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

Carolyn W. Swenson, MD¹, Lisa Kane Low, CNM, PhD^{1,2}, Katherine M. Kowalk, BS^{1,3}, Dee E. Fenner, MD¹

¹Department of Obstetrics and Gynecology, University of Michigan, Ann Arbor, Michigan ²School of Nursing, University of Michigan, Ann Arbor, Michigan ³Department of Physician Assistant Studies, University of Toledo, Toledo, Ohio (current location)

Conflicts of interest: The authors have no conflicts of interest to disclose.

Acknowledgements: Investigator support for CWS was provided by the National Institute of Child Health and Human Development WRHR Career Development Award K12 HD065257. The National Institutes of Health did not play a role in the study design, in the collection, analysis and interpretation of data; in the writing of the report; or in the decision to submit the article for publication. Data from this study were presented at the American College of Obstetricians and Gynecologists' Annual Clinical and Scientific Meeting in 2018 (Swenson CW, Low LK, Kowalk K, Seiler K, Fenner DE. Randomized Trial Comparing Three Methods of Perineal Skin Closure at the Time of Second Degree Repair. *Obstet Gynecol.* 2018;131:55S).

Corresponding Author:

Carolyn W. Swenson University of Michigan Department of Obstetrics and Gynecology L4000 University Hospital South 1500 E. Medical Center Dr., SPC 5276 Ann Arbor, MI 48109-5276 Phone: (734) 764-8429 Fax: (734) 647-9727

This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the <u>Version of Record</u>. Please cite this article as <u>doi:</u> <u>10.1111/jmwh.13020</u>.

E-mail: <u>scarolyn@med.umich.edu</u>

Word count: 2603

Précis

Compared to suture, leaving the perineal skin unsutured or using surgical glue for second-degree perineal laceration repair decreased postpartum pain without compromising wound healing.

ABSTRACT

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 post-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 McGill Short Form, a 100-mm visual analogue 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 Chi-Square, Mann-Whitney *U* test, or ANOVA where appropriate. **Results:** 35 women were randomized: 14 received suture, 11 had no suture, and 10

recieved 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 McGill (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 McGill Short Form compared to 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 to no suture and surgical glue, suturing the perineal skin was associated with the highest postpartum pain scores.

Keywords: perineum; lacerations; adhesives; sutures; postpartum period; pain

QUICK POINTS

- Perineal pain following perineal laceration repair is common, and while 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) re-approximation 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 to suture, leaving the perineal skin unsutured or using surgical glue for second-degree perineal laceration repair decreases postpartum pain without compromising wound healing.

INTRODUCTION

Perineal lacerations are common and occur in 70% to 90% of women during childbirth. The "gold standard" technique for repairing second-degree perineal lacerations in the United States is suture repair.² Compared to interrupted stitches of catgut suture, the use of a continuous, non-locking, 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 to 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 depression⁶ 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 to 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 amongst women after second-degree perineal laceration who had either: 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 CONSORT guidelines for reporting clinical trials.

Inclusion criteria included women age 18-45 years, greater than or equal to 36 weeks' gestation, proficient in English, and immediately post-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 where 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 pre-delivery study criteria were met, informed consent was provided and they were enrolled.

Once 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: no suturing: surgical glue) computer-generated randomization and allocation 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 delivery was subjectively determined by the delivering 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 U.S. Food and Drug Administration¹³ 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, non-locking 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 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 blotted dry, and skin edges approximated using forceps. The glue was then sparingly applied along the skin edges and manual approximation applied for 10-20 seconds. To participate in the study, obstetrical 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 McGill Pain Questionnaire Short Form,¹⁴ a 100-mm visual analogue (VAS) pain scale,¹⁵ and the Present Pain Index (PPI)¹⁶ to assess pain related to the perineal laceration. Three pain scales were used to ensure pain 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 0-15, 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 assess urinary symptoms over the prior month and has been validated for use in women at low risk for incontinence. The Fecal Incontinence Severity Index (FISI) 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 \geq 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 protocol. All women with scores 10 or higher are 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 baby are 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 obstetric history, medical 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 visual analog scale. Prior use of this scale in randomized trials has considered a 15-point difference as clinically significant.²³ For [alpha]=0.05, [beta]=0.10, and 90% power, 50 participants were required in each group. Demographic characteristics, pain scores, and questionnaire responses were compared across groups using Chi-Square, Mann-Whitney U test, or ANOVA where appropriate. Statistical analyses were generated using IBM SPSS Statistics software, Version 21.0.

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 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 three 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 2-3 cm and, it took approximately 15 minutes for the repairs to be completed for all three 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 McGill Short Form and the 100-mm VAS were significantly higher in the women in the suture group compared to 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 McGill Short Form, 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 McGill Short Form compared to 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 Present Pain Index 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 Genital Self-Image Scale and scores on the Intimate Relationship Scale were similar across and between groups at 6 weeks and 3 months postpartum.

