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Original Research

Randomized Trial of 3 Techniques of Perineal Skin Closure During Second-Degree Perineal Laceration Repair

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Introduction: Perineal lacerations during childbirth are common, and suturing the perineal skin during repair has been associated with increased postpartum pain. This study sought to test the hypothesis that no difference in postpartum perineal pain exists between 3 methods of skin closure for second-degree repair: suture, no suture, and surgical glue.

Methods: A single-blind randomized controlled trial of women after vaginal birth who had a second-degree perineal laceration was conducted at a tertiary care teaching hospital from August 2014 to April 2017. Women were randomized to perineal skin closure with suture, no suture, or surgical glue using a 1:1:1 allocation. Pain was assessed using the short-form McGill Pain Questionnaire, a 100-mm visual analog scale (VAS), and Present Pain Index (PPI) at one day, 2 weeks, 6 weeks, and 3 months postpartum. Wound healing was assessed at 6 weeks using the Redness, Edema, Ecchymosis, Drainage, Approximation (REEDA) scale. Pain scores were compared across groups using a chi-square test, Mann-Whitney *U* test, or analysis of variance where appropriate.

Results: A total of 35 women were randomized: 14 received suture, 11 had no suture, and 10 received surgical glue for perineal skin repair. Demographic characteristics were similar between groups. At 2 weeks postpartum, women with suture had higher median pain scores on the short-form McGill Pain Questionnaire (15.0 suture vs 2.0 glue vs 2.0 no suture, $P = .03$) and VAS (50.0 suture vs 3.0 glue vs 7.0 no suture, $P = .02$). Significant differences in pain were not seen on the PPI. At 3 months, women in the suture group had higher median pain scores on the short-form McGill Pain Questionnaire compared with surgical glue (1.0 vs 0, $P = .04$). Wound healing was similar across groups (REEDA score: 0 suture vs 1.0 no suture, vs 0 surgical glue, $P = .24$).

Discussion: Compared with no suture and surgical glue, suturing the perineal skin was associated with the highest postpartum pain scores.
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Keywords: perineum, lacerations, adhesives, sutures, postpartum period, pain

INTRODUCTION

Perineal lacerations are common and occur in 70% to 90% of women during childbirth.[1] The gold standard technique for repairing second-degree perineal lacerations in the United States is suture repair.[2] Compared with interrupted stitches of catgut suture, the use of a continuous, nonlocking, synthetic absorbable suture has been shown to improve postpartum pain and healing[3,4] However, even when the latter technique is used, postpartum pain associated with perineal lacerations is common. Compared with women with an intact perineum, those with second-degree perineal lacerations have 80% increased odds of experiencing dyspareunia at 3 months postpartum.[5] Postpartum pain is associated with an increased risk of depression[6] and other adverse effects on quality of life and sexual health; therefore, interventions aimed at decreasing pain from perineal lacerations warrant investigation.

Several studies have reported an association between suturing the perineal skin and increased postpartum pain.[7,8] In an effort to reduce postpartum perineal pain, 2 alternative techniques to suture repair of the perineal skin have been proposed: 1) leaving the perineal skin unsutured[7] and 2) using surgical glue.[9] However, studies that have assessed these techniques compared with suture repair have not shown that they decrease pain.[10,11]

No studies have been identified that compared postpartum perineal pain across the 3 perineal skin repair techniques. The primary goal of this study was to compare self-reports of pain among women after second-degree perineal laceration who had 1) perineal skin closure with suturing, 2) the perineal skin unsutured, or 3) closure of the perineal skin with surgical glue. There is a known association between postpartum pain, urinary incontinence, and depression in women who were referred to a specialty postpartum perineal clinic.[6] Therefore, the secondary aim was to explore associations between method of perineal skin closure and wound healing, sexual function, depression, and pelvic floor symptoms.

METHODS

This single-blind randomized controlled trial was conducted at a tertiary care university-based academic hospital from August 2014 to April 2017. The trial received institutional review board approval, and informed written consent was obtained from all participants. The study fully adheres to

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Quick Points

- Perineal pain following perineal laceration repair is common, and although studies show increased pain with suture closure, this is still the standard repair technique used in the United States.
- This randomized controlled trial compares patient pain, wound healing, and other pelvic floor symptoms among women with perineal skin closure using one of 3 techniques: 1) suture, 2) reapproximation but no suture, or 3) surgical glue.
- At 2 weeks postpartum, women with suture closure of the perineal skin had the highest pain scores.
- Compared with suture, leaving the perineal skin unsutured or using surgical glue for second-degree perineal laceration repair decreases postpartum pain without compromising wound healing.

Consolidated Standards of Reporting Trials guidelines for reporting clinical trials.

Inclusion criteria included women who were aged 18 to 45, had given birth at 36 weeks' gestation or later, proficient in English, and immediately after vaginal birth with a second-degree perineal laceration. Women were excluded if they had a cesarean birth or a vaginal birth without a second-degree perineal laceration, including those with third- or fourth-degree lacerations. Women with additional vaginal, periurethral, or cervical lacerations were not excluded. Other exclusions included induction of labor for fetal demise or any fetal condition in which immediate status of the newborn after birth was uncertain, maternal allergy to cyanoacrylate or formaldehyde, poorly controlled diabetes, systemic infection, history of connective tissue disorders (eg, scleroderma, Ehlers-Danlos), chronic steroid use, prior radiation to the pelvis, chronic immunosuppression, or history of neurologic conditions precluding informed consent. Women could withdraw from the study at any time after consenting.

