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# The Efficacy of the Close Rite™ System in Preventing Wound Separation during Healing

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## Abstract

We performed a prospective study comparing the effectiveness of skin staples vs. Close Rite, a novel skin closure device, in closing the skin incision during cesarean section. Nine women were enrolled in the study. Half of the incision in each patient was closed using skin staples and the other half, Close Rite. The result showed that all incisions were successfully closed using Close Rite without infection, bleeding or wound separation. Compared to the side closed with skin staples, there were no differences in patient satisfaction or pain scale. From this we conclude that Close Rite is an effective wound closing device and can be used safely to close surgical incisions.

## Introduction

The cesarean section rate in the US continues to rise. According to National Vital Statistics Reports, in 2009 the cesarean birth rate was 32.9% among singleton births, up from 20.7% in 1996 [1]. While skin closure after the cesarean section is considered an almost trivial portion of the surgery, depending on the technique, it can add additional operating room and staff time. Several options exist for closure of Pfannenstiel incision at the time of cesarean section. These include sutures, tissue adhesives, adhesive strips, and staples. An ideal technique should result in effective healing, prevent wound complications, and utilize minimal health care resources through speed and lack of necessary follow-up. The two most common techniques utilized for skin closure are non-absorbable skin staples and subcutaneous closure with absorbable sutures. A Meta analysis published in 2015 concluded that compared to subcutaneous skin closure with absorbable sutures, skin staples resulted in higher rate of wound complications largely due to increased incidence of skin separation and the need for enclosure when removed on postoperative day four. However, the rate of infection, hematoma, seroma and readmission were similar as well as cosmesis, pain perception and patient satisfaction at discharge [2]. The suture closure took 7 min longer than staple closure. Both techniques have advantages and disadvantages. While skin staples require less time in the operating room, they need to be removed after a variable period of time, requiring medical personnel time and, on occasion, a follow-up office visit just for the removal. Skin staples have also been associated with an increased rate of wound separation and overall patient dissatisfaction [3]. On the other hand the absorbable sutures require more operative time for placement than surgical staples and in the setting of a wound complication, the entire incision needs to be re-opened as the suture is usually placed in a continuous fashion. This leads to a marked delay in complete healing and may result in scarring that is cosmetically suboptimal. There remains a need for a fast and effective closure technique that offers partial drainage but more freedom in timing of removal. CloseRite™ is a novel skin closure product that utilizes skin adhesives allowing skin closure without staples or sutures. It consists of two separate pieces of a breathable substrate. The device is mounted on clear release liners and is color-coded, allowing for rapid and easy application. We conducted a pilot study to determine the feasibility of utilizing this device for closure of Pfannenstiel incisions after cesarean section.

## Materials and Methods

Women undergoing elective cesarean section at Beth Israel Deaconess Medical Center from 2011 to 2013 were asked to participate in the study. Nine patients consented. The exclusion criteria are known allergies to tape or other adhesives, history of keloid, morbid obesity (BMI >40 or >35 with other co-morbidities), any skin disorder in the area of the planned incision, and non-English speaking. The study was approved by the Institutional Review Board at Beth Israel Deaconess Medical Center. At the time of the skin closure, one half of the incision was closed using skin staples

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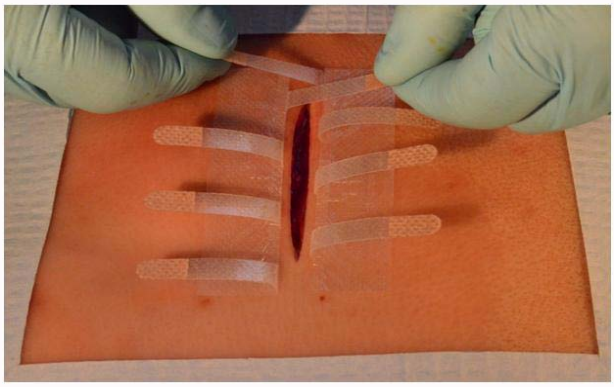