The percent of women in each group who had a positive postpartum depression screen (EPDS score \geq 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 non-significant). Urinary incontinence symptoms were also more severe among women in the surgical glue group, which reached marginal statistical significance when compared to 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 McGill pain scores as the outcome variable, while controlling for age, intervention arm, and scores on the Leakage Index and Edinburg Postnatal Depression Scale. 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 to those with no suture or surgical glue. At 3 months postpartum, pain scores remained significantly higher in the suture group compared to 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 our findings. However, this study provides important data for planning future research in this area.

While 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 seconddegree perineal lacerations, Gordon et al found women whose perineal skin was left unsutured had less perineal pain, less dyspareunia, and fewer interventions on their repairs at 3 months postpartum compared to 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 to 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 pain scores compared to 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 two 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 two groups.

The use of surgical adhesives has been employed for decades in other specialties, but its 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 two 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 re-approximation while avoiding sutures and the associated increased postpartum pain. Women in the surgical glue group did have statistically higher EBL compared to the other two groups. However, in the absence of significant differences in any other obstetrical factors, perineal laceration depth or time to repair, this may be a spurious finding due to small sample sizes and/or variations in estimating EBL.

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 McGill pain scores between the women in the suture and non-suture 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 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, provider compliance 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 while we attempted to blind study participants, it is possible women could have known which intervention they had received. CONCLUSION

In summary, 2 alternative methods to traditional suture repair of the perineal skin during second-degree perineal laceration repair are using surgical glue or leaving the skin unsutured. Compared to 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 in order to minimize postpartum pain and improve outcomes for childbearing women.

REFERENCES

- 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.
- 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.
- 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.
- 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.
- 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; discussion 888-890.
- 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 e331-335 e336.

 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.

- 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. U.S. Food & Drug Administration. Indermil Tissue Adhesive. [Internet]. https://www.accessdata.fda.gov/cdrh_docs/pdf/p010002c.pdf. Accessed February 19, 2018.
- 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.

- 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.
- 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.
- 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.
- 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.
- Bowen ML, Selinger M. Episiotomy closure comparing enbucrilate tissue adhesive with conventional sutures. *Int J Gynaecol Obstet.* 2002;78(3):201-205.

C	2
(Ŋ

Table 1. Survey instrument scales

Scale	What it Measures	Numb er of Items	Measureme nt Type	Rang e of Score s	Meaning of Scores	Cronbach Alpha
McGill Pain Questionnai re Short Form ¹⁴	Severity of 15 different pain characterist ics (e.g., throbbing, hot- burning, aching)	15	Likert scale from 0-3 per item Scores are summed	0-45	Higher score = greater pain severity	None reported Correlatio n coefficien ts between short and long- forms for postsurgi cal pain ranged from 0.67 to 0.90, p<.003
100-mm Visual Analogue Scale ¹⁵	Pain intensity	1	100 mm line with anchors at 0 (no pain) and 100 mm	0-100	Higher score = higher pain intensity	None reported Correlatio n coefficien

	Cript		(worst possible pain Patient marks an "X" representi ng pain intensity			ts with 11-point pain scale range from 0.91-0.95
Present Pain Index ¹⁶	Overall pain intensity	1	Likert scale from 0-5 (0=no pain, 5=excruci ating pain)	0-5	Higher score = greater overall pain intensity	None reported
Redness, Edema, Ecchymosis, Drainage, Approximati on (REEDA) scale ¹⁷	Perineal wound healing postpartum	5	Each of the 5 characteri stics is rated from 0-3, with 0=none and 3=worst appearan ce Scores are summed	0-15	Higher score = poorer wound healing	None reported
Antonakos Leakage Index ¹⁸	Urinary incontinenc e severity	8	Categorical response (Yes=1, No=0) Scores are summed	0-8	Higher score = worse urinary incontinenc e	0.72-0.84
The Fecal Incontinenc	Fecal incontinenc	24	Matrix of types of	0-61	Higher score = greater	None

