more realistic rate of 12–14%. However, after further considering 1) the new reports and meta-analyses suggesting potential benefits of suture closure on wound morbidity; and 2) the logistics required to continue this study, our research review group (comprising senior investigators, biostatisticians, and our research center leadership) decided to stop enrollment at approximately 400 participants. Therefore, the study was stopped without any interim data analyses to compare arms.

Statistical analyses were conducted using SAS 9.1. The randomization code was kept confidential by a single statistician until the end of study after the database had been cleaned and locked for data analysis. At this time the code was imported into the database. The χ^2 of association and Fisher's exact test were used for analysis of categorical data. The Pearson's χ^2 test was used where applicable. Where assumptions for this procedure were not met, Fisher's exact test was used. Quantitative measures were analyzed using the two-tailed unpaired Student's *t* test and the Wilcoxon rank sum test. Statistical significance was defined as $P \leq .05$ without adjustments for multiple comparisons. The analysis, although occurring earlier than originally planned, was the final planned analysis. Hence, no adjustments were made to preserve α for subsequent analyses. Relative risks and 95% confidence intervals are presented for primary and secondary outcomes. All analyses were by intent to treat.

RESULTS

From August 2009 through November 2010, a total of 833 patients were screened and 62 declined to participate. Among the 771 who consented, 373 were excluded from randomization because they did not meet inclusion criteria primarily because of a vaginal delivery. The remaining 398 were randomized: 198 to staples and 200 to suture (Fig. 1). Four women randomized to the suture group actually received staples but they were analyzed in the suture group according to the intent-to-treat principle. The baseline characteristics of the randomized cohort including body mass index (BMI [calculated as weight (kg)/[height (m)]^2] ≈36), race and ethnicity (predominantly African American), and prior cesarean delivery (47–49%) were similar between study groups. Of the 350 (88%) who had postoperative follow-up at 4–6 weeks, 179 were in the staple and 171 in the suture group. Baseline characteristics remained similar by group as shown in Table 1. Ninety-nine percent of women received perioperative antibiotic prophylaxis and 30% received intrapartum antibiotics (mainly for group B Streptococcus-positive status, chorioamnionitis, or both).

Table 1 Baseline Characteristics of Patients With 4- to 6-Week Follow-up

	Staples (n=179)	Suture (n=171)	*P*
Age (y)	26.7±6.1	26.9±5.9	.622*
BMI (kg/m^2)	36.8±8.1	35.9±8.5	.255*
Race			
African American	66.5	56.7	.106†
White	15.1	22.2	
Hispanic	17.9	18.7	
Other	0.6	2.3	
Smoking	10.6	12.3	.624
Primiparous	30.7	33.9	.523
Prior cesarean delivery	46.9	51.5	.396
Chronic hypertension	13.4	11.7	.629
Diabetes	19.6	18.7	.841
HIV	1.1	0	.499†
Chorioamnionitis	10.1	11.7	.622
Labor or induction	49.7	53.2	.513
Intrapartum antibiotics	30.7	28.1	.586
Vertical midline incision	8.4	8.8	.896
Intraoperative antibiotics	98.3	98.8	>.999†
Steroids	8.4	7.6	.789
Intraoperative bilateral tubal ligation	33.5	27.5	.221

BMI, body mass index; HIV, human immunodeficiency virus.
Data are mean±standard deviation or % unless otherwise specified.
* Wilcoxon rank sum test.
† Fisher's exact test.

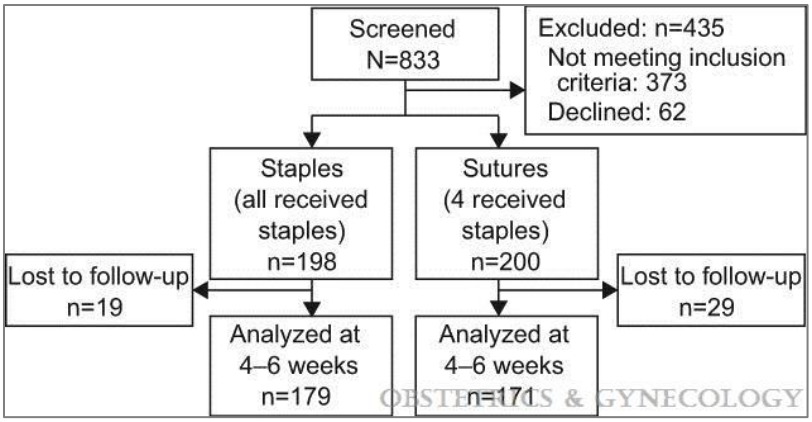

Figure 1 Study flow diagram.