Women receiving maternity care at our institution were mailed a letter in their third trimester of pregnancy informing them of the study. Women were given the option to decline participation at that time; if they did, it was noted by the study team and no further contact was made. If they did not decline prior to admission, once they were admitted to labor and delivery, women who passed initial chart review screening for eligibility were approached and informed about the study. Those who were interested underwent further screening, and if prebirth study criteria were met, informed consent was provided and they were enrolled.

Once the patient was enrolled, a sealed envelope with the perineal skin repair technique allocation was placed in the patient's labor and delivery room. The envelopes were not opened until vaginal birth with a second-degree perineal laceration was confirmed by the attending physician or midwife. Health care providers were instructed not to discuss the method of skin repair with participants to keep them blinded to their intervention arm. Randomization was performed using a 1:1:1 (suturing to no suturing to surgical glue) computer-generated randomization, and allocation was concealed in sequentially numbered, sealed envelopes. In addition to the allocation arm, these envelopes contained instructions regarding the repair techniques, a surgical glue sachet or decoy, Peri-Rule perineal ruler, and data collection sheet. The Peri-Rule is a single use, millimeter-scale ruler made of soft, pliable plastic used to measure perineal lacerations.[12] Health care providers were asked to record the length of the perineal laceration on the perineal skin, number of sutures used during the repair, and the length of time for the repair to be completed. Estimated blood loss at the time of birth was subjectively determined by the perinatal care provider at the completion of the repair per standard practice at our institution. We chose *N*-butyl 2-cyanoacrylate for the surgical glue based on what was available at our institution and also approved by the US Food and Drug Administration[13] for use on surgical incisions and traumatic lacerations.

For all 3 perineal skin repair techniques, closure of the vaginal and deep perineal tissues was performed using a continuous, nonlocking 3-0 polyglactin suture. The technique for suturing the perineal skin was as follows: once the deep perineal tissues were sutured, the suture was brought out through the most caudal part of the perineal incision and the skin edges closed using a running subcutaneous stitch using 3-0 polyglactin suture. A transitional stitch was performed at the level of the hymen and the suture knot tied inside the hymenal ring. The technique for leaving the perineal skin unsutured was as follows: after the deep perineal tissues were sutured, one or more ventrally traveling sutures were placed in the deep perineal tissues (avoiding the perineal skin), a transition stitch was performed, and the knot was tied inside the hymenal ring. Finally, the technique for surgical glue started the same as the previously described technique for no suture—after the deep perineal tissues were sutured, the surgical glue sachet was prepared per the packet instructions, the tissue was blotted dry, and skin edges were approximated using forceps. The glue was then sparingly applied along the skin edges, and manual approximation was applied for 10 to 20 seconds. To participate in the study, perinatal care providers participated in a training session that included a presentation by the authors and a training video detailing the above-outlined repair techniques. The training video was also sent via email to all providers to allow them to review it again if desired. As previously stated, instructions for each repair technique were also included in the study envelope.

Participants completed questionnaires on postpartum day one, 2 weeks postpartum, 6 weeks postpartum, and 3 months postpartum. The questionnaires are described in Table 1. At all time points, women completed the short-form McGill Pain Questionnaire,[14] a 100-mm visual analog scale (VAS),[15] and the Present Pain Index (PPI)[16] to assess pain related to the perineal laceration. Three pain scales were used to ensure pain

Table 1. Survey Instrument Scales

Scale	What It Measures	Number of Items	Measurement Type	Range of Scores	Meaning of Scores	Cronbach's α
Short-form McGill Pain Questionnaire[14]	Severity of 15 different pain characteristics (eg, throbbing, hot-burning, aching)	15	Likert scale from 0 to 3 per item Scores are summed	0-45	Higher score = greater pain severity	None reported Correlation coefficients between short and long forms for postsurgical pain ranged from 0.67 to 0.90; $P < .003$
100-mm visual analog scale[15]	Pain intensity	1	100-mm line with anchors at 0 (no pain) and 100 mm (worst possible pain Patient marks an X representing pain intensity	0-100	Higher score = higher pain intensity	None reported Correlation coefficients with 11-point pain scale range from 0.91 to 0.95
Present Pain Index[16]	Overall pain intensity	1	Likert scale from 0 to 5 (0 = no pain, 5 = excruciating pain)	0-5	Higher score = greater overall pain intensity	None reported
Redness, Edema, Ecchymosis, Drainage, Approximation scale[17]	Perineal wound healing postpartum	5	Each of the 5 characteristics is rated from 0 to 3, with 0 = none and 3 = worst appearance Scores are summed	0-15	Higher score = poorer wound healing	None reported
Leakage Index[18]	Urinary incontinence severity	8	Categorical response (yes = 1, no = 0) Scores are summed	0-8	Higher score = worse urinary incontinence	0.72-0.84
Fecal Incontinence Severity Index[19]	Fecal incontinence severity	24	Matrix of types of anal incontinence (gas, mucus, liquid, and solid stool) by frequency Scores are weighted based on severity and range from 0 to 19 per item (ie, 0 = never leaking solid stool vs 19 = leaking liquid stool ≥2 times per d) Scores are summed	0-61	Higher score = greater severity of anal incontinence Higher severity scores = lower quality of life in all 4 domains of lifestyle, coping and behavior, depression and self-perception, and embarrassment	None reported Correlations between severity scores and quality of life range from −.20 to −.45, $P < .05$, depending on the domain

