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Dermabond™ Prineo™ skin closure system in caesarean section: Preliminary experience and review of the literature

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Abstract

Background: Caesarean Section is one of the commonest abdominal surgeries performed worldwide. The reported incidence of surgical site infection in this procedure ranges between 1 and 21%. Four items have been found to have an impact on this problem: skin disinfection, antibiotic prophylaxis, placental manual extraction and skin closure technique. Concerning this last item, a new closing system, Dermabond™ Prineo™, has become available recently. We wanted to test, in a preliminary study on a high-risk group patients, whether this system could be introduced in our surgical routine comparing it to the gold standard (subcuticular stitches).

Methods: We randomly selected thirteen high-risk women undergoing both elective and urgent c-section from January to June 2022. To reduce variability all the skin closures were performed by the same surgeon (ADP), an experienced obstetrician. Wounds were checked the day after intervention (C1), on patient discharge (third day after c-section, C3), ten days after surgery (C10) and twenty days after surgery (C20) by an external physician. A cost analysis was also performed.

Results: All but one case did not develop SSI at C10 (7.7% incidence). The only case resulted in a complete healing after a 7-day course of antibiotic therapy. Four cases presented with minimal diastasis requiring no further treatment. The reduced operating time resulting from the use of this device resulted in a saving of nearly 200€ per patient.

Conclusion: Our preliminary results show that this skin closure system has a potential application for abdominal wall closure in case of C-section. It is at least equivalent of the gold standard suture method but, being undoubtedly faster it resulted in cost saving. Further studies with a higher number of patients are needed to confirm these preliminary observations.

Keywords: Dermabond™ Prineo™ skin closure system, surgical site infection, SSI, C-section, caesarean section, laparotomy, caesarian, cesarean, cesarean, stitches, staples

Introduction

Several variables have been evaluated to predict the development of a surgical site infection (SSI) in the event of a C-section [1]. In a 2011 paper, Conroy *et al* [2], using data from Edwards *et al* [3], defined three variables (operating time, class of wound and ASA status) (table 1) which classified patients' risk of surgical site infection (NHSN category 0,1,2,3). This universal index was then integrated in a specific risk evaluation for caesarian section classifying patients at low, moderate or high-risk (table 2). A Decalogue was then proposed to prevent SSI (table 3); of the ten items, only four has been universally accepted as important: skin disinfection, antibiotic prophylaxis, placental manual extraction and skin closure technique. In the same paper it was observed that the range of SSI incidence, when analyzing eighteen articles for a total of a million and half C-section and seventy thousand puerperal infections, deeply varied from 1% to 21% (mean 5%). It is highly likely that other aspects might also play an important role. In fact, the authors suggested that tertiary hospitals most probably treat high-risk patients who are more prone to SSI.

Searches for effective strategies to reduce SSI rate are still in progress. Recently, a variation in the C-section closing procedure consisting of fresh surgical instruments and new gloves and scrubs for surgeons and nurse, before fascia closure has been evaluated [4]. Unfortunately, this approach not only was ineffective in reducing SSI rate, but it turned out to be more expensive due to increased operating room time and cost. Also 2-octyl cyanoacrylate has been tested in c-section [5, 6, 7] with no differences in SSI, keloid formation and dehiscence rate.

A new method of abdominal wall closure, called Dermabond™ Prineo™ (Ethicon, Somerville, New Jersey) that combines the effectiveness of 2-octyl cyanoacrylate (Dermabond™) together with a self-adhering mesh^[8] became available in the last decade. The self-adhering mesh is applied on the skin just above the wound, and it is filled with 2-octyl cyanoacrylate delivered through a pen: the medication should not be removed before the 10th day after surgery. Originally used in various field of surgery^[9-11] it was recently introduced for C-section too^[12]. In that study it was tested against staples plus waterproof wound dressing: for the first time this system proved to be superior in terms of costs and SSI rate. Based on this result we performed a preliminary study comparing the Dermabond™ Prineo™ skin closure system to the conventional stiches, the gold standard method for skin closure^[13], in a subset of selected patients.