**Figure 1:** Video Instruction.
(https://www.youtube.com/watch?time_continue=16&v=M7LiVLaMhMM&feature=emb_title)

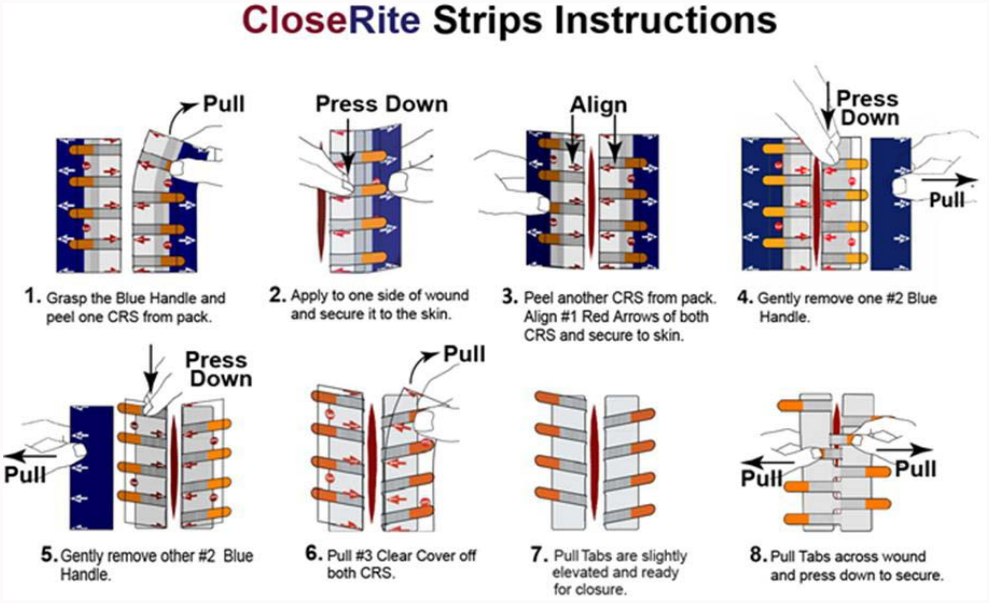


**Figure 2:** The wound closure can be performed without anesthesia using Close Rite by untrained personnel.

and the other, CloseRite. The description of the product is shown in Figure 1. Briefly, the substrate is coated with high and low tack medical grade, hypoallergenic non-latex adhesives. The low tack adhesive is designed to affix the pull-tabs in place. The high tack adhesive adheres the device to the patient's skin on either side of the wound and also secures the device, substrate to substrate, in the final closed position (Figure 2). The device spans the entire length of a wound and is capable of draping and curving with the incision. The pull-tabs allow for accurate approximation of the wound edges. It is delineated to identifiable segments, allowing for adjustment to various size wounds. The device is non-invasive and has the potential to result in greater patient comfort and less scarring than staples or sutures. All cesarean sections were performed in a usual manner. The dressing was removed on postoperative day one, and the incision was exposed to air. The patients were advised to cover the incision during shower to keep it dry. The skin staples were removed on postoperative day 4 before discharge unless otherwise indicated. CloseRite was not removed. The patients were advised to remove it after one week unless it fell off on its own before. The incision was rated by an observer and the patient for infection, cellulites, wound separation and any other complications. The incision appearance was rated using the Patient and Observer Scar Assessment Scale (POSAS) [4,5]. The Observer Scar Assessment Scale (OSAS) rated 6 variables: Vascularity, pigmentation, thickness, relief, pliability and surface area. Each variable used a 10 point scoring system with 1 representing normal skin. Ratings of individual variables may be summed to obtain a total score ranging from 6 to 60, with 6 representing normal skin. The Patient Scar Assessment Scale (PSAS) consisted of 6 items on scar-related pain, itchiness, color, stiffness, thickness, and irregularity. Each item used a 10 point scoring system. The scores can be summed to obtain a total score ranging from 6 to 10, with 6 representing normal skin with no associated symptoms. The patients were asked to rate the incision on post operative day 4 or 5. After rating the incision closed with staples and CloseRite separately, the patients were asked to compare the two sides using the PSAS scale. The score of 1 represented no difference between the two sides to 10, representing extreme difference. Because the study was designed to show that CloseRite is as effective in incision closure as staples, the appearance and complication rate shortly after the procedure was evaluated rather than the cosmetic appearance at a later date. Data were analyzed using Chi Square and Wilcoxon signed-rank test for analysis of ordinal data and small sample size. Each patient served

**Table 1:** Patient demographics: Majority of our patients were multiparous and were similar in age and BMI.

| Pts | Age (yo) | G | P | Wt (lbs) | Ht | GA | Race | Med/Surg hx |
|---|---|---|---|---|---|---|---|---|
| RP | 34 | 3 | 2 | 197 | 5'5" | 38.9 | White | Annal fissure |
| AC | 26 | 1 | 0 | 142 | 5' 5" | 31 | Hispani | Mono/di twins, PPROM, IUGR, Breech |
| SC | 32 | 4 | 2 | 140 | 5' 6" | 37.1 | White | hx IUFD, prev c/s |
| MT | 36 | 6 | 1 | 170 | 5'6" | 39.3 | AA/Hatian creole | Prior c/s, borderline HTN, GDM diet, hx of IUFD at 25 wks |
| GP | 30 | 5 | 2 | 156 | 4'11" | 32.7 | White | hx of NAIT, IUFD from IVH |
| JE | 33 | 1 | 0 | 170 | 5'4" | 36.6 | White | di/di twins, PPROM |
| KD | 33 | 4 | 1 | 171 | 5'4" | 38.6 | White | c/s x 1, GDM, fetus w. Noonan syndrome |
| FS | 39 | 2 | 1 | 140 | 5'5" | 39.6 | Mediterianian | Large fib obstructing labor, transv lie |
| HC | 35 | 2 | 1 | 165 | 5'3" | 39.9 | White | IgG deficiency, hx of C/S, fetus with VSD |
| AVG | 33.1 3.7 | | | 161.2 ± 18.8 | | | | |