(Continued)

Table 1. Survey Instrument Scales

Scale	What It Measures	Number of Items	Measurement Type	Range of Scores	Meaning of Scores	Cronbach's α
Edinburgh Postnatal Depression Scale[20]	Postpartum depression	10	Likert scale from 0 to 3 per item Scores are summed	0-30	Score of ≥10 indicates women at high risk for postpartum depression	0.87
Genital Self-Image Scale[22]	Woman's feelings about her own genitals (ie, genital self-image)	20	First 10 questions are a Likert scale from 0 to 3 per item, the second 10 items are categorical (0, 1) Scores are summed	0-40	Higher score = greater body satisfaction	0.79-0.89
Intimate Relationship Scale[21]	Perceived changes in sexuality and partner intimacy compared with prior to pregnancy	12	Likert scale from 1-5 per item Scores are summed	12-60	Higher score = more positive change	0.86 and 0.87, respectively, for women at 4 and 12 mo postpartum

assessment was comprehensively assessed across a range of potential sensations.

At the 6-week visit, health care providers were asked to complete a perineal wound healing assessment using the Redness, Edema, Ecchymosis, Drainage, Approximation (REEDA) scale[17] and, per standard of care, document any necessary interventions on the wound (eg, application of silver nitrate for granulation tissue, minor wound revisions). The REEDA score ranges from 0 to 15, with higher scores indicating poorer wound healing.

At the 6-week and 3-month postpartum time points, women were given additional validated questionnaires to assess for pelvic floor symptoms, postpartum depression, and changes in intimacy since birth. Urinary incontinence was quantified using the 8-item validated Leakage Index developed by Antonakos et al that assesses urinary symptoms over the prior month and has been validated for use in women at low risk for incontinence.[18] The Fecal Incontinence Severity Index was used to quantify anal incontinence symptoms.[19]

The Edinburgh Postnatal Depression Scale (EPDS) was used to assess symptoms of postpartum depression (range, 0-30; scores ≥10 identify patients at high risk of postpartum depression).[20] EPDS scores were reviewed for all study participants, and the plan for addressing concerning responses was consistent with our clinic guidelines. All women with scores of 10 or higher were offered referral to our peripartum mood disorders clinic and/or referral back to their obstetrician, midwife, or primary care provider for management of symptoms, if not already underway. Women reporting thoughts of self-harm or harming their infant were kept in clinic to be evaluated by social work or, if warranted, accompanied to the psychiatric emergency department.

In addition, a validated postpartum sexual function questionnaire called the Intimate Relationship Scale (IRS)[21] and the Genital Self-Image Scale (GSIS-20)[22] were completed. The IRS is a 12-item questionnaire that assesses perceived changes in intimacy and sexuality in postpartum couples. The GSIS-20 is a validated measure of an individual's perception of their genital body image.

Demographic characteristics, prior pregnancy and birth history, health history, and peripartum variables related to the incident birth were all abstracted via chart review. The sample size and power calculation were determined to detect a 15-mm difference in the primary outcome of participant-perceived pain between 2 groups using the 100-mm VAS. Prior use of this scale in randomized trials has considered a 15-point difference as clinically significant.[23] For an α of .05, β of .10, and 90% power, 50 participants were required in each group. Demographic characteristics, pain scores, and questionnaire responses were compared across groups using a chi-square test, Mann-Whitney *U* test, or analysis of variance where appropriate. Statistical analyses were generated using IBM SPSS Statistics software, version 21.0 (IBM, Armonk, NY).

RESULTS

The enrollment and randomization diagram for the study is provided in Figure 1. Of the 56 women with a second-degree perineal laceration, 35 (62.5%) received the allocated perineal skin intervention: 14 had suture repair, 11 had no suture, and 10 received surgical glue. The allocated type of perineal repair was not performed for 21 women because the health care provider either forgot to perform the allocated repair or chose to forego the allocation for standard suture repair. The study was discontinued at the end of the study period; however, this precluded attaining planned sample size goals.

All women had spontaneous second-degree perineal lacerations, and there were no episiotomies. There were no differences between the women in the 3 groups with regard to depth and severity of the lacerations or presence of other lacerations. Table 2 shows the demographic characteristics and birth characteristics for the 3 groups. There were no significant differences among the groups, with the exception of median estimated blood loss, which was highest in the surgical glue group and lowest in the suture group (325 mL suture vs 400 mL no suture vs 475 mL surgical glue; $P = .04$). The average depth of the perineal laceration was 2 to 3 cm, and it took approximately 15 minutes for the repairs to be completed for all 3 types of repair.