The cumulative incidence of the primary composite outcome and its components at the time of hospital discharge and at 4–6 weeks are presented in Table 2. The primary outcome at hospital discharge was 7.1% (n=14) for staples and 0.5% (n=1) for suture (*P*<.001, relative risk 14.1, 95% confidence interval [CI] 1.9–106); by 4–6 weeks, it was 14.5% for staples and 5.9% for suture (*P*=.008, relative risk 2.5, 95% CI 1.2–5.0). Not presented in the tables, examination of the size of the disruptions revealed that disruptions longer than 1 cm were more frequent in women with staples (6.2% compared with 0%, *P*=.009) as were disruptions of depth deeper than 0.5 cm (4.5% compared with 0.6%, *P*=.037). Of note, among the 36 patients with the primary outcome (within 4–6 weeks), the outcome was ascertained through an in-person evaluation in 23 (63.9%), whereas 13 (36.1%) were based on phone follow-up complemented by medical record review.

Table 2 Cumulative Incidence of the Primary Composite Outcome and Its Components

	Staples	Suture	Relative Risk (95% CI)
At hospital discharge	n=198	n=200	
Composite outcome	14 (7.1)	1 (0.5)	14.1 (1.9–106)
Infection*	0 (0)	1 (0.5)	N/A
Disruption*	14 (7.1)	1 (0.5)	14.1 (1.9–106)
At 4–6 wk	n=179	n=171	
Composite outcome	26 (14.5)	10 (5.9)	2.5 (1.2–5.0)
Infection*	4 (2.2)	6 (3.5)	0.6 (0.2–2.2)
Disruption*	24 (13.4)	6 (3.5)	3.8 (1.6–9.1)

CI, confidence interval; N/A, not applicable (as a result of small numbers).
Data are n (%) unless otherwise specified.
* Each subcategory includes women who had both a wound infection and wound disruption.

Stratified analyses of the cumulative primary outcome at 4–6 weeks by selected baseline variables (Table 3) revealed that the primary composite outcome was generally more frequent with staple closure regardless of subgroup including women with BMI less than 30 (15.8% compared with 0%, *P*=.007) and BMI 30 or greater (14.2% compared with 8.1%, *P*=.117) as well as presence or absence of prior cesarean delivery, labor or attempted induction, and chorioamnionitis. Also, only 30 patients (8.6%) had a vertical incision (15 in each group); the primary outcome occurred in one patient per group (*P*>.999). Results of secondary study outcomes are presented in Table 4. Total operative time was longer with suture closure with median of 58 minutes versus 48 minutes for staples (*P*<.001). The mean operative times were 51.0 versus 58.6 minutes. Analog pain scores at 72–96 hours and 4–6 weeks, cosmesis score, and scar satisfaction scores did not differ by skin closure method.

Table 3 Primary Outcome Incidence Stratified by Selected Characteristics

	Staples*	Suture*	*P*
BMI (kg/m^2) 30 or higher	141 (14.2)	124 (8.1)	.117
BMI lower than 30	38 (15.8)	46 (0)	.007
Prior cesarean delivery	84 (13.1)	88 (5.7)	.094
No prior cesarean delivery	95 (15.8)	83 (6.0)	.040
Labor or attempted induction	89 (16.0)	91 (5.5)	.015
No labor or attempted induction	90 (12.2)	80 (6.3)	.183
Vertical incision	15 (6.7)	15 (6.7)	>.999
Pfannenstiel incision	164 (15.2)	156 (5.8)	.006
Chorioamnionitis	18 (16.7)	20 (10)	.652
No chorioamnionitis	161 (14.3)	151 (5.3)	.008

BMI, body mass index.
Data are n (%) unless otherwise specified.
* n represents denominator (percentage of denominator with primary outcome).

Table 4 Prespecified Secondary Outcomes

	Staples (n=179)	Suture (n=171)	*P*
Procedure time (min)	48 (38–58) 20–150	58 (48–68) 26–103	.345
Analog pain score at 72–96 h	5 (3–7) 0–10	5 (4–7) 0–10	.285
Analog pain score at 4–6 wk*	0 (0–1) 0–10	0 (0–2) 0–7	.066
Composite cosmesis score*†	3 (3–4) 0–5	4 (3–5) 2–5	.750
Satisfaction with appearance of scar	4 (4–5) 2–5	4 (4–5) 1–5	.842
Satisfaction with comfort of scar	4 (4–5) 1–5	4 (4–5) 1–5	.894
Satisfaction with location of scar	4 (4–5) 1–5	4 (4–5) 1–5	.539

Data are median (interquartile range) and range unless otherwise specified.
* From 4- to 6-week follow-up only.
† Stony Brook Scar evaluation score.