**Table 2:** There was minimal difference in OSAS and PSAS score between the two sides.

| Pts | OSAS (staple) | OSAS (Close Rite) | OSAS (Comparison) | PSAS (staple) | PSAS (Close Rite) | PSAS (Comparison) |
|---|---|---|---|---|---|---|
| RP | 17 | 25 | 9 | 18 | 26 | 11 |
| AC | 17 | 17 | 6 | 20 | 15 | 7 |
| SC | 12 | 12 | 6 | 12 | 12 | 6 |
| MT | 16 | 16 | 6 | 16 | 11 | 8 |
| GP | 12 | 12 | 6 | 13 | 10 | 8 |
| JE | 12 | 12 | 6 | 13 | 11 | 6 |
| KD | 12 | 12 | 6 | 12 | 12 | 6 |
| FS | 12 | 12 | 6 | 12 | 12 | 6 |
| HC | 12 | 15 | 9 | 12 | 20 | 11 |
| AVG | 13.6 ± 2.6 | 14.8 ± 4.3 | 6.7 ± 1.3 | 14.2 ± 3.0 | 14.3 ± 5.3 | 7.7 ± 2.1 |

as her own control. The patient satisfaction will be scored on 1 to 5 scales and the average will be compared using the Mann-Whitney U test (Yet to be done).

## Results

Total of nine patients were enrolled and completed the study. The mean age for the group was 33 ± 3.7 years old (range 26 to 39 years), and the average body weight was 161.2 ± 18.8 lbs (Table 1). Two patients were nulliparous with twins, the rest multiparous women with singletons. The gestational age at delivery ranged from 31 to 39 weeks. None of the patients were in labor, and two patients with twin gestation presented with ruptured membranes. Each patient served as their own control to minimize variables in demographics or wound healing. Patient and Observer Scar Assessment Scale (POSAS) was used to rate the incisions and the total score for each patient is shown in Table 2. First the incision was rated separately then was compared. The average score for Observer Scar Assessment Scale (OSAS) for the staple side was 13.6 ± 2.4 and 14.8 ± 4.3 for the Close Rite. The Score for Patient Scale (PSAS) was 14.2 ± 3.0 for the staple side and 14.3 ± 5.3 for Close Rite (Table 2). When the two sides were compared, the average score of OSAS was 6.7 ± 1.3 and 7.7 ± 2.1 for PSAS (Table 2). Overall this suggests that there was a marginal difference between the two sides. All the incisions closed using Close Rites were intact without signs of infection or bleeding from the skin incision (Table 3). One of the patients had peritoneal fluid drain through the entire incision on post operative day 1 that soiled the Close Rite. The drainage stopped spontaneously on day 2 (Figure 3A). Close Rite remained intact (Figure 3B) and was changed at the bedside. With the exception of patients one and nine, there was minimal difference between the two sides in the parameters evaluated. In the first patient, the side that was closed with Close Rite was noted to be thicker than the side closed with staples. However, on a 6 week follow up, the difference became less pronounced and the patient no longer appreciated the difference (Figure 3C). In the ninth patient, there was a small area (3 mm × 2 mm) of subcutaneous tissue exposed on the Close Rite side. The area


**Figure 3:** A). Close Rite was used to close the skin incision alongside the skin staples during caesarean section B). On one of the patients, the Close Rite strip was soiled with exudate, but remained adherent. The soiled device was removed and a fresh one was applied over the incision by the bedside. C). The first patient initially had a scar that was thicker than the side with skin staples, incision healed well with satisfactory cosmesis on six week postpartum visit. D). One patient had a small area of the skin edge overlapping noted at 6 week post check which was coagulated with silver nitrate stick in the office. The area healed and no longer visible two weeks later (picture not shown).