The results of the pain scores at one day, 2 weeks, and 6 weeks postpartum, as well as results of the other questionnaires completed at 6 weeks and 3 months postpartum, are presented in Table 3. At 2 weeks postpartum, the median perineal pain scores on both the short-form McGill Pain Questionnaire and the 100-mm VAS were significantly higher in the women in the suture group compared with those with no suture or surgical glue (McGill: 15.0 suture vs 2.0 no suture vs 2.0 surgical glue, $P = .03$; and 100-mm VAS: 50.0 suture vs 7.0 no suture vs 3.0 surgical glue, $P = .02$.) A post hoc power calculation using the 100-mm VAS showed 93% and 68% power to detect these differences at 2 and 6 weeks postpartum, respectively. For the short-form McGill Pain Questionnaire, there was 93% and 99% power at 2 and 6 weeks postpartum, respectively.

At 3 months postpartum, the women in the suture group had higher median pain scores on the short-form McGill Pain Questionnaire compared with the women in the surgical glue group (1.0 vs 0, $P = .04$), and we had 96% power to detect this difference. No significant differences were seen either across or between groups on the PPI at any time point. The presence of additional laceration types was not associated with a significant difference in pain scores at any time point (data not shown).

Wound healing, as measured by health care providers at 6 weeks postpartum using the REEDA scale, did not differ significantly based on method of perineal skin repair. The prevalence of breastfeeding at 6 weeks postpartum was high and similar across groups (13 [92.86%] suture vs 10 [90.91%] no suture vs 7 [77.78%] surgical glue, $P = .66$). Patient-reported genital self-image as measured by the GSIS-20 and scores on the IRS were similar across and between groups at 6 weeks and 3 months postpartum.

The percentage of women in each group who had a positive result on a postpartum depression screen (EPDS score ≥10) was not statistically different (suture: 2 of 7 [28.6%] vs no suture: 1 of 6 [16.7%] vs surgical glue: 4 of 8 [50%], $P = .40$, pairwise comparisons nonsignificant). Urinary incontinence symptoms were also more severe among women in the surgical glue group, which reached marginal statistical