Material and Methods

As a preliminary study we decided to test it in the worst patients i.e. the moderate and high-risk patients as defined in table 2. We randomly selected thirteen women, based on chart number and risk definitions, among those undergoing a C-section from January to June 2022. Of those thirteen procedures seven were elective and six urgent ones with twelve single and one twin pregnancy. All pregnancies except two were at term (between 37 and 40 weeks). We decided to check wounds for dehiscence and sign of SSI the day after intervention (C1, figure 1), the day of patients' discharge (C3, third day after c-section, figure 2), ten days after surgery (C10, figure 3.a, 3.b) and twenty days after

surgery (C20). These evaluations were performed by external physicians. To reduce variability all the skin closures were performed by the same surgeon (ADP), an experienced obstetrician. Details of each case are showed in table 4. Besides surgical aspects also cost of implementing Dermabond™ Prineo™ have been studied. As this surgical device is approved for clinical use in Italy the local ethical committee judged the formal request of an ethical approval unnecessary.

Results

All wounds presented satisfying results when checked the day after c-section (C1). Three days after surgery (C3) two of them presented a central diastasis without signs of infection. Both patients had previous abdominal surgery and their c-section were performed in urgency. One of the Dermabond™ Prineo™ film was removed by mistake during medication but this did not have any impact on the final result. All but two had perfect results with no signs of dehiscence or inflammation. At the 10th day's follow-up (C10), three patients presented a central diastasis and a patient a median one. All but one had no signs of SSI: the only positive one, after a 7-day antibiotic course, resolved her SSI. All wounds were perfectly healed twenty days after surgery (C20). The economic impact of Dermabond™ Prineo™ have been evaluated by our pharmacoeconomists. Although an initial higher cost of the device (70€ for Dermabond™ Prineo™ versus 3€ for the stiches), its use resulted in a saving of almost 180€ per patient secondary to the reduced operating time (an average of ten minutes per patient).

Table 1: National Healthcare Safety Network Surgical Site Infection Basic Risk Index^[2]. Data from Mu Y, Edwards Jr^[3]

N°	Risk Point Assigned	Category	Reason for Assigning Points
1	1 Point	Duration of Surgery	More than 56 minutes for c-section
2	1 Point	Class of wound	If contaminated or dirty / infected
3	1 Point	Physical status of the patient	Class III, IV or V for American Society Classification of Physical Status

Table 2: Proposed New Risk Schema: Infectious Risk Following Caesarean Delivery. From Conroy *et al.*^[2]. In red, patients we considered in our study.

N°	Risk Category	Factors
1	Low	Elective c-section (no rupture of membranes) No diabetes BMI <25 kg/m ² Low risk surgical case (NHSN 0)
2	Moderate	Nonelective caesarean (urgent or rupture of membranes) Well-controlled pregestational or gestational diabetes MBI 25-35 kg/m ² Moderate surgical risk (NHSN 1) Manual extraction of placenta or closure of skin with staples
3	High	Emergency caesarean (often without antibiotic prophylaxis) Chorioamnionitis Poorly controlled pregestational or gestational diabetes BMI >35 kg/m ² High risk surgical case (NHSN 2 or 3) Manual extraction of placenta and closure of skin with staples

Table 3: 10 Strategies to Prevent Post cesarean Infectious Morbidity. From Conroy *et al.*^[2]. In green, items universally accepted and used also in our hospital (used in our study).

N°	
1	Shower with 9% chlorhexidine gluconate the night before elective surgery
2	If necessary, clip than shave pubic hair
3	Avoid unnecessary vaginal examinations in labor
4	Avoid unnecessary instrumentation in labor (fetal scalp, intrauterine catheters)
5	Prep the skin with an antiseptic agent (chlorhexidine) immediately prior to surgery
6	Administer appropriate intravenous antibiotic prophylaxis within 60 min prior to incision
7	Avoid manual removal of placenta and fetal membranes
8	Avoid closure of the skin with staples
9	Maintain strict glycemic control if diabetic patient
10	Consider early removal of bladder catheters postoperatively