e Severity	e severity		anal		severity of	reported
Index ¹⁹	o ooverity		incontine		anal	reported
maex			nce (gas,		incontinenc	
			mucus,		e	
			liquid,		C	Correlatio
			and solid		Higher	ns
					severity	between
-			stool) by		scores =	severity
			frequency		lower	scores
			Scores are		quality of	and
			weighted		life in all 4	quality of
			based on		domains of	life range
	\boldsymbol{n}		severity		lifestyle,	from20
			and		coping/beh	to45,
			range		avior,	p<.05,
			from 0-19		depression/	dependin
			per item		self-	g on the
			(i.e.		perception,	domain
			0=Never		and	
			leaking		embarrass	
			solid stool		ment	
_			VS			
			19=leakin			
			g liquid			
			stool ≥2			
_			times per			
			day)			
			Scores are			
			summed			
Edinburgh	Postpartum	10	Likert scale	0-30	Score of ≥10	0.87
Postnatal	depression		from 0-3		indicates	
Depression			per item		women at	
Scale ²⁰			Scores are		high risk for	
			summed		postpartum	
			Summed		depression	
Conital Calf	Mana aria	20	First 10	0.40	Llighor	0.70.0.00
Genital Self-	Woman's	20	First 10	0-40	Higher score	0.79-0.89
Image	feelings		questions		= greater	
Scale ²²	about her		are a		body	
	own		Likert		satisfaction	
	genitals		scale			
	(i.e., genital		from 0-3			

	self-image)		per item, the second 10 items are categoric al (0, 1) Scores are summed			
Intimate Relationship Scale ²¹	Perceived changes in sexuality and partner intimacy compared to 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, respectiv ely, for women at 4 and 12 months postpartu m

Author N

Table 2: Demographic characteristics and birth variables for women in 3groups of perineal skin closure

Demographic Characteristics	Surgical Glue	No Suture	Suture	P Value ^a
		n-11	n=14	
	n=10			
Age, me an (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, n (%)	1 (11.11)	0	1 (7.14)	.73
Body Mass Index, mean (SD), kg/m²	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, n (%	7 (70)	9 (81.82)	13 (92.86)	.33
Length of second stage,	73.67	90.40	85.14	.75
Time pushing, mean (SD),	64.57	89.60	66.21	.42
Estimated blood loss, median (IQR), mL	475 (388- 625)	400 (300- 700)	325 (250- 400)	.04
Infant weight, mean (SD), g	3684.50	3523.18	3628.57	.59

	(322.74)	(390.77)	(520.28)	
Infant head circumference, mean (SD), cm	35.54 (2.23)	34.40 (1.25)	34.78 (1.75)	.55
Delivering health care				.87
provider, n (%)				
	4 (40.0)	4 (0.4)	A (7 A)	
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,	25.88	27.64	20.36 (9.51)	.60
Number of sutures used,	1 (1, 2)	1 (1, 2)	1 (1, 1)	.58
Time to complete repair,	16.00 (12.5-	14.0 (6.0-	15.00 (8.5-	.79
Presence of additional	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

Abbreviations: IQR, interquartile range ^a*P* values determined using Chi-Square, ANOVA, or Mann-Whitney *U* test where appropriate.



Table 3. Pain score and postpartum symptom comparisons between women in 3 groups

of perineal skin closure

	Surgical	No Suture	Suture	P Value ^⁵				
Pain Indexes	n=10 ^a Median (IQR)	n=11ª Median (IQR)	n=14ª Median (IQR)	Overall	Surgical Glue vs No Suture	Surgical Glue vs Suture	Suture vs No Suture	
McGill Short Form ^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 weeks	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 weeks	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 months	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 (10	0mm Visual Analogi	ue Scale)		11		<u> </u>		
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 weeks	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 weeks	0 (0-6.0), n=8	0 (0-0), n=5	4.5 (0-14.0), n=8	.13	.24	.20	.07	
3 months	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	5 Likert)		I	<u> </u>			<u> </u>	
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 weeks	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 weeks	0 (0-0), n=8	0 (0-0.0), n=6	0.5 (0-2.0), n=8	.16	.83	.10	.17	
3 months	0 (0-0), n=7	0 (0-0), n=7	0 (0-2.0), n=6	.09	>.99	.11	.11	

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 ⁹	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 ⁱ	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-Month 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; VAS, visual analogue scale; REEDA, Redness, Edema, Ecchymosis, Drainage, Approximation;

^aNot all women in each group responded to all questionnaires, so individual n values may differ

^bP values determined using ANOVA for overall comparisons, Mann-Whitney U test for pairwise comparisons, and Chi-square for categorical variables.

^cMcGill Short Form: range 0-45, higher score indicates more pain

^d100-mm VAS: range 0-100, higher score indicates greater pain intensity ^ePresent Pain Index: range 0-5, higher score indicates more pain

^fRedness, Edema, Ecchymosis, Drainage, Approximation – perineal wound assessment scale, range 0-15, higher score indicates poorer wound healing

^aGenital Self-Image Scale: range 0-40, higher score is better body satisfaction ^hIntimate Relationship Scale, range 12-60, higher score indicates a more positive change ⁱAntonakos Leakage Index: range 0-8, higher score indicates more urinary incontinence

Fecal Incontinence Severity index: range 0-61, higher score indicates worsening symptoms

^kEdinburgh Postnatal Depression Score: range 0-30, higher score (≥10) indicates higher risk for postpartum depression



Figure Legend