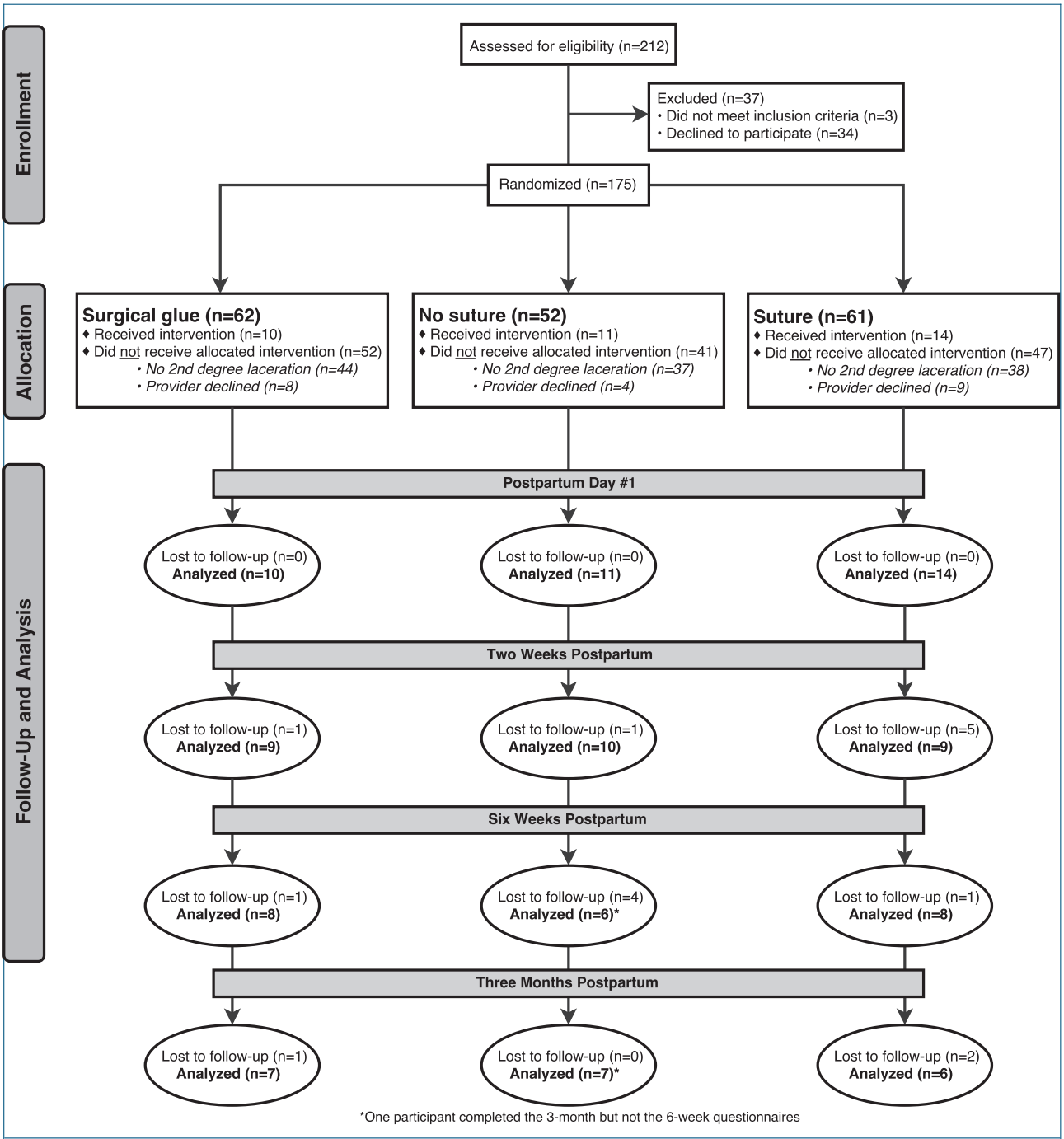

Figure 1. Study Enrollment and Randomization

significance when compared with those with no suture. Fecal incontinence symptoms did not differ significantly. To determine the association between these variables and postpartum perineal pain, a linear regression was performed with the short-form McGill Pain Questionnaire scores as the outcome variable while controlling for age, intervention arm, and scores on the Leakage Index and EPDS. None of the variables were significantly associated with pain scores at any of the 4 time points (data not shown). There were no complications or adverse events related to the use of the surgical glue in our study.

DISCUSSION

In this randomized trial comparing 3 techniques of perineal skin closure at the time of second-degree perineal laceration repair, women with suture repair had significantly higher pain scores at 2 weeks postpartum compared with those with no suture or surgical glue. At 3 months postpartum, pain scores remained significantly higher in the suture group compared with those who had surgical glue. There were no differences in repair time or perineal wound healing. Given the small sample size, our study is underpowered to make definitive conclusions regarding the statistical or clinical significance of

Table 2. Demographic Characteristics and Birth Variables for Women in 3 Groups of Perineal Skin Closure

Demographic Characteristics	Surgical Glue (n = 10)	No Suture (n = 11)	Suture (n = 14)	*P* Value[a]
Age, mean (SD), y	28.90 (6.81)	29.00 (5.23)	28.43 (5.30)	.90
Race, n (%)				.64
White	8 (80)	10 (90.91)	9 (64.29)	
African American	1 (10)	0	2 (14.29)	
Asian	1 (10)	1 (9.09)	3 (21.43)	
Hispanic ethnicity	1 (11.11)	0	1 (7.14)	.73
Body mass index, mean (SD), kg/m^2	31.69 (6.29)	33.85 (5.08)	31.35 (5.80)	.44
Parity, n (%)				
Nulliparous	5 (50)	8 (72.7)	8 (57.1)	.55
Multiparous	5 (50)	3 (27.3)	6 (42.9)	
Labor and birth characteristics				
Preterm, n (%)	1 (10)	1 (9.9)	0	.49
Term, n (%)	9 (90)	10 (90.9)	14 (100)	
Labor induced, n (%)	5 (50)	5 (45.45)	5 (35.71)	.77
Labor augmented, n (%)	6 (60)	8 (72.73)	10 (71.43)	.81
Epidural analgesia, n (%)	7 (70)	9 (81.82)	13 (92.86)	.33
Length of second stage, mean (SD), min	73.67 (81.32)	90.40 (65.99)	85.14 (102.91)	.75
Time pushing, mean (SD), min	64.57 (78.04)	89.60 (66.52)	66.21 (81.67)	.42
Estimated blood loss, median (IQR), mL	475 (388-625)	400 (300-700)	325 (250-400)	.04
Newborn weight, mean (SD), g	3684.50 (322.74)	3523.18 (390.77)	3628.57 (520.28)	.59
Newborn head circumference, mean (SD), cm	35.54 (2.23)	34.40 (1.25)	34.78 (1.75)	.55
Perinatal health care provider, n (%)				.87
Nurse-midwife	1 (10.0)	1 (9.1)	1 (7.1)	
Obstetrician	6 (60)	7 (63.6)	10 (71.4)	
Family medicine	3 (30.0)	3 (27.3)	2 (14.3)	
Resident	0	0	1 (7.1)	
Perineal laceration variables				
Depth of perineal laceration, mean (SD), mm	25.88 (11.91)	27.64 (16.71)	20.36 (9.51)	.60
Number of sutures used, median (IQR)	1 (1, 2)	1 (1, 2)	1 (1, 1)	.58
Time to complete repair, median (IQR), min	16.00 (12.5-22.5)	14.0 (6.0-15.0)	15.00 (8.5-20.0)	.79
Presence of additional lacerations, n (%)	6 (60.0)	2 (18.1)	6 (42.9)	.14
Periurethral	4 (66.7)	0	5 (83.3)	.06
Vaginal wall	1 (16.7)	0	0	.28
Sulcal	0	1 (50)	0	.33
Labial	1 (16.7)	1 (50)	2 (30)	.91

Abbreviation: IQR, interquartile range.
[a] *P* values determined using a chi-square test, analysis of variance, or Mann-Whitney *U* test where appropriate.

our findings. However, this study provides important data for planning future research in this area.

Although prior studies have investigated perineal skin closure using various pairwise combinations of the 3 techniques included in our study, this is the first randomized trial that includes a direct comparison of patient pain across all 3 methods. Our study adds to the growing body of literature suggesting that perineal skin closure methods other than suture repair may help reduce patient pain in the postpartum period without compromising wound healing, genital self-image, or changes in sexual intimacy.