| FEATURES | CloseRite™ | Sutures | Staples | Tape Strip | Skin Glue |
|---|---|---|---|---|---|
| No Follow-up Visit | Y | N | N | Y | Y |
| Clear Visual Inspection | Y | Y | Y | N | N |
| No Track Marks | Y | N | N | Y | Y |
| Fast Application | Y | N | Y | Y | Y |
| Wound Not Occluded | Y | Y | Y | N | N |
| Economical | Y | Y | N | Y | N |
| Primary Closure | Y | Y | Y | N | Y |
| Secondary Closure | Y | N | N | Y | N |
| Fast Learning Curve | Y | N | N | Y | N |
| Low Patient Risk | Y | N | N | Y | N |
| Drainage of Exudates | Y | Y | Y | Y | N |
| Non-Invasive | Y | N | N | Y | Y |
| Minimal Wound Contact | Y | N | N | N | N |
| Easy Replacement | Y | N | N | Y | N |

**Figure 4:** Close Rite offers several practical and economical advantages over other methods of wound closure.

**Table 3:** Comparing the incidence of wound separation between the two techniques. There were no cases of skin separation between the two. The skin staples were removed on postoperative day 4 while the Close Rite was left on until they peeled off on their own.

| Pts | Wound Separation | Infection | Cellulitis/Servoma |
|---|---|---|---|
| RP | 0 | 0 | 0 |
| AC | 0 | 0 | 0 |
| SC | 0 | 0 | 0 |
| MT | 0 | 0 | 0 |
| GP | 0 | 0 | 0 |
| JE | 0 | 0 | 0 |
| KD | 0 | 0 | 0 |
| FS | 0 | 0 | 0 |
| HC | 0 | 0 | 0 |

did not granulate on its own and needed to be coagulated with silver nitrate sticks in the office. After the coagulation, the area granulated well, and the scar was well healed on subsequent check (Figure 3D). Another patient showered without covering the incision on post op day 2 and Close Rite fell off. The incision remained intact and a fresh Close Rite strip was placed over the incision by the bedside. Finally, 8 patients required the skin staples to be removed on the day of the discharge by a nurse or a physician. One patient had diabetes and could not have the staples removed until postoperative day 7. She required a separate office visit for staple removal. The CloseRite was left on the incision at the time of the discharge and not required additional care. Most patients reported that the device fell off on its own in 7 to 10 days. A few patients had to remove it after 2 weeks.

## Discussion

Our data show that CloseRite can be as effective in closing Pfannenstiel incisions as skin staples. There was no difference in the rate of wound separation, infection or wound healing. As long as the device was kept dry, it remained intact at minimum 7 days. This study was not powered to assess the cosmetics of the closure, but our limited data suggest that there were minimal differences between the two methods at least on short term evaluation. On two patients (#1 and #9), the skin approximation was not as optimal with Close Rite. However, at six week follow-up, there was minimal difference in scar healing between the two sides. It is unclear if this is due to the device itself or poor approximation of the skin edges at the time of the placement of the device over the incision. If it is the latter, a careful attention to skin approximation should resolve the issue. We did not ever the skin edges with Adson clamps when Close Rite was being placed. This is an option if a surgeon chooses to do so. There are several advantages to an adhesive skin closure device (Figure 4). First is the ease of application. It is faster than subcuticular stitch and as nearly as fast as skin staples. Second, there are minimal foreign objects introduced into the incision when compared to subcuticular stitch or skin staples. This could potentially reduce the incidence of skin infection, especially in women with diabetes. Third, there is no need to remove device as it often falls off in 7 to 10 days and/or patients can easily remove it themselves at home. Finally, the device can be used at the bedside and does not require local anesthesia in the event delayed wound closure is desired. Our pilot trial showed that the device can be used to close Pfannenstiel incisions and may be as effective as skin staples. The device has potential to offer a few advantages over skin staples or subcuticular stitch. A larger clinical trial assessing the cosmetic outcome appears to be in order.

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## References

1. Martin JA, Hamilton BE, Ventura SJ, Osterman MJ, Kirmeyer S, Mathews TJ, et al. Births: Final data for 2009. Natl Vital Stat Rep. 2011;60(1):1-70.
2. Mackeen AD, Schuster M, Berghella V. Suture versus staples for skin closure after cesarean: A metaanalysis. Am J Obstet Gynecol. 2015;212(5):621.e1-10.
3. Basha SL, Rochon ML, Quinones JN, Coassolo KM, Rust OA, Smulian JC. Randomized controlled trial of wound complication rates of subcuticular suture *vs.* staples for skin closure at cesarean delivery. Am J Obstet Gynecol. 2010;203:285.e1-e8.
4. Draaijers LJ, Tempelman FR, Botman YA, Tuinebreijer WE, Middelkoop E, Kreis RW, et al. The patient and observer scar assessment scale: A reliable and feasible tool for scar evaluation. Plast Reconstr Surg. 2004;113(7):1960-5.
5. van de Kar AL, Corion LU, Smeulders MJ, Draaijers LJ, van der Horst M, van Zuijlen PP. Reliable and feasible evaluation of linear scars by the patient and observer scar assessment scale. Plast Reconstr Surg. 2005;116(2):514-22.