Table 4: Clinical characteristics of patients and outcomes of wounds

N°	Ref.	Age (year)	Parity	Gestational Age (weeks)	Previous Surgery	Comorbidity	C-section elective (E) vs urgent (U)	BMI (Kg/m ²)	C1	C3	C10	C20
1	GP	35	1021	26+6	2014 c-section 2019 Umbilical hernia repair	Obesity HBP Pre-eclampsia	U	34	OK	Left flap 1 cm diastasis	OK	OK
2	LL	38	1001	39+1	NO	GDM (i)	E	40	OK	Removed by mistake	Left flap 1 cm diastasis	OK
3	RM	24	1122	39	2018 c-section 2019 abdominoplasty	0	E	34	OK	OK	OK	OK
4	RR	35	1041	39+1	1994 appendectomy (laparotomy) 2006 c-section	0	U	31	OK	Central diastasis 1 cm	Central diastasis 1 cm	OK
5	CG	31	0000	39+2	NO	0	E	23	OK	OK	Central diastasis 1 cm	OK
6	SAMM	29	1001	29 (twin)	2017 c-section	0	U	34	OK	OK	OK	OK
7	BN	29	1001	39	NO	0	U	31	OK	OK	Central diastasis 1 cm, suspected infection: antibiotic therapy	OK
8	MA	38	1132	39	2017, 2019 c-section	0	E	30	OK	OK	OK	OK
9	CVA	25	0000	38+2	NO	0	U	27	OK	OK	OK	OK
10	PV	39	0030	39+1	2011 cholecystectomy (laparotomy) 2017 bowel resection 2019 sleeve gastrectomy	Incisional hernia Abdominal adhesion	E	29	OK	OK	OK	OK
11	UC	34	2002	39	2009, 2017 c-section	0	E	28	OK	OK	OK	OK
12	FF	41	1001	38+4	2015 c-section	0	E	30	OK	OK	OK	OK
13	AC	38	0000	40+3	NO	0	U	24	OK	OK	OK	OK

**Fig 1:** Day after surgery (C1)**Fig 2:** 3 days after surgery (C2)

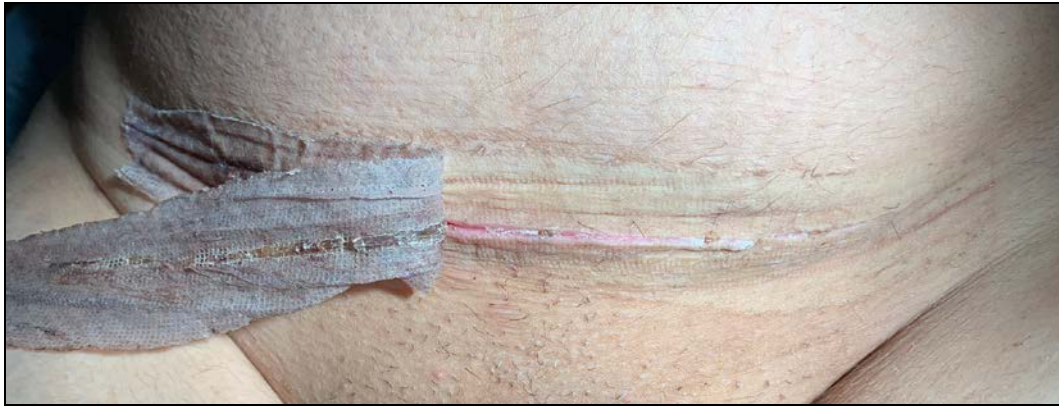


Fig 3a: 10 days after surgery (tape removal) (C10)



Fig 3b: 10 days after surgery (final view) (C10)

Conclusion

Our results showed a 7.7% SSI incidence in this selected group of moderate to high-risk patients. This rate is at least equal, if not lower than our average rate (10.5% in this group of patients) using standard subcuticular skin closure system. Further, the reduction in average surgical time resulted into a nearly 200 euro saving per patient. Following this preliminary study, we are in the process of introducing this skin closure system to the whole obstetric population undergoing a c-section in our hospital. In a year time (nearly 400 cases) we are confident to have definitive data supporting our clinical results as for the economical part the advantage is already proved.

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