In a large randomized trial of nearly 1800 women with first- and second-degree perineal lacerations, Gordon et al found that women whose perineal skin was left unsutured had less perineal pain, less dyspareunia, and fewer interventions on their repairs at 3 months postpartum compared with women with perineal skin sutures.[7] However, a Cochrane review concluded that the current evidence is insufficient to recommend that leaving the perineal skin unsutured significantly reduces pain compared with suture repair.[10] Our findings support those of Gordon et al by showing that women with suture repair of the perineal skin have significantly higher

Table 3. Pain Score and Postpartum Symptom Comparisons Between Women in 3 Groups of Perineal Skin Closure

Pain Indices	Surgical Glue (n = 10[a]) Median (IQR)	No Suture (n = 11[a]) Median (IQR)	Suture (n = 14[a]) Median (IQR)	*P* Value[b] Overall	Surgical Glue vs No Suture	Surgical Glue vs Suture	Suture vs No Suture
Short-form McGill Pain Questionnaire[c]							
Postpartum day 1	5.0 (3.5-9.5)	7.0 (7.0-13.0)	8.5 (6.0-15.0)	.14	.13	.06	.68
2 wk	2.0 (0.5-2.0), n = 9	2.0 (0-8.0), n = 7	15.0 (8.0-24.0), n = 9	.03	.59	.04	.02
6 wk	0 (0-1.0), n = 8	0.5 (0-3.0), n = 6	2.5 (0-7.0), n = 8	.13	.23	.06	.31
3 mo	0 (0-0), n = 7	0 (0-2.0), n = 7	1.0 (0-6.0), n = 6	.10	.14	.04	.29
Overall pain index[d] (100-mm VAS)							
Postpartum day 1	22.5 (17.5-22.5)	37.5 (25.0-47.0)	30.0 (19.5-75.0)	.20	.06	.19	.90
2 wk	3.0 (0-37.5), n = 9	7.0 (0-24.0), n = 7	50.0 (14.0-77.0), n = 9	.02	.74	.01	.02
6 wk	0 (0-6.0), n = 8	0 (0-0), n = 5	4.5 (0-14.0), n = 8	.13	.24	.20	.07
3 mo	0 (0-0), n = 7	0 (0-0) n = 7	0 (0-7.5), n = 6	.31	>.99	.28	.28
Present Pain Index[e] (0-5 Likert)							
Postpartum day 1	2.0 (1.0-2.0)	2.0 (1.0-2.0)	2.0 (1.5-3.0)	.42	>.99	.29	.27
2 wk	1.0 (0-2.0), n = 9	1.0 (0-2.0), n = 7	2.0 (1-2.5), n = 9	.29	.82	.11	.31
6 wk	0 (0-0), n = 8	0 (0-0.0), n = 6	0.5 (0-2.0), n = 8	.16	.83	.10	.17
3 mo	0 (0-0), n = 7	0 (0-0), n = 7	0 (0-2.0), n = 6	.09	>.99	.11	.11

(*Continued*)

Table 3. Pain Score and Postpartum Symptom Comparisons Between Women in 3 Groups of Perineal Skin Closure

Pain Indices	Surgical Glue (n = 10[a]) Median (IQR)	No Suture (n = 11[a]) Median (IQR)	Suture (n = 14[a]) Median (IQR)	*P* Value[b] Overall	*P* Value[b] Surgical Glue vs No Suture	*P* Value[b] Surgical Glue vs Suture	*P* Value[b] Suture vs No Suture
6-wk postpartum questionnaires							
REEDA[f]	0 (0-1.0), n = 7	1.0 (0-1.0), n = 7	0 (0-1.0), n = 9	.24	.84	.14	.14
Genital Self-Image Scale[g]	38.0 (25.0-40.0), n = 7	29.5 (23.0-34.0), n = 6	31.5 (25.0-34.0), n = 8	.17	.12	.10	.85
Intimate Relationship Scale[h]	34.5 (26.0-42.0), n = 8	32.0 (28.0-37.0), n = 6	31.0 (22.0-38.0), n = 7	.71	.63	.43	.72
Leakage Index[i]	4.5 (1.0-6.0), n = 8	0.5 (0-3.0), n = 6	3.0 (1.0-7.0), n = 8	.12	.05	>.99	.10
Fecal Incontinence Severity Index[j]	11.0 (3.0-34.0), n = 4	11.0 (3.0-13.0), n = 5	18.5 (0-18.5), n = 2	.98	.90	.81	.85
Edinburgh Postnatal Depression Score ≥10[k]	4 (50), n = 8	1 (16.7), n = 6	2 (28.6), n = 7	.40	.30	.40	>.99
3-mo postpartum questionnaires							
Genital Self-Image Scale[g]	32.0 (19.0-36.0), n = 7	35.0 (29.0-36.0), n = 7	35.0 (25.0-38.0), n = 6	.61	.34	.47	.77
Intimate Relationship Scale[h]	30.0 (18.0-36.0), n = 7	35.0 (30.0-39.0), n = 7	28.0 (22.0-42.0), n = 6	.73	.52	.89	.47