DISCUSSION

Overall, we observed that surgical staples were significantly associated with a higher incidence of cumulative composite wound morbidity than absorbable sutures at hospital discharge and up to 4–6 weeks after cesarean delivery. The difference was mainly the result of more wound disruptions among those randomized to staples. This observation remains robust in several subgroups or when the outcome is restricted to disruptions greater than 1 cm in length or greater than 0.5 cm in depth, which may be considered more clinically important and typically led to additional scheduled clinic follow-up visits. There were no differences in postoperative pain, cosmesis, or patient satisfaction. However, operative time was longer with suture closure.

Postoperative wound complications for women undergoing cesarean delivery constitute a major cause of morbidity and they are costly to both the patient and health system.[3,4] Before the initiation of our study, few studies had objectively evaluated the potential effect of cesarean skin closure technique and materials on wound disruption or infection but focused primarily on pain or cosmesis.[8,9] Recently, a number of reports including clinical trials and meta-analyses have addressed wound morbidity.[7,10,12] Our study is an important contribution to this developing literature. It is one of the two largest studies of this issue, several key outcomes are examined including an objective and clinically important primary outcome, and a considerable proportion of women were evaluated in person at 4–6 weeks. Specifically, our findings are consistent with the recent trial in which staple closure was associated with significantly higher self-reported wound morbidity compared with suture, a finding observed in both meta-analyses.[7,10,12] The median procedure times we observed seem consistent with recent reports of a 3- to 9-minute shorter operative time with staple closure.[7,9,10,12] Our results indicating no differences in pain score, cosmesis score, and patient satisfaction with scar is also consistent with the findings from meta-analyses.[7,12] In addition, prior studies were limited to planned cesarean deliveries, whereas our study included women undergoing postlabor cesarean delivery, enhancing the generalizability of our findings.[9,10] Furthermore, our study has a higher prevalence of obese participants for whom the risk of wound morbidity is highest.

We acknowledge a number of limitations. Up to 12% of women in our study lacked follow-up outcome information at 4–6 weeks. However, there were not material differences in characteristics among those who followed up and those who did not. It may be argued that wound complications involving complete wound disruption, readmission, or débridement may be more appropriate outcomes to evaluate. However, such outcomes are rare and a large proportion may occur independently of closure method. Still our results indicate that larger wound complications that would typically lead to additional clinic visits were more frequent with staples. Also, a very small proportion of women had vertical skin incisions limiting the generalizability of our findings to this subgroup. Finally, the decision to stop the trial is a legitimate concern. Based on the new studies and observations in our study population overall, we concluded that we had significantly underestimated the baseline incidence of wound morbidity. Further consideration of the ethical implications of the new studies suggesting that suture is beneficial and the logistics of continuing enrollment led to the decision to stop the study. Thus, although a formal Data Safety Monitoring Board was not in place for this trial, our research review committee provided oversight and monitored recruitment and evolving data. Of note, the decision was made without an interim review comparing outcomes by group (information linking the sequential randomization numbers to closure method was imported into the database at the end of the study).

The magnitude of the observed difference in cumulative incidence of wound morbidity between staples and suture closure methods was higher at the time of hospital discharge compared with 4–6 weeks postoperatively. This suggests that a higher proportion of wound complications after staples occurred by the time of hospital discharge, whereas most complications after suture occur afterward. Some may postulate that removal of staples later than postoperative days 3–4 may reduce the observed discrepancy in wound morbidity vis-à-vis suture closure. However, product information recommends removal of staples at 3–4 days. Among prior reports, timing of removal was on day 3 in one study,[9] whereas in another, it was left to the discretion of the health care provider (staples were associated with increased wound morbidity).[10] Our anecdotal experience suggests that many health care providers remove staples before hospital discharge for most patients. This avoids significant health care provider and patient time and costs involved in a clinic (or home) visit for staple removal. Therefore, although it may be academically attractive to evaluate whether staple removal after hospital discharge is associated with a similar incidence of wound morbidity compared with sutures,

pragmatically suture closure would remain advantageous in terms of costs to the patient and health system. Furthermore, we estimate that the price of a stapler (not even including a staple removal kit) is at least 2.5 times the price of the absorbable suture. Finally, a modest benefit in operative time with staple closure is likely to be grossly offset by the time required for subsequent removal. In sum, our results support the use of suture over staples among women undergoing cesarean delivery, particularly after a horizontal skin incision.

http://journals.lww.com/greenjournal/Fulltext/2013/01000/Surgical_Staples_Compared_With_Subcuticular_Suture.7.aspx

Surgical Staples Compared With Subcuticular Suture for Skin Closure After Cesarean Delivery: A Randomized Controlled Trial

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