Abbreviations: IQR, interquartile range; REEDA, Redness, Edema, Ecchymosis, Drainage, Approximation; VAS, visual analog scale.
[a] Not all women in each group responded to all questionnaires, so individual n values may differ.
[b] *P* values determined using analysis of variance for overall comparisons, Mann-Whitney *U* test for pairwise comparisons, and chi-square for categorical variables.
[c] Short-form McGill Pain Questionnaire: range 0-45, higher score indicates more pain.
[d] 100-mm VAS: range 0-100, higher score indicates greater pain intensity.
[e] Present Pain Index: range 0-5, higher score indicates more pain.
[f] Perineal wound assessment scale, range 0-15, higher score indicates poorer wound healing.
[g] Genital Self-Image Scale: range 0-40, higher score is better body satisfaction.
[h] Intimate Relationship Scale: range 12-60, higher score indicates a more positive change.
[i] Leakage Index: range 0-8, higher score indicates more urinary incontinence.
[j] Fecal Incontinence Severity index: range 0-61, higher score indicates worsening symptoms.
[k] Edinburgh Postnatal Depression Score: range 0-30, higher score (≥10) indicates higher risk for postpartum depression.

pain scores compared with women without suture repair. When we compared pain scores between women whose perineal skin was left unsutured and those who had surgical glue, we found no difference at any time point. One explanation for increased pain with suture closure of the perineal skin is the inflammatory response induced by the suture material. Pain accompanies this inflammatory response and can persist until the suture is removed or resorbed by the body.[24] Therefore, the 2 groups in which perineal suturing on the skin was avoided did not have this additional nidus of inflammation, which may explain the lower pain scores reported by the women in these 2 groups.

Surgical adhesives have been employed for decades in other specialties, but their use in obstetrics and gynecology is relatively limited. The few published studies employing the use of surgical glue as an adjunct to perineal wound closure[11,25–27] have shown varied results in terms of postpartum pain. In all of these studies, the vaginal incision and deep perineal tissues were sutured, and the perineal skin was closed using a surgical adhesive. In a recent randomized controlled trial comparing the use of surgical adhesive to suture repair of first-degree perineal lacerations, Feigenberg et al reported less pain, shorter procedure time, and greater patient satisfaction with surgical glue.[9] A randomized trial by Mota et al found no difference in pain between perineal skin closure with suture versus surgical adhesive following mediolateral episiotomy.[11] However, deep pain related to mediolateral episiotomy could have masked skin-related pain in this study, which may explain why no difference in pain scores was identified between the 2 perineal skin closure methods.

Our study extends the literature by providing data regarding the feasibility and effectiveness of using surgical glue for perineal skin closure following a spontaneous second-degree perineal laceration. Therefore, surgical glue may offer some advantage over traditional perineal repair techniques by ensuring tissue reapproximation while avoiding sutures and the associated increased postpartum pain. Women in the surgical glue group did have statistically higher estimated blood loss compared with the other 2 groups. However, in the absence of significant differences in any other pregnancy and birth factors, perineal laceration depth, or time to repair, this may be a spurious finding resulting from small sample sizes and/or variations in estimating estimated blood loss.

Strengths of this study include the fact that it was a randomized trial. We used validated questionnaires to assess pain, postpartum symptoms, changes in sexual function, genital self-image, and wound healing. Data were gathered at 4 different postpartum time points to assess changes in pain over time. The main limitation was the small sample size, which did not allow adequate power to detect differences in all the outcome measures. However, this study did have adequate power to detect significant differences in the 100-mm VAS and short-form McGill Pain Questionnaire scores between the women in the suture and nonsuture groups. The main reason 21 women who were eligible for participation did not receive the allocated repair and therefore were not participants in the study was failure of the health care provider to perform the study-allocated repair. This may have resulted in selection bias given our overall sample size. In the presence of any practice pattern change, health care provider adherence is a potential obstacle, and in the current study, resistance to performing a perineal repair other than the standard suture repair may have contributed to the low participation rate. Our study was also limited to women with spontaneous second-degree lacerations following an uncomplicated term vaginal birth and so may not be generalizable to other populations. All women had suture repair of the deeper perineal muscles, and it is possible that the presence of deeper sutures may have affected patient-perceived pain on the perineal skin. Additionally, we were unable to perform blinding of the health care providers, and although we attempted to blind study participants, it is possible women could have known which intervention they had received.

CONCLUSION

Two alternative methods to traditional suture repair of the perineal skin during second-degree perineal laceration repair are using surgical glue and leaving the skin unsutured. Compared with suturing, both alternative methods were associated with less perineal pain in the postpartum period, with similar repair time and wound healing. Future research is needed to optimize existing perineal repair techniques or develop novel techniques to minimize postpartum pain and improve outcomes for childbearing women.

CONFLICT OF INTEREST

The authors have no conflicts of interest to disclose.

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REFERENCES

1.Smith LA, Price N, Simonite V, Burns EE. Incidence of and risk factors for perineal trauma: a prospective observational study. *BMC Pregnancy Childbirth*. 2013;13:59.
2.Committee on Practice Bulletins-Obstetrics. ACOG practice bulletin no. 198: prevention and management of obstetric lacerations at vaginal delivery. *Obstet Gynecol*. 2018;132(3):e87-e102.
3.Kettle C, Dowswell T, Ismail KM. Continuous and interrupted suturing techniques for repair of episiotomy or second-degree tears. *Cochrane Database Syst Rev*. 2012;(11):CD000947.
4.Kettle C, Dowswell T, Ismail KM. Absorbable suture materials for primary repair of episiotomy and second degree tears. *Cochrane Database Syst Rev*. 2010;(6):CD000006.
5.Signorello LB, Harlow BL, Chekos AK, Repke JT. Postpartum sexual functioning and its relationship to perineal trauma: a retrospective

cohort study of primiparous women. *Am J Obstet Gynecol*. 2001; 184(5):881-888.
6. Swenson CW, DePorre JA, Haefner JK, Berger MB, Fenner DE. Postpartum depression screening and pelvic floor symptoms among women referred to a specialty postpartum perineal clinic. *Am J Obstet Gynecol*. 2018;218(3):335.e1-335.e6.
7. Gordon B, Mackrodt C, Fern E, Truesdale A, Ayers S, Grant A. The Ipswich Childbirth Study: 1. A randomised evaluation of two stage postpartum perineal repair leaving the skin unsutured. *Br J Obstet Gynaecol*. 1998;105(4):435-440.
8. Leeman LM, Rogers RG, Greulich B, Albers LL. Do unsutured second-degree perineal lacerations affect postpartum functional outcomes? *J Am Board Fam Med*. 2007;20(5):451-457.
9. Feigenberg T, Maor-Sagie E, Zivi E, et al. Using adhesive glue to repair first degree perineal tears: a prospective randomized controlled trial. *Biomed Res Int*. 2014;2014:526590.
10. Elharmeel SM, Chaudhary Y, Tan S, Scheermeyer E, Hanafy A, van Driel ML. Surgical repair of spontaneous perineal tears that occur during childbirth versus no intervention. *Cochrane Database Syst Rev*. 2011;(8):CD008534.
11. Mota R, Costa F, Amaral A, Oliveira F, Santos CC, Ayres-De-Campos D. Skin adhesive versus subcuticular suture for perineal skin repair after episiotomy–a randomized controlled trial. *Acta Obstet Gynecol Scand*. 2009;88(6):660-666.
12. Metcalfe A, Tohill S, Williams A, Haldon V, Brown L, Henry L. A pragmatic tool for the measurement of perineal tears. *Br J Midwifery*. 2002;10(7):412-417.
13. Indermil tissue adhesive [package insert]. Norwalk, CT: United States Surgical. https://www.accessdata.fda.gov/cdrh_docs/pdf/p010002c.pdf. Accessed February 19, 2018.
14. Melzack R. The short-form McGill Pain Questionnaire. *Pain*. 1987;30(2):191-197.
15. DeLoach LJ, Higgins MS, Caplan AB, Stiff JL. The visual analog scale in the immediate postoperative period: intrasubject variability and correlation with a numeric scale. *Anesth Analg*. 1998;86(1):102-106.
16. Melzack R. The McGill Pain Questionnaire: major properties and scoring methods. *Pain*. 1975;1(3):277-299.
17. Davidson N. REEDA: evaluating postpartum healing. *J Nurse Midwifery*. 1974;19(2):6-8.
18. Antonakos CL, Miller JM, Sampselle CM. Indices for studying urinary incontinence and levator ani function in primiparous women. *J Clin Nurs*. 2003;12(4):554-561.
19. Rockwood TH, Church JM, Fleshman JW, et al. Patient and surgeon ranking of the severity of symptoms associated with fecal incontinence: the fecal incontinence severity index. *Dis Colon Rectum*. 1999;42(12):1525-1532.
20. Cox JL, Holden JM, Sagovsky R. Detection of postnatal depression. Development of the 10-item Edinburgh Postnatal Depression Scale. *Br J Psychiatry*. 1987;150:782-786.
21. Fischman SH, Rankin EA, Soeken KL, Lenz ER. Changes in sexual relationships in postpartum couples. *J Obstet Gynecol Neonatal Nurs*. 1986;15(1):58-63.
22. Zielinski RE, Kane-Low L, Miller JM, Sampselle C. Validity and reliability of a scale to measure genital body image. *J Sex Marital Ther*. 2012;38(4):309-324.
23. Edelman A, Nichols MD, Leclair C, Astley S, Shy K, Jensen JT. Intrauterine lidocaine infusion for pain management in first-trimester abortions. *Obstet Gynecol*. 2004;103(6):1267-1272.
24. Sanz L, Smith S. Mechanisms of wound healing, suture material, and wound closure. In: Buchsbaum HJ, Walton LA, eds. *Strategies in Gynecologic Surgery*. New York, NY: Springer-Verlag; 1986:53-76.
25. Adoni A, Anteby E. The use of Histoacryl for episiotomy repair. *Br J Obstet Gynaecol*. 1991;98(5):476-478.
26. Rogerson L, Mason GC, Roberts AC. Preliminary experience with twenty perineal repairs using Indermil tissue adhesive. *Eur J Obstet Gynecol Reprod Biol*. 2000;88(2):139-142.
27. Bowen ML, Selinger M. Episiotomy closure comparing enbucrilate tissue adhesive with conventional sutures. *Int J Gynaecol Obstet*. 2002;78(3):201-205.